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Complete List of Authors:	Abbott, Allan; Linkoping University, Department of Medical and Health Sciences (IMH), Division of Physiotherapy Schröder, Karin; Linkoping University, Department of Medical and Health Sciences (IMH), Division of Physiotherapy Enthoven, Paul; Linkopings universitet, Department of Medical and Health Sciences (IMH), Divsion of Physiotherapy Nilsen, Per ; Linköping University, Department of Medical and Health Sciences (IMH), Division of Community Medicine, Faculty of Health Sciences Öberg, Birgitta ; Linkopings universitet, Department of Medical and Health Sciences (IMH), Division of Physiotherapy
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Note from the Editors: Instructions for reviewers of study protocols

Since launching in 2011, BMJ Open has published study protocols for planned or ongoing research studies. If data collection is complete, we will not consider the manuscript.

Publishing study protocols enables researchers and funding bodies to stay up to date in their fields by providing exposure to research activity that may not otherwise be widely publicised. This can help prevent unnecessary duplication of work and will hopefully enable collaboration. Publishing protocols in full also makes available more information than is currently required by trial registries and increases transparency, making it easier for others (editors, reviewers and readers) to see and understand any deviations from the protocol that occur during the conduct of the study.

The scientific integrity and the credibility of the study data depend substantially on the study design and methodology, which is why the study protocol requires a thorough peer-review.

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Some things to keep in mind when reviewing the study protocol:

- Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.
- Unfortunately we are unable to customize the reviewer report form for study protocols. As such, some of the items (i.e., those pertaining to results) on the form should be scores as Not Applicable (N/A).
- While some baseline data can be presented, there should be no results or conclusions present in the study protocol.
- For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected.

The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

Allan Abbott[1,2*], Karin Schröder[1], Paul Enthoven[1], Per Nilsen[3], Birgitta Öberg[1]
[1]Department of Medical and Health Sciences, Division of Physiotherapy, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.
[2] Faculty of Health Science and Medicine, Bond University, Gold Coast, Queensland, 4229, Australia.
[3] Department of Medical and Health Sciences, Division of Community Medicine, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.

Allan Abbott* - allan.abbott@liu.se (TEL: 0046 13 282495); Karin Schröder - karin.schroder@liu.se; Paul Enthoven - paul.enthoven@liu.se; Per Nilsen - per.nilsen@liu.se; Birgitta Öberg - birgitta.öberg@liu.se;

*Corresponding author

ABSTRACT

Introduction: Low back pain (LBP) is a major health problem commonly requiring health care. In Sweden, there is a user pull from health care practitioners (HCP) for the development, implementation and evaluation of a best practice primary health care model for LBP.

Aim: The overall aim is to investigate the effectiveness of the BetterBack☺ model of care for LBP implemented with a multi-facetted strategy in Swedish primary health care. The specific trial objectives: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing primary health care for patients with LBP (B) Improve and understand the mechanisms underlying illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate the implementation process and cost-effectiveness of the BetterBack☺ model of care for LBP in the Swedish primary health care context.

Methods: This study is an effectiveness-implementation hybrid type 2 trial. This involves a prospective cohort study investigating implementation on the HCP level and a patient blinded, pragmatic cluster randomized controlled trial with longitudinal follow-up at 3, 6 and 12 months post baseline for effectiveness on the patient level. A superiority trial design framework will be used. A parallel process and economic analysis will also be performed. Patients will be allocated to routine care (control group) or the BetterBack model of care (intervention group) according to the schedule of a dog leg design with 2 assessments in routine care. Experimental conditions will be compared and causal mediation analysis investigated. Qualitative HCP and patient experiences of the BetterBack☺ model of care will also be investigated.

Dissemination: The findings will be published in peer-reviewed journals and presented at national and international conferences. Further national dissemination and implementation in Sweden and associated national quality register data collection are potential future developments of the project.

Trial registration: ClinicalTrials.gov: NCT03147300

Date and version identifier: 30 Sept 2017, protocol version 2.

Key words: Low back pain, model of care, effectiveness, implementation.

Word count: 7343 words

Strengths and limitations of this study

- This will be the first study of effectiveness and implementation of a best practice model of care in LBP primary care in Sweden.
- An international consensus framework is used for the development, implementation and evaluation of the BetterBack☺ model of care.
- The main trial's a priori methodology has been informed and refined by an initial internal pilot phase.
- The study has received financing in Sweden from a competive grant rond with peer review process.

BACKGROUND

Low back pain (LBP) is one of the most prevalent and burdensome problems for individuals and society in Sweden and worldwide [1,2]. LBP is often defined in terms of its localization, duration, severity, frequency, and interference on activities of daily living [3]. Most new episodes of LBP are self-limiting with only approximately 20% having persistent symptoms but a large majority experience pain recurrence [1]. The aetiology of LBP is often classified as specific or non-specific, based upon if a pathoanatomical cause can be identified through objective diagnostic assessment and confirmed by medical imaging [4]. The prevalence of LBP caused by specific pathology of serious nature such as malignancy, spinal fracture, infection, or cauda equine syndrome requiring secondary or tertiary health care has been reported to range between < 1%-4% in the primary health care setting [5,6]. Furthermore, nerve root problems associated with radiculopathy or spinal stenosis are thought to explain approximately 5%-15% of cases [7,8]. Medical imaging studies have highlighted that approximately 50% of younger adults and 90% of older adults have degenerative findings and large variations in lumbar spine morphology [9]. This is however evident in both symptomatic and asymptomatic individuals suggesting that low back pain is more typically a result of benign dysfunctional biological and psychological functions as well as social contextual factors influencing the pain experience.

In Sweden, the health care process for patients with LBP tends to be fragmented with many health care practitioners (HCP) giving conflicting information and providing interventions of varying effectiveness [10,11]. Our studies have shown that only a third of patients on sick leave for musculoskeletal disorders receive evidence-based rehabilitation interventions in primary care [10,11]. Furthermore our research has also demonstrated that there are still interventions that physiotherapists in primary care consider to be relevant in clinical practice despite the absence of evidence or consensus about the effects [12]. Our preliminary data suggests that when patients with LBP are referred to a specialist clinics, up to 48% have not received adequate evidence-based rehabilitation in primary care. The development of clinical practice guidelines aims to provide HCP with recommendations based on strength of available evidence as well as professional consensus for the intervention's risk and benefits for the patients. Such guidelines are lacking in Sweden but have recently been developed by the Danish Health and Medicines Authority and the English National Institute for Health and Care Excellence [13-15]. These national guidelines provide a thorough assessment of current evidence and can be used in Sweden to form the basis for locally adapted recommendations that are feasible to integrate in local health care setting.

Common to LBP, central recommendations from evidence based clinical guidelines for arthritis are also education and exercise therapy aimed at improving patient self-care. These principles have been packaged in well-known models of care describing how complex patient interventions can be delivered by clinicians. These model of care include "Better Management of Patients with Osteoarthritis (BOA)" in Sweden [16] and "Good Life with Osteoarthritis" in Denmark (GLA:D) [17]. Annual reports from BOA and GLA:D indicate an HCP acceptance through a broad national use of the models of care [18,19]. Furthermore, improvements in patient reported pain, physical function and decreased use of pain medication after receiving these models of care have been

reported [18,19]. There is currently a paucity of evidence to determine if and how a similar best practice model of care for LBP could improve therapist and patient rated outcomes in the primary treatment and secondary prevention of LBP.

Recently an international consensus has been reached proposing a framework for the development, implementation and evaluation of musculoskeletal models of care [20]. The theoretical underpinning is important in developing a model of care aimed at behavioural change to understand and explain the mechanisms of change [20]. Social-cognitve theories are widely used to predict and explain behaviour change. For example, the Theory of Planned Behaviour (TPB) [21] can be utilised to explain how intentions and volition of behaviour such as HCP use of a model of care can potentially be influenced by an intervention aiming to strengthen associations with attitudes, social norms and perceived behavioural control concerning the model. Furthermore, the Common Sense Model of self-regulation (CSM) [22] can been utilised to explain how behavioural change such as improved patient reported pain, physical function, self-care enablement and quality of life can potentially be influenced by an intervention aiming to strengthen associations with improved patient cognitive and emotional illness representations and comprehensibility through coping procedures [22].

It is important to apply knowledge from implementation science to achieve effective implementation of a best practice model of care in primary health care [23-26]. Implementation science is the scientific study of uptake of research findings and evidence-based practices into routine practice to improve the quality and effectiveness of health care and services [27]. Implementation strategies focus on minimising barriers and maximising enablers that impact on the implementation and use of evidence-based practices. Recent implementation science studies investigating the uptake of national clinical guidelines for LBP in Denmark and the Netherlands have found multifaceted strategies to facilitate HCP behaviour change to be more cost-effective than single-faceted strategies [28,29].

There is therefore a clear rationale for evaluating the extent to which and how a best practice primary health care model for low back pain (BetterBack☺) implemented with a multi-facetted strategy is potentially effective in the Swedish context. This article describes the BetterBack☺ trial internal pilot and protocol for the main trial. The protocol conforms to the SPIRIT guidelines [30].

AIMS

The overall aim is to investigate the effectiveness of the BetterBack☺ model of care for LBP implemented with a multi-facetted strategy in a Swedish primary health care context. The specific trial objectives are to: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing primary health care for patients with LBP (B) Improve and understand the mechanisms underlying illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate the implementation process and cost-effectiveness of the BetterBack☺ model of care for LBP in the Swedish primary health care context.

HYPOTHESIS

1. HCP reported confidence, attitudes and beliefs for providing primary health care for LBP will show statistically significant improvement after a multifaceted implementation of the BetterBack☺ model of care compared to baseline before implementation. Intentional and volitional HCP rated determinants of implementation behaviour regarding the BetterBack☺ model of care will mediate improved confidence, attitudes and beliefs in a causal effects model.
2. The multifaceted implementation of the BetterBack☺ model of care will result in more statistically significant and greater clinically important improvement compared to current

routine care for LBP regarding patient-reported measures for illness beliefs, self-care enablement, pain, disability and quality of life. Improvements in illness beliefs will mediate the effect on these outcomes.

3. A multifaceted implementation of the BetterBack☺ model of care compared to current routine care will result in fewer patients with persisting LBP, fewer requiring specialist care and more statistically significant incremental cost-effectiveness ratio (ICER) based on cost per EuroQoL-5 Dimension Questionnaire (EQ-5D) quality-adjusted life years (QALY) gained.

METHODS

Study design

World Health Organization Trial Registration Data Set is presented in table 1. This study is an effectiveness-implementation hybrid type 2 trial [31]. This involves a prospective cohort study design investigating implementation on the HCP level and a patient blinded, pragmatic cluster randomized controlled trial with longitudinal follow up at 3, 6 and 12 months post baseline for effectiveness on the patient level. A superiority trial design framework will be used. A parallel process and economic analysis will also be performed. This design was chosen because the multifaceted implementation of the BetterBack☺ model of care will be first targeted at changing HCP level behaviour who will then in turn implement behavioral change strategies on a patient level. Randomisation at the patient level is not possible due to potential carry-over effects of the HCP transitioning back and forth between providing routine care or the BetterBack☺ model of care for different patients. Instead, patients will be allocated to routine care (control group) or the BetterBack☺ model of care (intervention group) depending upon the clinics allocation. Patients will remain in their allocated group throughout the study.

The main study design is a dog leg with 2 assessments in routine care [32,33]. This involves the first cluster being assessed after the implementation of the BetterBack☺ model of care. The second cluster is assessed after a period of current routine care (control), and assessed again after the implementation of the BetterBack☺ model of care. The third cluster will receive current routine care (control) throughout the trial. The initial implementation of the BetterBack☺ model of care in cluster 1 allows for an internal pilot to determine the HCP acceptability of the intervention and trial within the first cluster [34,35]. A progression criteria for continuing to the main trial requires that HCP who have completed the BetterBack☺ education workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ model of care will be useful (1 = agree completely - 5 = do not agree at all).

The internal pilot also monitors patient recruitment during the first 2 months to provide a check point to optimize the main study design while data generated will still contribute to the final analyses to maintain trial efficiency [34,35]. Clusters are expected to recruit and gather data for at least 20 LBP patients per month in the internal pilot. In the dogleg design it is possible to vary the time point of cluster 2 to cross forward from the control to intervention condition if the patient recruitment process in either cluster 1 or 3 is more or less than expected in the internal pilot. In the event that cluster 1 recruit less than expected and clusters 2 or 3 recruit more than expected, then cluster 2 will cross forward to the intervention condition immediately after the internal pilot. If cluster 1 recruit more than expected and cluster 2 or 3 recruit less than expected during the internal pilot phase, then cluster 2 will cross forward to the intervention condition later in the main trial to allow adequate current routine care data collection. Implementation of the BetterBack☺ model of care in cluster 3 will occur directly after the end of patient recruitment in cluster 3. The study design is outlined in table 2.

Study setting

The Östergötland public health care region has a total population of 453 596 inhabitants with approximately 5000 patients per year accessing primary care physiotherapy due to LBP. In the public health care region of Östergötland, a large majority of consultations for LBP are via direct access to the 15 primary care physiotherapy rehabilitation clinics. A smaller percentage of consultations are via referral to these rehabilitation clinics from the 36 primary health care general practices in the region. Therefore the focus of this study is on the physiotherapeutic rehabilitation process for LBP in primary care. The rehabilitation clinics form three clusters in Östergötland health care region. These clusters are based on municipal geographical area and organisational structure of the rehabilitation clinics which helps to minimize contamination between separate clusters of clinics (Figure 1). Cluster west is comprised of 5 clinics with 27 physiotherapists, cluster central is comprised of 6 clinics with 44 physiotherapists and cluster east is comprised of 6 clinics with 41 physiotherapists.

Eligibility criteria

Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP will be included in the study. These physiotherapists will assess the eligibility of consecutive patients before and after the implementation of the BetterBack☺ model of care based on the following criteria:

Inclusion criteria: Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a current episode of a first-time or recurrent debut of benign low back pain with or without radiculopathy.

Exclusion criteria: Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Spinal surgery during the last 2 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfil criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis.

A signed patient consent form will be collected by the physiotherapist before baseline measures are collected and intervention is commenced according to the study protocol. The therapist's intervention will not be effected by the patient's decision to participate or not participate in the study, only data collected will not be performed for those not participating.

Interventions

Control condition – current routine physiotherapeutic care for LBP in primary health care

Patients attending rehabilitation clinic clusters that have not have not yet completed the implementation of the BetterBack☺ model of care will receive treatment as usual according to current routine care clinical pathways (Figure 2). A clinical pathway specified in Östergötland public health care region requires that for patients accessing primary care due to LBP, a triage is to be performed by licensed HCPs (Physiotherapists, Nurses or General Practitioners (GP)), to triage for specific pathology of serious nature. These approximately 1-4% of patients with suspected specific pathology of serious nature are then to be examined by GPs and referred for specific intervention in secondary or tertiary health care. The majority of patients with LBP who on initial triage are assessed as having benign first-time or recurrent debut of LBP are then scheduled for physiotherapy consultation and implementation of a LBP management plan. If the patient has persistent functional impairment and activity limitation despite 2-3 months of primary care intervention, the clinical pathway specifies inclusion criteria for specialist care referral pathways (Figure 2).

Intervention condition – The BetterBack☺ model of care for LBP

Development and design of the BetterBack☺ model of care for LBP

A framework for the development of musculoskeletal models of care [20] was used to guide development of the BetterBack☺ model of care for LBP. The high prevalence and burden of LBP [1,2], discordance in evidence based rehabilitation processes [10-12], a lack of physiotherapeutic clinical practice guidelines and a user-pull for a best practice model of care requested by physiotherapy clinic managers in the Östergötland health care region have been identified in the primary care of LBP. Therefore, a case for change has been justified to improve current physiotherapeutic health service delivery for the primary care of LBP. The structure and components of BetterBack☺ where developed by engaging a work group of physiotherapy clinicians (clinical champions) from each primary care cluster in the Östergötland public health care region and physiotherapy academics at Linköping University. To identify which key areas of contemporary care were of relevance for BetterBack☺, the following tasks were performed by the work group:

1) Discussion and outline of the current routine care clinical pathway for LBP and areas needing improvement: The work group concluded that a best practice model of care needed to focus on the primary care physiotherapy process outlined by the red square in figure 2.

2) Analysis and discussion of existing international evidence based guidelines: The following thorough and up-to-date systematic critical literature reviews and international clinical guidelines [13-15, 36] were analysed and discussed by the work group.

3) Adaptation of evidence based recommendations to the Swedish context: The development of evidence based recommendations was based the Swedish National Board of Health and Welfare methods for guideline construction [37]. The overall grade of evidence together with a consensus position based on professional experience and patient net benefit versus harms and costs are the key aspects on which the work group has formulated local recommendations to reflect their strength [38]. The recommendations have been externally reviewed by local spinal physicians and international experts from the University of Southern Denmark. A summary of the Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of LBP with or without radiculopathy as well as the implementation tools used in the BetterBack☺ model of care is provided in the supplementary material to this protocol article.

4) Considering potential barriers to the uptake of evidence based recommendations by health care professionals [39] and patient adherence to LBP management interventions [40], the work group identified and discussed targeted physiotherapist and patient behaviour change priorities of relevance for BetterBack☺. The Behaviour Change Wheel [41] (figure 3) was used to describe how the BetterBack☺ model of care at the guideline policy level applies theory-informed HCP and patient focused intervention functions with specific behavioural change techniques [42]. To help understand the mechanism of action of behavioural change interventions, the Theoretical Domains Framework (TDF) [43] has been integrated into the Behavioural Change Wheel [41]. The TDF is comprised of 14 theoretical domains/determinants of behavioural change which can be matched with behavioural change techniques to understand their effect on the central source of behaviour [44]. The central source of behaviour in the behavioural change wheel is described by the COM-B model. In the COM-B model, a person's capability (physical and psychological), opportunity (social and physical) can influence on motivation (automatic and reflective) enacting behaviours that can then alter capability, motivation and opportunity [41]. The COM-B provides a broad model of behaviour where our causal assumptions of the BetterBack☺ model of care which are adapted from the TPB on a HCP level [21] and also adapted from the CSM on a patient level [22] can be applied in the Behavioural Change Wheel [41].

The first step in the BetterBack☺ model of care is to target HCP behaviour for the adoption of the

BetterBack☺ model of care. Impeding barrier behaviours requiring change include low awareness of the model, beliefs of negative consequences, a biomedical treatment orientation rather than a biopsychosocial orientation and primarily low beliefs about skills/capabilities for improving self-care patient management. Once HCP behaviour change has occurred, this can influence behaviour change on a patient level targeting patient understanding of the mechanisms and natural course of benign LBP and patient enablement of self-care. Impeding barrier behaviours requiring change include maladaptive beliefs on the cause and persistent course of LBP (low outcome expectation, anxiety, catastrophizing, fear-avoidance, and negative illness beliefs), contextual factors, low self-care enablement and low baseline physical activity. The potential outcomes of behavioural change could be improved illness beliefs, self-care enablement, pain, function, quality of life and health care utilization. The specific BetterBack☺ intervention content and mechanism of action for HCP behavioural change is outlined in table 3. A flow-diagram describing the BetterBack☺ model of care patient intervention process is displayed in figure 4.

Multifaceted implementation strategy for the BetterBack☺ model of care

The multifaceted implementation strategy is composed of the following 3 main facets:

1) Forming an **implementation forum** including head of departments/managers of the rehabilitation units and the clinical researchers.

- The implementation forum will collaborate on deciding overarching goals, timeline and logistics facilitating the implementation of the BetterBack☺ model of care in primary care rehabilitation clinic clusters in the Östergötland public health care region.

2) Forming a **support team** comprised of experience clinicians as local supervisors and faculty researchers as knowledge facilitators.

- The support team is composed by trusted clinicians with special skills in LBP treatment from each participating unit and have had involvement in the work group for local adaptation of the BetterBack☺ model of care in their health care region.

3) Forming a **package of education and training** that the support team can utilize to assist the use of the BetterBack☺ model of care by HCP.

- Physiotherapists in the 3 geographical clusters of public primary care rehabilitation clinics in Östergötland will be offered to participate in a 13.5 hours (2 days), continued medical education (CME) workshop. The workshop is designed by the support team with at least 2 clinical researcher and 1 experienced clinician (clinical champion) from the rehabilitation unit cluster present in the support team's delivery of the workshop for each cluster. The HCP education provided in the workshop format is described in supplementary file 2.
- Key components of the educational program are:
    - Education about evidence based recommendations for LBP care and the BetterBack☺ model of care through an experiential learning process applying problem based case studies and clinical reasoning tools.
    - Practical use of the standardized BetterBack☺ education and exercise programs aiming at self-care as well as function and activity restoration.
    - Access to a website describing the BetterBack☺ model of care. A chat forum will give an opportunity for clinicians to ask questions and share different experiences of the new strategy managed by the support team. Researchers will respond to questions from the participating clinicians.
- To consolidate education at the local clinics, the local support team member (clinical champion) will provide continued maintenance of education according to the BetterBack☺ model.

Outcomes

HCP outcomes:

1. Primary outcome measure

- Practitioner Confidence Scale (PCS) [45] mean change from baseline to 3 months post baseline. Practitioner reported confidence is the primary HCP behavioural change goal for the HCP education and training workshop in the multifaceted implementation of the BetterBack☺ model of care. The 3 month time frame allows for the development and consolidation of HCP behavioural change after application in repeated patient cases.

2. Secondary outcome measures

- PCS [45] mean immediate change from baseline to directly after the HCP education and training workshop as well as mean long term change from baseline to 12 months post baseline. This secondary outcome is important for the understanding of longitudinal HCP behavioural change.
- Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [46] mean change from baseline, to directly after the HCP education and training workshop as well as at 3 and 12 months post baseline.

Patient outcomes:

1. Primary outcome measure

- Numeric rating scale for lower back related pain intensity during the latest week (NRS-LBP) [47]. The mean difference between control and intervention groups in change between baseline and 3 months post baseline will be analysed. Pain intensity is the primary functional impairment that patients with LBP contact primary health care for and has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [48]. International consensus even recommends patient reported NRS change over 6 months as a core metric for pain management interventions [49].
- Oswestry disability index version 2.1(ODI) [50]. The mean difference between control and intervention groups in change between baseline and 6 months post baseline will be analysed. Disability, analogues to decreased physical functioning and activity limitation has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [48]. International consensus even recommends patient reported ODI change over 6 months as a core metric for functional restoration [49].

2. Secondary outcome measures

- NRS-LBP [47] and ODI [50] mean difference between control and intervention groups in short-term change from baseline to 3 months post baseline and mean long-term change from baseline to 12 months post baseline. These secondary outcomes are important for the understanding of longitudinal patient-rated changes in pain intensity and disability after primary care intervention.
- The European Quality of Life Questionnaire (EQ-5D) [51]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Health related quality of life has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [48]. International consensus even recommends patient reported EQ-5D change over 6 months as a core metric for pain management interventions [49].
- The Brief Illness Perception Questionnaire (BIPQ) [52]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Illness perception has been shown to predict longitudinal pain and disability outcomes in several LBP studies [53-57].
- Patient Enablement Index (PEI) [58], Patient Global Rating of Change (PGIC) [59] and Patient Satisfaction (PS) [60] mean difference between control and intervention groups at 3, 6 and 12 months post baseline will be analysed.

Health care process outcomes:

1. Primary outcome measure

- Proportional difference between control and intervention groups for incidence of participating patients receiving specialist care for LBP between baseline and 12 months after baseline. Incidence proportion, analogous to cumulative incidence or risk is calculated by taking the number of patients receiving specialist care of LBP and dividing it by the total number of patients recruited to the study. The main goal of both the control and interventions conditions in primary care for benign first-time or recurrent debut of LBP is to improve patient reported outcomes without the need of secondary or tertiary health care processes.

2) Secondary outcomes measures

- Mean difference between control and intervention groups for change between baseline and final clinical visit regarding grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP [61].
- The proportion of patients who receive the BetterBack☺ model of care.

Participant timeline

The trial timeline is shown in table 2. The intervention schedule started with the development of evidence based recommendations and the BetterBack☺ model of care which occurred during June 2016 - February 2017. The enrolment schedule started with cluster enrolment and randomisation in March 2017. This resulted in the first allocated cluster 1 (west) entering internal pilot of implementing the BetterBack☺ model of care HCP education and training workshop which occurred in March 2017. This was followed up with a 2 month internal pilot of patient enrolment schedule occurring in all 3 clusters during April-May 2017. In order to finalise a sample size calculation for the main trial, baseline data collected during the internal pilot is compared to follow-up data 3 months after baseline for the primary outcome measure questionnaires to analyse initial HCP and patient effects of the implementation of BetterBack☺ model of care in cluster 1 compared to the control conditions in clusters 2 & 3. In the transition to the main trial, patient enrolment and baseline assessments will then continue to occur until January 2018. The eventual time of crossing forward of cluster 2 into the implementation of the BetterBack☺ model of care is determined by the internal pilot trial results. Participants in the trial will be follow-up longitudinally at 3, 6 and 12 months after baseline measures. The schedule for assessments is also outlined in table 2.

Sample size

An initial sample size estimation in the planning stage of the study assumed at least a small Cohens d effect size (d=0.35) for the HCP behavioural change primary and secondary outcomes. This is based on previous literature showing small-moderate HCP behavioural change effects sizes using similar interventions to increase the uptake of evidence-based management of LBP in primary care [62-63]. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of BetterBack☺, 80% statistical power and a 20% loss to follow-up, a sample size of n = 63 HCP is needed for a matched pairs t-test statistics comparing baseline and follow-up means. We assume a possible carry-over of a similar effect size (d=0.35) on patient behavioural change primary and secondary outcomes. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of BetterBack☺ compared to usual care and a 80% statistical power, the number of patients required for an individually randomized simple parallel group design would be n = 204. Adjusting for the design effect due to clustering randomizing, an intracluster correlation of 0.01 and a cluster autocorrelation of 0.80, a dog leg design with 2 assessments in routine care and 100 patients in each cluster section would require at least n = 402 patients over 2.41 clusters according to algorithms described by Hooper & Bourke [32]. In a balanced recruitment schedule, this equates to 14 patient per months per cluster for a total of 3 clusters. Allowing for potential unbalanced recruitment flow and a potential drop-out in the longitudinal outcomes at 3, 6 and 12 months post baseline, each cluster will aim for up to 20 patients per month equating to a potential total study n = 600.

Recruitment

In an effort to curb recruitment difficulties, strategies to promote adequate enrolment of participants into the study will be used. We anticipate less problems with recruitment into the prospective cohort study design investigating the multifaceted implementation of the BetterBack☺ model of care on the HCP level. This is due to the study having a user-pull endorsed by clinical department managers calling all HCP working with patients with LBP at their clinics to participate. However, recruitment of patients into the cluster randomized controlled trial is dependent upon the feasibility of recruitment processes adapted to the context of each individual clinic and the compliance of HCP to administer recruitment of consecutive patients. A strategy to optimise the administration of patient recruitment will involve the author KS regularly visiting participating clinics to inform HCP of the study protocol and help streamline practical administration of the protocol in the context of the individual clinics. KS will also monitor weekly recruitment rates from the clinics and provide motivational feedback on recruitment flow to clinical department managers and designated clinical champions who will provide additional motivational feedback to HCP. In accordance with a Consolidated Standards of Reporting Trials, a flow diagram displaying participant enrolment, allocation, follow-up and analysis will be constructed [64]. Reasons for exclusion, declined participation, protocol violations and loss to follow-up will be monitored by KS.

Allocation and blinding

Random concealed allocation of clusters was performed by a blinded researcher randomly selecting from 3 sequentially numbered, opaque, sealed envelopes. The method resulted in the following order: 1=cluster west, 2=cluster central and 3=cluster east. The author KS informed the clinics in the different clusters of their allocation to the control or intervention study condition. Due to the nature of the study and intervention, HCP conducting patient measurements and treatment cannot be blinded to group allocation. Risk of bias is minimal as the primary and secondary outcomes are patient self-reported questionnaires. Patients will be blinded to group allocation. The researcher responsible for statistical analysis will not be blinded to group allocation but an independent statistician will review statistical analysis.

Data collection

HCP reported professional behaviour questionnaires:

- The PCS contains 4 items reported on 5-point Likert scales where a total score of 4 represents greatest self-confidence and 20 represents lowest self-confidence for managing patients with LBP. The structural validity in terms of internal consistency of the items have been shown to be good with a Cronbach α coefficient = 0.73 in a single factor model for self-confidence [45]. The questionnaire has been forward translated by our research group from English to Swedish.
- The PABS-PT consists of two factors where higher scores represent more treatment orientation regarding that factor. One factor with 10 items measures the biomedical treatment orientation (Score 0-60) and one with 9 items measures the biopsychosocial treatment orientation (Score 0-54) [45]. Each item is rated on a 6-point Likert scale ranging from 1='totally disagree' to 6='totally agree'. The internal consistency of the biomedical factor has been shown to be good with a range between Cronbach α=0.77-0.84. Futhermore, the biopsychosocial factor has been shown to be adequate with a range between Cronbach α=0.62-0.68 [65]. Construct validity and responsiveness to educational interventions has been shown to be positive along with the test-retest reliability with reported intra-class correlation coefficient (ICC) on the biomedical factor=0.81 and on the biopsychosocial factor=0.65 [65]. The questionnaire has been forward translated from English to Swedish in a previously published study [66].
- The Determinants of Implementation Behaviour Questionnaire (DIBQ) was originally constructed based on the domains of the TDF [43, 67]. Confirmatory factor analysis resulted

in a modified 93 item questionnaire assessing 18 domains with sufficient discriminant validity. Internal consistency of the items for the 18 domains was good, ranging from 0.68-0.93 for the Cronbach α coefficient [68]. The questionnaire has been forward translated by our research group from English to Swedish. After face validity consensus in our research group regarding relevant domains for the implementation of BetterBack☺ model of care, the questionnaire was shortened to the following domains: Knowledge, Skills, Beliefs about capabilities, Beliefs about consequences, Intentions, Innovation, Organisation, Patient, Social influence, Behavioural regulation totalling to 57 items. Questions were adapted to the context of HCP reported determinants of an "expected" implementation of BetterBack☺ model of care for measurement directly after the HCP education and training workshop. HCP reported determinants retained orginal wording for the questionnaires at 3 and 12 months after the implementation of BetterBack☺ model of care. The response scale used for each DIBQ question in our study is a 5-point Liket scale ranging from 1= `totally agree´ to 5=`totally disagree´.

Patient reported outcome measures:

- NRS-LBP intensity during the latest week is an 11-point scale consisting of integers from 0 through 10; 0 representing ''No pain'' and 10 representing ''Worst imaginable pain''. Previous research in a LBP cohort has shown a test-retest reliability ICC = 0.61, a common standard deviation=1.64 points, the standard error of measure = 1.02 and minimal clinically important difference (MCID) in LBP after treatment=2 [69,70].
- ODI version 2.1 assesses patient's current LBP related limitation in performing activities such as personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. The ODI consists of 10 items with response scales from 0 to 5, where higher values represent greater disability. The ODI is analysed as a 0 to100 percentage variable where lower scores represent lower levels of low back pain disability. A reduction of 10 points is considered the MCID in LBP after treatment [50,70]. In Scandinavian conditions, the coefficient of variation, ICC and internal consistency of the ODI is 12%, 0.88-0.91 and 0.94 respectively [71-73]. Good concurrent validity has also been shown [72].
- The EQ-5D measures generic health-related quality of life and is computed into a 0 to 1.00 scale from worst to best possible health state by using the Swedish value sets [74]. A reduction of 0.08 points is considered the MCID in LBP after treatment [75]. Mean change after treatment for LBP has been reported to be 0.12 (SD±0.30) [76].
- The BIPQ analyses cognitive illness representations (consequences, outcome expectancy, personal control, treatment control, and knowledge), emotional representations (concern and emotions) as well as illness comprehensibility. An overall score 0-80 represents the degree to which the LBP is perceived as threatening or benign where a higher score reflects a more threatening view of the illness [52]. The BIPQ has been shown to be valid and reliable in a Scandinavian sample of patients with subacute and chronic LBP. The BIPQ has a Cronbach's alpha =0.72 and a test-retest ICC = 0.86, an ICC range for individual items from 0.64 to 0.88, a standard error of measurement (SEM) = 0.63 and minimal detectable change (MDC) = 1.75[77].
- The PEI has a score range between 0 and 12 with a higher score intended to reflect higher patient self-care enablement [58].
- PGIC asks the patient to rate the degree of change in LBP related problems from the beginning of treatment to the present. This is measured with a balanced 11 point numerical scale. A reduction of 2 points is considered the MCID in LBP after treatment [59].
- PS is measured with a single item patient reported question. The question asks "Over the course of treatment for this episode of low back pain or leg pain, how satisfied were you with the care provided by your health-care provider?" Were you very satisfied (1), somewhat satisfied (2), neither satisfied nor dissatisfied (3), somewhat dissatisfied (4), or very dissatisfied (5)?'' [60].

Health care process measures:

- At 12 months after baseline, data will also be extracted from the public health care regional registry for the total number of patient visits for LBP, the number patients needing primary care multimodal pain team treatment, the number referred to specialist pain clinic, orthopedic or neurosurgical care and the number receiving surgery.
- Clinical reasoning and process evaluation tool (CRPE-tool): Grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP is assesses by the physiotherapist at baseline and final clinical contact where light, moderate, severe and very severe impairment/limitation is coded 0-4 respectively. A total score for baseline and follow-up measures is calculated from the sum of the functional impairment divided by the number of functional impairments and a similar total score is calculated for activity limitations [61]. ICD-10 diagnosis codes and Swedish Classification of Health Interventions (KVÅ) codes for treatment interventions will also be recorded.
- The Keele STarTBack Screening Tool is reported by patients at baseline providing a stratification of prognostic risk of persistent pain. The overall score ranging from 0-9 is used to separate the low risk patients from the medium-risk subgroups where patients who achieve a score of 0-3 are classified into the low-risk subgroup and those with scores of 4-9 into the medium-risk subgroup. To identify the high-risk subgroup, the last 5 items must score 4 or 5 [78-80]. The CRPE-tool data will be analysed in terms of STarTBack tool subgroups.
- Qualitative SWOT analyses will be performed by HCP between 3-6 months after implementation.
- Semi-stractured interviews with 10 HCP at 3 months after implementation will be conducted to investigate determinants of implementation behaviour and if other determinants need to be added to the DIBQ. The interviews will be deductively analysed according to the TDF [41] and BTW [43] frameworks.
- Semi-structured interviews investigating the patient experience of recieving care for LBP will be performed on 10 patients. These patients will have received care after implementation of the BetterBack☺ model of care.

Data management

All paper based questionnaire data will remain confidential and will be kept in a lockable filing cabinet in the research group office. A password-protected coded database only accessible to the research team will be kept on a data storage drive in the research department. The research team will regularly monitor the integrity of trial data. Trial conduct will be audited on a weekly basis by the research team.

Statistical analysis

Statistical significance will be assessed with an alpha level of 0.05. All results will be reported as estimates of mean ± standard deviation and also effect size (e.g. mean difference) with 95% confidence intervals (95% CI). An intention-to-treat (ITT) principle applying multiple imputation will be utilised. A sensitivity analysis will compare per protocol and ITT databases. A sensitivity analysis will also be used to assess the significance of a washout period by comparing the complete database against the same database without data collected during the 2 weeks in conjunction with the Betterback☺ implementation in each cluster. ANOVA statistics comparing baseline and follow-up means will be used for the HCP reported primary and secondary outcomes. Causal mediation analysis will be used to analyse indirect mediational effects of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education and training workshop (intention stage) or at 3 or 12 months (volition stages) on the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT. If the HCP education and training workshop does not have a casual effect on improved prospective outcomes we will

analyse where the causal pathway breaks down. Causal mediation analysis will be performed using the program PROCESS [81] within IBM SPSS (figure 5).

Patient reported outcome measures for the control and intervention groups will be compared using multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects with IBM SPSS. Fixed effect interactions between experimental condition and The Keele STarT Back Screening Tool will also be assessed. Patient population specific minimal clinically important difference will be assessed för primary and secondary outcomes based on an anchor method where PGIC serves as an anchor.

Applying a 1-1-1 multilevel mediation procedure with all effects random in MPLUS, the products of (1) the independent variable (Experimental condition: control or intervention) to the mediator (change in BIPQ), and (2) the mediator to the dependent variable (change in NRS, ODI or secondary outcome scores pre- to posttreatment) when the independent variable is taken into account, will be tested for mediation (figure 6).

The EQ5D will be used to calculate the ratio of costs to quality adjusted life years (QALY) saved for patients. Incremental cost-effectiveness and cost-utility ratios for the multifaceted implementation strategy and the usual care condition will be calculated. This is based on the Swedish guideline priced direct costs of health service utilisation, costs of medications and overall intervention clinical outcome effectiveness and social security system utilisation (sickness benefits) as well as indirect productivity costs due to absenteeism and return to work.

Data monitoring

All outcome questionnaires are formatted for use of scan processing software for automated data entry into the Statistical Package for the Social Sciences package. The author KS who is not blinded to treatment allocation will perform regular data checks during data entry and provide feedback when necessary to HPC regarding data omissions. JS will also double check data entry to detect and correct input errors, and range checks will be undertaken prior to data analysis.

Ethics and dissemination

Ethical clearance for the study (Dnr:2017-35/31) has been attained through the Regional Ethics Committee in Linköping.

Internal pilot trial results

The initial implementation of the BetterBack☺ model of care in cluster 1 allowed for an internal pilot to determine the HCP acceptability of the intervention and trial within the first cluster [34,35]. A progression criteria for continuing to the main trial required that HCP who have completed the BetterBack☺ education anf training workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ model of care will be useful (1 = agree completely - 5 = do not agree at all). The 27 HCP participating in the internal pilot in cluster 1 responded to the question with a mean value of 1.7 (SD 0.8) which subsequently fulfilled the HCP progression criteria.

The resulting internal pilot patient flow for april and may were n=28, n=28 for cluster 1 west (intervention) , n=5, n=12 for cluster 2 central (control) as well as n=14, n=22 for cluster 3 east (control) consecutively. This informed the decision to move the cluster 2 transition from control to intervention condition to occur later in the schedule, planned for september 2017 to allow for more control condition patient recruitement and data collection. The flow of patient recruitment and the process of 3 month follow-up in the internal pilot was used to inform the optimal time point of patient reported primary outcome for the main trial. Our initial planning was to measure patient reported primary outcome at 6 months post baseline based on the definition of

persistence/chronicity of symptoms being often defined in the literature to be of 3 and up to 6 months duration [82]. Our intern pilot study had a 3 month follow rate of 80% resulting after up to 3 reminders sent to many of these patients. This informed of a likely risk of non-response at later follow-up time points. Furthermor, feedback from participating HCP even reported a larger clinical interest in 3 month patient follow-up data. Therefore the internal pilot informed the choice to revise our patient reported primary outcomes to 3 month post-baseline with subsequent amendments of the trial registration on ClinicalTrials.gov: NCT03147300.

Our internal pilot study was also used to assess baseline variation and change over 3 months in HCP evaluation and patient reported primary outcome measures in the control and intervention arms to aid calibration of the sample size calculation. A multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects revealed a intracluster correlation of <0.01 for the all primary outcomes measures. Small effect sizes in favour of the intervention condition was shown for PCS (d=0.33) and NRS (d=0.28) primary outcome measures. Therefore, the internal pilot data supported our a priori sample size calculation for the main trial regarding PCS and NRS. However no effect size difference were observed between experimental conditions for ODI. It is possible that when statistical power improves within the main trail, potential differences in ODI may be detectable between experimental conditions.

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Authors' contributions: AA & BÖ formulated the trials orginal aims and hypothesis. AA, KS, BÖ developed interventions material. AA, KS, PE, PN, ÖB designed the study methodology. AA, PN, BÖ procured funding for the trial. AA, KS, PE, PN, ÖB have reviewed and finalised the protocol.

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Table 1. World health organisation trial registration data set.

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03147300
Date of registration in primary registry	03 May, 2017
Prospective Registration:	Yes
Secondary identifying numbers	N/A
Source(s) of monetary or material support	Linköping University
Primary sponsor	Linköping University
Secondary sponsor(s)	N/A
Contact for public queries	*Allan Abbott*, MPhysio, PhD [+46 (0)13 282495] [allan.abbott@liu.se]
Contact for scientific queries	*Allan Abbott*, MPhysio, PhD Linköping University, Linköping, Sweden
Public title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain BetterBack
Scientific title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain in Sweden (BetterBack): A Cluster Randomised Trial
Countries of recruitment	Sweden
Health condition(s) or problem(s) studied	Low back pain
Intervention(s)	Behavioral: Current routine practice Behavioral: Multifaceted implementation of the BetterBack
Key inclusion and exclusion criteria	Health care practitioner sample Inclusion Criteria: - Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP Patient sample Inclusion Criteria: - Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a current episode of a first-time or recurrent debut of benign low back pain with or without radiculopathy Exclusion Criteria: - Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfill criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis
Study type	Interventional
Date of first enrolment	April 1, 2017
Target sample size	600
Recruitment status	Recruiting
Primary outcome(s)	- Incidence of participating patients receiving specialist care [Time Frame: 12 months after baseline] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Change between baseline and 3 months post baseline] - Oswestry disability index (ODI) version 2.1 [Time Frame: Change between baseline and 3 months post baseline] - Practitioner Confidence Scale (PCS) [Time Frame: Change between baseline and 3 months post baseline]
Key secondary outcomes	- Clinician rated health care process measures [Time Frame: Baseline and final clinical contact (Up to 3 months where the time point is variable depending upon the amount of clinical contact required for each patient)] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Baseline, 3, 6 and 12 months] - Oswestry disability index (ODI) version 2.1 [Time Frame: Baseline, 3, 6 and 12 months] - Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [Time Frame: Baseline, directly after education and at 3 and 12 months afterwards] - Patient Enablement Index (PEI) [Time Frame: 3, 6 and 12 months] - Patient global rating of change (PGIC) [Time Frame: 3, 6 and 12 months] - Patient satisfaction [Time Frame: 3, 6 and 12 months] - Practitioner Confidence Scale (PCS) [Time Frame: Baseline, directly after commencement of implementation strategy and at 3 and 12 months afterwards] - The Brief Illness Perception Questionnaire (BIPQ) [Time Frame: Baseline, 3, 6 and 12 months] - The European Quality of Life Questionnaire (EQ-5D) [Time Frame: Baseline, 3, 6 and 12 months]

Table 2. Study design and schedule of enrolment, interventions and assessments.

Timeline		June 2016 - Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Final clinic visit	Follow-up 3 months after baseline	Follow-up 6 months after baseline	Follow-up 12 months after baseline
Enrolment schedule			HCP Cluster random allocation	Patient recruitment during internal pilot phase		Patient recruitment during main trial phase											
Intervention schedule		MOC and protocol development	Cluster 1 West MOC implementation internal pilot	1	1	1	1	1	1	1	1	1	1				
			Cluster 2 Central	0	0	0	0	0 MOC implementation	1	1	1	1	1				
			Cluster 3 East	0	0	0	0	0	0	0	0	0	0 MOC implementation				
Assessment schedule				Baseline data Internal pilot (T=0)		Baseline data Main trial (T=0)								Longitudinal repeated measures in cohorts (T=1)	(T=2)	(T=3)	(T=4)
HCP implementation	**PCS**		Cluster 1 before and after MOC implementation					Cluster 2 before and after MOC implementation					Cluster 3 before and after MOC implementation		x		x
	PABS-PT		Cluster 1 before MOC implementation					Cluster 2 before MOC implementation					Cluster 3 before MOC implementation		x		x
	DIBQ		Cluster 1 after MOC implementation					Cluster 2 after MOC implementation					Cluster 3 after MOC implementation		x		x
PROMS	**NRS back pain and leg pain**			x	x	x	x	x	x	x	x	x	x		x	x	x
	ODI			x	x	x	x	x	x	x	x	x	x		x	x	x
	EQ5D			x	x	x	x	x	x	x	x	x	x		x	x	x
	BIPQ			x	x	x	x	x	x	x	x	x	x		x	x	x
	PEI														x	x	x
	Patient satisfaction														x	x	x
	PGIC														x	x	x
Process	**HCP assessment, diagnosis and treatment of patients**			x	x	x	x	x	x	x	x	x	x	x			
	Referrals to specialist care																x

MOC=model of care, 0=Control condition, 1=Intervention condition, PROMS=Patient reported outcome measures, grey shaded cells=internal pilot, T= assessment time. ◄► Period where 2 week cross-over from control to intervention can occur dependent upon patient recruitment rates identified in the internal pilot study.

Table 3. Characterizing the BetterBack☺ model of care intervention content and mechanisms of action using the behaviour change wheel [41], Behavioural change technique (BCT) taxonomy (v1) [42], and the TDF [43].

Target behavior	Rationale based on barriers to be addressed	BetterBack☺ Intervention content to overcome the modifiable barriers				Mechanism of action	
		Mode	Content	BCT[42]	Functions	COM-B	TDF
Improved HCP confidence and biopsychosocial orientation in treating LBP through adoption of BetterBack☺ model of care	1) Low beliefs about skills/capabilities for improving self-care patient management 2) Use of a biomedical treatment orientation rather than a biopychosocial orientation 3) Low awareness of the model 4) Beliefs of negative consequences of the model	1) Workshop	Evidence based model of care and clinical implementation tools (See supplementary files 1 & 2)	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				1.4 Action planning	Enablement	Psychological capability	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.3 Information about social and environmental consequences	Persuasion	Social opportunity Physical opportunity	Social Influences Environmental context and resources
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.2 Pros and cons	Persuasion	Reflective motivation	Beliefs about Consequences
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		2) Report and website dissemination	Evidence based model of care and clinical implementation tools (See supplementary file 2)	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
Decreased patient LBP and disability as well as improved patient enablement of self-care	1) Maladaptive beliefs on the cause and course of LBP (Illness perception) = low outcome expectation, anxiety, catastrophizing, fear-avoidance, illness beliefs. 2) Low belief in ability to control pain. Low belief in ability to perform activities, low baseline physical activity.	1) BetterBack☺ Part 1. Individualised information at initial and follow-up visits.	Lay language pedagogical explanation of function impairment and activity limitation related assessement findings and matched goal directed treatment designed for these.	5.1 Information about health consequences	Education	Psychological capability	Knowledge
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
		2) BetterBack☺ Part 1. Patient education brochure	Lay language education on the spine's structure and function, natural course of benign LBP and advice on self-care	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
		3) BetterBack☺ Part 2. Group education	Pain physiology, biomechanics, psychological coping strategies and behavioural regulation	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform	Education	Psychological capability	Knowledge

				behaviour			
				4.3 Re-attribution	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.2 Behaviour substitution	Enablement	Psychological capability	Behavioral regulation
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				10.8 Incentive (CME diploma)	Enablement	Reflective motivation	Reinforcement
				11.2 Reduce negative emotions	Enablement	Reflective motivation	Emotion
				12.4 Distraction	Enablement	Reflective motivation	Memory, attention and decision processes
				12.6 Body changes	Training	Physical capability	Physical skills
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
		4) BetterBack☺ Part 1. Individualised physiotherapy	Physiotherapist mediated pain modulation strategies and functional restoration strategies. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				7.1 Prompts/cues	Environmental restructuring	Automatic motivation	Environmental Context and Resources
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		5) BetterBack☺ Part 2. Group or home based physiotherapy	Patient mediated self-care pain modulation strategies, functional restoration strategies and general exercise. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				1.8 Behavioural contract	Incentivisation	Reflective motivation	Intentions
				2.3 Self-monitoring of Behaviour (Training diary)	Training	Reflective motivation	Behavioral regulation
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities

Figure 1. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

Figure 2. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack☺ model of care for LBP.

Figure 3. The Behavioral Change Wheel [43] and TDF [41].

Figure 4. BetterBack☺ model of care for LBP.

Figure 5. Causal mediation model to analyse indirect mediational effects ($a^k b^k$) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c').

Figure 6. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=c_j', indirect=$a_j b_j$, and total effects= $c_j' + a_j b_j$) are allowed to vary between level-2 clusters.

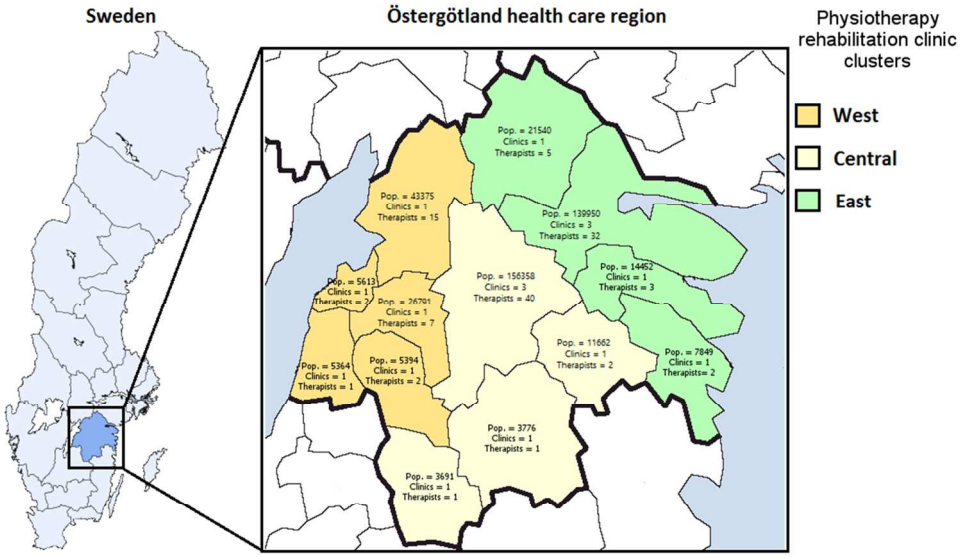

Figure 1. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

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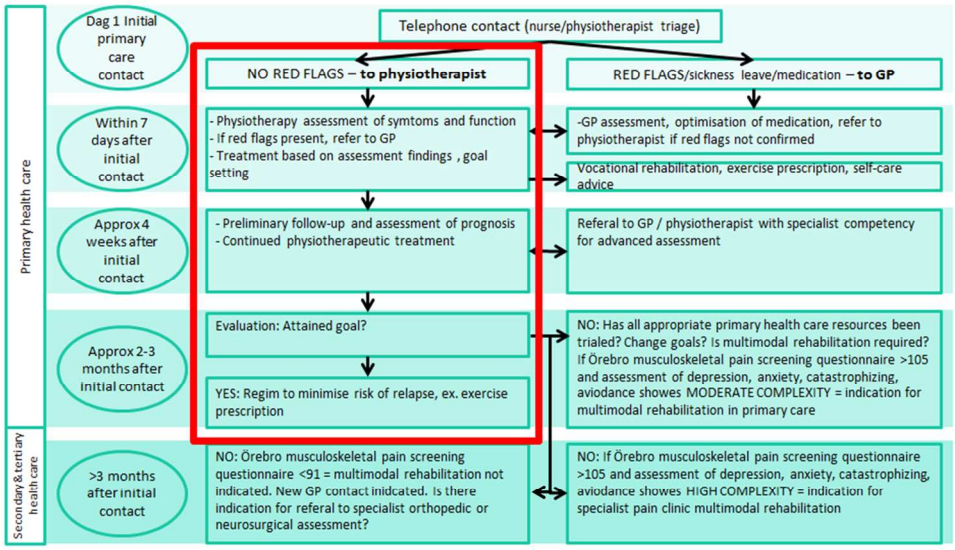

Figure 2. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack9 model of care for LBP.

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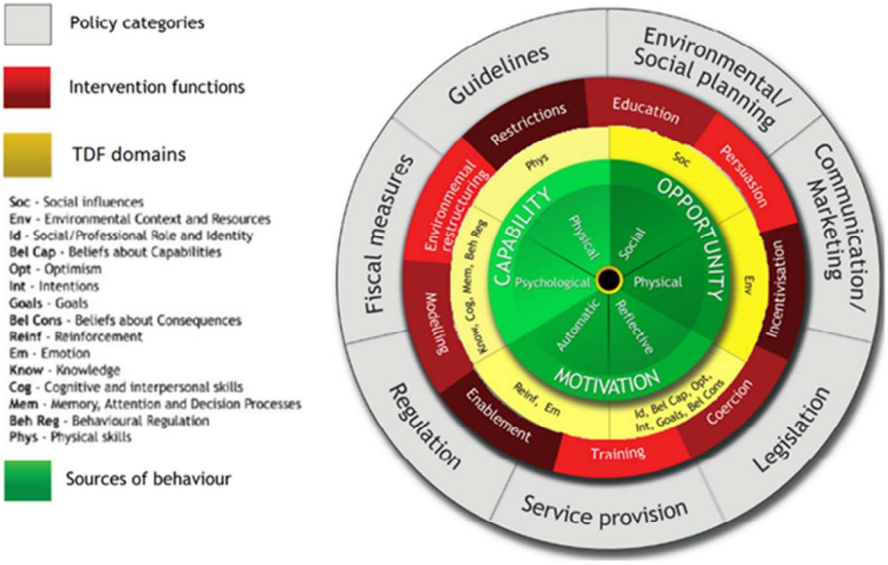

Figure 3. The Behavioral Change Wheel [43] and TDF [41].

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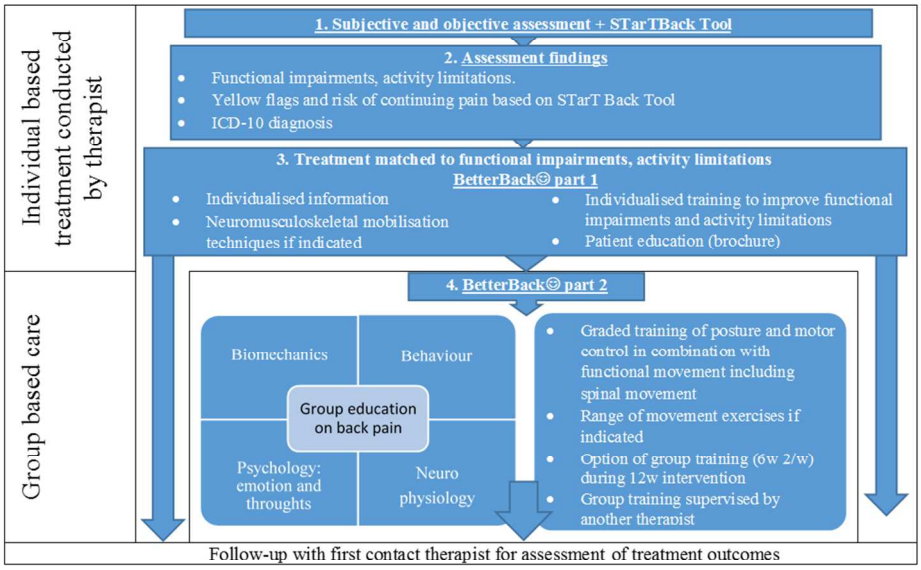


Figure 4. BetterBack model of care for LBP.

93x67mm (300 x 300 DPI)

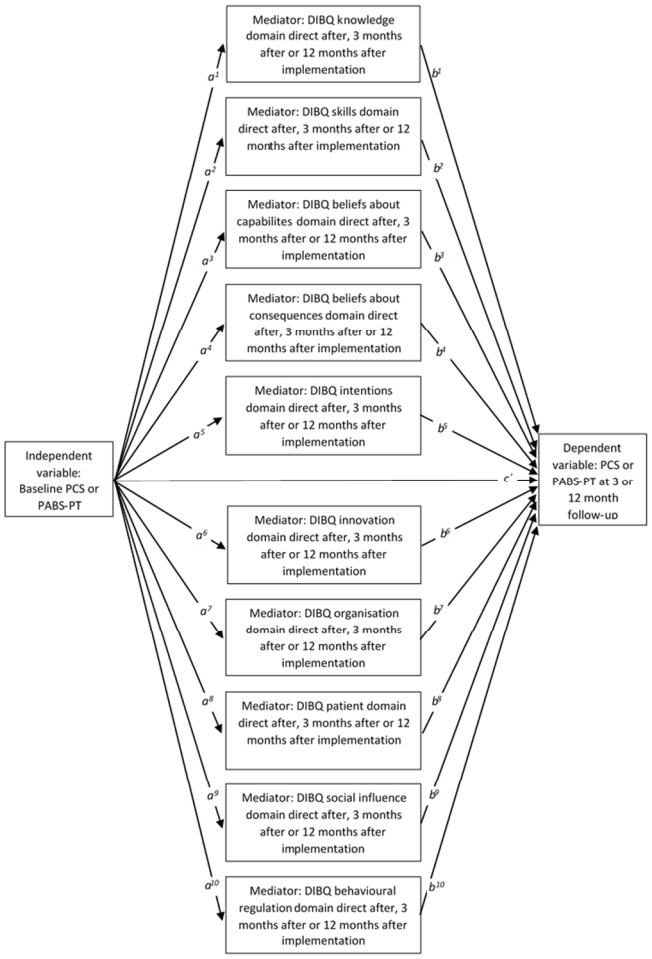


Figure 5. Causal mediation model to analyse indirect mediational effects (akbk) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c´).

67x118mm (300 x 300 DPI)

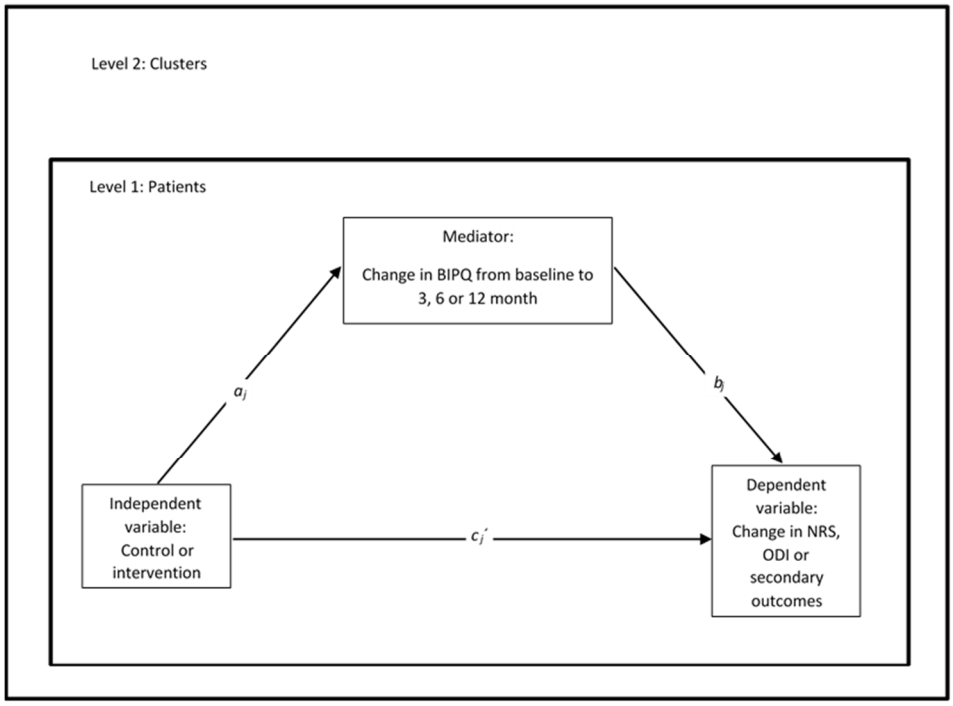


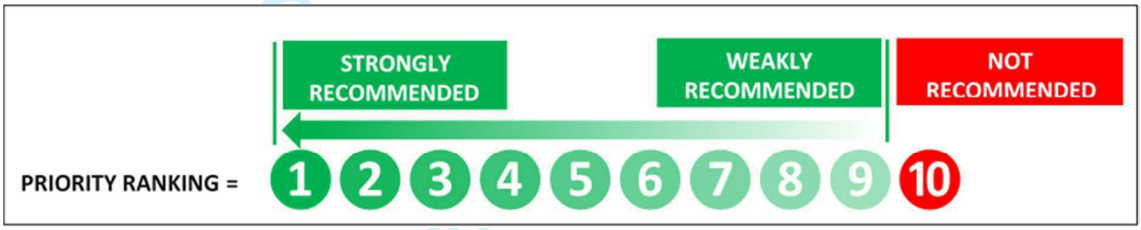
Figure 6. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=cj´, indirect=ajbj, and total effects= cj´+ ajbj) are allowed to vary between level-2 clusters.

71x59mm (300 x 300 DPI)

BetterBack☺ Model of care for LBP

Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of benign LBP with or without radiculopathy

Each evidence based guideline recommendation is supported by a clinical priority ranking. This is based on an overall assessment of the severity of the condition, reported effect of the intervention, strength of evidence assessment (GRADE), cost-effectiveness and the benefit of the intervention based on professional experience and patient benefit. A scale from 1 to 10 is used where the number 1 indicates recommended practices with the highest priority while the number 9 indicates recommended practices of low priority. The number 10 indicates recommendations that provide very little or no benefit or utility and are therefore not recommended.



Recommendation 1	PRIORITY RANKING = 1 2 3 4 5 6 7 8 9 10
Routine care should consist of standardised processes for subjective and objective assessment and diagnostics. A thorough screening of red flags is essential to rule out serious pathology. Treatment should be individualised for each patient. Basic treatment principles should be based on reassurance of a good prognosis, maintenance of appropriate physical activity and self-care enablement. Justification: The work group's reasoning is based on clinical experience of the importance of careful screening to rule out serious pathology. Furthermore, standardised assessment and diagnostics provide quality assurance but treatment needs to be individualised for each patient case. The work group also reasoned based on clinical experience that appropriate physical activity is likely to contribute to maintaining the patient's functional level, psychosocial and general health as well as have positive effects on self-care enablement. In some cases, may physical activity temporarily aggravate pain and symptoms, but there are no known persisting side effects. The work groups reasoning is also based on evidence showing a statistically significant advantage for maintaining appropriate physical activity compared to bed rest for improving pain and function. Despite this, evidence that proves the benefit of appropriate physical activity is so great to be clinically relevant is missing. In addition, the best available evidence has however a currently limited scientific basis (⊗⊗○○). *The working group proposes the following resources in the BetterBack☺ model of care to support the implementation of Recommendation 1 (See sections 1-5)*	
Recommendation 2	**PRIORITY RANKING = 1 2 3 4 5 6 7 8 9 10**
Do not perform routine medical imaging investigations (eg X-ray, CT, MRI) Justification: The work group´s reasoning is based on evidence that shows no differences in outcomes of pain, function and quality of life between patients who received or did not receive	

routine medical imaging investigations in the primary care context. The best available evidence has however a currently inadequate scientific basis (⊗○○○). It was also discussed that imaging cannot confirm or reject a preliminary diagnosis as the relationship between patient symptoms and degenerative imaging finding is usually weak. Moreover, degenerative secondary findings are common in asymptomatic individuals. *The work group however suggests that early use of medical imaging is motivated in the presence of symptoms or signs suggesting possible serious underlying pathology (red flags). Medical imaging may also be relevant when pain persists despite primary care treatment.*

Recommendation 3	**PRIORITY RANKING =** 1 2 3 4 5 **6** 7 8 9 10

Consider using a patient-reported tool (eg STarT Back risk assessment tool) as usual care during the early-stages of patient management to screen the risk of continued LBP

Justification: The work group's reasoning is based on studies showing that STarT Back Tool is the only valid tool to investigate the risk of continued back pain in the primary care context. It shows the highest accuracy for detecting patients with low risk profile (total score ≤3) and medium-high risk profile (total score ≥4) for continued back pain. Studies also show that STarT Back Tool has the best ability to predict functional and pain-related outcomes. The best available evidence has however a currently inadequate scientific basis (⊗○○○). No economical evaluations were identified but the working group discussed the importance of a simple and fast tool. STarT Back Tool can be filled in and analyzed in a few minutes to advantage over other tools that can be an administrative burden for patients and healthcare professionals. *The working group argues that the predictive value of the tool should support, but not replace, regular examination procedures and clinical decision making. See section 3 for STarT Back Tool.*

Recommendation 4	**PRIORITY RANKING =** 1 2 3 4 5 6 7 **8** 9 10

Consider using a patient-reported tool (such as the STarT Back risk assessment tool) and classification of examination findings during the early-stages of patient management to aid the stratification of care to prevent continued LBP

Justification: The work group reasoned that for the choice and scope of targeted treatment measures, consideration should be given to the assessment of risk profile for long-term LBP and classification of examination findings. This has been shown to have a better effect on pain, function and quality of life, as well as less economic costs compared to no treatment stratification. The best available evidence has however a currently inadequate scientific basis (⊗○○○). For a patient with low risk profile (total score ≤3 on STarT Back Tool) usual care is relevant and requires only few visits, but the working group recommends that adequate treatment measures directed at examination findings is of the highest importance. For patients with medium-high risk profile (total score ≥ 4 on STarT Back Tool), usual care will require additional visits. Information provided in questions 5-9 on STarT Back Tool that investigate anxiety with psychological risk factors can guide the need, focus and extent of behavioral medicine measures. *The working group argues that stratified care classified after assessing a risk profile for long-term back pain should support but not replace conventional examination procedures and clinical decision-making for treatment measures. The working group proposes the following resources to support the implementation of targeted treatments based on stratification (See sections 1-5).*

Recommendation 5	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider giving individualised patient education as a part of usual care (e.g. an explanatory model based on pain neuroscience and psychological mechanisms)

Justification: Based on the best available evidence, the work group reasoned that individualised patient education as part of usual care can result in reduced work sickness absenteeism. The priority of the recommendation has been strengthened by consensus within the work group based on proven experience that individual adapted patient education is an important part of patient-centered care. The best available evidence has however a currently inadequate scientific basis (⊗○○○). The intervention requires that the patient is receptive for education. The extent of patient education can depend upon whether the patient has a distorted image of the underlying mechanism of LBP and a high degree of negative outcome expectations, anxiety, and fear-avoidance or if they are inactive or passive in managing the LBP. Patient education should include a reassuring dialogue and other cognitive and behavioural therapeutic techniques of relevance to support change in the individual's maladaptive thoughts, feelings and behaviors. Pedagogical explanation models should be used to provide the patient with knowledge about symptoms and disorders, as well as to strengthen and support self-care ability to master everyday activities. *The work group proposes the following resources to support of the implementation of patient education (See sections 6-7)*

Recommendation 6	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider a supervised exercise program as part of usual care

Justification: Supervised training is defined as general or back-specific exercises or physical activities conducted under the guidance of a healthcare professionals. The work group's reasoning is based on scientific evidence and proven experience that supervised training as part of usual care can result in clinically relevant improvement in pain, function, quality of life and produces lower health care costs compared with no supervised training. There is however no evidence that a specific type of exercise would be superior to another. The best available evidence has however a currently limited scientific basis (⊗⊗○○).

The work group proposes the following resources to support the implementation of a supervised training program (see section 8).

Recommendation 7	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider mobilisation techniques for neuromusculoskeletal structures as part of usual care (including active or passive motion in an angular and / or translational plane)

Justification: The working group reasoning is based on evidence that for patients with segmental movement impairments, mobilization techniques can provide a statistically significant reduction in short-term pain. It is however uncertain whether the effect is sufficiently large so that patients experience a clear improvement overtime. At group level, there is no evidence that a particular technique is be superior to another. It cannot be ruled out that for subgroups of LBP patients, more positive effects on pain and function may be produced by specific mobilisation techniques. It is expected that these subgroups can be identified by careful diagnostics and short trial treatments. Mobilizing techniques as part of multimodal treatment provide better results. Serious side effects are rare. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○).

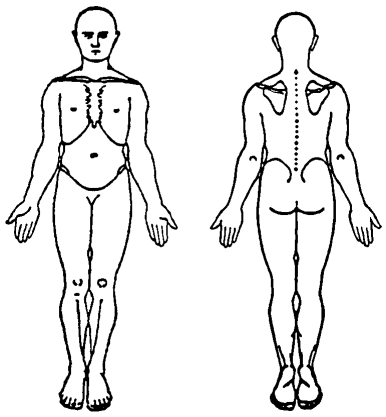
Recommendation 8	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 **9** 10

Consider acupuncture treatment in addition to usual care

Justification: The working group reasoned based on evidence that cannot exclude acupuncture has a short-term pain relief effect in addition to a placebo effect. Acupuncture has however no effect on function. Side effects in the form of brief superficial bleeding or inflammation may occur.

Pneumothorax and systemic infections are not common, but the prevalence is unknown. The best available evidence has however a currently inadequate scientific basis (⊗○○○).	
Recommendation 9	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer corset, shoes, traction, ultrasound or electrotherapy Justification: The work group's reasoning is based on evidence that passive treatments such as corset, shoots / soles, traction, ultrasound or electrotherapy do not reduce pain or improve function and quality of life in patients more than no treatment or when offered as part of multimodal treatment. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○). ***It cannot be ruled out that subgroups of patients may experience positive effects of these interventions when a hypothesised effect mechanism is aimed at specific functional impairment or activity limitation.***	
Recommendation 10	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Consider prescription-free NSAID medication if necessary in addition to usual treatment (lowest dose and shortest possible treatment time). NSAIDs: There is evidence of the effect of NSAID in patients with long-term LBP but the effect has not been highlighted on short-term pain or functional outcomes. There are no adverse reactions reported in systematic review studies on LBP, but potential transient side effects of NSAIDs such as reduced blood clotting, reduced stomach mucous function and reduced kidney function are known from studies on other conditions. The work group reasoned that lowest dose and shortest possible treatment time decreases the risk of side-effects. The work group anticipates that there are differences in patient preferences regarding NSAIDs, where some patients will agree to NSAID treatment, while others will decline. The best available evidence for NSAID effects on LBP outcomes is based on an inadequate scientific evidence (⊗○○○). The work group reasoned based on clinical experience that it cannot be excluded that the NSAID may have a pain relief effect in the short term.	
Recommendation 11	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer paracetamol or opioids Paracetomol: Has no effect on the degree of LBP and functional ability. There are no reported adverse reactions in studies, but side effects of paracetamol in the form of hepatic effects are known from studies on other conditions. The best available evidence is based on a moderately strong scientific basis (⊗⊗⊗○). Opioids: A weak analgesic effect of oxycodone in combination with paracetamol has been demonstrated in a study but the intervention has no effect on functional capacity for up to 12 weeks. Other positive effects or adverse effects were not shown. A wide range of opioid side effects are known from other studies. Therefore, the working group reasoned that treatment results in more risks than benefits to the patient. The best available evidence is based on a currently limited scientific basis (⊗⊗○○).	

BetterBack☺ model of care implementation support tools

LOW BACK SUBJECTIVE ASSESSMENT PROFORMER			
Name:…… Date of birth:…… Date:……			
History of the present condition (debut, duration, activity limitation)	**Symptom localisation** 		
Symptom Description	Localisation back	Localisation right leg	Localisation left leg
Pain nature (Dull, stabbing, radiating etc)			
Pain frequency (Constant/ Intermittent)			
Pain Intensity (NRS 0-10)			
Daily variation (am/pm, night time pain/disturbed sleep)			
Irritability (non-irritable/highly irritable)			
Aggravating factors (loading etc)			
Easing faktors (rest etc)			
Course (Improving/same/worse)			
Other symptoms (Instability, weakness, paresthesia, stiffness)			
Past medical history Previous level of function/activity: Previous treatment:	Red flags: (malignancy, unexplained weight loss, trauma, osteoporosis, infection, inflammatory disease, spinal cord compression symtoms, drug use) Other illnesses/ General health:		
Work, Social, Family history	**Patient förväntningar**		
Medication	**Medical imaging/Laboratory tests**		

1. Subjective assessment proformer for therapist use

2. Physical assessment proformer

LOW BACK PHYSICAL ASSESSMENT PROFORMER

1. INSPECTION – Postural screen

Sitting: good/fair/poor	Postural correction: Better/Worse/No effect	
Standing: good/fair/poor	Postural correction: Better/Worse/No effect	
Lordosis: Hyper/hypo/normal	Kyphosis: Hyper/hypo/normal	Lateralt shift: Right/Left/none
Spinal symmetry:	Shoulder symmetry:	Pelvic symmetry:
Leg & fot symmetry:	Muscular hypo/hypertrophy:	Scars:

2. SCREENING OF FUNCTIONAL MOVEMENT:

Shoes on/off, sit-stand, 2 leg/ 1 leg squat, lunge right/left

Gait: Trendelenburg right/left
Limp right/left
Weight transfer right/left
Toe walking right/left
Heel walking right/left

Work or sport specific:_____

3. SCREENING TEST IN STANDING/SITTING

	Right	Left
Slump test + sensitisation head/foot		
Foramen compression/unloading		
Hip loading/unloading in standing		

4. TEST IN STANDING/SITTING
LUMBAR ACTIVE ANGULAR MOVEMENT

	Range			Quality		Symptoms		
	Large	Med	Small	High	Low	During range	End range	Rep Mov
Flex								
Ext								
Lateral flex	R L	R L	R L	R L	R L	R L	R L	R L
Side Glide	R L	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L	R L

5. TEST IN SIDE LYING
LUMBAR PASSIVE ANGULAR MOVEMENT

	Range			Symptoms			
	Large	Med	Small	During range	End range	Rep Mov	Over press
Flex							
Ext							
Lat flex	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L

6. PRONE
ACCESSORY MOVEMENT/NERVE & MUSCLE FUNCTION

Spinal extension in prone	Better/Worse/No effect			
Segmental provocation	Movement			Pain
	Hyper	Hypo	Normal	
- Central P/A, Springing test - Unilateral P/A - Rotation provocation - Prone instability test				
Femoral nerve tension test				
Isometric/dynamic back muscle tests				

8. PALPATION

7. SUPINE
DIFFERENTIAL DIAGNOSTICS HIP/SI-JOINT/BACK

Spinal flexion in supine	Better/Worse/No effect	
Isometric/dynamic abdominal muscle tests		
	Right	Left
Hip: Angular movement, Patricks test, quadrant		
SI-joint provocation test, ASLR		
Passive SLR + head/foot sensitisation, crossed SLR		
Myotomes- L1-2(I), L2-3(Q), L4-5(TA), L5(EH), L5-S1(P), S1(TS)		
Dermatomes		
Reflexs: Patella L3-4, Achilles S1		
Babinski, Klonus		

3. STarT Back Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg**(s) at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

Total score (all 9): _____ **Sub Score (Q5-9):**_____

Funded by Arthritis Research UK

4. Clinical Reasoning and Process Evaluation tool (CRPE-tool) for therapists

PATIENT NAME:_____ **DATE OF BIRTH:_____**	**First assessment date:___/___/___** **Final assessment date:___/___/___** **Totalt number of physiotherapy visits:_____**

ASSESSMENT

- **First assessment - cross X relevant assessment findings**
- **Final assessment - circle ○ relevant assessment findings**

1. Assess grade of FUNCTIONAL IMPAIRMENT	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Energy and drive (motivation)	0	1	2	3	4	PA006
Sleep functions	0	1	2	3	4	PA007
Emotional functions (anxiety, low mood)	0	1	2	3	4	PA011
Thought functions (physical symptoms caused by cognitive/rational factors)	0	1	2	3	4	PA013
Sensory function (sensitivity for pain ”sensitisation”)	0	1	2	3	4	PB008
Pain (choose relevant category)						
Back pain	0	1	2	3	4	PB009
Lower extremity pain	0	1	2	3	4	PB009
Pain in a dermatome	0	1	2	3	4	PB009
Pain in another body part (Buttock, hip, groin, thigh)	0	1	2	3	4	PB009
Generalised pain localisation (3 of 4 body quadrats)	0	1	2	3	4	PB009
Exercise tolerance (endurance related activities)	0	1	2	3	4	PD009
Joint mobility	0	1	2	3	4	PG001
Joint stability	0	1	2	3	4	PG002
Muscle power	0	1	2	3	4	PG003
Muscle tone	0	1	2	3	4	PG003
Muscle endurance	0	1	2	3	4	PG003
Motor reflex funktions (decreased or increased)	0	1	2	3	4	PG004
Control of movement (Quality, coordination, balance)	0	1	2	3	4	PG006
Gait pattern	0	1	2	3	4	PG007
Sensation of muscle stiffness, tightness, spasm, contraction, heaviness	0	1	2	3	4	PG003
Mobility of spinal meningies, periferal nerves and surrounding tissue	0	1	2	3	4	PG000
2. Assess grade of ACTIVITY LIMITATION	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Perception of non-harmful sensory stimuli (kinesiophobia)	0	1	2	3	4	PJ001
Carrying out daily routine (ADL)	0	1	2	3	4	PK003
Handling stress and other psychological demands	0	1	2	3	4	PK004
Changing and maintaining body position (Shifting body weight away from the spine (increased lever arm)	0	1	2	3	4	PM001
Changing and maintaining body position (bending)	0	1	2	3	4	PM001
Maintaining a lying position	0	1	2	3	4	PM001
Maintaining a sitting position	0	1	2	3	4	PM001
Maintaining a standing position	0	1	2	3	4	PM001
Maintaining an upright neutral posture	0	1	2	3	4	PM001
Lyfting and carrying objects	0	1	2	3	4	PM004
Walkning	0	1	2	3	4	PM007

Moving around in different ways (crawling/climbing, running/joging, jumping)	0	1	2	3	4	PM008
Household tasks	0	1	2	3	4	PP003
Work ability and employment	0	1	2	3	4	PR002
Recreation and leisure activities	0	1	2	3	4	PS002

DIAGNOSTIC SUBGROUPING AND ICD-10 CODING

3. Matching assessment findings to diagnostic codes
Choose a primary assessment finding category:

- **First assessment: Cross X one or more related ICD-10 diagnostic codes in the same row**
- **Final assessment: Circle ○ a new diagnostic codes <u>if relevant</u>.**

Primary assessment category →	**ICD-10 diagnos**
LBP with muscular functional impairment	☐ M54.5 Lumbago
LBP with segmental mobility impairment	☐ M54.5 Lumbago ☐ M99.0 Segmental dysfunction
LBP with movement coordination impairment/ segmental instability	☐ M54.5 Lumbago ☐ M99.1K Segmental instability in the lumbar spine
LBP with referred lower extremity pain (nociceptive pain proximal of the knee)	☐ M54.5 Lumbago ☐ M51.2 Other specificed dislocation of intervertebral disc ☐ M47.9K Spondylosis in the lumbar spine
LBP with radiating pain (neuropathic pain)	☐ M54.5 Lumbago ☐ M54.1 Radiculopathy (femoralis) ☐ M54.4 Lumbago with ischias
LBP with related cognitive or affective tendensies	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity)
LBP with related generaliserad pain (pain in 3 of 4 body quadrants)	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity) ☐ F45.4 Chronic somatoform pain syndrome
LBP with postural related symptoms	☐ M54.5 Lumbago ☐ M40.3 Flatback syndrome ☐ M40.4 Hyperlodosis
SI-joint symptoms or Coccygodynia	☐ M53.3 Sacrococcygeal disorders
LBP radiating pain + Medical imaging disc pathology and nerve compression finding	☐ M51.1K Disc degeneration/disc herniation in the lumbar spine with radiculopathy
LBP with radiating pain/neurogenic claudication + Medical imaging verifieried degeneration and nerve compression findings	☐ M48.0K Central spinal stenos in the lumbar spine (bilateral symptoms) ☐ M99.6 Stenosis of intervertebral foramin (unilateralt symptoms)

Ländryggsbesvär med nedsatt rörelse kontroll i ryggen och/eller segmentell instabilitet + Medicinsk bild verifierad Spondylolys/Spondylolisthes	☐ M43.0 Spondylolys ☐ M43.1 Spondylolistes

TREATMENT

4. Record at final assessment:

Has the BetterBack☺ model of care Part 1 been applied?		☐ Yes ☐ No
Has the BetterBack☺ model of care Part 2 been applied?		☐ Yes ☐ No
Cross X all modes och types of treatments used		
Physical exercise	**MODE**	KVÅ code
	☐ Non-supervised individual training	
	☐ Supervised individual training	QV011
	☐ Supervised group training	QV012
	TYPE	
	☐ Muscle strengthening training	QG003
	☐ Range of movement training	QG001
	☐ Muscle endurance training	QG003
	☐ Cardiovascular training	QD016
	☐ Balance training	QB001
	☐ Postural control training	QG004
	☐ Coordination training	QG005
	☐ Pelvic floor training	QF001
	☐ Postural training	QM005
	☐ Relaxation training	QG007
	☐ Physical activity prescription (FaR®)	DV002
	☐ Other ……	
Behavioural medicine interventions	**MODE**	
	☐ Individual based intervention	QV011
	☐ Group based intervention	QV012
	TYPE	
	☐ Information / education on pain	QV007
	☐ Cognitive-behavioural therapy	DU011
	☐ Mindfulness	DU032
	☐ Motivational interviewing	DU118
	☐ Relapse prevention	DU119
	☐ Supportive conversation	DU007
	☐ Other ……	
Manual therapy	**TYPE**	
	☐ Joint mobilisation	DN006
	☐ Joint manipulation	DN008
	☐ Massage	QB007
	☐ Stretching	DN009
	☐ Nerve mobiliseration	QG001
	☐ Trigger point pressure	DN007
	☐ Traction	QG001
	☐ Other……	
Occupational medicine interventions	**TYPE**	
	☐ Workplace training	DV084
	☐ Training of work ability	QR003
	☐ Work and employment counciling	QR002
	☐ Information /education on ergonomics	QV010
	☐ Other ……	
Physical modalities	**TYPE**	
	☐ TENS	DA021
	☐ Cryotherapy	QB011
	☐ Heat	QB011
	☐ Ultrasound	QB011
	☐ Shockwave therapy	QB011

	☐ Laser therapy	QB011
	☐ Short wave diathermy	DV042
	☐ Interferential therapy	DA021
	☐ Orthosis	DN003
	☐ Taping	DN003
	☐ Bio-feedback	DV010
	☐ Acupunkture	DA001
	☐ Other……	
5. Rate overall treatment effect	☐ Much better ☐ Quite much better ☐ Unchanged ☐ Quite much worse ☐ Much worse	

5. Clinical reasoning and process pathway for therapists

A thorough history and adequate physical examination are of great importance in order to target treatment interventions. In addition, it is very important to exclude the few red flag cases that require acute medical or specialist referral for the investigation and treatment of tumors, infections, inflammatory diseases, more severe back pathology and neurological conditions, as well as the strong influence of psychosocial factors which can also cause back pain. StarT Back Tool can be used to support decision making regarding the extent of health care needed and the need for psychosocial focus based on an assessment of risk factors for continued back pain. The physical assessment should include an analysis of functional movements, posture, active movements, passive movements, combined movements and / or static positions, joint accessory movement / provocation tests and neuromuscular function. This is to investigate how the symptoms are related to motion dysfunction.

Based on assessment findings, relevant treatment measures with effect mechanisms directed at functional impairments and activity limitations should be tested. These may include range of movement exercises (active/passive or accessory joint mobilisation or neuromuscular structure mobilisation), motor control exercises, muscle stretching, balance exercises, coordination, muscle strength, muscle endurance, general physical fitness or cardiovascular exercise. For example:

1. In the identification of movement directions and positions that reduce or centralize the patient's localised pain, distal pain or radiculopathy, these may be considered as a treatment techniques. This allows the patient to learn strategies to control pain and thus take better responsibility for his or her own situation.

2. In the identification of movement restriction due to joint, muscle or nerve related impairment, mobilisation strategies for the relevant structure may be considered to reduce the movement restriction.

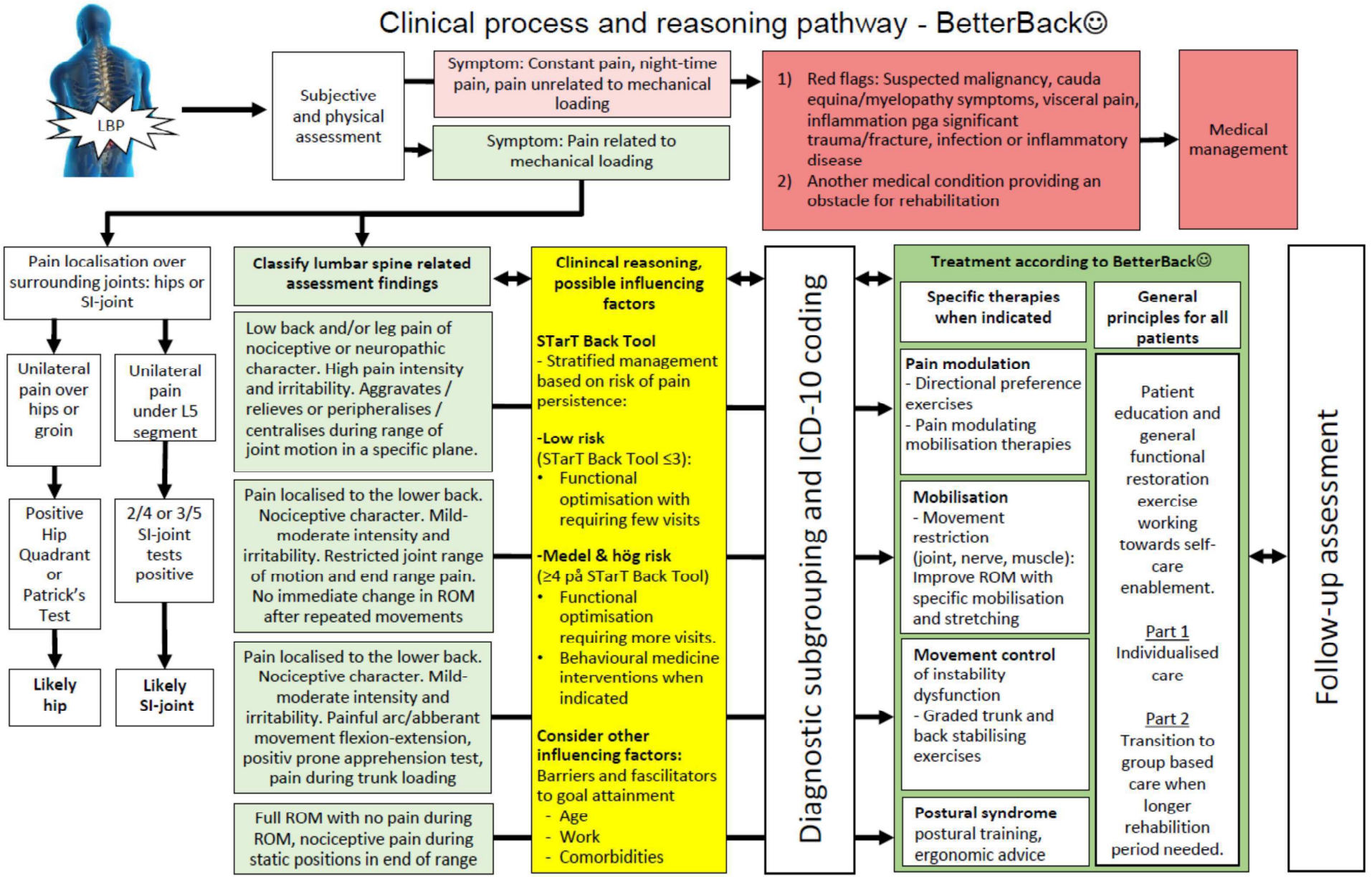
3. In the identification of segmental instability or trunk motor control impairment in the, exercises with a focus on movement control can be tested aiming to improve muscle function, reduce pain and optimise loading of the trunk during full body movement.

4. In the identification of a psychogenic causes of back pain, supervised exercise could be tested to minimize kinesiophobia. This can often be complemented with patient education that can help pain management and enable self-care.

5. In the identification of a postural impairment, posture correction and ergonomic interventions can be tested.

Dosage of treatment measures should be individualised and sufficient to achieve the desired effect. Initial targeted treatment should be through individual patient care. As a complement to the initial targeted treatments, the

purpose of a general training and patient education is to restore or improve function and activity. The suitability of group-based patient care is assessed in consultation with the patient as general training and patient education is considered relevant to support the patient's self-care.



Summary of the workshop to provide training in the use of the BetterBack☺ model of care.

Schedule	Content		Brief description	Learning objectives	BCTs used
Day 1 08:15-08:30	Presentation		Welcome and introduction		
Day 1 08:30-08:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 1 08:50-09:40	Presentation	LBP clinical guidelines	Present evidence based guideline recommendations and the development process behind the recommendations	To understand current evidence based recommendations for primary care of LBP and stakeholder involvement in their development	- Instruction on how to perform the behavior - Credible source - Information about other's approval
Day 1 09:40-10:00	Presentation	Background to BetterBack☺ model of care	Outlines the goals for the day, defines and conceptualizes the BetterBack☺ model of care and communicates need for the model of care	To understand aims, objectives and learning outcomes for the practitioner education	- Credible source - Social reward - Pros and cons - Comparative imagining of future outcomes
Day 1 10:00-10:20	Swedish fika	Reflection	Informal discussion about aims of the BetterBack☺ model of care compared to current practice	To evaluate the practical aims of the BetterBack☺ model	- Social support
Day 1 10:20-11:40	Demonstration	Use of implementation tools	Demonstration of how evidence based recommendations can be practically applied in the BetterBack☺ model of care	To understand how to practically use implementation tools to assist clinical reasoning for matching assessment findings with appropriate diagnosis and treatment	- Instruction on how to perform the behaviour - Demonstration of behaviour - Problem-solving - Feedback on behaviour
Day 1 11:45-12:00	Reflection	Use of implementation tools	In pairs, participants discuss reflections upon how they can practically apply the implementation tools into their clinical practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Framing/reframing
Day 1 12:00-13:00	Lunch break				
Day 1 13:00-14:30	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model implementation tools using therapist-	To develop practical skills in the use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

			patient role-play. Feedback is provided from the tutor and between peers		
Day 1 14:30-15:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To learn how peers used BetterBack☺ model clinical reasoning tools	- Graded task - Verbal persuasion about capability
Day 1 15:00-15:20	Swedish fika	Reflection	Informal discussion about the practical use of the BetterBack☺ model of care compared to current practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Social support
Day 1 15:20-15:40	Summary of the day	Question and answer session and close	Learning outcomes are summarised		- Feedback on behaviour
Day 2 08:15-08:30	Discussion		Reflections after the first day of the workshop		
Day 2 08:30-09:00	Presentation		Benefits of using the implementation tools for assessment, diagnosis and intervention	To appreciate how to practically use implementation tools to assist clinical reasoning for aligning assessment, diagnostics and treatment	- Instruction on how to perform the behaviour - Information about social and environmental Consequences - Credible source - Information about other's approval
Day 2 09:00-09:20	Demonstration	BetterBack☺ model treatment tools	Patient education (brochure)	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 09:20-10:00	Demonstration	BetterBack☺ model treatment tools	Group education	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 10:00-10:20	Swedish fika	Reflection	Informal discussion about which patients group education is relevant	To reflect on the practical use of the BetterBack☺ model	- Social support
Day 2 10:20-11:00	Demonstration	BetterBack☺ model treatment tools	Exercise program	To understand how to use the implementation tools for an exercise program for LBP	- Instruction on how to perform the behaviour
Day 2 11:00-12:00	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

Day 2 12:00-13:00	Lunch break				
Day 2 13:00-13:30	Task continued	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support
Day 2 13:30-14:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Graded task - Verbal persuasion about capability
Day 2 14:00-14:30	Demonstration	BetterBack☺ model of care website	Display of to navigate the BetterBack☺ model of care website	To understand how to use the BetterBack☺ model of care website	- Instruction on how to perform the behaviour
Day 2 14:30-15:00	Task	Potential future outcomes of the BetterBack☺ model of care implementation	Participants write on post-it notes the most important future outcomes of the BetterBack☺ model of care implementation based on: 1. A professional perspective 2. A patient perspective	To appreciate the potential outcomes of the BetterBack☺ model of care	- Comparative imagining of future outcomes
Day 2 15:00-15:30	Presentation		Clinical champion presents an administrative action plan (designed earlier in consensus with clinical colleagues) for the implementation of the BetterBack☺ model of care at their clinic	To reflect on the practical use of the BetterBack☺ model of care website	- Action planning
Day 2 15:30-15:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 2 15:50-16:00	Diploma		Participants completing the workshop receive a CME diploma		- Incentive

BMJ Open

The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

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The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

Allan Abbott[1*], Karin Schröder[1], Paul Enthoven[1], Per Nilsen[3], Birgitta Öberg[1]
[1]Department of Medical and Health Sciences, Division of Physiotherapy, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.
[2]Department of Medical and Health Sciences, Division of Community Medicine, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.

Allan Abbott* - allan.abbott@liu.se (TEL: 0046 13 282495); Karin Schröder - karin.schroder@liu.se; Paul Enthoven - paul.enthoven@liu.se; Per Nilsen - per.nilsen@liu.se; Birgitta Öberg - birgitta.öberg@liu.se;

*Corresponding author

ABSTRACT

Introduction: Low back pain (LBP) is a major health problem commonly requiring health care. In Sweden, there is a call from health care practitioners (HCP) for the development, implementation and evaluation of a best practice primary health care model for LBP.

Aim: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing best practice coherent primary health care for patients with LBP (B) Improve and understand the mechanisms underlying illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate a multi-facetted and sustained implementation strategy and the cost-effectiveness of the BetterBack☺ MOC for LBP from the perspective of the Swedish primary health care context.

Methods: This study is an effectiveness-implementation hybrid type 2 trial testing the hypothesised superiority of the BetterBack☺ MOC compared to current routine care. The trial involves simultaneous testing of MOC effects at the HCP, patient and implementation process levels. This involves a prospective cohort study investigating implementation on the HCP level and a patient blinded, pragmatic cluster randomized controlled trial with longitudinal follow-up at 3, 6 and 12 months post baseline for effectiveness on the patient level. A parallel process and economic analysis from an health care sector perspective will also be performed. Patients will be allocated to routine care (control group) or the BetterBack MOC (intervention group) according to a stepped cluster dog leg structure with 2 assessments in routine care. Experimental conditions will be compared and causal mediation analysis investigated. Qualitative HCP and patient experiences of the BetterBack☺ MOC will also be investigated.

Dissemination: The findings will be published in peer-reviewed journals and presented at national and international conferences. Further national dissemination and implementation in Sweden and associated national quality register data collection are potential future developments of the project.

Trial registration: ClinicalTrials.gov: NCT03147300

Date and version identifier: 13 Dec 2017, protocol version 3.

Key words: Low back pain, model of care, effectiveness, implementation.

Word count: 8156 words

Strengths and limitations of this study

- This will be the first study of effectiveness and implementation of a best practice model of care in LBP primary care in Sweden.
- An international consensus framework is used for the development, implementation and evaluation of the BetterBack☺ model of care.
- The main trial's a priori methodology has been informed and refined by an internal pilot phase.
- The study has received financing in Sweden from competitive grant rounds with peer review processes.

BACKGROUND

Low back pain (LBP) is one of the most prevalent and burdensome problems for individuals and society in Sweden and worldwide [1,2]. LBP is often defined in terms of its localization, duration, severity, frequency, and interference on activities of daily living [3]. Most new episodes of LBP are self-limiting with only approximately 20% having persistent symptoms but a large majority experience pain recurrence [1]. The aetiology of LBP is often classified as specific or non-specific, based upon if a pathoanatomical cause can be identified through objective diagnostic assessment and confirmed by medical imaging [4]. The prevalence of LBP caused by specific pathology of serious nature such as malignancy, spinal fracture, infection, or cauda equine syndrome requiring secondary or tertiary health care has been reported to range between < 1%-4% in the primary health care setting [5,6]. Furthermore, nerve root problems associated with radiculopathy or spinal stenosis are thought to explain approximately 5%-15% of cases [7,8]. Medical imaging studies have highlighted that approximately 50% of younger adults and 90% of older adults have degenerative findings and large variations in lumbar spine morphology [9]. This is however evident in both symptomatic and asymptomatic individuals suggesting that LBP is more typically a result of benign biological and psychological dysfunctions as well as social contextual factors influencing the pain experience.

In Sweden, previous studies by our research group suggest the health care process for patients with LBP tends to be fragmented with many health care practitioners (HCP) giving conflicting information and providing interventions of varying effectiveness [10,11]. Our studies have shown that only a third of patients on sick leave for musculoskeletal disorders receive evidence-based rehabilitation interventions in primary care [10,11]. Furthermore our research has also demonstrated that there are still interventions that physiotherapists in primary care consider to be relevant in clinical practice despite the absence of evidence or consensus about the effects [12]. Our preliminary data suggests that when patients with LBP are referred to specialist clinics, up to 48% have not received adequate evidence-based rehabilitation in primary care. There is therefore a strong case for change to address what care should be delivered for LBP and how to deliver it in the Swedish primary health care setting.

The development of best practice clinical guidelines aims to provide HCP with recommendations based on strength of available evidence as well as professional consensus for the intervention's risk and benefits for the patients. Best practice clinical guidelines for LBP are lacking in Sweden but have recently been developed by the Danish Health and Medicines Authority and the English National Institute for Health and Care Excellence [13-15]. These national guidelines provide a thorough assessment of current evidence and can be used in Sweden to form the basis for locally adapted recommendations. Common to LBP, central recommendations from best practice clinical guidelines for arthritis are also education and exercise therapy aimed at improving patient self-care. Guideline informed models of care (MOC) such as "Better Management of Patients with Osteoarthritis (BOA)" in Sweden [16] and "Good Life with Osteoarthritis" in Denmark (GLA:D) [17] have been successfully implemented with broad national HCP use [18,19]. Furthermore, improvements in patient reported pain, physical function and decreased use of pain medication after receiving these MOC have been reported [18,19]. A similar best practice MOC for LBP could

potentially improve HCP evidence based practice and patient rated outcomes in the Swedish primary health care setting.

Recently an international consensus framework has been established to support the development, implementation and evaluation of musculoskeletal MOC [20]. MOC readiness for implementation requires that the MOC is informed by best practice recommendations, has a user focus and engagement, has a clear structure, a description of components as well as a description of how they are to be delivered [20]. An important part of the MOC structure is the theoretical underpinning of how the MOC intends to act on behavioural change mechanisms to attain specific behavioural targets [20]. In order to achieve effective and efficient implementation of a MOC in primary health care, it is important to apply knowledge from implementation science [21-24]. Implementation science is the scientific study of uptake of research findings and evidence-based practices into routine practice to improve the quality and effectiveness of health care and services [25]. Implementation strategies focus on minimising barriers and maximising enablers that impact on the implementation and use of evidence-based practices. It has been suggested that a multifaceted strategy involving simultaneous use of several implementation strategies may be more effective than single-faceted strategies but the evidence base is inconclusive [26]. A recent systematic review however suggests that the most important aspects of successful implementation strategies are an increased frequency and duration of the implementation intervention and a sustained strategy [27].

There is therefore a clear rationale for evaluating the extent to which and how a best practice MOC for LBP (BetterBack☺) implemented with a sustained multi-facetted strategy is potentially effective in the Swedish primary care context. The costs in relation to effects are important to consider in order to deliver health care efficiently. This article describes a protocol for a BetterBack☺ MOC effectiveness and implementation process evaluation. The protocol conforms to the SPIRIT guidelines [28] with checklist provided in supplementary file 1.

AIMS

The overall aim is to investigate the effectiveness and implementation process of the BetterBack☺ MOC for LBP in a Swedish primary health care context. The specific trial objectives are to: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing best practice primary health care for patients with LBP (B) Improve and understand the mechanisms underlying change in illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate a multi-facetted and sustained implementation strategy and cost-effectiveness of the BetterBack☺ model of care for LBP in the Swedish primary health care context.

HYPOTHESIS

1. HCP reported confidence, attitudes and beliefs for providing primary health care for LBP will show statistically significant improvement after a sustained multifaceted implementation of the BetterBack☺ model of care compared to baseline before implementation. Intentional and volitional HCP rated determinants of implementation behaviour regarding the BetterBack☺ model of care will mediate improved confidence, attitudes and beliefs in a causal effects model. This will correlate with more coherent care according to best practice recommendations.
2. The sustained multifaceted implementation of the BetterBack☺ model of care will result in more statistically significant and greater clinically important improvement compared to current routine care for LBP regarding patient-reported measures for illness beliefs, self-care enablement, pain, disability and quality of life. Improvements in illness beliefs and adequate patient enablement of self care will mediate the effect on these outcomes.
3. A sustained multifaceted implementation of the BetterBack☺ model of care compared to current routine care will result in fewer patients with persisting LBP, fewer requiring

specialist care, increased adherence to best practice recommendations and more statistically significant incremental cost-effectiveness ratio (ICER) based on cost per EuroQoL-5 Dimension Questionnaire (EQ-5D) quality-adjusted life years (QALY) gained.

METHODS

Study design

World Health Organization Trial Registration Data Set is presented in table 1. This study is an effectiveness-implementation hybrid type 2 trial testing the hypothesised superiority of the BetterBack☺ MOC compared to current routine care [29]. The design involves an effectiveness evaluation of the BetterBack☺ MOC at the HCP and patient level as well as a process evaluation of a sustained multifaceted implementation strategy conducted simultaneuously. Evaluations are focused at the HCP and patient level because the MOC is targeted at changing HCP behaviour who then in turn implement behavioural change strategies on a patient level. This trial design was chosen for it's potential to provide more valid effectiveness estimates based on pragmatic implementation conditions. This is in contrast to best or worst case implementation conditions common in traditional efficacy or effectiveness trials [29]. Another advantage of the hybrid design is it's potential to accelerate the translation of the MOC to real world practice. This is in contrast to a time lag between efficacy, effectiveness and then dissemination steps in traditional research [29]. The trial design is outlined in figure 1.

As outlined in table 2, the design on the HCP level involves data collection in the cohort before and prospectively after implementation of the BetterBack☺ MOC. On a patient level, data is collected in a single blinded pragmatic randomized controlled stepped cluster format with longitudinal follow up at 3, 6 and 12 months post baseline. Randomisation at the patient level is not possible due to potential carry-over effects of the HCP transitioning back and forth between providing routine care or the BetterBack☺ MOC for different patients. Instead cluster randomisation is conducted at the start of the study, where patients are allocated thereafter to routine care (control group) or the BetterBack☺ MOC (intervention group) depending upon the clinic's allocation. Patients remain in their allocated group throughout the study.

A stepped cluster structure instead of a parallel structure of MOC implementation is applied due to the logistics involved in implementation in different geographical areas. The specific stepped cluster structure applied in the context of our study is classified as a dog leg with 2 assessments in routine care [30,31]. The term "dog leg" has been used by methodologists because the stepped structure resembles the form of a dog hind leg [30]. As displayed in table 2, this involves the first cluster being assessed after the implementation of the BetterBack☺ MOC. The second cluster is assessed after a period of current routine care (control), and assessed again after the implementation of the BetterBack☺ MOC. The third cluster receives current routine care (control) throughout the trial. However, studying the implementation of the BetterBack☺ MOC in cluster 3 is planned to occur as a final step at the end of the study.

An advantage of using the dog leg structure with 2 assessments in routine care is that it allows for an internal pilot phase of initial implementation of the BetterBack☺ MOC in cluster 1 compared to clusters receiving current routine care. Another advantage is that data generated will still contribute to the final analyses to maintain trial efficiency [32,33]. One objective for an internal pilot is to confirm the HCP acceptability of the intervention and trial within the first cluster [32,33]. A progression criteria for continuing the trial requires that HCP who have completed the BetterBack☺ education workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ model of care will be useful (1 = agree completely - 5 = do not agree at all).

Another objective of the internal pilot is to monitor patient recruitment in all 3 clusters during the

first 2 months to provide information on the optimal cross forward time for cluster 2. In the dogleg design it is possible to vary the time point of cluster 2 to cross forward from the control to intervention condition if the patient recruitment process in either cluster 1 or 3 is more or less than expected in the internal pilot (See table 2). In the event that cluster 1 recruit less than expected and clusters 2 or 3 recruit more than expected, then cluster 2 will then cross forward to the intervention condition immediately after the internal pilot. If cluster 1 recruit more than expected and cluster 2 or 3 recruited less than expected during the internal pilot phase, then cluster 2 will then cross forward to the intervention condition later in the trial to allow adequate current routine care data collection. Clusters were expected to recruit and gather data for at least 20 LBP patients per month in the internal pilot. A final objective with the internal pilot phase is to assess baseline variation and change over 3 months for implementation process and patient primary outcome measures to inform if our a-priori sample size calculation needed to be revised in the continuation of the trial.

Study setting

The Östergötland public health care region has a total population of 453 596 inhabitants with approximately 5000 patients per year accessing primary care physiotherapy due to LBP. In the public health care region of Östergötland, a large majority of consultations for LBP are via direct access to the 15 primary care physiotherapy rehabilitation clinics. A smaller percentage of consultations are via referral to these rehabilitation clinics from the 36 primary health care general practices in the region. Therefore the focus of this study is on the physiotherapeutic rehabilitation process for LBP in primary care. The rehabilitation clinics form three clusters in Östergötland health care region. These clusters are based on municipal geographical area and organisational structure of the rehabilitation clinics which helps to minimize contamination between separate clusters of clinics (Figure 2). Cluster west is comprised of 5 clinics with 27 physiotherapists, cluster central is comprised of 6 clinics with 44 physiotherapists and cluster east is comprised of 6 clinics with 41 physiotherapists.

Eligibility criteria

Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP will be included in the study. These physiotherapists will assess the eligibility of consecutive patients before and after the implementation of the BetterBack☺ MOC based on the following criteria:

Inclusion criteria: Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a first-time or recurrent episode of acute, subacute or chronic phase benign low back pain with or without radiculopathy.

Exclusion criteria: Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Spinal surgery during the last 2 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfil criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis.

Interventions

Control condition – current routine physiotherapeutic care for LBP in primary health care

Patients attending rehabilitation clinic clusters that have not have not yet completed the implementation of the BetterBack☺ MOC will receive treatment as usual according to current routine care clinical pathways (Figure 3). A clinical pathway specified in Östergötland public health care region requires that for patients accessing primary care due to LBP, a triage is to be performed by licensed HCP (Physiotherapists, Nurses or General Practitioners (GP)), to triage for specific

pathology of serious nature. These approximately 1-4% of patients with suspected specific pathology of serious nature are then to be examined by GPs and referred for specific intervention in secondary or tertiary health care. The majority of patients with LBP who on initial triage are assessed as having benign LBP are then scheduled for physiotherapy consultation and implementation of a LBP management plan. If the patient has persistent functional impairment and activity limitation despite 2-3 months of primary care intervention, the clinical pathway specifies inclusion criteria for specialist care referral pathways (Figure 3).

Intervention condition – The BetterBack☺ MOC for LBP

Development, design and implementation of the BetterBack☺ MOC for LBP

A framework for the development of musculoskeletal MOC [20] was used to guide development of the BetterBack☺ MOC for LBP. The high prevalence and burden of LBP [1,2], discordance in evidence based rehabilitation processes [10-12], a lack of clinical practice guidelines and a call for a best practice MOC requested by physiotherapy clinic managers in the Östergötland health care region have been identified in the primary care of LBP. Therefore, a case for change has been justified to improve current physiotherapeutic health service delivery for the primary care of LBP. The content and structure of the BetterBack☺ MOC where developed by engaging a work group of physiotherapy clinicians (clinical champions) from each primary care cluster in the Östergötland public health care region and physiotherapy academics at Linköping University. A Template for Intervention Description and Replication (TIDieR) Checklist [34] is described in supplementary file 2. To identify which key areas of contemporary care were of relevance for the BetterBack☺ MOC, the following tasks were performed by the work group:

1) Discussion and outline of the current routine care clinical pathway for LBP and areas needing improvement: The work group concluded that the BetterBack☺ MOC needed to focus on:

- WHO/WHERE: The primary care physiotherapy process for the management of patients with LBP in Östergötland health care region outlined by the red square in figure 3.

2) Analysis and discussion of existing international best practice clinical guidelines: The following thorough and up-to-date systematic critical literature reviews and international clinical guidelines [13-15, 35] were analysed and discussed by the work group.

3) Adaptation of best practice clinical guidelines to the Swedish context: The development of evidence based recommendations was based on the Swedish National Board of Health and Welfare methods for guideline construction [36]. The overall grade of evidence together with a consensus position based on professional experience and patient net benefit versus harms and costs are the key aspects on which the work group has formulated local recommendations to reflect their strength [37]. The recommendations have been externally reviewed by local physicians and international experts from the University of Southern Denmark. A summary of the Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of LBP with or without radiculopathy as well as the support tools used in the BetterBack☺ MOC is provided in the supplementary file 3.

4) Considering potential barriers to the uptake of evidence based recommendations by HCP [38], the work group identified and discussed targeted HCP behavioural change priorities of relevance for the BetterBack☺ MOC. The work group discussion lead to the following rationale for the BetterBack☺ MOC content and implementation described in table 3:

- WHY: The main HCP target behaviour was the adoption of the BetterBack☺ MOC to influence HCP delivery of care coherent with best practice recommendations.
- WHAT: This would require the contents of the MOC to change impeding barrier behaviours such as low confidence in skills/capabilities for improving LBP patient management, a biomedical treatment orientation rather than a biopsychosocial orientation, low awareness

or beliefs of negative consequences of the MOC [38].

- HOW: BetterBack☺ MOC content used to overcome the modifiable barriers includes support tools aimed at further education and enablement of HCP clinical reasoning in providing LBP assessment and treatment coherent with the Swedish adaptation of best practice clinical guidelines. The support tools include assessment proformers with associated instruction manual, clinical reasoning flow charts linking assessment findings to relevant treatment interventions, patient education brochures and group education material on LBP self-care as well as a functional restoration program (supplementary file 3).
- WHEN/HOW MUCH/TAILORING: The functional restoration program and patient education components used, their individual and group based delivery and dosing is individualised based on the HCP clinical reasoning of the type and grade of patient functional impairments and activity limitations (supplementary file 3).
- PROCEDURE: Figure 4 displays a flow diagram showing the steps involved for HCP in delivering the contents of the BetterBack☺ MOC.

The Behaviour Change Wheel (BCW) [39] was used by the work group as a logic model to theorise the process of how the BetterBack☺ MOC content applied at the guideline policy level could guide theory-informed intervention functions using specific behavioural change techniques [40]. To help investigate possible mediators of behavioural change interventions in the BetterBack☺ MOC, the Theoretical Domains Framework (TDF) [41] was integrated into the BCW. The TDF is comprised of 14 theoretical domains/determinants of behavioural change of which could potentially influence behavioural change technique effect on the central source of behaviour [42]. The central source of behaviour in the behavioural change wheel is described by the COM-B model. In the COM-B model, a person's capability (physical and psychological), opportunity (social and physical) can influence on motivation (automatic and reflective) enacting behaviours that can then alter capability, motivation and opportunity [39]. The BCW [39] and TDF [41] are displayed in figure 5.

5) The following sustained multifaceted implementation strategy for the BetterBack☺ MOC was developed:

- An **implementation forum** including rehabilitation unit managers and clinical researchers was formed. The implementation forum collaborated on forming overarching goals, timeline and logistics facilitating and sustaining the implementation of the BetterBack☺ MOC in the primary care rehabilitation clinic clusters in the Östergötland public health care region.
- A MOC **support team** was formed. This is comprised of experienced clinicians (clinical champions) from each rehabilitation unit together with clinical researchers fascilitating local implementation and sustainability of the BetterBack☺ MOC at the rehabilitation units.
- A **package of education and training** that the support team can utilise to assist the use of the BetterBack☺ MOC by HCP was developed.
  - Physiotherapists in the 3 geographical clusters of public primary care rehabilitation clinics in Östergötland will be offered to participate in a 13.5 hours (2 days), continued medical education (CME) workshop. The workshop is designed by the support team with at least 2 clinical researchers and 1 experienced clinician from the rehabilitation unit cluster present in the support team's delivery of the workshop for each cluster. The HCP education provided in the workshop format is described in supplementary file 4.
  - Key components of the educational program are:
    - Education and persuasion about evidence based recommendations for LBP care and the BetterBack☺ MOC through an experiential learning process applying problem based case studies and clinical reasoning tools.

- Traning and modeling of the practical use of the BetterBack☺ education and physical intervention programs aiming at self-care as well as function and activity restoration.
- Access to a website describing the BetterBack☺ MOC. A chat forum will give an opportunity for clinicians to ask questions and share different experiences of the new strategy managed by the support team. Researchers will respond to questions from the participating clinicians.

- To consolidate the BetterBack☺ MOC use at the local clinics, the local support team member and clinical researchers will mediate a 2 hour interactive follow-up workshop 3 months after BetterBack☺ MOC implementation. Aspects of the previous workshop content will be discussed and reinforced. To aid continued sustainability of the BetterBack☺ MOC implementation, the local support team member will provide continued maintenance of education at their clinics and even educate new staff.

6) Once HCP behaviour change has occurred, it is anticipated that HCP use of the BetterBack☺ MOC may influence patient outcomes. A rationale for causal mediation effects can be proposed based on the Common Sense Model of self-regulation (CSM) [43]. This suggests a potential effect of the BetterBack☺ MOC on improved patient reported pain, physical function, and quality of life may be mediated by improved patient illness beliefs such as cognitive and emotional illness representations as well as adequate coping through self-care enablement [43]. The patient target behaviours are therefore focused on the understanding of the mechanisms and natural course of benign LBP and the enablement of self-care. This requires content of the MOC to change patient impeding barrier behaviours such as maladaptive illness beliefs on the cause and persistent course of LBP (low outcome expectation, anxiety, catastrophizing, fear-avoidance, and negative illness beliefs), low self-care enablement and low baseline physical activity [44]. The content for the patient education and functional restoration program included in the BetterBack☺ MOC therefore reflects these aspects and is shown in supplementary file 3. These are also charactarised according to the Behavioural Change Wheel, behavioural change technique taxonomy and TDF in table 3.

Outcomes

Implementation process

1. Primary outcome measure

- Practitioner Confidence Scale (PCS) [45] mean change from baseline to 3 months post baseline. Practitioner reported confidence is the primary HCP behavioural change goal for the HCP education and training workshop in the multifaceted implementation of the BetterBack☺ MOC. The 3 month time frame allows for the development and consolidation of HCP behavioural change after application in repeated patient cases.

2. Secondary outcome measures

- PCS [45] mean immediate change from baseline to directly after the HCP education and training workshop as well as mean long term change from baseline to 12 months post baseline. This secondary outcome is important for the understanding of longitudinal HCP behavioural change.
- Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [46] mean change from baseline, to directly after the HCP education and training workshop as well as at 3 and 12 months post baseline.

Implementation outcomes

1. Primary outcome measure

- Proportional difference between control and intervention groups for incidence of participating patients receiving specialist care for LBP between baseline and 12 months after baseline. Incidence proportion, analogous to cumulative incidence or risk is calculated by

taking the number of patients receiving specialist care of LBP and dividing it by the total number of patients recruited to the study. The main goal of both the control and interventions conditions in primary care for benign first-time or recurrent debut of LBP is to improve patient reported outcomes without the need of secondary or tertiary health care processes.

2) Secondary outcomes measures

- Mean difference between control and intervention groups for change between baseline and final clinical visit regarding grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP [47].
- The proportion of patients who receive the BetterBack☺ MOC and registration of health care codes coherent with the Swedish best practice clinical recommendations.

Patient outcomes

1. Primary outcome measure

- Numeric rating scale for lower back related pain intensity during the latest week (NRS-LBP) [48]. The mean difference between control and intervention groups in change between baseline and 3 months post baseline will be analysed. Pain intensity is the primary functional impairment that patients with LBP contact primary health care for and has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported NRS change over 6 months as a core metric for pain management interventions [50].
- Oswestry disability index version 2.1(ODI) [51]. The mean difference between control and intervention groups in change between baseline and 6 months post baseline will be analysed. Disability, analogues to decreased physical functioning and activity limitation has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported ODI change over 6 months as a core metric for functional restoration [50].

2. Secondary outcome measures

- NRS-LBP [48] and ODI [50] mean difference between control and intervention groups in short-term change from baseline to 3 months post baseline and mean long-term change from baseline to 12 months post baseline. These secondary outcomes are important for the understanding of longitudinal patient-rated changes in pain intensity and disability after primary care intervention.
- The European Quality of Life Questionnaire (EQ-5D) [52]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Health related quality of life has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported EQ-5D change over 6 months as a core metric for pain management interventions [50].
- The Brief Illness Perception Questionnaire (BIPQ) [53]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Illness perception has been shown to predict longitudinal pain and disability outcomes in several LBP studies [54-58].
- Patient Enablement Index (PEI) [59], Patient Global Rating of Change (PGIC) [60] and Patient Satisfaction (PS) [61] mean difference between control and intervention groups at 3, 6 and 12 months post baseline will be analysed.

Participant timeline

The trial timeline is shown in table 2. The intervention schedule started with the development of evidence based recommendations and the BetterBack☺ MOC which occurred during June 2016 - February 2017. The enrolment schedule started with cluster enrolment and randomisation in March

2017. This resulted in the first allocated cluster 1 (west) entering internal pilot of implementing the BetterBack☺ MOC HCP education and training workshop which occurred in March 2017. This was followed up with a 2 month internal pilot of patient enrolment schedule occurring in all 3 clusters during April-May 2017. In order to finalise a sample size calculation for the main trial, baseline data collected during the internal pilot is compared to follow-up data 3 months after baseline for the primary outcome measure questionnaires to analyse initial HCP and patient effects of the implementation of BetterBack☺ MOC in cluster 1 compared to the control conditions in clusters 2 & 3. In the transition to the main trial, patient enrolment and baseline assessments will then continue to occur until January 2018. The eventual time of crossing forward of cluster 2 into the implementation of the BetterBack☺ MOC is determined by the internal pilot trial results. Participants in the trial will be follow-up longitudinally at 3, 6 and 12 months after baseline measures. The schedule for assessments is also outlined in table 2.

Sample size

An initial sample size estimation in the planning stage of the study assumed at least a small Cohens d effect size (d=0.35) for the HCP behavioural change primary and secondary outcomes. This is based on previous literature showing small-moderate HCP behavioural change effects sizes using similar interventions to increase the uptake of evidence-based management of LBP in primary care [62-63]. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of the BetterBack☺ MOC, 80% statistical power and a 20% loss to follow-up, a sample size of n = 63 HCP is needed for a matched pairs t-test statistics comparing baseline and follow-up means. We assume a possible carry-over of a similar effect size (d=0.35) on patient behavioural change primary and secondary outcomes. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of BetterBack☺ MOC compared to usual care and a 80% statistical power, the number of patients required for an individually randomized simple parallel group design would be n = 204. Adjusting for the design effect due to clustering randomizing, an intracluster correlation of 0.01 and a cluster autocorrelation of 0.80, a dog leg design with 2 assessments in routine care and 100 patients in each cluster section would require at least n = 402 patients over 2.41 clusters according to algorithms described by Hooper & Bourke [30]. In a balanced recruitment schedule, this equates to 14 patient per months per cluster for a total of 3 clusters. Allowing for potential unbalanced recruitment flow and a potential drop-out in the longitudinal outcomes at 3, 6 and 12 months post baseline, each cluster will aim for up to 20 patients per month equating to a potential total study n = 600.

Recruitment

In an effort to curb recruitment difficulties, strategies to promote adequate enrolment of participants into the study will be used. We anticipate less problems with recruitment into the prospective cohort study design investigating the multifaceted implementation of the BetterBack☺ MOC on the HCP level. This is due to the study having been endorsed by clinical department managers calling all HCP working with patients with LBP at their clinics to participate. However, recruitment of patients into the cluster randomized controlled trial is dependent upon the feasibility of recruitment processes adapted to the context of each individual clinic and the compliance of HCP to administer recruitment of consecutive patients. A strategy to optimise the administration of patient recruitment will involve the author KS regularly visiting participating clinics to inform HCP of the study protocol and help streamline practical administration of the protocol in the context of the individual clinics. KS will also monitor weekly recruitment rates from the clinics and provide motivational feedback on recruitment flow to clinical department managers and designated clinical champions who will provide additional motivational feedback to HCP. In accordance with a Consolidated Standards of Reporting Trials, a flow diagram displaying participant enrolment, allocation, follow-up and analysis will be constructed [64]. Reasons for exclusion, declined participation, protocol violations and loss to follow-up will be monitored by KS.

Allocation and blinding

Random concealed allocation of clusters was performed by a blinded researcher randomly selecting from 3 sequentially numbered, opaque, sealed envelopes. The method resulted in the following order: 1=cluster west, 2=cluster central and 3=cluster east. The author KS informed the clinics in the different clusters of their allocation to the control or intervention study condition. Due to the nature of the study and intervention, HCP conducting patient measurements and treatment cannot be blinded to group allocation. Risk of bias is minimal as the primary and secondary outcomes are patient self-reported questionnaires. Patients will be blinded to group allocation. The researcher responsible for statistical analysis will not be blinded to group allocation but an independent statistician will review statistical analysis.

Data collection

Data will be collected through quantitative questionnaires and qualitative focus group and semi-structured interviews. In the case of non-response to questionnaires, a questionnaire will be re-sent via post a total of 3 times. In case of continued non-response this will be complemented with a telephone call as a final effort for data collection.

Implementation process –

- The PCS contains 4 items reported on 5-point Likert scales where a total score of 4 represents greatest self-confidence and 20 represents lowest self-confidence for managing patients with LBP. The structural validity in terms of internal consistency of the items have been shown to be good with a Cronbach α coefficient = 0.73 in a single factor model for self-confidence [45]. The questionnaire has been forward translated by our research group from English to Swedish.
- The PABS-PT consists of two factors where higher scores represent more treatment orientation regarding that factor. One factor with 10 items measures the biomedical treatment orientation (Score 0-60) and one with 9 items measures the biopsychosocial treatment orientation (Score 0-54) [46]. Each item is rated on a 6-point Likert scale ranging from 1='totally disagree' to 6='totally agree'. The internal consistency of the biomedical factor has been shown to be good with a range between Cronbach α=0.77-0.84. Futhermore, the biopsychosocial factor has been shown to be adequate with a range between Cronbach α=0.62-0.68 [65]. Construct validity and responsiveness to educational interventions has been shown to be positive along with the test-retest reliability with reported intra-class correlation coefficient (ICC) on the biomedical factor=0.81 and on the biopsychosocial factor=0.65 [65]. The questionnaire has been forward translated from English to Swedish in a previously published study [66].
- The Determinants of Implementation Behaviour Questionnaire (DIBQ) was originally constructed based on the domains of the TDF [41, 67]. Confirmatory factor analysis resulted in a modified 93 item questionnaire assessing 18 domains with sufficient discriminant validity. Internal consistency of the items for the 18 domains was good, ranging from 0.68-0.93 for the Cronbach α coefficient [68]. The questionnaire has been forward translated by our research group from English to Swedish. After face validity consensus in our research group regarding relevant domains for the implementation of BetterBack☺ MOC, the questionnaire was shortened to the following domains: Knowledge, Skills, Beliefs about capabilities, Beliefs about consequences, Intentions, Innovation, Organisation, Patient, Social influence, Behavioural regulation totalling to 57 items. Questions were adapted to the context of HCP reported determinants of an "expected" implementation of BetterBack☺ MOC for measurement directly after the HCP education and training workshop. HCP reported determinants retained orginal wording for the questionnaires at 3 and 12 months after the implementation of BetterBack☺ MOC. The response scale used for each DIBQ question in our study is a 5-point Liket scale ranging from 1= `totally agree´ to 5=`totally disagree´.

Implementation outcome measures

- At 12 months after baseline, data will also be extracted from the public health care regional registry for the total number of patient visits for LBP, the number patients needing primary care multimodal pain team treatment, the number referred to specialist pain clinic, orthopedic or neurosurgical care and the number receiving surgery.
- Clinical reasoning and process evaluation tool (CRPE-tool): Grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP is assesses by the physiotherapist at baseline and final clinical contact where light, moderate, severe and very severe impairment/limitation is coded 0-4 respectively. A total score for baseline and follow-up measures is calculated from the sum of the functional impairment divided by the number of functional impairments and a similar total score is calculated for activity limitations [47]. A worsening of functional impairments and activity limitations measured att follow-up with the CRPE will be considered in the analysis of adverse events. Swedish Classification of Health Interventions (KVÅ) codes for assessment and treatment interventions will be assessed to analyse coherence with the Swedish best practice clinical recommendations. ICD-10 diagnosis codes and will also be recorded.
- The Keele STarTBack Screening Tool is reported by patients at baseline providing a stratification of prognostic risk of persistent pain. The overall score ranging from 0-9 is used to separate the low risk patients from the medium-risk subgroups where patients who achieve a score of 0-3 are classified into the low-risk subgroup and those with scores of 4-9 into the medium-risk subgroup. To identify the high-risk subgroup, the last 5 items must score 4 or 5 [69-71].
- Focus groups performing qualitative SWOT analyses will be conducted by HCP between 3-6 months after implementation.
- Semi-structured interviews with 10 HCP at 3 months after implementation will be conducted to investigate determinants of implementation behaviour and if other determinants need to be added to the DIBQ. The interviews will be deductively analysed according to the TDF [41] and BTW [39] frameworks.
- Semi-structured interviews investigating the patient experience of recieving care for LBP will be performed on 10 patients. These patients will have received care after implementation of the BetterBack☺ MOC.
- Economic costs of developing the BetterBack☺ MOC as well as performing the implementation strategy (staff time, HCP training, and printed resources).

Patient outcome measures

- NRS-LBP intensity during the latest week is an 11-point scale consisting of integers from 0 through 10; 0 representing ‘‘No pain’’ and 10 representing ‘‘Worst imaginable pain’’. Previous research in a LBP cohort has shown a test-retest reliability ICC = 0.61, a common standard deviation=1.64 points, the standard error of measure = 1.02 and minimal clinically important difference (MCID) in LBP after treatment=2 [72-73].
- ODI version 2.1 assesses patient’s current LBP related limitation in performing activities such as personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. The ODI consists of 10 items with response scales from 0 to 5, where higher values represent greater disability. The ODI is analysed as a 0 to100 percentage variable where lower scores represent lower levels of low back pain disability. A reduction of 10 points is considered the MCID in LBP after treatment [50,70]. In Scandinavian conditions, the coefficient of variation, ICC and internal consistency of the ODI is 12%, 0.88-0.91 and 0.94 respectively [74-76]. Good concurrent validity has also been shown [75].
- The EQ-5D measures generic health-related quality of life and is computed into a 0 to 1.00 scale from worst to best possible health state by using the Swedish value sets [77]. A reduction of 0.08 points is considered the MCID in LBP after treatment [78]. Mean change after treatment for LBP has been reported to be 0.12 (SD±0.30) [79].

- The BIPQ analyses cognitive illness representations (consequences, outcome expectancy, personal control, treatment control, and knowledge), emotional representations (concern and emotions) as well as illness comprehensibility. An overall score 0-80 represents the degree to which the LBP is perceived as threatening or benign where a higher score reflects a more threatening view of the illness [52]. The BIPQ has been shown to be valid and reliable in a Scandinavian sample of patients with subacute and chronic LBP. The BIPQ has a Cronbach's alpha =0.72 and a test-retest ICC = 0.86, an ICC range for individual items from 0.64 to 0.88, a standard error of measurement (SEM) = 0.63 and minimal detectable change (MDC) = 1.75[80].
- The PEI has a score range between 0 and 12 with a higher score intended to reflect higher patient self-care enablement [59].
- PGIC asks the patient to rate the degree of change in LBP related problems from the beginning of treatment to the present. This is measured with a balanced 11 point numerical scale. A reduction of 2 points is considered the MCID in LBP after treatment [60].
- PS is measured with a single item patient reported question. The question asks "Over the course of treatment for this episode of low back pain or leg pain, how satisfied were you with the care provided by your health-care provider?" Were you very satisfied (1), somewhat satisfied (2), neither satisfied nor dissatisfied (3), somewhat dissatisfied (4), or very dissatisfied (5)?" [61].
- Economic costs of health service utilisation.

Data management

All paper based questionnaire data will remain confidential and will be kept in a lockable filing cabinet in the research group office. A password-protected coded database only accessible to the research team will be kept on a data storage drive in the research department. The research team will regularly monitor the integrity of trial data. Trial conduct will be audited on a weekly basis by the research team.

Statistical analysis

Statistical significance will be assessed with an alpha level of 0.05. All results will be reported as estimates of mean ± standard deviation and also effect size (e.g. mean difference) with 95% confidence intervals (95% CI). An intention-to-treat (ITT) principle applying multiple imputation will be utilised. A sensitivity analysis will compare per protocol and ITT databases. A sensitivity analysis will also be used to assess the significance of a washout period by comparing the complete database against the same database without data collected during the 2 weeks in conjunction with the Betterback☺ implementation in each cluster.

Implementation process and outcome analysis

ANOVA statistics comparing baseline and follow-up means will be used for implementation process and outcome measures. Causal mediation analysis will be used to analyse indirect mediational effects of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education and training workshop (intention stage) or at 3 or 12 months (volition stages) on the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT. If the HCP education and training workshop does not have a casual effect on improved prospective outcomes we will analyse where the causal pathway breaks down. Causal mediation analysis will be performed using the program PROCESS [81] within IBM SPSS (figure 6).

Patient outcome measures for the control and intervention groups will be compared using multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects with IBM SPSS. Fixed effect interactions between experimental

condition and The Keele STarT Back Screening Tool will also be assessed. Patient population specific minimal clinically important difference will be assessed för primary and secondary outcomes based on an anchor method where PGIC serves as an anchor. Applying a 1-1-1 multilevel mediation procedure with all effects random in MPLUS, the products of (1) the independent variable (Experimental condition: control or intervention) to the mediator (change in BIPQ, PEI), and (2) the mediator to the dependent variable (change in NRS, ODI or secondary outcome scores pre- to posttreatment) when the independent variable is taken into account, will be tested for mediation (figure 7).

Economic analysis

The reference case analysis is based on a health care sector perspective. The EQ5D will be used to calculate the ratio of costs to quality adjusted life years (QALY) saved for patients. Incremental cost-effectiveness ratios (ICER) for the multifaceted implementation strategy and the usual care condition will be calculated and plotted on a cost-effectiveness plane. This is based on the Swedish guideline priced direct costs of health service utilisation, organisational costs of developing the BetterBack☺ MOC as well as performing the implementation strategy and overall intervention clinical outcome effectiveness. The ICER will also be calculated per patient avoiding specialist care. To estimate a distribution of costs and health measures and confidence intervals for ICER, boostrapping will be used.

Data monitoring

All outcome questionnaires are formatted for use of scan processing software for automated data entry into the Statistical Package for the Social Sciences package. The author KS who is not blinded to treatment allocation will perform regular data checks during data entry and provide feedback when necessary to HPC regarding data omissions. JS will also double check data entry to detect and correct input errors, and range checks will be undertaken prior to data analysis.

Ethics and dissemination

Ethical clearance for the study (Dnr:2017-35/31) has been attained through the Regional Ethics Committee in Linköping. The ethics application including consent forms in Swedish is available upon request to the authors. Their are no known risks for participants. Voluntarily participating HCP will complete questionnaires. All participating patients are informed orally and in writing about the study on the first visit at participating primary health care clinics. They are informed about that participation is voluntary and that they can at any time withdraw their participation. The HCP intervention will not be affected by the patient's decision to participate or not participate in the study. Data collection will not be performed for those not participating. A signed patient consent form will be collected from patients by the HCP before baseline measures are collected and intervention is commenced according to the study protocol. All collected data will be entered into a database accessable to the authors. A code list will be created where each participant will be represented by a code so that the database will be anonymous. The code list with personal data will be stored separately in locked filing cabinets at Linköping Univerity to protect confidentiality before, during and after the study. Data analyses and reporting will be performed using the de-identified database. The authors plan to disseminate the findings through manuscript publications in scientific journals and presentation at conferences.

Internal pilot trial results

The initial implementation of the BetterBack☺ MOC in cluster 1 allowed for an internal pilot to determine the HCP acceptability of the intervention and trial within the first cluster [32,33]. A progression criteria for continuing to the main trial required that HCP who have completed the BetterBack☺ education and training workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ MOC will be useful (1 = agree completely - 5 = do not agree at all). The 27 HCP

participating in the internal pilot in cluster 1 responded to the question with a mean value of 1.7 (SD 0.8) which subsequently fulfilled the HCP progression criteria.

The resulting internal pilot patient flow for april and may were n=28, n=28 for cluster 1 west (intervention) , n=5, n=12 for cluster 2 central (control) as well as n=14, n=22 for cluster 3 east (control) consecutively. This informed the decision to move the cluster 2 transition from control to intervention condition to occur later in the schedule, planned for september 2017 to allow for more control condition patient recruitement and data collection. The flow of patient recruitment and the process of 3 month follow-up in the internal pilot was used to inform the optimal time point of patient reported primary outcome for the main trial. Our initial planning was to measure patient reported primary outcome at 6 months post baseline based on the definition of persistence/chronicity of symptoms being often defined in the literature to be of 3 and up to 6 months duration [82]. Our intern pilot study had a 3 month follow rate of 80% resulting after up to 3 reminders sent to many of these patients. This informed of a likely risk of non-response at later follow-up time points. Furthermore, feedback from participating HCP even reported a larger clinical interest in 3 month patient follow-up data. Therefore the internal pilot informed the choice to revise our patient reported primary outcomes to 3 month post-baseline with subsequent amendments of the trial registration on ClinicalTrials.gov: NCT03147300.

Our internal pilot study was also used to assess baseline variation and change over 3 months in HCP and patient reported primary outcome measures in the control and intervention arms to aid calibration of the sample size calculation. A multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects revealed a intracluster correlation of <0.01 for the all primary outcomes measures. A small effect size in favour of the intervention condition was shown for HCP reported PCS (d=0.33) directly after implementation but increased to a moderate effect size after 3 months (d=0.51). Patient reported NRS showed a small effect size (d=0.28). Therefore, the internal pilot data supported our a priori sample size calculation for the main trial regarding PCS and NRS. However no effect size difference were observed between experimental conditions for ODI. It is possible that when statistical power improves when the trial progresses, potential differences in ODI may be detectable between experimental conditions.

CONCLUSION

The effectiveness-implementation hybrid type 2 trial with dog-leg stepped cluster structure allowed for the use of an internal pilot to inform feasibility and optimise method efficiency for the progression of the trial.

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Authors' contributions: AA & BÖ formulated the trials original aims and hypothesis. AA, KS, BÖ developed interventions material. AA, KS, PE, PN, ÖB designed the study methodology. AA, PN, BÖ procured funding for the trial. AA, KS, PE, PN, ÖB have reviewed and finalised the protocol.

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Table 1. World health organisation trial registration data set.

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03147300
Date of registration in primary registry	03 May, 2017
Prospective Registration:	Yes
Secondary identifying numbers	N/A
Source(s) of monetary or material support	Linköping University
Primary sponsor	Linköping University
Secondary sponsor(s)	N/A
Contact for public queries	*Allan Abbott*, MPhysio, PhD [+46 (0)13 282495] [allan.abbott@liu.se]
Contact for scientific queries	*Allan Abbott*, MPhysio, PhD Linköping University, Linköping, Sweden
Public title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain BetterBack
Scientific title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain in Sweden (BetterBack): A Cluster Randomised Trial
Countries of recruitment	Sweden
Health condition(s) or problem(s) studied	Low back pain
Intervention(s)	Behavioral: Current routine practice Behavioral: Multifaceted implementation of the BetterBack
Key inclusion and exclusion criteria	Health care practitioner sample Inclusion Criteria: - Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP Patient sample Inclusion Criteria: - Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a current episode of a first-time or recurrent debut of benign low back pain with or without radiculopathy Exclusion Criteria: - Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfill criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis
Study type	Interventional
Date of first enrolment	April 1, 2017
Target sample size	600
Recruitment status	Recruiting
Primary outcome(s)	- Incidence of participating patients receiving specialist care [Time Frame: 12 months after baseline] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Change between baseline and 3 months post baseline] - Oswestry disability index (ODI) version 2.1 [Time Frame: Change between baseline and 3 months post baseline] - Practitioner Confidence Scale (PCS) [Time Frame: Change between baseline and 3 months post baseline]
Key secondary outcomes	- Clinician rated health care process measures [Time Frame: Baseline and final clinical contact (Up to 3 months where the time point is variable depending upon the amount of clinical contact required for each patient)] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Baseline, 3, 6 and 12 months] - Oswestry disability index (ODI) version 2.1 [Time Frame: Baseline, 3, 6 and 12 months] - Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [Time Frame: Baseline, directly after education and at 3 and 12 months afterwards] - Patient Enablement Index (PEI) [Time Frame: 3, 6 and 12 months] - Patient global rating of change (PGIC) [Time Frame: 3, 6 and 12 months] - Patient satisfaction [Time Frame: 3, 6 and 12 months] - Practitioner Confidence Scale (PCS) [Time Frame: Baseline, directly after commencement of implementation strategy and at 3 and 12 months afterwards] - The Brief Illness Perception Questionnaire (BIPQ) [Time Frame: Baseline, 3, 6 and 12 months] - The European Quality of Life Questionnaire (EQ-5D) [Time Frame: Baseline, 3, 6 and 12 months]

Table 2. Study design and schedule of enrolment, interventions and assessments.

Timeline		June 2016 - Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Final clinic visit	Follow-up 3 months after baseline	Follow-up 6 months after baseline	Follow-up 12 months after baseline
Enrolment schedule			HCP Cluster random allocation	Patient recruitment during internal pilot phase		Patient recruitment during main trial phase											
Intervention schedule		MOC and protocol development	Cluster 1 West MOC implementation internal pilot	1	1	1	1	1	1	1	1	1	1				
			Cluster 2 Central	0	0	0	0	0 MOC implementation	1	1	1	1	1				
			Cluster 3 East	0	0	0	0	0	0	0	0	0	0 MOC implementation				
Assessment schedule				Baseline data Internal pilot (T=0)		Baseline data Main trial (T=0)								Longitudinal repeated measures in cohorts (T=1)	(T=2)	(T=3)	(T=4)
Implementation process	**PCS**		Cluster 1 before and after MOC implementation					Cluster 2 before and after MOC implementation					Cluster 3 before and after MOC implementation		x		x
	PABS-PT		Cluster 1 before MOC implementation					Cluster 2 before MOC implementation					Cluster 3 before MOC implementation		x		x
	DIBQ		Cluster 1 after MOC implementation					Cluster 2 after MOC implementation					Cluster 3 after MOC implementation		x		x
PROMS	**NRS back pain and leg pain**			x	x	x	x	x	x	x	x	x	x		x	x	x
	ODI			x	x	x	x	x	x	x	x	x	x		x	x	x
	EQ5D			x	x	x	x	x	x	x	x	x	x		x	x	x
	BIPQ			x	x	x	x	x	x	x	x	x	x		x	x	x
	PEI														x	x	x
	Satisfaction														x	x	x
	PGIC														x	x	x
Implementation	**HCP assessment, diagnosis and treatment codes**			x	x	x	x	x	x	x	x	x	x	x			
	Referrals to specialist care																x

MOC=model of care, 0=Control condition, 1=Intervention condition, PROMS=Patient reported outcome measures, grey shaded cells=internal pilot, T= assessment time. ◄► Period where 2 week cross-over from control to intervention can occur dependent upon patient recruitment rates identified in the internal pilot study.

Table 3. Characterising the BetterBack☺ model of care intervention content and mechanisms of action using the Behaviour Change Wheel [41], Behavioural change technique (BCT) taxonomy (v1) [42], and the TDF [43].

Target behavior	Rationale based on barriers to be addressed	BetterBack☺ MOC content to overcome the modifiable barriers				Mechanism of action	
		Mode	Content	BCT[42]	Functions	COM-B	TDF
Improved HCP confidence and biopsychosocial orientation in treating LBP through adoption of BetterBack☺ model of care	1) Low confidence in skills/capabilities for improving LBP patient management 2) Use of a biomedical treatment orientation rather than a biopychosocial orientation 3) Low awareness of the model 4) Beliefs of negative consequences of the model	1) Multifaceted implementation strategy - Workshop education	Evidence based model of care and clinical implementation tools (See supplementary files 1 & 2)	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				1.4 Action planning	Enablement	Psychological capability	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.3 Information about social and environmental consequences	Persuasion	Social opportunity Physical opportunity	Social Influences Environmental context and resources
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.2 Pros and cons	Persuasion	Reflective motivation	Beliefs about Consequences
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		2) Multifaceted implementation strategy - Report and website	Evidence based model of care and clinical implementation tools (See supplementary file 2)	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
Decreased patient LBP and disability as well as improved patient enablement of self-care	1) Maladaptive beliefs on the cause and course of LBP (Illness perception) = low outcome expectation, anxiety, catastrophizing, fear-avoidance, illness beliefs. 2) Low belief in ability to control pain. Low belief in ability to perform activities, low	1) BetterBack☺ Part 1. Individualised information at initial and follow-up visits.	Lay language pedagogical explanation of function impairment and activity limitation related assessement findings and matched goal directed treatment	5.1 Information about health consequences	Education	Psychological capability	Knowledge
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
		2) BetterBack☺ Part 1. Patient education brochure	Lay language education on the spine's structure and function, natural course of benign LBP and advice on self-care	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
		3) BetterBack☺ Part 2. Group education	Pain physiology, biomechanics, psychological coping strategies and behavioural regulation	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge

	baseline physical activity.			4.3 Re-attribution	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.2 Behaviour substitution	Enablement	Psychological capability	Behavioral regulation
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				10.8 Incentive (CME diploma)	Enablement	Reflective motivation	Reinforcement
				11.2 Reduce negative emotions	Enablement	Reflective motivation	Emotion
				12.4 Distraction	Enablement	Reflective motivation	Memory, attention and decision processes
				12.6 Body changes	Training	Physical capability	Physical skills
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
		4) BetterBack☺ Part 1. Individualised physiotherapy	Physiotherapist mediated pain modulation strategies and functional restoration strategies. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				7.1 Prompts/cues	Environmental restructuring	Automatic motivation	Environmental Context and Resources
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		5) BetterBack☺ Part 2. Group or home based physiotherapy	Patient mediated self-care pain modulation strategies, functional restoration strategies and general exercise. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				1.8 Behavioural contract	Incentivisation	Reflective motivation	Intentions
				2.3 Self-monitoring of Behaviour (Training diary)	Training	Reflective motivation	Behavioral regulation
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities

Figure 1. Effectiveness-implementation hybrid type 2 trial design

Figure 2. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

Figure 3. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack☺ model of care for LBP.

Figure 4. Steps involved for HCP in delivering the contents of the BetterBack☺ MOC.

Figure 5. The Behavioral Change Wheel [39] and TDF [41].

Figure 6. Causal mediation model to analyse indirect mediational effects ($a^k b^k$) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c').

Figure 7. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=c_j', indirect=$a_j b_j$, and total effects= $c_j' + a_j b_j$) are allowed to vary between level-2 clusters.

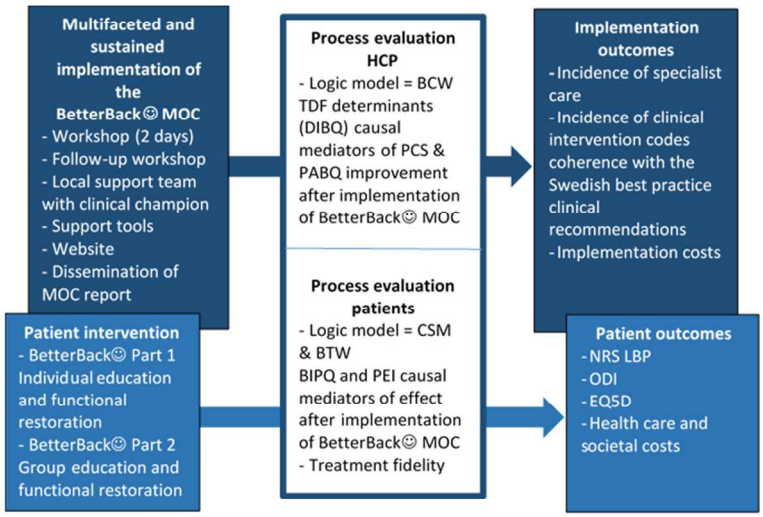

Figure 1. Effectiveness-implementation hybrid type 2 trial design

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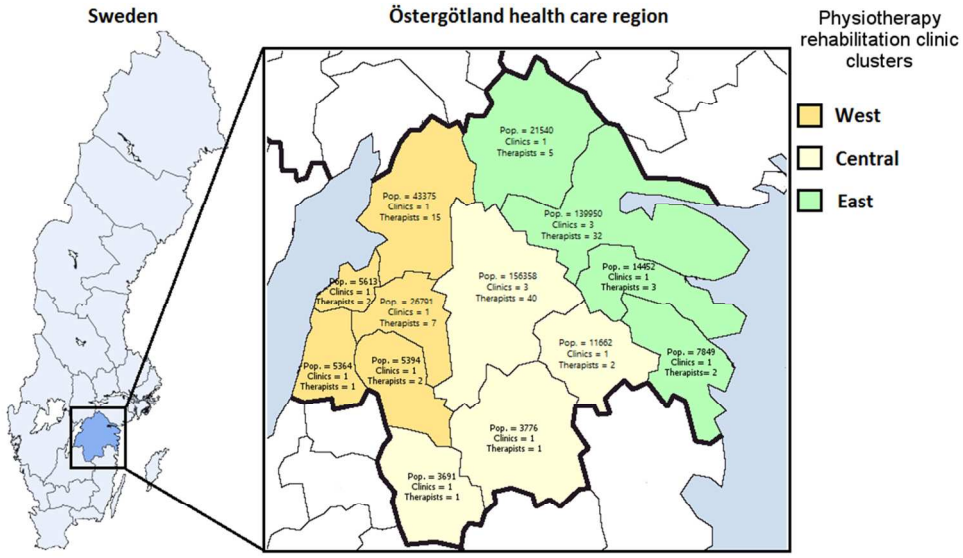

Figure 2. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

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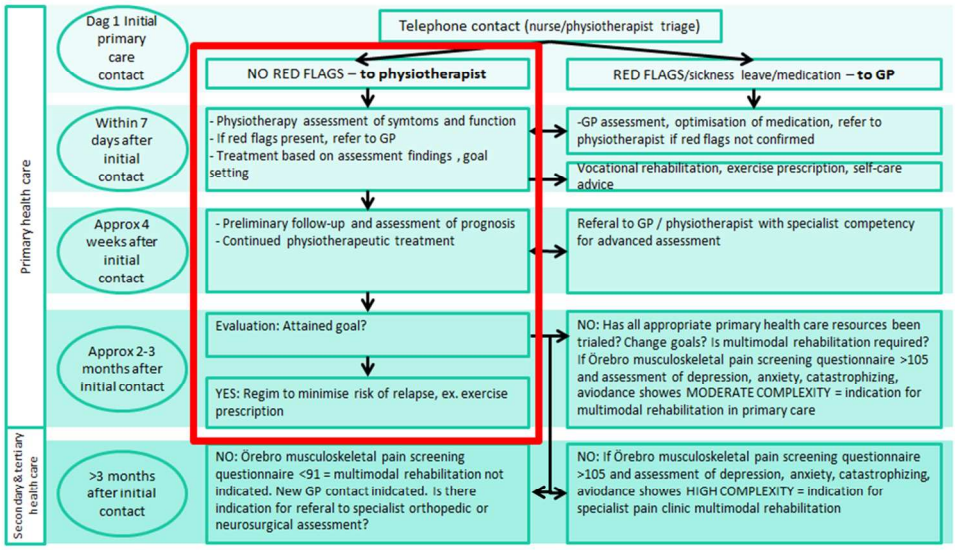

Figure 3. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack9 model of care for LBP.

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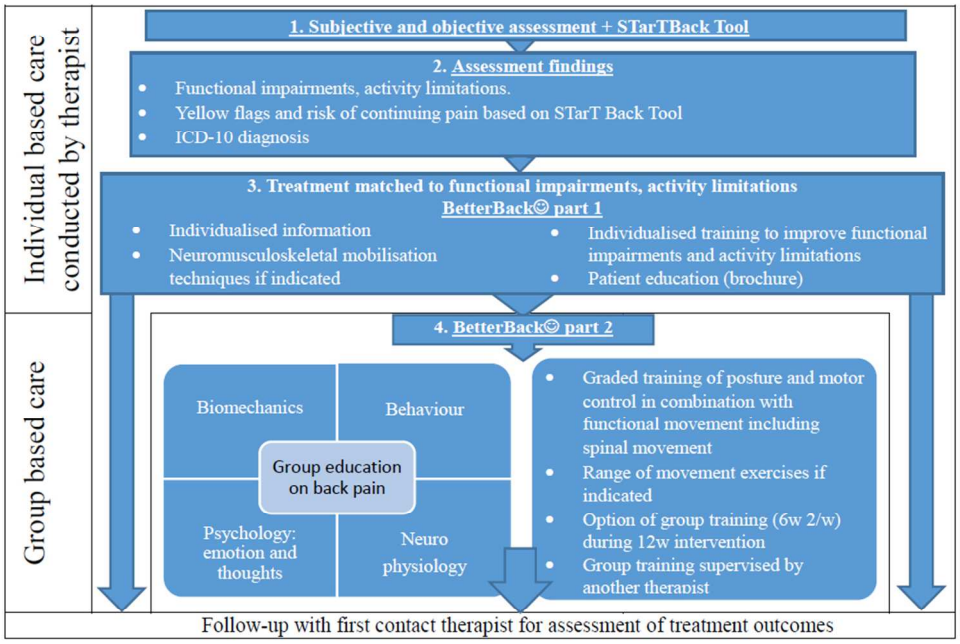

Figure 4. Steps involved for HCP in delivering the contents of the BetterBack MOC.

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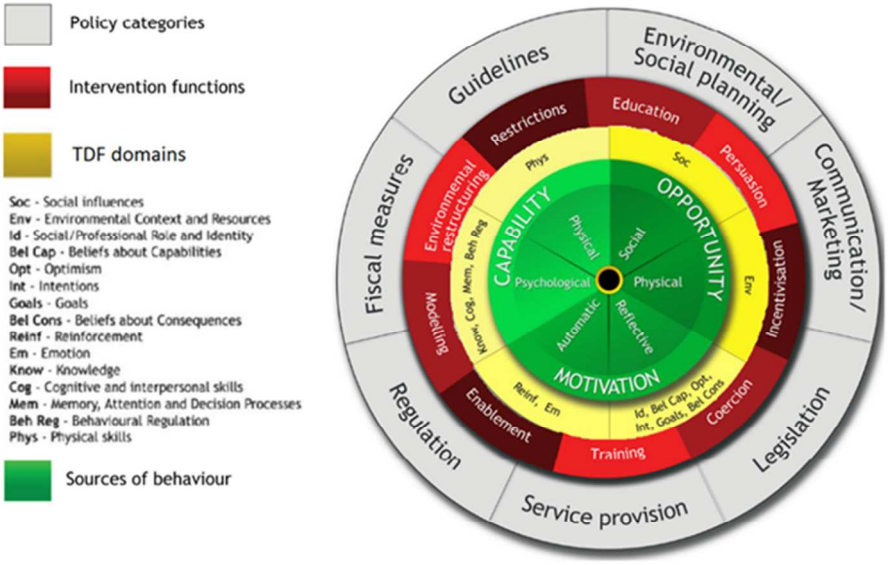

Figure 5. The Behavioral Change Wheel [39] and TDF [41].

127x84mm (300 x 300 DPI)

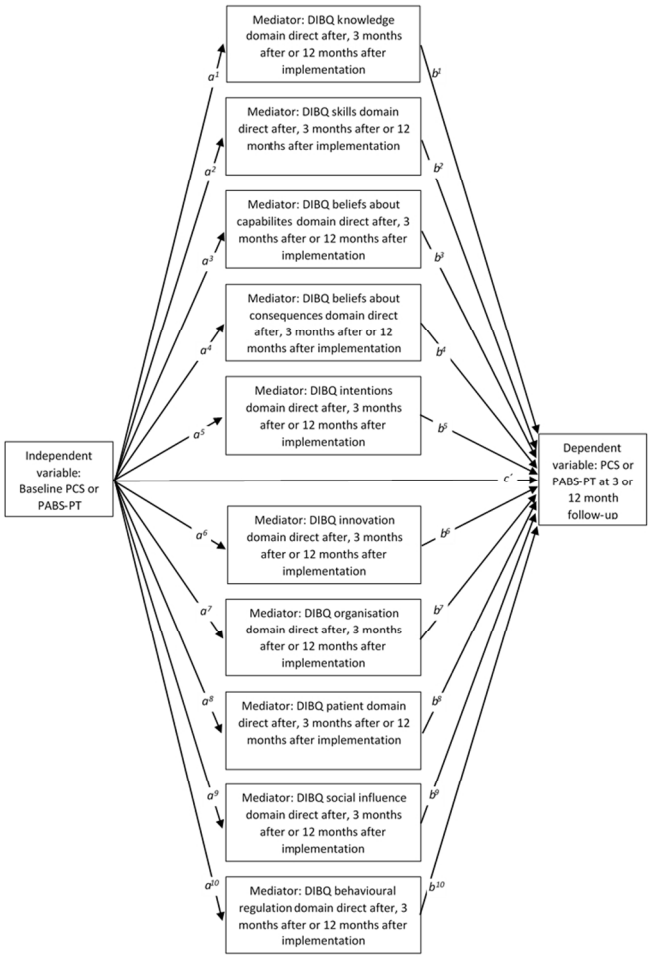

Figure 6. Causal mediation model to analyse indirect mediational effects (akbk) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c´).

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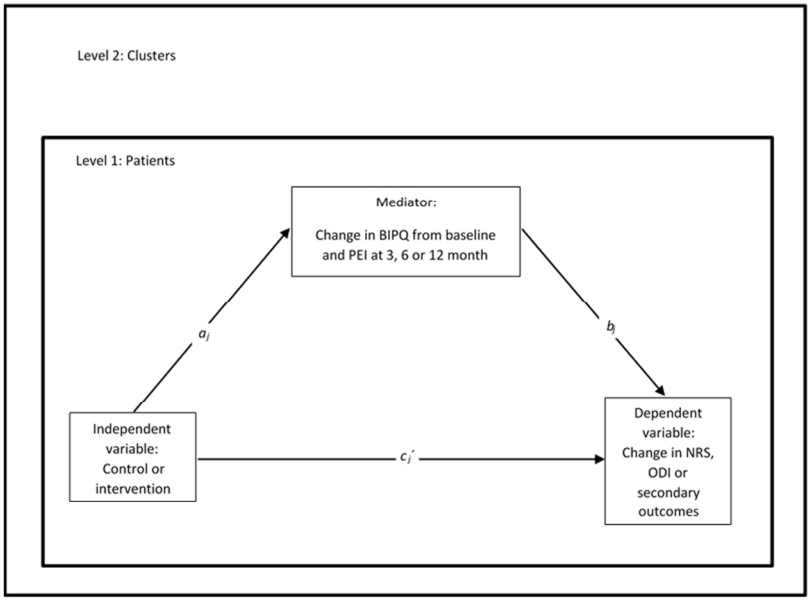

Figure 7. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=cj´, indirect=ajbj, and total effects= cj´+ ajbj) are allowed to vary between level-2 clusters.

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Manuscript page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1,19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-3
	6b	Explanation for choice of comparators	2-3
Objectives	7	Specific objectives or hypotheses	3-4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4-5, Table 2

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-8, table 3, figure 2-4, sup file 1-2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	5-8, Table 3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-10, Table 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10-11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10-11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-14
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13-14

Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	4-5, 14-15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	**BRIEF NAME** Provide the name or a phrase that describes the intervention.	p2	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	p6-8	Supplementary file 3
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p6-8, Table 3, Figures 2-4	Supplementary files 3&4
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p6-8, Table 3, Figures 2-4	Supplementary files 3&4
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	5	
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Table 3, Figure 4	Supplementary files 3&4
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	5 Figure 1	

8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p6-8, Table 3	Supplementary files 3&4
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p7-8	Supplementary files 3
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	p12	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

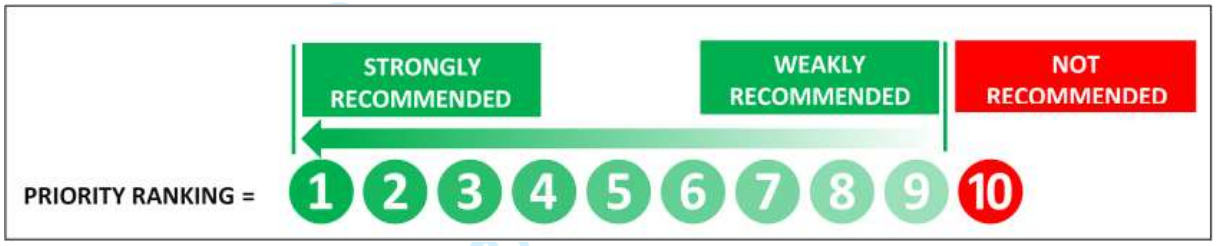
* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BetterBack☺ Model of care for LBP

Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of benign LBP with or without radiculopathy

Each evidence based guideline recommendation is supported by a clinical priority ranking. This is based on an overall assessment of the severity of the condition, reported effect of the intervention, strength of evidence assessment (GRADE), cost-effectiveness and the benefit of the intervention based on professional experience and patient benefit. A scale from 1 to 10 is used where the number 1 indicates recommended practices with the highest priority while the number 9 indicates recommended practices of low priority. The number 10 indicates recommendations that provide very little or no benefit or utility and are therefore not recommended.



Recommendation 1	PRIORITY RANKING = 1 **2** 3 4 5 6 7 8 9 10
Routine care should consist of standardised processes for subjective and objective assessment and diagnostics. A thorough screening of red flags is essential to rule out serious pathology. Treatment should be individualised for each patient. Basic treatment principles should be based on reassurance of a good prognosis, maintenance of appropriate physical activity and self-care enablement. Justification: The work group's reasoning is based on clinical experience of the importance of careful screening to rule out serious pathology. Furthermore, standardised assessment and diagnostics provide quality assurance but treatment needs to be individualised for each patient case. The work group also reasoned based on clinical experience that appropriate physical activity is likely to contribute to maintaining the patient's functional level, psychosocial and general health as well as have positive effects on self-care enablement. In some cases, may physical activity temporarily aggravate pain and symptoms, but there are no known persisting side effects. The work groups reasoning is also based on evidence showing a statistically significant advantage for maintaining appropriate physical activity compared to bed rest for improving pain and function. Despite this, evidence that proves the benefit of appropriate physical activity is so great to be clinically relevant is missing. In addition, the best available evidence has however a currently limited scientific basis (⊗⊗○○). *The working group proposes the following resources in the BetterBack☺ model of care to support the implementation of Recommendation 1 (See sections 1-5)*	
Recommendation 2	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 **10**
Do not perform routine medical imaging investigations (eg X-ray, CT, MRI) Justification: The work group´s reasoning is based on evidence that shows no differences in outcomes of pain, function and quality of life between patients who received or did not receive	

routine medical imaging investigations in the primary care context. The best available evidence has however a currently inadequate scientific basis (⊗○○○). It was also discussed that imaging cannot confirm or reject a preliminary diagnosis as the relationship between patient symptoms and degenerative imaging finding is usually weak. Moreover, degenerative secondary findings are common in asymptomatic individuals. *The work group however suggests that early use of medical imaging is motivated in the presence of symptoms or signs suggesting possible serious underlying pathology (red flags). Medical imaging may also be relevant when pain persists despite primary care treatment.*
Recommendation 3 — **PRIORITY RANKING =** 1 2 3 4 5 **6** 7 8 9 10
Consider using a patient-reported tool (eg STarT Back risk assessment tool) as usual care during the early-stages of patient management to screen the risk of continued LBP Justification: The work group's reasoning is based on studies showing that STarT Back Tool is the only valid tool to investigate the risk of continued back pain in the primary care context. It shows the highest accuracy for detecting patients with low risk profile (total score ≤3) and medium-high risk profile (total score ≥4) for continued back pain. Studies also show that STarT Back Tool has the best ability to predict functional and pain-related outcomes. The best available evidence has however a currently inadequate scientific basis (⊗○○○). No economical evaluations were identified but the working group discussed the importance of a simple and fast tool. STarT Back Tool can be filled in and analyzed in a few minutes to advantage over other tools that can be an administrative burden for patients and healthcare professionals. *The working group argues that the predictive value of the tool should support, but not replace, regular examination procedures and clinical decision making. See section 3 for STarT Back Tool.*
Recommendation 4 — **PRIORITY RANKING =** 1 2 3 4 5 6 7 **8** 9 10
Consider using a patient-reported tool (such as the STarT Back risk assessment tool) and classification of examination findings during the early-stages of patient management to aid the stratification of care to prevent continued LBP Justification: The work group reasoned that for the choice and scope of targeted treatment measures, consideration should be given to the assessment of risk profile for long-term LBP and classification of examination findings. This has been shown to have a better effect on pain, function and quality of life, as well as less economic costs compared to no treatment stratification. The best available evidence has however a currently inadequate scientific basis (⊗○○○). For a patient with low risk profile (total score ≤3 on STarT Back Tool) usual care is relevant and requires only few visits, but the working group recommends that adequate treatment measures directed at examination findings is of the highest importance. For patients with medium-high risk profile (total score ≥ 4 on STarT Back Tool), usual care will require additional visits. Information provided in questions 5-9 on STarT Back Tool that investigate anxiety with psychological risk factors can guide the need, focus and extent of behavioral medicine measures. *The working group argues that stratified care classified after assessing a risk profile for long-term back pain should support but not replace conventional examination procedures and clinical decision-making for treatment measures. The working group proposes the following resources to support the implementation of targeted treatments based on stratification (See sections 1-5).*
Recommendation 5 — **PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10
Consider giving individualised patient education as a part of usual care (e.g. an explanatory model based on pain neuroscience and psychological mechanisms)

Justification: Based on the best available evidence, the work group reasoned that individualised patient education as part of usual care can result in reduced work sickness absenteeism. The priority of the recommendation has been strengthened by consensus within the work group based on proven experience that individual adapted patient education is an important part of patient-centered care. The best available evidence has however a currently inadequate scientific basis (⊗○○○). The intervention requires that the patient is receptive for education. The extent of patient education can depend upon whether the patient has a distorted image of the underlying mechanism of LBP and a high degree of negative outcome expectations, anxiety, and fear-avoidance or if they are inactive or passive in managing the LBP. Patient education should include a reassuring dialogue and other cognitive and behavioural therapeutic techniques of relevance to support change in the individual's maladaptive thoughts, feelings and behaviors. Pedagogical explanation models should be used to provide the patient with knowledge about symptoms and disorders, as well as to strengthen and support self-care ability to master everyday activities. *The work group proposes the following resources to support of the implementation of patient education (See sections 6-7)*

Recommendation 6	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider a supervised exercise program as part of usual care

Justification: Supervised training is defined as general or back-specific exercises or physical activities conducted under the guidance of a healthcare professionals. The work group's reasoning is based on scientific evidence and proven experience that supervised training as part of usual care can result in clinically relevant improvement in pain, function, quality of life and produces lower health care costs compared with no supervised training. There is however no evidence that a specific type of exercise would be superior to another. The best available evidence has however a currently limited scientific basis (⊗⊗○○).

The work group proposes the following resources to support the implementation of a supervised training program (see section 8).

Recommendation 7	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider mobilisation techniques for neuromusculoskeletal structures as part of usual care (including active or passive motion in an angular and / or translational plane)

Justification: The working group reasoning is based on evidence that for patients with segmental movement impairments, mobilization techniques can provide a statistically significant reduction in short-term pain. It is however uncertain whether the effect is sufficiently large so that patients experience a clear improvement overtime. At group level, there is no evidence that a particular technique is be superior to another. It cannot be ruled out that for subgroups of LBP patients, more positive effects on pain and function may be produced by specific mobilisation techniques. It is expected that these subgroups can be identified by careful diagnostics and short trial treatments. Mobilizing techniques as part of multimodal treatment provide better results. Serious side effects are rare. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○).

Recommendation 8	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 **9** 10

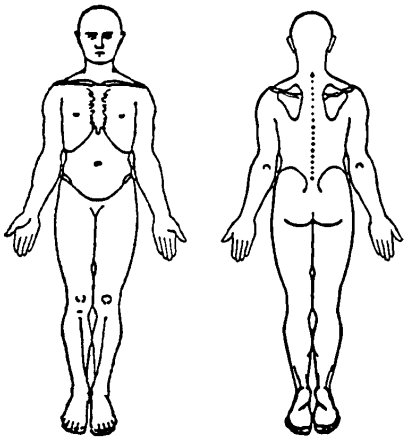
Consider acupuncture treatment in addition to usual care

Justification: The working group reasoned based on evidence that cannot exclude acupuncture has a short-term pain relief effect in addition to a placebo effect. Acupuncture has however no effect on function. Side effects in the form of brief superficial bleeding or inflammation may occur.

Pneumothorax and systemic infections are not common, but the prevalence is unknown. The best available evidence has however a currently inadequate scientific basis (⊗○○○).	
Recommendation 9	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer corset, shoes, traction, ultrasound or electrotherapy Justification: The work group's reasoning is based on evidence that passive treatments such as corset, shoots / soles, traction, ultrasound or electrotherapy do not reduce pain or improve function and quality of life in patients more than no treatment or when offered as part of multimodal treatment. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○). ***It cannot be ruled out that subgroups of patients may experience positive effects of these interventions when a hypothesised effect mechanism is aimed at specific functional impairment or activity limitation.***	
Recommendation 10	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Consider prescription-free NSAID medication if necessary in addition to usual treatment (lowest dose and shortest possible treatment time). NSAIDs: There is evidence of the effect of NSAID in patients with long-term LBP but the effect has not been highlighted on short-term pain or functional outcomes. There are no adverse reactions reported in systematic review studies on LBP, but potential transient side effects of NSAIDs such as reduced blood clotting, reduced stomach mucous function and reduced kidney function are known from studies on other conditions. The work group reasoned that lowest dose and shortest possible treatment time decreases the risk of side-effects. The work group anticipates that there are differences in patient preferences regarding NSAIDs, where some patients will agree to NSAID treatment, while others will decline. The best available evidence for NSAID effects on LBP outcomes is based on an inadequate scientific evidence (⊗○○○). The work group reasoned based on clinical experience that it cannot be excluded that the NSAID may have a pain relief effect in the short term.	
Recommendation 11	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer paracetamol or opioids Paracetomol: Has no effect on the degree of LBP and functional ability. There are no reported adverse reactions in studies, but side effects of paracetamol in the form of hepatic effects are known from studies on other conditions. The best available evidence is based on a moderately strong scientific basis (⊗⊗⊗○). Opioids: A weak analgesic effect of oxycodone in combination with paracetamol has been demonstrated in a study but the intervention has no effect on functional capacity for up to 12 weeks. Other positive effects or adverse effects were not shown. A wide range of opioid side effects are known from other studies. Therefore, the working group reasoned that treatment results in more risks than benefits to the patient. The best available evidence is based on a currently limited scientific basis (⊗⊗○○).	

BetterBack☺ model of care implementation support tools

1. Subjective assessment proformer for therapist use

LOW BACK SUBJECTIVE ASSESSMENT PROFORMER			
Name:…… Date of birth:…….. Date:……..			
History of the present condition (debut, duration, activity limitation)	**Symptom localisation** 		
Symptom Description	Localisation back	Localisation right leg	Localisation left leg
Pain nature (Dull, stabbing, radiating etc)			
Pain frequency (Constant/ Intermittent)			
Pain Intensity (NRS 0-10)			
Daily variation (am/pm, night time pain/disturbed sleep)			
Irritability (non-irritable/highly irritable)			
Aggravating factors (loading etc)			
Easing faktors (rest etc)			
Course (Improving/same/worse)			
Other symptoms (Instability, weakness, paresthesia, stiffness)			
Past medical history Previous level of function/activity: Previous treatment:	Red flags: (malignancy, unexplained weight loss, trauma, osteoporosis, infection, inflammatory disease, spinal cord compression symtoms, drug use) Other illnesses/ General health:		
Work, Social, Family history	**Patient förväntningar**		
Medication	**Medical imaging/Laboratory tests**		

2. Physical assessment proformer

LOW BACK PHYSICAL ASSESSMENT PROFORMER

1. INSPECTION – Postural screen

Sitting: good/fair/poor	Postural correction: Better/Worse/No effect	
Standing: good/fair/poor	Postural correction: Better/Worse/No effect	
Lordosis: Hyper/hypo/normal	Kyphosis: Hyper/hypo/normal	Lateralt shift: Right/Left/none
Spinal symmetry:	Shoulder symmetry:	Pelvic symmetry:
Leg & fot symmetry:	Muscular hypo/hypertrophy:	Scars:

2. SCREENING OF FUNCTIONAL MOVEMENT:

Shoes on/off, sit-stand, 2 leg/ 1 leg squat, lunge right/left
Gait: Trendelenburg right/left
Limp right/left
Weight transfer right/left
Toe walking right/left
Heel walking right/left
Work or sport specific:_____

3. SCREENING TEST IN STANDING/SITTING

	Right	Left
Slump test + sensitisation head/foot		
Foramen compression/unloading		
Hip loading/unloading in standing		

4. TEST IN STANDING/SITTING
LUMBAR ACTIVE ANGULAR MOVEMENT

	Range			Quality		Symptoms		
	Large	Med	Small	High	Low	During range	End range	Rep Mov
Flex								
Ext								
Lateral flex	R L	R L	R L	R L	R L	R L	R L	R L
Side Glide	R L	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L	R L

5. TEST IN SIDE LYING
LUMBAR PASSIVE ANGULAR MOVEMENT

	Range			Symptoms			
	Large	Med	Small	During range	End range	Rep Mov	Over press
Flex							
Ext							
Lat flex	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L

6. PRONE
ACCESSORY MOVEMENT/NERVE & MUSCLE FUNCTION

Spinal extension in prone	Better/Worse/No effect			
Segmental provocation	Movement			Pain
	Hyper	Hypo	Normal	
- Central P/A, Springing test - Unilateral P/A - Rotation provocation - Prone instability test				
Femoral nerve tension test				
Isometric/dynamic back muscle tests				

8. PALPATION

7. SUPINE
DIFFERENTIAL DIAGNOSTICS HIP/SI-JOINT/BACK

Spinal flexion in supine	Better/Worse/No effect	
Isometric/dynamic abdominal muscle tests		
	Right	Left
Hip: Angular movement, Patricks test, quadrant		
SI-joint provocation test, ASLR		
Passive SLR + head/foot sensitisation, crossed SLR		
Myotomes- L1-2(I), L2-3(Q), L4-5(TA), L5(EH), L5-S1(P), S1(TS)		
Dermatomes		
Reflexs: Patella L3-4, Achilles S1		
Babinski, Klonus		

3. STarT Back Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg**(s) at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): _____ **Sub Score (Q5-9):**_____

Funded by Arthritis Research UK

4. Clinical Reasoning and Process Evaluation tool (CRPE-tool) for therapists

PATIENT NAME:_____ **DATE OF BIRTH:_____**	**First assessment date:___/___/___** **Final assessment date:___/___/___** **Totalt number of physiotherapy visits:_____**

ASSESSMENT

- **First assessment - cross X relevant assessment findings**
- **Final assessment - circle ○ relevant assessment findings**

1. Assess grade of FUNCTIONAL IMPAIRMENT	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Energy and drive (motivation)	0	1	2	3	4	PA006
Sleep functions	0	1	2	3	4	PA007
Emotional functions (anxiety, low mood)	0	1	2	3	4	PA011
Thought functions (physical symptoms caused by cognitive/rational factors)	0	1	2	3	4	PA013
Sensory function (sensitivity for pain ”sensitisation”)	0	1	2	3	4	PB008
Pain (choose relevant category)						
Back pain	0	1	2	3	4	PB009
Lower extremity pain	0	1	2	3	4	PB009
Pain in a dermatome	0	1	2	3	4	PB009
Pain in another body part (Buttock, hip, groin, thigh)	0	1	2	3	4	PB009
Generalised pain localisation (3 of 4 body quadrats)	0	1	2	3	4	PB009
Exercise tolerance (endurance related activities)	0	1	2	3	4	PD009
Joint mobility	0	1	2	3	4	PG001
Joint stability	0	1	2	3	4	PG002
Muscle power	0	1	2	3	4	PG003
Muscle tone	0	1	2	3	4	PG003
Muscle endurance	0	1	2	3	4	PG003
Motor reflex funktions (decreased or increased)	0	1	2	3	4	PG004
Control of movement (Quality, coordination, balance)	0	1	2	3	4	PG006
Gait pattern	0	1	2	3	4	PG007
Sensation of muscle stiffness, tightness, spasm, contraction, heaviness	0	1	2	3	4	PG003
Mobility of spinal meningies, periferal nerves and surrounding tissue	0	1	2	3	4	PG000
2. Assess grade of ACTIVITY LIMITATION	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Perception of non-harmful sensory stimuli (kinesiophobia)	0	1	2	3	4	PJ001
Carrying out daily routine (ADL)	0	1	2	3	4	PK003
Handling stress and other psychological demands	0	1	2	3	4	PK004
Changing and maintaining body position (Shifting body weight away from the spine (increased lever arm)	0	1	2	3	4	PM001
Changing and maintaining body position (bending)	0	1	2	3	4	PM001
Maintaining a lying position	0	1	2	3	4	PM001
Maintaining a sitting position	0	1	2	3	4	PM001
Maintaining a standing position	0	1	2	3	4	PM001
Maintaining an upright neutral posture	0	1	2	3	4	PM001
Lyfting and carrying objects	0	1	2	3	4	PM004
Walkning	0	1	2	3	4	PM007
Moving around in different ways (crawling/climbing, running/joging, jumping)	0	1	2	3	4	PM008
Household tasks	0	1	2	3	4	PP003
Work ability and employment	0	1	2	3	4	PR002
Recreation and leisure activities	0	1	2	3	4	PS002

DIAGNOSTIC SUBGROUPING AND ICD-10 CODING

3. Matching assessment findings to diagnostic codes
Choose a primary assessment finding category:

- **First assessment: Cross X one or more related ICD-10 diagnostic codes in the same row**
- **Final assessment: Circle ○ a new diagnostic codes <u>if relevant</u>.**

Primary assessment category ⟶	**ICD-10 diagnos**
LBP with muscular functional impairment	☐ M54.5 Lumbago
LBP with segmental mobility impairment	☐ M54.5 Lumbago ☐ M99.0 Segmental dysfunction
LBP with movement coordination impairment/ segmental instability	☐ M54.5 Lumbago ☐ M99.1K Segmental instability in the lumbar spine
LBP with referred lower extremity pain (nociceptive pain proximal of the knee)	☐ M54.5 Lumbago ☐ M51.2 Other specificed dislocation of intervertebral disc ☐ M47.9K Spondylosis in the lumbar spine
LBP with radiating pain (neuropathic pain)	☐ M54.5 Lumbago ☐ M54.1 Radiculopathy (femoralis) ☐ M54.4 Lumbago with ischias
LBP with related cognitive or affective tendensies	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity)
LBP with related generaliserad pain (pain in 3 of 4 body quadrants)	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity) ☐ F45.4 Chronic somatoform pain syndrome
LBP with postural related symptoms	☐ M54.5 Lumbago ☐ M40.3 Flatback syndrome ☐ M40.4 Hyperlodosis
SI-joint symptoms or Coccygodynia	☐ M53.3 Sacrococcygeal disorders
LBP radiating pain + Medical imaging disc pathology and nerve compression finding	☐ M51.1K Disc degeneration/disc herniation in the lumbar spine with radiculopathy
LBP with radiating pain/neurogenic claudication + Medical imaging verifieried degeneration and nerve compression findings	☐ M48.0K Central spinal stenos in the lumbar spine (bilateral symptoms) ☐ M99.6 Stenosis of intervertebral foramin (unilateralt symptoms)
Ländryggsbesvär med nedsatt rörelse kontroll i ryggen och/eller segmentell instabilitet + Medicinsk bild verifierad Spondylolys/Spondylolisthes	☐ M43.0 Spondylolys ☐ M43.1 Spondylolistes

TREATMENT

4. Record at final assessment:

Has the BetterBack☺ model of care Part 1 been applied?		☐ Yes ☐ No
Has the BetterBack☺ model of care Part 2 been applied?		☐ Yes ☐ No
Cross X all modes och types of treatments used		
Physical exercise	**MODE**	KVÅ code
	☐ Non-supervised individual training	
	☐ Supervised individual training	QV011
	☐ Supervised group training	QV012
	TYPE	
	☐ Muscle strengthening training	QG003
	☐ Range of movement training	QG001
	☐ Muscle endurance training	QG003
	☐ Cardiovascular training	QD016
	☐ Balance training	QB001
	☐ Postural control training	QG004
	☐ Coordination training	QG005
	☐ Pelvic floor training	QF001
	☐ Postural training	QM005
	☐ Relaxation training	QG007
	☐ Physical activity prescription (FaR®)	DV002
	☐ Other ……	
Behavioural medicine interventions	**MODE**	
	☐ Individual based intervention	QV011
	☐ Group based intervention	QV012
	TYPE	
	☐ Information / education on pain	QV007
	☐ Cognitive-behavioural therapy	DU011
	☐ Mindfulness	DU032
	☐ Motivational interviewing	DU118
	☐ Relapse prevention	DU119
	☐ Supportive conversation	DU007
	☐ Other ……	
Manual therapy	**TYPE**	
	☐ Joint mobilisation	DN006
	☐ Joint manipulation	DN008
	☐ Massage	QB007
	☐ Stretching	DN009
	☐ Nerve mobiliseration	QG001
	☐ Trigger point pressure	DN007
	☐ Traction	QG001
	☐ Other……..	
Occupational medicine interventions	**TYPE**	
	☐ Workplace training	DV084
	☐ Training of work ability	QR003
	☐ Work and employment counciling	QR002
	☐ Information /education on ergonomics	QV010
	☐ Other ……..	
Physical modalities	**TYPE**	
	☐ TENS	DA021
	☐ Cryotherapy	QB011
	☐ Heat	QB011
	☐ Ultrasound	QB011
	☐ Shockwave therapy	QB011
	☐ Laser therapy	QB011
	☐ Short wave diathermy	DV042
	☐ Interferential therapy	DA021
	☐ Orthosis	DN003
	☐ Taping	DN003
	☐ Bio-feedback	DV010
	☐ Acupunkture	DA001
	☐ Other……..	

5. Rate overall treatment effect	☐ Much better ☐ Quite much better ☐ Unchanged ☐ Quite much worse ☐ Much worse

5. Clinical reasoning and process pathway for therapists

A thorough history and adequate physical examination are of great importance in order to target treatment interventions. In addition, it is very important to exclude the few red flag cases that require acute medical or specialist referral for the investigation and treatment of tumors, infections, inflammatory diseases, more severe back pathology and neurological conditions, as well as the strong influence of psychosocial factors which can also cause back pain. StarT Back Tool can be used to support decision making regarding the extent of health care needed and the need for psychosocial focus based on an assessment of risk factors for continued back pain. The physical assessment should include an analysis of functional movements, posture, active movements, passive movements, combined movements and / or static positions, joint accessory movement / provocation tests and neuromuscular function. This is to investigate how the symptoms are related to motion dysfunction.

Based on assessment findings, relevant treatment measures with effect mechanisms directed at functional impairments and activity limitations should be tested. These may include range of movement exercises (active/passive or accessory joint mobilisation or neuromuscular structure mobilisation), motor control exercises, muscle stretching, balance exercises, coordination, muscle strength, muscle endurance, general physical fitness or cardiovascular exercise. For example:

1. In the identification of movement directions and positions that reduce or centralize the patient's localised pain, distal pain or radiculopathy, these may be considered as a treatment techniques. This allows the patient to learn strategies to control pain and thus take better responsibility for his or her own situation.

2. In the identification of movement restriction due to joint, muscle or nerve related impairment, mobilisation strategies for the relevant structure may be considered to reduce the movement restriction.

3. In the identification of segmental instability or trunk motor control impairment in the, exercises with a focus on movement control can be tested aiming to improve muscle function, reduce pain and optimise loading of the trunk during full body movement.

4. In the identification of a psychogenic causes of back pain, supervised exercise could be tested to minimize kinesiophobia. This can often be complemented with patient education that can help pain management and enable self-care.

5. In the identification of a postural impairment, posture correction and ergonomic interventions can be tested.

Dosage of treatment measures should be individualised and sufficient to achieve the desired effect. Initial targeted treatment should be through individual patient care. As a complement to the initial targeted treatments, the purpose of a general training and patient education is to restore or improve function and activity. The suitability of group-based patient care is assessed in consultation with the patient as general training and patient education is considered relevant to support the patient's self-care.

Clinical process and reasoning pathway - BetterBack☺

Subjective and physical assessment

Symptom: Constant pain, night-time pain, pain unrelated to mechanical loading

Symptom: Pain related to mechanical loading

1) Red flags: Suspected malignancy, cauda equina/myelopathy symptoms, visceral pain, inflammation pga significant trauma/fracture, infection or inflammatory disease
2) Another medical condition providing an obstacle for rehabilitation

Medical management

Pain localisation over surrounding joints: hips or SI-joint

- Unilateral pain over hips or groin → Positive Hip Quadrant or Patrick's Test → **Likely hip**
- Unilateral pain under L5 segment → 2/4 or 3/5 SI-joint tests positive → **Likely SI-joint**

Classify lumbar spine related assessment findings

- Low back and/or leg pain of nociceptive or neuropathic character. High pain intensity and irritability. Aggravates / relieves or peripheralises / centralises during range of joint motion in a specific plane.
- Pain localised to the lower back. Nociceptive character. Mild-moderate intensity and irritability. Restricted joint range of motion and end range pain. No immediate change in ROM after repeated movements
- Pain localised to the lower back. Nociceptive character. Mild-moderate intensity and irritability. Painful arc/abberant movement flexion-extension, positiv prone apprehension test, pain during trunk loading
- Full ROM with no pain during ROM, nociceptive pain during static positions in end of range

Clinincal reasoning, possible influencing factors

STarT Back Tool
- Stratified management based on risk of pain persistence:

-Low risk
(STarT Back Tool ≤3):
- Functional optimisation with requiring few visits

-Medel & hög risk
(≥4 på STarT Back Tool)
- Functional optimisation requiring more visits.
- Behavioural medicine interventions when indicated

Consider other influencing factors:
Barriers and fascilitators to goal attainment
- Age
- Work
- Comorbidities

Diagnostic subgrouping and ICD-10 coding

Treatment according to BetterBack☺

Specific therapies when indicated

Pain modulation
- Directional preference exercises
- Pain modulating mobilisation therapies

Mobilisation
- Movement restriction (joint, nerve, muscle): Improve ROM with specific mobilisation and stretching

Movement control
of instability dysfunction
- Graded trunk and back stabilising exercises

Postural syndrome
postural training, ergonomic advice

General principles for all patients

Patient education and general functional restoration exercise working towards self-care enablement.

Part 1
Individualised care

Part 2
Transition to group based care when longer rehabilition period needed.

Follow-up assessment

6. BetterBack☺ Model part 1 – Patient education brochure

BetterBack☺

Information on Low Back Pain

LINKÖPINGS UNIVERSITET

Region Östergötland

Low Back Pain

Low back pain (LBP) is a common harmless condition that affects almost everyone at some point. Over a one-year period, 4 out of 10 adults experience LBP. It is often characterised by varying degrees of pain and discomfort that may impact on ability to perform activities. An episode of LBP usually improves within 2-6 weeks. Most have a fairly stable pattern of back health for many years, which may sometimes be interrupted by a period of LBP. This is a normal pattern and does not mean that the condition is getting worse over time.

Degenerative changes in the spine

Something that astonishes many is that there is no direct connection between degenerative changes in the spine and common LBP. This means that changes seen on X-rays, magnetic cameras and computer tomography can show pronounced age related changes or disc herniation in a completely painless person, while someone with LBP may have very little or no changes.

The structure and function of the lower back and common causes of LBP

The lower back consists of many structures such as bones, joints, discs, stabilising ligaments, nerves, as well as deep and superficial muscles. Pain sensations may potentially be signalled by one or more structures of the lower back. It is often difficult to specify exactly if and which structures signal pain sensations. How we maintain an upright position in different situations is called posture. An optimal posture means that the spine has the best conditions for good mobility with optimal distribution of body weight. Suboptimal posture, suboptimal loading of the back or even too little loading of the back can be possible contributing factors of LBP.

Experience of back pain

Pain is first experienced when interpreted in the brain. How the pain is interpreted depends on experience, thoughts, feelings and expectations. In some cases, pain may be experienced in the lower back but in the absence of pain signals from structures in the lower back. The pain system may also become hypersensitive and in some cases the pain can persist even though the original cause of the pain has resolved.

Figure 1. Pain is interpreted in the brain. This can be in the presence or absence of signals form lower back structures

Back pain symptoms

In addition to back pain, you may have pain in the buttocks and in one or both legs. You may have difficulty standing, sitting, walking, bending etc. This can lead to frustration, depressed mood and anxiety. Some may be afraid of physical activity and become inactive. All of this can impact negatively on you everyday life.

Tips when you have a particularly troublesome period

Think about what you have read in this brochure, that pain comes in periods but usually calms down. Also think about what relieves the symptoms and what you can do when you have a troublesome period. You may have a favorite exercise or other strategy to manage troublesome periods. Contact your physiotherapist for help if you feel after 2-6 weeks that pain doesn't subside. If you have numbness and tingling in both legs, loss of skin sensation or weak muscles in the legs and feet and especially if you have trouble controlling your bladder and bowel you should seek medical care. If you have LBP after an accident or have been previously treated for cancer or osteoporosis, it is also important to seek medical care. For the vast majority, however, back pain is a harmless and common condition that comes and goes.

Back Health

Good back health is a balance between the back's capacity on one side of the scale and physical / mental stresses on the other side as in the figure below.

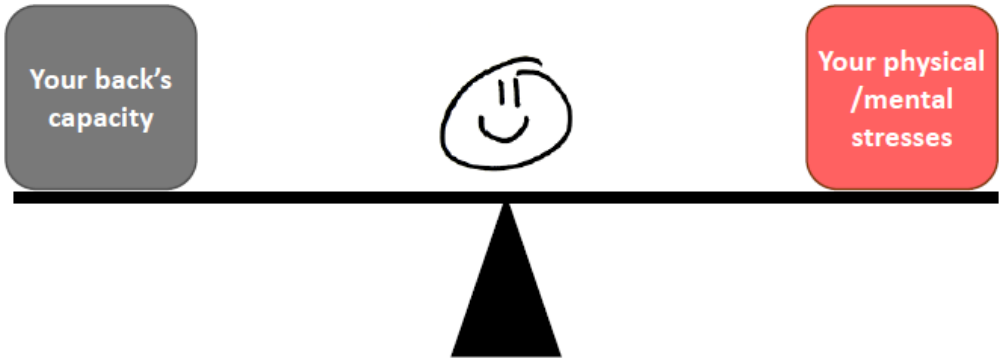


Figure 2. Balance between back capacity and stresses

Back pain occurs when imbalance occures between back capacity compared to physical / mental stresses as in the figure below.

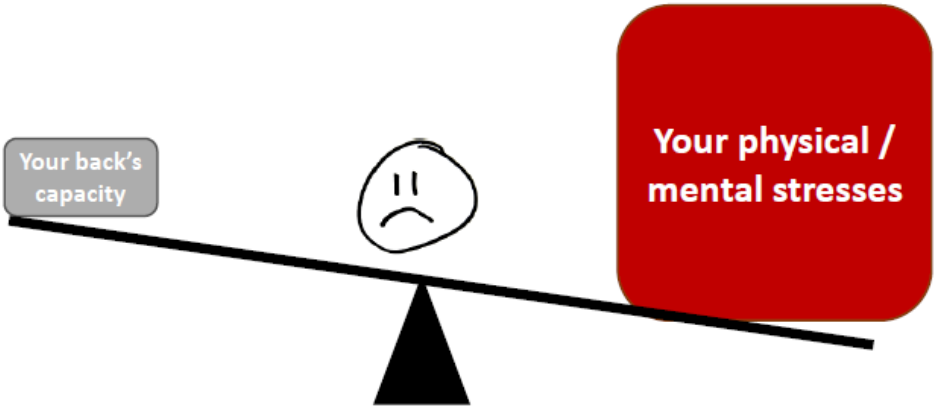


Figure 3. Imbalance between back capacity compared to physical / mental stresses

General advice / self-care

During the acute phase, most people are in need to take it easy and adjust their physical and mental stresses. Today, however, there is extensive research that recommends avoiding bedrest and instead modifying physical activity and successively returning to normal activities as quickly as possible. You can use a pain management scale to find the right level of back physical and mental stresses during everyday activities and also when you work out. This model is based on keeping you within acceptable perceived pain levels during an activity and within 24 hours after activity. This means that activity may increase the pain within acceptable pain levels during or after training, but it should return to initial levels within 24 hours. If you are unsure about the right level of back physical and mental stresses consult your physiotherapist.

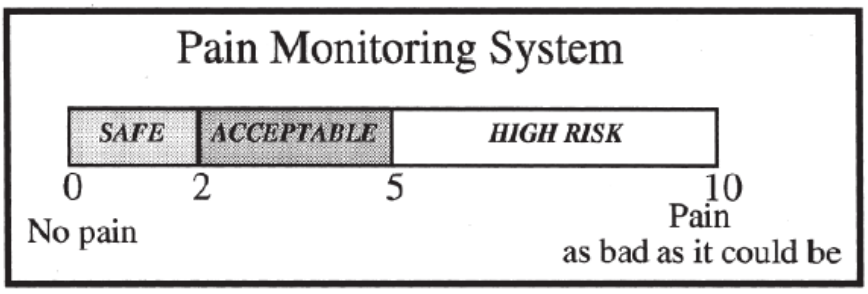


Bild 4. During activity, it is preferable that the pain is within safe to acceptable levels and that the pain returns to initial levels within 24 hours

Treatment for back pain

The goal is to increase your back's capacity and reduce your physical and mental stresses. You can increase your back's capacity by optimising your back posture, muscle stength, muscle endurance, agility, and improving your overall fitness. You can reduce your physical and mental stresses by optimising your back's physical loads, reducing negative emotions through a positive approach and reducing everyday stress and changing your thoughts about your LBP

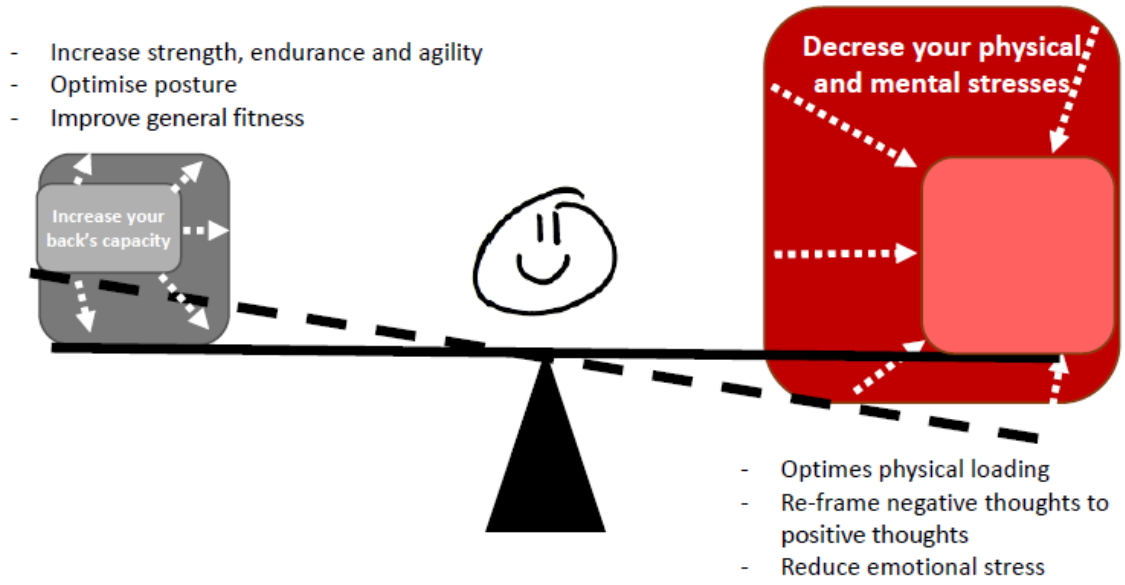
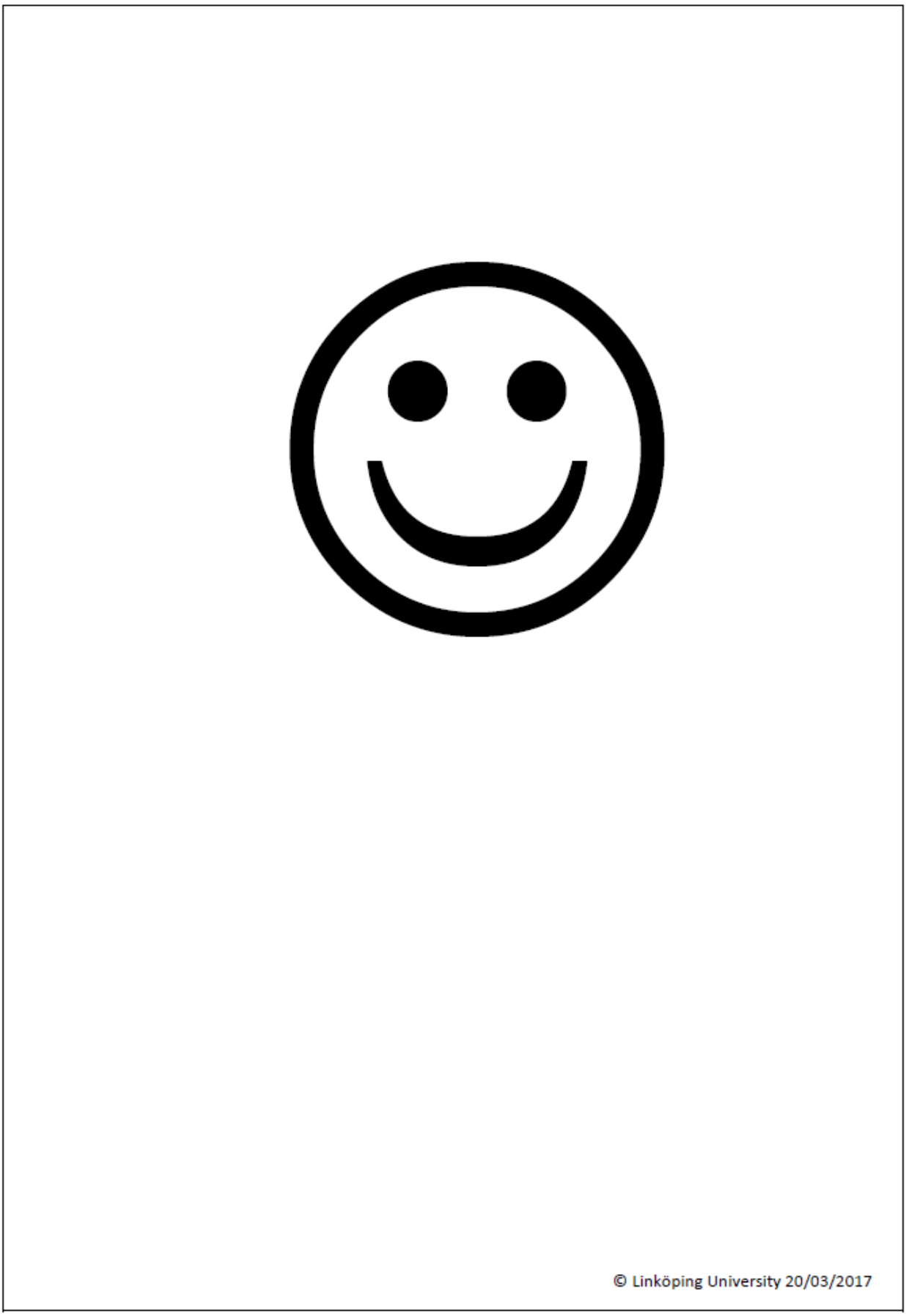


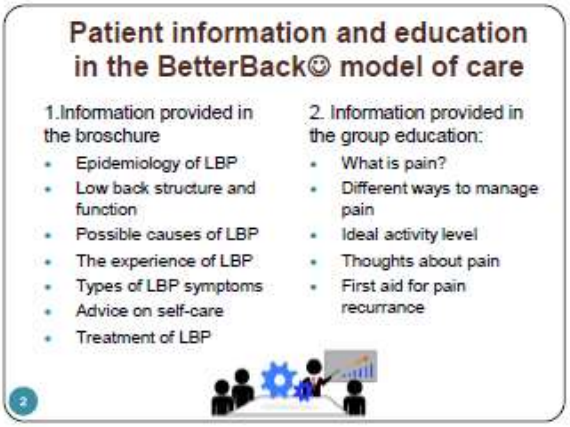
Figure 5. How to balance the back's capacity and stresses

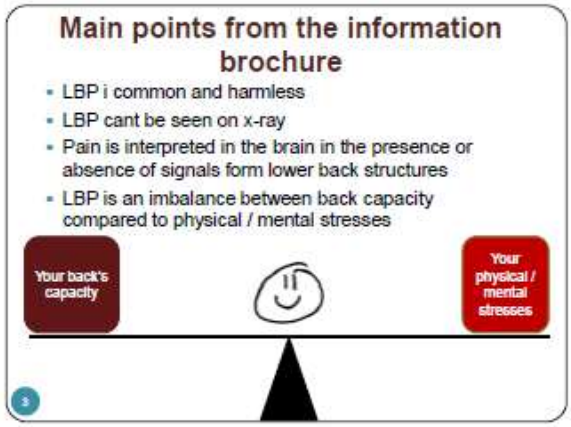
The BetterBack☺ model of care

The BetterBack☺ model of care for LBP focuses on evidence based physiotherapy, patient education and exercise. The main aim is to manage LBP symptoms and enable the patient's self-care ability. You will receive a thorough assessment and individualised care. Depending on your need for extended support in addition to your physiotherapist's initial interventions, pain education seminars and supervised exercise in a group format can be provided for 6 weeks, 2 times / week. The pain education seminars include explanatory models of what pain is, different ways of managing pain, as well as how to balance your back capacity and your physical and mental stresses you are exposed to. It is common for people to become less physically active after a troublesome period of LBP. It is therefore important to get started with some form of general fitness training. You can improve general fitness by walking, Nordic walking, cycling, jogging and swimming. If you experience pain during activity, you can use the pain management scale (see Figure 4). It is important that you feel motivated and can adapt your training to fit into your everyday life. In the BetterBack☺ model of care program, you can get help on how to get started!



7. BetterBack☺ Model part 2 – Group education seminar for patients





The situation affects the pain experience

7

Pain experience = warning from the body – interpretation in the brain

The body

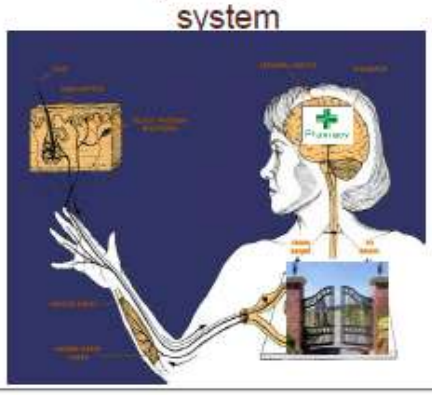
situation + thoughts + experience

Pain is inhibited or strengthened

Pain experience

8

The body's own pain relief system



9

Pain experience

- Pain can be **dampened**
  - If you understand it's cause
  - If it is predictable
  - If you know how to handle the pain
  - If it is manageable
  - If you have a positive attitude
  - If you are goal-focused

10

Pain experience

- Pain can be **dampened**
  - If you understand it's cause
  - If it is predictable
  - If you know how to handle the pain
  - If it is manageable
  - If you have a positive attitude
  - If you are goal-focused
- Pain can be **aggravated**
  - If you feel uncertain of its cause
  - If it is unpredictable
  - If you cant control the pain
  - If you have a depressed mood
  - If you generally feel pressured
  - If it is associated with bad experiences

- What dampens / aggravates your pain?

11

Thoughts affect our self-perception...,

12

… and thoughts affect the pain experience

You are going to be immunized against influenza. You know the needle hurts for a few days. How do you experience the pain?

You have back pain after a longer walk. How do you experience pain?

13

… and thoughts affect the pain experience

HEY MACARENA!

- Prolonged back pain can be like a bad song that gets stuck in your mind. The brain has learned it without you wanting to and it plays over and over again …. The more irritating the song the more easily it gets stuck in your mind

You started training but get more back pain afterwards. It may be muscle soreness or it may be the playing over and over again of pain memories like "the known song". How do you relate to this?

14

Pause exercise

Try to breathe relaxed and calm, focus on breathing for 2 minutes

Acknowledge your pains in a neutral way, but keep the focus on breathing

15

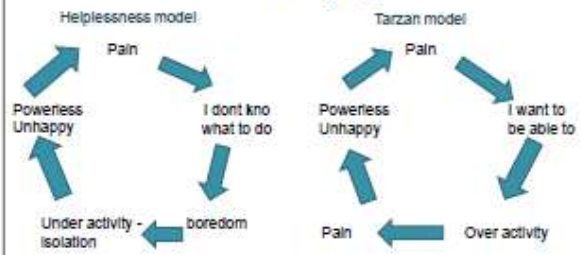
Pause Exercise -redirecting

What happens to your pain experience when you focus on your breathing?

Does this redirect your thoughts away from attention to pain?

16

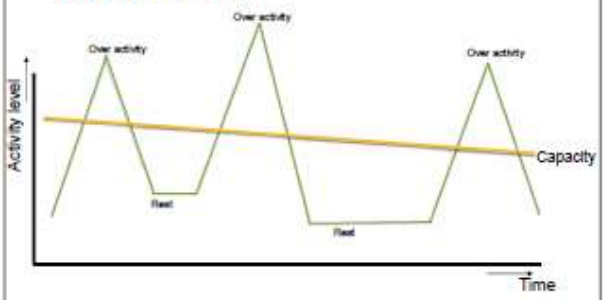
Pain coping



Different strategies. "Helplessness" or "Tarzan model"?
Are there other strategies? In which way do you react?
What consequences does this have?
Advantages/disadvantages?

17

Activity level – too much activity Tarzan model



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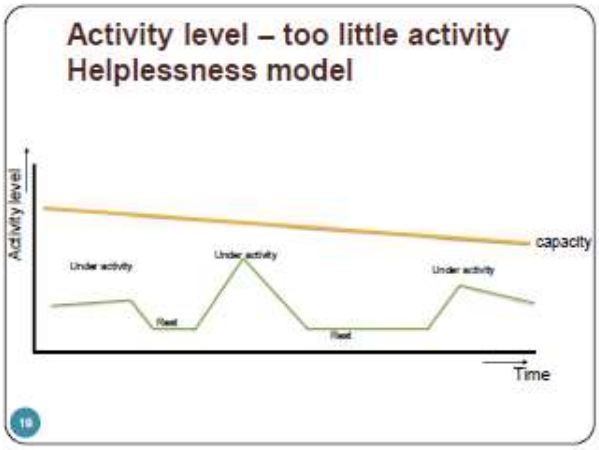
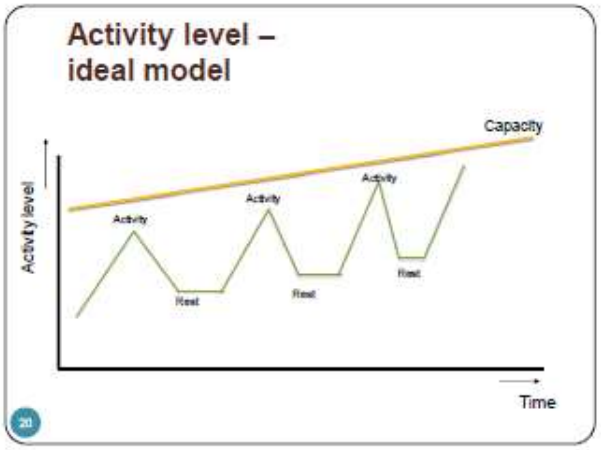
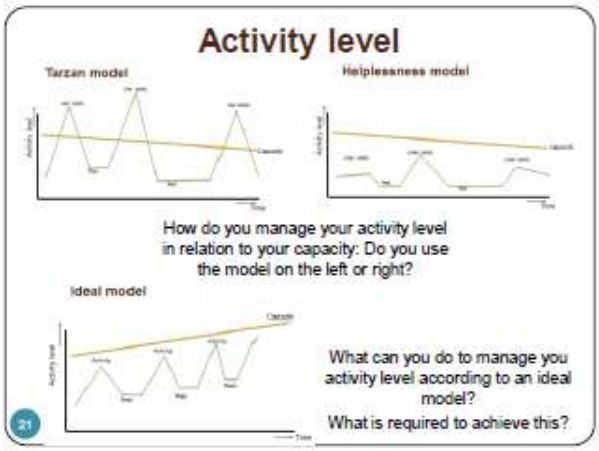
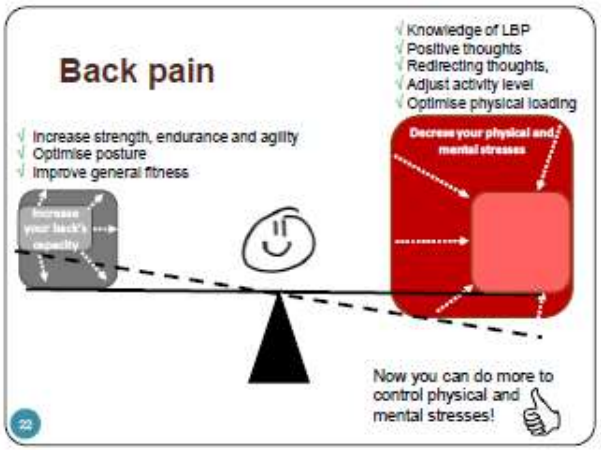
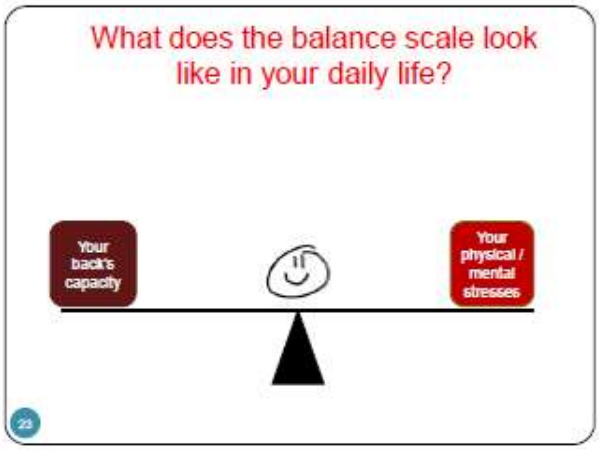
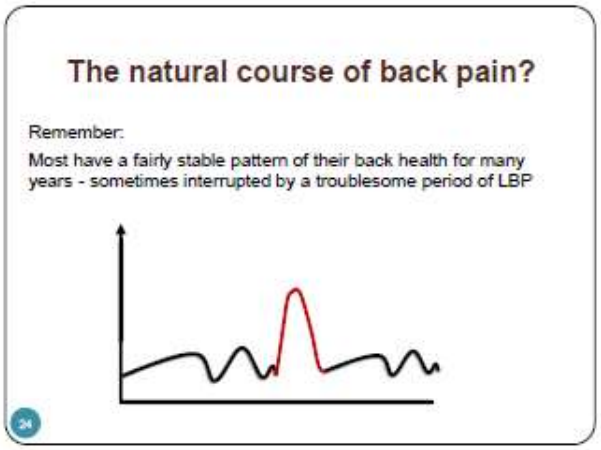












First aid when back pain flares up

- How long time do you expect the pain to be aggravated?
- What can you do when the pain gets worse?
- Do you have a favorite strategy to reduce pain?
- What can you do to make it easier for yourself?
- Ask for help?

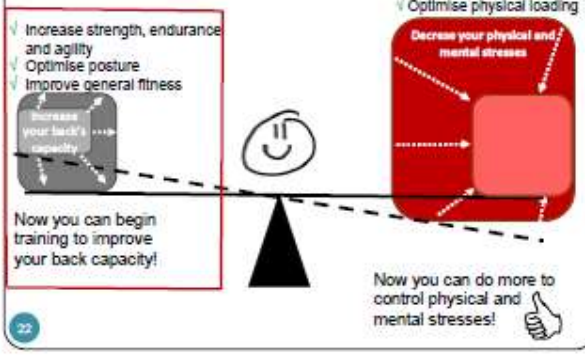
Tips…

- Adjust activity and load according to your back capacity, not too much not too little
- Distribute activity throughout the day
- Be active, take short breaks
- Think positive thoughts
- Help youself
- And ask for help from others

Back pain

√ Increase strength, endurance and agility
√ Optimise posture
√ Improve general fitness

√ Knowledge of LBP
√ Positive thoughts
√ Redirecting thoughts,
√ Adjust activity level
√ Optimise physical loading



Now you can begin training to improve your back capacity!

Now you can do more to control physical and mental stresses!

Increase your capacity – improve general fitness

Help yourself to be physically active to optimising brain and body's wellbeing.

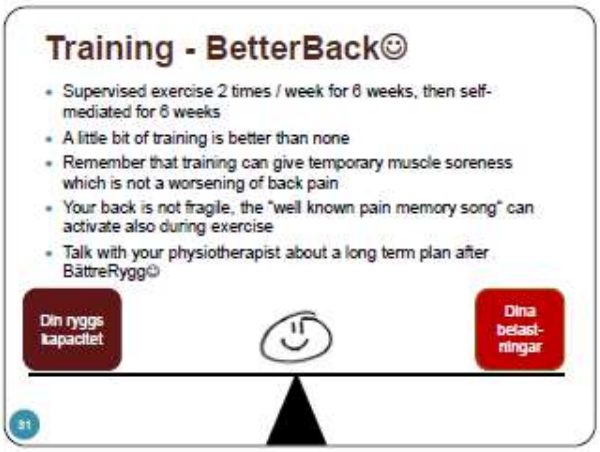
- Improved memory & concentration
- Better coping with stress
- Improved mood
- Divert negative thoughts
- Contributes to better health, physical and mental

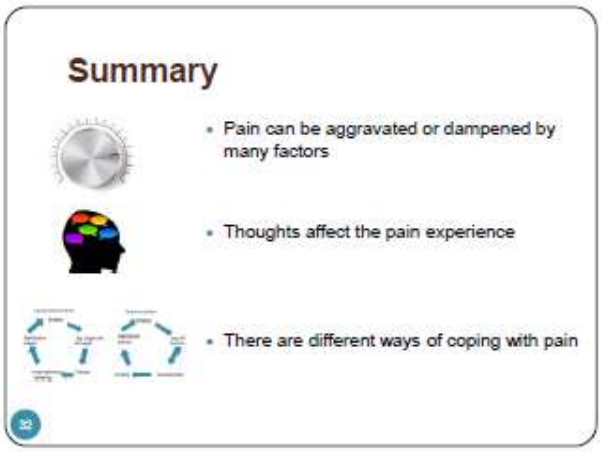
Physical activity during acute LBP?

Reduce sedentary behaviour

How can i change too little exercise and too much sitting ?

Increase your back's capacity! We will help you get started!





8. BetterBack☺ Model – Training program for patients

<table>
<tr><th colspan="3">Training program for patients receiving the BetterBack☺ model of care for LBP</th></tr>
<tr><td>Part 1: Posture, muscle control and coordination of basic body movements</td><td><u>Goal:</u> To ensure the patient has satisfactory posture and trunk muscle activation in static positions as well as in conjunction with basic body movement in the sitting, sitting and standing.
<u>Implementation*:</u> Exercises and dosages are individually adjusted by the treating therapist. Exercises are performed as home programs and daily training is recommended for optimal results.

The therapist assesses when basic competencies in program 1 are achieved before progressing to program 2.</td><td rowspan="2">Training range of movement
<u>Goal:</u> Restore normal mobility.

<u>Implementation</u>:
Individualise based on if the patient has movement restriction.</td></tr>
<tr><td>Part 2: Graded training of muscle strength, coordination and endurance</td><td><u>Goal:</u> To ensure the patient has satisfactory ability to perform more challenging body movements with adequate strength, corrdination and endurance.
<u>Implementation*:</u> Exercises and dosages are individually adjusted by the treating therapist. Exercises are performed twice a week for 12 weeks with follow-up conducted by the treating therapist. During the first 6 weeks, patients are offered the opportunity to train in a group supervised by a physiotherapist. The patient will then receive support and feedback regarding the practice of exercises and help to upgrade exercises if necessary. Patient education on self-care and management of back pain is also performed in groups.</td></tr>
<tr><td colspan="3">*Prerequisite for upgrading the training program is that the patient can satisfactorily perform basic exercises for posture and trunk control in Part 1. Using Part 2 as a basis, the physiotherapist selects and individualises relevant exercises and dosing based on the assessment findings. If support with the traning program is required (in addition to a self-mediated home based program), group traning supervised by another therapist can implemented. However, the follow-up of the patient is still the responsibility of the therapist who first assessed and initiated the patient's treatment plan. The program is designed with graded levels where difficulty level is increased by successively progressing from stages A through to C. Patients are to perform the exercises as instructed. Training can initially produce some muscle soreness, but this is normal and decreases gradually. Contact your physiotherapist if you have questions or feel unsure.</td></tr>
</table>

Part 1. Posture, muscle control and coordination of basic body movements	
1a. Basic trunk muscle activation and control in a lying position	**1b. Basic trunk muscle activation and control in conjunction with body movement in a lying position**
Pelvic control exercise • Lay on your back with your knees bent. Put your hands under your pelvis. Press your lower back down so it flattens down on the surface you are laying on. Feel how the pelvis tilts backwards and has rolled over your hands. Tip the pelvis forward and feel how the lower back rises again. Remove your hands and repeat the tipping forward and backward with less and less movement. Stop when you come to a normal neutral pelvic position. **Activating your inner trunk muscles** **This exercise focuses on the activation of core muscles in your back, abdomen and pelvis. It is also known as "<u>core activation</u>"** • Lay on your back with your knees bent and put your hands on your waist. • ① Breathe calmly in and out and make an ssss sound and feel your fingers how the inner muscles between your pelvis bones become activated. This muscle activation should be done slowly and with a minimal force where you feel that the lower part of the stomach is pulled inward-backward-upward. ○ Alternative instructions ▪ Draw the lower part of your stomach inwards from the waist of you pants ▪ Imagine that you activate your lower stomach muscles just like if you were tightening av belt around you waist ▪ Imagine that your holding on to go to the toalet • <u>Make sure that **you dont**</u>: ○ Hold your breath, press your lower back down or bend your back forward  	**In conjunction with leg movement** Lay on your back with your knees bent. ① Start with "core activation" ② Move your knee on one side out towards the side with and back to the middle with slow controlled movement. Repeat alternately on each side. Maintain a stable positioning of your trunk and pelvis. Repetitions_____  **Perform the same exercise in side lying with movement of one leg. Perform even on the other side thereafter** Repetitions_____ **In conjunction with arm movement** ① Start "core activation". ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis. Repetitions_____ 

2a. Basic trunk postural control in a sitting position

With neutral posture, loading of the spine is optimally distributed. Feel how the physical loading on your back increases when you sit with hunched posture, and how it relieves when you hold a neutral posture.

Training of posture in sitting position:

- Sit on a chair with your hands under your buttocks.
- ① Rotate your pelvis forward over your hands. You should feel like you are arching your back more. Rock your pelvis backward so you return to a neutral back posture. ② Rotate your pelvis backwards so that you have a hunched posture. Continue to rotate your pelvis backards and forwards a few times

- Stop in a position where you feel you have a even weight distribution over your hands and neutral back posture.
- Your ears, shoulders and hips should create a straight line vertically.

2b. Basic trunk muscle activation in a sitting position

Sit on a chair with good posture. ① Train holding a ”core activation”.

Repititions_____

2c. Basic trunk muscle activation and control in conjunction with body movement in a sitting position

In conjunction with leg movement

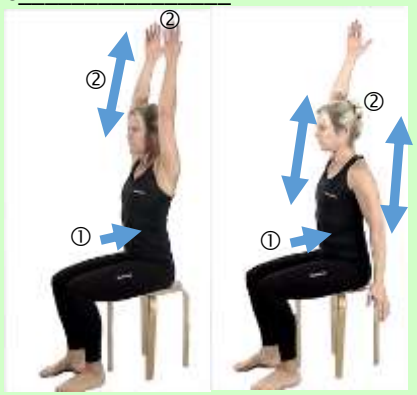
Sit on a chair or training ball. ① Start with ”core activation”. ② Lift up your knees alternately with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____

In conjunction with arm movement

① Start ”core activation”. ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____



3a. Basic trunk postural control in a standing position

With neutral posture, loading of the spine is optimally distributed. Feel how the physical loading on your back increases when you sit with hunched posture, and how it relieves when you hold a neutral posture.

Training of posture in sitting position:

- Stand with your feet hip width apart
- ① Shift your weight forwards and backwards and find a neutral weight distribution over the soles of your feet.
- ② Bend and straighten your knees a few times and find the position where your knees are slightly bent.
- ③ Tilt your pelvis forwards and backwards a few times and the position in the middle where you pelvis has a neutral position.
- ④ Move your head backwards with your chin in.
- ⑤ Bring your shoulders up and then relax your shoulders.
- Your ears, shoulders, hips, knees and feet should now be in a straight line.

① ② ③ ④ ⑤

3b. Basic trunk muscle activation in a standing position

Stand with a neutral posture. ① Train holding a ”core activation”.
Antal_____

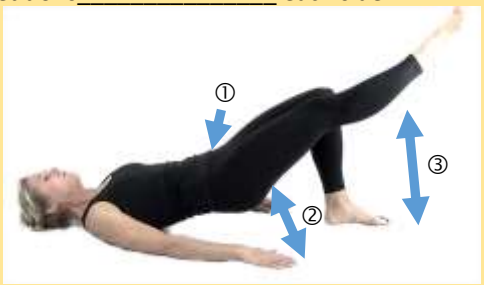
3c. Basic trunk muscle activation and control in conjunction with body movement in a standing position.

In conjunction with weight transfering

Stand with a neutral posture. Place you feet wide apart. ① Start ”core activation”. ② Transfer your weight from one leg to the other alternately. Maintain a stable positioning of your trunk and pelvis.
Repetitions_____

In conjunction with arm movement

Stand with a neutral posture. ①Start ”core activation”. ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.
Repetitions_____

Part 2: Graded training of muscle strength, coordination and endurance		
Difficulty level A	**Difficulty level B**	**Difficulty level C**
1A) Pelvis lifts in lying position Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor. Repetitions_____  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.  	**1B) Pelvis lifts + leg kicks in lying position** Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor. ③ Lift and extend one leg while maintaining a stable positioning of your trunk and pelvis. Lower your foot to the floor again and lower the pelvis. Repeat and change legs every time. Repetitions_____ each side  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.	**1C) Single leg pelvis lift i lying position** Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor and at the same time lift and extend one leg. Lower your foot to the floor again and lower the pelvis. Repeat and change legs every time. Repetitions_____ each side  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.

2A) Knee lifts in lying position Lay on your back with your knees bent and put your hands on your waist. ① Start with ”core activation”. ② Lift one fot slowly up by bending your hip while maintaining a stable positioning of your trunk and pelvis. Slowly bring your fot back to the floor. Repeat and change legs every time. Repetitions_____ each side  	**2B) Straight leg raises in lying position** Lay on your back with your knees bent and put your hands on your waist. ① Start with ”core activation”. ② Extend and lift one leg while maintaining a stable positioning of your trunk and pelvis. Slowly bring your leg back to the floor. Repeat and change legs every time. Repetitions_____ each side  	**2C) Rotating sit-ups in lying position** Lay on your back with your knees bent. ① Start with ”core activation”. ② Place your hands behind your head and bring your opposite knee and elbow together by bending you back forwards. Repeat alternately on each side. Repetitions_____ each side 

3A) Hip muscle training in lying position Lay on your back with your knees bent and arms by your side. Tie a theraband around your knees. ① Start with ”core activation”. ② Move your knees slowly away from each other and slowly back again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____  	**3B) Hip muscle training in side lying position** Lay on your side with your knees bent. Tie a theraband around your knees. ① Start with ”core activation”. ② Move your top knee slowly away from the other and slowly back down again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____ each side  	**3C) Hip muscle training in side lying position** Lay on your side with your legs straignt. Tie a theraband around your ankles. ① Start with ”core activation”. ② Move your top leg slowly away from the other and slowly back down again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____ each side  Alternative Stand on one leg in a crouched position. Straighten up and move your free leg diagonally backwards just like skating. Repeat alternately on each side.

4A) Side plank + arm movement

Lay on your side with support of your lower arm and knee and lift up your pelvis.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up over your head.

The exercise can be done with the pelvis still (static) or by moving the pelvis up and down (dynamically). Perform also on the other side.

Repetitions_____ each side

4B) Side plank + arm movement

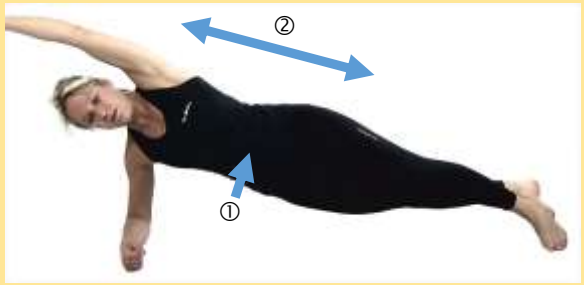
Lay on your side with support of your lower arm and feet and lift up your pelvis.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up over your head.

The exercise can be done with the pelvis still (static) or by moving the pelvis up and down (dynamically). Perform also on the other side.

Repetitions_____ each side



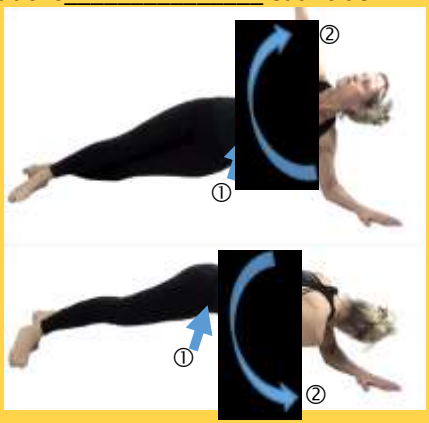
4C) Side plank + arm movement

Lay on your side with support of your lower arm and feet and lift up your pelvis.

① Start with ”core activation”.

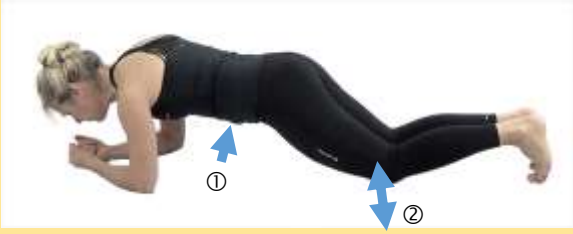
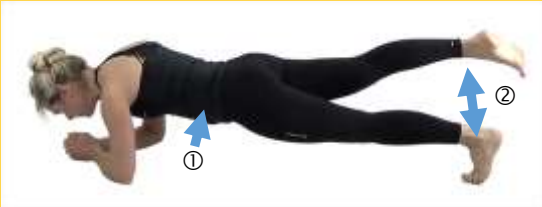
② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up and rotating your back.

Repetitions_____ each side



Alternative: Stand beside a therband tied to a pole. Pull the theraband diagonally across your body and rotate your back.

Repetitions_____ each side

5A) Chair plank Stand on your knees and support your lower arms on a chair or pilates ball. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor. Hold _____ seconds. Bring your knees back down to the floor. Repetitions_____  	**5B) Floor plank** Stand on your knees and support your lower arms on the floor. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor. Hold _____ seconds. Bring your knees back down to the floor. Repetitions_____  	**5C) The plank + leg lifts** Stand on your knees and support your lower arms on the floor. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor holding your legs straight. Lift one foot up from the floor and hold _____ seconds. Bring your foot back down to the floor. Repetitions_____ each side 

6A) 4-point kneeling superman exercise

Position yourself on your hands and knees with your back straight.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while you lift up and down one arm alternately. Try instead one leg alternately. When this is easily accomplished, combined these so that you lift an arm and opposite leg up and down simultaneously and alternate sides.

Repetitions_____ each side

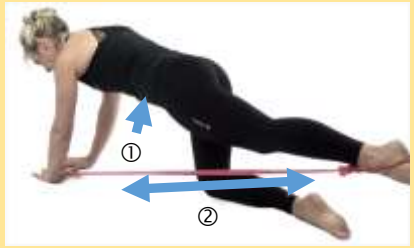
6B) 4-point kneeling theraband exercise

Positition yourself on your hands and knees with your back straight. Tie a theraband around your fot and hold on to the other end with your hands.

① Start with ”core activation”.

② Lift up and straighten your leg. Hold 5 seconds and then bring your leg down again.

Repetitions_____ each side



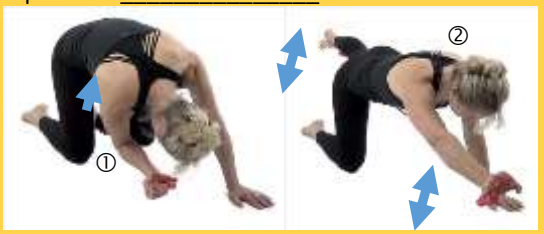
6C) Superman exercise with theraband

Position yourself on your hands and knees with your back straight. Tie a theraband around your fot and hold on to the other end with your opposite hand.

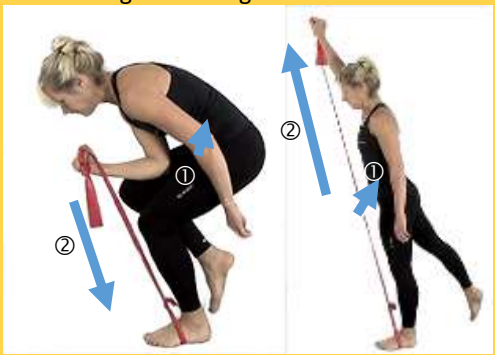
① Start with ”core activation”, curl your back and bring your opposite knee and elbow together while holding the theraband.

②. Slowly straighten your back, arm and opposite leg to stretch out the theraband. Perform the movement with good control of motion.

Repetitions_____ each side



Alternativ: Try performing the same exercise while standing on one leg.



7A) Push-ups against a wall
① Start with ”core activation”
② Perform push-ups against a wall while maintaining straight back posture.

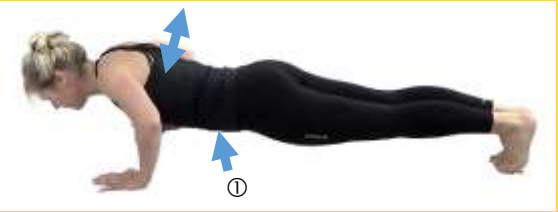
Repetitions_____

7B) Push-ups against a table
① Start with ”core activation”
② Perform push-ups against a table while maintaining straight back posture.

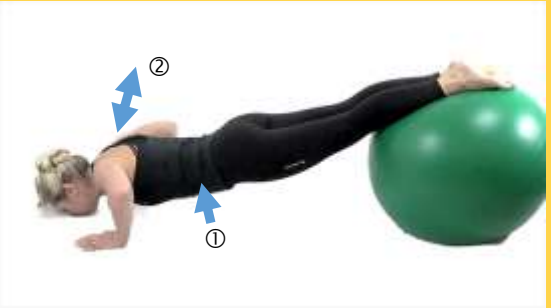
Repetitions_____

7C) Push-ups on the floor
① Start with ”core activation”
② Perform push-ups while maintaining straight back posture.

Repetitions_____



Alternativ: Try performing the same exercise with your feet on a pilates ball.



8A) Standing arm lifts

Hold on to the ends of a theraband and stand on the middle of theraband

① Start with ”core activation”.

② Maintain a straight back posture while you lift your arms up over your head against the resistance of a theraband.

Repetitions_____

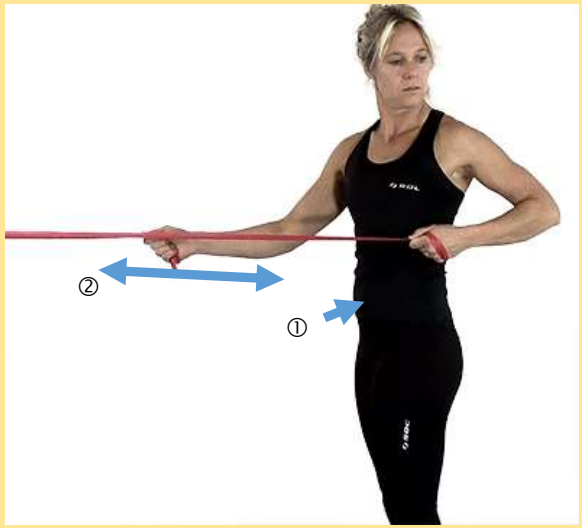
8B) Standing rows

Hold on to the ends of a theraband placed around a pole.

① Start with ”core activation”.

② Maintain a straight back posture while you perform arm rows alternately from side to side.

Repetitions_____



8C) Standing straight arm lifts

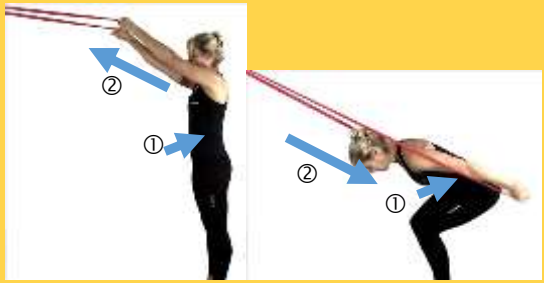
Hold on to the ends of a theraband and stand on the middle of theraband.

① Start with ”core activation”.

② Maintain a straight back posture and straight arms while you lift your arms alternately against the resistance of a theraband.

Repetitions_____ each side

Alternative: Try performing straight arm ski rows.



9A) Squats
Stand with your back against the wall or with a pilates ball between your back and the wall. Place your feet hip width apart.
① Start with ”core activation”.
② Maintain a straight back posture while you perform a squat up to about 90 degrees of knee and hip bending.

Repetitions_____

9B) Squats with your arms över your head
Stand with your back against the wall or with a pilates ball between your back and the wall. Place your feet hip width apart and your hands över your head.
① Start with ”core activation”.
② Maintain a straight back posture while you perform a squat up to about 90 degrees of knee and hip bending.

Repetitions_____

9C) Standing high knee lifts
Stand with your back against the wall, place your feet hip width apart and your arms on the wall.
① Start with ”core activation”.
② Maintain a straight back posture while you perform high knee lifts with alternating legs.

Repetitions_____ each side

10A) Tandem stance lunging weight tranfers
Stand with one foot a step length in front of the other foot.
① Start with ”core activation”.
② Maintain a straight back posture while you perform weight transfer forwards and backwards from foot to foot. Try even with your other foot forward.

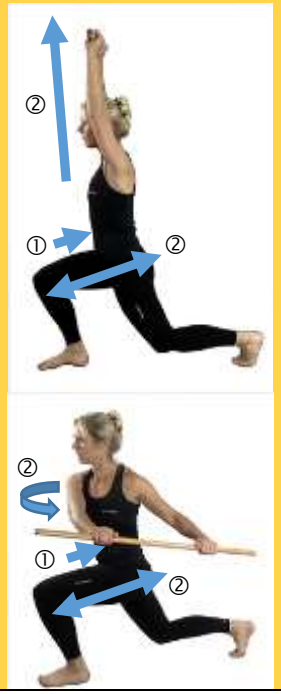
Repetitions_____ each side

10B) Lunges
Stand with your feet hip width apart and your arms up horizontal to your body.
① Start with ”core activation”.
② Maintain a straight back posture while you perform forward lunges by taking av step forward with your weight over that leg och then taking a step back again. Alternate which foot you step forward with.

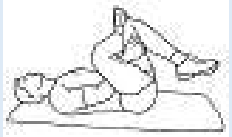
Repetitions_____ each side

10C) Lunges with simultaneous upper body movement
Stand with your feet hip width apart and your arms up horizontal to your body.
① Start with ”core activation”.
② Maintain a straight back posture while you perform forward lunges by taking av step forward with your weight over that leg och then taking a step back again. Alternate which foot you step forward with. At the same time as you lung, try lifting upp your arms over your head or rotating your upper body from side to side when holding a stick.

Repetitions_____ each side



Training range of movement		
1A) Backward bending (elbow support) Lay on your stomarch and support yourself on your underarms/elbows. Bend your back backwards by pressing up from your underarms/elbows and return to the start position again. Repetitions_____ 	**1B) Backward bending (bent arms)** Lay on your stomarch and support yourself with your hands. Bend your back backwards by pressing up from your hands but dont straighten your elbows and thereafter return to the start position again. Repetitions_____ 	**1C) Backward bending (straight arms)** Lay on your stomarch and support yourself with your hands. Bend your back backwards by pressing up from your hands and straightening your elbows and thereafter return to the start position again. Repetitions_____ 
2A) Foward bending while laying on your back Lay on your back and bring your knees up to your stomach, then return to the start position. Repetitions_____ 	**2B) Forward bending on hands and knees** Position yourself on your hands and knees with your back straight. Bend your back forward pressing your lower back upwards while bending your hips and knees so that your knees are in contact with your chest. Return to the starting position. Repetitions_____ 	**2C) Forward bending in sitting or standing** Stand/sit with your back straight. Starting bending forwards nd bringing your hands down towards the floor. Try to even bend your lower back. Return to your starting position. Repetitions_____ 

3A) Back rotation (lower back) Lay on your back and bring your knees down towards the floor on onside and then over to the other side. Repetitions_____ each side 	**3B) Back rotation (lower back and thoracic)** Lay on your back and bring your knees down towards the floor on one side while simultaneously reaching out with your opposite arm upwards and sidewards. Change sides by bringing your knees over to the other side and reach out with your opposite arm upwards and sidewards. Repetitions_____ each side 	**3C) Back roation (full range)** Lay on your back and bring your left knee down towards the floor on your left side while simultaneously reaching out with your left arm upwards and sidewards. Change sides by bringing your knee over to the other side and reach out with your opposite arm upwards and sidewards. Repetitions_____ each side 
Before and after exercise, stretching exercises help your muscles. Each stretch can be done several times, with <30 second holds. Here are suggestions for stretching.	**Stretching of your buttock muscles** 	**Stretching of your hip muscles** 
Stretching of your thigh muscles 	**Stretching of the back of your thighs** 	**Stetching of the inside of your thighs/groin** 

General training - getting in shape

Training form

Regular physical exercise as a part of everyday life is important for maintaining good health and fitness. For this, we recommend following a training program prescribed by your physiotherapist. Your training can consist of, for example: walks, nordic walking, cycling, jogging, swimming, dancing, gym. Choose which training form is best for you. You can work out alone or with others in a group. The most important thing is that you feel that you take the time for physical activity in your everyday life.

Training intensity

Training intensity can be regulated through a so-called "pacing model". This means that you slowly and gradually increase your training intensity without overloading. You "pace" yourself in a controlled way to reach your goals. You can monitor your level of exertion by using a scale of 6-20 where the scale is based on your approximate pulse when you multiply by 10.

You should preferably training with a level of exertion between

11 (fairly light) and 14 (somewhat hard).

You should start exercising at about 20% less duration than you are capacble of. If you feel that the exercise feels very easy (at level 9 or below), you can increase your exercise duration slightly so that you feel at least a farily light exertion level (level 11).

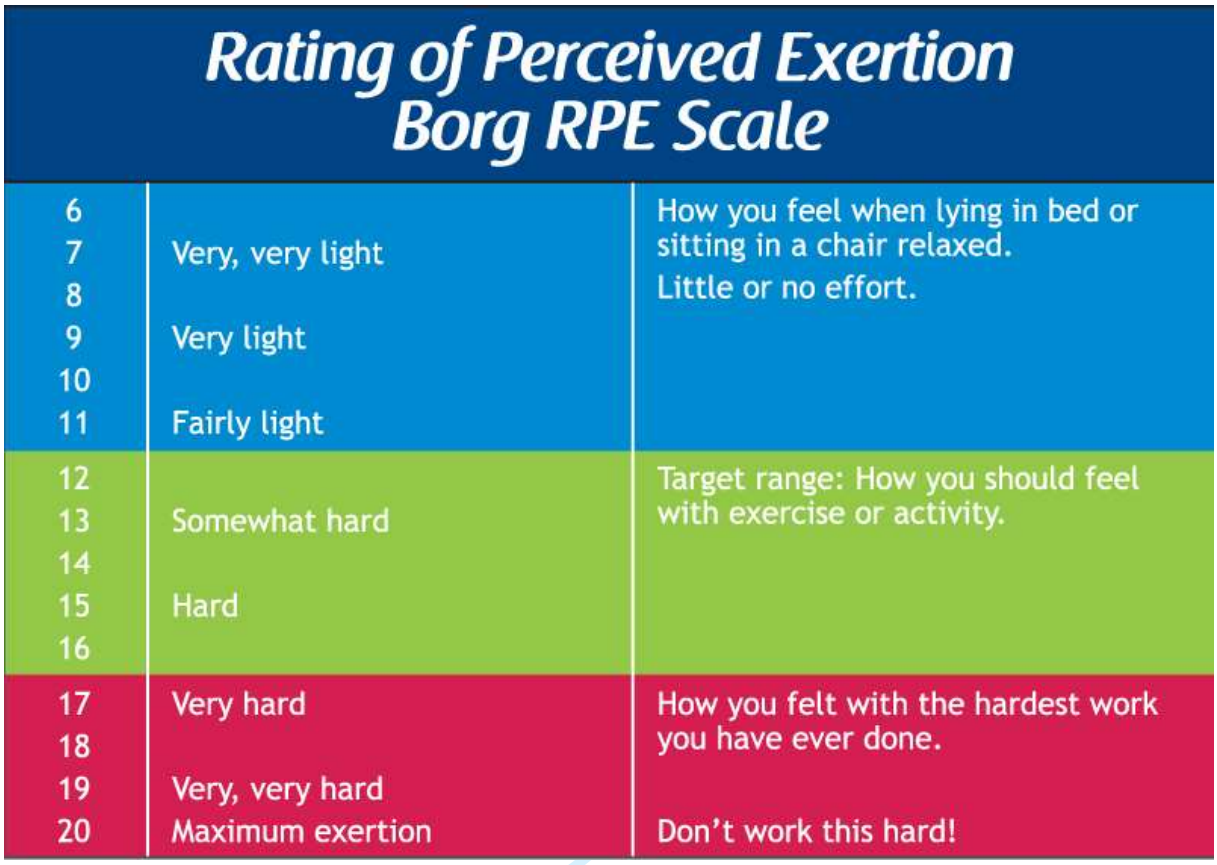
When you experience your exercise exertion is on average under a "somewhat hard" lavel (below 14), you can increase your exercise by 20% after 2 weeks. If you are on level 15 or more, you can continue with the same training for an additional 2 weeks.

When your training duration lasts 30 minutes, you can increase the load by increasing the intensity to 15/16 (Hard - you can not speak on at this intensity) in 10 minute intervals. Then you can increase the number of minutes on this intensity (15/16) every second week.

If you have a bad day, you should work out half of what you planned. In this way you can increase your exercise gradually, without risking doing too much.

Training Contract:

I will perform …….. as my training form
I will train 3 times/week
I will begin with …….. minutes
I will increase my training intensity with 20 % every second week until reach my goal capacity.



Training diary

Name:

Your physiotherapist will fill in which exercises you should train. You can cross off when you have performed the exercises.

Week	Day	BetterBack☺ Part 1			BetterBack☺ Part 2										BetterBack☺ Range of movement			General training
		1	**2**	**3**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**1**	**2**	**3**	**Borgskalan**
	Mon																	
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Summary of the workshop to provide training in the use of the BetterBack☺ model of care.

Schedule	Content		Brief description	Learning objectives	BCTs used
Day 1 08:15-08:30	Presentation		Welcome and introduction		
Day 1 08:30-08:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 1 08:50-09:40	Presentation	LBP clinical guidelines	Present evidence based guideline recommendations and the development process behind the recommendations	To understand current evidence based recommendations for primary care of LBP and stakeholder involvement in their development	- Instruction on how to perform the behavior - Credible source - Information about other's approval
Day 1 09:40-10:00	Presentation	Background to BetterBack☺ model of care	Outlines the goals for the day, defines and conceptualizes the BetterBack☺ model of care and communicates need for the model of care	To understand aims, objectives and learning outcomes for the practitioner education	- Credible source - Social reward - Pros and cons - Comparative imagining of future outcomes
Day 1 10:00-10:20	Swedish fika	Reflection	Informal discussion about aims of the BetterBack☺ model of care compared to current practice	To evaluate the practical aims of the BetterBack☺ model	- Social support
Day 1 10:20-11:40	Demonstration	Use of implementation tools	Demonstration of how evidence based recommendations can be practically applied in the BetterBack☺ model of care	To understand how to practically use implementation tools to assist clinical reasoning for matching assessment findings with appropriate diagnosis and treatment	- Instruction on how to perform the behaviour - Demonstration of behaviour - Problem-solving - Feedback on behaviour
Day 1 11:45-12:00	Reflection	Use of implementation tools	In pairs, participants discuss reflections upon how they can practically apply the implementation tools into their clinical practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Framing/reframing
Day 1 12:00-13:00	Lunch break				
Day 1 13:00-14:30	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model implementation tools using therapist-	To develop practical skills in the use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

			patient role-play. Feedback is provided from the tutor and between peers		
Day 1 14:30-15:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To learn how peers used BetterBack☺ model clinical reasoning tools	- Graded task - Verbal persuasion about capability
Day 1 15:00-15:20	Swedish fika	Reflection	Informal discussion about the practical use of the BetterBack☺ model of care compared to current practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Social support
Day 1 15:20-15:40	Summary of the day	Question and answer session and close	Learning outcomes are summarised		- Feedback on behaviour
Day 2 08:15-08:30	Discussion		Reflections after the first day of the workshop		
Day 2 08:30-09:00	Presentation		Benefits of using the implementation tools for assessment, diagnosis and intervention	To appreciate how to practically use implementation tools to assist clinical reasoning for aligning assessment, diagnostics and treatment	- Instruction on how to perform the behaviour - Information about social and environmental Consequences - Credible source - Information about other's approval
Day 2 09:00-09:20	Demonstration	BetterBack☺ model treatment tools	Patient education (brochure)	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 09:20-10:00	Demonstration	BetterBack☺ model treatment tools	Group education	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 10:00-10:20	Swedish fika	Reflection	Informal discussion about which patients group education is relevant	To reflect on the practical use of the BetterBack☺ model	- Social support
Day 2 10:20-11:00	Demonstration	BetterBack☺ model treatment tools	Exercise program	To understand how to use the implementation tools for an exercise program for LBP	- Instruction on how to perform the behaviour
Day 2 11:00-12:00	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

Day 2 12:00-13:00	Lunch break				
Day 2 13:00-13:30	Task continued	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support
Day 2 13:30-14:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Graded task - Verbal persuasion about capability
Day 2 14:00-14:30	Demonstration	BetterBack☺ model of care website	Display of to navigate the BetterBack☺ model of care website	To understand how to use the BetterBack☺ model of care website	- Instruction on how to perform the behaviour
Day 2 14:30-15:00	Task	Potential future outcomes of the BetterBack☺ model of care implementation	Participants write on post-it notes the most important future outcomes of the BetterBack☺ model of care implementation based on: 1. A professional perspective 2. A patient perspective	To appreciate the potential outcomes of the BetterBack☺ model of care	- Comparative imagining of future outcomes
Day 2 15:00-15:30	Presentation		Clinical champion presents an administrative action plan (designed earlier in consensus with clinical colleagues) for the implementation of the BetterBack☺ model of care at their clinic	To reflect on the practical use of the BetterBack☺ model of care website	- Action planning
Day 2 15:30-15:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 2 15:50-16:00	Diploma		Participants completing the workshop receive a CME diploma		- Incentive

BMJ Open

The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	low back pain, model of care, effectiveness, implementation

The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack☺) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

Allan Abbott[1*], Karin Schröder[1], Paul Enthoven[1], Per Nilsen[3], Birgitta Öberg[1]
[1]Department of Medical and Health Sciences, Division of Physiotherapy, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.
[2]Department of Medical and Health Sciences, Division of Community Medicine, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.

Allan Abbott* - allan.abbott@liu.se (TEL: 0046 13 282495); Karin Schröder - karin.schroder@liu.se; Paul Enthoven - paul.enthoven@liu.se; Per Nilsen - per.nilsen@liu.se; Birgitta Öberg - birgitta.öberg@liu.se;

*Corresponding author

ABSTRACT

Introduction: Low back pain (LBP) is a major health problem commonly requiring health care. In Sweden, there is a call from health care practitioners (HCP) for the development, implementation and evaluation of a best practice primary health care model for LBP.

Aim: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing best practice coherent primary health care for patients with LBP (B) Improve and understand the mechanisms underlying illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate a multi-facetted and sustained implementation strategy and the cost-effectiveness of the BetterBack☺ MOC for LBP from the perspective of the Swedish primary health care context.

Methods: This study is an effectiveness-implementation hybrid type 2 trial testing the hypothesised superiority of the BetterBack☺ MOC compared to current routine care. The trial involves simultaneous testing of MOC effects at the HCP, patient and implementation process levels. This involves a prospective cohort study investigating implementation on the HCP level and a patient blinded, pragmatic cluster randomized controlled trial with longitudinal follow-up at 3, 6 and 12 months post baseline for effectiveness on the patient level. A parallel process and economic analysis from an health care sector perspective will also be performed. Patients will be allocated to routine care (control group) or the BetterBack☺ MOC (intervention group) according to a stepped cluster dog leg structure with 2 assessments in routine care. Experimental conditions will be compared and causal mediation analysis investigated. Qualitative HCP and patient experiences of the BetterBack☺ MOC will also be investigated.

Dissemination: The findings will be published in peer-reviewed journals and presented at national and international conferences. Further national dissemination and implementation in Sweden and associated national quality register data collection are potential future developments of the project.

Trial registration: ClinicalTrials.gov: NCT03147300

Date and version identifier: 13 Dec 2017, protocol version 3.

Key words: Low back pain, model of care, effectiveness, implementation.

Word count: 8156 words

Strengths and limitations of this study

- This will be the first study of effectiveness and implementation of a best practice model of care in LBP primary care in Sweden.
- An international consensus framework is used for the development, implementation and evaluation of the BetterBack☺ model of care.
- The main trial's a priori methodology has been informed and refined by an internal pilot phase.

BACKGROUND

Low back pain (LBP) is one of the most prevalent and burdensome problems for individuals and society in Sweden and worldwide [1,2]. LBP is often defined in terms of its localization, duration, severity, frequency, and interference on activities of daily living [3]. Most new episodes of LBP are self-limiting with only approximately 20% having persistent symptoms but a large majority experience pain recurrence [1]. The aetiology of LBP is often classified as specific or non-specific, based upon if a pathoanatomical cause can be identified through objective diagnostic assessment and confirmed by medical imaging [4]. The prevalence of LBP caused by specific pathology of serious nature such as malignancy, spinal fracture, infection, or cauda equine syndrome requiring secondary or tertiary health care has been reported to range between < 1%-4% in the primary health care setting [5,6]. Furthermore, nerve root problems associated with radiculopathy or spinal stenosis are thought to explain approximately 5%-15% of cases [7,8]. Medical imaging studies have highlighted that approximately 50% of younger adults and 90% of older adults have degenerative findings and large variations in lumbar spine morphology [9]. This is however evident in both symptomatic and asymptomatic individuals suggesting that LBP is more typically a result of benign biological and psychological dysfunctions as well as social contextual factors influencing the pain experience.

In Sweden, previous studies by our research group suggest the health care process for patients with LBP tends to be fragmented with many health care practitioners (HCP) giving conflicting information and providing interventions of varying effectiveness [10,11]. Our studies have shown that only a third of patients on sick leave for musculoskeletal disorders receive evidence-based rehabilitation interventions in primary care [10,11]. Furthermore our research has also demonstrated that there are still interventions that physiotherapists in primary care consider to be relevant in clinical practice despite the absence of evidence or consensus about the effects [12]. Our preliminary data suggests that when patients with LBP are referred to specialist clinics, up to 48% have not received adequate evidence-based rehabilitation in primary care. There is therefore a strong case for change to address what care should be delivered for LBP and how to deliver it in the Swedish primary health care setting.

The development of best practice clinical guidelines aims to provide HCP with recommendations based on strength of available evidence as well as professional consensus for the intervention's risk and benefits for the patients. Best practice clinical guidelines for LBP are lacking in Sweden but have recently been developed by the Danish Health and Medicines Authority and the English National Institute for Health and Care Excellence [13-15]. These national guidelines provide a thorough assessment of current evidence and can be used in Sweden to form the basis for locally adapted recommendations. Common to LBP, central recommendations from best practice clinical guidelines for arthritis are also education and exercise therapy aimed at improving patient self-care. Guideline informed models of care (MOC) such as "Better Management of Patients with Osteoarthritis (BOA)" in Sweden [16] and "Good Life with Osteoarthritis" in Denmark (GLA:D) [17] have been successfully implemented with broad national HCP use [18,19]. Furthermore, improvements in patient reported pain, physical function and decreased use of pain medication after receiving these MOC have been reported [18,19]. A similar best practice MOC for LBP could potentially improve HCP evidence based practice and patient rated outcomes in the Swedish primary health care setting.

Recently an international consensus framework has been established to support the development, implementation and evaluation of musculoskeletal MOC [20]. MOC readiness for implementation requires that the MOC is informed by best practice recommendations, has a user focus and engagement, has a clear structure, a description of components as well as a description of how they are to be delivered [20]. An important part of the MOC structure is the theoretical underpinning of how the MOC intends to act on behavioural change mechanisms to attain specific behavioural targets [20]. In order to achieve effective and efficient implementation of a MOC in primary health care, it is important to apply knowledge from implementation science [21-24]. Implementation science is the scientific study of uptake of research findings and evidence-based practices into routine practice to improve the quality and effectiveness of health care and services [25]. Implementation strategies focus on minimising barriers and maximising enablers that impact on the implementation and use of evidence-based practices. It has been suggested that a multifaceted strategy involving simultaneous use of several implementation strategies may be more effective than single-faceted strategies but the evidence base is inconclusive [26]. A recent systematic review however suggests that the most important aspects of successful implementation strategies are an increased frequency and duration of the implementation intervention and a sustained strategy [27].

There is therefore a clear rationale for evaluating the extent to which and how a best practice MOC for LBP (BetterBack☺) implemented with a sustained multi-facetted strategy is potentially effective in the Swedish primary care context. The costs in relation to effects are important to consider in order to deliver health care efficiently. This article describes a protocol for a BetterBack☺ MOC effectiveness and implementation process evaluation. The protocol conforms to the SPIRIT guidelines [28] with checklist provided in supplementary file 1.

AIMS

The overall aim is to investigate the effectiveness and implementation process of the BetterBack☺ MOC for LBP in a Swedish primary health care context. The specific trial objectives are to: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing best practice primary health care for patients with LBP (B) Improve and understand the mechanisms underlying change in illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate a multi-facetted and sustained implementation strategy and cost-effectiveness of the BetterBack☺ MOC for LBP in the Swedish primary health care context.

HYPOTHESIS

1. HCP reported confidence, attitudes and beliefs for providing primary health care for LBP will show statistically significant improvement after a sustained multifaceted implementation of the BetterBack☺ MOC compared to baseline before implementation. Intentional and volitional HCP rated determinants of implementation behaviour regarding the BetterBack☺ MOC will mediate improved confidence, attitudes and beliefs in a causal effects model. This will correlate with more coherent care according to best practice recommendations.
2. The sustained multifaceted implementation of the BetterBack☺ MOC will result in more statistically significant and greater clinically important improvement compared to current routine care for LBP regarding patient-reported measures for illness beliefs, self-care enablement, pain, disability and quality of life. Improvements in illness beliefs and adequate patient enablement of self care will mediate the effect on these outcomes.
3. A sustained multifaceted implementation of the BetterBack☺ MOC compared to current routine care will result in fewer patients with persisting LBP, fewer requiring specialist care, increased adherence to best practice recommendations and more statistically significant incremental cost-effectiveness ratio (ICER) based on cost per EuroQoL-5 Dimension

Questionnaire (EQ-5D) quality-adjusted life years (QALY) gained.

METHODS

Study design

World Health Organization Trial Registration Data Set is presented in table 1. This study is an effectiveness-implementation hybrid type 2 trial testing the hypothesised superiority of the BetterBack☺ MOC compared to current routine care [29]. The design involves an effectiveness evaluation of the BetterBack☺ MOC at the HCP and patient level as well as a process evaluation of a sustained multifaceted implementation strategy conducted simultaneuously. Evaluations are focused at the HCP and patient level because the MOC is targeted at changing HCP behaviour who then in turn implement behavioural change strategies on a patient level. This trial design was chosen for it's potential to provide more valid effectiveness estimates based on pragmatic implementation conditions. This is in contrast to best or worst case implementation conditions common in traditional efficacy or effectiveness trials [29]. Another advantage of the hybrid design is it's potential to accelerate the translation of the MOC to real world practice. This is in contrast to a time lag between efficacy, effectiveness and then dissemination steps in traditional research [29]. The trial design is outlined in figure 1.

As outlined in table 2, the design on the HCP level involves data collection in the cohort before and prospectively after implementation of the BetterBack☺ MOC. On a patient level, data is collected in a single blinded pragmatic randomized controlled stepped cluster format with longitudinal follow up at 3, 6 and 12 months post baseline. Randomisation at the patient level is not possible due to potential carry-over effects of the HCP transitioning back and forth between providing routine care or the BetterBack☺ MOC for different patients. Instead cluster randomisation is conducted at the start of the study, where patients are allocated thereafter to routine care (control group) or the BetterBack☺ MOC (intervention group) depending upon the clinic's allocation. Patients remain in their allocated group throughout the study.

A stepped cluster structure instead of a parallel structure of MOC implementation is applied due to the logistics involved in implementation in different geographical areas. The specific stepped cluster structure applied in the context of our study is classified as a dog leg with 2 assessments in routine care [30,31]. The term "dog leg" has been used by methodologists because the stepped structure resembles the form of a dog hind leg [30]. As displayed in table 2, this involves the first cluster being assessed after the implementation of the BetterBack☺ MOC. The second cluster is assessed after a period of current routine care (control), and assessed again after the implementation of the BetterBack☺ MOC. The third cluster receives current routine care (control) throughout the trial. However, studying the implementation of the BetterBack☺ MOC in cluster 3 is planned to occur as a final step at the end of the study.

An advantage of using the dog leg structure with 2 assessments in routine care is that it allows for an internal pilot phase of initial implementation of the BetterBack☺ MOC in cluster 1 compared to clusters receiving current routine care. Another advantage is that data generated will still contribute to the final analyses to maintain trial efficiency [32,33]. One objective for an internal pilot is to confirm the HCP acceptability of the intervention and trial within the first cluster [32,33]. A progression criteria for continuing the trial requires that HCP who have completed the BetterBack☺ education workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ MOC will be useful (1 = agree completely - 5 = do not agree at all).

Another objective of the internal pilot is to monitor patient recruitment in all 3 clusters during the first 2 months to provide information on the optimal cross forward time for cluster 2. In the dogleg design it is possible to vary the time point of cluster 2 to cross forward from the control to

intervention condition if the patient recruitment process in either cluster 1 or 3 is more or less than expected in the internal pilot (See table 2). In the event that cluster 1 recruit less than expected and clusters 2 or 3 recruit more than expected, then cluster 2 will then cross forward to the intervention condition immediately after the internal pilot. If cluster 1 recruit more than expected and cluster 2 or 3 recruited less than expected during the internal pilot phase, then cluster 2 will then cross forward to the intervention condition later in the trial to allow adequate current routine care data collection. Clusters were expected to recruit and gather data for at least 20 LBP patients per month in the internal pilot. A final objective with the internal pilot phase is to assess baseline variation and change over 3 months for implementation process and patient primary outcome measures to inform if our a-priori sample size calculation needed to be revised in the continuation of the trial.

Study setting

The Östergötland public health care region has a total population of 453 596 inhabitants with approximately 5000 patients per year accessing primary care physiotherapy due to LBP. In the public health care region of Östergötland, a large majority of consultations for LBP are via direct access to the 15 primary care physiotherapy rehabilitation clinics. A smaller percentage of consultations are via referral to these rehabilitation clinics from the 36 primary health care general practices in the region. Therefore the focus of this study is on the physiotherapeutic rehabilitation process for LBP in primary care. The rehabilitation clinics form three clusters in Östergötland health care region. These clusters are based on municipal geographical area and organisational structure of the rehabilitation clinics which helps to minimize contamination between separate clusters of clinics (Figure 2). Cluster west is comprised of 5 clinics with 27 physiotherapists, cluster central is comprised of 6 clinics with 44 physiotherapists and cluster east is comprised of 6 clinics with 41 physiotherapists.

Eligibility criteria

Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP will be included in the study. These physiotherapists will assess the eligibility of consecutive patients before and after the implementation of the BetterBack☺ MOC based on the following criteria:

Inclusion criteria: Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a first-time or recurrent episode of acute, subacute or chronic phase benign low back pain with or without radiculopathy.

Exclusion criteria: Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Spinal surgery during the last 2 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfil criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis.

Interventions

Control condition – current routine physiotherapeutic care for LBP in primary health care

Patients attending rehabilitation clinic clusters that have not have not yet completed the implementation of the BetterBack☺ MOC will receive treatment as usual according to current routine care clinical pathways (Figure 3). A clinical pathway specified in Östergötland public health care region requires that for patients accessing primary care due to LBP, a triage is to be performed by licensed HCP (Physiotherapists, Nurses or General Practitioners (GP)), to triage for specific pathology of serious nature. These approximately 1-4% of patients with suspected specific pathology of serious nature are then to be examined by GPs and referred for specific intervention in

secondary or tertiary health care. The majority of patients with LBP who on initial triage are assessed as having benign LBP are then scheduled for physiotherapy consultation and implementation of a LBP management plan. If the patient has persistent functional impairment and activity limitation despite 2-3 months of primary care intervention, the clinical pathway specifies inclusion criteria for specialist care referral pathways (Figure 3).

Intervention condition – The BetterBack☺ MOC for LBP

Development, design and implementation of the BetterBack☺ MOC for LBP

A framework for the development of musculoskeletal MOC [20] was used to guide development of the BetterBack☺ MOC for LBP. The high prevalence and burden of LBP [1,2], discordance in evidence based rehabilitation processes [10-12], a lack of clinical practice guidelines and a call for a best practice MOC requested by physiotherapy clinic managers in the Östergötland health care region have been identified in the primary care of LBP. Therefore, a case for change has been justified to improve current physiotherapeutic health service delivery for the primary care of LBP. The content and structure of the BetterBack☺ MOC where developed by engaging a work group of physiotherapy clinicians (clinical champions) from each primary care cluster in the Östergötland public health care region and physiotherapy academics at Linköping University. A Template for Intervention Description and Replication (TIDieR) Checklist [34] is described in supplementary file 2. To identify which key areas of contemporary care were of relevance for the BetterBack☺ MOC, the following tasks were performed by the work group:

1) Discussion and outline of the current routine care clinical pathway for LBP and areas needing improvement: The work group concluded that the BetterBack☺ MOC needed to focus on:

- WHO/WHERE: The primary care physiotherapy process for the management of patients with LBP in Östergötland health care region outlined by the red square in figure 3.

2) Analysis and discussion of existing international best practice clinical guidelines: The following thorough and up-to-date systematic critical literature reviews and international clinical guidelines [13-15, 35] were analysed and discussed by the work group.

3) Adaptation of best practice clinical guidelines to the Swedish context: The development of evidence based recommendations was based on the Swedish National Board of Health and Welfare methods for guideline construction [36]. The overall grade of evidence together with a consensus position based on professional experience and patient net benefit versus harms and costs are the key aspects on which the work group has formulated local recommendations to reflect their strength [37]. The recommendations have been externally reviewed by local physicians and international experts from the University of Southern Denmark. A summary of the Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of LBP with or without radiculopathy as well as the support tools used in the BetterBack☺ MOC is provided in the supplementary file 3.

4) Considering potential barriers to the uptake of evidence based recommendations by HCP [38], the work group identified and discussed targeted HCP behavioural change priorities of relevance for the BetterBack☺ MOC. The work group discussion lead to the following rationale for the BetterBack☺ MOC content and implementation described in table 3:

- WHY: The main HCP target behaviour was the adoption of the BetterBack☺ MOC to influence HCP delivery of care coherent with best practice recommendations.
- WHAT: This would require the contents of the MOC to change impeding barrier behaviours such as low confidence in skills/capabilities for improving LBP patient management, a biomedical treatment orientation rather than a biopsychosocial orientation, low awareness or beliefs of negative consequences of the MOC [38].

- HOW: BetterBack☺ MOC content used to overcome the modifiable barriers includes support tools aimed at further education and enablement of HCP clinical reasoning in providing LBP assessment and treatment coherent with the Swedish adaptation of best practice clinical guidelines. The support tools include assessment proformers with associated instruction manual, clinical reasoning flow charts linking assessment findings to relevant treatment interventions, patient education brochures and group education material on LBP self-care as well as a functional restoration program (supplementary file 3).
- WHEN/HOW MUCH/TAILORING: The functional restoration program and patient education components used, their individual and group based delivery and dosing is individualised based on the HCP clinical reasoning of the type and grade of patient functional impairments and activity limitations (supplementary file 3).
- PROCEDURE: Figure 4 displays a flow diagram showing the steps involved for HCP in delivering the contents of the BetterBack☺ MOC.

The Behaviour Change Wheel (BCW) [39] was used by the work group as a logic model to theorise the process of how the BetterBack☺ MOC content applied at the guideline policy level could guide theory-informed intervention functions using specific behavioural change techniques [40]. To help investigate possible mediators of behavioural change interventions in the BetterBack☺ MOC, the Theoretical Domains Framework (TDF) [41] was integrated into the BCW. The TDF is comprised of 14 theoretical domains/determinants of behavioural change of which could potentially influence behavioural change technique effect on the central source of behaviour [42]. The central source of behaviour in the behavioural change wheel is described by the COM-B model. In the COM-B model, a person's capability (physical and psychological), opportunity (social and physical) can influence on motivation (automatic and reflective) enacting behaviours that can then alter capability, motivation and opportunity [39]. The BCW [39] and TDF [41] are displayed in figure 5.

5) The following sustained multifaceted implementation strategy for the BetterBack☺ MOC was developed:

- An **implementation forum** including rehabilitation unit managers and clinical researchers was formed. The implementation forum collaborated on forming overarching goals, timeline and logistics facilitating and sustaining the implementation of the BetterBack☺ MOC in the primary care rehabilitation clinic clusters in the Östergötland public health care region.
- A MOC **support team** was formed. This is comprised of experienced clinicians (clinical champions) from each rehabilitation unit together with clinical researchers fascilitating local implementation and sustainability of the BetterBack☺ MOC at the rehabilitation units.
- A **package of education and training** that the support team can utilise to assist the use of the BetterBack☺ MOC by HCP was developed.
    - Physiotherapists in the 3 geographical clusters of public primary care rehabilitation clinics in Östergötland will be offered to participate in a 13.5 hours (2 days), continued medical education (CME) workshop. The workshop is designed by the support team with at least 2 clinical researchers and 1 experienced clinician from the rehabilitation unit cluster present in the support team's delivery of the workshop for each cluster. The HCP education provided in the workshop format is described in supplementary file 4.
    - Key components of the educational program are:
        - Education and persuasion about evidence based recommendations for LBP care and the BetterBack☺ MOC through an experiential learning process applying problem based case studies and clinical reasoning tools.

- Traning and modeling of the practical use of the BetterBack☺ education and physical intervention programs aiming at self-care as well as function and activity restoration.
- Access to a website describing the BetterBack☺ MOC. A chat forum will give an opportunity for clinicians to ask questions and share different experiences of the new strategy managed by the support team. Researchers will respond to questions from the participating clinicians.

- To consolidate the BetterBack☺ MOC use at the local clinics, the local support team member and clinical researchers will mediate a 2 hour interactive follow-up workshop 3 months after BetterBack☺ MOC implementation. Aspects of the previous workshop content will be discussed and reinforced. To aid continued sustainability of the BetterBack☺ MOC implementation, the local support team member will provide continued maintenance of education at their clinics and even educate new staff.

6) Once HCP behaviour change has occurred, it is anticipated that HCP use of the BetterBack☺ MOC may influence patient outcomes. A rationale for causal mediation effects can be proposed based on the Common Sense Model of self-regulation (CSM) [42]. This suggests a potential effect of the BetterBack☺ MOC on improved patient reported pain, physical function, and quality of life may be mediated by improved patient illness beliefs such as cognitive and emotional illness representations as well as adequate coping through self-care enablement [42]. The patient target behaviours are therefore focused on the understanding of the mechanisms and natural course of benign LBP and the enablement of self-care. This requires content of the MOC to change patient impeding barrier behaviours such as maladaptive illness beliefs on the cause and persistent course of LBP (low outcome expectation, anxiety, catastrophizing, fear-avoidance, and negative illness beliefs), low self-care enablement and low baseline physical activity [43]. The content for the patient education and functional restoration program included in the BetterBack☺ MOC therefore reflects these aspects and is shown in supplementary file 3. These are also charactarised according to the BCW, behavioural change technique taxonomy [44] and TDF in table 3.

Outcomes

Implementation process

1. Primary outcome measure

- Practitioner Confidence Scale (PCS) [45] mean change from baseline to 3 months post baseline. Practitioner reported confidence is the primary HCP behavioural change goal for the HCP education and training workshop in the multifaceted implementation of the BetterBack☺ MOC. The 3 month time frame allows for the development and consolidation of HCP behavioural change after application in repeated patient cases.

2. Secondary outcome measures

- PCS [45] mean immediate change from baseline to directly after the HCP education and training workshop as well as mean long term change from baseline to 12 months post baseline. This secondary outcome is important for the understanding of longitudinal HCP behavioural change.
- Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [46] mean change from baseline, to directly after the HCP education and training workshop as well as at 3 and 12 months post baseline.

Implementation outcomes

1. Primary outcome measure

- Proportional difference between control and intervention groups for incidence of participating patients receiving specialist care for LBP between baseline and 12 months after baseline. Incidence proportion, analogous to cumulative incidence or risk is calculated by

taking the number of patients receiving specialist care of LBP and dividing it by the total number of patients recruited to the study. The main goal of both the control and interventions conditions in primary care for benign first-time or recurrent debut of LBP is to improve patient reported outcomes without the need of secondary or tertiary health care processes.

2) Secondary outcomes measures

- Mean difference between control and intervention groups for change between baseline and final clinical visit regarding grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP [47].
- The proportion of patients who receive the BetterBack☺ MOC and registration of health care codes coherent with the Swedish best practice clinical recommendations.

Patient outcomes

1. Primary outcome measure

- Numeric rating scale for lower back related pain intensity during the latest week (NRS-LBP) [48]. The mean difference between control and intervention groups in change between baseline and 3 months post baseline will be analysed. Pain intensity is the primary functional impairment that patients with LBP contact primary health care for and has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported NRS change over 6 months as a core metric for pain management interventions [50].
- Oswestry disability index version 2.1(ODI) [51]. The mean difference between control and intervention groups in change between baseline and 6 months post baseline will be analysed. Disability, analogues to decreased physical functioning and activity limitation has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported ODI change over 6 months as a core metric for functional restoration [50].

2. Secondary outcome measures

- NRS-LBP [48] and ODI [50] mean difference between control and intervention groups in short-term change from baseline to 3 months post baseline and mean long-term change from baseline to 12 months post baseline. These secondary outcomes are important for the understanding of longitudinal patient-rated changes in pain intensity and disability after primary care intervention.
- The European Quality of Life Questionnaire (EQ-5D) [52]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Health related quality of life has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported EQ-5D change over 6 months as a core metric for pain management interventions [50].
- The Brief Illness Perception Questionnaire (BIPQ) [53]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Illness perception has been shown to predict longitudinal pain and disability outcomes in several LBP studies [54-58].
- Patient Enablement Index (PEI) [59], Patient Global Rating of Change (PGIC) [60] and Patient Satisfaction (PS) [61] mean difference between control and intervention groups at 3, 6 and 12 months post baseline will be analysed.

Participant timeline

The trial timeline is shown in table 2. The intervention schedule started with the development of evidence based recommendations and the BetterBack☺ MOC which occurred during June 2016 - February 2017. The enrolment schedule started with cluster enrolment and randomisation in March

2017. This resulted in the first allocated cluster 1 (west) entering internal pilot of implementing the BetterBack☺ MOC HCP education and training workshop which occurred in March 2017. This was followed up with a 2 month internal pilot of patient enrolment schedule occurring in all 3 clusters during April-May 2017. In order to finalise a sample size calculation for the main trial, baseline data collected during the internal pilot is compared to follow-up data 3 months after baseline for the primary outcome measure questionnaires to analyse initial HCP and patient effects of the implementation of BetterBack☺ MOC in cluster 1 compared to the control conditions in clusters 2 & 3. In the transition to the main trial, patient enrolment and baseline assessments will then continue to occur until January 2018. The eventual time of crossing forward of cluster 2 into the implementation of the BetterBack☺ MOC is determined by the internal pilot trial results. Participants in the trial will be follow-up longitudinally at 3, 6 and 12 months after baseline measures. The schedule for assessments is also outlined in table 2.

Sample size

An initial sample size estimation in the planning stage of the study assumed at least a small Cohens d effect size (d=0.35) for the HCP behavioural change primary and secondary outcomes. This is based on previous literature showing small-moderate HCP behavioural change effects sizes using similar interventions to increase the uptake of evidence-based management of LBP in primary care [62-63]. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of the BetterBack☺ MOC, 80% statistical power and a 20% loss to follow-up, a sample size of n = 63 HCP is needed for a matched pairs t-test statistics comparing baseline and follow-up means. We assume a possible carry-over of a similar effect size (d=0.35) on patient behavioural change primary and secondary outcomes. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of BetterBack☺ MOC compared to usual care and a 80% statistical power, the number of patients required for an individually randomized simple parallel group design would be n = 204. Adjusting for the design effect due to clustering randomizing, an intracluster correlation of 0.01 and a cluster autocorrelation of 0.80, a dog leg design with 2 assessments in routine care and 100 patients in each cluster section would require at least n = 402 patients over 2.41 clusters according to algorithms described by Hooper & Bourke [30]. In a balanced recruitment schedule, this equates to 14 patient per months per cluster for a total of 3 clusters. Allowing for potential unbalanced recruitment flow and a potential drop-out in the longitudinal outcomes at 3, 6 and 12 months post baseline, each cluster will aim for up to 20 patients per month equating to a potential total study n = 600.

Recruitment

In an effort to curb recruitment difficulties, strategies to promote adequate enrolment of participants into the study will be used. We anticipate less problems with recruitment into the prospective cohort study design investigating the multifaceted implementation of the BetterBack☺ MOC on the HCP level. This is due to the study having been endorsed by clinical department managers calling all HCP working with patients with LBP at their clinics to participate. However, recruitment of patients into the cluster randomized controlled trial is dependent upon the feasibility of recruitment processes adapted to the context of each individual clinic and the compliance of HCP to administer recruitment of consecutive patients. A strategy to optimise the administration of patient recruitment will involve the author KS regularly visiting participating clinics to inform HCP of the study protocol and help streamline practical administration of the protocol in the context of the individual clinics. KS will also monitor weekly recruitment rates from the clinics and provide motivational feedback on recruitment flow to clinical department managers and designated clinical champions who will provide additional motivational feedback to HCP. In accordance with a Consolidated Standards of Reporting Trials, a flow diagram displaying participant enrolment, allocation, follow-up and analysis will be constructed [64]. Reasons for exclusion, declined participation, protocol violations and loss to follow-up will be monitored by KS.

Allocation and blinding

Random concealed allocation of clusters was performed by a blinded researcher randomly selecting from 3 sequentially numbered, opaque, sealed envelopes. The method resulted in the following order: 1=cluster west, 2=cluster central and 3=cluster east. The author KS informed the clinics in the different clusters of their allocation to the control or intervention study condition. Due to the nature of the study and intervention, HCP conducting patient measurements and treatment cannot be blinded to group allocation. Risk of bias is minimal as the primary and secondary outcomes are patient self-reported questionnaires. Patients will be blinded to group allocation. The researcher responsible for statistical analysis will not be blinded to group allocation but an independent statistician will review statistical analysis.

Data collection

Data will be collected through quantitative questionnaires and qualitative focus group and semi-structured interviews. In the case of non-response to questionnaires, a questionnaire will be re-sent via post a total of 3 times. In case of continued non-response this will be complemented with a telephone call as a final effort for data collection.

Implementation process –

- The PCS contains 4 items reported on 5-point Likert scales where a total score of 4 represents greatest self-confidence and 20 represents lowest self-confidence for managing patients with LBP. The structural validity in terms of internal consistency of the items have been shown to be good with a Cronbach α coefficient = 0.73 in a single factor model for self-confidence [45]. The questionnaire has been forward translated by our research group from English to Swedish.
- The PABS-PT consists of two factors where higher scores represent more treatment orientation regarding that factor. One factor with 10 items measures the biomedical treatment orientation (Score 0-60) and one with 9 items measures the biopsychosocial treatment orientation (Score 0-54) [46]. Each item is rated on a 6-point Likert scale ranging from 1='totally disagree' to 6='totally agree'. The internal consistency of the biomedical factor has been shown to be good with a range between Cronbach α=0.77-0.84. Futhermore, the biopsychosocial factor has been shown to be adequate with a range between Cronbach α=0.62-0.68 [65]. Construct validity and responsiveness to educational interventions has been shown to be positive along with the test-retest reliability with reported intra-class correlation coefficient (ICC) on the biomedical factor=0.81 and on the biopsychosocial factor=0.65 [65]. The questionnaire has been forward translated from English to Swedish in a previously published study [66].
- The Determinants of Implementation Behaviour Questionnaire (DIBQ) was originally constructed based on the domains of the TDF [41, 67]. Confirmatory factor analysis resulted in a modified 93 item questionnaire assessing 18 domains with sufficient discriminant validity. Internal consistency of the items for the 18 domains was good, ranging from 0.68-0.93 for the Cronbach α coefficient [68]. The questionnaire has been forward translated by our research group from English to Swedish. After face validity consensus in our research group regarding relevant domains for the implementation of BetterBack☺ MOC, the questionnaire was shortened to the following domains: Knowledge, Skills, Beliefs about capabilities, Beliefs about consequences, Intentions, Innovation, Organisation, Patient, Social influence, Behavioural regulation totalling to 57 items. Questions were adapted to the context of HCP reported determinants of an "expected" implementation of BetterBack☺ MOC for measurement directly after the HCP education and training workshop. HCP reported determinants retained orginal wording for the questionnaires at 3 and 12 months after the implementation of BetterBack☺ MOC. The response scale used for each DIBQ question in our study is a 5-point Liket scale ranging from 1= `totally agree´ to 5=`totally disagree´.

Implementation outcome measures

- At 12 months after baseline, data will also be extracted from the public health care regional registry for the total number of patient visits for LBP, the number patients needing primary care multimodal pain team treatment, the number referred to specialist pain clinic, orthopedic or neurosurgical care and the number receiving surgery.
- Clinical reasoning and process evaluation tool (CRPE-tool): Grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP is assesses by the physiotherapist at baseline and final clinical contact where light, moderate, severe and very severe impairment/limitation is coded 0-4 respectively. A total score for baseline and follow-up measures is calculated from the sum of the functional impairment divided by the number of functional impairments and a similar total score is calculated for activity limitations [47]. A worsening of functional impairments and activity limitations measured att follow-up with the CRPE will be considered in the analysis of adverse events. Swedish Classification of Health Interventions (KVÅ) codes for assessment and treatment interventions will be assessed to analyse coherence with the Swedish best practice clinical recommendations. ICD-10 diagnosis codes and will also be recorded.
- The Keele STarTBack Screening Tool is reported by patients at baseline providing a stratification of prognostic risk of persistent pain. The overall score ranging from 0-9 is used to separate the low risk patients from the medium-risk subgroups where patients who achieve a score of 0-3 are classified into the low-risk subgroup and those with scores of 4-9 into the medium-risk subgroup. To identify the high-risk subgroup, the last 5 items must score 4 or 5 [69-71].
- Focus groups performing qualitative SWOT analyses will be conducted by HCP between 3-6 months after implementation.
- Semi-structured interviews with 10 HCP at 3 months after implementation will be conducted to investigate determinants of implementation behaviour and if other determinants need to be added to the DIBQ. The interviews will be deductively analysed according to the TDF [41] and BCW [39] frameworks.
- Semi-structured interviews investigating the patient experience of recieving care for LBP will be performed on 10 patients. These patients will have received care after implementation of the BetterBack☺ MOC.
- Economic costs of developing the BetterBack☺ MOC as well as performing the implementation strategy (staff time, HCP training, and printed resources).

Patient outcome measures

- NRS-LBP intensity during the latest week is an 11-point scale consisting of integers from 0 through 10; 0 representing ‘‘No pain’’ and 10 representing ‘‘Worst imaginable pain’’. Previous research in a LBP cohort has shown a test-retest reliability ICC = 0.61, a common standard deviation=1.64 points, the standard error of measure = 1.02 and minimal clinically important difference (MCID) in LBP after treatment=2 [72-73].
- ODI version 2.1 assesses patient’s current LBP related limitation in performing activities such as personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. The ODI consists of 10 items with response scales from 0 to 5, where higher values represent greater disability. The ODI is analysed as a 0 to100 percentage variable where lower scores represent lower levels of low back pain disability. A reduction of 10 points is considered the MCID in LBP after treatment [50,70]. In Scandinavian conditions, the coefficient of variation, ICC and internal consistency of the ODI is 12%, 0.88-0.91 and 0.94 respectively [74-76]. Good concurrent validity has also been shown [75].
- The EQ-5D measures generic health-related quality of life and is computed into a 0 to 1.00 scale from worst to best possible health state by using the Swedish value sets [77]. A reduction of 0.08 points is considered the MCID in LBP after treatment [78]. Mean change after treatment for LBP has been reported to be 0.12 (SD±0.30) [79].

- The BIPQ analyses cognitive illness representations (consequences, outcome expectancy, personal control, treatment control, and knowledge), emotional representations (concern and emotions) as well as illness comprehensibility. An overall score 0-80 represents the degree to which the LBP is perceived as threatening or benign where a higher score reflects a more threatening view of the illness [52]. The BIPQ has been shown to be valid and reliable in a Scandinavian sample of patients with subacute and chronic LBP. The BIPQ has a Cronbach's alpha =0.72 and a test-retest ICC = 0.86, an ICC range for individual items from 0.64 to 0.88, a standard error of measurement (SEM) = 0.63 and minimal detectable change (MDC) = 1.75[80].
- The PEI has a score range between 0 and 12 with a higher score intended to reflect higher patient self-care enablement [59].
- PGIC asks the patient to rate the degree of change in LBP related problems from the beginning of treatment to the present. This is measured with a balanced 11 point numerical scale. A reduction of 2 points is considered the MCID in LBP after treatment [60].
- PS is measured with a single item patient reported question. The question asks "Over the course of treatment for this episode of low back pain or leg pain, how satisfied were you with the care provided by your health-care provider?" Were you very satisfied (1), somewhat satisfied (2), neither satisfied nor dissatisfied (3), somewhat dissatisfied (4), or very dissatisfied (5)?" [61].
- Economic costs of health service utilisation.

Data management

All paper based questionnaire data will remain confidential and will be kept in a lockable filing cabinet in the research group office. A password-protected coded database only accessible to the research team will be kept on a data storage drive in the research department. The research team will regularly monitor the integrity of trial data. Trial conduct will be audited on a weekly basis by the research team.

Statistical analysis

Statistical significance will be assessed with an alpha level of 0.05. All results will be reported as estimates of mean ± standard deviation and also effect size (e.g. mean difference) with 95% confidence intervals (95% CI). An intention-to-treat (ITT) principle applying multiple imputation will be utilised. A sensitivity analysis will compare per protocol and ITT databases. A sensitivity analysis will also be used to assess the significance of a washout period by comparing the complete database against the same database without data collected during the 2 weeks in conjunction with the Betterback☺ implementation in each cluster.

Implementation process and outcome analysis

ANOVA statistics comparing baseline and follow-up means will be used for implementation process and outcome measures. Causal mediation analysis will be used to analyse indirect mediational effects of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education and training workshop (intention stage) or at 3 or 12 months (volition stages) on the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT. If the HCP education and training workshop does not have a casual effect on improved prospective outcomes we will analyse where the causal pathway breaks down. Causal mediation analysis will be performed using the program PROCESS [81] within IBM SPSS (figure 6).

Patient outcome measures for the control and intervention groups will be compared using multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects with IBM SPSS. Fixed effect interactions between experimental

condition and The Keele STarT Back Screening Tool will also be assessed. Patient population specific minimal clinically important difference will be assessed för primary and secondary outcomes based on an anchor method where PGIC serves as an anchor. Applying a 1-1-1 multilevel mediation procedure with all effects random in MPLUS, the products of (1) the independent variable (Experimental condition: control or intervention) to the mediator (change in BIPQ, PEI), and (2) the mediator to the dependent variable (change in NRS, ODI or secondary outcome scores pre- to posttreatment) when the independent variable is taken into account, will be tested for mediation (figure 7).

Economic analysis

The reference case analysis is based on a health care sector perspective. The EQ5D will be used to calculate the ratio of costs to quality adjusted life years (QALY) saved for patients. Incremental cost-effectiveness ratios (ICER) for the multifaceted implementation strategy and the usual care condition will be calculated and plotted on a cost-effectiveness plane. This is based on the Swedish guideline priced direct costs of health service utilisation, organisational costs of developing the BetterBack☺ MOC as well as performing the implementation strategy and overall intervention clinical outcome effectiveness. The ICER will also be calculated per patient avoiding specialist care. To estimate a distribution of costs and health measures and confidence intervals for ICER, boostrapping will be used.

Data monitoring

All outcome questionnaires are formatted for use of scan processing software for automated data entry into the Statistical Package for the Social Sciences package. The author KS who is not blinded to treatment allocation will perform regular data checks during data entry and provide feedback when necessary to HPC regarding data omissions. JS will also double check data entry to detect and correct input errors, and range checks will be undertaken prior to data analysis.

Ethics and dissemination

Ethical clearance for the study (Dnr:2017-35/31) has been attained through the Regional Ethics Committee in Linköping. The ethics application including consent forms in Swedish is available upon request to the authors. Their are no known risks for participants. Voluntarily participating HCP will complete questionnaires. All participating patients are informed orally and in writing about the study on the first visit at participating primary health care clinics. They are informed about that participation is voluntary and that they can at any time withdraw their participation. The HCP intervention will not be affected by the patient's decision to participate or not participate in the study. Data collection will not be performed for those not participating. A signed patient consent form will be collected from patients by the HCP before baseline measures are collected and intervention is commenced according to the study protocol. All collected data will be entered into a database accessable to the authors. A code list will be created where each participant will be represented by a code so that the database will be anonymous. The code list with personal data will be stored separately in locked filing cabinets at Linköping Univerity to protect confidentiality before, during and after the study. Data analyses and reporting will be performed using the de-identified database. The authors plan to disseminate the findings through manuscript publications in scientific journals and presentation at conferences.

Internal pilot trial results

The initial implementation of the BetterBack☺ MOC in cluster 1 allowed for an internal pilot to determine the HCP acceptability of the intervention and trial within the first cluster [32,33]. A progression criteria for continuing to the main trial required that HCP who have completed the BetterBack☺ education and training workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ MOC will be useful (1 = agree completely - 5 = do not agree at all). The 27 HCP

participating in the internal pilot in cluster 1 responded to the question with a mean value of 1.7 (SD 0.8) which subsequently fulfilled the HCP progression criteria.

The resulting internal pilot patient flow for april and may were n=28, n=28 for cluster 1 west (intervention) , n=5, n=12 for cluster 2 central (control) as well as n=14, n=22 for cluster 3 east (control) consecutively. This informed the decision to move the cluster 2 transition from control to intervention condition to occur later in the schedule, planned for september 2017 to allow for more control condition patient recruitement and data collection. The flow of patient recruitment and the process of 3 month follow-up in the internal pilot was used to inform the optimal time point of patient reported primary outcome for the main trial. Our initial planning was to measure patient reported primary outcome at 6 months post baseline based on the definition of persistence/chronicity of symptoms being often defined in the literature to be of 3 and up to 6 months duration [82]. Our intern pilot study had a 3 month follow rate of 80% resulting after up to 3 reminders sent to many of these patients. This informed of a likely risk of non-response at later follow-up time points. Furthermore, feedback from participating HCP even reported a larger clinical interest in 3 month patient follow-up data. Therefore the internal pilot informed the choice to revise our patient reported primary outcomes to 3 month post-baseline with subsequent amendments of the trial registration on ClinicalTrials.gov: NCT03147300.

Our internal pilot study was also used to assess baseline variation and change over 3 months in HCP and patient reported primary outcome measures in the control and intervention arms to aid calibration of the sample size calculation. A multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects revealed a intracluster correlation of <0.01 for the all primary outcomes measures. A small effect size in favour of the intervention condition was shown for HCP reported PCS (d=0.33) directly after implementation but increased to a moderate effect size after 3 months (d=0.51). Patient reported NRS showed a small effect size (d=0.28). Therefore, the internal pilot data supported our a priori sample size calculation for the main trial regarding PCS and NRS. However no effect size difference were observed between experimental conditions for ODI. It is possible that when statistical power improves when the trial progresses, potential differences in ODI may be detectable between experimental conditions.

CONCLUSION

The effectiveness-implementation hybrid type 2 trial with dog-leg stepped cluster structure allowed for the use of an internal pilot to inform feasibility and optimise method efficiency for the progression of the trial.

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Authors' contributions: AA & BÖ formulated the trials original aims and hypothesis. AA, KS, BÖ developed interventions material. AA, KS, PE, PN, ÖB designed the study methodology. AA, PN, BÖ procured funding for the trial. AA, KS, PE, PN, ÖB have reviewed and finalised the protocol.

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Competing interests statement: The authors have no competing interests.

Table 1. World health organisation trial registration data set.

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03147300
Date of registration in primary registry	03 May, 2017
Prospective Registration:	Yes
Secondary identifying numbers	N/A
Source(s) of monetary or material support	Linköping University
Primary sponsor	Linköping University
Secondary sponsor(s)	N/A
Contact for public queries	*Allan Abbott*, MPhysio, PhD [+46 (0)13 282495] [allan.abbott@liu.se]
Contact for scientific queries	*Allan Abbott*, MPhysio, PhD Linköping University, Linköping, Sweden
Public title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain BetterBack☺
Scientific title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain in Sweden (BetterBack☺): A Cluster Randomised Trial
Countries of recruitment	Sweden
Health condition(s) or problem(s) studied	Low back pain
Intervention(s)	Behavioral: Current routine practice Behavioral: Multifaceted implementation of the BetterBack
Key inclusion and exclusion criteria	Health care practitioner sample Inclusion Criteria: - Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP Patient sample Inclusion Criteria: - Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a current episode of a first-time or recurrent debut of benign low back pain with or without radiculopathy Exclusion Criteria: - Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfill criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis
Study type	Interventional
Date of first enrolment	April 1, 2017
Target sample size	600
Recruitment status	Recruiting
Primary outcome(s)	- Incidence of participating patients receiving specialist care [Time Frame: 12 months after baseline] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Change between baseline and 3 months post baseline] - Oswestry disability index (ODI) version 2.1 [Time Frame: Change between baseline and 3 months post baseline] - Practitioner Confidence Scale (PCS) [Time Frame: Change between baseline and 3 months post baseline]
Key secondary outcomes	- Clinician rated health care process measures [Time Frame: Baseline and final clinical contact (Up to 3 months where the time point is variable depending upon the amount of clinical contact required for each patient)] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Baseline, 3, 6 and 12 months] - Oswestry disability index (ODI) version 2.1 [Time Frame: Baseline, 3, 6 and 12 months] - Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [Time Frame: Baseline, directly after education and at 3 and 12 months afterwards] - Patient Enablement Index (PEI) [Time Frame: 3, 6 and 12 months] - Patient global rating of change (PGIC) [Time Frame: 3, 6 and 12 months] - Patient satisfaction [Time Frame: 3, 6 and 12 months] - Practitioner Confidence Scale (PCS) [Time Frame: Baseline, directly after commencement of implementation strategy and at 3 and 12 months afterwards] - The Brief Illness Perception Questionnaire (BIPQ) [Time Frame: Baseline, 3, 6 and 12 months] - The European Quality of Life Questionnaire (EQ-5D) [Time Frame: Baseline, 3, 6 and 12 months]

Table 2. Study design and schedule of enrolment, interventions and assessments.

Timeline		June 2016 - Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Final clinic visit	Follow-up 3 months after baseline	Follow-up 6 months after baseline	Follow-up 12 months after baseline
Enrolment schedule			HCP Cluster random allocation	Patient recruitment during internal pilot phase		Patient recruitment during main trial phase											
Intervention schedule		MOC and protocol development	Cluster 1 West MOC implementation internal pilot	1	1	1	1	1	1	1	1	1	1				
			Cluster 2 Central	0	0	0	0	0 MOC implementation	1	1	1	1	1				
			Cluster 3 East	0	0	0	0	0	0	0	0	0	0 MOC implementation				
Assessment schedule				Baseline data Internal pilot (T=0)		Baseline data Main trial (T=0)								Longitudinal repeated measures in cohorts (T=1)	(T=2)	(T=3)	(T=4)
Implementation process	**PCS**		Cluster 1 before and after MOC implementation					Cluster 2 before and after MOC implementation					Cluster 3 before and after MOC implementation		x		x
	PABS-PT		Cluster 1 before MOC implementation					Cluster 2 before MOC implementation					Cluster 3 before MOC implementation		x		x
	DIBQ		Cluster 1 after MOC implementation					Cluster 2 after MOC implementation					Cluster 3 after MOC implementation		x		x
PROMS	**NRS back pain and leg pain**			x	x	x	x	x	x	x	x	x	x		x	x	x
	ODI			x	x	x	x	x	x	x	x	x	x		x	x	x
	EQ5D			x	x	x	x	x	x	x	x	x	x		x	x	x
	BIPQ			x	x	x	x	x	x	x	x	x	x		x	x	x
	PEI														x	x	x
	Satisfaction														x	x	x
	PGIC														x	x	x
Implementation	**HCP assessment, diagnosis and treatment codes**			x	x	x	x	x	x	x	x	x	x	x			
	Referrals to specialist care																x

MOC=model of care, 0=Control condition, 1=Intervention condition, PROMS=Patient reported outcome measures, grey shaded cells=internal pilot, T= assessment time. ◄► Period where 2 week cross-over from control to intervention can occur dependent upon patient recruitment rates identified in the internal pilot study.

Table 3. Characterising the BetterBack☺ model of care intervention content and mechanisms of action using the Behaviour Change Wheel [41], Behavioural change technique (BCT) taxonomy (v1) [44], and the TDF [43].

Target behavior	Rationale based on barriers to be addressed	BetterBack☺ MOC content to overcome the modifiable barriers				Mechanism of action	
		Mode	Content	BCT[44]	Functions	COM-B	TDF
Improved HCP confidence and biopsychosocial orientation in treating LBP through adoption of BetterBack☺ model of care	1) Low confidence in skills/capabilities for improving LBP patient management 2) Use of a biomedical treatment orientation rather than a biopychosocial orientation 3) Low awareness of the model 4) Beliefs of negative consequences of the model	1) Multifaceted implementation strategy - Workshop education	Evidence based model of care and clinical implementation tools (See supplementary files 1 & 2)	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				1.4 Action planning	Enablement	Psychological capability	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.3 Information about social and environmental consequences	Persuasion	Social opportunity Physical opportunity	Social Influences Environmental context and resources
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.2 Pros and cons	Persuasion	Reflective motivation	Beliefs about Consequences
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		2) Multifaceted implementation strategy - Report and website	Evidence based model of care and clinical implementation tools (See supplementary file 2)	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
Decreased patient LBP and disability as well as improved patient enablement of self-care	1) Maladaptive beliefs on the cause and course of LBP (Illness perception) = low outcome expectation, anxiety, catastrophizing, fear-avoidance, illness beliefs. 2) Low belief in ability to control pain. Low belief in ability to perform activities, low	1) BetterBack☺ Part 1. Individualised information at initial and follow-up visits.	Lay language pedagogical explanation of function impairment and activity limitation related assessement findings and matched goal directed treatment	5.1 Information about health consequences	Education	Psychological capability	Knowledge
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
		2) BetterBack☺ Part 1. Patient education brochure	Lay language education on the spine's structure and function, natural course of benign LBP and advice on self-care	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
		3) BetterBack☺ Part 2. Group education	Pain physiology, biomechanics, psychological coping strategies and behavioural regulation	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge

	baseline physical activity.			4.3 Re-attribution	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.2 Behaviour substitution	Enablement	Psychological capability	Behavioral regulation
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				10.8 Incentive (CME diploma)	Enablement	Reflective motivation	Reinforcement
				11.2 Reduce negative emotions	Enablement	Reflective motivation	Emotion
				12.4 Distraction	Enablement	Reflective motivation	Memory, attention and decision processes
				12.6 Body changes	Training	Physical capability	Physical skills
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
		4) BetterBack☺ Part 1. Individualised physiotherapy	Physiotherapist mediated pain modulation strategies and functional restoration strategies. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				7.1 Prompts/cues	Environmental restructuring	Automatic motivation	Environmental Context and Resources
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		5) BetterBack☺ Part 2. Group or home based physiotherapy	Patient mediated self-care pain modulation strategies, functional restoration strategies and general exercise. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				1.8 Behavioural contract	Incentivisation	Reflective motivation	Intentions
				2.3 Self-monitoring of Behaviour (Training diary)	Training	Reflective motivation	Behavioral regulation
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities

Figure 1. Effectiveness-implementation hybrid type 2 trial design with chronological sequence of intervention in each cluster.

Figure 2. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

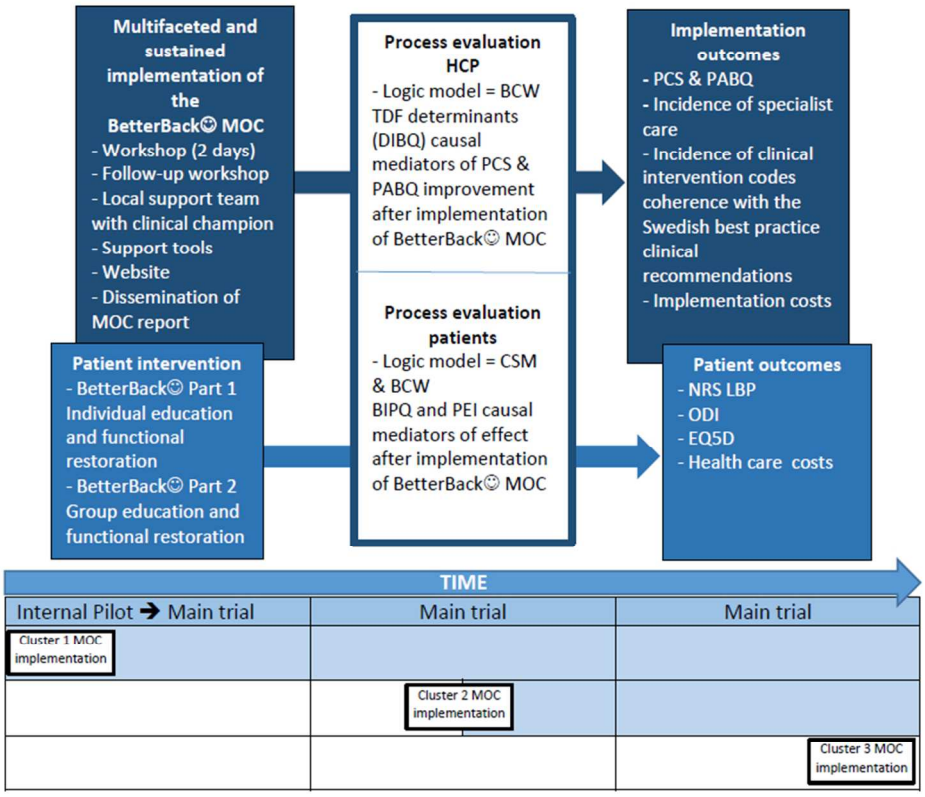
Figure 3. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack☺ model of care for LBP.

Figure 4. Steps involved for HCP in delivering the contents of the BetterBack☺ MOC.

Figure 5. The Behavioral Change Wheel [39] and TDF [41].

Figure 6. Causal mediation model to analyse indirect mediational effects ($a^k b^k$) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c').

Figure 7. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=c_j', indirect=$a_j b_j$, and total effects= $c_j' + a_j b_j$) are allowed to vary between level-2 clusters.



Effectiveness-implementation hybrid type 2 trial design with chronological sequence of intervention in each cluster.

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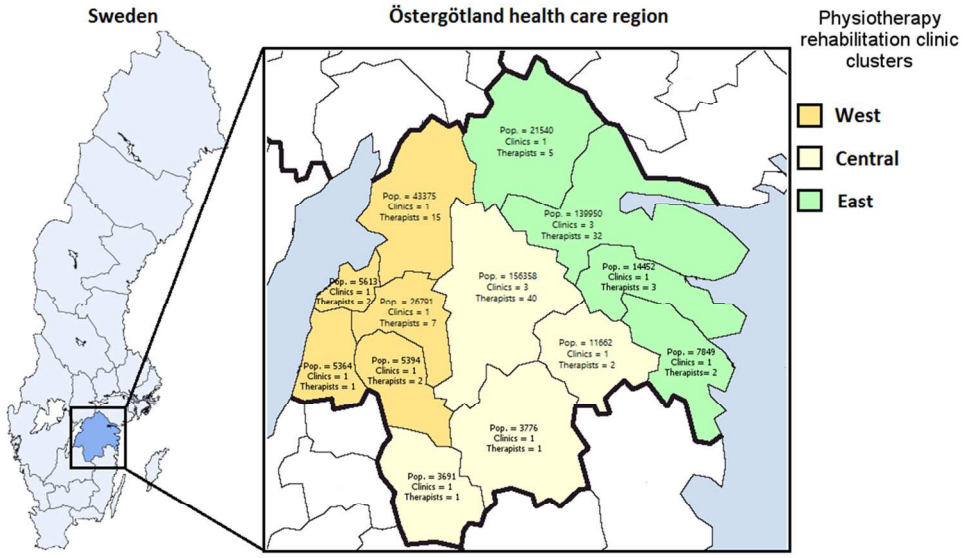

Figure 2. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

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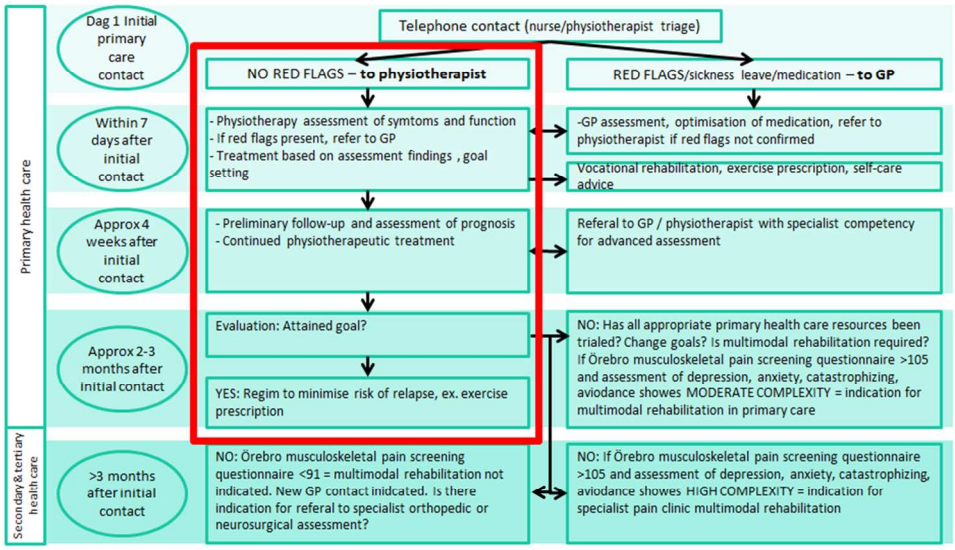

Figure 3. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack9 model of care for LBP.

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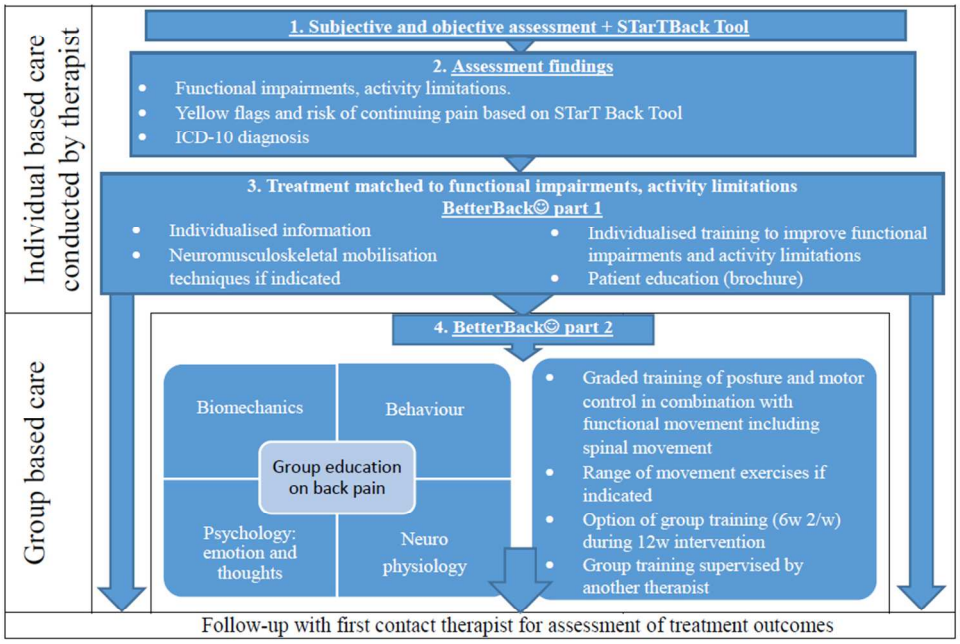

Figure 4. Steps involved for HCP in delivering the contents of the BetterBack MOC.

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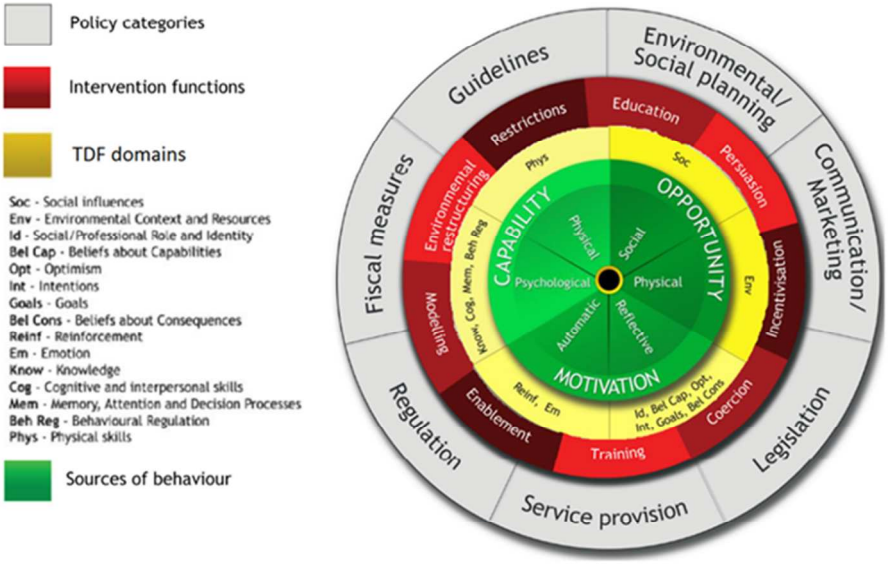


Figure 5. The Behavioral Change Wheel [39] and TDF [41].

127x84mm (300 x 300 DPI)

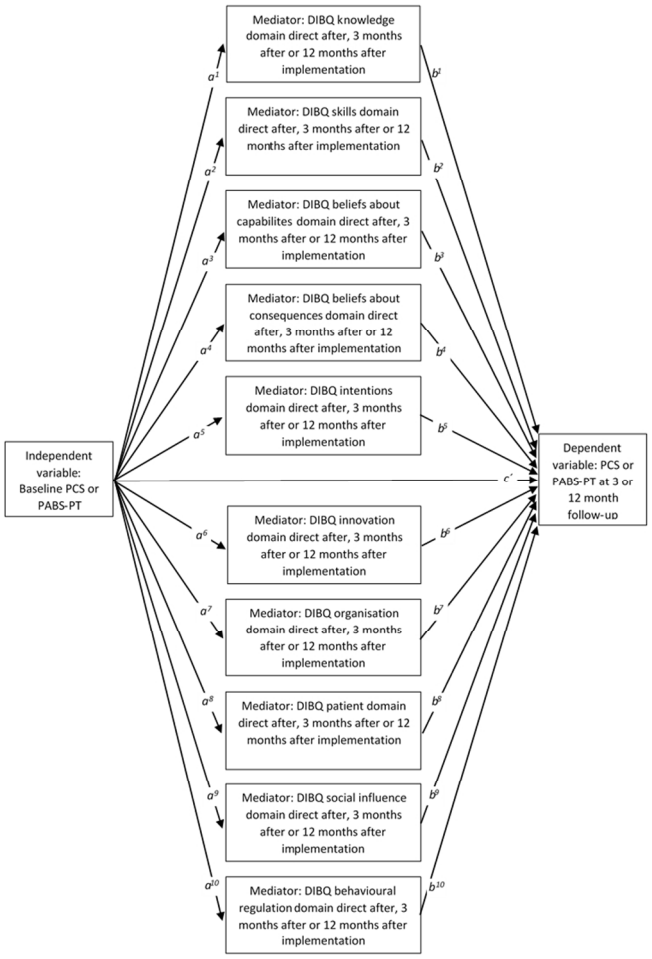


Figure 6. Causal mediation model to analyse indirect mediational effects (akbk) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c´).

67x118mm (300 x 300 DPI)

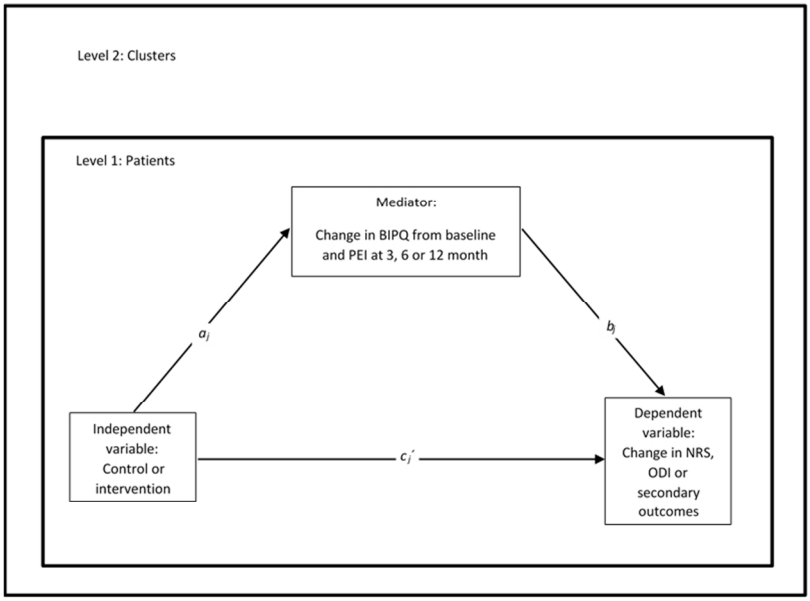


Figure 7. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=cj´, indirect=ajbj, and total effects= cj´+ ajbj) are allowed to vary between level-2 clusters.

84x67mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Manuscript page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1,19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-3
	6b	Explanation for choice of comparators	2-3
Objectives	7	Specific objectives or hypotheses	3-4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4-5, Table 2

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-8, table 3, figure 2-4, sup file 1-2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	5-8, Table 3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-10, Table 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10-11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10-11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-14
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13-14

Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	4-5, 14-15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	**BRIEF NAME** Provide the name or a phrase that describes the intervention.	p2	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	p6-8	Supplementary file 3
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p6-8, Table 3, Figures 2-4	Supplementary files 3&4
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p6-8, Table 3, Figures 2-4	Supplementary files 3&4
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	5	
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Table 3, Figure 4	Supplementary files 3&4
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	5 Figure 1	

8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p6-8, Table 3	Supplementary files 3&4
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p7-8	Supplementary files 3
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	p12	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

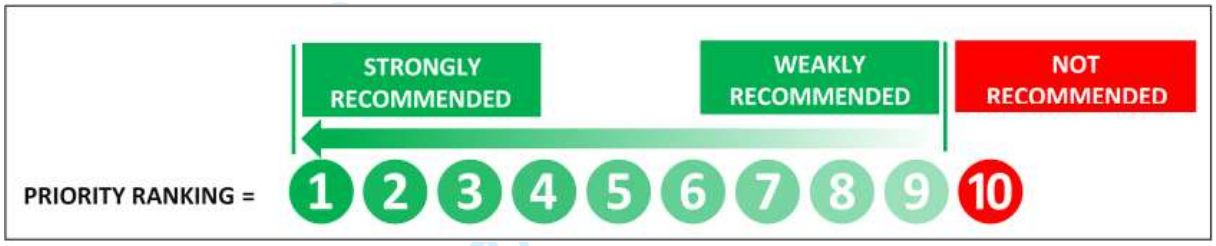
* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BetterBack☺ Model of care for LBP

Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of benign LBP with or without radiculopathy

Each evidence based guideline recommendation is supported by a clinical priority ranking. This is based on an overall assessment of the severity of the condition, reported effect of the intervention, strength of evidence assessment (GRADE), cost-effectiveness and the benefit of the intervention based on professional experience and patient benefit. A scale from 1 to 10 is used where the number 1 indicates recommended practices with the highest priority while the number 9 indicates recommended practices of low priority. The number 10 indicates recommendations that provide very little or no benefit or utility and are therefore not recommended.



Recommendation 1	PRIORITY RANKING = 1 **2** 3 4 5 6 7 8 9 10
Routine care should consist of standardised processes for subjective and objective assessment and diagnostics. A thorough screening of red flags is essential to rule out serious pathology. Treatment should be individualised for each patient. Basic treatment principles should be based on reassurance of a good prognosis, maintenance of appropriate physical activity and self-care enablement. Justification: The work group's reasoning is based on clinical experience of the importance of careful screening to rule out serious pathology. Furthermore, standardised assessment and diagnostics provide quality assurance but treatment needs to be individualised for each patient case. The work group also reasoned based on clinical experience that appropriate physical activity is likely to contribute to maintaining the patient's functional level, psychosocial and general health as well as have positive effects on self-care enablement. In some cases, may physical activity temporarily aggravate pain and symptoms, but there are no known persisting side effects. The work groups reasoning is also based on evidence showing a statistically significant advantage for maintaining appropriate physical activity compared to bed rest for improving pain and function. Despite this, evidence that proves the benefit of appropriate physical activity is so great to be clinically relevant is missing. In addition, the best available evidence has however a currently limited scientific basis (⊗⊗○○). *The working group proposes the following resources in the BetterBack☺ model of care to support the implementation of Recommendation 1 (See sections 1-5)*	
Recommendation 2	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 **10**
Do not perform routine medical imaging investigations (eg X-ray, CT, MRI) Justification: The work group´s reasoning is based on evidence that shows no differences in outcomes of pain, function and quality of life between patients who received or did not receive	

routine medical imaging investigations in the primary care context. The best available evidence has however a currently inadequate scientific basis (⊗○○○). It was also discussed that imaging cannot confirm or reject a preliminary diagnosis as the relationship between patient symptoms and degenerative imaging finding is usually weak. Moreover, degenerative secondary findings are common in asymptomatic individuals. *The work group however suggests that early use of medical imaging is motivated in the presence of symptoms or signs suggesting possible serious underlying pathology (red flags). Medical imaging may also be relevant when pain persists despite primary care treatment.*
Recommendation 3 — **PRIORITY RANKING =** 1 2 3 4 5 **6** 7 8 9 10
Consider using a patient-reported tool (eg STarT Back risk assessment tool) as usual care during the early-stages of patient management to screen the risk of continued LBP Justification: The work group's reasoning is based on studies showing that STarT Back Tool is the only valid tool to investigate the risk of continued back pain in the primary care context. It shows the highest accuracy for detecting patients with low risk profile (total score ≤3) and medium-high risk profile (total score ≥4) for continued back pain. Studies also show that STarT Back Tool has the best ability to predict functional and pain-related outcomes. The best available evidence has however a currently inadequate scientific basis (⊗○○○). No economical evaluations were identified but the working group discussed the importance of a simple and fast tool. STarT Back Tool can be filled in and analyzed in a few minutes to advantage over other tools that can be an administrative burden for patients and healthcare professionals. *The working group argues that the predictive value of the tool should support, but not replace, regular examination procedures and clinical decision making. See section 3 for STarT Back Tool.*
Recommendation 4 — **PRIORITY RANKING =** 1 2 3 4 5 6 7 **8** 9 10
Consider using a patient-reported tool (such as the STarT Back risk assessment tool) and classification of examination findings during the early-stages of patient management to aid the stratification of care to prevent continued LBP Justification: The work group reasoned that for the choice and scope of targeted treatment measures, consideration should be given to the assessment of risk profile for long-term LBP and classification of examination findings. This has been shown to have a better effect on pain, function and quality of life, as well as less economic costs compared to no treatment stratification. The best available evidence has however a currently inadequate scientific basis (⊗○○○). For a patient with low risk profile (total score ≤3 on STarT Back Tool) usual care is relevant and requires only few visits, but the working group recommends that adequate treatment measures directed at examination findings is of the highest importance. For patients with medium-high risk profile (total score ≥ 4 on STarT Back Tool), usual care will require additional visits. Information provided in questions 5-9 on STarT Back Tool that investigate anxiety with psychological risk factors can guide the need, focus and extent of behavioral medicine measures. *The working group argues that stratified care classified after assessing a risk profile for long-term back pain should support but not replace conventional examination procedures and clinical decision-making for treatment measures. The working group proposes the following resources to support the implementation of targeted treatments based on stratification (See sections 1-5).*
Recommendation 5 — **PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10
Consider giving individualised patient education as a part of usual care (e.g. an explanatory model based on pain neuroscience and psychological mechanisms)

Justification: Based on the best available evidence, the work group reasoned that individualised patient education as part of usual care can result in reduced work sickness absenteeism. The priority of the recommendation has been strengthened by consensus within the work group based on proven experience that individual adapted patient education is an important part of patient-centered care. The best available evidence has however a currently inadequate scientific basis (⊗○○○). The intervention requires that the patient is receptive for education. The extent of patient education can depend upon whether the patient has a distorted image of the underlying mechanism of LBP and a high degree of negative outcome expectations, anxiety, and fear-avoidance or if they are inactive or passive in managing the LBP. Patient education should include a reassuring dialogue and other cognitive and behavioural therapeutic techniques of relevance to support change in the individual's maladaptive thoughts, feelings and behaviors. Pedagogical explanation models should be used to provide the patient with knowledge about symptoms and disorders, as well as to strengthen and support self-care ability to master everyday activities. *The work group proposes the following resources to support of the implementation of patient education (See sections 6-7)*

Recommendation 6	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider a supervised exercise program as part of usual care

Justification: Supervised training is defined as general or back-specific exercises or physical activities conducted under the guidance of a healthcare professionals. The work group's reasoning is based on scientific evidence and proven experience that supervised training as part of usual care can result in clinically relevant improvement in pain, function, quality of life and produces lower health care costs compared with no supervised training. There is however no evidence that a specific type of exercise would be superior to another. The best available evidence has however a currently limited scientific basis (⊗⊗○○).

The work group proposes the following resources to support the implementation of a supervised training program (see section 8).

Recommendation 7	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider mobilisation techniques for neuromusculoskeletal structures as part of usual care (including active or passive motion in an angular and / or translational plane)

Justification: The working group reasoning is based on evidence that for patients with segmental movement impairments, mobilization techniques can provide a statistically significant reduction in short-term pain. It is however uncertain whether the effect is sufficiently large so that patients experience a clear improvement overtime. At group level, there is no evidence that a particular technique is be superior to another. It cannot be ruled out that for subgroups of LBP patients, more positive effects on pain and function may be produced by specific mobilisation techniques. It is expected that these subgroups can be identified by careful diagnostics and short trial treatments. Mobilizing techniques as part of multimodal treatment provide better results. Serious side effects are rare. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○).

Recommendation 8	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 **9** 10

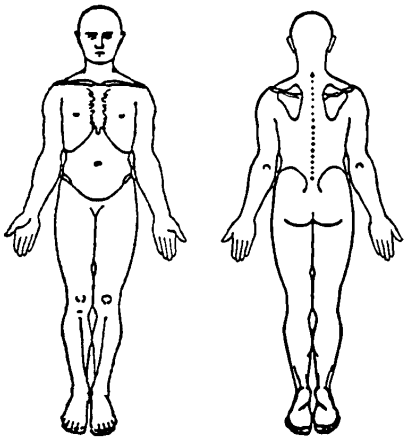
Consider acupuncture treatment in addition to usual care

Justification: The working group reasoned based on evidence that cannot exclude acupuncture has a short-term pain relief effect in addition to a placebo effect. Acupuncture has however no effect on function. Side effects in the form of brief superficial bleeding or inflammation may occur.

Pneumothorax and systemic infections are not common, but the prevalence is unknown. The best available evidence has however a currently inadequate scientific basis (⊗○○○).	
Recommendation 9	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer corset, shoes, traction, ultrasound or electrotherapy Justification: The work group's reasoning is based on evidence that passive treatments such as corset, shoots / soles, traction, ultrasound or electrotherapy do not reduce pain or improve function and quality of life in patients more than no treatment or when offered as part of multimodal treatment. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○). ***It cannot be ruled out that subgroups of patients may experience positive effects of these interventions when a hypothesised effect mechanism is aimed at specific functional impairment or activity limitation.***	
Recommendation 10	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Consider prescription-free NSAID medication if necessary in addition to usual treatment (lowest dose and shortest possible treatment time). NSAIDs: There is evidence of the effect of NSAID in patients with long-term LBP but the effect has not been highlighted on short-term pain or functional outcomes. There are no adverse reactions reported in systematic review studies on LBP, but potential transient side effects of NSAIDs such as reduced blood clotting, reduced stomach mucous function and reduced kidney function are known from studies on other conditions. The work group reasoned that lowest dose and shortest possible treatment time decreases the risk of side-effects. The work group anticipates that there are differences in patient preferences regarding NSAIDs, where some patients will agree to NSAID treatment, while others will decline. The best available evidence for NSAID effects on LBP outcomes is based on an inadequate scientific evidence (⊗○○○). The work group reasoned based on clinical experience that it cannot be excluded that the NSAID may have a pain relief effect in the short term.	
Recommendation 11	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer paracetamol or opioids Paracetomol: Has no effect on the degree of LBP and functional ability. There are no reported adverse reactions in studies, but side effects of paracetamol in the form of hepatic effects are known from studies on other conditions. The best available evidence is based on a moderately strong scientific basis (⊗⊗⊗○). Opioids: A weak analgesic effect of oxycodone in combination with paracetamol has been demonstrated in a study but the intervention has no effect on functional capacity for up to 12 weeks. Other positive effects or adverse effects were not shown. A wide range of opioid side effects are known from other studies. Therefore, the working group reasoned that treatment results in more risks than benefits to the patient. The best available evidence is based on a currently limited scientific basis (⊗⊗○○).	

BetterBack☺ model of care implementation support tools

1. Subjective assessment proformer for therapist use

LOW BACK SUBJECTIVE ASSESSMENT PROFORMER			
Name:…… Date of birth:…….. Date:……..			
History of the present condition (debut, duration, activity limitation)	**Symptom localisation** 		
Symptom Description	Localisation back	Localisation right leg	Localisation left leg
Pain nature (Dull, stabbing, radiating etc)			
Pain frequency (Constant/ Intermittent)			
Pain Intensity (NRS 0-10)			
Daily variation (am/pm, night time pain/disturbed sleep)			
Irritability (non-irritable/highly irritable)			
Aggravating factors (loading etc)			
Easing faktors (rest etc)			
Course (Improving/same/worse)			
Other symptoms (Instability, weakness, paresthesia, stiffness)			
Past medical history Previous level of function/activity: Previous treatment:	Red flags: (malignancy, unexplained weight loss, trauma, osteoporosis, infection, inflammatory disease, spinal cord compression symtoms, drug use) Other illnesses/ General health:		
Work, Social, Family history	**Patient förväntningar**		
Medication	**Medical imaging/Laboratory tests**		

2. Physical assessment proformer

LOW BACK PHYSICAL ASSESSMENT PROFORMER

1. INSPECTION – Postural screen

Sitting: good/fair/poor	Postural correction: Better/Worse/No effect	
Standing: good/fair/poor	Postural correction: Better/Worse/No effect	
Lordosis: Hyper/hypo/normal	Kyphosis: Hyper/hypo/normal	Lateralt shift: Right/Left/none
Spinal symmetry:	Shoulder symmetry:	Pelvic symmetry:
Leg & fot symmetry:	Muscular hypo/hypertrophy:	Scars:

2. SCREENING OF FUNCTIONAL MOVEMENT:

Shoes on/off, sit-stand, 2 leg/ 1 leg squat, lunge right/left
Gait: Trendelenburg right/left
Limp right/left
Weight transfer right/left
Toe walking right/left
Heel walking right/left
Work or sport specific:_____

3. SCREENING TEST IN STANDING/SITTING

	Right	Left
Slump test + sensitisation head/foot		
Foramen compression/unloading		
Hip loading/unloading in standing		

4. TEST IN STANDING/SITTING
LUMBAR ACTIVE ANGULAR MOVEMENT

	Range			Quality		Symptoms		
	Large	Med	Small	High	Low	During range	End range	Rep Mov
Flex								
Ext								
Lateral flex	R L	R L	R L	R L	R L	R L	R L	R L
Side Glide	R L	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L	R L

5. TEST IN SIDE LYING
LUMBAR PASSIVE ANGULAR MOVEMENT

	Range			Symptoms			
	Large	Med	Small	During range	End range	Rep Mov	Over press
Flex							
Ext							
Lat flex	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L

6. PRONE
ACCESSORY MOVEMENT/NERVE & MUSCLE FUNCTION

Spinal extension in prone	Better/Worse/No effect			
Segmental provocation	Movement			Pain
	Hyper	Hypo	Normal	
- Central P/A, Springing test - Unilateral P/A - Rotation provocation - Prone instability test				
Femoral nerve tension test				
Isometric/dynamic back muscle tests				

8. PALPATION

7. SUPINE
DIFFERENTIAL DIAGNOSTICS HIP/SI-JOINT/BACK

Spinal flexion in supine	Better/Worse/No effect	
Isometric/dynamic abdominal muscle tests		
	Right	Left
Hip: Angular movement, Patricks test, quadrant		
SI-joint provocation test, ASLR		
Passive SLR + head/foot sensitisation, crossed SLR		
Myotomes- L1-2(I), L2-3(Q), L4-5(TA), L5(EH), L5-S1(P), S1(TS)		
Dermatomes		
Reflexs: Patella L3-4, Achilles S1		
Babinski, Klonus		

3. STarT Back Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg**(s) at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): _____ **Sub Score (Q5-9):**_____

Funded by Arthritis Research UK

4. Clinical Reasoning and Process Evaluation tool (CRPE-tool) for therapists

PATIENT NAME:_____ **DATE OF BIRTH:_____**	**First assessment date:___/___/___** **Final assessment date:___/___/___** **Totalt number of physiotherapy visits:_____**

ASSESSMENT

- **First assessment - cross X relevant assessment findings**
- **Final assessment - circle ○ relevant assessment findings**

1. Assess grade of FUNCTIONAL IMPAIRMENT	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Energy and drive (motivation)	0	1	2	3	4	PA006
Sleep functions	0	1	2	3	4	PA007
Emotional functions (anxiety, low mood)	0	1	2	3	4	PA011
Thought functions (physical symptoms caused by cognitive/rational factors)	0	1	2	3	4	PA013
Sensory function (sensitivity for pain ”sensitisation”)	0	1	2	3	4	PB008
Pain (choose relevant category)						
Back pain	0	1	2	3	4	PB009
Lower extremity pain	0	1	2	3	4	PB009
Pain in a dermatome	0	1	2	3	4	PB009
Pain in another body part (Buttock, hip, groin, thigh)	0	1	2	3	4	PB009
Generalised pain localisation (3 of 4 body quadrats)	0	1	2	3	4	PB009
Exercise tolerance (endurance related activities)	0	1	2	3	4	PD009
Joint mobility	0	1	2	3	4	PG001
Joint stability	0	1	2	3	4	PG002
Muscle power	0	1	2	3	4	PG003
Muscle tone	0	1	2	3	4	PG003
Muscle endurance	0	1	2	3	4	PG003
Motor reflex funktions (decreased or increased)	0	1	2	3	4	PG004
Control of movement (Quality, coordination, balance)	0	1	2	3	4	PG006
Gait pattern	0	1	2	3	4	PG007
Sensation of muscle stiffness, tightness, spasm, contraction, heaviness	0	1	2	3	4	PG003
Mobility of spinal meningies, periferal nerves and surrounding tissue	0	1	2	3	4	PG000
2. Assess grade of ACTIVITY LIMITATION	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Perception of non-harmful sensory stimuli (kinesiophobia)	0	1	2	3	4	PJ001
Carrying out daily routine (ADL)	0	1	2	3	4	PK003
Handling stress and other psychological demands	0	1	2	3	4	PK004
Changing and maintaining body position (Shifting body weight away from the spine (increased lever arm)	0	1	2	3	4	PM001
Changing and maintaining body position (bending)	0	1	2	3	4	PM001
Maintaining a lying position	0	1	2	3	4	PM001
Maintaining a sitting position	0	1	2	3	4	PM001
Maintaining a standing position	0	1	2	3	4	PM001
Maintaining an upright neutral posture	0	1	2	3	4	PM001
Lyfting and carrying objects	0	1	2	3	4	PM004
Walkning	0	1	2	3	4	PM007
Moving around in different ways (crawling/climbing, running/joging, jumping)	0	1	2	3	4	PM008
Household tasks	0	1	2	3	4	PP003
Work ability and employment	0	1	2	3	4	PR002
Recreation and leisure activities	0	1	2	3	4	PS002

DIAGNOSTIC SUBGROUPING AND ICD-10 CODING

3. Matching assessment findings to diagnostic codes
Choose a primary assessment finding category:

- **First assessment: Cross X one or more related ICD-10 diagnostic codes in the same row**
- **Final assessment: Circle ○ a new diagnostic codes <u>if relevant</u>.**

Primary assessment category ⟶	**ICD-10 diagnos**
LBP with muscular functional impairment	☐ M54.5 Lumbago
LBP with segmental mobility impairment	☐ M54.5 Lumbago ☐ M99.0 Segmental dysfunction
LBP with movement coordination impairment/ segmental instability	☐ M54.5 Lumbago ☐ M99.1K Segmental instability in the lumbar spine
LBP with referred lower extremity pain (nociceptive pain proximal of the knee)	☐ M54.5 Lumbago ☐ M51.2 Other specificed dislocation of intervertebral disc ☐ M47.9K Spondylosis in the lumbar spine
LBP with radiating pain (neuropathic pain)	☐ M54.5 Lumbago ☐ M54.1 Radiculopathy (femoralis) ☐ M54.4 Lumbago with ischias
LBP with related cognitive or affective tendensies	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity)
LBP with related generaliserad pain (pain in 3 of 4 body quadrants)	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity) ☐ F45.4 Chronic somatoform pain syndrome
LBP with postural related symptoms	☐ M54.5 Lumbago ☐ M40.3 Flatback syndrome ☐ M40.4 Hyperlodosis
SI-joint symptoms or Coccygodynia	☐ M53.3 Sacrococcygeal disorders
LBP radiating pain + Medical imaging disc pathology and nerve compression finding	☐ M51.1K Disc degeneration/disc herniation in the lumbar spine with radiculopathy
LBP with radiating pain/neurogenic claudication + Medical imaging verifieried degeneration and nerve compression findings	☐ M48.0K Central spinal stenos in the lumbar spine (bilateral symptoms) ☐ M99.6 Stenosis of intervertebral foramin (unilateralt symptoms)
Ländryggsbesvär med nedsatt rörelse kontroll i ryggen och/eller segmentell instabilitet + Medicinsk bild verifierad Spondylolys/Spondylolisthes	☐ M43.0 Spondylolys ☐ M43.1 Spondylolistes

TREATMENT

4. Record at final assessment:

Has the BetterBack☺ model of care Part 1 been applied?		☐ Yes ☐ No
Has the BetterBack☺ model of care Part 2 been applied?		☐ Yes ☐ No
Cross X all modes och types of treatments used		
Physical exercise	**MODE**	KVÅ code
	☐ Non-supervised individual training	
	☐ Supervised individual training	QV011
	☐ Supervised group training	QV012
	TYPE	
	☐ Muscle strengthening training	QG003
	☐ Range of movement training	QG001
	☐ Muscle endurance training	QG003
	☐ Cardiovascular training	QD016
	☐ Balance training	QB001
	☐ Postural control training	QG004
	☐ Coordination training	QG005
	☐ Pelvic floor training	QF001
	☐ Postural training	QM005
	☐ Relaxation training	QG007
	☐ Physical activity prescription (FaR®)	DV002
	☐ Other ……	
Behavioural medicine interventions	**MODE**	
	☐ Individual based intervention	QV011
	☐ Group based intervention	QV012
	TYPE	
	☐ Information / education on pain	QV007
	☐ Cognitive-behavioural therapy	DU011
	☐ Mindfulness	DU032
	☐ Motivational interviewing	DU118
	☐ Relapse prevention	DU119
	☐ Supportive conversation	DU007
	☐ Other ……	
Manual therapy	**TYPE**	
	☐ Joint mobilisation	DN006
	☐ Joint manipulation	DN008
	☐ Massage	QB007
	☐ Stretching	DN009
	☐ Nerve mobiliseration	QG001
	☐ Trigger point pressure	DN007
	☐ Traction	QG001
	☐ Other……..	
Occupational medicine interventions	**TYPE**	
	☐ Workplace training	DV084
	☐ Training of work ability	QR003
	☐ Work and employment counciling	QR002
	☐ Information /education on ergonomics	QV010
	☐ Other ……..	
Physical modalities	**TYPE**	
	☐ TENS	DA021
	☐ Cryotherapy	QB011
	☐ Heat	QB011
	☐ Ultrasound	QB011
	☐ Shockwave therapy	QB011
	☐ Laser therapy	QB011
	☐ Short wave diathermy	DV042
	☐ Interferential therapy	DA021
	☐ Orthosis	DN003
	☐ Taping	DN003
	☐ Bio-feedback	DV010
	☐ Acupunkture	DA001
	☐ Other……..	

5. Rate overall treatment effect	☐ Much better ☐ Quite much better ☐ Unchanged ☐ Quite much worse ☐ Much worse

5. Clinical reasoning and process pathway for therapists

A thorough history and adequate physical examination are of great importance in order to target treatment interventions. In addition, it is very important to exclude the few red flag cases that require acute medical or specialist referral for the investigation and treatment of tumors, infections, inflammatory diseases, more severe back pathology and neurological conditions, as well as the strong influence of psychosocial factors which can also cause back pain. StarT Back Tool can be used to support decision making regarding the extent of health care needed and the need for psychosocial focus based on an assessment of risk factors for continued back pain. The physical assessment should include an analysis of functional movements, posture, active movements, passive movements, combined movements and / or static positions, joint accessory movement / provocation tests and neuromuscular function. This is to investigate how the symptoms are related to motion dysfunction.

Based on assessment findings, relevant treatment measures with effect mechanisms directed at functional impairments and activity limitations should be tested. These may include range of movement exercises (active/passive or accessory joint mobilisation or neuromuscular structure mobilisation), motor control exercises, muscle stretching, balance exercises, coordination, muscle strength, muscle endurance, general physical fitness or cardiovascular exercise. For example:

1. In the identification of movement directions and positions that reduce or centralize the patient's localised pain, distal pain or radiculopathy, these may be considered as a treatment techniques. This allows the patient to learn strategies to control pain and thus take better responsibility for his or her own situation.

2. In the identification of movement restriction due to joint, muscle or nerve related impairment, mobilisation strategies for the relevant structure may be considered to reduce the movement restriction.

3. In the identification of segmental instability or trunk motor control impairment in the, exercises with a focus on movement control can be tested aiming to improve muscle function, reduce pain and optimise loading of the trunk during full body movement.

4. In the identification of a psychogenic causes of back pain, supervised exercise could be tested to minimize kinesiophobia. This can often be complemented with patient education that can help pain management and enable self-care.

5. In the identification of a postural impairment, posture correction and ergonomic interventions can be tested.

Dosage of treatment measures should be individualised and sufficient to achieve the desired effect. Initial targeted treatment should be through individual patient care. As a complement to the initial targeted treatments, the purpose of a general training and patient education is to restore or improve function and activity. The suitability of group-based patient care is assessed in consultation with the patient as general training and patient education is considered relevant to support the patient's self-care.

Clinical process and reasoning pathway - BetterBack☺

Subjective and physical assessment

Symptom: Constant pain, night-time pain, pain unrelated to mechanical loading

Symptom: Pain related to mechanical loading

1) Red flags: Suspected malignancy, cauda equina/myelopathy symptoms, visceral pain, inflammation pga significant trauma/fracture, infection or inflammatory disease
2) Another medical condition providing an obstacle for rehabilitation

Medical management

Pain localisation over surrounding joints: hips or SI-joint

- Unilateral pain over hips or groin → Positive Hip Quadrant or Patrick's Test → **Likely hip**
- Unilateral pain under L5 segment → 2/4 or 3/5 SI-joint tests positive → **Likely SI-joint**

Classify lumbar spine related assessment findings

- Low back and/or leg pain of nociceptive or neuropathic character. High pain intensity and irritability. Aggravates / relieves or peripheralises / centralises during range of joint motion in a specific plane.
- Pain localised to the lower back. Nociceptive character. Mild-moderate intensity and irritability. Restricted joint range of motion and end range pain. No immediate change in ROM after repeated movements
- Pain localised to the lower back. Nociceptive character. Mild-moderate intensity and irritability. Painful arc/abberant movement flexion-extension, positiv prone apprehension test, pain during trunk loading
- Full ROM with no pain during ROM, nociceptive pain during static positions in end of range

Clinincal reasoning, possible influencing factors

STarT Back Tool
- Stratified management based on risk of pain persistence:

-Low risk
(STarT Back Tool ≤3):
- Functional optimisation with requiring few visits

-Medel & hög risk
(≥4 på STarT Back Tool)
- Functional optimisation requiring more visits.
- Behavioural medicine interventions when indicated

Consider other influencing factors:
Barriers and fascilitators to goal attainment
- Age
- Work
- Comorbidities

Diagnostic subgrouping and ICD-10 coding

Treatment according to BetterBack☺

Specific therapies when indicated

Pain modulation
- Directional preference exercises
- Pain modulating mobilisation therapies

Mobilisation
- Movement restriction (joint, nerve, muscle): Improve ROM with specific mobilisation and stretching

Movement control
of instability dysfunction
- Graded trunk and back stabilising exercises

Postural syndrome
postural training, ergonomic advice

General principles for all patients

Patient education and general functional restoration exercise working towards self-care enablement.

Part 1
Individualised care

Part 2
Transition to group based care when longer rehabilition period needed.

Follow-up assessment

6. BetterBack☺ Model part 1 – Patient education brochure

BetterBack☺

Information on Low Back Pain

LINKÖPINGS UNIVERSITET

Region Östergötland

Low Back Pain

Low back pain (LBP) is a common harmless condition that affects almost everyone at some point. Over a one-year period, 4 out of 10 adults experience LBP. It is often characterised by varying degrees of pain and discomfort that may impact on ability to perform activities. An episode of LBP usually improves within 2-6 weeks. Most have a fairly stable pattern of back health for many years, which may sometimes be interrupted by a period of LBP. This is a normal pattern and does not mean that the condition is getting worse over time.

Degenerative changes in the spine

Something that astonishes many is that there is no direct connection between degenerative changes in the spine and common LBP. This means that changes seen on X-rays, magnetic cameras and computer tomography can show pronounced age related changes or disc herniation in a completely painless person, while someone with LBP may have very little or no changes.

The structure and function of the lower back and common causes of LBP

The lower back consists of many structures such as bones, joints, discs, stabilising ligaments, nerves, as well as deep and superficial muscles. Pain sensations may potentially be signalled by one or more structures of the lower back. It is often difficult to specify exactly if and which structures signal pain sensations. How we maintain an upright position in different situations is called posture. An optimal posture means that the spine has the best conditions for good mobility with optimal distribution of body weight. Suboptimal posture, suboptimal loading of the back or even too little loading of the back can be possible contributing factors of LBP.

Experience of back pain

Pain is first experienced when interpreted in the brain. How the pain is interpreted depends on experience, thoughts, feelings and expectations. In some cases, pain may be experienced in the lower back but in the absence of pain signals from structures in the lower back. The pain system may also become hypersensitive and in some cases the pain can persist even though the original cause of the pain has resolved.

Figure 1. Pain is interpreted in the brain. This can be in the presence or absence of signals form lower back structures

Back pain symptoms

In addition to back pain, you may have pain in the buttocks and in one or both legs. You may have difficulty standing, sitting, walking, bending etc. This can lead to frustration, depressed mood and anxiety. Some may be afraid of physical activity and become inactive. All of this can impact negatively on you everyday life.

Tips when you have a particularly troublesome period

Think about what you have read in this brochure, that pain comes in periods but usually calms down. Also think about what relieves the symptoms and what you can do when you have a troublesome period. You may have a favorite exercise or other strategy to manage troublesome periods. Contact your physiotherapist for help if you feel after 2-6 weeks that pain doesn't subside. If you have numbness and tingling in both legs, loss of skin sensation or weak muscles in the legs and feet and especially if you have trouble controlling your bladder and bowel you should seek medical care. If you have LBP after an accident or have been previously treated for cancer or osteoporosis, it is also important to seek medical care. For the vast majority, however, back pain is a harmless and common condition that comes and goes.

Back Health

Good back health is a balance between the back's capacity on one side of the scale and physical / mental stresses on the other side as in the figure below.

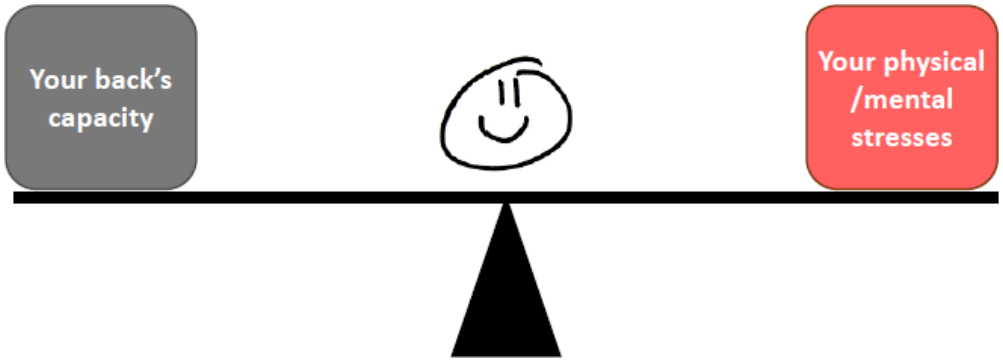


Figure 2. Balance between back capacity and stresses

Back pain occurs when imbalance occures between back capacity compared to physical / mental stresses as in the figure below.

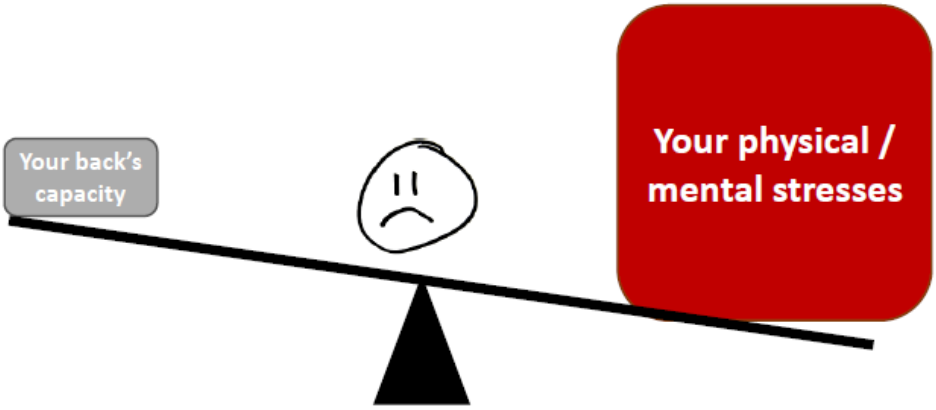


Figure 3. Imbalance between back capacity compared to physical / mental stresses

General advice / self-care

During the acute phase, most people are in need to take it easy and adjust their physical and mental stresses. Today, however, there is extensive research that recommends avoiding bedrest and instead modifying physical activity and successively returning to normal activities as quickly as possible. You can use a pain management scale to find the right level of back physical and mental stresses during everyday activities and also when you work out. This model is based on keeping you within acceptable perceived pain levels during an activity and within 24 hours after activity. This means that activity may increase the pain within acceptable pain levels during or after training, but it should return to initial levels within 24 hours. If you are unsure about the right level of back physical and mental stresses consult your physiotherapist.

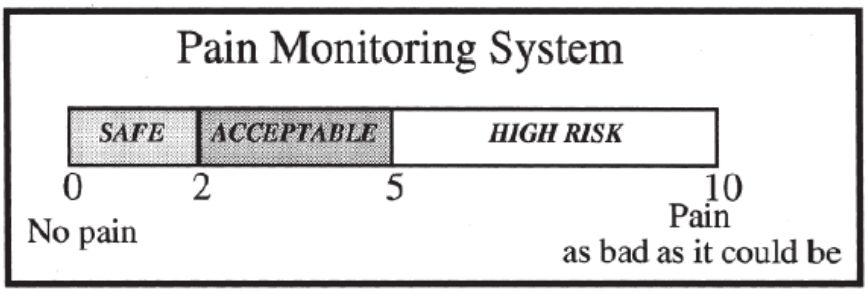


Bild 4. During activity, it is preferable that the pain is within safe to acceptable levels and that the pain returns to initial levels within 24 hours

Treatment for back pain

The goal is to increase your back's capacity and reduce your physical and mental stresses. You can increase your back's capacity by optimising your back posture, muscle stength, muscle endurance, agility, and improving your overall fitness. You can reduce your physical and mental stresses by optimising your back's physical loads, reducing negative emotions through a positive approach and reducing everyday stress and changing your thoughts about your LBP

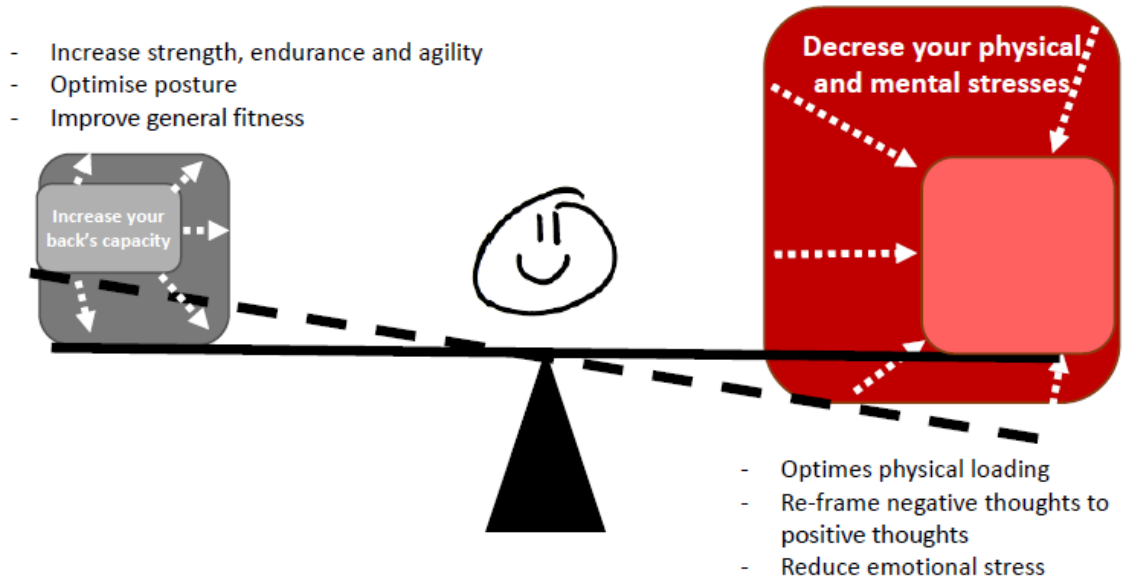
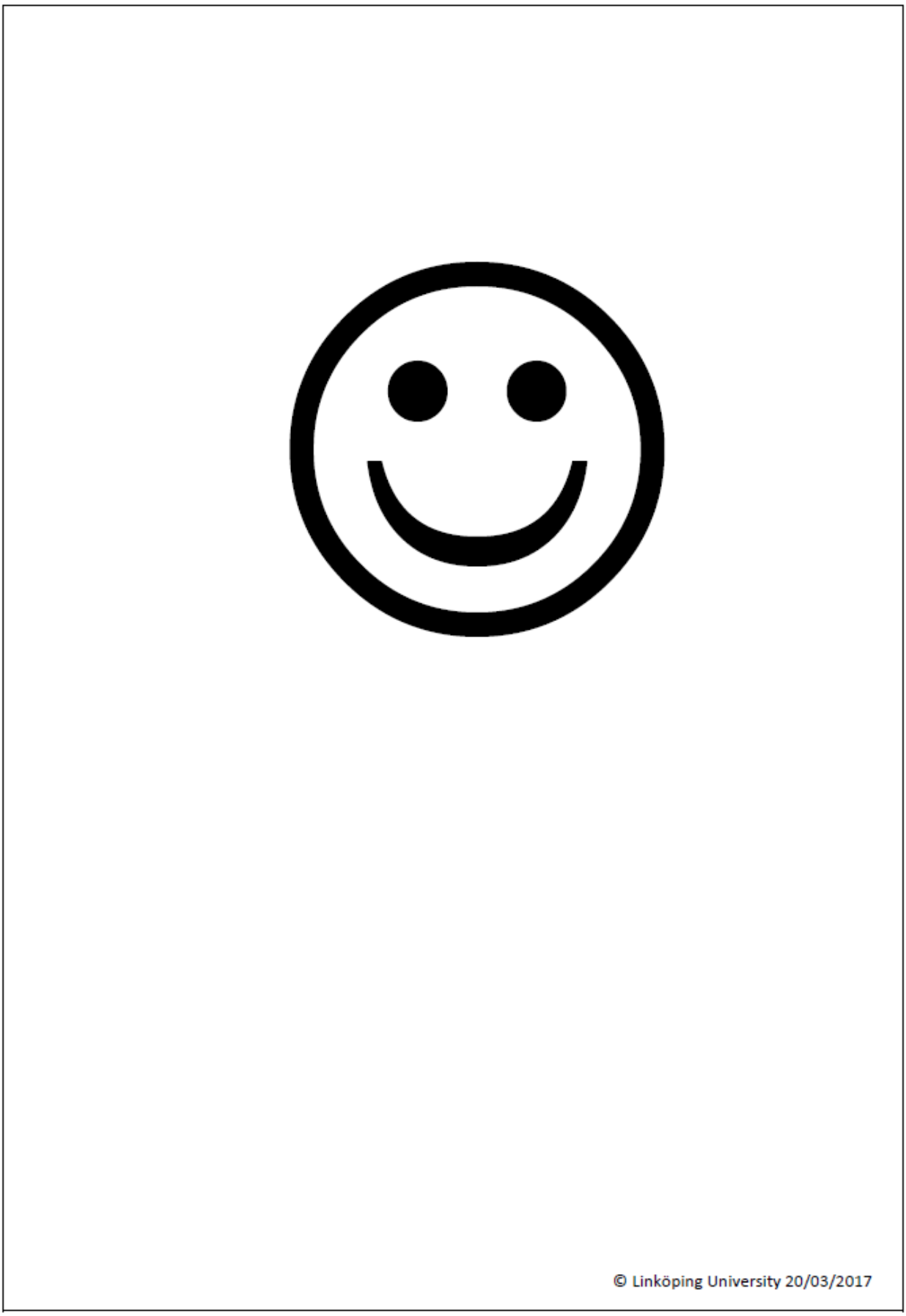


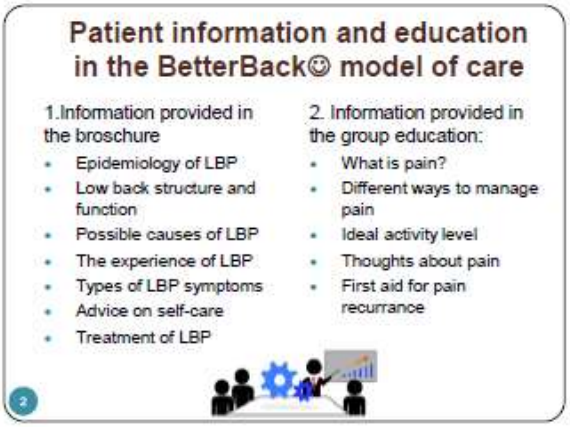
Figure 5. How to balance the back's capacity and stresses

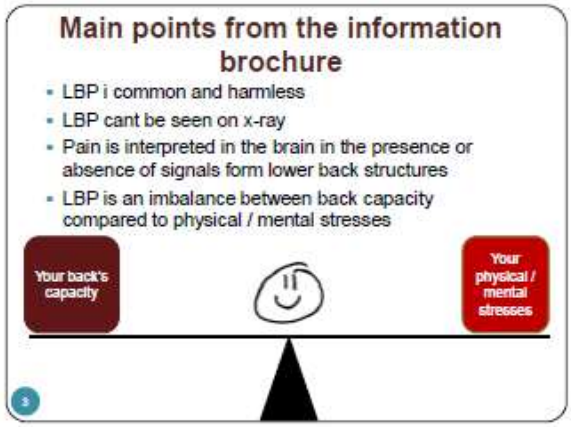
The BetterBack☺ model of care

The BetterBack☺ model of care for LBP focuses on evidence based physiotherapy, patient education and exercise. The main aim is to manage LBP symptoms and enable the patient's self-care ability. You will receive a thorough assessment and individualised care. Depending on your need for extended support in addition to your physiotherapist's initial interventions, pain education seminars and supervised exercise in a group format can be provided for 6 weeks, 2 times / week. The pain education seminars include explanatory models of what pain is, different ways of managing pain, as well as how to balance your back capacity and your physical and mental stresses you are exposed to. It is common for people to become less physically active after a troublesome period of LBP. It is therefore important to get started with some form of general fitness training. You can improve general fitness by walking, Nordic walking, cycling, jogging and swimming. If you experience pain during activity, you can use the pain management scale (see Figure 4). It is important that you feel motivated and can adapt your training to fit into your everyday life. In the BetterBack☺ model of care program, you can get help on how to get started!



7. BetterBack☺ Model part 2 – Group education seminar for patients





The situation affects the pain experience

7

Pain experience = warning from the body – interpretation in the brain

The body

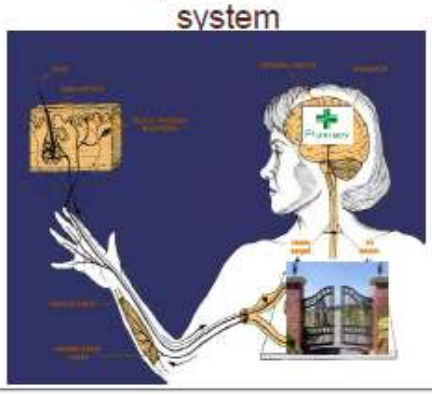
situation + thoughts + experience

Pain is inhibited or strengthened

Pain experience

8

The body's own pain relief system



9

Pain experience

- Pain can be **dampened**
  - If you understand it's cause
  - If it is predictable
  - If you know how to handle the pain
  - If it is manageable
  - If you have a positive attitude
  - If you are goal-focused

10

Pain experience

- Pain can be **dampened**
  - If you understand it's cause
  - If it is predictable
  - If you know how to handle the pain
  - If it is manageable
  - If you have a positive attitude
  - If you are goal-focused
- Pain can be **aggravated**
  - If you feel uncertain of its cause
  - If it is unpredictable
  - If you cant control the pain
  - If you have a depressed mood
  - If you generally feel pressured
  - If it is associated with bad experiences

- What dampens / aggravates your pain?

11

Thoughts affect our self-perception...,

12

… and thoughts affect the pain experience

You are going to be immunized against influenza. You know the needle hurts for a few days. How do you experience the pain?

You have back pain after a longer walk. How do you experience pain?

13

… and thoughts affect the pain experience

HEY MACARENA!

- Prolonged back pain can be like a bad song that gets stuck in your mind. The brain has learned it without you wanting to and it plays over and over again …. The more irritating the song the more easily it gets stuck in your mind

You started training but get more back pain afterwards. It may be muscle soreness or it may be the playing over and over again of pain memories like "the known song". How do you relate to this?

14

Pause exercise

Try to breathe relaxed and calm, focus on breathing for 2 minutes

Acknowledge your pains in a neutral way, but keep the focus on breathing

15

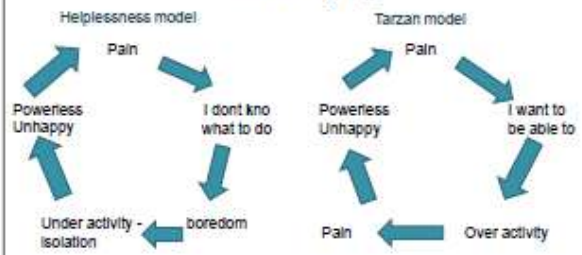
Pause Exercise -redirecting

What happens to your pain experience when you focus on your breathing?

Does this redirect your thoughts away from attention to pain?

16

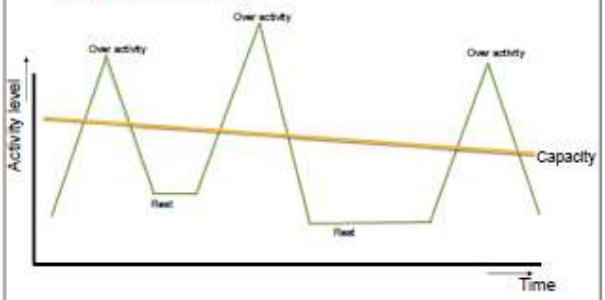
Pain coping



Different strategies. "Helplessness" or "Tarzan model"?
Are there other strategies? In which way do you react?
What consequences does this have?
Advantages/disadvantages?

17

Activity level – too much activity Tarzan model



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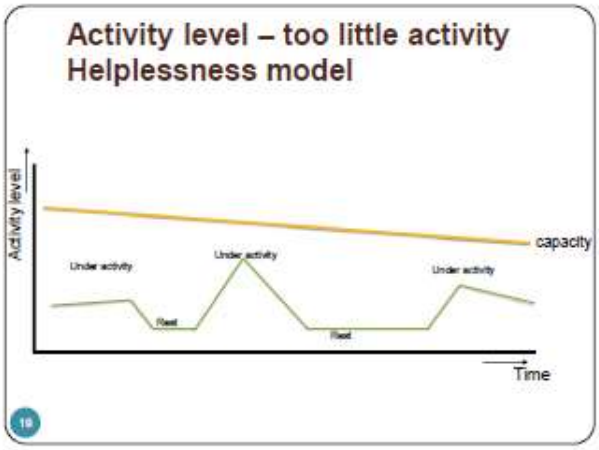
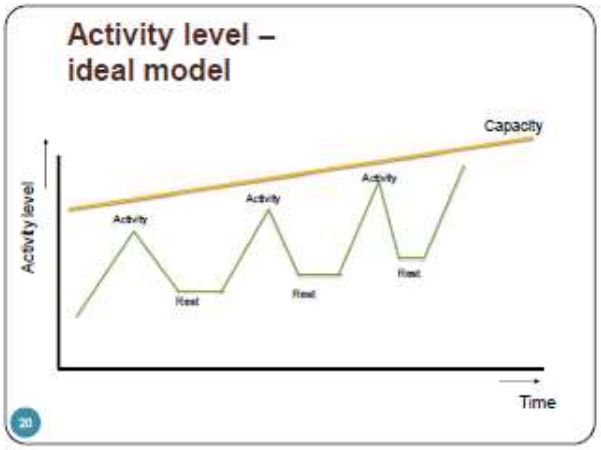
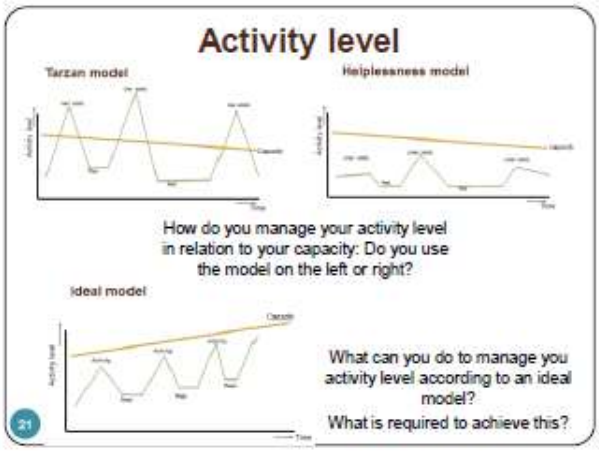
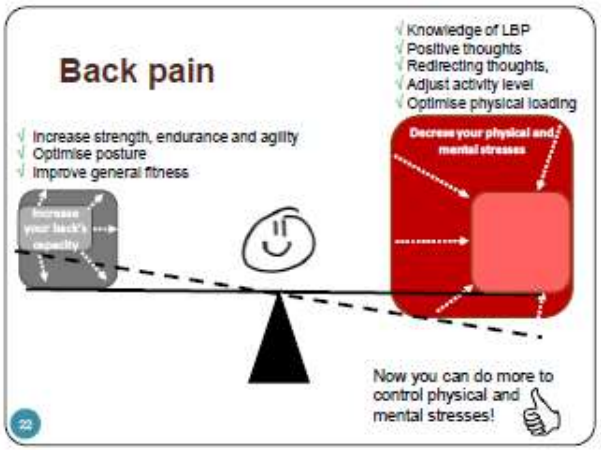
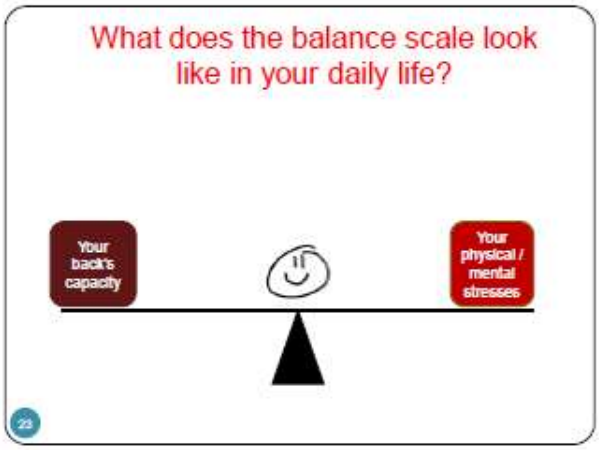
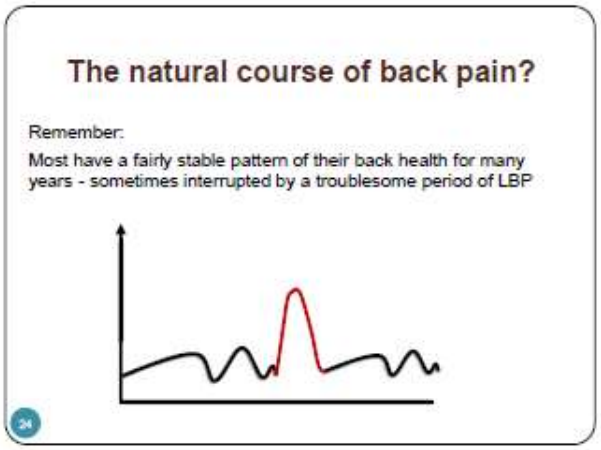












First aid when back pain flares up

- How long time do you expect the pain to be aggravated?
- What can you do when the pain gets worse?
- Do you have a favorite strategy to reduce pain?
- What can you do to make it easier for yourself?
- Ask for help?

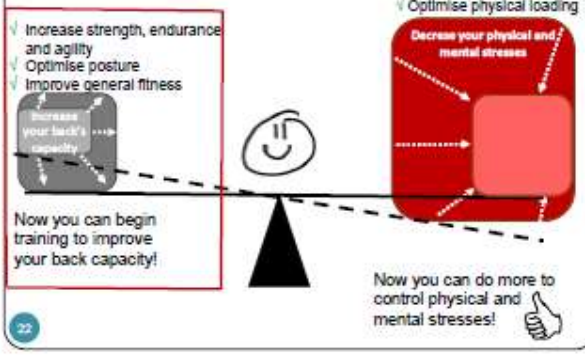
Tips…

- Adjust activity and load according to your back capacity, not too much not too little
- Distribute activity throughout the day
- Be active, take short breaks
- Think positive thoughts
- Help youself
- And ask for help from others

Back pain

√ Increase strength, endurance and agility
√ Optimise posture
√ Improve general fitness

√ Knowledge of LBP
√ Positive thoughts
√ Redirecting thoughts,
√ Adjust activity level
√ Optimise physical loading



Now you can begin training to improve your back capacity!

Now you can do more to control physical and mental stresses!

Increase your capacity – improve general fitness

Help yourself to be physically active to optimising brain and body's wellbeing.

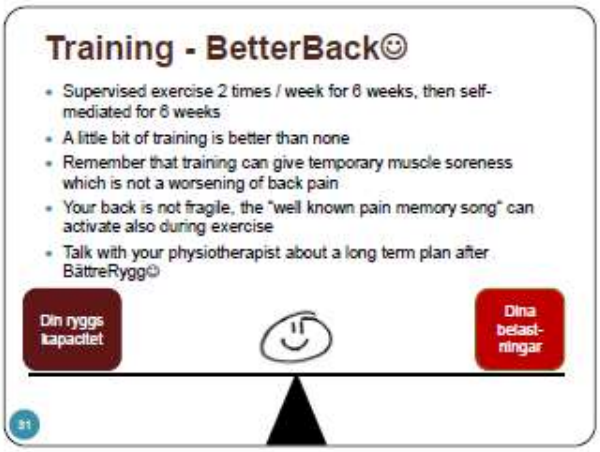
- Improved memory & concentration
- Better coping with stress
- Improved mood
- Divert negative thoughts
- Contributes to better health, physical and mental

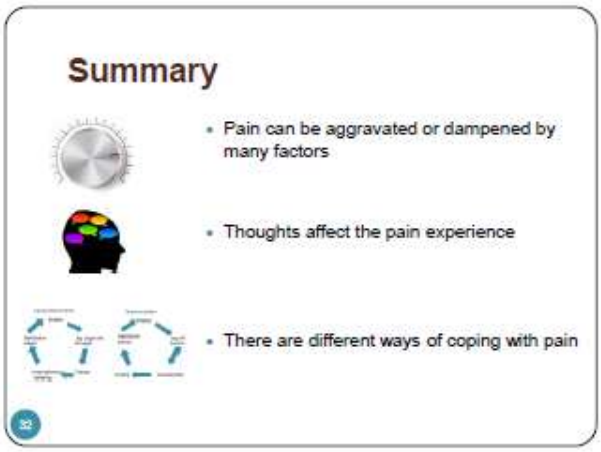
Physical activity during acute LBP?

Reduce sedentary behaviour

How can i change too little exercise and too much sitting ?

Increase your back's capacity! We will help you get started!





8. BetterBack☺ Model – Training program for patients

<table>
<tr><th colspan="3">Training program for patients receiving the BetterBack☺ model of care for LBP</th></tr>
<tr><td>Part 1: Posture, muscle control and coordination of basic body movements</td><td><u>Goal:</u> To ensure the patient has satisfactory posture and trunk muscle activation in static positions as well as in conjunction with basic body movement in the sitting, sitting and standing.
<u>Implementation*:</u> Exercises and dosages are individually adjusted by the treating therapist. Exercises are performed as home programs and daily training is recommended for optimal results.

The therapist assesses when basic competencies in program 1 are achieved before progressing to program 2.</td><td rowspan="2">Training range of movement
<u>Goal:</u> Restore normal mobility.

<u>Implementation</u>:
Individualise based on if the patient has movement restriction.</td></tr>
<tr><td>Part 2: Graded training of muscle strength, coordination and endurance</td><td><u>Goal:</u> To ensure the patient has satisfactory ability to perform more challenging body movements with adequate strength, corrdination and endurance.
<u>Implementation*:</u> Exercises and dosages are individually adjusted by the treating therapist. Exercises are performed twice a week for 12 weeks with follow-up conducted by the treating therapist. During the first 6 weeks, patients are offered the opportunity to train in a group supervised by a physiotherapist. The patient will then receive support and feedback regarding the practice of exercises and help to upgrade exercises if necessary. Patient education on self-care and management of back pain is also performed in groups.</td></tr>
<tr><td colspan="3">*Prerequisite for upgrading the training program is that the patient can satisfactorily perform basic exercises for posture and trunk control in Part 1. Using Part 2 as a basis, the physiotherapist selects and individualises relevant exercises and dosing based on the assessment findings. If support with the traning program is required (in addition to a self-mediated home based program), group traning supervised by another therapist can implemented. However, the follow-up of the patient is still the responsibility of the therapist who first assessed and initiated the patient's treatment plan. The program is designed with graded levels where difficulty level is increased by successively progressing from stages A through to C. Patients are to perform the exercises as instructed. Training can initially produce some muscle soreness, but this is normal and decreases gradually. Contact your physiotherapist if you have questions or feel unsure.</td></tr>
</table>

Part 1. Posture, muscle control and coordination of basic body movements	
1a. Basic trunk muscle activation and control in a lying position	**1b. Basic trunk muscle activation and control in conjunction with body movement in a lying position**
Pelvic control exercise • Lay on your back with your knees bent. Put your hands under your pelvis. Press your lower back down so it flattens down on the surface you are laying on. Feel how the pelvis tilts backwards and has rolled over your hands. Tip the pelvis forward and feel how the lower back rises again. Remove your hands and repeat the tipping forward and backward with less and less movement. Stop when you come to a normal neutral pelvic position. **Activating your inner trunk muscles** **This exercise focuses on the activation of core muscles in your back, abdomen and pelvis. It is also known as "<u>core activation</u>"** • Lay on your back with your knees bent and put your hands on your waist. • ① Breathe calmly in and out and make an ssss sound and feel your fingers how the inner muscles between your pelvis bones become activated. This muscle activation should be done slowly and with a minimal force where you feel that the lower part of the stomach is pulled inward-backward-upward. ○ Alternative instructions ▪ Draw the lower part of your stomach inwards from the waist of you pants ▪ Imagine that you activate your lower stomach muscles just like if you were tightening av belt around you waist ▪ Imagine that your holding on to go to the toalet • <u>Make sure that **you dont**</u>: ○ Hold your breath, press your lower back down or bend your back forward  	**In conjunction with leg movement** Lay on your back with your knees bent. ① Start with "core activation" ② Move your knee on one side out towards the side with and back to the middle with slow controlled movement. Repeat alternately on each side. Maintain a stable positioning of your trunk and pelvis. Repetitions_____  **Perform the same exercise in side lying with movement of one leg. Perform even on the other side thereafter** Repetitions_____ **In conjunction with arm movement** ① Start "core activation". ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis. Repetitions_____ 

2a. Basic trunk postural control in a sitting position

With neutral posture, loading of the spine is optimally distributed. Feel how the physical loading on your back increases when you sit with hunched posture, and how it relieves when you hold a neutral posture.

Training of posture in sitting position:

- Sit on a chair with your hands under your buttocks.
- ① Rotate your pelvis forward over your hands. You should feel like you are arching your back more. Rock your pelvis backward so you return to a neutral back posture. ② Rotate your pelvis backwards so that you have a hunched posture. Continue to rotate your pelvis backards and forwards a few times

- Stop in a position where you feel you have a even weight distribution over your hands and neutral back posture.
- Your ears, shoulders and hips should create a straight line vertically.

2b. Basic trunk muscle activation in a sitting position

Sit on a chair with good posture. ① Train holding a ”core activation”.

Repititions_____

2c. Basic trunk muscle activation and control in conjunction with body movement in a sitting position

In conjunction with leg movement

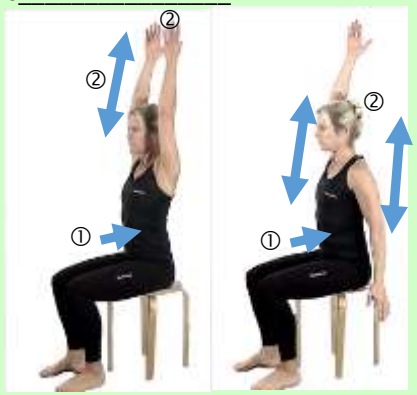
Sit on a chair or training ball. ① Start with ”core activation”. ② Lift up your knees alternately with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____

In conjunction with arm movement

① Start ”core activation”. ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____



3a. Basic trunk postural control in a standing position

With neutral posture, loading of the spine is optimally distributed. Feel how the physical loading on your back increases when you sit with hunched posture, and how it relieves when you hold a neutral posture.

Training of posture in sitting position:

- Stand with your feet hip width apart
- ① Shift your weight forwards and backwards and find a neutral weight distribution over the soles of your feet.
- ② Bend and straighten your knees a few times and find the position where your knees are slightly bent.
- ③ Tilt your pelvis forwards and backwards a few times and the position in the middle where you pelvis has a neutral position.
- ④ Move your head backwards with your chin in.
- ⑤ Bring your shoulders up and then relax your shoulders.
- Your ears, shoulders, hips, knees and feet should now be in a straight line.

① ② ③ ④ ⑤

3b. Basic trunk muscle activation in a standing position

Stand with a neutral posture. ① Train holding a ”core activation”.
Antal_____

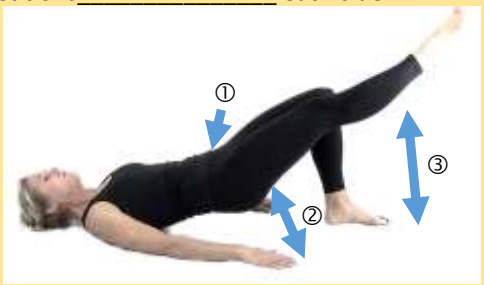
3c. Basic trunk muscle activation and control in conjunction with body movement in a standing position.

In conjunction with weight transfering

Stand with a neutral posture. Place you feet wide apart. ① Start ”core activation”. ② Transfer your weight from one leg to the other alternately. Maintain a stable positioning of your trunk and pelvis.
Repetitions_____

In conjunction with arm movement

Stand with a neutral posture. ①Start ”core activation”. ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.
Repetitions_____

Part 2: Graded training of muscle strength, coordination and endurance		
Difficulty level A	**Difficulty level B**	**Difficulty level C**
1A) Pelvis lifts in lying position Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor. Repetitions_____  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.  	**1B) Pelvis lifts + leg kicks in lying position** Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor. ③ Lift and extend one leg while maintaining a stable positioning of your trunk and pelvis. Lower your foot to the floor again and lower the pelvis. Repeat and change legs every time. Repetitions_____ each side  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.	**1C) Single leg pelvis lift i lying position** Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor and at the same time lift and extend one leg. Lower your foot to the floor again and lower the pelvis. Repeat and change legs every time. Repetitions_____ each side  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.

2A) Knee lifts in lying position Lay on your back with your knees bent and put your hands on your waist. ① Start with ”core activation”. ② Lift one fot slowly up by bending your hip while maintaining a stable positioning of your trunk and pelvis. Slowly bring your fot back to the floor. Repeat and change legs every time. Repetitions_____ each side  	**2B) Straight leg raises in lying position** Lay on your back with your knees bent and put your hands on your waist. ① Start with ”core activation”. ② Extend and lift one leg while maintaining a stable positioning of your trunk and pelvis. Slowly bring your leg back to the floor. Repeat and change legs every time. Repetitions_____ each side  	**2C) Rotating sit-ups in lying position** Lay on your back with your knees bent. ① Start with ”core activation”. ② Place your hands behind your head and bring your opposite knee and elbow together by bending you back forwards. Repeat alternately on each side. Repetitions_____ each side 

3A) Hip muscle training in lying position Lay on your back with your knees bent and arms by your side. Tie a theraband around your knees. ① Start with ”core activation”. ② Move your knees slowly away from each other and slowly back again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____  	**3B) Hip muscle training in side lying position** Lay on your side with your knees bent. Tie a theraband around your knees. ① Start with ”core activation”. ② Move your top knee slowly away from the other and slowly back down again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____ each side  	**3C) Hip muscle training in side lying position** Lay on your side with your legs straignt. Tie a theraband around your ankles. ① Start with ”core activation”. ② Move your top leg slowly away from the other and slowly back down again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____ each side  Alternative Stand on one leg in a crouched position. Straighten up and move your free leg diagonally backwards just like skating. Repeat alternately on each side.

4A) Side plank + arm movement

Lay on your side with support of your lower arm and knee and lift up your pelvis.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up over your head.

The exercise can be done with the pelvis still (static) or by moving the pelvis up and down (dynamically). Perform also on the other side.

Repetitions_____ each side

4B) Side plank + arm movement

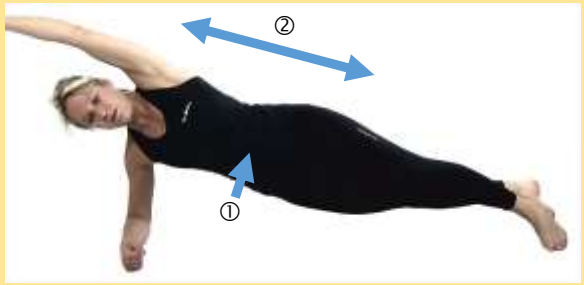
Lay on your side with support of your lower arm and feet and lift up your pelvis.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up over your head.

The exercise can be done with the pelvis still (static) or by moving the pelvis up and down (dynamically). Perform also on the other side.

Repetitions_____ each side



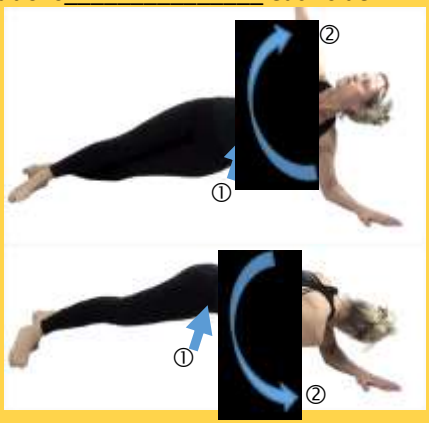
4C) Side plank + arm movement

Lay on your side with support of your lower arm and feet and lift up your pelvis.

① Start with ”core activation”.

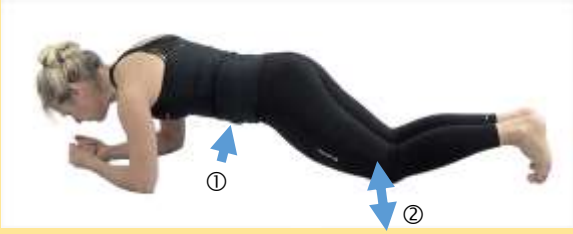
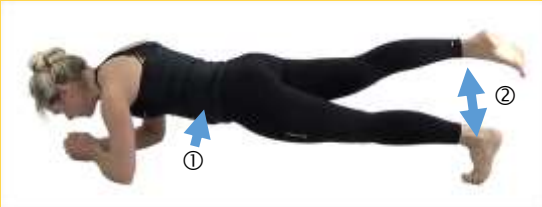
② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up and rotating your back.

Repetitions_____ each side



Alternative: Stand beside a therband tied to a pole. Pull the theraband diagonally across your body and rotate your back.

Repetitions_____ each side

5A) Chair plank Stand on your knees and support your lower arms on a chair or pilates ball. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor. Hold _____ seconds. Bring your knees back down to the floor. Repetitions_____  	**5B) Floor plank** Stand on your knees and support your lower arms on the floor. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor. Hold _____ seconds. Bring your knees back down to the floor. Repetitions_____  	**5C) The plank + leg lifts** Stand on your knees and support your lower arms on the floor. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor holding your legs straight. Lift one foot up from the floor and hold _____ seconds. Bring your foot back down to the floor. Repetitions_____ each side 

6A) 4-point kneeling superman exercise

Position yourself on your hands and knees with your back straight.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while you lift up and down one arm alternately. Try instead one leg alternately. When this is easily accomplished, combined these so that you lift an arm and opposite leg up and down simultaneously and alternate sides.

Repetitions_____ each side

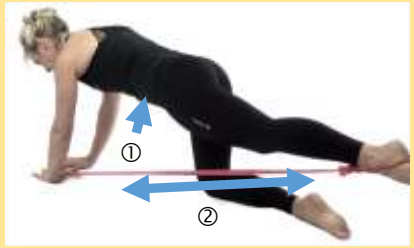
6B) 4-point kneeling theraband exercise

Positition yourself on your hands and knees with your back straight. Tie a theraband around your fot and hold on to the other end with your hands.

① Start with ”core activation”.

② Lift up and straighten your leg. Hold 5 seconds and then bring your leg down again.

Repetitions_____ each side



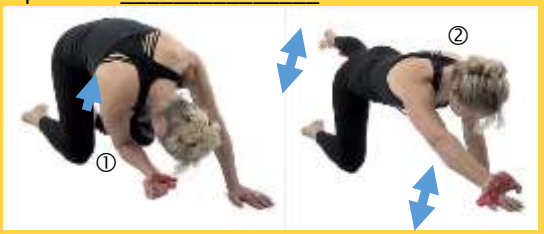
6C) Superman exercise with theraband

Position yourself on your hands and knees with your back straight. Tie a theraband around your fot and hold on to the other end with your opposite hand.

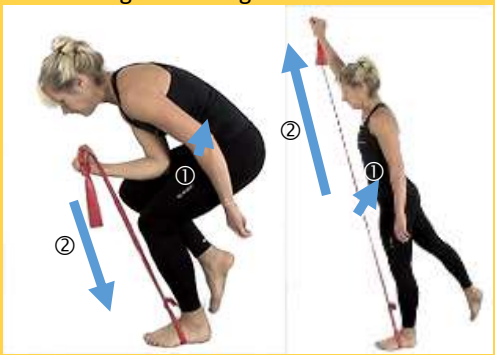
① Start with ”core activation”, curl your back and bring your opposite knee and elbow together while holding the theraband.

②. Slowly straighten your back, arm and opposite leg to stretch out the theraband. Perform the movement with good control of motion.

Repetitions_____ each side



Alternativ: Try performing the same exercise while standing on one leg.



7A) Push-ups against a wall
① Start with ”core activation”
② Perform push-ups against a wall while maintaining straight back posture.

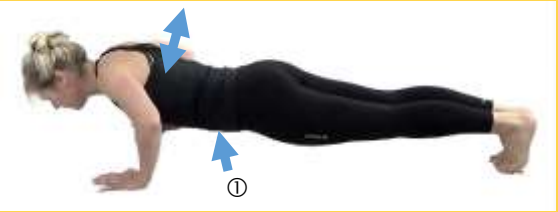
Repetitions_____

7B) Push-ups against a table
① Start with ”core activation”
② Perform push-ups against a table while maintaining straight back posture.

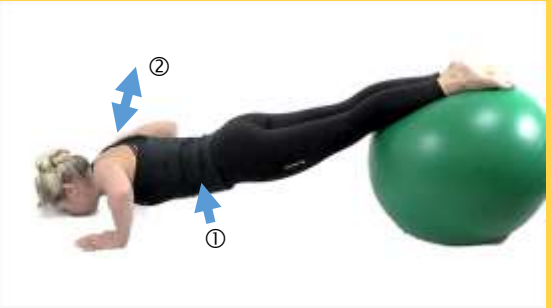
Repetitions_____

7C) Push-ups on the floor
① Start with ”core activation”
② Perform push-ups while maintaining straight back posture.

Repetitions_____



Alternativ: Try performing the same exercise with your feet on a pilates ball.



8A) Standing arm lifts

Hold on to the ends of a theraband and stand on the middle of theraband

① Start with ”core activation”.

② Maintain a straight back posture while you lift your arms up over your head against the resistance of a theraband.

Repetitions_____

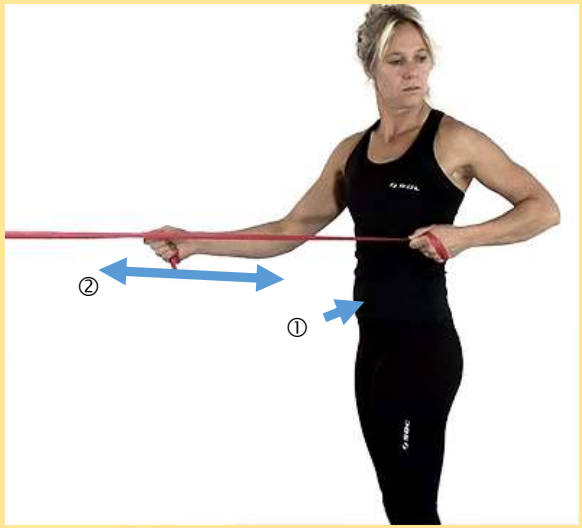
8B) Standing rows

Hold on to the ends of a theraband placed around a pole.

① Start with ”core activation”.

② Maintain a straight back posture while you perform arm rows alternately from side to side.

Repetitions_____



8C) Standing straight arm lifts

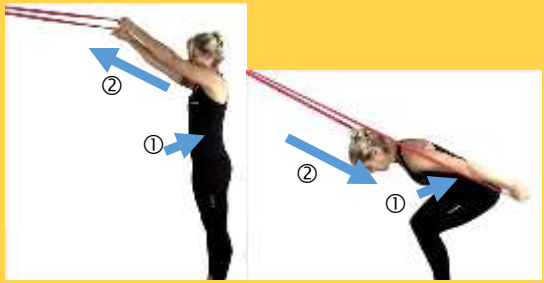
Hold on to the ends of a theraband and stand on the middle of theraband.

① Start with ”core activation”.

② Maintain a straight back posture and straight arms while you lift your arms alternately against the resistance of a theraband.

Repetitions_____ each side

Alternative: Try performing straight arm ski rows.



9A) Squats
Stand with your back against the wall or with a pilates ball between your back and the wall. Place your feet hip width apart.
① Start with ”core activation”.
② Maintain a straight back posture while you perform a squat up to about 90 degrees of knee and hip bending.

Repetitions_____

9B) Squats with your arms över your head
Stand with your back against the wall or with a pilates ball between your back and the wall. Place your feet hip width apart and your hands över your head.
① Start with ”core activation”.
② Maintain a straight back posture while you perform a squat up to about 90 degrees of knee and hip bending.

Repetitions_____

9C) Standing high knee lifts
Stand with your back against the wall, place your feet hip width apart and your arms on the wall.
① Start with ”core activation”.
② Maintain a straight back posture while you perform high knee lifts with alternating legs.

Repetitions_____ each side

10A) Tandem stance lunging weight tranfers
Stand with one foot a step length in front of the other foot.
① Start with ”core activation”.
② Maintain a straight back posture while you perform weight transfer forwards and backwards from foot to foot. Try even with your other foot forward.

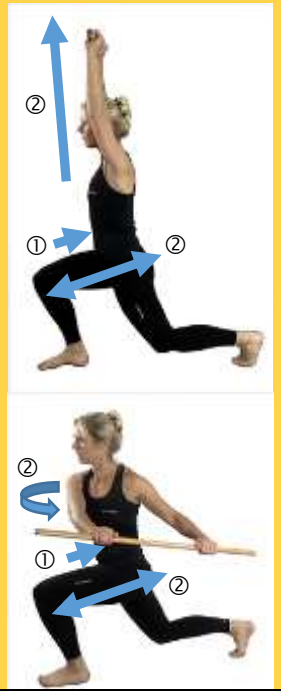
Repetitions_____ each side

10B) Lunges
Stand with your feet hip width apart and your arms up horizontal to your body.
① Start with ”core activation”.
② Maintain a straight back posture while you perform forward lunges by taking av step forward with your weight over that leg och then taking a step back again. Alternate which foot you step forward with.

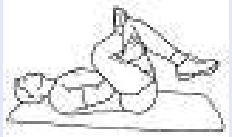
Repetitions_____ each side

10C) Lunges with simultaneous upper body movement
Stand with your feet hip width apart and your arms up horizontal to your body.
① Start with ”core activation”.
② Maintain a straight back posture while you perform forward lunges by taking av step forward with your weight over that leg och then taking a step back again. Alternate which foot you step forward with. At the same time as you lung, try lifting upp your arms over your head or rotating your upper body from side to side when holding a stick.

Repetitions_____ each side



Training range of movement		
1A) Backward bending (elbow support) Lay on your stomarch and support yourself on your underarms/elbows. Bend your back backwards by pressing up from your underarms/elbows and return to the start position again. Repetitions_____ 	**1B) Backward bending (bent arms)** Lay on your stomarch and support yourself with your hands. Bend your back backwards by pressing up from your hands but dont straighten your elbows and thereafter return to the start position again. Repetitions_____ 	**1C) Backward bending (straight arms)** Lay on your stomarch and support yourself with your hands. Bend your back backwards by pressing up from your hands and straightening your elbows and thereafter return to the start position again. Repetitions_____ 
2A) Foward bending while laying on your back Lay on your back and bring your knees up to your stomach, then return to the start position. Repetitions_____ 	**2B) Forward bending on hands and knees** Position yourself on your hands and knees with your back straight. Bend your back forward pressing your lower back upwards while bending your hips and knees so that your knees are in contact with your chest. Return to the starting position. Repetitions_____ 	**2C) Forward bending in sitting or standing** Stand/sit with your back straight. Starting bending forwards nd bringing your hands down towards the floor. Try to even bend your lower back. Return to your starting position. Repetitions_____ 

3A) Back rotation (lower back) Lay on your back and bring your knees down towards the floor on onside and then over to the other side. Repetitions_____ each side 	**3B) Back rotation (lower back and thoracic)** Lay on your back and bring your knees down towards the floor on one side while simultaneously reaching out with your opposite arm upwards and sidewards. Change sides by bringing your knees over to the other side and reach out with your opposite arm upwards and sidewards. Repetitions_____ each side 	**3C) Back roation (full range)** Lay on your back and bring your left knee down towards the floor on your left side while simultaneously reaching out with your left arm upwards and sidewards. Change sides by bringing your knee over to the other side and reach out with your opposite arm upwards and sidewards. Repetitions_____ each side 
Before and after exercise, stretching exercises help your muscles. Each stretch can be done several times, with <30 second holds. Here are suggestions for stretching.	**Stretching of your buttock muscles** 	**Stretching of your hip muscles** 
Stretching of your thigh muscles 	**Stretching of the back of your thighs** 	**Stetching of the inside of your thighs/groin** 

General training - getting in shape

Training form

Regular physical exercise as a part of everyday life is important for maintaining good health and fitness. For this, we recommend following a training program prescribed by your physiotherapist. Your training can consist of, for example: walks, nordic walking, cycling, jogging, swimming, dancing, gym. Choose which training form is best for you. You can work out alone or with others in a group. The most important thing is that you feel that you take the time for physical activity in your everyday life.

Training intensity

Training intensity can be regulated through a so-called "pacing model". This means that you slowly and gradually increase your training intensity without overloading. You "pace" yourself in a controlled way to reach your goals. You can monitor your level of exertion by using a scale of 6-20 where the scale is based on your approximate pulse when you multiply by 10.

You should preferably training with a level of exertion between

11 (fairly light) and 14 (somewhat hard).

You should start exercising at about 20% less duration than you are capacble of. If you feel that the exercise feels very easy (at level 9 or below), you can increase your exercise duration slightly so that you feel at least a farily light exertion level (level 11).

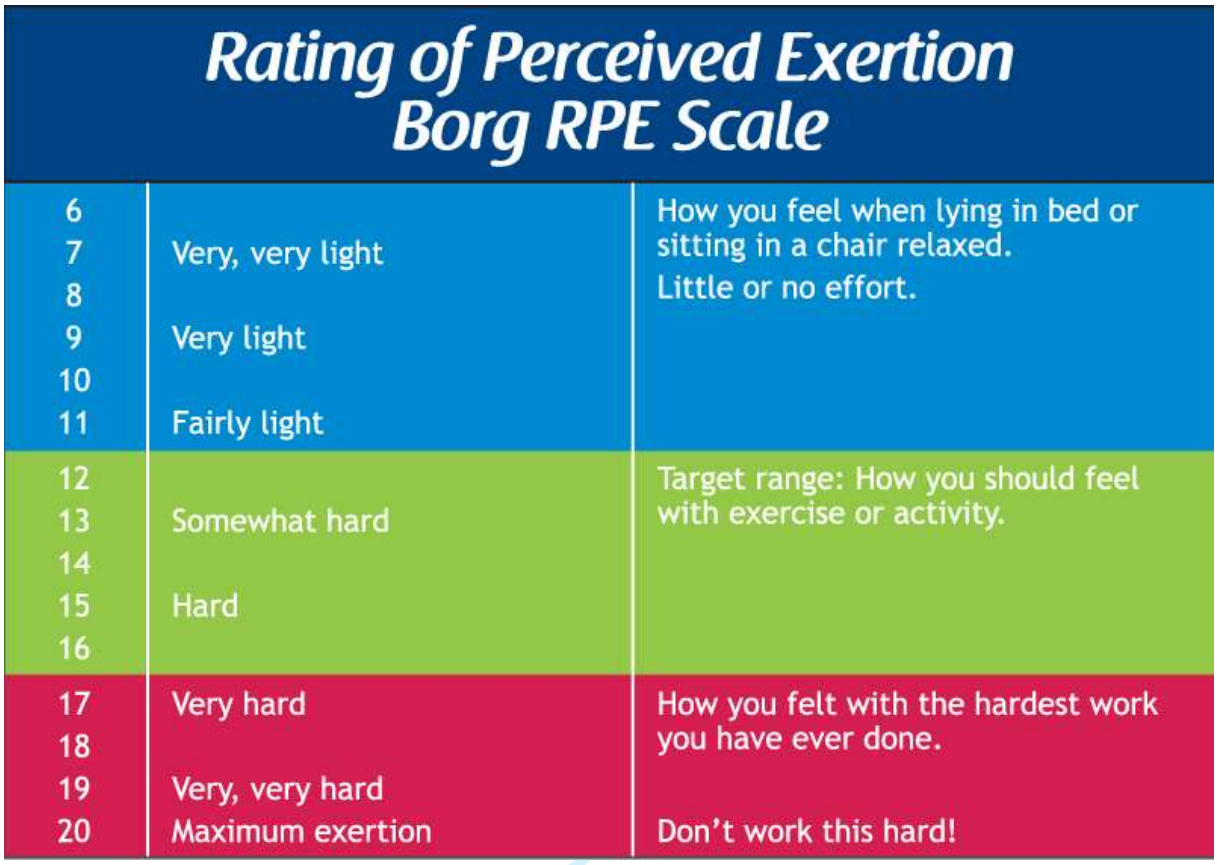
When you experience your exercise exertion is on average under a "somewhat hard" lavel (below 14), you can increase your exercise by 20% after 2 weeks. If you are on level 15 or more, you can continue with the same training for an additional 2 weeks.

When your training duration lasts 30 minutes, you can increase the load by increasing the intensity to 15/16 (Hard - you can not speak on at this intensity) in 10 minute intervals. Then you can increase the number of minutes on this intensity (15/16) every second week.

If you have a bad day, you should work out half of what you planned. In this way you can increase your exercise gradually, without risking doing too much.

Training Contract:

I will perform …….. as my training form
I will train 3 times/week
I will begin with …….. minutes
I will increase my training intensity with 20 % every second week until reach my goal capacity.



Training diary

Name:

Your physiotherapist will fill in which exercises you should train. You can cross off when you have performed the exercises.

Week	Day	BetterBack☺ Part 1			BetterBack☺ Part 2										BetterBack☺ Range of movement			General training
		1	**2**	**3**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**1**	**2**	**3**	**Borgskalan**
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Summary of the workshop to provide training in the use of the BetterBack☺ model of care.

Schedule	Content		Brief description	Learning objectives	BCTs used
Day 1 08:15-08:30	Presentation		Welcome and introduction		
Day 1 08:30-08:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 1 08:50-09:40	Presentation	LBP clinical guidelines	Present evidence based guideline recommendations and the development process behind the recommendations	To understand current evidence based recommendations for primary care of LBP and stakeholder involvement in their development	- Instruction on how to perform the behavior - Credible source - Information about other's approval
Day 1 09:40-10:00	Presentation	Background to BetterBack☺ model of care	Outlines the goals for the day, defines and conceptualizes the BetterBack☺ model of care and communicates need for the model of care	To understand aims, objectives and learning outcomes for the practitioner education	- Credible source - Social reward - Pros and cons - Comparative imagining of future outcomes
Day 1 10:00-10:20	Swedish fika	Reflection	Informal discussion about aims of the BetterBack☺ model of care compared to current practice	To evaluate the practical aims of the BetterBack☺ model	- Social support
Day 1 10:20-11:40	Demonstration	Use of implementation tools	Demonstration of how evidence based recommendations can be practically applied in the BetterBack☺ model of care	To understand how to practically use implementation tools to assist clinical reasoning for matching assessment findings with appropriate diagnosis and treatment	- Instruction on how to perform the behaviour - Demonstration of behaviour - Problem-solving - Feedback on behaviour
Day 1 11:45-12:00	Reflection	Use of implementation tools	In pairs, participants discuss reflections upon how they can practically apply the implementation tools into their clinical practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Framing/reframing
Day 1 12:00-13:00	Lunch break				
Day 1 13:00-14:30	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model implementation tools using therapist-	To develop practical skills in the use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

			patient role-play. Feedback is provided from the tutor and between peers		
Day 1 14:30-15:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To learn how peers used BetterBack☺ model clinical reasoning tools	- Graded task - Verbal persuasion about capability
Day 1 15:00-15:20	Swedish fika	Reflection	Informal discussion about the practical use of the BetterBack☺ model of care compared to current practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Social support
Day 1 15:20-15:40	Summary of the day	Question and answer session and close	Learning outcomes are summarised		- Feedback on behaviour
Day 2 08:15-08:30	Discussion		Reflections after the first day of the workshop		
Day 2 08:30-09:00	Presentation		Benefits of using the implementation tools for assessment, diagnosis and intervention	To appreciate how to practically use implementation tools to assist clinical reasoning for aligning assessment, diagnostics and treatment	- Instruction on how to perform the behaviour - Information about social and environmental Consequences - Credible source - Information about other's approval
Day 2 09:00-09:20	Demonstration	BetterBack☺ model treatment tools	Patient education (brochure)	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 09:20-10:00	Demonstration	BetterBack☺ model treatment tools	Group education	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 10:00-10:20	Swedish fika	Reflection	Informal discussion about which patients group education is relevant	To reflect on the practical use of the BetterBack☺ model	- Social support
Day 2 10:20-11:00	Demonstration	BetterBack☺ model treatment tools	Exercise program	To understand how to use the implementation tools for an exercise program for LBP	- Instruction on how to perform the behaviour
Day 2 11:00-12:00	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

Day 2 12:00-13:00	Lunch break				
Day 2 13:00-13:30	Task continued	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support
Day 2 13:30-14:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Graded task - Verbal persuasion about capability
Day 2 14:00-14:30	Demonstration	BetterBack☺ model of care website	Display of to navigate the BetterBack☺ model of care website	To understand how to use the BetterBack☺ model of care website	- Instruction on how to perform the behaviour
Day 2 14:30-15:00	Task	Potential future outcomes of the BetterBack☺ model of care implementation	Participants write on post-it notes the most important future outcomes of the BetterBack☺ model of care implementation based on: 1. A professional perspective 2. A patient perspective	To appreciate the potential outcomes of the BetterBack☺ model of care	- Comparative imagining of future outcomes
Day 2 15:00-15:30	Presentation		Clinical champion presents an administrative action plan (designed earlier in consensus with clinical colleagues) for the implementation of the BetterBack☺ model of care at their clinic	To reflect on the practical use of the BetterBack☺ model of care website	- Action planning
Day 2 15:30-15:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 2 15:50-16:00	Diploma		Participants completing the workshop receive a CME diploma		- Incentive

BMJ Open

The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

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The effectiveness of implementing a best practice primary health care model for low back pain (BetterBack) compared to current routine care in the Swedish context: An internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

Allan Abbott[1*], Karin Schröder[1], Paul Enthoven[1], Per Nilsen[3], Birgitta Öberg[1]
[1]Department of Medical and Health Sciences, Division of Physiotherapy, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.
[2]Department of Medical and Health Sciences, Division of Community Medicine, Faculty of Health Sciences, Linköping University, SE-58183 Linköping, Sweden.

Allan Abbott* - allan.abbott@liu.se (TEL: 0046 13 282495); Karin Schröder - karin.schroder@liu.se; Paul Enthoven - paul.enthoven@liu.se; Per Nilsen - per.nilsen@liu.se; Birgitta Öberg - birgitta.öberg@liu.se;

*Corresponding author

ABSTRACT

Introduction: Low back pain (LBP) is a major health problem commonly requiring health care. In Sweden, there is a call from health care practitioners (HCP) for the development, implementation and evaluation of a best practice primary health care model for LBP.

Aim: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing best practice coherent primary health care for patients with LBP (B) Improve and understand the mechanisms underlying illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate a multi-facetted and sustained implementation strategy and the cost-effectiveness of the BetterBack☺ MOC for LBP from the perspective of the Swedish primary health care context.

Methods: This study is an effectiveness-implementation hybrid type 2 trial testing the hypothesised superiority of the BetterBack☺ MOC compared to current routine care. The trial involves simultaneous testing of MOC effects at the HCP, patient and implementation process levels. This involves a prospective cohort study investigating implementation on the HCP level and a patient blinded, pragmatic cluster randomized controlled trial with longitudinal follow-up at 3, 6 and 12 months post baseline for effectiveness on the patient level. A parallel process and economic analysis from an health care sector perspective will also be performed. Patients will be allocated to routine care (control group) or the BetterBack☺ MOC (intervention group) according to a stepped cluster dog leg structure with 2 assessments in routine care. Experimental conditions will be compared and causal mediation analysis investigated. Qualitative HCP and patient experiences of the BetterBack☺ MOC will also be investigated.

Dissemination: The findings will be published in peer-reviewed journals and presented at national and international conferences. Further national dissemination and implementation in Sweden and associated national quality register data collection are potential future developments of the project.

Trial registration: ClinicalTrials.gov: NCT03147300

Date and version identifier: 13 Dec 2017, protocol version 3.

Key words: Low back pain, model of care, effectiveness, implementation.

Word count: 8256 words

Strengths and limitations of this study

- This will be the first study of effectiveness and implementation of a best practice model of care in LBP primary care in Sweden.
- An international consensus framework is used for the development, implementation and evaluation of the BetterBack☺ model of care.
- The main trial's a priori methodology has been informed and refined by an internal pilot phase.

BACKGROUND

Low back pain (LBP) is a prevalent and burdensome condition in Sweden and globally [1,2]. LBP can be described not only by it's location, but also it's intensity, duration, frequency, and influence on activity [3]. The natural course of LBP is often self-limiting, but a large majority experience pain recurrence and 20% may experience persistent symptoms [1]. LBP is commonly categorised as non-specific where a pathoanatomical cause can not be confirmed through diagnostic assessment [4]. Approximately < 1%-4% of LBP cases in primary health care may show signs underlying malignancy, fracture, infection, or cauda equine syndrome requiring medical intervention [5,6]. Furthermore, neuropathic pain may be present in 5%-15% of cases [7,8]. Medical imaging studies display a high prevalence of varying spinal morphology and degenerative findings in both symptomatic and non-symptomatic younger and older adults [9]. This suggests that LBP is more typically a result of benign biological and psychological dysfunctions as well as social contextual factors influencing the pain experience.

In Sweden, previous studies by our research group suggest the health care process for patients with LBP tends to be fragmented with many health care practitioners (HCP) giving conflicting information and providing interventions of varying effectiveness [10,11]. Our studies have shown that only a third of patients on sick leave for musculoskeletal disorders receive evidence-based rehabilitation interventions in primary care [10,11]. Furthermore our research has also demonstrated that there are still interventions that physiotherapists in primary care consider to be relevant in clinical practice despite the absence of evidence or consensus about the effects [12]. Our preliminary data suggests that when patients with LBP are referred to specialist clinics, up to 48% have not received adequate evidence-based rehabilitation in primary care. There is therefore a strong case for change to address what care should be delivered for LBP and how to deliver it in the Swedish primary health care setting.

The development of best practice clinical guidelines aims to provide HCP with recommendations based on strength of available evidence as well as professional consensus for the intervention's risk and benefits for the patients. Best practice clinical guidelines for LBP are lacking in Sweden but have recently been developed by the Danish Health and Medicines Authority and the English National Institute for Health and Care Excellence [13-15]. These national guidelines provide a thorough assessment of current evidence and can be used in Sweden to form the basis for locally adapted recommendations. Common to LBP, central recommendations from best practice clinical guidelines for arthritis are also education and exercise therapy aimed at improving patient self-care. Guideline informed models of care (MOC) such as "Better Management of Patients with Osteoarthritis (BOA)" in Sweden [16] and "Good Life with Osteoarthritis" in Denmark (GLA:D) [17] have been successfully implemented with broad national HCP use [18,19]. Furthermore, improvements in patient reported pain, physical function and decreased use of pain medication after receiving these MOC have been reported [18,19]. A similar best practice MOC for LBP could potentially improve HCP evidence based practice and patient rated outcomes in the Swedish primary health care setting.

Recently an international consensus framework has been established to support the development, implementation and evaluation of musculoskeletal MOC [20]. MOC readiness for implementation requires that the MOC is informed by best practice recommendations, has a user focus and

engagement, has a clear structure, a description of components as well as a description of how they are to be delivered [20]. An important part of the MOC structure is the theoretical underpinning of how the MOC intends to act on behavioural change mechanisms to attain specific behavioural targets [20]. In order to achieve effective and efficient implementation of a MOC in primary health care, it is important to apply knowledge from implementation science [21-24]. Implementation science is the scientific study of uptake of research findings and evidence-based practices into routine practice to improve the quality and effectiveness of health care and services [25]. Implementation strategies focus on minimising barriers and maximising enablers that impact on the implementation and use of evidence-based practices. It has been suggested that a multifaceted strategy involving simultaneous use of several implementation strategies may be more effective than single-faceted strategies but the evidence base is inconclusive [26]. A recent systematic review however suggests that the most important aspects of successful implementation strategies are an increased frequency and duration of the implementation intervention and a sustained strategy [27].

There is therefore a clear rationale for evaluating the extent to which and how a best practice MOC for LBP (BetterBack☺) implemented with a sustained multi-facetted strategy is potentially effective in the Swedish primary care context. The costs in relation to effects are important to consider in order to deliver health care efficiently. This article describes a protocol for a BetterBack☺ MOC effectiveness and implementation process evaluation. The protocol conforms to the SPIRIT guidelines [28] with checklist provided in supplementary file 1.

AIMS

The overall aim is to investigate the effectiveness and implementation process of the BetterBack☺ MOC for LBP in a Swedish primary health care context. The specific trial objectives are to: (A) To improve and understand the mechanisms underlying changes in HCP confidence, attitudes and beliefs for providing best practice primary health care for patients with LBP (B) Improve and understand the mechanisms underlying change in illness beliefs, self-care enablement, pain, disability and quality of life in patients with LBP; (C) Evaluate a multi-facetted and sustained implementation strategy and cost-effectiveness of the BetterBack☺ MOC for LBP in the Swedish primary health care context.

HYPOTHESIS

1. HCP reported confidence, attitudes and beliefs for providing primary health care for LBP will show statistically significant improvement after a sustained multifaceted implementation of the BetterBack☺ MOC compared to baseline before implementation. Intentional and volitional HCP rated determinants of implementation behaviour regarding the BetterBack☺ MOC will mediate improved confidence, attitudes and beliefs in a causal effects model. This will correlate with more coherent care according to best practice recommendations.
2. The sustained multifaceted implementation of the BetterBack☺ MOC will result in more statistically significant and greater clinically important improvement compared to current routine care for LBP regarding patient-reported measures for illness beliefs, self-care enablement, pain, disability and quality of life. Improvements in illness beliefs and adequate patient enablement of self care will mediate the effect on these outcomes.
3. A sustained multifaceted implementation of the BetterBack☺ MOC compared to current routine care will result in fewer patients with persisting LBP, fewer requiring specialist care, increased adherence to best practice recommendations and more statistically significant incremental cost-effectiveness ratio (ICER) based on cost per EuroQoL-5 Dimension Questionnaire (EQ-5D) quality-adjusted life years (QALY) gained.

METHODS

Study design

World Health Organization Trial Registration Data Set is presented in table 1. This study is an effectiveness-implementation hybrid type 2 trial testing the hypothesised superiority of the BetterBack☺ MOC compared to current routine care [29]. The design involves an effectiveness evaluation of the BetterBack☺ MOC at the HCP and patient level as well as a process evaluation of a sustained multifaceted implementation strategy conducted simultaneuously. Evaluations are focused at the HCP and patient level because the MOC is targeted at changing HCP behaviour who then in turn implement behavioural change strategies on a patient level. This trial design was chosen for it's potential to provide more valid effectiveness estimates based on pragmatic implementation conditions. This is in contrast to best or worst case implementation conditions common in traditional efficacy or effectiveness trials [29]. Another advantage of the hybrid design is it's potential to accelerate the translation of the MOC to real world practice. This is in contrast to a time lag between efficacy, effectiveness and then dissemination steps in traditional research [29]. The trial design is outlined in figure 1.

As outlined in table 2, the design on the HCP level involves data collection in the cohort before and prospectively after implementation of the BetterBack☺ MOC. On a patient level, data is collected in a single blinded pragmatic randomized controlled stepped cluster format with longitudinal follow up at 3, 6 and 12 months post baseline. Randomisation at the patient level is not possible due to potential carry-over effects of the HCP transitioning back and forth between providing routine care or the BetterBack☺ MOC for different patients. Instead cluster randomisation is conducted at the start of the study, where patients are allocated thereafter to routine care (control group) or the BetterBack☺ MOC (intervention group) depending upon the clinic's allocation. Patients remain in their allocated group throughout the study.

A stepped cluster structure instead of a parallel structure of MOC implementation is applied due to the logistics involved in implementation in different geographical areas. The specific stepped cluster structure applied in the context of our study is classified as a dog leg with 2 assessments in routine care [30,31]. The term "dog leg" has been used by methodologists because the stepped structure resembles the form of a dog hind leg [30]. As displayed in table 2, this involves the first cluster being assessed after the implementation of the BetterBack☺ MOC. The second cluster is assessed after a period of current routine care (control), and assessed again after the implementation of the BetterBack☺ MOC. The third cluster receives current routine care (control) throughout the trial. However, studying the implementation of the BetterBack☺ MOC in cluster 3 is planned to occur as a final step at the end of the study.

An advantage of using the dog leg structure with 2 assessments in routine care is that it allows for an internal pilot phase of initial implementation of the BetterBack☺ MOC in cluster 1 compared to clusters receiving current routine care. Another advantage is that data generated will still contribute to the final analyses to maintain trial efficiency [32,33]. One objective for an internal pilot is to confirm the HCP acceptability of the intervention and trial within the first cluster [32,33]. A progression criteria for continuing the trial requires that HCP who have completed the BetterBack☺ education workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ MOC will be useful (1 = agree completely - 5 = do not agree at all).

Another objective of the internal pilot is to monitor patient recruitment in all 3 clusters during the first 2 months to provide information on the optimal cross forward time for cluster 2. In the dogleg design it is possible to vary the time point of cluster 2 to cross forward from the control to intervention condition if the patient recruitment process in either cluster 1 or 3 is more or less than expected in the internal pilot (See table 2). In the event that cluster 1 recruit less than expected and clusters 2 or 3 recruit more than expected, then cluster 2 will then cross forward to the intervention condition immediately after the internal pilot. If cluster 1 recruit more than expected and cluster 2

or 3 recruited less than expected during the internal pilot phase, then cluster 2 will then cross forward to the intervention condition later in the trial to allow adequate current routine care data collection. Clusters were expected to recruit and gather data for at least 20 LBP patients per month in the internal pilot. A final objective with the internal pilot phase is to assess baseline variation and change over 3 months for implementation process and patient primary outcome measures to inform if our a-priori sample size calculation needed to be revised in the continuation of the trial.

Study setting

The Östergötland public health care region has a total population of 453 596 inhabitants with approximately 5000 patients per year accessing primary care physiotherapy due to LBP. In the public health care region of Östergötland, a large majority of consultations for LBP are via direct access to the 15 primary care physiotherapy rehabilitation clinics. A smaller percentage of consultations are via referral to these rehabilitation clinics from the 36 primary health care general practices in the region. Therefore the focus of this study is on the physiotherapeutic rehabilitation process for LBP in primary care. The rehabilitation clinics form three clusters in Östergötland health care region. These clusters are based on municipal geographical area and organisational structure of the rehabilitation clinics which helps to minimize contamination between separate clusters of clinics (Figure 2). Cluster west is comprised of 5 clinics with 27 physiotherapists, cluster central is comprised of 6 clinics with 44 physiotherapists and cluster east is comprised of 6 clinics with 41 physiotherapists.

Eligibility criteria

Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP will be included in the study. These physiotherapists will assess the eligibility of consecutive patients before and after the implementation of the BetterBack☺ MOC based on the following criteria:

Inclusion criteria: Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a first-time or recurrent episode of acute, subacute or chronic phase benign low back pain with or without radiculopathy.

Exclusion criteria: Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Spinal surgery during the last 2 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfil criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis.

Interventions

Control condition – current routine physiotherapeutic care for LBP in primary health care

Patients attending rehabilitation clinic clusters that have not have not yet completed the implementation of the BetterBack☺ MOC will receive treatment as usual according to current routine care clinical pathways (Figure 3). A clinical pathway specified in Östergötland public health care region requires that for patients accessing primary care due to LBP, a triage is to be performed by licensed HCP (Physiotherapists, Nurses or General Practitioners (GP)), to triage for specific pathology of serious nature. These approximately 1-4% of patients with suspected specific pathology of serious nature are then to be examined by GPs and referred for specific intervention in secondary or tertiary health care. The majority of patients with LBP who on initial triage are assessed as having benign LBP are then scheduled for physiotherapy consultation and implementation of a LBP management plan. If the patient has persistent functional impairment and activity limitation despite 2-3 months of primary care intervention, the clinical pathway specifies

inclusion criteria for specialist care referral pathways (Figure 3).

Intervention condition – The BetterBack☺ MOC for LBP

Development, design and implementation of the BetterBack☺ MOC for LBP
A framework for the development of musculoskeletal MOC [20] was used to guide development of the BetterBack☺ MOC for LBP. The high prevalence and burden of LBP [1,2], discordance in evidence based rehabilitation processes [10-12], a lack of clinical practice guidelines and a call for a best practice MOC requested by physiotherapy clinic managers in the Östergötland health care region have been identified in the primary care of LBP. Therefore, a case for change has been justified to improve current physiotherapeutic health service delivery for the primary care of LBP. The content and structure of the BetterBack☺ MOC where developed by engaging a work group of physiotherapy clinicians (clinical champions) from each primary care cluster in the Östergötland public health care region and physiotherapy academics at Linköping University. A Template for Intervention Description and Replication (TIDieR) Checklist [34] is described in supplementary file 2. To identify which key areas of contemporary care were of relevance for the BetterBack☺ MOC, the following tasks were performed by the work group:

1) Discussion and outline of the current routine care clinical pathway for LBP and areas needing improvement: The work group concluded that the BetterBack☺ MOC needed to focus on:

- WHO/WHERE: The primary care physiotherapy process for the management of patients with LBP in Östergötland health care region outlined by the red square in figure 3.

2) Analysis and discussion of existing international best practice clinical guidelines: The following thorough and up-to-date systematic critical literature reviews and international clinical guidelines [13-15, 35] were analysed and discussed by the work group.

3) Adaptation of best practice clinical guidelines to the Swedish context: The development of evidence based recommendations was based on the Swedish National Board of Health and Welfare methods for guideline construction [36]. The overall grade of evidence together with a consensus position based on professional experience and patient net benefit versus harms and costs are the key aspects on which the work group has formulated local recommendations to reflect their strength [37]. The recommendations have been externally reviewed by local physicians and international experts from the University of Southern Denmark. A summary of the Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of LBP with or without radiculopathy as well as the support tools used in the BetterBack☺ MOC is provided in the supplementary file 3.

4) Considering potential barriers to the uptake of evidence based recommendations by HCP [38], the work group identified and discussed targeted HCP behavioural change priorities of relevance for the BetterBack☺ MOC. The work group discussion lead to the following rationale for the BetterBack☺ MOC content and implementation described in table 3:

- WHY: The main HCP target behaviour was the adoption of the BetterBack☺ MOC to influence HCP delivery of care coherent with best practice recommendations.
- WHAT: This would require the contents of the MOC to change impeding barrier behaviours such as low confidence in skills/capabilities for improving LBP patient management, a biomedical treatment orientation rather than a biopsychosocial orientation, low awareness or beliefs of negative consequences of the MOC [38].
- HOW: BetterBack☺ MOC content used to overcome the modifiable barriers includes support tools aimed at further education and enablement of HCP clinical reasoning in providing LBP assessment and treatment coherent with the Swedish adaptation of best practice clinical guidelines. The support tools include assessment proformers with

associated instruction manual, clinical reasoning flow charts linking assessment findings to relevant treatment interventions, patient education brochures and group education material on LBP self-care as well as a functional restoration program (supplementary file 3).

- WHEN/HOW MUCH/TAILORING: The functional restoration program and patient education components used, their individual and group based delivery and dosing is individualised based on the HCP clinical reasoning of the type and grade of patient functional impairments and activity limitations (supplementary file 3).
- PROCEDURE: Figure 4 displays a flow diagram showing the steps involved for HCP in delivering the contents of the BetterBack☺ MOC.

The Behaviour Change Wheel (BCW) [39] was used by the work group as a logic model to theorise the process of how the BetterBack☺ MOC content applied at the guideline policy level could guide theory-informed intervention functions using specific behavioural change techniques [40]. To help investigate possible mediators of behavioural change interventions in the BetterBack☺ MOC, the Theoretical Domains Framework (TDF) [41] was integrated into the BCW. The TDF is comprised of 14 theoretical domains/determinants of behavioural change of which could potentially influence behavioural change technique effect on the central source of behaviour [42]. The central source of behaviour in the behavioural change wheel is described by the COM-B model. In the COM-B model, a person's capability (physical and psychological), opportunity (social and physical) can influence on motivation (automatic and reflective) enacting behaviours that can then alter capability, motivation and opportunity [39]. The BCW [39] and TDF [41] are displayed in figure 5.

5) The following sustained multifaceted implementation strategy for the BetterBack☺ MOC was developed:

- An **implementation forum** including rehabilitation unit managers and clinical researchers was formed. The implementation forum collaborated on forming overarching goals, timeline and logistics facilitating and sustaining the implementation of the BetterBack☺ MOC in the primary care rehabilitation clinic clusters in the Östergötland public health care region.
- A MOC **support team** was formed. This is comprised of experienced clinicians (clinical champions) from each rehabilitation unit together with clinical researchers fascilitating local implementation and sustainability of the BetterBack☺ MOC at the rehabilitation units.
- A **package of education and training** that the support team can utilise to assist the use of the BetterBack☺ MOC by HCP was developed.
  - Physiotherapists in the 3 geographical clusters of public primary care rehabilitation clinics in Östergötland will be offered to participate in a 13.5 hours (2 days), continued medical education (CME) workshop. The workshop is designed by the support team with at least 2 clinical researchers and 1 experienced clinician from the rehabilitation unit cluster present in the support team's delivery of the workshop for each cluster. The HCP education provided in the workshop format is described in supplementary file 4.
  - Key components of the educational program are:
    - Education and persuasion about evidence based recommendations for LBP care and the BetterBack☺ MOC through an experiential learning process applying problem based case studies and clinical reasoning tools.
    - Traning and modeling of the practical use of the BetterBack☺ education and physical intervention programs aiming at self-care as well as function and activity restoration.
    - Access to a website describing the BetterBack☺ MOC. A chat forum will give an opportunity for clinicians to ask questions and share different experiences of the

new strategy managed by the support team. Researchers will respond to questions from the participating clinicians.

- To consolidate the BetterBack☺ MOC use at the local clinics, the local support team member and clinical researchers will mediate a 2 hour interactive follow-up workshop 3 months after BetterBack☺ MOC implementation. Aspects of the previous workshop content will be discussed and reinforced. To aid continued sustainability of the BetterBack☺ MOC implementation, the local support team member will provide continued maintenance of education at their clinics and even educate new staff.

6) Once HCP behaviour change has occurred, it is anticipated that HCP use of the BetterBack☺ MOC may influence patient outcomes. A rationale for causal mediation effects can be proposed based on the Common Sense Model of self-regulation (CSM) [42]. This suggests a potential effect of the BetterBack☺ MOC on improved patient reported pain, physical function, and quality of life may be mediated by improved patient illness beliefs such as cognitive and emotional illness representations as well as adequate coping through self-care enablement [42]. The patient target behaviours are therefore focused on the understanding of the mechanisms and natural course of benign LBP and the enablement of self-care. This requires content of the MOC to change patient impeding barrier behaviours such as maladaptive illness beliefs on the cause and persistent course of LBP (low outcome expectation, anxiety, catastrophizing, fear-avoidance, and negative illness beliefs), low self-care enablement and low baseline physical activity [43]. The content for the patient education and functional restoration program included in the BetterBack☺ MOC therefore reflects these aspects and is shown in supplementary file 3. These are also charactarised according to the BCW, behavioural change technique taxonomy [44] and TDF in table 3.

Outcomes

Implementation process

1. Primary outcome measure

- Practitioner Confidence Scale (PCS) [45] mean change from baseline to 3 months post baseline. Practitioner reported confidence is the primary HCP behavioural change goal for the HCP education and training workshop in the multifaceted implementation of the BetterBack☺ MOC. The 3 month time frame allows for the development and consolidation of HCP behavioural change after application in repeated patient cases.

2. Secondary outcome measures

- PCS [45] mean immediate change from baseline to directly after the HCP education and training workshop as well as mean long term change from baseline to 12 months post baseline. This secondary outcome is important for the understanding of longitudinal HCP behavioural change.
- Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [46] mean change from baseline, to directly after the HCP education and training workshop as well as at 3 and 12 months post baseline.

Implementation outcomes

1. Primary outcome measure

- Proportional difference between control and intervention groups for incidence of participating patients receiving specialist care for LBP between baseline and 12 months after baseline. Incidence proportion, analogous to cumulative incidence or risk is calculated by taking the number of patients receiving specialist care of LBP and dividing it by the total number of patients recruited to the study. The main goal of both the control and interventions conditions in primary care for benign first-time or recurrent debut of LBP is to improve patient reported outcomes without the need of secondary or tertiary health care processes.

2) Secondary outcomes measures

- Mean difference between control and intervention groups for change between baseline and final clinical visit regarding grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP [47].
- The proportion of patients who receive the BetterBack☺ MOC and registration of health care codes coherent with the Swedish best practice clinical recommendations.

Patient outcomes

1. Primary outcome measure

- Numeric rating scale for lower back related pain intensity during the latest week (NRS-LBP) [48]. The mean difference between control and intervention groups in change between baseline and 3 months post baseline will be analysed. Pain intensity is the primary functional impairment that patients with LBP contact primary health care for and has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported NRS change over 6 months as a core metric for pain management interventions [50].
- Oswestry disability index version 2.1(ODI) [51]. The mean difference between control and intervention groups in change between baseline and 6 months post baseline will be analysed. Disability, analogues to decreased physical functioning and activity limitation has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported ODI change over 6 months as a core metric for functional restoration [50].

2. Secondary outcome measures

- NRS-LBP [48] and ODI [50] mean difference between control and intervention groups in short-term change from baseline to 3 months post baseline and mean long-term change from baseline to 12 months post baseline. These secondary outcomes are important for the understanding of longitudinal patient-rated changes in pain intensity and disability after primary care intervention.
- The European Quality of Life Questionnaire (EQ-5D) [52]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Health related quality of life has been recommended by international consensus to be included as a core outcome domain for clinical trials in non-specific low back pain [49]. International consensus even recommends patient reported EQ-5D change over 6 months as a core metric for pain management interventions [50].
- The Brief Illness Perception Questionnaire (BIPQ) [53]. The mean difference between control and intervention groups in change between baseline and 3, 6 and 12 months post baseline will be analysed. Illness perception has been shown to predict longitudinal pain and disability outcomes in several LBP studies [54-58].
- Patient Enablement Index (PEI) [59], Patient Global Rating of Change (PGIC) [60] and Patient Satisfaction (PS) [61] mean difference between control and intervention groups at 3, 6 and 12 months post baseline will be analysed.

Participant timeline

The trial timeline is shown in table 2. The intervention schedule started with the development of evidence based recommendations and the BetterBack☺ MOC which occurred during June 2016 - February 2017. The enrolment schedule started with cluster enrolment and randomisation in March 2017. This resulted in the first allocated cluster 1 (west) entering internal pilot of implementing the BetterBack☺ MOC HCP education and training workshop which occurred in March 2017. This was followed up with a 2 month internal pilot of patient enrolment schedule occurring in all 3 clusters during April-May 2017. In order to finalise a sample size calculation for the main trial, baseline data collected during the internal pilot is compared to follow-up data 3 months after baseline for the

primary outcome measure questionnaires to analyse initial HCP and patient effects of the implementation of BetterBack☺ MOC in cluster 1 compared to the control conditions in clusters 2 & 3. In the transition to the main trial, patient enrolment and baseline assessments will then continue to occur until January 2018. The eventual time of crossing forward of cluster 2 into the implementation of the BetterBack☺ MOC is determined by the internal pilot trial results. Participants in the trial will be follow-up longitudinally at 3, 6 and 12 months after baseline measures. The schedule for assessments is also outlined in table 2.

Sample size

An initial sample size estimation in the planning stage of the study assumed at least a small Cohens d effect size (d=0.35) for the HCP behavioural change primary and secondary outcomes. This is based on previous literature showing small-moderate HCP behavioural change effects sizes using similar interventions to increase the uptake of evidence-based management of LBP in primary care [62-63]. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of the BetterBack☺ MOC, 80% statistical power and a 20% loss to follow-up, a sample size of n = 63 HCP is needed for a matched pairs t-test statistics comparing baseline and follow-up means. We assume a possible carry-over of a similar effect size (d=0.35) on patient behavioural change primary and secondary outcomes. Considering also a 1-tailed p = 0.05 for the benefit of the multifaceted implementation of BetterBack☺ MOC compared to usual care and a 80% statistical power, the number of patients required for an individually randomized simple parallel group design would be n = 204. Adjusting for the design effect due to clustering randomizing, an intracluster correlation of 0.01 and a cluster autocorrelation of 0.80, a dog leg design with 2 assessments in routine care and 100 patients in each cluster section would require at least n = 402 patients over 2.41 clusters according to algorithms described by Hooper & Bourke [30]. In a balanced recruitment schedule, this equates to 14 patient per months per cluster for a total of 3 clusters. Allowing for potential unbalanced recruitment flow and a potential drop-out in the longitudinal outcomes at 3, 6 and 12 months post baseline, each cluster will aim for up to 20 patients per month equating to a potential total study n = 600.

Recruitment

In an effort to curb recruitment difficulties, strategies to promote adequate enrolment of participants into the study will be used. We anticipate less problems with recruitment into the prospective cohort study design investigating the multifaceted implementation of the BetterBack☺ MOC on the HCP level. This is due to the study having been endorsed by clinical department managers calling all HCP working with patients with LBP at their clinics to participate. However, recruitment of patients into the cluster randomized controlled trial is dependent upon the feasibility of recruitment processes adapted to the context of each individual clinic and the compliance of HCP to administer recruitment of consecutive patients. A strategy to optimise the administration of patient recruitment will involve the author KS regularly visiting participating clinics to inform HCP of the study protocol and help streamline practical administration of the protocol in the context of the individual clinics. KS will also monitor weekly recruitment rates from the clinics and provide motivational feedback on recruitment flow to clinical department managers and designated clinical champions who will provide additional motivational feedback to HCP. In accordance with a Consolidated Standards of Reporting Trials, a flow diagram displaying participant enrolment, allocation, follow-up and analysis will be constructed [64]. Reasons for exclusion, declined participation, protocol violations and loss to follow-up will be monitored by KS.

Allocation and blinding

Random concealed allocation of clusters was performed by a blinded researcher randomly selecting from 3 sequentially numbered, opaque, sealed envelopes. The method resulted in the following order: 1=cluster west, 2=cluster central and 3=cluster east. The author KS informed the clinics in the different clusters of their allocation to the control or intervention study condition. Due to the

nature of the study and intervention, HCP conducting patient measurements and treatment cannot be blinded to group allocation. Risk of bias is minimal as the primary and secondary outcomes are patient self-reported questionnaires. Patients will be blinded to group allocation. The researcher responsible for statistical analysis will not be blinded to group allocation but an independent statistician will review statistical analysis.

Data collection

Data will be collected through quantitative questionnaires and qualitative focus group and semi-structured interviews. In the case of non-response to questionnaires, a questionnaire will be re-sent via post a total of 3 times. In case of continued non-response this will be complemented with a telephone call as a final effort for data collection.

Implementation process –

- The PCS contains 4 items reported on 5-point Likert scales where a total score of 4 represents greatest self-confidence and 20 represents lowest self-confidence for managing patients with LBP. The structural validity in terms of internal consistency of the items have been shown to be good with a Cronbach α coefficient = 0.73 in a single factor model for self-confidence [45]. The questionnaire has been forward translated by our research group from English to Swedish.
- The PABS-PT consists of two factors where higher scores represent more treatment orientation regarding that factor. One factor with 10 items measures the biomedical treatment orientation (Score 0-60) and one with 9 items measures the biopsychosocial treatment orientation (Score 0-54) [46]. Each item is rated on a 6-point Likert scale ranging from 1='totally disagree' to 6='totally agree'. The internal consistency of the biomedical factor has been shown to be good with a range between Cronbach α=0.77-0.84. Futhermore, the biopsychosocial factor has been shown to be adequate with a range between Cronbach α=0.62-0.68 [65]. Construct validity and responsiveness to educational interventions has been shown to be positive along with the test-retest reliability with reported intra-class correlation coefficient (ICC) on the biomedical factor=0.81 and on the biopsychosocial factor=0.65 [65]. The questionnaire has been forward translated from English to Swedish in a previously published study [66].
- The Determinants of Implementation Behaviour Questionnaire (DIBQ) was originally constructed based on the domains of the TDF [41, 67]. Confirmatory factor analysis resulted in a modified 93 item questionnaire assessing 18 domains with sufficient discriminant validity. Internal consistency of the items for the 18 domains was good, ranging from 0.68-0.93 for the Cronbach α coefficient [68]. The questionnaire has been forward translated by our research group from English to Swedish. After face validity consensus in our research group regarding relevant domains for the implementation of BetterBack☺ MOC, the questionnaire was shortened to the following domains: Knowledge, Skills, Beliefs about capabilities, Beliefs about consequences, Intentions, Innovation, Organisation, Patient, Social influence, Behavioural regulation totalling to 57 items. Questions were adapted to the context of HCP reported determinants of an "expected" implementation of BetterBack☺ MOC for measurement directly after the HCP education and training workshop. HCP reported determinants retained orginal wording for the questionnaires at 3 and 12 months after the implementation of BetterBack☺ MOC. The response scale used for each DIBQ question in our study is a 5-point Liket scale ranging from 1= `totally agree´ to 5=`totally disagree´.

Implementation outcome measures

- At 12 months after baseline, data will also be extracted from the public health care regional registry for the total number of patient visits for LBP, the number patients needing primary care multimodal pain team treatment, the number referred to specialist pain clinic, orthopedic or neurosurgical care and the number receiving surgery.

- Clinical reasoning and process evaluation tool (CRPE-tool): Grade of patient functional impairment and activity limitation according to the ICF brief core set for LBP is assesses by the physiotherapist at baseline and final clinical contact where light, moderate, severe and very severe impairment/limitation is coded 0-4 respectively. A total score for baseline and follow-up measures is calculated from the sum of the functional impairment divided by the number of functional impairments and a similar total score is calculated for activity limitations [47]. A worsening of functional impairments and activity limitations measured att follow-up with the CRPE will be considered in the analysis of adverse events. Swedish Classification of Health Interventions (KVÅ) codes for assessment and treatment interventions will be assessed to analyse coherence with the Swedish best practice clinical recommendations. ICD-10 diagnosis codes and will also be recorded.
- The Keele STarTBack Screening Tool is reported by patients at baseline providing a stratification of prognostic risk of persistent pain. The overall score ranging from 0-9 is used to separate the low risk patients from the medium-risk subgroups where patients who achieve a score of 0-3 are classified into the low-risk subgroup and those with scores of 4-9 into the medium-risk subgroup. To identify the high-risk subgroup, the last 5 items must score 4 or 5 [69-71].
- Focus groups performing qualitative SWOT analyses will be conducted by HCP between 3-6 months after implementation.
- Semi-structured interviews with 10 HCP at 3 months after implementation will be conducted to investigate determinants of implementation behaviour and if other determinants need to be added to the DIBQ. The interviews will be deductively analysed according to the TDF [41] and BCW [39] frameworks.
- Semi-structured interviews investigating the patient experience of recieving care for LBP will be performed on 10 patients. These patients will have received care after implementation of the BetterBack☺ MOC.
- Economic costs of developing the BetterBack☺ MOC as well as performing the implementation strategy (staff time, HCP training, and printed resources).

Patient outcome measures

- NRS-LBP intensity during the latest week is an 11-point scale consisting of integers from 0 through 10; 0 representing "No pain" and 10 representing "Worst imaginable pain". Previous research in a LBP cohort has shown a test-retest reliability ICC = 0.61, a common standard deviation=1.64 points, the standard error of measure = 1.02 and minimal clinically important difference (MCID) in LBP after treatment=2 [72-73].
- ODI version 2.1 assesses patient's current LBP related limitation in performing activities such as personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and travelling. The ODI consists of 10 items with response scales from 0 to 5, where higher values represent greater disability. The ODI is analysed as a 0 to100 percentage variable where lower scores represent lower levels of low back pain disability. A reduction of 10 points is considered the MCID in LBP after treatment [50,70]. In Scandinavian conditions, the coefficient of variation, ICC and internal consistency of the ODI is 12%, 0.88-0.91 and 0.94 respectively [74-76]. Good concurrent validity has also been shown [75].
- The EQ-5D measures generic health-related quality of life and is computed into a 0 to 1.00 scale from worst to best possible health state by using the Swedish value sets [77]. A reduction of 0.08 points is considered the MCID in LBP after treatment [78]. Mean change after treatment for LBP has been reported to be 0.12 (SD±0.30) [79].
- The BIPQ analyses cognitive illness representations (consequences, outcome expectancy, personal control, treatment control, and knowledge), emotional representations (concern and emotions) as well as illness comprehensibility. An overall score 0-80 represents the degree to which the LBP is perceived as threatening or benign where a higher score reflects a more threatening view of the illness [52]. The BIPQ has been shown to be valid and reliable in a

Scandinavian sample of patients with subacute and chronic LBP. The BIPQ has a Cronbach's alpha =0.72 and a test-retest ICC = 0.86, an ICC range for individual items from 0.64 to 0.88, a standard error of measurement (SEM) = 0.63 and minimal detectable change (MDC) = 1.75[80].

- The PEI has a score range between 0 and 12 with a higher score intended to reflect higher patient self-care enablement [59].
- PGIC asks the patient to rate the degree of change in LBP related problems from the beginning of treatment to the present. This is measured with a balanced 11 point numerical scale. A reduction of 2 points is considered the MCID in LBP after treatment [60].
- PS is measured with a single item patient reported question. The question asks "Over the course of treatment for this episode of low back pain or leg pain, how satisfied were you with the care provided by your health-care provider?" Were you very satisfied (1), somewhat satisfied (2), neither satisfied nor dissatisfied (3), somewhat dissatisfied (4), or very dissatisfied (5)?" [61].
- Economic costs of health service utilisation.

Data management

All paper based questionnaire data will remain confidential and will be kept in a lockable filing cabinet in the research group office. A password-protected coded database only accessible to the research team will be kept on a data storage drive in the research department. The research team will regularly monitor the integrity of trial data. Trial conduct will be audited on a weekly basis by the research team.

Statistical analysis

Statistical significance will be assessed with an alpha level of 0.05. All results will be reported as estimates of mean ± standard deviation and also effect size (e.g. mean difference) with 95% confidence intervals (95% CI). An intention-to-treat (ITT) principle applying multiple imputation will be utilised. A sensitivity analysis will compare per protocol and ITT databases. A sensitivity analysis will also be used to assess the significance of a washout period by comparing the complete database against the same database without data collected during the 2 weeks in conjunction with the Betterback☺ implementation in each cluster.

Implementation process and outcome analysis

ANOVA statistics comparing baseline and follow-up means will be used for implementation process and outcome measures. Causal mediation analysis will be used to analyse indirect mediational effects of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education and training workshop (intention stage) or at 3 or 12 months (volition stages) on the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT. If the HCP education and training workshop does not have a casual effect on improved prospective outcomes we will analyse where the causal pathway breaks down. Causal mediation analysis will be performed using the program PROCESS [81] within IBM SPSS (figure 6).

Patient outcome measures for the control and intervention groups will be compared using multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects with IBM SPSS. Fixed effect interactions between experimental condition and The Keele STarT Back Screening Tool will also be assessed. Patient population specific minimal clinically important difference will be assessed för primary and secondary outcomes based on an anchor method where PGIC serves as an anchor. Applying a 1-1-1 multilevel mediation procedure with all effects random in MPLUS, the products of (1) the independent variable (Experimental condition: control or intervention) to the mediator (change in BIPQ, PEI),

and (2) the mediator to the dependent variable (change in NRS, ODI or secondary outcome scores pre- to posttreatment) when the independent variable is taken into account, will be tested for mediation (figure 7).

Economic analysis

The reference case analysis is based on a health care sector perspective. The EQ5D will be used to calculate the ratio of costs to quality adjusted life years (QALY) saved for patients. Incremental cost-effectiveness ratios (ICER) for the multifaceted implementation strategy and the usual care condition will be calculated and plotted on a cost-effectiveness plane. This is based on the Swedish guideline priced direct costs of health service utilisation, organisational costs of developing the BetterBack☺ MOC as well as performing the implementation strategy and overall intervention clinical outcome effectiveness. The ICER will also be calculated per patient avoiding specialist care. To estimate a distribution of costs and health measures and confidence intervals for ICER, boostrapping will be used.

Data monitoring

All outcome questionnaires are formatted for use of scan processing software for automated data entry into the Statistical Package for the Social Sciences package. The author KS who is not blinded to treatment allocation will perform regular data checks during data entry and provide feedback when necessary to HPC regarding data omissions. JS will also double check data entry to detect and correct input errors, and range checks will be undertaken prior to data analysis.

Ethics and dissemination

Ethical clearance for the study (Dnr:2017-35/31) has been attained through the Regional Ethics Committee in Linköping. The ethics application including consent forms in Swedish is available upon request to the authors. Their are no known risks for participants. Voluntarily participating HCP will complete questionnaires. All participating patients are informed orally and in writing about the study on the first visit at participating primary health care clinics. They are informed about that participation is voluntary and that they can at any time withdraw their participation. The HCP intervention will not be affected by the patient's decision to participate or not participate in the study. Data collection will not be performed for those not participating. A signed patient consent form will be collected from patients by the HCP before baseline measures are collected and intervention is commenced according to the study protocol. All collected data will be entered into a database accessable to the authors. A code list will be created where each participant will be represented by a code so that the database will be anonymous. The code list with personal data will be stored separately in locked filing cabinets at Linköping Univerity to protect confidentiality before, during and after the study. Data analyses and reporting will be performed using the de-identified database. The authors plan to disseminate the findings through manuscript publications in scientific journals and presentation at conferences.

Patient and public involvement

The adaptation of best practice clinical guidelines to the Swedish context, the construction of the BetterBack☺ MOC as well as the development of the research question, study design and outcomes measures involved interpretation of literature and professional experience of the patient net benefit versus harms and costs. Specific investigations of priorities, experience and preferences of the patients in the Östergötland health care region were not performed in this development phase. No patient advisors or other public are involved in the study. HCP working with patients with LBP at their clinics ask consecutive patients to participate in the study and adhere to the prescribed intervention. Patients have no other involvement in recruitment and conduct of the study. Semi-structured interviews on 10 patients randomly selected will investigate the priorities, experience, burden and preferences of the intervention. Patients satisfaction regarding the intervention is

assessed by the patients themselves through a questionnaire. The dissemination of the study findings to participating patients will occur through popular science summary publication.

Internal pilot trial results

The initial implementation of the BetterBack☺ MOC in cluster 1 allowed for an internal pilot to determine the HCP acceptability of the intervention and trial within the first cluster [32,33]. A progression criteria for continuing to the main trial required that HCP who have completed the BetterBack☺ education and training workshop rate on average a maximum of 2.5 out of 5 on the following determinant of implementation behaviour question: I expect that the application of BetterBack☺ MOC will be useful (1 = agree completely - 5 = do not agree at all). The 27 HCP participating in the internal pilot in cluster 1 responded to the question with a mean value of 1.7 (SD 0.8) which subsequently fulfilled the HCP progression criteria.

The resulting internal pilot patient flow for april and may were n=28, n=28 for cluster 1 west (intervention) , n=5, n=12 for cluster 2 central (control) as well as n=14, n=22 for cluster 3 east (control) consecutively. This informed the decision to move the cluster 2 transition from control to intervention condition to occur later in the schedule, planned for september 2017 to allow for more control condition patient recruitement and data collection. The flow of patient recruitment and the process of 3 month follow-up in the internal pilot was used to inform the optimal time point of patient reported primary outcome for the main trial. Our initial planning was to measure patient reported primary outcome at 6 months post baseline based on the definition of persistence/chronicity of symptoms being often defined in the literature to be of 3 and up to 6 months duration [82]. Our intern pilot study had a 3 month follow rate of 80% resulting after up to 3 reminders sent to many of these patients. This informed of a likely risk of non-response at later follow-up time points. Furthermore, feedback from participating HCP even reported a larger clinical interest in 3 month patient follow-up data. Therefore the internal pilot informed the choice to revise our patient reported primary outcomes to 3 month post-baseline with subsequent amendments of the trial registration on ClinicalTrials.gov: NCT03147300.

Our internal pilot study was also used to assess baseline variation and change over 3 months in HCP and patient reported primary outcome measures in the control and intervention arms to aid calibration of the sample size calculation. A multilevel analyses of repeated measurements and experiment condition as fixed effects and participants and clusters as random effects revealed a intracluster correlation of <0.01 for the all primary outcomes measures. A small effect size in favour of the intervention condition was shown for HCP reported PCS (d=0.33) directly after implementation but increased to a moderate effect size after 3 months (d=0.51). Patient reported NRS showed a small effect size (d=0.28). Therefore, the internal pilot data supported our a priori sample size calculation for the main trial regarding PCS and NRS. However no effect size difference were observed between experimental conditions for ODI. It is possible that when statistical power improves when the trial progresses, potential differences in ODI may be detectable between experimental conditions.

CONCLUSION

The effectiveness-implementation hybrid type 2 trial with dog-leg stepped cluster structure allowed for the use of an internal pilot to inform feasibility and optimise method efficiency for the progression of the trial.

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Authors' contributions: AA & BÖ formulated the trials original aims and hypothesis. AA, KS, BÖ developed interventions material. AA, KS, PE, PN, ÖB designed the study methodology. AA, PN, BÖ procured funding for the trial. AA, KS, PE, PN, ÖB have reviewed and finalised the protocol.

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Competing interests statement: The authors have no competing interests.

Table 1. World health organisation trial registration data set.

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03147300
Date of registration in primary registry	03 May, 2017
Prospective Registration:	Yes
Secondary identifying numbers	N/A
Source(s) of monetary or material support	Linköping University
Primary sponsor	Linköping University
Secondary sponsor(s)	N/A
Contact for public queries	*Allan Abbott*, MPhysio, PhD [+46 (0)13 282495] [allan.abbott@liu.se]
Contact for scientific queries	*Allan Abbott*, MPhysio, PhD Linköping University, Linköping, Sweden
Public title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain BetterBack☺
Scientific title	Implementation of a Best Practice Primary Health Care Model for Low Back Pain in Sweden (BetterBack☺): A Cluster Randomised Trial
Countries of recruitment	Sweden
Health condition(s) or problem(s) studied	Low back pain
Intervention(s)	Behavioral: Current routine practice Behavioral: Multifaceted implementation of the BetterBack
Key inclusion and exclusion criteria	Health care practitioner sample Inclusion Criteria: - Registered physiotherapists practicing in the allocated clinics and regularly working with patients with LBP Patient sample Inclusion Criteria: - Males and females 18-65 years; Fluent in Swedish; Accessing public primary care due to a current episode of a first-time or recurrent debut of benign low back pain with or without radiculopathy Exclusion Criteria: - Current diagnosis of malignancy, spinal fracture, infection, cauda equine syndrome, ankylosing spondylitis or systemic rheumatic disease, previous malignancy during the past 5 years; Current pregnancy or previous pregnancy up to 3 months before consideration of inclusion; Patients that fulfill criteria for multimodal/multi-professional rehabilitation for complex longstanding pain; Severe psychiatric diagnosis
Study type	Interventional
Date of first enrolment	April 1, 2017
Target sample size	600
Recruitment status	Recruiting
Primary outcome(s)	- Incidence of participating patients receiving specialist care [Time Frame: 12 months after baseline] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Change between baseline and 3 months post baseline] - Oswestry disability index (ODI) version 2.1 [Time Frame: Change between baseline and 3 months post baseline] - Practitioner Confidence Scale (PCS) [Time Frame: Change between baseline and 3 months post baseline]
Key secondary outcomes	- Clinician rated health care process measures [Time Frame: Baseline and final clinical contact (Up to 3 months where the time point is variable depending upon the amount of clinical contact required for each patient)] - Numeric rating scale (NRS) for lower back related pain intensity during the latest week [Time Frame: Baseline, 3, 6 and 12 months] - Oswestry disability index (ODI) version 2.1 [Time Frame: Baseline, 3, 6 and 12 months] - Pain Attitudes and Beliefs Scale for physical therapists (PABS-PT) [Time Frame: Baseline, directly after education and at 3 and 12 months afterwards] - Patient Enablement Index (PEI) [Time Frame: 3, 6 and 12 months] - Patient global rating of change (PGIC) [Time Frame: 3, 6 and 12 months] - Patient satisfaction [Time Frame: 3, 6 and 12 months] - Practitioner Confidence Scale (PCS) [Time Frame: Baseline, directly after commencement of implementation strategy and at 3 and 12 months afterwards] - The Brief Illness Perception Questionnaire (BIPQ) [Time Frame: Baseline, 3, 6 and 12 months] - The European Quality of Life Questionnaire (EQ-5D) [Time Frame: Baseline, 3, 6 and 12 months]

Table 2. Study design and schedule of enrolment, interventions and assessments.

Timeline		June 2016 - Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017	Jan 2018	Final clinic visit	Follow-up 3 months after baseline	Follow-up 6 months after baseline	Follow-up 12 months after baseline
Enrolment schedule			HCP Cluster random allocation	Patient recruitment during internal pilot phase		Patient recruitment during main trial phase											
Intervention schedule		MOC and protocol development	Cluster 1 West MOC implementation internal pilot	1	1	1	1	1	1	1	1	1	1				
			Cluster 2 Central	0	0	0	0	0 MOC implementation	1	1	1	1	1				
			Cluster 3 East	0	0	0	0	0	0	0	0	0	0 MOC implementation				
Assessment schedule				Baseline data Internal pilot (T=0)		Baseline data Main trial (T=0)								Longitudinal repeated measures in cohorts (T=1)	(T=2)	(T=3)	(T=4)
Implementation process	**PCS**		Cluster 1 before and after MOC implementation					Cluster 2 before and after MOC implementation					Cluster 3 before and after MOC implementation		x		x
	PABS-PT		Cluster 1 before MOC implementation					Cluster 2 before MOC implementation					Cluster 3 before MOC implementation		x		x
	DIBQ		Cluster 1 after MOC implementation					Cluster 2 after MOC implementation					Cluster 3 after MOC implementation		x		x
PROMS	**NRS back pain and leg pain**			x	x	x	x	x	x	x	x	x	x		x	x	x
	ODI			x	x	x	x	x	x	x	x	x	x		x	x	x
	EQ5D			x	x	x	x	x	x	x	x	x	x		x	x	x
	BIPQ			x	x	x	x	x	x	x	x	x	x		x	x	x
	PEI														x	x	x
	Satisfaction														x	x	x
	PGIC														x	x	x
Implementation outcomes	**HCP assessment, diagnosis and treatment codes**			x	x	x	x	x	x	x	x	x	x	x			
	Referrals to specialist care																x

MOC=model of care, 0=Control condition, 1=Intervention condition, PROMS=Patient reported outcome measures, grey shaded cells=internal pilot, T= assessment time. ◄► Period where 2 week cross-over from control to intervention can occur dependent upon patient recruitment rates identified in the internal pilot study.

Table 3. Characterising the BetterBack☺ model of care intervention content and mechanisms of action using the Behaviour Change Wheel [41], Behavioural change technique (BCT) taxonomy (v1) [44], and the TDF [43].

Target behavior	Rationale based on barriers to be addressed	BetterBack☺ MOC content to overcome the modifiable barriers				Mechanism of action	
		Mode	Content	BCT[44]	Functions	COM-B	TDF
Improved HCP confidence and biopsychosocial orientation in treating LBP through adoption of BetterBack☺ model of care	1) Low confidence in skills/capabilities for improving LBP patient management 2) Use of a biomedical treatment orientation rather than a biopychosocial orientation 3) Low awareness of the model 4) Beliefs of negative consequences of the model	1) Multifaceted implementation strategy - Workshop education	Evidence based model of care and clinical implementation tools (See supplementary files 1 & 2)	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				1.4 Action planning	Enablement	Psychological capability	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.3 Information about social and environmental consequences	Persuasion	Social opportunity Physical opportunity	Social Influences Environmental context and resources
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.2 Pros and cons	Persuasion	Reflective motivation	Beliefs about Consequences
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		2) Multifaceted implementation strategy - Report and website	Evidence based model of care and clinical implementation tools (See supplementary file 2)	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				6.3 Information about other's approval	Persuasion	Social opportunity	Social Influences
Decreased patient LBP and disability as well as improved patient enablement of self-care	1) Maladaptive beliefs on the cause and course of LBP (Illness perception) = low outcome expectation, anxiety, catastrophizing, fear-avoidance, illness beliefs. 2) Low belief in ability to control pain. Low belief in ability to perform activities, low	1) BetterBack☺ Part 1. Individualised information at initial and follow-up visits.	Lay language pedagogical explanation of function impairment and activity limitation related assessement findings and matched goal directed treatment	5.1 Information about health consequences	Education	Psychological capability	Knowledge
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
		2) BetterBack☺ Part 1. Patient education brochure	Lay language education on the spine's structure and function, natural course of benign LBP and advice on self-care	4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
		3) BetterBack☺ Part 2. Group education	Pain physiology, biomechanics, psychological coping strategies and behavioural regulation	1.2 Problem-solving	Enablement	Psychological capability	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				4.1 Instruction on how to perform behaviour	Education	Psychological capability	Knowledge

	baseline physical activity.			4.3 Re-attribution	Education	Psychological capability	Knowledge
				5.1 Information about health consequences	Education	Psychological capability	Knowledge
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.2 Behaviour substitution	Enablement	Psychological capability	Behavioral regulation
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				9.3 Comparative imagining of future outcomes	Enablement	Reflective motivation	Beliefs about Consequences
				10.8 Incentive (CME diploma)	Enablement	Reflective motivation	Reinforcement
				11.2 Reduce negative emotions	Enablement	Reflective motivation	Emotion
				12.4 Distraction	Enablement	Reflective motivation	Memory, attention and decision processes
				12.6 Body changes	Training	Physical capability	Physical skills
				13.2 Framing/reframing	Enablement	Psychological capability	Cognitive and interpersonal skills
		4) BetterBack☺ Part 1. Individualised physiotherapy	Physiotherapist mediated pain modulation strategies and functional restoration strategies. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				7.1 Prompts/cues	Environmental restructuring	Automatic motivation	Environmental Context and Resources
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities
		5) BetterBack☺ Part 2. Group or home based physiotherapy	Patient mediated self-care pain modulation strategies, functional restoration strategies and general exercise. Treatment matched to patient specific functional impairment and activity limitations. Individualised dosing.	1.1 Goal-setting	Enablement	Reflective motivation	Goals
				1.5 Review behaviour goal(s)	Enablement	Reflective motivation	Goals
				1.8 Behavioural contract	Incentivisation	Reflective motivation	Intentions
				2.3 Self-monitoring of Behaviour (Training diary)	Training	Reflective motivation	Behavioral regulation
				2.2 Feedback on behaviour	Training	Reflective motivation	Behavioral regulation
				3.1 Social support	Enablement	Social opportunity	Social Influences
				6.1 Demonstration of behaviour	Modelling	Psychological capability	Social Influences
				6.2 Social comparison	Persuasion	Social opportunity	Social Influences
				8.1 Behavioural practice/rehearsal	Training	Physical capability	Physical skills
				8.7 Graded task	Training	Physical capability	Physical skills
				9.1 Credible source	Persuasion	Reflective motivation	Reinforcement
				12.6 Body changes	Training	Physical capability	Physical skills
				15.1 Verbal persuasion about capability	Enablement	Psychological capability Physical capability	Beliefs about capabilities

Figure 1. Effectiveness-implementation hybrid type 2 trial design with chronological sequence of intervention in each cluster.

Figure 2. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

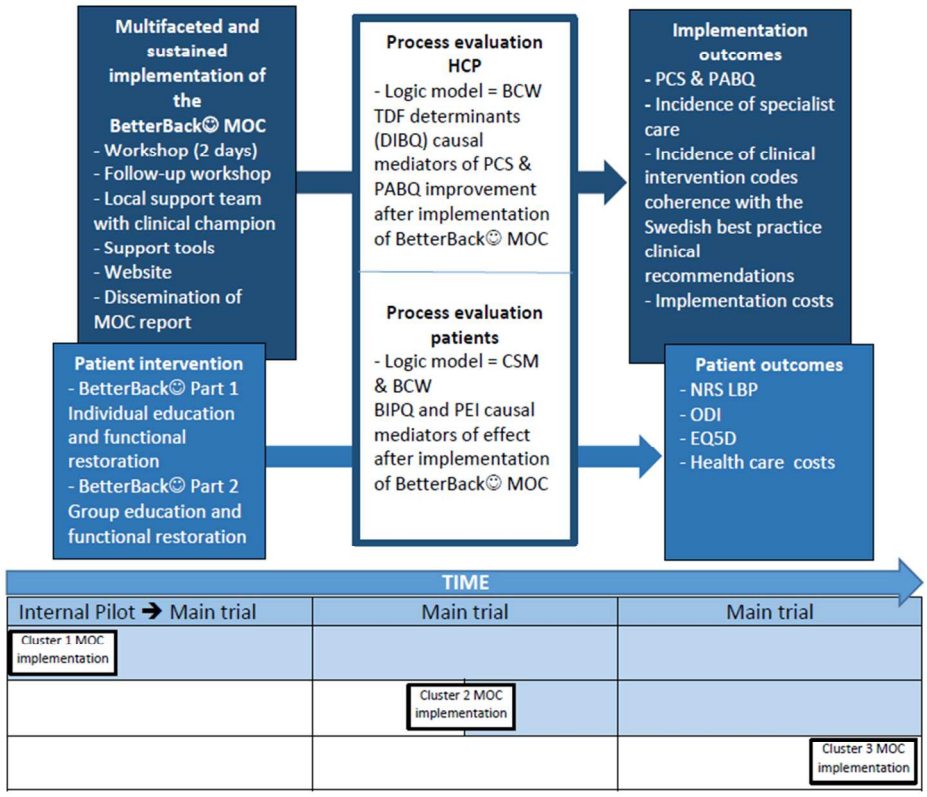
Figure 3. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack☺ model of care for LBP.

Figure 4. Steps involved for HCP in delivering the contents of the BetterBack☺ MOC.

Figure 5. The Behavioral Change Wheel [39] and TDF [41].

Figure 6. Causal mediation model to analyse indirect mediational effects ($a^k b^k$) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c').

Figure 7. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=c_j', indirect=$a_j b_j$, and total effects= $c_j' + a_j b_j$) are allowed to vary between level-2 clusters.



Effectiveness-implementation hybrid type 2 trial design with chronological sequence of intervention in each cluster.

71x63mm (300 x 300 DPI)

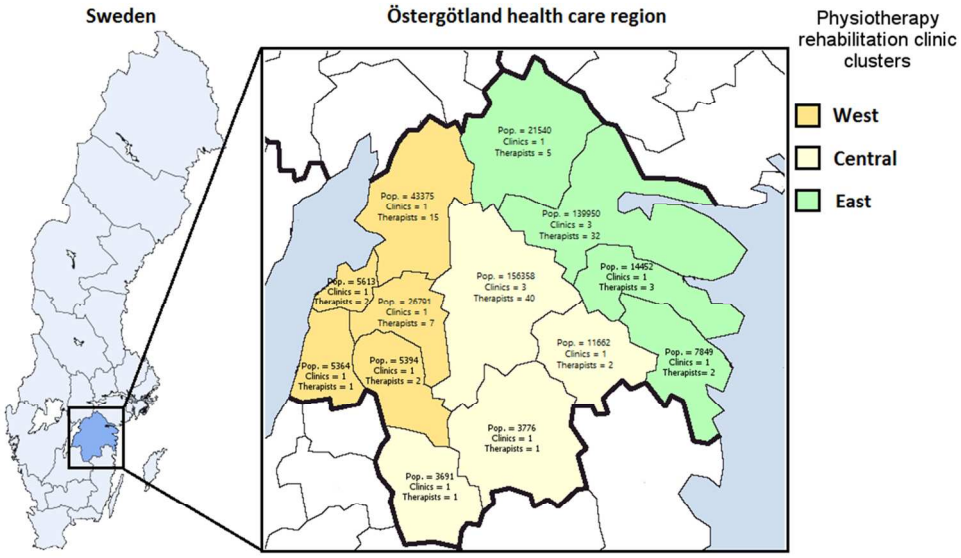


Figure 2. Municipal resident population and number of physiotherapy rehabilitation clinics and therapists in the west, central and east organisational clusters in Östergötland health care region.

127x76mm (300 x 300 DPI)

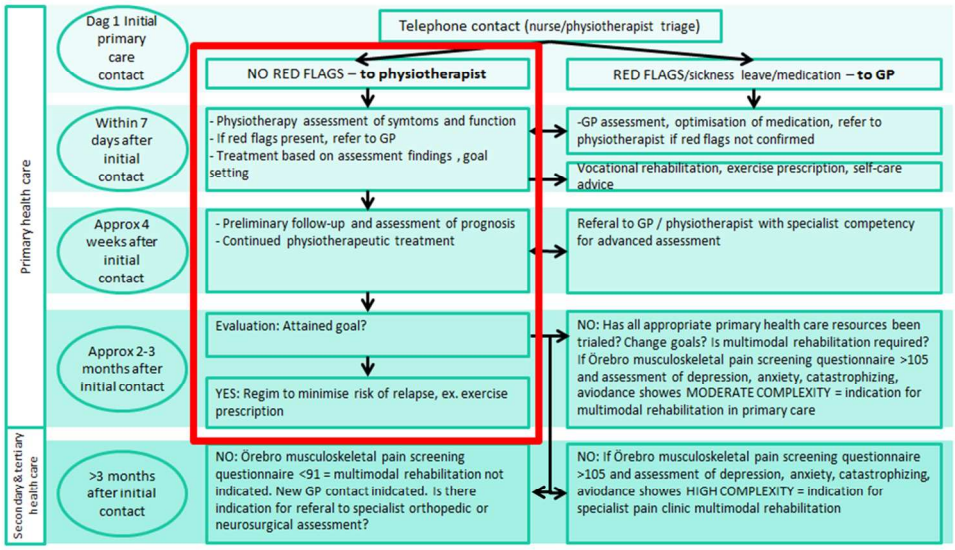


Figure 3. Current routine care clinical pathway for LBP in Östergötland health care region. The primary care physiotherapy process outlined by the red square is the focus area for the implementation of the BetterBack9 model of care for LBP.

135x84mm (300 x 300 DPI)

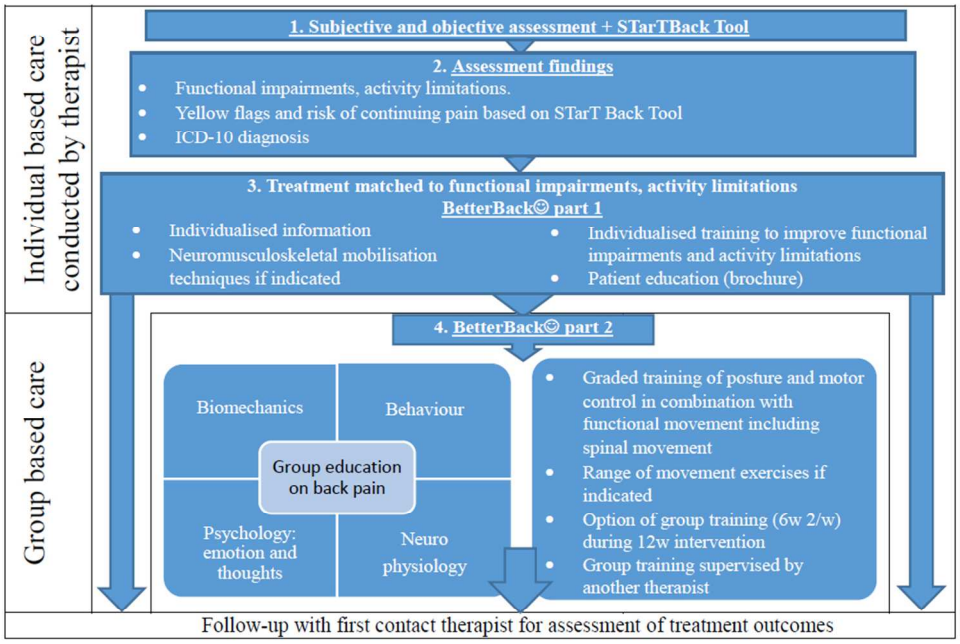


Figure 4. Steps involved for HCP in delivering the contents of the BetterBack MOC.

88x67mm (300 x 300 DPI)

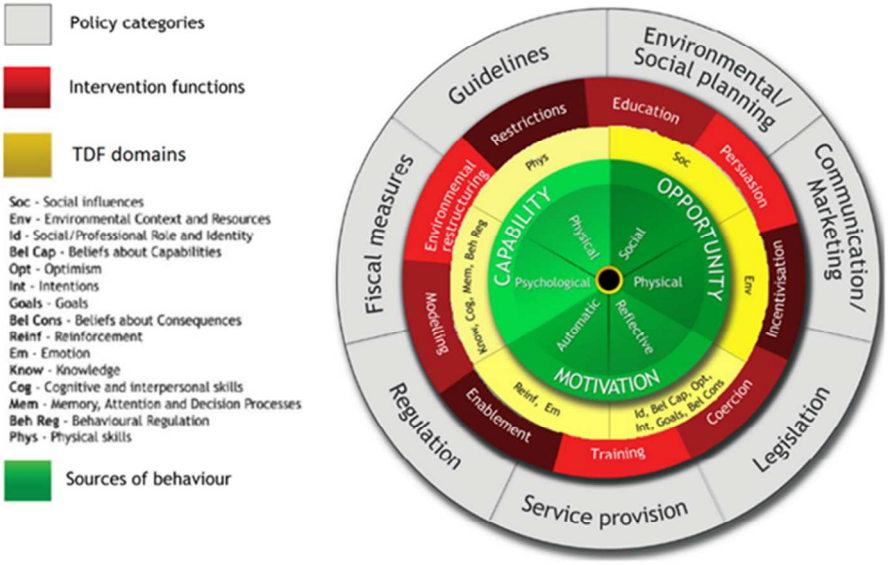


Figure 5. The Behavioral Change Wheel [39] and TDF [41].

127x84mm (300 x 300 DPI)

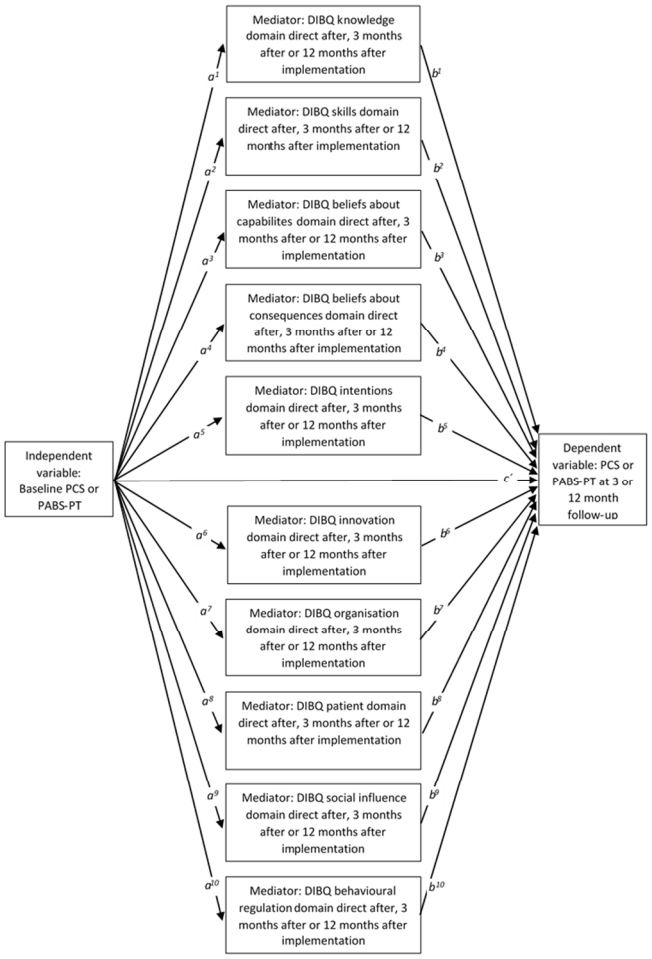


Figure 6. Causal mediation model to analyse indirect mediational effects (akbk) of multiple putative determinants of implementation behaviour measured with the DIBQ directly after the HCP education/training workshop (intention stage) or at 3 or 12 months (volition stages) for the effect of baseline PCS or PABS-PT on 3 or 12 months follow-up measurement of PCS or PABS-PT (c´).

67x118mm (300 x 300 DPI)

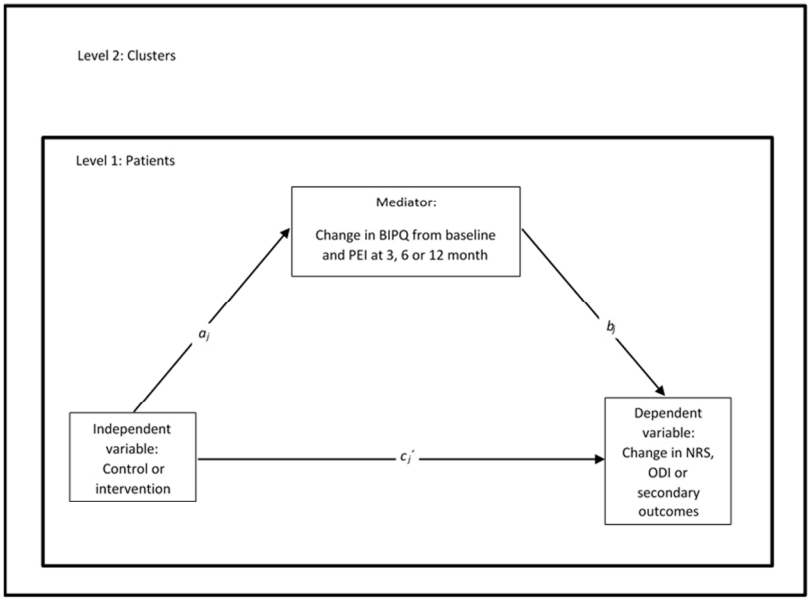


Figure 7. 1-1-1 multilevel mediation model with all variables measured at level-1 but all causal paths (direct=cj´, indirect=ajbj, and total effects= cj´+ ajbj) are allowed to vary between level-2 clusters.

84x67mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Manuscript page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	Table 1
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1,19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-3
	6b	Explanation for choice of comparators	2-3
Objectives	7	Specific objectives or hypotheses	3-4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4-5, Table 2

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-8, table 3, figure 2-4, sup file 1-2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	5-8, Table 3
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-10, Table 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10-11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10-11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-14
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13-14

Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	4-5, 14-15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	**BRIEF NAME** Provide the name or a phrase that describes the intervention.	p2	
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	p6-8	Supplementary file 3
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p6-8, Table 3, Figures 2-4	Supplementary files 3&4
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p6-8, Table 3, Figures 2-4	Supplementary files 3&4
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	5	
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Table 3, Figure 4	Supplementary files 3&4
7.	**WHERE** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	5 Figure 1	

8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p6-8, Table 3	Supplementary files 3&4
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p7-8	Supplementary files 3
10.‡	**MODIFICATIONS** If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
11.	**HOW WELL** Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	p12	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

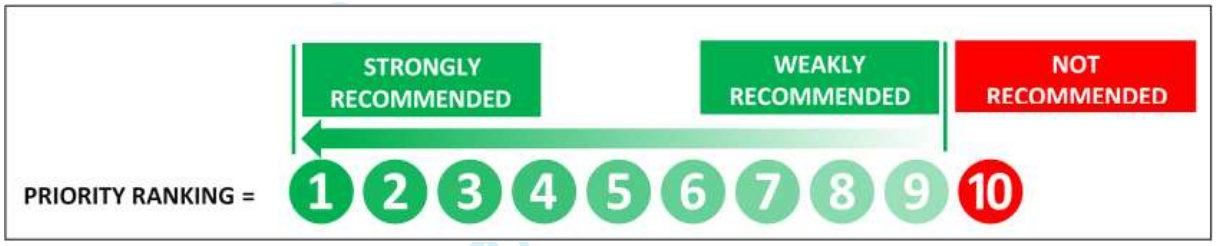
* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BetterBack☺ Model of care for LBP

Östergötland health care region physiotherapeutic clinical practice guideline recommendations for primary care management of benign LBP with or without radiculopathy

Each evidence based guideline recommendation is supported by a clinical priority ranking. This is based on an overall assessment of the severity of the condition, reported effect of the intervention, strength of evidence assessment (GRADE), cost-effectiveness and the benefit of the intervention based on professional experience and patient benefit. A scale from 1 to 10 is used where the number 1 indicates recommended practices with the highest priority while the number 9 indicates recommended practices of low priority. The number 10 indicates recommendations that provide very little or no benefit or utility and are therefore not recommended.



Recommendation 1	PRIORITY RANKING = 1 **2** 3 4 5 6 7 8 9 10
Routine care should consist of standardised processes for subjective and objective assessment and diagnostics. A thorough screening of red flags is essential to rule out serious pathology. Treatment should be individualised for each patient. Basic treatment principles should be based on reassurance of a good prognosis, maintenance of appropriate physical activity and self-care enablement. Justification: The work group's reasoning is based on clinical experience of the importance of careful screening to rule out serious pathology. Furthermore, standardised assessment and diagnostics provide quality assurance but treatment needs to be individualised for each patient case. The work group also reasoned based on clinical experience that appropriate physical activity is likely to contribute to maintaining the patient's functional level, psychosocial and general health as well as have positive effects on self-care enablement. In some cases, may physical activity temporarily aggravate pain and symptoms, but there are no known persisting side effects. The work groups reasoning is also based on evidence showing a statistically significant advantage for maintaining appropriate physical activity compared to bed rest for improving pain and function. Despite this, evidence that proves the benefit of appropriate physical activity is so great to be clinically relevant is missing. In addition, the best available evidence has however a currently limited scientific basis (⊗⊗○○). *The working group proposes the following resources in the BetterBack☺ model of care to support the implementation of Recommendation 1 (See sections 1-5)*	
Recommendation 2	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 **10**
Do not perform routine medical imaging investigations (eg X-ray, CT, MRI) Justification: The work group´s reasoning is based on evidence that shows no differences in outcomes of pain, function and quality of life between patients who received or did not receive	

routine medical imaging investigations in the primary care context. The best available evidence has however a currently inadequate scientific basis (⊗○○○). It was also discussed that imaging cannot confirm or reject a preliminary diagnosis as the relationship between patient symptoms and degenerative imaging finding is usually weak. Moreover, degenerative secondary findings are common in asymptomatic individuals. *The work group however suggests that early use of medical imaging is motivated in the presence of symptoms or signs suggesting possible serious underlying pathology (red flags). Medical imaging may also be relevant when pain persists despite primary care treatment.*
Recommendation 3 — **PRIORITY RANKING =** 1 2 3 4 5 **6** 7 8 9 10
Consider using a patient-reported tool (eg STarT Back risk assessment tool) as usual care during the early-stages of patient management to screen the risk of continued LBP Justification: The work group's reasoning is based on studies showing that STarT Back Tool is the only valid tool to investigate the risk of continued back pain in the primary care context. It shows the highest accuracy for detecting patients with low risk profile (total score ≤3) and medium-high risk profile (total score ≥4) for continued back pain. Studies also show that STarT Back Tool has the best ability to predict functional and pain-related outcomes. The best available evidence has however a currently inadequate scientific basis (⊗○○○). No economical evaluations were identified but the working group discussed the importance of a simple and fast tool. STarT Back Tool can be filled in and analyzed in a few minutes to advantage over other tools that can be an administrative burden for patients and healthcare professionals. *The working group argues that the predictive value of the tool should support, but not replace, regular examination procedures and clinical decision making. See section 3 for STarT Back Tool.*
Recommendation 4 — **PRIORITY RANKING =** 1 2 3 4 5 6 7 **8** 9 10
Consider using a patient-reported tool (such as the STarT Back risk assessment tool) and classification of examination findings during the early-stages of patient management to aid the stratification of care to prevent continued LBP Justification: The work group reasoned that for the choice and scope of targeted treatment measures, consideration should be given to the assessment of risk profile for long-term LBP and classification of examination findings. This has been shown to have a better effect on pain, function and quality of life, as well as less economic costs compared to no treatment stratification. The best available evidence has however a currently inadequate scientific basis (⊗○○○). For a patient with low risk profile (total score ≤3 on STarT Back Tool) usual care is relevant and requires only few visits, but the working group recommends that adequate treatment measures directed at examination findings is of the highest importance. For patients with medium-high risk profile (total score ≥ 4 on STarT Back Tool), usual care will require additional visits. Information provided in questions 5-9 on STarT Back Tool that investigate anxiety with psychological risk factors can guide the need, focus and extent of behavioral medicine measures. *The working group argues that stratified care classified after assessing a risk profile for long-term back pain should support but not replace conventional examination procedures and clinical decision-making for treatment measures. The working group proposes the following resources to support the implementation of targeted treatments based on stratification (See sections 1-5).*
Recommendation 5 — **PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10
Consider giving individualised patient education as a part of usual care (e.g. an explanatory model based on pain neuroscience and psychological mechanisms)

Justification: Based on the best available evidence, the work group reasoned that individualised patient education as part of usual care can result in reduced work sickness absenteeism. The priority of the recommendation has been strengthened by consensus within the work group based on proven experience that individual adapted patient education is an important part of patient-centered care. The best available evidence has however a currently inadequate scientific basis (⊗○○○). The intervention requires that the patient is receptive for education. The extent of patient education can depend upon whether the patient has a distorted image of the underlying mechanism of LBP and a high degree of negative outcome expectations, anxiety, and fear-avoidance or if they are inactive or passive in managing the LBP. Patient education should include a reassuring dialogue and other cognitive and behavioural therapeutic techniques of relevance to support change in the individual's maladaptive thoughts, feelings and behaviors. Pedagogical explanation models should be used to provide the patient with knowledge about symptoms and disorders, as well as to strengthen and support self-care ability to master everyday activities. *The work group proposes the following resources to support of the implementation of patient education (See sections 6-7)*

Recommendation 6	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider a supervised exercise program as part of usual care

Justification: Supervised training is defined as general or back-specific exercises or physical activities conducted under the guidance of a healthcare professionals. The work group's reasoning is based on scientific evidence and proven experience that supervised training as part of usual care can result in clinically relevant improvement in pain, function, quality of life and produces lower health care costs compared with no supervised training. There is however no evidence that a specific type of exercise would be superior to another. The best available evidence has however a currently limited scientific basis (⊗⊗○○).

The work group proposes the following resources to support the implementation of a supervised training program (see section 8).

Recommendation 7	**PRIORITY RANKING =** 1 2 3 **4** 5 6 7 8 9 10

Consider mobilisation techniques for neuromusculoskeletal structures as part of usual care (including active or passive motion in an angular and / or translational plane)

Justification: The working group reasoning is based on evidence that for patients with segmental movement impairments, mobilization techniques can provide a statistically significant reduction in short-term pain. It is however uncertain whether the effect is sufficiently large so that patients experience a clear improvement overtime. At group level, there is no evidence that a particular technique is be superior to another. It cannot be ruled out that for subgroups of LBP patients, more positive effects on pain and function may be produced by specific mobilisation techniques. It is expected that these subgroups can be identified by careful diagnostics and short trial treatments. Mobilizing techniques as part of multimodal treatment provide better results. Serious side effects are rare. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○).

Recommendation 8	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 **9** 10

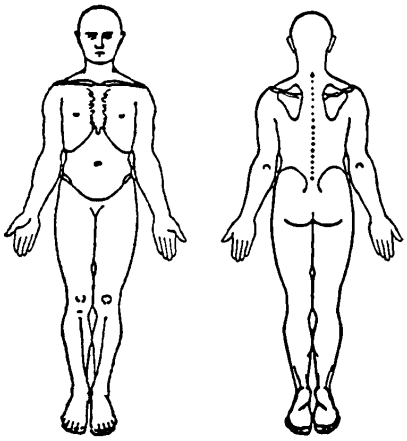
Consider acupuncture treatment in addition to usual care

Justification: The working group reasoned based on evidence that cannot exclude acupuncture has a short-term pain relief effect in addition to a placebo effect. Acupuncture has however no effect on function. Side effects in the form of brief superficial bleeding or inflammation may occur.

Pneumothorax and systemic infections are not common, but the prevalence is unknown. The best available evidence has however a currently inadequate scientific basis (⊗○○○).	
Recommendation 9	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer corset, shoes, traction, ultrasound or electrotherapy Justification: The work group's reasoning is based on evidence that passive treatments such as corset, shoots / soles, traction, ultrasound or electrotherapy do not reduce pain or improve function and quality of life in patients more than no treatment or when offered as part of multimodal treatment. However, the best available evidence is based on a currently limited scientific basis (⊗⊗○○). ***It cannot be ruled out that subgroups of patients may experience positive effects of these interventions when a hypothesised effect mechanism is aimed at specific functional impairment or activity limitation.***	
Recommendation 10	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Consider prescription-free NSAID medication if necessary in addition to usual treatment (lowest dose and shortest possible treatment time). NSAIDs: There is evidence of the effect of NSAID in patients with long-term LBP but the effect has not been highlighted on short-term pain or functional outcomes. There are no adverse reactions reported in systematic review studies on LBP, but potential transient side effects of NSAIDs such as reduced blood clotting, reduced stomach mucous function and reduced kidney function are known from studies on other conditions. The work group reasoned that lowest dose and shortest possible treatment time decreases the risk of side-effects. The work group anticipates that there are differences in patient preferences regarding NSAIDs, where some patients will agree to NSAID treatment, while others will decline. The best available evidence for NSAID effects on LBP outcomes is based on an inadequate scientific evidence (⊗○○○). The work group reasoned based on clinical experience that it cannot be excluded that the NSAID may have a pain relief effect in the short term.	
Recommendation 11	**PRIORITY RANKING =** 1 2 3 4 5 6 7 8 9 10
Do not offer paracetamol or opioids Paracetomol: Has no effect on the degree of LBP and functional ability. There are no reported adverse reactions in studies, but side effects of paracetamol in the form of hepatic effects are known from studies on other conditions. The best available evidence is based on a moderately strong scientific basis (⊗⊗⊗○). Opioids: A weak analgesic effect of oxycodone in combination with paracetamol has been demonstrated in a study but the intervention has no effect on functional capacity for up to 12 weeks. Other positive effects or adverse effects were not shown. A wide range of opioid side effects are known from other studies. Therefore, the working group reasoned that treatment results in more risks than benefits to the patient. The best available evidence is based on a currently limited scientific basis (⊗⊗○○).	

BetterBack☺ model of care implementation support tools

1. Subjective assessment proformer for therapist use

LOW BACK SUBJECTIVE ASSESSMENT PROFORMER			
Name:…… Date of birth:…….. Date:……..			
History of the present condition (debut, duration, activity limitation)	**Symptom localisation** 		
Symptom Description	Localisation back	Localisation right leg	Localisation left leg
Pain nature (Dull, stabbing, radiating etc)			
Pain frequency (Constant/ Intermittent)			
Pain Intensity (NRS 0-10)			
Daily variation (am/pm, night time pain/disturbed sleep)			
Irritability (non-irritable/highly irritable)			
Aggravating factors (loading etc)			
Easing faktors (rest etc)			
Course (Improving/same/worse)			
Other symptoms (Instability, weakness, paresthesia, stiffness)			
Past medical history Previous level of function/activity: Previous treatment:	Red flags: (malignancy, unexplained weight loss, trauma, osteoporosis, infection, inflammatory disease, spinal cord compression symtoms, drug use) Other illnesses/ General health:		
Work, Social, Family history	**Patient förväntningar**		
Medication	**Medical imaging/Laboratory tests**		

2. Physical assessment proformer

LOW BACK PHYSICAL ASSESSMENT PROFORMER

1. INSPECTION – Postural screen

Sitting: good/fair/poor	Postural correction: Better/Worse/No effect	
Standing: good/fair/poor	Postural correction: Better/Worse/No effect	
Lordosis: Hyper/hypo/normal	Kyphosis: Hyper/hypo/normal	Lateralt shift: Right/Left/none
Spinal symmetry:	Shoulder symmetry:	Pelvic symmetry:
Leg & fot symmetry:	Muscular hypo/hypertrophy:	Scars:

2. SCREENING OF FUNCTIONAL MOVEMENT:

Shoes on/off, sit-stand, 2 leg/ 1 leg squat, lunge right/left
Gait: Trendelenburg right/left
Limp right/left
Weight transfer right/left
Toe walking right/left
Heel walking right/left
Work or sport specific:_____

3. SCREENING TEST IN STANDING/SITTING

	Right	Left
Slump test + sensitisation head/foot		
Foramen compression/unloading		
Hip loading/unloading in standing		

4. TEST IN STANDING/SITTING
LUMBAR ACTIVE ANGULAR MOVEMENT

	Range			Quality		Symptoms		
	Large	Med	Small	High	Low	During range	End range	Rep Mov
Flex								
Ext								
Lateral flex	R L	R L	R L	R L	R L	R L	R L	R L
Side Glide	R L	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L	R L

5. TEST IN SIDE LYING
LUMBAR PASSIVE ANGULAR MOVEMENT

	Range			Symptoms			
	Large	Med	Small	During range	End range	Rep Mov	Over press
Flex							
Ext							
Lat flex	R L	R L	R L	R L	R L	R L	R L
Rot	R L	R L	R L	R L	R L	R L	R L
Coupled flex	R L	R L	R L	R L	R L	R L	R L
Coupled ext	R L	R L	R L	R L	R L	R L	R L

6. PRONE
ACCESSORY MOVEMENT/NERVE & MUSCLE FUNCTION

Spinal extension in prone	Better/Worse/No effect			
Segmental provocation	Movement			Pain
	Hyper	Hypo	Normal	
- Central P/A, Springing test - Unilateral P/A - Rotation provocation - Prone instability test				
Femoral nerve tension test				
Isometric/dynamic back muscle tests				

8. PALPATION

7. SUPINE
DIFFERENTIAL DIAGNOSTICS HIP/SI-JOINT/BACK

Spinal flexion in supine	Better/Worse/No effect	
Isometric/dynamic abdominal muscle tests		
	Right	Left
Hip: Angular movement, Patricks test, quadrant		
SI-joint provocation test, ASLR		
Passive SLR + head/foot sensitisation, crossed SLR		
Myotomes- L1-2(I), L2-3(Q), L4-5(TA), L5(EH), L5-S1(P), S1(TS)		
Dermatomes		
Reflexs: Patella L3-4, Achilles S1		
Babinski, Klonus		

3. STarT Back Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg**(s) at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐ 0	☐ 0	☐ 0	☐ 1	☐ 1

Total score (all 9): _____ **Sub Score (Q5-9):**_____

Funded by Arthritis Research UK

4. Clinical Reasoning and Process Evaluation tool (CRPE-tool) for therapists

PATIENT NAME:_____	**First assessment date:___/___/___**
DATE OF BIRTH:_____	**Final assessment date:___/___/___**
	Totalt number of physiotherapy visits:_____

ASSESSMENT

- **First assessment - cross X relevant assessment findings**
- **Final assessment - circle ○ relevant assessment findings**

1. Assess grade of FUNCTIONAL IMPAIRMENT	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Energy and drive (motivation)	0	1	2	3	4	PA006
Sleep functions	0	1	2	3	4	PA007
Emotional functions (anxiety, low mood)	0	1	2	3	4	PA011
Thought functions (physical symptoms caused by cognitive/rational factors)	0	1	2	3	4	PA013
Sensory function (sensitivity for pain ”sensitisation”)	0	1	2	3	4	PB008
Pain (choose relevant category)						
Back pain	0	1	2	3	4	PB009
Lower extremity pain	0	1	2	3	4	PB009
Pain in a dermatome	0	1	2	3	4	PB009
Pain in another body part (Buttock, hip, groin, thigh)	0	1	2	3	4	PB009
Generalised pain localisation (3 of 4 body quadrats)	0	1	2	3	4	PB009
Exercise tolerance (endurance related activities)	0	1	2	3	4	PD009
Joint mobility	0	1	2	3	4	PG001
Joint stability	0	1	2	3	4	PG002
Muscle power	0	1	2	3	4	PG003
Muscle tone	0	1	2	3	4	PG003
Muscle endurance	0	1	2	3	4	PG003
Motor reflex funktions (decreased or increased)	0	1	2	3	4	PG004
Control of movement (Quality, coordination, balance)	0	1	2	3	4	PG006
Gait pattern	0	1	2	3	4	PG007
Sensation of muscle stiffness, tightness, spasm, contraction, heaviness	0	1	2	3	4	PG003
Mobility of spinal meningies, periferal nerves and surrounding tissue	0	1	2	3	4	PG000
2. Assess grade of ACTIVITY LIMITATION	**None**	**Lite**	**Moderate**	**Severe**	**Complete**	KVÅ code
Perception of non-harmful sensory stimuli (kinesiophobia)	0	1	2	3	4	PJ001
Carrying out daily routine (ADL)	0	1	2	3	4	PK003
Handling stress and other psychological demands	0	1	2	3	4	PK004
Changing and maintaining body position (Shifting body weight away from the spine (increased lever arm)	0	1	2	3	4	PM001
Changing and maintaining body position (bending)	0	1	2	3	4	PM001
Maintaining a lying position	0	1	2	3	4	PM001
Maintaining a sitting position	0	1	2	3	4	PM001
Maintaining a standing position	0	1	2	3	4	PM001
Maintaining an upright neutral posture	0	1	2	3	4	PM001
Lyfting and carrying objects	0	1	2	3	4	PM004
Walkning	0	1	2	3	4	PM007
Moving around in different ways (crawling/climbing, running/joging, jumping)	0	1	2	3	4	PM008
Household tasks	0	1	2	3	4	PP003
Work ability and employment	0	1	2	3	4	PR002
Recreation and leisure activities	0	1	2	3	4	PS002

DIAGNOSTIC SUBGROUPING AND ICD-10 CODING

3. Matching assessment findings to diagnostic codes
Choose a primary assessment finding category:

- **First assessment: Cross X one or more related ICD-10 diagnostic codes in the same row**
- **Final assessment: Circle ○ a new diagnostic codes if relevant.**

Primary assessment category ⟶	**ICD-10 diagnos**
LBP with muscular functional impairment	☐ M54.5 Lumbago
LBP with segmental mobility impairment	☐ M54.5 Lumbago ☐ M99.0 Segmental dysfunction
LBP with movement coordination impairment/ segmental instability	☐ M54.5 Lumbago ☐ M99.1K Segmental instability in the lumbar spine
LBP with referred lower extremity pain (nociceptive pain proximal of the knee)	☐ M54.5 Lumbago ☐ M51.2 Other specificed dislocation of intervertebral disc ☐ M47.9K Spondylosis in the lumbar spine
LBP with radiating pain (neuropathic pain)	☐ M54.5 Lumbago ☐ M54.1 Radiculopathy (femoralis) ☐ M54.4 Lumbago with ischias
LBP with related cognitive or affective tendensies	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity)
LBP with related generaliserad pain (pain in 3 of 4 body quadrants)	☐ M54.5 Lumbago ☐ G96.8 Other specified disorders of the CNS (pain sensitivity) ☐ F45.4 Chronic somatoform pain syndrome
LBP with postural related symptoms	☐ M54.5 Lumbago ☐ M40.3 Flatback syndrome ☐ M40.4 Hyperlodosis
SI-joint symptoms or Coccygodynia	☐ M53.3 Sacrococcygeal disorders
LBP radiating pain + Medical imaging disc pathology and nerve compression finding	☐ M51.1K Disc degeneration/disc herniation in the lumbar spine with radiculopathy
LBP with radiating pain/neurogenic claudication + Medical imaging verifieried degeneration and nerve compression findings	☐ M48.0K Central spinal stenos in the lumbar spine (bilateral symptoms) ☐ M99.6 Stenosis of intervertebral foramin (unilateralt symptoms)
Ländryggsbesvär med nedsatt rörelse kontroll i ryggen och/eller segmentell instabilitet + Medicinsk bild verifierad Spondylolys/Spondylolisthes	☐ M43.0 Spondylolys ☐ M43.1 Spondylolistes

TREATMENT

4. Record at final assessment:

Has the BetterBack© model of care Part 1 been applied?		☐ Yes ☐ No
Has the BetterBack© model of care Part 2 been applied?		☐ Yes ☐ No
Cross X all modes och types of treatments used		
Physical exercise	**MODE**	KVÅ code
	☐ Non-supervised individual training	
	☐ Supervised individual training	QV011
	☐ Supervised group training	QV012
	TYPE	
	☐ Muscle strengthening training	QG003
	☐ Range of movement training	QG001
	☐ Muscle endurance training	QG003
	☐ Cardiovascular training	QD016
	☐ Balance training	QB001
	☐ Postural control training	QG004
	☐ Coordination training	QG005
	☐ Pelvic floor training	QF001
	☐ Postural training	QM005
	☐ Relaxation training	QG007
	☐ Physical activity prescription (FaR®)	DV002
	☐ Other ……	
Behavioural medicine interventions	**MODE**	
	☐ Individual based intervention	QV011
	☐ Group based intervention	QV012
	TYPE	
	☐ Information / education on pain	QV007
	☐ Cognitive-behavioural therapy	DU011
	☐ Mindfulness	DU032
	☐ Motivational interviewing	DU118
	☐ Relapse prevention	DU119
	☐ Supportive conversation	DU007
	☐ Other ……	
Manual therapy	**TYPE**	
	☐ Joint mobilisation	DN006
	☐ Joint manipulation	DN008
	☐ Massage	QB007
	☐ Stretching	DN009
	☐ Nerve mobiliseration	QG001
	☐ Trigger point pressure	DN007
	☐ Traction	QG001
	☐ Other……..	
Occupational medicine interventions	**TYPE**	
	☐ Workplace training	DV084
	☐ Training of work ability	QR003
	☐ Work and employment counciling	QR002
	☐ Information /education on ergonomics	QV010
	☐ Other ……..	
Physical modalities	**TYPE**	
	☐ TENS	DA021
	☐ Cryotherapy	QB011
	☐ Heat	QB011
	☐ Ultrasound	QB011
	☐ Shockwave therapy	QB011
	☐ Laser therapy	QB011
	☐ Short wave diathermy	DV042
	☐ Interferential therapy	DA021
	☐ Orthosis	DN003
	☐ Taping	DN003
	☐ Bio-feedback	DV010
	☐ Acupunkture	DA001
	☐ Other……..	

5. Rate overall treatment effect	☐ Much better ☐ Quite much better ☐ Unchanged ☐ Quite much worse ☐ Much worse

5. Clinical reasoning and process pathway for therapists

A thorough history and adequate physical examination are of great importance in order to target treatment interventions. In addition, it is very important to exclude the few red flag cases that require acute medical or specialist referral for the investigation and treatment of tumors, infections, inflammatory diseases, more severe back pathology and neurological conditions, as well as the strong influence of psychosocial factors which can also cause back pain. StarT Back Tool can be used to support decision making regarding the extent of health care needed and the need for psychosocial focus based on an assessment of risk factors for continued back pain. The physical assessment should include an analysis of functional movements, posture, active movements, passive movements, combined movements and / or static positions, joint accessory movement / provocation tests and neuromuscular function. This is to investigate how the symptoms are related to motion dysfunction.

Based on assessment findings, relevant treatment measures with effect mechanisms directed at functional impairments and activity limitations should be tested. These may include range of movement exercises (active/passive or accessory joint mobilisation or neuromuscular structure mobilisation), motor control exercises, muscle stretching, balance exercises, coordination, muscle strength, muscle endurance, general physical fitness or cardiovascular exercise. For example:

1. In the identification of movement directions and positions that reduce or centralize the patient's localised pain, distal pain or radiculopathy, these may be considered as a treatment techniques. This allows the patient to learn strategies to control pain and thus take better responsibility for his or her own situation.

2. In the identification of movement restriction due to joint, muscle or nerve related impairment, mobilisation strategies for the relevant structure may be considered to reduce the movement restriction.

3. In the identification of segmental instability or trunk motor control impairment in the, exercises with a focus on movement control can be tested aiming to improve muscle function, reduce pain and optimise loading of the trunk during full body movement.

4. In the identification of a psychogenic causes of back pain, supervised exercise could be tested to minimize kinesiophobia. This can often be complemented with patient education that can help pain management and enable self-care.

5. In the identification of a postural impairment, posture correction and ergonomic interventions can be tested.

Dosage of treatment measures should be individualised and sufficient to achieve the desired effect. Initial targeted treatment should be through individual patient care. As a complement to the initial targeted treatments, the purpose of a general training and patient education is to restore or improve function and activity. The suitability of group-based patient care is assessed in consultation with the patient as general training and patient education is considered relevant to support the patient's self-care.

Clinical process and reasoning pathway - BetterBack☺

Subjective and physical assessment

Symptom: Constant pain, night-time pain, pain unrelated to mechanical loading

Symptom: Pain related to mechanical loading

1) Red flags: Suspected malingnancy, cauda equina/myelopathy symptoms, visceral pain, inflammation pga significant trauma/fracture, infection or inflammatory disease
2) Another medical condition providing an obstacle for rehabilitation

Medical management

Pain localisation over surrounding joints: hips or SI-joint

Unilateral pain over hips or groin

Unilateral pain under L5 segment

Positive Hip Quadrant or Patrick's Test

2/4 or 3/5 SI-joint tests positive

Likely hip

Likely SI-joint

Classify lumbar spine related assessment findings

Low back and/or leg pain of nociceptive or neuropathic character. High pain intensity and irritability. Aggravates / relieves or peripheralises / centralises during range of joint motion in a specific plane.

Pain localised to the lower back. Nociceptive character. Mild-moderate intensity and irritability. Restricted joint range of motion and end range pain. No immediate change in ROM after repeated movements

Pain localised to the lower back. Nociceptive character. Mild-moderate intensity and irritability. Painful arc/abberant movement flexion-extension, positiv prone apprehension test, pain during trunk loading

Full ROM with no pain during ROM, nociceptive pain during static positions in end of range

Clinincal reasoning, possible influencing factors

STarT Back Tool
- Stratified management based on risk of pain persistence:

-Low risk
(STarT Back Tool ≤3):
- Functional optimisation with requiring few visits

-Medel & hög risk
(≥4 på STarT Back Tool)
- Functional optimisation requiring more visits.
- Behavioural medicine interventions when indicated

Consider other influencing factors:
Barriers and fascilitators to goal attainment
- Age
- Work
- Comorbidities

Diagnostic subgrouping and ICD-10 coding

Treatment according to BetterBack☺

Specific therapies when indicated

Pain modulation
- Directional preference exercises
- Pain modulating mobilisation therapies

Mobilisation
- Movement restriction (joint, nerve, muscle): Improve ROM with specific mobilisation and stretching

Movement control of instability dysfunction
- Graded trunk and back stabilising exercises

Postural syndrome postural training, ergonomic advice

General principles for all patients

Patient education and general functional restoration exercise working towards self-care enablement.

Part 1
Individualised care

Part 2
Transition to group based care when longer rehabilition period needed.

Follow-up assessment

6. BetterBack☺ Model part 1 – Patient education brochure

BetterBack☺

Information on Low Back Pain

LINKÖPINGS UNIVERSITET

Region Östergötland

Low Back Pain

Low back pain (LBP) is a common harmless condition that affects almost everyone at some point. Over a one-year period, 4 out of 10 adults experience LBP. It is often characterised by varying degrees of pain and discomfort that may impact on ability to perform activities. An episode of LBP usually improves within 2-6 weeks. Most have a fairly stable pattern of back health for many years, which may sometimes be interrupted by a period of LBP. This is a normal pattern and does not mean that the condition is getting worse over time.

Degenerative changes in the spine

Something that astonishes many is that there is no direct connection between degenerative changes in the spine and common LBP. This means that changes seen on X-rays, magnetic cameras and computer tomography can show pronounced age related changes or disc herniation in a completely painless person, while someone with LBP may have very little or no changes.

The structure and function of the lower back and common causes of LBP

The lower back consists of many structures such as bones, joints, discs, stabilising ligaments, nerves, as well as deep and superficial muscles. Pain sensations may potentially be signalled by one or more structures of the lower back. It is often difficult to specify exactly if and which structures signal pain sensations. How we maintain an upright position in different situations is called posture. An optimal posture means that the spine has the best conditions for good mobility with optimal distribution of body weight. Suboptimal posture, suboptimal loading of the back or even too little loading of the back can be possible contributing factors of LBP.

Experience of back pain

Pain is first experienced when interpreted in the brain. How the pain is interpreted depends on experience, thoughts, feelings and expectations. In some cases, pain may be experienced in the lower back but in the absence of pain signals from structures in the lower back. The pain system may also become hypersensitive and in some cases the pain can persist even though the original cause of the pain has resolved.

Figure 1. Pain is interpreted in the brain. This can be in the presence or absence of signals form lower back structures

Back pain symptoms

In addition to back pain, you may have pain in the buttocks and in one or both legs. You may have difficulty standing, sitting, walking, bending etc. This can lead to frustration, depressed mood and anxiety. Some may be afraid of physical activity and become inactive. All of this can impact negatively on you everyday life.

Tips when you have a particularly troublesome period

Think about what you have read in this brochure, that pain comes in periods but usually calms down. Also think about what relieves the symptoms and what you can do when you have a troublesome period. You may have a favorite exercise or other strategy to manage troublesome periods. Contact your physiotherapist for help if you feel after 2-6 weeks that pain doesn't subside. If you have numbness and tingling in both legs, loss of skin sensation or weak muscles in the legs and feet and especially if you have trouble controlling your bladder and bowel you should seek medical care. If you have LBP after an accident or have been previously treated for cancer or osteoporosis, it is also important to seek medical care. For the vast majority, however, back pain is a harmless and common condition that comes and goes.

Back Health

Good back health is a balance between the back's capacity on one side of the scale and physical / mental stresses on the other side as in the figure below.

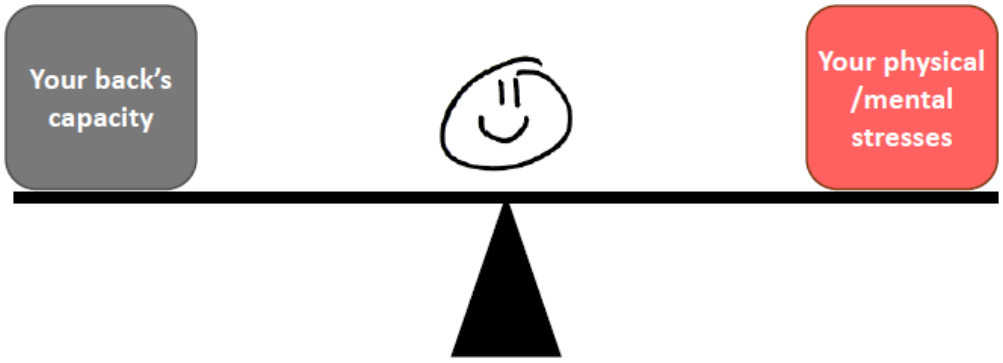


Figure 2. Balance between back capacity and stresses

Back pain occurs when imbalance occures between back capacity compared to physical / mental stresses as in the figure below.

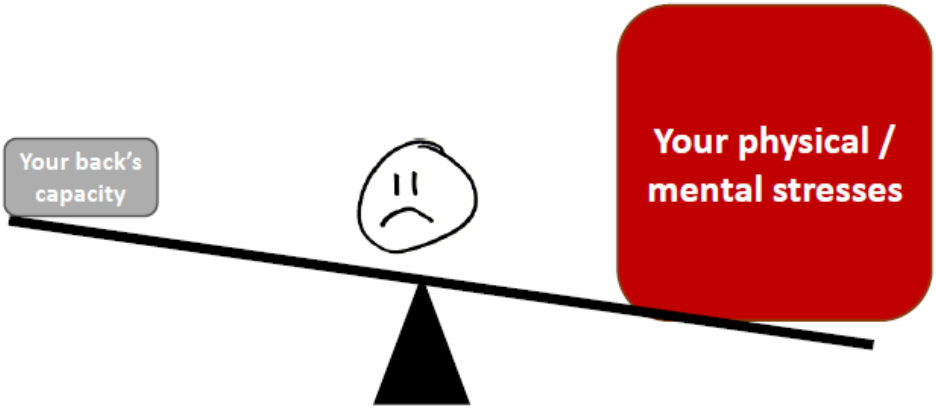


Figure 3. Imbalance between back capacity compared to physical / mental stresses

General advice / self-care

During the acute phase, most people are in need to take it easy and adjust their physical and mental stresses. Today, however, there is extensive research that recommends avoiding bedrest and instead modifying physical activity and successively returning to normal activities as quickly as possible. You can use a pain management scale to find the right level of back physical and mental stresses during everyday activities and also when you work out. This model is based on keeping you within acceptable perceived pain levels during an activity and within 24 hours after activity. This means that activity may increase the pain within acceptable pain levels during or after training, but it should return to initial levels within 24 hours. If you are unsure about the right level of back physical and mental stresses consult your physiotherapist.

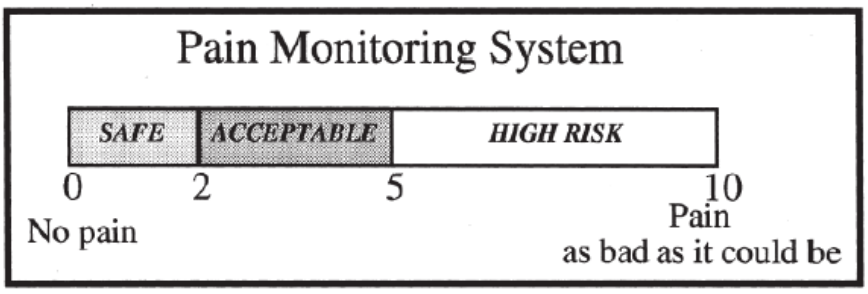


Bild 4. During activity, it is preferable that the pain is within safe to acceptable levels and that the pain returns to initial levels within 24 hours

Treatment for back pain

The goal is to increase your back's capacity and reduce your physical and mental stresses. You can increase your back's capacity by optimising your back posture, muscle stength, muscle endurance, agility, and improving your overall fitness. You can reduce your physical and mental stresses by optimising your back's physical loads, reducing negative emotions through a positive approach and reducing everyday stress and changing your thoughts about your LBP

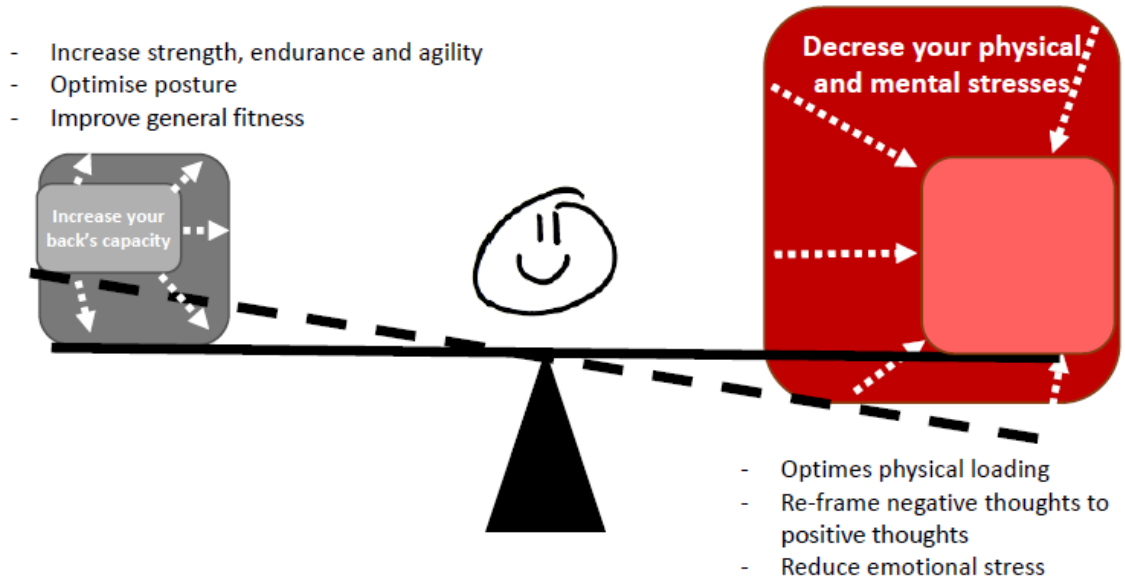
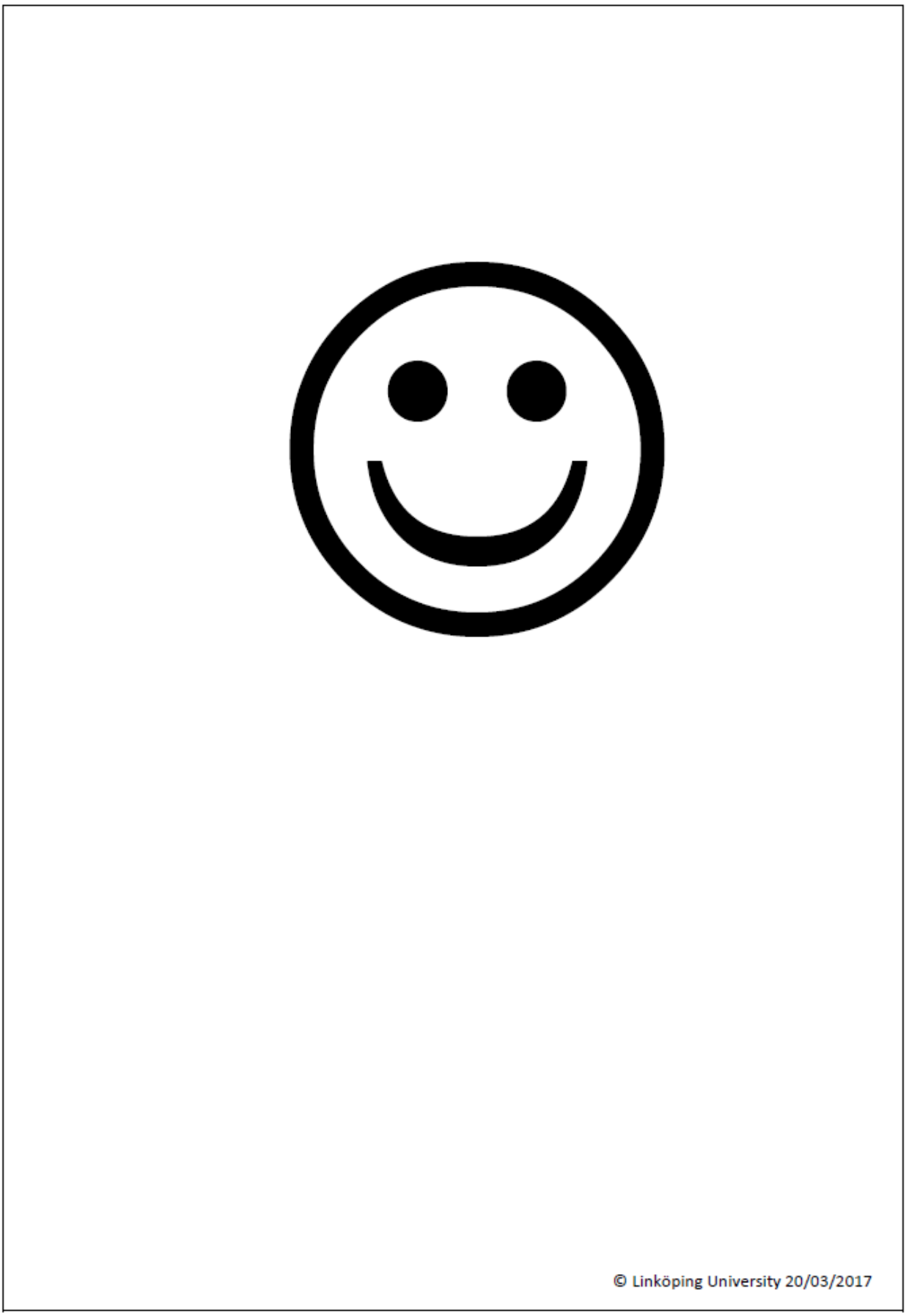


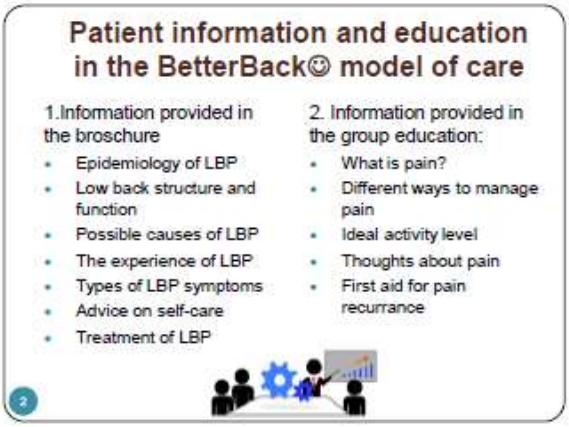
Figure 5. How to balance the back's capacity and stresses

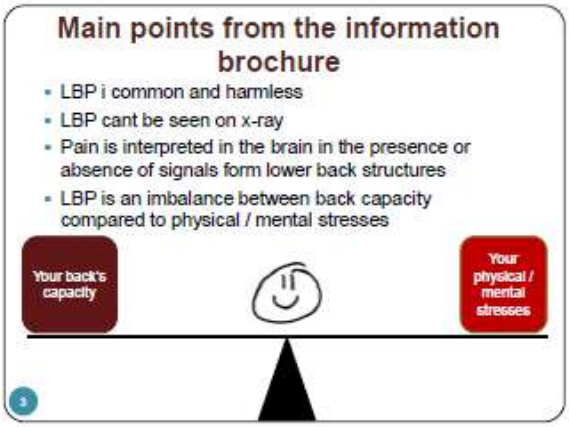
The BetterBack☺ model of care

The BetterBack☺ model of care for LBP focuses on evidence based physiotherapy, patient education and exercise. The main aim is to manage LBP symptoms and enable the patient's self-care ability. You will receive a thorough assessment and individualised care. Depending on your need for extended support in addition to your physiotherapist's initial interventions, pain education seminars and supervised exercise in a group format can be provided for 6 weeks, 2 times / week. The pain education seminars include explanatory models of what pain is, different ways of managing pain, as well as how to balance your back capacity and your physical and mental stresses you are exposed to. It is common for people to become less physically active after a troublesome period of LBP. It is therefore important to get started with some form of general fitness training. You can improve general fitness by walking, Nordic walking, cycling, jogging and swimming. If you experience pain during activity, you can use the pain management scale (see Figure 4). It is important that you feel motivated and can adapt your training to fit into your everyday life. In the BetterBack☺ model of care program, you can get help on how to get started!



7. BetterBack☺ Model part 2 – Group education seminar for patients





The situation affects the pain experience

7

Pain experience =
warning from the body – interpretation in the brain

The body

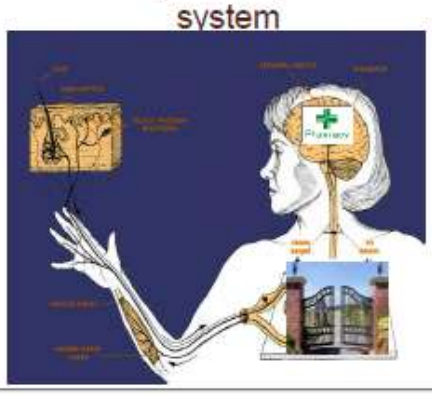
situation + thoughts + experience

Pain is inhibited or strengthened

Pain experience

8

The body's own pain relief system



9

Pain experience

- Pain can be **dampened**
  - If you understand it's cause
  - If it is predictable
  - If you know how to handle the pain
  - If it is manageable
  - If you have a positive attitude
  - If you are goal-focused

10

Pain experience

- Pain can be **dampened**
  - If you understand it's cause
  - If it is predictable
  - If you know how to handle the pain
  - If it is manageable
  - If you have a positive attitude
  - If you are goal-focused
- Pain can be **aggravated**
  - If you feel uncertain of its cause
  - If it is unpredictable
  - If you cant control the pain
  - If you have a depressed mood
  - If you generally feel pressured
  - If it is associated with bad experiences

- What dampens / aggravates your pain?

11

Thoughts affect our self-perception...,

12

… and thoughts affect the pain experience

You are going to be immunized against influenza. You know the needle hurts for a few days. How do you experience the pain?

You have back pain after a longer walk. How do you experience pain?

13

… and thoughts affect the pain experience

HEY MACARENA!

- Prolonged back pain can be like a bad song that gets stuck in your mind. The brain has learned it without you wanting to and it plays over and over again …. The more irritating the song the more easily it gets stuck in your mind

You started training but get more back pain afterwards. It may be muscle soreness or it may be the playing over and over again of pain memories like "the known song". How do you relate to this?

14

Pause exercise

Try to breathe relaxed and calm, focus on breathing for 2 minutes

Acknowledge your pains in a neutral way, but keep the focus on breathing

15

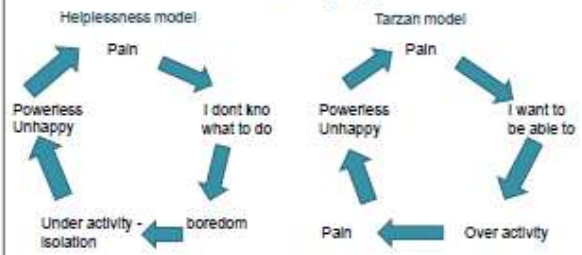
Pause Exercise -redirecting

What happens to your pain experience when you focus on your breathing?

Does this redirect your thoughts away from attention to pain?

16

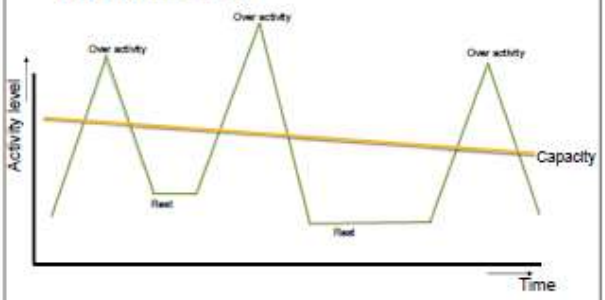
Pain coping



Different strategies. "Helplessness" or "Tarzan model"?
Are there other strategies? In which way do you react?
What consequences does this have?
Advantages/disadvantages?

17

Activity level – too much activity Tarzan model



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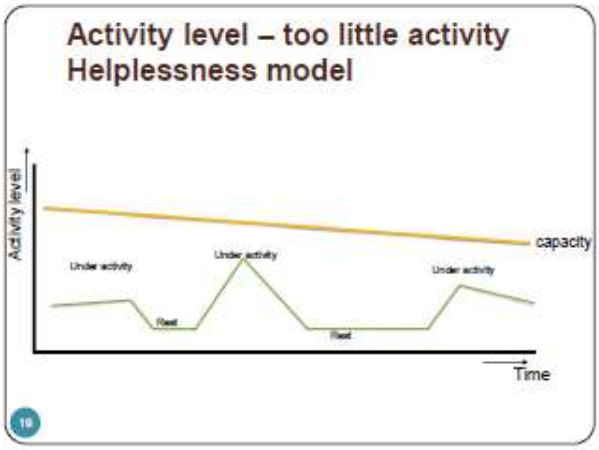

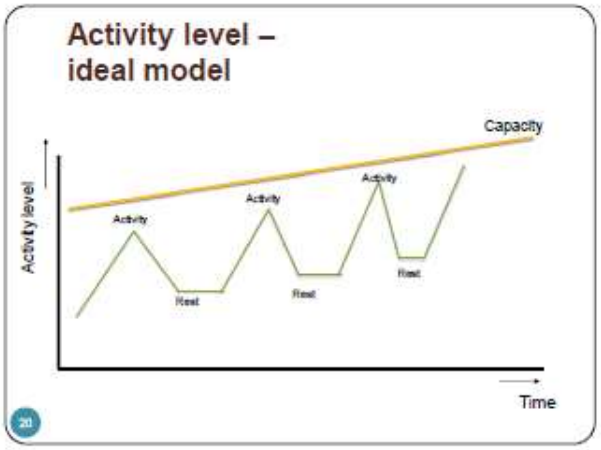

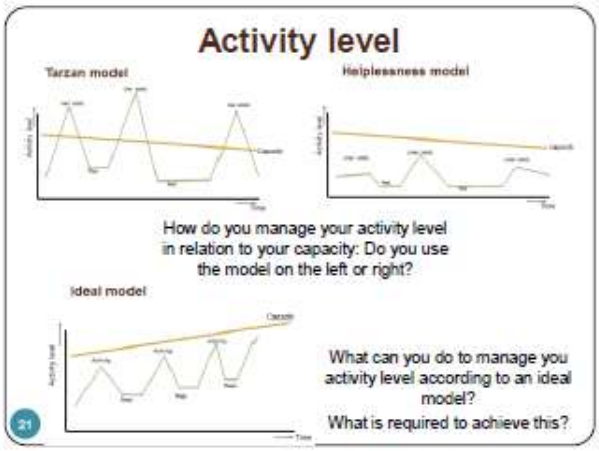

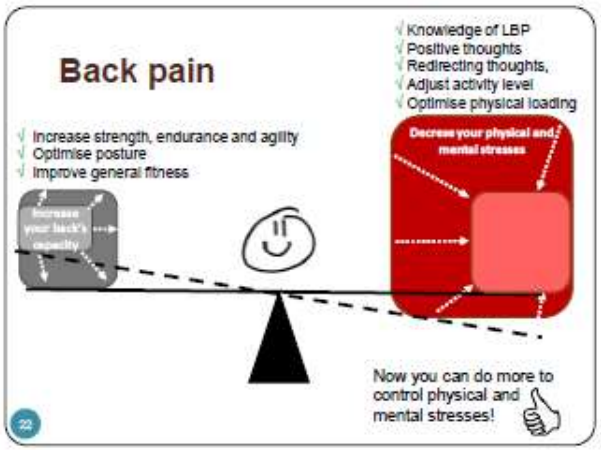

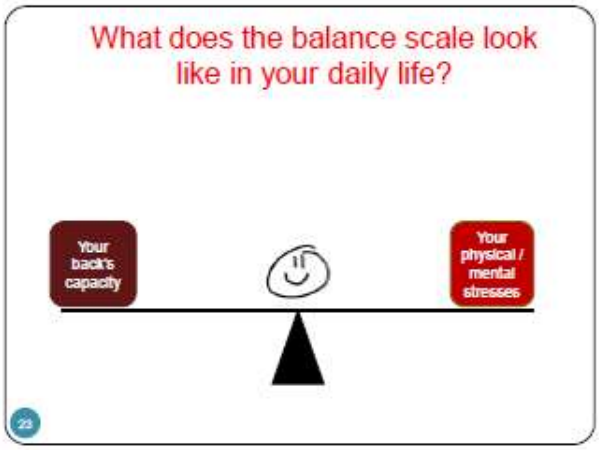

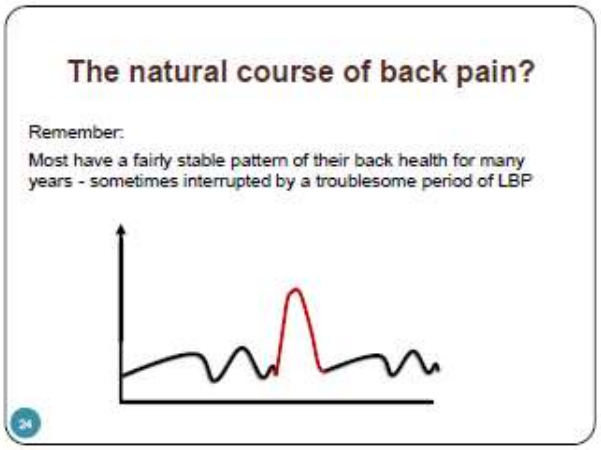

First aid when back pain flares up

- How long time do you expect the pain to be aggravated?
- What can you do when the pain gets worse?
- Do you have a favorite strategy to reduce pain?
- What can you do to make it easier for yourself?
- Ask for help?

25

Tips…

- Adjust activity and load according to your back capacity, not too much not too little
- Distribute activity throughout the day
- Be active, take short breaks
- Think positive thoughts
- Help youself
- And ask for help from others

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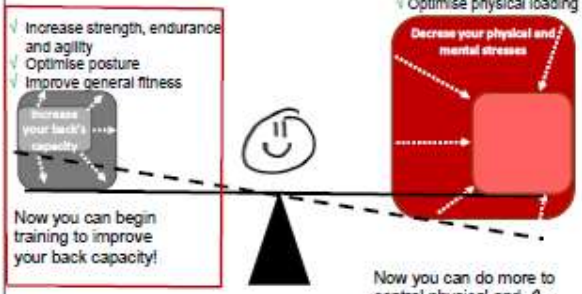
Back pain

√ Increase strength, endurance and agility
√ Optimise posture
√ Improve general fitness



√ Knowledge of LBP
√ Positive thoughts
√ Redirecting thoughts,
√ Adjust activity level
√ Optimise physical loading

Now you can begin training to improve your back capacity!

Now you can do more to control physical and mental stresses!

22

Increase your capacity – improve general fitness

Help yourself to be physically active to optimising brain and body's wellbeing.

- Improved memory & concentration
- Better coping with stress
- Improved mood
- Divert negative thoughts
- Contributes to better health, physical and mental

Physical activity during acute LBP?

28

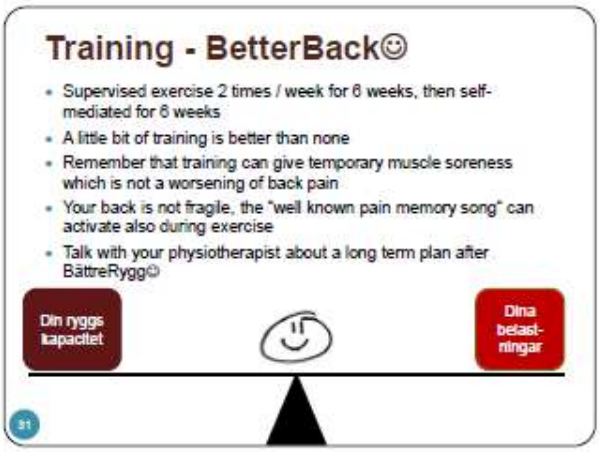
Reduce sedentary behaviour

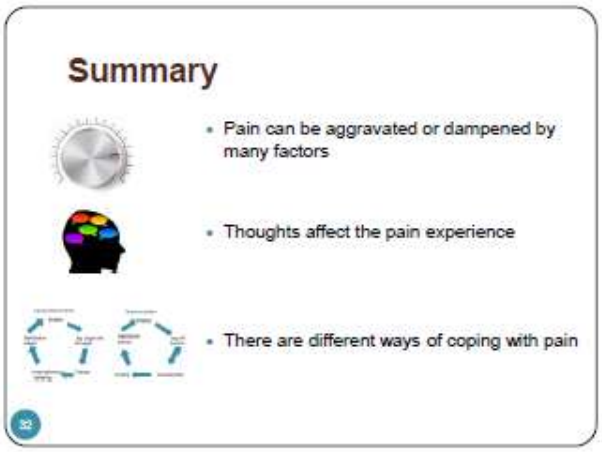
How can i change too little exercise and too much sitting ?

29

Increase your back's capacity! We will help you get started!

30





8. BetterBack☺ Model – Training program for patients

<table>
<tr><th colspan="3">Training program for patients receiving the BetterBack☺ model of care for LBP</th></tr>
<tr><td>Part 1: Posture, muscle control and coordination of basic body movements</td><td><u>Goal:</u> To ensure the patient has satisfactory posture and trunk muscle activation in static positions as well as in conjunction with basic body movement in the sitting, sitting and standing.
<u>Implementation*:</u> Exercises and dosages are individually adjusted by the treating therapist. Exercises are performed as home programs and daily training is recommended for optimal results.

The therapist assesses when basic competencies in program 1 are achieved before progressing to program 2.</td><td rowspan="2">Training range of movement
<u>Goal:</u> Restore normal mobility.

<u>Implementation</u>:
Individualise based on if the patient has movement restriction.</td></tr>
<tr><td>Part 2: Graded training of muscle strength, coordination and endurance</td><td><u>Goal:</u> To ensure the patient has satisfactory ability to perform more challenging body movements with adequate strength, corrdination and endurance.
<u>Implementation*:</u> Exercises and dosages are individually adjusted by the treating therapist. Exercises are performed twice a week for 12 weeks with follow-up conducted by the treating therapist. During the first 6 weeks, patients are offered the opportunity to train in a group supervised by a physiotherapist. The patient will then receive support and feedback regarding the practice of exercises and help to upgrade exercises if necessary. Patient education on self-care and management of back pain is also performed in groups.</td></tr>
<tr><td colspan="3">*Prerequisite for upgrading the training program is that the patient can satisfactorily perform basic exercises for posture and trunk control in Part 1. Using Part 2 as a basis, the physiotherapist selects and individualises relevant exercises and dosing based on the assessment findings. If support with the traning program is required (in addition to a self-mediated home based program), group traning supervised by another therapist can implemented. However, the follow-up of the patient is still the responsibility of the therapist who first assessed and initiated the patient's treatment plan. The program is designed with graded levels where difficulty level is increased by successively progressing from stages A through to C. Patients are to perform the exercises as instructed. Training can initially produce some muscle soreness, but this is normal and decreases gradually. Contact your physiotherapist if you have questions or feel unsure.</td></tr>
</table>

Part 1. Posture, muscle control and coordination of basic body movements

1a. Basic trunk muscle activation and control in a lying position

Pelvic control exercise

- Lay on your back with your knees bent. Put your hands under your pelvis. Press your lower back down so it flattens down on the surface you are laying on. Feel how the pelvis tilts backwards and has rolled over your hands. Tip the pelvis forward and feel how the lower back rises again. Remove your hands and repeat the tipping forward and backward with less and less movement. Stop when you come to a normal neutral pelvic position.

Activating your inner trunk muscles

This exercise focuses on the activation of core muscles in your back, abdomen and pelvis. It is also known as "core activation"

- Lay on your back with your knees bent and put your hands on your waist.
- ① Breathe calmly in and out and make an ssss sound and feel your fingers how the inner muscles between your pelvis bones become activated. This muscle activation should be done slowly and with a minimal force where you feel that the lower part of the stomach is pulled inward-backward-upward.
    - Alternative instructions
        - Draw the lower part of your stomach inwards from the waist of you pants
        - Imagine that you activate your lower stomach muscles just like if you were tightening av belt around you waist
        - Imagine that your holding on to go to the toalet
- Make sure that **you dont**:
    - Hold your breath, press your lower back down or bend your back forward

1b. Basic trunk muscle activation and control in conjunction with body movement in a lying position

In conjunction with leg movement

Lay on your back with your knees bent. ① Start with "core activation" ② Move your knee on one side out towards the side with and back to the middle with slow controlled movement. Repeat alternately on each side. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____

Perform the same exercise in side lying with movement of one leg. Perform even on the other side thereafter

Repetitions_____

In conjunction with arm movement

① Start "core activation". ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____

2a. Basic trunk postural control in a sitting position

With neutral posture, loading of the spine is optimally distributed. Feel how the physical loading on your back increases when you sit with hunched posture, and how it relieves when you hold a neutral posture.

Training of posture in sitting position:

- Sit on a chair with your hands under your buttocks.
- ① Rotate your pelvis forward over your hands. You should feel like you are arching your back more. Rock your pelvis backward so you return to a neutral back posture. ② Rotate your pelvis backwards so that you have a hunched posture. Continue to rotate your pelvis backards and forwards a few times

- Stop in a position where you feel you have a even weight distribution over your hands and neutral back posture.
- Your ears, shoulders and hips should create a straight line vertically.

2b. Basic trunk muscle activation in a sitting position

Sit on a chair with good posture. ① Train holding a ”core activation”.

Repititions_____

2c. Basic trunk muscle activation and control in conjunction with body movement in a sitting position

In conjunction with leg movement

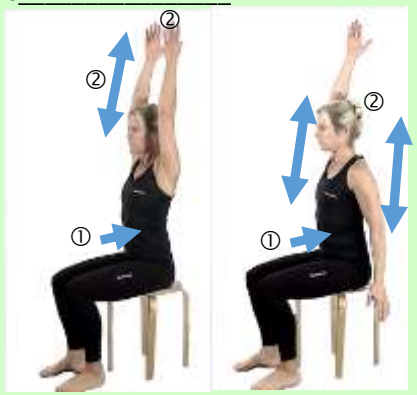
Sit on a chair or training ball. ① Start with ”core activation”. ② Lift up your knees alternately with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____

In conjunction with arm movement

① Start ”core activation”. ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.

Repetitions_____



3a. Basic trunk postural control in a standing position

With neutral posture, loading of the spine is optimally distributed. Feel how the physical loading on your back increases when you sit with hunched posture, and how it relieves when you hold a neutral posture.

Training of posture in sitting position:

- Stand with your feet hip width apart
- ① Shift your weight forwards and backwards and find a neutral weight distribution over the soles of your feet.
- ② Bend and straighten your knees a few times and find the position where your knees are slightly bent.
- ③ Tilt your pelvis forwards and backwards a few times and the position in the middle where you pelvis has a neutral position.
- ④ Move your head backwards with your chin in.
- ⑤ Bring your shoulders up and then relax your shoulders.
- Your ears, shoulders, hips, knees and feet should now be in a straight line.

① ② ③ ④ ⑤

3b. Basic trunk muscle activation in a standing position

Stand with a neutral posture. ① Train holding a ”core activation”.
Antal_____

3c. Basic trunk muscle activation and control in conjunction with body movement in a standing position.

In conjunction with weight transfering

Stand with a neutral posture. Place you feet wide apart. ① Start ”core activation”. ② Transfer your weight from one leg to the other alternately. Maintain a stable positioning of your trunk and pelvis.
Repetitions_____

In conjunction with arm movement

Stand with a neutral posture. ①Start ”core activation”. ② Bring your arms up över your head, together or alternately, with slow controlled movement. Maintain a stable positioning of your trunk and pelvis.
Repetitions_____

Part 2: Graded training of muscle strength, coordination and endurance		
Difficulty level A	**Difficulty level B**	**Difficulty level C**
1A) Pelvis lifts in lying position Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor. Repetitions_____  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.  	**1B) Pelvis lifts + leg kicks in lying position** Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor. ③ Lift and extend one leg while maintaining a stable positioning of your trunk and pelvis. Lower your foot to the floor again and lower the pelvis. Repeat and change legs every time. Repetitions_____ each side  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.	**1C) Single leg pelvis lift i lying position** Lay on your back with your knees bent and arms by your side. ① Start with ”core activation”. ② Lift up your pelvis from the floor and at the same time lift and extend one leg. Lower your foot to the floor again and lower the pelvis. Repeat and change legs every time. Repetitions_____ each side  Tip: Increase resistance by using theraband placed over you pelvis and hold the ends down with your hands.

2A) Knee lifts in lying position Lay on your back with your knees bent and put your hands on your waist. ① Start with ”core activation”. ② Lift one fot slowly up by bending your hip while maintaining a stable positioning of your trunk and pelvis. Slowly bring your fot back to the floor. Repeat and change legs every time. Repetitions_____ each side  	**2B) Straight leg raises in lying position** Lay on your back with your knees bent and put your hands on your waist. ① Start with ”core activation”. ② Extend and lift one leg while maintaining a stable positioning of your trunk and pelvis. Slowly bring your leg back to the floor. Repeat and change legs every time. Repetitions_____ each side  	**2C) Rotating sit-ups in lying position** Lay on your back with your knees bent. ① Start with ”core activation”. ② Place your hands behind your head and bring your opposite knee and elbow together by bending you back forwards. Repeat alternately on each side. Repetitions_____ each side 

3A) Hip muscle training in lying position	3B) Hip muscle training in side lying position	3C) Hip muscle training in side lying position
Lay on your back with your knees bent and arms by your side. Tie a theraband around your knees. ① Start with ”core activation”. ② Move your knees slowly away from each other and slowly back again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____  	Lay on your side with your knees bent. Tie a theraband around your knees. ① Start with ”core activation”. ② Move your top knee slowly away from the other and slowly back down again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____ each side  	Lay on your side with your legs straignt. Tie a theraband around your ankles. ① Start with ”core activation”. ② Move your top leg slowly away from the other and slowly back down again while maintaining a stable positioning of your trunk and pelvis. Repetitions_____ each side  Alternative Stand on one leg in a crouched position. Straighten up and move your free leg diagonally backwards just like skating. Repeat alternately on each side.

4A) Side plank + arm movement
Lay on your side with support of your lower arm and knee and lift up your pelvis.
① Start with ”core activation”.
② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up over your head.

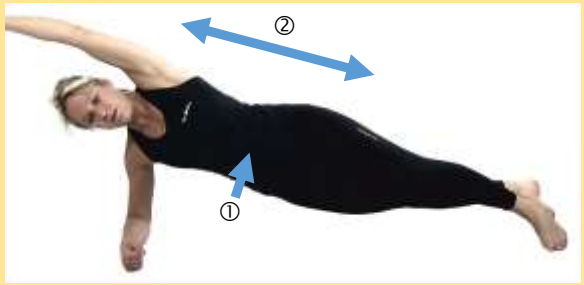
The exercise can be done with the pelvis still (static) or by moving the pelvis up and down (dynamically). Perform also on the other side.

Repetitions_____ each side

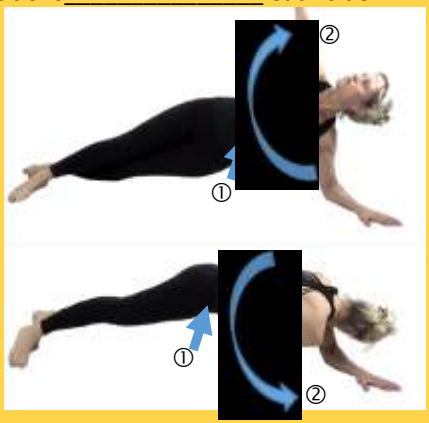
4B) Side plank + arm movement
Lay on your side with support of your lower arm and feet and lift up your pelvis.
① Start with ”core activation”.
② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up over your head.

The exercise can be done with the pelvis still (static) or by moving the pelvis up and down (dynamically). Perform also on the other side.

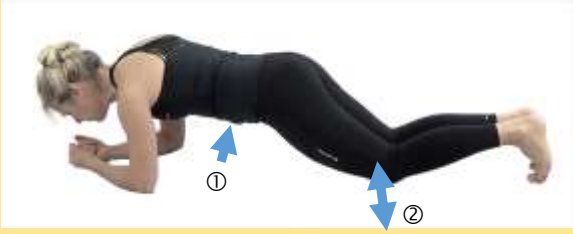
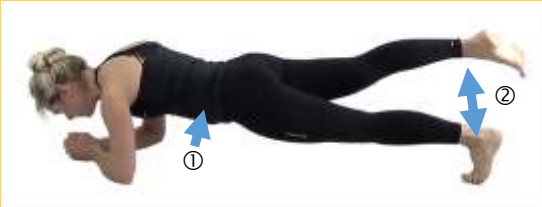
Repetitions_____ each side



4C) Side plank + arm movement
Lay on your side with support of your lower arm and feet and lift up your pelvis.
① Start with ”core activation”.
② Maintain a stable positioning of your trunk and pelvis while bringing your free arm up and rotating your back.
Repetitions_____ each side



Alternative: Stand beside a therband tied to a pole. Pull the theraband diagonally across your body and rotate your back.
Repetitions_____ each side

5A) Chair plank	**5B) Floor plank**	**5C) The plank + leg lifts**
Stand on your knees and support your lower arms on a chair or pilates ball. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor. Hold _____ seconds. Bring your knees back down to the floor. Repetitions_____  	Stand on your knees and support your lower arms on the floor. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor. Hold _____ seconds. Bring your knees back down to the floor. Repetitions_____  	Stand on your knees and support your lower arms on the floor. ① Start with ”core activation”. ② Maintain a stable positioning of your trunk and pelvis while you lift your knees from the floor holding your legs straight. Lift one foot up from the floor and hold _____ seconds. Bring your foot back down to the floor. Repetitions_____ each side 

6A) 4-point kneeling superman exercise

Position yourself on your hands and knees with your back straight.

① Start with ”core activation”.

② Maintain a stable positioning of your trunk and pelvis while you lift up and down one arm alternately. Try instead one leg alternately. When this is easily accomplished, combined these so that you lift an arm and opposite leg up and down simultaneously and alternate sides.

Repetitions_____ each side

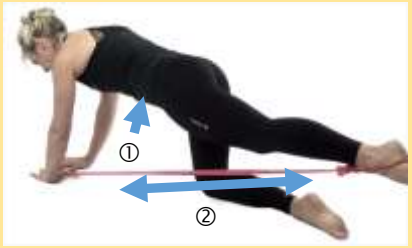
6B) 4-point kneeling theraband exercise

Positition yourself on your hands and knees with your back straight. Tie a theraband around your fot and hold on to the other end with your hands.

① Start with ”core activation”.

② Lift up and straighten your leg. Hold 5 seconds and then bring your leg down again.

Repetitions_____ each side



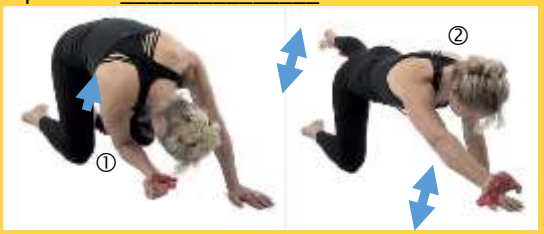
6C) Superman exercise with theraband

Position yourself on your hands and knees with your back straight. Tie a theraband around your fot and hold on to the other end with your opposite hand.

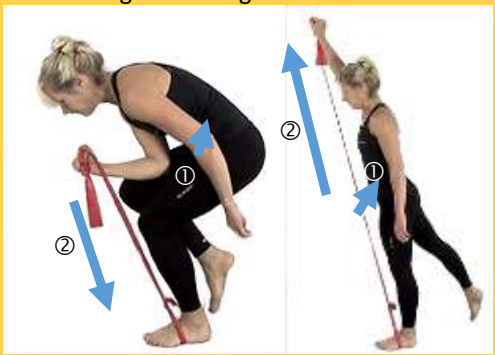
① Start with ”core activation”, curl your back and bring your opposite knee and elbow together while holding the theraband.

②. Slowly straighten your back, arm and opposite leg to stretch out the theraband. Perform the movement with good control of motion.

Repetitions_____ each side



Alternativ: Try performing the same exercise while standing on one leg.



7A) Push-ups against a wall

① Start with ”core activation”

② Perform push-ups against a wall while maintaining straight back posture.

Repetitions_____

7B) Push-ups against a table

① Start with ”core activation”

② Perform push-ups against a table while maintaining straight back posture.

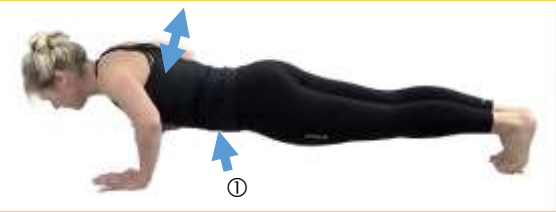
Repetitions_____

7C) Push-ups on the floor

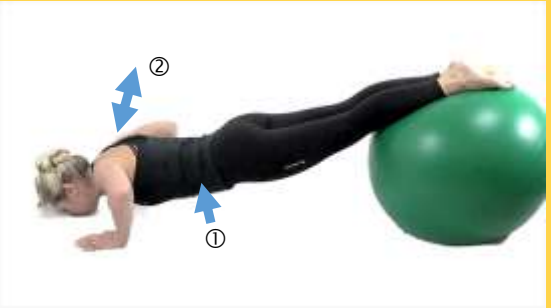
① Start with ”core activation”

② Perform push-ups while maintaining straight back posture.

Repetitions_____



Alternativ: Try performing the same exercise with your feet on a pilates ball.

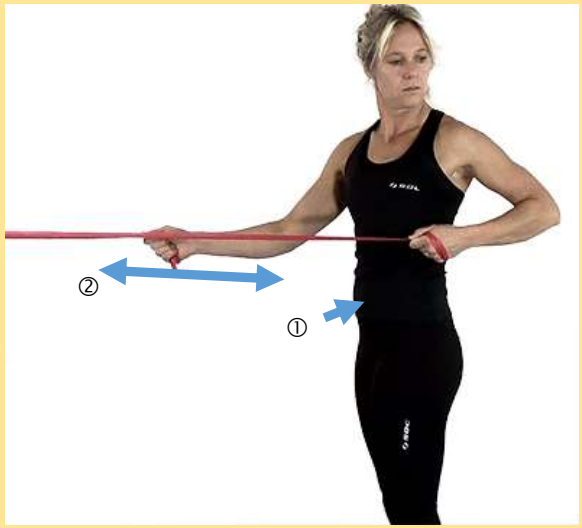


8A) Standing arm lifts
Hold on to the ends of a theraband and stand on the middle of theraband
① Start with ”core activation”.
② Maintain a straight back posture while you lift your arms up over your head against the resistance of a theraband.

Repetitions_____

8B) Standing rows
Hold on to the ends of a theraband placed around a pole.
① Start with ”core activation”.
② Maintain a straight back posture while you perform arm rows alternately from side to side.

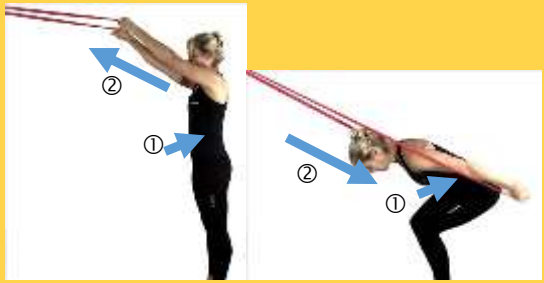
Repetitions_____



8C) Standing straight arm lifts
Hold on to the ends of a theraband and stand on the middle of theraband.
① Start with ”core activation”.
② Maintain a straight back posture and straight arms while you lift your arms alternately against the resistance of a theraband.

Repetitions_____ each side

Alternative: Try performing straight arm ski rows.



9A) Squats

Stand with your back against the wall or with a pilates ball between your back and the wall. Place your feet hip width apart.

① Start with ”core activation”.

② Maintain a straight back posture while you perform a squat up to about 90 degrees of knee and hip bending.

Repetitions_____

9B) Squats with your arms över your head

Stand with your back against the wall or with a pilates ball between your back and the wall. Place your feet hip width apart and your hands över your head.

① Start with ”core activation”.

② Maintain a straight back posture while you perform a squat up to about 90 degrees of knee and hip bending.

Repetitions_____

9C) Standing high knee lifts

Stand with your back against the wall, place your feet hip width apart and your arms on the wall.

① Start with ”core activation”.

② Maintain a straight back posture while you perform high knee lifts with alternating legs.

Repetitions_____ each side

10A) Tandem stance lunging weight tranfers
Stand with one foot a step length in front of the other foot.
① Start with ”core activation”.
② Maintain a straight back posture while you perform weight transfer forwards and backwards from foot to foot. Try even with your other foot forward.

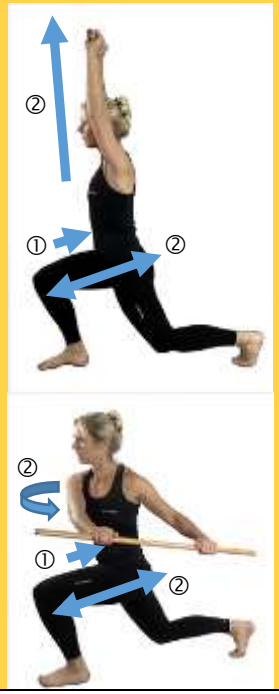
Repetitions_____ each side

10B) Lunges
Stand with your feet hip width apart and your arms up horizontal to your body.
① Start with ”core activation”.
② Maintain a straight back posture while you perform forward lunges by taking av step forward with your weight over that leg och then taking a step back again. Alternate which foot you step forward with.

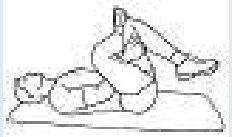
Repetitions_____ each side

10C) Lunges with simultaneous upper body movement
Stand with your feet hip width apart and your arms up horizontal to your body.
① Start with ”core activation”.
② Maintain a straight back posture while you perform forward lunges by taking av step forward with your weight over that leg och then taking a step back again. Alternate which foot you step forward with. At the same time as you lung, try lifting upp your arms over your head or rotating your upper body from side to side when holding a stick.

Repetitions_____ each side



Training range of movement		
1A) Backward bending (elbow support) Lay on your stomarch and support yourself on your underarms/elbows. Bend your back backwards by pressing up from your underarms/elbows and return to the start position again. Repetitions_____ 	**1B) Backward bending (bent arms)** Lay on your stomarch and support yourself with your hands. Bend your back backwards by pressing up from your hands but dont straighten your elbows and thereafter return to the start position again. Repetitions_____ 	**1C) Backward bending (straight arms)** Lay on your stomarch and support yourself with your hands. Bend your back backwards by pressing up from your hands and straightening your elbows and thereafter return to the start position again. Repetitions_____ 
2A) Foward bending while laying on your back Lay on your back and bring your knees up to your stomach, then return to the start position. Repetitions_____ 	**2B) Forward bending on hands and knees** Position yourself on your hands and knees with your back straight. Bend your back forward pressing your lower back upwards while bending your hips and knees so that your knees are in contact with your chest. Return to the starting position. Repetitions_____ 	**2C) Forward bending in sitting or standing** Stand/sit with your back straight. Starting bending forwards nd bringing your hands down towards the floor. Try to even bend your lower back. Return to your starting position. Repetitions_____ 

3A) Back rotation (lower back) Lay on your back and bring your knees down towards the floor on onside and then over to the other side. Repetitions_____ each side 	**3B) Back rotation (lower back and thoracic)** Lay on your back and bring your knees down towards the floor on one side while simultaneously reaching out with your opposite arm upwards and sidewards. Change sides by bringing your knees over to the other side and reach out with your opposite arm upwards and sidewards. Repetitions_____ each side 	**3C) Back roation (full range)** Lay on your back and bring your left knee down towards the floor on your left side while simultaneously reaching out with your left arm upwards and sidewards. Change sides by bringing your knee over to the other side and reach out with your opposite arm upwards and sidewards. Repetitions_____ each side 
Before and after exercise, stretching exercises help your muscles. Each stretch can be done several times, with <30 second holds. Here are suggestions for stretching.	**Stretching of your buttock muscles** 	**Stretching of your hip muscles** 
Stretching of your thigh muscles 	**Stretching of the back of your thighs** 	**Stetching of the inside of your thighs/groin** 

General training - getting in shape

Training form

Regular physical exercise as a part of everyday life is important for maintaining good health and fitness. For this, we recommend following a training program prescribed by your physiotherapist. Your training can consist of, for example: walks, nordic walking, cycling, jogging, swimming, dancing, gym. Choose which training form is best for you. You can work out alone or with others in a group. The most important thing is that you feel that you take the time for physical activity in your everyday life.

Training intensity

Training intensity can be regulated through a so-called "pacing model". This means that you slowly and gradually increase your training intensity without overloading. You "pace" yourself in a controlled way to reach your goals. You can monitor your level of exertion by using a scale of 6-20 where the scale is based on your approximate pulse when you multiply by 10.

You should preferably training with a level of exertion between

11 (fairly light) and 14 (somewhat hard).

You should start exercising at about 20% less duration than you are capacble of. If you feel that the exercise feels very easy (at level 9 or below), you can increase your exercise duration slightly so that you feel at least a farily light exertion level (level 11).

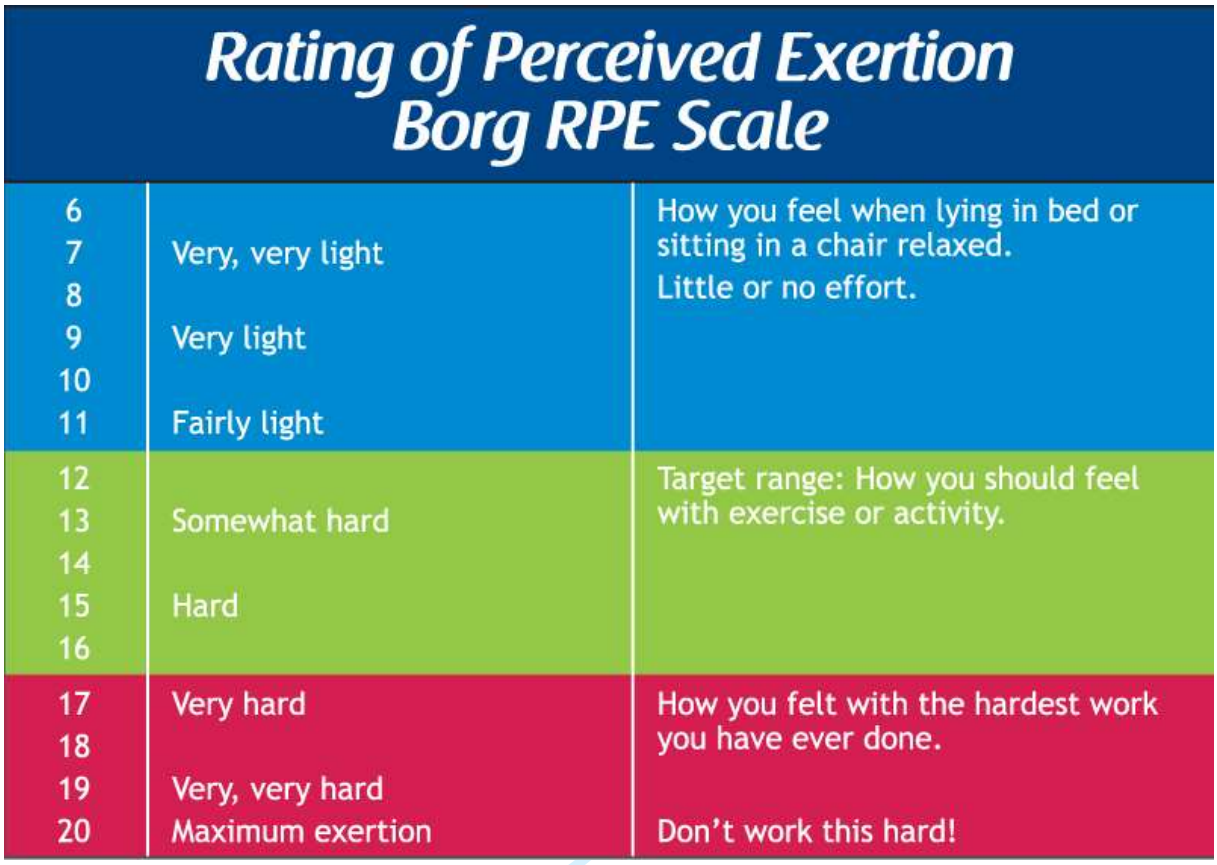
When you experience your exercise exertion is on average under a "somewhat hard" lavel (below 14), you can increase your exercise by 20% after 2 weeks. If you are on level 15 or more, you can continue with the same training for an additional 2 weeks.

When your training duration lasts 30 minutes, you can increase the load by increasing the intensity to 15/16 (Hard - you can not speak on at this intensity) in 10 minute intervals. Then you can increase the number of minutes on this intensity (15/16) every second week.

If you have a bad day, you should work out half of what you planned. In this way you can increase your exercise gradually, without risking doing too much.

Training Contract:

I will perform …….. as my training form
I will train 3 times/week
I will begin with …….. minutes
I will increase my training intensity with 20 % every second week until reach my goal capacity.



Training diary

Name:

Your physiotherapist will fill in which exercises you should train. You can cross off when you have performed the exercises.

Week	Day	BetterBack☺ Part 1			BetterBack☺ Part 2										BetterBack☺ Range of movement			General training
		1	**2**	**3**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**1**	**2**	**3**	**Borgskalan**
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Summary of the workshop to provide training in the use of the BetterBack☺ model of care.

Schedule	Content		Brief description	Learning objectives	BCTs used
Day 1 08:15-08:30	Presentation		Welcome and introduction		
Day 1 08:30-08:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 1 08:50-09:40	Presentation	LBP clinical guidelines	Present evidence based guideline recommendations and the development process behind the recommendations	To understand current evidence based recommendations for primary care of LBP and stakeholder involvement in their development	- Instruction on how to perform the behavior - Credible source - Information about other's approval
Day 1 09:40-10:00	Presentation	Background to BetterBack☺ model of care	Outlines the goals for the day, defines and conceptualizes the BetterBack☺ model of care and communicates need for the model of care	To understand aims, objectives and learning outcomes for the practitioner education	- Credible source - Social reward - Pros and cons - Comparative imagining of future outcomes
Day 1 10:00-10:20	Swedish fika	Reflection	Informal discussion about aims of the BetterBack☺ model of care compared to current practice	To evaluate the practical aims of the BetterBack☺ model	- Social support
Day 1 10:20-11:40	Demonstration	Use of implementation tools	Demonstration of how evidence based recommendations can be practically applied in the BetterBack☺ model of care	To understand how to practically use implementation tools to assist clinical reasoning for matching assessment findings with appropriate diagnosis and treatment	- Instruction on how to perform the behaviour - Demonstration of behaviour - Problem-solving - Feedback on behaviour
Day 1 11:45-12:00	Reflection	Use of implementation tools	In pairs, participants discuss reflections upon how they can practically apply the implementation tools into their clinical practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Framing/reframing
Day 1 12:00-13:00	Lunch break				
Day 1 13:00-14:30	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model implementation tools using therapist-	To develop practical skills in the use of the BetterBack☺ model clinical reasoning tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

			patient role-play. Feedback is provided from the tutor and between peers		
Day 1 14:30-15:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To learn how peers used BetterBack☺ model clinical reasoning tools	- Graded task - Verbal persuasion about capability
Day 1 15:00-15:20	Swedish fika	Reflection	Informal discussion about the practical use of the BetterBack☺ model of care compared to current practice	To evaluate the practical use of the BetterBack☺ model clinical reasoning tools	- Social support
Day 1 15:20-15:40	Summary of the day	Question and answer session and close	Learning outcomes are summarised		- Feedback on behaviour
Day 2 08:15-08:30	Discussion		Reflections after the first day of the workshop		
Day 2 08:30-09:00	Presentation		Benefits of using the implementation tools for assessment, diagnosis and intervention	To appreciate how to practically use implementation tools to assist clinical reasoning for aligning assessment, diagnostics and treatment	- Instruction on how to perform the behaviour - Information about social and environmental Consequences - Credible source - Information about other's approval
Day 2 09:00-09:20	Demonstration	BetterBack☺ model treatment tools	Patient education (brochure)	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 09:20-10:00	Demonstration	BetterBack☺ model treatment tools	Group education	To understand how to use the implementation tools for LBP patient education	- Instruction on how to perform the behaviour
Day 2 10:00-10:20	Swedish fika	Reflection	Informal discussion about which patients group education is relevant	To reflect on the practical use of the BetterBack☺ model	- Social support
Day 2 10:20-11:00	Demonstration	BetterBack☺ model treatment tools	Exercise program	To understand how to use the implementation tools for an exercise program for LBP	- Instruction on how to perform the behaviour
Day 2 11:00-12:00	Task	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support

Day 2 12:00-13:00	Lunch break				
Day 2 13:00-13:30	Task continued	Use of implementation tools	Participants are divided into 3 work groups who each transition between 3x30min patient scenario workstations. Participants practice the application of the BetterBack☺ model treatment tools using therapist-patient role-play. Feedback is provided from the tutor and between peers	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Behavioural practice/rehearsal - Feedback on behaviour - Social support
Day 2 13:30-14:00	Task	Feedback on work with patient scenarios	Each group discuss and give feedback on their work with the first patient scenario station (10min per group)	To develop practical skills in the use of the BetterBack☺ model treatment tools	- Graded task - Verbal persuasion about capability
Day 2 14:00-14:30	Demonstration	BetterBack☺ model of care website	Display of to navigate the BetterBack☺ model of care website	To understand how to use the BetterBack☺ model of care website	- Instruction on how to perform the behaviour
Day 2 14:30-15:00	Task	Potential future outcomes of the BetterBack☺ model of care implementation	Participants write on post-it notes the most important future outcomes of the BetterBack☺ model of care implementation based on: 1. A professional perspective 2. A patient perspective	To appreciate the potential outcomes of the BetterBack☺ model of care	- Comparative imagining of future outcomes
Day 2 15:00-15:30	Presentation		Clinical champion presents an administrative action plan (designed earlier in consensus with clinical colleagues) for the implementation of the BetterBack☺ model of care at their clinic	To reflect on the practical use of the BetterBack☺ model of care website	- Action planning
Day 2 15:30-15:50	Questionnaire	Participating physiotherapists record background information, PABQ, PCQ, DIBQ	Participants receive 20 minutes to complete the questionnaire	To generate descriptions recorded by physiotherapists before and after BetterBack☺ model of care	
Day 2 15:50-16:00	Diploma		Participants completing the workshop receive a CME diploma		- Incentive