PROTOCOL

Predictors of self-management in patients with chronic low back pain: a longitudinal cohort study protocol

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Abstract

Studies on self-management (SM) support programmes in chronic low back pain (CLBP) have failed to show clinically meaningful treatment benefit, which potentially highlights lack of research on predictors of effective SM. The purpose of this multi-centre non-experimental longitudinal cohort study is to identify the predictors of SM and its change over time in community ambulant adults (18-65 years) who are attending or have recently attended outpatient physiotherapy for their CLBP (approx. n=400). Self-reported validated measures for SM, pain intensity, disability, physical activity level, kinesiophobia, catastrophising, depression and global impression of change will be recorded at baseline and six-months. Descriptive statistics, correlation and multiple regression will be employed for the primary data analyses. This study protocol has ethical approval and is registered in ClinicalTrials.gov (ID: NCT02636777). Study results will inform patient selection for SM support in CLBP, and the development of tailored and targeted SM support programmes for this patient group.

Keywords: Self-management, Low back pain, Longitudinal study, Regression

BACKGROUND

Chronic low back pain (CLBP), which affects about 20% of general population world-wide (Hoy et al., 2012), is the most disabling condition in terms of Years Lived with Disability (YLDs) and it causes a significant burden to its sufferers (Vos et al., 2012). Patients with CLBP attend more consultations with general physicians and physiotherapists than matched patients without CLBP (Hong et al., 2013, Gore et al., 2012). High usage of healthcare in CLBP results in substantial costs to society (Hong et al., 2013, Maniadakis and Gray, 2000) and about 17% of direct treatment costs in CLBP are accounted by physiotherapy treatments alone (Dagenais et al., 2008).

Effective and optimal treatments for patients with CLBP remain challenging in clinical practice. Unlike passive physiotherapy treatments (Ebadi et al., 2014, Rubinstein et al., 2011), exercises are moderately effective in management and secondary prevention of CLBP (Hayden et al., 2005, Choi et al., 2010). Similarly, active behavioural treatments (Henschke et al., 2010) and intensive

multidisciplinary treatments (Kamper et al., 2014) are more effective for improving pain and disability in CLBP than usual care. Along with these active physical and psychological treatments, self-management is recommended as a crucial component for managing CLBP in all major national guidelines (Airaksinen et al., 2006, National Institute for Health and Clinical Excellence, 2009, Scottish Intercollegiate Guidelines Network, 2013).

Self-management (SM) can be defined as patient's dynamic and continuous ability to manage the disease symptoms, their treatment, physical and psychological wellbeing, life style modifications, and social and family roles (Barlow et al., 2002, Lorig and Holman, 2003). SM support programmes aim at fostering effective self-management behaviour and actions in patients with CLBP. Clinical trials on SM support programmes for patients with CLBP have showed potential benefits in decreasing pain and/or disability when delivered online (Carpenter et al., 2012, Chiauzzi et al., 2010), by 'expert patients' (Von Korff et al., 1998) and in primary care settings (Moore et al., 2000). However, recent systematic reviews have found insufficient evidence to recommend SM for patients with CLBP (Du et al., 2011) and failed to show clinically significant improvement in pain, disability and self efficacy in patients with CLBP (Foster et al., 2007, Oliveira et al., 2012).

The inconsistency of SM support benefits in CLBP, could be partially attributed to a lack of understanding on patient selection and treatment matching, which are essential to develop cost-effective treatment programmes (Turk and Okifuji, 2002, Turk et al., 1993). To date, predictors of SM in CLBP have been investigated in only one cross-sectional study (Kawi, 2014), which showed that age, education, overall health, SM support, and helpfulness in pain management significantly predict SM scores. Although a longitudinal cohort study is useful for exploring the causality and developing a testable hypothesis (Mansell et al., 2013), such a study to identify significant predictors of SM in CLBP is yet to be conducted.

Therefore, the primary aim of this study is to identify predictors of SM and its change over time in adult patients (aged between 18 and 65 years), who are attending or have recently attended outpatient physiotherapy treatment for their CLBP.

METHODS

This study will utilise a multi-centre prospective (non-experimental) longitudinal cohort study design involving adult patients with CLBP (approx. n = 400). This study protocol has ethical approval (Ref No 15/ES/1067) and is registered in ClinicalTrials.gov (ID: NCT02636777).

Participants

Participants will be recruited from the outpatient physiotherapy clinics within an acute care hospital trust and a community healthcare service provider in the East Midland, UK.

The study will include patients:

1. with low back pain, defined as pain in the posterior aspect of the body between the lower margins of the twelfth ribs and the gluteal folds with or without pain in the one or both legs (Hoy et al., 2014), for more than three months (Furlan et al., 2009);

2. who are aged between 18 and 65 years at baseline (to recruit from working age population associated with high socioeconomic impact and recognising the changing SM needs in older adults);

3. who are community ambulant without walking aids (to minimise confounding of the changing SM needs in presence of mobility limitation);

4. who are attending or have recently attended outpatient physiotherapy treatments for their CLBP; and

5. who are able to read, write and understand English for completing the questionnaires.

Patients will be excluded, if they:

1. are diagnosed with cancer or other self-reported specific cause (major trauma, fracture, inflammatory condition, ankylosing spondylitis, grade 3 & 4 spondylolisthesis, severe spinal canal stenosis, or lumbar intervertebral disc protrusion or extrusion, spinal deformity);

2. have undergone spinal surgery within last one year or are planning or scheduled for any major surgery in the coming six months (as surgery may drastically change the usual SM);

3. are pregnant women or women who had childbirth in the last one year (to avoid the confounding effects of pregnancy related low back pain);

4. have cognitive impairment and/or neurological diseases (to avoid the confounding effects of neurological condition); and

5. have severely impaired vision and hearing, which prevents them from completing the survey in any form even with maximum assistance.

Measures

Selection of the measures are based on known predictors for chronicity of low back pain (Campbell et al., 2013, Kovacs et al., 2011), validated measures recommended for CLBP research (Chapman et al., 2011, Grotle et al., 2005), consultations with clinical stakeholders and Outcome Measures in Rheumatology (OMERACT) recommendations (Boers et al., 2014) (summarised in Table 1).

Health Education Impact Questionnaire

Self-management will be measured using a multi-domain scale- Health Education Impact Questionnaire (heiQ) version 3 (Osborne et al., 2007). The heiQ was developed using the 'Program Logic Model', grounded theory based interviews with stakeholders, concept mapping and psychometrics (Osborne et al., 2007). The scale consists of 40 items, which measure eight different constructs of SM- Health Directed Activities (HDA), Positive and Active Engagement in Life (PAEL), Emotional Distress (ED), Self-Monitoring and Insight (SMI), Constructive Attitudes and Approaches (CAA), Skill and Technique Acquisition (STA), Social Integration and Support (SIS) and Health Service Navigation (HSN). Each of the 40 items is scored using four-point Likert scale options from 'strongly disagree' to 'strongly agree'. Each independent construct score is further divided by the number of items on it. This scale has satisfactory validity (Cronbach's α 0.70-0.89), good reliability and discriminant validity in patients with chronic diseases (Osborne et al., 2007, Elsworth et al., 2015). The heiQ scale has been chosen for its ability to capture multiple SM constructs, adequate psychometric property and low response bias (Nolte et al., 2013).

Numeric Pain Rating Scale

Pain intensity will be measured using 11-point (0 to 10) Numeric Pain Rating Scale (NPS) with two end-point descriptors- '0 means no pain' and '10 means worst possible pain'. Patients will be asked to rate their worst pain intensity in the last 24 hours. NPS is responsive (Ferreira-Valente et al., 2011) and

acceptable to patients with chronic pain for ease of reporting (Williams et al., 2000). NPS is valid and reliable tool (validity- correlation 0.86-0.95; reliability- correlation coefficient 0.95-0.96) (Hawker et al., 2011) in patients with CLBP (Dworkin et al., 2008, Farrar et al., 2001).

Roland Morris Disability Questionnaire

Physical function (or disability) will be assessed using a 24-item Roland Morris Disability Questionnaire (RMDQ), where each item is answered with yes or no producing a total score between 0 and 24. RMDQ is preferred when participants are expected to have less physical disability (Roland and Fairbank, 2000). RMDQ is valid and reliable (Cronbach's α 0.84-0.93) (Roland and Fairbank, 2000) tool for assessing physical function and its change over time in patients with CLBP (Chapman et al., 2011, Ostelo and de Vet, 2005).

International Physical Activity Questionnaire Short Form

Physical activity level will be measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF). The IPAQ-SF contains seven items asking the last seven days' physical activities. The total reported physical activity in last week (in minutes) will be used to calculate estimated metabolic equivalent (MET). It is a reliable (Spearman's r around 0.8) self-report instrument for assessing physical activity level (Lee et al., 2011).

Tampa Scale of Kinesiophobia

Kinesiophobia, 'irrational amount of pain related fear of physical movement or activity' (Kori et al., 1990), will be measured using the Tampa Scale of Kinesiophobia (TSK). The TSK consists of 17 four-point Likert scale items and each item is scored from '1 or strongly disagree' to '4 or strongly agree'. The total score varies from 17 to 68 and a score ≥ 37 indicates high kinesiophobia. TSK is valid (Cronbach's α 0.71-0.81) and correlates with disability and performance testing (correlation coefficient 0.43) in CLBP (Crombez et al., 1999, Roelofs et al., 2004, Vlaeyen and Linton, 2000).

Pain Catastrophising Scale

Catastrophising, 'exacerbated negative feeling in relation to pain' (Picavet et al., 2002), will be measured using the Pain Catastrophising Scale (PCS). PCS consists of 13 items, which are scored with a five-point Likert scale '0 or not at all' to '4 or all the time' (Sullivan et al., 1995). The PCS provides three sub-scores (rumination, magnification, and helplessness) and a total score for catastrophizing. The total score ranges between 0 and 52, where high scores indicate high catastrophising (Osman et al., 1997). The PCS is a valid (Cronbach's α 0.69-0.91) and reliable (Sullivan et al., 1995, Osman et al., 1997).

Patient Health Questionnaire-9

Depression will be assessed using the Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 consists of nine items with four-point Likert scale: from '0 or not at all' to '3 or nearly every day'. The total score ranges between 0 and 27 and can be interpreted in five different categories: no depression (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe depression (20-27) (Smarr and Keefer, 2011). This scale is valid (Cronbach's α 0.86), reliable (>0.8), good diagnostic ability (positive likelihood ratio 7.1 for scores > 10) and quick to administer (Kroenke and Spitzer, 2002, Kroenke et al., 2001).

Patient Global impression of Change

Patients' impression of change in SM at the follow up survey will be assessed with a

single-item 7-point rating scale using the Patient Global Impression of Change (PGIC) scale, where '1' means very much improved and '7' means very much worse. The PGIC ratings will be used to dichotomise patients into 'improved' ('very much improved' to 'improved') and 'unchanged' ('unchanged' to 'very much worse') (Fritz and Irrgang, 2001). The PGIC scale correlates with the change in pain intensity (Farrar et al., 2001) and is useful in chronic pain (Dworkin et al., 2008).

Table 1: The main measures of the study

Measures	Baseline survey	Agreement survey*	Follow up survey**
Numeric Pain Scale (NPS)	x	x	x
Roland Morris Disability Questionnaire (RMDQ)	x	x	x
Health Education Impact Questionnaire (heiQ)	x	x	x
International Physical Activity Questionnaire- Short Form (IPAQ-SF)	x		x
Patient Health Questionnaire-9 (PHQ-9)	x		x
Tampa Scale of Kinesiophobia (TSK)	x		x
Pain Catastrophising Scale (PCS)	x		x
Patient Global Impression of Change (PGIC)			x

** within two weeks from baseline; ** at six month from baseline*

Procedure

Patients with chronic low back pain (CLBP) will be recruited by approaching patients in the outpatient physiotherapy clinics; referral from treating therapists and inviting patients via advertisements. Willing patients will be screened against the study selection criteria in the clinic or over the phone. Eligible patients will be provided with a pre-approved information sheet and verbal explanation before obtaining written consent. All consenting patients will be required to complete the questionnaire survey on two occasions: at baseline and six month follow up. The questionnaires will be given to patients in the form of a paper-based survey at baseline. Options of paper/ telephone/ online format will be offered to patients at follow up to maximise convenience. Additionally, willing participants ($n \leq 60$) will be requested to complete a survey (via online or telephone) within two weeks of completing the baseline survey, to determine the agreement between the paper-based survey and telephone/online survey. Patients will be reminded using multiple strategies, for example phone call/ text message and email once a week (Chen et al., 2011, Robinson et al., 2007) to increase completion rate.

Data Analysis Plan

A priori sample size estimation

Sample size have been estimated using G*Power version 3.1.9.2 software (available from Heinrich Heine University, http://www.gpower.hhu.de/) for 80% power and Type I error (α) = 0.05 in three different scenarios using archived data of Health Directed Activities (HDA) of heiQ scale (Elsworth et al., 2015). Firstly, for the baseline cross-sectional data 324 participants will be sufficient to detect a change of 0.2 from 2.84 at baseline for a two-tailed independent t-test. Secondly, 324 completed questionnaires at the follow up will be sufficient to detect a change from 2.84 at baseline to 2.94 at the follow up in a two-tailed dependent t-test. Finally, 318 completed questionnaire will be sufficient to detect a difference in mean 'change in HDA scores over six month time period' from 0.2 in one group to 0.38 in another with an estimated equal variability (0.57) of change of scores in both groups.

Preliminary assessment and action plan

Data will be imported into a statistical software (IBM SPSS 22), where analyses will be performed with significance set at $p<0.05$. Data will be screened using stem-and-leaf plots and summaries to identify presence of any 'impossible' value. For missing observations, participants will be contacted (two to three attempts using multiple strategies) (Chen et al., 2011) to complete the questionnaire where feasible. Randomly missing observations will be replaced with mean substitution (Tabachnick and Fidell, 2007a). The non-random missing values will be substituted using multiple imputation method with sensitivity testing (Tabachnick and Fidell, 2007a). Scatter plots will be visually assessed for any outliers, and if found, those will be screened for data entry or imputation errors. As the sample size is large (approx. n=400) the normality and homogeneity will be visually examined for skewness and kurtosis. In case of non-symmetrical or non-normal distribution a Shapiro-Wilk test will be utilised (Razali and Wah, 2011). Homogeneity of variance will be further checked using Levene's test. Dummy variables will be created, as required.

Primary analyses plan

The agreement between paper survey and online/telephone survey methods will be assessed using interclass correlation coefficients and graphically using Bland-Altman limits of agreement plots. The concept of limits of agreement (LoA) is based on the assumption that the unbiased measurement difference is normally distributed and LoA is determined by the formula (mean difference between two measurements $\pm$ 1.96 x standard deviation of the difference) (Bland and Altman, 1999). Higher disagreement between the two measurements is represented by broader LoA.

For baseline and follow up survey data, descriptive statistics (mean with standard deviation or median with interquartile range) will be reported (Larson, 2006). For parametric data the between group differences at the baseline, will be investigated using independent t-test for two groups and one way between group analysis of variance (ANOVA) with post hoc Bonferroni correction (α=0.025) for more than two groups (Dixon et al., 2013a). For non-parametric variables between group differences (for rank) will be analysed with Mann-Whitney and Kruskal Wallis H-test (for > two groups) (Dancey et al., 2012). Bivariate and multivariate correlation will be tested (Dixon et al., 2013b). Variables having significant correlation with SM scores will be entered into regression analysis (Tabachnick and Fidell, 2007b). A multivariate analysis of

variance (MANOVA) will be performed (Tabachnick and Fidell, 2007b). As this is a multi-centre study, regression models will be adjusted for different centres of treatment or the types of treatment received.

DISCUSSION

This study aims to identify demographic, socioeconomic, physical or psychological factors, which significantly predict effective SM in patients attending or who have recently attended outpatient physiotherapy for their CLPB. As we intend to recruit community ambulant patients (approx. n=400) with CLBP, the findings should be generalisable in wider context for patients attending outpatient physiotherapy. Further, to increase generalisability the demographic details of this study participants will be compared with that of the non-responders of this study (where available) and participants of similar published reports. Future study may verify the predictive models generated by this study in other countries or cohorts. The significant predictors of effective SM identified from this study will inform appropriate patient selection for SM support programmes for patients with CLBP. The findings will provide information which will help to determine the most appropriate factors to be targeted in SM support for patients with CLBP and may therefore assist in the development of tailored and targeted SM support programmes in the future.

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