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Effectiveness of Physical Exercise on gait performance in Individuals with Down Syndrome: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - 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 29 April 2025 and was last updated on 29 April 2025.

INTRODUCTION

Review question / Objective This systematic review and meta-analysis aims to assess the effectiveness of structured physical exercise programs in improving gait-related outcomes among individuals with Down syndrome.

Rationale Individuals with Down syndrome frequently experience gait abnormalities that negatively impact their functional mobility, independence, and quality of life. Although previous research has demonstrated the general benefits of physical exercise in this population, the specific effects on gait performance remain underexplored. Given the important role of gait ability in overall health and daily functioning, there is a need to systematically synthesize current evidence on the effectiveness of structured physical exercise interventions targeting gait outcomes in individuals with Down syndrome.

Condition being studied Down syndrome is a genetic disorder caused by the presence of an extra full or partial copy of chromosome 21. It is the most common chromosomal abnormality, affecting approximately 1 in 800 live births worldwide. Individuals with DS commonly present with intellectual disability, hypotonia, delayed motor development, and distinctive physical features. Neuromotor impairments, including balance deficits and gait abnormalities, are hallmark characteristics that contribute to reduced mobility, increased fall risk, and limitations in daily functioning. Improving gait performance is essential for enhancing independence, participation, and quality of life in this population.

METHODS

Search strategy A comprehensive literature search was conducted across the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science Core Collection, EBSCO,

and Scopus. The search included studies published up to April 2025. Both Medical Subject Headings (MeSH) and free-text terms were used to maximize retrieval sensitivity. The search terms included combinations of keywords related to "Down syndrome," "physical exercise," and "gait performance." Reference lists of relevant systematic reviews and included articles were also manually screened to identify additional eligible studies.

Participant or population Individuals diagnosed with Down syndrome of any gender, aged 10 years and older, will be included in the review. Eligible participants may be adolescents or adults with Down syndrome who present with gait impairments. There will be no restrictions based on comorbidities, ethnicity, or geographical location. Only studies that explicitly report a clinical diagnosis of Down syndrome and assess gait-related outcomes will be considered.

Intervention The interventions of interest include structured physical exercise programs specifically designed for individuals with Down syndrome. These programs may involve aerobic training, resistance training, exergaming (e.g., Wii-based exercises), swimming, Nordic walking, dance therapy, or other structured physical activities. Eligible interventions must be conducted at least once per week for a minimum duration of three weeks, and aim to improve gait-related outcomes such as functional mobility, walking distance, or walking speed.

Comparator The comparator will be control groups receiving no structured physical exercise intervention. This may include usual care, maintenance of daily activities, social activities without structured exercise, or standard educational support. Studies with active exercise interventions in the control group will be excluded.

Study designs to be included This review will include randomized controlled trials (RCTs) and quasi-randomized controlled trials (quasi-RCTs) that evaluate the effects of structured physical exercise interventions on gait-related outcomes in individuals with Down syndrome. Only peer-reviewed, full-text articles published in English will be considered. Observational studies, case reports, case series, and conference abstracts will be excluded.

Eligibility criteria In addition to the predefined PICOS framework, the following eligibility criteria will be applied. Only full-text articles published in peer-reviewed journals will be included, and studies must be published in English. Studies are required to involve a sample size greater than five participants per group to ensure minimal statistical validity. Conference abstracts, dissertations, editorials, commentaries, protocols, case reports, and case series will be excluded. Furthermore, eligible studies must report quantitative outcomes specifically related to gait performance. Duplicate publications and secondary analyses without new data will also be excluded from the review.

Information sources A comprehensive search will be conducted across the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science Core Collection, EBSCO, and Scopus. The search will include studies published up to April 2025. Additionally, the reference lists of all eligible articles and relevant systematic reviews will be manually screened to identify any additional studies that meet the inclusion criteria. No restrictions on publication date will be applied. Grey literature sources, conference abstracts, and trial registries will not be actively searched, and only peer-reviewed full-text articles published in English will be considered.

Main outcome(s) The primary outcomes of this review are gait-related functional performance measures in individuals with Down syndrome following structured physical exercise interventions. Specifically, functional mobility assessed by the Timed Up and Go Test (TUG) and 8-ft Up-and-Go test, walking endurance assessed by the six-minute walk test (6MWT), and walking speed measured through standardized gait assessments will be included. Outcomes will be evaluated immediately after the intervention period. Effect measures will include mean differences (MD) for outcomes measured on the same scale, and standardized mean differences (SMD) when different measurement scales are used across studies, both with 95% confidence intervals.

Additional outcome(s) Adverse events will be recorded as reported by the original studies to assess the safety of physical exercise interventions in individuals with Down syndrome.

Data management All identified records will be imported into EndNote (Clarivate Analytics) for initial management, including the removal of duplicate entries. After deduplication, the records will be exported into Rayyan, a web-based platform for systematic review management, for title and abstract screening. Two reviewers will independently screen all records and full texts for eligibility. Any discrepancies will be resolved

through discussion or consultation with a third reviewer if necessary. Data from eligible studies will be extracted into a predesigned Excel spreadsheet, which will include study characteristics, participant details, intervention features, outcomes, and risk of bias assessments. The extracted data will be cross-verified by two reviewers to ensure accuracy. All files will be securely stored and regularly backed up to prevent data loss.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of included studies will be assessed independently by two reviewers. For randomized controlled trials (RCTs), the Physiotherapy Evidence Database (PEDro) scale will be used, which evaluates methodological quality across 11 criteria, including randomization, allocation concealment, blinding, and statistical reporting. Each item will be scored as "yes" (1 point) or "no" (0 points), with a total score reflecting overall study quality. For quasi-randomized controlled trials (quasi-RCTs), the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool will be applied, assessing bias across seven domains such as confounding, selection of participants, and measurement of outcomes. Any discrepancies between reviewers will be resolved through discussion, and a third reviewer will be consulted if consensus cannot be reached. The results of quality assessment will be used to interpret the reliability of the findings and to inform sensitivity analyses.

Strategy of data synthesis Meta-analyses will be conducted using Review Manager (RevMan 5.3) and Stata version 12.0 software. For continuous outcomes measured using the same scale, mean differences (MDs) with 95% confidence intervals (CIs) will be calculated. When different measurement scales are used across studies, standardized mean differences (SMDs) with 95% CIs will be reported. Heterogeneity across studies will be assessed using Cochran's Q test and quantified with the I^2 statistic. I^2 values of 50% will be interpreted as low, moderate, and high heterogeneity, respectively. A random-effects model will be applied if substantial heterogeneity is detected (p 50%); otherwise, a fixed-effect model will be used. Sensitivity analyses will be performed by omitting studies one by one to assess the robustness of the results. If sufficient data are available, subgroup analyses based on intervention types, participant age groups, and exercise intensity will be conducted. In cases where meta-analysis is not feasible due to data limitations or study heterogeneity, findings will be summarized narratively.

Subgroup analysis If sufficient data are available, subgroup analyses will be conducted to explore potential sources of heterogeneity. Planned subgroup analyses include: (1) type of physical exercise intervention (e.g., aerobic training, resistance training, balance exercises, or multimodal programs); (2) participant age groups (e.g., adolescents vs. adults); (3) intervention duration (e.g., less than 12 weeks vs. 12 weeks or longer); and (4) exercise intensity or frequency. These subgroup analyses will help to identify whether specific intervention characteristics or participant features are associated with differential effects on gait performance outcomes.

Sensitivity analysis Sensitivity analyses will be performed to assess the robustness and stability of the meta-analysis results. Specifically, leave-one-out analyses will be conducted by sequentially removing each included study to evaluate the impact on the overall effect size. Additionally, sensitivity analyses excluding studies with high risk of bias, as identified by PEDro or ROBINS-I assessments, will be carried out. Alternative statistical models (fixed-effect vs. random-effects) will also be applied to explore the influence of model selection on the pooled estimates. The consistency of findings across these sensitivity analyses will help to verify the reliability of the conclusions.

Language restriction English.

Country(ies) involved Poland.

Other relevant information None.

Keywords Down syndrome; gait; functional mobility; physical exercise, meta-analysis.

Dissemination plans We plan to publish this systematic review and meta-analysis in a peer-reviewed journal.

Contributions of each author

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