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## RESEARCH ARTICLE

### Exercise Improves the Impact of Chronic Pain in Older Adults: Results of an RCT

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#### Abstract:

##### Background:

Chronic Pain (CP) is a crucial determinant for disability in older adults. CP amplifies the impact of other common age-related diseases and increases cardiovascular risk. Physical exercise can improve CP. Randomized Controlled Trials (RCTs) with high-intensity exercise in older adults excluded people with Moderate Chronic Illness (MCI) and CP.

##### Objective:

This study aimed at evaluating in an RCT whether moderate exercise training can improve chronic pain in a sample of older adults, including people with MCI, and if any modification persists over time.

##### Methods:

A sample of 120 older adults was randomly selected for a moderate-intensity exercise program or cultural activities (control group). Chronic pain was assessed at t0, at t12 (end of the trial), and t48 weeks, by means of the Italian version of the SIP-Roland Scale.

##### Results:

Seventy-nine participants completed the follow-up (age 72.3±4.7, women 55.3%). At the end of RCT, an improvement in the SIP scale score was found in the exercise group (p=0.035), showing a lower score than the control group; this difference was not maintained at 48 weeks (p=0.235).

##### Conclusion:

Our study highlighted that a moderate-intensity exercise intervention reduced chronic pain in older adults, but this effect disappeared at follow-up after 36 weeks from the end of the training program. These findings suggested that such kinds of programs, easily accessible to old people even with MCI, should be implemented and supported over time, thus promoting active aging and preventing CP of age-related diseases.

**Clinical Trial Registration:** Clinical.Trials.gov.NCT03858114

**Keywords:** Chronic pain, Moderate chronic illness, Survey, Randomized controlled trial, Cerebrovascular, Cardiac, Metabolic disorders.

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## 1. BACKGROUND

Chronic pain (CP) is associated with restrictions in mobility and daily activities and is one of the most common reasons for older adults to seek medical care [1 - 3]. Community-based surveys have found that 20.4% of U.S. adults suffer from CP and 8.0% from high-impact CP, but the prevalence increases to 27.6% in people aged between 65 and 84 years (10.7% having high impact CP) and to 33.6% in people over 85 years (15.8% having high impact CP) [4]. A recently published epidemiological study in Taiwan found CP to be associated with an increased risk of major adverse cardiac and cerebrovascular events [5]. The authors suggested early detection and interventions [5]. CP is also associated with a psychosocial and physical disability, poor quality of life, and mood and anxiety disorders in older adults [2, 3, 6]. Thus, CP is a clinical and public health issue in the elderly, owing to the relevant burden on individual health and the impact on health care services and community well-being as a whole [7].

Exercise is associated with low chronic pain in older adults in the community [8, 9]. However, this may also be due to the fact that those with pain are less active. A Randomized Controlled Trial (RCT) on pain control in older people who have also had increased mobility in the context of an integrated treatment showed a decrease in pain as one of the outcomes [10]. Most RCTs on exercise and well-being in older adults involved high-intensity exercise and this was not compatible with most clinical conditions associated with chronic pain [11]. Thus, results give inadequate information on the efficacy of exercise for chronic pain.

## 2. OBJECTIVE

The objective of this study was to evaluate, by means of an RCT design, whether a program of moderate physical exercise may be associated with an improvement in CP in a sample of older adults, and if this improvement persists over time even after the end of physical exercise training.

## 3. METHODS

The study was designed as an RCT registered as ClinicalTrials.gov, NCT03858114, and a cohort study followed the RCT [12, 13]. One hundred and twenty older adults were randomly selected and assigned to two groups: one, a 12-week program of moderate-intensity, mixed aerobic-anaerobic, physical exercise (three sessions per week), and the other, a control protocol underweaving cultural activities. The study sample included people of both genders, 65 years and older, living at home, recruited through public notices. All participants were certified for attending non-competitive physical activity by the sports medicine center of the University of Cagliari after accurate evaluation to reveal the occurrence of medical illness. Exclusion criteria were: age  $\leq$  65, BMI  $>$  35, unsuitability for moderate exercise due to medical condition, lifetime diagnosis of psychosis and/or mania, organic brain disease, and involvement in a program of physical exercise.

As described above in detail [12], exercise was administered in 3 sessions per week. Physical activity was fixed at 60–80% of the Heart Rate Reserve. The heart rate parameters were monitored continuously during activity and transmitted system to the fitness professionals *via* telemetry. The activity foresaw a mixture of aerobic and anaerobic exercises with integrated drills of “life movements,” strength, and balance.

The assessment of widespread chronic pain in a sample of older people living at home requires an easy-to-use tool in a framework having different outcome measures, given the main objectives of our RCT [8]. We chose the Italian validated version of the 23-item SIP-Roland Scale [14, 15], a shorter measure directly derived from the more extensive Sickness Impact Profile (SIP) [16]. The SIP Roland Scale measures functional problems as related to health rather than just pain [11]. Each item is dichotomous (yes/no), and the score is the sum of the 23 items [15].

Chronic pain was evaluated as SIP scores at baseline (t0), at the end of the RCT (t12), and at 48 weeks (t48).

The comparison of SIP scores within groups by time (0, 12, and 48 weeks) and between groups for each time, was performed by one-way ANOVA (for repeated measures within groups by time).

## 4. RESULTS

Seventy-nine participants completed the RCT and follow-up and were then evaluated after 48 weeks. The mean age was  $72.3 \pm 4.7$ , the women were  $N=42$ , 55.3% of the whole sample.

Table 1 shows that the two experimental (exercise) and control (cultural activities) samples were homogeneous by sex, age, and education level. None of the detected illnesses showed differences in frequencies in the two samples.

Table 2 shows the comparison of SIP scores within groups by time (0, 12, and 48 weeks) and between groups for each time. At the starting point, the exercise group had a mean score on the SIP scale similar to the control group ( $1.75 \pm 1.47$  vs.  $1.73 \pm 1.78$ ;  $F=0.003$ ;  $df$  1,79;  $p=0.954$ ). The result changed at the end of the trial (t12) when the control group had a higher score than the exercise group (Exercise  $1.11 \pm 1.40$  vs. Control  $1.77 \pm 1.12$ ;  $F=5.151$ ;  $df$  1,79;  $p=0.026$ ); at the 48-week follow-up, the difference in the SIP score between the two groups did not reach the statistical significance (Exercise  $1.60 \pm 2.48$  vs. Control  $2.31 \pm 2.79$ ;  $F=1.430$ ;  $df$  1,79;  $p=0.235$ ).

Homogeneously, the comparison of SIP scores within groups at different times Table 2 showed a lower SIP score at the end of the RCT in the group that underwent physical exercise compared to the initial evaluation ( $1.75 \pm 1.47$  vs.  $1.11 \pm 1.40$ ;  $F=4.373$ ;  $df$  1,87;  $p=0.035$ ). However, the statistical difference observed at the end of the RCT, compared to the baseline, was not maintained at the end of the follow-up compared to the initial score ( $1.75 \pm 1.47$  vs.  $1.60 \pm 2.48$ ;  $F=0.119$ ;  $df$  1,87;  $p=0.731$ ). As shown in Table 2, no difference was noted in the comparison of the SIP score at the three-time evaluations within the control group.

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**Table 1. Characteristics of exercise and control groups.**

-		Exercise Group	Control Group	Likelihood and Statistic
Number		44	35	-
Gender	Men	21 (47.7%)	16 (52.1%)	$\chi^2=0.04, p=0.838$
	Women	23 (42.3%)	19 (47.9%)	
Age		72.6 (4.6)	72.2 (4.7)	F (1;103)=0.76, p=0.385
Years of education		14.0 (4.3)	13.1 (4.9)	F (1;103)=2.27, p=0.124
Thyroid Diseases		10 (27.7%)	4 (11.4%)	$\chi^2=1.86, p=0.179$
Bronchial Asthma, Chronic Bronchitis, Heart disease		2 (4.5%)	2 (5.7%)	$\chi^2=0.001, p=0.999 *$
Painful sequelae cancer, Fibromyalgia, Irritable Bowel		2 (4.5%)	3 (8.6%)	$\chi^2=0.001, p=0.999 *$
Osteoporosis or Osteoarthritis		5 (11.4%)	8 (22.8%)	$\chi^2=1.130, p=0.288 *$
Hypertension		16 (36.4%)	18 (51.4%)	$\chi^2=3.449, p=0.063$
Type 2 Diabetes		3 (6.8%)	5 (14.2%)	$\chi^2=0.581, p=0.466 *$

Data: counts (%) or mean (± SD); \* (with Yates correction)

**Table 2. SIP Roland Score in the two Groups at t0, at t12 and at t48.**

-	t0	t12	t48	t0 vs. t12	t0 vs. t48
<b>Exercise Group (Ex)</b>	1.75±1.47	1.11±1.40	1.60±2.48	F=4.73 – df 1,87 p=0.035	F=0.19 – df 1,87 p=0.731
<b>Control Group (C)</b>	1.73±1.78	1.77±1.22	2.31±2.79	F=0.013 – df 1,69 p=0.911	F=1.075 – df 1,69 p=0.303
<b>Ex vs. C</b>	F=0.03 – df 1,79 ρ=0.954	F=5.151 – df 1,79 ρ=0.026	F=1.430 – df 1,79 ρ=0.235	-	-

Data: mean (± SD)

**5. DISCUSSION**

Our study highlighted that a moderate-intensity exercise program administered three times a week for three months can lower chronic pain in a sample of older adults living at home. This result was not observed in the control sample subjected to group cultural activity. However, in the exercise group, the improvement disappeared at the 48-week evaluation after the start and 36 weeks after the end of the RCT.

The choice of an exercise of mild to moderate intensity was made to avoid exclusion of people with mild medical conditions common in older adults who live at home (hypertension, diabetes, overweight, class I obesity) and found to be frequently associated with CP [4]. RCT carried out in older adults routinely have adopted intense levels of physical activity, thus excluding older adults with mild chronic diseases [11], people affected by overweight or mild-moderate obesity and metabolic syndrome [17], depressive status [18], and psychosocial disabilities [19], which could greatly benefit from exercise concerning CP and, in general, from tertiary prevention, particularly concerning cardiovascular risks [5]. The kind of exercise administered in the present trial was therefore accessible to older adults with mild disabilities, such as joint and musculoskeletal disorders of the not severe entity as well [8]. Moreover, guidelines concerning exercise recommended for seniors living at home have sometimes been built more on the agreement of experts than based on reliable data [20, 21]. The results of our study showed that a physical exercise program of the type used can improve the state of chronic pain in the elderly in a few weeks, although the results obtained are not maintained a few months after the interruption of physical exercise.

The average initial SIP score of 1.75 points with a relatively large standard deviation (about 1.50) is certainly compatible with a sample of healthy older adults in the general population or with mild chronic disorders typical of this condition, as shown in the description of the study sample. If we take a clinical sample such as the one used for validation of the instrument as a yardstick, which consisted of 243 adult outpatients (62.1% females) attending three physical medicine units and one rehabilitation research hospital unit, they had a SIP score of 7.23 with a 5.03 standard deviation. The study sample, therefore, showed a non-negligible average basal chronic pain score (although certainly lower than that of a clinical sample), but with respect to which physical exercise involved an average decrease of 40%. If we consider the impact that chronic pain has on the quality of daily life and depressive risk and the extent to which these variables are potentially burdening in older adults [3, 4, 14], especially if suffering from associated mild medical conditions, we believe that the results of our study represent an interesting fact. Another element that should be emphasized is that our study was based on three months, but moderate exercise as administered in our trial is easily accessible to older people even with mild ailments for a very long period, given the great need to improve active aging in the elderly and to prolong their autonomy [22].

**6. LIMITATIONS**

This study has some limitations that need to be emphasized.

First, despite the significant improvement observed in the exercise group after the intervention period, the sample size

was too small in order to analyze the role of potential covariates, such as gender differential efficacy or limited efficacy in people with specific chronic diseases. Furthermore, a study with a larger sample size could allow us to investigate the reasons for abandoning the trial such as the occurrence of fatigue syndrome, as a possible side effect of the intervention program *per se*.

From this point of view, this study is to be considered a starting point for future research works. In fact, having indicated the feasibility of interventions of longer duration, this study may lead to hypothesizing new intervention models also scheduled with periods of exercise interspersed over time (*i.e.* 12-week exercise period twice a year, avoiding the hottest and coldest seasons in temperate climates).

## CONCLUSION

It is therefore desirable to introduce this type of intervention and pursue it, even if our results need to be replicated with randomized controlled trials on larger samples and with prolonged exercise programs over time.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The Independent Medical Committee for Medical and Health Research Ethics of the “Azienda Ospedaliera Universitaria di Cagliari, Sardinia Region” approved the study on 25<sup>th</sup> October, 2018 (PG/2018/15546). Participants were provided with written information about the study and they signed informed consent before enrolment.

## HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or research committee and with the 1975 Declaration of Helsinki, as revised in 2013.

## CONSENT FOR PUBLICATION

Written informed consent was obtained from all participants.

## STANDARDS OF REPORTING

CONSORT guidelines and methodologies were followed in this study.

## AVAILABILITY OF DATA AND MATERIALS

Not applicable.

## FUNDING

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## CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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Declared none.

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