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Publication Date	2016-08-01
Publisher	Oxford University Press
Repository DOI	10.2522/ptj.20150446

Running head: Complex Physiotherapy-Led Self-Management Intervention

Research Report

Development of a Feasible Implementation Fidelity Protocol Within a Complex Physiotherapy-Led Self-Management Intervention

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[Toomey E, Matthews J, Guerin S, Hurley DA. Development of a feasible implementation fidelity protocol within a complex physiotherapy-led self-management intervention. *Phys Ther.* 2016;96:xxx-xxx.]

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Published Ahead of Print: xxxx

Accepted: February 24, 2016

Submitted: August 14, 2015

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Abstract

Background: Implementation fidelity (IF) is poorly addressed within physiotherapy interventions which may be due to limited research on how to develop and implement an IF protocol (IFP).

Objective: To develop a feasible IFP within a pilot study of a physiotherapy-led intervention to promote self-management for people with chronic low back pain (CLBP) and/or osteoarthritis (OA).

Design: A two-phase mixed methods design.

Methods: Phase 1 involved the development of an initial IFP using qualitative interviews with potential stakeholders to explore the acceptability of proposed strategies to enhance and assess IF. Phase 2 involved testing and refining the initial IFP to develop a finalised IFP. Specifically, the feasibility of three different strategies (physiotherapist self-report checklists, independently-rated direct observations and audio-recorded observations) for assessing IF of intervention delivery was tested, followed by additional stakeholder interviews which explored the overall feasibility of the IFP.

Results: Phase 1 interviews determined the proposed IF strategies to be acceptable to stakeholders. Phase 2 found that independently-rated audio-recordings (n=6) and provider self-report checklists (n=12) were easier to implement than independently-rated direct observations (n=12) for assessing IF of intervention delivery. Good agreement (92.8-79.8%) was found between all methods. Qualitative stakeholder interviews confirmed the acceptability, practicality and implementation of the IFP.

Limitations: The reliability and validity of assessment checklists used in this study have yet to be fully tested and blinding of independent raters was not possible.

Conclusions: A feasible IFP was developed based on a two-phase development process involving intervention stakeholders. This study provides valuable information on the

feasibility of rigorously addressing IF within physiotherapy interventions and provides recommendations for researchers wishing to address IF in similar areas.

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Introduction

Implementation fidelity has been defined as ‘the degree to which an intervention, treatment or program is implemented as intended’,¹ and helps to increase scientific confidence that changes in study outcomes are due to the influence of the intervention being investigated, and not due to differences or variability in the implementation of the intervention.² The importance of addressing fidelity within research is well established and the recently published Template for Intervention Description and Replication (TIDieR) reporting guidelines (produced to improve completeness of intervention reporting for replication and implementation purposes) have emphasised the importance of addressing fidelity within clinical research.³ Despite its importance, implementation fidelity is still poorly addressed within physiotherapy interventions⁴ and our recent review found that 18 of 22 included studies of physiotherapy-led self-management interventions had ‘low’ fidelity scores (<50%).⁵ The reasons for this are unclear, but may be attributed to a lack of knowledge of fidelity and the practicalities and logistics of addressing it in a comprehensive and rigorous manner.^{6,7} Currently, there is limited guidance in the literature on the processes involved in developing and implementing a feasible and rigorous implementation fidelity protocol within complex interventions.⁸

In 2005 the National Institutes of Health Behaviour Change Consortium (NIHBCC) developed fidelity guidance which was later updated in 2011.^{2,9} The 40-component framework details a combination of strategies or methods that aim to enhance, establish and ensure fidelity (e.g. intervention manuals) and to assess or monitor it (e.g. direct observations) (Appendix 1). The framework categorises implementation fidelity into five specific domains: Study Design, Training of Providers, Treatment Delivery, Treatment Receipt and Treatment Enactment (Table 1).¹⁰ Developed specifically to address the fidelity

of behaviour change interventions in pragmatic clinical settings, the framework has been shown to have good inter-rater reliability^{9, 11} and good construct validity.¹¹ Despite its rigorous development and relevance for addressing implementation fidelity, it is still not used widely.¹² Of the studies that have used it, most have not used the updated 2011 version, nor have they addressed all of the five domains.¹³⁻¹⁵ Furthermore, few studies have fully explained the rationale for choosing certain fidelity strategies over others where numerous options exist, limiting the translation of implementation fidelity approaches to other settings.^{12, 16} For example, in-vivo observations or self-report records are two potential strategies for assessing Treatment Delivery¹⁷ but studies that have directly compared and contrasted these methods to inform selection are lacking.

The Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) pilot study aims to evaluate the feasibility of a group-based complex behaviour change intervention to promote self-management for people with osteoarthritis (OA) of the hip/knee and/or chronic low back pain (CLBP) compared to usual individual physiotherapy.¹⁸ OA was defined according to the NICE (2014) criteria (i.e. 45 years of age or older, activity-related joint pain and either no morning joint stiffness or stiffness lasting no longer than 30 minutes)¹⁹ and CLBP was defined as non-specific low back pain of mechanical origin with or without radiation to the lower limb for 3 or more months.²⁰ The intervention consists of six weekly 90-minute sessions delivered in person by primary care physiotherapists to groups of six to eight participants. Each session targets a specific self-management behaviour or skill and is structured to include an educational discussion, exercise and facilitated goal-setting. Additional materials such as pedometers are provided to supplement and enhance participant understanding and uptake of skills (Appendix 2).

The aim of this study is to describe the development of a comprehensive, feasible implementation fidelity protocol based on existing evidence-based fidelity guidelines. The study aims to provide a working example of how this guidance was applied and tested within the context of the SOLAS pilot study and in doing so, to offer further information for researchers wishing to address implementation fidelity in similar areas. The study focuses on exploring the overall feasibility of applying this protocol within a research setting, with a specific emphasis on the processes involved in the development of assessment strategies within the domain of Treatment Delivery. The development of the enhancement and assessment strategies in the remaining domains are beyond the scope of this paper and will be published separately. To the best of our knowledge, this is the first study to provide in-depth description of the practical development of a feasible implementation fidelity protocol, engaging and involving all stakeholders, in the context of a complex physiotherapy intervention.

Methods

The implementation fidelity protocol was developed in two phases (Figure 1), consistent with Medical Research Council guidance for complex interventions which promote the inductive, iterative processes of 1) Development and 2) Feasibility/piloting.²¹ First, an Exploratory Phase (Phase 1) informed the development of an initial implementation fidelity protocol using the NIHBCC framework. Next, a Testing/Refinement Phase (Phase 2) took place which involved testing this initial fidelity protocol during the SOLAS pilot study and subsequently refining it to develop a feasible finalised implementation fidelity protocol. Ethical approval for the research was granted by the University College Dublin Human Research Ethics Committee. For clarity, physiotherapist participants will be referred to as ‘physiotherapists’ and people with CLBP and/or OA will be referred to as ‘participants’ throughout this paper.

Exploratory Phase (Phase 1)

The exploratory phase aimed to explore the potential barriers and enablers to using strategies for enhancing and assessing implementation fidelity from the perspective of both physiotherapist and participant.

Phase 1a and 1b: Qualitative studies with physiotherapists and participants

Prior to the commencement of the SOLAS pilot study, two focus groups (n=14x2) were conducted with primary care physiotherapists from all geographic areas that would potentially be involved in the pilot study (Phase 1a). Purposive sampling was used to recruit physiotherapists who were currently providing group physiotherapy classes, had previously provided group classes, or were likely to be providing group classes as part of the SOLAS pilot study, as identified by their managers. During the focus groups, strategies used to assess and enhance implementation fidelity previously in similar studies⁵ were presented to physiotherapists, followed by a semi-structured discussion to explore potential barriers and enablers to these strategies. Following the focus groups, six semi-structured individual interviews were also conducted with a convenience sample of adults with CLBP and/or spinal OA (as defined earlier) who had recently participated in a similar group-based primary care physiotherapy intervention to promote self-management (Phase 1b). Invitation letters were sent to all who had completed the intervention in the preceding six months (n=22), identified through records by the physiotherapist who had delivered the intervention because of ethical requirements. Data for both focus groups and interviews were audio-recorded, transcribed verbatim and analysed separately using content analysis.²² This analytic approach was deemed the most appropriate for these datasets given the structured nature of the research questions and the limited depth of the responses.²³

Testing/Refinement Phase (Phase 2)

Based on the findings from the Exploratory Phase, an initial implementation fidelity protocol was designed. The Testing/Refinement Phase then sought to test the feasibility of this initial protocol in order to develop a refined and feasible finalised protocol. First, the Treatment Delivery assessment strategies were tested within the SOLAS pilot study (Phase 2a), where two intervention sites (n=3 physiotherapists; n=8 participants) participated. Subsequently, stakeholder interviews (Phase 2b and 2c) were conducted to explore the overall feasibility of the full fidelity protocol in practice, including feedback on any specific enhancement or assessment strategies from any NIHBCC domain. Informal feedback from the researchers involved in this phase was also sought regarding the feasibility of the fidelity protocol from a research viewpoint (e.g. conducting observations). Feasibility was addressed across three key areas; practicality, acceptability and implementation as defined previously by Bowen et al.²⁴ Successful feasibility was determined if issues pertaining to any of these areas emerged from the integrated results of the Testing/Refinement Phase and could be easily addressed in a finalised protocol (i.e. continue with modifications).^{25, 26} Integration of mixed methods occurred at an interpretative level during narration of results²⁷ between the qualitative physiotherapist interviews (Phase 2b) and the quantitative Treatment Delivery assessment strategies findings (Phase 2a) in relation to feasibility of these strategies.

Phase 2a: Treatment Delivery assessment strategies

This phase aimed to test the feasibility of three methods of assessing implementation fidelity within Treatment Delivery: 1) direct observations, 2) audio-recordings and 3) self-report checklists, and to ascertain the agreement of audio-recordings and self-report methods with the 'gold standard' approach of direct observations.¹⁰ Direct observations were conducted

during all intervention sessions (n=12, 6 sessions per site) during the **SOLAS** pilot study. The direct observations were conducted using a checklist developed by the research team to assess the fidelity of the delivery of sessions and the treatment dose (Appendix 3). Items on the checklists were scored as present ('yes'), absent ('no') or 'attempted/unsure'. Audio-recordings were selected as a potentially more feasible alternative and were chosen over video-recordings as previous evidence suggests they are less intrusive and more feasible to implement.¹⁷ Audio-recordings of half of the intervention sessions (n=6, 3 sessions per site) were completed during the pilot study and were used to evaluate fidelity retrospectively, using the same checklist as the direct observations. Two raters (ET and AK) independently rated the audio-recorded data to give an estimate of the inter-rater reliability of rating implementation fidelity using the observation checklist and audio-recorded data. Self-report treatment record checklists developed by the research team were used by physiotherapists in the intervention sites (n=12, 6 sessions per site) to assess self-reported fidelity in both groups (Appendix 4). The levels of agreement between the findings of the audio-recordings and the self-report with direct observations for the intervention group were analysed using concordance (% level of agreement). Due to the predominance of 'yes' replies within all checklists, Cohen's kappa was found to be invalid and therefore not applied.^{28,29}

Phase 2b and 2c: Qualitative interviews with SOLAS intervention physiotherapists and participants

Approximately one week after the last SOLAS intervention session, individual semi-structured telephone interviews were conducted with the three physiotherapists who had delivered the intervention (Phase 2b). Within two weeks of the last SOLAS session, individual semi-structured telephone interviews were conducted with a convenience sample of five people with CLBP and/or OA from the intervention sites of the SOLAS pilot study

who were willing to participate in interviews (Phase 2c). Participants were recruited at the end of the pilot study by research physiotherapists who had been observing classes in intervention sites. Data from all interviews were audio-recorded and transcribed verbatim. Deductive thematic analysis³⁰ was used to analyse the interviews to enable the findings to refine the implementation fidelity protocol by coding for constructs relevant to the specific domains of the NIHBCC fidelity framework.² Relevant units of text were summarised and coded within each interview which were then grouped across interviews. Initial codes were reviewed and continually refined into more concise final themes. A reflective diary of the analytical process was kept (by ET) and the method for analysis was discussed and planned with another member of the research team (JM) a priori. Data from both sets of interviews (i.e. physiotherapists and participants) were initially analysed separately, with the findings then integrated using triangulation³¹, to give overall feedback on the feasibility of the full implementation fidelity protocol in practice. Any findings specific to the feasibility of the Treatment Delivery assessment strategies were extracted from the physiotherapist interview results and triangulated with quantitative findings from Phase 2a following analysis.³¹

Results

Exploratory Phase (Phase 1)

Phase 1a and 1b: Integrated findings of qualitative studies with physiotherapists and participants

The participant demographics and characteristics of the Exploratory Phase qualitative studies are provided in Table 2. Table 3 details the integrated findings of the studies and how they influenced the development of the initial implementation fidelity protocol. The assessment and enhancement strategies of the initial fidelity protocol that was developed as a result of the Exploratory Phase are detailed in Table 4.

Testing/Refinement Phase (Phase 2)

Phase 2a and 2b: Integrated findings of Treatment Delivery assessment strategies and SOLAS physiotherapist interviews – feasibility of assessment strategies

Overall levels of agreement ranged from 79.8% (between direct observations and Rater 2 audio-recordings) to 92.8% agreement (between direct observations and self-report), suggesting good to excellent agreement (Table 5).³² Inter-rater agreement for the audio-recordings was 82.3%. Of the sections of the intervention, ‘Introduction/Recap and Review’ and ‘Review and Planning’ (e.g. goal setting) had the lowest agreement between all three methods.

A minor issue emerged regarding the implementation of assessment strategies in relation to the checklists’ scoring system, as the ‘unsure/attempted’ option lacked clarity due to the difference in meaning between ‘attempted’ and ‘unsure’. Direct observation was the most comprehensive method for assessing fidelity of Treatment Delivery, consistent with its ‘gold standard’ status, as the audio-recordings were unable to detect the performance of certain items on the checklist such as ‘room set up for exercise’ and due to technical issues, one audio-recording was unusable. However in terms of implementation, direct observations were time-consuming and resource-intensive, and the self-report forms and audio-recordings were found to be more practical for researchers. In the Testing/Refinement Phase interviews (Phase 2b), the physiotherapists felt that the three assessment strategies were acceptable and raised no concerns regarding their implementation; however, one physiotherapist suggested that direct observations may be more intrusive for participants stating ‘...more for the patients than anything else. I think that they felt there was an awful lot of people in the room watching’ (Physiotherapist 3, Site B).

For assessing Treatment Delivery in the finalised implementation fidelity protocol, it was therefore proposed to obtain self-report checklists and audio-recordings of all intervention sessions because of their good agreement with the ‘gold standard’, and to directly observe 24 randomly selected sessions from across all intervention sites. A sample of 24 was chosen as it has been previously shown to be the minimum number needed for initial instrument development within pilot studies.³³ Based on feedback from the Testing/Refinement Phase, it was decided to refine the scoring system of the checklists for the finalised fidelity protocol, changing the option for ‘unsure/attempted’ on all checklists to ‘attempted’. As agreement within the scoring of ‘Introduction/Recap and Review’ and ‘Review and Planning’ sections had been low, it was decided to ensure that the structure, aims and strategies relevant to these sections (e.g. adequate goal-setting) would be clarified further with physiotherapists during physiotherapist training, and also with the raters of the audio-recorded data prior to completion of rating in the finalised implementation fidelity protocol.

Phase 2b and 2c: Integrated findings of qualitative interviews with SOLAS physiotherapist and participants – overall feedback on implementation fidelity protocol

The participant demographics and characteristics of the Testing/Refinement Phase qualitative interviews are detailed in Table 2. Overall, the stakeholder feedback obtained regarding the specific SOLAS enhancement and assessment strategies within the five domains found the implementation fidelity protocol to be feasible from both physiotherapist and participant perspectives. In terms of acceptability, participants found the intervention materials and resources that comprised strategies to *enhance* Treatment Receipt/Enactment very useful, particularly the pedometer, but they were unsure of whether they would continue using activity diaries as self-monitoring tools in the long term. However, as a potential strategy of

assessing Treatment Receipt, participants felt that the collection of activity diaries by researchers would be acceptable; *'No, I wouldn't have minded that [collection of activity diaries] at all. As I say I would have only filled in, maybe filled in one or two, because I wouldn't have been there for the some of them. But no, I wouldn't have minded'* (Participant 1, Site B). The participant interviews themselves were also found to be a useful and acceptable means of further assessing Treatment Receipt and Enactment as participants spoke about an enhanced knowledge of their condition and pain management skills, and of increasing physical activity levels and use of pain management strategies since completing the programme.

Regarding the practicality of the implementation fidelity protocol, physiotherapists reported minor technical issues surrounding relaxation CDs and access to the projectors used to deliver the education component (Treatment Delivery *enhancement* strategies), as one physiotherapist remarked *'It's just the hassle if you like, of setting up the powerpoint, and I had to get used to that'*(Physiotherapist 1, Site A). In terms of implementation of the **fidelity protocol** strategies, physiotherapists felt that they delivered the SOLAS intervention with good levels of fidelity but that the goal-setting section was challenging. One physiotherapist also felt that the fidelity of delivery had been adversely affected by the amount of time between their training and the intervention start; *'The training was completed a little bit earlier and there was a bit of a gap then....Things were a lot fresher in my head after the initial training....it was a good bit earlier than the start of the programme'* (Physiotherapist 2, Site B).

Subsequent to this feedback it was deemed necessary to ensure that in future, any intervention materials and equipment should be carefully tested in each site in advance to

avoid any technical issues, and the time between training and delivery would need to be considered. Compounding the earlier findings regarding Treatment Delivery assessment strategies, it was felt that appropriate and adequate goal-setting would be of paramount importance in the finalised implementation fidelity protocol. For assessing Treatment Receipt and Treatment Enactment in the finalised fidelity protocol, it was decided to assess participants' activity diary use at the end of the six-week intervention and also to conduct further participant interviews.

Testing/Refinement Phase output – Finalised implementation fidelity protocol

Based on the findings of the Testing/Refinement Phase, a feasible finalised implementation fidelity protocol was developed that addresses each component of the NIHBCC framework. The finalised implementation fidelity protocol structured according to domain is available online (Supplementary File) due to its comprehensive nature and length.

Discussion

This study describes the development of a feasible implementation fidelity protocol using the SOLAS pilot study as a vehicle for its development. The paper provides a working example of each component of the updated NIHBCC fidelity framework addressed in a complex behaviour change intervention, and is one of the first papers to explore pragmatic issues of implementation fidelity from all stakeholder perspectives.

A key strength of this paper is that it evaluates the feasibility and appropriateness of multiple strategies for assessing implementation fidelity within the domain of Treatment Delivery. In a special series report on implementation research within physiotherapy research, Huijg et al⁴ highlighted the need for multiple methods of data collection in order to comprehensively

address implementation fidelity. Ideally, interventions should aim for gold-standard methods, e.g. direct observations.^{10, 15} However, implementation fidelity assessment strategies ought to be tailored to the intervention in question³⁴; therefore the appropriateness and feasibility of these ‘gold-standard’ measures may need to be explored and alternative methods such as provider self-report or audio-recordings, concurrently evaluated for suitability in context and feasibility as shown in this study.

The use of qualitative data collection involving all intervention stakeholders is an important aspect of implementation fidelity³⁵, and crucial in developing an acceptable implementation fidelity protocol. By collecting qualitative data in the Exploratory Phase, we identified and explored potential barriers to implementation fidelity strategies consistent with previously identified barriers to fidelity such as participant characteristics³⁶, time constraints^{6, 37, 38} and availability of resources.³⁹ This allowed us to develop a more feasible initial fidelity protocol from the outset, thus reducing potential waste of research resources. The interviews completed in the Testing/Refinement Phase provided valuable feedback regarding the overall feasibility of implementing the fidelity protocol and the enhancement and assessment strategies that had been used within each domain of the implementation fidelity protocol. To the authors’ knowledge, no other studies have both prospectively and retrospectively explored the acceptability of implementation fidelity strategies to stakeholders to develop an implementation fidelity protocol.

This paper is also the first study to develop an implementation fidelity protocol through a two-phase process of testing and refinement. In a recent editorial, Vernooij-Dassen and Moniz-Cook³⁵ highlighted the need for more interventions that use feasible implementation fidelity protocols to plan for and address implementation fidelity from the outset. Previously,

Poltawski et al³⁹ described their experience of addressing fidelity in the development of a clinical stroke rehabilitation trial, using the NIHBC framework to structure their work. Although their mixed methodology study explored implementation fidelity in more depth than previous work, the study focuses more on how the protocol was *applied*, rather than how the protocol was *developed*. The authors acknowledge the lack of further testing of the protocol as a limitation of their study for which future research was indicated. We believe the two-phase process described in this study further strengthens the comprehensiveness of the finalised fidelity protocol.

There are some limitations to the current study. First, the assessment checklists have been developed to be specific to the intervention in question and their reliability and validity has yet to be thoroughly tested, which may limit the internal validity of the study. However, we have attempted to address criterion (concurrent) validity of the audio-recording and self-report checklists by assessing their agreement with the 'gold standard' of direct observation checklist, which was developed to address all intervention components. Second, the use of blinded raters would enhance the assessment of Treatment Delivery; however this was not possible in the current study due to availability of resources. Third, the physiotherapist and participant samples used in this study were specific to the SOLAS pilot study inclusion and exclusion criteria, and the intervention took place in a primary care setting, which may limit the generalizability of findings. Nonetheless, this study contains pragmatic information about implementation fidelity that is applicable across a variety of research contexts and will facilitate how fidelity is addressed in future complex interventions.

Key 'take-home' points

The following points summarise how and when researchers may best use the findings of this study. First, the finalised implementation fidelity protocol (Supplemental File) can be used as a pragmatic and feasible example of how to address each component of the NIHBCC framework within complex interventions – thus ensuring a comprehensive approach to addressing implementation fidelity in their research. The finalised implementation fidelity protocol can be used during the planning and development stages of a complex intervention to plan for addressing implementation fidelity in a research study. Second, the assessment checklists (Appendices 3 and 4) can be used by researchers as templates for developing similar Treatment Delivery fidelity assessment checklists. Finally, the finalised implementation fidelity protocol can also be used as an aid in evaluating the implementation fidelity of similar complex interventions with the knowledge that this is an example that has actually been tested and found to be feasible for use in a research setting.

Conclusions

This paper describes the development of a comprehensive implementation fidelity protocol within the context of a complex physiotherapy intervention. Future work will apply the finalised protocol to a randomised controlled feasibility trial and explore the factors influencing implementation fidelity results.¹⁸ This paper contributes much needed guidance on the feasibility of addressing fidelity in complex intervention and findings can be used to enhance how implementation fidelity is addressed in physiotherapy research in addition to other research fields.

Acknowledgments

All authors provided concept/idea/research design. Ms Toomey and Dr Hurley provided writing and project management. Ms Toomey and Dr Guerin provided data collection. Ms Toomey provided data analysis. Dr Hurley provided facilities/equipment. Dr Matthews and Dr Hurley provided consultation (including review of manuscript before submission). The authors thank Alison Keogh for her help in independently rating of audio-recorded data.

This study was funded as part of Health Research Award HRA_HSR/2012/24 by the Health Research Board of Ireland.

DOI: 10.2522/ptj.20150446

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Table 1: Definitions of National Institutes of Health Behaviour Change Consortium (NIHBCC) Fidelity Framework domain¹⁰	
NIHBCC Domain	Definition
Study Design	<i>Study Design</i> addresses factors that should be considered when designing the trial, and are intended to enable the study to adequately assess its hypotheses in relation to the underlying theory and mechanisms of action of the study
Training of Providers	<i>Training of Providers</i> aims to ensure and assess that providers are able to deliver the intervention satisfactorily and as intended
Treatment Delivery	<i>Treatment Delivery</i> relates to processes that assess and enhance the actual delivery of the intervention so that it is delivered as intended
Treatment Receipt	<i>Treatment Receipt</i> involves using strategies to enhance and assess participant knowledge and use of intervention skills and learning <i>during</i> the intervention. It also considers factors that aim to enhance the acceptability of the intervention to the participant
Treatment Enactment	<i>Treatment Enactment</i> uses strategies to enhance and assess their actual practice of the intervention skills and knowledge in daily life

Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol.* 2004;23(5):443-451, adapted with permission.

	Method of data collection	Mean interview duration (range)	Number of pts	Gender	Diagnoses	Average duration of diagnosis (range)	Age range	Physiotherapy grade (PTs) /Employment status (pts)	Intervention attendance rates (%)
Phase 1: Exploratory Phase	Phase 1a: Physiotherapist Focus Groups	30 minutes (27-33)	28 (2 groups of 14)	5 male 23 female	N/A	N/A	Unknown	Senior (n=18) Staff (basic) (n=9) Unknown (n=1)	N/A
	Phase 1b: Participant Interviews	20.5 minutes (14-26)	6	2 male 4 female	CLBP	13.88 years (0.75-32)	46-55 (n=4) 56-65 (n=1) 66-75 (n=1)	Unemployed due to disability (n=4) Retired (n=1)	100% (n=5) 67% (n=1)
Phase 2: Testing/Refinement Phase	Phase 2b: Physiotherapist Interviews	46 minutes (40.5-50)	3*	1 male 2 female	N/A	N/A	Unknown	Senior (n=2) Staff (basic) (n=1)	N/A
	Phase 2c: Participant Interviews	20 minutes (17-23)	5	1 male 4 female	CLBP (n=3) CLBP + OA (hip) (n=2)	13.6 years (3-21)	62 (54-75)	Unemployed due to disability (n=1) Retired (n=1) Housewife/husband (n=3)	100% (n=1) 83% (n=2) 67% (n=2)

*Two of the physiotherapists interviewed in Phase 2b had also participated in the focus groups (Phase 1a). PTs = physiotherapist, pts = participants

Table 3: Exploratory Phase – findings from qualitative stakeholder data collection				
NIHBCC Domain	Factor Identified	Source (Physiotherapist/ Participant)	Relevant Component from NIHBCC framework	How addressed/what actions considered in developing initial IFP
Study Design	<ul style="list-style-type: none"> • Time constraints and the availability of resources and services (specifically administration, venues and staffing) were identified as a potential barrier to IF e.g. physiotherapists felt that if sessions were too long or too frequent, they may not be able to deliver the sessions as intended • Inappropriate participant selection/screening was identified as a potential barrier to IF e.g. physiotherapists felt the inclusion of participants with too much variety in terms of ability/age might hinder their ability to deliver the intervention as intended 	Physiotherapist Focus Groups (Phase 1a)	<ul style="list-style-type: none"> • Plan to address possible setbacks in implementation 	<ul style="list-style-type: none"> • Intervention designed to be a weekly session of no longer than 1.5 hours in duration • Intervention to be delivered by one physiotherapist • Two physiotherapists to be trained per site • Careful recruitment (meticulous screening and selection) of participants for the pilot study to be completed by research physiotherapists
Training of Providers	<ul style="list-style-type: none"> • The need to individualise and tailor treatment was identified as a potential barrier to IF • Regular contact between the physiotherapists and the research team to prevent skill drift was deemed acceptable 	Physiotherapist Focus Groups (Phase 1a)	<ul style="list-style-type: none"> • At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g., ensure that providers find 	<ul style="list-style-type: none"> • Training of physiotherapists to address how to individualise care within the intervention protocol • Training to discuss regular two-way channels of communication between the research team and physiotherapists

			<p>the intervention acceptable and credible)</p> <ul style="list-style-type: none"> • Assessment and monitoring of provider skill maintenance over time 	
Treatment Delivery	<ul style="list-style-type: none"> • Direct observations and audio-recordings of intervention sessions were deemed acceptable to monitor fidelity of treatment delivery • Physiotherapist self-report record forms deemed to be acceptable to enhance and monitor fidelity of treatment delivery • Physiotherapist self-report forms in a checklist-style desirable 	Physiotherapist Focus Groups (Phase 1a)	<ul style="list-style-type: none"> • Method to ensure that the content of the intervention is delivered as specified • Method to ensure that the dose of the intervention is delivered as specified • Mechanism to assess if the provider actually adhered to the intervention plan • Assessment of nonspecific treatment effects • There is a plan for the assessment of whether or not the active ingredients were delivered • There is a plan for the assessment of whether or not proscribed components were delivered 	<ul style="list-style-type: none"> • Direct observations and audio-recordings to be used to monitor treatment delivery • Physiotherapist self-report checklists to be used to monitor treatment delivery
Treatment Receipt/Enactment	<ul style="list-style-type: none"> • Attendance not sufficient on its own to monitor treatment receipt • Activity diaries may be useful for <i>enhancing</i> treatment receipt/enactment but unsure of use for <i>assessing</i> treatment receipt/enactment 	Participant Interviews (Phase 1b)	<ul style="list-style-type: none"> • The participants' ability to perform the intervention skills will be assessed during the intervention period. • A strategy will be used to improve subject 	<ul style="list-style-type: none"> • Attendance will not be used as the only measure of Treatment Receipt but will be monitored for potential use in explaining fidelity results in addition to other methods

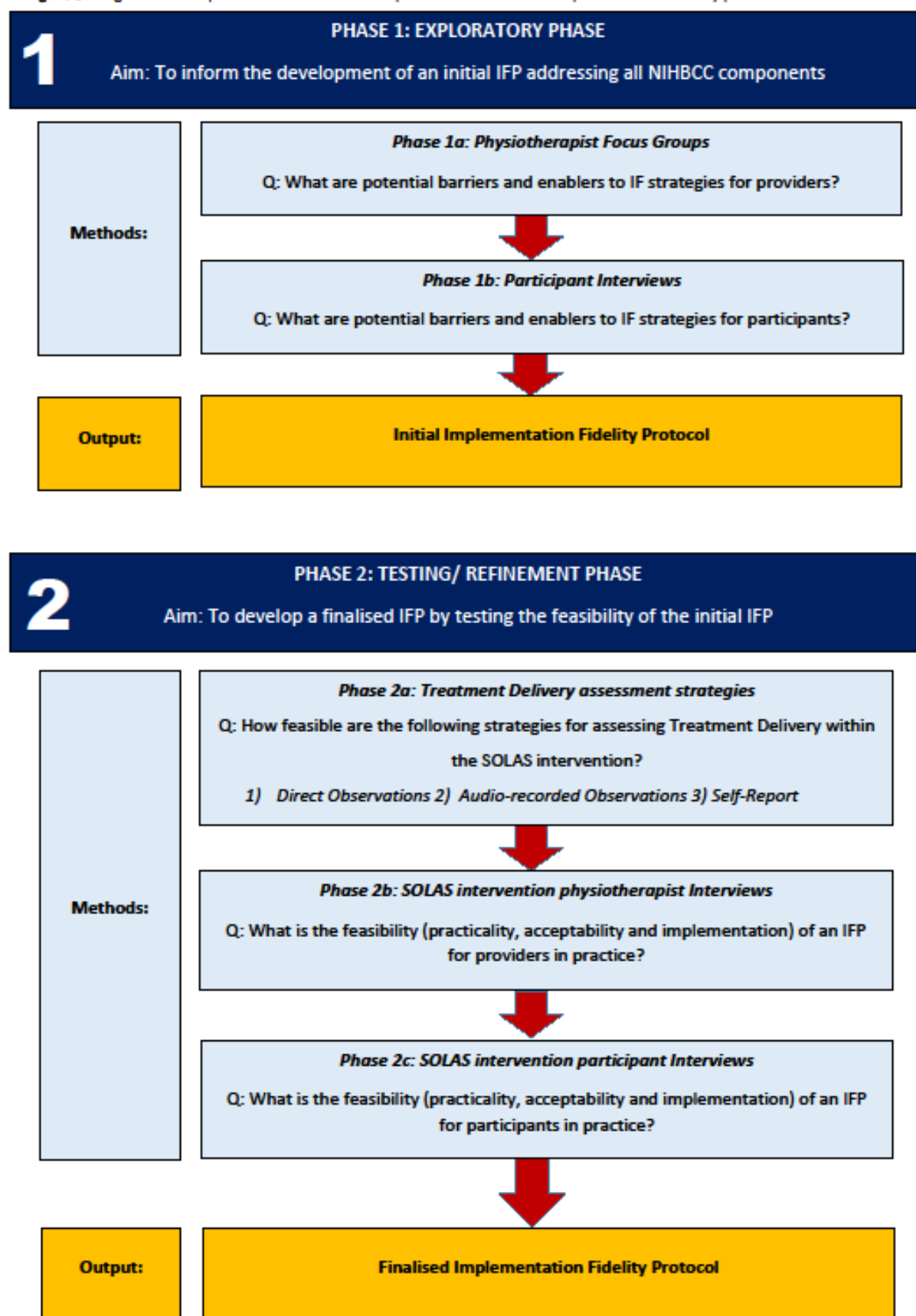
			<p>performance of intervention skills during the intervention period</p> <ul style="list-style-type: none"> • Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied • A strategy will be used to improve performance of the intervention skills in settings in which the intervention might be applied. 	<ul style="list-style-type: none"> • Activity diaries will be used to enhance treatment receipt/enactment • Qualitative feedback will be sought after the pilot study on the acceptability of using activity diaries to assess receipt/enactment
<p>NIHBCC = National Institutes of Health Behaviour Change Consortium, IFP = implementation fidelity protocol, IF = implementation fidelity</p>				

Table 4: Initial Implementation Fidelity Protocol – strategies to enhance and assess IF in pilot study					
	Study Design	Training of Providers	Treatment Delivery	Treatment Receipt	Treatment Enactment
Enhancement strategies	<ul style="list-style-type: none"> • Intervention Manual • Information sheets given to TAU physiotherapists 	<ul style="list-style-type: none"> • Training Manual • Scripted roleplays 	<ul style="list-style-type: none"> • Intervention manual • Information sheets given to TAU physiotherapists 	<ul style="list-style-type: none"> • Intervention materials <ul style="list-style-type: none"> ○ Participant manual ○ Action planning/goal setting sheets ○ Activity diaries ○ Pedometer ○ Relaxation CD ○ Tape measure ○ Healthy Eating booklet ○ Healthy Eating cookbook • Group discussions with physiotherapist feedback • Group exercise with physiotherapist feedback 	<ul style="list-style-type: none"> • Intervention materials <ul style="list-style-type: none"> ○ Participant manual ○ Action planning/goal setting sheets ○ Activity diaries ○ Pedometer ○ Relaxation CD ○ Tape measure ○ Healthy Eating booklet ○ Healthy Eating cookbook ○ List of community supports/resources • Group discussions with physiotherapist feedback • Group exercise with physiotherapist feedback • Long-term goal setting
Assessment strategies	<ul style="list-style-type: none"> • Physiotherapist characteristics assessment form 	<ul style="list-style-type: none"> • Pre-post training evaluation forms 	<ul style="list-style-type: none"> • Self-Report checklist • Direct Observations 	<ul style="list-style-type: none"> • Self-management behaviours questionnaire 	<ul style="list-style-type: none"> • Assessment of delivery of enhancement strategies using

	<ul style="list-style-type: none"> • Self-Report checklist • Direct Observations • Audio-recorded Observations • Physiotherapist interviews post-intervention 	<ul style="list-style-type: none"> • Physiotherapist characteristics assessment form • Post-training record form (research team) • Physiotherapist interviews post-intervention 	<ul style="list-style-type: none"> • Audio-recorded Observations • Physiotherapist interviews post-intervention 	<ul style="list-style-type: none"> • Assessment of delivery of enhancement strategies using <ul style="list-style-type: none"> ○ Self-Report checklist ○ Direct Observations ○ Audio-recorded Observations • Participant interviews post-intervention • Physiotherapist interviews post-intervention 	<ul style="list-style-type: none"> ○ Self-Report checklist ○ Direct Observations ○ Audio-recorded Observations • Participant interviews post-intervention – assessing short-term enactment
IF = implementation fidelity, TAU = treatment as usual					

Table 5: Testing/refinement Phase 2a: Agreement between Treatment Delivery assessment strategies					
		Direct Observations v Self-Report	Audio-recorded Observations: Rater 1 v Rater 2	Direct Observations v Audio-recordings Rater 1	Direct Observations v Audio-recordings Rater 2
Overall % Agreement (95% CI) (number of checklist items)		92.8% (± 4.31) (n=138)	82.3% (± 8.42) (n=79)	79.8% (± 8.59) (n=84)	80.5% (± 8.33) (n=87)
<i>% Agreement within sections</i>					
% Agreement (95% CI) (number of checklist items)	Materials	85.7% (± 12.97) (n=28)	88.8% (± 20.6) (n=9)	77.8% (± 27.15) (n=9)	90.9% (± 17) (n=11)
	Introduction/ Recap & Review	87.5% (± 16.2) (n=16)	63.6% (± 28.43) (n=11)	76.9% (± 22.91) (n=13)	72.7% (± 26.33) (n=11)
	Education	98.4% (± 3.12) (n=62)	86% (± 10.37) (n=43)	83.7% (± 11.04) (n=43)	83.7% (± 11.04) (n=43)
	Exercise	100% (± 0) (n=24)	92.3% (± 14.49) (n=13)	75% (± 21.22) (n=16)	78.9% (± 18.35) (n=19)
	Relaxation	100% (± 0) (n=1)	n/a (n=0)	n/a (n=0)	n/a (n=0)
	Review & Planning	57.1% (± 36.66) (n=7)	33.3% (± 53.33) (n=3)	33.3% (± 53.33) (n=3)	33.3% (± 53.33) (n=3)

Figure 1: Diagrammatic representation of the development of the finalised implementation fidelity protocol



IFP = implementation fidelity protocol, NIHBCC = National Institutes for Health Behaviour Change Consortium, TD = Treatment Delivery, IF = Implementation Fidelity, SOLAS = Self-management of Osteoarthritis and Low back pain through Activities and Skills

Appendix 1: National Institutes of Health Behaviour Change Consortium (NIHBCC) fidelity framework (Borrelli et al. 2011)

Domain	Fidelity component
Study Design	1) Provided information about treatment dose in the intervention condition:
	<input type="checkbox"/> Length of contact (minutes)
	<input type="checkbox"/> Number of contacts
	<input type="checkbox"/> Content of treatment
	<input type="checkbox"/> Duration of contact over time
	2) Provided information about treatment dose in the comparison condition:
	<input type="checkbox"/> Length of contact (minutes)
	<input type="checkbox"/> Number of contacts
	<input type="checkbox"/> Content of treatment
	<input type="checkbox"/> Duration of contact over time
	<input type="checkbox"/> Method to ensure that dose is equivalent between conditions
	<input type="checkbox"/> Method to ensure that dose is equivalent for participants within conditions
	3) Specification of provider credentials that are needed
	4) Theoretical model upon which the intervention is based is clearly articulated
<input type="checkbox"/> The active ingredients are specified and incorporated into the intervention	
<input type="checkbox"/> Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines	
<input type="checkbox"/> Plan to ensure that the measures reflect the hypothesized theoretical constructs/mechanisms of action	
5) Potential confounders that limit the ability to make conclusions at the end of the trial are identified?	
6) Plan to address possible setbacks in implementation (i.e., back-up systems or providers)	
7) If more than one intervention is described, all described equally well.	
Training of Providers	8) Description of how providers will be trained (manual of training procedures)
	9) Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers)
	10) Assessment of provider skill acquisition
	11) Assessment and monitoring of provider skill maintenance over time
	12) Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori
	13) At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g., ensure that providers find the intervention acceptable, credible and potentially efficacious)
	14) There is a training plan that takes into account trainees' different education and experience and learning styles
Treatment Delivery	15) Method to ensure that the content of the intervention is delivered as specified
	16) Method to ensure that the dose of the intervention is delivered as specified
	17) Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information
	18) Assessment of nonspecific treatment effects
	19) Used treatment manual
	20) There is a plan for the assessment of whether or not the active ingredients were delivered
	21) There is a plan for the assessment of whether or not proscribed components were delivered. (e.g., components that are unnecessary or unhelpful)
	22) There is a plan for how will contamination between conditions be prevented
	23) There is an a priori specification of treatment fidelity (e.g, providers adhere to delivering >80% of components)
	24) There is an assessment of the degree to which participants understood the intervention
Treatment Receipt	25) There is specification of strategies that will be used to improve participant comprehension of the intervention.
	26) The participants' ability to perform the intervention skills will be assessed during the

	intervention period.
	27) A strategy will be used to improve subject performance of intervention skills during the intervention period
	28) Multicultural factors considered in the development and delivery of the intervention (e.g., provided in native language; protocol is consistent with the values of the target group)
Treatment Enactment	29) Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.
	30) A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.

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Appendix 2: Structure of SOLAS intervention	
Section	Aim/content of section
Materials	Participants are provided with materials intended to supplement and enhance participant understanding and uptake of skills, such as pedometers, participant activity diaries and relaxation CDs
Introduction/ Recap & Review	At the start of each session the physiotherapist reviews goals and action plans with participants and problem-solving where necessary
Education	Physiotherapist facilitates a group discussion on the targeted self-management skill/behaviour of the session using Powerpoint slides
Exercise	Participants are provided with an opportunity to attempt and practice a variety of exercises
Relaxation	Participants are provided with the opportunity to practice relaxation skills facilitated by use of a relaxation CD (session 5 only)
Review & Planning	Before the session concludes, the physiotherapist briefly recaps participants planned activity levels and action plans for the week ahead

INTERVENTION SESSION OBSERVATION CHECKLIST (ADHERENCE):

Date:	
Venue:	
Physiotherapist Name:	
Other staff involved:	Name(s): Role: (e.g. set-up/delivery/support)
Session number (tick):	1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/>
Start time (class):	
Finish time (class):	
Time spent on education (mins):	
Time spent on exercise (mins):	
Adverse event(s)/issue(s) (circle):	If yes give brief details:
Y/N	
Deviations from protocol?	
General notes on fidelity of session:	

INTERVENTION COMPONENT CHECKLIST:		YES (2)	NO (0)	ATTEMPTED (1)
Session 1:				
Materials				
	Activity Action Plan given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Booklet handout and folders given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Name stickers/badges given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Introduction				
	Welcome address given	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Introductions made between group	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Set clear expectations – aims, content and structure of programme outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Rationale for weekly attendance addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education				
	Rationale for self-management given	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Rationale for weekly attendance given	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Cycle of change addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Prevalence of OA/CLBP addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Disease characteristics of OA and CLBP addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Causes of OA and CLBP addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Recommended activity levels addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Benefits of exercise addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Reflection on individual activity levels facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Goal setting addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Action planning addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise				
	Room set-up for all exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Sheets for exercises on walls by exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Protocol exercises explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Protocol exercises demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Participants encouraged to try all/different protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Review and Planning				
	Session review - activity levels and goal setting recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Total score (Yes = 2, Attempted = 1, No =0)			
	Overall Adherence score			

Session 2:

INTERVENTION COMPONENT CHECKLIST:	YES (2)	NO (0)	ATTEMPTED (1)
Materials			
Intervention folder reminder to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Name stickers/badges given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pedometers offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking diary offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review			
Welcome made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activity-rest cycle and pacing explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reflection on current practice of pacing/activity-rest facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activity-rest cycle and pacing related to individual practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Factors influencing pain addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Goal setting facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Action planning facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Room set-up for all exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sheets for exercises on walls by exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol exercises explanation and demo reviewed (if needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants encouraged to try all/different protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total score (Yes = 2, Attempted = 1, No =0)			
Overall Adherence score			

Session 3:

INTERVENTION COMPONENT CHECKLIST:	YES (2)	NO (0)	ATTEMPTED (1)
Materials			
Intervention folder reminder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Healthy Eating Booklet in folder made aware to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Food diary in folder made aware to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tape measures offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pedometers offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking diary offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem solving addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rationale for addressing diet/weight given (obesity and effect on pain)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Balanced between activity and healthy diet/weight addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waist measurement addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Portion control addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Food and exercise diary encouraged for use as self-monitoring tool	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Room set-up for all exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sheets for exercises on walls by exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol exercises explanation and demo reviewed (if needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants encouraged to try all/different protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap integrating food and exercise diary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total score (Yes = 2, Attempted = 1, No =0)			
Overall Adherence score			

Session 4:

INTERVENTION COMPONENT CHECKLIST:	YES (2)	NO (0)	ATTEMPTED (1)
Materials			
Intervention folder reminder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pedometers offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking diary offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Midway Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rationale for using pain relief given (e.g. pain pathway explained)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heat/ice addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Safety tips given	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drug management/medication addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Alternative treatments addressed (acupuncture, TENS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Room set-up for all exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sheets for exercises on walls by exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol exercises explanation and demo reviewed (if needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants encouraged to try all/different protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total score (Yes = 2, Attempted = 1, No =0)			
Overall Adherence score			

Session 5:

INTERVENTION COMPONENT CHECKLIST:	YES (2)	NO (0)	ATTEMPTED (1)
Materials			
Intervention folder reminder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relaxation CD offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information/rationale about flare-ups given	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual reflection about flare-ups facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recognising and managing flare-ups addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Effect of mood on pain addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Room set-up for all exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sheets for exercises on walls by exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol exercises explanation and demo reviewed (if needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants encouraged to try all/different protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relaxation Session			
Relaxation techniques explained and practiced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap with integration of relaxation techniques	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total score (Yes = 2, Attempted = 1, No =0)			
Overall Adherence score			

Session 6:

INTERVENTION COMPONENT CHECKLIST:	YES (2)	NO (0)	ATTEMPTED (1)
Materials			
Intervention folder reminder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Handouts/information on local resources and supports provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Core skills of programme reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aims of long-term self-management addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Programme review conducted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Information on local resources and supports provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Final long-term goal setting/action planning facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Room set-up for all exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sheets for exercises on walls by exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protocol exercises explanation and demo reviewed (if needed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants encouraged to try all/different protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review –goal setting and action planning recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feedback Questionnaire given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total score (Yes = 2, Attempted = 1, No =0)			
Overall Adherence score			



Study title:

Group versus individual physiotherapy for people with osteoarthritis of the lumbar spine, hip or knee and/or chronic low back pain in primary care physiotherapy: a feasibility cluster randomised controlled trial



**PHYSIOTHERAPY TREATMENT RECORD FORM –
INTERVENTION GROUP**

**Thank you for completing this form after each class and returning to
Research Team at end of Wave 1**

PCCC Site:	Date:	Class: circle 1 2 3 4 5 6	Physiotherapist Name:
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PERSONNEL

Other staff involved in setting up class:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Names/Staff Grade:
Other staff involved in providing class:	Yes <input type="checkbox"/> No <input type="checkbox"/>	Names/Staff Grade:

ATTENDANCE

	Present	Absent
Number of Clients:		
Names of non-attenders:	Reasons for non-attendance [if known]	
1.		
2.		
3.		
4.		

CLASS PREPARATION

Time to review materials [mins]:	Time to set up class [mins]:	Time to take down class [mins]:
Start Time:	End Time:	Comments:

CLASS DELIVERY

	Education	Exercise
Time to deliver [mins]:		
Comments:		
Deviations from protocol: Content/time	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
If 'yes' give details and reason[s]		

TREATMENT-RELATED EVENT – any unforeseen event/issue should be reported to PI on

During class: Yes <input type="checkbox"/> No <input type="checkbox"/>	After class: Yes <input type="checkbox"/> No <input type="checkbox"/>	Reported Yes <input type="checkbox"/> No <input type="checkbox"/>
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When patient is discharged please give this completed form to UCD Research Physiotherapist or scan and email

FIDELITY TO INTERVENTION COMPONENTS – SELF-REPORT

Please indicate whether or not you addressed/completed the following during today's class

	YES	NO	UNSURE
SESSION 1:			
Materials			
Intervention folder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Name stickers/badges given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activity Action Plan given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Introduction			
Introductions/welcome made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aims, content and structure of programme addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rationale for weekly attendance addressed			
Education			
Self-management/cycle of change addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disease characteristics, prevalence and causes of OA/CLBP addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activity levels/benefits of exercise addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reflection on activity/recommendations facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Goal setting/action planning introduced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Protocol exercises explained and demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Review and Planning			
Session review - activity levels and goal setting recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FIDELITY TO INTERVENTION COMPONENTS – SELF-REPORT

Please indicate whether or not you addressed the following during today's class

	YES	NO	UNSURE
SESSION 2:			
Materials			
Welcome made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intervention folder reminder to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Name stickers/badges given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pedometers offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking diary offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Activity-rest cycle and pacing explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reflection on current practice of pacing/activity-rest facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Factors influencing pain addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Goal setting/action planning developed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Protocol exercises explained and demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*please leave 'if needed' questions blank if not needed

FIDELITY TO INTERVENTION COMPONENTS – SELF-REPORT

Please indicate whether or not you addressed the following during today's class.

	YES	NO	UNSURE
SESSION 3:			
Materials			
Intervention folder reminder to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tape measure offered to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Food diary awareness within folder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Healthy Eating Booklet awareness within folder given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pedometers offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking diary offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Obesity and effect on pain condition addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Balance between weight/activity addressed			
Skills for maintaining healthy weight addressed (e.g. waist measurement, food diary)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Food diary encouraged for use as self-monitoring tool	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Protocol exercises explained and demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap integrating food and exercise diary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*please leave 'if needed' questions blank if not needed

FIDELITY TO INTERVENTION COMPONENTS – SELF-REPORT

Please indicate whether or not you addressed the following during today's class

	YES	NO	UNSURE
SESSION 4:			
Materials			
Intervention folder reminder to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pedometers offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking diary offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Midway Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Rationale for using pain control given (e.g. pain pathway explained)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methods of pain management addressed (e.g. heat/ice, medication, TENS/Acupuncture)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Protocol exercises explained and demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*please leave 'if needed' questions blank if not needed

FIDELITY TO INTERVENTION COMPONENTS – SELF-REPORT

Please indicate whether or not you addressed the following during today's class

	YES	NO	UNSURE
SESSION 5:			
Materials			
Intervention folder reminder to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relaxation CD offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Information about flare-ups with individual reflection facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recognising and managing flare-ups addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Effect of mood on pain addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Protocol exercises explained and demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relaxation Session			
Relaxation techniques explained and practiced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session Planning and Review			
Session review - goal setting and action planning recap with integration of relaxation techniques	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*please leave 'if needed' questions blank if not needed

FIDELITY TO INTERVENTION COMPONENTS – SELF-REPORT

Please indicate whether or not you addressed the following during today's class

	YES	NO	UNSURE
SESSION 6:			
Materials			
Activity Action Plan given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Handouts/information on local resources and supports provided			
Recap and Review			
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problem-solving of previous week Activity Action Plan (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education			
Core skills of programme reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aims of long-term self-management addressed			
Local resources and supports discussed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Long-term goal setting and action planning facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise			
Protocol exercises explained and demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual follow-up (if needed*)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Session review – goal setting and action planning recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feedback Questionnaire given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Qualitative Interviews mentioned given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Importance of participating in follow-up by phone or post at 2 and 6 months given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*please leave 'if needed' questions blank if not needed

Supplemental Files: online-only materials

Supplemental file: Finalised Implementation Fidelity Protocol				
NIHBCC Framework Fidelity Domain ^{12, 13}	NIHBCC Framework Fidelity Component ⁴	Addressed in SOLAS Fidelity Protocol	Strategies to enhance	Strategies to assess
STUDY DESIGN	<ul style="list-style-type: none"> • Provided information about treatment dose in the intervention condition: <ul style="list-style-type: none"> ○ Length of contact (minutes) ○ Number of contacts ○ Content of treatment ○ Duration of contact over time 	✓ YES	<ul style="list-style-type: none"> • An intervention manual will be used so that therapists know the content and dose of intervention sessions. • Self-report treatment record checklist will also serve as a post-session reminder to improve fidelity to the protocol 	<ul style="list-style-type: none"> • A self-report treatment checklist for each session will be completed by physiotherapists to assess content, dose, date and attendance • As an objective method of measurement, audio-recordings will be completed for every session using an observation checklist (very similar to treatment record checklist) to assess content, dose, date and attendance. Direct observations of up to 3/6 sessions in all sites (24 sessions across all sites) using the observation checklist will also be conducted as a means of strengthening data collection
	<ul style="list-style-type: none"> • Provided information about treatment dose in the comparison condition (TAU) <ul style="list-style-type: none"> ○ Length of contact (minutes) ○ Number of contacts ○ Content of treatment ○ Duration of contact over time 	✓ YES	<ul style="list-style-type: none"> • The TAU group should receive individual physiotherapy and treatment advice consistent with usual care as per evidence-based guidelines. An information sheet will be provided to physiotherapists in the control group to inform them of this • Self-report treatment record checklist will also serve as a post-session reminder to improve fidelity to the protocol 	<ul style="list-style-type: none"> • A self-report treatment record checklist for each session will be completed by physiotherapists to assess content, dose, date and attendance • As an objective method of measurement, audio-recording of one session per physiotherapist will be completed
	<ul style="list-style-type: none"> • Method to ensure that dose is equivalent between conditions 	✗ No - dose will not be equivalent between conditions due	n/a	n/a

		to the nature of the study design		
<ul style="list-style-type: none"> Method to ensure that dose is equivalent for participants within conditions 	✓ YES	<ul style="list-style-type: none"> In the intervention group, the intervention manual has outlined ideal dose and content. However, as it is a group intervention, in certain circumstances (participant may miss session) it may not be possible to ensure exactly equivalent dose In the TAU group, the information sheet for physiotherapists states the participants must receive usual care. As the treatment is individualised, dose may vary between participants 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by each physiotherapist in both intervention and TAU groups to record content, dose, date and attendance Audio-recording of all intervention sessions and of the first TAU session in addition to direct observations of up to 3/6 sessions in all intervention sites using the observation checklist will help verify dose received by participants in both groups as reported in the treatment record forms 	
<ul style="list-style-type: none"> Specification of provider credentials that are needed 	✓ YES	<ul style="list-style-type: none"> Explicit inclusion criteria in the SOLAS trial protocol specify that the providers in both intervention and TAU group must be chartered physiotherapists working in primary care sites who are willing to participate 	<ul style="list-style-type: none"> Provider credentials in both groups will be recorded using a physiotherapist characteristics assessment form 	
<ul style="list-style-type: none"> Theoretical model upon which the intervention is based is clearly articulated 	✓ YES	<ul style="list-style-type: none"> The theoretical map of the intervention will be published and described further in the SOLAS trial protocol 	n/a	
<ul style="list-style-type: none"> The active ingredients are specified and incorporated into the intervention 	✓ YES	<ul style="list-style-type: none"> The theoretical map of the intervention and the active ingredients have been specified in the SOLAS trial protocol and will be described further in a separate publication. In order to enhance fidelity to these active ingredients, they have been specified and delineated within the intervention manual 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by physiotherapists to record delivery of these active ingredients As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess delivery of the active ingredients. Direct observations of up to 3/6 sessions in all sites using the observation checklist will 	

				also be conducted as a means of strengthening data collection
<ul style="list-style-type: none"> Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines 	✓ YES	<ul style="list-style-type: none"> An international steering committee has been put in place and utilised to ensure that the intervention protocol reflects the underlying theoretical model. 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by physiotherapists to record delivery of the theory-based intervention protocol As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist (similar, slightly modified version of treatment record form) to assess delivery of the theory-based intervention protocol. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection 	
<ul style="list-style-type: none"> Plan to ensure that the measures reflect the hypothesized theoretical constructs/ mechanisms of action 	✓ YES	<ul style="list-style-type: none"> The chosen outcome measures have been specified in the SOLAS trial protocol, and mapped to the underlying theoretical model. 	n/a	
<ul style="list-style-type: none"> Potential confounders that limit the ability to make conclusions at the end of the trial are identified? 	✓ YES	<ul style="list-style-type: none"> Steps have been taken to identify any potential confounders and will be measured where possible and appropriate e.g. underpowered sample size as it is a feasibility trial. 	n/a	
<ul style="list-style-type: none"> Plan to address possible setbacks in implementation (i.e., back-up systems or providers) 	✓ YES	<ul style="list-style-type: none"> The intervention has been designed to be delivered by one physiotherapist. Two physiotherapists will be trained per site to address potential setbacks in terms of providers. This plan is specified in the training manual which will be described fully elsewhere 	<ul style="list-style-type: none"> Provider attendance will be recorded using a post-training record form which will be completed by the research team trainers subsequent to the training Potential setbacks in terms of providers delivering the intervention will be recorded by the self-report treatment record checklist in addition to the audio-recordings and direct observations of sessions Interviews with intervention physiotherapists will be conducted when 	

				finished delivering the intervention to further assess implementation setbacks
	<ul style="list-style-type: none"> If more than one intervention is described, all described equally well 	✓ YES	<ul style="list-style-type: none"> The details of both intervention and TAU groups are described equally and accurately in the SOLAS trial protocol 	n/a
TRAINING OF PROVIDERS	<ul style="list-style-type: none"> Description of how providers will be trained (manual of training procedures) 	✓ YES	<ul style="list-style-type: none"> A standardised training manual detailing content, structure, timing and setting will be used by the research team to deliver the training. Scripted role-plays will be used Pre-developed written case studies will be used The development of Training of Providers enhancement strategies will be detailed fully elsewhere 	<ul style="list-style-type: none"> The content, structure, timing, setting and the number and characteristics of trainers will be recorded on a post-training record form which will be completed by the research team trainers subsequent to the training. The development of Training of Providers assessment strategies will be detailed fully elsewhere Audio-recordings of roleplays used during the training will be conducted
	<ul style="list-style-type: none"> Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers) 	✓ YES	<ul style="list-style-type: none"> A standardised training manual detailing content, structure, timing, and setting will be used by the research team to deliver the training for each training wave For each wave, providers from all sites will attend the same training Scripted role-plays will be used Pre-developed written case studies will be used 	<ul style="list-style-type: none"> The content, structure, timing, setting and the number and characteristics of trainers will be recorded on a post-training record form which will be completed by the research team trainers subsequent to the training Audio-recordings of roleplays used during the training will be conducted
	<ul style="list-style-type: none"> Assessment of provider skill acquisition 	✓ YES	n/a	<ul style="list-style-type: none"> Provider skill acquisition will be assessed through pre-post training evaluation forms to be completed by each physiotherapist who participates in the training (self-report). Audio-recordings of roleplays used will be conducted Pre-developed written case studies will be assessed pre and post training by the research team Interviews with intervention physiotherapists will be conducted when

				finished delivering the intervention to further assess skill acquisition
<ul style="list-style-type: none"> Assessment and monitoring of provider skill maintenance over time 	✓ YES	<ul style="list-style-type: none"> Contact details for the research team will be provided to the physiotherapists for use if needed for skill maintenance or other intervention delivery concerns. 	<ul style="list-style-type: none"> The self-report treatment record checklist for each session will be completed by physiotherapists to assess self-reported skill in delivery of the intervention As an objective method of measurement of the maintenance of provider skill over time, audio-recordings will be completed for each session using an observation checklist. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection 	
<ul style="list-style-type: none"> Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori 	✓ YES - however once necessary inclusion/exclusion are fulfilled, due to the pragmatic nature of the trial it is not possible to restrict providers based on characteristics	<ul style="list-style-type: none"> Explicit inclusion criteria in the SOLAS trial protocol specify that the providers in both intervention and TAU group must be chartered physiotherapists working in primary care sites who are willing to participate 	<ul style="list-style-type: none"> Provider credentials and characteristics in both groups will be recorded using a physiotherapist characteristics assessment form 	
<ul style="list-style-type: none"> At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g., ensure that providers find the intervention acceptable, credible and potentially efficacious) 	✓ YES	<ul style="list-style-type: none"> To ensure that the intervention would be acceptable, credible and feasible to physiotherapists, they were involved in the development of the intervention through a number of methods including preliminary focus groups to explore potential barriers and enablers and a 	<ul style="list-style-type: none"> The attitude and opinions of the physiotherapists to the intervention were explored and assessed through the initial preliminary focus groups, a physiotherapist characteristics assessment form, a post-training feedback form and interviews with 	

			symposium workshop to clarify final details of the intervention.	physiotherapists after participation in the pilot study
	<ul style="list-style-type: none"> There is a training plan that takes into account trainees' different education and experience and learning styles 	✓ YES	<ul style="list-style-type: none"> A standardised training manual detailing the content and structure of training will be developed and used by the research team to deliver the training, taking into account physiotherapists' previous experience 	<ul style="list-style-type: none"> Provider credentials and levels of experience and education in both groups will be recorded using a physiotherapist characteristics assessment form The content and structure of the training will be recorded on a post-training record form which will be completed by the research team trainers subsequent to the training
TREATMENT DELIVERY	<ul style="list-style-type: none"> Method to ensure that the content of the intervention is delivered as specified 	✓ YES	<ul style="list-style-type: none"> To enhance the fidelity of the intervention content delivery, an intervention manual detailing the content, dose, setting and structure of the intervention will be provided to physiotherapists 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by physiotherapists to assess content, dose, date and attendance As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess content, dose, date and attendance. Direct observations of up to 3/6 sessions in all sites (24 in total) using the observation checklist will also be conducted as a means of strengthening data collection Interviews with intervention physiotherapists will be conducted when finished delivering the intervention to further assess fidelity of delivery
	<ul style="list-style-type: none"> Method to ensure that the dose of the intervention is delivered as specified 	✓ YES	<ul style="list-style-type: none"> To enhance the fidelity of the intervention content delivery, an intervention manual detailing the content, dose, setting and structure of the intervention will be provided to physiotherapists 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by physiotherapists to assess content, dose, date and attendance As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess content, dose, date and attendance. Direct observations of up to 3/6 sessions in all sites using the observation checklist will

				also be conducted as a means of strengthening data collection
<ul style="list-style-type: none"> Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information 	✓ YES	<ul style="list-style-type: none"> To enhance the adherence of the physiotherapists to the intervention plan, an intervention manual detailing the content, dose, setting and structure of the intervention will be provided to physiotherapists 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by physiotherapists to assess content, dose, date and attendance As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess content, dose, date and attendance. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection Interviews with intervention physiotherapists will be conducted when finished delivering the intervention to further assess fidelity of delivery 	
<ul style="list-style-type: none"> Assessment of nonspecific treatment effects 	✓ YES	n/a	<ul style="list-style-type: none"> Nonspecific treatment effects (defined as provider warmth, credibility etc) will be assessed using audio-recordings which will be completed for each session using an observation checklist. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection Six-month participant interviews may also contribute to the assessment of this 	
<ul style="list-style-type: none"> Used treatment manual 	✓ YES	<ul style="list-style-type: none"> To enhance the fidelity of the intervention content delivery, an intervention manual detailing the content, dose, setting and structure of the intervention will be provided to physiotherapists 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by physiotherapists to assess fidelity to the intervention manual As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to fidelity to the intervention manual. Direct 	

				<p>observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection</p> <ul style="list-style-type: none"> • Interviews with intervention physiotherapists will be conducted when finished delivering the intervention to further assess use of the intervention manual
<ul style="list-style-type: none"> • There is a plan for the assessment of whether or not the active ingredients were delivered 	✓ YES	<ul style="list-style-type: none"> • To enhance the fidelity of the delivery of active ingredients, an intervention manual specifying and emphasising the active ingredients of the intervention will be provided to physiotherapists 	<ul style="list-style-type: none"> • A self-report treatment record checklist for each session will be completed by physiotherapists to record delivery of these active ingredients • As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess delivery of the active ingredients. Direct observations of 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection • Interviews with intervention physiotherapists will be conducted when finished delivering the intervention to further assess fidelity of delivery 	
<ul style="list-style-type: none"> • There is a plan for the assessment of whether or not proscribed components were delivered. (e.g., components that are unnecessary or unhelpful) 	✓ YES	<ul style="list-style-type: none"> • To enhance the delivery of proscribed components and restrict the delivery of proscribed components, an intervention manual specifying and emphasising the active ingredients of the intervention will be provided to physiotherapists. 	<ul style="list-style-type: none"> • A self-report treatment record checklist for each session will be completed by physiotherapists to record delivery of any proscribed components or deviations from protocol • As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess delivery of any proscribed components or deviations from protocol. Direct observations of 3/6 sessions in all 	

				sites using the observation checklist will also be conducted as a means of strengthening data collection
	<ul style="list-style-type: none"> There is a plan for how will contamination between conditions be prevented 	✓ YES	<ul style="list-style-type: none"> Cluster randomisation by site with separate physiotherapists delivering each arm has been used to minimise contamination between conditions. In addition, information and discussions during preliminary focus groups, symposium workshops and training with physiotherapists emphasised the importance of fidelity and minimising contamination. 	<ul style="list-style-type: none"> Although difficult to monitor and assess contamination, the self-report treatment record checklist to be completed by both intervention and control physiotherapists will record which physiotherapist delivers the session and will also assess the delivery of any active ingredients in the control group.
	<ul style="list-style-type: none"> There is an a priori specification of treatment fidelity (e.g, providers adhere to delivering >80% of components) 	✗ No	<ul style="list-style-type: none"> This was not done as this is a pilot feasibility study of a novel intervention, therefore it was uncertain as to which components were most important for fidelity and what the cutoff level would need to be. It is hoped that this will be addressed in the larger trial using the results of the feasibility study 	n/a
TREATMENT RECEIPT	<ul style="list-style-type: none"> There is an assessment of the degree to which participants understood the intervention 	✓ YES	n/a – enhancement strategies addressed in next component	<ul style="list-style-type: none"> Participant interviews will be conducted 6 months after the intervention and may contribute to assessment of participant understanding of the intervention Interviews with intervention physiotherapists will be conducted when finished delivering the intervention and may provide further information regarding participant understanding by proxy
	<ul style="list-style-type: none"> There is specification of strategies that will be used to improve participant comprehension of the intervention 	✓ YES	<ul style="list-style-type: none"> Participant understanding of the intervention will be enhanced using the intervention materials, namely the participant manual, action planning/goal setting sheets, and activity diaries 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by intervention physiotherapists to record use/delivery of each of the intervention materials and discussions

			<ul style="list-style-type: none"> The group discussions facilitated by the physiotherapist during the education component will also serve to improve comprehension 	<ul style="list-style-type: none"> As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess use of the strategies. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection
<ul style="list-style-type: none"> The participants' ability to perform the intervention skills will be assessed during the intervention period 	✓ YES	n/a – enhancement strategies addressed in next component	<ul style="list-style-type: none"> The participants' ability to perform the intervention skills will be assessed using a self-developed self-management behaviours questionnaire Use of activity diaries will be assessed after the intervention The use of study outcome measures such as physical activity levels (IPAQ), and perceived competence for self-management will be explored as a strategy to assess ability to perform intervention skills Interviews with intervention physiotherapists will be conducted when finished delivering the intervention and may provide further information regarding participant ability to perform skills by proxy 	
<ul style="list-style-type: none"> A strategy will be used to improve subject performance of intervention skills during the intervention period 	✓ YES	<ul style="list-style-type: none"> Participant ability to perform intervention will be enhanced using the intervention materials, namely the participant manual, action planning/goal setting sheets, activity diaries, pedometers, tape measures, healthy eating cookbooks and relaxation CDs The group discussions facilitated by the physiotherapist during the education component will also serve to improve comprehension 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by intervention physiotherapists to record use/delivery of each of the intervention materials, discussions and exercise with feedback As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess use of the strategies. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be 	

			<ul style="list-style-type: none"> The group exercise component with individual feedback from the physiotherapist will also serve to improve comprehension 	<p>conducted as a means of strengthening data collection</p>
	<ul style="list-style-type: none"> Multicultural factors considered in the development and delivery of the intervention (e.g., provided in native language; protocol is consistent with the values of the target group) 	✓ YES	<ul style="list-style-type: none"> The participant manuals and accompanying material were developed mindful of participants with low literacy levels. In addition, the research team liaised with physiotherapists to develop a list of appropriate community resources and supports. The development of these materials will be fully discussed in the trial protocol Post-pilot wave participant interviews were conducted after the completion of the pilot wave of the intervention to evaluate the acceptability and appropriateness of the intervention and materials and to refine the intervention for subsequent waves if necessary 	<ul style="list-style-type: none"> Post-intervention participant interviews will be conducted 6 months after the intervention to evaluate the acceptability and appropriateness of the intervention and materials.
TREATMENT ENACTMENT	<ul style="list-style-type: none"> Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied 	✓ YES	n/a – enhancement strategies addressed in next component	<ul style="list-style-type: none"> Participants’ performance of skills in real-life settings will be assessed using a self-management behaviours questionnaire at 6 months after the intervention The use of study outcome measures such as physical activity levels (IPAQ), and perceived competence for self-management will be explored as a strategy to assess long-term enactment at 6 months after the intervention Participant interviews will be conducted 6 months after the intervention to assess long-term enactment

	<ul style="list-style-type: none"> A strategy will be used to improve performance of the intervention skills in settings in which the intervention might be applied 	<p>✓ YES</p>	<ul style="list-style-type: none"> Participant's performance of the intervention skills in real-life settings will be enhanced using the intervention materials, namely the participant manual, action planning/goal setting sheets, activity diaries, pedometers, tape measures, healthy cookbooks and relaxation CDs In addition to the above materials, a list of community resources/long-term supports will be provided In the last session physiotherapists will carry out long-term goal-setting with participants 	<ul style="list-style-type: none"> A self-report treatment record checklist for each session will be completed by intervention physiotherapists to record use/delivery of each of the intervention materials As an objective method of measurement, audio-recordings will be completed for each session using an observation checklist to assess use of the strategies. Direct observations of up to 3/6 sessions in all sites using the observation checklist will also be conducted as a means of strengthening data collection
<p>NIHBCC = National Institutes of Health Behaviour Change Consortium, TAU = treatment as usual, SOLAS = Self-management for Osteoarthritis and Low back pain through Activity and Skills, IPAQ = International Physical Activity Questionnaire</p>				

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