Study protocol

Clinical Trials ID no. 2023-05968-01

The PainSMART Project: Protocol for a research program on effectiveness, mechanisms of effect and patient-practitioner experiences of the PainSMART- strategy as an adjunct to usual primary care physiotherapy management of musculoskeletal pain

2023 December 15

The PainSMART Project: Protocol for a research program on effectiveness, mechanisms of effect and patient-practitioner experiences of the PainSMART-strategy as an adjunct to usual primary care physiotherapy management for musculoskeletal pain

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This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement and the SPIRIT-Patient Reported Outcomes guidelines (Chan et al., 2013; Calvert et al., 2021)

Registration

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Introduction

Background and rationale

Musculoskeletal disorders are a major health problem and entail a significant burden for individuals and healthcare systems (Liu et al., 2022). In Sweden, musculoskeletal disorders, in particular spinal pain, are one of the leading causes of disability and their burden is increasing (Vos et al., 2020). As of February 2023, around 33,000 people in Sweden were unfit to work due to musculoskeletal disorders (Försäkringskassan, 2023). Approximately 30,000 unique individuals visit primary care physiotherapy departments within Region Östergötland (population 450 000) for musculoskeletal disorders each year (2017-2022; Rebus Vård, Region Östergötland, 2023). High-value musculoskeletal healthcare is therefore imperative for individuals, healthcare systems and society at large (Elshaug et al., 2017). With an increasing demand for services there is a need to move towards new ways of managing musculoskeletal pain (MSKP). The 'Nära Vård' (Close care) initiative in Sweden has been developed with the aim of creating a more patient-centered, accessible healthcare system where practitioners and patients share responsibility for managing the patient's health (Sveriges Kommuner och Regioner 2022; Region Östergötland 2022). Part of this initiative involves the evolution of healthcare pathways (Sweden's councils & regions [Sveriges Kommuner och Regioner] 2022; Region Östergötland 2022).

Managing MSKP is complex and depends on an array of biopsychosocial factors. Improving MSKP care requires a paradigm shift in the understanding of pain and an increased focus on helping people deal well and simply with MSKP episodes (Caneiro et al., 2020; O'Sullivan et al., 2019). Effective early management of MSKP is critical as prolonged activity in the nervous system can drive neuroplastic changes that make pain more difficult to treat (Caneiro et al., 2020; Kiverstein et al. 2022; Moseley & Butler, 2017; Moseley & Vlayean, 2015; O'Sullivan et al., 2019). According to the Common-sense model of self-regulation (CSM) how an individual manages MSKP depends on how they perceive their MSKP, what coping strategies they adopt and how their MSKP progresses over time (Leventhal et al., 2016). A significant body of evidence supports the CSM and indicates that more negative MSKP illness representations are associated with increased pain intensity and poorer physical function (Caneiro et al., 2020; De Raaij et al., 2018). The influence of MSKP illness perceptions are further highlighted by modern pain theories, such as the predictive processing theory, that consider pain the product of an individual's perception of the potential threat to bodily integrity (Kiverstein et al. 2022; Moseley & Butler, 2017). As such, an individual's MSKP experience is regulated by the meaning, perceived causes and consequences they assign to their MSKP (Melzack 2001; Kiverstein et al. 2022; Moseley & Vlayean, 2015; Moseley & Butler, 2017). For example, it is common amongst the general public and even some healthcare professionals, for the body to be likened to a machine and MSKP considered a sign of damage (Caneiro et al., 2020; Toye et al., 2013; Setchell et al., 2017). Such misconceptions have been reported to lead to increased pain intensity, disability, use of passive coping-strategies, over-medicalization and an overuse of imaging and surgical interventions that are often iatrogenic (Buchbinder et al., 2020; Caneiro et al., 2020; De Raaij et al., 2018). Other psychological factors, such as pain self-efficacy or psychological flexibility, further influence

an individual's management of MSKP and affect prognosis (Caneiro et al., 2020; Martinez-Calderon, 2018). For instance, pain self-efficacy, defined as the perception of one's ability to carry out activities when in pain, has been found on meta-analysis to link pain to disability, whilst higher pain self-efficacy is thought to be protective of the development of chronic MSKP (Lee et al., 2015; Martinez-Calderon et al., 2018; Miles et al., 2011). Psychological flexibility has been found to be significantly associated with physical function whilst fear of movement, fear of pain and avoidant or passive coping strategies are risk factors for the development of chronic pain (Bruls et al., 2015; Caneiro et al., 2020; Delotti et al., 2012; Hartvigsen et al., 2018; Vowles et al., 2014). Collectively, this evidence highlights why MSKP illness perceptions and psychological factors, such as pain self-efficacy, are considered important targets for MSKP interventions.

Educational interventions have the potential to improve outcomes for people with MSKP by targeting factors such as MSKP illness perceptions and pain self-efficacy. However, more evidence is required to establish the most effective educational interventions. The need for improved MSKP educational materials was highlighted in 2020 when The Lancet published a list of ten recommendations to improve care of low back pain (LBP) (Buchbinder et al., 2020). Six of these recommendations stated the need for improved educational and self-care support materials and the need to scientifically evaluate such materials (Buchbinder et al., 2020). Previous evidence has shown that online and in-person MSKP educational interventions can have positive effects on pain intensity and disability (Foster et al., 2018; de Oliveira Lima et al., 2021; Tegner et al., 2018). However, these studies have only included chronic pain populations, been limited to LBP or used educational interventions based on outdated pain theories and not developed in collaboration with people with MSKP (Foster et al., 2018; de Oliveira Lima et al., 2021; Tegner et al., 2018; Treager et al., 2018). National and international guidelines already recommend pain education as standard practice for acute and chronic MSKP, but guideline uptake has been poor (Delitto et al. 2012; Hartvigsen et al., 2018; National institute for health and care excellence, 2023; Nationelltklinisktkunskapsstod.se, 2023). A meta-review found that barriers to the implementation of guidelines, such as providing MSKP education, are a lack of time for professionals to keep up to date with research and to communicate research based guidelines to patients (Correa et al., 2020). A more efficient MKSP management pathway may therefore be facilitated by the development of educational interventions that are concise, easily administered and delivered directly to people with MSKP (Correa et al., 2020).

Communication between people with MSKP and healthcare practitioners can be difficult and may be hampered by a divergence in understanding and expectations between the healthcare practitioner and the patient (Parsons et al., 2007). For example, qualitative evidence consistently finds that people with MSKP want definitive diagnoses and an explanation of the cause of their pain (Lim et al., 2019; Toye et al., 2013; Verbeek et al., 2004). However, as MSKP is considered an emergent neurophysiological phenomenon explaining it can be complex and providing a definitive diagnosis is often impossible (Moseley & Butler, 2017; O'Sullivan et al, 2019). A divergence in expectations can therefore arise in a clinical consultation when for example a physiotherapist approaches MSKP as a complex emergent phenomenon and a patient views MSKP through a traditional biomedical lens. Indeed, a patient's lack of knowledge or uncertainty about their condition has been shown to hinder effective consultations and the implementation of evidence-based healthcare (Correa et al., 2020; Parsons et al., 2007). An idealistic strategy may be that educational interventions are administered prior to a healthcare consultation to help reduce divergence in understanding between a patient and healthcare practitioner by providing a shared basis for communication

(PainSMART-strategy). This may facilitate patient-practitioner interaction and result in improved patient outcomes compared to usual healthcare management.

Objectives

The PainSMART-project is a research program with a collective suite of studies utilising mixed methods. The objective of the PainSMART-project is to evaluate the effects of administering the PainSMART-strategy as an adjunct to usual physiotherapy management compared to usual physiotherapy management alone.

Hypotheses

Hypotheses for confirmatory research questions:

1. Exposure to the PainSMART-strategy as an adjunct to usual physiotherapy management improves the following outcomes significantly more than usual physiotherapy management alone for patients with MSKP (* = primary outcomes)
    - Reduction in pain intensity*.
    - Higher pain self-efficacy*.
    - Lower MSKP illness perceptions.
    - Higher levels of reassurance of the benign nature of MSKP.
    - More adaptive MSKP coping and psychological flexibility.
    - Higher self-reported levels of physical activity.
    - More positive global ratings of change.
    - Lower number of healthcare visits, referrals for diagnostic imaging and to specialist/tertiary care for MSKP, lower analgesic medication use, and fewer days absent from work.
    - More positive and concordant patient and physiotherapist evaluations of MSKP-related shared understanding, communication, participation, involvement and emotional support at the initial physiotherapy consultation.
2. Improvements in MSKP illness perceptions and higher levels of reassurance of the benign nature of MSKP mediate improved pain intensity and pain self-efficacy as a result of exposure to the PainSMART-strategy compared to usual physiotherapy management alone.

Null hypothesis (H0): no statistically significant or clinically relevant differences between the intervention group (PainSMART-strategy as an adjunct to usual physiotherapy management) and the control group (usual physiotherapy management alone).

Exploratory research questions:

1. What baseline factors are predictive of improved patient outcomes after exposure to the PainSMART-strategy?
2. What baseline factors are predictive of the persistence of MSKP?
3. What type of psychological factors and strategies are associated with patient outcomes after exposure to the PainSMART-strategy?
4. What are patients and physiotherapists experiences of the PainSMART-strategy?

Methods

Trial design

The PainSMART-project is centred around a randomised, control group blinded, superiority trial with two parallel groups. A 1:1 group allocation ratio will be applied. The results of the randomized controlled trial (RCT) will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement and the CONSORT patient-reported outcomes checklist (Calvert et al., 2013; Schulz et al., 2010).

Study setting

This study is a multi-centre RCT that will be conducted at five primary care physiotherapy departments within the Swedish regions of Östergötland (RÖ) and Jönköping (RJL). All four physiotherapy departments within RÖ and one physiotherapy department within RJL have agreed to participate. Collectively these centres employ around 130 physiotherapists and provide initial consultations to approximately 30 000 unique individuals in a one-year period. A list of the participating physiotherapy departments is available from the corresponding author on request.

Eligibility criteria

Potentially eligible patient participants are all adults (18 years or older) seeking primary care for MSKP who are triaged and booked for an initial physiotherapy consultation at one of the participating physiotherapy departments. Inclusion and exclusion criteria are shown in Table 1. A flow chart of the patient participants' path through the study is shown in Figure 1.

Table 1. Randomized controlled trial inclusion & exclusion criteria

Inclusion criteria • Patients who, via telephone or online text-based triage, are judged to have benign MSKP and are booked for an initial physiotherapy consultation • Adult patients (18 years or older)
Exclusion criteria • Patients who are judged to require urgent medical examination due to suspected serious pathology (red flags) • Patients who are booked for an initial physiotherapy consultation on the same day as, or the day directly following triage • Patients referred for physiotherapy following consultation with a tertiary care practitioner (e.g. orthopaedic surgeon, rheumatologist, neurologist) • Patients who cannot communicate in Swedish to the equivalent of a 12-year-old native speaker (as judged by the triaging physiotherapist) • Patients who, through visual impairments, are unable to complete the necessary questionnaires for the study • Patients who are booked for an initial consultation with a physiotherapist who has not consented to taking part in the study

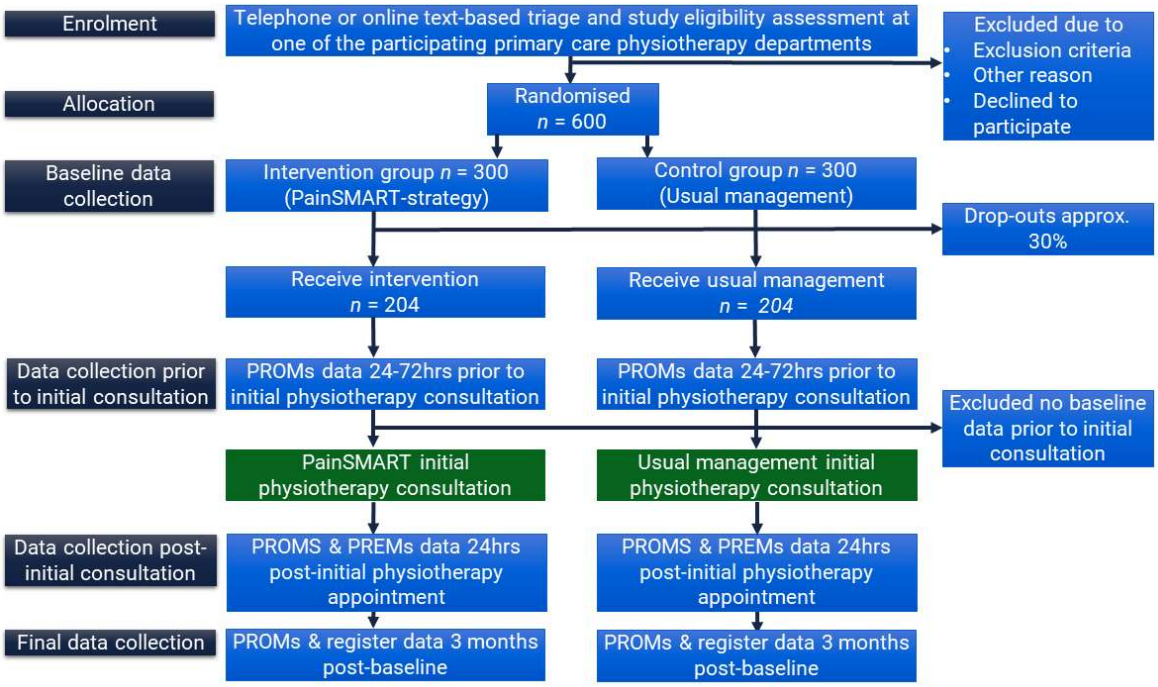

Figure 1: CONSORT flow chart of participants' path through the study. PROMS, patient reported outcome measures, PREMs, patient and physiotherapist reported experience measures.

All physiotherapists who provide care to patients booked for a consultation for MSKP at one of the participating physiotherapy departments are eligible to participate.

Intervention description and rationale

The intervention in this study is the PainSMART-strategy as an adjunct to usual physiotherapy care and is described according to the Template for Intervention Description and Replication (TIDieR; Hoffmann et al., 2014).

The PainSMART-strategy is a two stage intervention. Stage one consists of the administration of an educational film and reflection and reinforcement of the film's key messages prior to the initial physiotherapy consultation. The educational film is entitled 'Be PainSMART:er' and will be hereafter named simply as the film. Stage two is a discussion based on the film at the initial physiotherapy consultation. For details of usual physiotherapy MSKP management see the information relating to the control group.

What

Stage one: The film was produced and tested by the PainSMART-research group during 2022. The format and content of the film are based on qualitative interview pilot studies (March-April 2022) with patients seeking primary care physiotherapy for MSKP (n = 10) and primary care practitioners (n = 9) (physiotherapists, occupational therapists, physicians and nurses) (Barkman, 2022; Stjärnskog, 2022). The results of these two studies were combined with cognitive science theories to produce a design framework for the film (Öhman, 2022). The PainSMART-research group then combined the design framework and the results of the two interview studies with modern pain theories, such as the predictive processing theory, Grand Poobah Pain Theory and the CSM, to generate the film's manuscript and guide the film's production (Caneiro et al., 2020; Kiverstein et al. 2022; Leventhal et al., 2016; Moseley & Vlayean, 2015; Moseley & Butler, 2017). The film was produced in the period of June-

August 2022. The film was then pilot tested (September-November 2022) with patients seeking primary care physiotherapy for MSKP (n = 10) and primary care practitioners (n = 13; physiotherapists, occupational therapists, physicians and nurses) to ensure its key messages were comprehensible and that the film addressed relevant targets (Johansson et al., 2022; Karlén & Lindgren, 2022). Following these pilot studies minor edits were made to the film.

The film shows a dialog between a physician and a patient with MSKP. The film is seven minutes long and divided into three sections. Section one (4 minutes 30 secs) presents the idea that MSKP is a complex and necessary biopsychosocial protective system that does not accurately reflect the anatomical state of the body (Moseley & Butler, 2017). Section one also provides reassurance that MSKP is very rarely caused by serious pathology (Finucane et al. 2020). Section two (1 minute 30 secs) provides advice on active coping strategies, such as encouraging exercise and work despite some pain, in an attempt to reconceptualise the commonly held belief that a painful body part needs to be rested (Caneiro et al., 2020; Setchell et al., 2017). Section three (50 secs) aims to prepare patients for their initial physiotherapy consultation by encouraging them to reflect on the time when their MSKP first developed and their overall life situation with the aim of facilitating a more biopsychosocial consultation. Following the film the patients will rate eight statements that summarize the film's key-messages as listed in Table 2.

The film aims to target patients' impeding MSKP illness perceptions, improve pain self-efficacy and encourage adaptive self-management strategies, all factors that are hypothesized to improve pain intensity over time. This requires the content of the film to improve factors such as maladaptive perceptions of the causes of MSKP and its persistence (for example, low outcome expectation, anxiety, catastrophizing, and fear avoidance beliefs) and low pain self-efficacy. The content of the film addresses all the dimensions of the CSM and this is outlined in Table 2 (Leventhal et al., 2016).

Stage two: The consulting physiotherapist will, via four structured questions, initiate a discussion about the film's contents and the questionnaires the patient has completed prior to the initial consultation. The four questions ask the patient if any of the content within the questionnaires they have completed have generated any thoughts or reflections, whether they had actually seen the film, whether the film generated any thoughts or reflections and if there was anything in particular they took from the film. It is hoped that these questions, in addition to the film providing a shared basis for patient-centered MSKP communication, will facilitate a higher value initial consultation (Epstein et al., 2005; Lehman, 2017).

Who

All patients randomised to the intervention group (PainSMART) will receive the PainSMART-strategy as an adjunct to usual physiotherapy management. The physiotherapists who discuss the film at the initial physiotherapy consultation are all registered physiotherapists employed at one of the five participating physiotherapy departments (n = approx. 130). All participating physiotherapists will have seen the film and received written and verbal information about the study, and their role in the study, prior to the start of patient recruitment. No incentives are provided to the physiotherapists for taking part in the study.

Table 2: Content in the film addressing the illness perception dimensions in the Common-sense model of self-regulation (CSM) (Leventhal et al., 2016).

CSM dimension	Key messages presented within the film
Identity	• Pain doesn't necessarily mean damage and pain is a protective system that is necessary and often helpful.
Timeline	• Pain can improve and change over time, irrespective of how long you have had your pain. Many pain problems resolve by themselves, but it can take time.
Consequences	• Pain does not need to stop you from working, exercising or taking part in valued activities. But it can signal that you need to make some adjustments in your life.
Causes	• Pain is very rarely caused by serious pathology. • Pain is not always caused by injury. Pain can also be caused by physical overload, inactivity, imbalance in life or a combination of these factors.
Control	• You can influence your pain through your thoughts and actions but support is available from healthcare professionals. • You can act to improve your pain by staying active, adjusting sleep and diet if necessary.
Emotional representations	• Your thoughts and feelings towards your pain and your mental health influence your pain experience.

Where and how?

The intervention group will be exposed to the film on two occasions. Access to the film is imbedded within the intervention group's online questionnaires and the film is first made available immediately following completion of baseline background and PROM data collection. Further exposure occurs at the data collection time point prior to the initial physiotherapy consultation. The time from baseline to the initial physiotherapy consultation will vary for each participating patient depending on clinical prioritization and the accessibility of initial consultations at the participating physiotherapy departments. The film is hosted on RÖ's Quick channel, viewable on any electronic device and is exclusively available to the intervention group via the questionnaires. In order to reduce the risk of contamination bias the film is not shareable or available via online searching.

All participating physiotherapists will provide initial consultations to patients in both the intervention and control groups. For the intervention group the initial physiotherapy consultations will take place as usual with the addition of the discussion around the film and questionnaires. Any tailoring of the physiotherapists' responses to the patients' answers will occur according to the preferences and skills of each individual physiotherapist. The physiotherapists will not have access to the results of the questionnaires completed by the patients prior to the initial consultation.

Why

Stage one: The theoretical rationale for the film's causal effects can be based on an integration of modern pain theories, the CSM and the concept of self-efficacy (Bandura, 1977; Leventhal et al., 2016; Kiverstein et al., 2022; Moseley & Butler, 2017). The film and patient's reflections on the film's key messages are hypothesised to effect patient health outcomes and be mediated by improved cognitive and emotional illness perceptions. The potential direct effects of the film on pain intensity can be linked to factors such as MSKP related concern which directly influence the individual's perceived threat to bodily integrity (Kiverstein et al., 2022; Moseley & Butler, 2017). Self-efficacy and illness perceptions have been suggested in respective theoretical models to influence behaviour, including self-management strategies, and thereby health outcomes. Individuals´ perceptions about their illness, such as how they perceive its causes and consequences, may influence their self-efficacy. An integration of the CSM and concept of self-efficacy to explain health outcomes has been previously suggested (Breland et al., 2020; Lau-Walker, 2004). Figure 3 illustrates such an integration where illness perceptions are hypothesised to influence behaviour and health outcomes directly or indirectly through improved self-efficacy. Therefore, both MSKP illness perceptions and pain self-efficacy could act as mediators of the effects of the PainSMART-strategy. Improvement in an individual's MSKP illness perceptions and reassurance as to the benign nature of MSKP may improve pain self-efficacy which may in turn change behaviour and affect health outcomes, such as reduced pain intensity, increased levels of physical activity and reduced work absence.

Stage two: The rationale for discussing the film at the initial physiotherapy consultation can be based on reinforcing the mechanisms of effect described in stage one, encouraging adherence to the viewing of the film and on the film's aims to facilitate the initial consultation. All participating physiotherapists will have seen the film prior to the start of patient recruitment, and this enables the physiotherapists to build on and reinforce the film's key messages (Table 2). As the film is administered prior to the initial physiotherapy consultation it can prepare patients for their consultation and potentially make the patients more central to the process of MSKP-related conceptual change (Moseley & Butler, 2017). A discussion between the patient and physiotherapist about the film and aspects salient to the individual patient aims to facilitate a more biopsychosocial consultation, enhance patient participation in their care and improve shared understanding and communication around MSKP (Lehman, 2017).

Adherence promotion and monitoring

Patients randomised to the intervention group will rate eight statements about the clarity of the film's key messages following first exposure (at baseline) and be asked how many times they have viewed the film (out of a maximum of two) as part of the data collection prior to the initial physiotherapy consultation. Patients randomised to the intervention group will be informed that they will discuss the film with the physiotherapist at their initial consultation to improve adherence. Non-responders to the questionnaires will receive short messaging service (SMS) and telephone reminders to improve adherence to the intervention.

Control condition: Usual physiotherapy management alone

Patients first contact their physiotherapy department via telephone or online text-based service and are triaged by a certified physiotherapist. During triage the patients may receive some tailored or generalised advice regarding their presenting condition and possible management strategies or simple exercises. Following triage, the usual management group will receive online data collection questionnaires identical to those of the intervention group apart from the film and the questions directly related to the film. The initial physiotherapy consultation

will take place as usual according to the preferences of the physiotherapist with the addition of one question asking the patient to reflect on the questionnaires they have completed as part of the study.

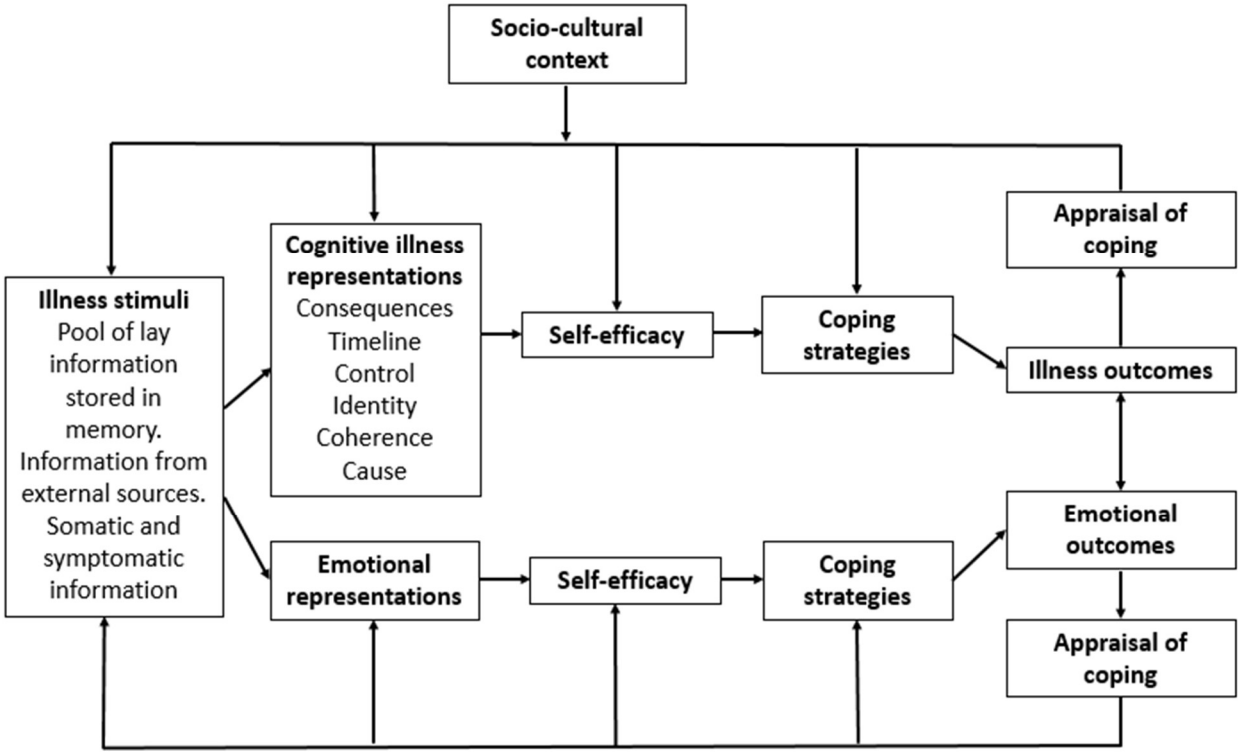

Figure 3: The Common-sense model of self-regulation with integration of the concept of self-efficacy. The figure is modified from Fors (2023).

Concomitant care

No limitations will be placed on patients in either group regarding their access to other educational materials, medical advice or treatments during the study. Patients will self-report previous healthcare consultations that they have attended for their MSKP prior to and during the study at baseline, 24-72 hours prior to the initial physiotherapy consultation and at three months post-baseline. Additional information about healthcare visits that have occurred during the study period (baseline to three months) for MKSP complaints will be collected from RÖ's and RJL's data register after the completion of PROM and PREM data collection for all participants.

Outcomes

The outcomes chosen for this study reflect its aims and theoretical underpinnings.

To aid the selection of PROMs and evaluation of PROMs psychometric properties, the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) database was searched on the 22nd of February 2023 for systematic reviews evaluating potentially relevant PROMs. Two patient co-designers educated in research methods were also involved in the final choice of study outcome measures in order to incorporate a patient perspective (Mercieca-Bebber et al., 2018).

Demographic data

Patient participants: Basic demographic data of age, sex, height and weight will be collected at baseline. Key baseline covariate factors, such as duration of symptoms, location of symptoms, number of pain sites, previous health care interventions, co-morbidities, use of pain medication, educational level, employment and self-reported sick leave will also be established at baseline.

Physiotherapist participants: Basic demographic data of age, sex, department, educational level and number of years of clinical experience will be collected prior to the start of patient recruitment.

Patient Reported Outcome Measures (PROMs)

Primary outcome measures

Both primary outcome measures will be collected and analysed as mean aggregate change from baseline and proportion of responders from baseline to 24-72 hours prior to the initial physiotherapy consultation, 24 hours post-initial physiotherapy consultation and at three months post-baseline.

Pain intensity is chosen as a primary outcome for this study as it is a core outcome measure for intervention studies on pain (Chiarotto et al., 2018). Average pain intensity, worst pain intensity and best pain intensity in the previous 24 hours will be measured using three separate numerical rating scales (NRS) (0-11 from 0 = no pain to 10 = worst imaginable pain). NRS rating related to the past 24 hours has been chosen to reduce overlap of the ratings at the separate data collection time points. The three-item NRS is preferred to a single-item scale as multi-item scales can be more sensitive to treatment effects (Chiarotto et al., 2018; Jensen et al., 1999). To enable sample size calculation and to analyse the proportion of responders in each group the minimal clinically important difference (MCID) for pain intensity in this study is set at two points. The choice of two points is based on consensus from the VIII International Forum on Primary Care Research on LBP and the median of study results from systematic reviews of pain intensity ratings in acute and chronic pain (Olsen et al., 2017; Olsen et al., 2018; Ostelo et al., 2008).

The second primary outcome in this study is pain self-efficacy. Pain self-efficacy is defined as "a belief in one's ability to carry out activities even when in pain" (Nicholas et al., 2015, p. 153). Pain self-efficacy will be measured using the PSEQ-10 (Nicholas et al., 2007). The PSEQ-10 is a ten-item scale scored as a total (0-60). The PSEQ-10 includes ten statements where participants are asked to rate, from zero to six, how confident they are that they can do certain things despite their pain (Nicholas et al., 2007). The PSEQ is grounded in Bandura's concept of self-efficacy and has been frequently used in MSKP research (Dube et al., 2021; Nicholas, 2007). The PSEQ-10 was judged to have good content validity, structural validity, test-retest reliability and responsiveness whilst its internal consistency was judged as excellent in the COSMIN guided systematic review conducted by Dube et al. (2021). Furthermore, the PSEQ was recommended as the most appropriate PROM for measuring pain self-efficacy in Sleijser-Koehorst et al.'s Delphi-study (2019). The PSEQ-10 has been cross-culturally adapted to Danish in a chronic LBP population and a Swedish cross-cultural adaptation of the PSEQ-2 in a MSKP population is ongoing but unpublished (Ekhammer et al., personal communication, 2023; Vejlgaard et al., 2021). The MCID for the PSEQ-10 has been cited to be 5.5-8.5 (Dube et al., 2021). The PSEQ-10's standard error of the mean (SEM) has been cited to range from 1.23 to 5.66 and the minimal detectable change 11.52 (Dube et al., 2021). Pain self-efficacy has been chosen as a primary outcome in this study as it has the potential to change rapidly in response to an educational intervention, is thought to mediate the

relationship between pain and disability and because higher pain self-efficacy is thought to be protective of the development of chronic MSKP (Lee et al., 2015; Martinez-Calderon et al., 2018; Miles et al., 2011).

Secondary outcome measures

- *Secondary outcome PROMs*

Secondary outcome measure PROMs will be collected and analysed as mean aggregate change from baseline from baseline to 24-48 hours prior to the initial physiotherapy consultation, 24 hours post-initial physiotherapy consultation and at three months post-baseline.

MSKP illness perceptions will be measured using the Brief Illness Perception Questionnaire (BIPQ; Broadbent et al., 2006). Illness perceptions are defined in this study as "the mental representations and personal ideas that people have about an illness" (Broadbent et al., 2015, p. 1362). The BIPQ was developed based on the CSM to provide a simple and quick assessment of illness representations, emotional representations and illness comprehensibility (Broadbent et al., 2015). The BIPQ contains nine questions, eight use an eleven-point numerical rating scale with anchor statements whilst the final question is a free text question asking participants to list the three most important factors that they believe caused their MSKP (Broadbent et al., 2006). The BIPQ covers the following constructs; cognitive illness representations (consequences, timeline, personal control, treatment control and identity), emotional representations (concerns and emotions), illness comprehensibility and causes (Broadbent et al., 2006). BIPQ will be analysed both as individual items and as a total score (out of 80) according to the scoring instructions from Broadbent et al. (2015). The total score gives an impression of the participant's perception of the threat or benign nature of their MSKP, with a higher score reflecting a higher threat (Broadbent et al., 2015). For the intervention group only, the BIPQ will be repeated directly after first exposure to the film and questions related to the film's key messages to assess any immediate change in MSKP illness perceptions. The causal item question will be collected at baseline, directly following first exposure to the intervention, 24-72 hours prior to the initial physiotherapy appointment and again 24 hours after the initial consultation. The BIPQ has been widely used in MSKP research, is validated in Swedish and Norwegian and has shown good concurrent and predictive validity, sensitivity to change and test-retest reliability on meta-analysis (Broadbent et al., 2015; Emilsson et al., 2020; Løchting et al., 2013). MSKP illness perceptions are chosen as a secondary outcome in this study as they have the potential to change rapidly in response to an educational intervention, can mediate the effects of the PainSMART-strategy and as evidence suggests that more negative MSKP illness perceptions are associated with higher pain intensity and poorer physical function (De Raaij et al., 2018).

Self-reported level of reassurance of the benign nature of MSKP will be measured using a single reassurance NRS with an eleven-point scale. This question asks the patient how reassured they are that there is not a serious condition causing their MSKP. This question has been adapted from the original research by Sox et al. (1981) and has been previously used in research on acute LBP (Deyo et al., 1987). For the intervention group only, the reassurance NRS will be repeated directly after first exposure to the film and questions related to the film's key messages to assess any immediate change in reassurance. Reassurance is an important measure of the PainSMART-strategy's effects as the overall level of threat ascribed to a MSKP condition has been linked to pain intensity, disability and pain behaviours (Lee et al., 2015; Leventhal et al, 2016: Moseley & Butler, 2017).

Traditional MSKP coping strategies and psychological flexibility will be measured using the Brief Pain Coping Inventory 2 (BPCI-2; Vowles et al., 2014). The BPCI-2 is a 19-item

questionnaire, where participants are asked to report on how many days during the last week they adopted certain pain management strategies (0-7 days). The BPCI-2 contains two sub-scales measuring traditional pain coping strategies and psychological flexibility (Vowles et al., 2014). Psychological flexibility is defined as "one's ability to directly and openly contact experiences in the present moment and persisting or changing behaviour according to what the situation affords and one's personal goals and values" (Vowles & McCracken, 2010 p. 141). Higher total (0-133), or subscale scores (0-56 for traditional MSKP coping strategies and 0-77 for psychological flexibility) on the BPCI-2 indicate more adaptive coping (Vowles et al., 2014). The BPCI-2 is based on the Acceptance and Commitment therapy model and has been developed and validated in chronic MSKP populations (Vowles et al., 2014). The majority of experts who knew of the BPCI-2 in Sleijser-Koehorst et al.'s (2019) Delphi study recommended its use. However, the BPCI-2 had not been validated in Swedish or in a primary care population. As such the PainSMART-research group has conducted (May-December 2023) a cross-cultural adaptation and validation of the BPCI-2 in a population of patients seeking primary care physiotherapy for MSKP (Bowling, 2004: Mokkink et al., 2019). Provisional results from this study indicate that the BPCI-2 has acceptable psychometric properties in this population. The BPIC-2 has been chosen as an outcome measure in this study as coping is included in the CSM, passive coping strategies are a risk factor for the development of chronic pain and because psychological flexibility has been found to be significantly associated with pain intensity, physical functioning and psychosocial disability (Caneiro et al., 2020; Vowles et al., 2014).

Self-reported global rating of change will be measured using a single item Global rating of change scale (GRoCs) scored on an eleven-point scale. The eleven-point scale is scored from minus five to plus five, anchored by the terms very much worse (minus 5), unchanged (0) and completely recovered (plus 5) in accordance with the recommendation made by Kamper et al. (2009). The score is based on the period from when the patient first contacted the physiotherapy department to the GRoCs data collection time points. GRoCs are widely used in MSKP research and despite being vulnerable to recall bias, have good face and construct validity, test-retest reliability and good sensitivity to change (Kamper et al., 2009). GRoCs have been recommended as a core outcome measure for MSKP research as they are sensitive to patients' priorities and are flexible to diverse conditions or pain sites, all factors pertinent to this study (Kamper et al., 2009). The GRoCs is also included in this study as an anchor for analysis of the ÖMPSQ's predictive ability.

Levels of physical activity will be collected via three self-report screening questions developed for the Swedish national board of health and welfare (Kallings, 2014). These three questions ask the patients how many minutes in the last week they have performed activity that makes them breathless, how many minutes they have been otherwise physically active, for example doing housework or gardening, and how many hours they usually sit during a day (not including sleeping). These questions are included as a secondary outcome measure as the PainSMART-strategy aims to impart the message that maintaining physical activity, even whilst in pain, is important (Caneiro et al., 2022).

- *Healthcare register data*

Data on participating patient's healthcare consumption, work absence, referral for diagnostic imaging and referral to specialist/tertiary care for MSKP during the study period (from baseline data collection to three months) will be collected from RÖ's and RJLs healthcare data registers and the national social security database (Försäkringskassan) following the completion of all PROMs and PREMs data collection. Patients will also self-report if they are currently on sick leave for the MSKP complaint they are seeking physiotherapy for at baseline, 24-72 hours prior to initial physiotherapy consultation, 24 hours post-initial

consultation and three months post-baseline. Comparison will be made between the intervention and control groups to establish if the PainSMART-strategy can improve health outcomes and the effectiveness of the physiotherapy management pathway.

- *Screening tool*

The short form of the Örebro musculoskeletal pain screening questionnaire (ÖMPSQ) will be collected a baseline (Linton et al., 2011). The ÖMPSQ is a ten-item questionnaire which assesses five constructs; self-perceived function, pain experience, distress, fear-avoidance beliefs and return to work expectancy (Linton et al., 2011). The ÖMPSQ was developed in a primary care setting and the questionnaire is scored from 0-100 where a higher score indicates higher risk for future work-related disability (Linton et al., 2011). However, the predictive ability of the ÖMPSQ remains uncertain (Silva et al., 2022). The ÖMPSQ is included in this study to evaluate whether a certain sub-group of patients, based on ÖMPSQ scores, respond to the PainSMART-strategy.

Patient and Physiotherapist Reported Experience Measures (PREMs)

In this study PREMs will be assessed after the film for the intervention group only, and 24 hours after the initial physiotherapy consultation for both groups.

- *Evaluation of the intervention group's experiences of the film*

The intervention group will rate the clarity of the key-messages in the film (Table 2) on a numerical rating scale of zero to ten anchored by the terms, not at all clear and completely clear. These questions are obligatory to increase adherence, reinforce the film's key-messages and to assess whether the patients receiving the intervention pick up on the film's intended messages.

- *Evaluation of MSKP-related shared understanding, communication, participation, involvement and emotional support at the initial physiotherapy consultation*

To examine the effects of the PainSMART-strategy on the initial physiotherapy consultation the patients will answer seven questions, and the physiotherapists three questions, 24 hours following the initial consultation. Both the physiotherapists and the patients will complete PREMs in order to capture the patient perspective, physiotherapist perspective and to evaluate the interaction as recommended by Epstein et al. (2005). The PREMs collected in this study are questions adapted from the Swedish National Patient Survey (Nationell Patientenkät, 2015). The National Patient Survey questions are based on validated and reliable instruments and the questions have been adjusted and translated to suit the Swedish healthcare system (Nationell Patientenkät, 2015). The questions the patients will answer cover four dimensions; namely shared understanding of the patients MSKP, participation and involvement, exchange of information and knowledge (communication) and emotional support (Nationell Patientenkät, 2015). The seven questions evaluate if the patients felt that they had the possibility to talk sufficiently about their MSKP, whether they felt included in decision making around their care, whether they had the opportunity to discuss any worries or concerns they had regarding their MSKP and to what extent they discussed what they themselves could do to improve their MSKP and health. The patients will also be asked if they felt they could reach a consensus in understanding with the physiotherapist regarding their MSKP, if they felt the physiotherapist considered their personal MSKP experiences and explained MSKP in a way that they could understand. The physiotherapists in turn will answer three questions rating whether they felt they received sufficient information from the patient to adequately make clinical judgements regarding the patient's MSKP, whether they and the patient could reach a consensus regarding the patient's MSKP and whether they felt the patient actively took part in decision making regarding their care. Both the patients' and physiotherapists'

questions are answered via an eleven-point NRS with anchor statements. A higher score on individual items or total scores indicates a more positive evaluation. These questions have been chosen as they allow evaluation of the patients' and physiotherapists' experiences of shared understanding, communication, involvement and support rather than satisfaction as satisfaction levels are known to be biased to patients' expectations (Nationell Patientenkät, 2015). These questions are included in the study as the dimensions they cover are central to a high-quality consultation (Epstein et al., 2005; Lehman, 2017).

Patient participant timeline

Questionnaires will be sent to each patient participant at the following time points:

1. Baseline: the same day as initial triage.
2. 24-72 hours prior to the initial physiotherapy consultation.
3. 24 hours post initial physiotherapy consultation.
4. Three months post-baseline.

For details of what data is collected at each time point see Figure 4.

All patient participants will be enrolled via the standard access pathways to the participating physiotherapy departments in RÖ and RJL. All patient participant data will be collected using the Webropol online questionnaire management service (Linköping, Sweden). For those patients who consent to be contacted by the study coordinators, a SMS-link to the baseline questionnaires will be sent the same day as the initial triage (Time point 1). The baseline questionnaires contain more extensive information about the study and the possibility to provide definitive consent. Patients that consent then obtain access to and complete the baseline demographic data and PROMs questionnaires (Time point 1). For patients randomised to the intervention group the film is included at the end of the baseline questionnaire, followed by the questions regarding the film´s key-messages, a repeat of the BIPQ and reassurance NRS. Both groups will then receive follow-up PROMs questionnaires approximately 24-72 hours prior to the initial physiotherapy consultation (Time point 2) and again 24 hours after the initial physiotherapy consultation (Time point 3). PREMs data will be collected at time point 3. The final data collection will occur three months after each patient's inception to the study (Time point 4).

Physiotherapist consent and data collection

Physiotherapist consent and background data will be collected via Webropol questionnaires prior to the start of patient recruitment. The physiotherapists' evaluations of the initial consultation will be sent to the study coordinators via the messenger function of the electronic journal system within RÖ and RJL.

English language copies of the data collection questionnaires (patient and physiotherapist PROMs and PREMs) are available from the corresponding author on request.

Sample size

The sample size calculation for this study is based on its primary hypotheses. The calculations are based on the MCID of two for the NRS for pain intensity and a minimal detectable change of 11.52 for the PSEQ-10 (Dube et al, 2021; Olsen et al., 2017; Olsen et al., 2018; Ostelo et al., 2008). Sample size calculations were computed for both of the primary outcomes (NRS and PSEQ-10) using a Cohen's d effect size of = 0.25 (i.e. small-moderate) and a single-sided p-value of p=0.05 plus a statistical strength of 0.8 (=Power 80%). The largest sample size calculated was for analysis of the NRS (n = 102 per group) and this was adopted as the sample size for this study. To enable mediation and sub-group analyses two subgroups are

required. This gives a total sample size of 408 patients. A drop-out rate of approximately 30% was factored into the randomisation sequence giving a total sample of 600 patients.

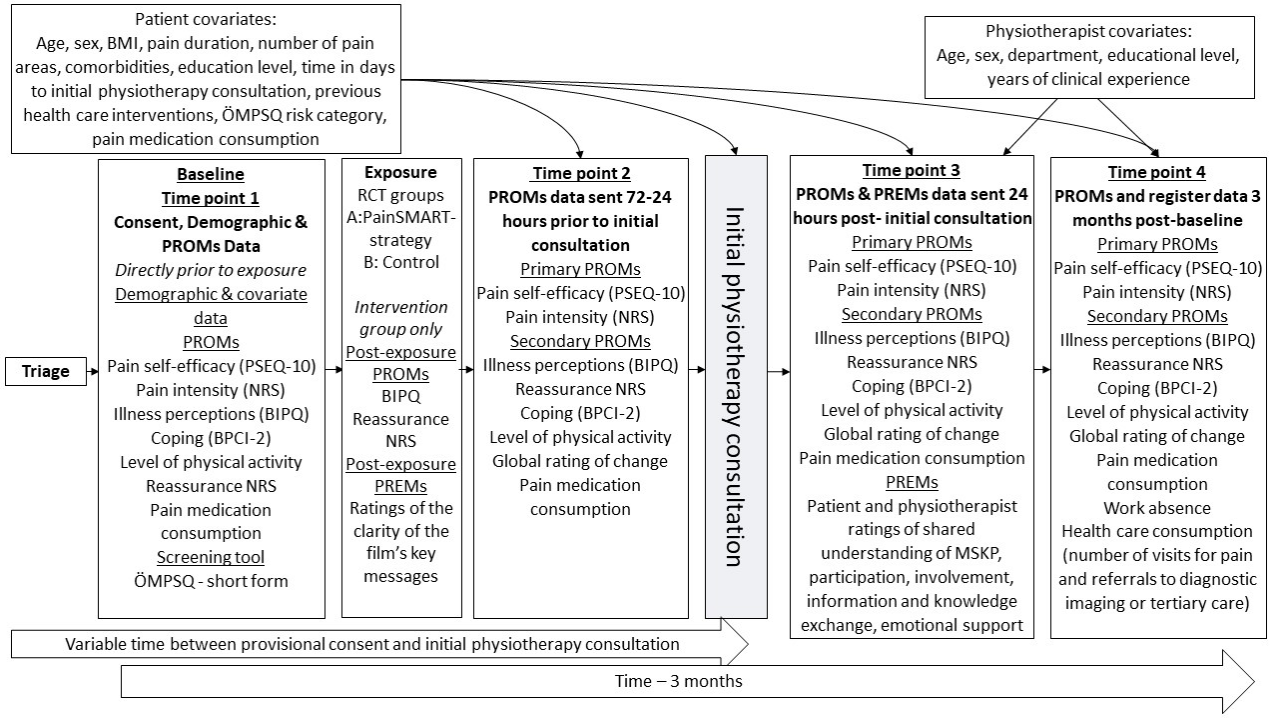

Figure 4: PainSMART-RCT Directed acyclic graph (DAG) showing data collection time points and data collected at each time point. BIPQ, Brief Illness Perception Questionnaire; BPCI-2, Brief Pain Coping Inventory-2; NRS, Numerical Rating Scales; PSEQ-10, Pain Self-Efficacy Questionnaire; PROMS, patient reported outcome measures, PREMs, patient and physiotherapist reported experience measures; RCT, randomized controlled trial.

Recruitment

Patient participants will be recruited via the five participating primary care physiotherapy departments within RÖ and RJL. To access physiotherapy, patients contact their local rehabilitation or healthcare centre via telephone (TeleQ) or an online text-based service (1177-direkt) and are triaged by a certified physiotherapist. Eligibility for the study will be assessed by the triaging physiotherapist. Potentially eligible patients will be asked via standardised oral or text information for an initial consent to share their contact details with the study's coordinators. For those patients who consent to be contacted, the study coordinators will send a SMS with a link to the baseline Webropol questionnaire that contains further information about the study and the possibility to provide definitive consent. SMS reminders will be sent to potential participants to encourage recruitment. One practicing physiotherapist has been appointed as a local PainSMART-champion at each of the participating physiotherapy departments. The PainSMART-champions role is to facilitate patient recruitment, communication between the research team and the department and guide study design and implementation. The PainSMART-research group will, along with each PainSMART-champion, provide introductory information about the study prior to the start of patient recruitment. Ongoing communication between the research team and participating departments and their local champions will take place during the patient recruitment period to assist with the study and encourage recruitment. Members of the research team will make further visits to the participating departments as necessary during the study. No incentives are provided to encourage patient recruitment. Recruitment will continue until the sample size is

met. Ongoing patient recruitment will be monitored by the study coordinators and is expected to take between six months to one year.

Participating physiotherapists will be all the certified physiotherapists employed at the five participating physiotherapy departments. The management team at all five participating departments have consented to the study and encourage all employed physiotherapists to consent to partake in the study.

Allocation and sequence generation

All patients who consent to share their contact details with the study coordinators will be randomised. The study coordinators will then input the patients into the code-key system that contains a computerised randomisation sequence for 600 patients into group A or B. This randomisation sequence has been generated using SPSS by a blinded statistician prior to the start of patient recruitment. Patients will therefore be randomly allocated to the intervention or control group based on the order of their inception to the study. Once patient participants have consented to the study the study coordinators will document the patients' participation and group allocation in the electronic journal system. This will enable the physiotherapists to have knowledge of the patient's participation and group allocation.

Allocation concealment mechanism

Only patients randomised to the intervention group will be provided access to the film (at time points 1 and 2). Patients randomised to the intervention group will receive the questionnaire battery that includes the film and the control group will receive an identical questionnaire battery aside from the inclusion of the film. No mention will be made of the existence of an educational film in the questionnaires or information provided to participants prior to the completion of baseline data collection.

Blinding

All patients will receive identical information and questionnaires until completion of baseline data collection. Only after completion of baseline data collection will the intervention group receive knowledge of, and access to, the film. The participants in the intervention group, study coordinators and participating physiotherapists will not be blinded to the intervention or to patient group allocation. It is not possible to blind for an educational intervention and part of the intervention is aimed at facilitating the initial physiotherapy consultation. This necessitates the physiotherapist having knowledge of whether the patient has been allocated to the intervention or control group. Patients randomised to the control group will be blinded to the existence of an educational film. Data analysis will be performed by researchers and statisticians blinded to group allocation.

Data collection and management

All participant data will be handled and processed by the research team responsible for the study. All participants will be pseudonymised via the use of a code-key system. All patient participant data will be collected electronically via the Webropol system. Webropol data is hosted on a secure server within RÖ. Non-responders to the questionnaires will receive SMS and telephone reminders in order to reduce dropouts and missing data. At the conclusion of the study all Webropol data will be transferred to Linköping University's secure server for analysis. In addition physiotherapist background data will be collected via Webropol questionnaires and physiotherapy PREMs data via secure messages within RÖs and RJLs electronic journal system. Reminders will be sent to the physiotherapists via the electronic journal system regarding the evaluation of the initial physiotherapy consultation. Physiotherapist initial consultation evaluation data will be stored pseudonymised via code-key

on an excel-file and transfer to Linköping University's server for analysis. The code-keys for patients and physiotherapists will be stored separately from the online data. Data management will comply with the European Union's General Data Protection Regulation (GDPR). The information provided to potential participants will clearly state that their data will be handled and stored securely whilst analysis and reporting of results will be pseudonymised and at group level so that it is not possible to identify individuals. Secure data storage will continue throughout the study and for a minimum of ten years after its conclusion according to current Swedish legislation for research data (IMY, 2023). Only the research team will have access to the data in the study and will be responsible for data processing together with statistical support staff at Linköping University.

Statistical methods

This protocol outlines the principal features of the statistical analysis for this study. A full statistical analysis plan (SAP) will be published on Clinicaltrials.gov prior to the start of data analysis.

Participant characteristics

Patient: Group characteristics will be presented as average (mean) values, standard deviations, and frequencies. Baseline analysis between groups A & B will be conducted to ensure the comparability of the groups.

Physiotherapist participants: Group characteristics (age, sex, department, highest educational level, number of years of clinical experience) will be presented as average (mean) values, standard deviations, and frequencies.

Analysis of primary outcomes

Magnitude of within and between-group change on primary outcomes from baseline to 24-72 hours prior to the initial physiotherapy consultation, 24 hours post the initial physiotherapy consultation and three months post-baseline will be analyzed through mixed models. The proportion of responders in each group will be presented as percentages and between group difference analysed statistically using logistic regression (Coens et al., 2020). For pain intensity a responder is defined as an individual with a two-point reduction in NRS between baseline and three months post-baseline (Olsen et al., 2017; Olsen et al., 2018). For pain self-efficacy a responder is defined as an individual with an increase of 11.52 points on the PSEQ-10 between baseline and three months post-baseline (Dube et al., 2021). Sensitivity analyses applying study specific MCID associated with dichotomized anchor response on the GRoC will be explored. Sensitivity analyses to adjust for all measured baseline covariates will also be performed to investigate the presence of equipoise as the result of randomisation (Thabane et al., 2013).

Multiplicity/ type I (α) error

The outcomes collected in the study are considered as separate entities and, therefore, restrictive multiplicity penalization of the model is not required (Dmitrienko & D'Agostino 2013). Adjustment will be used for repeated measures over time for separate test conditions.

Analysis of secondary outcomes

Magnitude of within and between-group change on secondary PROM outcomes from baseline to 24-72 hours prior to the initial physiotherapy consultation, 24 hours post the initial physiotherapy consultation and three months post-baseline will be analyzed through mixed models. The causal item question of the BIPQ will be analysed via the grouping of answers into categories, as recommended by Broadbent et al. (2015). Additional analysis will be

conducted for the intervention group only of mean aggregate change in the BIPQ (item and total score) and reassurance NRS directly after the first exposure to stage one of the intervention.

Analysis of healthcare register outcomes

Number of healthcare visits, referrals to diagnostic imaging and to specialist/tertiary care and sickness absence and certification from baseline to three months post-baseline will be presented as percentages for both groups and between group differences analysed statistically using logistic regression (Coens et al., 2020).

Additional analyses

MSKP illness perceptions and level of reassurance as to the benign nature of MSKP are hypothesized, based on an integration of the CSM and concept of self-efficacy (Figure 3), to be potential mediators of the effect of the PainSMART-strategy on pain intensity as well as other secondary outcomes. The integrated model also hypothesizes pain self-efficacy to be a mediator in a series of mediators of the PainSMART-strategy's effects. The effect of MSKP illness perceptions and level of reassurance as to the benign nature of MSKP on pain self-efficacy act as a first step in the causal pathway of the PainSMART-strategy´s effect on health outcomes. Single causal mediation analysis will be used to analyse indirect effects on pain intensity (NRS) and pain self-efficacy (PSEQ-10) through improvement in MSKP illness perceptions (BIPQ) and reassurance (NRS). The direct acyclic graph model in Figure 5 summarizes these causal inferences. We assume there to be no confounding of the intervention–mediator and intervention–outcome relationships due to random allocation of the intervention (intervention or control group) (Valeri & VanderWeele, 2013). Identified potential confounders of the mediator–outcome relationship will be adjusted for in the single mediation analyses. Potential confounders were identified using the disjunctive cause criterion, which involves selection of measured pre-intervention covariates that are hypothesized to be a cause of the mediator, outcome, or both (VanderWeele, 2019). The minimum sufficient adjustment set includes age, sex, BMI, pain duration, number of pain sites, comorbidity, employment, level of education, days to initial physiotherapy consultation, pain medication consumption and previous health care interventions. The analyses will also be adjusted for physiotherapist characteristics: age, sex, clinical experience and educational level. Pre-intervention measures of the mediator and outcome will also be included in the models. The interaction term between the intervention allocation and the mediator will be analysed to examine its impact on the indirect effects (MacKinnon et al., 2020). The results will be reported according to A Guideline for Reporting Mediation Analyses (AGReMA; Lee et al., 2021).

Exploratory analysis

Regression based statistics will be used to explore baseline predictors and mechanisms of longitudinal outcomes. Future qualitative research will further explore the PainSMART-strategy.

Analysis of patient and physiotherapist experience outcomes (PREMs)

The intervention group's scores related to the clarity of the film's key messages will be presented descriptively.

Outcomes relating to the evaluations of the initial physiotherapy consultation will be analysed through aggregated mean differences between the intervention and control group and logistic regression (total scores and individual item scores). Additional analysis will be conducted of

the aggregate mean divergence between the patients and physiotherapists scores on the three paired questions for both groups.

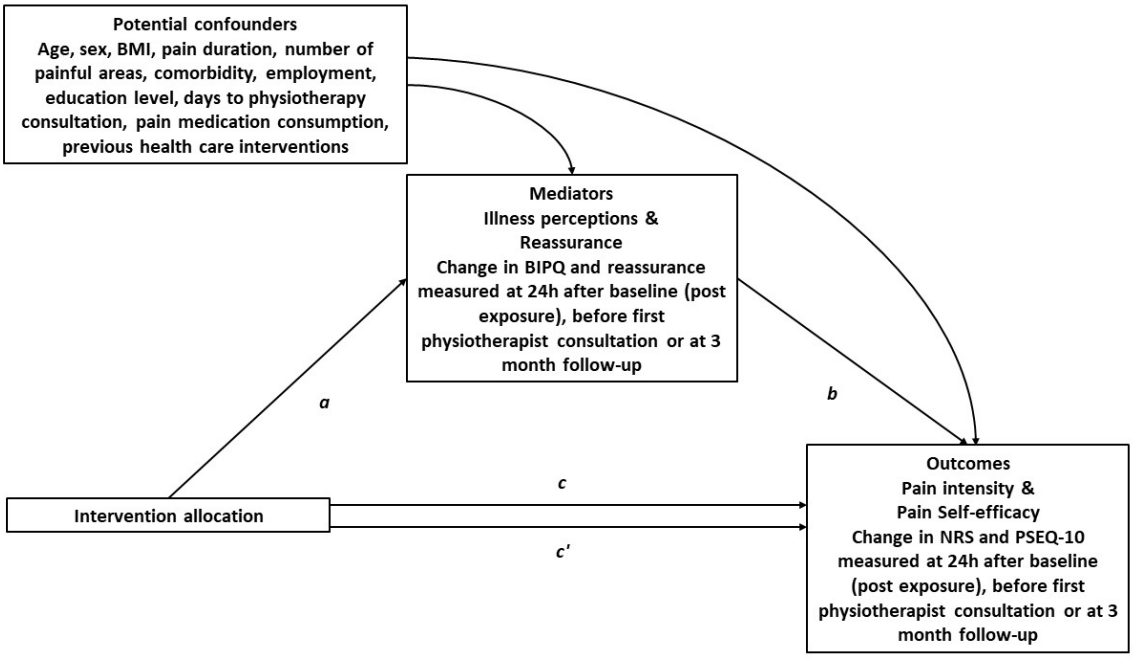

Figure 5. Directed Acyclic Graph (DAG) of the causal pathways for the effect of the PainSMART-strategy on the outcomes pain intensity and pain self-efficacy via the hypothesized mediators and the estimated averaged effects adjusted for confounding effects. The potential confounders are measured at baseline. The indirect effect (ab-product) is the average intervention effect through the mediator. a, a-path (the intervention-mediator effect); b, b-path (the mediator-outcome effect); c, c-path (the total effect of the intervention on the outcome, without accounting for potential mediator); c´ (the direct effect of the intervention on the outcome, that works through all other mechanisms excluding the selected potential mediator). BIPQ, Brief Illness Perception Questionnaire; NRS, Numerical Rating Scale; PSEQ-10, Pain Self-Efficacy Questionnaire.

Missing data

Missing data will be analyzed by comparing characteristics (average age, sex) of study participants to non-participants during the study period as well as providing compliance rates for the intervention group, comparing participants with and without missing PROM data and analyzing the impact of missing data on generalizability (Mercieca-Bebber et al., 2018). Outcome data will be compared based on the 'intention to treat' (ITT) principle. This means that all patients that have been randomized remain in the analysis based on their group allocation. In the event of substantial missing data, evaluation of the mechanisms for missing data will be used (Enders, 2011). Missing data will otherwise be handled under the missing at random assumption (Enders, 2011). Multiple Imputation or Maximum Likelihood estimation will be used assuming that missing data is conditional on variables included in the model. Imputation method considering missing at random or not missing at random will be used in the ITT analysis. Patients who cancel their initial physiotherapy consultation will be excluded from the PREM analysis but will remain in the study for PROM and healthcare register data analyses.

Study monitoring and harms

There will be no data monitoring committee since the study is independent from the sponsor and the intervention is implemented as an adjunct to usual physiotherapy management with low risk for unexpected adverse events. The PROMs included in the study are sensitive to worsening in the patients' condition. No interim analysis is planned.

Ancillary and post-trial care

All patient participants will follow the usual physiotherapy care pathway within RÖ and RJL and will therefore have access to other healthcare professions, resources and healthcare levels for additional consultation or management should any unexpected adverse event occur. There will be no restrictions placed on seeking other care during the trial period. Following completion of the study the patients will follow the usual management pathway.

Ethics

This study has been approved by the Swedish Ethical Review Authority (Etikprövningsmyndigheten). Dnr: 2023-05968-01 (25/10/2023).

Contact details:
Swedish Ethical Review Authority, Box 2110, 750 02 Uppsala.
Email: registrator@etikprovning.se. Telephone: +46104750800

Consent

Participant recruitment: All potentially eligible patient participants will receive standardized verbal or text information about the study from the triaging physiotherapist and be asked for consent to share their contact details with the study coordinators. If preliminary consent is obtained then standardized information will be sent to potential participants via a SMS-link to a Webropol questionnaire. This information contains contact details to the study coordinators and those responsible for the study. Patients who provide consent will gain immediate access to the baseline questionnaire.

Physiotherapist recruitment: All participating physiotherapists will provide definitive consent after receiving verbal information at workplace meetings and further written information in-line with the patient participant recruitment. Consent will be collected via online Webropol questionnaires.

Confidentiality

The personal details of eligible patients will be shared with the study coordinators via the secure electronic journal system used within RÖ and RJL. All participants (patients and physiotherapists) will receive a unique code-key number to enable pseudonymization of data and secure data storage within the Webropol system (RÖ) and SPPS program (Linköping's University). The code-keys for the patient and physiotherapist participants will be stored separately from the secure Webropol (RÖ) sever and Linköping's University data analysis programs. The physiotherapists' evaluations of the initial consultations will be stored pseudonymized by the use of a code-key. All results will be published at group level.

Declaration of interests

No conflicting interests. To reduce bias, the study coordinators (RT & MF) will not treat any patients participating in the study in their roles as physiotherapists at the participating departments in Finspång and Linköping.

Access to data

Study data will only be accessible to the PainSMART-research group and statistical support team at Linköping's University. Group level and individual patient data will be available from the research team on reasonable request following completion of the study and publication of the study results.

Dissemination

This study protocol will be published via Clinicaltrials.gov to enable public access prior to the inception of patient recruitment. The study's findings will be disseminated and made publicly available in peer-reviewed publications and conference presentations. The study's results will also be disseminated through regular communication channels within healthcare and university contexts. If the results of the study are positive the film can be hosted on the 1177 healthcare information platform and be integrated into the primary care physiotherapy MSKP care pathway in RÖ and RJL and even across Sweden.

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