STUDY PROTOCOL

Exploring perceived barriers and enablers to fidelity of training and delivery of an intervention to reduce imaging for low back pain: a qualitative interview study protocol [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background: Diagnostic imaging has limited utility in the assessment and management of non-specific low back pain (LBP), but remains commonly used in clinical practice. Interventions have been designed to reduce non-indicated imaging for LBP; however, evidence of effectiveness has been variable. It is unclear whether intervention fidelity was adequately assessed in these interventions, which may have an impact on the interpretation of trial results. Within implementation research, intervention fidelity refers to the degree to which an intervention was delivered as intended and to the strategies used to monitor and enhance this process. Intervention fidelity covers five domains: design, training, delivery, receipt, and enactment.
Objectives: The objectives of this study are to explore perceived barriers and enablers to fidelity of training and delivery of a proposed theory-informed intervention aimed at reducing non-indicated imaging for LBP by general practitioners (GPs) and chiropractors in Newfoundland and Labrador (NL), Canada.
Methods: Semi-structured interviews will be conducted with GPs and chiropractors in NL to explore their views on barriers and enablers towards enhancing and/or assessing fidelity of training and delivery. Interviews will be audio-recorded, transcribed verbatim, and analysed with the Theoretical Domains Framework. Relevant domains related to perceived barriers and enablers will be identified by: the frequency of beliefs; the presence of conflicting beliefs; and the perceived strength

Open Peer Review

Approval Status ✓ ?

	1	2
version 1 10 May 2021	✓ view	? view

1. **Hazel Jenkins**, Macquarie University, Macquarie Park, Australia

2. **Robert Vining**, Palmer College of Chiropractic, Davenport, USA

Any reports and responses or comments on the article can be found at the end of the article.

of the impact a belief may have on the target behaviours.
Discussion: Results of this study will aid in the development of a fidelity protocol for an upcoming cluster randomised controlled trial of a theory-informed intervention aimed at reducing non-indicated imaging for LBP. Our results may help to ensure that the proposed intervention will be delivered with good fidelity and that fidelity can be appropriately assessed.

Keywords
intervention fidelity, implementation science, behaviour change, low back pain, imaging, primary care

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Author roles: To D: Conceptualization, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **De Carvalho D**: Conceptualization, Methodology, Project Administration, Writing – Review & Editing; **Pike A**: Conceptualization, Methodology, Project Administration, Writing – Review & Editing; **Etchegary H**: Conceptualization, Methodology, Writing – Review & Editing; **Patey A**: Methodology, Writing – Review & Editing; **Toomey E**: Conceptualization, Methodology, Writing – Review & Editing; **Hall A**: Conceptualization, Methodology, Project Administration, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

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Introduction

Intervention fidelity refers both to the degree to which the intervention was delivered as intended and to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions[1,2]. Intervention fidelity can impact both the internal and external validity of trials evaluating the effectiveness of behavioural interventions, and knowledge of the level of intervention fidelity in the intervention can result in greater confidence in the results of these trials[1]. If the intervention was found to be effective but fidelity was low, the effect may be due to unknown factors that were omitted from, or added to, the intervention. If the intervention was found to be ineffective and fidelity was also low, it would be unknown whether the intervention itself was ineffective or whether it was ineffective due to poor delivery of a potentially effective intervention. Without knowledge of intervention fidelity, there is a risk of applying ineffective interventions in clinical settings or prematurely discarding effective interventions; these are costly for both patients and the healthcare system[3,4]. Despite the importance of intervention fidelity addressed in both the Consolidated Standards of Reporting Trials statement[5] and the Template for Intervention Description and Replication checklist and guide[6], intervention fidelity is still often overlooked in trials of behaviour change interventions[7].

The National Institutes of Health Behavior Change Consortium (NIH BCC), in 2005, developed a framework for intervention fidelity which includes five areas: design, training, delivery, receipt, and enactment[1]. Fidelity of study design refers to the study adequately testing its hypothesis in relation to an underlying theoretical framework (e.g., using a protocol review group and pilot testing the intervention). Fidelity of training refers to adequate training and the fidelity with which this training is delivered to the providers who will be implementing the intervention. Fidelity of delivery refers to the delivery of the intervention by providers as intended by the intervention developers. Fidelity of receipt refers to the ability of patients to understand and perform the treatment-related skills during the intervention. Fidelity of enactment refers to the ability of the patient to perform the treatment-related skills in relevant real-life settings. The framework, which was updated in 2011, provides strategies to enhance and assess intervention fidelity in each of these areas[2,3].

Non-specific low back pain (LBP) is a common condition[8], a leading cause of disability globally[9], and associated with large economic and social burdens[10]. As most cases of LBP have no pathoanatomical cause of pain, diagnostic imaging has limited utility[11]. Despite clinical practice guidelines recommending against the use of routine imaging for the assessment and management of LBP[12,13], lumbar radiography for non-specific LBP remains common in clinical practice[14,15].

A cluster randomised controlled trial will be used to evaluate the effectiveness of a theory-informed intervention to reduce non-indicated imaging for LBP. This intervention will be adapted from a similar intervention that used the Behaviour Change Wheel and the Theoretical Domains Framework[16] and targeted both general practitioners (GPs) and patients. In the previous intervention, preliminary testing was conducted with international LBP experts to determine consistency with clinical guidelines, and with GPs and health consumers to determine barriers and enablers to its implementation in clinical practice, resulting in the development of a clinical resource. The clinical resource is an LBP management and education booklet designed to: 1) provide GPs with a clinical decision support tool; 2) remind GPs of appropriate clinical indicators for imaging for LBP; 3) facilitate communication between GPs and patients through providing reassurance and education; 4) provide patients with an individualised management plan; and 5) provide patients with educational resources to take home. In the cluster randomised controlled trial, GPs and chiropractors in Newfoundland and Labrador, Canada, will undergo a training session and be responsible for the delivery of the clinical resource to patients.

It is unknown whether previous studies aiming to reduce unnecessary imaging for LBP have adequately addressed intervention fidelity. As such, the aim of this study will be to provide an understanding of the perceived barriers and enablers to ensuring intervention fidelity (fidelity of training and delivery) of a proposed theory-informed intervention to reduce imaging for LBP by GPs and chiropractors.

Objectives

Our study has two objectives:

1. To explore perceived barriers and enablers to ensuring *fidelity of training* of GPs and chiropractors to deliver a proposed intervention aimed at reducing imaging for low back pain.

2. To explore perceived barriers and enablers to ensuring *fidelity of delivery* of a proposed intervention aimed at reducing imaging for low back pain by GPs and chiropractors.

Methods

Design

This will be an exploratory, qualitative interview study describing the perceptions of GPs and chiropractors on the training and delivery of a proposed intervention aimed at reducing imaging for LBP. We will use the Atkins *et al.* (2017)[17] guide for applying the Theoretical Domains Framework (TDF) to assess barriers and enablers to behaviour change. The TDF was initially developed to identify factors that influence healthcare providers' behaviours related to the implementation of evidence-based recommendations[17,18]. It was revised and validated to include 14 domains covering 84 theoretical constructs[17,19]. The final study will be reported according to the Consolidated criteria for reporting qualitative research (COREQ)[20].

Participants

Fee-for-service GPs and chiropractors who hold a license, are registered in the province of Newfoundland and Labrador (NL), are currently in practice (involved in direct patient care), and regularly manage patients with LBP will be eligible for this study. Both these healthcare providers routinely manage patients with LBP and have the ability to order imaging, particularly radiographs.

Purposive snowball sampling will be used to identify study participants. This form of sampling was chosen to ensure wide representation of participants across NL from a geographical and clinical practice perspective. Participants will be recruited through professional and research networks and associations across NL. At the end of each interview, participants will be asked to identify an additional two people who may be interested in participating in the study. With all recruitment strategies, emphasis will be placed on seeking GPs and chiropractors from both urban and rural regions of NL. Emphasis will also be placed on seeking participants who may have differing views or practice patterns to ensure a wide range of perspectives and to avoid premature saturation.

We will use the principles for deciding saturation in theory-based interviews proposed by Francis *et al.* (2010)[21] to determine our sample size. A minimum of 10 interviews will be conducted and analysed to determine if we have reached thematic saturation (the point where no new themes are identified) and geographic diversity. A stopping criterion of three will be used, meaning that if new themes are identified in the last three interviews, an additional three interviews will be conducted. This iterative process will be repeated either to saturation or to a maximum of 20 interviews. If researchers identify major differences between the two professions during this process, analysis and thematic saturation will be assessed separately by profession, otherwise the participants will be analysed as a single group.

Data collection

Interview procedure. Semi-structured interviews with open-ended questions will be conducted by two members of the research team. Additional members of the research team may be present to take field notes. Interviews will be conducted over phone or a videoconferencing platform, Cisco Webex (Cisco Systems, Milpitas, United States). The interviews are expected to take approximately 60 minutes. At the start of the interview, participants will be asked demographic questions on the following: profession (GP or chiropractor); practice location (urban or rural); and years in practice. Then, the researcher will provide a brief presentation on intervention fidelity (what it is and why it is important), the aim of the interview, and the goal of the intervention that the participants will be delivering as part of the future trial. Participants will be provided with examples of proposed strategies to enhance and/or assess intervention fidelity for the proposed intervention. All interviews will be audio-recorded and transcribed verbatim.

Interview guide. The interview guide (see extended data[22]) will be adapted from a previous study by Toomey *et al.* (2016)[23], which aimed to develop an intervention fidelity protocol for an intervention to promote self-management for people with chronic LBP or osteoarthritis. More specific questions about perceived barriers and enablers will be included in our interview guide. Additionally, questions in our interview guide will be guided by a checklist developed by the NIH BCC to assess the various components of intervention fidelity[3]. We chose to prioritise questions directly related to the intervention fidelity checklist rather than using an interview guide based on the TDF to ensure the various components of intervention fidelity were addressed. The interview guide will include questions related to (i) participants' attitudes towards the proposed intervention material, (ii) participants' thoughts on how to enhance and/or assess fidelity of provider training by the research team based on the examples they were shown, and (iii) participants' thoughts on how to enhance and/or assess fidelity of the proposed intervention delivery by the providers to the patients based on the examples they were shown. Content experts in qualitative research, intervention fidelity, and LBP will be consulted to establish face validity of the interview guide. The interview guide will be pilot tested with two of the participants and refined if necessary.

Data analysis

Coding will begin after 3–5 interviews have been completed and transcribed using NVivo (V12, QSR International, Melbourne, Australia). Two reviewers will read transcripts until they are familiar with the data prior to beginning coding. The TDF will be used as a coding framework to code and analyse the data.

Data will be analysed using a three-step process: (1) domain coding; (2) generating specific belief statements; and (3) identifying relevant domains. Two reviewers will independently code participant responses into the relevant theoretical domain(s). We will use the 14 domains from the revised version of the TDF as well as an additional "other" domain to capture any responses that do not fit into one of the TDF domains. The reviewers will meet after coding the first two transcripts to compare results and Fleiss' kappa (κ) will be calculated for all domains to assess how reliably the reviewers coded the same response to the same domains. Any domains with $\kappa < 0.8$ will be coded to consensus. The remaining interviews will be coded independently by the same two reviewers and once all interviews have been completed, κ will again be calculated, with any domains with $\kappa < 0.8$ reviewed and coded to consensus. Then, one reviewer will generate a statement representing the key message of each response (specific belief). The list of specific beliefs will be reviewed by another reviewer for completeness and accuracy. Lastly, the two reviewers will use discussion to identify which domains likely represent the perceived barriers and enablers to ensuring fidelity of training or delivery. The domains most likely representing perceived barriers and enablers to ensuring fidelity of training or delivery will be identified through consideration of: the frequency of the belief statements; the presence of conflicting beliefs; and the perceived strength of the impact a belief may have on the target behaviours[17].

Responses will be coded into the "other" domain if they do not reflect barriers or enablers related to the behaviour of interest (i.e., enhancing and/or assessing fidelity of training or delivery). These responses may relate to clinicians' general perceptions of the intervention material or perceived acceptability of this intervention by patients. Responses in the "other" domain will be analysed inductively to establish categories and themes.

Ethics
This study has received ethics approval from the Newfoundland and Labrador Health Research Ethics Board (HREB #2020.299). Clinicians interested in participating in the study will be provided with a project information letter prior to the interview. At the start of each interview, participants will be asked if they have read the information letter, if they have any questions, and whether or not they consent to participating in this study. Members of the research team will be available to answer any questions. Verbal consent, if obtained, will be documented. Completion of the interview will imply that the participant consented to the entire interview and consent was not withdrawn during this period.

Plans for dissemination
Study results will be disseminated through publication in a peer-reviewed journal, presentation at national and/or international conferences of various disciplines, and infographic summaries to relevant stakeholders and interest groups.

Study status
Ethics approval has been obtained for this study. At the time of submission of this manuscript, recruitment has not yet begun.

Discussion
Non-indicated imaging for LBP is a form of low-value care and the routine use of imaging is not recommended in clinical practice[24]. Interventions that are aimed at targeting this behaviour are needed to improve patient outcomes and reduce overutilisation of healthcare resources. By developing an understanding of barriers and enablers to intervention fidelity prior to the start of a trial, intervention developers will have the opportunity to further refine the intervention and make the trial more feasible and pragmatic. Specifically, exploring barriers and enablers to fidelity of training and delivery will allow for the development of strategies to enhance and assess fidelity of training and delivery during the trial, thereby improving the confidence we may have in the results of the trial. This study will be an important step in developing a fidelity protocol for the upcoming cluster randomised controlled trial of the theory-informed intervention aimed at reducing non-indicated imaging for LBP in NL. Our results may help to ensure that the proposed intervention will be delivered with good fidelity and that fidelity can be appropriately assessed.

Data availability
Underlying data
No underlying data are associated with this article.

Extended data
Open Science Framework: Exploring perceived barriers and enablers to fidelity of training and delivery of an intervention to reduce imaging for low back pain: a qualitative interview study protocol (extended files). https://doi.org/10.17605/OSF.IO/2R45Z[22].

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Version 1

Reviewer Report 25 January 2022

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Robert Vining
Palmer Center for Chiropractic Research, Palmer College of Chiropractic, Davenport, IA, USA

The submission describes a protocol for a qualitative study designed to inform a follow-up cluster randomized clinical trial assessing the fidelity of an intervention designed to reduce inappropriate imaging use by general practitioners and chiropractors. The following comments are designed to improve the submission.

Introduction

1. First paragraph:
    1. Please revise the second sentence of the introduction. It is difficult to follow in its present form and the final portion appears to contain an error rendering the message confusing.

    2. Consider replacing passive language, which allows for condensed text and more clarity. For example, the sentence: “If the intervention was found to be effective but fidelity was low…” can be made more active, such as: “If an intervention is effective but fidelity is low…”

2. The statement “As most cases of LBP have no pathoanatomical cause of pain…” is errant and oversimplifies the problem of inappropriate imaging and clinical decision making related to imaging for LBP. It is however accurate to state that in most cases, a single definitive pathoanatomic cause for LBP cannot be identified. This sentence could be accurate if revised to something like: “Because diagnostic imaging can seldom definitively confirm specific pathoanatomic pain sources, there is limited utility in routine use for uncomplicated, or new onset, LBP without signs or symptoms of significant trauma or pathology.”

3. The introduction briefly addresses only 1 component of imaging guidelines, which is to avoid routine imaging for LBP. However, routine imaging is not clearly described nor is it differentiated from the numerous situations for which guidelines recommend imaging. Without clearly distinguishing between inappropriate and appropriate imaging and how

they relate to decision making complexities clinicians encounter, the text implies all imaging for LBP is inappropriate. Consider more thoroughly describing the problem.

4. Is the clinical resource booklet described toward the end of the Introduction section the intervention referred to in the Methods? Consider making this explicit.

5. If available, a reference for the booklet described toward the end of the Introduction section is needed.

6. The booklet described in the Introduction section appears to include sections for providers and patients. Is this a single booklet or 2 different booklets? Please clarify.

Methods

1. Please clarify if interviewed participants are automatically included in a follow-up trial. The informed consent description suggests providers agree to an interview, whereas the interview procedure text suggests providers agree to be interviewed prior to participating in a trial.

2. Please add information describing the plan for using qualitative results to inform the follow-up trial.

3. Please more fully describe the presentation on intervention fidelity, including elements such as the presentation format, main topics, key points, length…

Discussion

1. The text contains the following statements “exploring barriers and enablers to fidelity of training and delivery will allow for the development of strategies to enhance…” and “our results may help ensure that the proposed intervention will be delivered with good fidelity…” Both statements suggest the investigative team might not use data collected in the qualitative study, only that there will be an opportunity to use data. Presuming data will be used to inform the follow-up trial, even though it isn’t known yet what specific aspects will be informed, consider revising the language in both the Discussion and Abstract to more definitively state this point.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Chiropractic practitioner, educator, and clinician scientist with experience in

explanatory and pragmatic clinical trials, research and publications in the area of clinical decision making and experience training clinicians participating in clinical trials.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 01 June 2021

https://doi.org/10.21956/hrbopenres.14468.r29461

Hazel Jenkins
Faculty of Science and Engineering, Macquarie University, Macquarie Park, NSW, Australia

Thank you for the invitation to review this study protocol. The protocol addressed the design of a qualitative study to assess barriers to the enhancement and assessment of fidelity amongst GPs and chiropractors. Assessment of fidelity is important and should be considered before the conduct of an RCT as planned by the authors.

Introduction
Generally good. Perhaps might be worthwhile to describe the current lack of an effective intervention to decrease imaging for LBP, before discussing that this could be due to poor intervention fidelity.

Objectives
In the methods section of the abstract the aim also includes assessing the barriers to the *assessment* of fidelity. This is not described in the current objectives - please add if relevant

Methods
Please describe the experience of the researchers who will be conducting the interviews and performing the analysis

Discussion
Would be informative to include the planned methods to develop strategies to address identified barriers to intervention delivery fidelity. Will this be a theory informed process? Will the TDF be used in this process or other strategies?

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: I was the lead author of the development of the intervention that is planned to be tested in the eventual RCT (ref 16)

Reviewer Expertise: Intervention development and feasibility testing, particularly in the area of reducing imaging for low back pain.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.