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Study protocol for an investigation of the effectiveness of the pain toolkit for people with low back pain: double-blind randomised controlled trial

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ABSTRACT

Introduction The Pain Toolkit is a self-management tool for people with persistent pain. It is available for use worldwide in multiple formats. To date, no studies have investigated the effectiveness of this intervention. This study aims to investigate the effectiveness of the Pain Toolkit in comparison with a simple education control for people with low back pain.

Methods and analysis Participants who have been discharged from the North of England Regional Back Pain Pathway will be randomised using sealed, consecutively numbered opaque envelopes to receive either the Pain Toolkit and the Back Book (intervention group) or the Back Book only (control group). Both the therapist and the participant will be blind to group allocation. The primary outcome measure will be disability (Oswestry Disability Index (ODI)). Secondary outcome measures will be pain (0–10 numerical scale), healthcare use (number of healthcare professional visits) and quality of life (EuroQol-5D). Outcome measures will be completed at baseline and at 6 and 12 months. Data will be analysed using analysis of covariance, adjusting for baseline values. A change of 10 points in the ODI will be considered a clinically important change. Additionally, a subsample of participants from the intervention group will undergo semistructured interviews to explore individuals' experience of the Pain Toolkit. Participants will be asked questions about the ease of use and acceptability of the Pain Toolkit and also for how long they used the Toolkit. The qualitative data will be analysed using thematic analysis.

Ethics and dissemination Approval for the study was given by the Health Research Authority and the North East Newcastle, North Tyneside 2 Regional Ethics Committee (reference 18/NE/0144) and Teesside University (reference 176/17). Findings will be disseminated through peer-reviewed journals and presentation at relevant patient groups, and local, national and international conferences.

Trial registration number NCT03791164; Pre -results.

Strengths and limitations of this study

- This randomised controlled trial will investigate a simple, inexpensive way of supporting patients with low back pain.
- The study team and the participants are blinded to the intervention in each of the groups.
- Restriction to participants being discharged from a course of therapy and speaking English may limit the generalisability of the findings.

INTRODUCTION

Low back pain (LBP) is the leading cause of disability-adjusted life years worldwide.[1–3] This causes a significant burden on health services, with 14% of primary care consultations being for LBP.[4] Annual healthcare costs for patients with LBP are double those of matched control patients without back pain.[5] LBP accounts for a significant disease burden and loss in productivity among working people.[3 6] Bevan estimates that in 2015, 'the total cost of lost productivity attributable to musculoskeletal disorders among people of working age in the EU could be as high as 2% of gross domestic product'.[7] The WHO's definition of LBP states that 'in many instances, …., the cause is obscure, and only in a minority of cases does a direct link to some defined organic disease exist'.[8 9]

Across the North of England, there is a regional back pain pathway[10] that provides a consistent approach to the management of patients based on the National Institute for Health and Care Excellence (NICE) guidelines for the management of LBP.[6] Early evidence demonstrates positive outcomes for patients on this regional back pain pathway.[11 12] Within these guidelines, many of the options relate to self-management.[6] Although self-management is an integral part of the North of England Regional Back Pain Pathway, no specific information is given as to the preferred nature of the self-management advocated, and the Pain Toolkit and the Back Book are not specifically referenced.[10] Self-management can be defined as 'day to day tasks that an individual must undertake to control or reduce the impact of disease on physical health status'.[13] With evidence to support its

clinical effectiveness,[14–17] self-management is a persuasive option for resource-limited services. However, there is little clarity on exactly what constitutes self-management within the Back Pain Pathway and which approaches are best.[13 18 19]

The Pain Toolkit[20] is a self-management tool for people with persistent pain. It has been developed by a non-healthcare professional with long-standing back pain. The goal of the Pain Toolkit is to facilitate patients to self-manage their pain condition. The Pain Toolkit has been available for 17 years, is available in multiple countries and has been made available by national healthcare providers such as NHS Choices.[21] The Pain Toolkit remains popular with healthcare professionals and patients; however, the effectiveness of this widely available tool has not yet been investigated. The aim of this study is to investigate the effectiveness of the Pain Toolkit as a self-management tool for people with back pain following discharge from a treatment pathway. The outcome of the study may help to support a recommendation to the North of England Regional Back Pain Pathway about the nature of self-management tools to be recommended.

OBJECTIVES

Primary objective

The primary objective of the study is to investigate the effectiveness of the Pain Toolkit for disability as measured by the Oswestry Disability Index (ODI) for people with LBP who have been discharged from a treatment pathway in comparison with a usual care control.

Secondary objectives

The secondary objectives of this study are as follows:

To investigate the effectiveness of the Pain Toolkit for pain as measured by a numerical pain rating scale (NRS) for people with LBP who have been discharged from a treatment pathway in comparison with a usual care control.

To investigate the effectiveness of the Pain Toolkit for healthcare use as measured by reported healthcare professional visit numbers for people with LBP who have been discharged from a treatment pathway in comparison with a usual care control.

To investigate the effectiveness of the Pain Toolkit for quality of life as measured by EuroQol-5D (EQ5D) for people with LBP who have been discharged from a treatment pathway in comparison with a usual care control.

To explore participants' experiences of using the Pain Toolkit.

METHODS AND ANALYSIS

Description of the study

This will be a mixed-methods, double-blind, randomised controlled trial.

Patient and public involvement

In developing the ideas for this study, the author met with the Patient Reference Group of the North Durham Clinical Commissioning Group. This is a group of patients and members of the public registered with general practices in the North Durham area. Patients were not involved in recruitment for the study. Patients were shown copies of the Pain Toolkit and the Back Book and were asked about their opinions on the usefulness of the information contained and the ease of understanding of the materials. They gave opinions on the time at which the information would be useful within the care pathway and whether people with learning disabilities would be able to access support to use the materials. This information was used to shape the timing of the intervention within the pathway. They concluded that the self-management approach should be promoted and that the use of the self-management tools did not appear to be overburdensome. Results of the study will be fedback to this group and other patient groups once the study has concluded.

Sample selection

Setting

Participants will be a convenience sample of patients with LBP who have been discharged from the North of England Regional Back Pain Pathway. The North of England Regional Back Pain Pathway is an evidence-based pathway of care for people with back pain that operationalises the NICE guidelines.[6] Participants will be approached to participate in the study at the point of discharge from the pathway by their healthcare practitioner.

Participants

We will include individuals with pain in the lower back of any duration that is not associated with any serious disease or potentially serious condition in keeping with the NICE guidelines.[6] Individuals will be eligible for the study if they are over 18 years of age, have recently been discharged/are in the process of being discharged from the North of England Regional Back Pain Pathway, and are fluent in written and spoken English. Individuals will be excluded if they present with red flag indicators indicative of the need for onward referral for medical investigation[6] or if they are unable to provide informed consent to participate in the study.

Recruitment

At the point of discharge from the North of England Regional Back Pain Pathway, clinicians will give potential participants a brief overview of the study and will ask if they are willing to have a member of the research team contact them. The research team will contact potential participants and will explain the study in detail. If the individual meets the inclusion/exclusion criteria and is willing to participate, a baseline questionnaire and consent form will then be posted to the participant. Additional recruiting sites will be added to the study until the sample size is achieved.

Randomisation

On receipt of the completed consent form and baseline questionnaire in the post from the participant, the research team will randomise the participant to either the intervention or the control group using sealed, opaque, sequentially numbered envelopes. The randomisation order will be generated by an online random number generator[22] by a member of the research team not involved in the recruitment process. The participant will be posted the appropriate material dependent on group allocation.

Interventions

The intervention group will receive the Pain Toolkit, which is a self-management advice tool. The Pain Toolkit is widely available in paper and electronic format in English and other formats. For the purposes of this study, a paper version will be used. The Pain Toolkit gives 12 options for managing pain, covering topics such as acceptance, goal setting, relaxation, exercise and pacing.[23] The reader is encouraged to choose up to 3 of the 12 options and to use them until they feel confident in using the intervention, and then to choose a 3 further options and repeat the process. Using all 12 options is not essential but is encouraged. While using the Pain Toolkit, patients are encouraged to see pain as a chronic condition over which they need to take control. Self-management as an active form of pain management is encouraged, rather than passive expectations that healthcare professionals will address the patient's pain. In preparation for the study, a group of patient representatives were asked to review and comment on the Pain Toolkit. While not part of the formal evaluation of the study, this preparatory work provided valuable insight into patients' perception of the Pain Toolkit. The patients present felt that the document was easy to understand, although people with learning disabilities may need some help to understand it. They also felt that because the Pain Toolkit was a useful guide, it should be offered as early as possible into the pathway.

Control

The control group will receive a copy of the Back Book.[24] The Back Book is a guidance-based, patient information leaflet that aims to promote acceptance of back pain as an enduring feature and to encourage the patient to undertake light activity. It is one of the most widely used sources of patient information for patients with LBP.[25 26] It has been reported that the Back Book has improved outcomes in patients who had a fear of physical activity.[25 27]

The intervention group will also receive a copy of the Back Book so that the only difference between the groups is the intervention of interest, that is, the Pain Toolkit. Both groups will be instructed to carry on with their usual routine of activities and therapy as prescribed by their therapist on discharge.

Outcomes

Primary outcome measure

The primary outcome measure for the study will be the ODI.[28] The ODI is a measure of pain-related disability. The ODI, first published in 1980,[28] is one of the most commonly used outcome measures used with people with LBP.[29] The ODI has been shown to be a valid and reliable measure of pain-related disability.[30] In 2006, an international expert panel determined that a change of 10 points (approximately 30% change) equates to a minimally important difference (MID)[31]; thus, for the purposes of this study, a 10-point change in the ODI will be used as the MID.

Secondary outcome measures

A number of secondary outcome measures will also be used to investigate the effectiveness of the intervention. Pain intensity will be measured using an NRS, which is a validated outcome measure of pain.[32 33]

Healthcare usage will be measured using a self-reported number of contacts with a healthcare professional during the intervention period. It is reported that general health, including mental health, can impact on a patient's perception of pain.[34] It is therefore important to consider a patient's overall quality of life. Quality of life will be measured using the EQ5D.[35] EQ5D is an assessment of health status and has been shown to correlate to the ODI and has the ability to identify clinically important changes.[36] The EQ5D system has five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Participants answer questions in each of the areas, and this is reported as a single health status value.

At each follow-up point, participants are asked the extent to which they have used the intervention that they have received and whether there has been any change in their medication or therapy regime that may impact on their outcome measures. This information will be analysed by the research team as per the statistical analysis plan.

A subgroup of participants from the intervention group will be identified and purposively sampled by a member of the research team, which is otherwise uninvolved with the study so as not to interfere with the study blinding. The researcher will attempt to select participants with a range of backgrounds with regard to age, gender and duration of symptoms. The interviews will be audio-recorded and will last approximately 1 hour. This part of the study will assess how acceptable the interventions were to the participants. The participants will be asked whether they found the tool helpful and easy to use. They will also be asked how much of the toolkit they have used and for how long to assess intervention fidelity. They will be asked whether they will continue to use the Pain Toolkit and whether they would recommend it to other patients.

Data analysis plan

Blinding

Sequentially numbered, sealed, opaque envelopes containing the study intervention and control literature will be prepared in advance by a member of the research

team not involved in the recruitment or statistical analysis of the data. The randomisation list will be created by an online random number generator. The participants will be informed that they will be sent one (or two) of a number of leaflets to use to compare which one is most effective. They will not be aware which is the intervention leaflet and which is the control leaflet, nor will the therapist know which intervention they have been sent. Thus, both participants and researchers will be blinded to group allocation.

Sample size calculations

Using the NQuery software V.3 (Statistical Solutions, Cork, Ireland), we estimate that a sample size of 70 in each group will have 90% power to detect a mean difference of 10 points between the intervention and control groups, assuming that the common SD of change is 18 points using a two-group t-test with a 0.050 two-sided significance level. The estimate of SD of change scores was obtained from previously collected data involving 967 participants. Ultimately, the data will be analysed with a similar between-subjects model for comparison of change scores but with covariate adjustment for baseline measurements, age and sex. In total, 100 participants will be recruited to each group, which will allow for a 30% drop-out rate while retaining adequate statistical power.

The study will also record refusals, drop-outs and losses to follow-up. This may include participants who do not use the Pain Toolkit during the study period or who do not complete the outcome measures. It would potentially impact on the interpretation of the study results if either of these groups were large in number; it will therefore be important to determine how their results will be reported at the end of the study. There is no clear consensus on how missing data should be handled; however, we will complete an intention-to-treat analysis in which all participants are analysed in the group to which they were originally randomised. The statistical analysis described below involves a linear mixed model using restricted maximum likelihood, which is a principled approach to addressing missing outcome data.

Statistical analysis

Data will be cleaned and checked for missing entries before any analysis begins. An IBM SPSS programme will be used for descriptive and inferential statistical analysis. Analysis will follow an intention-to-treat framework, using linear mixed models to compare outcomes between the two groups. Data will be analysed using a linear mixed analysis of covariance model, adjusting for chance imbalances in outcome between groups at baseline. There will also be analysis of the covariates collected, including age, gender and duration of symptoms. This will be conducted by a statistician blinded to the group allocation. A 5% level of statistical significance will be used throughout. The research team will be unblinded once the analysis is complete.

Qualitative data gathered as part of the semistructured interviews will be transcribed and analysed using pragmatic, inductive analysis.[37] Following familiarisation with the data, initial codes will be generated, and then the data will be searched for themes. Themes may relate to prevalence of a topic being mentioned or may be identified because of their importance in relation to the research question. The themes will then be reviewed and refined. A second reader within the research team will read all transcripts to enhance study credibility and that the themes are rooted in the data.

Ethical considerations

Ethical approval for the study has been given by the Health Research Authority and the North East Newcastle, North Tyneside 2 Regional Ethics Committee (reference 18/NE/0144) and Teesside University's School of Health and Social Care Research Ethics and Governance Committee (reference 176/17). Participation in the study is based on informed consent of individuals, and participants are informed that usual treatment will be maintained whether or not they wish to participant in the study.

Dissemination

Dissemination of the findings will include presentations at relevant patient groups and at local, national and international conferences, and publication in peer-reviewed journals.

CONCLUSIONS

This paper describes the protocol for a study to investigate the effectiveness of a structured self-management programme (the Pain Toolkit) compared with standard treatments. This study will be of interest to all who work in the field of LBP, including service commissioners. The study should provide valuable information about the effectiveness of the Pain Toolkit in assisting patients after discharge from services.

Contributors GF is a Professional Doctorate Student at Teesside University and this paper is written as part of the Professional Doctorate Programme. DM is the director of studies for Gillian Findley; CR is the academic supervisor for GF. AC is a research assistant for the project. All authors listed have made a substantial contribution to the design of the study or to the development of the work and/or interpretation of the data.

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REFERENCES

1 Hoy D, March L, Woolf A, *et al*. The global burden of neck pain: estimates from the global burden of disease 2010 study. *Ann Rheum Dis* 2014;73:1309–15.

2 Murray CJL, Lopez AD. Measuring the global burden of disease. *N Engl J Med* 2013;369:448–57.
3 Murray CJL, Vos T, Lozano R, *et al*. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the global burden of disease study 2010. *The Lancet* 2012;380:2197–223.
4 Jordan KP, Kadam UT, Hayward R, *et al*. Annual consultation prevalence of regional musculoskeletal problems in primary care: an observational study. *BMC Musculoskelet Disord* 2010;11:144. [Internet].
5 Hong J, Reed C, Novick D, *et al*. Costs associated with treatment of chronic low back pain: an analysis of the UK general practice research database. *Spine* 2013;38:75–82.
6 National Institute for Health and Care Excellence. Low back pain and sciatica in over 16S: assessment and management. low back pain and sciatica in over 16S: assessment and management 2016.
7 Bevan S. Economic impact of musculoskeletal disorders (MSDs) on work in Europe. *Best Pract Res Clin Rheumatol* 2015;29:356–73.
8 Refshauge K, *et al*, WHO (World Health Organization), Collaborators GB of DS 2013. Priority diseases and reasons for inclusion. Priority Medicines for Europe and the World "A Public Health Approach to Innovation. 2013.
9 Ehrlich GE. Low back pain TT - Lombalgie TT - Lumbalgia. *Bull World Health Organ* 2003;81:671–6.
10 Pathway N of ERBP. The Pathway - North of England Regional Back Pain Programme [Internet], 2017. Available: https://www.noebackpainprogramme.nhs.uk/about-the-programme/the-pathway/ [Accessed cited 2019 Feb 27].
11 Jess M-A, Ryan C, Hamilton S, *et al*. Does duration of pain at baseline influence clinical outcomes of low back pain patients managed on an evidence-based pathway? *Spine* 2018;43:E998–1004.
12 Ryan C, Greenough C, Coxon A, *et al*. The North East back pain pathway: preliminary evaluation findings. *Spine J* 2017;17.
13 Barlow J, Wright C, Sheasby J, *et al*. Self-Management approaches for people with chronic conditions: a review. *Patient Educ Couns* 2002;48:177–87.
14 Engers JP, Wensing M, Dawm VDW, *et al*. Individual patient education for low back pain (review). *Cochrane Libr* 2011.
15 Dianne Liddle S, Gracey JH, David Baxter G. Advice for the management of low back pain: a systematic review of randomised controlled trials. *Man Ther* 2007;12:310–27.
16 Roland M, Dixon M. Randomized controlled trial of an educational booklet for patients presenting with back pain in general practice. *J R Coll Gen Pract* 1989;39:244–6.
17 Hazard RG, Reid S, Haugh LD, *et al*. A controlled trial of an educational pamphlet to prevent disability after occupational low back injury. *Spine* 2000;25:1419–23.
18 Clark NM, Becker MH, Janz NK, *et al*. Self-Management of chronic disease by older adults: a review and questions for research. *J Aging Health* 1991;3:3–27.
19 Schulman-Green D, Jaser S, Martin F, *et al*. Processes of self-management in chronic illness. *J Nurs Scholarsh* 2012;44:136–44.
20 Pain toolkit. Pain Self Management | How Can The Pain Toolkit Help? | Pain Toolkit [Internet], 2002. Available: https://www.paintoolkit.org/about/pain-toolkit [Accessed 27 Feb 2019].
21 NHS. LinkListing, 2019. Available: https://www.nhs.uk/Pages/LinkListing.aspx?&StartsWith=P [Accessed 20 Feb 2019].
22 Sealed envelope. Create a blocked randomisation list | Sealed Envelope [Internet], 2017. Available: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 27 Feb 2019].
23 Moore P. For Patients | Resources | The Pain Toolkit [Internet], 2019. Available: https://www.paintoolkit.org/resources/for-patients [Accessed 10 Apr 2019].
24 Martin R, Gordon W, Jennifer KM, *et al*. *The back book. 2nd ED*. Norwich: The Stationery Office, 2002.
25 Burton AK, Waddell G, Tillotson KM, *et al*. Information and advice to patients with back pain can have a positive effect: a randomized controlled trial of a novel educational booklet in primary care. *Spine* 1999;24:2484–91.
26 Rantonen J, Luoto S, Vehtari A, *et al*. The effectiveness of two active interventions compared to self-care advice in employees with non-acute low back symptoms: a randomised, controlled trial with a 4-year follow-up in the occupational health setting. *Occup Environ Med* 2012;69:12–20.
27 Moffett JK, Klaber Moffett J. Back pain: encouraging a self-management approach. *Physiother Theory Pract* 2002;18:205–12.
28 Fairbank JC, Couper J, Davies JB, *et al*. The Oswestry low back pain disability questionnaire. *Physiotherapy* 1980;66:271–3.
29 Fairbank JCT, Pynsent PB. The Oswestry disability index. *Spine* 2000;25:2940–53.
30 Banerjee A, Hendrick P, Bhattacharjee P, *et al*. A systematic review of outcome measures utilised to assess self-management in clinical trials in patients with chronic pain. *Patient Educ Couns* 2018;101:767–78.
31 Ostelo R, Deyo RA, Stratford P, *et al*. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine* 2008;33:90–4.
32 Fraenkel L, Falzer P, Fried T, *et al*. Measuring pain impact versus pain severity using a numeric rating scale. *J Gen Intern Med* 2012;27:555–60.
33 Jensen MP, Chen C, Brugger AM. Interpretation of visual analog scale ratings and change scores: a reanalysis of two clinical trials of postoperative pain. *J Pain* 2003;4:407–14.
34 Nicholas MK, Asghari A, Corbett M, *et al*. Is adherence to pain self-management strategies associated with improved pain, depression and disability in those with disabling chronic pain? *EJP* 2012;16:93–104.
35 Rabin R, Oemar M, Oppe M. *EQ5D user guide*, 2015.
36 Whynes DK, McCahon RA, Ravenscroft A, *et al*. Responsiveness of the EQ-5D health-related quality-of-life instrument in assessing low back pain. *Value in Health* 2013;16:124–32.
37 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.