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RESEARCH ARTICLE

Improving Quality of Life in Older Adults Living at Home by a Moderate Exercise Training

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Abstract:

Background:

Physical activity is associated with a higher quality of life (QoL) in older adults, but there is no evidence whether its effects on healthy individuals or individuals with a mild disability performing a medium-intensity exercise program can be assessed.

Objective:

This randomized controlled trial aims to evaluate whether moderate exercise training can improve QoL, and whether this model is suitable for older adults with mild chronic diseases living in the community.

Methods:

120 participants, randomized 1/1 to either perform a physical exercise protocol or to undergo a social program (control group), were recruited in a 12-week randomized controlled trial registered at ClinicalTrials.Gov (NCT03858114). QoL was measured through the Health-Related Quality of Life Survey Short Form - 12 items tool (SF-12).

Results:

The participants involved in the exercise-training program had a moderate QoL improvement, compared to those involved in cultural activities, who experienced no change or even a worsening of their QoL. However, the between-groups differences did not attain the statistically significant threshold, when globally assessed, $F[1, 103] = 2.98$, $p = .087$, nor when the analysis was restricted to the physical ($F[1, 103] = 2.78$, $p = .099$) or mental components ($F[1, 103] = 3.83$, $p = .053$).

Conclusion:

Data from this study are not conclusive, although suggestive of possible efficacy. An effort to collect a larger amount of evidence is advisable. Research published only as protocols, not providing final results, might be useful to demonstrate or reject the hypothesis that physical exercise improves QoL in older adults. On a heuristic level, the sum of results that are not conclusive individually might be decisive if meta-analyzed.

(Randomized Controlled Blind trial NCT03858114).

Keywords: Moderate physical exercise, Elderly, Quality of life, Randomized controlled trial, Moderate disability, Mild chronic diseases.

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1. INTRODUCTION

Quality of life (QoL) is a multidimensional and complex concept, summarizing different operational definitions, spanning from studies conducted over the past 40 years [1, 2]. QoL is not synonymous with a standard of living concerning income satisfaction and employment status, nor an objective measure of these indicators, but it includes the satisfaction with environmental, physical and mental health, education, recreation and leisure time, optimism about personal objectives, satisfaction with own network and friends [3, 4]. Despite that disease occurrence is associated with a worse quality of life [5 - 8], a good level of QoL before the diagnosis is an indicator of a good outcome when a disabling disease occurs [9 - 12]. This association between quality of life and disease occurrence with biunivocal consequences has particular relevance in the older population, where chronic disabling disorders are more frequent, and a previous good QoL can motivate coping and counteract negative outcomes, including loss of autonomy [13, 14]. Implementation of interventions to improve QoL is of extreme relevance for public health in a general framework that sees the world's population going downhill and the prevalence of chronic and disabling diseases increases with age. The impacts in terms of social and health costs will exponentially grow [15]. Experimental evidence found that regular physical exercise (PE) for at least three months causes an improvement in the perceived quality of life in adults and young adults with psychosocial disability [4, 5, 16, 17], as well as in individuals with motor and neurological diseases [18]. Exercise has also been investigated among the numerous factors able to influence the Quality of Life in old adults living at home [19 - 21]. However, the causal link of this association, specifically in older adults, is not yet fully clarified, as it is merely based on the fact that, as evidenced by community studies, individuals with more disabilities (and therefore with lower QoL) do less physical exercise, and not on the fact that physical activity improves the quality of life. Recent meta-analysis of randomized controlled trials (RCT) considers the use of high or medium-high intensity physical exercise, with sessions from up to 3 times a week to more than 5 times a week [22 - 24]. This methodology, although it is useful to demonstrate the efficacy of physical exercise "in an ideal perspective" [25], is difficult to apply in the daily life of elderly people living in the community, who are often affected by mild chronic diseases, such as hypertension and diabetes, that limit the feasibility of high-intensity training. Despite exercise lowers the impact of disability, counteracts the decline in motor function, improves cognitive performance, the risk of depressive disorders in older adults and even immune responses, with positive effects on metabolic disorders, such as diabetes [5], it is not yet ascertained whether an exercise of medium intensity, administered for a number of weekly sessions accessible to old people living in the community, can improve the quality of life, as well as other parameters of interest for personal suffering and public health.

A recent randomized controlled study conducted by our group [26] demonstrated that a mixed aerobic-anaerobic, medium-intensity exercise program can improve cognitive performance in a group of community-living seniors, without severe chronic diseases [27]. The program was designed in such a way that it could be easily applied in everyday life.

The aging of the world's population is a significant public health problem [28 - 30], as the number of individuals with disabilities and lack of autonomy has increased, and it is, therefore, relevant to investigate the type and the feasibility of physical activity in the elderly population (even with an initial disability).

The objective of this study is to measure, by means of secondary data analysis from the above mentioned NCT03858114 RCT, whether a medium intensity physical exercise performed only 3 times a week is accessible to a rather healthy or slightly disabled old individual (like the people currently living in the community) can improve their quality of life, as it was already demonstrated in the case of a high or medium-high intensity exercise, with a higher number of sessions per week.

2. MATERIALS AND METHODS

2.1. Protocol

The present study is a second data analysis from a 12-week RCT, registered with the number NCT03858114 at ClinicalTrials.Gov (http://www.clinicaltrials.gov). The complete protocol has been described in detail in a previous publication [26], and followed the Standard Protocol Items, according to the Recommendations for Interventional Trials (SPIRIT). The Consort Checklist and the flow-chart, based on published guidelines [31], have also been provided as additional materials used in our study.

2.2. Assignment and Masking

Participants were allocated in a 1:1 ratio, using computer-based, double-blind randomization generating permuted blocks and blind codes, masking both the participants' identities and status and their activity (*i.e.*, exercise or cultural and recreational activities). The previously published document also fully presented the methodology that was used to choose the sample size, so that the study could confirm the starting hypothesis, which was based on the literature related to the primary outcome (exercise). Regarding the psycho-social outcome indicators, literature indicated that moderate-to-vigorous PA was associated with a medium effect size of 0.64 (95% CI, 0.27 to 1.01) in reducing depressive symptoms [29]. As explained in the introduction, as there was not much knowledge of the effectiveness of moderate exercise, we estimated that the experimental intervention could produce a change in the exposed group with an effect size of 0.45 SD. A sample of 60 participants per group was required to achieve 80% power to detect a difference with a medium effect size h = 0.45, at a two-sided significance level of 0.05. At this estimated power, the risk reduction was estimated at 0.215, with a number needed to treat (NNT) = 5. Although "Quality of Life" was not among the outcomes of this study, its medium-high sample and its power could have offered useful information on this parameter compared to the studies conducted so far.

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2.3. Participant Flow and Follow-up

As already previously described in detail [26], 120 participants (N = 120) were involved in exercise or control interventions.

After receiving detailed information about the study and releasing a written informed consent, the participants were recruited. Participants' medical and psychological status before the intervention (T0), and at the end of the exercise or control intervention (12 weeks, T1), was assessed. Trained staff was responsible for the supervision of the experimental and the control interventions. The researchers who carried out the evaluations were blinded to the participants' allocation (experimental or control intervention).

2.3.1. Study Tool

The "Health-Related Quality of Life Survey Short Form" is a 12 items tool (SF-12) [32] that has been adopted to assess the perceived Quality of Life. By measuring the different components of QoL, such as social functioning, emotional status, pain, general health status, vitality, and mental wellbeing, regrouped in two sub-scales (physical and psychological Quality of Life), the tool generates three different scores: total QoL, physical QoL, and psychological QoL. The tool measures the perceived state in the last month. The higher the score, the better the perception of QoL.

2.3.2. Recruitment and Participants

To be eligible for the trial, participants from both genders had to be 65 years or older, to be living at home, to pass a medical examination and to obtain a medical clearance to participate in non-competitive physical activity at the University of Cagliari and a fitness certificate containing information on any current or past medical conditions.

The exclusion criteria included a body mass index (BMI) higher than 35, medical conditions preventing participation in moderate physical exercise and participation in physical exercise in the previous two years.

People were recruited through advertisements in media, general practitioners, and the Italian Olympic Committee (CONI).

2.3.3. Ethical Approval

The independent Ethical Committee of the "Azienda Ospedaliero-Universitaria di Cagliari" approved the study protocol (number PG/2018/15546 of October 25th, 2018). The researchers provided information about the study and informed the participants about the possibility of discontinuing their participation if they wished. Data were collected in an anonymous database. Each participant signed an informed consent form. The procedures were based on the 1964 Helsinki declaration and its later amendments.

2.3.4. Interventions

Exercise Group. The exercise intervention was administered in three sessions per week. The exercise was at a maximum of 60-80% of the heart rate reserve (HRR). HRR was monitored, recorded, and transmitted to professionals by wireless telemetry. Baseline HHR was registered and assessed before the treatment for each participant as a mean of 3-day records (Estimated Maximal Heart Rate Formula).

Each exercise session was provided according to a three phases schema: warm-up, about 10-min, at 60% maximum of HRR; active phase, about 40-min, at maximum 60-80% HRR; cool down, about 10-min, at maximum 60% HRR. The active phase was a mixture of aerobic and anaerobic exercises, including "life movements". The active phase included a mixture of aerobic and anaerobic exercises, with drills of "life movements," balance and strength.

Control Group activities. The cultural and recreational activities of the control group were focused on the history of local culture, visits to historical sites, and education on wellness. A professional conducted the program working in groups of the same size as the intervention group. Time spent in the control activities was the same as in the exercise group. The activities of the control group were conceived to create a comparator that could balance at most all the possible confounding factors associated, but independent from, physical exercise and capable of influencing the main outcomes of the protocol (as the quality of life) (*e.g.*, sociality, amusement, bonding, sharing of time, companionship).

2.3.5. Statistical Analysis

All statistical analysis was two-tailed with alpha fixed at $p < 0.05$. The effect of physical exercise (independent variable) on the perceived QoL quality measured through the SF-12 scale score (dependent variable) was first studied as improvement before vs. after treatment by means of ANOVA 1-way statistic. The RCT results were analyzed by multivariate analysis of variance MANOVA through the integrated measurement of the variables time (before intervention vs. after intervention) and group (exercise vs. control group). The analysis was conducted both for the total SF-12 score and for the physical and psychological well-being subscales. This analysis was integrated with an ancillary analysis: by one-way ANOVA analysis, the pre-post treatment difference of every single item of the SF-12 in the two comparison groups was calculated. It was also measured in the two groups (exercise and control) whether the distribution of items with a score after the intervention > 10 points, between -10 and 10 points and <10 points was homogeneous.

3. RESULTS

Table **1** shows the characteristics of the sample: the group that completed the sports intervention does not differ from the one that completed the control treatment for the variables of mean age, gender, and years of schooling. Loss during 12 weeks of intervention was 8 out of 60 people in the exercise group (13.3%) and 7 out of 60 people in the control group (11.6%).

Table 1. Study Sample.

-	Exercise (N =52)	Control Group (N =53)	Statistics
Gender (Women%)	29 (56%)	34 (64%)	χ^2=0.77, p=0.381
Age (mean)	71.8 (4.7)	72.7 (4.7)	F(1;103)=0.76, p=0.385
Education (mean Years)	14.1(4.6)	12.7 (4.9)	F(1;103)=2.27, p=0.124

Abbreviations: N: numbers, χ2 : chi-square test; F: Anova F-test; p: p-value

Table **2** shows the Mean Score at SF-12 before and after 12 weeks of treatment in the experimental and control group. The three-month exercise-training program had not a statistically significant effect on QoL, globally assessed, F[1, 103] = 2.98, p = .087, nor it did when the analysis was restricted to the physical component of QoL (F[1, 103] = 2.78, p = .099) or its mental component (F[1, 103] = 3.83, p = .053). We also applied a repeated multivariate analysis of variance (MANOVA) to the measures of QoL (global, physical, and mental components). The sphericity assumption was confirmed (Mauchly's test p>0.50). Again, the results suggest that the three-month exercise-training program had not a statistically significant effect on QoL when measured as a latent variable and its components (Wilks' lambda [2, 102] = 0.96, p = .155). Thus, despite a modest improvement in global QoL (F[1, 103] = 2.98, p = .087, and in physical (F[1, 103] = 0.14, p = .706) and mental QoL (F[1, 103] = 3.83, p = .053) among those who underwent the exercise-training program, with those involved in cultural activities undergoing no change or experiencing a modest worsening of their physical and mental QoL, the between-groups differences did not attain the statistically significant threshold.

Table **3** shows the differences between T0 and T1 in each item of SF-12 in the two groups (exercise and control). Only in Item 1, there was a difference with improvements in the score at T1 and regarded the experimental (exercise) group (F with df 1,103 = 3.874, with Bonferroni correction, P=0,049). In six SF-12 items, an increase of at least 10 points at T1 compared to T0 was seen in the experimental group (Item N ° 1,6,7, 9, 10, 11), against only 1 item in the control group (item N ° 5); In only one item in the experimental group (N° 8) a 10-point greater worsening at T1 compared to T0 was found, versus 4 items in the control group (item N° 4,6,8,9).

Considering the set of items with an improvement greater than 10 points, Table **4** shows items in which the result at T1 does not vary by more than 10 points and items that worsen at T1 <10 points. The distribution differs between exercise and control groups, with a tendency to improve in the experimental exercise group (Kruskal Wallis test H = 4.4408, N = 24, p = 0.03509).

Table 2. Mean Score at the Health-Related Quality of Life Survey Short Form - 12 items tool (SF-12) before and after 12 weeks treatment in the experimental (exercise) and control group.

-					95% Confidence interval	
Measure	**Group**		**Mean**	**S.E.**	**Lower Limit**	**Upper Limit**
Global QoL	Control Group	Baseline	34,808	,731	33,359	36,257
		End of intervention	34,058	,683	32,703	35,412
	Exercise	Baseline	35,151	,724	33,716	36,586
		End of intervention	36,057	.676	34,715	37,398
Physical QoL	Control Group	Baseline	13,808	,300	13,213	14,402
		End of intervention	13,808	,302	13,209	14,406
	Exercise	Baseline	14,321	,297	13,732	14,910
		End of intervention	14,491	,299	13,898	15,083
Mental QoL	Control Group	Baseline	21,000	,517	19,975	22,025
		End of intervention	20,250	,511	19,236	21,264
	Exercise	Baseline	20,830	,512	19,815	21,846
		End of intervention	21,566	,506	20,562	22,570

Abbreviations: QoL: quality of life; SE: standard error.

Table 3. Differences between T0 and T1 in each item of the Health-Related Quality of Life Survey Short Form - 12 items tool (SF-12) in the two groups.

Item SF-12	T0 exercise	T1 exercise	Fdf 1,103	With Bonferroni Correction P	T0 Control	T1 Control	Fdf 1,105	With Bonferroni Correction P
1	2.94±0,73	3.24±0.81	3.874	0.049	3.05±0.63	3.01±0.66	0.088	0.768
2	1.73± 0.44	1.77±0.41	0.230	0.633	1.67±0.46	1.71±0.45	0.205	0.652
3	1.76±0.43	1.77±0.41	0.015	0.904	1.69±0.46	1.73±0.44	0.209	0.648
4	1.79±0.40	1.83± 0.37	0.280	0.598	1.80±1.10	1.69±0.46	0.451	0.503

(Table 3) contd.....

5	1.79±0.40	1.83± 0.37	0.280	0.598	1.65±0.47	1.76±0.42	1.614	0.207
6	1.77±0.41	1.88±0.31	2.326	0.130	1.73±0.44	1.62±0.47	1.547	0.216
7	1.81±0.41	1.92±0.26	2.669	0.105	1.75±0.43	1.78±0.41	0.135	0.714
8	4.28±0.80	4.03±0.88	2.298	0.133	4.02±0.86	3.91±0.93	0.330	0.577
9	4.43±1.10	4.56±1.00	0.398	0.530	4.51±1.02	4.29±1.10	1.140	0.288
10	3.98 ±1.39	4.35±1.08	2.346	0.129	4.25±1.10	4.21±1.02	0.038	0.846
11	4.75±1.21	4.90±0.97	0.486	0.486	4.73±0.94	4.78±1.13	0.061	0.805
12	4.07±0.74	4.00±0.94	0.171	0.680	4.01±0.84	3.98±0.80	0.031	0.860

Abbreviation: SF-12: the Health-Related Quality of Life Survey Short Form - 12 items tool: T0: baseline; T1: after 12 weeks of treatment; Fdf: F statistics with degree of freedom

Table 4. Items with improvement >10 points (Rank 1), items in which the result at T1 does not vary by 10 points (Rank 2), and items that worsen at T1 <10 points in the two groups (Rank 3).

Ranking	Exercise	Control Group
Rank 1: >10 Score points T1	6 (50%) [N=1,6,7,9,10,11]	1 (8.3%) [N=5]
Rank 2: Score between >10 and <10 T1	5 (41.6%) [N=2,3,4,5,12]	7 (58.3%) [N=1,2,3,7,10,11,12]
Rank 3: <10 Score points T1	1 (8.3%) [N=8]	4 (33.3%) [N=4,6,8,9]

Kruskal Wallis test H = 4.4408 (N = 24), p= 0.03509.

4. DISCUSSION

The study showed that a 12-week mild-moderate intensity physical exercise, potentially suitable for older adults, even with mild disabling chronic disorders, does not improve the perceived quality of life to a statistically significant extent compared to a homogeneous sample of older people, who conducted a control treatment, characterized by cultural activities. Results in both groups are similar, suggesting that interventions capable of balancing the aspects of socialization and the pleasure of being together, which is also proper for physical exercise conducted in a group, are as effective but independently from the physical activity "in itself", whose effectiveness was to be measured.

Apparently, the study, at least on first reading, seems to add nothing new to the subject, sometimes contradictory [22, 23, 33]. However, it is necessary to specify some important points that can allow to frame and exploit the set of results in a broader context. Some elements are strongly suggestive of a difference, which is probably not reached due to the insufficient power of the study, which is the main limitation of the study. First of all, some differences are valuable, at least in the dimension of the psychological quality of life, which reaches the limits of statistical significance (P = 0.05); in addition, there is a strong trend towards improvement in the individual items of the scale in the exercise group compared to the control group, with a greater number of items with at least 10 points of improvement and a lower number of items with no improvement or worsening. Finally, in at least one item of the SF-12 scale, the exercise group improves statistically significantly. It should also be noted that this specific item (N ° 1) is a key and general item, which summarize the overall answers of the scale, asking about the perception of wellness: "you say your health is " with an answer from 1 (poor health) to five points (excellent health) scale.

These considerations cannot lead us to affirm that the study has achieved a positive result, however, given the general uncertainty of the results in the literature, it is still positive to collect even only suggestive data, which advice on the need to further investigate and collect data, to perform a meta-analysis in the future.

In commenting on our results, it is necessary to consider some relevant elements:

(1) Healthy individuals have starting average scores of QoL higher than people with disabilities or mental health problems, thus, an improvement in QoL generated by exercise could be of lesser entity than those generated by similar exercises in people with consistent health problems.

(2) Previous studies based on higher intensity exercise have established that increased QoL level in people living in the community was closely related to symptoms of pathology and psychopathology (*i.e.* depressive symptoms). For example, de Oliveira [19] showed a strong correlation between the domain quality of life, level of vitality, and compromised mental health (r = 0.77) in old adults living in the community. Therefore, it is intuitive that healthy individuals underwent lower improvement in the QoL score than those who initially had depressive symptoms.

(3) The patients that were recruited included individuals that decided to participate on a voluntary basis, people that adhered to the advertising campaign or at their general practitioner's suggestion. Although we expected a certain prevalence of mild-moderate chronic medical conditions in older patients living in the community, a large portion of our sample did not suffer from disabling medical conditions and showed high QoL scores at baseline. Therefore, the potential improvement was even more difficult to be documented. More extensive and heterogeneous samples should be recruited to highlight an improvement, which would be very important in terms of public health.

We must note that the results concerning QoL in the present study are not homogeneous with expectations from our primary RCT analysis [27], showing a satisfactory result for the other main outcomes, especially the improvement of cognitive performance in the exercise compared to the control group [26]. Although the study was not initially sized to measure the improvement in QoL, the sample was worth investigating to explore the possible effects of moderate

intensity and limited weekly sessions of physical exercise, accessible to seniors living in the "real life" community. From this point of view, a non-exclusive but highly suggestive result is interesting because it can still be re-interpreted and challenged further expressly designed studies. The possibility of a meta-analysis, as the sum of data that can be singly considered as partial, is another fundamental opportunity to realize a high-powered study, as a single conclusive RCT would be very difficult to conduct due to the need for a very large sample and/or a more lasting intervention. Numerous studies on physical exercise and other rehabilitation interventions [33, 34] have shown that QoL is an outcome that improves more slowly than others. Therefore, considering the good adherence to the trial in our experience and the fact that moderate exercise does not excessively stress participants, we suggest to conduct longer-term trials.

The concept of quality of life is a very complex construct that, in the aging population, is correlated to different factors, such as functional cognitive and physical status, autonomy, social network, and practice of psychical activity [35 - 40]. It is nevertheless conceivable that its modification may be slow and may show up after a long time. From this point of view, it is important to note that in the face of numerous studies on the subject that have recently been presented as research protocols [41 - 43], the published data are scarce [33, 36]. It is possible that an absence of conclusive results caused the publication bias. However, it would be interesting to have the set of overall results, the sum of which could provide interesting data.

CONCLUSION

The question of whether moderate physical exercise (accessible to seniors living in the community in real life) can improve the perceived quality of life in older adults still maintains some uncleared aspects. Although this study was limited as it was not initially specifically sized to test this question, it was conducted on a large sample, and its results are strongly suggestive of possible efficacy. Further studies or an effort to collect a larger amount of evidence are needed, as much research on the topic is only published as protocols and not as results. It is, in fact, possible, on a heuristic level, that the sum of results that are not conclusive individually can be decisive if meta-analyzed.

LIST OF ABBREVIATIONS

Qol = Quality of Life

RcT = Randomized Clinical Trial

SPIRIT = Standard Protocol Items, according to the Recommendations for the Interventional Trials

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by Ethics Committee of the Azienda Ospedaliero-Universitaria di Cagliari (Approval no PG/2018/15546).

HUMAN AND ANIMAL RIGHTS

No Animals were used that are the basis of this study. All the human procedures were conducted in accordance with the Declaration Helsinki.

CONSENT FOR PUBLICATION

Each author had the opportunity to revise and approve the final manuscript for publication.

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None.

AVAILABILITY OF DATA AND MATERIALS

The authors confirm that the data supporting the findings of this study are available within the article. Supplementary materials are available from the corresponding author, [A.L], on special request.

STANDARDS OF REPORTING

CONSORT Guideline were followed.

CONFLICT OF INTEREST

All authors declared no conflict of interest.

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