BMJ Open

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| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2018-027516 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 26-Oct-2018 |
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| Keywords: | Low back pain, health literacy, internet resources |
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# MyBackPain: Evaluation of an innovative consumer-focused website for low back pain - study protocol for a randomised controlled trial

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Word count: 3219

## ABSTRACT

### Introduction

Despite the prevalence of low back pain (LBP) worldwide, many people with the condition do not receive evidence-based care or achieve the best possible outcomes. There is a gap in the dissemination of evidence-based information across the globe. The advent of the internet has changed the way people obtain health information. As such, trustworthy, tailored and validated LBP resources may help bridge the gap. This study aims to measure the effectiveness of a new website (MyBackPain) in improving spinal health literacy, treatment preferences and clinical outcomes for people with LBP, in comparison to other online resources.

### Methods and analysis

This online, pragmatic, randomised controlled trial will comprise 440 people with non-specific LBP of any duration. In addition to access to publicly available online information (control group), the intervention group will be given access to the MyBackPain.org.au website. Participants and research staff, including the biostatistician, will be blinded to treatment allocation. Data will be collected at baseline, 1, 3 (primary end-point), 6 and 12 months via online surveys and questionnaires. The primary outcome is spinal health literacy. Secondary outcomes include quality of treatment preferences (stated and observed) and LBP clinical outcomes (pain, disability and quality of life). Analyses will be by intention-to-treat and include outcome data on all randomised participants. Descriptive statistics will be presented for demographic and clinical characteristics.

### Ethics and dissemination

This trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry and has ethical approval from the University of Queensland Human Research Ethics

Committee (2017000995). Trial outcomes will be shared via national and international conference presentations and peer-reviewed journal publications.

**Trial registration number:** ACTRN12617001292369 (registered on 7th September 2017).

## Article Summary

### Strengths and limitations of this study

- The study will test a new evidence-based low back pain website developed in collaboration with individuals with LBP, clinicians, and an international team of experts
- An entirely online randomised clinical trial will allow engagement of people with low back pain across Australia to increase generalisability of the results
- The study will provide valuable information about how people with acute and chronic low back pain use the internet to research their condition and investigate if provision of concise evidence-based information can change their health literacy and clinical outcomes

## INTRODUCTION

According to the global burden of disease study, low back pain (LBP) is the leading cause of disability worldwide [1] placing an enormous burden on individuals and economies. Up to 80% of individuals experience LBP at least once in their lifetime [2] and when it persists it accounts for 30% of all chronic pain.[3] Total annual expenditure in Australia includes approximately $4.8 billion in direct costs [4] and over $8 billion in indirect costs.[5] Much of this burden involves unnecessary and ineffective assessments and treatments.[6] The impact of LBP is worsened by negative messages and beliefs, and poor-quality management.[7, 8] Early education and access to the most effective treatments could reduce much of this excessive burden. There is a clear role for a LBP education/guidance portal to empower patients to optimise active participation in their negotiation of treatments and healthcare providers.

People increasingly use the Internet to obtain health-related information.[9, 10] It has great potential to educate and engage patients in the management of health conditions. People with LBP consistently report a desire for trustworthy information about their condition [11-14] and the internet, with its capacity to provide tailored information in varied formats at a time and place of the user's choosing, is ideal to provide such information. Positive features of internet use include the potential for patients to become better informed about their condition and potential treatment options,[15-18] to become more engaged with their treatment,[19] and to improve health outcomes with more appropriate use of health resources.[18, 20, 21] Access and reflection on information prior to clinical visits could also ensure efficient use of clinical consultation time,[15, 20] enhance relationships between patients and clinicians [18] and foster informed decision-making.[20]

When evaluated against criteria developed from relevant guidelines and research evidence,[22-24] LBP websites are consistently rated as "poor" in overall quality and do not meet the expressed needs of patients with LBP [Nielsen, unpublished data]. In addition, the language and terminology used on many LBP websites are not tailored to the intended audience making the information difficult for users to understand.[23]

We have shown that people with LBP are interested in a range of information topics including diagnostic and treatment information, lay or experience-based information, practical self-help strategies, recognition and discussion of psychosocial concerns.[25] These are often lacking in current websites [Nielsen, unpublished data]. Consumer preferences regarding presentation of information emphasise multimodality, readability, quality assurance, and interactivity [Nielsen, unpublished data], none of which are satisfactorily achieved with the resources currently available.

As a part of this randomised controlled trial, we have developed a comprehensive LBP website (MyBackPain.org.au) that integrates evidence-based LBP information and tailored guidance and explicitly considers the needs and preferences of individuals with LBP. The highest quality information for people with both acute and chronic LBP has been identified and distilled to easily understood resources in multiple formats (patient and clinician videos, information sheets, quizzes) and uses evidence-based algorithms to create tailored consumer guidance. The MyBackPain website is designed to improve health outcomes by: (i) enhancing consumer confidence in managing their condition and making treatment choices with emphasis on evidence-based assessments and treatments; and avoidance of investigations and treatments that are ineffective, unnecessary or harmful; (ii) de-medicalising and normalising LBP with messages in multiple formats that reinforce that back pain is a natural part of life for many and in most

cases can be managed with early return to activity; (iii) providing tools for individuals to identify if further investigation and/or management may be required, and (iv) engaging patients in healthy behaviours and attitudes to reduce the burden of LBP.

### Aim

The aim of this randomised controlled trial is to evaluate the effectiveness of the newly developed, multifaceted MyBackPain website compared to existing internet resources. We hypothesise that the MyBackPain website will be more effective than existing internet resources in improving health literacy, choice of evidence-based treatments, and clinical outcomes in people with LBP.

## METHODS AND ANALYSIS

### Study design

This manuscript describes a research protocol for the MyBackPain randomised controlled trial. This prospectively registered, pragmatic, online-based, randomised controlled trial with assessor and participant blinding, will recruit individuals with LBP from across Australia. Participants will be randomised to groups that could either; (i) access any existing online resources (control group) or (ii) have access to the MyBackPain online resource in addition to other readily available online resources (intervention group). The comparison with self-directed use of the internet will provide a pragmatic comparison of the effects of the MyBackPain website. Central, computerized randomisation will be used to ensure allocation concealment. This protocol has been developed in accordance with SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials).[26]

**Participant Recruitment**

Participants will be recruited from the community using newsletters, email lists, consumer groups (e.g. Arthritis Australia, Chronic Pain Australia), websites, social media, and talks at group meetings. Our partner health insurer (Medibank Private) will also make available their insurance membership cohort for recruitment purposes. This study will recruit participants with LBP from November 2017 until the sample size is achieved.

Potential participants will be provided with a web-link to a page that provides the participant information sheet and consent form where they will be asked if they have read and understood the information and if they consent to participate in the trial. Consent will be provided by checking the appropriate box. Those who consent to participate will then be directed to a screening form to determine their eligibility. Eligible participants will complete the baseline data questionnaires/surveys before randomisation into the intervention or control group. To encourage retention in the study, participants will be offered entry into a draw for an iPad mini on completion of all time points of the data collection. One iPad will be awarded for each 44 participants.

**Participants**

Inclusion criteria

Participants will be included if they meet **all** the following criteria:

- Current low back pain of any duration
- Aged 18 years and above (no upper age limit)
- Reside in Australia

- Adequate English to complete outcome measures and interact with the MyBackPain website
- Internet access for the duration of the trial

Participants will be excluded if they have a previous or existing serious spinal pathology (defined as fracture, cancer, infection) or been diagnosed with specific spinal pathology including sciatica, lumbar spinal stenosis or nerve root compromise.

**Study Treatments**

Participants will be randomised to an Intervention or Control group. Stratified permuted block randomisation will be used, with blocks of sizes 6 to 12 stratified by symptom duration (acute or chronic). An episode of acute LBP will be considered to be pain of less than 6 weeks duration with at least 4 weeks between pain episodes.[27] All other pain presentations will be considered chronic LBP. All participants will be advised that the study aims to investigate the impact of the use of the Internet on LBP. Participants are free to use web resources in any manner in which they feel appropriate and for any amount of time.

Intervention - MyBackPain website

The content and framework of the MyBackPain website has been developed according to an extensive process of consultation and collaboration with individuals with LBP and clinicians, and with an international team of experts who were engaged to contribute to the development of evidence-based content (Table 1).

**Table 1: Steps involved in the development of the MyBackPain website**

| Step | Process |
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|---|---|
| 1. Identification of consumer needs – website content and presentation | Qualitative study of consumer needs involving focus groups and interviews with patients with LBP [25] and clinicians [28] |
| 2. Evaluation of existing LBP websites | Review comparing content of existing websites to content and format criteria developed from step 1 (Nielsen et al., unpublished data). |
| 3. Establishment of expert steering committee | An international advisory committee established with representation of multiple disciplines (medicine; physiotherapy; chiropractic; occupational therapy, etc.) and multiple regions (Australia; Europe; North America; Asia). |
| 4. Identification of key messages | Evidence-based messages were identified from the literature (clinical practice guidelines; systematic reviews). Experts were consulted using a Delphi process to review, add, edit and refine the key messages. Language was optimised with consumer focus groups. Priority order of presentation was assessed using an on-line process with consumers and international experts from multiple disciplines. A final list of 30 messages was identified for reinforcement throughout all materials on the website and all formats (French et al., in preparation). |
| 5. Generation of list of frequently asked questions | Qualitative study with focus groups |
| 6. Content consensus | Consensus workshop at "LBP Forum" international conference |
| 7. Development of treatment summaries | Orthodox and complimentary treatments were identified by the expert steering committee with consumer input. A draft description of each treatment and a synthesis of research evidence from the best available evidence (systematic reviews; clinical trials and clinical practice guidelines) was developed by an independent expert group and a consumer writer. International experts were identified to review each treatment summary and allocate an "evidence grade badge" to enable quick identification of evidence levels for treatments or the potential for harm. All summaries and evidence grades were reviewed for consistency by the international advisory board and 6 additional experts. |
| 8. Profession descriptions | Consultation with respective professional societies |
| 9. Content development | Content was developed in a range of formats including: an algorithm aligned to that used by clinicians to tailor information for people with acute and chronic LBP and create a management plan; multilayered information content enabling users to access as little or as much detail on a topic as they prefer; self-monitoring applications to track status and recovery as determined by measures of activity and participation; and responses to the "frequently asked questions". All content was aligned to the 'key messages'. |

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| 10. Development/refinement of algorithms to guide content utilisation | Two algorithms were developed on the basis of existing stratification/prognostic tools. The StartBack tool and Pick-up tool were adapted to guide the user experience for individuals with LBP of greater than or less than 3 months duration, respectively. The tools were used to evaluate possible risk of poorer outcome and tailoring information regarding advice to access psychologically informed resources if required. |
| 11. Consumer input, review and feedback | Consumers contributed to focus groups in the planning phases and review and refinement of content in the latter phases. Professional groups with an interest in LBP and relevant consumer groups were consulted to assist with refinement of the website content. Extensive testing of formats and information was undertaken using a variety of methods including focus groups. |
| 12. Beta testing | A full beta version of the website was constructed and extensively reviewed with consumer feedback |

Participants randomised to the Intervention group will be given access to the MyBackPain website for the duration of the trial via a unique username and password to minimise crossover from the Control to the Intervention group. The website is not publicly available and no content can be accessed without the username/password combination individually provided to participants in the Intervention group. Participants will be able to use the website in multiple ways: self-directed browsing and searching of the content; inbuilt automated guided content tailored to the features of their presentation and identified information priorities; and the opportunity to "opt-in" to receive regular e-mails that highlight key messages about LBP. Participants will be free to determine how, when and how often they access the website. They will be free to decide which content they use and the format they prefer (e.g. text, video, patient stories etc.). The website will send automated messages to encourage users to return and access additional content and refresh their knowledge if they have opted to receive the regular emails. They will be encouraged to save information of interest to their "dashboard" for easy access and print out relevant information for later reference or use in visits with their healthcare provider.

Control

Participants randomised to the Control group will be asked to record the address of any websites they access for information about LBP throughout the trial and relay this information in the weekly (weeks 1-12) and monthly (months 3-12) online diaries. They will not have access to, or knowledge of, the MyBackPain website until it is launched to the public; i.e. after completion of the trial.

**Data collection**

All data will be collected online using REDCap (Research Electronic Data Capture, Vanderbilt University). Online data collection was chosen to allow inclusion of participants from any location in Australia. This approach enhances the feasibility of the trial and the generalisabilty of the results. Participants will complete an online questionnaire at baseline to provide demographic data (e.g. age, sex, height, weight, education, job and job status) and details about their low back symptoms (including location, intensity, duration, frequency and past treatments).

All other data will be collected at baseline, 1 month, 3 months (primary end-point), 6 months and 12 months (Table 2). In addition, weekly diaries will be used to gather information about current pain levels, treatments used, and websites visited for information about LBP. At the 3-month time point, the diaries will be sent monthly for the remainder of the trial. The time of primary outcome (3 months) has been selected as we expect access to the resource to modify treatment choices and outcome over an extended period.

Data pertaining to the information sought and frequency of use of the intervention website will be collected using OpenTracker software and assessed via website-use statistics.

**Treatment adherence**

Each user's history of access to the MyBackPain website will be recorded based on their unique log-in (Intervention group only), and the use of other websites will be recorded via participant entries into the online weekly diary.

**Blinding**

Participants and investigators (except the project manager) will be blinded to treatment allocation. All participants will be advised that the study aims to investigate the impact of use of the internet on LBP, but will be unaware of which specific website will be evaluated. Data analyses will be conducted by a blinded biostatistician. We anticipate no reason for revealing a participant's intervention allocation during the trial.

**Outcome measures**

Primary Outcomes

The primary outcome will be the spinal health literacy evaluation measured with the Health Literacy Questionnaire (HLQ).[29] The HLQ includes 44 items and nine dimensions. Dimensions 2 and 3 will be included as co-primary outcome measures: "having sufficient information to manage my health" and "actively managing my health". These dimensions will be assessed using a 4-point Likert scale (1 - completely disagree; 4 - completely agree) and a 0-100 score will be presented for each dimension. The preamble to the survey will ask participants to consider their LBP when answering the survey.

Secondary outcomes

Secondary outcomes include dimensions 1 ("feeling understood and supported by healthcare providers"), and 4-9 ("social support for health"; "appraisal of health information"; "ability to actively engage with healthcare providers"; "navigating the healthcare system"; "ability to find

good health information", and "understand health information well enough to know what to do" respectively) of the HLQ. These 7 dimensions will be assessed using a 4-point Likert scale (1 - completely disagree; 4 - completely agree).

We will also investigate patient preference for a number of treatment choices mentioned in the MyBackPain website in terms of the likelihood of healthy (i.e. treatments rated as strong evidence and some evidence) or unhealthy treatment choices. The treatments patients indicate as being healthy or unhealthy (stated) and the treatments they actually use (observed) will be measured in each group in three ways:

i) Quality of treatment preference (stated): Patient decision-making will be measured by evaluation of stated effectiveness of treatment choices. Patients will be asked to click on a 5-item scale (effective, somewhat effective, unsure, not very effective, not effective) if they think a subset of treatments discussed in the MyBackPain website are effective for people's LBP in general (but not specifically their own pain). Treatment choices will be scored against the recommendations provided in the MyBackPain website according to the classifications of "good evidence", "may work", "not enough evidence", "unlikely to work" and "may be harmful".

ii) Quality of treatment preference (observed - scored): Treatments that are used by participants will be evaluated against the recommendations provided in the MyBackPain website according to the classifications of "good evidence", "may work", "not enough evidence", "unlikely to work" and "may be harmful". Participants of both groups will be asked to record weekly in the online diary any treatments received for their LBP.

iii) Quality of treatment preference (observed - proportion): The proportion of participants who choose treatments that are, according to the MyBackPain website, either recommended or considered to have no effect or be harmful in each group will be assessed separately (recommended; no effect; harmful), using data from the online participant diary.

LBP clinical outcomes will also be included as secondary outcomes and measured with the following validated tools:

(i) Pain – Visual analogue scale (VAS) of average overall LBP in the last week recorded on a scale anchored with "no pain" at 0 and "worst pain imaginable" at 10

(ii) Disability - Roland Morris Disability questionnaire [30]

(iii) Quality of life - AQoL-8D [31]

**Table 2: Schedule of enrolment, intervention and assessments**

| | Enrolment | Baseline | Allocation | Post-Allocation (months) | | | |
|---|---|---|---|---|---|---|---|
| Time point | | | 0 | 1 | 3 | 6 | 12 |
| **Enrolment:** | | | | | | | |
| Eligibility screen | X | | | | | | |
| Informed consent | X | | | | | | |
| Randomisation | | | X | | | | |
| **Intervention:** | | | | | | | |
| Control | | | | | | | |
| MyBackPain | | | ← | — | — | — | → |
| **Assessment:** | | | | | | | |
| Demographics | | X | | | | | |
| HLQ | | X | | X | X | X | X |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| RMDQ | | X | | X | X | X | X |
| AQoL-8D | | X | | X | X | X | X |
| Treatment choices | | X | | X | X | X | X |
| Weekly diary – Pain VAS, websites visited, treatments used | | | ← | — | → | | |
| Monthly diary Pain VAS, websites visited, treatments used | | | | | ← | — | → |

**Data Integrity**

All data will be directly collected into a custom-built Electronic Data Capture program, with a prompt for double checking of the accuracy of the primary outcomes. Any inconsistencies in the data will be explored and resolved. The database will be backed-up regularly on a secure network and be compliant with the ICH Guideline for Good Clinical Practice,[32] according to our Data Management Plan. Study personnel will only be able to access the database with a personal login and password.

**Retention of documents**

The study investigators will maintain adequate and accurate records to enable the conduct of the study to be fully documented and the study data to be subsequently verified. Should the study investigators wish to assign the study records to another party or move them to another location, the sponsor will be notified in advance. After the completion of the study, study data will be archived by The University of Queensland for a minimum of 15 years.

## Data analysis

Analyses will be by intention-to-treat of all randomised participants who completed the baseline surveys. To assess the difference in the primary outcome between groups, longitudinal linear regression models will be fit, including all data from 1, 3, 6 and 12 months as an outcome for each participant. Models will be adjusted for baseline values of outcomes and the stratification variable symptom duration and also include a term for month, and an interaction between month and randomised group included as fixed effects, with random effects for participants. Similar longitudinal logistic regression models will be used for binary outcomes. These models will be interrogated to yield differences between groups at each time point. Standard diagnostic plots will be used to assess regression assumptions. Descriptive statistics on demographics and clinical characteristics will be presented for both the control and intervention group as the mean change (standard deviation, 95% confidence intervals) or counts and percentages for categorical variables. Multiple imputation methodology will be employed to account for missing data. No statistical adjustment will be made for multiple testing. All tests will be carried out at the 5% level of significance.

Sample size calculation is based on an effect size of 0.30, for "having sufficient information to manage my health" and "actively managing my health" dimensions of the HLQ. A sample size of 440 participants (minimum of 25% acute participants) will achieve 80% power to detect the desired effect size, allowing for a conservative loss to follow-up rate of 20% at three months.

## Ethics and dissemination

The study has been approved by the University of Queensland Human Research Ethics Committee and is registered with the Australian New Zealand Clinical Trials Registry (Table 3). The study is sponsored by the National Health and Medical Research Council of Australia

(NHMRC) and Medibank Health Research Fund and centrally managed by staff at the University of Queensland. The trial sponsor has had no role in the design or conduct of the trial. The current protocol is version 1 (7th September 2017) and any modifications to the protocol will require formal amendment following the approval of the principal investigator (PWH).

Participants will be provided with the contact details of the project manager for any queries or concerns. Any complaints arising from the trial will be recorded and acted upon in accordance with institutional policy. Participants will be informed they are free to withdraw from the study at any time without consequence. They will be asked if they would like to receive a copy of the manuscript at the completion of the trial.

All data will be stored in electronic format in a de-identified manner on a secure server. The database will be password protected and only accessible by the research team. At the completion of the trial, the data collection portal will be closed and data will be retained in a de-identified format on the protected server at The University of Queensland. The MyBackPain website will remain active and launched to the public at the completion of the trial. Users of the MyBackPain website will have the option to create a user account on the website. This information will not be collected or used by the project team and will be housed on a host server managed by Arthritis Australia. Users of the MyBackPain website will be told of the purpose and protection of the user account prior to its creation.

We do not anticipate further use of the data, but participants will be asked to give consent to the potential future use of de-identified data so as not to limit this possibility. Any potential plan to use the data for an additional purpose will be considered by the investigative team.

**Table 3: Trial registration data**

| Data category | Information |
|---|---|
| Primary registry and trial identifying number | Australia New Zealand Clinical Trials Registry ACTRN12617001292369 |
| Date of registration in primary registry | 07/09/2017 |
| Secondary identifying numbers | Universal Trial Number U1111-1196-6323 |
| Sources of monetary or material support | Sponsors (below) |
| Primary sponsor | National Health and Medical Research Council - Research Committee Secretariat NHMRC GPO Box 1421 Canberra ACT 2601 |
| Secondary sponsor | Medibank Health Research Fund - 720 Bourke Street, Docklands, VIC 3008 |
| Contact for public queries | PH (p.hodges@uq.edu.au) |
| Contact for scientific queries | PH (p.hodges@uq.edu.au) |
| Public title | Efficacy of a multi-faceted web-based resource on spinal health literacy in patients with low back pain - a randomised controlled trial |
| Scientific title | Efficacy of a multi-faceted web-based resource on spinal health literacy in patients with low back pain - a randomised controlled trial |
| Countries of recruitment | Australia |
| Health condition or problem studied | Low back pain |
| Intervention | Multi-faceted web-based resource “MyBackPain” |
| Key inclusion and exclusion criteria | Inclusion criteria: > 18 years of age, current low back pain, reside in Australia, adequate English to complete surveys, internet access for the duration of the trial |
| | Exclusion criteria: previous or existing spinal pathology (e.g. fracture, cancer, infection, nerve root compromise) |
| Study type | Randomised controlled trial, participant and assessor blinding, central computerised randomisation |
| Date of first enrolment | 06/12/2017 |
| Target sample size | 440 (at least 25% acute participants i.e. pain < 6 weeks with a minimum of 1 month without symptoms) |
| Recruitment status | Recruiting |
| Primary outcome(s) | Health Literacy Questionnaire |
| Key secondary outcomes | Quality of treatment preference (observed) Patient decision-making - measured by evaluation of observed treatment choices. Treatments used by the participant during the follow-up period will be scored against the recommendations provided in the MyBackPain website, and based on a 5-point |

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| | rating: “strong evidence”, “some evidence”, “unclear evidence/untested”, “evidence of no effect” and “harmful”. The average score will be used. |

Data will be analysed and results published in a peer-reviewed scientific journal after study completion and will be presented at scientific meetings. Conference presentation opportunities would be proactively targeted at the leading multidisciplinary conferences on pain, LBP and primary care.

Manuscript(s) will be submitted to major peer-reviewed journal(s) after the completion of randomised clinical trial. Leading multidisciplinary conferences on pain, LBP and primary care will also be targeted for dissemination of the study findings.

**Author Contributions**

All authors have contributed equally to the design of the trial and preparation of the study protocol manuscript.

**Funding statement**

This work was supported by the NHMRC (APP1079078) and a grant from the Medibank Health Research Fund (Table 3). MF is funded by an NHMRC Career Development Fellowship (APP1143593) and a Sydney Medical Foundation Fellowship. DJH is supported by an NHMRC Practitioner Fellowship. KLB is supported by a NHMRC Principal Research Fellowship (APP1058440). JS is supported by an NHMRC Early Career Fellowship (APP1157179).

**Competing interests statement**

DJH is on advisory boards for Merck Serono, Tissuegene, TLC Bio and Flexion, outside of the submitted work. All other authors have no interests to declare.

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# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

MyBackPain: Evaluation of an innovative consumer-focused website for low back pain - study protocol for a randomised controlled trial



| | | Reporting Item | Page Number |
|---|---|---|---|
| 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 | 2-3 and Table 3 |
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | Table 3 |
| Protocol version | #3 | Date and version identifier | 16 |
| Funding | #4 | Sources and types of financial, material, and other support | Table 3 |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | 17 |
| Roles and responsibilities: | #5b | Name and contact information for the trial sponsor | Table 3 |

| | | | |
|---|---|---|---|
| sponsor contact information | | | |
| 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 | 16 |
| 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) | NA |
| 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 | 5-7 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 5-7 |
| Objectives | #7 | Specific objectives or hypotheses | 7 |
| 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) | 7-8 |

| | | | |
|---|---|---|---|
| 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 | 8 |
| 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) | 8-9 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 9-10 |
| 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 improving / worsening disease) | 16 |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | 11 |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | #12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final | 11-13 |

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| | | 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 | |
| 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) | Table 2 |
| 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 | 7-8 and 15 |
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8-9 |
| 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 | 8 |
| Allocation concealment mechanism | #16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed | 8 |

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| | | envelopes), describing any steps to conceal the sequence until interventions are assigned | |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 12 |
| 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 | 12 |
| 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 | 11-12 |
| 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 |

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| 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 | 15-16 |
| 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 | 16-17 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 16-17 |
| 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) | 16-17 |
| 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 | NA |
| Data monitoring: interim analysis | #21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |

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| 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 | 17 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 17 |
| 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) | 17 |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 17-18 |
| 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 | 17-18 |

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| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 20 |
| 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 | 17-18 |
| 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 | NA |
| 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 | 19 |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 19 |
| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | n/a |
| 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 | n/a |

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| | the current trial and for future use in ancillary studies, if applicable |

BMJ Open

# MyBackPain: Evaluation of an innovative consumer-focused website for low back pain - study protocol for a randomised controlled trial



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| Journal: | *BMJ Open* |
| Manuscript ID | bmjopen-2018-027516.R1 |
| Article Type: | Protocol |
| Date Submitted by the Author: | 08-Feb-2019 |
| Complete List of Authors: | Hall, Leanne; The University of Queensland, School of Health and Rehabilitation Sciences<br>Ferreira, Manuela; University of Sydney Institute of Bone and Joint Research,<br>Setchell, Jenny; The University of Queensland, School of Health and Rehabilitation Sciences<br>French, Simon; Macquarie University, Department of Chiropractic<br>Kasza, Jessica; Monash University, Department of Epidemiology and Preventive Medicine<br>Bennell, Kim; University of Melbourne, CHESM<br>Hunter, David; The University of Sydney,<br>Vicenzino, Bill; The University of Queensland, Physiotherapy<br>Dickson, Chris; Arthritis Australia<br>Hodges, Paul; The University of Queensland, School of Health and Rehabilitation Sciences |
| Primary Subject Heading: | Rehabilitation medicine |
| Secondary Subject Heading: | Evidence based practice |
| Keywords: | Low back pain, health literacy, internet resources |
| | |

# MyBackPain: Evaluation of an innovative consumer-focused website for low back pain - study protocol for a randomised controlled trial

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Word count: 3219

## ABSTRACT

### Introduction

Despite the prevalence of low back pain (LBP) worldwide, many people with the condition do not receive evidence-based care or achieve the best possible outcomes. There is a gap in the dissemination of evidence-based information across the globe. The advent of the internet has changed the way people obtain health information. As such, trustworthy, tailored and validated LBP resources may help bridge the gap. This study aims to measure the effectiveness of a new website (MyBackPain) in improving spinal health literacy, treatment preferences and clinical outcomes for people with LBP, in comparison to other online resources.

### Methods and analysis

This online, pragmatic, randomised controlled trial will comprise 440 people with non-specific LBP of any duration. In addition to access to publicly available online information (control group), the intervention group will be given access to the MyBackPain.org.au website. Participants and research staff, including the biostatistician, will be blinded to treatment allocation. Data will be collected at baseline, 1, 3 (primary end-point), 6 and 12 months via online surveys and questionnaires. The primary outcome is spinal health literacy. Secondary outcomes include quality of treatment preferences (stated and observed) and LBP clinical outcomes (pain, disability and quality of life). Analyses will be by intention-to-treat and include outcome data on all randomised participants. Descriptive statistics will be presented for demographic and clinical characteristics.

### Ethics and dissemination

This trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry and has ethical approval from the University of Queensland Human Research Ethics

Committee (2017000995). Trial outcomes will be shared via national and international conference presentations and peer-reviewed journal publications.

**Trial registration number:** ACTRN12617001292369 (registered on 7th September 2017).

## Article Summary

### Strengths and limitations of this study

- Involves the collaboration of individuals with low back pain, clinicians and international experts in back pain to conceptualise a new evidence-based low back pain website
- An entirely online randomised clinical trial that allows engagement of people with low back pain across Australia to increase generalisability of the results
- Contamination of study groups is not high risk given the password protected website and specific instruction to participants not to share site information but we cannot measure adherence to this request

## INTRODUCTION

According to the global burden of disease study, low back pain (LBP) is the leading cause of disability worldwide [1] placing an enormous burden on individuals and economies. Up to 80% of individuals experience LBP at least once in their lifetime [2] and when it persists it accounts for 30% of all chronic pain.[3] Total annual expenditure in Australia includes approximately $4.8 billion in direct costs [4] and over $8 billion in indirect costs.[5] Much of this burden involves unnecessary and ineffective assessments and treatments.[6] The impact of LBP is worsened by negative messages and beliefs, and poor-quality management.[7, 8] Early education and access to the most effective treatments could reduce much of this excessive burden. There is a clear role for a LBP education/guidance portal to empower patients to optimise active participation in their negotiation of treatments and healthcare providers.

People increasingly use the Internet to obtain health-related information.[9, 10] It has great potential to educate and engage patients in the management of health conditions. People with LBP consistently report a desire for trustworthy information about their condition [11-14] and the internet, with its capacity to provide tailored information in varied formats at a time and place of the user's choosing, is ideal to provide such information. Positive features of internet use include the potential for patients to become better informed about their condition and potential treatment options,[15-18] to become more engaged with their treatment,[19] and to improve health outcomes with more appropriate use of health resources.[18, 20, 21] Access and reflection on information prior to clinical visits could also ensure efficient use of clinical consultation time,[15, 20] enhance relationships between patients and clinicians [18] and foster informed decision-making.[20]

When evaluated against criteria developed from relevant guidelines and research evidence,[22-24] LBP websites are consistently rated as "poor" in overall quality and do not

meet the expressed needs of patients with LBP [Nielsen, unpublished data]. In addition, the language and terminology used on many LBP websites are not tailored to the intended audience making the information difficult for users to understand.[23]

We have shown that people with LBP are interested in a range of information topics including diagnostic and treatment information, lay or experience-based information, practical self-help strategies, recognition and discussion of psychosocial concerns.[25] These are often lacking in current websites [Nielsen, unpublished data]. Consumer preferences regarding presentation of information emphasise multimodality, readability, quality assurance, and interactivity [Nielsen, unpublished data], none of which are satisfactorily achieved with the resources currently available.

As a part of this randomised controlled trial, we have developed a comprehensive LBP website (MyBackPain.org.au) that integrates evidence-based LBP information and tailored guidance and explicitly considers the needs and preferences of individuals with LBP. The highest quality information for people with both acute and chronic LBP has been identified and distilled to easily understood resources in multiple formats (patient and clinician videos, information sheets, quizzes) and uses evidence-based algorithms to create tailored consumer guidance. The MyBackPain website is designed to improve health outcomes by: (i) enhancing consumer confidence in managing their condition and making treatment choices with emphasis on evidence-based assessments and treatments; and avoidance of investigations and treatments that are ineffective, unnecessary or harmful; (ii) de-medicalising and normalising LBP with messages in multiple formats that reinforce that back pain is a natural part of life for many and in most cases can be manageded with early return to activity; (iii) providing tools for individuals to identify if further investigation and/or management may be required, and (iv) engaging patients in healthy behaviours and attitudes to reduce the burden of LBP.

### Aim

The aim of this randomised controlled trial is to evaluate the effectiveness of the newly developed, multifaceted MyBackPain website compared to existing internet resources. We hypothesise that the MyBackPain website will be more effective than existing internet resources in improving health literacy, choice of evidence-based treatments, and clinical outcomes in people with LBP.

## METHODS AND ANALYSIS

### Study design

This manuscript describes a research protocol for the MyBackPain randomised controlled trial. This prospectively registered, pragmatic, online-based, randomised controlled trial with assessor and participant blinding, will recruit individuals with LBP from across Australia. Participants will be randomised to groups that could either; (i) access any existing online resources (control group) or (ii) have access to the MyBackPain online resource in addition to other readily available online resources (intervention group). The comparison with self-directed use of the internet will provide a pragmatic comparison of the effects of the MyBackPain website. Central, computerized randomisation will be used to ensure allocation concealment. This protocol has been developed in accordance with SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials).[26]

### Participant Recruitment

Participants will be recruited from the community using newsletters, email lists, consumer groups (e.g. Arthritis Australia, Chronic Pain Australia), websites, social media, and talks at group meetings. Our partner health insurer (Medibank Private) will also make available their insurance membership cohort for recruitment purposes. This study will recruit participants with LBP from November 2017 until the sample size is achieved.

Potential participants will be provided with a web-link to a page that provides the participant information sheet and consent form where they will be asked if they have read and understood the information and if they consent to participate in the trial. Consent will be provided by checking the appropriate box. Those who consent to participate will then be directed to a screening form to determine their eligibility. Eligible participants will complete the baseline data questionnaires/surveys before randomisation into the intervention or control group. To encourage retention in the study, participants will be offered entry into a draw for an iPad mini on completion of all time points of the data collection. One iPad will be awarded for each 44 participants.

**Participants**

Inclusion criteria

Participants will be included if they meet **all** the following criteria:

- Current low back pain of any duration
- Aged 18 years and above (no upper age limit)
- Reside in Australia
- Adequate English to complete outcome measures and interact with the MyBackPain website
- Internet access for the duration of the trial

Participants will be excluded if they have a previous or existing serious spinal pathology (defined as fracture, cancer, infection) or been diagnosed with specific spinal pathology including sciatica, lumbar spinal stenosis or nerve root compromise.

**Study Treatments**

Participants will be randomised to an Intervention or Control group. Stratified permuted block randomisation will be used, with blocks of sizes 6 to 12 stratified by symptom duration (acute or chronic). An episode of acute LBP will be considered to be pain of less than 6 weeks duration with at least 4 weeks between pain episodes.[27] All other pain presentations will be considered chronic LBP. All participants will be advised that the study aims to investigate the impact of the use of the Internet on LBP. Participants are free to use web resources in any manner in which they feel appropriate and for any amount of time.

Intervention - MyBackPain website

The content and framework of the MyBackPain website has been developed according to an extensive process of consultation and collaboration with individuals with LBP and clinicians, and with an international team of experts who were engaged to contribute to the development of evidence-based content (Table 1).

**Table 1: Steps involved in the development of the MyBackPain website**

| Step | Process |
|---|---|
| 1. Identification of consumer needs – website content and presentation | Qualitative study of consumer needs involving focus groups and interviews with patients with LBP [25] and clinicians [28] |
| 2. Evaluation of existing LBP websites | Review comparing content of existing websites to content and format criteria developed from step 1 (Nielsen et al., unpublished data). |
| 3. Establishment of expert steering committee | An international advisory committee established with representation of multiple disciplines (medicine; physiotherapy; chiropractic; occupational therapy, etc.) and multiple regions (Australia; Europe; North America; Asia). |
| 4. Identification of key messages | Evidence-based messages were identified from the literature (clinical practice guidelines; systematic reviews). Experts were consulted using a Delphi process to review, add, edit and refine the key messages. Language was optimised with consumer focus groups. Priority order of presentation was assessed using an on-line process with consumers and international experts from multiple disciplines. A final list of 30 messages was identified for reinforcement throughout all materials on the website and all formats (French et al., in preparation). |

| | |
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| 5. Generation of list of frequently asked questions | Qualitative study with focus groups |
| 6. Content consensus | Consensus workshop at "LBP Forum" international conference |
| 7. Development of treatment summaries | Orthodox and complimentary treatments were identified by the expert steering committee with consumer input. A draft description of each treatment and a synthesis of research evidence from the best available evidence (systematic reviews; clinical trials and clinical practice guidelines) was developed by an independent expert group and a consumer writer. International experts were identified to review each treatment summary and allocate an "evidence grade badge" to enable quick identification of evidence levels for treatments or the potential for harm. All summaries and evidence grades were reviewed for consistency by the international advisory board and 6 additional experts. |
| 8. Profession descriptions | Consultation with respective professional societies |
| 9. Content development | Content was developed in a range of formats including: an algorithm aligned to that used by clinicians to tailor information for people with acute and chronic LBP and create a management plan; multilayered information content enabling users to access as little or as much detail on a topic as they prefer; self-monitoring applications to track status and recovery as determined by measures of activity and participation; and responses to the "frequently asked questions". All content was aligned to the 'key messages'. |
| 10. Development/refinement of algorithms to guide content utilisation | Two algorithms were developed on the basis of existing stratification/prognostic tools. The StartBack tool and Pick-up tool were adapted to guide the user experience for individuals with LBP of greater than or less than 3 months duration, respectively. The tools were used to evaluate possible risk of poorer outcome and tailoring information regarding advice to access psychologically informed resources if required. |
| 11. Consumer input, review and feedback | Consumers contributed to focus groups in the planning phases and review and refinement of content in the latter phases. Professional groups with an interest in LBP and relevant consumer groups were consulted to assist with refinement of the website content. Extensive testing of formats and information was undertaken using a variety of methods including focus groups. |
| 12. Beta testing | A full beta version of the website was constructed and extensively reviewed with consumer feedback |

Participants randomised to the Intervention group will be given access to the MyBackPain website for the duration of the trial via a unique username and password to minimise

crossover from the Control to the Intervention group. The website is not publicly available and no content can be accessed without the username/password combination individually provided to participants in the Intervention group, with a request not to share the website or its content with others. Participants will be able to use the website in multiple ways: self-directed browsing and searching of the content; inbuilt automated guided content tailored to the features of their presentation and identified information priorities; and the opportunity to "opt-in" to receive regular e-mails that highlight key messages about LBP. Participants will be free to determine how, when and how often they access the website. They will be free to decide which content they use and the format they prefer (e.g. text, video, patient stories etc.). The website will send automated messages to encourage users to return and access additional content and refresh their knowledge if they have opted to receive the regular emails. They will be encouraged to save information of interest to their "dashboard" for easy access and print out relevant information for later reference or use in visits with their healthcare provider.

Control

Participants randomised to the Control group will be asked to record the address of any websites they access for information about LBP throughout the trial and relay this information in the weekly (weeks 1-12) and monthly (months 3-12) online diaries. They will not have access to, or knowledge of, the MyBackPain website until it is launched to the public; i.e. after completion of the trial.

**Data collection**

All data will be collected online using REDCap (Research Electronic Data Capture, Vanderbilt University). Online data collection was chosen to allow inclusion of participants from any location in Australia. This approach enhances the feasibility of the trial and the

generalisabilty of the results. Participants will complete an online questionnaire at baseline to provide demographic data (e.g. age, sex, height, weight, education, job and job status) and details about their low back symptoms (including location, intensity, duration, frequency and past treatments).

All other data will be collected at baseline, 1 month, 3 months (primary end-point), 6 months and 12 months (Table 2). In addition, weekly diaries will be used to gather information about current pain levels, treatments used, and websites visited for information about LBP. At the 3-month time point, the diaries will be sent monthly for the remainder of the trial. The time of primary outcome (3 months) has been selected as we expect access to the resource to modify treatment choices and outcome over an extended period.

Data pertaining to the information sought and frequency of use of the intervention website will be collected using OpenTracker software and assessed via website-use statistics.

**Treatment adherence**

Each user's history of access to the MyBackPain website will be recorded based on their unique log-in (Intervention group only), and the use of other websites will be recorded via participant entries into the online weekly diary.

**Patient and Public Involvement**

Patients with low back pain were extensively involved in the development of the MyBackPain website. This involved a multi-step process that included identification of consumer needs and preferences for content and presentation (ref). Extensive testing of the website was undertaken with consumers. Patients were consulted for design of outcome measures of treatment preferences. Patients or public were not otherwise involved in study design. Participants will contribute to dissemination of RCT proposed in this protocol.

**Blinding**

Participants and investigators (except the project manager) will be blinded to treatment allocation. All participants will be advised that the study aims to investigate the impact of use of the internet on LBP, but will be unaware of which specific website will be evaluated. Data analyses will be conducted by a blinded biostatistician. We anticipate no reason for revealing a participant's intervention allocation during the trial.

**Outcome measures**

Primary Outcomes

The primary outcome will be the spinal health literacy evaluation measured with the Health Literacy Questionnaire (HLQ).[29] The HLQ includes 44 items and nine dimensions. Dimensions 2 and 3 will be included as co-primary outcome measures: "having sufficient information to manage my health" and "actively managing my health". These dimensions will be assessed using a 4-point Likert scale (1 - completely disagree; 4 - completely agree) and a 0-100 score will be presented for each dimension. The preamble to the survey will ask participants to consider their LBP when answering the survey.

Secondary outcomes

Secondary outcomes include dimensions 1 ("feeling understood and supported by healthcare providers"), and 4-9 ("social support for health"; "appraisal of health information"; "ability to actively engage with healthcare providers"; "navigating the healthcare system"; "ability to find good health information", and "understand health information well enough to know what to do" respectively) of the HLQ. These 7 dimensions will be assessed using a 4-point Likert scale (1 - completely disagree; 4 - completely agree).

We will also investigate patient preference for a number of treatment choices mentioned in the MyBackPain website in terms of the likelihood of healthy (i.e. treatments rated as strong

evidence and some evidence) or unhealthy treatment choices. The treatments patients indicate as being healthy or unhealthy (stated) and the treatments they actually use (observed) will be measured in each group in three ways:

i) Quality of treatment preference (stated): Patient decision-making will be measured by evaluation of stated effectiveness of treatment choices. Patients will be asked to click on a 5-item scale (effective, somewhat effective, unsure, not very effective, not effective) if they think a subset of treatments discussed in the MyBackPain website are effective for people's LBP in general (but not specifically their own pain). Treatment choices will be scored against the recommendations provided in the MyBackPain website according to the classifications of "good evidence", "may work", "not enough evidence", "unlikely to work" and "may be harmful".

ii) Quality of treatment preference (observed - scored): Treatments that are used by participants will be evaluated against the recommendations provided in the MyBackPain website according to the classifications of "good evidence", "may work", "not enough evidence", "unlikely to work" and "may be harmful". Participants of both groups will be asked to record weekly in the online diary any treatments received for their LBP.

iii) Quality of treatment preference (observed - proportion): The proportion of participants who choose treatments that are, according to the MyBackPain website, either recommended or considered to have no effect or be harmful in each group will be assessed separately (recommended; no effect; harmful), using data from the online participant diary.

LBP clinical outcomes will also be included as secondary outcomes and measured with the following validated tools:

(i) Pain – Visual analogue scale (VAS) of average overall LBP in the last week recorded on a scale anchored with "no pain" at 0 and "worst pain imaginable" at 10

(ii) Disability - Roland Morris Disability questionnaire [30]

(iii) Quality of life - AQoL-8D [31]

**Table 2: Schedule of enrolment, intervention and assessments**

| | Enrolment | Baseline | Allocation | Post-Allocation (months) | | | |
|---|---|---|---|---|---|---|---|
| Time point | | | 0 | 1 | 3 | 6 | 12 |
| **Enrolment:** | | | | | | | |
| Eligibility screen | X | | | | | | |
| Informed consent | X | | | | | | |
| Randomisation | | | X | | | | |
| **Intervention:** | | | | | | | |
| Control | | | | | | | |
| MyBackPain | | | ← | — | — | — | → |
| **Assessment:** | | | | | | | |
| Demographics | | X | | | | | |
| HLQ | | X | | X | X | X | X |
| RMDQ | | X | | X | X | X | X |
| AQoL-8D | | X | | X | X | X | X |
| Treatment choices | | X | | X | X | X | X |
| Weekly diary – Pain VAS, websites visited, treatments used | | | ← | — | → | | |
| Monthly diary Pain VAS, websites visited, treatments used | | | | | ← | — | → |

**Data Integrity**

All data will be directly collected into a custom-built Electronic Data Capture program, with a prompt for double checking of the accuracy of the primary outcomes. Any inconsistencies in the data will be explored and resolved. The database will be backed-up regularly on a secure network and be compliant with the ICH Guideline for Good Clinical Practice,[32] according to our Data Management Plan. Study personnel will only be able to access the database with a personal login and password.

**Retention of documents**

The study investigators will maintain adequate and accurate records to enable the conduct of the study to be fully documented and the study data to be subsequently verified. Should the study investigators wish to assign the study records to another party or move them to another location, the sponsor will be notified in advance. After the completion of the study, study data will be archived by The University of Queensland for a minimum of 15 years.

**Data analysis**

Analyses will be by intention-to-treat of all randomised participants who completed the baseline surveys. To assess the difference in the primary outcome between groups, longitudinal linear regression models will be fit, including all data from 1, 3, 6 and 12 months as an outcome for each participant. Models will be adjusted for baseline values of outcomes and the stratification variable symptom duration and also include a term for month, and an interaction between month and randomised group included as fixed effects, with random effects for participants. Similar longitudinal logistic regression models will be used for binary outcomes. These models will be interrogated to yield differences between groups at each time point. Standard diagnostic plots will be used to assess regression assumptions. Descriptive statistics on demographics and clinical characteristics will be presented for both the control and intervention group as the mean change (standard deviation, 95% confidence

intervals) or counts and percentages for categorical variables. Multiple imputation methodology will be employed to account for missing data. No statistical adjustment will be made for multiple testing. All tests will be carried out at the 5% level of significance.

Sample size calculation is based on an effect size of 0.30, for "having sufficient information to manage my health" and "actively managing my health" dimensions of the HLQ. A sample size of 440 participants (minimum of 25% acute participants) will achieve 80% power to detect the desired effect size, allowing for a conservative loss to follow-up rate of 20% at three months.

**Ethics and dissemination**

The study has been approved by the University of Queensland Human Research Ethics Committee and is registered with the Australian New Zealand Clinical Trials Registry (Table 3). The study is sponsored by the National Health and Medical Research Council of Australia (NHMRC) and Medibank Health Research Fund and centrally managed by staff at the University of Queensland. The trial sponsor has had no role in the design or conduct of the trial. The current protocol is version 1 (7th September 2017) and any modifications to the protocol will require formal amendment following the approval of the principal investigator (PWH).

Participants will be provided with the contact details of the project manager for any queries or concerns. Any complaints arising from the trial will be recorded and acted upon in accordance with institutional policy. Participants will be informed they are free to withdraw from the study at any time without consequence. They will be asked if they would like to receive a copy of the manuscript at the completion of the trial.

All data will be stored in electronic format in a de-identified manner on a secure server. The database will be password protected and only accessible by the research team. At the

completion of the trial, the data collection portal will be closed and data will be retained in a de-identified format on the protected server at The University of Queensland. The MyBackPain website will remain active and launched to the public at the completion of the trial. Users of the MyBackPain website will have the option to create a user account on the website. This information will not be collected or used by the project team and will be housed on a host server managed by Arthritis Australia. Users of the MyBackPain website will be told of the purpose and protection of the user account prior to its creation.

We do not anticipate further use of the data, but participants will be asked to give consent to the potential future use of de-identified data so as not to limit this possibility. Any potential plan to use the data for an additional purpose will be considered by the investigative team.

**Table 3: Trial registration data**

| Data category | Information |
|---|---|
| Primary registry and trial identifying number | Australia New Zealand Clinical Trials Registry ACTRN12617001292369 |
| Date of registration in primary registry | 07/09/2017 |
| Secondary identifying numbers | Universal Trial Number U1111-1196-6323 |
| Sources of monetary or material support | Sponsors (below) |
| Primary sponsor | National Health and Medical Research Council - Research Committee Secretariat NHMRC GPO Box 1421 Canberra ACT 2601 |
| Secondary sponsor | Medibank Health Research Fund - 720 Bourke Street, Docklands, VIC 3008 |
| Contact for public queries | PH (p.hodges@uq.edu.au) |
| Contact for scientific queries | PH (p.hodges@uq.edu.au) |
| Public title | Efficacy of a multi-faceted web-based resource on spinal health literacy in patients with low back pain - a randomised controlled trial |
| Scientific title | Efficacy of a multi-faceted web-based resource on spinal health literacy in patients with low back pain - a randomised controlled trial |
| Countries of recruitment | Australia |
| Health condition or problem studied | Low back pain |
| Intervention | Multi-faceted web-based resource “MyBackPain” |
| Key inclusion and exclusion criteria | Inclusion criteria: > 18 years of age, current low back pain, reside in Australia, adequate English to |

| | |
|---|---|
| | complete surveys, internet access for the duration of the trial |
| | Exclusion criteria: previous or existing spinal pathology (e.g. fracture, cancer, infection, nerve root compromise) |
| Study type | Randomised controlled trial, participant and assessor blinding, central computerised randomisation |
| Date of first enrolment | 06/12/2017 |
| Target sample size | 440 (at least 25% acute participants i.e. pain < 6 weeks with a minimum of 1 month without symptoms) |
| Recruitment status | Recruiting |
| Primary outcome(s) | Health Literacy Questionnaire |
| Key secondary outcomes | Quality of treatment preference (observed)<br>Patient decision-making - measured by evaluation of observed treatment choices. Treatments used by the participant during the follow-up period will be scored against the recommendations provided in the MyBackPain website, and based on a 5-point rating: "strong evidence", "some evidence", "unclear evidence/untested", "evidence of no effect" and "harmful". The average score will be used. |

Manuscript(s) will be submitted to major peer-reviewed journal(s) after the completion of randomised clinical trial. Leading multidisciplinary conferences on pain, LBP and primary care will also be targeted for dissemination of the study findings.

**Author Contributions**

LH contributed to design of the study; prepared the trial registration and application for ethical approval; drafted and revised the manuscript

MF designed and conceptualised the study; prepared the trial registration and application for ethical approval; drafted and revised the manuscript

JS designed and developed the MyBackPain website

SF contributed to designed and conceptualised the study; drafted and revised the manuscript.

JK designed the data/statistical analysis plan.

KB contributed to designed and conceptualised the study; revised the manuscript.

DH contributed to designed and conceptualised the study; revised the manuscript.

BV contributed to designed and conceptualised the study; revised the manuscript.

CD designed and developed of the MyBackPain website.

PH designed and conceptualised the study; designed and developed the MyBackPain website; prepared the trial registration and application for ethical approval; drafted and revised the manuscript.

All authors reviewed and approved the final manuscript.

**Funding statement**

This work was supported by the NHMRC (APP1079078) and a grant from the Medibank Health Research Fund (Table 3). MF is funded by an NHMRC Career Development Fellowship (APP1143593) and a Sydney Medical Foundation Fellowship. DJH is supported by an NHMRC Practitioner Fellowship. KLB is supported by a NHMRC Principal Research Fellowship (APP1058440). JS is supported by an NHMRC Early Career Fellowship (APP1157179).

**Competing interests statement**

DJH is on advisory boards for Merck Serono, Tissuegene, TLC Bio and Flexion, outside of the submitted work. All other authors have no interests to declare.

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# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

MyBackPain: Evaluation of an innovative consumer-focused website for low back pain - study protocol for a randomised controlled trial



| | | Reporting Item | Page Number |
|---|---|---|---|
| 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 | 2-3 and Table 3 |
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | Table 3 |
| Protocol version | #3 | Date and version identifier | 16 |
| Funding | #4 | Sources and types of financial, material, and other support | Table 3 |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | 17 |
| Roles and responsibilities: | #5b | Name and contact information for the trial sponsor | Table 3 |

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| sponsor contact information | | | |
| 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 | 16 |
| 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) | NA |
| 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 | 5-7 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 5-7 |
| Objectives | #7 | Specific objectives or hypotheses | 7 |
| 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) | 7-8 |

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|---|---|---|---|
| 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 | 8 |
| 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) | 8-9 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 9-10 |
| 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 improving / worsening disease) | 16 |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | 11 |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | #12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final | 11-13 |

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| | | 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 | |
| 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) | Table 2 |
| 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 | 7-8 and 15 |
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8-9 |
| 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 | 8 |
| Allocation concealment mechanism | #16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed | 8 |

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| | | envelopes), describing any steps to conceal the sequence until interventions are assigned | |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 12 |
| 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 | 12 |
| 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 | 11-12 |
| 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 |

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| 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 | 15-16 |
| 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 | 16-17 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 16-17 |
| 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) | 16-17 |
| 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 | NA |
| Data monitoring: interim analysis | #21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |

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| 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 | 17 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 17 |
| 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) | 17 |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 17-18 |
| 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 | 17-18 |

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| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 20 |
| 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 | 17-18 |
| 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 | NA |
| 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 | 19 |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 19 |
| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | n/a |
| 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 | n/a |

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| | the current trial and for future use in ancillary studies, if applicable |