






# BMJ Open Evaluating the impact of a champion on implementation of the Back Skills Training (BeST) programme in Canada: a mixed methods feasibility study protocol

Amanda Hall,<sup>1</sup> Helen Richmond ,<sup>1</sup> Krystal Bursey ,<sup>1</sup> Zara Hansen,<sup>2</sup> Esther Williamson ,<sup>2</sup> Bethan Copsey ,<sup>3</sup> Charlotte Albury,<sup>4</sup> Shabnam Asghari,<sup>1</sup> Vernon Curran,<sup>5</sup> Andrea Pike ,<sup>1</sup> Holly Etchegary,<sup>5</sup> Sarah Lamb<sup>3,6</sup>

**To cite:** Hall A, Richmond H, Bursey K, *et al*. Evaluating the impact of a champion on implementation of the Back Skills Training (BeST) programme in Canada: a mixed methods feasibility study protocol. *BMJ Open* 2020;**10**:e040834. doi:10.1136/bmjopen-2020-040834

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-040834>).

Received 26 May 2020

Revised 28 October 2020

Accepted 06 November 2020



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Dr Amanda Hall;  
amanda.hall@med.mun.ca

## ABSTRACT

**Introduction** There is global recognition that low back pain (LBP) should be managed with a biopsychosocial approach. Previous implementation of this approach resulted in low uptake and highlighted the need for ongoing support. This study aims to explore the feasibility of (i) training and using a champion to support implementation, (ii) using a cluster randomised controlled trial (RCT), (iii) collecting patient reported outcome measures in a Canadian public healthcare setting and to identify contextual barriers to implementation.

**Methods** A pragmatic cluster RCT with embedded qualitative study with physiotherapists treating LBP in publicly funded physiotherapy departments in Newfoundland and Labrador, Canada. Participants will complete a previously developed online training course to equip them to deliver a biopsychosocial intervention for LBP. Clusters randomised to the intervention arm will receive additional support from a champion. A minimum champion training package has been developed based on known barriers in the literature. This includes strategies to target barriers relating to group-based scheduling issues, lack of managerial support, perceived patient factors such as addressing patient expectations for other types of treatments or selecting which patients might be best suited for this intervention, and anxiety about delivering something new. This package will be further codeveloped with study champions based on identified implementation barriers using the Behaviour Change Wheel. Clusters will be monitored for 6 months to assess champion and physiotherapist recruitment and retention, acceptability and implementation of the champion training, and the viability of conducting a cluster RCT in this setting. A purposive sample of physiotherapists will be interviewed from both arms.

**Ethics and dissemination** This study was approved by Newfoundland and Labrador Health Research Ethics Authority in December 2018. Results will be disseminated to academic audiences through conferences and peer reviewed publications; to all study participants, their clinical leads, and patients with LBP.

## Strengths and limitations of this study

- Codevelopment of the implementation intervention with stakeholders aligns with best practices regarding knowledge translation to maximise the usefulness of the intervention in practice.
- Developing an intervention based on theory and a comprehensive behavioural analysis aligns with best practice implementation methodology.
- Integration of quantitative and qualitative data will provide a comprehensive picture of feasibility.
- A definitive trial would be necessary to evaluate the effectiveness of the implementation intervention.

**Trial registration number** ClinicalTrials.gov Identifier: NCT04377529; Memorial University of Newfoundland Protocol Record 20190025; Pre-results.

## INTRODUCTION

Guidelines for persistent low back pain (LBP) recommend assessment and treatment using a biopsychosocial approach. This includes addressing physical, psychological, social and environmental factors that can inhibit recovery.<sup>1</sup> Until recently, there has been limited information on how physiotherapists treat patients with LBP. However, in 2019, Zadro *et al* conducted a comprehensive systematic review including 94 studies of self-reported practice and audits of practice to explore physiotherapists' adherence to evidence-based guidelines when treating musculoskeletal (MSK) conditions.<sup>2</sup> The results indicated that physiotherapy treatment choices for LBP were often not based on research evidence, with treatments that were not recommended or had no recommendation delivered more frequently than evidence-based recommended treatments

(median percentages of treatments that were aligned to recommendations were: 35% (self-report data) and 50% (audit data)). Importantly, no physiotherapists reported using a cognitive behavioural approach (CBA) to manage acute LBP (as recommended in the guidelines) and only 10% of physiotherapists reported using a CBA in subacute or chronic LBP (as recommended in the guidelines). There were no examples of a CBA being used from audit data in either patient population. These findings suggest that use of a CBA is not common in the physiotherapy profession.

### Current practice in Newfoundland and Labrador, Canada

We conducted a survey of public healthcare physiotherapists in Eastern Health (EH), the largest health authority in Newfoundland servicing 70% of the population, to explore how physiotherapists treat LBP in Newfoundland and Labrador (NL). The results showed that while all surveyed physiotherapists agreed with guidelines that a biopsychosocial approach would be good for their patients, over 65% reported having no training to use this approach and did not feel confident to implement it (n=56 respondents who treated LBP).<sup>3</sup> These findings align with evidence from multiple countries that the majority of physiotherapists do not use a CBA in the management of LBP.<sup>2</sup>

### Adopting a biopsychosocial approach

While the use of a biopsychosocial approach has been advocated in clinical guidelines for two decades, guidelines themselves provide little information on how to implement it.<sup>4,5</sup> Without access to sufficient upskilling in how to adopt a biopsychosocial approach, clinicians (such as physiotherapists) may struggle to successfully implement this guideline recommendation. A recent systematic review of 12 qualitative studies explored physiotherapists' perceptions of learning and implementing biopsychosocial interventions to treat MSK pain conditions.<sup>6</sup> The review synthesised four key themes, one of which was 'clinical challenges', where physiotherapists resisted/questioned the new biopsychosocial approach, felt overwhelmed by the amount of new information, felt that there was limited support for the transition of a biomedical to a biopsychosocial approach and had difficulty changing long standing practices. Another key theme was 'learning requirements', where physiotherapists felt that workshops alone were insufficient for learning and that ongoing support was essential. In particular, physiotherapists wanted long term support and mentoring. However, there is little information on the best way to provide implementation mentoring and support to physiotherapists.<sup>6</sup>

A review of the evidence identified at least five physiotherapy-led biopsychosocial interventions that were more effective than physiotherapists' usual care for improving LBP patient outcomes.<sup>4</sup> One of which, the Back Skills Training (BeST) intervention, was found to be clinically and cost effective in a large (n=701 patients) pragmatic

randomised controlled trial (RCT)<sup>7</sup> and was the only study to have tested the long-term effects of the intervention at 3 years post-treatment.<sup>8</sup> While all five physiotherapy-led biopsychosocial interventions required physiotherapist training, only two offer this training to physiotherapists working in clinical practice: (i) the Start Back intervention offers a combination of online and face-to-face training<sup>9</sup> and (ii) the BeST intervention offers an interactive online-training course.<sup>10</sup> Being able to complete the training online decreases training cost, increases reach, allows greater training flexibility and ongoing access to materials. Thus, the BeST intervention was selected for implementation in publicly funded physiotherapy settings in NL.

### BeST intervention

The BeST intervention has been described in detail elsewhere.<sup>11</sup> In brief, it consists of the following components:

- ▶ One 60–90 min individual session with the patient. This consists of: (i) history taking including current problems and eliciting beliefs on LBP and activity; (ii) collaborative goal setting including a plan on how to start an activity goal; (iii) choosing exercises collaboratively from a range of options; (iv) practicing exercises and discussing progression; and (v) a referral to six group sessions.
- ▶ Six 90 min group sessions with 5–10 patients. The group sessions consist of education (eg, importance of regular exercise, relationship between activity levels and pain, the role of negative thoughts) and skill development (eg, problem-solving ways to modify activities provoking back pain, goal setting, baseline setting, thought challenging, relaxation, activity pacing and activity progression). Each session includes problem-solving practice and the opportunity to exercise.

### Implementation strategy

Previous implementation work in the UK reported several barriers to implementing the BeST intervention including a perceived lack of suitable patients with LBP, patient drop-out and reluctance to attend, space constraints, time to introduce service changes, staff capacity/time, rotational staff, lack of managerial/organisational support and funding issues.<sup>12</sup> While some of these early implementation issues have been addressed by enhancing the online training, for example, by adding the ability to interact with the course tutor and other learners, there are many that have not. Thus, in light of these findings, along with Holopainen *et al's* systematic review<sup>6</sup> that identified the need for ongoing support, there may be value in supplementing the online provider training with additional strategies to support implementation.

In other areas of implementation research, the addition of a local champion has been used to facilitate the implementation of new interventions.<sup>13</sup> The term 'champion' is often adopted to characterise a number of diverse roles of groups or individuals, whose goal is to effect positive change.<sup>14,15</sup> These groups or individuals are typically

influential and charismatic people with high social and institutional status.<sup>16</sup> Studies suggest that having at least one on-site staff member (normally a healthcare professional) who has undertaken some form of supplementary training in a specific topic area will help improve the practice in that area, the quality of care and the health outcomes for the service users.<sup>14 17–21</sup> Therefore, providing additional training a local healthcare professional who has a key role in the implementation of the new intervention to create a local champion seems a viable approach to test and determine whether it results in better implementation and, ultimately, better patient outcomes.

Before evaluating the effectiveness of a champion to support implementation of the BeST intervention, it is important to investigate its feasibility.<sup>22</sup> This information is useful to optimise the champion training intervention for implementation. It is equally important to determine the optimal design for evaluation. Therefore, this study aims to:

1. Ascertain the feasibility of both training and using a champion to support implementation of the BeST intervention in a Canadian public healthcare setting.
2. Explore the feasibility of using a cluster RCT as a potential design for testing the effectiveness of the implementation strategy.
3. Explore the feasibility of collecting patient reported outcome measures in a Canadian public healthcare setting.
4. Identify further contextual barriers to the implementation of the BeST intervention.

## METHODS

### Design

For this mixed methods feasibility study, we will explore the feasibility of using a pragmatic cluster RCT to evaluate our implementation strategy. A qualitative interview study will provide further contextual information (figure 1). The trial is open and has completed recruitment of physiotherapists. Data collection and delivery of the champion intervention is ongoing.

### Inclusion and exclusion criteria

Publicly funded physiotherapy departments within NL, Canada, treating adult patients with LBP were eligible to participate. Additionally, clinical leads needed to be able to identify at least one departmental champion should they be allocated to the champion arm. We defined a champion as an MSK physiotherapist who (i) could commit the additional time for training, (ii) would be willing to provide support to their peers and (iii) demonstrated enthusiasm towards the intervention to their manager. Physiotherapy departments who did not treat adult patients with LBP were excluded.

### Site recruitment

For this feasibility study, we targeted all physiotherapy departments within NL's public health sector who offer services to adult patients with LBP (n=17), with the aim

of targeting a range of provinces across Canada should a fully powered study be conducted. Departments were sent a study information sheet and invited to participate. Interested departments were screened for eligibility and, where eligible, the clinical lead forwarded the study information sheet and consent form to physiotherapists treating LBP in their department. Physiotherapists who wanted to take part were asked to email their signed consent forms to the principal investigator.

### Randomisation and allocation

To avoid contamination, we are using a cluster trial where the cluster is the physiotherapy department or a grouping of physiotherapy departments. The unit of randomisation is at the cluster level (eg, physiotherapy departments).

### Special considerations when using a cluster design

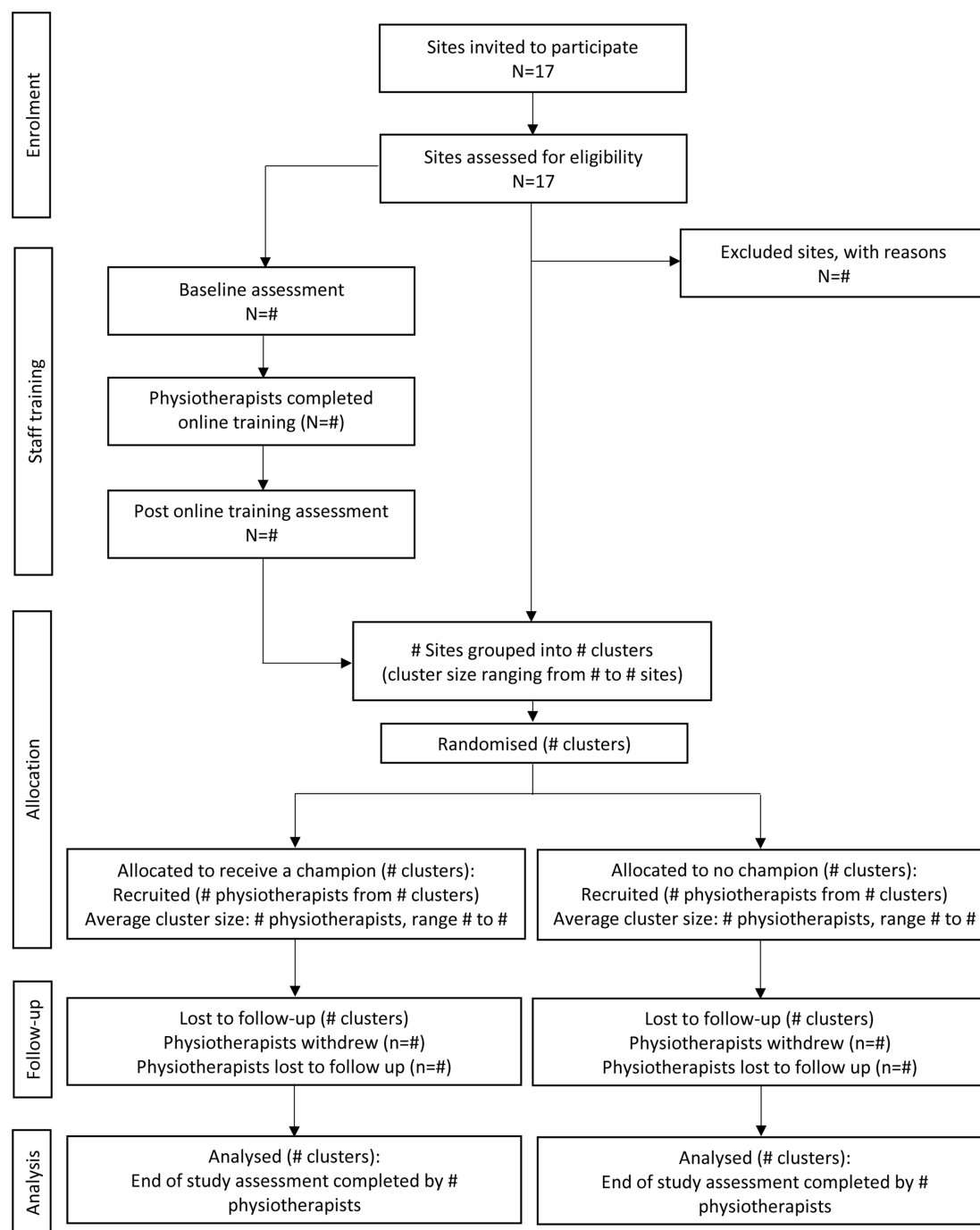
A cluster design will not protect from all potential sources of contamination and therefore, we employed the following strategies to either mitigate or measure contamination:

- ▶ Within EH, physiotherapists may move between the two largest teaching hospitals. We will track any movement of physiotherapists to ensure this is measured.
- ▶ Physiotherapist post-training outcomes are measured prior to randomisation to avoid performance bias.

### Eligible clusters

While 17 physiotherapy departments in NL offer services to adult patients with LBP, the number of full time equivalent (FTE) physiotherapists at each department varies considerably (from 1 to 7) based on the department's geographic location. For this feasibility study, small rural sites with one FTE were grouped with the closest site to their region that had a larger number of physiotherapists to form a cluster.

Each cluster was pair matched on three factors prior to randomisation: (i) the number of full time physiotherapists within the cluster, since we anticipate that this will impact implementation of the BeST intervention, (ii) geography, since we anticipate that rural sites will face unique challenges to implementing the BeST intervention group sessions and (iii) organisational relationships, since pre-existing relationships between rural sites could result in contamination. Prior to the start of recruitment, the allocation sequence was generated using the random number function in Excel by an investigator not involved in outcome data collection. Treatment codes were placed sequentially into sealed opaque envelopes. After receiving a participant's signed consent form, they were provided with details on how to complete the online BeST provider training. Once all participants within a cluster had completed the online training, the cluster was issued with a sealed envelope containing their group allocation to either the intervention (champion) or control (no champion) arm. Each cluster was given a unique ID and each physiotherapist within a cluster was given a unique ID.



**Figure 1** Overview of participant flow through the study.

## Description of interventions

### Online BeST provider training

1. The online content is provided by the University of Oxford through FutureLearn, a digital education platform. It includes self-directed reading, elective practice, skill rehearsal, multiple-choice questions, formative tests with feedback, interactive exercises, discussion forums, multimedia (including videos demonstrating core skills in clinical scenarios) and stakeholder engagement materials.<sup>10</sup>
2. There are six core modules to complete (taking about 12 hours) over a 6-week period. During this 6-week pe-

riod, course tutors from the University of Oxford moderate discussions between learners and engage with the online community by answering questions about the course and the intervention.

3. All study participants retain permanent access to the training course.

### Online BeST provider training+champion

The aim of the champion is to facilitate implementation of the BeST intervention into routine clinical practice by problem solving and developing solutions to identified implementation barriers. To address implementation

barriers, champions will receive additional training and support. To maximise the usefulness of this training and support, it needs to be based on a good understanding of known or perceived barriers to carrying out the target behaviour.<sup>23</sup> Several barriers to the implementation of the BeST intervention have been identified from previous work in the UK (detailed in the Introduction section). Two authors (HR and KB) have mapped these barriers to domains in the theoretical domains framework (TDF)<sup>24</sup> and to components of the Capability, Opportunity, Motivation and Behaviour (COM-B) model,<sup>23 25</sup> enabling relevant behaviour change techniques (BCTs) from the BCT taxonomy to be identified. The BCT taxonomy provides a hierarchy of 93 BCTs based on psychological theory that can be used to target changes in desired behaviour (<https://www.bct-taxonomy.com/>).<sup>26</sup> Identified BCTs were then critiqued against the APEASE criteria (Affordability, Practicality, Effectiveness/Cost-effectiveness, Acceptability, Safety/Side-effects, Equity) to produce a shorter list of plausible BCTs to consider including in the champion intervention. The condensed list of BCTs encompass strategies that could be included in the champion training itself such as educating champions on the health consequences of not using a biopsychosocial approach, as well as implementation strategies that the champions could use within their cluster such as modelling the behaviour (use of a biopsychosocial approach) to peers (see [table 1](#)). To supplement this data from the UK, each champion will complete the COM-B self-evaluation questionnaire v1 to identify what support or training the champions believe they need to successfully implement the BeST intervention.<sup>25</sup> The results from the COM-B questionnaire will be mapped by the same two authors (HR and KB) to the relevant TDF domains and, from this, BCTs known to target each domain will be identified. These BCTs will also be critiqued according to the APEASE criteria by the same two authors (HR and KB). At this point, the results from both the UK behavioural analysis and the COM-B questionnaire completed by the champions will be reviewed with the champions themselves. The purpose of this is to collaboratively decide which BCTs to include in (i) the champion training itself and (ii) the implementation strategies that the champions could use within their cluster, based on how useful and feasible the champions perceive the BCTs to be.

### Outcomes

We will explore seven outcomes, designed to provide the information needed to design and conduct a fully powered implementation effectiveness type 3 hybrid study in the future.<sup>27</sup> Type 3 hybrid studies test an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.<sup>27</sup> Thus, the primary outcome in type 3 hybrid designs is the effectiveness of the implementation strategy on measures of adoption and fidelity to the clinical intervention, and secondary outcome measures are patient-level effects (such as symptoms, function and service use),

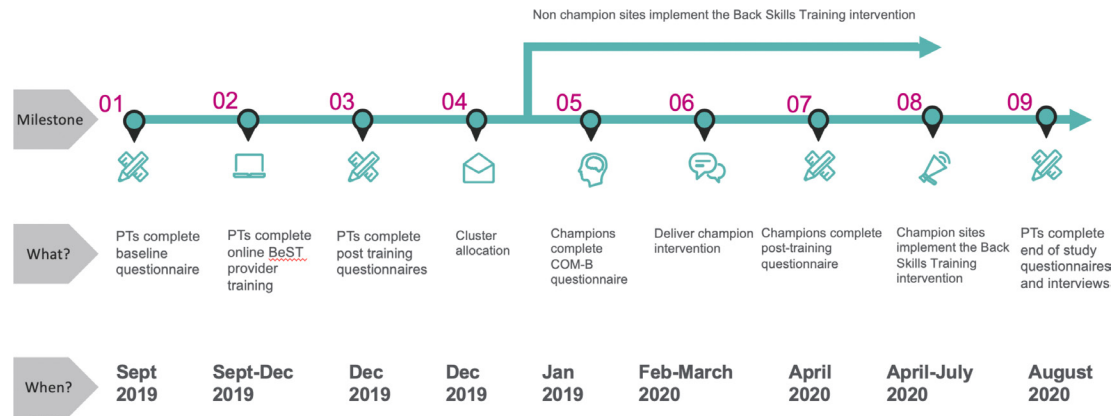
as well as health system-level effects (such as wait-times and efficiency). [Figure 2](#) provides a timeline of key events through the study. The seven outcomes we will explore are:

1. Recruitment and retention of champions (physiotherapists): we will aim to recruit and retain at least one champion per champion site for the study duration.
2. Recruitment of physiotherapists to complete the online BeST provider training: we will assess reach of the online provider training by measuring the total number of physiotherapists who completed the training out of the total number of physiotherapists in NL who provide treatment to LBP patients in NL's public healthcare sector.
3. BeST intervention implementation:
  - We anticipate that multiple physiotherapists per site will be recruited to complete the online BeST provider training. Given this, it may not be possible for each participating physiotherapist to deliver the BeST intervention in clinical practice within the study time period. Thus, we will measure how many times the BeST intervention is delivered per cluster.
  - We will calculate the percentage of LBP patients being treated in each physiotherapy department that received the BeST intervention and record reasons for any LBP patient who did not receive the BeST intervention. We currently plan to have this outcome as our primary outcome if a fully powered study was conducted in the future.
  - We will record the process that each site worked through to deliver the BeST intervention.
  - Additionally, we will explore the best way to assess fidelity to the BeST intervention.
4. Identification of barriers to both the champion training intervention and the BeST intervention: we will explore barriers that inhibited implementation through semi-structured qualitative interviews with physiotherapists (see the [Qualitative interview study](#) section).
5. Feasibility of collecting outcome assessment data (physiotherapists): we will collect self-reported data digitally on three occasions for all physiotherapists (i) baseline (pre-online BeST provider training), (ii) on completion of the online BeST provider training (prior to randomisation) and (iii) 6 months after completion of the online BeST provider training. The local champions will complete an additional assessment post champion training. These outcomes are detailed in [table 2](#).
6. Feasibility of collecting outcome assessment data (patients): clinical outcomes in a fully powered trial would be pain, disability, perceived recovery and satisfaction with treatment. Early engagement with physiotherapy departments in NL identified that most of these outcome measures have been approved for use by the local Health Authorities in NL. However, we do not know how regularly these outcomes are used by physiotherapists and thus, we will explore the feasibility of standardised use of these outcomes at baseline (first appointment) and discharge for all LBP patients.

**Table 1** Classification of known barriers from UK implementation data to the COM-B model and TDF with corresponding mapping to relevant BCTs

Identified implementation barriers	COM-B component identified in the behavioural analysis	TDF domains linking to COM-B component	BCTs linked with TDF domain that met the APEASE* criteria	Contextual example of BCTs
<ul style="list-style-type: none"> <li>▶ Logistics of setting up group sessions including (i) referral process for group sessions, (ii) space to run groups, (iii) making changes to clinical diaries and (iv) changing care pathways.</li> <li>▶ Length of appointment times for initial assessment session.</li> <li>▶ Staff capacity.</li> <li>▶ Time to facilitate change.</li> <li>▶ Funding/commissioning issues with group treatment sessions.</li> </ul>	Physical opportunity	Environmental context and resources	<ol style="list-style-type: none"> <li>1. Prompts/cues.</li> <li>2. Restructuring of the physical environment.</li> <li>3. Restructuring the social environment.</li> </ol>	<ol style="list-style-type: none"> <li>1. Place a note on each LBP referral card to prompt physiotherapists to consider the Back Skills Training intervention for that patient.</li> <li>2. Negotiate with local governing bodies to use community facilities for the group sessions.</li> <li>3. Encourage staff to support each other when making changes to clinical diaries.</li> </ol>
<ul style="list-style-type: none"> <li>▶ Lack of managerial support to implement the organisational changes needed.</li> <li>▶ Peers who have not done the training failing to refer LBP patients to the Back Skills Training programme.</li> </ul>	Social opportunity	Social influences	<ul style="list-style-type: none"> <li>▶ Information about others' approval.</li> <li>▶ Social support (emotional).</li> <li>▶ Social support (practical).</li> <li>▶ Modelling or demonstrating the behaviour.</li> <li>▶ Identification of self as role model.</li> <li>▶ Social reward.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Provide information that a CBT based approach is being used internationally and is recommended in latest guidelines.</li> <li>▶ Provide emotional (such as reassurance) and practical support (such as providing materials) to peers.</li> <li>▶ Provide peer modelling by enabling peers to observe Back Skills Training intervention sessions.</li> <li>▶ Identify a physiotherapist as a 'champion' of the intervention.</li> <li>▶ Provide verbal reward when implementing the Back Skills Training intervention.</li> </ul>
<ul style="list-style-type: none"> <li>▶ Concerned that patients expect more manual treatment from physiotherapy.</li> <li>▶ Concerned about patient drop out.</li> <li>▶ Sceptical about the intervention working.</li> </ul>	Reflective motivation	Social/professional role/identity  Beliefs about capabilities  Optimism  Intentions  Goals	No BCTs for this domain  <ul style="list-style-type: none"> <li>▶ Verbal persuasion about capability.</li> <li>▶ Verbal persuasion about capability.</li> <li>▶ Behavioural contract.</li> <li>▶ Goal setting (outcome).</li> <li>▶ Goal setting (behaviour).</li> <li>▶ Review of outcome goal(s).</li> <li>▶ Review behaviour goals.</li> <li>▶ Action planning (including implementation intentions).</li> </ul>	<ul style="list-style-type: none"> <li>▶ Verbal persuasion that their peers can deliver Back Skills Training intervention.</li> <li>▶ See above.</li> <li>▶ Sign a contract agreeing to implement the Back Skills Training intervention.</li> <li>▶ Set goals based on outcomes such as to have delivered two cycles of the Back Skills Training intervention within 6 months.</li> <li>▶ Set goals on behaviour such as to refer 80% of NS LBP patients to the Back Skills Training intervention.</li> <li>▶ Review goals at staff meetings.</li> <li>▶ Produce a detailed action plan on how the goals will be achieved.</li> <li>▶ Provide education around the anticipated impact on wait list times by delivering the Back Skills Training intervention.</li> </ul>
<ul style="list-style-type: none"> <li>▶ Anxiety about delivering something new.</li> </ul>	Automatic motivation	Emotion	<ul style="list-style-type: none"> <li>▶ Reduce negative emotions.</li> <li>▶ Monitoring of emotional consequences.</li> <li>▶ Social support (emotional).</li> </ul>	<ul style="list-style-type: none"> <li>▶ Problem solving with peers.</li> <li>▶ Self-reflection after delivering each Back Skills Training intervention session (for champion and peers).</li> <li>▶ Social support (emotional)—see above.</li> </ul>
<ul style="list-style-type: none"> <li>▶ Difficulty selecting which patients are suitable for the programme.</li> </ul>	Psychological capability	Knowledge	<ul style="list-style-type: none"> <li>▶ Feedback on behaviour.</li> <li>▶ Health consequences.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Assess whether patients not referred to the intervention would have been eligible and give this feedback to physiotherapists.</li> <li>▶ Provide education on the effectiveness of the intervention compared with routine physiotherapy.</li> </ul>

\*Affordability, Practicality, Effectiveness/Cost-effectiveness, Acceptability, Safety/Side-effects, Equity  
 APEASE, Affordability, Practicality, Effectiveness/Cost-effectiveness, Acceptability, Safety/Side-effects, Equity; BCT, behaviour change technique; COM-B, Capability, Opportunity, Motivation and Behaviour; LBP, low back pain; TDF, theoretical domains framework.



**Figure 2** Timeline showing key events. BeST, Back Skills Training; COM-B, Capability, Opportunity, Motivation and Behaviour; PT, physiotherapists.

7. Acceptability of the champion training intervention: acceptability is a multifaceted construct and should be assessed from a variety of angles.<sup>28</sup> Therefore, we will measure (i) attrition of the champions (assessing burden), (ii) attendance at training sessions (these can be delivered to individuals where clinical diaries prevent a group format) (assessing opportunity cost),

(iii) training satisfaction (assessing experience), (iv) training usefulness (assessing affective attitude), (v) champions perception of their competence to overcome implementation issues in the clinic and (assessing perceived competence) (vi) intention to use the training strategies in the clinic setting (assessing intention).

**Table 2** Physiotherapist outcomes, assessment tools and time points

Outcomes	Assessment tool	Timepoint			
		Pretraining	Post online BeST training	Post champion training	End of study assessment
<b>All physiotherapists</b>					
Training completion	Training certificate on completion of all modules		x		
Knowledge	Multiple-choice questionnaire testing theoretical and procedural knowledge of BeST	x	x		
Attitudes and beliefs	The Pain Attitudes and Beliefs Scale for Physiotherapists (PABS-PT)	x	x		
Self-efficacy	Four item Perceived Competence Scale (PCS)		x		x
Training satisfaction	Single-item satisfaction question		x		x
Implementation intention	Single-item intention to implement the BeST intervention question		x		x
Usefulness	Single-item usefulness question		x		x
<b>Champions only</b>					
Attendance	No. of training sessions attended			x	
Attrition	No. of dropouts			x	
Training satisfaction	Single-item satisfaction question			x	
Training usefulness	Single-item usefulness question			x	x
Competency	Four item Perceived Competence Scale (PCS)			x	x
Intention to use champion training	Single-item implementation of training intention question			x	

BeST, Back Skills Training.

**Table 3** Feasibility study progression criteria

	Red	Amber	Green
<b>Recruitment:</b> number of champions recruited per cluster	0	1	2
<b>Outcome data:</b> percentage of champions completing post champion training outcomes	<33% (ie, <2 of 6 champions)	33%–83% (ie, 2–4 champions)	>83% (95% CI 46.3% to 97.0%) (ie, >4 of 6 champions)
<b>Adherence:</b> percentage of champion training sessions attended	<33% (ie, <2 of 6 champions)	33%–66% (ie, 2–3 of 6 champions)	>66% (95% CI 30.0% to 90.3%) (ie, >3 of 6 champions)

When planning modifications for the main trial we will also look at the usefulness and satisfaction of the champion training from the quantitative and qualitative data collected and make modifications where necessary. We will also assess whether there was contamination between clusters when considering future study design.

### Sample size

As this is a feasibility trial, a formal (effectiveness-based) sample size calculation was not conducted. We pragmatically recruited all eligible public health sector physiotherapy departments in NL, Canada.

### Data analysis

Participant characteristics will be summarised using mean and SD for continuous variables and number and percent for categorical variables. We will use descriptive statistics to report outcomes. Continuous measures will be reported as mean differences with 95% CIs and binary outcomes will be reported as proportions.

Between group inferential comparisons will not be performed since the study is not powered for this analysis. All analyses will follow the intention-to-treat principle.

We will measure cluster effect to inform future study design. The intraclass correlation coefficient (ICC) will be calculated between the different clusters for the outcome of the percentage of LBP patients being treated that received the BeST intervention. The ICC value will inform the sample size calculation for the future phase III trial.<sup>29</sup>

Since this is a feasibility study, we have developed criteria based on recommendations from Avery *et al*<sup>30</sup> to determine whether to progress to a fully powered trial (table 3).

### Qualitative interview study

We will conduct semi-structured interviews with physiotherapists to explore physiotherapists' experiences of using the online BeST provider training and delivering the BeST intervention including barriers and facilitators to setting up the groups as part of routine care. Additionally, we will explore the champions' experiences of both the champion training and the implementation of the BeST intervention. We will use a purposive sampling method, interviewing at least one physiotherapist from each cluster and will target an equal mix of physiotherapists who implemented the BeST intervention and those who did not. We will interview all physiotherapy champions.

The interview guide will be divided into two parts. The first part will explore the physiotherapists' experiences of using the online BeST provider training and delivering the BeST intervention. The second part will explore physiotherapists' barriers and facilitators with implementing the BeST intervention in practice, this section will be informed by the COM-B model within the Behaviour Change Wheel.<sup>23 25</sup> Using this model ensures the interview guide covers all factors thought to be important to the implementation of an intervention from individual and organisational context to personal motivation. Semi-structured interviews will be conducted over the phone at physiotherapists' convenience by a research assistant trained with a master's degree in psychology and trained in qualitative interviewing techniques. All interviews will be audio-recorded, transcribed and uploaded into NVivo for data processing and analysis by two research assistants.

### Data analysis

Physiotherapist experience data will be based on an inductive thematic analysis drawing on constructivist grounded theory (open coding and constant comparison).<sup>31</sup> Barriers and facilitators data will be analysed based on the COM-B model will be used to understand and contextualise the data around barriers and facilitators for future implementation.<sup>24</sup>

### Integration of quantitative and qualitative data

Integration of both quantitative and qualitative data is essential for mixed methods research.<sup>32</sup> Both data sets will be analysed concurrently and independently of each other. Subsequently, datasets will be assessed for complementarity. This will include using the qualitative data to illuminate and expand on quantitative outcomes to achieve a more comprehensive and meaningful understanding of (i) the feasibility and acceptability of the implementation strategy (online BeST provider training+champion) and (ii) barriers to completing the online BeST provider training (and champion training where applicable) and implementing the BeST intervention in practice.<sup>33</sup>



## Patient and public involvement

Patients and members of the public were involved at the collaborative level in identifying and prioritising this research project during a key stakeholder engagement session for improving the management of LBP at Memorial University. Our patient partner, BT, was involved in the development of this protocol at an ‘inform’ level as per the IASP2 guidelines<sup>34</sup> and will be involved at the ‘consult’ level at the dissemination stage to help translate key messages from the results.

## ETHICS AND DISSEMINATION

This study was approved by the NL Health Research Ethics Authority in December 2018. Participants gave their informed consent to participate and were made aware that they can withdraw from the study at any time. Data will be stored securely on a password-protected computer accessible only to the research team. Study data and materials sent for publication will be aggregated and anonymised. Results will be disseminated through peer-reviewed academic journals, national and international conferences and public events. Results will be disseminated to all participants as well as patients with LBP through our patient partner and their network. Additionally, we will produce a research snapshot of the study results that will be shared on social media. The study has been open for recruitment since September 2019 and will continue until July 2020.

### Author affiliations

<sup>1</sup>Primary Healthcare Research Unit, Memorial University of Newfoundland Faculty of Medicine, St. John's, Newfoundland and Labrador, Canada

<sup>2</sup>Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford University, Oxford, UK

<sup>3</sup>Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK

<sup>4</sup>Primary Care Health Sciences, Oxford University, Oxford, UK

<sup>5</sup>Faculty of Medicine, Memorial University of Newfoundland, St. John's, Newfoundland and Labrador, Canada

<sup>6</sup>College of Medicine and Health, University of Exeter, Exeter, UK

**Twitter** Bethan Copsey @bethan\_copsey

**Contributors** All authors (AH, EW, SL, ZH, HR, BC, CA, AP, VC, SA, HE and KB) conceived and contributed to the design of this study. AH, BC, EW, SL, ZH, HR, AP, HE, SA and VC designed or consulted on specific sections of the study methods based on their area of expertise. HR, KB and ZH conducted the behavioural analysis from the implementation work conducted in the UK and together with AH, SL and EW developed the strategy for developing the implementation intervention. All authors (AH, EW, SL, ZH, HR, BC, CA, AP, VC, SA, HE and KB) reviewed and contributed to this manuscript.

**Funding** This work was supported by the NL support patient research grants competition, grant application number 20190025. The funders have had no involvement in any aspect of protocol design, protocol operation or write up.

**Competing interests** ZH provides private training to healthcare professionals in cognitive behavioural therapy.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

### ORCID iDs

Helen Richmond <http://orcid.org/0000-0002-2149-6637>

Krystal Burseay <http://orcid.org/0000-0002-6501-0002>

Esther Williamson <http://orcid.org/0000-0003-0638-0406>

Bethan Copsey <http://orcid.org/0000-0001-9783-6549>

Andrea Pike <http://orcid.org/0000-0003-4020-2291>

## REFERENCES

- Richmond H, Hall AM, Copsey B, *et al*. The effectiveness of cognitive behavioural treatment for non-specific low back pain: a systematic review and meta-analysis. *PLoS One* 2015;10:e0134192.
- Zadro J, O'Keefe M, Maher C. Do physical therapists follow evidence-based guidelines when managing musculoskeletal conditions? systematic review. *BMJ Open* 2019;9:e032329.
- Simmons K, Penney T, Logan G, *et al*. What are the areas for physiotherapy service improvement for low back pain? *St John's, NL* 2018.
- Hall A, Richmond H, Copsey B, *et al*. Physiotherapist-delivered cognitive-behavioural interventions are effective for low back pain, but can they be replicated in clinical practice? A systematic review. *Disabil Rehabil* 2018;40:1–9.
- O'Connell NE, Cook CE, Wand BM, *et al*. Clinical guidelines for low back pain: a critical review of consensus and inconsistencies across three major guidelines. *Best Pract Res Clin Rheumatol* 2016;30:968–80.
- Holopainen R, Simpson P, Piirainen A, *et al*. Physiotherapists' perceptions of learning and implementing a biopsychosocial intervention to treat musculoskeletal pain conditions: a systematic review and metasynthesis of qualitative studies. *Pain* 2020;161:1150–68.
- Lamb SE, Hansen Z, Lall R, *et al*. Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. *Lancet* 2010;375:916–23.
- Lamb SE, Mistry D, Lall R, *et al*. Group cognitive behavioural interventions for low back pain in primary care: extended follow-up of the back skills training trial (ISRCTN54717854). *Pain* 2012;153:494–501.
- Hill JC, Whitehurst DGT, Lewis M, *et al*. Comparison of stratified primary care management for low back pain with current best practice (start back): a randomised controlled trial. *Lancet* 2011;378:1560–71.
- Richmond H, Hall AM, Hansen Z, *et al*. Using mixed methods evaluation to assess the feasibility of online clinical training in evidence based interventions: a case study of cognitive behavioural treatment for low back pain. *BMC Med Educ* 2016;16:163.
- Hansen Z, Daykin A, Lamb SE. A cognitive-behavioural programme for the management of low back pain in primary care: a description and justification of the intervention used in the Back Skills Training Trial (BeST; ISRCTN 54717854). *Physiotherapy* 2010;96:87–94.
- Sugavanam T, Williamson E, Ali U, *et al*. *PI-1254 the use of an online training programme to facilitate implementation of the back skills training programme*. Geneva: World Confederation for Physical Therapy, 2019.
- Woo K, Milworm G, Dowding D. Characteristics of quality improvement champions in nursing homes: a systematic review with implications for evidence-based practice. *Worldviews Evid Based Nurs* 2017;14:440–6.
- Shaw EK, Howard J, West DR, *et al*. The role of the champion in primary care change efforts: from the state networks of Colorado ambulatory practices and partners (SNOCAP). *J Am Board Fam Med* 2012;25:676–85.
- Soo S, Berta W, Baker GR. Role of champions in the implementation of patient safety practice change. *Healthc Q* 2009;12 Spec No Patient:123–8.
- Shetty P, Martin McKee: champion of public health in Europe. *The Lancet* 2013;381:1089.
- Damschroder LJ, Banaszak-Holl J, Kowalski CP, *et al*. The role of the champion in infection prevention: results from a multisite qualitative study. *Qual Saf Health Care* 2009;18:434–40.
- Gaskill D, Isenring EA, Black LJ, *et al*. Maintaining nutrition in aged care residents with a train-the-trainer intervention and nutrition coordinator. *J Nutr Health Aging* 2009;13:913–7.



- 19 Lee R, Scott F. Competent to care. A train-the-trainer method of teaching as a way of implementing the correct use of the 'Malnutrition Universal Screening Tool' in Norfolk: is it effective? *Proc Nutr Soc* 2009;68:300–5.
- 20 Nicol R, Petrina Sweeney M, McHugh S, *et al.* Effectiveness of health care worker training on the oral health of elderly residents of nursing homes. *Community Dent Oral Epidemiol* 2005;33:115–24.
- 21 Siddiqi N, Young J, Cheater FM, *et al.* Educating staff working in long-term care about delirium: the Trojan horse for improving quality of care? *J Psychosom Res* 2008;65:261–6.
- 22 Campbell NC, Murray E, Darbyshire J, *et al.* Designing and evaluating complex interventions to improve health care. *BMJ* 2007;334:455–9.
- 23 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
- 24 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci* 2012;7:37.
- 25 Michie S, Atkins L, West R. *The Behaviour Change Wheel Book - A Guide To Designing Interventions*. Great Britain: Silverback Publishing, 2014. <http://www.behaviourchangewheel.com/>
- 26 Michie S, Richardson M, Johnston M, *et al.* The behavior change technique taxonomy (V1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46:81–95.
- 27 Curran GM, Bauer M, Mittman B, *et al.* Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50:217–26.
- 28 Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17:88.
- 29 Rutterford C, Copas A, Eldridge S. Methods for sample size determination in cluster randomized trials. *Int J Epidemiol* 2015;44:1051–67.
- 30 Avery KNL, Williamson PR, Gamble C, *et al.* Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* 2017;7:e013537.
- 31 Bernard R, Ryan G. *Analyzing qualitative data: systematic approaches*. Thousand Oaks, Sage: Cardiff., 2010.
- 32 Bazeley P. *Integrating analyses in mixed methods research*. Great Britain: Sage, 2017.
- 33 Bryman A. Barriers to integrating quantitative and qualitative research. *J Mix Methods Res*.
- 34 International association for public participation. Available: <https://www.iap2.org/mpage/Home> [Accessed 2 Apr 2020].