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Complete List of Authors:	Marcos-Pardo, Pablo Jorge; Universidad de Almeria, Department of Education Abelleira-Lamela, Tomás; Universidad Católica San Antonio de Murcia, Faculty of Sport Vaquero-Cristobal, Raquel; Universidad Católica San Antonio de Murcia, Faculty of Sport González-Gálvez , Noelia; Universidad Católica San Antonio de Murcia, Faculty of Sport
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Changes in life satisfaction, depression, general health and sleep quality of Spanish middle-aged and older adult women during Covid-19 lockdown and their relationship with lifestyle: a follow-up study

Pablo Jorge Marcos-Pardo[1], Tomás Abelleira-Lamela[2], Raquel Vaquero-Cristóbal[2*], Noelia González-Gálvez[2].

[1] SPORT Research Group (CTS-1024), CERNEP Research Center, Department of Education, Faculty of Education Sciences, University of Almería, Almería, Spain
[2] Injury prevention in sport Research Group (PRELEDE), Faculty of Sport, UCAM, Murcia, Spain

*** Correspondence:**
Raquel Vaquero-Cristóbal
rvaquero@ucam.edu

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Abstract

Objetives: to analyze the effects of COVID-19 lockdown on mental well-being variables of middle-aged and older adult women, and to determine the influence of lifestyle and age on such effects. The hypothesis of the study was that all parameters related to mental well-being would worsen in older women during the COVID-19 lockdown. **Design:** Observational follow-up study. Pre-lockdown measurements were taken before the lockdown. Post-lockdown measurements were taken as soon as began the de-escalation. **Setting:** Senior centers in the Region of Murcia (Spain). **Participants:** The sample was composed of 40 adult female volunteers, over 54 years of age (mean age= 62.35±8.15 years). **Primary and secondary outcome measures:** Pre and Post-Lockdown evaluations were carried out face to face. The following questionnaires were completed: Satisfaction with Life Scale, The Center for Epidemiologic Studies Depression Scale, The Short Form 36 Health Survey, The Pittsburgh Sleep Quality Index, the Global Physical Activity Questionnaire, and Prevention with Mediterranean Diet. **Results:** Post-lockdown, a worsening was found in the variables of life satisfaction (p=.001); depression (p=.000) quality of life in physical role (p=.006), pain (p=.004), emotional role (p=.000), and mental health (p=.000); and sleep quality (p=.018), sleep latency (p=.004), sleep disturbances, (p=.002) and global sleep quality score (p=.002). It was found how age influenced the variables of pain (p=0.003) and social role (p=.047); as well as the influence of a healthy lifestyle on the variables analyzed (F=6.214; p=.017). Adherence to the Mediterranean diet was shown to be a protective factor against increased depression (p=.03). Spending time sitting was shown to be a risk factor for physical role health (p=.002), as was advanced age on health due to worsening pain (p=.005), or an unhealthy lifestyle on increased consumption of sleeping aids (p=.017). **Conclusion:** The lockdown had a great negative impact on adult Spanish women on mental well-being variables.

ClinicalTrials.gov Identifier: NCT04958499

Strengths and limitations of this study

- The main strength of the present investigation was the possibility of carrying out a follow-up study to analyze the effects of lockdown on psychological and health-related variables of older adult women.
- Face-to-face surveys were used, which made possible the avoidance of the bias that is commonly implied by the use of technology with the adult and older population.
- It should be noted that the post-lockdown surveys could not be conducted until the limitations of mobility and access to the center where the study was conducted
- Another limitation was the absence of a control group that was not in a lockdown situation.

Word count: 3901.

Introduction

The outbreak of Coronavirus disease (COVID-19), an infectious disease caused by the SARS-Cov-2 virus that started in China and is now present all over the world, has become a major global headline, causing great public panic and concern [1].

On Wednesday, March 11, 2020, the World Health Organization (WHO) upgraded the public health emergency situation caused by COVID-19 to an international pandemic [1]. Following this announcement, on Saturday, March 14, 2020, the Government of Spain, declared the State of Alarm and the start of confinement measures (Royal Decree 463/2020), to decrease the basic reproduction number (R0) of SARS-CoV-2 and thus reduce its transmission [2]. This marked the beginning of a 14-week lockdown [2,3]. Public health guidelines in many countries, including Spain, suggested that people stay at home to avoid person-to-person transmission of the virus [1]. However, the lockdown in Spain was more restrictive than in other countries, with no one allowed to go outside the home for anything that was not considered an essential activity, which meant the closure of most of the country's activity and the establishment of a teleworking regime for most of the workers who could continue their activity during the lockdown period [4].

This situation induced changes in the lifestyles of the Spanish population. Some studies found a reduction in the levels of physical activity [5,6]; negative diet disturbances [5]; an increase in social isolation which can induces changes in psychological health, such as increased anxiety and depression [7,8]; or a worsening of sleep quality [6,8–11], as a psychological response to the pandemic. Such effects may be particularly problematic in older adults and especially in women [7,8,12], due to reduced physical capabilities and the possibility of increased chronic diseases and mental health problems.

It has been shown that women as a population, especially during old age, were most affected by the lockdown measures, with significant increases in stress, anxiety and other psychological variables as compared to men [7,8,12]. Similar studies have been found analyzing the effect of the lockdown on different population groups such as workers or students [6,13]. However, no follow-up or longitudinal studies have been found that have analyzed the evolution of the health status of older women during lockdown. For this reason, the objective of this study was to analyze the effects of the COVID-19 lockdown on life satisfaction, depression, general health, and sleep quality of older adult women, and to determine the influence of lifestyle and age on such effects. The hypothesis of the study was that all parameters related to mental well-being would worsen in older women during the COVID-19 lockdown, with those women with a poorer lifestyle experiencing the greatest change.

Material and Methods

Study design

This study is a part of the ongoing project entitled Smart Bio-healthy Machinery: Design and manufacture of new ergonomic, efficient, and healthy outdoor fitness machinery, including an application for mobile devices (app) to assess and monitor training (ClinicalTrials.gov Identifier: NCT04958499) (Supplementary file 1). The study was approved by the institutional ethics committee of the Catholic University of Murcia in accordance with the Declaration of Helsinki (code: CE111908) (Supplementary file 2). All the participants were informed, and voluntarily signed the informed consent form before participating in the study.

Pre-test measurements were taken to begin the intervention specified in this clinical trial. However, this intervention could not be carried out due to the emergence of the COVID-19 pandemic and the associated confinement regulations, which did not allow the subjects to travel to the training centre where the intervention machines were located. Instead, the present research was conducted, for which

external funding was obtained, with additional permission provided by the institutional ethics committee for it to be carried out (code: CE052002) (Supplementary file 3).
This observational follow-up study design followed the Strobe Statement [14] (Supplementary file 4). Pre-lockdown measurements were taken between zero to two weeks before the lockdown in Spain. Post-lockdown measurements were taken as soon as the Spanish government began the de-escalation phase, in which the population was allowed to go outside for a maximum of two-three hours per day per age group, and the non-essential workers could return to face-to-face work; and always before the lockdown measures were completely abolished. In both pre-lockdown and post-lockdown tests, the participants self-completed a printed survey about sociodemographic information, life satisfaction, depression, general health, sleep quality, physical activity, and diet (Figure 1).

Sampling method and sample size

The participants volunteered through advertisements and presentations in senior centers in the Region of Murcia (Spain). The SF-36 survey's standard deviation from a previous study was used to establish the power and sample size [15]. With an estimated error of 2.59 points, the total sample size for this study consisted of 40 participants, which provided a power of 95% and a significance level of $\alpha = 0.05$. Rstudio 3.15.0 software was used to establish the sample size. The sample was composed of 40 adult female volunteers, over 50 years of age (mean age= 62.35±8.15 years).
The inclusion criteria were as follows: (a) female; and (b) aged between 50 and 85 years. The exclusion criteria were as follows: (a) having suffered SARS-CoV-2 infection during confinement; (b) having a job considered essential during the confinement period; (c) suffering from any cardiovascular, renal, hepatic, respiratory or metabolic pathology, (d) suffering from any psychiatric disease, (e) taking any medication that could alter the psychological state, or (f) having any pathology or any SARS-CoV-2 symptom that prevented performing any of the evaluation tests.

Patient and public involvement

Patients and the public were not involved in the development of the research questions, design and conduct of the study. However, participants were involved in the recruitment of others through the snowball method. The study results was shared with the participants with an individual inform and will be shared with other relevant stakeholders through various social media handles and conferences after the publication of the paper.

Procedures

The sociodemographic questionnaire was created ad hoc for this study, and included questions about age, marital status, occupation, education level and living status. Furthermore, the Satisfaction with Life Scale (SWLS) was used to measure the degree of satisfaction with the participant's own life [16]. The questionnaire consists of five questions with a scale from 1 to 7 depending on the degree of agreement. To obtain the final score, the scores for each of the questions were summed following the methodology from Pavot and Diener [16]. The scores of this scale range from 5 to 35, with a higher value indicating greater satisfaction with life [16]. The Center for Epidemiologic Studies Depression Scale (CESD) was used to screen for depression [17]. On this scale, composed of 20 items, each item has a value between 0-3, and a maximum total score of 60 points. CESD can judge depression and can even confirm the severity of the depression symptoms (no to mild: ≤16; moderate: 17-23; severe: ≥24) [18]. The Short Form 36 Health Survey (SF-36) (Medical Outcomes Trust, Boston, MA) was used to measure health state. It includes four physical health scales (physical functioning, role-physical, bodily pain and general health); and four mental health scales (vitality, social functioning, role-emotional, and mental health) [19]. For its calculation, the methodology proposed by Ware et al. [20] was utilized. The Pittsburgh Sleep Quality Index (PSQI) scale was used to evaluate sleep quality

in the previous month. With 19 items, it evaluates 7 subcomponent factors of sleep quality: subjective sleep quality, sleep latency, total sleep duration, sleep efficiency, sleep disturbances, daytime dysfunction, and use of sleep medication. The range of subscores for each component is 0 to 3, with a maximum total score of 21:Good sleep quality (scores of 0 to 5) and poor sleep quality (scores of 6) [21]. Physical activity was analyzed using the Global Physical Activity Questionnaire (GPAQ). GPAQ was developed by the World Health Organization (WHO) with 16 questions that revolve around three domains: occupational physical activity, transport-related and leisure physical activity. In addition, it can also assess sedentary behavior by recording minutes spent sitting [22]. With the data compiled through this questionnaire, we summed the minutes of physical activity of the participants according to type of activity and its level of intensity. Finally, the adherence to the Mediterranean diet was assessed using the previously validated 14-item questionnaire for the assessment of Prevention with Mediterranean Diet (PMD) [23]. The score for each item was 1 or 0 and the PREDIMED score was calculated with the following ranges: 0-5, lowest adherence; score 6-9, average adherence; score ≥10, highest adherence [24].
Subsequently, all participants had their height and body mass measured following the protocols of the International Society for the Advancement of Kinanthropometry (ISAK). Body mass index (BMI) was calculated as body mass (kg) divided by height (m) squared [25].

Statistical analysis

The Kolmogorov–Smirnov test and Mauchly's W-test were used to evaluate the normality and the sphericity of the data. The means and standard deviations were calculated from the quantitative variables, and frequency and percent were used for the qualitative variables. The participants were categorized as having a Healthy lifestyle or Unhealthy lifestyle. A Healthy lifestyle was considered for those who complied with at least 150 min of moderate to vigorous physical activity (MVPA) a week and who maintained adherence to the Mediterranean diet (above 7 points) vs an unhealthy lifestyle, those who did not comply with either or both parameters. A two-way analysis of variance (ANOVA) with repeated measures in 1 factor (time) was used to analyze inter- and intra-group differences and to analyze the interaction between groups and time. This analysis was performed unadjusted and adjusted by age. The Bonferroni post-hoc test was used to evaluate the statistical significance of the parametric variables. Stepwise multiple linear regression models were used to explore the associations between the dependent variables and each independent variable. To analyse whether a nonlinear multiple regression model provided the best explanation of the variance, a curvilinear estimation analysis was used to explore the best model association between the dependent (satisfaction with life, depression, health state and sleep quality) and independents variables (age, Mediterranean diet adherence, MVPA, sitting time a day and life style The statistical analysis was performed using the statistical package SPSS 21.0 for Windows.
Technical appendix, statistical code, and dataset available from the Dryad repository, DOI: https://doi.org/10.5061/dryad.rfj6q57cp.

Results

Table 1 shows the anthropometric characteristics and sociodemographic variables of the sample.

Table 1. Characteristics of the sample

Variable	%(n) or M±SD
Age (year-old)	62.35±8.15
Height (cm)	154.70±7.09
Body mass (kg)	72.50±14.02
BMI (Body mass(kg)/height^2)	30.30±5.50
Marital status	

Single	5.00 (2)
Married	57.50 (23)
Separated	10.00 (4)
Widowed	27.50 (11)
Occupation	
Full-Time Worker	17.50 (7)
Part-Time Worker	12.50 (5)
Unemployed	17.50 (7)
Retired	52.50 (21)
Education level	
No education	12.50 (5)
Elementary school	57.50 (23)
High school	12.50(5)
Bachelor´s Degrees or higher	17.50(7)
Living status	
Living with someone	72.50(29)
Living alone	27.50(11)
Sitting time during lockdown (min per day)	385.20±152.66
MVPA during lockdown (min per week)	340.50±403.95
Active vs Inactive (WHO 150 min/week)	
Active	72.50(29)
Inactive	27.50(11)
MDA	9.13±2.22
MDA Classification	
No Adherence (≤7 points)	25(10)
Adherence (>7 points)	75(30)
Lifestyle (Active and MDA vs No Active or No Adherence)	
Healthy	50.00(20)
Unhealthy	50.00(20)

BMI = body mass index; MDA = Mediterranean Diet Adherence; MVPA = moderate to vigorous physical activity; WHO = World Health Organization.

Table 2 shows the results of the differences between pre and post adjusted and unadjusted for age, of the perception of life satisfaction, depression, general health and sleep quality. Post-lockdown, the sample significantly had worse results in satisfaction with life; depression values; quality of life in physical role, pain, emotional role and mental health; and sleep quality, sleep latency, sleep disturbance and global sleep quality score (Table 2). The results of the time*age interaction analysis were significant for pain (F=10.07; p=.003) and social function (F=4.23; p=.047), meaning that age adversely influenced the change in these variables post-lockdown. For the rest of the variables, no significant values were observed.

When the differences in these variables were analyzed as a function of group and measurement, it was found that the pre-test differences were not significant for the Healthy Lifestyle group (mean difference= -.158±473; p=.473) while it was significant for the Unhealthy Lifestyle group (mean difference= .600; p=.008). In addition, the effect of the time*Lifestyle interaction during lockdown was found to be significant (F=6.214; p=.017), indicating that maintaining a healthy lifestyle during lockdown was key in the maintenance of the variables analyzed.

203 **Table 2.** Effect of lockdown due to the COVID pandemic (unadjusted and adjusted by age).

				Unadjusted			Adjusted by age		
		Pre-test (M±SD)	Post-test (M±SD)	Difference post-pre (M±SD)	p	95% CI (Mpost-Mpre)	Difference post-pre (M±SD)	p	95% CI (Mpost-Mpre)
Satisfaction with live (SWLS scale)		19.93±3.38	17.68±4.76	-2.25±0.66	.001	-3.58; -.93	-2.25±0.66	.001	-3.58; -.93
Depression (CESD scale)		13.18±8.52	20.13±11.29	6.95±1.68	.000	-3.56; 10.35	6.95±1.67	.000	-3.57; 10.33
Physical Health (SF-36 scale)	Physical functioning	82.74±12.66	82.14±8.87	-.60±1.70	.726	-4.03; 2.84	-.60±1.696	.725	-4.02; 2.82
	Role-physical	89.10±17.95	79.81±18.94	-9.30±3.21	.006	-15.78; -2.81	-9.30±3.18	.006	-15.73; -2.86
	Bodily pain	72.03±20.15	62.00±22.35	-10.02±3.29	.004	-16.68; -3.37	-10.02±2.95	.002	-16.01; -4.04
	General health	73.19±14.65	69.29±18.08	-3.90±2.37	.108	-8.69; .89	-3.90±2.36	.107	-8.67; .88
Mental Health (SF-36 scale)	Vitality	71.05±14.99	69.87±14.70	-1.18±2.18	.592	-5.58; 3.23	-1.18±2.20	.596	-5.63; 3.28
	Social functioning	89.23±14.21	88.72±21.66	-.51±3.62	.888	-7.84; 6.81	-.51±3.47	.883	-7.55; 6.52
	Role-emotional	91.88±16.61	76.50±21.53	15.39±3.89	.000	-23.26; -7.51	15.39±3.83	.000	-23.14; -7.63
	Mental health	77.78±12.85	65.89±14.01	-11.88±2.10	.000	-16.12; -7.64	-11.88±2.12	.000	-16.18; -7.58
Sleep (PSQI scale)	C1 Sleep Quality component	1.11±.57	1.36±.68	.25±.10	.018	.05;.45	.25±.10	.019	.04;.46
	C2 Sleep latency	1.28±1.03	1.78±1.17	.50±.16	.004	.17;.83	.50±.16	.004	.17;.83
	C3 Sleep duration	1.00±.76	1.08±.77	.08±.11	.446	-.14;.30	.08±.11	.452	-.14;.31
	C4 Habitual Sleep efficiency	.92±1.11	.81±1.01	-.11±.13	.401	-.38; .15	-.11±.13	.390	-.37; .15
	C5 Step disturbances	1.39±.60	1.75±.60	36±.11	.002	.15; .58	.36±.11	.002	.15; .58
	C6 Use of sleeping medication	1.00±1.39	1.28±1.47	.28±.17	.115	-.07; .63	.28±.17	.115	-.072; .63
	C7 Day time dysfunction	.50±.61	.64±.59	.14±.13	.281	-.12; .40	.14± .13	.287	-.12; .40
	Global score	7.19±4.06	8.69±3.91	1.50±.46	.002	.57; 2.43	1.50±.46	.003	.56; 2.44

CESD= center for epidemiologic studies depression scale; C=component; PSQI= Pittsburgh sleep quality index; SF-36= short form 36 health survey; SWLS= satisfaction with life scale.

When performing linear regression models, it was found that adherence to the Mediterranean diet during lockdown was shown to be a protective factor against increased depression due to the lockdown (Standardized Coefficient (β) = -.341; p=.031; r2=.116). Spending time sitting was shown as a risk factor for physical role health (Standardized Coefficient (β) = -.474; p=.002; r2=.224). An older age was found to be a health risk factor for worsening pain (Standardized Coefficient (β) = -.438; p=.005; r2=.192). Volunteers who showed an unhealthy lifestyle (inactive or No Mediterranean diet Adherence) had a greater risk in increasing the use of sleeping medication (PSQI Component 6 use of sleeping medication) (Standardized Coefficient (β) = .379; p=.017; r2=.144).

Discussion

The main objective of this study was to analyze the effects of COVID-19 lockdown on life satisfaction, depression, sleep quality, and pain of older adult women. It was found that life satisfaction, quality of life in the physical component, quality of life perfection with respect to emotional role, and mental health, worsened after lockdown. The measurement using the SWLS denoted scores of mild dissatisfaction with life [16], with a significant worsening with respect to values before the lockdown. This is in line with other studies, in which people who underwent a period of lockdown reported a lower life satisfaction, as well as symptoms of psychological distress [26]. Previous studies have found that the restrictive lockdown measures implemented as a consequence of COVID19 had a significant influence on the perception of quality of life and mental health [27]. In this regard, it should be noted that Spain was one of the countries where the policies were the most restrictive with respect to the lockdown of its citizens [4], which could explain the results found in the present research study. In fact, the lockdown limited the possibilities of leisure time, which was especially noticeable for those who did not work, as was the case for the majority of the sample in the present investigation. During this period of time, the employment situation in Spain was affected by the pandemic. Therefore, in addition to the unemployed people, others were in a situation of record of temporary employment regulation, and among the people who worked, only those sectors considered essential such as supermarkets and the health sector (Royal Decree 463/2020) could work in person, leaving the rest of the workers in a situation of teleworking [4]. In this sense, previous studies have pointed out that the worsening of health during the pandemic was directly affected by the work situation [26] and that there was a direct relationship between being busy at work and greater life satisfaction [12]. It is important to take into consideration the findings of this research in future situations of partial or total lockdown to reduce its negative psychological effects. Depression has been one of the most classically studied psychological variables. In the present research, we found an increase in depression values after lockdown, as was in previous cross-sectional studies [1,6,8], with the percentage of women with depression increasing over 21% as compared to epidemiological studies conducted in a normal setting [7,8,10,28]. Also, age was a potentiating factor for this phenomenon [29], as found in the present research. One of the aspects that could have most affected this increase in depression was loneliness. However, almost 1 out of 3 women in the present study spent the lockdown alone. In a sample of people over 65 years of age analyzed after the lockdown, a greater presence of depressive symptoms was observed in those who were alone [30,31], while those who were not alone did not show significant increases in depression even when under lockdown [30]. This is an important aspect to take into account in situations of social isolation.

Along the same line, the participants in the present investigation showed a worsening of sleep quality after the lockdown. Variables such as depression or anxiety have been found to be negatively related to sleep quality [21]. In this study, sleep quality was analyzed using the PSQI questionnaire. It was found that before lockdown, subjects already showed an overall score above 5 points, denoting poor sleep quality. But in addition, after lockdown, a significant worsening of sleep latency, subjective sleep quality, sleep disturbances, and the global score were found. As observed in previous studies, sleep quality is fundamental to physical health, emotional well-being, mental health, stress, depression, and anxiety, so its importance lies in the fact that everything is interconnected [6]. In previous studies conducted on businessmen and university students, it was observed that lockdown negatively affected their health, well-being, and sleep, which could be due to the loss of daily life routine, isolation, stress, or sedentary attitudes [6]. In addition, it was shown that being a woman could be a factor that favored the presence of sleep disorders during lockdown [8,10]. In the study by Gualano et al. [10], 42.2% of a sample of 1515 people presented sleep disturbances, of which 17.4% reported moderate/severe insomnia. However, so far we have not found studies conducted on adult-older women, so the results of the present study represent a first approach to understanding how lockdown situations affect this factor.

The women in the present investigation also showed higher pain scores after lockdown. The population analyzed was composed of adults and elderly people, who frequently perceive bodily pain. In addition, the quarantine meant a limitation of physical activity, which may have led to increased pain perception [13]. Therefore, both age and inactivity may have preceded a greater perception of such pain, which should be taken into account in the future.

Another objective of the present research was to analyze the variables with a significant influence on the evolution of psychological variables during lockdown. It was found that age, lifestyle, diet, and sedentary lifestyle had an influence these variables. With respect to age, a worsening of pain and social function variables was observed in older people. The relationship between pain and age has been broadly documented in previous studies [32], with the prevalence of pain being higher among women and older people. This could be due to a greater sensitization to pain in the case of women, or to a greater vulnerability of older people to different types of chronic pain [32,33]. In terms of social function, the lockdown increased the risk of social isolation and loneliness in general [30], but especially in the elderly, as this population group is usually less familiar with new technologies, which have been essential at the social level during the quarantine period [34]. Indeed, studies carried out during the lockdown found that a lack of knowledge about the functioning of new technologies was associated with feelings of exclusion, self-isolation, and vulnerability [34], although this could be remedied with prior training on the use of this type of device. In addition, the elderly population was the most affected by the COVID-19 virus [35], leading to a greater sense of isolation among the elderly than in other population groups [30,34,36].

The lockdown strategies adopted to limit the spread of COVID-19 infection, including home confinement, may have led to the adoption of Unhealthy lifestyles as a result of decreased physical activity [12,36–38] and the acquisition of less healthy eating habits [12]. These factors, in turn, could have had an impact on the decline of mental health well-being [12,39]. Along this line, the present investigation found that adult-older women who had a healthy lifestyle during the lockdown, defined as having a good adherence to the Mediterranean diet and adding at least 150 minutes of physical activity per day, did not show a worsening of the variables after the lockdown analyzed.

Previous studies have already indicated that a high adherence to the Mediterranean diet

may be associated with a reduced risk of depression [40]. The findings of the present study are particularly relevant, considering that previous studies showed that almost one third of the participants decreased their adherence to the Mediterranean diet, more than one third of the sample reduced their physical activity, and almost 70% increased their inactivity time during the lockdown [39]. On the contrary, those who did not adhere to the Mediterranean diet and/or whose daily physical activity did not reach the established standards, suffered the effects of quarantine to a greater extent. Thus, the preventive effect on health and psychological variables of a healthy lifestyle during a situation of home isolation is corroborated.

During the lockdown, people increased their daily sitting time and reduced physical activity. These results are consistent with those shown in previous studies [36–38]. More specifically, increases of 164.3 minutes on average per day of sitting time were found [38], while 53.5% of some populations shifted from exercising frequently to never exercising at all [41]. In the present investigation, it was found that spending time sitting was a risk factor for health in the physical role. This is because more time spent sitting uses the time that could otherwise be utilized for physical activity. In addition, it was found that regardless of physical activity levels, spending more than 4 hours a day sitting was a risk factor for premature death and this may increase by 5% for each hour beyond 7 hours sitting [41]. Therefore, since physical activity cannot eliminate the detrimental effects of sitting for long periods of time, it is advisable to maintain a high level of daily activity and limit sitting time [42], or break up those long periods of sitting with 2-3 minutes of light activity every 20-30 minutes [41]. All the changes produced were negative for the population. The linear regression models showed how adherence to the Mediterranean diet, spending less time sitting, and being younger were protective factors against increased depression, reduced physical role health, and increased pain respectively, as found in past studies [43].

Lastly, it was observed that an unhealthy lifestyle increased the likelihood of taking sleeping aids. Previous studies have shown that during lockdown, the consumption of sleeping aids increased by 20%, and also associated the lack of physical activity to the worsening of sleep quality during lockdown [9,11]. However, the paucity of literature on this topic calls for future research in this area.

The main strength of the present investigation was the possibility of carrying out a follow-up study to analyze the effects of lockdown on psychological and health-related variables of older adult women. For this purpose, face-to-face surveys were used, which made possible the avoidance of the bias that is commonly implied by the use of technology with the adult and older population [34]. Therefore, the results of the present study could be taken into consideration in possible future and similar lockdown situations. In this way, a better management of the health of the population could be achieved. To this end, further research will be necessary to better understand the needs of each population group, more specifically referring to mental health well-being in the present study. However, the present research also had some limitations. Among them, it should be noted that the post-lockdown surveys could not be conducted until the limitations of mobility and access to the center where the study was conducted, or the absence of a control group that was not in a lockdown situation, were eliminated.

Conclusions

As a main conclusion of this research, it was observed that the lockdown measures had a great negative psychological impact on adult Spanish women. In addition, it was found that adherence to the Mediterranean diet may have been a protective factor against depression during lockdown, while long periods of sitting, advanced age, or an

unhealthy lifestyle, were health risk factors for physical role, pain, or increased consumption of sleeping aids. For future lockdown situations, in order to prevent possible psychological problems and taking into account the present investigation, the recommendations would be to be accompanied, to practice exercise, to spend as few hours as possible sitting down, to adhere to a Mediterranean diet, and to know how to use new technologies to maintain social relationships.

Author Contributions

P.J.M.-P. conceptualized and P.J.M.-P., T.A.-L., R.V.-C. and N.G.-G. designed the study. N.G.-G. carried out the statistical analysis. T.A.-L. recruited the participants. P.J.M.-P., T.A.-L., R.V.-C. and N.G.-G collected the data. T.A.-L., R.V.-C. and N.G.-G. organized the database. P.J.M.-P., T.A.-L., R.V.-C. and N.G.-G. wrote the first manuscript draft, the final manuscript draft, conducted the English proofreading, and reviewed and edited the final version of the manuscript. All authors contributed to the manuscript revision and approved the final version.

Acknowledgments

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Conflict of Interests

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Data Sharing

Technical appendix, statistical code, and dataset available from the Dryad repository, DOI: https://doi.org/10.5061/dryad.rfj6q57cp.

Ethics Committee Approval

Institutional ethics committee of the Catholic University of Murcia (code: CE111908 and CE052002) was obtained.

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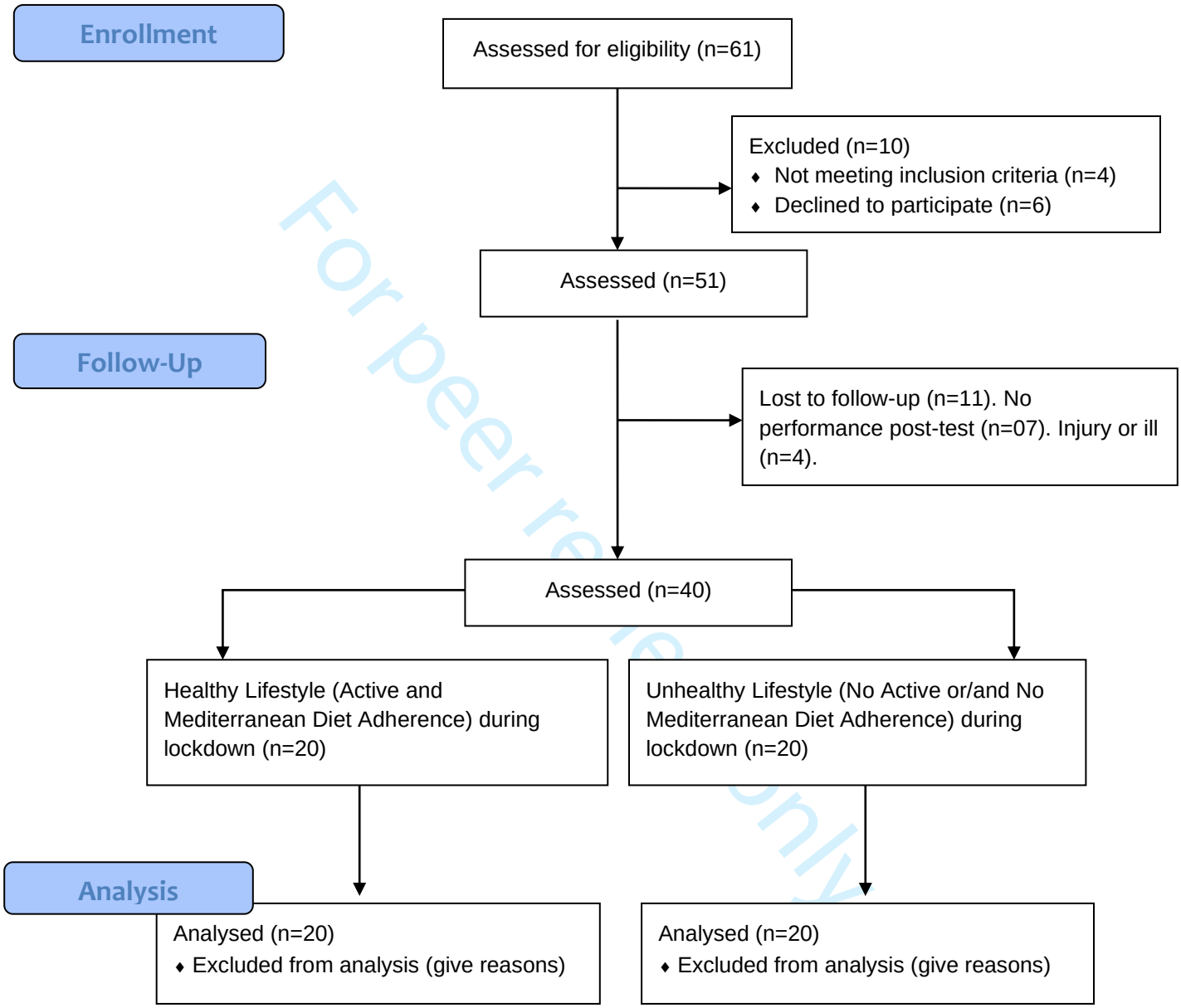
Figure legends

Figure 1. Flow Diagram

Figure 1. Flow Diagram



ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 07/01/2021 04:49

ClinicalTrials.gov ID: NCT04958499

Study Identification

Unique Protocol ID:	UCMurcia-BiohealthyPark
Brief Title:	Effectiveness of Bio-Healthy Park on Adult
Official Title:	Physical and Psychological Effectiveness of Bio-Healthy Park on Adult
Secondary IDs:	

Study Status

Record Verification:	July 2021
Overall Status:	Not yet recruiting
Study Start:	July 15, 2021 [Anticipated]
Primary Completion:	August 1, 2021 [Anticipated]
Study Completion:	September 30, 2021 [Anticipated]

Sponsor/Collaborators

Sponsor:	Universidad Católica San Antonio de Murcia
Responsible Party:	Principal Investigator Investigator: Noelia González-Gálvez [ngonzalez-galvez] Official Title: Principal investigator Affiliation: Universidad Católica San Antonio de Murcia
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: CE111908 Board Name: Maquinaria Bio-saludable: Diseño y fabricación de nueva maquinaria de fitness outdoor ergonómica, eficiente, saludable y con aplicación para dispositivos móviles (App) de valoracióin y control del entrenamiento Board Affiliation: UCAM Phone: Email: ngonzalez@ucam.edu Address:

Av. de los Jerónimos, 135, 30107 Guadalupe, Murcia

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Bio-healthy parks are an alternative for practicing physical activity outdoors and free of charge. However, there is no research that analyzes the effect of a planned training program in these parks. There are two types of parks under development, with and without externally added resistance. Therefore, general objective of this project are to evaluate the effect of 8 weeks of targeted training in bio-healthy parks on body composition, bone mineral density, blood pressure, strength, functional capacity, sarcopenia, sagittal disposition of the spine, quality of life, life satisfaction and Mediterranean diet adherence in adults and older adults. The present project will be developed through a randomized controlled trial, with 1 experimental and 1 control group, with pre-test and post-test, with intra-group and inter-group analysis for each of the dependent variables of the study. It will be measure body composition, bone mineral density, blood pressure, upper limb strength, lower limb strength, functional capacity, sarcopenia, sagittal disposition of the spine, Health-related quality of life, satisfaction with life and Mediterranean diet adherence. Experimental group will receive the exercise program on bio-healthy park machine with a frequency of 2 sessions per week of 55 minutes for 8 weeks. The control group will not perform any intervention program following their usual activity.

Detailed Description: The aging process is associated with physiological, psychological and functional deterioration. It has been demonstrated that the practice of physical activity can prevent, slow or reduce this deterioration. Bio-healthy parks are an alternative for practicing physical activity outdoors and free of charge. However, there is no research that analyzes the effect of a planned training program in these parks. There are two types of parks under development, with and without externally added resistance.

Therefore, the objectives of this project are to evaluate the effect of 8 weeks of targeted training in bio-healthy parks, with a frequency of 2 sessions per week on body composition, bone mineral density, blood pressure, strength, functional capacity, sarcopenia, sagittal disposition of the spine, quality of life, life satisfaction and mediterranean diet satisfaction in adults and older adults.

The present project will be developed through a randomized controlled trial, with 1 experimental and 1 control group, with pre-test and post-test, with intra-group and inter-group analysis for each of the dependent variables of the study.

The inclusion criteria are: (a) not having participated in a structured exercise program for at least 1 year, (b) being older than 50 years of age, and (c) being physically independent. The exclusion criteria are: (a) having musculoskeletal injuries or limitations that could affect the health and physical performance of the person; (b) being under medical prescription for taking medications that could influence physical performance; (c) not regularly attending the proposed sessions.

Body composition and bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA).

Blood pressure by means of an automatic device (Colin BP 880, Inc., Tampa, FL). Strength by manual dynamometry (TKK 5401; Co., Ltd., Tokyo, Japan) and maximal isometric strength of knee extension and biceps flexion.

Functional capacity will be assessed by means of the Chari stand test, gait speed, time up and go test and Short physical performance battery

(SPPB), Sarcopenia will be assessed taking into account the reference values established for muscle quality (hand grip strength and chair stand test), muscle quantity (DEXA fat-free mass) and functional competence (gait speed, time up and go test, SPPB and 400 meter walk) established by the European Consensus (EWGSOP2).

The Spinal Mouse device (Switzerland) will be used to assess the sagittal disposition of the spine (thoracic curve, lumbar curve and pelvic tilt) in standing and relaxed sitting. This technique is non-invasive.

Health-related quality of life and satisfaction with life will be assessed by means of the SF36 and The Satisfaction with Life Scale (SWL) questionnaires.

Mediterranean diet adherence will be assess with a Mediterranean diet adherence questionaire.

Experimental group 1 will receive the exercise program on bio-healthy machinery with a frequency of 2 sessions per week of 55 minutes for 8 weeks. The machines used will be rider, low gemini, high gemini, walk, bottoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be controlled by subjective perception of effort and heart rate (Polar 420). There will be a warm-up 8-10 minutes, a main part 40-45 minutes and a return to calm 5-10 minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be progressed every 2 weeks. The control group will not perform any intervention program following their usual activity.

Conditions

Conditions:	Adult Disease
Keywords:	Adults Older Physical activity Exercise Bio-healthy park Training

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	120 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Bio-Healthy Park	Behavioral: Bio-healthy Park

Arms	Assigned Interventions
This group is the experimental group. The intervention program consisted in the realization of the program on bio-healthy machinery.	Experimental group will receive the exercise program on bio-healthy machinery with a frequency of 2 sessions per week of 55 minutes for 8 weeks. Experimental group 1 will perform the intervention program using machinery designed for self-loading use. The machines used will be rider, low gemini, high gemini, walk, bottoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be controlled by subjective perception of effort and heart rate (Polar 420). There will be a warm-up 8-10 minutes, a main part 40-45 minutes and a return to calm 5-10 minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be progressed every 2 weeks.
No Intervention: Control Adults and older assigned to the control group will not received any structured exercise programme. They will maintain their usual physical activities.	

Outcome Measures

Primary Outcome Measure:

1. Muscle quality sarcopenia
   Sarcopenia will be assessed taking into account the reference values established for muscle quality. The muscle quality will be measure by hand grip strength test. This test will be performance with manual dynamometry (TKK 5401; Scientific Instruments Co., Ltd., Tokyo, Japan). Maximal isometric upper limb strength will be performance by maximal isometric strength. Upper strength will be register by kilogrammes. Higher value show high strength.

   [Time Frame: Changes from baseline to 8 weeks]

Secondary Outcome Measure:

2. Change Body composition
   Body composition will be assessed by dual energy X-ray absorptiometry (DEXA). This is noninvasive technique. The result will be register in absolutes and percentages results.

   [Time Frame: Changes from baseline to 8 weeks]
3. Change Blood pressure
   Blood pressure and heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). This is noninvasive technique. The result will be register in millimeters of mercury (bood pressure) and number of pulse per minutes (heart rate).

   [Time Frame: Changes from baseline to 8 weeks]
4. Change Chair stand test
   Chair stand test measure the functional capacity. This is a easy physical test. This test measures the functionality of getting up and sitting down from a chair five times. The participant have to performance the test as faster as possible. The total time is recorded in seconds. A better time indicates better functional ability.

   [Time Frame: Changes from baseline to 8 weeks]
5. Change Upper strength
   Maximal isometric upper limb strength will be performance by maximal isometric strength of knee extension and biceps flexion with load cell. Maximal isometric lower limb will be registered in newton. Higher value show high strength.

   [Time Frame: Changes from baseline to 8 weeks]
6. Change Sagittal spinal curvature

Sagittal spinal curvature will be assess with the Spinal Mouse device (Switzerland). It will be measured: angle of the dorsal and lumbar curve and pelvic tilt when standing and in asthenic sitting. This is noninvasive technique. The result is register in grades.

[Time Frame: Changes from baseline to 8 weeks]

7. Health-related quality
Health-related quality of life will be assessed by means of the Short Form 36 questionaire. This questionaire have 11 questions and show result for 9 area: physical role, pain, general health, vitality, social function, emotional role, mental health, and evolution of the health care system. Each area is reported from 0 to 100 point. Higher score represent better health-related quality.

[Time Frame: Changes from baseline to 8 weeks]

8. Satisfaction with Life Scale (SWL)
Satisfaction with Life Scale (SWL) questionnaires include 5 affirmation about the satisfaction with the life and the participant have to answers from strongly agree to strongly disagree. The final score is reported from 5 to 35 point. Higher value show better satisfaction with life.

[Time Frame: Changes from baseline to 8 weeks]

9. Adherence to the Mediterranean diet
It will be used the Adherence to the Mediterranean diet. This questionaire have 14 questions (yes and no answer) about their adherence to the mediterranean diet. The sum of the answers are collect. Higher score show higher adherence to mediterranean diet.

[Time Frame: Changes from baseline to 8 weeks]

10. Functional competence 400 meter walk
Functional competence 400 meter walk is a test included in the European Consensus (EWGSOP2) to measure sarcopenia. Participant have to walk as fast as possible 400 meter. The total time is register.

[Time Frame: Changes from baseline to 8 weeks]

11. Change bone mineral density
Bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA). This is noninvasive technique. The result will be register in absolutes and percentages results.

[Time Frame: Changes from baseline to 8 weeks]

12. Change heart rate
Heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). This is noninvasive technique. The result will be register in number of pulse per minutes (heart rate).

[Time Frame: Changes from baseline to 8 weeks]

13. Gait speed change
Gait speed will be measure by 4. 6 and 10 meter test. This is easy physical test in with the participant have to walk 4. 6 and 10 metres as faster as possible. The result will be register in seconds. Less time indicates better functional ability.

[Time Frame: Changes from baseline to 8 weeks]

14. Time up and go test change
Time up and go test measure the functional capacity of getting up, walking and sitting down form a chair. Participant have to performance this test as faster as possible. This is a easy physical test. Total seconds are records. Less seconds indicates better functional ability.

[Time Frame: Changes from baseline to 8 weeks]

15. Short physical performance battery (SPPB)
Short physical performance battery (SPBB) include three test (balance, chair stand test and gait speed) and report a final score. Chair stand test and gait speed were describe in other outcome. Balance test is a easy physical test. The participant must maintain three balancing positions for 10 seconds to overcome it. Each test offers a different score. Higher score show better functional capacity.

[Time Frame: Changes from baseline to 8 weeks]

16. Change in lower limb strenght

Maximal isometric lower limb will be performance by maximal isometric strength of knee extension with load cell. Maximal isometric lower limb will be registered in newton. Higher value show high strength.

[Time Frame: Changes from baseline to 8 weeks]

Eligibility

Minimum Age:	50 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- not having participated in a structured exercise program for at least 1 year;
- being older than 50 years of age
- being physically independent.

Exclusion Criteria:

- having musculoskeletal injuries or limitations that could affect the person's health and physical performance
- being under medical prescription for taking medications that could influence physical performance
- not regularly attending the proposed sessions.

Contacts/Locations

Central Contact Person: Pablo Jorge Marcos-Pardo, PhD
Telephone: 696243274
Email: pjmarcos@ual.es

Central Contact Backup: Noelia Gonzalez-Galvez, PhD
Telephone: 627146613
Email: ngonzalez@ucam.edu

Study Officials: Pablo Jorge Marcos-Pardo, PhD
Study Principal Investigator
Universidad de Almería

Noelia Gonzalez-Galvez, PhD
Study Principal Investigator
UCAM

Locations: **Spain**
Pablo Jorge Marcos-Pardo
Murcia, Spain
Contact: Pablo Jorge Marcos-Pardo, PhD 696243274 pjmarcos@ual.es
Contact: Noelia Gonzalez-Galvez, PhD 627146613 ngonzalez@ucam.edu

IPDSharing

Plan to Share IPD: No

References

Citations:

NOTE : Either PubMed ID or Citation Text should be specified.

Links:

Available IPD/Information:

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COMITÉ DE ÉTICA DE LA UCAM

DATOS DEL PROYECTO

Título:	"Maquinaria Bio-saludable Inteligente: Diseño y fabricación de nueva maquinaria de fitness outdoor ergonómica, eficiente, saludable y con aplicación para dispositivos móviles (App) de valoración y control del entrenamiento"

Investigador Principal	**Nombre**	**Correo-e**
Dr.	Pablo Jorge Marcos Pardo	pmarcos@ucam.edu

INFORME DEL COMITÉ

Fecha	**29/11/2019**

Código	**CE111908**

Tipo de Experimentación

Investigación experimental clínica con seres humanos	
Utilización de tejidos humanos procedentes de pacientes, tejidos embrionarios o fetales	
Utilización de tejidos humanos, tejidos embrionarios o fetales procedentes de bancos de muestras o tejidos	
Investigación observacional con seres humanos, psicológica o comportamental en humanos	X
Uso de datos personales, información genética, etc.	X
Experimentación animal	
Utilización de agentes biológicos de riesgo para la salud humana, animal o las plantas	
Uso de organismos modificados genéticamente (OMGs)	

Comentarios Respecto al Tipo de Experimentación
Nada Obsta

Comentarios Respecto a la Metodología de Experimentación
Nada Obsta

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COMITÉ DE ÉTICA DE LA UCAM

Sugerencias al Investigador

A la vista de la solicitud de informe adjunto por el Investigador y de las recomendaciones anteriormente expuestas el dictamen del Comité es:

Emitir Informe Favorable	**X**
Emitir Informe Desfavorable	
Emitir Informe Favorable condicionado a Subsanación	

MOTIVACIÓN
Incrementará conocimientos en su área

Vº Bº El Presidente,

Fdo.: José Alberto Cánovas Sánchez

El Secretario,

UNIVERSIDAD CATOLICA SAN ANTONIO · COMITE DE ETICA ·

Fdo.: José Alarcón Teruel

UCAM
UNIVERSIDAD CATÓLICA SAN ANTONIO

COMITÉ DE ÉTICA DE LA UCAM

DATOS DEL PROYECTO

Título:	"COVID-19 y aislamiento social: Efectos sobre la condición física y la salud psico-fisiológica en adultos mayores"

Investigador Principal	**Nombre**	**Correo-e**
Dr.	Pablo Jorge Marcos Pardo	pmarcos@ucam.edu

INFORME DEL COMITÉ

Fecha	**29/05/2020**

Código	**CE052002**

Tipo de Experimentación

Investigación experimental clínica con seres humanos	
Investigación experimental no clínica con seres humanos	**X**
Utilización de tejidos humanos procedentes de pacientes, personas sanas, tejidos embrionarios o fetales	
Utilización de tejidos humanos, tejidos embrionarios o fetales procedentes de bancos de muestras o tejidos	
Investigación observacional con seres humanos, psicológica o comportamental en humanos	**X**
Uso de datos personales	**X**
Experimentación animal	
Utilización de agentes biológicos de riesgo para la salud humana, animal o las plantas	
Uso de organismos modificados genéticamente (OMGs)	

Comentarios Respecto al Tipo de Experimentación
Nada Obsta

Comentarios Respecto a la Metodología de Experimentación
Nada Obsta

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COMITÉ DE ÉTICA DE LA UCAM

Directrices al Investigador
No podrá iniciar el proyecto hasta que no disponga del permiso oficial del "Comité de Seguimiento UCAM COVID-19" para garantizar la seguridad de los participantes.

A la vista de la solicitud de informe adjunto por el Investigador y de las directrices anteriormente expuestas el dictamen del Comité es:

Emitir Informe Favorable	**X**
Emitir Informe Desfavorable	
Emitir Informe Favorable condicionado a Subsanación	

MOTIVACIÓN
Incrementará conocimientos en su área

Vº Bº El Presidente,

Fdo.: José Alberto Cánovas Sánchez

El Secretario,

UNIVERSIDAD CATOLICA SAN ANTONIO · COMITE DE ETICA ·

Fdo.: José Alarcón Teruel

Supplementary file 3. STROBE Statement

	Item No	Recommendation	Pag
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*3-4*
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	4-5
		(*b*) Describe any methods used to examine subgroups and interactions	4-5
		(*c*) Explain how missing data were addressed	4-5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	4-5
		(*e*) Describe any sensitivity analyses	4-5

Continued on next page

Results			**Pag**
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3
		(b) Give reasons for non-participation at each stage	3
		(c) Consider use of a flow diagram	3
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	5
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	5
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*5*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*5*
		Cross-sectional study—Report numbers of outcome events or summary measures	*5*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	5
		(*b*) Report category boundaries when continuous variables were categorized	5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	5
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	5
Discussion			
Key results	18	Summarise key results with reference to study objectives	6
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	6-7-8
Generalisability	21	Discuss the generalisability (external validity) of the study results	6-7-8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Changes in life satisfaction, depression, general health and sleep quality of Spanish older women during Covid-19 lockdown and their relationship with lifestyle: an observational follow-up study

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Changes in life satisfaction, depression, general health and sleep quality of Spanish older women during Covid-19 lockdown and their relationship with lifestyle: an observational follow-up study

Pablo Jorge Marcos-Pardo[1,2,4], Tomás Abelleira-Lamela[3], Raquel Vaquero-Cristóbal[3,4*], Noelia González-Gálvez[3,4].

[1] SPORT Research Group (CTS-1024), CERNEP Research Center, University of Almería, Almería, Spain.
[2]Department of Education, Faculty of Education Sciences, University of Almería, Almería, Spain
[3] Injury prevention in sport Research Group (PRELEDE), Faculty of Sport, Catholic University of Murcia, Murcia, Spain
[4]Active Aging, Exercise and Health/HEALTHY-AGE Network, Consejo Superior de Deportes (CSD), Ministry of Culture and Sport of Spain, Madrid 28040, Spain

*** Correspondence:**
Raquel Vaquero-Cristóbal
rvaquero@ucam.edu

Keywords: Adult$_1$, Lockdown$_2$, Mediterranean diet adherence$_3$, Physical activity$_4$, Psychology$_5$, SARS-CoV-2$_6$, Sleep quality$_7$, Well-being$_8$

Abstract

Objetives: to analyze the effects of COVID-19 lockdown on mental well-being variables of older women, and to determine the influence of lifestyle and age on such effects. The hypothesis of the study was that all parameters related to mental well-being would worsen in older women during the COVID-19 lockdown. **Design:** Observational follow-up study. Pre-lockdown measurements were taken before the lockdown. Post-lockdown measurements were taken as soon as began the de-escalation. **Setting:** Senior centers in the Region of Murcia (Spain). **Participants:** The sample was composed of 40 older women volunteers, over 54 years of age (mean age= 62.35±8.15 years). **Primary and secondary outcome measures:** Pre and Post-Lockdown evaluations were carried out face to face. The following questionnaires were completed: Satisfaction with Life Scale, The Center for Epidemiologic Studies Depression Scale, The Short Form 36 Health Survey, The Pittsburgh Sleep Quality Index, the Global Physical Activity Questionnaire, and Prevention with Mediterranean Diet. **Results:** Post-lockdown, a worsening was found in the variables of life satisfaction (p=.001); depression (p<.001) quality of life in physical role (p=.006), pain (p=.004), emotional role (p<.001), and mental health (p<.001); and sleep quality (p=.018), sleep latency (p=.004), sleep disturbances, (p=.002) and global sleep quality score (p=.002). It was found how age influenced the variables of pain (p=0.003) and social role (p=.047); as well as the influence of a healthy lifestyle on the variables analyzed (F=6.214; p=.017). Adherence to the Mediterranean diet was shown to be a protective factor against increased depression (p=.03). Spending time sitting was shown to be a risk factor for physical role health (p=.002), as was advanced age on health due to worsening pain (p=.005), or an unhealthy lifestyle on increased consumption of sleeping aids (p=.017). **Conclusion:** The lockdown had a great negative impact on Spanish older women on mental well-being variables.

ClinicalTrials.gov Identifier: NCT04958499

Strengths and limitations of this study

- The main strength of the present investigation was the possibility of carrying out a follow-up study to analyze the effects of lockdown on psychological and health-related variables of older women.
- Face-to-face surveys were used, which made possible the avoidance of the bias that is commonly implied by the use of technology with older women population.
- It should be noted that the post-lockdown surveys could not be conducted until the limitations of mobility and access to the center where the study was conducted
- Another limitation was the absence of a control group that was not in a lockdown situation.

Word count: 4830.

Introduction

The outbreak of Coronavirus disease (COVID-19), an infectious disease caused by the SARS-Cov-2 virus that started in China and is now present all over the world, has become a major global headline, causing great public panic and concern [1].

On Wednesday, March 11, 2020, the World Health Organization (WHO) upgraded the public health emergency situation caused by COVID-19 to an international pandemic [1]. Following this announcement, on Saturday, March 14, 2020, the Government of Spain, declared the State of Alarm and the start of confinement measures (Royal Decree 463/2020), to decrease the basic reproduction number (R0) of SARS-CoV-2 and thus reduce its transmission [2]. This marked the beginning of a 14-week lockdown [2,3]. Public health guidelines in many countries, including Spain, suggested that people stay at home to avoid person-to-person transmission of the virus [1]. However, the lockdown in Spain was more restrictive than in other countries, with no one allowed to go outside the home for anything that was not considered an essential activity, which meant the closure of most of the country's activity and the establishment of a teleworking regime for most of the workers who could continue their activity during the lockdown period [4].

This situation induced changes in the lifestyles of the Spanish population. Some studies found a reduction in the levels of physical activity [5,6]; negative diet disturbances [5]; an increase in social isolation which can induces changes in psychological health, such as increased anxiety and depression [7–9]; or a worsening of sleep quality [6,8,10–12], as a psychological response to the pandemic. More specifically, during the COVID-19 pandemic, it has been found that fear and anxiety provoked by the situation were related to psychological distress, sleep disturbances and life satisfaction [13]. In addition, there could be large individual differences in the psychological affects suffered by the population, with self-compassion being a mediating factor in the transformation of negative thoughts and emotions, improving self-acceptance and decreasing anxiety and depression, resulting in an improvement in overall well-being, although intolerance to uncertainty and fear provoked by the COVID-19 situation mediated the relationship between self-compassion and well-being [14]. Such effects may be particularly problematic in older adults and especially in women [7,8,15], due to reduced physical capabilities and the possibility of increased chronic diseases and mental health problems.

It has been shown that women as a population, especially during old age, were most affected by the lockdown measures, with significant increases in stress, anxiety and other psychological variables as compared to men [7,8,15,16]. This could be related to their greater tendency to feel lonely and isolated or to their greater economic vulnerability [16,17]. Similar studies have been found analyzing the effect of the lockdown on different population groups such as workers or students [6,18] or older adults in general [19]. However, no follow-up or longitudinal studies have been found that have analyzed the evolution of the health status of older women during lockdown. For this reason, the objective of this study was to analyze the effects of the COVID-19 lockdown on life satisfaction, depression, general health, and sleep quality of older women, and to determine the influence of lifestyle and age on such effects. The hypothesis of the study was that all parameters related to mental well-being would worsen in older women during the COVID-19 lockdown, with those women with a poorer lifestyle experiencing the greatest change.

Material and Methods

Study design

This study is a part of the ongoing project entitled Smart Bio-healthy Machinery: Design and manufacture of new ergonomic, efficient, and healthy outdoor fitness machinery, including an

application for mobile devices (app) to assess and monitor training (ClinicalTrials.gov Identifier: NCT04958499) (See Supplementary file 1). The study was approved by the institutional ethics committee of the Catholic University of Murcia in accordance with the Declaration of Helsinki (code: CE111908) (See Supplementary file 2), with additional permission provided by the institutional ethics committee to adapt this project to the situation of COVID-19 (code: CE052002) (See Supplementary file 3). All the participants were informed, and voluntarily signed the informed consent form before participating in the study.

This observational follow-up study design followed the Strobe Statement [20] (See Supplementary file 4). Pre-lockdown measurements were taken between zero to two weeks before the lockdown in Spain. Post-lockdown measurements were taken as soon as the Spanish government began the de-escalation phase, in which the population was allowed to go outside for a maximum of two-three hours per day per age group, and the non-essential workers could return to face-to-face work; and always before the lockdown measures were completely abolished. In both pre-lockdown and post-lockdown tests, the participants self-completed a printed survey about sociodemographic information, life satisfaction, depression, general health, sleep quality, physical activity, and diet (Figure 1). The duration from pre-lockdown to post-lockdown was thirteen weeks.

Sampling method and sample size

The participants volunteered through advertisements and presentations in senior centers in the Region of Murcia (Spain). The SF-36 survey's standard deviation from a previous study was used to establish the power and sample size [21]. With an estimated error of 2.59 points, the total sample size for this study consisted of 40 participants, which provided a power of 95% and a significance level of $\alpha = 0.05$. Rstudio 3.15.0 software was used to establish the sample size. The sample was composed of 40 adult female volunteers, over 50 years of age (mean age= 62.35±8.15 years).

The Inclusion criteria were as follows: (a) female; and (b) aged between 50 and 85 years. The exclusion criteria were as follows: (a) having suffered SARS-CoV-2 infection during confinement; (b) having a job considered essential during the confinement period; (c) suffering from any cardiovascular, renal, hepatic, respiratory or metabolic pathology, (d) suffering from any psychiatric disease, (e) taking any medication that could alter the psychological state, or (f) having any pathology or any SARS-CoV-2 symptom that prevented performing any of the evaluation tests.

Patient and public involvement

Patients and the public were not involved in the development of the research questions, design and conduct of the study. However, participants were involved in the recruitment of others through the snowball method. The study results were shared with the participants with an individual inform and will be shared with other relevant stakeholders through various social media handles and conferences after the publication of the paper.

Procedures

The participants completed the questionnaire anonymously and individually, without being under pressure. After signing the informed consent, they could start completing the questionnaire. The participants did not receive any additional explanation about the purpose of the questionnaire apart from that contained in the questionnaire itself. The questionnaire was accessed by hard-copy. For all the questionnaires included in this research, the validated Spanish version of the questionnaires was used. The participants completed it during 20–30 min.

The sociodemographic questionnaire was created ad hoc for this study, and included questions about age, marital status, occupation, education level and living status.

Furthermore, the Satisfaction with Life Scale (SWLS) was used to measure the degree of satisfaction with the participan''s own life [22]. This questionnaire has been validated in Spanish, the version that

was used for the present research, showing an internal consistency of the scale of Cronbach's alpha's = .88 [23]. The questionnaire consists of five questions with a scale from 1 to 7 depending on the degree of agreement. To obtain the final score, the scores for each of the questions were summed following the methodology from Pavot and Diener [22]. The scores of this scale range from 5 to 35, with a higher value indicating greater satisfaction with life [22].

The Center for Epidemiologic Studies Depression Scale (CESD) was used to screen for depression [24]. This scale has been validated in Spanish [25], the version used in this research, showing acceptable internal consistencies (Cronbach's alpha =.80-.86) [26].On this scale, composed of 20 items, each item has a value between 0-3, and a maximum total score of 60 points. CESD can judge depression and can even confirm the severity of the depression symptoms (no to mild: ≤16; moderate: 17-23; severe: ≥24) [27].

The Short Form 36 Health Survey (SF-36) (Medical Outcomes Trust, Boston, MA) was used to measure health state. It includes four physical health scales (physical functioning, role-physical, bodily pain and general health); and four mental health scales (vitality, social functioning, role-emotional, and mental health) [28]. This scale has been validated in Spanish, the version used in the present study, showing acceptable internal consistencies (Cronbach's alpha <.70) [29]. For its calculation, the methodology proposed by Ware et al. [30] was utilized.

The Pittsburgh Sleep Quality Index (PSQI) scale was used to evaluate sleep quality in the previous month. With 19 items, it evaluates 7 subcomponent factors of sleep quality: subjective sleep quality, sleep latency, total sleep duration, sleep efficiency, sleep disturbances, daytime dysfunction, and use of sleep medication. This questionnaire has been validated in Spanish, the version that was used for the present research, showing an internal consistency of the scale of Cronbach's alpha = .67-.88 [31,32]. The range of subscores for each component is 0 to 3, with a maximum total score of 21:Good sleep quality (scores of 0 to 5) and poor sleep quality (scores of 6) [33].

Physical activity was analyzed using the Global Physical Activity Questionnaire (GPAQ). GPAQ was developed by the World Health Organization (WHO) with 16 questions that revolve around three domains: occupational physical activity, transport-related and leisure physical activity. In addition, it can also assess sedentary behavior by recording minutes spent sitting [34]. With the data compiled through this questionnaire, we summed the minutes of physical activity of the participants according to type of activity and its level of intensity. This instrument has been validated in Spanish [33]. Furthermore, this questionnaire was validated, showing an internal consistency of the physical activities of Cronbach's alpha of .52-.67 [35,36].

Finally, the adherence to the Mediterranean diet was assessed using the previously validated 14-item questionnaire for the assessment of Prevention with Mediterranean Diet (PMD) [37]. The score for each item was 1 or 0 and the PREDIMED score was calculated with the following ranges: 0-5, lowest adherence; score 6-9, average adherence; score ≥10, highest adherence [38]. This instrument has been validated in Spanish [39] and has shown an acceptable accuracy and reliability (r and ICC = .69) [40].

After completing the questionnaires, all participants had their height and weight measured following the protocols of the International Society for the Advancement of Kinanthropometry (ISAK) measured by an ISAK accredited anthropometrist. A SECA 862 scale (SECA, Hamburg, Germany) with an accuracy of 100 g was used for measuring weight; a SECA 213 stadiometer (SECA, Hamburg, Germany) with an accuracy of 0.1 cm for measuring standing height. All variables were measured twice and the final value being the mean of both assessments. A third measurement was taken when the difference between the first and second measurements was greater than 1% and in this case the median was taken as the final value. Body mass index (BMI) was calculated as weight (kg) divided by height (m) squared [41]. The same researchers performed all the measurements in a single session between 8:00 and 14:00 h. The participants were examined barefoot with the temperature of laboratory standardized at 24 °C.

Statistical analysis

The Kolmogorov–Smirnov test and Mauchly's W-test were used to evaluate the normality and the sphericity of the data. The means and standard deviations were calculated from the quantitative variables, and frequency and percent were used for the qualitative variables. The participants were categorized as having a Healthy lifestyle or Unhealthy lifestyle. A Healthy lifestyle was considered for those who complied with at least 150 min of moderate to vigorous physical activity (MVPA) a week and who maintained adherence to the Mediterranean diet (above 7 points) vs an unhealthy lifestyle, those who did not comply with either or both parameters. A two-way analysis of variance (ANOVA) with repeated measures in 1 factor (time) was used to analyze inter- and intra-group differences and to analyze the interaction between groups and time. This analysis was performed unadjusted and adjusted by age and living status. The Bonferroni post-hoc test was used to evaluate the statistical significance of the parametric variables. Stepwise multiple linear regression models were used to explore the associations between the dependent variables and each independent variable. To analyse whether a nonlinear multiple regression model provided the best explanation of the variance, a curvilinear estimation analysis was used to explore the best model association between the dependent (satisfaction with life, depression, health state and sleep quality) and independents variables (age, Mediterranean diet adherence, sitting time a day and life style). The relationship between sample size and variables included in the regression were stablished in 10/1 [42]. The statistical analysis was performed using the statistical package SPSS 21.0 for Windows. In a complementary way, a generalizability analysis was carried out to assume that the estimated results were reliable and generalizable by the SAGT v1.0 software [43,44].

Technical appendix, statistical code, and dataset available from the Dryad repository, DOI: https://doi.org/10.5061/dryad.rfj6q57cp [45].

Results

Table 1 shows the anthropometric characteristics and sociodemographic variables of the sample (n=40). Sociodemographic variables remained stable and unchanged Post-lockdown.

Table 1. Characteristics of the sample

Variable	%(n) or M±SD
Age (year-old)	62.35±8.15
Height (cm)	154.70±7.09
Weight (kg)	72.50±14.02
BMI (weight (kg)/height^2)	30.30±5.50
Marital status	
Single	5.00 (2)
Married	57.50 (23)
Separated	10.00 (4)
Widowed	27.50 (11)
Occupation	
Full-Time Worker	17.50 (7)
Part-Time Worker	12.50 (5)
Unemployed	17.50 (7)
Retired	52.50 (21)
Education level	
No education	12.50 (5)
Elementary school	57.50 (23)

High school	12.50 (5)
Bachelor´s Degrees or higher	17.50 (7)
Living status	
Living with someone	72.50 (29)
Living alone	27.50 (11)
Sitting time during lockdown (min per day)	385.20±152.66
MVPA during lockdown (min per week)	340.50±403.95
Active vs Inactive (WHO 150 min/week)	
Active	72.50 (29)
Inactive	27.50 (11)
MDA Classification	
No Adherence (≤7 points)	25 (10)
Adherence (>7 points)	75 (30)
Lifestyle (Active and MDA vs No Active or No Adherence)	
Healthy	50.00 (20)
Unhealthy	50.00 (20)

BMI = body mass index; MDA = Mediterranean Diet Adherence; MVPA = moderate to vigorous physical activity; WHO = World Health Organization.

Table 2 shows the results of the differences between pre and post adjusted and unadjusted for age, of the perception of life satisfaction, depression, general health and sleep quality. Post-lockdown, the sample significantly had worse results in satisfaction with life; depression values; quality of life in physical role, pain, emotional role and mental health; and sleep quality, sleep latency, sleep disturbance and global sleep quality score (Table 2). The results of the time*age interaction analysis were significant for pain (F=10.07; p=.003) and social function (F=4.23; p=.047), meaning that age adversely influenced the change in these variables post-lockdown. The results of the time*living status interaction analysis were significant for role-physical (F=5.021; p=.005) and bodily pain (F=4.640; p=.004), meaning that be alone adversely influence the change in these variables post-lockdown. For the rest of the variables, no significant values were observed.

When the differences in these variables were analyzed as a function of group and measurement, it was found that the pre-test differences were not significant for the Healthy Lifestyle group (mean difference= -.158±473; p=.473) while it was significant for the Unhealthy Lifestyle group (mean difference= .600; p=.008). In addition, the effect of the time*Lifestyle interaction during lockdown was found to be significant (F=6.214; p=.017), indicating that maintaining a healthy lifestyle during lockdown was key in the maintenance of the variables analyzed.

Table 2. Effect of lockdown due to the COVID pandemic in older women (n=40) (unadjusted and adjusted by age and living status).

				Unadjusted			Adjusted by age			Adjusted by living status		
		Pre-test (M±SD)	Post-test (M±SD)	Difference post-pre (M±SD)	p	95% CI (Mpost-Mpre)	Difference post-pre (M±SD)	p	95% CI (Mpost-Mpre)	Difference post-pre (M±SD)	p	95% CI (Mpost-Mpre)
Satisfaction with live (SWLS scale)		19.93±3.38	17.68±4.76	-2.25±0.66	.001	-3.58; -.93	-2.25±0.66	.001	-3.58; -.93	-2.25±0.66	.002	-3.59; -.91
Depression (CESD scale)		13.18±8.52	20.13±11.29	6.95±1.68	<.001	-3.56; 10.35	6.95±1.67	<.001	3.57; 10.33	6.95±1.69	<.001	9.527; 10.37
Physical Health (SF-36 scale)	Physical functioning	82.74±12.66	82.14±8.87	-.60±1.70	.726	-4.03; 2.84	-.60±1.696	.725	-4.03±2.88	-.60±1.696	.730	-7.079±2,88
	Role-physical	89.10±17.95	79.81±18.94	-9.30±3.21	.006	-15.78; -2.81	-9.30±3.18	.006	-15.839±-2.88	-9.30±3.15	.005	-15.67±-2.916
	Bodily pain	72.03±20.15	62.00±22.35	-10.02±3.29	.004	-16.68; -3.37	-10.02±2.95	.002	-15.97±-.95	-10.02±3.24	.004	3.45±16.59
	General health	73.19±14.65	69.29±18.08	-3.90±2.37	.108	-8.69; .89	-3.90±2.36	.108	-8.76±0.90	-3.30±2.27	.094	-8.49±.69
Mental Health (SF-36 scale)	Vitality	71.05±14.99	69.87±14.70	-1.18±2.18	.592	-5.58; 3.23	-1.21±2.22	.588	-3.288±5.711	-1.18±2.13	.584	-5.48±3.1
	Social functioning	89.23±14.21	88.72±21.66	-.51±3.62	.888	-7.84; 6.81	-.51±3.52	.886	-6.636±7.65	-.51±3.50	.884	-7.608±6.58
	Role-emotional	91.88±16.61	76.50±21.53	15.39±3.89	<.001	-23.26; -7.51	-15.39±3.83	<.001	7.52±23.26	-15.39±3.91	<.001	-23.32±-7.45
	Mental health	77.78±12.85	65.89±14.01	-11.88±2.10	<.001	-16.12; -7.64	-11.88±2.12	<.001	-7.59±16.26	-11.88±2.12	<.001	-16.18±-7.58
Sleep (PSQI scale)	C1 Sleep Quality component	1.11±.57	1.36±.68	.25±.10	.018	.05;.45	.25±.10	.021	.04±.460	.25±.10	.019	.43±.45
	C2 Sleep latency	1.28±1.03	1.78±1.17	.50±.16	.004	.17;.83	.50±.16	.005	.167±.834	.50±.16	.004	.17±.83
	C3 Sleep duration	1.00±.76	1.08±.77	.08±.11	.446	-.14;.30	.08±.11	.459	-.143±.310	.08±.11	.446	-.14±.30

C4 Habitual Sleep efficiency	.92±1.11	.81±1.01	-.11±.13	.401	-.38; .15	-.11±.13	.396	-.37±.15	-.11±.13	.369	-.359±.14
C5 Step disturbances	1.39±.60	1.75±.60	36±.11	.002	.15; .58	.36±.11	.002	.141±.58	.36±.11	.002	.14±.58
C6 Use of sleeping medication	1.00±1.39	1.28±1.47	.28±.17	.115	-.07; .63	.28±.16	.089	-.601±.045	.28±.17	.116	.08±.63
C7 Day time dysfunction	.50±.61	.64±.59	.14±.13	.281	-.12; .40	.14± .13	.295	-.126± .404	.14± .13	.288	.12±.40
Global score	7.19±4.06	8.69±3.91	1.50±.46	.002	.57; 2.43	1.50±.46	.002	.568±2.43	1.50±.46	.003	.56±2.44

CESD= center for epidemiologic studies depression scale; C=component; PSQI= Pittsburgh sleep quality index; SF-36= short form 36 health survey; SWLS= satisfaction with life scale.

When performing linear regression models, it was found that adherence to the Mediterranean diet during lockdown was shown to be a protective factor against increased depression due to the lockdown (Standardized Coefficient (β) = -.341; p=.031; r2=.116). Spending time sitting was shown as a risk factor for physical role health (Standardized Coefficient (β) = -.474; p=.002; r2=.224). An older age was found to be a health risk factor for worsening pain (Standardized Coefficient (β) = .438; p=.005; r2=.192). Volunteers who showed an unhealthy lifestyle (inactive or No Mediterranean diet Adherence) had a greater risk in increasing the use of sleeping medication (PSQI Component 6 use of sleeping medication) (Standardized Coefficient (β) = .379; p=.017; r2=.144) (Table 3).

Table 3. Nonlinear multiple regression analysis of the relationship of dependent and independent variables.

	R^2	*p* Value	Included independent variables	Standarized Coefficient (β)
Depression	.116	.031	Adherence Mediterranean Diet	-.341
Physical role health	.224	.002	Spending time sitting	-.474
Age	. 192	.005	Pain	.438
Use of sleeping medication	.144	.017	Unhealthy lifestyle	.379

Finally, the analysis of generalizability (Tables 4 y 5) shows in the first design a Generalizability coefficient (GC) between .656 and .882. This result shows a medium-high reliability of the test. The percentage of variance (see Table 5) is found high in all test.

Table 4. Absolute generalizability coefficient, relative generalizability coefficient, absolute standard deviation, and relative standard deviation in each of the designs.

Design		Absolute generalizability coefficient	Relative generalizability coefficiemt	Absolute standard deviation	Relative standard deviation
Satisfaction with live (SWLS scale)		.734	.748	.353	.340
Depression (CESD scale)		,778	,812	,206	,186
Physical Health (SF-36 scale)	Physical functioning	.579	.755	.269	.187
	Role-physical	.873	.882	.127	.122
	Bodily pain	.677	.712	.647	.587
	General health	,633	,656	,448	,425
Mental Health (SF-36 scale)	Vitality	,767	,770	,423	,420
	Social functioning	.630	.669	.440	.403
	Role-emotional	.871	.871	.118	.118
	Mental health	.714	.735	.421	.399
Sleep (PSQI scale)		.782	.789	.316	.310

Table 5. Sources of variation, sum of squares, degrees of freedom, mean squares, % and standard error.

Design		Sum of squares	DF	Mean squares	%	Standard error
Satisfaction with live (SWLS scale)		90.120	156	.578	59.583	.065
Depression (CESD scale)		512.376	741	.691	69.069	.036
Physical Health (SF-36 scale)	Physical functioning	57.413	234	.244	39.811	.022
	Role-physical	6.931	117	.0590	33.780	.008
	Bodily pain	26.888	39	.689	40.793	.152
	General health	141.2	156	.905	67.139	.102
Mental Health (SF-36 scale)	Vitality	82.650	117	.706	54.059	.092
	Social functioning	12.688	390	.325	45.373	.072
	Role-emotional	3.267	78	.042	30.769	.007
	Mental health	124.270	156	.797	60.048	.090
Sleep (PSQI scale)		112.317	195	.576	60.067	.058

Discussion

The main objective of this study was to analyze the effects of COVID-19 lockdown on life satisfaction, depression, sleep quality, and pain of older women. It was found that life satisfaction, quality of life in the physical component, quality of life perfection with respect to emotional role, and mental health, worsened after lockdown. The measurement using the SWLS denoted scores of mild dissatisfaction with life [22], with a significant worsening with respect to values before the lockdown. This is in line with other studies, in which people who underwent a period of lockdown reported a lower life satisfaction, as well as symptoms of psychological distress [46]. Previous studies have found that the restrictive lockdown measures implemented as a consequence of COVID19 had a significant influence on the perception of quality of life and mental health [47]. These changes being related to the fear and anxiety provoked by the situation experienced with COVID-19 [13]. In this regard, it should be noted that Spain was one of the countries where the policies were the most restrictive with respect to the lockdown of its citizens [4], which could explain the results found in the present research study. In fact, the lockdown limited the possibilities of leisure time, which was especially noticeable for those who did not work, as was the case for the majority of the sample in the present investigation. During this period of time, the employment situation in Spain was affected by the pandemic. Therefore, in addition to the unemployed people, others were in a situation of record of temporary employment regulation, and among the people who worked, only those sectors considered essential such as supermarkets and the health sector (Royal Decree 463/2020) could work in person, leaving the rest of the workers in a situation of teleworking [4]. In this sense, previous studies have pointed out that the worsening of health during the pandemic was directly affected by the work situation [46] and that there was a direct relationship between being busy at work and greater life satisfaction [15]. It is important to take into

consideration the findings of this research in future situations of partial or total lockdown to reduce its negative psychological effects.

Depression has been one of the most classically studied psychological variables. In the present research, we found an increase in depression values after lockdown, as was in previous cross-sectional studies [1,6,8], with the percentage of women with depression increasing over 21% as compared to epidemiological studies conducted in a normal setting [7,8,11,48]. Also, age was a potentiating factor for this phenomenon [49], as found in the present research. One of the aspects that could have most affected this increase in depression was loneliness. However, almost 1 out of 3 women in the present study spent the lockdown alone and be alone has adversely influence the effect of the lowndown in role-physical and bodily pain. In a sample of people over 65 years of age analyzed after the lockdown, a greater presence of depressive and anxiety symptoms was observed in those who were alone, especially in women [16,50,51], while those who were not alone did not show significant increases in depression even when under lockdown [50]. This is an important aspect to take into account in situations of social isolation.

Along the same line, the participants in the present investigation showed a worsening of sleep quality after the lockdown. Variables such as depression, anxiety or fear have been found to be negatively related to sleep quality in general [33] and during COVID-19 pandemic [13]. In this study, sleep quality was analyzed using the PSQI questionnaire. It was found that before lockdown, subjects already showed an overall score above 5 points, denoting poor sleep quality. But in addition, after lockdown, a significant worsening of sleep latency, subjective sleep quality, sleep disturbances, and the global score were found. As observed in previous studies, sleep quality is fundamental to physical health, emotional well-being, mental health, stress, depression, and anxiety, so its importance lies in the fact that everything is interconnected [6]. In previous studies conducted on businessmen and university students, it was observed that lockdown negatively affected their health, well-being, and sleep, which could be due to the loss of daily life routine, isolation, stress, or sedentary attitudes [6]. In addition, it was shown that being a woman could be a factor that favored the presence of sleep disorders during lockdown [8,11]. In the study by Gualano et al. [11], 42.2% of a sample of 1515 people presented sleep disturbances, of which 17.4% reported moderate/severe insomnia. However, so far we have not found studies conducted on older women, so the results of the present study represent a first approach to understanding how lockdown situations affect this factor.

The women in the present investigation also showed higher pain scores after lockdown. The population analyzed was composed of older adults, who frequently perceive bodily pain. In addition, the quarantine meant a limitation of physical activity, which may have led to increased pain perception [18]. Therefore, both age and inactivity may have preceded a greater perception of such pain, which should be taken into account in the future.

Another objective of the present research was to analyze the variables with a significant influence on the evolution of psychological variables during lockdown. It was found that age, lifestyle, diet, and sedentary lifestyle had an influence these variables. With respect to age, a worsening of pain and social function variables was observed in older people. The relationship between pain and age has been broadly documented in previous studies [52], with the prevalence of pain being higher among women and older people. This could be due to a greater sensitization to pain in the case of women, or to a greater vulnerability of older adults to different types of chronic pain [52,53]. In terms of social function, the lockdown increased the risk of social isolation and loneliness in

general [50], but especially in the older adults, as this population group is usually less familiar with new technologies, which have been essential at the social level during the quarantine period [54]. Indeed, studies carried out during the lockdown found that a lack of knowledge about the functioning of new technologies was associated with feelings of exclusion, self-isolation, and vulnerability [54], although this could be remedied with prior training on the use of this type of device. In addition, the older population was the most affected by the COVID-19 virus [55], leading to a greater sense of isolation among the older adults than in other population groups [50,54,56]. The lockdown strategies adopted to limit the spread of COVID-19 infection, including home confinement, may have led to the adoption of Unhealthy lifestyles as a result of decreased physical activity [15,56–58] and the acquisition of less healthy eating habits [15]. These factors, in turn, could have had an impact on the decline of mental health well-being [15,59]. Along this line, the present investigation found that older women who had a healthy lifestyle during the lockdown, defined as having a good adherence to the Mediterranean diet and adding at least 150 minutes of physical activity per day, did not show a worsening of the variables after the lockdown analyzed. Previous studies have already indicated that a high adherence to the Mediterranean diet may be associated with a reduced risk of depression [60]. The findings of the present study are particularly relevant, considering that previous studies showed that almost one third of the participants decreased their adherence to the Mediterranean diet, more than one third of the sample reduced their physical activity, and almost 70% increased their inactivity time during the lockdown [59]. On the contrary, those who did not adhere to the Mediterranean diet and/or whose daily physical activity did not reach the established standards, suffered the effects of quarantine to a greater extent. Thus, the preventive effect on health and psychological variables of a healthy lifestyle during a situation of home isolation is corroborated.

During the lockdown, people increased their daily sitting time and reduced physical activity. These results are consistent with those shown in previous studies [56–58]. More specifically, increases of 164.3 minutes on average per day of sitting time were found [58], while 53.5% of some populations shifted from exercising frequently to never exercising at all [61]. In the present investigation, it was found that spending time sitting was a risk factor for health in the physical role. This is because more time spent sitting uses the time that could otherwise be utilized for physical activity. In addition, it was found that regardless of physical activity levels, spending more than 4 hours a day sitting was a risk factor for premature death and this may increase by 5% for each hour beyond 7 hours sitting [61]. Therefore, since physical activity cannot eliminate the detrimental effects of sitting for long periods of time, it is advisable to maintain a high level of daily activity and limit sitting time [62], or break up those long periods of sitting with 2-3 minutes of light activity every 20-30 minutes [61]. All the changes produced were negative for the population. The linear regression models showed how adherence to the Mediterranean diet, spending less time sitting, and being younger were protective factors against increased depression, reduced physical role health, and increased pain respectively, as found in past studies [63].

Lastly, it was observed that an unhealthy lifestyle increased the likelihood of taking sleeping aids. Previous studies have shown that during lockdown, the consumption of sleeping aids increased by 20%, and also associated the lack of physical activity to the worsening of sleep quality during lockdown [10,12]. However, the paucity of literature on this topic calls for future research in this area.

The main strength of the present investigation was the possibility of carrying out a follow-up study to analyze the effects of lockdown on psychological and health-related

variables of older women. Women, and especially older women, are a highly psychologically vulnerable population in situations of lockdown [7,8,15]. However, the studies that have analysed this population have done so from a less broad spectrum of psychological variables, and generally without relating it to other aspects of their health such as their physical activity and eating habits [6–8,10–12,15], despite the interaction between these parameters [7,8,12]. Therefore, the analysis of the evolution of psychological variables in situations such as COVID-19 could help to understand the parameters that change the most in this vulnerable population in lockdown situations and how the management of their healthy habits could help to maintain psychological well-being. More specifically, strategies should be implemented to improve adherence to the Mediterranean diet, increase physical activity time and decrease sitting time, because of their influence on psychological variables, including the use of medication for sleep. Other strengths of this research were that face-to-face surveys were used, which made possible the avoidance of the bias that is commonly implied by the use of technology with older adults [54]. Therefore, the results of the present study could be taken into consideration in possible future and similar lockdown situations. In this way, a better management of the health of the population could be achieved. To this end, further research will be necessary to better understand the needs of each population group, more specifically referring to mental health well-being in the present study. However, the present research also had some limitations. Among them, it should be noted that the post-lockdown surveys could not be conducted until the limitations of mobility and access to the center where the study was conducted, or the absence of a control group that was not in a lockdown situation, were eliminated. Furthermore, due to the particularity of the sample and the situation in which the sample was found, ability to infer from the results is very limited, although the model of generality of the data could minimize this limitation.

Conclusions

As a main conclusion of this research, it was observed that the lockdown measures had a great negative psychological impact on Spanish older women. In addition, it was found that adherence to the Mediterranean diet may have been a protective factor against depression during lockdown, while long periods of sitting, advanced age, or an unhealthy lifestyle, were health risk factors for physical role, pain, or increased consumption of sleeping aids. For future lockdown situations, in order to prevent possible psychological problems and taking into account the present investigation, the recommendations would be to be accompanied, to practice exercise, to spend as few hours as possible sitting down, to adhere to a Mediterranean diet, and to know how to use new technologies to maintain social relationships.

Although the conclusions of the study should be taken with caution, these results should be taken into account because of the potential negative impact on public health at the physical, psychological, social and emotional levels that a situation of confinement and social isolation such as the one experienced could have, so it is considered necessary to apply non-pharmacological strategies such as motivating physical exercise programs and a healthy diet to ensure the health of older women in possible future situations of lockdown. Furthermore, it is essential to highlight the need for future studies that investigate not only the impact of COVID-19 confinement restrictions on psychological and general health parameters, but also the short- and long-term effects of specific interventions that aim to improve comprehensive health and include a home-adapted physical exercise program virtually or online. Further research is needed to assess the cost-effectiveness of exercise interventions delivered online.

Author Contributions

P.J.M.-P. conceptualized and P.J.M.-P., T.A.-L., R.V.-C. and N.G.-G. designed the study. N.G.-G. carried out the statistical analysis. T.A.-L. recruited the participants. P.J.M.-P., T.A.-L., R.V.-C. and N.G.-G collected the data. T.A.-L., R.V.-C. and N.G.-G. organized the database. P.J.M.-P., T.A.-L., R.V.-C. and N.G.-G. wrote the first manuscript draft, the final manuscript draft, conducted the English proofreading, and reviewed and edited the final version of the manuscript. All authors contributed to the manuscript revision and approved the final version.

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Conflict of Interests

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Data Sharing

No additional data available.

Ethics Committee Approval

Institutional ethics committee of the Catholic University of Murcia (code: CE111908 and CE052002) was obtained.

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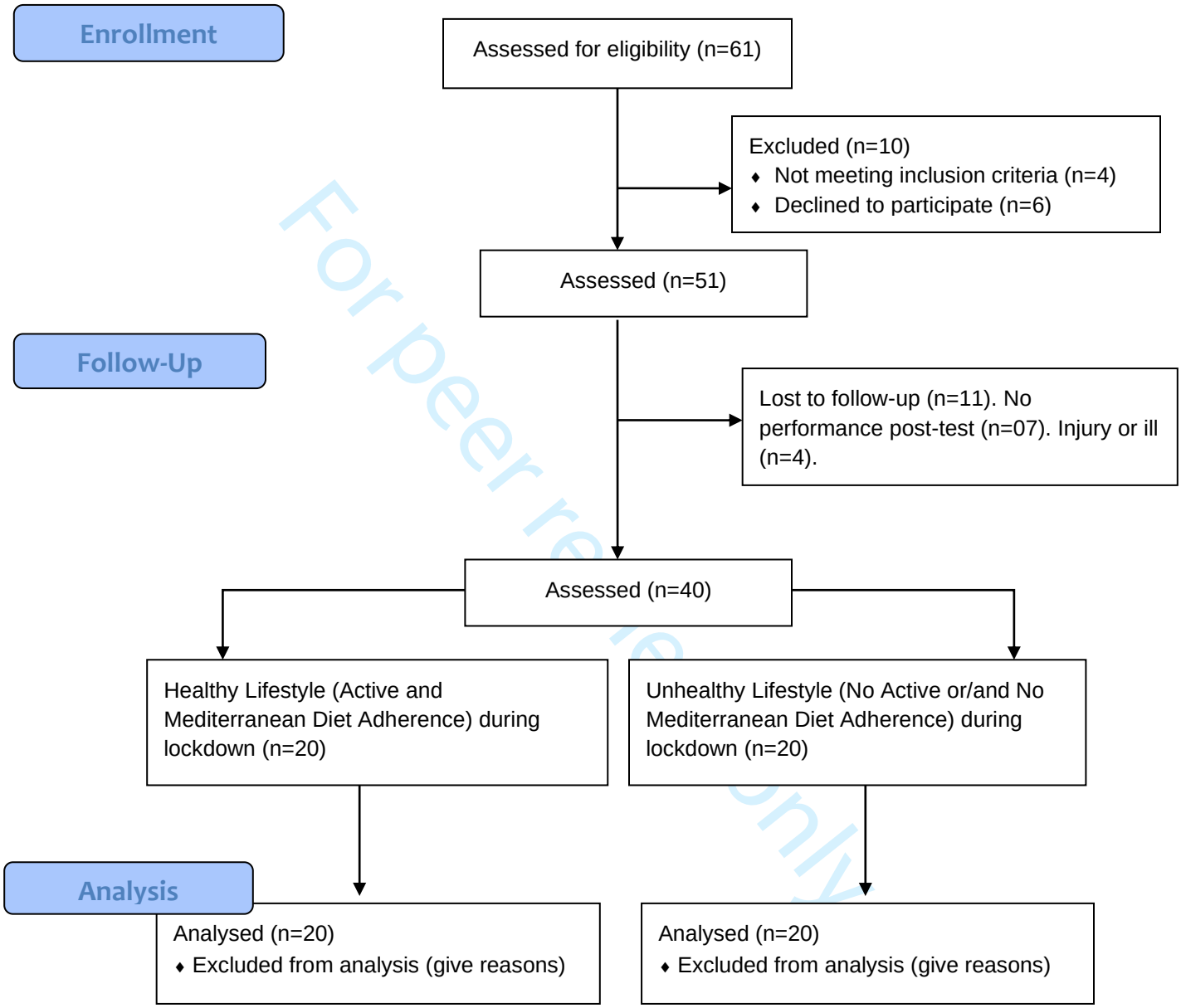
Figure legends

Figure 1. Flow Diagram

Figure 1. Flow Diagram



ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 07/01/2021 04:49

ClinicalTrials.gov ID: NCT04958499

Study Identification

Unique Protocol ID:	UCMurcia-BiohealthyPark
Brief Title:	Effectiveness of Bio-Healthy Park on Adult
Official Title:	Physical and Psychological Effectiveness of Bio-Healthy Park on Adult
Secondary IDs:	

Study Status

Record Verification:	July 2021
Overall Status:	Not yet recruiting
Study Start:	July 15, 2021 [Anticipated]
Primary Completion:	August 1, 2021 [Anticipated]
Study Completion:	September 30, 2021 [Anticipated]

Sponsor/Collaborators

Sponsor:	Universidad Católica San Antonio de Murcia
Responsible Party:	Principal Investigator Investigator: Noelia González-Gálvez [ngonzalez-galvez] Official Title: Principal investigator Affiliation: Universidad Católica San Antonio de Murcia
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: CE111908 Board Name: Maquinaria Bio-saludable: Diseño y fabricación de nueva maquinaria de fitness outdoor ergonómica, eficiente, saludable y con aplicación para dispositivos móviles (App) de valoracióin y control del entrenamiento Board Affiliation: UCAM Phone: Email: ngonzalez@ucam.edu Address:

Av. de los Jerónimos, 135, 30107 Guadalupe, Murcia

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Bio-healthy parks are an alternative for practicing physical activity outdoors and free of charge. However, there is no research that analyzes the effect of a planned training program in these parks. There are two types of parks under development, with and without externally added resistance. Therefore, general objective of this project are to evaluate the effect of 8 weeks of targeted training in bio-healthy parks on body composition, bone mineral density, blood pressure, strength, functional capacity, sarcopenia, sagittal disposition of the spine, quality of life, life satisfaction and Mediterranean diet adherence in adults and older adults. The present project will be developed through a randomized controlled trial, with 1 experimental and 1 control group, with pre-test and post-test, with intra-group and inter-group analysis for each of the dependent variables of the study. It will be measure body composition, bone mineral density, blood pressure, upper limb strength, lower limb strength, functional capacity, sarcopenia, sagittal disposition of the spine, Health-related quality of life, satisfaction with life and Mediterranean diet adherence. Experimental group will receive the exercise program on bio-healthy park machine with a frequency of 2 sessions per week of 55 minutes for 8 weeks. The control group will not perform any intervention program following their usual activity.

Detailed Description: The aging process is associated with physiological, psychological and functional deterioration. It has been demonstrated that the practice of physical activity can prevent, slow or reduce this deterioration. Bio-healthy parks are an alternative for practicing physical activity outdoors and free of charge. However, there is no research that analyzes the effect of a planned training program in these parks. There are two types of parks under development, with and without externally added resistance.

Therefore, the objectives of this project are to evaluate the effect of 8 weeks of targeted training in bio-healthy parks, with a frequency of 2 sessions per week on body composition, bone mineral density, blood pressure, strength, functional capacity, sarcopenia, sagittal disposition of the spine, quality of life, life satisfaction and mediterranean diet satisfaction in adults and older adults.

The present project will be developed through a randomized controlled trial, with 1 experimental and 1 control group, with pre-test and post-test, with intra-group and inter-group analysis for each of the dependent variables of the study.

The inclusion criteria are: (a) not having participated in a structured exercise program for at least 1 year, (b) being older than 50 years of age, and (c) being physically independent. The exclusion criteria are: (a) having musculoskeletal injuries or limitations that could affect the health and physical performance of the person; (b) being under medical prescription for taking medications that could influence physical performance; (c) not regularly attending the proposed sessions.

Body composition and bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA).

Blood pressure by means of an automatic device (Colin BP 880, Inc., Tampa, FL). Strength by manual dynamometry (TKK 5401; Co., Ltd., Tokyo, Japan) and maximal isometric strength of knee extension and biceps flexion.

Functional capacity will be assessed by means of the Chari stand test, gait speed, time up and go test and Short physical performance battery

(SPPB), Sarcopenia will be assessed taking into account the reference values established for muscle quality (hand grip strength and chair stand test), muscle quantity (DEXA fat-free mass) and functional competence (gait speed, time up and go test, SPPB and 400 meter walk) established by the European Consensus (EWGSOP2).

The Spinal Mouse device (Switzerland) will be used to assess the sagittal disposition of the spine (thoracic curve, lumbar curve and pelvic tilt) in standing and relaxed sitting. This technique is non-invasive.

Health-related quality of life and satisfaction with life will be assessed by means of the SF36 and The Satisfaction with Life Scale (SWL) questionnaires.

Mediterranean diet adherence will be assess with a Mediterranean diet adherence questionaire.

Experimental group 1 will receive the exercise program on bio-healthy machinery with a frequency of 2 sessions per week of 55 minutes for 8 weeks. The machines used will be rider, low gemini, high gemini, walk, bottoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be controlled by subjective perception of effort and heart rate (Polar 420). There will be a warm-up 8-10 minutes, a main part 40-45 minutes and a return to calm 5-10 minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be progressed every 2 weeks. The control group will not perform any intervention program following their usual activity.

Conditions

Conditions:	Adult Disease
Keywords:	Adults Older Physical activity Exercise Bio-healthy park Training

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	N/A
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	120 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Bio-Healthy Park	Behavioral: Bio-healthy Park

Arms	Assigned Interventions
This group is the experimental group. The intervention program consisted in the realization of the program on bio-healthy machinery.	Experimental group will receive the exercise program on bio-healthy machinery with a frequency of 2 sessions per week of 55 minutes for 8 weeks. Experimental group 1 will perform the intervention program using machinery designed for self-loading use. The machines used will be rider, low gemini, high gemini, walk, bottoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be controlled by subjective perception of effort and heart rate (Polar 420). There will be a warm-up 8-10 minutes, a main part 40-45 minutes and a return to calm 5-10 minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be progressed every 2 weeks.
No Intervention: Control Adults and older assigned to the control group will not received any structured exercise programme. They will maintain their usual physical activities.	

Outcome Measures

Primary Outcome Measure:

1. Muscle quality sarcopenia
   Sarcopenia will be assessed taking into account the reference values established for muscle quality. The muscle quality will be measure by hand grip strength test. This test will be performance with manual dynamometry (TKK 5401; Scientific Instruments Co., Ltd., Tokyo, Japan). Maximal isometric upper limb strength will be performance by maximal isometric strength. Upper strength will be register by kilogrammes. Higher value show high strength.

   [Time Frame: Changes from baseline to 8 weeks]

Secondary Outcome Measure:

2. Change Body composition
   Body composition will be assessed by dual energy X-ray absorptiometry (DEXA). This is noninvasive technique. The result will be register in absolutes and percentages results.

   [Time Frame: Changes from baseline to 8 weeks]
3. Change Blood pressure
   Blood pressure and heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). This is noninvasive technique. The result will be register in millimeters of mercury (bood pressure) and number of pulse per minutes (heart rate).

   [Time Frame: Changes from baseline to 8 weeks]
4. Change Chair stand test
   Chair stand test measure the functional capacity. This is a easy physical test. This test measures the functionality of getting up and sitting down from a chair five times. The participant have to performance the test as faster as possible. The total time is recorded in seconds. A better time indicates better functional ability.

   [Time Frame: Changes from baseline to 8 weeks]
5. Change Upper strength
   Maximal isometric upper limb strength will be performance by maximal isometric strength of knee extension and biceps flexion with load cell. Maximal isometric lower limb will be registered in newton. Higher value show high strength.

   [Time Frame: Changes from baseline to 8 weeks]
6. Change Sagittal spinal curvature

Sagittal spinal curvature will be assess with the Spinal Mouse device (Switzerland). It will be measured: angle of the dorsal and lumbar curve and pelvic tilt when standing and in asthenic sitting. This is noninvasive technique. The result is register in grades.

[Time Frame: Changes from baseline to 8 weeks]

7. Health-related quality
Health-related quality of life will be assessed by means of the Short Form 36 questionaire. This questionaire have 11 questions and show result for 9 area: physical role, pain, general health, vitality, social function, emotional role, mental health, and evolution of the health care system. Each area is reported from 0 to 100 point. Higher score represent better health-related quality.

[Time Frame: Changes from baseline to 8 weeks]

8. Satisfaction with Life Scale (SWL)
Satisfaction with Life Scale (SWL) questionnaires include 5 affirmation about the satisfaction with the life and the participant have to answers from strongly agree to strongly disagree. The final score is reported from 5 to 35 point. Higher value show better satisfaction with life.

[Time Frame: Changes from baseline to 8 weeks]

9. Adherence to the Mediterranean diet
It will be used the Adherence to the Mediterranean diet. This questionaire have 14 questions (yes and no answer) about their adherence to the mediterranean diet. The sum of the answers are collect. Higher score show higher adherence to mediterranean diet.

[Time Frame: Changes from baseline to 8 weeks]

10. Functional competence 400 meter walk
Functional competence 400 meter walk is a test included in the European Consensus (EWGSOP2) to measure sarcopenia. Participant have to walk as fast as possible 400 meter. The total time is register.

[Time Frame: Changes from baseline to 8 weeks]

11. Change bone mineral density
Bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA). This is noninvasive technique. The result will be register in absolutes and percentages results.

[Time Frame: Changes from baseline to 8 weeks]

12. Change heart rate
Heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). This is noninvasive technique. The result will be register in number of pulse per minutes (heart rate).

[Time Frame: Changes from baseline to 8 weeks]

13. Gait speed change
Gait speed will be measure by 4. 6 and 10 meter test. This is easy physical test in with the participant have to walk 4. 6 and 10 metres as faster as possible. The result will be register in seconds. Less time indicates better functional ability.

[Time Frame: Changes from baseline to 8 weeks]

14. Time up and go test change
Time up and go test measure the functional capacity of getting up, walking and sitting down form a chair. Participant have to performance this test as faster as possible. This is a easy physical test. Total seconds are records. Less seconds indicates better functional ability.

[Time Frame: Changes from baseline to 8 weeks]

15. Short physical performance battery (SPPB)
Short physical performance battery (SPBB) include three test (balance, chair stand test and gait speed) and report a final score. Chair stand test and gait speed were describe in other outcome. Balance test is a easy physical test. The participant must maintain three balancing positions for 10 seconds to overcome it. Each test offers a different score. Higher score show better functional capacity.

[Time Frame: Changes from baseline to 8 weeks]

16. Change in lower limb strenght

Maximal isometric lower limb will be performance by maximal isometric strength of knee extension with load cell. Maximal isometric lower limb will be registered in newton. Higher value show high strength.

[Time Frame: Changes from baseline to 8 weeks]

Eligibility

Minimum Age:	50 Years
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- not having participated in a structured exercise program for at least 1 year;
- being older than 50 years of age
- being physically independent.

Exclusion Criteria:

- having musculoskeletal injuries or limitations that could affect the person's health and physical performance
- being under medical prescription for taking medications that could influence physical performance
- not regularly attending the proposed sessions.

Contacts/Locations

Central Contact Person: Pablo Jorge Marcos-Pardo, PhD
Telephone: 696243274
Email: pjmarcos@ual.es

Central Contact Backup: Noelia Gonzalez-Galvez, PhD
Telephone: 627146613
Email: ngonzalez@ucam.edu

Study Officials: Pablo Jorge Marcos-Pardo, PhD
Study Principal Investigator
Universidad de Almería

Noelia Gonzalez-Galvez, PhD
Study Principal Investigator
UCAM

Locations: **Spain**
Pablo Jorge Marcos-Pardo
Murcia, Spain
Contact: Pablo Jorge Marcos-Pardo, PhD 696243274 pjmarcos@ual.es
Contact: Noelia Gonzalez-Galvez, PhD 627146613 ngonzalez@ucam.edu

IPDSharing

Plan to Share IPD: No

References

Citations:

NOTE : Either PubMed ID or Citation Text should be specified.

Links:

Available IPD/Information:

UCAM
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COMITÉ DE ÉTICA DE LA UCAM

DATOS DEL PROYECTO

Título:	"Maquinaria Bio-saludable Inteligente: Diseño y fabricación de nueva maquinaria de fitness outdoor ergonómica, eficiente, saludable y con aplicación para dispositivos móviles (App) de valoración y control del entrenamiento"

Investigador Principal	**Nombre**	**Correo-e**
Dr.	Pablo Jorge Marcos Pardo	pmarcos@ucam.edu

INFORME DEL COMITÉ

Fecha	**29/11/2019**

Código	**CE111908**

Tipo de Experimentación

Investigación experimental clínica con seres humanos	
Utilización de tejidos humanos procedentes de pacientes, tejidos embrionarios o fetales	
Utilización de tejidos humanos, tejidos embrionarios o fetales procedentes de bancos de muestras o tejidos	
Investigación observacional con seres humanos, psicológica o comportamental en humanos	X
Uso de datos personales, información genética, etc.	X
Experimentación animal	
Utilización de agentes biológicos de riesgo para la salud humana, animal o las plantas	
Uso de organismos modificados genéticamente (OMGs)	

Comentarios Respecto al Tipo de Experimentación
Nada Obsta

Comentarios Respecto a la Metodología de Experimentación
Nada Obsta

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COMITÉ DE ÉTICA DE LA UCAM

Sugerencias al Investigador

A la vista de la solicitud de informe adjunto por el Investigador y de las recomendaciones anteriormente expuestas el dictamen del Comité es:

Emitir Informe Favorable	**X**
Emitir Informe Desfavorable	
Emitir Informe Favorable condicionado a Subsanación	

MOTIVACIÓN
Incrementará conocimientos en su área

Vº Bº El Presidente,

Fdo.: José Alberto Cánovas Sánchez

El Secretario,

UNIVERSIDAD CATOLICA SAN ANTONIO · COMITE DE ETICA ·

Fdo.: José Alarcón Teruel

UCAM
UNIVERSIDAD CATÓLICA SAN ANTONIO

COMITÉ DE ÉTICA DE LA UCAM

DATOS DEL PROYECTO

Título:	"COVID-19 y aislamiento social: Efectos sobre la condición física y la salud psico-fisiológica en adultos mayores"	
Investigador Principal	**Nombre**	**Correo-e**
Dr.	Pablo Jorge Marcos Pardo	pmarcos@ucam.edu

INFORME DEL COMITÉ

Fecha	**29/05/2020**	**Código**	**CE052002**

Tipo de Experimentación

Investigación experimental clínica con seres humanos	
Investigación experimental no clínica con seres humanos	**X**
Utilización de tejidos humanos procedentes de pacientes, personas sanas, tejidos embrionarios o fetales	
Utilización de tejidos humanos, tejidos embrionarios o fetales procedentes de bancos de muestras o tejidos	
Investigación observacional con seres humanos, psicológica o comportamental en humanos	**X**
Uso de datos personales	**X**
Experimentación animal	
Utilización de agentes biológicos de riesgo para la salud humana, animal o las plantas	
Uso de organismos modificados genéticamente (OMGs)	

Comentarios Respecto al Tipo de Experimentación
Nada Obsta

Comentarios Respecto a la Metodología de Experimentación
Nada Obsta

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COMITÉ DE ÉTICA DE LA UCAM

Directrices al Investigador
No podrá iniciar el proyecto hasta que no disponga del permiso oficial del "Comité de Seguimiento UCAM COVID-19" para garantizar la seguridad de los participantes.

A la vista de la solicitud de informe adjunto por el Investigador y de las directrices anteriormente expuestas el dictamen del Comité es:

Emitir Informe Favorable	**X**
Emitir Informe Desfavorable	
Emitir Informe Favorable condicionado a Subsanación	

MOTIVACIÓN
Incrementará conocimientos en su área

Vº Bº El Presidente,

Fdo.: José Alberto Cánovas Sánchez

El Secretario,

UNIVERSIDAD CATOLICA SAN ANTONIO · COMITE DE ETICA ·

Fdo.: José Alarcón Teruel

Supplementary file 4. STROBE Statement

	Item No	Recommendation	Pag
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*3-4*
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4-5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	4-5
		(*b*) Describe any methods used to examine subgroups and interactions	4-5
		(*c*) Explain how missing data were addressed	4-5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	4-5
		(*e*) Describe any sensitivity analyses	4-5

Continued on next page

Results			**Pag**
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3
		(b) Give reasons for non-participation at each stage	3
		(c) Consider use of a flow diagram	3
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5
		(b) Indicate number of participants with missing data for each variable of interest	5
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	5
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*5*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*5*
		Cross-sectional study—Report numbers of outcome events or summary measures	*5*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	5
		(*b*) Report category boundaries when continuous variables were categorized	5
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	5
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	5
Discussion			
Key results	18	Summarise key results with reference to study objectives	6
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	6-7-8
Generalisability	21	Discuss the generalisability (external validity) of the study results	6-7-8
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.