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Contexts, behavioural mechanisms and outcomes to optimise therapeutic exercise prescription for persistent low back pain: a realist review

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Contributorship

All authors contributed to the research protocol, funding award, research results and interpretation. AB performed all searches and acted as second reviewer with LW for title and abstract and full text review. LW extracted data from included texts, engaged with patient and public involvement groups, developed initial context-mechanism-outcome configurations and programme theory. LW drafted the manuscript, and all authors have contributed to and reviewed the final manuscript.

Abstract

Objective:

Therapeutic exercises are a core treatment for low back pain (LBP), but it is uncertain how rehabilitative exercise facilitates change in outcomes. Realist reviews explore how the context (C) of certain settings or populations and underlying mechanisms (M) create intended or unintended outcomes (O). Our objective was to explore and understand the behavioural mechanisms by which therapeutic exercise creates change in outcomes of adherence, engagement and clinical outcomes for patients with LBP.

Methods:
This was a realist review reported following the Realist and Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) guidance. We developed initial programme theories, modified with input from a steering group (experts, n=5), stakeholder group (patients and clinicians, n=10) and a scoping search of the published literature (n=37). Subsequently, an information specialist designed and undertook an iterative search strategy, and we refined and tested CMO configurations.

Results:
Of 522 initial papers identified, 75 papers were included to modify and test CMO configurations. We found that the patient-clinician therapeutic consultation builds a foundation of trust and was associated with improved adherence, engagement and clinical outcomes, and that individualised exercise prescription increases motivation to adhere to exercise and thus also impacts clinical outcomes. Provision of support such as timely follow-up and supervision can further facilitate motivation and confidence to improve adherence to therapeutic exercises for LBP.

Conclusions:
Engagement in and adherence to therapeutic exercises for LBP, as well as clinical outcomes, may be optimised using mechanisms of trust, motivation, and confidence. These CMO configurations provide a deeper understanding of ways to optimise exercise prescription for patients with LBP.

WHAT IS ALREADY KNOWN:

- Therapeutic exercises are widely recommended in the management of persistent low back pain.
- There is strong evidence that rehabilitative exercise is moderately effective in comparison to no treatment in improving pain and physical function.
- Realist reviews answer the question of 'what works for whom, in what circumstances, and how'.

WHAT ARE THE NEW FINDINGS:

- Adherence to and clinical outcomes following therapeutic exercise prescription are optimised when the mechanisms of trust, motivation and confidence are utilised.
- The therapeutic alliance and development of rapport are foundations to the development of trust, facilitate holistic assessment and the identification of individual needs and beliefs.
- Exercise prescribed in such a way that it is tailored to the individual's goals, with personalised advice and education to reassure and build confidence increases motivation and adherence.
- Timely follow-up, perceived benefit and support from peers, and supervision can further facilitate motivation to continue to adhere to exercise prescription, positively impacting clinical outcomes.

Contexts, behavioural mechanisms and outcomes to optimise therapeutic exercise prescription for persistent low back pain: a realist review

INTRODUCTION

Low back pain (LBP) is the leading cause of disability worldwide,(1,2) with more than 540 million people experiencing LBP at any one time.(3) Persistent LBP is a multifactorial condition with underpinning mechanism(s) that can vary for each individual, and is defined as LBP lasting more than three months.(3) Exercise is a core recommended treatment for persistent LBP in international guidelines.(4–6) However, exercise has been shown to have, at best, small to moderate effects on outcomes such as pain and physical function when compared to non-exercise controls. (7)

It is recommended that randomised controlled trials (RCTs) comparing exercise interventions versus other treatments use reporting checklists such as the Consensus on Exercise Reporting Template (CERT)(8) and the Template for Intervention Description and Replication (TIDieR).(9) Despite this, many RCTs are still incompletely reported,(10,11) and the rationale for how the prescribed exercise intervention is anticipated to 'work' is poorly described. (12,13) The specified treatment targets of prescribed exercise for LBP are rarely the primary outcome of these RCTs, a potential explanation for the modest effect sizes reported.(13) RCTs which do not include process evaluations and conventional systematic reviews are seldom designed to explain why an intervention 'works', or to identify the most important components and mechanisms underpinning the treatment effect.(14)

Realist methods aim to provide understanding about the fundamental components that render an intervention successful (14) and can enhance the evidence base. Interventions trigger certain mechanisms (M), according to the characteristics and circumstances of the participants (contexts) (C), leading to a variety of outcomes (O).(14,15) In realist research, causal connections are established by considering "CMO-configurations" (CMOcs). These CMOcs are, therefore, better able to explain detail and recognise the different mechanisms and contextual factors that may be linked to an outcome, compared to conventional systematic reviews.(14) This detail may help researchers and clinicians to better understand an intervention and the contextual factors needed to produce certain outcomes.

Therapeutic exercise has been proposed to reduce LBP through neuromuscular, behavioural, psychosocial, neurophysiological, cardiometabolic, or tissue healing mechanisms.(16) However, it is unclear how these mechanisms are triggered, whether all are at play in similar contexts and proportions, or whether certain contexts favour activation of different mechanisms. It is further unknown whether each of these alternate mechanisms leads to a different outcome of importance. A core outcome set for RCTs of LBP was agreed in 2019, including pain, physical function and quality of life.(17) We did not specify what outcomes of importance for people with persistent LBP were when this review began. To date, mediation analyses of exercise RCTs have found supporting evidence for psychosocial factors to mediate a change in outcomes such as pain and physical function,(18–20) suggesting that this may be an important area to focus on. Increasingly, the importance of contextual factors such as the therapeutic alliance, practitioner and patient beliefs, and other non-specific effects is recognised. However, limited value has traditionally been placed on these components. Their importance has been highlighted (21,22) but it remains unknown how much they contribute to changes in outcomes of importance.

The aim of this research was to understand how therapeutic exercise prescription creates change in outcomes of adherence, engagement and clinical outcomes for those with persistent LBP. The research questions for the review were:

a. How does therapeutic exercise prescription create change in outcomes of adherence, engagement, and clinical outcomes for patients with persistent LBP?
b. What are the key behavioural mechanisms of exercise prescription?
c. Under what contexts is exercise prescription optimised?

METHODS

Study Design

This realist review followed the stages described by Pawson, (14) including i) articulating key initial programme theories, ii) searching for relevant evidence, ii) appraising quality of evidence, iv) extracting the data, and v) synthesising evidence. We have structured the methods to reflect the two key phases of the realist review: the development of programme theories, and the testing and refinement of initial theories. A full protocol was published (CRD42017072023) and the results are reported according to the Realist and Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES)(23,24) guidance (see attached). In this paper, programme theory refers to the overarching theory or understanding of how therapeutic exercise prescription creates change in outcomes for those with LBP.

Phase 1: Programme theory development

Initial Theory Development

An initial programme theory was developed using three steps: 1) a logic model was developed as the output of a systematic review and international consensus workshop as part of the lead author's (LW) PhD program.(25) 2) An initial scoping search was undertaken by the team's information specialist (AB) to identify key papers to direct the search strategy. This search used the key terms of 'low back pain', 'exercise' and 'theory' and identified 20 candidate papers. A further 17 papers were added by the steering committee for review using their expert knowledge of the available literature. 3) Stakeholder group meetings included patients with lived experience of LBP, exercise prescribers (physiotherapists and personal trainers), and a behaviour change expert (see protocol for more information (26)). The author team informed the development of the research protocol, funding application and met quarterly to refine and discuss the research process and findings.

Equity, Diversity and Inclusion

The stakeholder group was recruited using advertisements through the local Patient and Public Involvement and Engagement groups, physiotherapy department, and approaching known experts in the field of chronic pain. Only four female patient members responded to the advertisements. The clinician respondents were mixed equally between genders. The author team was predominantly female with one male realist expert.

Identification and inclusion of studies

Search Processes

An electronic search was conducted on the 15 August 2022 of Ovid MEDLINE, Ovid PsycInfo, and Ovid Embase. The search strategy was developed and performed by the information specialist (AB). Keywords and controlled language terms were adapted to each database for the terms *exercise prescription, therapeutic alliance*, and *back pain* (see supplement for search strategies used) based on the initial programme theory. Two steps were performed in the search strategy (see Supplement 1).

Data Selection

Based on the initial programme theory, studies were included that focussed on *the therapeutic alliance*, *prescribed exercise for persistent LBP*, the *patient's perspective* and were published in English. Based on discussions with patients, and the results of our scoping search, we focussed our inclusion on studies exploring behavioural and/ or psychosocial changes. All titles and abstracts and full-text studies were screened by two reviewers, and where disagreement occurred, discussion mediated final inclusion. All potentially relevant full texts were obtained and reasons for exclusion were documented. Confirmation of full text selection was tested on a random sample of 10% of excluded studies with three members of the steering group, prior to proceeding with data extraction.

Quality Appraisal and Data extraction

Realist syntheses employ an approach to quality assessment that prioritises relevance alongside rigour and richness.(27) Studies were rated for relevance, richness and rigour on a five-point scale (where: 1 = none whatsoever, 2 = poor, 3 = fair, 4 = good, 5 = exceptional) resulting in three assessments as seen in Supplement 2.(27–29) Studies were prioritised but no studies were excluded based on these assessments.

Data extraction was undertaken by one author using a table to document: author, year, country, aim, study design, participant characteristics, outcome measures. CERT (8) components were extracted as per supplement 5. Data were sought that substantiated, refined, or refuted the programme theories and described contextual characteristics. Data were extracted to explain contexts (e.g., settings), mechanisms (e.g., fear of movement) and outcomes (e.g., pain) and their influence on the CMOcs recorded through annotations. Relevant material was highlighted, labelled, and recorded using PDF annotation (Adobe Acrobat 2023), Microsoft Word and Excel (Microsoft 365) documents. Two reviewers pilot tested the data extraction table (LW and AB) with 10% of studies. Discrepancies were discussed and resolved before proceeding with data extraction from the remaining studies. Coding themes were developed using the pre-existing logic model and stakeholder engagement, namely therapeutic consultation, the exercise prescription, and follow-up/ monitoring.

Developing and Refining the Initial Programme Theory

Data were tabulated and synthesised for all included studies. A narrative approach was used to synthesise data using a data matrix.(24) One reviewer familiarised themselves with the results of included studies, systematically and comprehensively assessing each study's results, highlighting important study characteristics and findings. The data coding and mapping was checked and discussed with a further reviewer, and discrepancies discussed with the author team. Preliminary mapping was discussed with the stakeholder and author team. The data matrix documented CMOcs

under each of three key themes: therapeutic consultation, exercise prescription components, and follow-up and monitoring. Once data were extracted and cleaned for consistency, they were synthesised according to similarities within these categories and to the three identified outcome types, namely adherence, engagement and patient reported outcomes. We used these terms broadly, as reported in the literature and did not attempt to place meaning on them beyond what the text reported.

Phase 2: Testing the Theory

Testing Process Undertaken

The refined CMOcs were presented to both author and stakeholder groups for further input, modification, and refinement. We returned to the initial list of excluded papers for studies that might contain evidence to enable further exploration of components of the programme theory (for example a study may have been initially excluded for focusing on therapeutic alliance in a non-LBP population but subsequently included because the therapeutic alliance theory extends beyond LBP-specific populations). We also revisited the initial scoping review studies included in the programme theory development phase and checked the citations of key studies. (30–32) The refined CMOcs were then tested with quantitative and qualitative evidence, as well as identified theory to support or refute the statements. For quantitative data, we extracted the overall certainty of results where synthesis had incorporated Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework recommendations.(33) We extracted meta-analysed between-group mean differences or odds ratios (with 95% confidence intervals (CIs) or credible intervals (CrIs) as reported) or single study data as available. The final programme theory used graphical presentation to illustrate the chain of reasoning underpinning how components of therapeutic exercise produce mechanisms that lead to outcomes and impacts.(34) The stakeholder and author groups were involved at key stages to assist with interpreting and analysing the results.

Confidence in results

We assigned an overall assessment of confidence in each of the CMOcs based on the rigour (methodological limitations), relevance, coherence and adequacy assessments of the individual and summative studies underpinning each statement where possible using the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) series. (35–40) The GRADE-CERQual system criteria are listed in Supplement 3.

Changes to initial protocol

The initial research questions were refined to reflect a stronger realist perspective and to emphasise therapeutic exercise *prescription*, rather than exercise more generally. These changes were agreed by the author team. The GRADE-CERQUAL grading system was applied to each CMOc.

RESULTS

Search Results

A total of 522 unique papers were found with the initial systematic search. Confirmation of full-text exclusion was performed with 45 full-text papers, resulting in two papers recategorized as included (96% agreement). A total of 42 papers were included after screening for the programme theory development (see Figure 1). An additional 33 papers were added for theory testing (secondary searching (n=10), reference searching (n=6), and other methods (recommended by experts) (n=17)).

Included Studies

Twenty-two of the 75 included studies comprised qualitative research designs [12 patient perspective;(31,41–51) 5 physiotherapist perspective;(52–56) 5 mixed perspectives (57–61)], followed by quantitative designs (n=15) [longitudinal cohort studies n=11,(22,62–71) secondary analysis of randomised controlled trials n=4 (72–75)), randomised controlled trials (n=15)(76–90), systematic reviews (n=15)(21,32,47,91–102), mixed methods (n=3)(30,103,104), commentary (n=2)(105,106), case reports (n=2)(107,108) and narrative reviews (n=1)(109). See Supplement 4 for details of included studies and their quality appraisal. Data were extracted regarding exercise characteristics from 16 reports (15 studies) (See Supplement 5).

Data Synthesis: Building of Context-Mechanism-Outcome configurations.

The programme theory (see Figure 2) explains how exercise prescription is optimally delivered by considering therapeutic consultation, specific exercise prescription components and the provision of support through follow-up and monitoring. Therapeutic consultation was chosen as a more comprehensive term to encompass the sub-themes of include 'rapport', 'holistic assessment' and 'therapeutic alliance'. Three different key outcomes were grouped: engagement with exercise (including participation), adherence to exercise, and clinically important outcomes (including patient reported outcomes). For more detail regarding the data extraction and CMOc creation please see Supplement 6&7.

Mechanisms Associated with Exercise Adherence, Engagement, and Improved Outcomes

The key mechanisms identified underpinning change in outcomes related to exercise prescription were trust, motivation, and confidence.

Trust as a Mechanism

Trust emerged as a mechanism from 27 well-conducted studies (22,31,32,41,48,50–52,54,56,58,62,65,67,70,74,90,93,95,96,98,100,101,103,113,116,117) and was identified as a key mechanism to all identified outcomes (adherence, engagement, and clinical outcomes). Consistently high confidence underpinned the CMOcs as seen in Table 1, with moderate confidence in only three of the ten CMOcs. Trust is a component of the interpersonal bond, which is part of the therapeutic alliance. (118–120) Although few quantitative studies measured trust as a component of the therapeutic alliance (22,62,67,70,115) we found frequent reference to it, particularly within the qualitative studies(46,48,51,54,56,113).

Both the development and maintenance of trust were impacted by contexts and mechanisms related to communication, education and collaboration through individualised assessment and management. The development of trust was initially facilitated by the clinician's ability to develop rapport through communication skills, which enabled individualised holistic assessment and the provision of "specific explanations" to "reassure patients" and "win their trust". Trust was further

developed through collaboration which enabled individualised prescription of exercise. Time was seen as a key enabler to the development of trust, by allowing the development of the therapeutic alliance using holistic assessment and supervision, and patients felt their trust was validated when they had more opportunities for follow-up with the clinician.

Table 1: Summary of the context-mechanism-outcome configurations for trust as a key mechanism of exercise

Subthemes of the Mechanism	**Context Mechanism Outcome Configurations**	**Person related to**	**Confidence* in findings**
Win/ Build / Develop Trust	When clinicians and patients first meet, they develop a rapport (C)through use of a communication style (M)which establishes their initial therapeutic relationship (O)(46,48,51,56,95,96,113)	Clinician and patients	High confidence
	When rapport is established within the therapeutic relationship (C)there is a foundation from which to build trust (M) and the clinician can explore and understand the patients' beliefs and fears (O)(46,54–56,61,113,121)	Clinician	Moderate confidence
	When a clinician provides a holistic assessment (C) they build trust in the therapeutic relationship (M) as the patient feels heard and understood as a person (O) (43,44,47,48,54,56,60,102,103,122)	Clinician	High confidence
	When the clinician provides specific explanations tailored to the individual's beliefs and fears (C) they will build trust in the therapeutic relationship (M) and this will provide reassurance to the patient (O)(21,49,55,57,62,92,96,113)	Clinician	High confidence
	When a clinician provides individualised reassurance-(C) using well-developed communication skills (M) this will reconcile unhelpful beliefs of the patient (O) (43,44,47–49,54,93,101,113)	Clinician	High confidence
	When the clinician can reconcile the patient's unhelpful beliefs (C) the physiotherapist will win trust (M) and the patient is more likely to engage with therapy (O) which will result in improved outcomes (O) (22,43,50,51,54,62,66,70,74,75,81,84,90,93,96,100,101,123)	Clinician and Patient	Moderate confidence
Maintain Trust	When there is facilitated disclosure in the therapeutic relationship-(C) this allows opportunity to reconcile unhelpful patient beliefs (M) and will lead to enhanced adherence (O) (50,54,59)	Clinician and patient	High confidence
	When there is collaboration in the therapeutic relationship(C) the development of trust occurs (M) and leads to an individualised exercise prescription (M)which will improve adherence (O) (43,45,46,53,54,56–58,78,95,100,101,103,109)	Clinician and patient	High confidence
	When a clinician prescribes a holistic treatment plan (C) that is individualised to the patient (M) the patient's adherence is likely to be increased (O)(45,47,53,63,75,95,101)	Clinician and patient	Moderate confidence
	When a clinician provides regular feedback (C)then trust is facilitated through the development and maintenance of the therapeutic alliance (M) which will in turn support further engagement with exercise therapy (O) (51,61,113)	Clinician	High confidence

*confidence derived by CERQual assessment (see Supplement 5)

Motivation as a Mechanism

Motivation was a key mechanism underpinning engagement and adherence to exercise prescription in 13 studies. (31,32,42,48,49,58,59,78,79,92,93,99,113) It appears that motivation to engage and adhere with exercise prescription comprised three main subthemes of motivation that could impact the CMOcs: a *feeling of support*, *individualised assessment and prescription*, and the *perceived benefit* (See Table 2). These CMOcs were underpinned by evidence; most at a high confidence level, two CMOcs with moderate confidence and one CMOc with low confidence. Motivation as a mechanism relied on the presence of an ongoing positive therapeutic relationship, holistic assessment, and individualised treatment plan. When these contexts were in place, the patient would feel supported, which increased motivation and allowed them to change their established behaviours and engage with self-management strategies.(48) Both the feeling of support and individualised assessment required clinician skill to facilitate the motivation.(48,61,103) Further, the perceived competence (confidence) of the clinician appears to influence the patient's motivation which can impact clinical outcomes.(63) Perceived benefit relied on the patient's perception of improvement, enjoyment, and safety to facilitate motivation and could act as a barrier or facilitator to the mechanism of motivation, with impact on resultant engagement and adherence.

Table 2: Summary of the context-mechanism-outcome configurations for motivation as a key mechanism of exercise

Subthemes of the Mechanism	**Context Mechanism Outcome Configurations**	**Person related to**	**Overall Confidence***
Feeling of Support	When the clinician and patient develop a positive therapeutic relationship built on trust (C) this leads to collaboration (M) which allows the patient to feel supported (O)(43,54,69)	Clinician and patient	High confidence
	When the clinician and patient develop a positive therapeutic relationship (C) the patient feels supported (M) to engage with treatment (O)(48,51,54,92,113)	Clinician and patient	High confidence
	When the patient feels supported (C) they feel motivated (M) to continue to self-manage (O) (48,61,103)	Patient	Moderate confidence
	When the clinician puts a collaborative plan in place (C) the patient feels supported (M) and is more likely to perform the exercises (O)(31,42,48,49,58,61,65,69)	Clinician	High confidence
	When the clinician allocates timely monitoring and follow-up(C) this increases the patient's motivation to perform the exercises (M) which increases adherence (O)(31,42,48,49,57,58,61,95)	Clinician	High confidence
	When the clinician allocates timely monitoring and follow-up(C) this motivates patients (M) to change established habits (O)(31,42,48,49,58,61,124)	Clinician	High confidence
	When a clinician provides individualised support to help the patient fit the exercise into their daily life	Clinician	High confidence

	(C) they will be more motivated to routinely prioritise the exercise (M) which will increase their adherence (O)(31,48,49,54,56–58,63,65,73,102,113,124)		
	When a clinician undertakes a holistic assessment (C) then individual goals can be assessed and agreed-(M)and clinicians are more likely to recommend a group setting with similar interests/ goals (O)(48,54,56,61,92,93,102,103,113)	Clinician	High confidence
	When members of a therapeutic exercise group have similar interests and or goals (C) this provides social support to the patient (M) and there is a sense of accountability and commitment to the group (M) which increases motivation to adhere to the exercise prescription (O) (76,80,99,102)	Clinician/Patient	High confidence
Individualised assessment and explanations	When a positive therapeutic trusting relationship has been developed between patient and clinician (C)then a holistic assessment can take place (M) for individual needs identified (O)(48,54,56,61,103,113)	Clinician /Patient	Moderate confidence
	When the patient's individual needs are identified and there is an individualised prescription of exercise (C) and the purpose of the exercise program is communicated to the patient in understandable terms(M) then they are motivated to engage with exercise (O)(31,45,48,49,54,56,57,99,103,109,113)	Clinician	High confidence
	When the clinician provides an explanation of the patient's clinical condition and justifiable treatment options (C) which is understandable to the patient (M) then they can partake in individualised goal setting (O)(31,47–49,54,57,93,109)	Clinician	High confidence
	When individualised goal setting occurs with clinician direction (C) this can facilitate the patient's motivation (M) which will increase the patient's engagement and adherence and outcomes (O)(32,56,58,63,80,83,93,99)	Clinician	High confidence
Perceived benefit	When patients do their prescribed exercises, and they recognise an improvement in their condition (immediate or short-term) (C) this will increase their motivation (M) to adhere to the exercises (O)(31,42,50,53,66,113)	Patient	High confidence
	When patients enjoy doing their exercise (C) they are more motivated to routinely prioritise (M) which leads to increased engagement and adherence (O)(46,48,53)	Patient	High confidence
	However, if patients perceive that the exercise is too difficult to complete or patients do not enjoy	Patient	High confidence

	doing them (C)they will be less motivated to perform (M) and thus less adherent to the prescription (O)(22,31,42,48,59,61,65,95,102)		
	When patients do their exercises and experience an increase in pain during or after performing the exercises (C) they may be less motivated to do the exercise (M) and thus become non-adherent (O)(31,42,66)	Patient	Low confidence
	If clinicians prescribe exercises in a space wherein patients feel safe (C) they will have increased motivation (M) to perform exercise and adhere (O)(22,43,58,92)	Clinician	High confidence

*confidence derived by CERQual assessment (see Supplement 5)

Confidence as a Mechanism

Confidence featured as a mechanism only in the outcome of adherence to exercise and was mentioned in eight studies.(31,42,46,65,68,69,92,113) Six CMOcs were created all with high underpinning confidence (see Table 3). Confidence appeared to be linked to either the clinician or the patient. We included the terms of mastery and self-efficacy under the umbrella term of confidence. There was evidence that the clinician's confidence in managing LBP, and their perceived expertise and credibility, impacted the provision of information, reassurance, and individualised prescription of exercise, which influenced the development and maintenance of positive therapeutic alliance.(68,72,105,125) This was both in part due to patients perceiving greater attention from the clinicians, as well as the reinforcement of trust through patient's perceptions of clinicians being highly credible. Clinicians who were more confident, and thus more credible, due to greater experience or knowledge were able to provide tailored delivery of education and treatment (exercise prescription), as well as detailed goal planning to facilitate longer-term management, which impacted on patient's confidence and mastery in performing the prescribed exercises. Patient confidence was further facilitated by familiarity with the exercise environment, therapeutic exercise prescription or physiotherapy treatment more generally.(43,93,102) Support was considered to include aspects of follow-up, monitoring, supervision, education, and reassurance. The success of these supportive strategies was tied to the knowledge and clinical experience of the clinician delivering these components, as well as the patient's self-reported confidence in managing LBP.

Table 3: Summary of the context-mechanism-outcome configurations for confidence as a key mechanism of exercise

Subthemes of the Mechanism	**Context Mechanism Outcome Configurations**	**Person related to**	**Overall Confidence***
Previous Positive Experience	When a patient has had a previous positive experience with exercise or physiotherapy (C) they have an increased familiarity and confidence with exercise environment (M) which improves engagement (O) (22,55,92,93,102)	Patient	High confidence
	When a patient is fearful of performing an exercise (C) then they have opportunity to increase their confidence through practice (M) which will increase their engagement and	Patient	High confidence

	(31,43,92,93,95,102,109)		
Education	When patients feel that the prescribed exercise are aligned to their goals(C) because the connections between them were well explained (M) then patients had increased confidence to perform the exercises (O)(42,43,48,54,57,95,109)	Patient	High confidence
Supervision	When patients have opportunity to perform exercises with a clinician present (C) then there is opportunity for individual correction (M)and when the clinician provides support and reassurance (M) led to increased confidence of the patient to perform the exercise (O)(31,32,42,92,99,109,113)	Patient	High confidence
	When clinicians supervise patients performing prescribed exercise, and this leads to correction and progression of exercises (C) this increases the patient's confidence in performing the exercise (M) which increases their adherence and can lead to improved outcomes (O)(31,42–44,87,92,113)	Clinician	High confidence
Credibility	When clinicians are more confident in prescribing exercise within a biopsychosocial model, they are perceived to be more credible (C) which increases the confidence of the patient (M) and can impact their adherence (O)(51,57,68,72)	Clinician and Patient	High confidence

*confidence derived by CERQual assessment (see Supplement 6)

Stakeholder Group Involvement

The stakeholder group met on four occasions (range n=4-8), discussing and considering initial versions and processes of the programme theory and the CMOcs. For example, in discussions about holistic assessment, stakeholders felt that this needed to be individualised. Points were raised regarding co-design and how to define enjoyment – linking these back to the individual and their specific needs. Similar discussions refined the use of 'regular' follow-up which is routinely found in the literature, and the word 'timely' was agreed to replace this.

DISCUSSION

Summary of findings

This realist review found that the development and maintenance of trust, motivation and confidence are the key mechanisms involved in therapeutic exercise prescription bringing about changes for those with persistent LBP. These mechanisms impact the engagement, adherence to exercise and clinically important outcomes. Trust appeared to underpin the therapeutic exercise prescription as a marker and measure of the therapeutic alliance and was necessary for the development of confidence and motivation. A holistic assessment, initial development of rapport and therapeutic alliance, and consideration of the individual's previous experiences was important to facilitate a trusting relationship. When trust was established, an individualised exercise prescription was possible, and when this was prescribed in a way that was perceived to be beneficial, enjoyable, and tailored to the individual's preferences (both in difficulty, setting and exercise type) then motivation was likely to be enhanced. When clinicians provide tailored education and reassurance, supervision of exercises, timely follow-up, and peer support (when necessary), this facilitates confidence, motivation to engage and adhere to the exercise prescription. Further, clinician confidence (and

credibility) can impact the support provided, development of a trusting relationship, as well as the patient's motivation through individualised exercise prescription.

Comparison with Existing Literature: Mechanisms of exercise prescription

Trust as Mechanism:

Within this review, the emergent key themes highlighted the importance of the therapeutic alliance for successful exercise prescription and our findings are consistent with recent literature. Other realist reviews have similarly highlighted the importance of trusting relationships in different populations.(126) The importance of trusting, therapeutic relationships as a platform from which a co-designed, individualised treatment can grow through use of collaboration, has been previously emphasised in other health service settings.(127–129) In patient-centred care, enhanced communication skills are key, resulting in proximal outcomes of improved trust and recall of clinician advice, with temporal consequences of improved health outcomes.(130) Recently, mechanisms enhancing the development of the therapeutic alliance in health care have been explored. (131,132) However, the relationship is complex, and requires multiple simultaneous components to be met for a positive alliance to be established.(30) Some of the features that predict positive therapeutic alliance (namely communication, individualisation, collaborative goal setting, relationship building and empathy, and patient education) were identified within this review, highlighting the importance of the therapeutic alliance for successful therapeutic exercise prescription.(30) In the field of LBP, the therapeutic relationship is recognised as an important component of treatment, however, it remains poorly operationalised.(52,101) The therapeutic alliance is a dynamic construct, influenced by both the person seeking care and the clinician, moderated by communication and time.(130,131) The importance of addressing the 'psychosocial' elements of their pain experience have been documented in the literature for several decades,(133–135) yet, despite this, many clinicians report feeling inadequately trained and lack confidence to manage psychosocial barriers to recovery, even though they have undergone dedicated training.(122,136,137) There remains a need for clinicians to understand how best to define the therapeutic alliance within musculoskeletal consultations, and further, to operationalise it into clinical practice.(52)

Motivation as a Mechanism

This review found that motivation was facilitated by the specific exercise prescription components, including, individualised prescription, perceived benefit, and enjoyment of exercise. Motivation, and the contexts of support and perceived benefit have previously been described in a realist review of exercise for older adults with dementia.(138) However, in that study, the focus was on the carer, their perceived benefit and the carer's provision of support to enable participation in exercise, in contrast to this study which focussed on individuals with persistent LBP. Individualised exercise prescription, delivered alongside a psychological intervention (such as cognitive behavioural therapy) has been shown to be more effective than passive or active controls, with statistically significant effects on pain in the short term. (139) This supports the findings of this review and suggests clinicians should consider individualised exercise prescription wherever possible.

Motivation may be considered within many different frameworks and theories. One is the Self-Determination Theory framework, wherein three motivational types exist: autonomous (most self-determined), controlled, and amotivation (least self-determined).(63,140) Within this theory, they posit that when individuals experience satisfaction with their basic psychological needs (autonomy,

competence and relatedness) then they are able to foster autonomous motivation.(140) Motivation can be internally or externally driven and can be catalysed by different social environments (or contexts).(140) For example, long-term motivation can be facilitated within the therapeutic setting through co-designed, goal relevant exercise prescription that is enjoyable. Goal setting theory is another framework that may enhance motivation, through the premise that conscious goals affect action.(141) Exercise interventions paired with motivational strategy have been shown to improve long-term adherence and outcomes at 5-years follow-up, suggesting this may be an important consideration for clinicians to include in treatment. (142) Another useful theory is Self-Efficacy. (143) A mediation analysis of an observational study demonstrated that perceived mastery influenced motivation, which impacted outcomes over a 6-week period.(63) However, there are no long-term studies of perceived mastery and outcomes beyond this time period. Perceived mastery may be a necessary context to trigger motivation, thus, the presence of both trust and mastery activates motivation.

Confidence as a Mechanism

In this review we found that clinician confidence was related to support provision, education, individualisation of care and exercise prescription. Cognitive functional therapy is one example of an individualised LBP treatment, coupled with exercise and education to support an individual to return to function.(80,144) A recent evaluation of a cognitive functional therapy training program (>16 hours training) found that clinicians reported improved confidence in using new assessment styles, communication strategies and functional approaches, with greater appreciation of the therapeutic alliance.(145) Importantly, a mediation analysis of one cognitive functional therapy trial demonstrated that most of the effect was mediated through pain self-efficacy. (146) These results support the findings of this review, suggesting that patient self-efficacy (or belief in their own ability to get on with life despite the LBP) is an important component of exercise prescription.

Patient confidence appears to be directly linked to clinician confidence, through provision of support. Perceived self-efficacy is defined as “people’s judgement of their capabilities to organise and execute courses of action required to attain designated types of performances”.(147) It focusses less on the actual skills one has than with the judgements, or beliefs, of what one can do with the skills one has.(147) Self-efficacy is specific to situations, thus may relate to exercise or pain management, in contrast to self-esteem or self-confidence or locus of control (143) which are general characteristics of an individual.(148) The Self-Efficacy Theory was established by Bandura in 1977, as a component of Social Cognitive Theory.(143) This three-way reciprocal causation model suggests that the behaviour of a person, the characteristics of that person, and the environment within which the behaviour is performed, are constantly interacting. This theory suggests that people are motivated to perform behaviour that will produce desired outcomes, however, the behaviour is more reliant on mastery (efficacy expectations) which predict performance better than outcome expectations. (143,149) What has been less explored in terms of Self-Efficacy Theory is the notion of needing optimal physiological arousal to gain mastery, and this may be important when considering the impact of fear (often associated with LBP) which may interfere with or hinder the cognitive processing of information (such as exercise instructions).

Relationship of Outcomes

This review found many literature sources exploring the role of contexts and mechanisms of exercise prescription to enhance exercise adherence and engagement, with fewer studies exploring the contexts and mechanisms for exercise related to clinical outcomes. It may be that engagement and adherence are used interchangeably within the literature and encompass a wider umbrella term for adherence including compliance or concordance. However, our searches were constructed to retrieve items regardless of the specific use of these terms. Further, few quantitative studies explored the relationship between mechanisms and contexts and clinical outcomes. Although exercise adherence is poorly defined in studies of exercise for musculoskeletal pain (150), and poorly reported in RCTs (in a sample of 100 RCTs only 28% measured and reported adherence),(10) most of our included studies considered the contexts and mechanisms of exercise prescription relevant to adherence. However, although we know it is therapeutic to prescribe exercise for persistent LBP,(7) we do not know what the therapeutic dose is.(11) Other studies have identified predictors of adherence, and barriers and facilitators to adherence to exercise for LBP, (32,44,99,151,152) but few studies to date have explored the impact of adherence on clinical outcomes.(63) One study that has explored this relationship reported that competence perceptions and motivations may impact patient outcomes through their influence on rehabilitation adherence. (63)

Strengths and Limitations

Realist reviews and evaluations add depth of understanding regarding which interventions may work best for whom, and in what contexts, whilst also highlighting the active ingredients of interventions. This realist review, focused on exercise and LBP, used an iterative search strategy that was comprehensive and focussed on the psychosocial components relating to patient experience of exercise prescription. The large number of included studies, with different methodological perspectives and participant perspectives, adds strength to the review findings, and the addition of further studies is unlikely to change the conclusions of this review. The initial programme theories were developed with input from people with lived experience of LBP, clinicians prescribing exercise, behaviour change specialists, and published literature. However, this review did not explore biomedical, mechanical, or other physiological mechanisms of how exercise may impact LBP and relevant outcomes and thus may be limited in its conclusions. The aim of realist inquiry is to prioritise an overarching programme theory and not to explore each line of inquiry to exhaustion. The review sought to provide an overview of the literature and starting point for further realist inquiry and to stimulate this line of thinking regarding mechanisms and contexts within exercise for LBP, and how they might be applied within clinical practice and research.

Clinical and Research Implications

We identified possible mechanisms to support prescription of therapeutic exercise. Further research could explore how to better activate these mechanisms (of trust, motivation, and confidence) through adequate training and skills development of the clinicians. Future research is required to test whether these proposed mechanisms do mediate the effects of exercise through targeted exercise interventions and a priori specified mediation analyses. This review was not able to explore temporal relationships between the identified outcomes. Further research into the association between the outcomes of adherence, engagement, and clinical outcomes in those with persistent LBP is needed. To develop and harness the benefits of a strong therapeutic alliance, (67) clinicians

may wish to consider performing a holistic assessment to build and win the patient's trust, to co-design and individualise the exercise prescription around the patient's own goals, accounting for their previous experience, preferences, and available time to perform exercises. The ability to check in with patients, through timely follow-up to supervise or progress exercise may be restricted by service level factors, but where possible will facilitate the maintenance of trust and motivation. Not all clinicians, regardless of confidence or knowledge of LBP, have the service flexibility required to offer long-term follow up, or ongoing monitoring. This service constraint may act as a barrier for long-term adherence to exercise prescription.

CONCLUSIONS

Engagement with, adherence to, and outcomes following therapeutic exercise prescription might be optimised when the mechanisms of trust, motivation and confidence are activated. The therapeutic alliance and development of rapport are foundational to the development of trust, and facilitate holistic assessment, and identification of individual needs and beliefs. Exercise that is tailored to the individual's goals, with personalised advice and education to reassure and build confidence, increases motivation to adhere to exercise. Timely follow-up, the perception of benefit and support from peers and from supervision can further facilitate motivation to adhere to exercise prescription, and these positively impact clinical outcomes. Further research is required to explore the relationship between adherence and clinical outcomes, and how to implement and optimise these mechanisms in clinical practice.

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Legend

Figure 1: PRISMA flow diagram summarising the systematic search and included studies for programme theory development and testing.

Figure 2: Proposed programme theory of how therapeutic exercise prescription affects change in outcomes of importance for those with persistent LBP

In this figure, each theme of the programme theory is represented by a circle (therapeutic consultation is green, provision of support is orange and exercise specific considerations in blue) with sub-themes in boxes within. Where these circles intersect, the outcomes of adherence, engagement and clinical outcomes are optimised, and the mechanisms of trust, motivation, and confidence (in yellow) support the translation of the contexts into outcomes.