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STUDY PROTOCOL

REVISED Evidence-based exercise recommendations to improve functional mobility in older adults - A study protocol for living systematic review and meta-analysis

[version 2; peer review: 2 approved]

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Abstract

Background and objectives

This is a protocol for a living systematic review and meta-analysis.

This review will assess the effects of state-of-the-art exercise interventions designed to promote functional mobility. Therefore, after identifying all potential interventions, we will use the F.I.T.T. principles (frequency, intensity, time, type) as well as the physical and health status of the participants as moderators to analyse the mechanisms for the positive benefits of exercise interventions.

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The main research questions are:

Which exercise types are most beneficial for improving functional mobility in various populations of older adults?

Which physical exercise characteristics in terms of frequency, intensity, time and duration will achieve the greatest benefit in terms of the defined outcomes, i.e, the functional mobility of older adults?

Methods

The systematic literature research according to PRISMA guidelines will search databases like MEDLINE, APA Psych-Info and Web of Science.

Inclusion criteria are: healthy older people ≥ 50 years, randomized-controlled trials including exercise intervention and a walking or mobility assessments (eg., TUG, SPPB) as an outcome measure. A preliminary search revealed more than 33,000 hits that will be screened by pairs of independent reviewers. The results will be summarized according to the effects regarding functional mobility and potential dose-response relations via respective meta-analysis.

Conclusion

The systematic review will comprise the knowledge of the existing literature with regards to the effects of the physical activity interventions compared to an active or inactive control group.

We will summarize the effects with respect to the F.I.T.T.. They provide a foundation for structuring an optimal exercise training program. If possible, we will also compare interventions from the different categories (eg. cardiovascular, resistance, motor-coordinative, multicomponent or mind-body exercise) as a network analysis and report the influence of moderator variables. Based on the results evidence-based guidelines following GRADE for physical exercise interventions to improve functional mobility in older adults will be provided.

Keywords
functional mobility, older adults, physical training interventions, evidence-based exercise

This article is included in the COST Actions gateway.

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Any reports and responses or comments on the article can be found at the end of the article.

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REVISED **Amendments from Version 1**

First, following the suggestions of Reviewer 1 and Reviewer 2, we have revised the manuscript to ensure a clearer distinction between "mobility" and "functional mobility" throughout the text. We have synchronized these terms to provide consistency and enhance the clarity of the manuscript. Specifically, we have included additional explanations to define each term in the introduction and methods sections, ensuring that the reader can easily distinguish between the two concepts and understand their relevance to the study.

In response to Reviewer 1's request, we have expanded the section on the FITT principles (Frequency, Intensity, Time, and Type) to provide more detailed information. This includes a discussion on how these principles were applied in the included interventions and how they relate to mobility outcomes.

Regarding the methods section, we have revised and clarified several aspects to align with the study language used in the included studies. This includes specifying the age range of participants, detailing the types of interventions, and clearly categorizing the outcome measures assessed across studies. Additionally, we have addressed the risk of bias assessment by explaining the tools and criteria used to evaluate study quality.

Finally, we have revised the method of the network meta-analysis to provide a more comprehensive explanation of the methodology, including how we handled missing data and the statistical models used. These revisions should provide a clearer, more robust explanation of our approach and improve the overall clarity and rigor of the manuscript.

We hope these changes meet your expectations, and we look forward to your further feedback.

Any further responses from the reviewers can be found at the end of the article

Introduction

The increasing life expectancy of older adults is coupled with a rising number of older adults needing support for (instrumental) activities of daily living and/or living in nursing homes (England & Azzopardi-Muscat, 2017). Factors of dependency and morbidity in old age have substantial impacts on public health systems worldwide, primarily due to escalating healthcare costs (Albert *et al.*, 2015). Functional mobility of older adults is a crucial determinant of health and independence (Braun *et al.*, 2022). Functional mobility can reverse or delay age-related health issues and promote independence, while immobility or limitations in functional mobility (such as difficulty rising from a chair, balance problems, or reduced walking capacity) can cause or increase dependency. This underscores the significance of fostering mobility among the growing population of older adults. Moreover, in some settings (eg.in stationary or ambulatory care) older adults are a vulnerable population with an increased risk of discrimination and exclusion from society, partly due to unmet mobility needs (Nanninga *et al.*, 2018; Van Biljon *et al.*, 2022). The development of tailored exercise programs targeting the independence of older adults is one of the motivators for the improvement of crucial policy action areas described by WHO in the Equity Policy Tool, namely *'living conditions'* and *'social and human capital'* (WHO, 2019)

Exercise can be seen as a preventive measure, so that, without adequate physical activity levels, the ageing process may be associated with premature development of disease and dysfunction (Izquierdo *et al.*, 2021).

Functional mobility in older adults

According to the World Health Organization's (WHO) International Classification of Functioning (ICF) model, overall mobility comprises activities such as "moving by changing body position or location or by transferring from one place to another by carrying, moving, or manipulating objects, by walking, running, or climbing, and by using various forms of transportation" (Liu, 2017). The ICF highlights the interdependence of activities with body functions and structures, participation, and personal and environmental factors for overall mobility.

The key outcomes related to functional mobility in older age include gait, walking capacity, and balance. Additionally, aspects of life-space mobility, such as the overall walking distance within the environment, are significant factors that characterize mobility in older adults. These outcomes were rated as highly important in the Delphi study on mobility (Vogel *et al.*, 2023). Moreover, functional mobility deficits have important clinical implications, as the magnitude of these deficits significantly influences the prognosis and benefits of certain interventional therapies (Pavasini *et al.*, 2016). Functional mobility is assessed by different outcome measures, and these parameters have been associated with different health outcomes.

Walking capacity and gait performance

Walking capacity and gait performance are components of functional mobility and affect the overall mobility of older adults. Decreased walking capacity (e.g., expressed by the 6-minute walking test (6MWT or the ability to walk > 400 m) as well as a rapid age-related decline in gait speed, are associated with increased mortality (Cesari *et al.*, 2005; Ferrucci & Guralnik, 2013; Studenski *et al.*, 2011; Van Kan *et al.*, 2009; White *et al.*, 2013), social isolation, and dependency (Bevilacqua *et al.*, 2021; Hinrichs *et al.*, 2022). Conversely, improvement in gait speed predicts an increased lifespan (Hardy *et al.*, 2007). Moreover, to navigate in daily traffic situations, a walking speed of 1.2 m/s is required to cross the street during the green phase of traffic lights (Donoghue *et al.*, 2016). In addition to walking capacity and gait speed, gait performance is assessed by use of gait parameters of rhythm and phase (e.g., "stance time", "single support time", "double support time," and cadence), as well as gait variability (for an overview cf. Beauchet *et al.*, 2017).

Other functional performance measurements

The risk of inability to cope with everyday life situations increases with age. The reasons for this vary. However, the clinical picture is typically consistent, including functional mobility, strength, and balance problems (Fried *et al.*, 2001; Pavasini *et al.*, 2016). There are many assessments for measuring the extent of these deficits and the degree to which a person's independence is limited. Two of the most frequently used assessments are the Timed Up and Go (TUG) (Podsiadlo & Richardson, 1991) and the Short Physical Performance Battery (SPPB) (Guralnik *et al.*, 1994). Due to their practicability and validity, they are particularly recommended for assessing functional mobility in older adults (Vogel *et al.*, 2023). The TUG is also recommended as a routine screening test for the examination of basic everyday movements and daily life tasks (standing, walking, and turning; Soubra *et al.*, 2019). The SPPB is used to examine gait, balance, and strength in older adults. SPPB scores are predictors of a wide range of health outcomes, such as the disability score in Activities of Daily Living (ADLs), loss of functional mobility, and future hospitalization (Gómez *et al.*, 2013). Moreover, recent studies have shown that the SPPB total score was independently associated with reported falls in older outpatients (Lauretani *et al.*, 2019).

Physical Activity (PA) level

In addition to the individuals´ gait and balance performance, functional mobility is often described by the level of PA. To avoid biased self-reported methods of assessing PA, accelerometers have been used as a valid objective measure. Besides PA level, accelerometers can be used to assess posture, posture changes, and estimated energy expenditure (Yang & Hsu, 2010). Devices differ in the number and type of gathered parameters, captured movement axis, and reported metrics, complicating the comparability of results. In general, a measurement period of seven days and 10 hours each day is recommended to reliably capture habitual physical activity (Gabrys *et al.*, 2015).

Exercise interventions to increase functional mobility in older adults

It has been shown that different types of exercise such as resistance and aerobic exercises (or cardiovascular exercise), especially multicomponent training, act as stimulants to functional mobility (Da Silveira Langoni *et al.*, 2019). For example, a multicomponent exercise program with progressive, individualized resistance tasks, coupled with walking and balance activities, is helpful to preserve or improve physical determinants of mobility, particularly strength, balance and flexibility (Brahms *et al.*, 2021; Sáez de Asteasu *et al.*, 2020). With respect to gait performance, a previous meta-analysis compared specific training modalities (strength/power, coordination, and multimodal exercise training) (Hortobágyi *et al.*, 2015). It demonstrated the efficacy of commonly used interventions for the improvement of habitual and increased gait speed in significant and clinically relevant ways for healthy older adults aged 65 and older (Hortobágyi *et al.*, 2015). Interestingly, the authors considered the number of included studies as relatively low and mentioned the need for an update as soon as an adequate number of studies are available.

Moreover, there is some evidence that exercise interventions positively affect other functional mobility outcomes, such as balance assessed by the SPPB and/or the Timed Up and Go test (Chou *et al.*, 2012; Falck *et al.*, 2019; Hortobágyi *et al.*, 2015; Zhang *et al.*, 2020). The systematic review by Cordes *et al.* (2021) compared different chair-based exercise interventions for nursing home residents. They found that a multicomponent strength (or resistance exercise) and flexibility program with ankle and wrist weights (Baum *et al.*, 2003) as well as a seated range of motions (ROM) training with ROM exercises for the fingers, hands, arms, and legs and low intensity physical activity (Lazowski *et al.*, 1999) increased the TUG score in correlation to increased physical functions. In addition, a high-speed resistance exercise training on cognitive function and physical performance twice a week for one hour over a 16-week intervention period conducted by Yoon, Lee, & Song (2018) improved the SPPB in older adults.

A recent review contextualized physical exercise benefits and the individual functional mobility status with respect to physical fitness (walking capacity) at baseline. Older adults with low walking capacity (i.e., walking speed <0.8 (m·s−1)) appear to benefit most from an untargeted intervention, while older adults with more preserved walking capacity probably benefit most from specific balance and strength training (Brahms *et al.*, 2021). However, this model still requires additional verification. Moreover, motor-coordinative exercises, considered those that focus on improving motor skills, coordination, balance, and agility have been shown to have specific benefits on motor performance in older adults (Hübner & Voelcker-Rehage, 2017). These exercises often involve complex movements that challenge the neuromuscular system and improve coordination between muscles and nerves. Examples include agility drills, balance exercises (e.g., standing on one leg), and sports-specific drills (e.g., dribbling in basketball, footwork in soccer).

Current exercise healthcare trends include mind-body exercises, which integrate physical movement with mental focus and relaxation techniques to promote overall well-being. These exercises aim to improve mind-body connection, reduce stress, and enhance mental clarity and emotional balance. Examples include yoga, tai chi, qigong, and Pilates. Studies have highlighted their benefits on overall coordination and cognitive function (Blomstrand *et al.*, 2023). Furthermore, exergames might also be used on contemporary exercise programs. They typically use motion-sensing technology, such as motion controllers or cameras, to track players' movements and translate them into in-game actions. Exergames have a great potential to improve cognitive-motor performance in older adults (Gallou-Guyot *et al.*, 2020).

Moreover, different training types will enhance outcomes of functional mobility via specific pathways. For example, walking capacity has an endurance and a strength component. Accordingly, aerobic training will improve walking capacity by enhancing cardio-respiratory fitness, as shown within different clinical trials with older patient cohorts (MacKay-Lyons *et al.*, 2020). Resistance training helps to increase muscle strength in the lower limb, which increases gait stability (Brach & Van Swearingen, 2013; Fragala *et al.*, 2019) and muscle power improvement increases functional capacity (Alcazar *et al.*, 2018). However, recent literature reviews showed that a combination of both interventions might be more sufficient to gain most benefits on walking capacity (Lee & Stone, 2020).

In addition, gait performance, evaluated through the different gait parameters previously mentioned, relies on numerous physiological functions which undergo age-related declines. Mechanisms through which physical exercise training can improve gait performances in older adults are related to the effect of the different types of exercises on these physiological functions: proprioception can be improved by balance exercises, motor control can be improved by coordination exercises, muscular function can be improved by strength exercises (Hortobágyi *et al.*, 2015; Lopopolo *et al.*, 2006). Among those, increasing muscle strength may be the most beneficial type of exercise to improve gait speed (Hortobágyi *et al.*, 2015). Regardless of exercise type, higher intensity, frequency and duration are shown to have greater effects on gait speed (Lopopolo *et al.*, 2006). Moreover, there is a lot of evidence, that cognitive-motor exercise can improve gait parameters in different target groups of older adults (eg., with hearing impairments, Parkinsons disease, with a history of falls (De Freitas *et al.*, 2020; Fritz *et al.*, 2015; Wollesen *et al.*, 2022). The effects of these interventions are explained by brain-body facilitation processes that help to coordinate motor control (Herold *et al.*, 2018).

Improved walking capacity and gait stability via different exercise forms might further lead to increased physical activity with higher distances of walking or other forms of mobility in the environment (eg., increased life space mobility, Johnson *et al.*, 2020). This increase of activity caused by functional mobility can be assessed by the number of steps per day or lower energy costs (Dunlap *et al.*, 2022).

Finally, relevant training parameters are often defined using the F.I.T.T. principles (Garber *et al.*, 2011). These include Frequency, Intensity, Time (duration), and Type (form) of training. According to evidence-based training principles and control mechanisms, physical training should be designed so that it is specific to the aim of the training, tailored to the individual preconditions and needs, induce an adequate overload of physiological adaptation, and be designed progressively to continuously adjust the load to the individual's performance (progressive challenge) (Hecksteden *et al.*, 2018; Herold *et al.,* 2019). Training progression could be achieved by increasing the training load (e.g., higher number of repetitions or training sets, walking distances, and prolonged training duration), the training frequency (higher number of training units per week), and/or the training intensity (additional weights and more difficult exercise variants). All these aspects are considered as important prerequisits for muscular and cardiovascular adaptation/improvement through exercise interventions (exercise interventions (Chodzko-Zajko *et al.*, 2009; Jahanpeyma *et al.*, 2021). The assessment of these training principles and training control mechanisms helps to provide evidence of the effectiveness of different training interventions and their composition (dose-response relationships). Thus, in order to conduct a systematic review and meta-analysis aiming to develop evidence-based guidelines for physical exercise to improve mobility in older adults, it is necessary to comprehensively assess the exercise principles. This review will only consider studies that report/describe the training intervention according to FITT principles for their interventions and delivery modalities.

Objectives

This review will systematically assess the effects of state-of-the-art exercise interventions designed to promote functional mobility. Therefore, after identifying all potential interventions, we will use the F.I.T.T. principles as well as the physical and health status of the participants as moderators to analyse the mechanisms for the positive benefits of exercise interventions. The ultimate aim is to provide evidence-based guidelines for the optimal type and dose of exercise to preserve and enhance functional mobility in diverse populations of older adults. A comprehensive network and moderator metanalysis is needed to answer the following research questions:

- Which exercise types are most beneficial for improving functional mobility in various populations of older adults?
- Which physical exercise characteristics in terms of frequency, intensity, time and duration will achieve the greatest benefit in terms of the defined outcomes, i.e the functional mobility of older adults?

Methods

Study design

This living systematic review aims to address the broad and holistic exploration that is required to answer the research questions. To design, review, and report this review, we will use the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extensions protocol (PRISMA-P; Moher *et al.*, 2015).

Eligibility criteria

The following section describes the eligibility criteria according to the PICO(S) scheme.

Types of studies

The review will include randomized controlled trials (RCTs), considering both published and unpublished sources. This will include randomized cross-over, cluster, and parallel-arm trials. All interventions competing in the review will be eligible for randomization together. Quasi-randomized studies will be excluded from consideration.

The search will span all eligible studies in English language accessible through databases (Lefebvre *et al*., 2019). Only studies reporting trial results will be incorporated. In cases where multiple studies cover the same or overlapping populations, priority will be given to the study with the highest participant count or the one following pre-registration in a trial register.

Reference lists from included studies and relevant systematic reviews will be examined. Additionally, efforts will be made to identify trials by checking clinical trial registers such as ClinicalTrials.gov, the International Clinical Trials Registry Platform (ICTRP), or the German Clinical Trials Register (DRKS). Any missing data from RCTs will also prompt further investigation.

Types of participants
We will include studies involving participants aged > 50, according to the WHO definition of "older adults" (mean age of 60 years ± SD, with a minimum age of 50). This will cover older individuals from various settings, including community-dwelling individuals, those residing in residential homes, nursing homes, assisted living facilities, retirement communities, and similar environments. Exclusions will be applied to trials focusing exclusively on specific conditions or medical diagnoses (e.g., rheumatoid arthritis, stroke), as well as studies reporting interventions exclusively aimed at inpatient rehabilitation (e.g., post-surgery care).

In addressing studies with a mixture of eligible and non-eligible participants, we will adopt a systematic approach during screening.

Firstly, we will meticulously assess each study's eligibility criteria to ascertain if they meet our age inclusion (mean age of 60 years, age range starting at 50 years) and exclusion criteria for specific conditions. Studies clearly indicate inclusion of participants within our age range and not exclusively focused on excluded conditions will be deemed eligible.

For studies including both eligible and non-eligible participants, we will extract data solely from eligible participants. If needed, we will contact study authors for clarification on participant demographics and eligibility.

During data synthesis and analysis, we will ensure appropriate interpretation and reporting of findings from studies with mixed participant populations. This may involve subgroup or sensitivity analyses to gauge the impact of including non-eligible participants on our review's overall outcomes and conclusions.

Types of interventions
The descriptions of interventions used in individual trials will be examined and the exercise interventions will be categorized according to the definition of the American College of Sports Medicine (Swain *et al.*, 2014) as any kind of "planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness". This can be cardiovascular exercise, resistance exercise, motor-coordinative exercise, multicomponent exercise, mind-body exercise, exergames, combined exercise (e.g., the combination of aerobic and resistance exercises) and concurrent training (e.g., cognitive and motor training simultaneously). The frequency, duration and type of exercise has to be defined/reported within the study. Studies assessing the effect of acute (single session) exercise will be excluded.

The F.I.T.T. principle, a widely-used framework in exercise science, is based on four key factors: frequency, intensity, time, and type. The F.I.T.T. principle provides a framework for the structure of exercise programmes, with a particular focus on the following four key elements: the frequency of exercise, the intensity of the workout, the duration of the exercise session, and the specific form of the activity. This principle is fundamental to the prescription of exercise, allowing for adjustments to be made to meet individual fitness levels and goals. As a result, it has become an enduring tool in the fields of health and fitness (Schmitz *et al*., 2010).

The term 'frequency' pertains to the number of times an individual engages in physical activity on a weekly basis, typically expressed as the number of sessions completed per week. The evidence indicates that undertaking moderate-intensity aerobic exercise on three to five occasions per week is beneficial for cardiovascular health and overall wellbeing. Similarly, resistance training is recommended on two to three occasions per week to improve muscle mass and strength (Garber *et al*., 2011).

The term 'intensity' refers to the level of effort or difficulty associated with a particular exercise. It is a crucial factor in the adaptation of exercise programmes to suit different fitness levels and goals. The intensity of an exercise can be gauged by a number of means, including heart rate, perceived exertion, or metabolic equivalents (METs). Higher intensities, such as those employed in high-intensity interval training (HIIT), have been demonstrated to confer distinct cardiovascular and metabolic benefits (Hwang *et al*., 2016).

The term "time" refers to the duration of each exercise session. For example, the general recommendation is to engage in 150 minutes per week of moderate aerobic activity or 75 minutes of vigorous activity. The duration of the exercise session is adjusted based on the intensity. Shorter sessions can be effective if the intensity is higher, as demonstrated by Hillman *et al*. (2020) in the case of HIIT.

The term "type" denotes the specific category of exercise, encompassing aerobic activities such as running and swimming, anaerobic exercises like weightlifting, and flexibility training. The different types of exercise have been shown to have varying beneficial effects on health. For example, aerobic exercise has been demonstrated to have positive effects on cardiovascular health, while resistance training has been shown to be effective in building muscle and bone strength (Lima *et al*., 2015).

For our main comparisons, we will include trials where the intervention was compared with 'usual care' (i.e., no change in usual activities) or a control intervention (i.e., waiting list, stretching, health education recreational activities). Treatment as usual includes for example classical therapy for the diagnosed pathology in the control group.

In our review, some studies may meet certain inclusion criteria but not others. For example, a study may meet the criteria for intervention type and comparator but may lack clear reporting on exercise parameters such as frequency, duration, and type. In such cases, these studies may still be included in the overall analysis but may be excluded from specific analysis steps within the moderator analysis. However, the corresponding authors will be asked for additional information, e.g., on F.I.T.T. principles, to ensure that all eligible studies can be integrated into the analysis. This approach is to ensure consistency and rigor in the analysis while maximizing the inclusion of relevant studies. By including these studies in the overall analysis, we maintain a comprehensive assessment of the available evidence. However, for specific analysis steps within the moderator analysis where clear and consistent reporting of certain criteria is crucial, such as subgroup analyses based on exercise parameters, studies lacking this information may not provide meaningful data and could potentially introduce bias or confound the analysis. Therefore, excluding these studies from specific analysis steps within the moderator analysis helps to ensure the robustness and validity of the results.

For this review, "classical therapy' refers to traditional or conventional forms of therapy or treatment that have been established and used for a significant period, which might differ considering settings or pathologies. It might be standard pharmacological treatments or established medical procedures. In rehabilitation, it usually consists of conventional exercise programs, manual therapy techniques, or standard rehabilitation protocols commonly used for a particular condition or injury.

Acute exercise studies (studies assessing the effect of acute (single session)) will be excluded.

Types of outcome measures

We will systematically collect data from studies that provide both baseline assessments and at least one post-intervention assessment. For studies with multiple post-intervention assessments, we will select the assessment closest to the completion of the exercise intervention as the primary data point for the meta-analysis. This choice aims to provide a consistent benchmark across studies. Additionally, to capture longer-term outcomes and the sustainability of intervention effects, follow-up assessments will be analyzed and reported separately. These follow-up results will help describe the maintenance of effects over time and offer insights into the durability of the intervention benefits.

The clinically meaningful timing of outcome assessments will be determined by the nature of the intervention program and the specific pathology being addressed. For instance, shorter intervention periods may be more appropriate for acute conditions, whereas chronic conditions might require longer durations for meaningful outcomes to emerge. Consequently, our review will include evaluations categorized as short-term (within the first six months of treatment) and intermediate-term (from six to 12 months of treatment). This stratification allows for a nuanced understanding of how different interventions perform across varying timelines.

Primary outcomes

Parameters representing functional mobility (*The Short Physical Performance Battery* (SPPB) (Guralnik *et al.*, 1994); *Timed up and Go* test (TUG) (Podsiadlo & Richardson, 1991), i.e., the standard or mobile assessment of the TUG (Herman *et al.*, 2011); *6minute walk test* 6MWT (Sciurba & Slivka, 1998) for walking capacity; *Walking distance and number of steps per day (*according to accelerometer dat *a)* will be assessed as primary outcomes to evaluate the intervention effects.

Secondary outcomes

The secondary outcomes include additional *Gait parameters.* Selection of gait parameters is based on a factor analysis by Hollman *et al.* (2011) that identified five domains of gait performance (see Table 1) and the Canadian Guidelines

Table 1. Summary of the recommended gait parameters.

Domains (Hollmann *et al.*, 2011)	Parameters
Rhythm (steps/min; s)	Cadence, step time (Hollman *et al.*, 2011) stride time, swing time, *stance time, single support time* (Beauchet *et al.*, 2017; Hollman *et al.*, 2011)
Phase (%GC)	temporophasic parameters swing and stance (Hollman *et al.*, 2011) *single and double support, double support time* (Beauchet *et al.*, 2017; Hollman *et al.*, 2011)
Variablility (%CV)	gait cycle, step variability parameters step length and step time (Hollman *et al.*, 2011) *stride length*, stride time, swing time, *stance time, stride speed* (Beauchet *et al.*, 2017; Hollman *et al.*, 2011)
Pace (cm/s; cm)	*gait speed and stride length* (Beauchet *et al.*, 2017; Hollman *et al.*, 2011) step length (Beauchet *et al.*, 2017)
Base of support (cm)	step width (Beauchet *et al.*, 2017; Hollman *et al.*, 2011) step width variability (Hollman *et al.*, 2011)

Adapted by Beauchet *et al.*, 2017; Hollman *et al.*, 2011.

(Beauchet *et al.*, 2017) for the assessment of gait parameters (see Table 1 for an overview of all parameters).

The review will also include the following adverse effect outcomes reported within the included studies:

- Musculoskeletal injuries: older adults may be at increased risk of musculoskeletal injuries such as strains, sprains, or fractures due to factors like reduced bone density, muscle mass, and joint flexibility. Exercises with high impact or high intensity, improper form, or inadequate warm-up may increase the risk of these injuries.
- Falls and Balance Issues: certain exercises that challenge balance or involve rapid movements may increase the risk of falls, especially in older adults with balance impairments or functional mobility issues. Falls can lead to serious injuries such as fractures, head trauma, or lacerations.
- Exacerbation of pre-existing conditions: exercise interventions that are not tailored to individual health status or medical conditions may exacerbate pre-existing health issues such as arthritis, osteoporosis, or chronic pain. For example, high-impact exercises may worsen joint pain in individuals with arthritis.

Information sources

Literature searches will mainly be conducted in electronic databases: Medline (1946 to current), Embase (1974 to current), APA PsycInfo and Web of Science databases.

The preliminary search strategy (e.g., MEDLINE (Ovid)) will be adapted for use in other electronic bibliographic databases. Additional searches will be conducted in ClinicalTrials.gov (www.ClinicalTrials.gov), the World Health Organization International Clinical Trials Registry Platform (ICTRP) and search Portal (apps.who.int/trialsearch/). The results of the literature search using the search terms listed above will be then checked for duplications.

We will check reference lists in included studies and any relevant systematic reviews identified. We will also contact researchers and organizations in the field to identify ongoing and unpublished trials if we identified them in clinical trial registers such as, the ClinicalTrials.gov, the International Clinical Trials Registry Platform (ICTRP) or the German Clinical Trials Register (DRKS); or if we miss any data in the found RCT. To identify as much relevant evidence as possible, we will also search relevant grey literature sources such as reports, dissertations theses and conference abstracts.

Search strategy

The search will include the study type according to the PICO(S) scheme. As such, no additional filters will be integrated.

The review is planned as a living review. The search update is planned to be done twice a year (April and October). If more than three articles for one of the primary outcomes will be identified, the meta-analysis will be repeated respectively, and the new updated results will be published. Within the review team there are at least three researchers with a research team and a lifetime position (Y.N., U.M., B.W., A.L.) who will be responsible for this.

Study records

Overall data management

To standardize the process of data collection and analysis and ensure the overall quality, we will proceed as follows.

1. We will separate the process into different tasks and set up a team for each task. The team will be guided by the first and second author to ensure the quality and standardization of the task.
2. For some tasks (how to use Rayyan and Redcap), we will develop a short training program for the teams. The training will be supported by manuals that refer to each step of the process.
3. The whole group has regular meetings to discuss difficulties and ensure standardization. All decisions and changes will be recorded.

Study selection process

After removing duplicates both manually and electronically, at least two review authors of the whole author team will independently screen the titles and abstracts of the citations retrieved by the searches for relevance using the Rayyan software (Ouzzani *et al.*, 2016; https://www.rayyan.ai/) Duplicates will be removed with help from the software. After this initial assessment, we will obtain full-text copies of all potentially relevant studies. Again at least two review authors will independently check the full papers for eligibility, resolving any disagreements by consensus and the input of a third review author. We will contact the corresponding authors, if studies cannot be found via the data sources or librarians.

Afterwards we will record the reasons for exclusion of studies obtained as full text in the excluded studies' table. Where there are several reports of a study, we attempt to obtain all reports. The process of the study selection will be presented in a PRISMA flowchart (Page *et al.*, 2021).

Data collection process

The same review authors responsible for the study selection will independently perform data extraction using a standardized data extraction form. All authors will be involved in data extraction.

We will pilot the data extraction form using a representative sample of studies to identify missing items or unclear coding instructions. Any disagreements will be resolved by consensus or by third-party adjudication. We will enter data into the Redcap software (https://projectredcap.org/software/) (and check for accuracy and consistency against the data extraction form. The review authors will not be blinded to the authors and sources.

The final number of studies will equally be shared within the whole author team.

Data items

We will record the following information in a 'Characteristics of included studies' table by using Redcap.

- General information: first author's name; date of data extraction; study ID; author's contact address (if available); citation of paper; and trial objectives.
- Detailed description of included participants (number or % of male/female, BMI, height, weight, comorbidities, MoCA/MMSE score, accommodation [independent, nursing home etc.] as well as socioeconomic level.
- Trial details: trial design; location; setting; sample size; inclusion and exclusion criteria; comparability of groups; length of follow-up; stratification reported in the study methods; stopping rules; and funding sources.
- 'Risk of bias' assessment: sequence generation; allocation concealment; blinding (participants, personnel, outcome assessors); incomplete outcome data; selective outcome reporting; and other biases (recall bias).
- Characteristics of participants: age; gender; ethnicity; health conditions; level of mobility/activity (according to SPPB, TUG, or gait speed); physical activity level at baseline (according to IPAQ, GPAQ, fitness level at baseline with measurements like VO_2max (Stelmach, 2018), or walking capacity using the 6MWT, falls in the last 6 or 12 months before the intervention; Fear of Falling; Level of Global Cognition (assessed with the MMSE or MoCA); years of education; number of randomized participants; analyzed; lost to follow-up; and dropouts in each arm (with reasons).
- Interventions: experimental and control interventions; timing of intervention; intensity, duration, volume and frequency of intervention/s; adherence (compliance) with experimental and control interventions and associated data; who delivered the intervention; and additional co-interventions (such as motivational strategies).

Outcomes and prioritization

The primary outcomes will include parameters representing functional mobility: Short Physical Performance Battery (SPPB); Timed up and Go test (TUG), 6minute walk test 6MWT, and walking capacity: Walking distance and number of steps per day (according to accelerometer data). The secondary outcomes will include additional gait parameters (cf. Table 1)

Outcomes measures:

We plan the following analyzing steps:

1. Effects of the intervention vs (a) the active or (b) inactive control groups
2. Effects with respect to the frequency and duration (time (i.e. weeks or months), volume (total duration in minutes))
3. We will also consider comparisons of high- versus low-intensity interventions
4. If possible, we will also compare interventions from the different categories (cardiovascular exercise, resistance exercise, motor-coordinative exercise, multicomponent exercise, mind-body exercise, exergames, hybrid exercise, and concurrent training) as a network analysis
5. Influence of the moderator variables described in the "subgroup analysis" section

The final proofing of the data extraction will be done by the first and second author of the study. We will collect as much information as we can on control interventions, including assessing what 'usual care' comprises. We will retrieve data from both full-text and abstract reports of studies, including those with multiple reports. Where information is insufficient, we will contact the study authors for additional details.

Risk of bias in individual studies

The whole author team subdivided into pairs including experienced review authors will independently assess the risk of bias using Cochrane's Risk of Bias 2 tool (Sterne *et al.*, 2019). Any disagreement will be resolved by consensus or third-party adjudication. We will rate the risk of bias as either low, some concerns, or high by the use of the Risk of Bias 2 tool (ROB2) based on the following domains:

- bias arising from the randomization process (the allocation sequence was random; the allocation sequence was adequately concealed; baseline differences between intervention groups suggesting a problem with the randomization process).
- bias due to deviations from intended interventions (participants were aware of their assigned intervention during the trial; people delivering the interventions were aware of participants' assigned intervention during the trial, deviations from the intended intervention arose because of the experimental context, an appropriate analysis was used to estimate the effect of assignment to intervention, important non-protocol interventions were balanced across intervention groups; (if applicable) failures in implementing the intervention could have affected the outcome; (if applicable) study participants adhered to the assigned intervention regimen; (if applicable) an appropriate analysis was used to estimate the effect of adhering to the intervention.
- bias due to missing outcome data (data for this outcome were available for all, or nearly all, participants randomized; (if applicable) there was evidence that the result was not biased by missing outcome data; (if applicable) missingness in the outcome was likely to depend on its true value (e.g., the proportions of missing outcome data, or reasons for missing outcome data, differ between intervention groups).
- bias in measurement of the outcome (data for this outcome were available for all, or nearly all, participants randomized; (if applicable) there was evidence that the result was not biased by missing outcome data; (if

applicable) missingness in the outcome was likely to depend on its true value (e.g., the proportions of missing outcome data, or reasons for missing outcome data, differ between intervention groups).

- bias in selection of the reported result (data for this outcome were available for all, or nearly all, participants randomized; (if applicable) there was evidence that the result was not biased by missing outcome data; (if applicable) missingness in the outcome was likely to depend on its true value (e.g., the proportions of missing outcome data, or reasons for missing outcome data, differ between intervention groups).

We will contact study authors for additional information about the studies included, or for clarification of the study methods if required.

The domain with the highest risk of bias per outcome will be used to report an overall risk of bias for each respective outcome. Only studies with a low to medium risk of bias will be included in the analyses. Studies exhibiting a high risk of bias will be reported but not included in meta-analyses. Results of the risk of bias assessment will be made available on reasonable request.

We will provide the risk of bias assessment results in the review through standard tables. The assessed risk of bias will be visualized in dedicated figures and, if feasible, in visualizations of meta-analyses as well as tables such as the summary of findings and GRADE (GRADEpro GDT).

Measures of treatment effect

We will process data in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks *et al.*, 2019; Higgins *et al.*, 2019).

All described functional mobility outcomes are continuous measures. For these continuous outcomes, we will present the mean difference (MD) with 95% CIs where the same outcome measure was used. If more than one study measures the same outcome using different tools, we will calculate the standardized mean difference (SMD) and 95% CI using the inverse variance method in R or Stata. This method enables pooling of the adjusted and unadjusted treatment effect estimates reported in the individual studies or calculated from data presented in the published article.

For any dichotomous outcomes (with respect to potential subgroup analysis) resulting risk ratios (RR) will be calculated.

For cluster RCTs data adjustments will be done according to the *Cochrane Handbook for Systematic Reviews of Interventions*. Ideal information to extract will be a direct estimate of the required effect measure and standard error from analysis made by the authors. Alternatively, data will be analysed as if each cluster was a single individual, using a summary measurement from each cluster.

Unit of analysis issues

This review of RCTs will include studies with two or more parallel groups, cross-over and cluster designs.

For trials with multiple arms, we will include multiple pair-wise comparisons (intervention versus control) in analyses, but to avoid the same group of participants being included twice, we will 'split' the control group by distributing the number of control group participants to each analysis considering whether (1) no irreversible events such as mortality had occurred, and (2) appropriate statistical approaches had been used.

For the crossover randomized trials, the unique design of the trials will be considered with respect to the multiple treatments or interventions in a predetermined sequence. Within the review, the unit of analysis issues addressed in individual studies will be reported with giving details about the statistical methods used, the handling of carryover and period effects, and any assumptions made. To account for carryover effects in the analysis, the data from the different periods will be treated separately. Data from the first period in crossover trials will be included. Within crossover randomized trials, washout periods durations for physical training intervention effects in older adults are not precisely known but are believed to be lasting months or even years. Due to the inclusion of an aging population, this would lead to important changes and possibly mortality between periods. Therefore, including following periods do not seem suitable for this meta-analysis and only Data from the first period in crossover trials will be included.

For data from cluster trials, we will consider whether the reported data analysis had appropriately considered the aggregated nature of the data. When a direct estimate of the required effect measure from an analysis that properly accounts for the cluster design is not available, to avoid unit-of-analysis error, data will be analyzed as if each cluster was a single individual, using a summary measurement from each cluster.

Approximately analyses will be performed in case of randomization performed on the individuals rather than the clusters in the trial, and if if the following information can be extracted: the number of clusters randomized to each intervention group, the total number of participants in the study or the average (mean) size of each cluster, the outcome data ignoring the cluster design for the total number of individuals and an estimate of the intracluster (or intraclass) correlation coefficient (ICC). The design effect will be calculated as 1 + (m - 1) * ICC, where "m" is the average cluster size to adjust the sample size calculation. Moreover, sensitivity analyses to assess the impact of different ICC values or clustering assumptions on the results to evaluate the robustness of the findings will be conducted.

Moreover, sensitivity analyses to assess the impact of different ICC values or clustering assumptions on the results to evaluate the robustness of the findings will be conducted.

Dealing with missing data
We will contact the corresponding authors of the included studies for any key missing numerical data or information on their trial. If data cannot be retrieved, we will conduct sensitivity analysis to explore the effects of missing data (incomplete outcome data) on the treatment effect.

If a study does not report SDs for continuous outcomes, we will calculate these from standard errors, CIs, or exact probability (P) values where possible. We will not impute missing SDs.

Assessment of heterogeneity
The decision about whether to combine the results of individual studies depends on an assessment of clinical and methodological heterogeneity. To investigate heterogeneity among the included studies, various potential sources of variation are explored. These factors include differences in participant characteristics (see inclusion criteria), effect of the type of exercise intervention, exercise intensity and outcome measures. The investigation of heterogeneity may suggest that differences in baseline levels of functional mobility and comorbidity profiles across studies will contribute to heterogeneity in effect sizes.

If we consider studies sufficiently homogeneous in their study design (participants, interventions, measurement tools), we will carry out meta-analyses and assess the statistical heterogeneity. The heterogeneity-rating will be displayed in the results section. We will assess statistical heterogeneity of treatment effects between trials by funnel plots, Chi^2 test with a significance level at $P < 0.10$, and the I^2 statistic. We will base our interpretation of the I^2 values suggested by Higgins *et al*. (2019):

- 0% to 40% might not be important;
- 30% to 60% may represent moderate heterogeneity;
- 50% to 90% may represent substantial heterogeneity; and
- 75% to 100% may represent very substantial ('considerable') heterogeneity.

Cases of considerable heterogeneity will be reported, further investigated by subgroup analyses, and considered interpreting the results of affected meta-analyses.

Assessment of reporting biases
We will assess reporting bias according to ROB 2 and do additional quality checks based on the characteristics of the included studies (e.g., if only studies with small sample sizes indicate positive findings), and if information obtained from contacting experts and authors of studies suggests there are relevant unpublished studies. In the NMA, a comparison-adjusted funnel plot will be utilised to identify potential small-study effects (Chaimani & Salanti, 2012)

To assess the possibility of publication bias and other reporting biases, we will conduct tests for funnel plot asymmetry for any analyses that include more than 10 data points. This threshold is consistent with the recommendations by Higgins *et al*., 2019), ensuring adequate power and reliability in identifying asymmetry. The funnel plot asymmetry tests will be applied separately for each comparison within the network, provided there are sufficient data points for meaningful analysis.

In addition, comparison-adjusted funnel plots will be constructed as part of the network meta-analysis to detect potential small-study effects, which may arise from studies with smaller sample sizes reporting disproportionately large intervention effects. These plots will aid in identifying and interpreting potential biases across the network structure of the meta-analysis.

A further measure to ensure impartiality in our review process will be implemented should any of the authors be contributors to a study included in the meta-analysis. In such cases, the involved authors will recuse themselves from conducting the risk of bias assessment and from participating in any GRADE (Grading of Recommendations Assessment, Development, and Evaluation) assessments that utilize data from their study. This measure safeguards the objectivity and transparency of our evaluation process.

Data synthesis
When considered appropriate, we will pool the results of comparable studies using random-effects models. The choice of model will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors, such as the number and size of included studies. We will use 95% CIs throughout (Cumming, 2014)

When considered appropriate, we will pool data using the generic inverse variance method in R or Stata. This method enables pooling of the adjusted and unadjusted treatment effect estimates (rate ratios or risk ratios) reported in the individual studies or calculations from data presented in the published article (see Measures of treatment effect). We will consider not pooling data where there is considerable heterogeneity ($I^2 \geq 75\%$) that cannot be explained by the diversity of methodological or clinical features among trials. Where pooling data is inappropriate, we will still present trial data in the tables, for illustrative purposes, and in the text.

We will use a random-effect model, considering the correlated treatment effects in multi-arm studies. We assume a common estimate for heterogeneity variance across different comparisons.

To evaluate the extent to which the treatments are connected, we will provide a network plot of our outcomes. For each comparison, we will report the estimated treatment effect along with its 95% CI. We will graphically present the results using forest plots, with comparisons of passive and active control groups as reference treatments.

Meta-bias(es)
With additional mixed treatment network meta-analysis (NMA), we aim to compare multiple treatments in the context of meta-analysis. It incorporates direct comparisons of interventions

within randomized controlled trials and indirect comparisons across trials based on a common comparator. Through NMA, we will estimate the relative effectiveness of multiple interventions, even if they haven't been directly compared in primary studies.

The analysis will start with a standard pairwise meta-analysis of the intervention effects of the different identified exercise interventions to understand the efficacy of individual interventions. At this stage a mixed treatment comparison is planned to combine evidence from both direct and indirect comparisons to estimate relative treatment effects (consistancy model). If possible, transitivity will be evaluated by comparing the distribution of effect modifiers across the different comparisons for studies with the same study characteristics and aims. A network plot will be created to visualize the available direct connections between the treatments. In addition to examining the overall effects of exercise interventions, the NMA is used to explore the influence of various study levels or participant-level characteristics (e.g., age, gender, exercise intensity) as moderators or subgroup analyses. Depending on potential identified inconsistency, adjustments to the analysis will be undertaken (e.g., incorporating study level covariates).

Our review will employ a network meta-analysis (NMA) to comprehensively compare multiple exercise interventions and their effects. This method extends traditional meta-analysis by incorporating both direct comparisons (interventions compared within randomized controlled trials) and indirect comparisons (interventions compared across trials via a shared comparator). The NMA framework allows us to estimate the relative effectiveness of multiple interventions, even if some have not been directly compared in primary studies.

Initially, a standard pairwise meta-analysis will be conducted to evaluate the intervention effects of individual exercise interventions. This preliminary step will establish the efficacy of each intervention in isolation. Subsequently, a mixed treatment comparison will integrate evidence from both direct and indirect comparisons using a consistency model to estimate relative treatment effects. Transitivity will be assessed by examining the distribution of effect modifiers (e.g., baseline characteristics, study design features) across the included studies to ensure that the conditions required for valid indirect comparisons are met.

A network plot will be generated to visually represent the direct connections between different interventions, providing a clear depiction of the evidence base. The NMA will also allow us to investigate the influence of various moderators, such as participant characteristics (e.g., age, gender, baseline fitness levels) and intervention-specific factors (e.g., exercise intensity, frequency, and duration).

To address potential inconsistencies within the network, inconsistency models may be employed. These models incorporate study-level covariates to account for variations across studies. If significant inconsistency is detected, we will explore adjustments such as including additional covariates or revising the model structure. This iterative process aims to ensure the robustness and reliability of the network meta-analysis findings.

Meta-regressions will examine the relationship between one or more moderators and the treatment effect. The treatment effect will be the dependent variable and the selected moderators will be independent variables. The estimation of the coefficients (β values) for each moderator will be reported for the strength and direction of their association with the treatment effect. The examined p-values associated with each moderator in the meta-regression model indicate if the moderator has a statistically significant effect on the treatment effect. Additionally, we will conduct confidence intervals for the moderator coefficients to assess the precision of the estimated effects.

It is planned to use the R or Stata to conduct the network meta-analyses and mixed treatment comparisons.

Where outcome data from individual trials are not sufficiently similar to be combined within meta-analyses, or for studies excluded from meta-analysis due to low quality (according to RoB2) we will describe results from clinically comparable trials narratively using the synthesis without meta-analysis (SWiM) approach (Campbell *et al.*, 2020). We will report information by grouping studies (e.g., by population, outcome, study design), and describing the standardised metrics and any transformations used, synthesis methods, the criteria used to prioritize results for synthesis (e.g. based on study design, risk of bias assessment), and limitation of the synthesis.

Confidence in cumulative evidence

Moderator analysis will explore the impact of categorical and metric variables on the study effect sizes. With categorical variables, we will analyze whether different levels of a factor (e.g., intervention type) might explain variability in results. Metric variables in moderator analysis (meta-regression) allow the examination of the influence of continuous variables, like dosage or duration, on effect sizes.

We plan to carry out the following moderator analyses when sufficient data exist.

Related to participants:

- Sex: male, female.
- Age: 60–70, 71–80, >80
- Level of functional mobility/activity at baseline: SPPB </> 8; TUG </>15 sec; gait speed < 0.8 m/s; .08-1.0 m/s; > 1.0 m/s
- Health conditions: no disease, orthopedic diseases, brain diseases, mental disorders, other diseases
- Falls in the last 6 or 12 months before the intervention: yes, no

- Fear or concerns of falling (reported or rated by the FES-I): low, moderate, high concern about falling; reported or rated by the FES-I
- Level of global cognition: MMSE, MOCA at baseline (< 24 or ≥ 24)
- Years of education: <8,8-10, >10 years

Fitness level at baseline: low, moderate or high according to IPAQ or GPAQ or physical measurements like VO_2max (Stelmach, 2018)

Related to the interventions:

- The frequency of the exercise training (number of sessions a week)
- The intensity of the prescribed physical activity
- The type of physical exercise intervention
- The time (duration) of the intervention (number of weeks)
- The time (duration) in average of each session (in minutes)
- Related to the study design: Type of control group (active vs. non active; type of intervention)

Sensitivity analysis

Where possible, we will assess the robustness of our findings by conducting sensitivity analyses.

We will examine the effects of the following aspects:

- Inclusion of trials at high or unclear risk of selection bias due to inadequate concealment of allocation.
- Inclusion of trials at high or unclear risk of detection bias due to inadequate blinding of outcome assessors.
- Inclusion of trials at high or unclear risk of attrition bias due to incomplete outcome data.
- The effect of time on the impact of the intervention (i.e. comparing differences in treatment effect over time earlier trials versus later trials).
- The choice of statistical model for pooling (fixed-effect versus random-effects).

Summary of findings and assessment of the certainty of the evidence

We will create summary of findings (SoF) tables for all our main comparisons of the NMA (Yepes-Nuñez *et al.*, 2019). The summary of findings tables will report the comparisons findings of: exercise interventions versus active or inactive controls; exercise type and potential effects on functional mobility. The main comparatives will be the following outcomes (separate table per comparison)

- The Short Physical Performance Battery (SPPB)
- Timed up and Go test (TUG)
- 6MWT
- Walking distance/ number of steps per day
- Gait performance

The summary of finding tables will include: a description of patient populations included in the comparison, the intervention, outcome and setting/settings. The tables will also include total participant number, relative effect for the outcomes of interest [reported as odds ratio, credible intervals], anticipated absolute effect, certainty of evidence [according to GRADE], ranking of treatment [using SUCRA ranking and credible intervals], and interpretation (eg., positive or negative direction) of findings. The tables will also include a graphical presentation of the comparisons (Brignardello-Petersen *et al.*, 2018; Mbuagbaw *et al.*, 2017; Salanti *et al.*, 2011). We will use the GRADE approach to assess the quality of evidence as it relates to the primary and secondary outcomes listed in the Types of outcome measures section. In assessing the quality of evidence using the GRADE approach, we will specify the comparisons and timing of follow-up to be included in the GRADE assessment and SoF table(s) (Brożek *et al.*, 2011; Schünemann *et al.*, 2022). Additionally, we will explicitly state whether adverse effects of the interventions will be included in the SoF and GRADE assessments Within the GRADE the quality rating 'high' is reserved for a body of evidence based on randomised controlled trials. We may downgrade the quality rating to 'moderate', 'low', or 'very low' depending on the presence and extent of five factors: study limitations, inconsistency of effect, imprecision, indirectness, and publication bias. Two people will work independently to assess the certainty of the body of evidence and third will resolve disagreement.

Discussion

A growing number of older adults worldwide are losing their independence due to decreased functional mobility (Braun *et al.*, 2022). Balance and walking are essential for independence as they are key factors of locomotion. The positive effect of physical activity on functional mobility has been well documented (Taylor *et al.*, 2023; Valenzuela *et al.*, 2023). However, a sedentary lifestyle (Harvey *et al.*, 2015) as well as huge variability in functional mobility (Netz *et al.*, 2019) is common in older adults. Not all exercise regimens are universally effective, and inter-individual differences in response to exercise exist (Bonafiglia *et al.*, 2021). Moreover, adaptations to physical exercises are specific to the training contents (e.g., balance or walking capacity). Therefore, there is an urgent need for assessing which exercise programs and delivery modes are effective to improve older adult's functional mobility.

Surprisingly, to date, no systematic review has been published which systematically assessed aspects of individualization as well as the frequency, intensity, type, and time (duration) (F.I.T.T.) of the exercises, to derive specific dose-response relationships with respect to the exercise effects on functional mobility. A recent review regarding training to increase functional mobility and functioning in older adults included independent community-dwelling frail older adults but excluded other populations such as non-frail older adults or those living in residential homes (Treacy *et al.*, 2022). Moreover, the review disregarded training principles concerning F.I.T.T. principles. Other reviews focused on certain training interventions like progressive resistance training (PRT) for improving physical functions in older adults but excluded other types of exercise such as endurance and balance training (Liu & Latham, 2009). Other reviews focused on outcomes that could be associated with mobility impairment like falls (Treacy *et al.*, 2022), or fear of falling (Kumar *et al.*, 2016), but did not assess functional mobility. Numerous other reviews examined multiple exercise regimens, but they all focused on specific populations, e.g. frail older adults (Treacy *et al.*, 2022), adults post-hip fracture surgery (Fairhall *et al.*, 2022), acutely hospitalized older adults (Hartley *et al.*, 2022), patients with hip or knee osteoarthritis (Regnaux *et al.*, 2015) or ankylosing spondylitis (Regnaux *et al.*, 2019), patients with multiple sclerosis (Rietberg *et al.*, 2005), patients with cerebral palsy (Ryan *et al.*, 2017) and other similar specific population subgroups.

Our intention in this comprehensive living review and meta-analysis is to identify the optimal exercise characteristics to increase functional mobility (based on objective, well-established measures) in older adults. We will utilise an evidence-based approach. Subsequently, policymakers, health professionals, and practitioners will be able to provide dedicated and effective evidence-based exercise programs for improving functional mobility in older adults for both, prevention (in the healthy population), as well as for rehabilitation (in the mobility-impaired population) and consequently, promote the independence of older adults.

The proposed review has the potential to provide evidence-based data on exercise interventions that target functional mobility.

In summary, the planned review goes beyond the already published work as it aims to analyze a range of functional mobility outcomes (walking capacity, gait, balance, and overall physical activity levels) concerning several moderators including:

- physical and health status
- exercise interventions with respect to F.I.T.T principles

Furthermore, the evidence of the studies included will be reported according to GRADE guidelines.

The GRADE approach for quality of evidence assessment will be utilised for all outcomes and measures, including all factors referred to by these guidelines (Brignardello-Petersen *et al.*, 2018).

Ethics and consent

Ethical approval and consent were not required

Data availability

Underlying data

No data are associated with this article.

Extended data

Open science framework (OSF): Evidence-based exercise recommendations to improve functional mobility in older adults - A study protocol for living systematic review and meta-analysis _material https://doi.org/10.17605/OSF.IO/4V5P3 (Wollesen, 2024)

This project contains the following extended data:

- Preliminary Search Strategy.docx
- PRISMA-P_checklist.docx

Reporting guidelines

The PRISMA-P checklist for this review can be found here: https://doi.org/10.17605/OSF.IO/4V5P3 (Wollesen, 2024)

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 2

Reviewer Report 27 January 2025

https://doi.org/10.21956/openreseurope.20770.r49731

✔

Paulo Cesar Barauce Bento
Department of Physical Education, Graduate Program in Physical Education, Federal University of Paraná, Curitiba, Brazil
Neiry Arsie
Phisycal Education, Federal University of Paraná, Curitiba, PR, Brazil

Once again, I appreciate the opportunity to review the manuscript. I believe the authors have fully addressed the requests and clarifications asked.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: My area of expertise is the effects of physical activity and exercise on physical function in older adults.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 15 January 2025

https://doi.org/10.21956/openreseurope.20770.r49730

✔

Luis A Berlanga
[1] Centro de Estudios Universitarios Cardenal Spínola CEU, Sevilla, Spain
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Authors have conducted a careful review of the comments provided by the reviewers and have made the appropriate modifications. No further modifications to the manuscript are necessary from my point of view. I appreciate the work of all co-authors and the relevance of the article.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Exercise Physiology; Physical Fitness Assessment

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 06 November 2024

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?

Luis A Berlanga
[1] Centro de Estudios Universitarios Cardenal Spínola CEU, Sevilla, Spain
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Authors described a very well-designed and rigorous study protocol to perform a systematic review with meta-analysis for helping policymakers, health professionals, and practitioners to achieve practical tools and knowledge for developing effective evidence-based exercise programs for improving functional mobility in older adults.

The introduction presents the content in a clear, orderly and rigorous manner; state of the art is well reflected. The authors correctly define the concept of ‘functional mobility’. However, in my opinion, it would be more accurate to refer to this concept as ‘functional capacity’, as this term is much more commonly used in the scientific literature to describe what authors described. Readers may confuse ‘functional mobility’ with the concept of ‘mobility’, associated with flexibility or range of motion; therefore, in case authors refused to replace the term, I would suggest that it should be used throughout the manuscript as ‘functional mobility’ to avoid possible confusion (i.e.: first sentence in ‘Objective’ section; or the 3rd sentence in 'Discussion').

I consider that the section ‘Short Physical Performance Battery (SPPB) and Timed Up and Go (TUG)’ should not be titled with the name of the tests, but with the outcomes that these tests assess (like the previous section, which is titled ‘Walking capacity and Gait performance’ instead of ‘6MWT’). A proposed title for this section could be ‘Other functional mobility assessments’, since the tests mentioned assess different components of functional capacity (strength, balance...), and are related to the ability to perform activities of daily living, risk of falls, etc.

Regarding the type of training interventions, it would be important to mention the importance of resistance training focused on muscle power improvement due to its importance for the increase of functional capacity in older people (i.e.: 10.1093/gerona/glx216)-ref-2.

The proposed methodological design is solid and rigorous. However, in the section 'Types of participants' it is not clear whether the age of inclusion is greater than 60 or 50 years old; please clarify. In addition, please delete the last sentence within 'Types of intervention' section as this information is repeated. Furthermore, please do not repeat the explanation of abbreviations already used within the manuscript (section 'Primary outcomes' and 'Outcomes and prioritization').

In page 12, authors explained that fitness would be classified according to IPAQ. Nevertheless, this questionnaire does not assess fitness, but the amount of physical activity daily and sedentary behavior. Obviously, both are related to fitness, but IPAQ has not been designed to assess physical condition. It would be more accurate to classify the results according to cardiorespiratory fitness assessed with 6MWT, for example, using different values (meters covered within the 6-min test) for each sex (male, female) and each range of age (60-70, 71-80, and >80) (author may be interested in this publication: 10.1183/09031936.00194909). On the other hand, results from IPAQ could be used to classify participants as low, moderate or high physically active; which it differs from fitness level.

Additionally, I consider that training volume should be also important to be registered (numbers of set, repetitions and exercise per training session); and not only duration of each session since time may not reflected the amount of work performed. This concern it would be important even though American Collège of Sport Medicine commonly uses FITT principles, where training volume may not be clearly described.

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Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Exercise Physiology; Physical Fitness Assessment

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 13 Dec 2024

Bettina WOLLESEN

Response to reviewer 2 Authors described a very well-designed and rigorous study protocol to perform a systematic review with meta-analysis for helping policymakers, health professionals, and practitioners to achieve practical tools and knowledge for developing effective evidence-based exercise programs for improving functional mobility in older adults. **Answer:** We thank you for your overall estimation and the time you spent in critically reviewing our manuscript. We included your suggestions into the manuscript asnd highlighted them in light blue.

The introduction presents the content in a clear, orderly and rigorous manner; state of the art is well reflected. The authors correctly define the concept of 'functional mobility'. However, in my opinion, it would be more accurate to refer to this concept as 'functional capacity', as this term is much more commonly used in the scientific literature to describe what authors described. Readers may confuse 'functional mobility' with the concept of 'mobility', associated with flexibility or range of motion; therefore, in case authors refused to replace the term, I would suggest that it should be used throughout the manuscript as 'functional mobility' to avoid possible confusion (i.e.: first sentence in 'Objective' section; or the 3rd sentence in 'Discussion').
Answer: We thank the reviewer for this suggestion and changed the whole manuscript accordingly.

I consider that the section 'Short Physical Performance Battery (SPPB) and Timed Up and Go (TUG)' should not be titled with the name of the tests, but with the outcomes that these tests assess (like the previous section, which is titled 'Walking capacity and Gait performance' instead of '6MWT'). A proposed title for this section could be 'Other functional mobility assessments', since the tests mentioned assess different components of functional capacity (strength, balance...), and are related to the ability to perform activities of daily living, risk of falls, etc.
Answer: We agree with the reviewers idea and changed it accordingly.

Regarding the type of training interventions, it would be important to mention the importance of resistance training focused on muscle power improvement due to its importance for the increase of functional capacity in older people (i.e.: 10.1093/gerona/glx216)-ref-2.
Answer: We thank the reviewer for this advice and inserted this aspect on page 5 as follows: "Resistance training helps to increase muscle strength in the lower limb, which increases gait stability (Brach & Van Swearingen, 2013; Fragala et al., 2019) and muscle power improvement increases functional capacity (Alcazar et al., 2018)."

The proposed methodological design is solid and rigorous. However, in the section ‘Types of participants’ it is not clear whether the age of inclusion is greater than 60 or 50 years old; please clarify.
Answer: We agree with the reviewers conconcern and changed the section as follows: Types of participants We will include studies involving participants aged > 50, according to the WHO definition of "older adults" (mean age of 60 years ± SD, with a minimum age of 50). And in the next section: Firstly, we will meticulously assess each study's eligibility criteria to ascertain if they meet our age inclusion (mean age of 60 years, age range starting at 50 years) and exclusion criteria for specific conditions.

In addition, please delete the last sentence within ‘Types of intervention’ section as this information is repeated. Answer: We thank the reviwer for this advice and deleted the sentence as suggested. Furthermore, please do not repeat the explanation of abbreviations already used within the manuscript (section ‘Primary outcomes’ and ‘Outcomes and prioritization’).
Answer: We changed the text according to this advice.

In page 12, authors explained that fitness would be classified according to IPAQ. Nevertheless, this questionnaire does not assess fitness, but the amount of physical activity daily and sedentary behavior. Obviously, both are related to fitness, but IPAQ has not been designed to assess physical condition. It would be more accurate to classify the results according to cardiorespiratory fitness assessed with 6MWT, for example, using different values (meters covered within the 6-min test) for each sex (male, female) and each range of age (60-70, 71-80, and >80) (author may be interested in this publication: 10.1183/09031936.00194909). On the other hand, results from IPAQ could be used to classify participants as low, moderate or high physically active; which it differs from fitness level.
Answer: We thank the reviwer for this comment. We changed this section as follows: Characteristics of participants: age; gender; ethnicity; health conditions; level of mobility/activity (according to SPPB, TUG, or gait speed); physical activity level at baseline (according to IPAQ, GPAQ, fitness level at baseline with measurements like VO_2max (Stelmach, 2018) or walking capacity using the 6MWT, falls in the last 6 or 12 months before the intervention

Additionally, I consider that training volume should be also important to be registered (numbers of set, repetitions and exercise per training session); and not only duration of each session since time may not reflected the amount of work performed. This concern it would be important even though American Collège of Sport Medicine commonly uses FITT principles, where training volume may not be clearly described.
Answer: We definitely agree with this comment! We added the training volume into the manuscript. We classified this in our internal papers as “training characteristics” but did not transfer this into the study protocol. We now added the volume into the protocol as follows: Interventions: experimental and control interventions; timing of intervention; intensity, duration, volume and frequency of intervention/s;

Competing Interests: No competing interests were disclosed.

Reviewer Report 28 October 2024

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Firstly, I would like to thank you for the opportunity to review the article "Evidence-based exercise recommendations to improve functional mobility in older adults—A study protocol for living systematic review and meta-analysis."

The proposed article develops a comprehensive systematic review and meta-analysis research regarding evidence-based exercise recommendations for functional mobility in older adults. Given the various existing protocols on this topic and the difficulty of standardization, I consider this idea extremely important.
The article is well written, presenting an introduction with a solid literature review and adequately explaining the study's rationale and objectives. Given the various existing protocols on this topic and the difficulty of establishing a dose-response relationship of physical exercise for mobility improvement, I consider this idea extremely important.
The methodological aspects are presented in detail, but some aspects deserve attention:

- I missed a definition of F.I.I.T. It is in the abstract or right at the introduction but only appears at the end of the discussion.
- The search mechanisms are clear, but the feasibility of searching for unpublished data, depending on the availability of the authors, is confusing. It also mentions different languages, which I consider quite broad.
- The keywords are not listed in the MeSH terms.
- The study selection initially indicates that articles evaluating people aged 50 and over will be included, but the study is for the aged population. At another point in the methods, it appears that people aged 60 and over will be included. Please clarify this point.
- Regarding the outcome of "functional mobility," it was unclear why the daily walking distance and the number of daily steps were included among the primary outcomes. These outcomes are more directly related to the level of physical activity and could be on the list of secondary outcomes or just included as moderator variables.
- The description of the analyses for the meta-analysis is presented in detail, as are the strategies for presenting the results.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: My area of expertise is the effects of physical activity and exercise on physical function in older adults.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 13 Dec 2024

Bettina WOLLESEN

Dear reviewers, we thank you for the time and effort you spent on reading and commenting our manuscript. We revised the manuscript following your recommendations, highlighting the changes according to reviewer 1 in yellow and to reviewer 2 in light blue.

Firstly, I would like to thank you for the opportunity to review the article "Evidence-based exercise recommendations to improve functional mobility in older adults—A study protocol for living systematic review and meta-analysis."

The proposed article develops a comprehensive systematic review and meta-analysis research regarding evidence-based exercise recommendations for functional mobility in older adults. Given the various existing protocols on this topic and the difficulty of standardization, I consider this idea extremely important.
The article is well written, presenting an introduction with a solid literature review and adequately explaining the study's rationale and objectives. Given the various existing protocols on this topic and the difficulty of establishing a dose-response relationship of physical exercise for mobility improvement, I consider this idea extremely important.
Answer: We thank the reviewer for this estimation.

The methodological aspects are presented in detail, but some aspects deserve attention:

- I missed a definition of F.I.I.T. It is in the abstract or right at the introduction but only appears at the end of the discussion.

Answer: We agree with the reviewers advice and changed the sections as follows:
Abstract: *Background and objectives* This is a protocol for a living systematic review and meta-analysis. It will assess the effects of state-of-the-art exercise interventions designed to

promote functional mobility. Therefore, after identifying all potential interventions, we will use the F.I.T.T. principles (frequency, intensity, time, type) as well as the physical and health status of the participants as moderators to analyse the mechanisms for the positive benefits of exercising. The main research questions are: Which exercise types are most beneficial for improving functional mobility in various populations of older adults? Which physical exercise characteristics in terms of frequency, intensity, time and duration will achieve the greatest benefit in terms of the defined outcomes, i.e, the functional mobility of older adults? Methods According to PRISMA guidelines will search databases like MEDLINE, APA Psych-Info and Web of Science. Inclusion criteria are: healthy older people ≥ 50 years, randomized-controlled trials including exercise intervention and a walking or mobility assessments (eg., TUG, SPPB) as an outcome measure. A preliminary search revealed more than 33,000 hits that will be screened by pairs of independent reviewers. The results will be summarized according to the effects regarding functional mobility and potential dose-response relations via respective meta-analysis.
Conclusion The systematic review will comprise the knowledge of the existing literature with regards to the effects of the physical activity interventions compared to an active or inactive control group. We will summarize the effects with respect to the F.I.T.T.. They provide a foundation for structuring an optimal exercise training program. If possible, we will also compare interventions from the different categories (eg. cardiovascular, resistance, motor-coordinative, multicomponent or mind-body exercise) as a network analysis and report the influence of moderator variables. Based on the results evidence-based guidelines following GRADE for physical exercise interventions to improve functional mobility in older adults will be provided. Methods - **Types of interventions F.I.T.T. principle** The F.I.T.T. principle, a widely-used framework in exercise science, is based on four key factors: frequency, intensity, time, and type. The F.I.T.T. principle provides a framework for the structure of exercise programmes, with a particular focus on the following four key elements: the frequency of exercise, the intensity of the workout, the duration of the exercise session, and the specific form of the activity. This principle is fundamental to the prescription of exercise, allowing for adjustments to be made to meet individual fitness levels and goals. As a result, it has become an enduring tool in the fields of health and fitness (Schmitz et al., 2010). The term 'frequency' pertains to the number of times an individual engages in physical activity on a weekly basis, typically expressed as the number of sessions completed per week. The evidence indicates that undertaking moderate-intensity aerobic exercise on three to five occasions per week is beneficial for cardiovascular health and overall wellbeing. Similarly, resistance training is recommended on two to three occasions per week to improve muscle mass and strength (Garber et al., 2011). The term 'intensity' refers to the level of effort or difficulty associated with a particular exercise. It is a crucial factor in the adaptation of exercise programmes to suit different fitness levels and goals. The intensity of an exercise can be gauged by a number of means, including heart rate, perceived exertion, or metabolic equivalents (METs). Higher intensities, such as those employed in high-intensity interval training (HIIT), have been demonstrated to confer distinct cardiovascular and metabolic benefits (Hwang et al., 2016). The term "time" refers to the duration of each exercise session. For example, the general recommendation is to engage in 150 minutes per week of moderate aerobic activity or 75 minutes of vigorous activity. The duration of the exercise session is adjusted based on the intensity. Shorter sessions can be effective if the intensity is higher, as demonstrated by Hillman et al. (2020) in the case of HIIT. The term "type" denotes the specific category of exercise, encompassing aerobic activities such as

running and swimming, anaerobic exercises like weightlifting, and flexibility training. The different types of exercise have been shown to have varying beneficial effects on health. For example, aerobic exercise has been demonstrated to have positive effects on cardiovascular health, while resistance training has been shown to be effective in building muscle and bone strength (Lima et al., 2015).

- The search mechanisms are clear, but the feasibility of searching for unpublished data, depending on the availability of the authors, is confusing. It also mentions different languages, which I consider quite broad.

Answer: We agree with the reviewers concerns and revised the section. We deleted the part incorporating different languages. We clarified the second aspect as follws: The search will span all eligible studies in English language accessible through databases (Lefebvre 2022). Only studies reporting trial results will be incorporated. In cases where multiple studies cover the same or overlapping populations, priority will be given to the study with the highest participant count or the one following pre-registration in a trial register. Reference lists from included studies and relevant systematic reviews will be examined. Additionally, efforts will be made to identify trials by checking clinical trial registers such as ClinicalTrials.gov, the International Clinical Trials Registry Platform (ICTRP), or the German Clinical Trials Register (DRKS). Any missing data from RCTs will also prompt further investigation.

- The keywords are not listed in the MeSH terms.

Answer: We thank you for this comment. Our original key words were: functional mobility, older adults, physical training interventions, evidence-based exercise The MeSH terms adjusted keywords were: **Aged, Human, exercise, exercise therapy, motor activity** We added this to the information in the appendix.

- The study selection initially indicates that articles evaluating people aged 50 and over will be included, but the study is for the aged population. At another point in the methods, it appears that people aged 60 and over will be included. Please clarify this point.

Answer: We apologize if this was misleading. We revised this aspect as follows: Types of participants We will include studies involving participants aged > 50, according to the WHO definition of "older adults" (mean age of 60 years ± SD, with a minimum age of 50). And in the next section: Firstly, we will meticulously assess each study's eligibility criteria to ascertain if they meet our age inclusion (mean age of 60 years, age range starting at 50 years) and exclusion criteria for specific conditions.

- Regarding the outcome of "functional mobility," it was unclear why the daily walking distance and the number of daily steps were included among the primary outcomes. These outcomes are more directly related to the level of physical activity and could be on the list of secondary outcomes or just included as moderator variables.

Answer: We thank you for this comment. We discussed ist comprehensivly in our group and would like to keep this aspect like it is, as the level of functional mobility is related to walking capacity and daily mobility as described in our introduction..

- The description of the analyses for the meta-analysis is presented in detail, as are the strategies for presenting the results

Answer. We thank you for this comment and changed the sections as follows: On page 8 We will systematically collect data from studies that provide both baseline assessments and at least one post-intervention assessment. For studies with multiple post-intervention assessments, we will select the assessment closest to the completion of the exercise intervention as the primary data point for the meta-analysis. This choice aims to provide a consistent benchmark across studies. Additionally, to capture longer-term outcomes and the sustainability of intervention effects, follow-up assessments will be analyzed and reported separately. These follow-up results will help describe the maintenance of effects over time and offer insights into the durability of the intervention benefits. The clinically meaningful timing of outcome assessments will be determined by the nature of the intervention program and the specific pathology being addressed. For instance, shorter intervention periods may be more appropriate for acute conditions, whereas chronic conditions might require longer durations for meaningful outcomes to emerge. Consequently, our review will include evaluations categorized as short-term (within the first six months of treatment) and intermediate-term (from six to 12 months of treatment). This stratification allows for a nuanced understanding of how different interventions perform across varying timelines. And on page 14 To assess the possibility of publication bias and other reporting biases, we will conduct tests for funnel plot asymmetry for any analyses that include more than 10 data points. This threshold is consistent with the recommendations by Higgins et al. (2022), ensuring adequate power and reliability in identifying asymmetry. The funnel plot asymmetry tests will be applied separately for each comparison within the network, provided there are sufficient data points for meaningful analysis. In addition, comparison-adjusted funnel plots will be constructed as part of the network meta-analysis to detect potential small-study effects, which may arise from studies with smaller sample sizes reporting disproportionately large intervention effects. These plots will aid in identifying and interpreting potential biases across the network structure of the meta-analysis. A further measure to ensure impartiality in our review process will be implemented should any of the authors be contributors to a study included in the meta-analysis. In such cases, the involved authors will recuse themselves from conducting the risk of bias assessment and from participating in any GRADE (Grading of Recommendations Assessment, Development, and Evaluation) assessments that utilize data from their study. This measure safeguards the objectivity and transparency of our evaluation process. On page 15 Our review will employ a network meta-analysis (NMA) to comprehensively compare multiple exercise interventions and their effects. This method extends traditional meta-analysis by incorporating both direct comparisons (interventions compared within randomized controlled trials) and indirect comparisons (interventions compared across trials via a shared comparator). The NMA framework allows us to estimate the relative effectiveness of multiple interventions, even if some have not been directly compared in primary studies. Initially, a standard pairwise meta-analysis will be conducted to evaluate the intervention effects of individual exercise interventions. This preliminary step will establish the efficacy of each intervention in isolation. Subsequently, a mixed treatment comparison will integrate evidence from both direct and indirect comparisons using a consistency model to estimate relative treatment effects. Transitivity will be assessed by examining the distribution of effect modifiers (e.g., baseline characteristics, study design features) across the included studies to ensure that the conditions required for valid indirect comparisons are met. A network plot will be generated to visually represent the direct connections between different interventions, providing a clear depiction of the evidence base. The NMA will also allow us to investigate the influence of various moderators, such as participant characteristics (e.g., age, gender, baseline fitness levels) and intervention-specific factors (e.g., exercise intensity, frequency, and duration). To address potential inconsistencies within the network, inconsistency models may be employed. These models incorporate study-level covariates to account for variations across studies. If significant inconsistency is detected, we will explore adjustments such as including additional covariates or revising the model structure. This iterative process aims to ensure the robustness and reliability of the network meta-analysis findings.

Competing Interests: No competing interests were disclosed.