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An Investigation of the effectiveness of the Pain Toolkit for people with low back pain: a 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 to a simple education control for people with low back pain.

Method 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 utilisation (number of health care professional visits) and quality-of-life (EuroQol (EQ5D)). Outcome measures will be completed at baseline, 6 months and at 12 months. Data will be analysed using ANCOVA 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 semi-structured interviews to explore individuals' experience of the Pain Toolkit. The qualitative data will be analysed using thematic analysis.

Ethics and dissemination

Approval for the study was given by the Heath 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, local, national and international conferences. Protocol registration number NCT03791164, registered in December 2018.

Key Words: Self-management, Low back pain, Pain Toolkit, Randomised controlled trial, mixed-methods

Article Summary

Strengths and limitations of the study

- This randomised control trial will investigate a simple, inexpensive way of supporting patients with low back pain
- The study team and 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 in the world.[(Hoy *et al.*, 2014),(Murray and Lopez, 2013), (Murray *et al.*, 2012)]. This causes a significant burden on health services with 14% of primary care consultations being for LBP.[(Jordan *et al.*, 2010)] Annual healthcare costs for patients with LBP are double that of matched control patients without back pain.[(Hong *et al.*, 2013)] LBP accounts for a significant disease burden and loss in productivity among working people.[(Murray *et al.*, 2012)(National Institute for Health and Care Excellence, 2016)]. 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". [(Bevan, 2015)] The World Health Organisation'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".[(WHO (World Health Organization) *et al.*, 2013)(Ehrlich, 2003)]

Across the North of England there is a regional back pain pathway[(Pathway, 2017)] which provides a consistent approach to the management of patients based upon the NICE guidelines for the management of LBP.[(National Institute for Health and Care Excellence, 2016)] Early evidence demonstrates positive outcomes for patients on this regional back pain pathway.[(Jess *et al.*, 2018)(Ryan *et al.*, 2017)] Within these guidelines many of the options relate to self-management[(National Institute for Health and Care Excellence, 2016)] and self-management is an integral part of the North of England Regional Back Pain Pathway.[(Pathway, 2017)] 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". [(Barlow *et al.*, 2002)] With evidence to

support its clinical effectiveness[(Dianne Liddle, Gracey and David Baxter, 2007; Engers *et al.*, 2011)(Roland and Dixon, 1989)(Hazard *et al.*, 2000)], self-management is a persuasive option for resource-limited services. However, there is little clarity on exactly what constitutes self-management and which approaches are best.[(Barlow *et al.*, 2002)(Clark *et al.*, 1991)(Schulman-Green *et al.*, 2012)]

The Pain Toolkit[(Pain Toolkit, 2002)] is a self-management tool for people with persistent pain. It has been developed by a non-healthcare professional with longstanding 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[(NHS, 2019)]. However, the effectiveness of this widely available tool has not been investigated. The aim of this study will be to investigate the effectiveness of the Pain Toolkit as a self-management tool for people with back pain following discharge from a treatment pathway.

OBJECTIVES

Primary Objective

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 to a usual care control.

Secondary Objectives

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 to a usual care control.

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

To investigate the effectiveness of the Pain Toolkit for quality-of-life as measured by EQ5D for people with LBP who have been discharged from a treatment pathway in comparison to 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.

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, which operationalises the NICE guidelines [(National Institute for Health and Care Excellence, 2016)]. 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.[(National Institute for Health and Care Excellence, 2016)] Individuals will be eligible for the study if: they are over 18 years of age, they 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[(National Institute for Health and Care Excellence, 2016)] 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[(Sealed envelope, 2017)] by a member of the research team not involved in the recruitment process. The participant will be posted the appropriate material dependent upon 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 twelve options for managing pain covering topics such as acceptance, goal setting, relaxation, exercise and pacing.[(Moore, 2019)] The reader is encouraged to choose up to three of the twelve options and use them until they feel comfortable doing so and then choose a further three and repeat the process. In preparation for the study a group of patient representatives were asked to review and comment upon the Pain Toolkit. Whilst not part of the formal evaluation of the study, this preparatory work provided valuable insight into patient's perception of the 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[(Martin *et al.*, 2002)]. 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.[(Burton *et al.*, 1999)(Rantonen *et al.*, 2012)] It has been reported that the Back Book has improved outcomes in patients who had a fear of physical activity.[(Burton *et al.*, 1999)(Klaber Moffett, 2002)]

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 i.e. The Pain Toolkit. Both groups will be instructed to carry on with their usual routine of activities and therapy as prescribed by their therapist upon discharge.

Outcomes

Primary Outcome Measure

The primary outcome measure for the study will be the ODI.[(Fairbank *et al.*, 1980)] The ODI is a measure of pain related disability. The ODI, first published in 1980,[(Fairbank *et al.*, 1980)] is one of the most commonly used outcome measures used with people with LBP.[(Fairbank and Pynsent, 2000)] The ODI has been shown to be a valid and reliable measure of pain related disability[(Banerjee *et al.*, 2018)] In 2006, an international expert panel determined that a change of 10 points (approx. 30% change) equates to a minimally important difference (MID)[(Ostelo *et al.*, 2008)] 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.[(Jensen, Chen and Brugger, 2003; Fraenkel *et al.*, 2012)]

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 upon a patient's perception of pain[(Nicholas *et al.*, 2011)]. It is therefore important to consider a patient's overall quality-of-life. Quality-of-life will be measured using the EuroQOL5D (EQ5D) ((Group, 2009)). 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.[(Whynes *et al.*, 2013)] The EQ-5D system has 5 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.

A sub group of participants from the intervention group will be identified and purposively sampled by a member of the research team who 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 last approximately 1 hour.

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 generated by an online random number generator. 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 (version 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 group assuming that the common standard deviation (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 whilst retaining adequate statistical power.

The study will also record refusals; drop outs and loses to follow-up. This may include participants who do not use the Pain Toolkit during the study period or who do not complete the outcomes 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 and we will carry forward the last value for participants where data are missing. We will also complete an available case analysis (per protocol analysis) using only complete data sets with not imputation.

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. 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 semi structured interviews will be transcribed and analysed using pragmatic, inductive analysis [(Braun and Clarke, 2006)]. Following familiarisation with the data, initial codes will be generated and then the data 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. Themes will then be reviewed and refined. A second reader within the research team will read all transcripts to ensure the credibility of the data and that the themes are rooted in the data.

Ethical Considerations

Ethical approval for the study was given by the Heath 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. Protocol registration number NCT03791164.

Dissemination

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

Data Availability Statement

Quantitative data will be provided as a technical appendix to any article and data from the trial will be made available upon reasonable request once the results are published.

CONCLUSIONS

This paper describes the protocol for a study to investigate the effectiveness of a structured self-management programme (the Pain Toolkit) compared to 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.

Author Statement: Gillian Findley is a Professional Doctorate at Teesside University and this paper is written as part of the Professional Doctorate Programme. Professor Denis Martin is the

Director of Studies for Gillian Findley; Dr Cormac Ryan is the academic supervisor for Gillian Findley. Dr Amy Cartwright is a research assistant for the project.

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Competing Interests: None declared

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	10
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	9
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/a

Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	4-5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	6

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8

Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8-9
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8-9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8-9
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	8-9
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	8-9
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a as this is part of an academic qualification
Data monitoring:	#21b	Description of any interim analyses and stopping guidelines, including who will	Academic tutors

interim analysis		have access to these interim results and make the final decision to terminate the trial	will review work
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Academic tutors will supervise work
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Academic tutors will ensure independence
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	9
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	9
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9 – covered in the ethic committee applications
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	10
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	9

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

An Investigation of the effectiveness of the Pain Toolkit for people with low back pain: a double blind randomised controlled trial

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Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	self-management, low back pain, Pain Toolkit, randomised controlled trial, mixed methods

An Investigation of the effectiveness of the Pain Toolkit for people with low back pain: a double blind randomised controlled trial

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Word count 3509 (excluding title page, abstract, tables and references)

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 to a simple education control for people with low back pain.

Method 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 utilisation (number of health care professional visits) and quality-of-life (EuroQol (EQ5D)). Outcome measures will be completed at baseline, 6 months and at 12 months. Data will be analysed using ANCOVA 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 semi-structured 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, local, national and international conferences. Protocol registration number NCT03791164, registered in December 2018.

Key Words: Self-management, Low back pain, Pain Toolkit, Randomised controlled trial, mixed-methods

Article Summary

Strengths and limitations of the study

- This randomised control trial will investigate a simple, inexpensive way of supporting patients with low back pain
- The study team and 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 in the world.[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 that 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 World Health Organisation'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] which provides a consistent approach to the management of patients based upon the 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 longstanding 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 will be 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 from 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

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 to a usual care control.

Secondary Objectives

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 to a usual care control.

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

To investigate the effectiveness of the Pain Toolkit for quality-of-life as measured by EQ5D for people with LBP who have been discharged from a treatment pathway in comparison to 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 North Durham Clinical Commissioning Group. This is a group of patients and members of the public registered with GP 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 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 over burdensome. Results of the study will be feedback 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, which 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, they 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 upon 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 twelve options for managing pain covering topics such as acceptance, goal setting, relaxation, exercise and pacing.[23] The reader is encouraged to choose up to three of the twelve options and use them until they feel confident in using the intervention and then choose a further three 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 health care professionals will address the patient's pain. In preparation for the study a group of patient representatives were asked to review and comment upon the Pain Toolkit. Whilst not part of the formal evaluation of the study, this preparatory work provided valuable insight into patient's perception of the 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 i.e. The Pain Toolkit. Both groups will be instructed to carry on with their usual routine of activities and therapy as prescribed by their therapist upon 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 (approx. 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 upon 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 EuroQOL5D (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 EQ-5D system has 5 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 questionnaire participants are asked the extent to which they have used the intervention that they received and whether there has been any change in their medication or therapy regime that may impact upon their outcomes measures. This information will be analysed be the research team as per the statistical analysis plan.

A sub group of participants from the intervention group will be identified and purposively sampled by a member of the research team who 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 last approximately 1 hour. This part of the study will assess how acceptable the interventions were to participants. 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 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 generated by an online random number generator. 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 (version 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 group assuming that the common standard deviation (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 whilst 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 outcomes 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 ANCOVA 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 semi structured 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 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. Themes will then be reviewed and refined. A second reader within the research team will read all transcripts to ensure the credibility of the data and that the themes are rooted in the data.

Ethical Considerations

Ethical 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'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. Protocol registration number NCT03791164.

Dissemination

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

Data Availability Statement

Quantitative data will be provided as a technical appendix to any article and data from the trial will be made available upon reasonable request once the results are published.

CONCLUSIONS

This paper describes the protocol for a study to investigate the effectiveness of a structured self-management programme (the Pain Toolkit) compared to 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.

Author Statement: Gillian Findley is a Professional Doctorate at Teesside University and this paper is written as part of the Professional Doctorate Programme. Professor Denis Martin is the Director of Studies for Gillian Findley; Dr Cormac Ryan is the academic supervisor for Gillian Findley. Dr Amy Cartwright 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.

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors

Competing Interests: None declared

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	10
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	9
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/a

Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	4-5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	6

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8

Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8-9
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8-9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8-9
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	8-9
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	8-9
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a as this is part of an academic qualification
Data monitoring:	#21b	Description of any interim analyses and stopping guidelines, including who will	Academic tutors

interim analysis		have access to these interim results and make the final decision to terminate the trial	will review work
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Academic tutors will supervise work
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Academic tutors will ensure independence
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	9
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	9
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9 – covered in the ethic committee applications
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	10
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	9

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

A Study Protocol for an Investigation of the effectiveness of the Pain Toolkit for people with low back pain: a double blind randomised controlled trial

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A Study Protocol for an Investigation of the effectiveness of the Pain Toolkit for people with low back pain: a 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 to a simple education control for people with low back pain.

Method 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 utilisation (number of health care professional visits) and quality-of-life (EuroQol (EQ5D)). Outcome measures will be completed at baseline, 6 months and at 12 months. Data will be analysed using ANCOVA 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 semi-structured 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, local, national and international conferences. Protocol registration number NCT03791164, registered in December 2018.

Key Words: Self-management, Low back pain, Pain Toolkit, Randomised controlled trial, mixed-methods

Article Summary

Strengths and limitations of the study

- This randomised control trial will investigate a simple, inexpensive way of supporting patients with low back pain
- The study team and 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 in the world.[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 that 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 World Health Organisation'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] which provides a consistent approach to the management of patients based upon the 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 longstanding 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 will be 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 from 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

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 to a usual care control.

Secondary Objectives

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 to a usual care control.

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

To investigate the effectiveness of the Pain Toolkit for quality-of-life as measured by EQ5D for people with LBP who have been discharged from a treatment pathway in comparison to 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 North Durham Clinical Commissioning Group. This is a group of patients and members of the public registered with GP 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 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 over burdensome. Results of the study will be feedback 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, which 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, they 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 upon 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 twelve options for managing pain covering topics such as acceptance, goal setting, relaxation, exercise and pacing.[23] The reader is encouraged to choose up to three of the twelve options and use them until they feel confident in using the intervention and then choose a further three 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 health care professionals will address the patient's pain. In preparation for the study a group of patient representatives were asked to review and comment upon the Pain Toolkit. Whilst not part of the formal evaluation of the study, this preparatory work provided valuable insight into patient's perception of the 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 i.e. The Pain Toolkit. Both groups will be instructed to carry on with their usual routine of activities and therapy as prescribed by their therapist upon 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 (approx. 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 upon 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 EuroQOL5D (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 EQ-5D system has 5 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 questionnaire participants are asked the extent to which they have used the intervention that they received and whether there has been any change in their medication or therapy regime that may impact upon their outcome measures. This information will be analysed by the research team as per the statistical analysis plan.

A sub group of participants from the intervention group will be identified and purposively sampled by a member of the research team who 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 last approximately 1 hour. This part of the study will assess how acceptable the interventions were to participants. 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 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 generated by an online random number generator. 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 (version 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 group assuming that the common standard deviation (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 whilst 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 outcomes 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 ANCOVA 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 semi structured 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 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. Themes will then be reviewed and refined. A second reader within the research team will read all transcripts to ensure the credibility of the data and that the themes are rooted in the data.

Ethical Considerations

Ethical 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'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. Protocol registration number NCT03791164.

Dissemination

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

Data Availability Statement

Quantitative data will be provided as a technical appendix to any article and data from the trial will be made available upon reasonable request once the results are published.

CONCLUSIONS

This paper describes the protocol for a study to investigate the effectiveness of a structured self-management programme (the Pain Toolkit) compared to 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.

Author Statement: Gillian Findley is a Professional Doctorate at Teesside University and this paper is written as part of the Professional Doctorate Programme. Professor Denis Martin is the Director of Studies for Gillian Findley; Dr Cormac Ryan is the academic supervisor for Gillian Findley. Dr Amy Cartwright 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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Competing Interests: None declared

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	10
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	9
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/a

Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	4-5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	6

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	5
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	8
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7-8

Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8-9
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8-9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8-9
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	8-9
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	8-9
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a as this is part of an academic qualification
Data monitoring:	#21b	Description of any interim analyses and stopping guidelines, including who will	Academic tutors

interim analysis		have access to these interim results and make the final decision to terminate the trial	will review work
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Academic tutors will supervise work
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Academic tutors will ensure independence
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	9
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	9
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9 – covered in the ethic committee applications
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	10
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	9

Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a