

# THE LANCET

## **Supplementary webappendix**

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Hill JC, Whitehurst DGT, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet* 2011; published online Sept 29. DOI:10.1016/S0140-6736(11)60937-9.

## Webappendix 1: The Keele STarT Back Screening Tool ([www.keele.ac.uk/startback](http://www.keele.ac.uk/startback))

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

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

Not at all	Slightly	Moderately	Very much	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	0	0	1	1

Total score (all 9): \_\_\_\_\_

Sub Score (Q5-9): \_\_\_\_\_

Low = total score 0-3

High = sub score 4-5

Medium = the rest

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## **Webappendix 2: Content of the Interventions**

### **Initial assessment clinic**

Patients who consulted with back pain at one of the 10 participating GP practices within the Keele GP Research Partnership were automatically invited using practice computer systems to attend one of three half-day initial assessment clinics held weekly. Clinics were held in NHS local community physiotherapy premises staffed by physiotherapists, a study nurse and an administrator. On arrival at clinic patients first met with a study nurse to check eligibility, gain informed consent and complete the baseline questionnaire including the Keele STarT Back Screening Tool. A study administrator then telephoned the clinical trials unit telephone randomisation service and provided patient answers to each of the STarT Back Tool 9-items, so that randomisation could be stratified by risk-group. Once the patient was allocated to a treatment arm, the administrator passed them on to either the control or intervention physiotherapist as appropriate to undertake a 30 minute individual consultation including assessment, examination and initial treatment.

### **Content of the current best practice (control) intervention**

#### **Control clinic consultation**

There were nine Physiotherapists who undertook the control arm's clinic assessment and treatment. Six of these nine therapists were provided by 2 local NHS physiotherapy service managers who were responsible for providing the NHS physiotherapy services for the 10 GP practices involved in the study. Three of the nine clinic control arm therapists were hired on temporary contracts by the study team as recruitment was quicker than expected and more staff were therefore required to staff the clinics. Six of the nine physiotherapists (66%) had more than 5 years experience specialised in treating back pain problems. Therapists were provided with a half-day of training by the study team to standardise case report form data for treatment quality control purposes. Decisions about onward referral to further NHS physical therapy treatment were made using clinical judgement, based on clinical need, without knowledge of an individual's STarT Back Tool classification.

#### **Ongoing control physiotherapy**

These sessions were individualised treatments lasting 30-minutes, and were held in NHS local community outpatient premises delivered by 37 physiotherapists who already provided NHS care to back pain patients for the 10 general practices involved.

- No guidance was provided on the number of sessions or length of treatment course. However, local physiotherapy managers informed the trial team that up to 6 treatments, over a 3-month period matched their local practice.
- The first session re-assessed/examined the patient and included a detailed differential diagnosis (particularly for patients with referred leg pain/radiculopathy).
- The main treatment modalities used were Maitland and McKenzie approaches including advice, reassurance, education, exercise (some in gym classes), manual therapy and acupuncture.

## **Content of the stratified (active) intervention**

### **Stratified intervention clinic consultation**

There were six Physiotherapists who undertook the stratified arm's clinic assessment and treatment. These therapists were provided by two sources: the 2 local NHS physiotherapy service managers who were responsible for providing the NHS physiotherapy services for the 10 GP practices involved in the study, and by clinical members of research team. Four of the six physiotherapists (66%) had more than 5 years experience specialised in treating back pain problems – the same as the control therapists. Therapists were provided with a day of training by the study team to standardise the treatment provided and to explain how to treat patients within the stratified model of care including:

- The use of Keele STarT Back Screening Tool score and risk-group pathways. Prior to meeting the patient, physiotherapists were provided with administrative clinical information about the patient including their STarT Back Screening Tool score.
- A structure of the standardised 30-minute assessment and examination which included a screen for potential serious pathology (red flags) and neurological examination (lower limb changes to reflexes, sensation and muscle power). Patients were asked about their symptom history, concerns and treatment expectations. A brief examination was also made of back pain movements (including optional testing for a directional preference) and to identify any hip pathology.
- Patients received reassurance to address concerns related to their back pain and any resulting loss of function. Reassurance topics were guided by the results of the patient's STarT Back Tool score so that specific concerns could be identified and addressed on an individual basis. Messages of advice focussed on:
  - appropriate levels of activity including return to work (if appropriate) and avoiding bed rest. This was supplemented with information of local exercise venues and self-help groups together with a 15-minute educational video entitled 'Get Back Active'<sup>20</sup> to reinforce messages (which was to be organised by the clinic administrator on request from the therapist).
  - addressing patient fears supported by the 'Back Book'.<sup>21</sup>
  - addressing an individual's uncertainty about issues such as use of pain relief (medication), the role of further investigations, work issues, and the patient's likely future prognosis including methods to deal with future episodes of back pain.

### **Stratified intervention pathways for ongoing physiotherapy**

#### ***Low risk-group***

Patients allocated to the 'low risk-group' received the one-off clinic appointment described above, were reassured that further treatment was unlikely to be beneficial or necessary and were encouraged not to seek further treatment. They were, however, advised that if their symptoms deteriorated they should re-visit their GP. They were therefore discharged from further physiotherapy care at the end of the clinic consultation. Physiotherapists were responsible for providing good clinical governance to their patients and were allowed to over-rule the stratified tool if they believed the pathway being recommended for a patient was inappropriate.

#### ***Medium risk-group***

In addition to the first clinic session described above, all medium-risk patients were recommended for referral to ongoing physiotherapy treatment with one of five physiotherapists who attended three days training. The training was designed to standardise the pathway for medium-risk patients as follows:

- Individualised 30-minute physiotherapy sessions focussed on restoring function and targeting physical characteristics (disabling back pain, referred leg pain and co-morbid pain).
- Treatments were held in NHS local community physiotherapy outpatient premises staffed with guidance that patients should receive up to 6 sessions over a 3-month period.
- The first session re-assessed/examined the patient and included making a differential diagnosis particularly for patients with referred leg pain/radiculopathy.
- The main focus of treatment was to reduce back-related disability. A tailored management plan was negotiated using evidence-based treatments, including advice and explanation, reassurance, education, exercise, manual therapy and acupuncture.
- Consistent with evidence based guidelines,<sup>10</sup> bed rest, traction, massage and electrotherapy were not included in the treatment protocol.
- Moderate levels of psychological prognostic indicators were addressed, but specific training on techniques to target psychological factors was not provided for physiotherapists treating the medium risk-group of patients.
- Therapists were advised to refer non-responders on for further investigations or secondary care interventions, with supervision provided if required from a spinal specialist physiotherapist.

### ***High risk-group***

In addition to the first clinic session described above, all high-risk patients were recommended for referral to ongoing physiotherapy treatment with one of four physiotherapists who attended a total of nine days training. The training was designed to standardise the pathway for high-risk patients as follows:

- Individualised 45-minute physiotherapy sessions focussed on restoring function using combined physical and psychological approaches and targeting physical and psychological obstacles to recovery.
- Treatments were held in NHS community outpatient premises with guidance that patients should receive up to 6 sessions over a 3-month period.
- The first session re-assessed/examined the patient and included a differential diagnosis particularly for patients with referred leg pain/radiculopathy, and biopsychosocial assessment to explore patient concerns, adopting cognitive behavioural principles to address unhelpful beliefs and behaviours.
- Therapists were trained to use 'stem & leaf' questions to identify unhelpful beliefs and behaviours.
- Physical treatment modalities (exercise and manual therapy) were integrated with psychologically informed techniques to provide a credible explanation for symptoms, reassurance, education, collaborative goal setting, problem solving, pacing, graded activity, and relaxation.
- There was a specific focus on the prognostic psychological indicators identified by the STarT Back Tool such as low mood, anxiety, pain-related fear and catastrophising.
- Reasons for psychological distress were addressed using enhanced communication skills with a focus on promoting appropriate levels of activity, return to normal activities and the management of future back pain recurrences.
- Patient expectations about prognosis and implications for function were addressed and the role of active self-management emphasised. Advice about sleep and work was provided and if necessary a return to work plan implemented.
- Patients were encouraged to put management plans into practice between treatment sessions and help was given to problem solve any difficulties that arose.
- Monthly group mentoring sessions were held for physiotherapists to discuss individual cases and consolidate the training throughout the trial, with supervision provided from a Consultant Physiotherapist (pain management expertise) and a Professor of Clinical Psychology.
- Therapists were advised to refer non-responders on for further investigations or secondary care interventions.

**Webappendix 3: Details of the unit costs assigned to health care resource use data and periods of work absence collected at 12-month follow-up.<sup>a</sup>**

Health care resource	Unit Cost (£)
Study back pain clinic and physiotherapy:	
Initial clinic session (30 minutes)	21.50 <sup>b</sup>
First post-clinic session: high risk 'intervention' group (1 hour)	43.00 <sup>b</sup>
First post-clinic session: all other patients (45 minutes)	32.25 <sup>b</sup>
Follow-up sessions: high risk intervention group (45 minutes)	32.25 <sup>b</sup>
Follow-up sessions: all other patients (30 minutes)	21.50 <sup>b</sup>
Primary care contacts:	
General Practitioner: surgery consultation	31.00 <sup>b</sup>
General Practitioner: home visit	105.00 <sup>b</sup>
Practice Nurse: surgery consultation	11.00 <sup>b</sup>
Practice Nurse: home visit	20.00 <sup>b</sup>
'Other' health care professional: surgery consultation	16.00 <sup>b</sup>
Hospital-based care:	
Consultant: first attendance	124.00 <sup>c</sup>
Consultant: follow-up	103.00 <sup>c</sup>
Diagnostic tests: x-ray	31.99 <sup>d</sup>
Diagnostic tests: CT scan	100.00 <sup>c</sup>
Diagnostic tests: MRI scan	179.00 <sup>c</sup>
Diagnostic tests: blood test	17.28 <sup>e</sup>
Epidural injections	204.57 <sup>f</sup>
Other health care professionals: <sup>g</sup>	
First consultation	38.00 <sup>c</sup>
Follow-up consultation	27.00 <sup>c</sup>
Out-of-pocket treatments	Patient reported costs
Prescribed medication	Patient-specific <sup>h</sup>
Periods of work absence	Patient-specific <sup>i</sup>

<sup>a</sup> Study back pain clinic consultations were the exception; these were identified from an audit of physiotherapy service databases. Unit costs are per visit/test unless otherwise stated. Unit costs are expressed as UK averages in 2008/09 prices; unit cost estimates prior to 2008/09 were inflated using the Health Service Cost Index (Curtis L. Unit Costs of Health and Social Care 2009. Canterbury: *Personal Social Services Research Unit*, University of Kent, 2009). In the base case analysis, private care was costed as the NHS equivalent. No back pain-related hospital admissions were reported in the 12-month postal questionnaires.

<sup>b</sup> Curtis L. Unit Costs of Health and Social Care 2009. Canterbury: *Personal Social Services Research Unit*, University of Kent, 2009.

<sup>c</sup> NHS Executive. National Schedule of Reference Costs 2008. London: *Department of Health*, 2009.

- <sup>d</sup> Castelnovo E, Cross P, Mt-Isa S, Spencer A, Underwood M; TOIB study team. Cost-effectiveness of advising the use of topical or oral ibuprofen for knee pain; the TOIB study [ISRCTN: 79353052]. *Rheumatology (Oxford)* 2008; **47(7)**: 1077–81.
- <sup>e</sup> Wright M, Grieve R, Roberts J, Main J, Thomas HC; UK Mild Hepatitis C Trial Investigators. Health benefits of antiviral therapy for mild chronic hepatitis C: randomised controlled trial and economic evaluation. *Health Technol Assess* 2006; **10(21)**: 1–113.
- <sup>f</sup> NHS Executive. National Schedule of Reference Costs, 2004. London: *Department of Health*, 2005.
- <sup>g</sup> Hospital-based or private practice, e.g. physiotherapy, acupuncture, osteopathy etc.
- <sup>h</sup> British Medical Association, Royal Pharmaceutical Society of Great Britain. British National Formulary. 55th ed. London: *BMJ Books*, 2008.
- <sup>i</sup> Annual survey of hours and earnings (ASHE). London: *Office for National Statistics*, 2008. (Accessed September 6, 2011, at <http://www.ons.gov.uk/ons/rel/ashe/annual-survey-of-hours-and-earnings/2008-results/index.html>)

**Webappendix 4a: Cost components analysed in the economic evaluation of the STarT Back trial. Values are mean (sd) back pain-related resource use and costs (£) per patient, by treatment group, for patients providing health care utilisation data at 12 months (n=567), unless stated otherwise.**

Resource/cost component	Resource use (units)		Cost (£)	
	Intervention (n = 386)	Control group (n = 181)	Intervention (n = 386)	Control group (n = 181)
Study back pain clinic and physiotherapy	4.02 (2.6)	4.04 (3.7)	107.50 (92.8)	92.77 (83.2)
Primary care contacts:				
General Practitioner	1.08 (2.1)	1.30 (2.1)	33.54 (63.6)	40.27 (63.9)
Practice Nurse	0.12 (0.9)	0.12 (0.5)	1.33 (9.8)	1.27 (6.0)
Hospital-based care:				
NHS Consultant	0.22 (0.8)	0.24 (0.7)	25.15 (86.5)	27.63 (79.7)
Private Consultant	0.04 (0.3)	0.04 (0.3)	4.82 (36.1)	4.72 (30.5)
NHS x-ray	0.05 (0.2)	0.10 (0.4)	1.66 (7.5)	3.18 (11.2)
NHS CT scan	0.01 (0.1)	0.01 (0.1)	1.04 (12.4)	1.10 (10.5)
NHS MRI scan	0.07 (0.3)	0.08 (0.3)	12.06 (48.5)	14.83 (53.0)
NHS blood tests	0.02 (0.1)	0.03 (0.2)	0.27 (2.1)	0.48 (3.8)
NHS epidural injections	0.01 (0.1)	0.01 (0.1)	2.72 (23.2)	2.31 (21.4)
Private diagnostic tests (combined)	0.01 (0.1)	0.01 (0.1)	0.93 (12.9)	0.99 (13.3)
Private epidural injections	0.00 (0.1) <sup>a</sup>	0.01 (0.1)	0.55 (10.4)	1.14 (15.2)
Other health care professionals:				
Additional (non-study) NHS physiotherapy	0.59 (2.0)	1.14 (2.7)	17.25 (57.5)	33.13 (75.6)
Private physiotherapy	0.06 (0.6)	0.22 (1.2)	1.86 (17.2)	6.42 (35.5)
NHS 'other'	0.04 (0.5)	0.12 (0.9)	1.45 (17.0)	3.53 (26.8)
Private 'other'	0.30 (1.6)	0.14 (0.9)	8.52 (44.6)	4.38 (27.2)
Out-of-pocket treatments: <sup>b</sup>				
Non-opioid analgesics	87 (23)	36 (19)	1.23 (4.7)	1.14 (3.9)
Weak opioid analgesics	33 (9)	19 (10)	0.68 (8.0)	0.27 (0.8)



Non-steroidal anti-inflammatory drugs	87 (23)	39 (22)	1.01 (4.1)	1.00 (3.6)
Gels/creams/sprays	48 (12)	21 (12)	0.73 (3.4)	0.53 (1.6)
Others	101 (26)	63 (35)	6.80 (35.2)	10.29 (28.7)
Prescribed medication: <sup>b</sup>				
Non-opioid analgesics	48 (13)	19 (10)	0.86 (4.3)	1.59 (7.3)
Weak opioid analgesics	98 (27)	42 (23)	6.66 (48.9)	6.92 (31.5)
Non-steroidal anti-inflammatory drugs	88 (23)	41 (23)	1.75 (6.5)	3.47 (18.9)
Gels/creams/sprays	2 (1)	1 (1)	0.05 (0.7)	0.35 (3.7)
Others	15 (4)	9 (5)	3.44 (41.4)	1.86 (17.1)
Work-related outcomes: <sup>c</sup>				
Time off work due to low back pain <sup>d</sup>	46 (23)	33 (34)	-	-
Back pain-related work absence days	4.45 (21.2)	12.18 (35.1)	£440 (2045.0)	£1115 (3423.9)
Total health care cost scenarios:				
Total health care cost (primary imputed analysis, n = 851)			240.01 (356.3)	274.40 (350.8)
Mean difference (95% CI; p-value) <sup>e</sup>			-34.39 (-80.3 to 11.5; 0.14)	
Total health care cost (observed data, n = 567)			243.85 (285.8)	265.60 (309.6)
Mean difference (95% CI; p-value) <sup>e</sup>			-21.76 (-73.7 to 30.2; 0.41)	
Total health care cost (complete case analysis, n = 458)			239.83 (297.7)	281.75 (329.9)
Mean difference (95% CI; p-value) <sup>e</sup>			-41.93 (-104.7 to 20.9; 0.19)	

<sup>a</sup> The value of 0.00 is positive, rounded to two decimal places.

<sup>b</sup> The number (percentage) of participants reporting usage within the out-of-pocket and prescribed medication categories are given, instead of mean (sd) items/prescriptions, because of the inability to distinguish between multiple purchases and/or prescriptions. The majority of items in the 'other' category for out-of-pocket treatments were TENS machines, heat pads, supports, and corsets.

<sup>c</sup> The evaluation of work-related outcomes and the estimation of indirect costs focused on the subsample of respondents in paid employment at 12-month follow-up (298 out of 567; 200 (52%) in the intervention group, 98 (54%) in the control group).

<sup>d</sup> Value represents the number (percentage) relating to the subsample of respondents in paid employment at 12-month follow-up.

<sup>e</sup> Difference = targeted intervention - control group. Confidence intervals were generated using conventional parametric methods.

**Webappendix 4b: Descriptive and incremental health outcomes over 12 months for the primary analysis and the complete case analyses. Values are mean (sd) scores unless stated otherwise.<sup>a</sup>**

Health outcomes	Intervention	Control group	Mean difference <sup>b</sup> (95% C.I.)
Primary (imputed) analysis:	n=568	n=283	
Baseline EQ-5D	0.529 (0.31)	0.525 (0.33)	0.004 (-0.04 to 0.05)
4 month EQ-5D	0.695 (0.33)	0.656 (0.33)	0.039 (-0.01 to 0.09)
12 month EQ-5D	0.673 (0.35)	0.621 (0.37)	0.052 (0.00 to 0.10) <sup>c</sup>
QALYs over 12 months <sup>d</sup>	-	-	0.039 (0.01 to 0.07) p-value = 0.01 (2 d.p.)
Complete case analysis:	n=309	n=149	
Baseline EQ-5D	0.554 (0.30)	0.552 (0.30)	0.002 (-0.06 to 0.06)
4 month EQ-5D	0.722 (0.25)	0.691 (0.27)	0.031 (-0.02 to 0.05)
12 month EQ-5D	0.690 (0.28)	0.649 (0.29)	0.041 (-0.01 to 0.10)
QALYs over 12 months <sup>d</sup>	-	-	0.033 (0.00 to 0.06) <sup>c</sup> p-value = 0.04 (2 d.p.)

<sup>a</sup> QALYs = quality-adjusted life years; 95% CI = 95% confidence interval.

<sup>b</sup> Difference = targeted intervention - control group. Confidence intervals were generated using conventional parametric methods.

<sup>c</sup> The true value of the '0.00' figure is positive, rounded to two decimal places.

<sup>d</sup> Incremental QALY estimates following multiple regression-based adjustment for age, gender, duration of pain at baseline, and baseline scores on the RMDQ and EQ-5D.

**Webappendix 5: Cost-effectiveness acceptability curve comparing the stratified management approach (intervention group) with current best practice (control group), based on 25 000 bootstrapped cost-effect pairs**

