

Prescription of multicomponent exercise in a population aged 80 and over in a Latin American city: randomized clinical trial

Prescripción de ejercicio multicomponente en una población de 80 años o más en una ciudad Latinoamericana: ensayo clínico aleatorizado

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Abstract

Objective: To assess the effects of a structured multicomponent exercise program (VIVIFRAIL) on physical function, autonomy, and health-related quality of life in older adults aged 80 years and over.

Methods: A randomized controlled trial was conducted with 158 participants (79 per group), with a median age of 85 years. The intervention group received individualized exercise prescriptions based on the VIVIFRAIL protocol. Follow-up lasted 24 months, with five assessment points using the Short Physical Performance Battery (SPPB), Barthel Index, Lawton-Brody Scale, and European Quality of Life Visual Analogue Scale (EQ-VAS).

Results: No significant between-group differences were found in physical function (SPPB) or autonomy (Lawton-Brody), as both groups showed functional decline over time. However, subjective health perception (EQ-VAS) remained stable in the intervention group while decreasing significantly in the control group.

Conclusion: Although the intervention did not significantly modify the trajectory of physical decline, it had a positive effect on psychosocial well-being domains.

Keywords: aged 80 and over, physical exercise, functional status, autonomy, quality of life.

Clinical Trial Registration: Retrospectively registered at ClinicalTrials.gov, identifier NCT07447492.

Resumen

Objetivo: Evaluar los efectos de un programa estructurado de ejercicio multicomponente (VIVIFRAIL) sobre la capacidad funcional física, la autonomía y la calidad de vida relacionada con la salud en adultos mayores de 80 años o más.

Métodos: Se realizó un ensayo clínico aleatorizado con 158 participantes (79 por grupo), con una mediana de edad de 85 años. El grupo de intervención recibió una prescripción de ejercicio individualizada basada en el protocolo VIVIFRAIL. El seguimiento duró 24 meses, con cinco puntos de evaluación utilizando el Short Physical Performance Battery (SPPB), el Índice de Barthel, la Escala de Lawton-Brody y la EuroQol Visual Analogue Scale (EQ-VAS), integrados en una Valoración Geriátrica Integral.

Resultados: No se observaron diferencias significativas entre los grupos en cuanto a la capacidad funcional física (SPPB) o la autonomía (Lawton-Brody), ya que ambos grupos mostraron un deterioro funcional progresivo a lo largo del tiempo. Sin embargo, la percepción subjetiva de salud (EQ-VAS) se mantuvo estable en el grupo de intervención, mientras que disminuyó de forma marcada en el grupo control.

Conclusión: Los hallazgos sugieren que, aunque la intervención no modificó significativamente la trayectoria del deterioro físico, tuvo un efecto positivo en las dimensiones psicosociales del bienestar y la calidad de vida.

Palabras clave: ancianos de 80 o más años, ejercicio físico, estado funcional, autonomía, calidad de vida.

Registro de ensayos clínicos: Registrado retrospectivamente en ClinicalTrials.gov, identificador NCT07447492.

INTRODUCTION

The growing proportion of older adults has become one of the most transformative social, economic, and health care phenomena worldwide. In Colombia, this global trend is reflected in the steady growth of the population aged 60 years and older, which now accounts for 15% of the overall population, according to the National Administrative Department of Statistics (Departamento Administrativo Nacional de Estadística, DANE).¹ This trend is particularly evident in capital cities, where both the number of older adults and the complexity of their health care demands and needs are increasing.

The World Health Organization defines healthy aging as a guiding framework, emphasizing maintenance of autonomy, social integration, and safety. This approach seeks to enhance physical and mental capacities by leveraging the influence of supportive environments. In this setting, information and communication technologies have emerged as important facilitators, improving access to health care services, enabling the creation of support networks, and promoting quality of life. These factors motivated the development of the project “Creation and validation of a teleassistance system focused on active aging, with an emphasis on social support and individualized management for older adults,” to which this study is linked.

Healthy aging is highly dependent on the maintenance of functional capacity, understood as the ability to perform activities that ensure autonomy and well-being in the individual’s usual environment.^{2,3} Functional decline in older adults is a strong predictor of adverse outcomes, including disability, hospitalization, institutionalization, and mortality.⁴⁻⁷ Therefore, regular assessment using validated tools, such as the Barthel Index and the Lawton-Brody Scale for autonomy, and the Short Physical Performance Battery (SPPB) for physical function,⁷ is essential, as it enables quantification of the effects of interventions.

An extensive and consistent body of global evidence supports the effectiveness of multicomponent physical exercise programs, including VIVIFRAIL (VF), in preventing and reversing frailty. By integrating strength, balance, and endurance training, these programs have demonstrated significant improvements in SPPB scores, the main measure of physical function.^{8,9}

However, the applicability and impact of standardized European programs such as VF have not been consistently documented or validated within the specific context of older adults living in Latin American capital cities.

The evidence gap is twofold. First, from a demographic and social perspective, since most high-quality studies on

VF have been conducted in European settings. Therefore, few controlled clinical trials have assessed the effectiveness of VF in Colombian older adults, particularly those living in urban areas, whose adherence patterns, comorbidity profiles, and socioeconomic context (access to services, social support, and use of information and communication technologies) differ markedly from those of the European populations already studied.

Furthermore, important gaps persist in the comprehensive assessment of outcomes. Although the literature has primarily emphasized improvements in physical function as measured by the SPPB,^{8,9} the combined effects of VF on autonomy, assessed using the Barthel Index and the Lawton-Brody Scale, and on perceived health-related quality of life,^{10,11} evaluated using sensitive tools such as the European Quality of Life Five Dimensions Five Levels Scale and the European Quality of Life Visual Analogue Scale (EQ-VAS),^{12,13} remain unclear in the urban Latin American geriatric population. Therefore, local research is required to adapt, validate, and quantify the effectiveness of a structured program such as the VF in this population, employing a multidimensional evaluation that includes physical function, autonomy, and quality of life.

In light of this evidence gap, the main objective of this study was to assess the effect of a structured multicomponent exercise program (VF) on physical function (SPPB), autonomy (Barthel Index and Lawton-Brody Scale) and health-related quality of life (EQ-VAS) among older adults living in a Latin American city, compared with a control group.

METHODS

A randomized controlled trial with two parallel groups (an intervention group and a control group) was designed. Its primary objective was to assess the effect of the VF multicomponent exercise program on physical function, autonomy, and quality of life in older adults. Participants were longitudinally followed for 24 months, with five assessment points (baseline, 26, 52, 78 and 104 weeks).

The study population consisted of 158 adults aged 80 years and over, who were distributed into two groups of 79 participants each. Potential participants were identified by reviewing databases from the Health Promotion Entity (Entidad Promotora de Salud, EPS) and contacted by telephone.

Participants were affiliated with Compensar EPS, an entity within Colombia’s General System of Social Security in Health (Sistema General de Seguridad Social en Salud). This organization serves a large urban population, mainly located

in Bogotá, D.C. and Cundinamarca. As of December 2020, this EPS reported 1 753 935 affiliated members. The recruited population predominantly belonged to the Contributory Regime and to middle and lower-middle socioeconomic strata.

Sample size was determined based on the primary outcome, using a difference-in-mean approach for repeated measures within the same group, assuming a confidence level of 95%, a type I error of 0.05%, a statistical power of 90%, a type II error of 20%, a proportion of 70% in the reference group and 40% in the intervention group, and an estimated loss to follow-up of 20%. The resulting sample size was 63 individuals per arm, adjusted to 76 individuals per arm (152 individuals in total). Calculations were performed using the *pwr* package in R software, version 4.3.0.

Inclusion criteria comprised individuals aged 80 years and over, with a Barthel Index score > 80 points, available for telephone contact, living in an urban area of a Latin American city, and who voluntarily agreed to participate. Exclusion criteria were moderate to severe dementia, as defined by a Global Deterioration Scale stage 5–7, and any medical or psychiatric condition that, in the opinion of the research team, indicated a poor short-term functional or survival prognosis or posed a safety risk to the participant. These conditions included, but were not limited to, acutely decompensated chronic diseases, poor adherence to essential medical therapies, or severe dementia-related behavioral disturbances that would preclude appropriate implementation of the intervention.

The 158 participants were randomly assigned in a 1:1 ratio to the intervention or the control group. Simple randomization was applied, with no block stratification or matching, and was conducted using an online computerized system (<https://www.randomizer.org>).

Baseline group comparisons revealed no statistically significant differences in demographic or clinical variables ($p > 0.05$), suggesting that randomization effectively minimized bias from known confounders. However, a statistically significant difference was observed in baseline SPPB scores.

Neither participants nor personnel administering the intervention (exercise prescription) were blinded. Nevertheless, the statistical analysts responsible for outcome evaluation were blinded to group allocation.

The primary outcome was the percentage change in physical function as measured by the SPPB. Secondary outcomes comprised changes in scores on the Barthel index, the Lawton-Brody Scale, and EQ-VAS between the baseline visit and each follow-up assessment. Additional variables included demographic variables (age and sex), comorbidities, and anthropometric measures (weight, height, body

mass index, calf circumference, and handgrip strength). Five assessments were conducted, all of which incorporated the Comprehensive Geriatric Assessment.

Access to and use of the VF protocol for this trial were managed directly with the lead author team. No franchise or commercial licensing were paid, and the protocol was not acquired through EPS funding.

The use of the VF protocol in this investigation was authorized formally and directly by the lead author as part of an academic and research collaboration focused on validating the protocol in an urban Latin American geriatric population. This authorization enabled the application and assessment of the exercise protocol within the scope of this study.

The control group received usual care according to their clinical condition. The intervention group received exercise prescription using the VF protocol, guided by SPPB assessment,⁹ along with education on healthy aging. Based on this assessment, each participant was assigned an individualized “exercise passport.” These passports (types A, B, C, and D) corresponded to different functional levels. Each passport included a tailored “exercise wheel” specifying the type of exercise, number of sets and repetitions, and weekly progression. Data collection was performed using the instruments previously described. Due to the COVID-19 pandemic, part of data collection was conducted remotely via landline and mobile telephone and internet-based platforms.

All statistical analyses were performed using R software (version 4.3.0). Baseline comparisons and bias control were conducted using chi-square tests for categorical variables and the Mann-Whitney U test for nonparametric continuous variables. For within-group longitudinal analysis, the Friedman for nonparametric repeated measures was applied, followed by Bonferroni-adjusted post hoc Wilcoxon tests to assess changes within each group across the five assessment time points.

Furthermore, an analysis was conducted to control for between-group confounding. To evaluate differences in both the trajectory and magnitude of functional decline and to mitigate potential bias arising from baseline differences in SPPB scores, delta changes (Δ) were calculated for each outcome as the difference between week 104 and baseline values. Between-group comparisons of delta changes were performed using the Mann-Whitney U test.

For the management of missing data, a proportion of less than 3% was deemed acceptable, and mean column imputation was used to enable subsequent statistical analyses. The threshold for statistical significance was set at $p < 0.05$.

This randomized controlled trial with two parallel groups (an intervention group and a control group) was retrospectively

registered on ClinicalTrials.gov (NCT07447492) on 02-11-2026 to ensure complete publication of all results.

The protocol for this randomized clinical trial was reviewed and approved by the institutional Research Ethics Committee of the School of Medicine at Pontificia Universidad Javeriana in an ordinary session on August 13, 2020, as recorded in Approval Act No. 17/2020. Prior to initiating any study procedures, potential participants were contacted by telephone to receive information about study objectives. Individuals who agreed to participate and met inclusion and exclusion criteria provided written informed consent, thereby ensuring that their participation in the study was entirely voluntary.

RESULTS

A total of 158 adults aged ≥ 80 years were enrolled and randomly assigned to control and intervention groups ($n = 79$ each). Baseline comparisons revealed no statistically significant differences in demographic or clinical variables between the groups ($p > 0.05$), supporting the effectiveness of the randomization process. The median age was 85 years, and

the sample was predominantly female. The most frequent comorbidities included arterial hypertension, gastrointestinal diseases, and dyslipidemia. Moreover, approximately 25% of participants reported at least one fall in the preceding 6 months, and over 45% reported fear of falling. Median values for anthropometric and muscle strength parameters were indicative of relatively preserved physical function, despite individual variability (Table 1). Weight, height, body mass index, calf circumference, and muscle strength were within expected reference ranges for this geriatric population.

Baseline assessment

Baseline analysis demonstrated homogeneity between groups across all evaluated variables, except for SPPB scores, which were higher in the intervention group (median = seven points vs. six points in the control group). In both groups, participants were independent in basic activities of daily living, showed mild dependence in instrumental activities of daily living, had preserved cognitive function and normal emotional status, and were at risk of malnutrition, with no significant differences between groups. Perceived health status was comparable at baseline (Table 2).

TABLE 1. Baseline sociodemographic and clinical characteristics of control and intervention groups.

Characteristics	Control group $n = 79^*$	Intervention group $n = 79^*$	p-value [†]
Demographic			
Sex (%)			
Male	20 (25)	21 (27)	0.9
Female	59 (75)	58 (73)	
Age	85 (84-88)	85 (83-88)	0.7
Comorbidities (%)			
Arterial hypertension	54 (68)	52 (66)	0.7
Arrhythmias	10 (13)	9 (11)	0.8
Heart disease	5 (6.3)	4 (5.1)	> 0.9
Gastrointestinal disease	22 (28)	28 (35)	0.3
Kidney disease	3 (3.8)	6 (7.6)	0.5
Lung disease	3 (3.8)	7 (8.9)	0.2
Parkinsonism	5 (6.3)	6 (7.6)	0.8
Psychiatric disease	6 (7.6)	5 (6.3)	0.8
Dyslipidemia	21 (27)	14 (18)	0.2
Alcoholism	0 (0)	1 (1.3)	> 0.9
Fall in the preceding 6 months	18 (23)	19 (24)	0.9
Fear of falling	46 (58)	37 (47)	0.2
Anthropometric			
Weight	60 (54-70)	60 (53-67)	0.5
Height	152 (147-159)	153 (149-158)	0.6
Body mass index	25.9 (22.8-30.1)	25.3 (23.1-28.1)	0.3
Calf circumference	32 (30-35)	32.5 (30.5-34)	0.7
Muscle strength	14 (10-22)	18 (12-22)	0.1

*n (%) of positive responses; median (IQR); [†]p-values for chi-square or Fisher's exact tests and the Mann-Whitney U test.

Temporal evolution

SPPB scores declined significantly in both groups ($p < 0.01$), although the intervention group consistently demonstrated higher performance (decrease from eight to seven points vs. from six to five points in controls). Regarding basic activities of daily living, both groups maintained functional independence, with no significant decline (scores > 10 points). The Lawton-Brody Index indicated a more pronounced decrease in the control group (from six to four points; $p < 0.001$) than in the intervention group (from six to five points; $p = 0.014$). EQ-VAS scores differed substantially: the control group showed a marked decrease (from 80 to 60 points; $p < 0.001$), whereas the intervention group remained unchanged (≈ 80 points, $p = 0.513$).

Comparative analysis of changes

Analysis of change scores (week 104 vs. baseline) revealed that only EQ-VAS scores differed significantly between groups ($p < 0.001$), with a negative median change in the control group (median = -13 points) and no meaningful change in the intervention group (median = 0). Functional autonomy, as

assessed by the Barthel Index, decreased in the control group (median = -7 points; IQR, -15 to 0), whereas the intervention group remained functionally stable (median = 0; IQR, -8 to 0), yielding a statistically significant between-group difference ($p = 0.050$). The remaining scales demonstrated parallel declining trends in both groups, without significant between-group differences (Table 3).

DISCUSSION

Over a 24-month period, this study assessed an intervention designed to promote healthy aging among adults aged 80 years and over. Its main findings demonstrated that between-group differences in the progression of physical function and autonomy in basic and instrumental activities of daily living were not statistically significant. However, a significant protective effect was observed with respect to overall self-perceived health. Specifically, the control group experienced a marked decline in this outcome, whereas the intervention group remained clinically stable over time.

TABLE 2. Baseline comparison of assessment scale scores between control and intervention groups.

Scales	Control group n = 79 Median (IQR)	Intervention group n = 79 Median (IQR)	p-value*
Short Physical Performance Battery	6 (4-9)	7 (5-10)	0.027
Barthel Index	95 (85-100)	100 (95-100)	0.063
Lawton-Brody Scale	5 (2-7)	6 (3-7)	0.3
European Quality of Life Visual Analogue Scale	80 (60-90)	80 (69-90)	0.7
Mini Mental State Examination	26 (21-28)	26 (22-29)	0.5
Memory Complaint Scale	17 (9-24)	13 (5-23)	0.13
Geriatric Depression Scale	2 (0-5)	1 (0-4)	0.5
Mini Nutritional Assessment	11 (10-13)	12 (10-13)	0.4

*p-values for the Mann-Whitney U test.

TABLE 3. Comparison of delta changes in assessment scale scores from baseline to week 104 between the control and intervention groups.

Scales	Control group n = 50 Median delta change (IQR)	Intervention group n = 44 Median delta change (IQR)	p-value*
Short Physical Performance Battery	-1 (-3 to 1)	-1.50 (-4 to 1)	0.5
Barthel Index	-7 (-15 to 0)	0 (-8 to 0)	0.050
Lawton-Brody Index	-1 (-3 to 0)	-0.5 (-3 to 0)	0.7
European Quality of Life Visual Analog Scale	-13 (-25 to 0)	0 (-10 to 10)	< 0.001
Mini Mental State Examination	-2 (-4 to 0)	-1 (-3 to 0.5)	0.3
Memory Complaint Scale	0 (-8 to 6)	-1 (-5 to 6)	> 0.9
Geriatric Depression Scale	2 (1-4)	2 (1-4)	0.7
Mini Nutritional Assessment	-1 (-3 to 0)	-1 (-2 to 0)	0.3

*p-values for the Mann-Whitney U test.

The maintenance of perceived health in the intervention group is a particularly relevant finding in individuals of advanced age. This observation is in line with research showing the positive impact of comprehensive interventions on subjective well-being.¹⁴⁻¹⁶ The data suggest that, although the intervention failed to significantly modify physical functional decline, it may have positively influenced psychosocial factors that are central to healthy aging.

The lack of statistically significant differences in functional outcomes may be attributable to several factors. First, the profile of the sample, characterized by extremely advanced age (median age of 85 years) and a probable multimorbidity, may have limited the ability to modify the trajectory of functional decline. Second, intervention parameters (exercise intensity and frequency) may have been insufficient to elicit detectable effects in this population. Moreover, the higher baseline SPPB scores in the intervention group (seven points vs. six points in the control group) may have produced a ceiling effect, limiting the capacity to observe additional functional gains.¹⁷

The improvement found in EQ-VAS scores may be attributable to the non-physical components of the intervention, such as training sessions, social support, and telecare. Such components may have promoted greater self-efficacy, mitigation of social isolation, and an enhanced sense of safety among participants, factors known to impact health-related quality of life, independently of objective physical functioning.¹⁵

The main methodological strengths of this study include its randomized design, minimizing selection bias; its focus on a frequently underrepresented population (adults 80 years and over); the long-term follow-up of 24 months, enabling assessment of outcome trajectories; and use of validated, domain-specific instruments (SPPB, Barthel Index, Lawton-Brody Scale, EQ-VAS). Furthermore, delta changes were calculated to adjust for and mitigate confounding bias.

Despite the aforementioned methodological strengths, including randomization and long-term follow-up, this study has inherent limitations that warrant consideration. First, simple randomization did not ensure complete baseline homogeneity, leading to a statistically significant difference in baseline SPPB scores in favor of the intervention group. Although delta change analysis (week 104 vs. baseline) was implemented to adjust for this potential confounding bias, the baseline imbalance may have reduced the sensitivity to detect between-group differences in physical function outcomes.

Second, the extremely advanced age of our study population (median of 85 years) and the probable multimorbidity pose challenges to modifying functional decline. This may have resulted in a ceiling effect on SPPB scores for the intervention group, suggesting that the intensity and frequency of

the exercise protocol may have been insufficient to achieve clinically significant changes in physical decline in this population. Finally, remote collection of some follow-up data due to the COVID-19 pandemic, although necessary, may have introduced measurement of reporting biases in functional and subjective variables.

The findings of this study illustrate the complexity of implementing effective interventions in populations with advanced frailty, in which psychosocial determinants may outweigh the influence of physical components.¹⁸⁻²⁰ Future research should explore higher-intensity protocols specifically tailored to this population, in order to evaluate the dose-response relationship of multicomponent exercise, develop strategies to improve physical function outcomes, and conduct subgroup analyses based on baseline frailty levels.

This study provides valuable evidence on the potential benefits of multidimensional interventions in very old adults, emphasizing the relevance of incorporating psychosocial components into geriatric care models. Although physical decline may be difficult to modify in this population, the results indicate that comprehensive, well-structured interventions can help preserve critical dimensions of subjective well-being.²¹

CONCLUSIONS

Over 24 months, this study assessed a multimodal exercise program aimed at promoting health aging in adults aged 80 years and over. While no significant between-group differences were identified in objective parameters, such as physical function or autonomy in basic and instrumental activities of daily living, a statistically significant protective effect was observed on subjective health perception. Both groups exhibited a progressive decline in physical measures, as expected in this geriatric population, whereas stability in self-rated health was observed exclusively in the intervention group.

Although the intervention did not significantly modify the trajectory of physical decline, it had a positive effect on psychosocial well-being domains. The stabilization of health perception is particularly relevant from a clinical perspective, given its well-established prognostic value for treatment adherence and health-related outcomes in older adults. These findings highlight the importance of implementing multidimensional assessments in gerontological research and of developing interventions specifically tailored to the characteristics of the older population, in which subjective components play a central role. Future studies should further examine the mechanisms underlying this differential effect and refine multicomponent exercise protocols to enhance overall intervention benefits.

DECLARATIONS

Conflict of interest

The authors declare no conflicts of interest.

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Author contributions

Carlos Cano-Gutiérrez: formal analysis, conceptualization, writing – review & editing, investigation, methodology, funding acquisition, supervision.

Carlos Andrés Orjuela Rolón: formal analysis, conceptualization, writing – original draft, writing – review & editing, investigation, methodology, supervision.

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Daniela del Pilar Rey Melendez: project administration, formal analysis, conceptualization, writing – original draft, writing – review & editing, investigation, methodology, resources, software, supervision.

Ethical approval and informed consent

Comité de Investigaciones y ética de la facultad de medicina, Pontificia Universidad Javeriana, Bogotá, Colombia. Protocolo 2020/178. Retrospectively registered at ClinicalTrials.gov, identifier NCT07447492.

Data availability statement

Data will be made available on request.

Reporting standards guidelines

CONSORT.

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