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## Effectiveness of a combined lifestyle intervention for older people in long-term care: A randomized controlled trial

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### HIGHLIGHTS

- A three-months lifestyle medicine intervention combining group physical exercise, a healthy diet, and psychological wellbeing sessions was effective in improve functionality in older people living in LTC.
- Despite not all the intervention components reached the study targets, patients from the intervention group had a significant improvement in the measured outcomes.
- This lifestyle program should be considered a complex intervention, with several components and underlying factors interacting between each other to determine the final effect.

### ARTICLE INFO

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Lifestyle medicine  
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Complex intervention

### ABSTRACT

**Purpose:** Lifestyle medicine interventions combining physical, nutritional, and psychological components have been found effective in general older population. However, evidence from the long-term care (LTC) is scarce.

**Methods:** We conducted a pragmatic, two-arm, parallel group, superiority randomized controlled trial. Residents living in a LTC facility for one or more years, able to discern and to express informed consent, and requiring nursing care were considered eligible. The three-months intervention combined bi-weekly physical exercise groups, a healthy diet, and weekly psychological wellbeing sessions. Patients of the control group were subjected to routine care. At the end of the study participants were assessed using Barthel Index, Katz Activities of Daily Living, and Tinetti scales.

**Results:** A total of 54 patients with a mean age of 84 years took part to the study. Physical exercise and psychological wellbeing sessions were mostly attended by all the subjects of the intervention group. Both groups took less calories than planned in the diets; in addition, the intervention group showed a lower energy and carbohydrates intake than the control group. At the end of the study, the intervention group showed a significant improvement in the total scores of all the scales.

**Conclusions:** This intervention was effective in improving functionality in older people living in the LTC setting. Results were achieved in a short timeframe, likely due to synergistic interactions between components. However, a further exploration of underlying factors is needed, to better understand the barriers that hampered a complete intervention delivery in this context.

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## 1. Introduction

The global phenomenon of population aging, known as the Third Demographic Transition, has led to a substantial rise in the utilization of long-term care (LTC) services. Furthermore, demographic projections indicate a significant escalation of this trend in the next years (Vereinte Nationen, 2023). Considering this demographic shift, it becomes imperative to explore innovative and comprehensive approaches aimed to enhance the well-being and quality of life among older individuals. In older people, several studies showed how personal lifestyle, including adequate physical activity, mental wellbeing, and healthy foods habits, could significantly contribute to increase longevity and to mitigate the negative outcomes of chronic conditions (English et al., 2021; Langhammer et al., 2018). This approach has been defined “Lifestyle Medicine”, a medical specialty that uses therapeutic lifestyle interventions as the primary approach to promote health and wellbeing, and to treat chronic conditions (American College of Lifestyle Medicine, n.d.). In LTC, chronic conditions such as cardiovascular diseases (Ahmed & Ekundayo, 2009), sarcopenia (Janssen et al., 2002), dehydration (Nagae et al., 2020), and osteoporosis (Zanker & Duque, 2019) significantly contribute to patient’s morbidity and mortality. The worsening of these conditions could be reasonably mitigated, delayed, or reversed adopting lifestyle medicine interventions (Bodai et al., 2018; Kushner & Sorensen, 2013). However, barriers such as understaffing, low salaries, lack of specialized personnel, or absence of dedicated spaces and equipment could affect the implementation of these interventions in the LTC setting (Chen, 2010; Crogan et al., 2001). For these reasons, evidence about the implementation of lifestyle medicine programs in LTC is currently limited and fragmented (Anandarajah et al., 2020).

Therefore, we conducted a pragmatic randomized controlled trial to assess the effectiveness of a lifestyle medicine-based intervention aimed to improve functionality in older people. In detail, we developed a three-months lifestyle program combining physical exercise, healthy diet, and psychological wellbeing for LTC patients requiring nursing care. Our study aims to present the results of the trial.

## 2. Methods

### 2.1. Study design

We designed a pragmatic two-arm, parallel group, superiority trial, conducted and reported according to the CONSORT Statement (Schulz et al., 2010). The CONSORT checklist is available in Appendix. The study was approved by the local ethics committee and written informed consent from participant was obtained.

### 2.2. Participants and setting

The study took place at the “Belletti Bona” nursing home, a 144-beds LTC facility located in Biella (Piedmont, Italy) managed by the not-for-profit private company Anteo Impresa Sociale. Eligible participants have been living in a LTC facility for one or more years, were able to discern and to express informed consent, with a care intensity (CI) score ranging from 5 to 12. This score is defined within the PAI (Piano Assistenziale Individualizzato), a multidimensional personalized plan designed and adopted by the Piedmont Regional Council to support LTC staff in the care process and to identify the amount of resources required by each patient (Regione Piemonte, 2008). Indeed, according to the regional law, all LTC facilities must periodically perform a comprehensive geriatric assessment (CGA) on the patients within the PAI framework. The CGA is a “multidimensional, multidisciplinary process which identifies medical, social and functional needs, and the development of an integrated/co-ordinated care plan to meet those needs” (Parker et al., 2018). Moreover, during the CGA, the abovementioned CI score is obtained combining 4 different validated scales (i.e., ADL, SPMSQ, DISCO, and DMI). The CI score can range from 1 to 12 and is classified in four

distinct levels. Patients with a score equal to or lower than 4 are identified as autonomous subjects necessitating minimal care. Scores within the range of 5 to 6 denote patients requiring mild care, while a score of 7 to 8 designates those in need of intermediate care. Furthermore, patients with scores ranging from 9 to 12 are allocated to the level necessitating continuous, intensive care. It is worth mentioning that the CI level can be modified by the CGA multidisciplinary team in case of clear signs of stability/instability of the patient. Moreover, the same law requires nursing home to use also additional scales to perform initial and periodical patients’ assessment, such as the Barthel Index (Mahoney & Barthel, 1965). An English translation of the CI score and CI levels, along with the four scales, is available in the Annex. Eligible participants were informed about the content and structure of the proposed lifestyle intervention by the Medical Director of the facility, and written consent was obtained before inclusion.

### 2.3. Intervention

The goal of our intervention was to obtain a synergistic effect from the combination of physical exercise, healthy diet, and psychological wellbeing on functionality in older people (Damanti et al., 2019). In this regard, it has been suggested that physical exercise and a healthy diet can be effective in preventing and mitigating sarcopenia (Robinson et al., 2015), one of the main conditions influencing functionality, independence, and risk of falls in older people (Clark & Manini, 2010). Furthermore, the psychological wellbeing aimed to increase patients’ self-confidence and motivation to comply with the intervention, ultimately supporting the overall intervention effectiveness (Chen et al., 2021).

The physical exercise sessions were structured in bi-weekly 45-minutes groups, requiring moderate-to-high effort to subjects (level 7–8/10 on a visual analog scale). Each session was designed to burn about 190 Kcal and 170 MET per session, calculated on an average weight of 60 kg. The diet offered four different meals (breakfast, lunch, afternoon snack, and dinner), and was designed to provide at least 30 g of proteins with high content of leucine, with the aim of stimulating protein synthesis in skeletal muscles (Holwerda et al., 2019). Daily calcium intake was managed to reach the minimum quantity suggested by the recommended daily intake levels (Società Italiana di Nutrizione Umana, n.d.), and phytate- and oxalate-rich food (e.g., spinach) were limited, to increase intestinal calcium absorption (López-Moreno et al., 2022). To ensure a controlled food intake, both participants and their families were asked to avoid any food supplementation. In addition, as a routine procedure of the facility, relatives are asked to report healthcare workers any additional food brought from outside, and the workers must report such events in the individual patient report. The psychological wellbeing consisted in music-based reminiscence therapy delivered in weekly groups (Gramaglia et al., 2021; Istvandy, 2017). In detail, each session consisted in music listening followed by group exploration of the emotional, cognitive, and mnemonic responses evoked by the song. Songs were chosen before the intervention by the patients, based on significant memories, life phases, or other meaningful episodes. Detailed protocol of the lifestyle intervention is described in the Appendix.

### 2.4. Outcomes

The primary endpoint of the study was the improvement of the functionality, measured using the Barthel Index (BI) (Mahoney & Barthel, 1965). As secondary outcomes, we measured Katz Activity of Daily Living (Katz, 1963) and Tinetti scales (Tinetti, 1986), to investigate whether the lifestyle intervention also increased subjects’ independence and reduced the risk of falls, respectively.

### 2.5. Sample size

Sample size was calculated considering a baseline BI of 25 (standard

deviation (SD) 5), to detect a 15 % increase after the intervention with a one-sided 5 % significance level and a power of 80 %, a sample size of 27 subjects per group was necessary, given an anticipated dropout rate of 10 % (Grossini et al., 2021; Liu et al., 2020).

## 2.6. Randomization and blinding

Patients were stratified according to CI score (two strata: CI score 5–7, and 8–12) and allocated with a balanced randomization. In detail, a researcher (AC) used a random generator software to gather two different numeric sequences, one for each stratum. Participants were recruited by a research physician (DC), who also obtained the informed consent and performed a medical examination to exclude subjects with a clinical condition for which the intervention was contraindicated. Because of the characteristics of the intervention, blinding of participants and interventionists was not possible.

## 2.7. Statistical analysis

The statistical analysis was conducted under the intention-to-treat approach using R version 4.2.0 (R Foundation for Statistical Computing, Vienna, Austria), and results with  $p < 0.05$  were considered significant. The Shapiro–Wilk test was used to assess the normal distribution of continuous variables. The Student's T and the Mann–Whitney-U tests were used to assess numerical continuous variables normally and non-normally distributed, respectively. Fisher's exact test was used for nominal categorical data. In addition, the association between the dependent and independent variables was assessed using the Spearman's ranks correlation test.

## 3. Results

Ninety-eight patients were evaluated for inclusion, and a total of 54 subjects took part to the study (Fig. 1). Before the intervention, clinical records were screened to assess demographic information, current therapy, comorbidities, use of restraints, and use of tobacco. Baseline characteristics of the two groups are shown in Table 1. In brief, participants were mostly normal-weight women with a mean age of 84.06 years. Most of the participants never smoked or were former smokers,

and the majority did not use restraints. Baseline mean BI and Katz ADL scores were 33.87, and 2.30, respectively. The mean care intensity score was 8.07, and mean energy intake was 1551.04 Kcal. No external food supply from patients' families has been reported. Physical exercise was attended by all the subjects of the intervention group, with an average participation to 9 out of the 13 total sessions (68.98 %, SD 21.75). Supportive therapy registered an average participation to 5 out of 7 sessions (82.0 %, SD 25.02). Table 2 shows the real calories consumption and food intake for the two groups. Both groups took less calories than proposed diets; furthermore, the intervention group showed a lower energy and carbohydrates intake than the control group.

Measured outcomes are shown in Table 3. Overall, the intervention group showed a significant improvement in the total scores of all the measured scales. Similarly, a significant improvement was observed for the functional dimension of the BI and for both Tinetti scale dimensions (walk and balance) (Fig. 2). None of the participants reported adverse effects.

## 4. Discussion

To the best of our knowledge, this is the first randomized controlled trial evaluating the effectiveness of a lifestyle intervention combining physical exercise, healthy diet, and psychological wellbeing for older people in LTC setting. In brief, the intervention group was engaged in more structured physical activity, introduced fewer carbohydrates, and received more psychological support than the control group.

As a major result, we observed better BI scores in the intervention group, meaning better patient functional outcomes. We also observed higher levels of autonomy and a lower risk of falls in the intervention group, as it has been shown by the Katz ADL and Tinetti scores, respectively. Our findings confirmed the results of previous studies conducted in older people living in other settings, such as home or community; furthermore, our results were also achieved in three months, whereas previous interventions lasted longer (6–12 months) (Hsieh et al., 2019; Ng et al., 2015). Despite we observed a significant overall effectiveness, it is important to mention that our intervention did not achieve all its specific goals. Therefore, we hypothesized the influence of unplanned factors on the delivery of our intervention, with a positive impact on its outcomes (James et al., 2017).

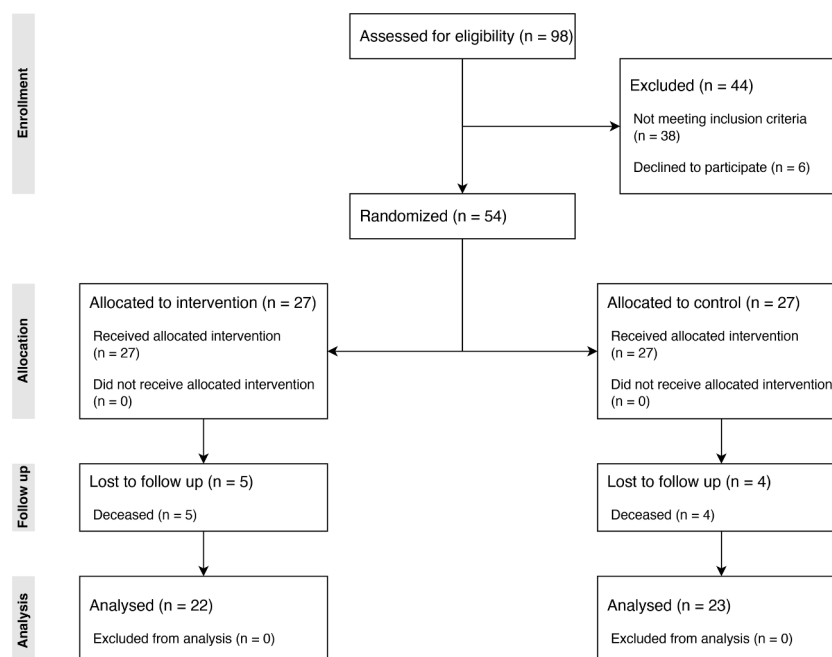


Fig. 1. Study participants flowchart.

**Table 1**

Baseline characteristic of participants allocated to the Lifestyle vs Standard Care groups. MWU: Mann–Whitney-U test; F: Fisher’s exact test.

	Control group (n = 27)	Intervention group (n = 27)	p-value	Test
<i>Demographic</i>				
Age at enrollment (years, mean, SD)	83.26 (9.10)	84.85 (7.87)	0.78	MWU
Gender (female, n,%)	17 (62.96)	22 (81.48)	0.22	F
Weight (kg, SD)	59.68 (16.17)	63.36 (13.26)	0.26	MWU
Body mass index (kg/m <sup>2</sup> , SD)	22.27 (4.83)	23.98 (5.01)	0.24	MWU
<i>Tobacco use</i>				
Never (n,%)	19 (70.4)	16 (59.3)	0.18	MWU
Ex-smoker (n,%)	4 (14.8)	2 (7.4)		
Current smoker (n,%)	4 (14.8)	3 (11.1)		
Unknown (n,%)	0 (0)	6 (22.2)		
Cigarettes/ day (in smokers) (n, SD)	0.70 (1.96)	0.52 (1.50)	0.7	MWU
<i>Health</i>				
Comorbidities (n, SD)	5.85 (2.68)	7.11 (3.27)	0.16	MWU
Number of drugs (n, SD)	7.48 (2.85)	8.30 (3.27)	0.45	MWU
Use of restraints (daily use, n,%)	12 (44.44)	10 (37.03)	0.78	F
Food intake (mean Kcal, SD)	1615 (152)	1486 (217)	0.51	MWU
<i>Scales</i>				
CI score (mean, SD)	8.30 (2.03)	7.85 (2.16)	0.39	MWU
Barthel Index - functionality (mean, SD)	19.15 (17.83)	22.00 (16.07)	0.26	MWU
Barthel Index - mobility (mean, SD)	11.70 (12.26)	14.89 (12.42)	0.25	MWU
Barthel index - total (mean, SD)	30.85 (28.44)	36.89 (27.73)	0.25	MWU
Tinetti Score - walk (mean, SD)	4.93 (4.39)	7.04 (3.63)	0.09	MWU
Tinetti score - balance (mean, SD)	4.96 (4.78)	7.44 (4.23)	0.06	MWU
Tinetti score - total (mean, SD)	9.89 (9.02)	14.48 (7.67)	0.08	MWU
CI Katz ADL* (mean, SD)	1.93 (2.20)	2.67 (2.35)	0.20	MWU
CI SPMSQ score* (mean, SD)	1.00 (0.78)	0.59 (0.57)	0.06	MWU
CI DISCO score* (mean, SD)	0.81 (0.62)	0.96 (0.64)	0.46	MWU
CI DMI score* (mean, SD)	1.70 (0.57)	1.81 (0.40)	0.52	MWU

\* the complete description of the scales is available in the Annex.

**Table 2**

Real weekly calories consumption and food intake of control and intervention groups. T: Student’s T test; MWU: Mann–Whitney-U test; MET: metabolic equivalent of tasks.

	Control group (mean, SD)	Intervention group (mean, SD)	p-value	Test
<i>Physical exercise during 45-minutes sessions</i>				
Burned calories per week (Kcal, SD)	87.5 (32.1)	287.4 (96.3)	<0.001	T
MET per weeks (MET, SD)	64.3 (25.4)	239.2 (75.4)	<0.001	T
<i>Healthy diet (daily intake)</i>				
Energy intake (Kcal, SD)	1615.54 (152.31)	1456.61 (212.16)	0.01	MWU
Proteins intake(g, SD)	71.24 (10.99)	68.41 (14.06)	0.43	T
Lipids intake (g, SD)	53.70 (6.82)	51.55 (9.75)	0.37	T
Carbohydrates intake (g, SD)	224.34 (35.57)	190.44 (34.14)	0.001	T
Fibers intake (g, SD)	19.80 (6.16)	16.91 (7.12)	0.13	T
Calcium intake (mg, SD)	828.25 (211.25)	830.57 (331.43)	0.97	T
Leucine intake (mcg, SD)	3947.49 (614.16)	3974.15 (823.06)	0.89	T

**Table 3**

Univariate analysis of scales after the combined intervention. MWU: Mann–Whitney-U test.

	Control group (mean, SD)	Intervention group (mean, SD)	p-value	Test
Barthel (total)	30.04 (29.54)	44.96 (26.72)	0.02	MWU
Barthel (functional)	18.93 (18.63)	28.00 (15.72)	0.02	MWU
Barthel (mobility)	11.11 (11.94)	16.96 (11.95)	0.06	MWU
Katz ADL (total)	1.85 (2.17)	3.52 (1.93)	0.01	MWU
Tinetti (total)	9.26 (8.65)	16.04 (8.17)	0.01	MWU
Tinetti (walk)	4.59 (4.27)	7.85 (3.87)	0.01	MWU
Tinetti (balance)	4.67 (4.59)	8.19 (4.55)	0.01	MWU

First, the physical exercise was attended by the intervention group through collective sessions held in a dedicated room (the facility’s gym). Additionally, the physiotherapist promoted social interaction between the patients. In contrast, patients receiving usual care underwent individual sessions within their everyday living environment (i.e., bedrooms and corridors), without being required to reach a specific level of physical effort. Since support from caregivers/peers and an attractive environments are acknowledged as facilitating factors for physical activity in older people (Dijkstra et al., 2022), we think that they might have contributed to the overall effectiveness.

This did not happen with the healthy diet. Indeed, health assistants did not receive any instructions to support food intake, and the meals were served simultaneously and without differences in both groups. As a consequence, we failed in achieving the nutritional goal, that was the energy shift from carbohydrates to proteins (Liu et al., 2019, 2020). However, this incidentally led to a decrease in food intake including carbohydrates, that were significantly lower than in the usual diet followed by the control group. We think that this unplanned carbohydrates over-restriction contributed to glycemic control, subsequently increasing the effectiveness of the overall intervention (Åström et al., 2018; Barber et al., 2021).

Last, almost all the intervention group patients fully attended psychological wellbeing sessions. These sessions, delivered on a weekly basis for small groups, supported patients in increasing personal motivation, self-confidence, and social interactions. In contrast, the control group did not receive any specific empowering intervention. Evidence shows that frail subjects with low cognitive, physical, and functional status are particularly responsive to such activities (Karlsson et al., 2021; Song et al., 2004). Therefore, psychological wellbeing might have boosted the diet and exercise through the improvement of self-confidence (Van Stralen et al., 2009) and personal motivation of participants (Liu et al., 2017).

Therefore, according to the Medical Research Council framework, our program should be considered a complex intervention (Skivington et al., 2021). Indeed, it has been developed integrating three different components, namely exercise, diet, and psychological wellbeing, that interacted boosting each other (Dominguez et al., 2021). Reasonably, we think that these components also might have interacted with other underlying factors, such as patient motivation, interventionists behavior, and social context influence (Anandarajah et al., 2020). In brief, we think that such combination of different components might have led to a synergistic effect (Squires et al., 2013), determining the overall effectiveness within a short timeframe. However, the suboptimal adherence to physical exercise and to healthy diet suggests that a thorough investigation of underlying factors is needed in the LTC context to improve the intervention, ultimately obtaining even better outcomes. (Karlsson et al., 2021; Song et al., 2004).

Our findings could have been affected by other limitations. First, it was not possible to blind participants or researchers because of the study design and intervention characteristics. Second, both the intervention

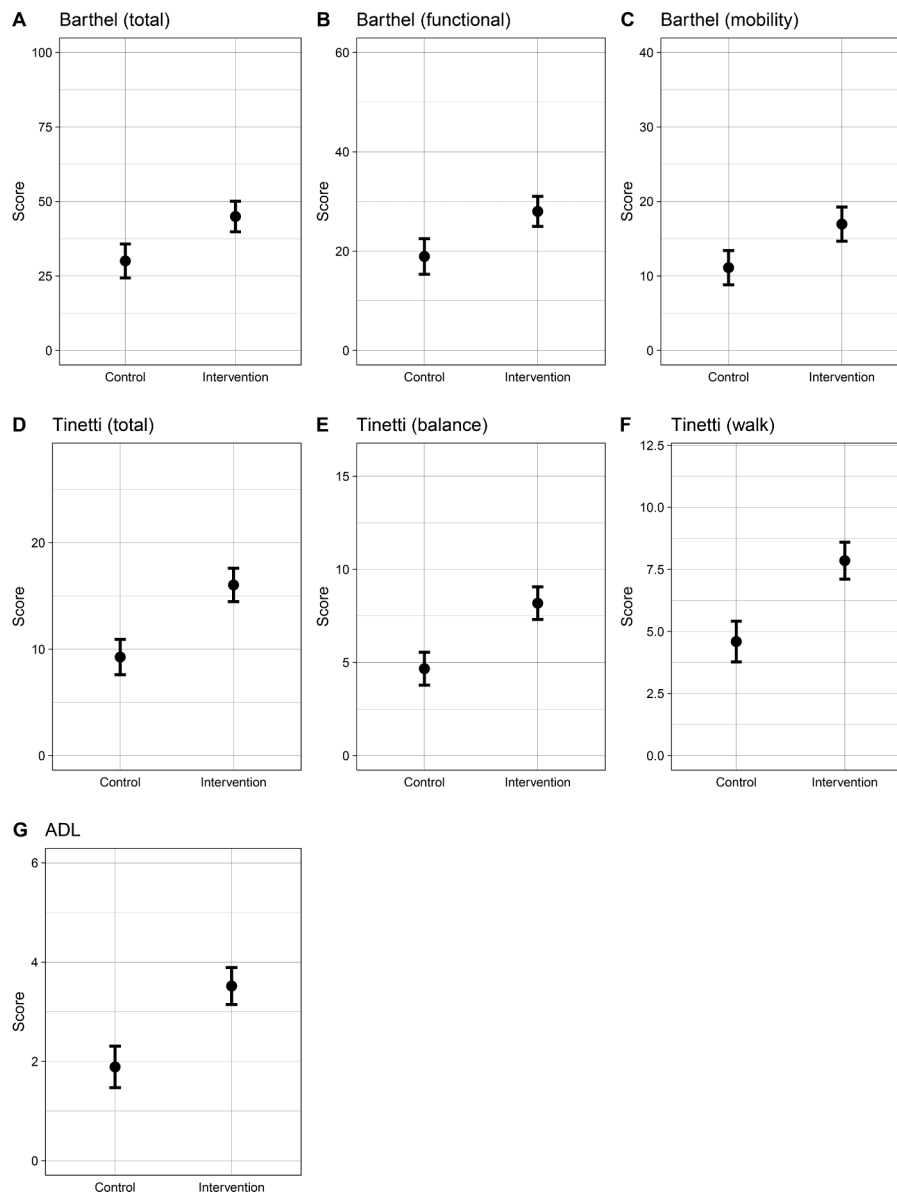


Fig. 2. Plot of the scales after the intervention.

and control groups belonged to the same nursing home and shared bedrooms, common spaces, and healthcare professionals, potentially leading to a contamination bias (Robinson et al., 2020). Third, voluntary enrollment might have introduced a selection bias. However, we designed a pragmatic RCT, which has been acknowledged as the best study design to evaluate complex interventions in single-center studies, and we adopted the “intention to treat” analysis (Foster & Little, 2012). It is also worth mentioning that this pragmatic approach, despite its validity to support clinical or policy decisions for the adoption of a specific intervention in real-world practices (Ford & Norrie, 2016), did not take in consideration specific clinical characteristics such as comorbidities or cognitive status. However, despite our results could not be fully translated to different population or settings, we think that our rigorous methodology has mitigated such limitations.

## 5. Conclusions

Our study demonstrated that lifestyle medicine interventions are effective in the older people, also in the complex setting of LTC. Significant results are achievable in a short timeframe, likely due to the

synergistic interactions between intervention components together with underlying factors. However, the suboptimal adherence to physical exercise and healthy diet suggests the need for further exploration of underlying factors and a better understanding of barriers and facilitators in this context.

Also, despite our sample is representative of the majority of LTC patients, and no subject withdrew from the study, the translation of our findings to the general older population should be cautious due to the intervention complexity and results interpretation. Therefore, we think that future research should consider the adoption of cluster randomized controlled trial design to better evaluate the effectiveness of lifestyle interventions.

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## Ethical approval

The study was carried out according to the Declaration of Helsinki guidelines and was approved by the Ethics Committee of Maggiore Hospital, Novara, Italy (approval ID: CE232/20 of 30 September 2020). Informed consent was obtained from all participants.

## Sponsor's role

The present study was not sponsored. The institutional fund provider (Italian Ministry of University and Research – program “Department of Excellence 2023–2027”) did not have any role nor influence on the study.

## CRediT authorship contribution statement

**Andrea Conti:** Writing – review & editing, Writing – original draft, Visualization, Validation, Data curation. **Diego Concina:** Writing – review & editing, Visualization, Methodology, Investigation, Data curation. **Annalisa Opizzi:** Writing – review & editing, Data curation, Conceptualization. **Agatino Sanguedolce:** Writing – review & editing, Data curation, Conceptualization. **Carmela Rinaldi:** Writing – review & editing, Conceptualization. **Sophia Russotto:** Writing – review & editing, Conceptualization. **Elena Grossini:** Methodology, Investigation, Conceptualization. **Carla Maria Gramaglia:** Investigation, Conceptualization. **Patrizia Zeppego:** Methodology, Conceptualization. **Mas-similiano Panella:** Writing – review & editing, Writing – original draft, Supervision.

## Declaration of competing interest

All the Authors declare that they have no conflicts of interest.

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## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.archger.2024.105340](https://doi.org/10.1016/j.archger.2024.105340).

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