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Exercise Prescribing for Persistent Pain in Older Adults: Protocol for a Stepped-Wedge Implementation Trial

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Abstract

Structured exercise has strong guideline-level evidence as first-line management for common causes of persistent pain in older adults, yet audit and observational literature consistently documents a substantial gap between guideline recommendation and routine prescribing practice in this population. This protocol describes a stepped-wedge cluster randomised implementation trial evaluating a structured exercise-prescribing pathway, combining clinician training, decision support, and referral-pathway simplification, against usual care across six primary and community care clinic sites. Sites will cross over from control to intervention condition in a randomly allocated sequence over six time steps. The primary outcome is patient-reported pain interference at twelve months; secondary and process outcomes include physical function, exercise adherence, and clinic-level guideline-concordant prescribing rate. This protocol is registered prospectively and reports the planned design, outcomes, and analysis approach in advance of trial data collection.

Keywords: Persistent pain; Older adults; Exercise prescribing; Implementation science; Stepped-wedge trial; Study protocol

Introduction

Persistent pain, most commonly musculoskeletal in origin, affects a substantial proportion of older adults and is consistently associated with reduced physical function, mood disturbance, and healthcare utilisation [1,2,3]. Assessment and measurement of pain in this population carries its own recognised challenges, including higher rates of cognitive impairment and communication difficulty that can lead to persistent pain being under-recognised and under-treated relative to younger populations [4]. Structured exercise has strong guideline-level evidence as first-line, non-pharmacological management for the most common causes of persistent pain in this population, including knee and hip osteoarthritis and chronic low back pain, with evidence quality summarised across multiple Cochrane overviews and comparative effectiveness reviews [5,6,7].

Despite this evidence base, audit and observational literature consistently documents a substantial gap between guideline recommendation and routine prescribing practice for older adults specifically, with adherence-support and referral-pathway barriers repeatedly identified as contributing factors distinct from the underlying exercise evidence itself [8,10,11]. Implementation science offers established frameworks and trial designs for closing exactly this kind of

evidence-to-practice gap in routine clinical settings, including the stepped-wedge cluster randomised design, which allows every participating site to eventually receive the intervention while preserving a controlled comparison [13,16].

This protocol describes a stepped-wedge cluster randomised implementation trial evaluating a structured exercise-prescribing pathway for persistent pain in older adults across primary and community care clinic sites, reporting the planned design, outcomes, and analysis approach in advance of trial data collection, consistent with prospective trial registration and reporting standards [23].

Study Design

This is a stepped-wedge cluster randomised implementation trial. Six primary and community care clinic sites will be randomly allocated to one of six sequential crossover time steps, at which point each site transitions from the control condition, usual-care exercise prescribing, to the intervention condition, a structured exercise-prescribing pathway. Once a site crosses over, it remains in the intervention condition for the remainder of the trial. This design was selected because it allows every participating site to eventually receive the intervention, addressing a common practical and ethical objection to withholding a guideline-supported intervention from control sites for the trial's full duration, while retaining a controlled, randomised comparison [14,16]. Figure 1 sets out the planned stepped-wedge design schematic.

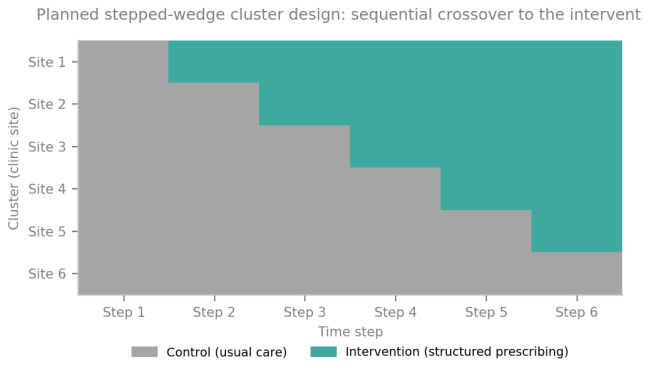

Figure 1: Planned stepped-wedge cluster design: six clinic sites are randomly allocated to sequential crossover time steps, transitioning from control (usual-care prescribing) to intervention (structured prescribing pathway) and remaining in the intervention condition thereafter.

Rationale for the implementation gap this trial addresses

The specific gap this trial targets is well documented in the existing observational and audit literature. Figure 2 sets out reported guideline-to-practice gaps in exercise prescribing for older adults with persistent pain drawn from this literature, illustrating the scale of the gap the intervention pathway is designed to close.

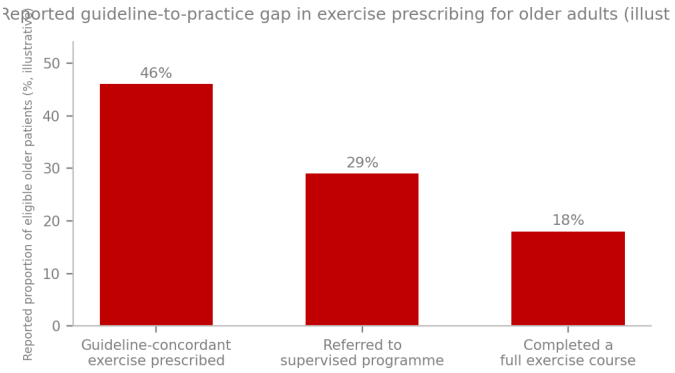

Figure 2: Reported guideline-to-practice gap in exercise prescribing for older adults with persistent pain, drawn from the cited audit and observational literature (illustrative synthesis, not a single pooled estimate) [8,9,10,11].

A cluster randomised trial of a rehabilitation programme integrating exercise, self-management, and active coping strategies for chronic knee pain found clinically meaningful benefit when such a structured programme was actually delivered, reinforcing that the evidence-to-practice gap, rather than the underlying exercise evidence, is the more proximate barrier this trial is designed to address [9,26].

Setting and Participants

The trial will be conducted across six primary and community care clinic sites serving adults aged 65 years and older presenting with persistent musculoskeletal pain of at least three months' duration, most commonly related to knee or hip osteoarthritis or chronic low back pain [27,28]. Eligible participants will be identified through routine clinical presentation at each participating site during both the control and intervention periods, consistent with the pragmatic, routine-care orientation of the stepped-wedge design [15]. Exclusion criteria will include an absolute contraindication to exercise, a diagnosis specifically requiring urgent surgical or oncological referral rather than exercise-based management, and inability to provide informed consent.

Intervention and Comparator

The intervention condition is a structured exercise-prescribing pathway combining clinician training on guideline-concordant exercise prescription, point-of-care decision support embedded in the clinical workflow, and a simplified, standardised referral pathway to supervised exercise programmes, informed by established implementation-science frameworks for designing and characterising behaviour-change interventions [21,22]. The comparator is usual care: exercise prescribing at the treating clinician's discretion without structured training, decision support, or referral-pathway simplification, reflecting current routine practice at each site prior to its scheduled crossover.

Outcomes

The primary outcome is patient-reported pain interference, assessed using the Brief Pain Inventory interference subscale, at twelve months from enrolment. Secondary outcomes include objectively assessed physical function using the Short Physical Performance Battery and self-reported exercise adherence, both assessed at six and twelve months. Process outcomes include clinic-level guideline-concordant exercise prescribing rate, tracked continuously across the trial period at each site, consistent with recommended implementation-outcome frameworks distinguishing clinical from implementation-specific endpoints [19,20]. Figure 3 sets out the planned outcome-assessment timeline, and Figure 4 sets out the planned primary, secondary, and process outcome measures.

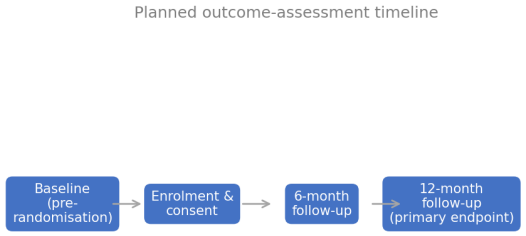

Figure 3: Planned outcome-assessment timeline: baseline assessment prior to randomisation, enrolment and consent, six-month interim follow-up, and twelve-month follow-up at which the primary endpoint is assessed.

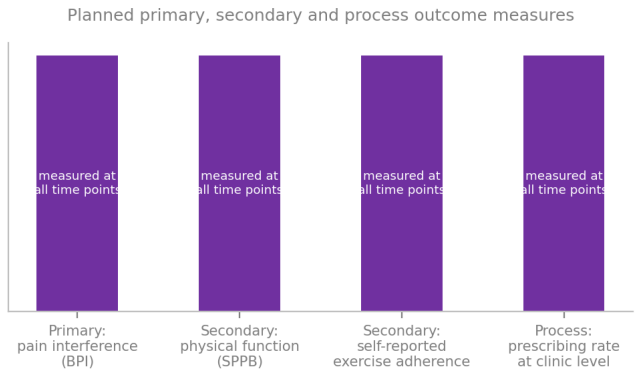

Figure 4: Planned primary (pain interference), secondary (physical function, exercise adherence), and process (clinic-level prescribing rate) outcome measures, each assessed at all specified time points.

Sample Size

Sample size for this stepped-wedge design will be calculated using methods specific to stepped-wedge and cluster randomised trials, which must account for both within-cluster correlation and the correlation structure introduced by the sequential crossover design, rather than standard parallel-group sample size formulae [17]. The final calculation will specify the assumed intracluster correlation coefficient, the anticipated effect size on the primary pain-interference outcome informed by the cited exercise-therapy trial literature, and the number of participants expected to be recruited per site per time step, following established unified approaches to stepped-wedge sample size calculation [17,18].

Randomisation and Blinding

The sequence in which the six clinic sites cross over from control to intervention condition will be determined by computer-generated random allocation, conducted independently of the trial's clinical and analysis teams. Given the nature of the intervention, a structured clinical prescribing pathway, blinding of participating clinicians and clinic staff to allocation status is not feasible once a site has crossed over; however, outcome assessors collecting patient-reported and physical performance outcomes will be kept blinded to each site's current allocation status where practicable, and statistical analysis will be conducted with the analyst blinded to site identity during the primary analysis, consistent with recommended stepped-wedge design and reporting standards [16,18].

Statistical Analysis Plan

The primary analysis will compare the primary outcome between control and intervention periods using a mixed-effects regression model appropriate to the stepped-wedge design, incorporating fixed effects for calendar time step and intervention condition and random effects for clinic site, following established stepped-wedge analytic guidance [16]. All analyses will follow the intention-to-treat principle at the level of site-period, and reporting will follow the pragmatic trial extension of the CONSORT statement given the trial's routine-care, implementation-focused orientation [24]. A pre-specified process evaluation, informed by an implementation-science framework for identifying contextual barriers and facilitators, will accompany the primary clinical analysis to help interpret variation in intervention effect across sites [21,25].

Trial Status and Registration

This protocol describes the planned design of a trial that has not yet begun recruitment at the time of this protocol's preparation. The trial will be prospectively registered prior to the enrolment of the first participant, and any subsequent protocol amendments will be documented and reported transparently, consistent with SPIRIT guidance for the reporting of clinical trial protocols [23].

Discussion

This protocol describes a stepped-wedge cluster randomised implementation trial addressing a well-documented, specific gap between strong guideline-level evidence for exercise in persistent pain management in older adults and routine prescribing practice [1,5,8]. The stepped-wedge design was selected specifically because it allows every participating site to eventually receive an intervention with strong pre-existing evidence, avoiding the ethical and practical objection of indefinitely withholding a guideline-supported pathway from control sites, while retaining the methodological rigour of a randomised, controlled comparison [14,16].

Anticipated significance of this trial lies in directly targeting implementation, rather than efficacy, as the primary research question, addressed through combining clinician training, decision support, and referral-pathway simplification, a combination informed by established implementation-science frameworks rather than assembled ad hoc [21,22]. If effective, this pathway would offer a replicable, exportable model for closing a well-documented evidence-to-practice gap that affects a large and growing population of older adults living with persistent pain [2,3,27].

Study limitations

As a protocol, this article does not yet report trial results, and several design limitations should be anticipated. The absence of clinician and site blinding to intervention status once crossover has occurred is an inherent limitation of the stepped-wedge design for this kind of prescribing-pathway intervention, and secular trends in prescribing practice occurring independently of the intervention could confound the time-step comparisons the stepped-wedge analysis relies on, a risk the planned mixed-effects analytic approach is specifically designed to address but cannot eliminate entirely [16,18].

Recommendations for future research

Should this trial demonstrate a meaningful effect on guideline-concordant prescribing and downstream patient-reported outcomes, future research priorities would include examining sustainability of the prescribing-pathway effect beyond the trial's twelve-month primary endpoint, and testing whether the same structured pathway, and its constituent training, decision-support, and referral-simplification components, generalises to persistent pain presentations beyond knee and hip osteoarthritis and chronic low back pain specifically [12,19,20].

Context, complexity, and anticipated implementation challenges

Implementation trials of this kind operate within genuinely complex clinical and organisational contexts, and taking account of this complexity explicitly, rather than treating the intervention as a simple, context-independent input, is increasingly recognised as important to both trial design and the eventual interpretation of its results [25]. Prior trials of structured, tailored exercise therapy in older adults with osteoarthritis and comorbidity have found meaningful clinical benefit when delivery was genuinely structured and individually tailored, reinforcing that the intervention pathway's specific design features, not simply the presence of any exercise recommendation, are likely to matter for this trial's eventual effect [26]. Broader epidemiological and clinical-management literature on knee and hip osteoarthritis, and on the pharmacological alternatives that structured exercise prescribing may help reduce reliance on, situates this trial's anticipated clinical and public-health relevance within the wider persistent-pain management literature this protocol has drawn on throughout [28,29,30].

Conclusion

This protocol describes a stepped-wedge cluster randomised implementation trial evaluating a structured exercise-prescribing pathway for persistent pain in older adults, designed specifically to close a well-documented gap between guideline recommendation and routine practice. The trial combines established implementation-science design principles with a pragmatic, routine-care evaluation approach, and its results, once available, are anticipated to inform how structured prescribing pathways of this kind might be more widely adopted across primary and community care settings serving older adults with persistent pain.

Implications for Sports Medicine Practice

For clinicians and service planners involved in persistent pain management for older adults, three practical points follow from this protocol. First, the well-documented gap between exercise-prescribing guidelines and routine practice for older adults is a genuine, addressable implementation problem distinct from any uncertainty in the underlying exercise evidence [5,8,10]. Second, structured, multi-component implementation pathways combining training, decision support, and referral simplification, rather than guideline dissemination alone, are likely necessary to close this gap in routine practice [12,21,22]. Third, services considering similar prescribing-pathway interventions should anticipate the value of building in a structured process evaluation alongside any clinical outcome evaluation, given how much context appears to shape implementation success in this literature [25].

Author Contributions

Ahlmquist L conceived the trial design and protocol, developed the statistical analysis plan outline, and drafted the manuscript. Featherstonhaugh R contributed the geriatric medicine and outcome-measure selection input and critically revised the manuscript for clinical content. Popovici-Manea A contributed the exercise-intervention design and physiotherapy delivery protocol and revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this protocol.

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This protocol received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors at the time of preparation.

Data Availability Statement

This is a study protocol; no trial data have yet been collected. The statistical analysis plan and de-identified trial dataset will be made available upon reasonable request following completion of the primary analysis, consistent with the trial's eventual data-sharing statement to be finalised prior to trial registration.

Acknowledgments

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Ethics Approval and Consent to Participate

This trial protocol will be submitted for approval to the relevant institutional research ethics committee at each participating site prior to the enrolment of any participant. Written informed consent will be obtained from all trial participants prior to enrolment. This article reports the planned protocol only and did not involve the collection of new participant data.

Search Strategy

The literature informing this protocol's background rationale and design was identified through targeted searches of MEDLINE, Embase, and the Cochrane Library, combined with manual forward and backward citation tracking from the foundational exercise-adherence and prescribing-gap literature, the stepped-wedge and cluster trial methodology literature, and the implementation-science framework literature, restricted to peer-reviewed studies and methodological guidance reported in English.