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#### Abstract

This deliverable provide an overview of the most common outcome measures used in randomised controlled trials conducted in patients with non-specific low back pain. Most of the listed outcome measures are available in the all languages needed in the SELFBACK trial; however, not all translations are validated.



## Document History

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## 1 Introduction

Choosing the best primary outcome measure for a randomised controlled trial is contingent on a number of factors. Not only should the outcome measure reflect the core domain that is expected to change as a result of the intervention, but it should also be able to detect relevant change in all participants, i.e., have appropriate psychometric properties.

In previous clinical trials conducted in patients with low back pain (LBP), inconsistent reporting of outcomes has hindered comparison of findings. To overcome this, Deyo et al. have published several papers suggesting standardised outcomes for use [1, 2] and in their latest paper recommend the use of composite outcomes covering several domains [2]. An example is the Oswestry Disability Index (ODI). The ODI total score is calculated based on questions regarding both pain and functional impairments [3]. In 2015, based on a 3-round Delphi study including stakeholders (i.e., health-care researchers and providers), as well as patient with LBP, Chiarotto et al. [4] identified three domains as the most important core outcomes in trials of patients with LBP.

The three domains were:

- Physical functioning
  - Definition: Impact on patient's ability to carry out daily physical activities required to meet basic needs, ranging from self-care to more complex activities that require a combination of skills [4].
- Pain intensity
  - Definition: Impact on how much a patient hurts, reflecting the overall magnitude of the pain experience [4].
- Health-related Quality of life.
  - Definition: Impact on physical, psychological and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations and perceptions [4].

These three domains were rated highest of the 41 included domains in the Delphi rounds. Additionally, the three domains were rated highest by most of the stakeholders, but patients with LBP rated psychological functioning and self-rated health over physical functioning and pain intensity [4].

## 2 The SELFBACK intervention and domain of expected change

In the SELFBACK intervention, patients with non-specific LBP will wear a wristband that logs their level of physical activity and sleep. In order to promote the patient's self-management of their LBP, the information from the wristband is combined with data from databases containing information on characteristics and outcomes of other LBP patients. This will provide a departure point for development of individualised, or targeted, information and guidance to the individual patient via a mobile app or web interface. Pain-related disability is proposed as the primary outcome for the trial. The goal of the SELFBACK Intervention is to reduce pain-related disability in the intervention group with 20% after 9 months' follow-up compared to patients receiving treatment as usual.

This report acts as the first step in consolidating the primary outcome for the SELFBACK trial. We provide information about the consensus process regarding which domains to evaluate in LBP trials and present outcomes frequently used to assess these domains.

In addition, potentially relevant outcomes used in previous trials on self-management or web/app-based interventions are presented. A more detailed overview of these outcomes will be presented as part of a systematic review (deliverable 1.1, part A). The review will comprehensively and systematically focus on content, characteristics and outcomes of previous digital self-management intervention for LBP, and thus provide the knowledge that will ultimately inform the final choice of primary outcome in SELFBACK.

The aim of this report is therefore to inform the decision concerning choice of primary outcome measure for the SELFBACK trial by identifying relevant outcome measures, describe their psychometric properties and potentials in patients with non-specific LBP of different duration, intensity and impact.

### 2.1 Methods

The information outlined in this report is based on a purposeful literature search aimed to identify reviews and overviews of core outcome domains, and outcome measures used in previous trials of patients with LBP. The body of literature was identified by members of the SELFBACK group, and based on existing studies known to the experienced researchers and experts on LBP managements within the SELFBACK group. This was combined with a search for additional relevant studies. The literature was reviewed and combined with expert opinion and experience within the research field to provide the presented overview.

The SELFBACK project entails a self-management intervention that may target substantially different domains than the outcomes outlined by reviews from Chiarotto et al. and Chapman et al. [4, 5]. Consequently, outcomes assessing other domains than the three core domains suggested by Chiarotto et al. may be equally relevant to evaluate. Therefore, already known studies on LBP patients entailing self-management interventions and web- or app-based interventions were reviewed to identify alternative outcomes.

The data is presented in tables to create an overview of the content and psychometric properties of the different outcomes, as well as to enable direct comparison between the listed outcome measures.

## 2.2 Results

### Core outcome domains

In tables 1-3, six frequently used self-reported outcome measures assessing each of the three core domains (i.e., physical function, pain intensity, and health related quality of life) are described by a number of variables as recommended by Chiarotto et al. and Chapman et al. [4, 5]. The questionnaires used to assess these core outcomes are included in Appendix 1.

### Outcomes frequently used in LBP trials or in self-management trials.

The outcome measures ‘the Pain Self-Efficacy Scale’, ‘the Tampa Scale for Kinesiophobia’ and ‘the Fear Avoidance Belief Questionnaire’ were identified as potentially relevant from experts’ previous trial experiences. The outcome measures ‘the Preparation for Decision Making Scale’ and ‘the Decisional Conflict Scale’ were identified when reviewing trials from the literature search on self-management, web or app based interventions in LBP patients. The above mentioned outcome measures are described in table 4, with the same psychometric properties as for the core outcome domains. The questionnaires listed above that is frequently used in trials are included in Appendix 2.

### Summary

This report presents outcome measures identified in a purposeful literature search, consensus recommendations and expert opinion. Although many of the listed outcome measures are recommended by international experts, other outcome measures not yet identified may be relevant. Additionally, this report identified knowledge gaps, i.e. although some questionnaires are available in several languages, not all translations are validated. The systematic review in deliverable 1.1 will offer more details that will inform the decision of the primary outcome in the SELFBACK trial.

Table 1 Outcomes	Purpose	Content	Items and response scales	Psychometric properties	Languages	Examples of use
<b>Roland and Morris disability Questionnaire (RMDQ)</b>	The RMDQ was developed to assess physical disability due to LBP in primary care research [3, 6].	The items assess performance of daily physical activities and functions.  Entail elements of impairment, disability and handicap according to the ICF [3].	24 items  The total score range from 0 to 24 with higher scores indicating more disability due to LBP [3].  The total score is calculated as the number of items answered with “yes” [3].	<i>Reliability:</i> Good internal consistency (0.84 – 0.96), test-retest reliability higher for short time (1-2 weeks) than above 6 weeks [3]. Good interclass coefficients ranging between 0.93 for LBP patients [7].  <i>Validity:</i> Good correlation with other outcomes assessing pain-related disability [3].	Original language is English.  Translated into 36 languages, including: Danish Norwegian English (US)	Hill et al. used the RMDQ as the primary outcome at 12 months follow-up for evaluating a stratified primary care intervention for patients with LBP [8].
<b>Oswestry Disability Index (ODI)</b>	The purpose of the ODI is to assess pain-related disability in people with acute, subacute or chronic LBP [3, 9].	Six sections assess pain intensity (1 item), and aspects of function and activities of daily living (9 items) [3].  The patient is asked to indicate which option that closely describes their level of disability [9].	10 items  Each section is scored on a 6-point ordinal scale, the first answer is scored 0 and the last answer is scored 5, higher score indicates higher disability.  The total score of the answered section is divided by the highest score possible and transformed into a percentage [9].	<i>Reliability:</i> High test-retest reliability (ICC 0.84 and SEM between 4 and 6) [3].  <i>Validity:</i> Adequate content and face validity, high internal construct validity [10, 11], high external construct. ODI correlates well with RMDQ and SF-36 [3].	English Danish Dutch Finnish French German Greek Norwegian Spanish Swedish	Vibe et al. used the ODI as primary outcome at 12-months follow-up to evaluate a behavioural approach compared to traditional manual therapy in chronic LBP patients [12].

*Table 1: self-reported outcomes frequently used to assess disability in non-specific low back pain patients. RMDQ: Roland-Morris disability Questionnaire, ODI: Oswestry Disability Index, LBP: low back pain*

<b>Table 2 Outcomes</b>	<b>Purpose</b>	<b>Content</b>	<b>Items and response scales</b>	<b>Psychometric properties</b>	<b>Languages</b>	<b>Examples of use</b>
The visual analogue <b>pain scale (VAS)</b>	The VAS is a multidimensional measure of pain intensity.	A continuous scale oriented either horizontally or vertically (most common). The scale has verbal anchors at each extreme, most commonly used are “no pain” and “worst imaginable pain” [13].	Single item  A 100 mm VAS ranges from 0 to 100 mm. Higher scores represent higher pain intensity.  The scale is most often 100 mm in length, but can be varied in length.	<i>Reliability:</i> Test-retest reliability is good, though higher for literate than illiterate patients [13].  <i>Validity:</i> High correlation with other pain intensity scales, such as 5-point Likert scales [13].	All languages	Simon et al. used VAS as a measure of pain intensity in evaluating the effectiveness of a web-based, individually tailored decision aid for depression or acute LBP in a randomised controlled trial [14].
Numerical Rating <b>pain Scale (NRS)</b>	The NRS is a measure of pain intensity [15].	A continuous scale of numeric values. Verbal anchors are used in the extremes, most commonly used are “no pain” and “worst imaginable pain”.  The NRS scales can be used to assess pain intensity for worst, least, average and current pain [16].	Single item  Most commonly, an 11-point scale ranging from 0 to 10 is used. Higher scores represent higher pain intensity.	<i>Reliability:</i> ICC values ranging for 0.96 to 0.95 for assessing pain intensity in other musculoskeletal pain groups [13].  <i>Validity:</i> The 11-point NRS scales has shown good validity to assess pain intensity [15].	All languages	Chapman et al. performed a systematic review to evaluate the most commonly used outcomes in LBP treatment. NRS was the most frequently used measure of pain intensity [5].

Table 2: self-reported outcome measures used to assess pain intensity in low back pain patients. VAS: visual analogue scale, NRS: Numerical rating Scale, LBP: low back pain.

Table 3 Outcomes	Purpose	Content	Items and response scales	Psychometric properties	Languages	Examples of use
<b>Euro-QOL-5D (EQ-5D)</b>	The EQ-5D is a measure of health statuses providing a simple generic measure of health ( <a href="http://www.euroqol.org">www.euroqol.org</a> ).	<p>The EQ-5D measures health-related quality of life by assessing 5 dimensions; mobility, self-care, activities of daily living, pain and anxiety/depression.</p> <p>A single item rate patients self-reported current health state on a 0 to 100 scale.</p> <p>The EQ-5D enables health-economic analysis.</p>	<p>5 items with a categorical scale (1-3) The responses to the 5 items are combined to a 5-digit number describing the health status. (<a href="http://www.euroqol.org">www.euroqol.org</a>) Lower score indicate greater disability [5].</p> <p>1 single item with a continuous scale (100mm horizontal VAS). Higher score, indicate better health.</p>	<p><i>Reliability</i> in LBP: - No data reported [5].</p> <p><i>Validity</i> in LBP: - No data reported [5].</p> <p><i>Responsiveness</i>: For the 5-items scale, responsiveness was borderline sufficient (Area under curve 0.71), and responsiveness for VAS item was sufficient (AUC 0.70) [17].</p>	<p>EQ-5D-5L in 133 languages for paper version, 58 for web version.</p> <p>English, Danish and Norwegian in both versions.</p>	<p>Del Pozo-Cruz et al. used the EQ-5D to evaluate quality of life at 9-months follow-up for a web-based intervention of daily emails of educational videos and link to exercises for patients with non-specific LBP [18].</p>
<b>Short Form health-survey (SF-36)</b>	The SF-36 was developed as a generic measure of general health [19].	The SF-36 questionnaire entail 8 subscales, that can be combined to two components scores, a Physical and mental component score.	<p>36 items</p> <p>The 8 subscales are scored from a subset of items. The scores range from 0-100, lower score indicate greater disability.</p>	<p><i>Reliability</i>: Reliability of the two components score have been reported to be over 0.90 on average [20].</p> <p><i>Validity</i>: The SF-36 have good validity in studies involving physical and mental health criteria [20, 21]</p>	Translated into 121 languages, Including Danish, Norwegian and English versions.	Nolet et al. used SF-36 to evaluate health-related quality of life (QOL) in a cohort study of 1100 individuals, and found reduced QOL at 6 months for patients with LBP [21].

Table 3: self-reported outcome measures used to assess health-related quality of life in low back pain patients. EQ-5D: the EuroQOL 5 dimension questionnaire, SF-36: the Short-Form Health-Survey, QOL: quality of life, LBP: low back pain.

Table 4 Outcomes	Purpose	Content	Items and response scales	Psychometric properties	Languages	Examples of use
<b>Pain Self-Efficacy Questionnaire (PSEQ)</b>	The PSEQ assess how confident a patient is that they can complete a task at present despite pain [22].	The PSEQ was developed to assess self-efficacy in patients with chronic pain and has been applied in a number of clinical settings, including patients with chronic LBP.  The PSEQ assess self-efficacy for both physical tasks as well as social functioning and general health [23].	10 items [23].  All items are score on a 7-point ordinal scale ranging from 0, representing “not confident at all”, to 6 “completely confident”.  The maximal score is 60. Higher numbers indicate stronger self-efficacy beliefs. [22]	<i>Reliability:</i> Internal consistency. Cronbach’s alpha ranging from 0.92 – 0.94 in LBP population [22].  <i>Validity:</i> Similarly, good factorial structure of the PSEQ was reported for LBP populations.	English Norwegian Danish	Petrozzi et al. reports the PSEQ as primary outcome to evaluate an online psychological intervention to multimodal manual therapy for chronic LBP patients (published study protocol) [24].
<b>Tampa scale of Kinesiophobia (TSK)</b>	The TSK aimed to identify kinesiophobia [25].	The questionnaire measures the patient fear of injury related to exercise or physical activity [25].	17 items are scored on a 4-point Likert scale, scores ranging from 1 (strongly disagree) to 4 (strongly agree).  The total score is calculated by summing the items, after reversing items 4, 8, 12 and 16.  Total scores range within 17 to 68.	<i>Reliability:</i> Internal consistency good (chronic LBP, $\alpha = 0.68$ to $0.80$ , acute LBP, $\alpha = 0.70$ – $0.76$ ). Test-retest (Pearson’s $r$ ). acute LBP $r = 0.78$ [25].  <i>Concurrent validity:</i> Acute LBP. Strong correlation between TSK and FABQ PA subscale, moderate correlation TSK and FABQ work subscale [25].	English Norwegian Danish	Monticone et al. used TSK as a secondary outcome and found reduced kinesiophobia in chronic LBP treated with group exercises and a cognitive behavioural therapy compared to group exercises alone [26].
<b>Fear Avoidance Belief Questionnaire (FABQ)</b>	The FABQ aims to investigate patient’s beliefs about how physical activity and work will affect their pain [27].	The FABQ can be applied as a whole including all 16 items, or it can be evaluated by two subscales, one assessing physical activities and one assessing work related fear avoidance [25, 28].	4 items are included in the subscale for work-related fear avoidance. Scores range from 0 to 24 [28].  7 items are included in the subscale for physical activity. Scores range from 0 to 42 [28].  All items are scored on a 7-point Likert scale ranging from 0 (strongly disagree) to 6 (strongly agree) [25].	<i>Reliability:</i> Test-retest reliability was high in patients with chronic LBP patients [27].  Pearson’s product-moment correlation coefficient was 0.95 and 0.88 for the subscales in chronic LBP patients [27].  <i>Validity:</i> Concurrent validity described under TSK.	English Norwegian Danish	Carpenter et al. used the FABQ as secondary outcome to evaluate an immediate or delayed online intervention to reduce pain in chronic LBP patients, and found reduced fear avoidance in the intervention group starting treatment immediately [29].

<p><b>Preparation for decision making scale (PrepDM)</b></p>	<p>The PrepDM assesses the patient's perception of how useful a decision aid or decision support intervention is in preparing the patient to make a decision or change [30].</p>	<p>The PrepDM entails questions to assess how helpful an educational material is to aid a patient to make a decision [30].</p>	<p>10 items assessed on a 5-point Likert Scale ranging from 1 (not at all) to 5 (a great deal) [30].</p>	<p><i>Reliability:</i> The Cronbach's <math>\alpha</math> ranging from 0.92 to 0.96 across 5 different populations, one being chronic LBP patients (n=94) [30].</p> <p><i>Validity:</i> The PrepDM had significant correlations with the decision conflict scale assessing information (r=-0.21) and support (r=-0.13) in decision making [30].</p>	<p>English French German Italian</p>	<p>Simon et al. used the PrepDM as a secondary outcome to evaluate the effectiveness of a web-based, individually tailored decision aid for depression or acute LBP in an RCT [14].</p>
<p><b>Decision conflict scale (DCS)</b></p>	<p>The DCS evaluates health-care consumers decision aids [31].</p>	<p>The conceptual framework of the DCS is that decisional conflict is a state of the patient's uncertainty about what course of action to take in health-care [31].</p>	<p>16 items. 3 subscales evaluating uncertainty, selected factors contributing to uncertainty and perception of effective decision making. All items are answered on a 5 point Likert scale.</p>	<p><i>Reliability:</i> Test-retest reliability was 0.81 [31]. Internal consistency ranged from 0.78 to 0.92 [31]. The DCS showed ability to discriminate between patients willing or unwilling to accept treatment [31].</p> <p><i>Validity:</i> The DCS was found to be valid in a interventions regarding influence immunization and hormone replacement therapy in women with breast cancer [31].</p>	<p>English French Danish Chinese Spanish German Japanese Italian</p>	<p>Simon et al. used the DCS as primary outcome to evaluate the effectiveness of a web-based, individually tailored decision aid for depression or acute LBP in a randomized controlled trial [14]</p>

Table 4: self-reported outcomes measures used frequently in trials of low back pain patients and in self-management or web or app-based intervention for this patient group. PSEQ: Pain self-efficacy questionnaire, LBP: low back pain, TSK: Tampa scale of Kinesiophobia, FABQ: Fear Avoidance Belief Questionnaire, PrepDM: the Preparation for decision making scale, DCS: the decision conflict scale.

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## 4 Appendix 1

### **The Roland-Morris Disability Questionnaire**

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly than usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all the time.
14. I find it difficult to turn over in bed because of my back.
15. My appetite is not very good because of my back pain.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of my back.
18. I sleep less well because of my back.
19. Because of my back pain, I get dressed with help from someone else.
20. I sit down for most of the day because of my back.
21. I avoid heavy jobs around the house because of my back.
22. Because of my back pain, I am more irritable and bad tempered with people than usual.
23. Because of my back, I go upstairs more slowly than usual.
24. I stay in bed most of the time because of my back.

#### **Note to users:**

This questionnaire is taken from: Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983; 8: 141-144

The score of the RDQ is the total number of items checked – i.e. from a minimum of 0 to a maximum of 24.

It is acceptable to add boxes to indicate where patients should tick each item.

The questionnaire may be adapted for use on-line or by telephone.

## Oswestry Low Back Pain Disability Questionnaire

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Sources: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. *Spine*, 25(22):2940-2953.

Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. *Physical Therapy* 2002;82:8-24.

The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools <sup>[1]</sup>.

### Scoring instructions

For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, it = 5. If all 10 sections are completed the score is calculated as follows:

Example:        16 (total scored)  
                      50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

                     16        (total scored)  
                      45 (total possible score) x 100 = 35.5%

Minimum detectable change (90% confidence): 10% points (change of less than this may be attributable to error in the measurement)

### Interpretation of scores

<b>0% to 20%: minimal disability:</b>	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
<b>21%-40%: moderate disability:</b>	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
<b>41%-60%: severe disability:</b>	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
<b>61%-80%: crippled:</b>	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
<b>81%-100%:</b>	These patients are either bed-bound or exaggerating their symptoms.

## Oswestry Low Back Pain Disability Questionnaire

### Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

#### Section 1 – Pain intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

#### Section 2 – Personal care (washing, dressing etc)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, I wash with difficulty and stay in bed

#### Section 3 – Lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

#### Section 4 – Walking\*

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than 1/2 mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time

**Section 5 – Sitting**

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

**Section 6 – Standing**

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

**Section 7 – Sleeping**

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

**Section 8 – Sex life (if applicable)**

- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

**Section 9 – Social life**

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

**Section 10 – Travelling**

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

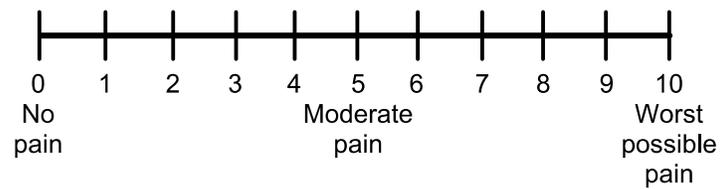
**References**

1. Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940-52; discussion 52.

### Visual Analog Scale



### 0–10 Numeric Pain Rating Scale





*(English version for the UK)*

SAMPLE

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Under each heading, please tick the ONE box that best describes your health TODAY

**MOBILITY**

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

**SELF-CARE**

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

**USUAL ACTIVITIES** (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

**PAIN / DISCOMFORT**

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

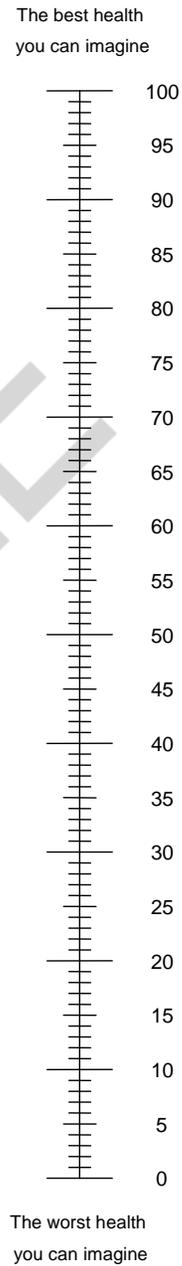
**ANXIETY / DEPRESSION**

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

2  
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- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



3  
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### SF-36 QUESTIONNAIRE

Name: \_\_\_\_\_ Ref. Dr: \_\_\_\_\_ Date: \_\_\_\_\_  
 ID#: \_\_\_\_\_ Age: \_\_\_\_\_ Gender: M / F

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

**GENERAL HEALTH:**

In general, would you say your health is:

- Excellent       Very Good       Good       Fair       Poor

Compared to one year ago, how would you rate your health in general now?

- Much better now than one year ago  
 Somewhat better now than one year ago  
 About the same  
 Somewhat worse now than one year ago  
 Much worse than one year ago

**LIMITATIONS OF ACTIVITIES:**

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

**Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.**

- Yes, Limited a lot       Yes, Limited a Little       No, Not Limited at all

**Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Lifting or carrying groceries**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Climbing several flights of stairs**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Climbing one flight of stairs**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Bending, kneeling, or stooping**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Walking more than a mile**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Walking several blocks**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Walking one block**

- Yes, Limited a Lot       Yes, Limited a Little       No, Not Limited at all

**Bathing or dressing yourself**

- Yes, Limited a Lot     
  Yes, Limited a Little     
  No, Not Limited at all

**PHYSICAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

**Cut down the amount of time you spent on work or other activities**

- Yes     
  No

**Accomplished less than you would like**

- Yes     
  No

**Were limited in the kind of work or other activities**

- Yes     
  No

**Had difficulty performing the work or other activities (for example, it took extra effort)**

- Yes     
  No

**EMOTIONAL HEALTH PROBLEMS:**

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

**Cut down the amount of time you spent on work or other activities**

- Yes     
  No

**Accomplished less than you would like**

- Yes     
  No

**Didn't do work or other activities as carefully as usual**

- Yes     
  No

**SOCIAL ACTIVITIES:**

Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- Not at all     
  Slightly     
  Moderately     
  Severe     
  Very Severe

**PAIN:**

How much bodily pain have you had during the past 4 weeks?

- None     
  Very Mild     
  Mild     
  Moderate     
  Severe     
  Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all     
  A little bit     
  Moderately     
  Quite a bit     
  Extremely

**ENERGY AND EMOTIONS:**

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

**Did you feel full of pep?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you been a very nervous person?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt so down in the dumps that nothing could cheer you up?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt calm and peaceful?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you have a lot of energy?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you felt downhearted and blue?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you feel worn out?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Have you been a happy person?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**Did you feel tired?**

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

**SOCIAL ACTIVITIES:**

**During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?**

- All of the time
- Most of the time
- Some of the time
- A little bit of the time
- None of the Time

**GENERAL HEALTH:**

How true or false is each of the following statements for you?

**I seem to get sick a little easier than other people**

- Definitely true     Mostly true     Don't know     Mostly false     Definitely false

**I am as healthy as anybody I know**

- Definitely true     Mostly true     Don't know     Mostly false     Definitely false

**I expect my health to get worse**

- Definitely true     Mostly true     Don't know     Mostly false     Definitely false

**My health is excellent**

- Definitely true     Mostly true     Don't know     Mostly false     Definitely false

## 5 Appendix 2

### PAIN SELF EFFICACY QUESTIONNAIRE (PSEQ)

M.K.Nicholas (1989)

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle **one** of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:

0	1	2	3	4	5	6
Not at all Confident						Completely confident

Remember, this questionnaire is **not** asking whether or not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain**.

---

1. I can enjoy things, despite the pain.

0	1	2	3	4	5	6
Not at all Confident						Completely confident

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.

0	1	2	3	4	5	6
Not at all Confident						Completely confident

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

0	1	2	3	4	5	6
Not at all Confident						Completely confident

4. I can cope with my pain in most situations.

0	1	2	3	4	5	6
Not at all Confident						Completely confident

Turn over

5. I can do some form of work, despite the pain. (“work” includes housework, paid and unpaid work).

0 1 2 3 4 5 6  
 Not at all Completely  
 Confident confident

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.

0 1 2 3 4 5 6  
 Not at all Completely  
 Confident confident

7. I can cope with my pain without medication.

0 1 2 3 4 5 6  
 Not at all Completely  
 Confident confident

8. I can still accomplish most of my goals in life, despite the pain.

0 1 2 3 4 5 6  
 Not at all Completely  
 Confident confident

9. I can live a normal lifestyle, despite the pain.

0 1 2 3 4 5 6  
 Not at all Completely  
 Confident confident

10. I can gradually become more active, despite the pain.

0 1 2 3 4 5 6  
 Not at all Completely  
 Confident confident

Source: Nicholas M.K. Self-efficacy and chronic pain. Paper presented at the annual conference of the British Psychological Society. St. Andrews, 1989.  
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### Tampa Scale for Kinesiophobia (Miller , Kori and Todd 1991)

- 1 = strongly disagree
- 2 = disagree
- 3 = agree
- 4 = strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Reprinted from:

*Pain*, Fear of movement/(re) injury in chronic low back pain and its relation to behavioral performance, 62, Vlaeyen, J., Kole-Snijders A., Boeren R., van Eek H., 371.  
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Scoring Information  
Tampa Scale for Kinesiophobia  
(Miller et al 1991)

A total score is calculated after inversion of the individual scores of items 4, 8, 12 and 16.

Reprinted from:  
*Pain*, Fear of movement/(re) injury in chronic low back pain and its relation to behavioral performance, 62, Vlaeyen, J., Kole-Snijders A., Boeren R., van Eek H., 371.  
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## FEAR AVOIDANCE BELIEFS QUESTIONNAIRE (FABQ)

**Purpose:** The FABQ was developed by Waddell to investigate fear-avoidance beliefs among LBP patients in the clinical setting.<sup>3</sup> This survey can help predict those that have a high pain avoidance behavior. Clinically, these people may need to be supervised more than those that confront their pain.

**Scoring:** The FABQ consists of 2 subscales, which are reflected in the division of the outcome form into 2 separate sections. The first subscale (items 1-5) is the Physical Activity subscale (FABQPA), and the second subscale (items 6-16) is the Work subscale (FABQW). Interestingly, not all items contribute to the score for each subscale; however the patient should still complete all items as these items were included when the reliability and validity of the scale was initially established. A low FABQW score (less than 19) was one of 5 variables in a clinical prediction rule that increased the probability of success from SI region manipulation in individuals with low back pain.<sup>1</sup> Each subscale is graded separately by summing the responses respective scale items (0 – 6 for each item); for scoring purposes, only 4 of the physical activity scale items are scored (24 possible points) and only 7 of the work items (42 possible points). The method to score each subscale is outlined below. (Note: It is extremely important to ensure all items are completed, as there is no procedure to adjust for incomplete items.)

### Scoring the Physical Activity subscale (FABQPA)

Sum items 2, 3, 4, and 5 (the score circled by the patient for these items).

### Scoring the Work subscale (FABQW)

Sum items 6, 7, 9, 10, 11, 12, and 15.

**Measurement Characteristics:** The FABQ has been demonstrated to be valid and reliable in a chronic LBP population<sup>3</sup> and appears to be a useful screening tool for identifying acute LBP patients who will not return to work by 4wks.<sup>2</sup>

### References:

1. Flynn T, Fritz J, Whitman J, Wainner R, et al. Clinical Prediction Rule for Classifying Patients with Low Back Pain Likely to Respond to a Manipulation Technique. Spine (In Press) 2002.
2. Fritz JM, George SZ, Delitto A. The role of fear-avoidance beliefs in acute low back pain: relationships with current and future disability and work status. Pain 2001; 94:7-15.
3. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. Pain 1993; 52:157-168

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

	COMPLETELY DISAGREE		UNSURE				COMPLETELY AGREE	
1. My pain was caused by physical activity	0	1	2	3	4	5	6	
2. Physical activity makes my pain worse	0	1	2	3	4	5	6	
3. Physical activity might harm my back	0	1	2	3	4	5	6	
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6	
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6	

The following statements are about how your normal work affects or would affect your back pain.

	COMPLETELY DISAGREE		UNSURE				COMPLETELY AGREE	
6. My pain was caused by my work or by an accident at work	0	1	2	3	4	5	6	
7. My work aggravated my pain	0	1	2	3	4	5	6	
8. I have a claim for compensation for my pain	0	1	2	3	4	5	6	
9. My work is too heavy for me	0	1	2	3	4	5	6	
10. My work makes or would make my pain worse	0	1	2	3	4	5	6	
11. My work might harm my back	0	1	2	3	4	5	6	
12. I should not do my normal work with my present pain	0	1	2	3	4	5	6	
13. I cannot do my normal work with my present pain	0	1	2	3	4	5	6	
14. I cannot do my normal work until my pain is treated	0	1	2	3	4	5	6	
15. I do not think that I will be back to my normal work within 3 months	0	1	2	3	4	5	6	
16. I do not think that I will ever be able to go back to that work	0	1	2	3	4	5	6	

### Preparation for Decision Making Scale

Please indicate your opinion about the effect of the educational material by circling the appropriate number to show the extent to which you agree with each statement.

Did this educational material . . .	Not at all	A little	Some-what	Quite a bit	A great deal
1. Help you recognize that a decision needs to be made?	1	2	3	4	5
2. Prepare you to make a better decision?	1	2	3	4	5
3. Help you think about the pros and cons of each option?	1	2	3	4	5
4. Help you think about which pros and cons are most important?	1	2	3	4	5
5. Help you know that the decision depends on what matters most to you?	1	2	3	4	5
6. Help you organize your own thoughts about the decision?	1	2	3	4	5
7. Help you think about how involved you want to be in this decision?	1	2	3	4	5
8. Help you identify questions you want to ask your doctor?	1	2	3	4	5
9. Prepare you to talk to your doctor about what matters most to you?	1	2	3	4	5
10. Prepare you for a follow-up visit with your doctor?	1	2	3	4	5

Preparation for Decision Making Scale © ID Graham, AM O'Connor 1996, revised 2005 University of Ottawa

ID Graham & AM O'Connor, Preparation for Decision Making Scale. © 1995 [updated 2005]. Available from [www.ohri.ca/decisionaid..](http://www.ohri.ca/decisionaid..)

**Traditional Decisional Conflict Scale (DCS) – Statement Format: 16 item 5 response categories**

This is our most tested version. Many people like the personal response format. However, it is more difficult to respond to than questions in those with limited reading and response skills. Note: We always precede the DCS with an option preference question, which is not included in scoring. [See item ‘A’ below].

**My difficulty in making this choice**

A. Which [insert treatment/screening] option do you prefer? Please check  one.

- [Option 1]
- [Option 2]
- [Option 3]
- Unsure

B. Considering the option you prefer, please answer the following questions:

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
	[0]	[1]	[2]	[3]	[4]
1. I know which options are available to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I know the benefits of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I know the risks and side effects of each option.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am clear about which benefits matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I am clear about which risks and side effects matter most to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am clear about which is more important to me (the benefits or the risks and side effects).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I have enough support from others to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I am choosing without pressure from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have enough advice to make a choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am clear about the best choice for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel sure about what to choose.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. This decision is easy for me to make.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

AM O'Connor, Decisional Conflict Scale. © 1993 [updated 2005]. Available from [www.ohri.ca/decisionaid](http://www.ohri.ca/decisionaid).