Trial Protocol:

Does targeting pain-related beliefs in people with knee osteoarthritis increase physical activity? A randomised, sham-controlled, feasibility trial.

- Reported in accordance with the SPIRIT 2013 Statement[1]

Section 1. Administrative Information

Title
Does targeting pain-related beliefs in people with knee osteoarthritis increase physical activity? A randomised, sham-controlled, feasibility trial.

Trial Registration
This trial will be registered on the ANZCTR prior to commencement (www.anzctr.org.au).
Trial registration will include details of all items from the World Health Organisation Trial Registration Data Set (See Table 1 at end of Protocol).

Protocol Version
Issue date: 20 June, 2018, original
Authors: TS, EK, KB, CH, LM, DB, TC

This protocol has been developed in accordance with the *SPIRIT* (Standard Protocol Items: Recommendations for Interventional Trials) *2013 Checklist*[1] (see www.spirit-statement.org).

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Roles and Responsibilities

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Roles:
TS (together with GLM) conceived the idea.
TS, GLM, KB, and CH designed the study.
TS led the development of the intervention protocol, with contributions from DB, TC, EK and KB.
TS, DB, TC, GLM and EK will be involved with training of the treating clinicians.
TS, EK, and CH will recruit participants.

TS and EK will be responsible for all participant follow-up, data collection, data analysis and interpretation of the results and will draft the reports and manuscripts arising from this study. GLM, CH, and KB made contributions to study planning, and will assist with interpretation of the results.
All study authors will be involved in the review of reports and manuscripts arising from this study.

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Role of study sponsors and funders:
The funders (Arthritis SA, the Sansom Institute for Health Research [UniSA], and NHMRC) played no role in the design of this study. They will have no role in the future collection, management, analysis or interpretation of data; writing of the report; or decision to publish.

Section 2. Introduction

Background and Rationale

Osteoarthritis affects 1 in 11 Australians and this prevalence increases to 1 in 2 for Australians over the age of 65.[2] OA occurs most often in the lower limb (e.g., hip and/or knee) and is associated with significant problems with movement. Indeed, 9 out of 10 Australians with OA are not active enough to maintain their general health.[3] This has serious consequences: given the heightened cardiovascular mortality risk in OA (versus general population), low activity levels increase mortality.[4] Further, 1 in 2 people with painful OA are obese[5] and low physical activity levels may impair weight loss and/or weight maintenance efforts. This creates a vicious cycle: being obese increases the likelihood of surgical intervention for OA[6] while also resulting in increased rates of complications and decreased survivorship of the replaced joint,[7] which further reduces activity level. Inactivity has serious financial consequences: it costs Australia $13.7b per year.[8] Given the debilitating health and financial ramifications of inactivity, it is essential to understand why people with knee OA aren't moving and importantly, to find treatments that are more effective at getting them moving.

It is tempting to think that the only reason that people with knee OA are inactive is because movement hurts. However, contrary to assumptions, regular structured physical activity, such as strengthening or walking programs, actually reduce pain and increase function in people with painful knee OA (i.e., opposite to what we might expect).[9] Unfortunately, people with knee OA still have low adherence to sustained physical activity which reduces its long-term benefits.[10] We are considering a new hypothesis: low physical activity levels (and low adherence to activity) occur, at least in part, because people with knee OA often have unhelpful (and unchallenged) beliefs about pain and movement.

Why might we think beliefs about pain and movement are the problem? Members of our research team and others have found that inactive adults with OA are much more likely than active adults with OA to have beliefs that they are physically unable to exercise and that physical activity is unsafe.[11, 12] This is despite the fact that high-quality research shows that physical activity does not further damage the joint.[13, 14] A recent qualitative study found that people with knee OA focus heavily on pain and hold beliefs that OA is an incurable, progressive disease.[15] However, it is critical to note that even in people with end stage OA awaiting joint replacement (i.e., severely affected), systematic review results show that physical activity is effective in reducing pain and improving function.[16]

Aspects of the medical system may support patients' beliefs that movement is dangerous for a damaged joint. People with knee OA commonly receive x-rays that provide them with convincing visual evidence of (often) severe joint damage. This may support beliefs that further weight-bearing and activity should be avoided. It is not uncommon for patients to describe their knee as being 'bone-on-bone', referring to the characteristic joint space narrowing and loss of intra-articular cartilage that occurs with OA. And labelling of OA by clinicians as being due to 'wear and tear', suggests that movement ('wear') will further damage the knee ('tear'). Indeed, people with knee OA have been shown to have a fear of movement and injury.[17, 18] Last, there is also belief by some clinicians that physical activity is not appropriate for all people with knee OA and that activity can be harmful,[19] providing important (but inaccurate) medical reinforcement of patient's beliefs.

Our past work has shown that unhelpful pain-related beliefs can reduce activity levels, can increase pain, and can impair function.[20] Given this, we wanted to determine whether an intervention aimed at challenging these unhelpful beliefs – Explain Pain – could increase activity levels. This educational intervention aims to change the meaning of pain from that of a marker of tissue damage (i.e., more pain means more damage) to that of a need to protect the body from real or perceived danger. Note that this differs from current education programs because it aims to reconceptualise beliefs about pain. Explain Pain has shown excellent results for pain, function and disability in chronic back pain populations that have pain-related fears and beliefs about movement.[20-22] Thus, we decided to explore whether such an intervention may be beneficial in people with knee OA.

Our findings were promising. Our clinical audit data show that in people with knee OA (n=139), a 4 week period of Explain pain (1hr/wk, one-on-one with physiotherapist), followed by therapist-guided exposure to movement significantly improves self-rated activity (Fig. 1) with successive improvements over a 12 month period. It also reduces pain intensity (Fig.1) and catastrophising ($p<0.01$ at 6 &12 months). While promising, these data are unable to rule out whether benefits were primarily due to non-specific effects of treatment (i.e., the benefit from seeing an empathic clinician, getting relevant

information, feeling that your condition is under control, etc…). The best way to evaluate the contribution of non-specific treatment effects to outcome is by comparing to a sham treatment. Such knowledge is needed before we can recommend our treatment for clinical practice.

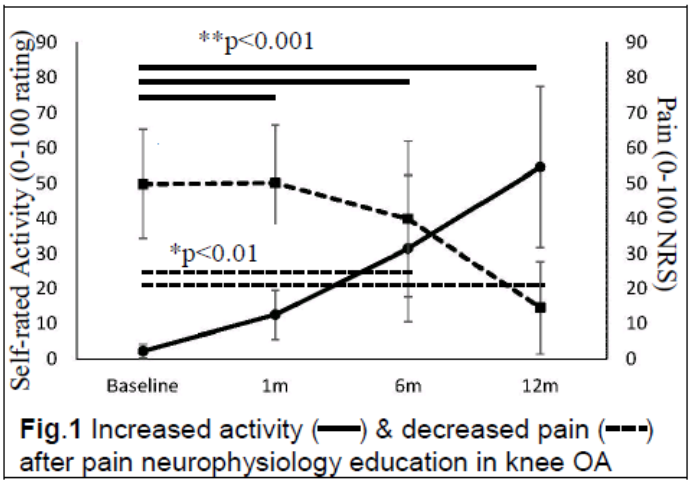

Fig.1 Increased activity (——) & decreased pain (- - -) after pain neurophysiology education in knee OA

Before completing a large scale study, it is critical to determine the feasibility of a randomised clinical trial, including the assessment of traditional parameters such as ease of participant recruitment, eligibility rates (and willingness to be randomised), follow-up rates, and validity of objective measures in this population. Given that our pilot data evaluated self-reported activity levels, it is critical to evaluate objective measures of physical activity in response to interventions to both determine viability of such measurement in an older population, but also to inform future power calculations based on objective activity levels.

It is also imperative to fully pilot both treatments prior to a large trial to assess how they run in real-time from a logistical and practical sense. By piloting these treatments, we will be able to determine how we may need to adjust them to maximise the results. First, the credibility of a sham treatment to people with painful knee OA needs to be evaluated. Our past trials in back pain have used sham education, however, we need to use a sham that is targeted specifically to people with OA and is more realistic. Second, it is key to get feedback from people with knee OA about the Explain Pain intervention so that we can improve it, and its delivery, as much as possible. We have shown that tailoring Explain pain education to the condition (e.g., back pain) has better results[20] – this is exciting given that a relatively untailored intervention had excellent effects in knee OA (clinical audit pilot data). We would expect tailored education to be even better.

Aim

To perform a pilot study to assess the feasibility of successfully conducting a randomised controlled trial that investigates the effect of adding Explain Pain (vs adding sham treatment) to an individualised, physiotherapist-led physical activity and general education program in people with painful knee osteoarthritis.

Objectives

The primary feasibility objectives relate to:

i) Participant eligibility and recruitment
ii) Participant follow-up
iii) Objective physical activity measurement (i.e., valid wear time)
iv) Fidelity of intervention delivery

The primary pilot objectives relate to:

i) Credibility of the sham intervention
ii) Acceptability of Explain Pain content and its delivery format (for participants and clinicians)

The secondary objectives are to:

i) To identify barriers to participation
ii) Provide estimates of treatment effect (and its variance) for pain and physical activity to inform power calculations for a full-scale RCT

Study Design

This study is a randomised, parallel group, sham-controlled feasibility and pilot trial. It fits the feasibility criteria because it is a study conducted prior to a main trials, asking the question “can this piece of research be done”. It will provide an estimate of the key parameters needed to inform a future main trial, for example, willingness of the patients to be randomised, fidelity of intervention delivery, follow-up rates. It is also a pilot study as it includes “a version of the main study in miniature to test whether components can run together”.[23] For example, it will evaluate recruitment processes, randomisation, intervention delivery as they would be tested together in the future main trial.

This investigation will adopt an *adaptive trial design,* which will allow modifications to be made during its conduct with the purpose of increasing the probability of success of the study procedure or the intervention. Any adaptations required to recruitment/study procedures or the intervention will be made during recruitment of the first one-third of participants.

Section 3. Methods: Participants, Interventions and Outcomes

Study Setting
This study will take place in the Sansom Institute Clinical Trials Centre and the Physiotherapy Clinic (University of South Australia).

Eligibility Criteria
Inclusion criteria:
- Adults aged ≥50yrs
- Painful knee OA of at least 6 months duration that meets the American College of Rheumatology (ACR) clinical criteria for knee OA.[24]
- Average knee pain (overall and/or during walking) over one week rated as ≥40mm on a 0-100mm visual analogue scale (VAS)

Exclusion criteria:
- Conditions that prevent safe participation in physical activity (e.g., severe cardiac/lung disease); neurological disorders affecting lower limb (e.g., stroke, multiple sclerosis); inflammatory arthritis; fibromyalgia
- Cognitive impairment (e.g., Alzheimer's, dementia); severe depression (>21 on DASS[25])
- Recent intra-articular therapy (past 3 months)
- Previous knee replacement (on painful knee) or planned knee replacement or surgery (next 6 months)
- Report moderate/vigorous activity levels above guideline recommendation (>150mins/wk; assessed via International Physical Activity Questionnaire; IPAQ)
- Do not have a radiograph or other imaging report of their affected knee

Interventions
The interventions will be described in accordance with the TIDieR (Template for Intervention Description and Replication) Checklist[26] (see www.equator-network.org). The TIDier checklist has been recommended for use in conjunction with the SPIRIT statement as an extension of Item 11[1].

Participants in both groups will attend 4 x 60-90 minute, one-on-one sessions with a Physiotherapist at weekly intervals and will be provided with OA and physical activity education on top of a graded walking program. This treatment dosage reflects what was used in our knee OA pilot study and in many chronic back pain RCTs of Explain Pain. Following completion of the one-on-one sessions, participants will perform 4 weeks of at-home workbook activities combined with further progression of a graded walking program.

Both of the intervention groups will receive the following:
- A standard knee assessment (subjective and objective)
- Provision of general information about knee osteoarthritis and physical activity
- Discussion of knee x-ray findings (note: content will differ significantly between groups)
- Guidance regarding graded progression of a walking program
- Individualised goal setting
- At home workbook activities (over 4 weeks) with weekly check-in phone calls by the treatment clinician.

Graded walking program and goal setting:
Participants in both groups will be guided to measure their baseline walking tolerance (i.e. how far, on average, they are able to walk before their pain level increases). They will then reduce this time/distance by 20% - with this activity level becoming their 'start' walking level. Participants will be guided to set a weekly program (beginning at this 'start' level) and then plan gradual weekly increases at a rate of approximately 10% each week. Participants will also be guided to set activity-related short and long-term goals. *One* of these goals will be a walking goal (if appropriate) – such that the 'pacing' approach can be demonstrated and practiced.

In addition, participants in each group will receive the following during the one-on-one session and the 4 week at-home intervention:

1. One-on-one sessions:

Explain Pain Group:
Participants randomised to this group will receive 4 sessions of enhanced pain education which will expand upon routinely provided information about OA and activity. This education will be based on contemporary pain science understanding, will aim to reduce the perceived danger associated with the knee, and will incorporate proven principles and strategies of conceptual change science (See Table 2 and 3).[20] These strategies will include challenging existing knowledge and refining learning strategies for new concepts using principles of multimedia learning.[20] Explain Pain is a cutting edge educational approach that moves away from didactic lectures/seminars. Participants will receive the Explain Pain book and the Protectometer book which both discuss concepts from this intervention.

Control group – Standard education and Sham Ultrasound:
Participants allocated to this group will receive 4 sessions of 'standard' information about knee OA and activity (using Arthritis Australia resources; See Table 2 and 3). In order to match time with the treating therapist between groups, this group will also receive sham treatment in the form of inactive ultrasound using inert gel (as per previous work[27]); see Table 4. While the sham treatment is being administered, the treating clinician will aim to engage the participant in general conversation. If participants discuss their knee pain and related concerns, the treating clinician will endeavor to only offer advice and/or information consistent with the readily available, quality resource for knee osteoarthritis (Arthritis Australia resources).

Table 2 highlights the group differences in education objectives and principles. **Table 3** expands upon the how the general OA and activity knowledge provided to the control group is enhanced in the Explain Pain group. **Table 4** provides the Session specific intervention breakdown between groups, including assessments, education, graded walking program, and sham control.

	Enhanced education – Explain Pain	**Standard education – Control**
Overall objective:	To shift participants' conceptualisation of pain from that of a marker of tissue damage to that of a marker of the perceived need to protect the body. To educate that pain is a protective feature of our system, not a 'damage-meter'; thus, pain can be modulated by other things besides tissue damage and danger messages (i.e. nociception).	To increase participants' knowledge about OA and the importance of physical activity in reducing osteoarthritic pain and increasing general health.
Pain education topics:	Basic nervous system anatomy/function; distinction between nociception and pain; protective function of pain; peripheral/central sensitization; up-regulation of brain mechanisms that serve protection; the state of 'hyper-protection' offered by normal bio-logical adaptations; the concept of an internal 'Protectometer' (modulated by multifaceted danger and safety cues).	Basic OA and pain information as per the Arthritis Australia handbook.
Activity education:	That physical activity does not increase joint damage but does have wide-ranging health benefits and OA-specific benefits. That physical activity is key to bioplasticity – i.e., inducing changes in our system – and that it decreases overprotectiveness of our system, a change that often occurs with persistent pain.	That physical activity has wide-ranging health benefits as well as OA-specific benefits and that even people with severe OA benefit.
X-Ray interpretation:	The aim is to 'de-threaten' radiological findings. A detailed analysis of participants' own x-ray will be undertaken, focusing on positive features (e.g. excellent bone density) using standardised wording. Education about the poor correlation between x-ray findings and pain will be provided.	The aim is to discuss radiological findings, focusing on the interpretation section as would occur in regular practice. We will focus on discussing the xray features that resulted in participants receiving a diagnosis of OA.

Table 2. Education features of the intervention groups

THE 'USUAL' STORY OF KNEE OA **(Standard)** *(From Arthritis Australia booklet)*	**Session**	**THE 'MODERN' STORY OF KNEE OA** *The 'usual' story +* ***current understanding of pain***	**Session**
What is osteoarthritis? OA is a condition that affects the whole joint including bone, cartilage, ligaments and muscles.	**1**	OA affects the whole joint – but it is a condition that also effects the *whole of you (*- it's not just about 'wear and tear'). Wear is ok!	**2, 3 & 4**
OA tends to come on slowly. Joint pain or stiffness is usually worst with activity initially but can become more constant in later disease.	**1**	Progressive decline is not inevitable - even people with advanced OA can improve.	**2 & 4**
What causes osteoarthritis? Risk factors for OA include being overweight, having a previous knee injury or a job involving lots of kneeling or squatting, and getting older.	**1**	Having risk factors for OA does not mean that you can't improve with the right treatment. We all have 'wrinkles on the inside' (- aging is no excuse!)	**2 & 4**
Symptoms are variable but often affect your ability to do normal daily activities.	**1**	Bioplasticity means that being able to return to and gradually increase your daily activity is a reasonable expectation.	**3 & 4**
Your doctor may refer you for an x-ray of your knee (or another type of scan) to assist with the diagnosis of osteoarthritis.	**2**	The severity of changes shown on a knee x-ray do not have much relationship with how much pain you currently have or are likely to have in the future. Pain is complex and influenced by many things – not just what's going on in your knee.	**2 & 3**
There is no cure for OA, but treatments can help to reduce symptoms and maintain function.	**2**	It may be beneficial to review current treatments based on new knowledge. Learning about pain is an effective treatment – but learning and change takes time	**1 & 4**
If you are overweight, losing weight is key to managing osteoarthritis	**2**	Being overweight increases the load through your knee, but can also contribute to the progression of joint changes via the hormones/chemicals that circulate throughout your body if you are overweight.	**2, 3 & 4**
Doing regular physical activity can help to reduce your pain, strengthen your muscles, maintain your joint function and improve your sleep and overall health.	**3**	Regular physical activity has countless health benefits (at any age) and enhances bioplastic change in your *whole* system. This helps make your system *less* sensitive = able to do more with less pain. There is very strong evidence that activity and exercise are safe and do not lead to further structural damage.	**3 & 4**
It is normal to feel some pain in your muscles when you start an exercise program or new activity. However, if pain feels unusual or severe, or lasts for more than 2 hours after you have stopped, it is probably best to avoid or change that activity.	**3 & 4**	Understanding what pain means can powerfully influence pain. It is often not necessary to stop an activity if it is painful. Your own brain can make powerful medications to reduce pain.	**All**

Table 3: Educational topics in the Usual care [standard education] control group and enhanced education provided in the Explain Pain intervention group

Treatment component	Interventions - Graded walking program combined with:		Timing Considerations
	Standard Education + Sham US (Control)	***Enhanced education (Explain Pain)***	
Session 1			To more closely match treatment duration and therapist time between groups, the Control group will have: 1. Increased time taken for the Standard physiotherapy assessment (go slow!) 2. Inactive ultrasound application
Baseline assessment	Standard physical examination Standard subjective examination	Standard physical examination Enhanced subjective examination ('standard' + identification of participants' education targets for EP).	
Education	General education Provide inactive ultrasound to 4 locations on the most painful knee (~5 mins each). Introduce participants to the AA handbook (to take home)	Enhanced education Introduce participants to 'Explain Pain Handbook' and the 'The Protectometer' (to take home)	
Graded walking program	Instructions for following week re: Establish baseline walking tolerance that does not result in sustained, increased pain following walking (for next session)		
Session 2			For Sessions 2-4: To more closely match treatment duration and therapist time between groups, the Control group will have: 1. A longer re-assessment at the beginning of the session 2. Inactive ultrasound application
Assessment	Standard subjective and physical re-assessment	Brief subjective evaluation and re-cap of session 1	
Education	General education Discussion of x-ray findings (read interpretation section) Provide inactive ultrasound to 4 locations on the most painful knee (~5 mins each).	Enhanced education Discussion of x-ray findings (focus on normal age-related changes; positive reframing of structural findings)	
Graded walking program, goal-setting	Use baseline walking tolerance to calculate a 'start' walking level and set a walking program for the week ahead. Set activity goals (short and long term)		
Session 3			
Assessment	Standard subjective and physical re-assessment	Brief subjective evaluation and re-cap of sessions 1&2	
Education	General education Provide inactive ultrasound to 4 locations on the most painful knee (~5 mins each).	Enhanced education	
Graded walking program	Check in. Increase activity by 10% during the next week. Discuss general principles of activity pacing. Provide the Practical considerations of activity handout		
	N/A	Discuss and consider context when planning walking/activity this week	
Session 4			
Assessment	Standard subjective and physical re-assessment	Brief subjective evaluation and re-cap of sessions 1-3	
Education	General education Provide inactive ultrasound to 4 locations on the most painful knee (~5 mins each).	Enhanced education	
Graded walking program, goal-setting	Check in. Increase activity by 10% during the next week. Set-up walking and general activity plan over the next 4 weeks.		
	Discuss flare-ups and how to reduce activity.	Review flare-ups – what they mean (pain science) and the activity plan.	

Table 4: In-person treatment session by session breakdown for each group. US, Ultrasound; EP, Explain Pain; AA, Arthritis Australia

2. At-home treatment sessions (over 4 weeks, following in-person sessions):

At the completion of the 4 in-person sessions, participants in both groups will receive weekly individualised walking goals that aim to promote a graded activity progression. During the 4 weeks of at-home treatment activities, the treating clinician will call participants 1x/week to check in and follow their progress. A home diary will be used to record workbook/walking goal completion; our work has shown that diary use increases compliance.[28]

Explain Pain Group
Participants will be asked to complete tasks at home which will involve using the Protectometer handbook to identify the unique safety and danger cues that are present for activity tasks and that may influence pain levels during activity.

Standard education and Sham control Group:
Participants will receive a workbook that includes information and questions about the known benefits of activity, health risk of inactivity, and the relevance to OA. They will complete sections of this workbook over the 4 weeks.

Treating physiotherapists:
Different physiotherapists will provide each intervention, with each physiotherapist providing only one of the interventions. Use of physiotherapists specific to each treatment group will be used to minimise participant un-blinding and to reduce therapeutic cross-over between intervention groups (i.e., it may be difficult to not discuss Explain Pain principles once trained). Each treating physiotherapist will receive group-specific training by the study researchers. The therapist providing Explain Pain will receive additional training via the Noigroup Explain Course. The treatment sessions of both groups will be audio recorded to evaluate intervention fidelity.

Outcomes

Primary Outcomes:

The primary outcome of this study is to pilot and to assess the feasibility of successfully conducting a large RCT that investigates the effect of adding Explain Pain (vs adding sham treatment) to an individualised, physiotherapist-led physical activity and general education program in adults with painful knee OA – through the evaluation of pre-specified feasibility criteria.

Feasibility outcomes: Participant recruitment rates will be recorded, including the number of eligible participants that agree to participate and the reasons why participants choose not to participate. The proportion of participants completing the in-person and at-home treatment will be evaluated, as will the proportion of participants with valid accelerometry wear-time (used to assess physical activity levels – see Secondary outcomes below). We will also assess loss to follow-up (% with valid data). Using the audio recorded treatments, we will assess the proportion of the treatments that were completed in full. The following decision making criteria (Table 5) will be used to determine feasibility and the ability to progress to a full RCT.

Progression criteria to proceed to the main trial		
Proceed	**Proceed with protocol amendments**	**Do not proceed**
At least 1 adult (on average) per week can be identified as eligible for inclusion	Less than 1 adult per week (on average) can be identified as eligible for inclusion.	Less than 1 adult per fortnight (on average) can be identified as eligible for inclusion.
1 (or more) in 4 eligible participants recruited	At least 1 in 6 eligible participants recruited	Less than 1 in 6 eligible participants recruited
75% or higher follow-up rate at 6 months	At least 50% follow-up rate at 6 months	Less than 50% follow-up rate at 6 months
75% or more of participants randomised to the Explain Group attend at least 3 intervention sessions	At least 50% of participants complete at least 3 intervention sessions	Less than 50% of participants complete 3 intervention sessions
60% or more of at-home treatments are completed	At least 50% of at-home treatments are completed	Less than 50% of at-home treatments are completed.
70% or more of participants have at least 4 days of ≥10hrs of valid wear time (accelerometry)	At least 50% of participants have at least 4 days of ≥10hrs of valid wear time (accelerometry)	Less than 50% of participants have at least 4 days of ≥10hrs of valid wear time (accelerometry)
At least 80% of interventions provided in full (all content covered)	At least 50% of interventions provided in full (all content covered)	Less than 50% of interventions provided in full (all content covered)

Table 5. Progression criteria decision aid to lead to a full RCT.

Pilot outcomes: These outcomes will assess participants' and treating clinicians' perspectives on the clinical interventions with the aim to maximise benefit in future studies. These ratings will not inform feasibility of progression to a full trial, but will be used to improve the interventions. Treatment content acceptability/usefulness, treatment delivery acceptability, and sham credibility will be assessed. Agreement with treatment acceptability/usefulness statements will be rated using 5-point Likert scales ranging from "strongly agree" to "strongly disagree" in both participants and clinicians. Sham ultrasound credibility will be assessed in participants using an identical Likert scale.

We will assess the proportion of participants that consider: i) the sham intervention to be a credible treatment; ii) the content of the Explain Pain sessions to be acceptable/useful; ii) the intervention format/delivery to be acceptable. The proportion of participants that "agree" or "strongly agree" with the statements will be calculated. Ratings of acceptability will be taken at 4 weeks, 8 weeks and 6 months. Additionally, acceptability will also be informed by a telephone interview at completion of the trial. For treating clinicians, usefulness/acceptability of the intervention will be rated by evaluating agreement to statements that: i) the delivery of the required Explain Pain content can be feasibly achieved in the time available; ii) the content of the Explain Pain session is acceptable. These ratings will be assessed at 4 weeks and via informal interview at the completion of the trial.

*Note: These primary outcomes will also be evaluated at the interim stage of the feasibility trial – after recruitment of 1/3 of the study participants.

Secondary outcomes:

- To identify barriers to participation (asking eligible participants that decline participation their reason for declining)
- To identify improvements in the delivery or content of Explain Pain Sessions (considering both participants' and treating clinicians' ratings of acceptability) and sham treatment
- To identify any modifications needed in the design of a larger efficacy trial.
- To undertake calculation of an appropriately powered sample for a subsequent RCT using estimates of treatment effect (and its variance) provided for pain, physical activity and function.

The planned primary and secondary outcome measures of a future efficacy trial (and the time-point of assessment in this feasibility trial) are indicated in Table 3. Physical activity level (average daily step count over 7-days measured using wrist-based accelerometry; GT9X Actigraph), average knee pain intensity (0-100 visual analogue scale) and the WOMAC pain and function subscale will be assessed at baseline, after the 4 weeks of clinician-led sessions, at 8 weeks when full treatment is complete and at 26 weeks (6 months). Measures were chosen based on OARSI recommendations for clinical trials of knee OA.[29]

Table 3. Visit schedule (Rx = treatment; WB = workbook; * = phone call once a week)

Visit	Phone	1	2	3	4	5	6	7
Week	**Screen**	**0**	**1**	**2**	**3**	**4**	**8**	**26**
Clinical measures								
Knee x-ray		X						
Physical activity measures		X				X	X	X
Demographic								
Age, gender, OA duration, IPAQ	X							
ACR criteria for OA; FCI		X						
Questionnaires								
Pain VAS, WOMAC		X				X	X	X
PSEQ/ DASS/Fear/PCS/Beliefs		X				X	X	X
Credibility/Usefulness						X	X	X
Intervention								
Real			Rx 1	Rx 2	Rx 3	Rx 4	WB *	
Sham			Rx 1	Rx 2	Rx 3	Rx 4	WB *	

Abbreviations: OA, osteoarthritis; IPAQ, ; ACR, American College of Radiology; FCI, ; VAS, Visual Analogue Scale; WOMAC, ; PSEQ, Pain Self Efficacy Questionnaire; DASS, Distress Anxiety and Stress Scale; PCS, Pain Catastrophising Scale

Sample Size

20-30 participants will be recruited and subsequently randomly allocated to intervention or control groups. This sample size is considered adequate for a feasibility study (designed principally to assess feasibility of recruitment and procedures), and will provide information to inform a sample size calculation for a subsequent randomised controlled trial.

Recruitment

Participants with painful knee OA will be recruited from the community in South Australia via local and national newspapers, Arthritis Australia newsletters, radio advertisements, and social media platforms. At recruitment, participants will be asked about x-rays of their affected knee. If they do not have an xray of their knee, they will not be included.

Procedure (see also Table 2)

1. Baseline assessment (Visit 1): The study coordinator will contact interested participants by telephone to perform an initial screen and schedule the clinic baseline assessment. At the baseline assessment, written consent will be attained, and demographic information collected (including co-morbidities [Functional Comorbidity Index; FCI]), and all outcome measures assessed (Pain VAS, Western Ontario McMaster Universities OA Index (WOMAC), Pain knowledge/beliefs Questionnaire, Pain Self-Efficacy Questionnaire (PSEQ), Depression anxiety and stress scale (DASS), Brief fear of movement scale for OA, the Pain Catastrophizing Scale (PCS)).

2. Follow-up (Visits 2-): Treatment visits will occur at week 1, 2, 3, and 4. Participants' first intervention visit will be scheduled ~1 week after the baseline assessment to allow for measurement of baseline physical activity levels. Follow-up assessments will occur at week 4, 8, and 26 weeks, and will be performed by the same blinded assessor. Baseline and 4 week assessments will occur in person and 8 and 26 weeks assessments will occur via return reply paid mail-out (paper questionnaires) or via emailing the assessment link (online questionnaires via survey monkey), based on participant preference.

Note: all participants receiving sham intervention will be offered a version of the Explain Pain intervention after the study concludes.

Section 4. Methods: Assignment of Interventions

Allocation
Participants will be randomly allocated (1:1) to intervention groups using a randomisation schedule generated by Excel's randomisation function, using random permutated blocks of 4 and 6. Allocation will be concealed in sequentially numbered, sealed, opaque envelopes created by an investigator not involved in the study data collection or interventions. Eligible patients who have provided informed consent will be allocated to the treatment groups by an independent investigator who will then coordinate treatment appointment scheduling with the appropriate therapist.

Blinding
Participants and the outcome assessor will be blinded to group assignment. Participants will be advised that they will be randomised to receive one of two physiotherapy treatments that aim to improve overall health (i.e., limited disclosure). Given that both groups include active treatment and given that we will not identify the primary outcomes of the study, we anticipate that this will be sufficient for blinding. The outcome assessor will be a researcher whose role is independent to treatment allocation and delivery, thus will remain blinded to group. Participants will be explicitly instructed not to discuss their treating therapist with the outcome assessor. Follow-up assessments will occur at week 4, 8, and 26 weeks, and will be performed by the same, blinded assessor. The treating clinician will be unavoidably aware of group assignment, but will not be involved in any outcome assessment.

Section 5. Methods: Data Collection, Management and Analysis

Data Collection
Collection of baseline and outcome data:
Baseline demographic and outcome data will be hand-recorded by participants on purpose-designed paper forms or via on-line questionnaires. Follow-up data will be completed either via postal questionnaires, or online questionnaires – depending on participant preference.

Description of instruments:
Data collection forms are included in the Appendices (3-18)

- Eligibility screening (Appendix 3)
- Baseline/Demographic Questions (Appendix 4)
- Pain Visual Analogue Scale (Pain VAS) (Appendix 5)
- Functional Comorbidity Index (FCI) (Appendix 6)
- International Physical Activity Questionnaire (IPAQ) (Appendix 7)
- Western Ontario McMaster Universities OA Index (WOMAC) (Appendix 8)
- Patient Specific Functional Scale (PSFS) (Appendix 9)
- Pain Self-Efficacy Questionnaire (PSEQ) (Appendix 10)
- Brief fear of movement scale for OA (Appendix 11)
- Pain Catastrophizing Scale (PCS) (Appendix 12)
- Pain Beliefs Questionnaire (Appendix 13)
- Pain knowledge – revised Pain Neurophysiology Questionnaire (Appendix 14)
- Depression Anxiety and Stress Scale (DASS) (Appendix 15)
- Participant Experience Questions (credibility, acceptability & satisfaction) (Appendix 16)
- Participant Short Answer Questions (Appendix 17)
- Clinician Short Answer Questions (Appendix 18)

Data Management
The raw data will be transferred onto a password-protected Excel spreadsheet. Electronic and hard copies will be stored in a secure location for a minimum of 15 years.

Statistical Methods
Baseline clinical and demographic characteristics of the participants will be reported using descriptive statistics. Patient eligibility, recruitment and retention rates will be calculated. Reasons for refused consent and study withdrawal will be recorded when possible. Questionnaire completion rates will also be calculated.

Change scores (and 95% confidence intervals) for pain, activity and function from baseline to follow-up will reported. Estimates of treatment effect (and its variance) for the primary outcome measures planned for the subsequent RCT (pain VAS score and step count from accelerometry) will be used to assist calculation of an appropriately powered sample size for the larger trial.

Section 6. Methods: Monitoring

Data Monitoring – Interim Evaluation

Interim evaluation of the trial (led by the principal researcher) will occur after 1 month follow-up data has been received from 30% of participants. At this stage:

- Any issues/problems with participant recruitment procedures will be identified.
- Discussions will the treating clinicians to seek feedback and concerns regarding
    a. Feasibility of study procedures
    b. Content of the interventions
    c. Any other issues
- Collected data will be assessed for completeness
- Participant Experience Questionnaires will be reviewed for feedback regarding treatment credibility and acceptability.

Issues identified will be discussed with the clinical and research team (as appropriate) and any modifications to the study protocol or the intervention will be made and recorded. An external data monitoring committee is not needed since this is a low risk study and no data analysis will occur at the interim stage.

Harms

There are no anticipated risks or harms associated with this study. Any unanticipated adverse events will be documented and reported and managed appropriately.

Auditing

No auditing of the feasibility trial will occur.

Section 7. Ethics and Dissemination

Research Ethics Approval

This study has been approved by the Human Research Ethics Committee at the University of South Australia.

Protocol Amendments

Protocol modifications (prior to commencing the study or at interim stage) will be communicated with the human research ethics committees at the University of South Australia and the clinical trials registry (ANZCTR).

Consent

The study coordinator will contact interested participants by telephone to perform an initial screen and schedule the clinic baseline assessment. At the baseline assessment, written informed consent will be obtained.

Confidentiality

All study-related information will be stored securely in password-protected electronic format or in a locked filing cabinet at the study site. All participant information will be stored in a locked filing cabinet in an area with limited access. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems. Participants' study information will not be released outside of the study without the written permission of the participant, unless required by law.

Declaration of Interests

CH, KB, and EK have no competing interests or conflicts of interest to declare.

Competing Interests:
TRS received support from Eli Lilly Ltd for travel and accommodation expenses; this was unrelated to the present study.
LM has received support from Pfizer Australia, Workers' Compensation Boards in Australia, North American and Europe, NOIgroup Australasia, Kaiser Permanente California, Results Physiotherapy, Agile Physiotherapy, the International Olympic Committee and the Port Adelaide Football Club and receives royalties from the following books: Explain Pain; Explain Pain Handbook: Protectometer; Explain Pain Supercharged; Painful Yarns – Metaphors and Stories to Help Understand the Biology of Pain; the Graded Motor Imagery Handbook.
DB and TC are owners of Noigroup, the company that teaches Explain Pain courses and creates Explain Pain materials.

Access to Data
TS, EK and GLM will have full access to the final trial dataset.

Ancillary and Post-Trial Care
Planning for the provision of ancillary care is not deemed necessary due to the low risk of this study.

Dissemination Policy
Trial results will be disseminated to key stakeholders within 6 months of study completion. This will include the communication of results to the University of South Australia (Research Ethics Committee), the ANZCTR, and Arthritis Australia. Publication of the results of the feasibility study in a peer-reviewed journal is planned and will occur regardless of the study outcomes, and without restrictions. Study participants will be sent a link (via SMS) to the 'Body in Mind' website where open access publications arising from this study will be available.

The full study protocol will be made publicly available via the Open Science Framework website prior to enrolment of participants. There is no intention to make the complete data set publicly available for this feasibility study.

Discussion

The results of this feasibility study will inform the subsequent development of a definitive randomised controlled trial of a neurophysiology educational intervention for adults with symptomatic knee OA. The reporting of this study will be carried out according to the ***CONSORT 2010 guideline*** for transparent and quality reporting of randomised pilot and feasibility trials (see www.consort-statement.org).

Date of Proposed Commencement and Duration

The feasibility study will commence during July 2018. The clinical intervention phase will take 4-6 months. Follow-up data collection will be completed by July 2019.

Appendices

Informed Consent Materials
See Appendices 1 and 2

Questionnaires/Outcome Measures
See Appendices 3 – 18

Table 1. Trial Registration Data

Data Category	Information
Primary registry and trial identifying number	ANZCTR:
Date of registration in primary registry	June, 2018
Secondary identifying numbers	Not applicable
Source(s) of monetary or material support	Arthritis SA; Sansom Institute for Health Research (University of South Australia)
Primary sponsor	Tasha Stanton
Secondary sponsor(s)	None
Contact for public queries	TS, Tasha.Stanton@unisa.edu.au
Contact for scientific queries	TS, Tasha.Stanton@unisa.edu.au; LM, Lorimer.Moseley@unisa.edu.au
Public title	Does targeting pain-related beliefs in people with knee osteoarthritis increase physical activity? A randomised, sham controlled, feasibility trial
Scientific title	Does targeting pain-related beliefs in people with knee osteoarthritis increase physical activity? A randomised, sham controlled, feasibility trial
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Knee Osteoarthritis
Intervention(s)	Intervention group: Explain Pain intervention (4 sessions) plus usual care,
	Control group: Sham ultrasound intervention (4 sessions)
Key inclusion and exclusion criteria	Ages eligible for study: ≥50 years; Sexes eligible for study: all; Accepts healthy volunteers: no
	Inclusion criteria: adults aged over 50 years with painful knee osteoarthritis (≥40mm on a 0-100mm visual analogue scale; VAS) of at least 6 months duration that meets the American College of Rheumatology (ACR) clinical criteria for knee OA
	Exclusion criteria: Conditions that prevent safe participation in exercise (e.g., severe cardiac/lung disease); neurological disorders affecting lower limb (e.g., stroke, multiple sclerosis); inflammatory arthritis; fibromyalgia; cognitive impairment (e.g., Alzheimer's, dementia); severe depression (>21 on DASS23); intra-articular therapy (past 3 months); previous knee replacement (on painful knee) or future or planned replacement (in the next 6 months); moderate/vigorous activity levels above guideline recommendation (>150mins/wk; assessed via International Physical Activity Questionnaire; IPAQ); lack of knee radiograph/imaging.
Study type	A randomised, sham controlled, feasibility trial
Data of first enrolment	July, 2018
Target sample size	20-30 (10-15 intervention, 10-15 control)
Recruitment status	Will commence July, 2018
Primary outcomes(s)	Determine the feasibility of recruitment and retention, assessment procedures, implementation, acceptability and credibility of an Explain Pain intervention and a sham intervention for knee osteoarthritis
Key secondary outcomes	Identify any modifications needed in the design of a larger effectiveness trial

	Determine the variability of pain and physical activity levels outcomes (i.e., standard deviations) for each group to inform power calculations for a full-scale randomised-controlled clinical trial

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Appendix 1

University of South Australia

PARTICIPANT INFORMATION STATEMENT

HREC Project Number:	HREC200791
Project Title:	Evaluating the feasibility of two treatments to improve health in people with painful knee osteoarthritis. A pilot study
Division/Unit:	Division of Health Science, School of Health Sciences
Principal Investigator:	Dr Tasha Stanton, PhD Tasha.stanton@unisa.edu.au

You are invited to participate in a feasibility pilot study evaluating two different physiotherapy treatments that aim to improve health outcomes in people with knee osteoarthritis. You have been invited to participate because you have been identified as having painful knee osteoarthritis. Before you sign the consent form, it is important that you read and understand the following information.

What is the study about?

This study aims to test the feasibility and acceptability of two different physiotherapy treatments for people with painful knee osteoarthritis. Specifically, we are interested in getting your opinion on how helpful these treatments are. We are also interested in whether you think that we can change certain parts of the treatments to make them better. Your opinion on these treatments is important to know before we test these treatments in a large clinical trial because we want to test the best option.

Due to the nature of this study, some information will be withheld from you until the end of your involvement. However, there is no added risk of harm or any reason to suspect you would not consent if you had all the details at the start. After testing is completed, you will be given a full explanation of the study, including reasons for concealing some details. You will then be able to ask further questions about the research.

Do I have to participate?

No. As with all research at the University, participation is completely voluntary. You can request to withdraw at any time without any prejudice, now or in the future, and any information collected prior to your withdrawal will not be used.

In the case of participants discontinuing the study without notification some of the information previously collected may be used (without identification).

Who can participate?

People who have painful knee osteoarthritis (which has been present for at least 6 months) and who do not currently meet physical activity recommendations for moderate or vigorous activity can participate (>150 minutes per week).

Participants that have health conditions that prevent safe participation in physical activity (e.g., severe heart or lung disease) will not be eligible to participate. Additionally, participants with neurological problems affecting the lower limb (e.g., stroke, multiple sclerosis), inflammatory arthritis, fibromyalgia, previous or planned knee replacement surgery, use of intra-articular therapy (previous 3 months), severe depression or cognitive impairment (e.g., diagnosed Alzheimer's disease or dementia) will not be eligible to participate. The study coordinator will go through these thoroughly with you.

If you do not have recent knee x-ray reports (e.g., x-rays in the last 12 months) we will need you to have x-rays of your affected knee taken again. The study coordinator will help you arrange this and you will be reimbursed for the cost of these x-rays.

What will I have to do?

Participation in this study involves attending 5 appointments at City East Campus (corner of North Terrace and Frome Road), the University of South Australia. This involves a baseline assessment and 4 treatment sessions. These appointments will occur either at the Physiotherapy Clinic (Centenary Building, Level 8) or at the Sansom Clinical Trial Facility (Bonython Jubilee Building, Level 1) – you will be told where your sessions are. The treatment also involves 4 weeks of at home activities.

At the baseline assessment, you will be asked to complete questionnaires asking you about your knee pain, your overall function (e.g., ability to do different activities), your mood, your beliefs about pain, and your thoughts about physical activity and movement. These will take approximately 30-40 minutes to complete. We will also measure your height and your weight at the baseline. We will then send you home with an activity monitor that you will wear on your wrist or your hip. We will ask you to wear this for 7 days and to wear this as much as possible (e.g., all waking hours).

After the baseline assessment, you will be randomised into one of two treatment groups. Both groups will receive a physiotherapy treatment that has been shown to be helpful in reducing pain and increasing function in people with osteoarthritis. All participants will receive four, one-on-one treatment sessions with an experienced, licensed physiotherapist. These will occur once a week and will be scheduled over a one month period. You will need to attend the University of South Australia, City East Campus for these treatment sessions. In order to make sure the physiotherapist is giving the correct treatment to the correct person, we will be audio-recording these treatment sessions. This recording also allows us to review the content of the sessions and see if we can make the treatments even better. Your name/ID number will not be matched with these recordings – each will be given a random code such that we cannot identify which recording involved you. Only the research team will have access to these recordings and the recordings will be stored in a locked filing cabinet (C7-31, City East Campus) and/or on a secure UniSA server with a password protected file.

After receiving these four treatment sessions, we will again have you fill in the same questionnaires and will ask you some questions about what you thought about the treatment (e.g., is there anything we could do to make it better)? We will audio record your answers to the questions so that we do not miss anything. We will store these recordings as we have described above. We will also ask you to wear the activity monitor for a one week period. You will be supplied with a reply paid envelope so that you can send us back the activity monitor once the 7 day period is over.

After the 4 treatment sessions, you will be given workbook activities for you to complete at home over the next 4 weeks. During these at-home activities, the physiotherapist will call you once a week to see how you are going and to answer any questions you might have. We will ask you to fill in a

diary to record how often you are completing these workbook activities. Again, after this 4 week period, the questionnaires will be repeated (sent via mail or email) and we will ask you questions about what you thought about the workbook activities (via telephone; these will be audio recorded so we fully capture your answer; we will use the same storage process as above). We will also ask you to wear the activity monitor again for a one week period (sent to you via mail). Again, a return reply envelope will be provided so that you can return the activity monitor (and paper questionnaires) to us.

The final assessment will occur 4 months after you have finished all the one-one-one treatment sessions and the at home activities. This will allow us to understand if the treatments had longer lasting effects. We will have you fill in the questionnaires (sent via mail or email) and wear the activity monitor for a one week period (sent to via mail with a return reply paid envelope provided).

What are the risks in participating?

As with any physiotherapy intervention, there is a risk that you may sustain a physical injury. However, all treatments are provided by an experienced, licensed physiotherapist and you will be screened for any conditions that might make physical activity unsafe. This makes the risk of such injury very small. If you suffer a physical injury, please let the treating physiotherapist know as soon as possible. The physiotherapist will provide you with advice and if needed, will arrange a time to see you. Further, if necessary, the study team will also coordinate a medical follow-up with your GP.

There is also a risk that you may experience increased pain or discomfort as a result of the treatment. This pain or discomfort is commonly short-lasting (<2 days). The physiotherapist will monitor this very closely and will help you to make changes to your treatment should an increase pain or discomfort not abate.

Last, there is a small risk that you may find talking about your knee pain distressing. If this is the case, please notify the physiotherapist. If needed, the study team will coordinate a follow-up with your GP or with a psychologist at UniSA.

What are the benefits to participating?

All participants will receive physiotherapy treatments that have been shown to increase function and reduce pain in people with knee osteoarthritis. Thus you may receive personal benefit from participating. Your participation will also provide wider benefits to the community by providing important information on the treatment feasibility/credibility (i.e., what you think about the treatment and what we should change) so that we can test the treatments in a larger clinical trial. Large clinical trials are needed to change clinical practice.

Who will have access to my information?

After completing the questionnaires, you will be given an identification number and your personal identifiable information will be separated from the questionnaires. You will not be identified in the analysis of the data or when the results are published in scientific journals. Also, information on the questionnaires will be grouped for reporting (e.g., we will present only group averages). Individual questionnaire results will not be presented in any way. All information supplied will be stored securely in room C7-26 in the School of Health Sciences, University of South Australia for 5 years and the researcher will not supply this information to the public without explicit permission, unless

required by law. Every effort is made so that the information you supply will remain completely confidential.

Will you tell me the results of the research?

Yes. A summary of the results can be provided to you at the completion of the study if you indicate your interest at the end of the questionnaire together with an email or home address.

This project has been approved by the University of South Australia's Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant please contact the Executive Officer of this Committee, Tel: +61 8 8302 3118; Email: vicki.allen@unisa.edu.au.

If you wish to lodge a complaint about either the study or the way it is being conducted please contact the Executive Officer of UniSA HREC in the first instance, email: humanethics@unisa.edu.au or tel: 8302 3118.

Appendix 2

University of South Australia

PARTICIPANT CONSENT FORM

HREC Project Number:	HREC200791
Project Title:	Evaluating the feasibility of two treatments to improve health in people with painful knee osteoarthritis: A pilot study.
Division/Unit:	Division of Health Science, School of Health Sciences
Principal Investigator:	Dr Tasha Stanton, PhD Tasha.stanton@unisa.edu.au

Participant Certification

In signing this form, I confirm that:

- I have read the Participant Information Sheet and the nature and purpose of the research project has been explained to me. I understand and agree to take part.
- I understand the purpose of the research project, the risks and benefits involved, and I understand my involvement in it.
- I understand that I may withdraw from the research project at any stage and that this will not affect my status now or in the future.
- I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential, unless required by law.
- I confirm that I am over 18 years of age.
- I understand that I will be audiotaped during the treatment sessions and at two of the follow-up sessions (4 weeks and 8 weeks).
- I understand that the recordings will be stored in a locked filing cabinet (room C7-31, City East Campus) and/or on a secure UniSA server with a password protected file. I understand that only the research team will have access to the recordings.

Participant Signature	*Printed Name*	*Date*

Researcher Certification

I have explained the study to subject and consider that he/she understands what is involved.

Researcher Signature	*Printed Name*	*Date*

Appendix 3

Knee OA Feasibility Pilot – Eligibility Screening Form

Date: _____

Participant information:

Name: _____

Phone number: _____

Home address: _____

Email: _____

Inclusion criteria: All must be checked yes to be included:

☐ Aged ≥50 years

☐ Meets the American College of Rheumatology (ACR) clinical criteria for symptomatic knee OA

☐ Painful knee OA (≥40mm on a 0-100mm visual analogue scale; VAS; at rest or during walking) **note if only on telephone, use a 0-100 numerical rating scale*

☐ Painful knee OA of at least 6 months duration

Exclusion criteria – No criteria can be present in order to be included

☐ Conditions that prevent safe participation in physical activity (e.g., severe cardiac or lung disease)

☐ Neurological disorders affecting movement of the lower limb (e.g., multiple sclerosis, stroke)

☐ Inflammatory arthritis (including rheumatoid arthritis)

☐ Fibromyalgia

☐ Previous knee replacement (on painful knee) or planned knee replacement or surgery (next 6 months)

☐ Use of intra-articular therapy in the 3 months preceding enrolment

☐ Any diagnosed cognitive impairment (e.g., Alzheimer's, dementia)

☐ Severe depression (Depression subscale scores >28 on the DASS-21)

☐ Current moderate/vigorous PA levels above guidelines recommendations (>150 minutes/week; assessed using the International Physical Activity Questionnaire; IPAQ)

☐ Knee x-ray or imaging available (or if not, participant is happy to get an x-ray themselves prior to baseline assessment)

Is the participant eligible for inclusion?

☐ Yes ☐ No

Knee OA Feasibility Pilot – Eligibility Screening Form

Average pain over the past week (telephone)

Please rate the average pain you have felt in your knee over the past week on a scale from 0-100 where 0 = no pain at all and 100 = worst pain imaginable.

_____

Average pain during walking over the past week (telephone)

Please rate the average pain you have felt in your knee over the past week <u>when you were walking</u> on a scale from 0-100 where 0 = no pain at all and 100 = worst pain imaginable.

_____

Screening ACR criteria for symptomatic knee OA

Clinical and radiographic criteria (preferred criteria)

Left knee		**Right knee**	
☐ Knee pain		☐ Knee pain	
☐ At least 1 of:	☐ Age > 50 years	☐ At least 1 of:	☐ Age > 50 years
	☐ Stiffness < 30 min		☐ Stiffness < 30 min
	☐ Crepitus		☐ Crepitus
☐ Osteophytes		☐ Osteophytes	

OR

Clinical criteria (use only when no recent knee radiographs available)

Left knee		**Right knee**	
☐ Knee pain		☐ Knee pain	
☐ At least 3 of:	☐ Age > 50 years	☐ At least 3 of:	☐ Age > 50 years
	☐ Stiffness < 30 min		☐ Stiffness < 30 min
	☐ Crepitus		☐ Crepitus
	☐ Bony tenderness		☐ Bony tenderness
	☐ Bony enlargement		☐ Bony enlargement
	☐ no palpable warmth		☐ no palpable warmth

Appendix 4 – Baseline/Demographic Questions

1. What is your age? (in years)
2. What is your gender? (male/female/other)
3. Select the educational level that best applies to you
    - I did not complete high school
    - I completed high school
    - I have enrolled in or completed a non-university qualification (e.g. TAFE certificate or diploma)
    - I have enrolled in or completed a university qualification (e.g. Bachelor degree)
    - I have enrolled in or completed a university post-graduate degree (e.g. Graduate Diploma, Masters, PhD)
4. What is your postcode?
5. Do you have pain in one or both knees?

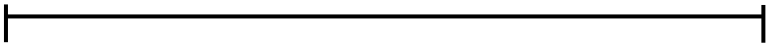
    If you experience pain in both knees:

    Which is your worst knee? (Left / Right / Both the same / It varies)
6. How long have you experienced regular pain in your worst knee?
    - Less than 6 months
    - 6-12 months
    - 1-2 years
    - 3-5 years
    - 5-10 years
    - 10-20 years
    - More than 20 years
7. If you have pain in both knees, how long have you experienced regular pain in your other (best) knee?
    - Less than 6 months
    - 6-12 months
    - 1-2 years
    - 3-5 years
    - 5-10 years
    - 10-20 years
    - More than 20 years
8. How long have you regularly limited your daily activities due to knee pain?
    - Less than 6 months
    - 6-12 months
    - 1-2 years
    - 3-5 years
    - 5-10 years

- 10-20 years
- More than 20 years

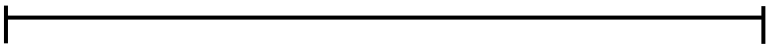
9. Do you regularly experience knee-related symptoms apart from pain? (yes/no)
10. If yes, what sort of symptoms do you experience (mark all that apply)
    - Stiffness
    - Clicking/creaking/grating
    - Pins and needles or tingling
    - Weakness in your affected knee(s)
    - Giving way of your knee
10. On a scale of 1-10, indicate how bothersome these symptoms (apart from pain) are:

Symptom 1: _____



Not at all bothersome Extremely bothersome

Symptom 2: _____



Not at all bothersome Extremely bothersome

Symptom 3: _____

Not at all bothersome Extremely bothersome

Appendix 5

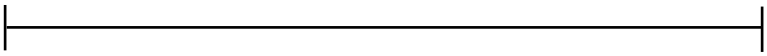
Pain intensity:

My most painful knee is my:

☐ Right knee ☐ Left knee

Average pain over the past week (most painful knee)

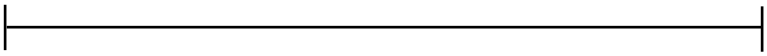
Please rate the average pain that you have felt in your knee over the past week, by placing a line on the following scale:



No pain at all **Worst pain imaginable**

Average pain during walking over the past week (most painful knee)

Please rate the average pain you have felt in your knee over the past week when you were walking by placing a line on the following scale:

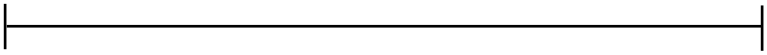


No pain at all **Worst pain imaginable**

If you experience pain in both knees:

Average pain over the past week (other knee)

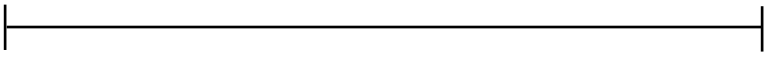
Please rate the average pain that you have felt in your knee over the past week, by placing a line on the following scale:



No pain at all **Worst pain imaginable**

Average pain during walking over the past week (other knee)

Please rate the average pain you have felt in your knee over the past week when you were walking by placing a line on the following scale:



No pain at all **Worst pain imaginable**

Current medications (type, dosage [mg], frequency)

Appendix 6 – Functional Comorbidity Index (FCI)

Do you have any of the following health conditions?

1.	Arthritis (rheumatoid and osteoarthritis)	Yes / No
2.	Osteoporosis	Yes / No
3.	Asthma	Yes / No
4.	Chronic obstructive pulmonary disease (COPD), acquired respiratory distress syndrome (ARDS), or emphysema	Yes / No
5.	Angina	Yes / No
6.	Congestive heart failure (or heart disease)	Yes / No
7.	Heart attack (myocardial infarct)	Yes / No
8.	Neurological disease (such as multiple sclerosis or Parkinson's)	Yes / No
9.	Stroke or Transient Ischaemic Attack	Yes / No
10.	Peripheral vascular disease	Yes / No
11.	Diabetes types I and II	Yes / No
12.	Upper gastrointestinal disease (ulcer, hernia, reflux)	Yes / No
13.	Depression	Yes / No
14.	Anxiety or panic disorders	Yes / No
15.	Visual impairment (such as cataracts, glaucoma, macular degeneration)	Yes / No
16.	Hearing Impairment (very hard of hearing, even with hearing aids)	Yes / No
17.	Degenerative disc disease (back disease, spinal stenosis, or severe chronic back pain)	Yes / No
18.	Obesity and/or body mass index >30 (weight in kg/height in metres^2)	Yes / No
	Height _____ (cm / inches), weight _____ (kg / lbs) → BMI = ____	

TOTAL _____

Appendix 7

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

   ☐ Yes

   ☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

   _____ **days per week**

   ☐ No vigorous job-related physical activity → ***Skip to question 4***

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

   _____ **hours per day**
   _____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

   _____ **days per week**

   ☐ No moderate job-related physical activity → ***Skip to question 6***

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

☐ No job-related walking → ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

☐ No traveling in a motor vehicle → ***Skip to question 10***

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No bicycling from place to place → ***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place → ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

☐ No vigorous activity in garden or yard → ***Skip to question 16***

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

☐ No moderate activity in garden or yard → ***Skip to question 18***

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

☐ No moderate activity inside home → ***Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
_____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

☐ No walking in leisure time → ***Skip to question 22***

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
_____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

☐ No vigorous activity in leisure time → ***Skip to question 24***

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

☐ No moderate activity in leisure time → ***Skip to PART 5: TIME SPENT SITTING***

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?
_____ **hours per day**
_____ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **hours per day**
_____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ **hours per day**
_____ **minutes per day**

This is the end of the questionnaire, thank you for participating.

Appendix 8 – The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Pain and Physical Function scales)

Instructions: Please rate the activities in each category according to the following scale of difficulty:
0 = None, **1** = Slight, **2** = Moderate, **3** = Very, **4** = Extremely

Circle **one number** for each activity:

Pain	1. Walking	0	1	2	3	4
	2. Stair climbing	0	1	2	3	4
	3. Nocturnal	0	1	2	3	4
	4. Rest	0	1	2	3	4
	5. Weight-bearing	0	1	2	3	4
Physical Function	1. Descending stairs	0	1	2	3	4
	2. Ascending stairs	0	1	2	3	4
	3. Rising from sitting	0	1	2	3	4
	4. Standing	0	1	2	3	4
	5. Bending to floor	0	1	2	3	4
	6. Walking on flat surface	0	1	2	3	4
	7. Getting in/out of car	0	1	2	3	4
	8. Going shopping	0	1	2	3	4
	9. Putting on socks	0	1	2	3	4
	10. Lying in bed	0	1	2	3	4
	11. Taking off socks	0	1	2	3	4
	12. Rising from bed	0	1	2	3	4
	13. Getting in/out of bath	0	1	2	3	4
	14. Sitting	0	1	2	3	4
	15. Getting on/off toilet	0	1	2	3	4
	16. Heavy domestic duties	0	1	2	3	4
	17. Light domestic duties	0	1	2	3	4

Total Score: _____ / 88 = _____%

Comments / Interpretation (to be completed by therapist only):

Appendix 9

The Patient-Specific Functional Scale

This useful questionnaire can be used to quantify activity limitation and measure functional outcome for patients with any orthopaedic condition.

Clinician to read and fill in below: Complete at the end of the history and prior to physical examination.

Initial Assessment:

I am going to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your _____ problem. Today, are there any activities that you are unable to do or having difficulty with because of your _____ problem? (Clinician: show scale to patient and have the patient rate each activity).

Follow-up Assessments:

When I assessed you on (state previous assessment date), you told me that you had difficulty with (read all activities from list at a time). Today, do you still have difficulty with: (read and have patient score each item in the list)?

Patient-specific activity scoring scheme (Point to one number):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	**Initial**					
1.						
2.						
3.						
4.						
5.						
Additional						
Additional						

Total score = sum of the activity scores/number of activities
Minimum detectable change (90%CI) for average score = 2 points
Minimum detectable change (90%CI) for single activity score = 3 points

PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

Appendix 10

PAIN SELF EFFICACY QUESTIONNAIRE (PSEQ)

M.K.Nicholas (1989)

NAME: _____ DATE: _____

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle **one** of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:

0	1	2	3	4	5	6
Not at all Confident						**Completely confident**

Remember, this questionnaire is **not** asking whether of not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain.**

---

1. I can enjoy things, despite the pain.

0	1	2	3	4	5	6
Not at all Confident						**Completely confident**

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.

0	1	2	3	4	5	6
Not at all Confident						**Completely confident**

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

0	1	2	3	4	5	6
Not at all Confident						**Completely confident**

4. I can cope with my pain in most situations.

0	1	2	3	4	5	6
Not at all Confident						**Completely confident**

Turn over

5. **I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work).**

0	1	2	3	4	5	6
Not at all Confident						Completely confident

6. **I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.**

0	1	2	3	4	5	6
Not at all Confident						Completely confident

7. **I can cope with my pain without medication.**

0	1	2	3	4	5	6
Not at all Confident						Completely confident

8. **I can still accomplish most of my goals in life, despite the pain.**

0	1	2	3	4	5	6
Not at all Confident						Completely confident

9. **I can live a normal lifestyle, despite the pain.**

0	1	2	3	4	5	6
Not at all Confident						Completely confident

10. **I can gradually become more active, despite the pain.**

0	1	2	3	4	5	6
Not at all Confident						Completely confident

Source: Nicholas M.K. Self-efficacy and chronic pain. Paper presented at the annual conference of the British Psychological Society. St. Andrews, 1989.
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Appendix 11 – Brief Fear of Movement Scale

Please answer ALL statements and indicate whether you strongly disagree, disagree, agree or strongly agree with each statement by circling the appropriate number on the scale.

		Strongly Disagree	Disagree	Agree	Strongly Agree
1.	I'm afraid that I might injure myself if I exercise	0	1	2	3
2.	If I were to try to overcome it, my pain would increase	0	1	2	3
3.	I am afraid that I might injure myself accidentally	0	1	2	3
4.	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	0	1	2	3
5.	It's really not safe for a person with a condition like mine to be physically active	0	1	2	3
6.	I can't do all the things normal people do because it's too easy for me to get injured	0	1	2	3

Appendix 12

PCS

Client No.: _____ Age: _____ Sex: M(__) F(__) Date: _____

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0 – not at all **1** – to a slight degree **2** – to a moderate degree **3** – to a great degree **4** – all the time

When I'm in pain …

1. ☐ I worry all the time about whether the pain will end.
2. ☐ I feel I can't go on.
3. ☐ It's terrible and I think it's never going to get any better.
4. ☐ It's awful and I feel that it overwhelms me.
5. ☐ I feel I can't stand it anymore.
6. ☐ I become afraid that the pain will get worse.
7. ☐ I keep thinking of other painful events.
8. ☐ I anxiously want the pain to go away.
9. ☐ I can't seem to keep it out of my mind.
10. ☐ I keep thinking about how much it hurts.
11. ☐ I keep thinking about how badly I want the pain to stop.
12. ☐ There's nothing I can do to reduce the intensity of the pain.
13. ☐ I wonder whether something serious may happen.

… Total

Appendix 13

Pain Beliefs Questionnaire

For each item please indicate your opinion by checking one of the following boxes for each sentence: always, almost always, often, sometimes, rarely, never. There are no right or wrong answers: it is important that you respond according to your actual beliefs, not according to how you feel you should believe, or how you think we want you to believe.

	Always	Almost always	Often	Sometimes	Rarely	Never
1. Pain is the result of damage to the tissues of the body						
2. Doctors/GPs are the people best able to relieve pain.						
3. Physical exercise makes pain worse.						
4. Taking medication is the best way to relieve pain						
5. It is impossible to do much for oneself to relieve pain.						
6. When in pain it is advisable to rest						
7. Being anxious makes pain worse						
8. Experiencing pain is a sign that something is wrong with the body.						
9. When relaxed pain is easier to cope with.						
10. Being in pain prevents you from enjoying hobbies and social activities						
11. The amount of pain is related to the amount of damage.						
12. A cause for pain can be found by doctors.						
13. Pain can be reduced by concentrating on other things.						
14. Women can tolerate more pain than men.						
15. Thinking about pain makes it worse.						
16. Pain can be dealt with by ignoring it.						
17. When injured one feels pain.						
18. It is impossible to control pain on your own.						
19. Pain is a sign of illness.						
20. Feeling depressed makes pain seem worse.						

Appendix 14

Revised Neurophysiology of Pain Questionnaire		T	F	U
1	It is possible to have pain and not know about it.			
2	When part of your body is injured, special pain receptors convey the pain message to your brain.			
3	Pain only occurs when you are injured or at risk of being injured.			
4	When you are injured, special receptors convey the danger message to your spinal cord.			
5	Special nerves in your spinal cord convey 'danger' messages to your brain.			
6	Nerves adapt by increasing their resting level of excitement.			
7	Chronic pain means that an injury hasn't healed properly.			
8	The body tells the brain when it is in pain.			
9	Nerves adapt by making ion channels stay open longer.			
10	Descending neurons are always inhibitory.			
11	Pain occurs whenever you are injured.			
12	When you injure yourself, the environment that you are in will not affect the amount of pain you experience, as long as the injury is exactly the same.			
13	The brain decides when you will experience pain.			

Appendix 15

DASS21

Name: *Date:*

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Appendix 16 – Participant Experience Questionnaire

(Credibility – 1, 2, 3; Acceptability – 4, 5, 6; Perceived usefulness – 7, 8, 9, 10)

Consider the following statements and place a tick in the box that best describes your response:

	Strongly disagree	Disagree	Unsure	Agree	Strongly agree
1. I would recommend this treatment to other people with knee osteoarthritis					
2. I had confidence in the expertise of the Physiotherapist who treated me					
3. It was easy to believe what the Physiotherapist told me					
4. I enjoyed attending the treatment sessions					
5. The treatment sessions were relevant to me					
6. It was worthwhile attending the treatment sessions					
7. The treatment sessions have increased my knowledge and understanding					
8. As a result of the treatment sessions I am likely to increase my activity level in the **short** term (the next 3-6 months)					
9. As a result of the treatment sessions I am likely to increase my activity level in the **long** term (beyond 3-6 months)					
10. The treatment sessions have changed the way I think about my knee pain					

Appendix 17 – Participant short answer questions

Please provide a short answer to the following questions:

1. What did you like most about the treatment that you received?

2. What did you like least about the treatment that you received?

3. Do you have any suggestions for how the CONTENT of the treatment sessions could be improved?

4. Do you have any suggestions for how the FORMAT of the treatment sessions could be improved? (e.g. number of sessions, duration of sessions)

Appendix 18 – Clinician Short Answer Questions (Explain Pain Intervention Group only)

Please provide a short answer to the following questions:

1. Briefly describe your experience as the therapist delivering the Explain Pain intervention in this study:

1. Do you think the participant considered the intervention to be an acceptable treatment?
   Yes / No (circle). If 'No': please describe any aspects that were not well accepted.

3. Do you have any suggestions for how the CONTENT of the treatment sessions could be improved?

4. Do you have any suggestions for how the FORMAT of the treatment sessions could be improved? (e.g. number of sessions, duration of sessions)

2. Do you have any other suggestions?