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THE SYSTEMATIC DEVELOPMENT AND PRELIMINARY TESTING OF A BEHAVIOUR CHANGE INTERVENTION TO ENHANCE EXERCISE ADHERENCE IN PEOPLE WITH PERSISTENT MUSCULOSKELETAL PAIN

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Purpose: To describe the design and testing of an empirically and theoretically informed intervention aimed at increasing adherence to prescribed exercise in people with persistent musculoskeletal pain.

Methods: To systematically design an intervention to target exercise adherence, the first four stages of Intervention Mapping were applied and supported by the involvement of a patient engagement group. A systematic review and qualitative study (step one) informed intervention content and context. A theoretical framework supporting exercise adherence was described (step two) to inform study methods (step three). How these methods could be utilised to support behaviour change and enhance exercise adherence was discussed (step four). The resulting intervention was assessed in a proof of concept feasibility and acceptability study.

Results: The Health Action Process Approach was identified as an appropriate theoretical framework to underpin an intervention encompassing virtually delivered motivational interviewing and an app-based exercise program to support adherence to exercise. The intervention was shown to be feasible and acceptable.

Conclusions: An Intervention Mapping approach was successfully employed to develop an intervention aimed at supporting the development of self-management behaviours and addressing maladaptive beliefs as a means to enhance exercise adherence. Future evaluation and implementation of the intervention should now be determined.

Keywords: Adherence, pain, exercise, intervention development

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INTRODUCTION

Persistent musculoskeletal (PMSK) pain, such as low back pain, has substantial personal, social and economic impacts.[1,2] Evidence-based nonpharmacological strategies, including prescribed exercise are a recommended treatment plan for patients with PMSK pain.[3] Evidence supports the effects of prescribed exercise in alieviating pain and improving function and quality of life.[4] However, less than half of people with PMSK pain adhere to the exercises they have been prescribed by a healthcare provider.[5] In order to address this challenge, there is a need for programs to identify and target the barriers to exercise adherence. Yet, there is a lack of empirical evidence to guide the development of a targeted intervention to inform practice.[6] The

systematic reporting of intervention development is essential to enhance understanding and address this problem via informing future research and decision-making.

Increasing exercise adherence is often challenging, as it requires people to change their behaviour. Supporting behaviour change entails an understanding of internal and external influences, such as access to resources or beliefs about the behaviour.[7] Intervention Mapping provides systematic guidance on developing complex behaviour change interventions to address these influences, while acknowledging the importance of evidence, theory, process and outcomes.[8] It is compatible with any theory and can help identify appropriate theory-informed methods and behaviour change techniques (BCTs; the smallest identifiable active ingredient of behaviour change interventions, see Abraham & Michie,[9] for more information). This method could be useful in developing a complex behaviour change intervention in people with PMSK pain. The approach guides users iteratively from problem identification to problem solving to facilitate a comprehensive consideration of the influences enacting on the behaviour. The completion of each of the six steps within Intervention Mapping informs the subsequent step.[10] Reporting on the development of an intervention promotes transparency, improves interpretation of results and allows researchers to learn from one another.[11] There is currently limited research outlining the development and theoretical justification of an intervention to target exercise adherence in a PMSK pain population.[6] It is therefore imperative to clearly outline the steps taken to gather and disseminate the data to support the development of further research in the field.

The aim of this research was to design an intervention to enhance adherence to exercise in people with PMSK pain following the Intervention Mapping approach. The objectives were to (i) describe the initial development of an intervention using the first four stages of Intervention

Mapping; (ii) describe a small feasibility and acceptability study; and (iii) propose refinements to the intervention to be tested in the next step of intervention development and testing.

METHODS

Following the Strategy for Patient Oriented Research (SPOR)[12] a patient engagement (PE) group was consulted throughout each step of this research. Members were individuals with PMSK pain identified from three outpatient physiotherapy clinics in London, United Kingdom (UK). Six individuals met four times over two years to inform this research. The methods are presented following the Intervention Mapping approach.[10]

Step One: Needs assessment of the content and contextual factors influencing exercise adherence

In step one of the Intervention Mapping approach, the problem is assessed to determine risk factors, existing supporting evidence and gaps in the literature. This step consisted of a systematic review and a qualitative study.

Systematic review of behaviour change techniques associated with exercise adherence

The methods and comprehensive reporting of study findings are reported elsewhere.[6] However, in brief, this review identified five BCTs that were found to be the most influential on exercise adherence:

(i) Social support (e.g., from family members or the physiotherapist).

(ii) Behaviour goal setting (e.g., completing prescribed exercises twice per week after dinner).

(iii) Behaviour practice/rehearsal (e.g., practicing prescribed exercises during a clinical appointment).

(iv) Demonstration of behaviour (e.g., the therapist thoroughly demonstrates how to accurately perform the prescribed exercise).

(v) Instruction of the behaviour (e.g., providing written or verbal instruction on how to accurately perform the prescribed exercise).

The review identified interventions that employed seven or less BCTs were most effective at enhancing exercise adherence in this population, suggesting that overburdening patients negatively impacts adherence. However, the review did not identify the context in which these BCTs are most effectively delivered to people with PMSK pain. Understanding the context of an intervention informs researchers and practitioners about the suitability and transferability of the intervention to the context they are considering using for the intervention.[11] To build on these findings, a qualitative study was conducted to further explore the contextual components that influence exercise adherence in people with PMSK pain.

Qualitative study exploring the barriers and facilitators to exercise adherence

This step aimed to identify the contextual factors, such as environment and relationships that influence exercise adherence. Semi-structured interviews were conducted with people with PMSK pain (n=20) to explore their experience of adhering to prescribed exercise. Two focus groups were conducted with physiotherapists (n=10) to explore their perceptions of exercise adherence and prescribing exercise to people with PMSK pain. The methods and findings have been published elsewhere.[13] Four main themes were identified:

(i) The role of the physical and social environment to facilitate adherent behaviours.

(ii) The impact of a collaborative therapeutic relationship to develop a tailored exercise prescription.

(iii) Facilitating self-management by providing support to overcome environmental barriers and establishing realistic treatment expectations.

(iv) Understanding the influence and impact of pain and negative affect.

This study highlighted the need for personalised support to facilitate exercise adherence in people with PMSK pain and to elucidate to patients the importance of identifying internal and external barriers to behaviour in order to establish coping strategies to support self-management.

The PE group was consulted prior to, and following, the qualitative study to inform the topic guide development and check the resonance of findings. Feedback on the topic guide resulted in changes to language used when discussing exercise behaviours and ensuring the questions elicited answers pertaining to prescribed exercise as opposed to general physical activity (i.e., walking to work). Following data collection and generation of themes, a mind map and description of the themes was shared, and members discussed the resonance of the themes. The members understood the themes and could relate to them personally. The PE members shared their preliminary ideas on how these finding might inform intervention progression. For example, members discussed the importance of accessible instructions and reminders to do their exercises throughout their day (for example, when waiting for a train).

Summary of findings from step one

The preliminary research identified the need for the intervention to be tailored and accessible to the participants. Instruction, demonstration and practice of behaviour were identified as important in the prescription of exercise as well as a component of goal setting and social support. Personal and professional relationships influence adherent behaviours and there is a recognised need to foster this to support patients in adhering to their prescribed exercises. The influential content and context identified in the two studies were further explored in step two.

Step Two: Develop theoretically informed performance objectives to form a matrix of program objectives

The second step in Intervention Mapping requires the specification of program objectives. First, the findings identified in step one were matched to appropriate theoretical constructs to develop a logic model (Figure 1). This allowed for a systematic conceptualisation of appropriate theoretical models to underpin the intervention and target the behavioural factors.

[Insert Figure 1 here]

The logic model informed the development of a matrix of change objectives. This matrix identified pathways to influence behaviour change by targeting program objectives and identifying intervention methods and strategies. Each cell within the matrix contains one change objective, identifying what the participant must change to accomplish the program objective (Table 1). Intervention Mapping suggests referring to theory to inform this development.[10] Considering multiple theoretical constructs is fruitful during initial steps of intervention development to identify relevant constructs and begin to conceptualise how the constructs may be modified.[14] However, the predictive properties of the constructs cannot be tested if determinants from multiple theories are employed. Therefore, one theory was selected to underpin the intervention and inform the program objectives.

Participants in the empirical research and PE members spoke about the importance of their exercises being tailored to support their physical and psychological needs, as well as their current level of engagement with their program. An appropriate multi-staged theoretical framework is the Health Action Process Approach (HAPA).[15] This framework aims to move individuals towards adherence by targeting planning and coping activities and factors identified

as having the strongest predictive power depending on their current stage of behaviour change. HAPA theorises that risk perception, outcome expectations and task self-efficacy are most influential for pre-intenders; intentions, planning and maintenance self-efficacy for intenders; and recovery self-efficacy and action control for actors. These constructs align with the findings identified in step one.

The authors of HAPA posit that self-regulatory and self-management processes are necessary to achieve adherence to behaviour.[15] Therefore, an intervention to enhance exercise adherence may target these constructs with a tailored approach to support individuals' attempts at exercise self-management. To target the behavioural and environmental factors as per the logic model, the two key program objectives of this intervention were to:

i. Assist people with PMSK pain to enhance self-management techniques and skills
ii. Provide tailored, accessible instructions to aid adherence to a prescribed exercise program

[Insert Table 1 here]

Step Three: Select methods and practical applications

The third step comprised the operationalisation of the change objectives outlined in Table 1 into theoretically informed methods. The PE members were consulted during this stage. Information on the HAPA and how it informed the intervention development, as well as a draft of the logic model informing the intervention development was shared. The members discussed how the findings and their previous input shaped the intervention and confirmed that the two program objectives aligned with their feedback. The members discussed the conceptualisation and description of each point of contact of the intervention. Their input informed the methods described below.

Methods to address program objective one: assist people with PMSK pain to enhance self-management techniques and skills

To address the first program objective, the preliminary research identified the need for a patient-centred intervention that is tailored and accessible. An approach that is often employed to facilitate health behaviour change is motivational interviewing (MI).[16] MI is a patient-centred counselling style that has been found to be an appropriate method for use by healthcare providers dealing with musculoskeletal issues.[17] It has the flexibility to be employed by a variety of healthcare professionals. This could enable the intervention to be readily implemented and was therefore selected to target self-management and facilitate exercise adherence.

Methods to address program objective two: provide tailored and accessible instructions to aid adherence to a prescribed exercise program

Virtual health programming (including digital, mobile and telehealth systems) has been shown to produce positive return on investments[18] and increase patient access and clinician productivity.[19] It is not surprising that its use has grown rapidly worldwide.[10,20,21] Virtual health offers greater flexibility than clinic based healthcare and is a promising approach to deliver a theoretically and empirically supported tailored program.[22] It has been recognised as an advantageous option for influencing exercise adherence.[20,23] Due to its accessibility it was therefore selected as an appropriate platform to deliver the intervention. The second intervention objective was met by using online and app-based technologies to provide tailored and accessible exercise instruction.

Step Four: Describe the program plan

The fourth step of Intervention Mapping encompasses the comprehensive reporting of intervention components. The Template for Intervention Description and Replication (TIDiER)[24]

and the GUIDance for the rEporting of intervention Development (GUIDED)[11] were followed to provide the description of the behaviour change intervention.

Intervention content and mode of delivery

The intervention was underpinned by the HAPA model. This model was used to identify the constructs most salient to each individual and these constructs were mapped onto BCTs and delivered using MI. The intervention was delivered virtually; MI was delivered over the video conferencing platform Zoom (Version 2.0) and complimented by an app-based tailored exercise program.

Training in MI is required by the healthcare practitioner to ensure consistent delivery. The sessions were delivered by the first author, a PhD candidate in health psychology who underwent training in MI supplied by the British Psychological Society. The delivery of each MI session was guided by a structured session format to support consistency and fidelity to MI practices. The intervention comprised four MI sessions, delivered online over seven weeks.

The primary purpose of the first session was to develop a rapport and relationship with the participant. A goal for them to strive towards over the coming week was set in collaboration with the participant. The subsequent sessions explored their experience with the goal and any successes and challenges they encountered. Focus started to shift towards long-term planning and to identifying barriers and solutions to overcome them. The last session explored maintaining exercise behaviours by identifying support needs beyond the program; and how they could find support for long-term adherence (Table 2).

Following the initial in-person physiotherapy assessment, the personalised exercise prescription was provided by a physiotherapist through the app Physitrack. This app was chosen

for its access to an extensive library of exercises complete with video demonstration and instruction of the exercises.[25] Once the physiotherapist created a prescribed exercise program the participant received their personal link. The participant could then access the program and indicate when they completed their exercises.

[Insert Table 2 here]

Intervention delivery schedule

Participant burden was taken into consideration in regard to session frequency and duration. Consultations with the PE group verified the decision to reduce session frequency throughout the intervention to facilitate self-management behaviours. Duration between MI sessions therefore increased by a week each time until intervention completion. Following MI guidelines, session duration was 30 to 50 minutes.[16]

RESULTS

Initial program implementation and proof of concept testing

The intervention was initially investigated in a small single arm proof of concept study with a pre-post study design incorporating qualitative acceptability interviews. The aim was to determine feasibility of delivery (recruitment, retention and adherence to study protocol) and acceptability (to provide insight on what participants and study personnel liked or did not like about the intervention) to inform intervention refinement. The study was approved by the King's College London BDM Research Ethics Panel (Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences), and informed consent was obtained by all participants. Participants were identified by the physiotherapist during their routine physiotherapy assessment at a private physiotherapy clinic in central London, UK. Inclusion criteria included adults aged 18 and above, with musculoskeletal pain for three months or longer and receiving physiotherapy and prescribed exercise for PMSK pain from the study physiotherapist.

Thirteen eligible patients were approached over two months by the researchers and ten people enrolled in the study (76.9% recruitment rate). Eight (80% adherence rate) participants completed all measures before and after the intervention. Eight participants completed all

intervention sessions (80% retention rate) and the eight participants who completed the study participated in the qualitative acceptability interview. Data was analysed thematically and three themes regarding intervention acceptability were identified:

(i) A holistic approach to treatment

Many participants reported that the intervention provided a holistic approach to support exercise adherence. The multimodal delivery of the intervention assisted them in integrating their prescribed exercises into their lives by providing additional support and personalised care.

(ii) The pros and cons of using virtual health to support exercise adherence

Virtual health was discussed both in terms of using the Physitrack app as well as the online delivery of the MI sessions. Participants were favourable to the convenience and accessibility of virtual health programs and felt it supported their efforts to exercise. However, there was some rigidity and some of the participants expressed a desire for more tailoring in the appointment schedule or more personal contact. While the online sessions may have been convenient, some participants felt they needed more personal interaction than what was offered.

(iii) The impact of the intervention on supporting self-management of exercise

Many participants discussed the aspects of structure and accountability that the intervention had on their broader attempts to self-manage and adhere to exercise. Participants reflected that MI facilitated a sense of control of their care and that their program could be tailored to their lifestyle. Some noted they felt accountable to the MI practitioner, while recognising that reliance on the practitioner may not support independent skill development to learn to manage and self-monitor their own behaviours for long term adherence.

The physiotherapist who administered the exercise prescription also provided feedback during an informal interview regarding the experience of using the app. The physiotherapist felt that the app was time-intensive when searching for exercises within the library. It also did not allow for small adjustments to be made to the exercises to highlight the effective execution (i.e., accurate range of motion or angle of joint) tailored to the need of the participant. The physiotherapist suggested that it would be more appropriate to record the participant accurately executing their exercises while recording them to upload onto Physitrack to accompany the written instruction. The physiotherapist noted, however, that Physitrack encouraged patients to engage with the exercises and this was seen as a benefit.

Refinements and modifications to the intervention following the proof of concept study

The feasibility results and insight from the acceptability interviews informed study refinement and progression. Refinement to the two components of the intervention were made (i) adapted utilisation of the exercise app (ii) revision to the MI schedule to be more flexible and tailored.

Participants responded positively to using the app to access their exercises, however an improved utilisation of its capabilities would have minimised the need for more physiotherapist contact. Participants may be positively influenced by the knowledge that their physiotherapist can provide feedback remotely, and regular remote engagement by the physiotherapist has been found to support adherence.[26] Messaging through the app may support engagement with exercise and ensure participants are reliably and consistently documenting exercise completion. Furthermore, uploading videos of the participant accurately demonstrating the proper execution of the exercise would provide additional individualisation for the participant while ensuring the exercises provided are in line with the physiotherapist's prescription.

Refinements to the MI schedule may increase flexibility and alignment with the needs of the participant. Based on the HAPA model, individual needs differ depending on their current exercise engagement.[15] While the intervention aimed to target the constructs identified by the HAPA, the predetermined session timetable may have hindered this. For example, a patient actively engaged in their exercises (*actor*) may not require the same MI schedule as someone still struggling to overcome barriers and initiate their exercise (*intende*r). Once a behaviour has been initiated, other constructs begin to influence maintenance of the behaviour.[27] A more flexible, step-down approach may be more effective in eliciting self-management and supporting exercise adherence.

DISCUSSION

The Intervention Mapping approach was successfully used to develop a behaviour change intervention aimed at enhancing adherence to prescribed exercise in people with PMSK pain. The approach guided the identification of program objectives, methods and theoretical underpinning. The developed intervention was found to be feasible and acceptable to people with PMSK pain.

This research described the explicit links between the existing evidence, underpinning theory, and content to support future intervention implementation and evaluation. Consultation and collaboration with PE members and stakeholders enhanced the likelihood of acceptability and implementation in future clinical practice. The feasibility now needs to be determined by further investigation of implementation and practicality of the intervention.

Following an implementation model such as the ORBIT model[28] would provide a structured framework for further progression. The model proposes four phases (i) design, (ii)

proof of concept and pilot, (iii) efficacy trial and (iv) effectiveness trial. This paper described the methods aligned to phase one and the beginning of phase two. To complete phase two, a full feasibility study will be conducted to inform study parameters, such as sample size for a randomised controlled trial to investigate intervention effectiveness, an assessment of who is best suited to deliver the intervention, the feasibility of training other health professionals to deliver the intervention, as well as the development and testing of a training package for the healthcare professionals delivering the intervention.

Phase three will encompass an efficacy trial to ascertain clinical efficacy and provide empirical insight. This will allow for an exploration of clinical significance and provide empirical insight into the delivery of the intervention by different healthcare providers and clinical settings.[28] Finally, if deemed appropriate, phase four will complete a full trial of the revised intervention to determine effectiveness, cost-effectiveness, and provide a complete process evaluation reporting implementation (e.g., treatment fidelity, dose, and reach).[29]

Strengths and limitations

A strength of this study was the systematic development of an intervention using an Intervention Mapping approach. The design was based on evidence from a robustly conducted systematic review and qualitative research including patients and clinicians. A further strength was the assessment of feasibility and independent qualitative assessment of acceptability of the resulting intervention to inform modifications.

The intervention utilises virtual health technology, which is a strength, particularly following the outbreak of the COVID-19 pandemic. The extent of the effects of COVID-19 are still unknown, however adaptability of program delivery, particularly for individuals already

experiencing barriers to adherence, offers flexibility to withstand additional service delivery barriers. It may also offer further opportunity for accessible, cost effective delivery to promote service integration.

Assessing the intervention within current clinical practice was not determined. While physiotherapists could be well positioned to deliver MI, this was not assessed and is a limitation in terms of intervention implementation. Another important limitation is that the intervention comprised both MI and an app-based exercise prescription that were delivered together and it is not possible to identify the effects of the two in isolation. While this was a pragmatic approach often used in intervention development; the separate assessment of these intervention components should be investigated.

The intervention was developed and tested in a UK context. Participant recruitment in London, UK may not be representative of a wider population base. However, the findings are applicable to a Canadian healthcare system to inform practice.

Implications for practice

The intervention is well aligned with recommendations calling for further development informing the treatment and management of PMSK pain.[30] Complementing physiotherapy with virtual interventions has drastically and rapidly increased and there is evidence to support its role in enhancing adherence to treatment recommendations.[20,31] While the intervention supports the current clinical directions in the treatment and management of PMSK pain,[31] it is still not clear who is best to deliver it. Canada is leading the way in biomedical pain research, however there is a need to provide insight into cost effective therapies while ensuring knowledge translation activities to provide further integration into practice.[30] It is believed that the transparent and

systematic approach of this research will aid in further development of effective programs to support exercise adherence in a PMSK pain population.

In summary, the intervention is promising and may provide a strategy to promote enhanced engagement with prescribed exercise in people with PMSK pain. Reinforcing physiotherapy treatment guidelines with the skill sets of other health professionals would enable the comprehensive, multidisciplinary care this population needs. Future research could explore the delivery of this intervention by allied health or non-clinical staff, such as fitness professionals, healthcare assistants or technical instructors.[31]

CONCLUSIONS

The Intervention Mapping approach was useful to guide the development and initial testing of an intervention to enhance exercise adherence in people with PMSK pain. There are many avenues to pursue in the next steps of this research agenda, however the intervention aligns well with current clinical directions in the treatment and management of PMSK pain.

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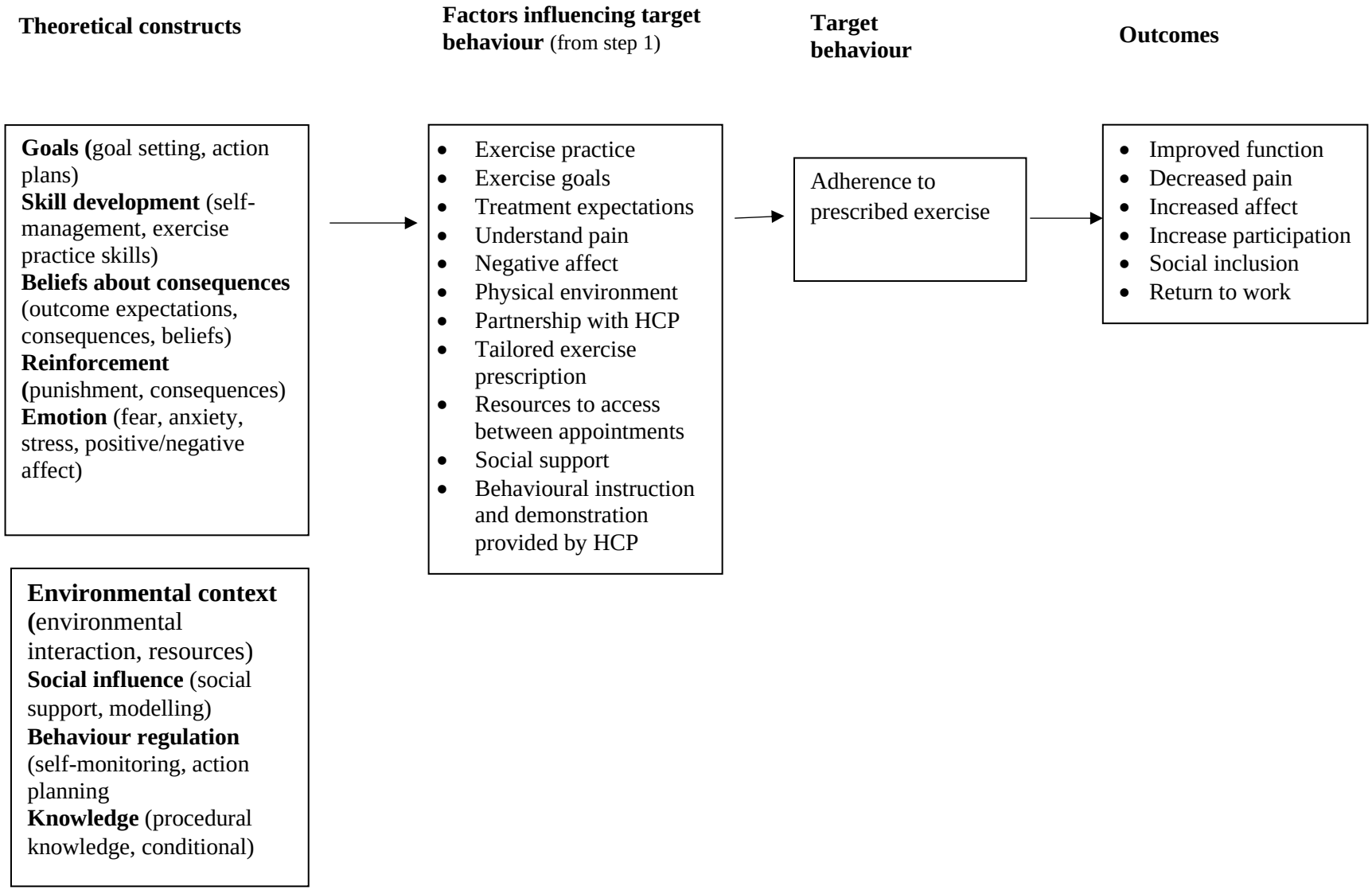
474 **Figure 1 Intervention Logic Model**



475 **Table 1 Matrix of Change Objectives for the Two Program Objectives**

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Program Objective One: Assist People with PMSK Pain to Enhance Self-management Techniques and Skills								
	Behavioural constructs *(from logic model)*							
Performance objective	Goal setting	Skill development	Emotional regulation	Outcome expectations	Self-monitoring	Action planning	Self-efficacy	Knowledge
Formulate individualised strategies to overcome barriers to exercise	Set goals of when, where and how to complete exercises	Teach how to do exercises in space available	Awareness of fear around reinjury or increased pain	Awareness and understanding of treatment and exercise outcomes	Monitor behaviours and lapse in adherence	Detailed plan about how goals will be achieved	Express ability/ confidence to complete exercises	Understand how to do exercises and where to access additional support
	External/environmental constructs *(from logic model)*							
	Physical prompts		Restructure physical environment		Tailoring		Social support	
	Add objects to the environment to facilitate exercise		Develop an accessible space to facilitate exercise		Tailor program to lifestyle and needs		Identify sources of support necessary to facilitate behaviour	
Program Objective Two: Provide Tailored and Accessible Instructions to Aid Adherence to a Prescribed Exercise Program								
	Behavioural constructs *(from logic model)*							
Performance objective	Knowledge		Skill development		Emotional regulation		Self-efficacy	
Have access to tailored prescription of exercise	Provide demonstration of proper exercise technique		Provide instruction and motivation on how to complete exercise correctly		Develop skills to manage emotions		Expresses confidence in completing exercises correctly	
	External/environmental determinants *(from logic model)*							
	Physical prompts/reminders		Social support/influence		Consequences		Tailoring	
	Initiate practice of exercises		Provide therapeutic support for patient		Provide expected outcomes of exercise		Provide opportunity to select more suitable exercises	

Table 2 Intervention Components

Motivational interviewing sessions				
	Session one	Session two	Session three	Session four
Aim	Assess expectations and level of understanding	Taking constructive steps towards behaviour change	Tackling unhelpful thoughts	Looking long term
Content	Building collaborative therapeutic relationships; establishing realistic treatment expectations; goal setting	Exploring current physical and social environment; goal setting	Exploring the relationship with pain and negative affect; goal setting	Barrier identification and long-term planning; planning for relapse; goal setting

Physitrack app					
Aim	Provide a tailored and personalised exercise prescription and additional social support				
Content	Written instruction	Video demonstration	Behavioural practice	Exercise reminders	Adherence tracker