INPLASY

Effects of Non-Pharmacological Interventions on Self-Reported Vitality and Fatigue in Older Adults: A Systematic Review and Meta-Analysis Using the SF-36/RAND-36

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ADMINISTRATIVE INFORMATION

Support - No support.

Review stage at the time of initial registration - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 November 2026 and was last updated on 3 November 2026.

INTRODUCTION

Review question / Objective This systematic review and meta-analysis aimed to evaluate the overall efficacy of non-pharmacological interventions compared to standard care or control conditions on Vitality/Energy-Fatigue scores (measured by SF-36 or RAND-36) among older adults in Randomised controlled trials.

Rationale Fatigue, low energy, and diminished vitality are common and potentially disabling experiences in later life that may restrict independence, social participation, and functional rehabilitation. Within the World Health Organization (WHO) Healthy Ageing and Integrated Care for Older People (ICOPE) framework, vitality capacity refers to a broader physiological domain related to energy metabolism, nutritional status, and the biological processes that support an individual's functional reserves. However, this construct should be distinguished from self-reported vitality as assessed by health-related quality-of-life instruments. The SF-36 Vitality and RAND-36 Energy/Fatigue domains assess an individual's perceived position along a continuum ranging from tiredness and fatigue to energy and vitality. Therefore, the present review focuses specifically on this patient-reported Vitality/Energy-Fatigue construct and does not interpret SF-36/RAND-36 scores as a direct measure of WHO vitality capacity.

Given the limitations, adverse drug reactions, and polypharmacy risks associated with pharmacological management in older populations, non-pharmacological interventions, particularly structured physical exercise and behavioural or lifestyle approaches, may influence perceived vitality through multiple physical, functional, and psychosocial pathways. However, the present review evaluates their effects on patient-reported Vitality/Energy-Fatigue and does not directly assess the biological mechanisms underlying these changes.

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Although numerous Randomised controlled trials (RCTs) have evaluated non-pharmacological interventions in older populations, primary study findings remain highly heterogeneous and conflicting. Prior reviews have often aggregated disparate functional outcomes, examined mixed age cohorts without isolating older adults, or failed to differentiate between specific non-pharmacological modalities [4,6–8]. The SF-36 has demonstrated adequate feasibility, reliability, and validity in community-dwelling older adults [9]. Its Vitality domain captures a bipolar continuum ranging from perceived fatigue and tiredness to energy and vitality [10]. Furthermore, despite the widespread utilization of the SF-36 and RAND-36 Vitality scales across clinical trials, a comprehensive, standardized quantitative synthesis focusing specifically on these established 0–100 continuous metrics in RCTs of older adults is currently lacking.

Consequently, significant uncertainty remains regarding the relative efficacy of distinct non-pharmacological modalities on SF-36/RAND-36 Vitality scores in this population, as well as the extent to which study duration, intervention type, or baseline participant characteristics modify these effects.

Condition being studied Fatigue and reduced vitality are common in later life and can limit independence and participation.
To address this gap, this systematic review and meta-analysis aimed to evaluate the overall efficacy of non-pharmacological interventions—compared to usual care or control conditions—on vitality/energy-fatigue scores (measured using the SF-36 or RAND-36) in older adults, based on randomized controlled trials.
Furthermore, despite the widespread use of the SF-36 and RAND-36 vitality scales in clinical trials, there is currently no standardized, comprehensive quantitative synthesis that focuses specifically on these continuous metrics (ranging from 0 to 100) within randomized controlled trials involving older adults. Consequently, there remains considerable uncertainty regarding the relative efficacy of various non-pharmacological modalities on SF-36/RAND-36 vitality scores in this population, as well as the extent to which study duration, type of intervention, or participants' baseline characteristics may influence these effects. In this study, we evaluate the effects of non-pharmacological interventions on vitality/energy-fatigue—as perceived by the patients themselves—in older adults.

METHODS

Search strategy This systematic review and meta-analysis was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) statement.
A systematic search was conducted across four electronic databases: PubMed/MEDLINE, Latin American and Caribbean Health Sciences Literature (LILACS), Physiotherapy Evidence Database (PEDro), and Epistemonikos Database of Trials (ED-Trials). Searches covered all indexed literature from inception to October 2026. The last search was executed on October 1, 2026. Electronic database searches were complemented by backward and forward citation searching of included studies and relevant systematic reviews. Search strategies were developed around four main conceptual domains: (1) older adults, (2) SF-36/RAND-36 measurement tools, (3) non-pharmacological interventions, and (4) Randomised controlled trials. Controlled vocabulary terms (e.g., MeSH/DeCS) and free-text terms in titles and abstracts were adapted for each database interface. Terms for "vitality" or "energy/fatigue" were deliberately omitted from the title/abstract search strings to prevent omitting eligible RCTs where these subscales were reported only within full-text bodies or supplementary tables.

Participant or population Study eligibility was established according to the Population, Intervention, Comparator, Outcome, and Study Design (PICOS) framework. Population (P): Older adults aged ≥60 years from general, community-dwelling, or institutionalized populations, who were not specifically selected based on a single clinical diagnosis or disease. Participants with common age-related comorbidities were eligible, provided that these conditions were not the primary inclusion criterion for trial enrolment. Interventions (I): Structured non-pharmacological interventions, including physical exercise/activity, rehabilitation, psychological or behavioural therapies, mind-body interventions, patient education/self-management, behavioural sleep interventions, occupational therapy, social interventions, and multicomponent programs.

Intervention Structured non-pharmacological interventions, including physical exercise/activity, rehabilitation, psychological or behavioural therapies, mind-body interventions, patient education/self-management, behavioural sleep interventions, occupational therapy, social interventions, and multicomponent programs. For descriptive and exploratory analyses, included

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interventions were classified according to their primary component as: (1) exercise/physical activity, including mind-body exercise; (2) behavioural or educational physical-activity promotion; (3) occupational/lifestyle interventions; (4) multicomponent interventions; (5) monitoring/feedback interventions; or (6) device/footwear/other interventions. Comparators (C): Usual care, waitlist, minimal/attention control, or alternative non-pharmacological interventions. Outcomes (O): Patient-reported vitality, energy, or fatigue assessed specifically using the Vitality subscale of the Short Form-36 (SF-36) or the Energy/Fatigue subscale of the RAND-36. The primary continuous endpoint for quantitative synthesis was the Vitality/Energy-Fatigue score expressed on the conventional 0–100 scale. For the purposes of this review, this outcome was considered a patient-reported measure of vitality/energy-fatigue within health-related quality of life and not a direct measure of WHO vitality capacity. Studies reporting the SF-36 Vitality or RAND-36 Energy/Fatigue domain using norm-based or otherwise non-comparable scoring systems remained eligible for the systematic review and were included in the narrative synthesis. Such studies were excluded only from quantitative pooling unless the outcome could be validly expressed on the conventional 0–100 metric. Study Design and Report Characteristics: Randomised controlled trials (RCTs) with published original results were included. Trial registries, protocols, conference abstracts, and records lacking published result reports were excluded. No restrictions were placed on language, publication year, or healthcare setting.

A systematic search was conducted across four electronic databases: PubMed/MEDLINE, Latin American and Caribbean Health Sciences Literature (LILACS), Physiotherapy Evidence Database (PEDro), and Epistemonikos Database of Trials (ED-Trials). Searches covered all indexed literature from inception to October 2026. The last search was executed on October 1, 2026. Electronic database searches were complemented by backward and forward citation searching of included studies and relevant systematic reviews. Search strategies were developed around four main conceptual domains: (1) older adults, (2) SF-36/RAND-36 measurement tools, (3) non-pharmacological interventions, and (4) Randomised controlled trials. Controlled vocabulary terms (e.g., MeSH/DeCS) and free-text terms in titles and abstracts were adapted for each database interface. Terms for "vitality" or "energy/fatigue" were deliberately omitted from the title/abstract search strings to prevent omitting eligible RCTs where these subscales were reported only within full-text bodies or supplementary tables. Detailed search strategies for all databases are provided in Supplementary Material 1.

Comparator Analyses were stratified a priori according to comparator type. Comparisons with inactive or minimal controls including no intervention, usual care, waitlist, maintenance of usual activities, or minimal assessment constituted the primary meta-analysis. Trials using another structured non-pharmacological intervention as the comparator were synthesized separately as a secondary active-comparator analysis.

Study designs to be included This systematic review and meta-analysis was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) statement.

Eligibility criteria Titles and abstracts were independently screened by two reviewers according to the eligibility criteria. Full-text articles of potentially eligible records were subsequently assessed by a single reviewer. Data extraction was performed by a single reviewer using a standardized data collection form. Extracted variables included study characteristics (first author, publication year, country, and setting), participant characteristics (sample size, mean age, sex distribution, and relevant health status), intervention characteristics (type, duration, frequency, delivery mode, and supervision), comparator characteristics, and SF-36/RAND-36 Vitality/Energy-Fatigue outcomes. Zotero, Mendeley, and Microsoft Excel were used during the review process for reference management, study screening, and data organisation.

Information sources A systematic search was conducted across four electronic databases: PubMed/MEDLINE, Latin American and Caribbean Health Sciences Literature (LILACS), Physiotherapy Evidence Database (PEDro), and Epistemonikos Database of Trials (ED-Trials). Searches covered all indexed literature from inception to October 2026. The last search was executed on October 1, 2026. Electronic database searches were complemented by backward and forward citation searching of included studies and relevant systematic reviews. Search strategies were developed around four main conceptual domains: (1) older adults, (2) SF-36/RAND-36 measurement tools, (3) non-pharmacological interventions, and (4) Randomised controlled trials. Controlled vocabulary terms (e.g., MeSH/DeCS) and free-text terms in titles and abstracts were adapted for each database interface. Terms for "vitality" or "energy/

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fatigue" were deliberately omitted from the title/abstract search strings to prevent omitting eligible RCTs where these subscales were reported only within full-text bodies or supplementary tables.

Main outcome(s) The primary continuous endpoint for quantitative synthesis was the Vitality/Energy-Fatigue score expressed on the conventional 0–100 scale. For the purposes of this review, this outcome was considered a patient-reported measure of vitality/energy-fatigue within health-related quality of life and not a direct measure of WHO vitality capacity. Studies reporting the SF-36 Vitality or RAND-36 Energy/Fatigue domain using norm-based or otherwise non-comparable scoring systems remained eligible for the systematic review and were included in the narrative synthesis. Such studies were excluded only from quantitative pooling unless the outcome could be validly expressed on the conventional 0–100 metric. Study Design and Report Characteristics: Randomised controlled trials (RCTs) with published original results were included. Trial registries, protocols, conference abstracts, and records lacking published result reports were excluded. No restrictions were placed on language, publication year, or healthcare setting.

Additional outcome(s) Non-pharmacological interventions may improve vitality in older adults, but the magnitude and consistency of benefit remain uncertain.

Data management This systematic review and meta-analysis evaluated the effects of non-pharmacological interventions on patient-reported Vitality/Energy-Fatigue in older adults, using the SF-36 or RAND-36 domain as a common outcome.

When at least 10 studies were available, potential small-study effects were evaluated by visual inspection of funnel plots and formally tested using Egger's regression test. Funnel-plot asymmetry was interpreted cautiously because asymmetry may arise from sources other than publication bias, particularly in the presence of between-study heterogeneity. All statistical analyses were performed in R using the metafor package. A two-sided p-value <0.05 was considered statistically significant.

Quality assessment / Risk of bias analysis Risk of bias was assessed by a single reviewer using the Cochrane Risk of Bias 2 (RoB 2) tool. The standard RoB 2 framework was applied to parallel-group randomised trials, while the appropriate adaptations were used for cluster-randomised and crossover trials, as applicable. Five domains were assessed: (1) bias arising from the randomisation process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in measurement of the outcome, and (5) bias in selection of the reported result. Overall risk of bias for each study result was categorised as low risk, some concerns, or high risk .

Strategy of data synthesis Intervention effects on the SF-36/RAND-36 Vitality/Energy-Fatigue domain were expressed as mean differences (MDs) with 95% confidence intervals (CIs), with positive values indicating higher vitality (lower fatigue) in the intervention group. Quantitative synthesis was restricted to outcomes reported on, or compatible with, the conventional 0–100 scale. Post-intervention scores and change-from-baseline scores were eligible for pooling because they were expressed on the same measurement scale. When an appropriate adjusted treatment effect and its standard error or confidence interval were reported by the study authors, this estimate was preferentially used; otherwise, MDs and corresponding variances were calculated from reported sample sizes, means, and standard deviations.

Pooled effects were estimated using random-effects meta-analysis. Between-study variance (?2) was estimated using the restricted maximum likelihood (REML) method, and confidence intervals and tests of the pooled effect were calculated using the Hartung–Knapp adjustment. Statistical heterogeneity was assessed using Cochran's Q test, the ? 2 statistic, and ?2. Ninety-five percent prediction intervals were calculated to describe the range of effects that might be expected across comparable settings when sufficient studies were available.

Analyses were stratified a priori according to comparator type. Comparisons with inactive or minimal controls including no intervention, usual care, waitlist, maintenance of usual activities, or minimal assessment constituted the primary meta-analysis. Trials using another structured non-pharmacological intervention as the comparator were synthesized separately as a secondary active-comparator analysis.

For trials including more than one eligible intervention arm and a single shared comparator, eligible intervention arms were combined to avoid double-counting participants in the control group. Combined sample sizes were obtained by summing participants across intervention arms; combined means were calculated as sample-size-weighted means, and combined standard deviations incorporated both within-group variability and differences between arm means.

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Influence diagnostics and leave-one-out analyses were performed to examine the effect of individual studies on the pooled estimate and between-study heterogeneity. Exploratory analyses according to intervention category were conducted, and differences between intervention categories were evaluated using meta-regression and the corresponding test of moderators. These analyses were considered exploratory because of the limited number of studies within individual intervention categories.

Subgroup analysis none.

Sensitivity analysis Exploratory analyses according to intervention category were conducted, and differences between intervention categories were evaluated using meta-regression and the corresponding test of moderators. These analyses were considered exploratory because of the limited number of studies within individual intervention categories.
When at least 10 studies were available, potential small-study effects were evaluated by visual inspection of funnel plots and formally tested using Egger's regression test. Funnel-plot asymmetry was interpreted cautiously because asymmetry may arise from sources other than publication bias, particularly in the presence of between-study heterogeneity. All statistical analyses were performed in R using the metafor package. A two-sided p-value <0.05 was considered statistically significant.

Language restriction English.

Country(ies) involved México.

Other relevant information Background: Fatigue and reduced vitality are common in later life and may limit independence and participation. We evaluated the effects of non-pharmacological interventions on patient-reported Vitality/Energy-Fatigue in older adults.
Methods: We systematically searched PubMed/MEDLINE, LILACS, PEDro and Epistemonikos from inception to 1 October 2026 for randomised controlled trials including adults aged ≥60 years and reporting the SF-36 Vitality or RAND-36 Energy/Fatigue domain. Random-effects meta-analyses used mean differences (MDs) on the conventional 0–100 scale, with inactive/minimal and active comparators analysed separately. Risk of bias was assessed using RoB 2.

Keywords Older adults, Vitality, Fatigue, Non-pharmacological interventions, Systematic review and meta-analysis.

Dissemination plans Consequently, significant uncertainty remains regarding the relative efficacy of distinct non-pharmacological modalities on SF-36/RAND-36 Vitality scores in this population, as well as the extent to which study duration, intervention type, or baseline participant characteristics modify these effects. To address this gap, this systematic review and meta-analysis aimed to evaluate the overall efficacy of non-pharmacological interventions compared to standard care or control conditions on Vitality/Energy-Fatigue scores (measured by SF-36 or RAND-36) among older adults in Randomised controlled trials.• Non-pharmacological interventions were associated with improved SF-36/RAND-36 Vitality/Energy-Fatigue scores compared with inactive or minimal controls.

Contributions of each author

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