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Effects of a community-based multicomponent rehabilitation programme for patients with fibromyalgia: Protocol for a randomised controlled trial

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Abstract

Introduction People with fibromyalgia suffer from symptoms such as widespread pain, nonrefreshing sleep, fatigue and reduced quality of life. Efficacy of pharmacological treatment is questionable and non-pharmacological treatments are recommended as first-line therapy. To date the majority of fibromyalgia patients in Norway are not offered any targeted treatment. The aim of this randomised controlled trial is to investigate the effects of a community-based multicomponent rehabilitation program comprising an acceptance- and mindfulness-based group intervention, the Vitality Training Programme (VTP), followed by tailored physical activity counselling.

Materials and methods General practitioners refer potential participants to a rheumatologist in specialist health care for diagnostic clarification and assessment of comorbidities. Inclusion criteria are widespread pain/fibromyalgia ≥ three months, age 20 to 50 and work participation (minimum part-time) within the last two years. The intervention group attends the VTP comprising ten weekly four-hour group sessions plus a booster session after six months. Thereafter, they receive twelve weeks of individually tailored physical activity counselling by physiotherapists at community-based Healthy Life Centers. The control group follows treatment as usual. The primary outcome is Patient Global Impression of Change. Secondary outcomes include self-reported pain, fatigue and sleep quality, psychological distress, mindfulness, health-related quality of life, physical activity, work ability and exercise beliefs and habits. To achieve a power of 80% and allow for 10% dropout, 70 participants are needed in each arm. All analyses will be conducted on intention-to-treat bases and measured as differences between groups at 12 months follow-up.

Ethics and dissemination The study is approved and granted by the Norwegian South-Eastern Regional Health Authority (reference 2016015). Ethics approval was obtained from Regional Committee for Medical and Health Research Ethics (reference 2015/2447/REK sør-øst A).

Results will be submitted to appropriate journals and presented in relevant conferences and social media.

Trial registration ISRCTN 96836577. Registered 12 July 2016.

Strengths and limitations of the study

- The multicomponent rehabilitation programme consists of modalities that have previously been found to be effective for people with rheumatic and musculoskeletal diseases.
- Sustainability of effects will be measured at one year follow-up.
- The inclusion of patients from both rural and urban communities will enhance the generalisability of the results.
- It is not possible to examine the effectiveness of single components of the programme.
- Some participants may experience the multicomponent rehabilitation programme to be too comprehensive and time-consuming.

Introduction

Fibromyalgia (FM) is a heterogeneous and still unexplained disease that poses major personal and societal challenges in terms of costs and complexity. It is one of the most common chronic pain conditions with an estimated prevalence of 2 % worldwide[1]. In Norway, it is estimated that FM affects as much as 6% of the women and 3 % of the men [2]. The cardinal symptom of FM is widespread pain characterised by reduced pressure pain thresholds and hyperalgesia. In 2010 the American College of Rheumatology (ACR) introduced new diagnostic criteria that also included other somatic symptoms, such as nonrefreshing sleep, fatigue, difficulties with memory and concentration, irritable bowel syndrome, headache and depression [3]. The complexity of FM symptoms constitutes a major burden for individuals and is a common cause of sick leave, disability benefit and extensive use of health care services [2]. Although the FM diagnosis has become increasingly recognised during the last decades, there are still some physicians who question its validity. Several patients experience disbelief, lack of understanding and stigmatisation from their general practitioners (GPs) as well as from the social security systems, colleagues and family [1 4].

Current treatments for FM are non-curative and the efficacy of pharmacological treatment alone is questionable [5]. Recent updated evidence-based recommendations from the European League Against Rheumatism (EULAR) conclude that optimal management requires prompt diagnosis and thereafter a graduated follow-up [6]. The initial management of FM should focus on patient education and non-pharmacological interventions, such as graded physical exercise and individually tailored psychological therapies for those with mood disorder or unhelpful coping strategies. The interventions may be combined in multicomponent rehabilitation programmes. Pharmacotherapy is only recommended for severe pain and sleep disturbances [6].

In Norway the main responsibility for management of FM is assigned to the primary health care services [7]. Some FM patients are referred to physiotherapists and a few to rehabilitation

in specialist care. However, to date, the majority of FM patients are not offered any tailored treatment in the primary health care.

Mindfulness- and acceptance-based training for FM patients

Mindfulness training has been defined as training in moment-to-moment awareness of internal experiences, such as thoughts, emotions and body sensations with an attitude of openness, curiosity, patience and acceptance [8]. In mindfulness practices, thoughts, emotions and sensations are not judged as good or bad, positive or negative, but as experiences and objects of awareness that we can relate to. Increased acceptance is believed to decrease the struggle to control what might not be controllable and seems to be associated with better treatment outcomes for pain patients [9]. Systematic reviews on mindfulness training for patients with FM have shown evidence for small, but significant improvements of pain and quality of life [10 11].

A Norwegian a mindfulness- and acceptance-based group intervention, the Vitality Training Programme (VTP) was developed for patients with chronic musculoskeletal pain in the late 1990s [12]. It was later adjusted for patients with inflammatory arthritis (IA) [13]. The VTP incorporates mindfulness training, values-based action and various creative methods. The main goals are to enhance participants' awareness of their health promoting resources and to strengthen their inner authority and abilities to make conscious choices in line with their personal values. Two randomized controlled trials on the VTP, one in patients with chronic musculoskeletal pain and one in patients with IA, showed reduced emotional distress, improved pain coping and mental well-being in the intervention groups compared to the control groups. The group with IA also showed decreased fatigue and increased self-efficacy. The effects were sustained or increased at one year follow-up [13 14]. However, a longitudinal pre-post-test study on the VTP in patients with IA and FM showed substantial improvements in the IA group, but no changes in the FM group. The reason for these differences remains unclear, but it may be related to the long disease duration in the FM patients. Living with pain

over many years without access to relevant treatment might lead to development of maladaptive coping strategies that may be difficult to change. Hence, it was suggested that future studies should investigate effects of the VTP in FM patients with more recent disease onset [15 16]. The VTP is implemented in some rheumatology specialist departments and in specialist rehabilitation, but to date there is no systematic implementation and evaluation in primary health care.

Physical exercise for FM patients

Studies have demonstrated that compared to healthy women people with FM are less physically active and have lower perceived functional ability [17]. Two systematic reviews on physical exercise in FM patients found evidence that aerobic exercise reduces pain, fatigue and depressed mood and improves health-related quality of life and physical fitness [17 18]. The amount and intensity of initial aerobic exercises should be adapted to the individual level of physical fitness and patients should start at a level just below their capacity and gradually increase the duration and intensity [18]. Studies have demonstrated that appropriately progressed muscle strengthening activities is safe and effective for individuals with FM and should be considered as part of a multi-faceted treatment plan [17].

Since 2004, Healthy Life Centres (HLC) have been established in most Norwegian municipalities [19]. The HLCs are based on a salutogenic framework aiming at strengthening peoples' capacities to use their own health resources and make health-friendly choices. They provide low-threshold easily accessible activities and interventions targeted at supporting behavioural changes and management of lifestyle issues, such as indoor and outdoor physical activity, healthy diet courses, smoking cessation and short mental health interventions. The physical activity interventions include aerobic and strengthening exercises usually twice a week for a 12-week period. Some HLCs also offer yoga and mindfulness exercises. Health professionals working at HLCs are mainly physiotherapists and nutritionists. All are educated

in Motivational interviewing (MI), which is both a treatment philosophy and a set of methods employed to help people increase intrinsic motivation by exploring and resolving ambivalence about behavioural change. MI has demonstrated effectiveness for clients regardless of problem severity, age, and gender [20]. One of the main groups that utilise HLCs is people with chronic pain condition, including FM. However, many FM patients are reluctant to participate in the general exercises because they are afraid of increasing their pain. For FM patients it seems to be important that the exercise programmes are individually tailored and that the graded approach is followed.

Aim and research questions

The overall aim of this trial is to evaluate the effectiveness of a multicomponent rehabilitation programme for patients with newly diagnosed FM delivered in primary health care.

The primary objective is to study the hypothesis that patients with newly diagnosed FM who participate in a community-based multicomponent rehabilitation programme will improve their self-perceived health compared to patients who follow their "treatment as usual". The rehabilitation programme comprises the VTP plus 12 weeks physical activity counselling at a HCL.

More specifically, the study will investigate the following research questions:

1. Does a community-based multicomponent rehabilitation programme relieve newly diagnosed FM patients' symptoms burden in terms of reduced pain, fatigue, sleep disturbances and psychological distress?
2. Does a community-based multicomponent rehabilitation programme increase FM patients' physical activity?
3. Does a community-based multicomponent rehabilitation programme increase newly diagnosed FM patients' work ability?

Trial development and design

A project group including a patient representative, two GPs, a representative for community rehabilitation service, a rheumatologist and health professionals educated as VTP facilitators have been involved in the project development and will be consulted throughout the trial. The study is a pragmatic parallel randomised controlled trial with two arms (ISRCTN 96836577). The multicomponent rehabilitation program is a complex intervention with several interacting components and has followed the new Medical Research Council guidance for Developing and evaluating complex interventions [21]. The protocol has been developed in line with the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) [22].

Methods

Study setting and recruitment of participants

The trial is a collaboration between the rheumatology specialist department at Diakonhjemmet Hospital in Oslo, two municipal districts in the city of Oslo and six rural municipalities in geographical proximity to Oslo. GPs and physiotherapists in the eight municipalities will identify potential participants and refer the patients to a rheumatologist at Diakonhjemmet Hospital for diagnosis clarification and assessment of comorbidities. To enhance recruitment the project coordinator (TH) and the project leader (HAZ) have visited all GP offices in the eight municipalities and written information is sent by e-mail and per post. Moreover, flyers have been distributed to offices and waiting areas for potential patients to inform them to contact their GP if they are in the target group for the project. Information is also shared in relevant website and social media.

Patients will be examined and screened for eligibility by the rheumatologist. All eligible patients will be offered a three-hour FM group education programme by a rheumatologist and

a nurse, aimed at providing basic understanding about FM, pain mechanisms, psychological factors, physical activity and coping strategies. Short mindfulness and yoga exercises will be introduced. This programme is currently part of standard care for FM patients at Diakonhjemmet Hospital. Additionally, the project coordinator will inform about the VTP and present the logistics of the study. The participants have the opportunity to ask questions before they consent to participate. The programme will be arranged regularly throughout the recruitment period until the target sample size is obtained.

The multicomponent rehabilitation programme will be conducted in the municipalities. HAZ and TH will organise the VTP at central places in Oslo and the rural municipalities. The physical activity counselling will take place at a HCL in the participants' home communities. If the community has not yet established a HCL the participants will be referred to a HCL in a nearby community. Participants will follow the HLC's ordinary 12-week physical activity counselling group programme (see Figure 1).

Eligibility criteria

Patients are eligible for inclusion if they are diagnosed with FM according to the ARC 2010 criteria for fibromyalgia [3] and aged between 20 and 50 years. Patients will be excluded if they have a comorbid inflammatory rheumatic disease, have been out of work for more than two years due to their pain condition, have a serious psychiatric disorder, have another disease that does not allow physical exercise, or are unable to understand and write Norwegian.

Interventions

The Vitality Training Program

The VTP comprises ten weekly four-hour group sessions plus a booster session after about six months. Each group have between eight and twelve participants. Every session addresses a

specific topic related to living with long-lasting health challenges: If my body could talk/ Who am I?/ Values – what is important to me?/ What do I need?/ Strengths & limitations/ Bad conscience/ Anger/ Joy/ Resources, potentials and choices/ The way ahead [12 13]. The participants are invited to explore these topics by using various creative methods, such as guided imagery, music, drawing, poetry and metaphors. The purpose is to provide opportunities for personal discoveries by intentionally attending to emotional, cognitive and bodily experiences. Participants are also invited to write logs from all exercises and to share their experiences and discoveries with other group participants. Moreover, participants are invited to attend to mindfulness meditation exercises, i.e. body scan, sitting and walking meditation and breathing exercises. They are provided with guided mindfulness audio files and are encouraged to practice these exercises in everyday life and to train awareness in daily activities. Moreover, the VTP includes gentle yoga exercises that can help patients explore their physical boundaries and overcome barriers to movement. Throughout the programme participants learn how to balance rest with activity, identify activities that are important and healthful to them, and how to overcome barriers to prioritise these activities (values-based action).

All groups have two facilitators who are certified through a one-year university training programme (30 crd) at VID Specialized University in Oslo. They follow a manual with a thorough program description [12]. Adherence to the intervention, i.e. attendance in group sessions will be recorded by the group facilitators. They will also be asked to report any adverse events.

Individual physical activity counselling and tailored physical activity

After completing the VTP, participants will be offered individual physical activity counselling by a physiotherapist at the HLCs. Interviews based on MI with focus on individual planning and goalsetting will be conducted before start up, after six weeks and at the end of week 12.

The purpose of the counselling is to help patients identify and overcome barriers to physical activity, to find exercises that can be easily continued in their everyday life and gradually increase their levels of physical activity. The physical activity will be adapted to each patient's individual level of physical fitness. The physiotherapists will record adherence to the HLC intervention and any adverse events during the 12-week period.

Control group

Patients randomised to the control group will not receive any intervention other than the three-hour FM education. They will follow their "treatment as usual" in primary care, i.e. GP consultations and any physical activity they may choose. At the FM course all participants are told that they can follow any new information as they would like. This means that control group participants may initiate life-style changes on their own initiative. There are no restrictions on participation in physical activities during the trial. The control group will be offered the VTP after completion of the last data collection, i.e. one year after inclusion.

Outcomes

Outcome measures are selected according to the core set of domains for FM defined by the Outcome Measures in Rheumatology Clinical Trials (OMERACT) [23]. All outcomes are self-reported.

Primary outcome will be Patient Global Impression of Change (PGIC) measured by a 7-point self-reported Likert scale ranging from 1 ("I feel very much worse") through 4 ("no change") to 7 ("I feel very much better") one year after inclusion. Scores of 6 and 7 are considered clinically relevant improvement [24]. This measure has previously been used in FM trials [25-27].

Secondary outcomes related to the specific research questions will be collected at baseline, 3 and 12 months. The outcomes include:

- *Pain, fatigue and sleep quality* assessed by Numerical Rating Scales (NRS) scored from 0 - 10 (10 is intolerable pain/fatigue/very bad sleep quality).
- *Psychological distress* assessed by the General Health Questionnaire-12 (GHQ-12), a widely used screening instrument measuring aspects of psychological health during the last two weeks [28]. The GHQ-12 comprises six positively phrased items, indicating psychological health, and six negatively phrased items, indicating psychological distress. The respondents are requested to compare their current status with what they consider as their "normal" condition on a four point Likert scale, scored from 0 (less than usual) to 3 (much more than usual). This gives a possible sum score between 0 (no distress at all) and 36 (much more distress than usual) [28 29].
- *Mindfulness* assessed by The Five Factor Mindfulness Questionnaire (FFMQ) that measures a general tendency to be mindful in daily life. FFMQ comprises 39 items rated on a five-point Likert scale from 1 (never or very rarely true) to 5 (always or almost always true) [30 31].
- *Health-related quality of life* assessed by the EuroQol (EQ-5D-5 L) comprising five dimensions of mobility, self-care, usual activities, pain/ discomfort and anxiety/ depression. Each dimension is scored on five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Additionally, "perceived health today" is scored from 0 (as bad as it could be) to 100 (as good as it could be) [32]. The instrument has been validated in similar populations [33] and in Norwegian context [34].
- *Physical activity* assessed by three questions addressing the average number of times exercising each week, and the average intensity and average duration each week [35].
- *Motivation and barriers for physical activity* assessed by the Exercise Beliefs and Exercise Habits questionnaire comprising twenty items that reflect beliefs about one's ability to exercise, barriers to exercise, benefits of exercise, and impact of exercise on

muscular pain. Items are scored on a five-points Likert scale, ranging from strongly agree to strongly disagree [36].

- *Work ability* assessed by the Work Productivity and Activity Impairment General Health version 2.1 (WPAI:GH) that comprises six questions to determine employment status, hours missed from work because of health problems or other reasons, hours actually worked, the degree to which health problems affected work productivity while at work and activities outside of work [37]. WPAI outcomes are expressed as impairment percentages with higher numbers indicating greater impairment and less productivity.

Moreover, the data collection includes self-reported health care consumption, i.e. visits to GP, rheumatologist, physiotherapist and other health care professionals, use of medication and alternative treatments. Self-reported harmful events will be assessed at 12 months.

Sample size

Sample size calculation is based on the primary outcome assuming that 10 % in the control group will report that they "feel much better" or "very much better" after 12 months [25] and that at least a 20 % absolute difference in improvement rate between the groups can be considered as a minimal clinically relevant difference. We anticipate 10 % losses to follow-up and will need 70 participants in each group to have at least 80 % power of detecting differences with 5 % alpha level.

Randomisation and allocation concealment

A statistician has generated an electronic randomisation list based on blocks of 20 to 24 for each geographical area to ensure approximately equal sample sixes. Participants will be given consecutive numbers. A secretary not involved in the data collection or the intervention will allocate each participant to the corresponding number on the randomisation list and inform the

patients about group allocation by telephone and written letter. Due to the nature of the implementation strategy it is not possible to blind the patients or the health professionals. The project leader and the research coordinator who are responsible for the data collection and data analyses will not be aware of group allocation.

Data collection

Participant flow is shown in Figure 1. Data will be collected electronically by a solution delivered by Infopad (www.infopad.no) before randomisation (baseline), after the VTP (3 months), and at 12-months follow-up. This electronic solution is risk evaluated and follows the Code of Conduct for information security in the health care and care services [38]. Participants will be registered in the electronic system by the project coordinator. Participants receive an e-mail with a unique link to the questionnaire at each assessment point and can respond to the questionnaire on their individual electronic device (computer, mobile phone or tablet). Participants who do not possess an electronic device will receive a paper version of the questionnaire.

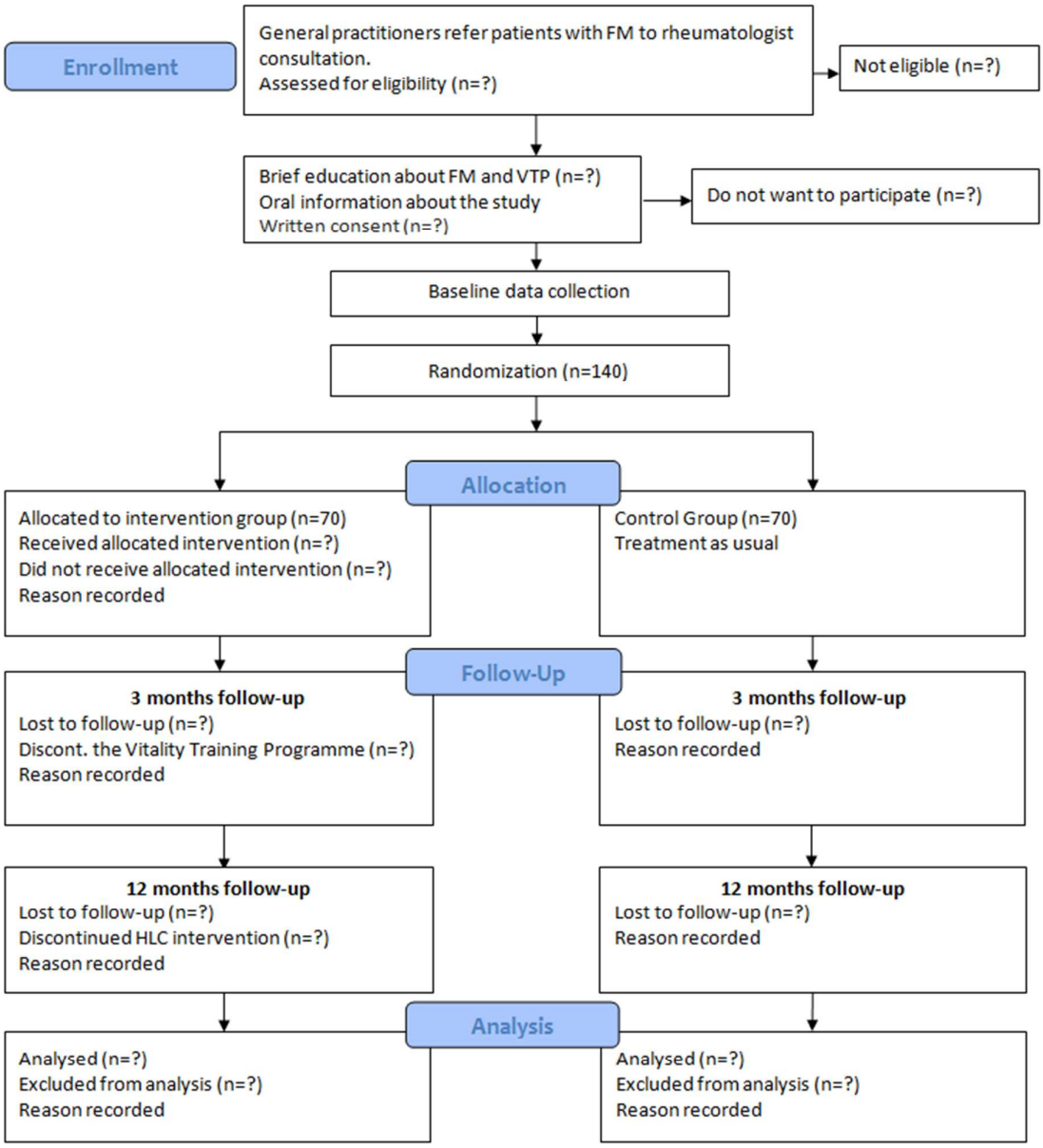

Fig. 1 Study Flow chart

Statistical analysis

The treatment effects will be analysed on an intention-to-treat basis with all randomised participants retaining their original allocated group and measured as differences between groups at 12 months. Analyses of covariance (ANCOVA) will be used for continuous outcomes and logistic regression analyses for dichotomous outcomes. The level of

significance will be set to $p \leq 0.05$ and the confidence level to 95 %. We will use the IBM SPSS Statistics 24 (IBM Corporation) to analyse the data.

Ethical approval

Study design, information strategy, written consent formula, and data security are approved by the Regional Committee for Medical and Health Research Ethics (2015/2447/REK sør-øst A). The trial will be carried out in accordance with the Helsinki Declaration. Participants will receive written and oral information about the study processes and interventions before they sign a written declaration of voluntary participation. They have the right to withdraw from the study at any time without any explanation.

All included participants will receive a consultation with a rheumatologist and a brief patient education intervention that either corresponds to or is better than their currently provided care. Participants who are randomised to the multicomponent rehabilitation programme will receive a potentially more effective intervention. Control group participants will receive the current standard of care that is delivered in their respective community. Thus, no participants will receive an intervention that is below standard treatment. Any potential treatment harms will be registered throughout the trial period.

DISCUSSION

Fibromyalgia is a complex chronic condition with high levels of disability, extensive use of health care services and important impact on patients' quality of life. Current pharmacological treatments for patients with FM are not curative and initial management should be non-pharmacological [6]. Patients with FM should be treated in primary health care, but to date the majority of FM patients are not offered any targeted interventions. This paper describes the rationale and design of an RCT investigating the effects of a multicomponent community-

based rehabilitation programme for patients with FM. The rehabilitation programme will fill a gap in the management of people with FM and if found effective, can be recommended as a rehabilitation model for people with FM in primary health care. We aim at reaching patients at an early stage of their disease to prevent further development of disability and therefore we will include only patients of 50 years and below. The design of the multicomponent rehabilitation programme is based on updated international recommendations for management of FM, including a group-based coping intervention to strengthen patients' health promoting resources (the VTP) and graded physical exercise [6]. The rationale for offering patients the VTP before the physical exercise counselling is that many patients may have previous stressful life experiences and emotional burdens that may be a barrier to behavioural change [39]. Throughout the VTP the participants may acquire alternative coping strategies and more constructive ways to deal with stress, which may facilitate their participation in physical activity. The individual physical activity counselling will follow the current practice at the HLCs and thus ensure the feasibility of the intervention and strengthen the external validity of the study. The inclusion of patients from both rural and urban communities will also enhance the generalisability of the results.

Some participants may experience the multicomponent rehabilitation programme to be too comprehensive and recruiting sufficient number of patients may be a challenge. GPs in the respective municipalities will be approached with information about the project before and during the study period. Moreover, potential participants will be given extensive information about the programme before they consent to participate and again before they start the VTP in order to enhance adherence. Previous research shows that behavioural change takes time and that interventions that include multiple strategies are more successful [40]. Many patients with FM express frustration about the lack of treatment possibilities and have felt neglected by the health care system [41]. They are likely to be motivated to receive any treatment that can

improve their condition. Moreover, the Norwegian social security system can provide "sick-leave for single treatment days" to facilitate participation during work time.

The effect of the intervention will be measured in accordance with its aims and content. The validity of the primary outcome measure, PGIC, has been assessed in a prospective observational cohort study in FM patients and was found to be a clinically relevant measure to assess perceived impact of disease management [27]. The secondary outcomes are based on a recommended core set from OMERACT [24] and thus enable comparison with results from other studies.

The study has been developed in close collaboration with a project group comprising a patient partner, a rheumatologist, two GPs and a health professional representing rehabilitation service in one of the communities. If the intervention is proven effective, this group will contribute to disseminating and implementing the results in clinical practice.

Trial status and publication

Enrolment for the trial began in November 2016 and recruitment is still in progress. Data collection will continue until the target sample size is reached, approximately December 2018. Results will be published in peer-reviewed scientific journals and communicated to patients and clinicians in national journals, conferences and social media.

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Footnotes

Contributers

HAZ, KBH and EB conceived the project idea and designed the study. TH, HAZ and SAP are responsible for recruitment. TH and HAZ are responsible for acquisition of data and data management. TH has drafted the manuscript. HAZ has critically revised the manuscript. SAP, KBH and EB have read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interest.

Ethics approval

The researchers have obtained approval from the Regional Committee for Medical and Health Research Ethics in South East Norway (2015/2447/REK sørøst A). Written consent to participate will be collected before enrolment to the trial.

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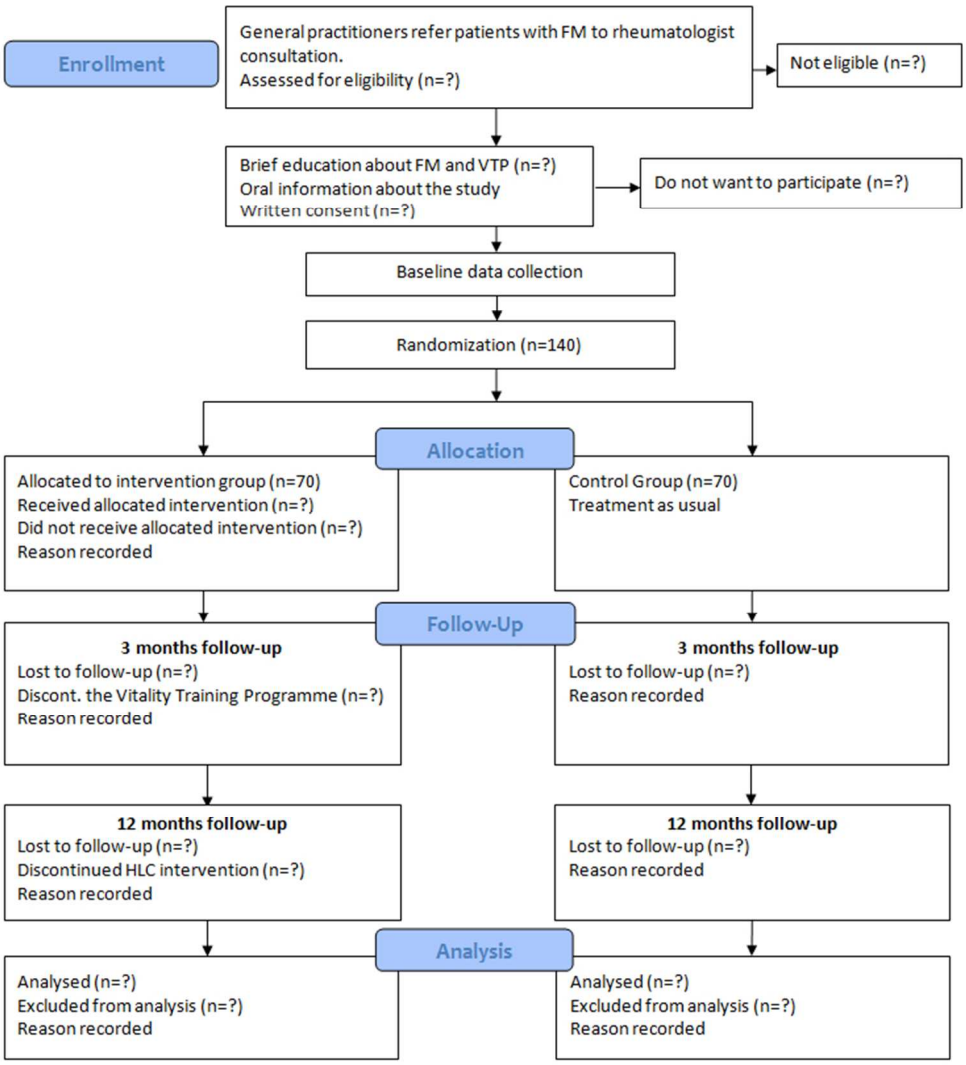

Fig. 1 Study Flow chart

Figure 1. Study Flow chart

201x224mm (96 x 96 DPI)

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

Section/item	Item No	Description	Addressed on page number
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	3
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	3
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	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	NA
	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)	NA

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	___4 - 8_____
	6b	Explanation for choice of comparators	____NA_____
Objectives	7	Specific objectives or hypotheses	____7_____
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)	____8_____

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	___8 - 9_____
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)	____9_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	___11 - 12_____
	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)	____NA_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____NA_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	____12_____
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	___13 - 14_____
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)	Figure 1 p. 16

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	13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9 – 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	13
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	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
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	12-14
	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	17

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	14
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	15 - 16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	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)	15 - 16
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	NA
	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	NA
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	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
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)	NA

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
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	16
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	NA
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	NA
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	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA (available in Norwegian)
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	NA

*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.

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Effects of a community-based multicomponent rehabilitation programme for patients with fibromyalgia: Protocol for a randomised controlled trial

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Effects of a community-based multicomponent rehabilitation programme for patients with fibromyalgia: Protocol for a randomised controlled trial

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Keywords: fibromyalgia, rehabilitation, primary health care, mindfulness- and acceptance based interventions, physical activity, health promotion

Abstract

Introduction People with fibromyalgia suffer from symptoms such as widespread pain, non-refreshing sleep, fatigue and reduced quality of life. Effects of pharmacological treatment are questionable and non-pharmacological treatments are recommended as first-line therapy. To date the majority of fibromyalgia patients in Norway are not offered any targeted treatment. The aim of this randomised controlled trial is to investigate the effects of a community-based multicomponent rehabilitation program comprising an acceptance- and mindfulness-based group intervention, the Vitality Training Programme (VTP), followed by tailored physical activity counselling.

Materials and methods General practitioners refer potential participants to a rheumatologist in specialist health care for diagnostic clarification and assessment of comorbidities. Inclusion criteria are widespread pain/fibromyalgia ≥ three months, age 20 to 50 and work participation (minimum part-time) within the last two years. The intervention group attends the VTP comprising ten weekly four-hour group sessions plus a booster session after six months. Thereafter, they receive twelve weeks of individually tailored physical exercise counselled by physiotherapists at community-based Healthy Life Centers. The control group follows treatment as usual. The primary outcome is Patient Global Impression of Change. Secondary outcomes include self-reported pain, fatigue and sleep quality, psychological distress, mindfulness, health-related quality of life, physical activity, work ability and exercise beliefs and habits. To achieve a power of 80 % and allow for 10 % dropout, 70 participants are needed in each arm. All analyses will be conducted on intention-to-treat bases and measured as differences between groups at 12 months follow-up.

Ethics and dissemination The study is approved and granted by the Norwegian South-Eastern Regional Health Authority (reference 2016015). Ethics approval was obtained from Regional Committee for Medical and Health Research Ethics (reference 2015/2447/REK sør-

øst A). Results will be submitted to appropriate journals and presented in relevant conferences and social media.

Trial registration ISRCTN 96836577. Registered 12 July 2016.

Strengths and limitations of the study

- The multicomponent rehabilitation programme consists of modalities that have previously been found to be effective for people with rheumatic and musculoskeletal diseases.
- Sustainability of effects will be measured at one year follow-up.
- The inclusion of patients from both rural and urban communities will enhance the generalisability of the results.
- It is not possible to examine the effectiveness of single components of the programme.
- Some participants may experience the multicomponent rehabilitation programme to be too comprehensive and time-consuming.

Introduction

Fibromyalgia (FM) is a heterogeneous and still unexplained disease that poses major personal and societal challenges in terms of disease burden, non-fatal health loss and costs [1 2]. It is one of the most common chronic pain conditions with an estimated prevalence of 2 % worldwide [3]. In Norway, it is estimated that FM affects as much as 6 % of the women and 3 % of the men [4]. The cardinal symptom of FM is widespread pain characterised by reduced pressure pain thresholds and hyperalgesia. In 2010 the American College of Rheumatology (ACR) introduced new diagnostic criteria that also included other somatic symptoms, such as non-refreshing sleep, fatigue, difficulties with memory and concentration, irritable bowel syndrome, headache and depression[5]. The complexity of FM symptoms commonly reduces patients' wellbeing and has an important influence on their quality of life[6]. In Norway FM is a common cause of sick leave, disability benefit and extensive use of health care services [4]. Although the FM diagnosis has become increasingly recognised during the last decades, there are still some physicians who question its validity. Several patients experience disbelief, lack of understanding and stigmatisation from their general practitioners (GPs) as well as from the social security systems, colleagues and family [3 7].

Current treatments for FM are non-curative and the efficacy of pharmacological treatment alone is questionable [8]. Recent updated evidence-based recommendations from the European League Against Rheumatism (EULAR) conclude that optimal management requires prompt diagnosis and thereafter a graduated follow-up [9]. The initial management of FM should focus on patient education and non-pharmacological interventions, such as graded physical exercise and individually tailored psychological therapies for those with mood disorder or unhelpful coping strategies. The interventions may be combined in multicomponent rehabilitation programmes. Pharmacotherapy is only recommended for severe pain and sleep disturbances [9].

In Norway the main responsibility for management of FM is assigned to the primary health care services [10]. Some FM patients are referred to physiotherapists and a few to rehabilitation in specialist care. However, to date, the majority of FM patients are not offered any tailored treatment in the primary health care.

Mindfulness- and acceptance-based training for FM patients

It has been shown that women with FM may have maladaptive emotion regulation styles, such as difficulty in identifying and expressing feelings, which amplify pain and impede their adjustment to the disease. Moreover, women with FM commonly experience stressful and negative emotions related to depressive mood and anxiety [11 12]. In mindfulness- and acceptance-based therapies participants learn to accept their experiences of pain and stressful thoughts and emotions as part of human life that one can relate to rather than judging them as good or bad, positive or negative, and thus fostering better emotional regulation [13]. The core aspect of mindfulness is training in moment-to-moment awareness of internal experiences, such as thoughts, emotions and body sensations with an attitude of openness, curiosity, patience and acceptance [14]. Increased acceptance is believed to decrease the struggle to control what might not be controllable and seems to be associated with better treatment outcomes for pain patients [15]. Systematic reviews on mindfulness training for patients with FM have shown evidence for small, but significant improvements of pain, depression, anxiety and quality of life [16 17].

A Norwegian mindfulness- and acceptance-based group intervention, the Vitality Training Programme (VTP) was developed for patients with chronic musculoskeletal pain in the late 1990s [18]. It was later adjusted for patients with inflammatory arthritis (IA) [19]. The VTP incorporates mindfulness training, values-based action and various creative methods. The main goals are to enhance participants' awareness of their health promoting resources and to

strengthen their inner authority and abilities to make conscious choices in line with their personal values. Two randomized controlled trials on the VTP, one in patients with chronic musculoskeletal pain, including FM, and one in patients with IA, showed reduced psychological distress, improved pain coping and mental well-being in the intervention groups compared to the control groups. The group with IA also showed decreased fatigue and increased self-efficacy. The effects were sustained or increased at one year follow-up [19 20]. However, a longitudinal pre-post-test study on the VTP in patients with IA and FM showed substantial improvements in the IA group, but no changes in the FM group [21]. The reason for these differences remains unclear, but it may be related to the long symptoms duration without any targeted treatment in the FM patients. On average, these patients had experienced pain symptoms more than 10 years before they were diagnosed with FM. Living with pain over many years without access to relevant treatment might lead to development of maladaptive coping strategies that may be difficult to change. Hence, it was suggested that future studies should investigate effects of the VTP in FM patients with more recent disease onset [21 22]. The VTP is implemented in some rheumatology specialist departments and in specialist rehabilitation, but to date there is no systematic implementation and evaluation in primary health care.

Physical exercise for FM patients

Physical exercise has been defined as physical activity that is planned, structured, and repetitive with the goal to maintain or improve physical fitness, i.e. cardiorespiratory endurance, muscular strength and flexibility [23]. Studies have demonstrated that compared to healthy women people with FM are less physically active [24]. Two systematic reviews on physical exercise in FM patients found evidence that aerobic exercise reduces pain, fatigue and depressed mood and improves health-related quality of life and physical fitness [25 26]. The

amount and intensity of initial aerobic exercises should be adapted to the individual level of physical fitness and patients should start at a level just below their capacity and gradually increase the duration and intensity [25]. Studies have demonstrated that appropriately progressed muscle strengthening activities is safe and effective for individuals with FM and should be considered as part of a multicomponent rehabilitation programme [26].

Since 2004, Healthy Life Centres (HLC) have been established in most Norwegian municipalities [27]. The HLCs are based on a salutogenic framework aiming at strengthening peoples' capacities to use their own health resources and make health-friendly choices. They provide low-threshold easily accessible activities and interventions targeted at supporting behavioural changes and management of lifestyle issues, such as indoor and outdoor physical activity, healthy diet courses, smoking cessation and short mental health interventions. The physical activity interventions include aerobic and strengthening exercises usually twice a week for a 12-week period. Some HLCs also offer yoga and mindfulness exercises. Health professionals working at HLCs are mainly physiotherapists and nutritionists. All are educated in Motivational interviewing (MI), which is both a treatment philosophy and a set of methods employed to help people increase intrinsic motivation by exploring and resolving ambivalence about behavioural change. MI has demonstrated effectiveness for clients regardless of problem severity, age, and gender [28]. One of the main groups that utilise HLCs is people with chronic pain condition, including FM. However, many FM patients are reluctant to participate in the general exercises because they are afraid of increasing their pain. For FM patients it seems to be important that the exercise programmes are individually tailored and that the graded approach is followed.

Aim and research questions

The overall aim of this trial is to evaluate the effects of a multicomponent rehabilitation programme for patients with newly diagnosed FM delivered in primary health care.

The primary objective is to study the hypothesis that patients with newly diagnosed FM who participate in a community-based multicomponent rehabilitation programme will improve their self-perceived health compared to patients who follow their "treatment as usual". The rehabilitation programme comprises the VTP plus 12 weeks physical activity counselling at a HCL.

More specifically, the study will investigate the following research questions:

1. Does a community-based multicomponent rehabilitation programme relieve newly diagnosed FM patients' symptoms burden in terms of reduced pain, fatigue, sleep disturbances and psychological distress?
2. Does a community-based multicomponent rehabilitation programme increase FM patients' physical activity?
3. Does a community-based multicomponent rehabilitation programme increase newly diagnosed FM patients' work ability?

Trial development and design

A project group including a patient representative, two GPs, a representative for community rehabilitation service, a rheumatologist and health professionals educated as VTP facilitators have been involved in the project development and will be consulted throughout the trial. The study is a pragmatic parallel randomised controlled trial with two arms (ISRCTN 96836577). The multicomponent rehabilitation programme is a complex intervention with several interacting components, such as a group intervention with several interactive methods plus individually tailored physical exercise counselling. The project group has followed the new Medical Research Council guidance for Developing and evaluating complex interventions [29].

The protocol has been developed in line with the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) [30] (Online Supplementary file 1).

Methods

Study setting and recruitment of participants

The trial is a collaboration between the rheumatology specialist department at Diakonhjemmet Hospital in Oslo, two municipal districts in the city of Oslo and six rural municipalities in geographical proximity to Oslo. GPs and physiotherapists in the eight municipalities will identify potential patients and refer the patients to a rheumatologist at Diakonhjemmet Hospital for diagnosis clarification and assessment of comorbidities. To enhance recruitment the project coordinator (TH) and the project leader (HAZ) have visited all GP offices in the eight municipalities and written information is sent by e-mail and per post. Moreover, flyers have been distributed to offices and waiting areas for potential patients informing them to contact their GP if they are in the target group for the project. Information is also shared in relevant website and social media.

Patients will be examined and screened for eligibility by the rheumatologist. All eligible patients will be offered a three-hour FM group education programme by a rheumatologist and a nurse, aimed at providing basic understanding about FM, pain mechanisms, psychological factors, physical activity and coping strategies. Short mindfulness and yoga exercises will be introduced. This programme is currently part of standard care for FM patients at Diakonhjemmet Hospital. Additionally, the project coordinator will inform about the VTP and present the logistics of the study. The patients have the opportunity to ask questions before they consent to participate. The programme will be arranged regularly throughout the recruitment period until the target sample size is obtained.

The multicomponent rehabilitation programme will be conducted in the municipalities. HAZ and TH will organise the VTP at central places in Oslo and the rural municipalities. The physical exercise will take place at a HCL in the participants' home communities. If the community has not yet established a HCL the participants will be referred to a HCL in a nearby community. Participants will follow the HLC's ordinary 12-week physical activity counselling and exercise programme (Figure 1).

Eligibility criteria

Patients are eligible for inclusion if they are diagnosed with FM according to the ARC 2010 criteria for fibromyalgia [5] and aged between 20 and 50 years. Patients will be excluded if they have a comorbid inflammatory rheumatic disease, have been out of work for more than two years due to their pain condition, have a serious psychiatric disorder, have another disease that does not allow physical exercise, or are unable to understand and write Norwegian.

Interventions

The Vitality Training Program

The VTP comprises ten weekly four-hour group sessions plus a booster session after about six months. Each group have between eight and twelve participants. Every session addresses a specific topic related to living with long-lasting health challenges: If my body could talk/ Who am I?/ Values – what is important to me?/ What do I need?/ Strengths & limitations/ Bad conscience/ Anger/ Joy/ Resources, potentials and choices/ The way ahead [18 19] (Online Supplementary file 2). The participants are invited to explore these topics by using various creative methods, such as guided imagery, music, drawing, poetry and metaphors. The purpose is to provide opportunities for personal discoveries by intentionally attending to emotional, cognitive and bodily experiences. Participants are also invited to write logs from

all exercises and to share their experiences and discoveries with other group participants. Moreover, participants are invited to attend to mindfulness meditation exercises, i.e. body scan, sitting and walking meditation and breathing exercises. They are provided with guided mindfulness audio files and are encouraged to practice these exercises in everyday life and to train awareness in daily activities. Moreover, the VTP includes gentle yoga exercises that can help participants explore their physical boundaries and overcome barriers to movement. Throughout the programme participants learn how to balance rest with activity, identify activities that are important and healthful to them, and how to overcome barriers to prioritise these activities (values-based action).

All groups have two facilitators who are certified through a one-year university training programme (30 crd) at VID Specialized University in Oslo. They follow a manual with a thorough program description [18]. Adherence to the intervention, i.e. attendance in group sessions will be recorded by the group facilitators. The participants need to attend at least 50 % of the sessions to expect effect. They will also be asked to report any adverse events (Online Supplementary 3).

Individual physical activity counselling and tailored physical exercise

After completing the VTP, participants will be offered individual physical activity counselling by a physiotherapist at the HLCs. Interviews based on MI with focus on individual planning and goalsetting on activity and participation level will be conducted before start-up, after six weeks and at the end of week 12. The goals will be defined by the participant in collaboration with a physiotherapist. A common goal may be to reduce pain. An activity plan may be to perform strengthening and aerobic exercises, for example cycling or Nordic walking three times a week. Another aim is to learn the balance between activity and rest and find the right dosage of the exercises. The purpose of the counselling is to help participants identify and overcome barriers to physical activity, to find exercises that can be easily continued in their

everyday life and gradually increase their levels of physical activity. The physical exercise will be adapted to each participant's individual level of physical fitness. The physiotherapists will record adherence to the HLC intervention and any adverse events during the 12-week period.

Control group

Patients randomised to the control group will not receive any intervention other than the three-hour FM education. They will follow their "treatment as usual" in primary care, i.e. GP consultations and any physical activity they may choose. At the FM course all participants are told that they can follow any new information as they would like. This means that control group participants may initiate life-style changes on their own initiative. There are no restrictions on participation in physical activities during the trial. The control group will be offered the VTP after completion of the last data collection, i.e. one year after inclusion.

Outcomes

Outcome measures are selected according to the core set of domains for FM defined by the Outcome Measures in Rheumatology Clinical Trials (OMERACT) [31 32]. All outcomes are self-reported.

Primary outcome will be Patient Global Impression of Change (PGIC) that evaluates overall health status as perceived by the patient in a 7-point single-item scale ranging from 1 ("I feel very much worse") through 4 ("no change") to 7 ("I feel very much better") one year after inclusion[33]. Scores of 6 and 7 are considered clinically relevant improvement [34]. This measure has previously been used in FM trials [33 35 36].

Secondary outcomes related to the specific research questions will be collected at baseline, 3 and 12 months. The outcomes include:

- *Pain, fatigue and sleep quality* assessed by Numerical Rating Scales (NRS) scored from 0 - 10 (10 is intolerable pain/fatigue/very bad sleep quality).
- *Psychological distress* assessed by the General Health Questionnaire-12 (GHQ-12), a widely used screening instrument measuring aspects of psychological health during the last two weeks [37]. The GHQ-12 comprises six positively phrased items, indicating psychological health, and six negatively phrased items, indicating psychological distress. The respondents are requested to compare their current status with what they consider as their "normal" condition on a four point Likert scale, scored from 0 (less than usual) to 3 (much more than usual). This gives a possible sum score between 0 (no distress at all) and 36 (much more distress than usual) [37 38].
- *Mindfulness* assessed by The Five Factor Mindfulness Questionnaire (FFMQ) that measures a general tendency to be mindful in daily life. FFMQ comprises 39 items rated on a five-point Likert scale from 1 (never or very rarely true) to 5 (always or almost always true) [39 40].
- *Health-related quality of life* assessed by the EuroQol (EQ-5D-5 L) comprising five dimensions of mobility, self-care, usual activities, pain/ discomfort and anxiety/ depression. Each dimension is scored on five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Additionally, "perceived health today" is scored from 0 (as bad as it could be) to 100 (as good as it could be) [41]. The instrument has been validated in similar populations [42] and in Norwegian context [43].
- *Physical activity* assessed by three questions addressing the average number of times exercising each week, and the average intensity and average duration each week [44].
- *Motivation and barriers for physical activity* assessed by the Exercise Beliefs and Exercise Habits questionnaire comprising twenty items that reflect beliefs about one's ability to exercise, barriers to exercise, benefits of exercise, and impact of exercise on

muscular pain. Items are scored on a five-point Likert scale, ranging from strongly agree to strongly disagree [45].

- *Work ability* assessed by the Work Productivity and Activity Impairment General Health version 2.1 (WPAI:GH) that comprises six questions to determine employment status, hours missed from work because of health problems or other reasons, hours actually worked, the degree to which health problems affected work productivity while at work and activities outside of work [46]. WPAI outcomes are expressed as impairment percentages with higher numbers indicating greater impairment and less productivity.

Moreover, the data collection includes self-reported health care consumption, i.e. visits to GP, rheumatologist, physiotherapist and other health care professionals, use of medication and alternative treatments. Self-reported adverse events will be collected electronically at 12 months. The respondents report if they have or have not experienced any adverse events. If relevant, the respondents report whether they perceived the events caused by the VTP or the HLC intervention with the possibility to elaborate (Online Supplementary file 3).

Sample size

Sample size calculation is based on the primary outcome assuming that 10 % in the control group will report that they "feel much better" or "very much better" after 12 months [35] and that at least a 20 % absolute difference in improvement rate between the groups can be considered as a minimal clinically relevant difference. We anticipate 10 % losses to follow-up and will need 70 participants in each group to have at least 80 % power of detecting differences with 5 % alpha level.

Randomisation and allocation concealment

A statistician has generated an electronic randomisation list based on blocks of 20 to 24 for each geographical area to ensure approximately equal sample sixes. Participants will be given consecutive numbers. A secretary not involved in the data collection or the intervention will allocate each participant to the corresponding number on the randomisation list and inform the patients about group allocation by telephone and written letter. Due to the nature of the implementation strategy it is not possible to blind the patients or the health professionals. The project leader and the research coordinator who are responsible for the data collection and data analyses will not be aware of group allocation.

Data collection

Participant flow is shown in Figure 1. Data will be collected electronically by a solution delivered by Infopad (www.infopad.no) before randomisation (baseline), after the VTP (3 months), and at 12-months from baseline. This electronic solution is risk evaluated and follows the Code of Conduct for information security in the health care and care services [47]. Participants will be registered in the electronic system by the project coordinator. Participants receive an e-mail with a unique link to the questionnaire at each assessment point and can respond to the questionnaire on their individual electronic device (computer, mobile phone or tablet). Participants who do not possess an electronic device will receive a paper version of the questionnaire.

Statistical analysis

The treatment effects will be analysed on an intention-to-treat basis with all randomised participants retaining their original allocated group and measured as differences between groups at 12 months. Analyses of covariance (ANCOVA) will be used for continuous outcomes with baseline values as covariates. Logistic regression analyses for dichotomous

outcomes. The level of significance will be set to $p \leq 0.05$ and the confidence level to 95 %. We will use the STATA 14.0 (Texas, USA) to analyse the data.

Ethical approval

Study design, information strategy, written consent formula, and data security are approved by the Regional Committee for Medical and Health Research Ethics (2015/2447/REK sør-øst A). The trial will be carried out in accordance with the Helsinki Declaration. Participants will receive written and oral information about the study processes and interventions before they sign a written declaration of voluntary participation. They have the right to withdraw from the study at any time without any explanation.

All included participants will receive a consultation with a rheumatologist and a brief patient education intervention that either corresponds to or is better than their currently provided care. Participants who are randomised to the multicomponent rehabilitation programme will receive a potentially more effective intervention. Control group participants will receive the current standard of care that is delivered in their respective community. Thus, no participants will receive an intervention that is below standard treatment. Any potential adverse events will be registered throughout the trial period. All personal information about potential and enrolled patients as well as patient consent forms will be securely stored in paper formats in a locked closet in a locked room. Electronical data will be stored in a password protected solution (www.infopad.no) during the study and for five years after completion. The project leader (HAZ) will regularly review the data collection process, and ensure that the data are collected, stored and handled in accordance with the current guidelines. The data are only available to the project leader (HAZ), the project coordinator (TH) and the project secretary.

Patient and Public Involvement

The VTP was developed in the1990s in close collaboration with people with chronic musculoskeletal pain [18]. The burden of the intervention has been assessed in the two previous randomised controlled trials [18 22]. The present project emerged from informal conversations between the project manager (KBH), the project leader (HAZ) and the leader of the FM group in the Norwegian Rheumatism Association (EB). Further development of the project, such as study design, research questions and recruitment of patients has been thoroughly discussed with representatives for the Patient Advisory Board at the rheumatology department at Diakonhjemmet Hospital. The electronic questionnaire has been tested and amended by user representatives.

In addition to publishing in international peer-reviewed journals, the results of the study will be disseminated through various information channels to the project group members and the public, including web-sites, social media, national and international networks, conferences and congresses. Moreover, the results will be published in a yearly special issue of the journal of the Norwegian Rheumatism Association that focuses on resent research and communicated to patients in relevant meetings arranged by this association.

DISCUSSION

Fibromyalgia is a complex chronic condition with extensive use of health care services and important impact on patients' quality of life. Current pharmacological treatments for patients with FM are not curative and initial management should be non-pharmacological [9]. Patients with FM should be treated in primary health care, but to date the majority of FM patients are not offered any targeted interventions. This paper describes the rationale and design of an RCT investigating the effects of a multicomponent community-based rehabilitation programme for patients with FM. The rehabilitation programme will fill a gap in the management of people with FM and if found effective, can be recommended as a

rehabilitation model for people with FM in primary health care. We aim at reaching patients at an early stage of their disease to prevent further development of disability and therefore we will include only patients of 50 years and below, and patients who have not been out of work for more than two years due to their pain condition. The design of the multicomponent rehabilitation programme is based on updated international recommendations for management of FM, including a group-based coping intervention to strengthen patients' health promoting resources (the VTP) and graded physical exercise [9]. The rationale for offering patients the VTP before the physical activity counselling is that many patients may have previous stressful life experiences and emotional burdens that may be a barrier to lifestyle change [48]. Throughout the VTP the participants may acquire alternative coping strategies and more constructive ways to deal with stress, which may facilitate their participation in physical exercise. The individual physical activity counselling will follow the current practice at the HLCs and thus ensure the feasibility of the intervention and strengthen the external validity of the study. The inclusion of patients from both rural and urban communities will also enhance the generalisability of the results.

Some participants may experience the multicomponent rehabilitation programme to be too comprehensive and recruiting sufficient number of patients may be a challenge. GPs in the respective municipalities will be approached with information about the project before and during the study period. Moreover, potential participants will be given extensive information about the programme before they consent to participate and again before they start the VTP in order to enhance adherence. Previous research shows that behavioural change takes time and that interventions that include multiple strategies are more successful [49]. Many patients with FM express frustration about the lack of treatment possibilities and have felt neglected by the health care system [50]. They are likely to be motivated to receive any treatment that can

improve their condition. Moreover, the Norwegian social security system can provide "sick-leave for single treatment days" to facilitate participation during work time.

The effect of the intervention will be measured in accordance with its aims and content. The validity of the primary outcome measure, PGIC, has been assessed in a prospective observational cohort study in FM patients and was found to be a clinically relevant measure to assess perceived impact of disease management [33]. The secondary outcomes are based on a recommended core set from OMERACT [32] and thus enable comparison with results from other studies.

The study has been developed in close collaboration with a project group comprising a patient partner, a rheumatologist, two GPs and a health professional representing rehabilitation service in one of the communities. If the intervention is proven effective, this group will contribute to disseminating and implementing the results in clinical practice.

Trial status

Enrolment for the trial began in November 2016 and recruitment is still in progress. Data collection will continue until the target sample size is reached, approximately December 2018.

Footnotes

Contributers

HAZ, KBH and EB conceived the project idea and designed the study. TH, HAZ and SAP are responsible for recruitment. TH and HAZ are responsible for acquisition of data and data management. TH has drafted the manuscript. HAZ has critically revised the manuscript. SAP, KBH and EB have read and approved the final manuscript.

Funding

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Competing interests

The authors declare that they have no competing interest.

Ethics approval

The researchers have obtained approval from the Regional Committee for Medical and Health Research Ethics in South East Norway (2015/2447/REK sørøst A). Written consent to participate will be collected before enrolment to the trial.

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Figure legend

Figure 1. Study Flow chart

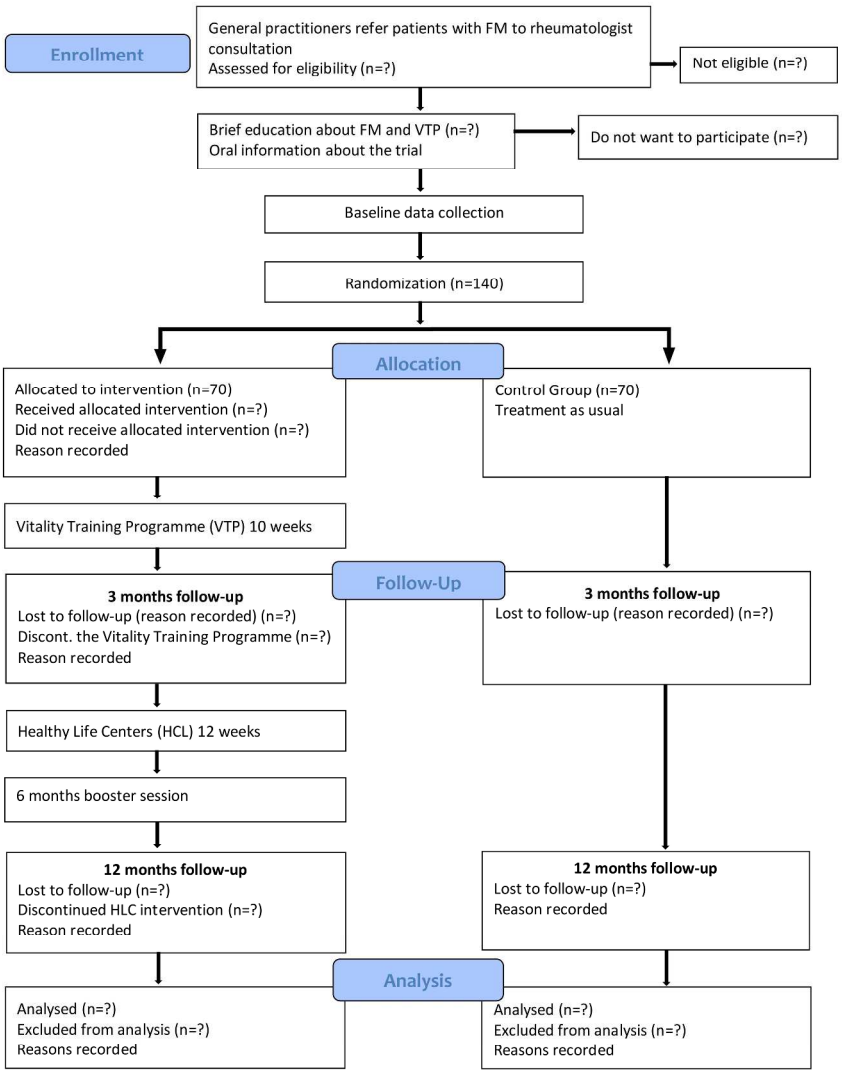

Figure 1. Study Flow chart

279x361mm (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	Item No	Description	Addressed on page number
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	3
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	3
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	20
	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	NA
	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)	NA

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	4 - 8
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	7 - 8
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)	8
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	9 - 10
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)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10 - 12
	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)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
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	12 - 14
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)	Figure 1

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	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9 – 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	14
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	14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
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	12 - 15
	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	15

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	15 - 16
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	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	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)	15 - 16
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	NA
	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	NA
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	14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
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)	NA

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
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	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
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	16
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	NA
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	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA (available in Norwegian)
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	NA

*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.

Online Supplementary file 2

Example from group session 6: Anger

The first part of the programme is common in all sessions: Participants are invited to share their reflection on experiences from home exercises after previous session in group of three to four persons. They are encouraged to read their reflective diaries for each other and to share and listen with an open, non-judgemental attitude without discussing or giving advice. Next, participants are invited to take part in an awareness exercise instructed by one of the group facilitators. They are guided to attend to their thoughts, feelings and bodily senses in the present moment with openness, acceptance and curiosity. After the exercise, they are invited to share their experiences with one other person in the group.

In the next part of the session, the group facilitators introduce the topic "anger" by giving a short introduction about relationship between chronic illness and emotions and the purpose of addressing emotions. The participants are then invited to take part in an exercise with awareness of anger, introduced by one of the facilitators: "Think of the word anger… or to be angry. Notice what you become aware of… thoughts, maybe concrete situations, perhaps memories from the past… Are the situations that you become aware of new or old? Maybe both?... What do you experience in your body right now when you think of anger or being angry?... Also note whether the word anger or being angry evokes any other feelings…"

Awareness of anger is continued in movement to music. The music allows participants to express anger with their body and they are invited to let their bodies do what they want to do while listening to the music. Then, written hypothetical sentences are used to enhance discovery to tactic knowledge, for example: "If there are any other emotions related to my feeling of anger, it must be…" Participants are further invited to share and reflect upon experiences and discoveries from the exercise in small groups and in a plenary session.

The next exercise is a guided imagery intending to help individuals to connect to their experiences of anger in the present moment, and to explore its meaning. Further, crayons and white paper are used to draw an image of anger as experienced here and now. Again, participants are invited to share and reflect in small groups and in plenary, with focus on new discoveries and the consequences of these discoveries from the participants` daily life. Finally, they write a diary about their experiences from the whole session.

Before closing the session, participants are asked to be aware of how they relate both to their own anger and anger from others in their daily lives. They are provided with guided mindfulness audio files and are encouraged to practice these exercises in everyday life and to train awareness in daily activities. They are asked to write reflective diaries about their thoughts, emotions and bodily senses. The session ends with a relaxation exercise. Each session follow the same structure with exercise adapted to the particular topic.

The group facilitators in the SALSA trial are health professionals, such as nurses and physiotherapists, and certified through a one-year university training programme (30 crd) at VID Specialized University in Oslo.

Online Supplementary file 3

Self-reported adverse events assessed at 12-months.

Have you carried out any type of treatment during the last year? (With treatment we mean medication, physical exercise, self-management course or any alternative treatments) Yes/ No Have you experienced any adverse event as a result of the treatment? Yes/ No If yes, which adverse events as a result of treatment? Elaborate In your opinion, which treatment(s) do you think the adverse event was/were caused by? Elaborate