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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

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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

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9 Keywords: Adult₁, Lockdown₂, Mediterranean diet adherence₃, Physical activity₄, Psychology₅, 10 SARS-CoV-2₆, Sleep quality₇, Well-being₈

11 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 vears). 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

1 2	39	Strengths and limitations of this study
3 4 5 6 7 8 9 10 11 12	40 41 42 43 44 45 46 47	 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
$\begin{array}{c} 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 9\\ 20\\ 22\\ 23\\ 24\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 23\\ 34\\ 35\\ 36\\ 7\\ 38\\ 90\\ 41\\ 42\\ 43\\ 44\\ 50\\ 51\\ 52\\ 54\\ 55\\ 56\\ 7\\ 58\end{array}$	48 49 50	Word count: 3901.
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml 2

2 51 Introduction

1

- 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].
- 54 causing great public panic and concern [1].
 55 On Wednesday, March 11, 2020, the World Health Organization (WHO) upgraded the public health
 56 emergency situation caused by COVID 10 to an international pandemia [1]. Following this
- 6 6 emergency situation caused by COVID-19 to an international pandemic [1]. Following this 10 57 approximate on Saturday, March 14, 2020, the Covernment of Spain, declared the State of
- 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
- ¹³ 60 14-week lockdown [2,3]. Public health guidelines in many countries, including Spain, suggested that
- 61 people stay at home to avoid person-to-person transmission of the virus [1]. However, the lockdown
 62 in Spain was more restrictive than in other countries, with no one allowed to go outside the home for
- 62 In Spain was more restrictive than in other countries, with no one allowed to go outside the home
 63 anything that was not considered an essential activity, which meant the closure of most of the
- 64 country's activity and the establishment of a teleworking regime for most of the workers who could
 65 continue their activity during the lockdown period [4].
- ²⁰ 66 This situation induced changes in the lifestyles of the Spanish population. Some studies found a
- ²¹ 67 reduction in the levels of physical activity [5,6]; negative diet disturbances [5]; an increase in social
- 68 isolation which can induces changes in psychological health, such as increased anxiety and
- 69 depression [7,8]; or a worsening of sleep quality [6,8–11], as a psychological response to the
- 70 pandemic. Such effects may be particularly problematic in older adults and especially in women
 71 [7,8,12], due to reduced physical capabilities and the possibility of increased chronic diseases and
 72 mental health problems.
- 73 It has been shown that women as a population, especially during old age, were most affected by the
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- 75 compared to men [7,8,12]. Similar studies have been found analyzing the effect of the lockdown on
 76 different population groups such as workers or students [6,13]. However, no follow-up or
- relation population groups such as workers of students [0,15]. However, no follow-up of
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 relation groups such as workers of students [0,15]. However, no follow-up of
- ³⁴ 78 women during lockdown. For this reason, the objective of this study was to analyze the effects of the
 ³⁵ 79 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
- women, and to determine the influence of mestyle 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
- 81 study was that all parameters related to mental well-being would worsen in older women during th
 82 COVID-19 lockdown, with those women with a poorer lifestyle experiencing the greatest change.
- 4041 83 Material and Methods
- 42 43 84

44 85 Study design

- 45 86 This study is a part of the ongoing project entitled Smart Bio-healthy Machinery: Design and 46 manufacture of new ergonomic, efficient, and healthy outdoor fitness machinery, including an 87 47 application for mobile devices (app) to assess and monitor training (ClinicalTrials.gov Identifier: 88 48 89 NCT04958499) (Supplementary file 1). The study was approved by the institutional ethics committee 49 90 of the Catholic University of Murcia in accordance with the Declaration of Helsinki (code: 50
- 51 91 CE111908) (Supplementary file 2). All the participants were informed, and voluntarily signed the 52 92 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
- 58 59
- 60

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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

Sampling method and sample size

(Figure 1).

- 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

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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,

- ⁴ 148 daytime dysfunction, and use of sleep medication. The range of subscores for each component is 0 to
- 5 149 3, with a maximum total score of 21:Good sleep quality (scores of 0 to 5) and poor sleep quality
- 6 7 150 (scores of 6) [21]. Physical activity was analyzed using the Global Physical Activity Questionnaire
- 8 151 (GPAQ). GPAQ was developed by the World Health Organization (WHO) with 16 questions that
- 9 152 revolve around three domains: occupational physical activity, transport-related and leisure physical
 10 153 activity. In addition, it can also assess sedentary behavior by recording minutes spent sitting [22].
- ¹¹ 154 With the data compiled through this questionnaire, we summed the minutes of physical activity of the
- ¹² 155 participants according to type of activity and its level of intensity. Finally, the adherence to the
- ¹³ 156 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-
- 17 159 9, average adherence; score ≥10, highest adherence [24].
 18 160 Subsequently all participants had their height and hody mass m
- 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)
- $\frac{20}{21}$ $\frac{162}{162}$ was calculated as body mass (kg) divided by height (m) squared [25].
- 163
 164 Statistical analysis

165 The Kolmogorov–Smirnov test and Mauchly's W-test were used to evaluate the normality and the 24 sphericity of the data. The means and standard deviations were calculated from the quantitative 25 166 26 167 variables, and frequency and percent were used for the qualitative variables. The participants were 27 168 categorized as having a Healthy lifestyle or Unhealthy lifestyle. A Healthy lifestyle was considered 28 169 for those who complied with at least 150 min of moderate to vigorous physical activity (MVPA) a 29 170 week and who maintained adherence to the Mediterranean diet (above 7 points) vs an unhealthy 30 lifestyle, those who did not comply with either or both parameters. A two-way analysis of variance 171 31 172 (ANOVA) with repeated measures in 1 factor (time) was used to analyze inter- and intra-group 32 33 173 differences and to analyze the interaction between groups and time. This analysis was performed 34 174 unadjusted and adjusted by age. The Bonferroni post-hoc test was used to evaluate the statistical 35 175 significance of the parametric variables. Stepwise multiple linear regression models were used to 36 176 explore the associations between the dependent variables and each independent variable. To analyse 37 whether a nonlinear multiple regression model provided the best explanation of the variance, a 177 38 178 curvilinear estimation analysis was used to explore the best model association between the dependent 39 179 (satisfaction with life, depression, health state and sleep quality) and independents variables (age, 40 41 180 Mediterranean diet adherence, MVPA, sitting time a day and life style The statistical analysis was 42 181 performed using the statistical package SPSS 21.0 for Windows. 43

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

46 47 184 **Results**

60

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) Marital status	30.30±5.50	

1						
1 2		Single	5.00 (2)			
3		Married	57.50 (23)			
4		Separated	10.00 (4)			
5		Widowed				
6			27.50 (11)			
7		Occupation	17.50 (7)			
8		Full-Time Worker	17.50 (7)			
9		Part-Time Worker	12.50 (5)			
10 11		Unemployed	17.50 (7)			
12		Retired 52.50 (21)				
13		Education level				
14		No education	12.50 (5)			
15		Elementary school	57.50 (23)			
16		High school	12.50(5)			
17		Bachelor's Degrees or higher 17.50(7)				
18		Living status				
19		Living with someone	72.50(29)			
20 21		Living alone	27.50(11)			
22		Sitting time during lockdown (min per	385.20±152.66			
23		day)	383.20±132.00			
24		MVPA during lockdown (min per week)	340.50±403.95			
25		Active vs Inactive (WHO 150	min/week)			
26		Active	72.50(29)			
27		Inactive	27.50(11)			
28		MDA	9.13±2.22			
29 30		MDA Classification				
31		No Adherence (≤7 points)	25(10)			
32		Adherence (>7 points)	75(30)			
33		Lifestyle (Active and MDA vs No Active of				
34		Healthy	50.00(20)			
35		Unhealthy	50.00(20)			
36	187					
37		BMI = body mass index; MDA = Mediterranean Diet Adherence; MVPA = moderate to vigorous				
38 39	188	physical activity; WHO = World Health Organization.				
40	189	Table 2 shows the results of the differences between pre and	nest adjusted and unadjusted for ago of			
41	189	1	1 5 5 5 5			
42	190 191	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				
43						
44	192	physical role, pain, emotional role and mental health; and sle				
45	193	disturbance and global sleep quality score (Table 2). The resu				
46	194	were significant for pain (F=10.07; p=.003) and social function (F=4.23; p=.047), meaning that age				
47 48	195	adversely influenced the change in these variables post-lockd	nown. For the rest of the variables, no			
40	196	significant values were observed.				
50	197	When the differences in these variables were analyzed as a fu	• •			
51	198	was found that the pre-test differences were not significant for				
52	199	difference=158±473; p=.473) while it was significant for the				
53	200	difference= .600; p=.008). In addition, the effect of the time*				
54	201	was found to be significant (F=6.214; p=.017), indicating that				
55	202	lockdown was key in the maintenance of the variables analyz	zed.			
56 57						
57 50						

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1	Table 2. Effect of lockdown due to the COVID pandemic (unadjusted and adjusted by								
² 203	Table 2. Effect	of lockdown du	e to the COVID			0	2		
4 5					Unadjust		Adjusted by age		
6		Pre-test	Post-test	Difference		95% CI	Difference		95% CI
7 8		(M±SD) (M±SD)		post-pre	р	(Mpost-Mpre)	post-pre	р	
9				$(M \pm SD)$		(wipost-wipic)	(M±SD)		(wipost-wipic)
10 Spatisfaction with	th 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
Bepression (CE	SD 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
14 15Dhucical	Physical functioning	82.74±12.66	82.14±8.87	60±1.70	.726	-4.03; 2.84	$\frac{5}{2}$ 60±1.696	.725	-4.02; 2.82
15Physical 16 Health (SF-	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
¹⁸ 36 scale) 19 - 20	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
21	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
22 Mental 23 Haealth (SF-	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
²⁵ 36 scale) 26	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
27 28 Sleep	C1 Sleep Quality component	1.11±.57	1.36±.68	.25±.10	.018	.05;.45	.25±.10	.019	.04;.46
²⁹ 30 (PSQI	C2 Sleep latency	1.28±1.03	1.78±1.17	.50±.16	.004	.05;.45 .17;.83 14;.30	.50±.16	.004	.17;.83
31 scale) 32	C3 Sleep duration	$1.00 \pm .76$	$1.08 \pm .77$.08±.11	.446			.452	14;.31
33	C4 Habitual Sleep efficiency	.92±1.11	.81±1.01	11±.13	.401	38; .15	9911±.13	.390	37; .15
34 35	C5 Step disturbances	1.39±.60	$1.75 \pm .60$	36±.11	.002	.15; .58 07; .63		.002	.15; .58
36 37	C6 Use of sleeping medication	1.00±1.39	1.28 ± 1.47	.28±.17	.115			.115	072; .63
38	C7 Day time dysfunction	.50±.61	.64±.59	.14±.13	.281	12; .40	.14±.13	.287	12; .40
39 40	Global score	7.19±4.06	8.69±3.91	$1.50 \pm .46$.002	.57; 2.43	1.50±.46	.003	.56; 2.44
41 42							}		
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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; $r^{2=.116}$). 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;

 $^{13}_{14}$ 215 r2=.144).

16 216 **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.

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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.

348 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.

359 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.

378 Data Sharing

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

7 381 Ethics Committee Approval

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

References

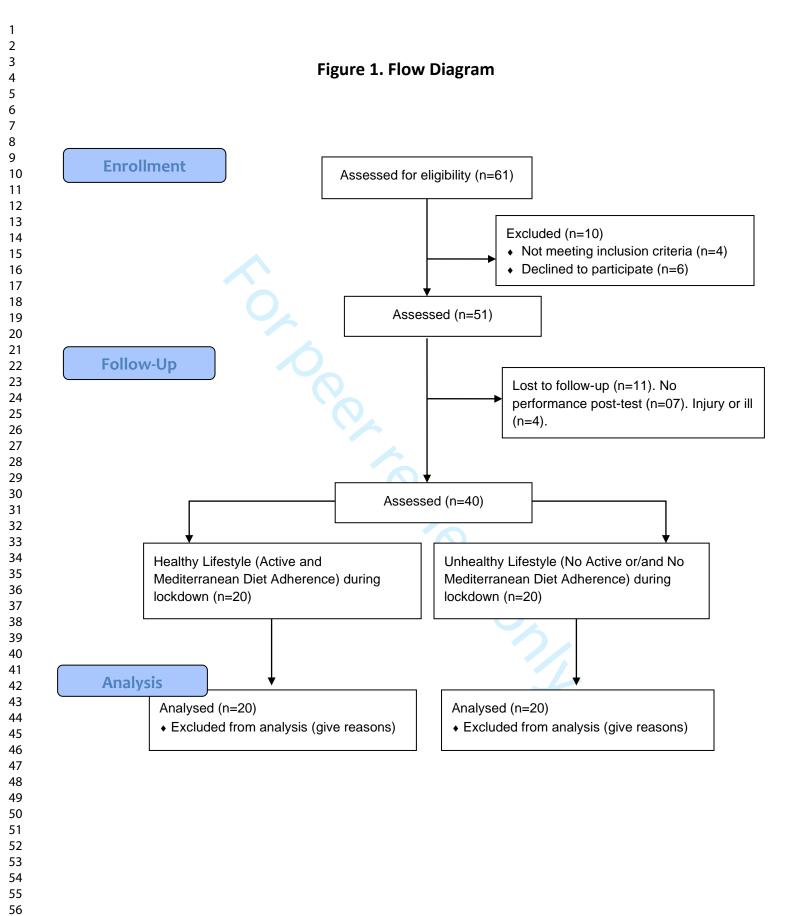
- 343851Gutiérrez-Hernández ME, Fanjul LF, Díaz-Megolla A, et al. COVID-1955386Lockdown and Mental Health in a Sample Population in Spain: The Role of Self-57387Compassion. International journal of environmental research and public health583882021;18:1–14. doi:10.3390/IJERPH18042103

23892Agencia Estatal Boletín Oficial del Estado. Real Decreto 463/24390marzo, por el que se declara el estado de alarma para la gestió5391de crisis sanitaria ocasionada por el COVID-19. Madrid: : Min7392Presidencia, Relaciones con las Cortes y Memoria Democrática83933Agencia Estatal Boletín Oficial del Estado. Orden SND/388/20.9394por la que se establecen las condiciones para la apertura al pú10395determinados comercios y servicios, y la apertura de archivos,11396práctica del deporte profesional y federado. Madrid: Ministerio12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403Dietary Habits of Almost Half the Population in an Italian Samj204042020;9. doi:10.3390/foods9050675224056403Majumdar P, Biswas A, Sahu S. COVID-19 pandemic and lock	n de la situación listerio de la 2020. 20, de 3 de mayo, blico de así como para la o de la 2020. l health-related ID-19 lockdown: pwn Modified ple. <i>Foods</i> down: cause of
43002Agencia Estatal Dotem Oneal del Estado. Real Decreto 405/25390marzo, por el que se declara el estado de alarma para la gestió6391de crisis sanitaria ocasionada por el COVID-19. Madrid: : Min7392Presidencia, Relaciones con las Cortes y Memoria Democrática83933Agencia Estatal Boletín Oficial del Estado. Orden SND/388/20.9394por la que se establecen las condiciones para la apertura al púl10395determinados comercios y servicios, y la apertura de archivos,11396práctica del deporte profesional y federado. Madrid: Ministerio12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods905067521405Mairman P. Biarca A. Schu S. COVID 10 nondemic and back	n de la situación listerio de la 2020. 20, de 3 de mayo, blico de así como para la o de la 2020. l health-related ID-19 lockdown: pwn Modified ple. <i>Foods</i> down: cause of
5390marzo, por el que se dectara el estado de diarma para la gestio6391de crisis sanitaria ocasionada por el COVID-19. Madrid: : Min7392Presidencia, Relaciones con las Cortes y Memoria Democrática83933Agencia Estatal Boletín Oficial del Estado. Orden SND/388/20.9394por la que se establecen las condiciones para la apertura al pú10395determinados comercios y servicios, y la apertura de archivos,11396práctica del deporte profesional y federado. Madrid: Ministerica12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403Dietary Habits of Almost Half the Population in an Italian Samj204042020;9. doi:10.3390/foods905067521405Maium den P. Digmer A. Salva S. COVID: 10 pendemia and lack	isterio de la 2020. 20, de 3 de mayo, blico de así como para la o de la 2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
0392Presidencia, Relaciones con las Cortes y Memoria Democrática83933Agencia Estatal Boletín Oficial del Estado. Orden SND/388/20.9394por la que se establecen las condiciones para la apertura al pú10395determinados comercios y servicios, y la apertura de archivos,11396práctica del deporte profesional y federado. Madrid: Ministerio12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods9050675214056	2020. 20, de 3 de mayo, blico de así como para la o de la 2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
83933Agencia Estatal Boletín Oficial del Estado. Orden SND/388/20.9394por la que se establecen las condiciones para la apertura al púr determinados comercios y servicios, y la apertura de archivos, práctica del deporte profesional y federado. Madrid: Ministerio Presidencia, Relaciones con las Cortes y Memoria Democrática 12 397133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia behaviors for pre-school and school-aged children during COV A narrative review. Preventive Medicine 2021;143:106349.16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.106349184025204042020;9. doi:10.3390/foods9050675214056	20, de 3 de mayo, blico de así como para la o de la 2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
9394por la que se establecen las condiciones para la apertura al pún10395determinados comercios y servicios, y la apertura de archivos,11396práctica del deporte profesional y federado. Madrid: Ministerio12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia143984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403204042020;9. doi:10.3390/foods9050675214056	blico de así como para la o de la 2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
10395determinados comercios y servicios, y la apertura de archivos,11396práctica del deporte profesional y federado. Madrid: Ministerio12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods9050675214056	así como para la o de la 2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
11396práctica del deporte profesional y federado. Madrid: Ministerio12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403204042020;9. doi:10.3390/foods9050675214056	o de la 2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
12390practical der deporte projestonal y federado. Madrid. Ministerie12397Presidencia, Relaciones con las Cortes y Memoria Democrática133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.1063491840251940320404202020;9. doi:10.3390/foods9050675214056	2020. Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
13397Presidencia, Relaciones con las Cortes y Memoria Democratica133984López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.1063491840251940320404202020;9. doi:10.3390/foods9050675214056	Il health-related ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
143984Lopez-Bueno R, Lopez-Sanchez GF, Casajus JA, et al. Potentia15399behaviors for pre-school and school-aged children during COV16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.1063491840251940320404202020;9. doi:10.3390/foods9050675214056	ID-19 lockdown: own Modified ple. <i>Foods</i> down: cause of
16400A narrative review. Preventive Medicine 2021;143:106349.17401doi:10.1016/J.YPMED.2020.10634918402519403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods9050675214056	own Modified ple. <i>Foods</i> down: cause of
17401doi:10.1016/J.YPMED.2020.106349184025Scarmozzino F, Visioli F. Covid-19 and the Subsequent Lockdo19403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods905067521405(ple. <i>Foods</i> down: cause of
184025Scarmozzino F, Visioli F. Covid-19 and the Subsequent Lockdo19403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods905067521405Covid-19 and the Subsequent Lockdo	ple. <i>Foods</i> down: cause of
19403Dietary Habits of Almost Half the Population in an Italian Samp204042020;9. doi:10.3390/foods905067521405(ple. <i>Foods</i> down: cause of
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21 404 2020;9. doi:10.3390/foods9050675	
105 (Maximud and Difference (Nature 10, 10, 10, 10, 10, 10, 10, 10, 10, 10,	
	exposure of
23 406 sleep disruption, depression, somatic pain, and increased screen	1
24 407 office workers and students of India. <i>Chronobiology internation</i>	1al 2020; 37 :1191–
25 408 200. doi:10.1080/07420528.2020.1786107	
 409 7 Cárdaba-García RM, Pérez Pérez L, Martín VN, <i>et al.</i> Evaluation 410 A prioty and/or Depression during Confinement Due to COVID 	
28 410 Anxiety and/or Depression during Commement Due to COVID	
29 411 Spain. Public Health 2021;18:5/32. doi:10.3390/ijerph18115/3	
30 412 8 Pieh C, Budimir S, Probst T. The effect of age, gender, income,	work, and
31 413 physical activity on mental health during coronavirus disease (C	COVID-19)
32 414 lockdown in Austria. <i>Journal of psychosomatic research</i> 2020;	136.
³³ 415 doi:10.1016/J.JPSYCHORES.2020.110186	
³⁴ 416 9 Beck F, Léger D, Fressard L, <i>et al.</i> Covid-19 health crisis and le	ockdown
 ³⁵ 417 associated with high level of sleep complaints and hypnotic upt 	ake at the
³⁰ 418 population level. <i>Journal of sleep research</i> 2021; 30 :e13119–e1	3119.
38 419 doi:10.1111/jsr.13119	
39 420 10 Gualano MR, lo Moro G, Voglino G, et al. Effects of COVID-1	9 lockdown on
40 421 mental health and sleep disturbances in Italy. <i>International Jour</i>	rnal of
41 422 Environmental Research and Public Health 2020;17:1–13.	
⁴² 423 doi:10.3390/ijerph17134779	
43 44 424 11 Mandelkorn U, Genzer S, Choshen-Hillel S, <i>et al.</i> Escalation of	sleep
44 425 disturbances amid the COVID-19 pandemic: A cross-sectional	international
46 426 study. Journal of Clinical Sleep Medicine 2021;17:45–53.	
47 427 doi:10.5664/JCSM.8800/SUPPL_FILE/JCSM.8800.DS001.PD	F
48 428 12 Gonzalez-Bernal JJ, Rodríguez-Fernández P, Santamaría-Peláez	z M, <i>et al</i> . Life
49 429 Satisfaction during Forced Social Distancing and Home Confin	ement Derived
⁵⁰ 430 from the COVID-19 Pandemic in Spain. <i>International Journal</i>	of Environmental
51 431 Research and Public Health 2021, Vol 18, Page 1474 2021;18:	1474.
doi:10.3390/IJERPH18041474	
54 433 13 Argus M, Pääsuke M. Effects of the COVID-19 lockdown on m	usculoskeletal
55 434 pain, physical activity, and work environment in Estonian office	
transitioning to working from home. <i>Work (Reading, Mass)</i> 202	
⁵⁷ 436 doi:10.3233/WOR-210033	
⁵⁸ 437 14 von Elm E, Altman DG, Egger M, <i>et al.</i> The Strengthening the	Reporting of
⁵⁹ 60 438 Observational Studies in Epidemiology (STROBE) statement: §	1 0

1			
2			
3	439		reporting observational studies. Journal of clinical epidemiology 2008;61:344-9.
4	440		doi:10.1016/J.JCLINEPI.2007.11.008
5 6	441	15	Chang Y, Li Y, Zhang X. Benefits of Grandparental Caregiving in Chinese Older
0 7	442		Adults: Reduced Lonely Dissatisfaction as a Mediator. Frontiers in Psychology
8	443		2020;11. doi:10.3389/FPSYG.2020.01719
9	444	16	Pavot W, Diener E. Review of the Satisfaction With Life Scale. Psychological
10	445		Assessment 1993;5:164-72. doi:10.1037/1040-3590.5.2.164
11	446	17	Park SH, Yu HY. How useful is the center for epidemiologic studies depression
12	447		scale in screening for depression in adults? An updated systematic review and
13 14	448		meta-analysis \Rightarrow . <i>Psychiatry research</i> 2021; 302 .
15	449		doi:10.1016/J.PSYCHRES.2021.114037
16	450	18	Carleton RN, Thibodeau MA, Teale MJN, <i>et al.</i> The center for epidemiologic
17	451		studies depression scale: a review with a theoretical and empirical examination of
18	452		item content and factor structure. <i>PloS one</i> 2013; 8 .
19	453		doi:10.1371/JOURNAL.PONE.0058067
20 21	454	19	Ware JE. SF-36 health survey update. <i>Spine</i> 2000; 25 :3130–9.
21	455	- /	doi:10.1097/00007632-200012150-00008
23	456	20	Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I.
24	457		Conceptual framework and item selection - PubMed. Medical Care
25	458		1992; 30 :473–83.https://pubmed.ncbi.nlm.nih.gov/1593914/ (accessed 1 Feb
26	459		2022).
27	460	21	Lee S, Kin JH, Chung JH. The association between sleep quality and quality of
28 29	461		life: a population-based study. <i>Sleep medicine</i> 2021; 84 :121–6.
30	462		doi:10.1016/J.SLEEP.2021.05.022
31	463	22	Keating XD, Zhou K, Liu X, et al. Reliability and Concurrent Validity of Global
32	464		Physical Activity Questionnaire (GPAQ): A Systematic Review. International
33	465		Journal of Environmental Research and Public Health 2019;16.
34	466		doi:10.3390/IJERPH16214128
35 36	467	23	Barrea L, Muscogiuri G, di Somma C, et al. Association between Mediterranean
37	468		diet and hand grip strength in older adult women. <i>Clinical nutrition (Edinburgh,</i>
38	469		Scotland) 2019;38:721-9. doi:10.1016/J.CLNU.2018.03.012
39	470	24	Martínez-González MA, García-Arellano A, Toledo E, et al. A 14-item
40	471		Mediterranean diet assessment tool and obesity indexes among high-risk
41	472		subjects: the PREDIMED trial. <i>PloS one</i> 2012;7.
42 43	473		doi:10.1371/JOURNAL.PONE.0043134
43 44	474	25	Kvamme JM, Holmen J, Wilsgaard T, et al. Body mass index and mortality in
45	475		elderly men and women: the Tromso and HUNT studies. Journal of
46	476		epidemiology and community health 2012;66:611–7.
47	477		doi:10.1136/JECH.2010.123232
48	478	26	Zhang SX, Wang Y, Rauch A, et al. Unprecedented disruption of lives and work:
49 50	479		Health, distress and life satisfaction of working adults in China one month into
50 51	480		the COVID-19 outbreak. Psychiatry research 2020;288.
52	481		doi:10.1016/J.PSYCHRES.2020.112958
53	482	27	Benke C, Autenrieth LK, Asselmann E, et al. Lockdown, quarantine measures,
54	483		and social distancing: Associations with depression, anxiety and distress at the
55	484		beginning of the COVID-19 pandemic among adults from Germany. Psychiatry
56	485		research 2020;293. doi:10.1016/J.PSYCHRES.2020.113462
57 58	486	28	Karageorghis CI, Bird JM, Hutchinson JC, et al. Physical activity and mental
58 59	487		well-being under COVID-19 lockdown: a cross-sectional multination study.
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2	488		BMC Public Health 2021;21:1–13. doi:10.1186/S12889-021-10931-
4	489		5/FIGURES/4
5	490	29	Fountoulakis KN, Apostolidou MK, Atsiova MB, et al. Self-reported changes in
6	491	2)	anxiety, depression and suicidality during the COVID-19 lockdown in Greece.
7	492		Journal of affective disorders 2021; 279 :624–9. doi:10.1016/J.JAD.2020.10.061
8 9	493	30	Müller F, Röhr S, Reininghaus U, <i>et al.</i> Social Isolation and Loneliness during
10	494	50	COVID-19 Lockdown: Associations with Depressive Symptoms in the German
11	495		Old-Age Population. International journal of environmental research and public
12	496		health 2021;18. doi:10.3390/IJERPH18073615
13	497	31	di Santo SG, Franchini F, Filiputti B, <i>et al.</i> The Effects of COVID-19 and
14	498	51	Quarantine Measures on the Lifestyles and Mental Health of People Over 60 at
15 16	499		Increased Risk of Dementia. <i>Frontiers in psychiatry</i> 2020;11.
17	500		doi:10.3389/FPSYT.2020.578628
18	501	32	Schwan J, Sclafani J, Tawfik VL. Chronic Pain Management in the Elderly.
19	502	52	Anesthesiology clinics 2019; 37 :547–60. doi:10.1016/J.ANCLIN.2019.04.012
20	502	33	Tsang A, von Korff M, Lee S, <i>et al.</i> Common chronic pain conditions in
21	503 504	55	developed and developing countries: gender and age differences and comorbidity
22	505		with depression-anxiety disorders. <i>The journal of pain</i> 2008; 9 :883–91.
23 24	505		doi:10.1016/J.JPAIN.2008.05.005
25	507	34	Rolandi E, Vaccaro R, Abbondanza S, <i>et al.</i> Loneliness and Social Engagement
26	508	54	in Older Adults Based in Lombardy during the COVID-19 Lockdown: The Long-
27	509		Term Effects of a Course on Social Networking Sites Use. <i>International journal</i>
28	510		of environmental research and public health 2020;17:1–12.
29	511		doi:10.3390/IJERPH17217912
30 31	512	35	Zhao ZY, Zhu YZ, Xu JW, <i>et al.</i> A five-compartment model of age-specific
32	512	55	transmissibility of SARS-CoV-2. <i>Infectious Diseases of Poverty</i> 2020; 9 :1–15.
33	514		doi:10.1186/S40249-020-00735-X/FIGURES/11
34	515	36	Salman D, Beaney T, E Robb C, <i>et al.</i> Impact of social restrictions during the
35	516	20	COVID-19 pandemic on the physical activity levels of adults aged 50-92 years: a
36	517		baseline survey of the CHARIOT COVID-19 Rapid Response prospective cohort
37 38	518		study. BMJ open 2021;11. doi:10.1136/BMJOPEN-2021-050680
39	519	37	Janssen X, Fleming L, Kirk A, et al. Changes in Physical Activity, Sitting and
40	520		Sleep across the COVID-19 National Lockdown Period in Scotland.
41	521		International Journal of Environmental Research and Public Health 2020, Vol
42	522		17, Page 9362 2020;17:9362. doi:10.3390/IJERPH17249362
43	523	38	Sadarangani KP, de Roia GF, Lobo P, et al. Changes in Sitting Time, Screen
44 45	524		Exposure and Physical Activity during COVID-19 Lockdown in South American
45 46	525		Adults: A Cross-Sectional Study. International Journal of Environmental
47	526		Research and Public Health 2021, Vol 18, Page 5239 2021;18:5239.
48	527		doi:10.3390/IJERPH18105239
49	528	39	di Santo SG, Franchini F, Filiputti B, et al. The Effects of COVID-19 and
50	529		Quarantine Measures on the Lifestyles and Mental Health of People Over 60 at
51 52	530		Increased Risk of Dementia. Frontiers in Psychiatry 2020;11:1052.
52 53	531		doi:10.3389/FPSYT.2020.578628/BIBTEX
55	532	40	Psaltopoulou T, Sergentanis TN, Panagiotakos DB, et al. Mediterranean diet,
55	533		stroke, cognitive impairment, and depression: A meta-analysis. Annals of
56	534		Neurology 2013; 74 :580–91. doi:10.1002/ANA.23944
57	535	41	Kass L, Desai T, Sullivan K, et al. Changes to Physical Activity, Sitting Time,
58 50	536		Eating Behaviours and Barriers to Exercise during the First COVID-19
59 60			-
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1 2 3 4 5 6 7 8 9 10 11 12 13 14	537 538 539 540 541 542 543 544 545 546	 "Lockdown" in an English Cohort. <i>International journal of environmental research and public health</i> 2021;18. doi:10.3390/IJERPH181910025 Meyer J, Herring M, McDowell C, <i>et al.</i> Joint prevalence of physical activity and sitting time during COVID-19 among US adults in April 2020. <i>Preventive medicine reports</i> 2020;20. doi:10.1016/J.PMEDR.2020.101256 Veronese N, Stubbs B, Noale M, <i>et al.</i> Adherence to the Mediterranean diet is associated with better quality of life: data from the Osteoarthritis Initiative. <i>The American journal of clinical nutrition</i> 2016;104:1403–9. doi:10.3945/AJCN.116.136390
15 16	547	Figure legends
17 18	548	Figure 1. Flow Diagram
$\begin{array}{c} 19\\ 20\\ 21\\ 22\\ 23\\ 24\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 32\\ 33\\ 34\\ 35\\ 36\\ 37\\ 38\\ 940\\ 41\\ 42\\ 43\\ 44\\ 45\\ 46\\ 47\\ 48\\ 49\\ 50\\ 51\\ 52\\ 53\\ 54\\ 55\\ 56\\ 57\\ 58\\ 59\\ 60\end{array}$		Figure 1. Flow Diagram
		16



57 58 59

Page 19 of 30

ClinicalTrials.gov PRS Protocol Registration and Results System

2 -										
2 3 4 5 6	ClinicalTrials.gov PRS DRAFT Receipt (Working Version) Last Update: 07/01/2021 04:49									
7	ClinicalTrials.gov ID: NCT04958499									
8 ⁻ 9										
10 11	Study Identification									
12	Unique Protocol ID:	UCMurcia-BiohealthyPark								
13 14	Brief Title:	Effectiveness of Bio-Healthy Park on Adult								
15	Official Title:	Physical and Psychological Effectiveness of Bio-Healthy Park on Adult								
16	Secondary IDs:									
17 18										
19	Study Status									
20	-									
21 22	Record Verification:	July 2021								
23	Overall Status:	Not yet recruiting								
24 25	Study Start:	July 15, 2021 [Anticipated]								
26	Primary Completion:	August 1, 2021 [Anticipated]								
27	Study Completion:	September 30, 2021 [Anticipated]								
28 29										
30	Sponsor/Collaborators									
31 32	•									
33		Universidad Católica San Antonio de Murcia								
34	Responsible Party:	Principal Investigator Investigator: Noelia González-Gálvez [ngonzalez-galvez]								
35 36		Official Title: Principal investigator								
37		Affiliation: Universidad Católica San Antonio de Murcia								
38 39	Collaborators:									
40										
41	Oversight									
42 43	U.S. FDA-regulated Drug:	No								
44	с с									
45 46	U.S. FDA-regulated Device:									
47	U.S. FDA IND/IDE:									
48	Human Subjects Review:	Board Status: Approved Approval Number: CE111908								
49 50		Board Name: Maquinaria Bio-saludable: Diseño y fabricación de nueva								
51		maquinaria de fitness outdoor ergonómica, eficiente, saludable y con aplicación								
52 53		para dispositivos móviles (App) de valoracióin y control del entrenamiento Board Affiliation: UCAM								
55		Phone:								
55		Email: ngonzalez@ucam.edu Address:								
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BMJ Open

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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

Pag	e 21 of 30	BMJ Open				
1 2 3		(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).				
4 5 6 7		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.				
8 9		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.				
10 11 12		Mediterranean diet adherence will be assess with a Mediterranean diet adherence questionaire.				
13 14 15 16 17 18 19 20 21 22 23		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.				
24						
25 26	Conditions					
27	Conditions:	Adult Disease				
28	Keywords:					
29 30	Reywords.	Older				
31		Physical activity				
32		Exercise Bio-healthy park				
33 34		Training				
35		J. J				
36						
37 38	Study Design					
39	Study Type:	Interventional				
40	Primary Purpose:	Treatment				
41 42	Study Phase:	N/A				
43	Interventional Study Model:	Parallel Assignment				
44 45	Number of Arms:					
45 46						
47	-	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)				
48		Randomized				
49 50	Enrollment:	120 [Anticipated]				
51						
52 53	Arms and Interventions					
55 54						
55	Arms Experimental: Bio-Healthy Park	Assigned Interventions Behavioral: Bio-healthy Park				
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60	60 For peer review only - http://မွာဥာဖြားနားbကြားနာမှာ/site/about/guidelines.xhtml					

	BMJ	l Open Page	e 2
	Arms	Assigned Interventions	
) 2 3 4	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	l e ate
5	No Intervention: Control		
5 7 8	Adults and older assigned to the control group will not received any structured exercise programme. They will maintain their usual physical activities.		
)			
)			
	outcome Measures		
ļ	Primary Outcome Measure:		
5 7 3 9	quality will be measure by hand grip strength test. This	eference values established for muscle quality. The muscle s test will be performance with manual dynamometry (TKK 5 nal isometric upper limb strength will be performance by max kilogrammes. Higher value show high strength.	
2	Secondary Outcome Measure:		
3	-		
4 5 5	 Change Body composition Body composition will be assessed by dual energy X-ra result will be register in absolutes and percentages res 	ray absorptiometry (DEXA). This is noninvasive technique. T sults.	Γhe
7	[Time Frame: Changes from baseline to 8 weeks]		
)) 2		eans of an automatic device (Colin BP 880, Inc., Tampa, FL). millimeters of mercury (bood pressure) and number of pulse	

[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

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Pag	age 23 of 30 BMJ Open	
1	Sagittal spinal curvature will be assess with the Spinal Mouse device (Switzerland). It will dorsal and lumbar curve and pelvic tilt when standing and in asthenic sitting. This is nonin is register in grades.	
2 3	Lime Frame. Changes from baseline to 8 Meeksi	
4 5 6 7 8	7. Health-related quality Health-related quality of life will be assessed by means of the Short Form 36 questionaire, questions and show result for 9 area: physical role, pain, general health, vitality, social fun health, and evolution of the health care system. Each area is reported from 0 to 100 point. better health-related quality.	ction, emotional role, mental
9 10	[Time Frame: Changes from baseling to 8 weeks]	
11 12 13 14 15	 8. Satisfaction with Life Scale (SWL) Satisfaction with Life Scale (SWL) questionnaires include 5 affirmation about the satisfacti participant have to answers from strongly agree to strongly disagree. The final score is rep Higher value show better satisfaction with life. 	
16	6 [Time Frame: Changes from baseline to 8 weeks]	
17 18 19 20 21	 It will be used the Adherence to the Mediterranean diet. This questionaire have 14 question about their adherence to the mediterranean diet. The sum of the answers are collect. High adherence to mediterranean diet. 	() ,
22	2 [Time Frame: Changes from baseline to 8 weeks]	
23 24 25 26	 Functional competence 400 meter walk is a test included in the European Consensus (EV sarcopenia. Participant have to walk as fast as possible 400 meter. The total time is regist 	
20	[Time Frame, Changes from baseling to Quesks]	
28 29 30 31	 Bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA). This The result will be register in absolutes and percentages results. 	is noninvasive technique.
32	IT is a France of the second france is a structure in the france is a second seco	
33 34 35 36	 Heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, technique. The result will be register in number of pulse per minutes (heart rate). 	FL). This is noninvasive
37		
38 39 40 41	 Gait speed will be measure by 4. 6 and 10 meter test. This is easy physical test in with the and 10 metres as faster as possible. The result will be register in seconds. Less time indic 	• •
42	2 [Time Frame: Changes from baseline to 8 weeks]	
43 44 45 46 47	 Time up and go test change Time up and go test measure the functional capacity of getting up, walking and sitting dow have to performance this test as faster as possible. This is a easy physical test. Total seconds indicates better functional ability. 	
48	8 [Time Frame: Changes from baseline to 8 weeks]	
49 50 51 52 53 54	 Short physical performance battery (SPPB) Short physical performance battery (SPBB) include three test (balance, chair stand test ar final score. Chair stand test and gait speed were describe in other outcome. Balance test participant must maintain three balancing positions for 10 seconds to overcome it. Each te Higher score show better functional capacity. 	is a easy physical test. The
55	5 [Time Frame: Changes from baseline to 8 weeks]	
56 57		
58 59 60	8 9	1

Page	24	of	20
raye	24	υı	50

BMJ Open 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

1

6		
7	Minimum Age:	50 Years
8 9	Maximum Age:	
10	Sex:	ΔΙΙ
11		
12	Gender Based:	
13 14	Accepts Healthy Volunteers:	Yes
15	Criteria:	Inclusion Criteria:
16		 not having participated in a structured exercise program for at least 1 year;
17		 being older than 50 years of age
18 19		 being physically independent.
20		Exclusion Criteria:
21		 having musculoskeletal injuries or limitations that could affect the person's
22 23		health and physical performance
24		 being under medical prescription for taking medications that could influence a busical approximation
25		influence physical performancenot regularly attending the proposed sessions.
26		not regularly attending the proposed bescienc.
27 28		
29	Contacts/Locations	
30	Central Contact Person:	Pablo Jorge Marcos-Pardo, PhD
31 32		Telephone: 696243274
33		Email: pjmarcos@ual.es
34	Central Contact Backup:	Noelia Gonzalez-Galvez, PhD
35 36		Telephone: 627146613 Email: ngonzalez@ucam.edu
37		
38	Study Officials:	Pablo Jorge Marcos-Pardo, PhD Study Principal Investigator
39		Universidad de Almería
40 41		
42		Noelia Gonzalez-Galvez, PhD Study Principal Investigator
43		UCAM
44 45		
46	Locations:	Spain
47		Pablo Jorge Marcos-Pardo
48		Murcia, Spain Contact: Pablo Jorge Marcos-Pardo, PhD 696243274 pjmarcos@ual.es
49 50		Contact: Noelia Gonzalez-Galvez, PhD 627146613 ngonzalez@ucam.edu
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53 54	IPDSharing	
55	Plan to Share IPD:	No
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Page 25 of 30

	References
1 2	Citations:
3 4	NOTE : Either PubMed ID or Citation Text should be specified. Links:
5 6	Available IPD/Information:
$\begin{array}{c} 7 & -8 \\ 9 \\ 10 \\ 11 \\ 12 \\ 13 \\ 14 \\ 15 \\ 16 \\ 17 \\ 18 \\ 19 \\ 20 \\ 21 \\ 22 \\ 23 \\ 24 \\ 25 \\ 26 \\ 27 \\ 28 \\ 29 \\ 30 \\ 31 \\ 22 \\ 23 \\ 24 \\ 25 \\ 26 \\ 27 \\ 28 \\ 29 \\ 30 \\ 31 \\ 32 \\ 33 \\ 34 \\ 55 \\ 36 \\ 37 \\ 38 \\ 39 \\ 40 \\ 41 \\ 45 \\ 46 \\ 47 \\ 48 \\ 49 \\ 50 \\ 51 \\ 55 \\ 56 \\ 57 \\ 58 \\ 59 \\ 60 \end{array}$	U.S. National Library of Medicine U.S. National Institutes of Health U.S. Department of Health & Human Services



COMITÉ DE ÉTICA DE LA UCAM

DATOS DEL PROYECTO

Título:	maquinaria aplicación	Maquinaria Bio-saludable Inteligente: Diseño y fabricación de nueva aquinaria de fitness outdoor ergonómica, eficiente, saludable y con plicación para dispositivos móviles (App) de valoración y control del ntrenamiento"	
Investigad	or 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 embrionario	os o
fetales	
Utilización de tejidos humanos, tejidos embrionarios o fetales procedentes	de
bancos de muestras o tejidos	
Investigación observacional con seres humanos, psicológica o comportame	ntal
en humanos	A
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

BMJ Open



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		

V° B° El Presidente,

1. Maiera

Fdo.: José Alberto Cánovas Sánchez

El Secretario,

Fdo.: José Alarcón Teruel

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COMITÉ DE ÉTICA DE LA UCAM

Código

CE052002

DATOS DEL PROYECTO

		9 y aislamiento social: Efectos -fisiológica en adultos mayores"	social: Efectos sobre la condición física y la lultos mayores"		
Investigador Principal		Nombre	Correo-e		
Dr.		Pablo Jorge Marcos Pardo	pmarcos@ucam.edu		

INFORME DEL COMITÉ

Fecha	29/05/2020

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	l
Experimentación animal		-
Utilización de agentes biológicos de riesgo para la salud humana, animal o las		
plantas		
Uso de organismos modificados genéticamente (OMGs)		l

Comentarios Respecto al Tipo de Experimentación

Nada Obsta

Comentarios Respecto a la Metodología de Experimentación

Nada Obsta





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	1.	
Emitir Informe Favorable condicionado a	R. M. M	
Subsanación	1947 - 1947 M	
MOTIVACIÓN		
Incrementará conocimientos en su área		

Vº Bº El Presidente,

Mairos

Fdo.: José Alberto Cánovas Sánchez

El Secretario, MITE DE Fdo.: José Alarcón Teruel

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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	1
	-	abstract	-
		(b) Provide in the abstract an informative and balanced summary of what was	1
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	2-3
8	_	reported	
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	3-4
8		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods	3
1		of selection of participants. Describe methods of follow-up	
		<i>Case-control study</i> —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	
		(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	3-4
		effect modifiers. Give diagnostic criteria, if applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	3-4
measurement		assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
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	4-5
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for	4-5
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	4-5
		(c) Explain how missing data were addressed	4-5
		(<i>d</i>) Cohort study—If applicable, explain how loss to follow-up was addressed	4-5
		<i>Case-control study</i> —If applicable, explain how matching of cases and	
		controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking	
		account of sampling strategy	
		(e) Describe any sensitivity analyses	4-5
Continued on next page		(v) 2000100 any bondering analyses	ч·J

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

*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.

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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review only

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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Keywords: Adult₁, Lockdown₂, Mediterranean diet adherence₃, Physical activity₄, Psychology₅, SARS-CoV-2₆, Sleep quality₇, Well-being₈

²⁹ 15 **Abstract** 30

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.

38 ClinicalTrials.gov Identifier: NCT04958499

1 2	39	
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5	41 42	Strengths and limitations of this study
7 8 9 10	43 44 45	• 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.
10 11 12 13 14	46 47 48	 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
15 16	49 50	of mobility and access to the center where the study was conductedAnother limitation was the absence of a control group that was not in a lockdown situation.
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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

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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.

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37131Patient 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.

45 137 46 138 *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

- $_{53}^{52}$ 144 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

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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: \geq 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 Ouestionnaire (GPAO). GPAO 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.

3 199 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:

²⁸ 221 https://doi.org/10.5061/dryad.rfj6q57cp [45].

222 Results

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

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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)

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2	High school	12.50 (5)
3	Bachelor's Degrees or higher	17.50 (7)
4	Living status	
5	Living with someone	72.50 (29)
6	Living alone	27.50 (11)
7 8	Sitting time during lockdown (min per	
9	day)	385.20±152.66
10	MVPA during lockdown (min per week)	340.50±403.95
11	Active vs Inactive (WHO 15	
12	Active	72.50 (29)
13	Inactive	27.50 (11)
14 15	MDA Classification	
16	No Adherence (≤ 7 points)	25 (10)
17	Adherence (>7 points)	75 (30)
18	Lifestyle (Active and MDA vs No Active	
19	Healthy	50.00 (20)
20	Unhealthy	50.00 (20)
21 22 227	BMI = body mass index; MDA = Mediterranean Diet Ac	
23 228	physical activity; WHO = World H	
24	physical activity, who wond h	catti organization.
25 229	Table 2 shows the results of the differences between pre an	d post adjusted and unadjusted for age, of
26 230	the perception of life satisfaction, depression, general healt	
27 221	sample significantly had worse results in satisfaction with l	
$ \begin{array}{cccc} 28 & 231 \\ 29 & 232 \end{array} $	physical role, pain, emotional role and mental health; and s	
²⁹ 30 233	disturbance and global sleep quality score (Table 2). The re-	
31 234	were significant for pain (F=10.07; p=.003) and social func	
32 235	adversely influenced the change in these variables post-loc	
³³ 236	status interaction analysis were significant for role-physica	e
$\frac{34}{237}$	(F=4.640; p=.004), meaning that be alone adversely influen	
$ \begin{array}{c} 35 \\ 36 \end{array} \begin{array}{c} 237 \\ 238 \end{array} $	lockdown. For the rest of the variables, no significant value	
30_{37} 239	When the differences in these variables were analyzed as a	
38 240	was found that the pre-test differences were not significant	for the Healthy Lifestyle group (mean
39 241	difference=158±473; p=.473) while it was significant for	the Unhealthy Lifestyle group (mean
40 242	difference= .600; p=.008). In addition, the effect of the tim	e*Lifestyle interaction during lockdown
⁴¹ 243	was found to be significant (F=6.214; p=.017), indicating the	hat maintaining a healthy lifestyle during
$ \begin{array}{c} 42 \\ 43 \end{array} $ 244	lockdown was key in the maintenance of the variables anal	yzed.
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1 2 245	Table 2. Effe	ect of lockdov	wn due to the	e COVID pand	emic ir	n older wome	n (n=40) (una	ndjusted	and adjusted	y age and livir	ng status))
4				U	Jnadjusted	d	А	djusted by	age u	Adjus	ted by living	g status
5 6 7 8		Pre-test (M±SD)	Post-test (M±SD)	Difference post- pre (M±SD)	р	95% CI (Mpost-Mpre)	Difference post-pre (M±SD)	р	95% CI (Mpost-9 Mpre)	(M±SD)	р	95% CI (Mpost-Mpre)
9 Satisfactio 10scale)	on with live (SWLS	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
11 _{Depressio} 12 1 3	on (CESD scale)	13.18±8.52	20.13±11.2 9	6.95±1.68	<.001	-3.56; 10.35	6.95±1.67	<.001	3.57; 10.33		<.001	9.527; 10.37
14 15	Physical functioning	82.74±12.6 6	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
16 _{Physica} 17 18 ^{l Health}	Role-physical	89.10±17.9 5	79.81±18.9 4	-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
19(SF-36 20 _{scale)}	Bodily pain	72.03±20.1 5	62.00±22.3 5	-10.02±3.29	.004	-16.68; -3.37	-10.02±2.95	.002	-15.97±95 -8.76±0.90	-10.02±3.24	.004	3.45±16.59
21 22 23	General health	73.19±14.6 5	69.29±18.0 8	-3.90±2.37	.108	-8.69; .89	-3.90±2.36	.108	-8.76±0.90	·	.094	-8.49±.69
24 25	Vitality	71.05±14.9 9	69.87±14.7 0	-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
26 27 ^{Mental} 28 Health	Social functioning	89.23±14.2 1	88.72±21.6 6	51±3.62	.888	-7.84; 6.81	51±3.52	.886	-6.636±7.65	51±3.50	.884	-7.608±6.58
29 _{(SF-36} 30 _{scale)}	Role-emotional	91.88±16.6 1	76.50±21.5 3	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
31 32 33	Mental health	77.78±12.8 5	65.89±14.0 1	-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
34 _{Sleep} 35 36 ^{(PSQI}	C1 Sleep Quality component	1.11±.57	1.36±.68	.25±.10	.018	.05;.45	.25±.10	.021	.04±.460 guest.	.25±.10	.019	.43±.45
37 ^{scale)} 38	C2 Sleep latency	1.28±1.03	1.78±1.17	.50±.16	.004	.17;.83	.50±.16	.005			.004	.17±.83
39 40 41	C3 Sleep duration	1.00±.76	1.08±.77	.08±.11	.446	14;.30	.08±.11	.459	.167±.834	.08±.11	.446	14±.30
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2	C4 Habitual									open-2022-061 993 0n .36±.11		
3		.92±1.11	.81±1.01	11±.13	.401	38; .15	11±.13	.396	37±.15	611±.13	.369	359±.14
4	Sleep efficiency									993		
5	C5 Step	1.39±.60	1.75±.60	36±.11	.002	.15; .58	.36±.11	.002	.141±.58	9 .36±.11	.002	.14±.58
6 7	disturbances									24		
8	C6 Use of	1.00±1.39	1.28±1.47	.28±.17	.115	07; .63	.28±.16	.089	601±.045	Aug .28±.17	.116	.08±.63
9	sleeping medication	1.0021.09	1.2021.17	.202.17		.07,.05	.202.10	.009		ust	.110	.002.05
10	C7 Day time	.50±.61	.64±.59	.14±.13	.281	12; .40	.14±.13	.295	126±.404	NON .14±.13	.288	.12±.40
11	dysfunction	.50±.01	.04±.39	.14±.15	.201	12, .40	.14±.15	.295	120±.404	•	.200	.12±.40
12 13	Global score	7.19±4.06	8.69±3.91	$1.50 \pm .46$.002	.57; 2.43	$1.50 \pm .46$.002	.568±2.43	Do 1.50±.46	.003	.56±2.44
14 246	CESD= center fo	r epidemiolo	gic studies de	pression scal	le; C=cor	.57; 2.43 mponent; PSO	QI= Pittsburg	gh sleep c	quality index	;्रेSF-36= short t	form 36	
15 247	health survey; SV		ction with life	scale.		-				ade		
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	248 249 250 251 252 253 254 255 256 257 258 259 260	When performing linear Mediterranean diet durin increased depression due r2=.116). Spending time (Standardized Coefficien health risk factor for wor r2=.192). Volunteers wh diet Adherence) had a gr Component 6 use of slee r2=.144) (Table 3). Table 3. Nonlinear mutindependent variables.	ng lockdow e to the loc e sitting wa nt (β) =4' rsening pai to showed a reater risk i eping medi	n was sho kdown (St s shown as 74; p=.002 in (Standar an unhealt in increasin cation) (St	wn to be a protective fac andardized Coefficient (s a risk factor for physica ; r2=.224). An older age rdized Coefficient (β) = . hy lifestyle (inactive or 1 ng the use of sleeping m andardized Coefficient (etor against β) =341; p=.031; al role health e was found to be a 438; p=.005; No Mediterranean edication (PSQI β) = .379; p=.017;
18			R ²	<i>p</i> Value	Included independent	Standarized
19					variables	Coefficient (β)
20		Depression	.116	.031	Adherence	341
21					Mediterranean Diet	
22 23		Physical role health	.224	.002	Spending time sitting	474
23 24		Age	. 192	.005	Pain	.438
24		Use of cleaning	144	017	Unhaalthy lifestyle	270

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 mediumhigh reliability of the test. The percentage of variance (see Table 5) is found high in all
test.

.017

Unhealthy lifestyle

.379

.144

Use of sleeping

medication

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 v	with live (SWLS scale)	.734	.748	.353	.340
Depression (CESD scale)	,778	,812	,206	,186
	Physical functioning	.579	.755	.269	.187
Physical	Role-physical	.873	.882	.127	.122
Health (SF-	Bodily pain	.677	.712	.647	.587
36 scale)	General health	,633	,656	,448	,425
	Vitality	,767	,770	,423	,420
Mental	Social functioning	.630	.669	.440	.403
Health (SF-	Role-emotional	.871	.871	.118	.118
36 scale)	Mental health	.714	.735	.421	.399
Sleep (PSQI	scale)	.782	.789	.316	.310
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3 270 4 271		f variation, sum of squares, deg	grees of freed	om, mean squar	res, % and	
6 7	Design	Sum of squares	DF	Mean squares	%	Standard error
Satisfaction v	with live (SWLS scale)	90.120	156	.578	59.583	.065
Depression (CESD scale)	512.376	741	.691	69.069	.036
11	Physical functioning	57.413	234	.244	39.811	.022
12 Physical	Role-physical	6.931	117	.0590	33.780	.008
Health (SF- 15 36 scale)	Bodily pain	26.888	39	.689	40.793	.152
apg scale) 17	General health	141.2	156	.905	67.139	.102
18	Vitality	82.650	117	.706	54.059	.092
Mental 20	Social functioning	12.688	390	.325	45.373	.072
Marcalth (SF-	Role-emotional	3.267	78	.042	30.769	.007
$\frac{22}{36}$ scale)	Mental health	124.270	156	.797	60.048	.090
24 Steep (PSQI	scale)	112.317	195	.576	60.067	.058

²⁸₂₉ 273 **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

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3	299	consideration the findings of this research in future situations of partial or total
4	300	lockdown to reduce its negative psychological effects.
5 6	301	Depression has been one of the most classically studied psychological variables. In the
7	302	present research, we found an increase in depression values after lockdown, as was in
8	303	previous cross-sectional studies [1,6,8], with the percentage of women with depression
9	304	increasing over 21% as compared to epidemiological studies conducted in a normal
10	305	setting [7,8,11,48]. Also, age was a potentiating factor for this phenomenon [49], as
11	306	found in the present research. One of the aspects that could have most affected this
12	307	increase in depression was loneliness. However, almost 1 out of 3 women in the present
13	308	study spent the lockdown alone and be alone has adversely influence the effect of the
14	309	lowndown in role-physical and bodily pain. In a sample of people over 65 years of age
15	310	
16 17		analyzed after the lockdown, a greater presence of depressive and anxiety symptoms
17	311	was observed in those who were alone, especially in women [16,50,51], while those
19	312	who were not alone did not show significant increases in depression even when under
20	313	lockdown [50]. This is an important aspect to take into account in situations of social
21	314	isolation.
22	315	Along the same line, the participants in the present investigation showed a worsening of
23	316	sleep quality after the lockdown. Variables such as depression, anxiety or fear have
24	317	been found to be negatively related to sleep quality in general [33] and during COVID-
25	318	19 pandemic [13]. In this study, sleep quality was analyzed using the PSQI
26	319	questionnaire. It was found that before lockdown, subjects already showed an overall
27 29	320	score above 5 points, denoting poor sleep quality. But in addition, after lockdown, a
28 29	321	significant worsening of sleep latency, subjective sleep quality, sleep disturbances, and
30	322	the global score were found. As observed in previous studies, sleep quality is
31	323	fundamental to physical health, emotional well-being, mental health, stress, depression,
32	324	and anxiety, so its importance lies in the fact that everything is interconnected [6]. In
33	325	previous studies conducted on businessmen and university students, it was observed that
34	326	lockdown negatively affected their health, well-being, and sleep, which could be due to
35	327	the loss of daily life routine, isolation, stress, or sedentary attitudes [6]. In addition, it
36	328	was shown that being a woman could be a factor that favored the presence of sleep
37	329	disorders during lockdown [8,11]. In the study by Gualano et al. [11], 42.2% of a
38 39	330	sample of 1515 people presented sleep disturbances, of which 17.4% reported
39 40	331	moderate/severe insomnia. However, so far we have not found studies conducted on
41	332	older women, so the results of the present study represent a first approach to
42	333	
43	333 334	understanding how lockdown situations affect this factor.
44		The women in the present investigation also showed higher pain scores after lockdown.
45	335	The population analyzed was composed of older adults, who frequently perceive bodily
46	336	pain. In addition, the quarantine meant a limitation of physical activity, which may have
47	337	led to increased pain perception [18]. Therefore, both age and inactivity may have
48 49	338	preceded a greater perception of such pain, which should be taken into account in the
49 50	339	future.
50	340	Another objective of the present research was to analyze the variables with a significant
52	341	influence on the evolution of psychological variables during lockdown. It was found
53	342	that age, lifestyle, diet, and sedentary lifestyle had an influence these variables. With
54	343	respect to age, a worsening of pain and social function variables was observed in older
55	344	people. The relationship between pain and age has been broadly documented in
56	345	previous studies [52], with the prevalence of pain being higher among women and older
57	346	people. This could be due to a greater sensitization to pain in the case of women, or to a
58 59	347	greater vulnerability of older adults to different types of chronic pain [52,53]. In terms
59 60	348	of social function, the lockdown increased the risk of social isolation and loneliness in
00		

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

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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.

448 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.
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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464 Conflict of Interests

465 The authors declare that the research was conducted in the absence of any commercial466 or financial relationships that could be construed as a potential conflict of interest.

467 Data Sharing

468 No additional data available.

469 Ethics Committee Approval

470 Institutional ethics committee of the Catholic University of Murcia (code: CE111908471 and CE052002) was obtained.

References

- Gutiérrez-Hernández ME, Fanjul LF, Díaz-Megolla A, et al. COVID-19 Lockdown and Mental Health in a Sample Population in Spain: The Role of Self-Compassion. Int J Environ Res Public Health 2021;18:1-14. doi:10.3390/IJERPH18042103 Agencia Estatal Boletín Oficial del Estado. Real Decreto 463/2020, de 14 de marzo, por el que se declara el estado de alarma para la gestión de la situación de crisis sanitaria ocasionada por el COVID-19. Madrid: : Ministerio de la Presidencia, Relaciones con las Cortes y Memoria Democrática 2020. Agencia Estatal Boletín Oficial del Estado. Orden SND/388/2020, de 3 de mayo,
- 482 por la que se establecen las condiciones para la apertura al público de
 483 determinados comercios y servicios, y la apertura de archivos, así como para la
 - *práctica del deporte profesional y federado*. Madrid: : Ministerio de la
- 485
 485
 Presidencia, Relaciones con las Cortes y Memoria Democrática 2020.

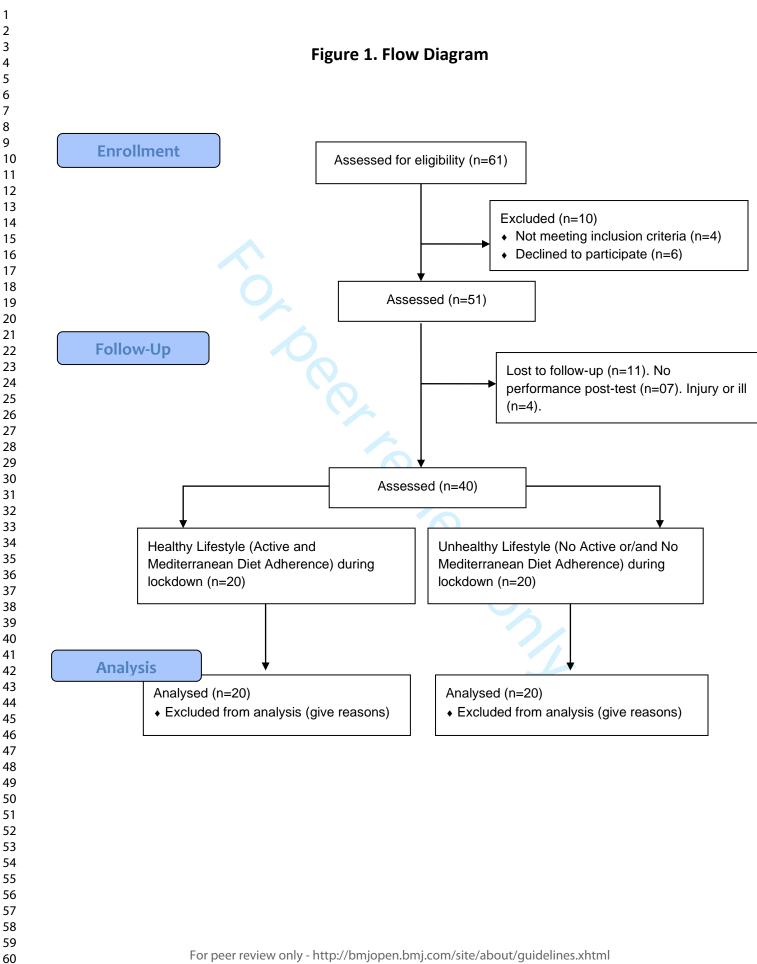
1			
2			
3	486	4	López-Bueno R, López-Sánchez GF, Casajús JA, et al. Potential health-related
4 5	487		behaviors for pre-school and school-aged children during COVID-19 lockdown:
5 6	488		A narrative review. Preventive Medicine 2021;143:106349.
7	489		doi:10.1016/J.YPMED.2020.106349
8	490	5	Scarmozzino F, Visioli F. Covid-19 and the Subsequent Lockdown Modified
9	491		Dietary Habits of Almost Half the Population in an Italian Sample. Foods
10	492		2020; 9 . doi:10.3390/foods9050675
11	493	6	Majumdar P, Biswas A, Sahu S. COVID-19 pandemic and lockdown: cause of
12 13	494		sleep disruption, depression, somatic pain, and increased screen exposure of
14	495		office workers and students of India. Chronobiol Int 2020;37:1191-200.
15	496		doi:10.1080/07420528.2020.1786107
16	497	7	Cárdaba-García RM, Pérez Pérez L, Martín VN, et al. Evaluation of the Risk of
17	498		Anxiety and/or Depression during Confinement Due to COVID-19 in Central
18	499		Spain. Public Health 2021;18:5732. doi:10.3390/ijerph18115732
19 20	500	8	Pieh C, Budimir S, Probst T. The effect of age, gender, income, work, and
20	501		physical activity on mental health during coronavirus disease (COVID-19)
22	502		lockdown in Austria. J Psychosom Res 2020;136.
23	503		doi:10.1016/J.JPSYCHORES.2020.110186
24	504	9	Reche-García C, Hernández Morante JJ, Trujillo Santana JT, et al. Bienestar
25	505		psicológico de deportistas adolescentes mexicanos confinados por la pandemia
26 27	506		del COVID-19. Cultura, Ciencia y Deporte 2022;17.
27	507		doi:10.12800/ccd.v17i52.1681
29	508	10	Beck F, Léger D, Fressard L, et al. Covid-19 health crisis and lockdown
30	509		associated with high level of sleep complaints and hypnotic uptake at the
31	510		population level. J Sleep Res 2021;30:e13119-e13119. doi:10.1111/jsr.13119
32	511	11	Gualano MR, lo Moro G, Voglino G, et al. Effects of COVID-19 lockdown on
33 34	512		mental health and sleep disturbances in Italy. International Journal of
35	513		Environmental Research and Public Health 2020;17:1–13.
36	514	10	doi:10.3390/ijerph17134779
37	515	12	Mandelkorn U, Genzer S, Choshen-Hillel S, <i>et al.</i> Escalation of sleep
38	516		disturbances amid the COVID-19 pandemic: A cross-sectional international
39	517		study. Journal of Clinical Sleep Medicine 2021;17:45–53.
40 41	518	10	doi:10.5664/JCSM.8800/SUPPL_FILE/JCSM.8800.DS001.PDF
41	519 520	13	Duong CD. The impact of fear and anxiety of Covid-19 on life satisfaction:
43	520		Psychological distress and sleep disturbance as mediators. <i>Personality and Individual Differences</i> 2021; 178 :110869.
44	521 522		<i>.</i>
45	522 523	14	doi:https://doi.org/10.1016/j.paid.2021.110869 Deniz ME. Self-compassion, intolerance of uncertainty, fear of COVID-19, and
46	523 524	14	well-being: A serial mediation investigation. <i>Personality and Individual</i>
47 48	524 525		Differences 2021;177:110824. doi:https://doi.org/10.1016/j.paid.2021.110824
49	525 526	15	Gonzalez-Bernal JJ, Rodríguez-Fernández P, Santamaría-Peláez M, <i>et al.</i> Life
50	520 527	15	Satisfaction during Forced Social Distancing and Home Confinement Derived
51	527		from the COVID-19 Pandemic in Spain. <i>International Journal of Environmental</i>
52	528 529		Research and Public Health 2021, Vol 18, Page 1474 2021;18:1474.
53 54	530		doi:10.3390/IJERPH18041474
54 55	530	16	Duarte F, Jiménez-Molina Á. Psychological distress during the COVID-19
56	532	10	epidemic in Chile: The role of economic uncertainty. <i>PLOS ONE</i>
57	533		2021; 16 :e0251683https://doi.org/10.1371/journal.pone.0251683
58	534	17	Kokkinos CM, Tsouloupas CN, Voulgaridou I. The effects of perceived
59	535	11	psychological, educational, and financial impact of COVID-19 pandemic on
60	220		

536		Greek university students' satisfaction with life through Mental Health. Journal
		of Affective Disorders 2022; 300 :289–95.
		doi:https://doi.org/10.1016/j.jad.2021.12.114
	18	Argus M, Pääsuke M. Effects of the COVID-19 lockdown on musculoskeletal
		pain, physical activity, and work environment in Estonian office workers
		transitioning to working from home. <i>Work</i> 2021; 69 :741–9. doi:10.3233/WOR-
		210033
	19	López J, Pérez-Rojo G, Noriega C, <i>et al.</i> Longitudinal Impact of the COVID-19
	17	Pandemic on Older Adults' Wellbeing. <i>Frontiers in Psychiatry</i> 2022; 13 .
		doi:10.3389/fpsyt.2022.837533
	20	von Elm E, Altman DG, Egger M, <i>et al.</i> The Strengthening the Reporting of
	20	Observational Studies in Epidemiology (STROBE) statement: guidelines for
		reporting observational studies. J Clin Epidemiol 2008;61:344–9.
		doi:10.1016/J.JCLINEPI.2007.11.008
	21	Chang Y, Li Y, Zhang X. Benefits of Grandparental Caregiving in Chinese Older
	21	Adults: Reduced Lonely Dissatisfaction as a Mediator. <i>Frontiers in Psychology</i>
		2020; 11 . doi:10.3389/FPSYG.2020.01719
	22	Pavot W, Diener E. Review of the Satisfaction With Life Scale. <i>Psychological</i>
		Assessment 1993; 5 :164–72. doi:10.1037/1040-3590.5.2.164
	23	Vázquez C, Duque A, Hervás G. Satisfaction with Life Scale in a Representative
	25	Sample of Spanish Adults: Validation and Normative Data. <i>The Spanish Journal</i>
		of Psychology 2013;16:E82. doi:10.1017/sjp.2013.82
	24	Park SH, Yu HY. How useful is the center for epidemiologic studies depression
	21	scale in screening for depression in adults? An updated systematic review and
		meta-analysis \Rightarrow . <i>Psychiatry Res</i> 2021; 302 .
		doi:10.1016/J.PSYCHRES.2021.114037
	25	Ruiz-Grosso Paulo AND Loret de Mola CANDV-
	23	DJMANDAJMANDCKANDVAANDLMANDHJ. Validation of the Spanish
		Center for Epidemiological Studies Depression and Zung Self-Rating Depression
		Scales: A Comparative Validation Study. <i>PLOS ONE</i> 2012;7:1–9.
	26	doi:10.1371/journal.pone.0045413
	26	González P, Nuñez A, Merz E, <i>et al.</i> Measurement properties of the Center for
		Epidemiologic Studies Depression Scale (CES-D 10): Findings from
		HCHS/SOL. Psychological Assessment 2017;29:372–81.
	27	doi:10.1037/pas0000330
	27	Carleton RN, Thibodeau MA, Teale MJN, <i>et al.</i> The center for epidemiologic
		studies depression scale: a review with a theoretical and empirical examination of
		item content and factor structure. <i>PLoS One</i> 2013; 8 .
	20	doi:10.1371/JOURNAL.PONE.0058067
	28	Ware JE. SF-36 health survey update. <i>Spine (Phila Pa 1976)</i> 2000; 25 :3130–9.
	20	doi:10.1097/00007632-200012150-00008
	29	Vilagut G, Ferrer M, Rajmil L, <i>et al.</i> El Cuestionario de Salud SF-36 español:
		una década de experiencia y nuevos desarrollos. <i>Gaceta Sanitaria</i> 2005; 19 :135–
	20	50. doi:https://doi.org/10.1157/13074369
	30	Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I.
		Conceptual framework and item selection - PubMed. <i>Medical Care</i>
		1992; 30 :473–83.https://pubmed.ncbi.nlm.nih.gov/1593914/ (accessed 1 Feb
	21	
584 585	31	Hita-Contreras F, Martínez-López EJ, Latorre Román P, <i>et al.</i> Reliability and validity of the Spanish version of the Pittsburgh Sleep Quality Index (PSQI) in
		VALUATE AT THE SPANICH VERSION OF THE PITTCHURCH SLEEP (JUBLITY INDEX (USI)) IN
	536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 571 572 573 574 575 576 577 578 579 580 581 582 583 584	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

1			
2			
3	586		patients with fibromyalgia. Rheumatol Int 2014;34. doi:10.1007/s00296-014-
4	587		2960-z
5 6	588	32	Zhang C, Zhang H, Zhao M, et al. Reliability, Validity, and Factor Structure of
7	589		Pittsburgh Sleep Quality Index in Community-Based Centenarians. Frontiers in
8	590		Psychiatry 2020;11. doi:10.3389/fpsyt.2020.573530
9	591	33	Lee S, Kin JH, Chung JH. The association between sleep quality and quality of
10	592		life: a population-based study. <i>Sleep Med</i> 2021;84:121–6.
11 12	593		doi:10.1016/J.SLEEP.2021.05.022
12	594	34	Keating XD, Zhou K, Liu X, et al. Reliability and Concurrent Validity of Global
14	595		Physical Activity Questionnaire (GPAQ): A Systematic Review. International
15	596		Journal of Environmental Research and Public Health 2019;16.
16	597		doi:10.3390/IJERPH16214128
17	598	35	Meh K, Sember V, Djuric S, et al. Reliability and Validity of Slovenian Versions
18 19	599		of IPAQ-SF, GPAQ and EHIS-PAQ for Assessing Physical Activity and
20	600		Sedentarism of Adults. International Journal of Environmental Research and
21	601	26	Public Health 2021;19:430. doi:10.3390/ijerph19010430
22	602	36	Ács P, Betlehem J, Oláh A, <i>et al.</i> Cross-cultural adaptation and validation of the
23	603		Global Physical Activity Questionnaire among healthy Hungarian adults. <i>BMC</i>
24	604	27	Public Health 2020;20:1056. doi:10.1186/s12889-020-08477-z
25 26	605	37	Barrea L, Muscogiuri G, di Somma C, <i>et al.</i> Association between Mediterranean diat and hand arin attant th in older a dult warran. <i>Clin Netr</i> 2010; 29 ;721–0
27	606 607		diet and hand grip strength in older adult women. <i>Clin Nutr</i> 2019; 38 :721–9. doi:10.1016/J.CLNU.2018.03.012
28		20	
29	608 609	38	Martínez-González MA, García-Arellano A, Toledo E, <i>et al.</i> A 14-item
30	610		Mediterranean diet assessment tool and obesity indexes among high-risk subjects: the PREDIMED trial. <i>PLoS One</i> 2012;7.
31 32	611		doi:10.1371/JOURNAL.PONE.0043134
33	612	39	Schröder H, Fitó M, Estruch R, <i>et al.</i> A Short Screener Is Valid for Assessing
34	613	57	Mediterranean Diet Adherence among Older Spanish Men and Women. <i>The</i>
35	614		Journal of Nutrition 2011; 141 :1140–5. doi:10.3945/jn.110.135566
36	615	40	Papadaki A, Johnson L, Toumpakari Z, <i>et al.</i> Validation of the English Version
37 38	616		of the 14-Item Mediterranean Diet Adherence Screener of the PREDIMED
39	617		Study, in People at High Cardiovascular Risk in the UK. Nutrients 2018;10.
40	618		doi:10.3390/nu10020138
41	619	41	Kvamme JM, Holmen J, Wilsgaard T, et al. Body mass index and mortality in
42	620		elderly men and women: the Tromso and HUNT studies. <i>J Epidemiol Community</i>
43	621		Health (1978) 2012;66:611–7. doi:10.1136/JECH.2010.123232
44 45	622	42	Bull SB, Mak C, Greenwood CMT. A modified score function estimator for
46	623		multinomial logistic regression in small samples. Computational Statistics &
47	624		Data Analysis 2002;39:57-74. doi:https://doi.org/10.1016/S0167-
48	625		9473(01)00048-2
49 50	626	43	Hernández Mendo A, Villaseñor A, Pastrana Brincones J, et al. SAGT: New
50 51	627		software for generalizability analysis. Revista Iberoamericana de Psicología del
52	628		<i>Ejercicio y el Deporte</i> 2016; 11 :77–89.
53	629	44	Anguera MT, Portell M, Chacón-Moscoso S, et al. Indirect Observation in
54	630		Everyday Contexts: Concepts and Methodological Guidelines within a Mixed
55	631		Methods Framework. Frontiers in Psychology 2018;9.
56 57	632	F 1 -	doi:10.3389/fpsyg.2018.00013
57 58	633	[data	aset] 45 Marcos-Pardo PJ, Abelleira-Lamela T, Vaquero-Cristóbal R, <i>et al.</i> Data
59	634		from: Changes in life satisfaction, depression, general health and sleep quality of
60	635		Spanish older women during Covid-19 lockdown and their relationship with

1			
2 3	(2)		life stales an abar motion of fully service at the 2022 Denied Divited Deniet and
4	636		lifestyle: an observational follow-up study. 2022. Dryad Digital Repository,
5	637	10	January 11, 2022. https://doi.org/10.5061/dryad.rfj6q57cp
6	638	46	Zhang SX, Wang Y, Rauch A, <i>et al.</i> Unprecedented disruption of lives and work:
7	639		Health, distress and life satisfaction of working adults in China one month into
8	640		the COVID-19 outbreak. <i>Psychiatry Res</i> 2020; 288 .
9	641		doi:10.1016/J.PSYCHRES.2020.112958
10 11	642	47	Benke C, Autenrieth LK, Asselmann E, et al. Lockdown, quarantine measures,
12	643		and social distancing: Associations with depression, anxiety and distress at the
13	644		beginning of the COVID-19 pandemic among adults from Germany. <i>Psychiatry</i>
14	645		<i>Res</i> 2020; 293 . doi:10.1016/J.PSYCHRES.2020.113462
15	646	48	Karageorghis CI, Bird JM, Hutchinson JC, et al. Physical activity and mental
16	647		well-being under COVID-19 lockdown: a cross-sectional multination study.
17	648		BMC Public Health 2021;21:1–13. doi:10.1186/S12889-021-10931-
18	649		5/FIGURES/4
19 20	650	49	Fountoulakis KN, Apostolidou MK, Atsiova MB, et al. Self-reported changes in
20	651		anxiety, depression and suicidality during the COVID-19 lockdown in Greece. J
22	652		Affect Disord 2021;279:624–9. doi:10.1016/J.JAD.2020.10.061
23	653	50	Müller F, Röhr S, Reininghaus U, et al. Social Isolation and Loneliness during
24	654		COVID-19 Lockdown: Associations with Depressive Symptoms in the German
25	655		Old-Age Population. Int J Environ Res Public Health 2021;18.
26	656		doi:10.3390/IJERPH18073615
27	657	51	di Santo SG, Franchini F, Filiputti B, et al. The Effects of COVID-19 and
28	658		Quarantine Measures on the Lifestyles and Mental Health of People Over 60 at
29 30	659		Increased Risk of Dementia. Front Psychiatry 2020;11.
31	660		doi:10.3389/FPSYT.2020.578628
32	661	52	Schwan J, Sclafani J, Tawfik VL. Chronic Pain Management in the Elderly.
33	662	• -	Anesthesiol Clin 2019; 37 :547–60. doi:10.1016/J.ANCLIN.2019.04.012
34	663	53	Tsang A, von Korff M, Lee S, <i>et al.</i> Common chronic pain conditions in
35	664	00	developed and developing countries: gender and age differences and comorbidity
36	665		with depression-anxiety disorders. <i>J Pain</i> 2008; 9 :883–91.
37	666		doi:10.1016/J.JPAIN.2008.05.005
38 39	667	54	Rolandi E, Vaccaro R, Abbondanza S, <i>et al.</i> Loneliness and Social Engagement
40	668	54	in Older Adults Based in Lombardy during the COVID-19 Lockdown: The Long-
41	669		Term Effects of a Course on Social Networking Sites Use. Int J Environ Res
42	670		<i>Public Health</i> 2020; 17 :1–12. doi:10.3390/IJERPH17217912
43	670 671	55	Zhao ZY, Zhu YZ, Xu JW, <i>et al.</i> A five-compartment model of age-specific
44	671 672	55	transmissibility of SARS-CoV-2. Infectious Diseases of Poverty 2020;9:1–15.
45			
46	673	56	doi:10.1186/S40249-020-00735-X/FIGURES/11
47	674	56	Salman D, Beaney T, E Robb C, <i>et al.</i> Impact of social restrictions during the
48 49	675		COVID-19 pandemic on the physical activity levels of adults aged 50-92 years: a
50	676		baseline survey of the CHARIOT COVID-19 Rapid Response prospective cohort
51	677		study. <i>BMJ Open</i> 2021; 11 . doi:10.1136/BMJOPEN-2021-050680
52	678	57	Janssen X, Fleming L, Kirk A, <i>et al.</i> Changes in Physical Activity, Sitting and
53	679		Sleep across the COVID-19 National Lockdown Period in Scotland.
54	680		International Journal of Environmental Research and Public Health 2020, Vol
55	681		17, Page 9362 2020;17:9362. doi:10.3390/IJERPH17249362
56	682	58	Sadarangani KP, de Roia GF, Lobo P, et al. Changes in Sitting Time, Screen
57	683		Exposure and Physical Activity during COVID-19 Lockdown in South American
58 59	684		Adults: A Cross-Sectional Study. International Journal of Environmental
60			
50			

1		
2		
3	685	Research and Public Health 2021, Vol 18, Page 5239 2021;18:5239.
4	686	doi:10.3390/IJERPH18105239
5	687	di Santo SG, Franchini F, Filiputti B, <i>et al.</i> The Effects of COVID-19 and
6	688	Quarantine Measures on the Lifestyles and Mental Health of People Over 60 at
7	689	
8		Increased Risk of Dementia. <i>Frontiers in Psychiatry</i> 2020; 11 :1052.
9	690	doi:10.3389/FPSYT.2020.578628/BIBTEX
10 11	691	60 Psaltopoulou T, Sergentanis TN, Panagiotakos DB, et al. Mediterranean diet,
12	692	stroke, cognitive impairment, and depression: A meta-analysis. Annals of
13	693	Neurology 2013;74:580–91. doi:10.1002/ANA.23944
14	694	61 Kass L, Desai T, Sullivan K, <i>et al.</i> Changes to Physical Activity, Sitting Time,
15	695	Eating Behaviours and Barriers to Exercise during the First COVID-19
16	696	"Lockdown" in an English Cohort. Int J Environ Res Public Health 2021;18.
17	697	doi:10.3390/IJERPH181910025
18	698	62 Meyer J, Herring M, McDowell C, <i>et al.</i> Joint prevalence of physical activity and
19	699	sitting time during COVID-19 among US adults in April 2020. Prev Med Rep
20	700	2020; 20 . doi:10.1016/J.PMEDR.2020.101256
21	701	63 Veronese N, Stubbs B, Noale M, <i>et al.</i> Adherence to the Mediterranean diet is
22 23	702	associated with better quality of life: data from the Osteoarthritis Initiative. Am J
23 24	702	<i>Clin Nutr</i> 2016; 104 :1403–9. doi:10.3945/AJCN.116.136390
25	703	Cun Ivun 2010,104.1405 7. doi:10.5745/145CIV.110.150570
26	704	
27	705	Figure legends
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ClinicalTrials. gov PRS Protocol Registration and Results System

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		Clinica	alTrials.gov PRS DRAFT Receipt (Working Version) Last Update: 07/01/2021 04:49
-			ClinicalTrials.gov ID: NCT04958499
	Study Identific	cation	
		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:	
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		-	July 15, 2021 [Anticipated]
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		Study Completion:	September 30, 2021 [Anticipated]
	Sponsor/Colla	borators	
		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
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	U.S.	FDA-regulated Drug:	No
	U.S. FI	DA-regulated Device:	No
		U.S. FDA IND/IDE:	No
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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

(SPPD). Sarcopenia will be assessed taking into account the reference values established for muscle quality (Index Pash and 40 meter value) established by the European Consensus (EWGSOP2). The Spinal Mouse device (Switzerland) will be used to assess the sagital disposition of the spine (horacic curve, lumbar curve and petvici thi) in standing and relaxed stiting. This technique is non-invasive. Heatth-related quality of the and satisfaction with life will be assessed by means of the SF36 and The Satisfaction with life Scale (SWL) questionnaires. Mediterranean dist adherence will be assess with a Mediterranean dist adherence questionaire. Experimental group 1 will receive the exercise program on bio-healthy mechnicers questionaire. Experimental group 1 will receive the exercise program on bio-healthy mechnices used will be rider; low gemini, high gemini, walk, botoms, flywheels crides, flywheels cri	Pao	e 25 of 34	BMJ Open
In the Spinal Mouse device (Switzerland) will be used to assess the sagittal disposition of the spine (throad: curve, lumbar curve and pelvic tilt) in standing and relaxed sitting. This technique is non-invasive. Health-related quality of life and salisfaction 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 drive, low gennih, high gennih, walk, botoms, flywheels circles, flywheels rotation, twin swing, surf, swing press and rowing. Intensity will be curved in 51 of minutes. The intervention programs will be developed by a graduate in Physical Activity and Sport Sciences. The load will be developed by a graduate in 51 of minutes. The intervention programs will be developed by a graduate in 51 of 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 Adult Disease Keywords: Adults Older Physical activity. Exercise Bio-healthy park Training 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 Assesso	1 2		(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
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 direr, low gemini, high gemin, waik, bottoms, flywheets crickes, flywheets, cric	5 6		disposition of the spine (thoracic curve, lumbar curve and pelvic tilt) in standing
Mediterranean diet adherence questionaire. 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. 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 program following their usual activity. Conditions Keywords: Adult Disease Keywords: Adult Disease Study Design Study Type: Study Design Study Type: Study Model Parallel Assignment Number of Arms: 2 Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) Allocation: Randing (Participant, Care Provider, Investigator, Outcomes Assessor) Allocation: Randing (Participant, Care Provider, Investigator, Outcomes Assessor) Allocation: Randing (Participant, Care Provider, Investigator, Outcomes Assessor) Allocation:	8 9		
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53 Arms and Interventions 54 Arms 55 Arms 56 Experimental: Bio-Healthy Park 57 Behavioral: Bio-healthy Park			
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56 Experimental: Bio-Healthy Park Behavioral: Bio-healthy Park 57		Arms	Assigned Interventions
		Experimental: Bio-Healthy Park	Behavioral: Bio-healthy Park
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	BMJ C	Page 2
	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.
N	lo Intervention: Control Adults and older assigned to the control group will not received any structured exercise programme. They will maintain their usual physical activities.	
Outco	ome Measures	
Prim	ary Outcome Measure:	
1.	quality will be measure by hand grip strength test. This	erence values established for muscle quality. The muscle test will be performance with manual dynamometry (TKK 540 I isometric upper limb strength will be performance by maxim ogrammes. Higher value show high strength.
	[Time Frame: Changes from baseline to 8 weeks]	
	ondary Outcome Measure:	
2	 Change Body composition Body composition will be assessed by dual energy X-ra result will be register in absolutes and percentages result 	y absorptiometry (DEXA). This is noninvasive technique. The Ilts.
	[Time Frame: Changes from baseline to 8 weeks]	
3		ns of an automatic device (Colin BP 880, Inc., Tampa, FL). T nillimeters of mercury (bood pressure) and number of pulse p
	[Time Frame: Changes from baseline to 8 weeks]	
4.		s a easy physical test. This test measures the functionality of participant have to performance the test as faster as possible cates better functional ability.
	[Time Frame: Changes from baseline to 8 weeks]	
5		nce by maximal isometric strength of knee extension and bic be registered in newton. Higher value show high strength.
	[Time Frame: Changes from baseline to 8 weeks]	
6	. Change Sagittal spinal curvature	

Pag	ge 27 of 34 BMJ Open	
1	Sagittal spinal curvature will be assess with the Spinal Mouse device (Switzerland). It will be mea dorsal and lumbar curve and pelvic tilt when standing and in asthenic sitting. This is noninvasive is register in grades.	
2 3	[Time Frame: Changes from baseline to 8 weeks]	
4 5 6 7 8	7. Health-related quality Health-related quality of life will be assessed by means of the Short Form 36 questionaire. This of questions and show result for 9 area: physical role, pain, general health, vitality, social function, e health, and evolution of the health care system. Each area is reported from 0 to 100 point. Highe better health-related quality.	emotional role, mental
9 10	[Time Frame: Changes from baseline to 8 weeks]	
11		
12 13 14	participant have to answers from strongly agree to strongly disagree. The final score is reported Higher value show better satisfaction with life.	
15 16	[Time Frame: Changes from baseline to 8 weeks]	
17 18 19 20 21	It will be used the Adherence to the Mediterranean diet. This questionaire have 14 questions (ye about their adherence to the mediterranean diet. The sum of the answers are collect. Higher sco adherence to mediterranean diet.	
22	[Time Freme, Changes from baseling to Quesks]	
23 24 25 26	Functional competence 400 meter walk is a test included in the European Consensus (EWGSOF sarcopenia. Participant have to walk as fast as possible 400 meter. The total time is register.	2) to measure
20	[Time Frame, Changes from baseling to Queska]	
28 29 30 31	Bone mineral density will be assessed by dual energy X-ray absorptiometry (DEXA). This is noni The result will be register in absolutes and percentages results.	nvasive technique.
32	IT is a France of the second france is a structure in the second se	
33 34 35 36	Heart rate will be assessed by means of an automatic device (Colin BP 880, Inc., Tampa, FL). The technique. The result will be register in number of pulse per minutes (heart rate).	is is noninvasive
37		
38 39 40 41	Gait speed will be measure by 4. 6 and 10 meter test. This is easy physical test in with the partic and 10 metres as faster as possible. The result will be register in seconds. Less time indicates be	•
42		
43 44 45 46 47	Time up and go test measure the functional capacity of getting up, walking and sitting down form have to performance this test as faster as possible. This is a easy physical test. Total seconds ar seconds indicates better functional ability.	
48	[Time Frame: Changes from baseline to 8 weeks]	
49 50 51 52 53 54	Short physical performance battery (SPBB) include three test (balance, chair stand test and gait final score. Chair stand test and gait speed were describe in other outcome. Balance test is a ear participant must maintain three balancing positions for 10 seconds to overcome it. Each test offe Higher score show better functional capacity.	sy physical test. The
55	[Time Frame: Changes from baseline to 8 weeks]	
56 57		
58 59 60		

Page	28	of	34
rage	20	UI.	5

BMJ Open 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

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6		
7	Minimum Age:	50 Years
8 9	Maximum Age:	
10	Sex:	ΔΙΙ
11		
12	Gender Based:	
13 14	Accepts Healthy Volunteers:	Yes
15	Criteria:	Inclusion Criteria:
16		 not having participated in a structured exercise program for at least 1 year;
17		 being older than 50 years of age
18 19		 being physically independent.
20		Exclusion Criteria:
21		 having musculoskeletal injuries or limitations that could affect the person's
22 23		health and physical performance
24		 being under medical prescription for taking medications that could influence a busical approximation
25		influence physical performancenot regularly attending the proposed sessions.
26		not regularly attending the proposed bescienc.
27 28		
29	Contacts/Locations	
30	Central Contact Person:	Pablo Jorge Marcos-Pardo, PhD
31 32		Telephone: 696243274
33		Email: pjmarcos@ual.es
34	Central Contact Backup:	Noelia Gonzalez-Galvez, PhD
35 36		Telephone: 627146613 Email: ngonzalez@ucam.edu
37		
38	Study Officials:	Pablo Jorge Marcos-Pardo, PhD Study Principal Investigator
39		Universidad de Almería
40 41		
42		Noelia Gonzalez-Galvez, PhD Study Principal Investigator
43		UCAM
44 45		
46	Locations:	Spain
47		Pablo Jorge Marcos-Pardo
48		Murcia, Spain Contact: Pablo Jorge Marcos-Pardo, PhD 696243274 pjmarcos@ual.es
49 50		Contact: Noelia Gonzalez-Galvez, PhD 627146613 ngonzalez@ucam.edu
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53 54	IPDSharing	
55	Plan to Share IPD:	No
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Page 29 of 34

BMJ Open

Pag	ge 29 of 34	BMJ Open
	References	
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1	Citations:	
2		NOTE : Either PubMed ID or Citation Text should be specified.
3		
4	Links:	
5 6	Available IPD/Information:	
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COMITÉ DE ÉTICA DE LA UCAM

DATOS DEL PROYECTO

Título:	maquinaria	ia Bio-saludable Inteligente: Dis de fitness outdoor ergonómica para dispositivos móviles (App) nto"	, eficiente, saludable y con
Investigad	lor 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	V
en humanos	А
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

BMJ Open



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		

V° B° El Presidente,

1. Maiera

Fdo.: José Alberto Cánovas Sánchez

El Secretario,

Fdo.: José Alarcón Teruel

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COMITÉ DE ÉTICA DE LA UCAM

Código

CE052002

DATOS DEL PROYECTO

salud psico		9 y aislamiento social: Efectos sobre la condición física y la -fisiológica en adultos mayores"		
Investigado	or Principal	Nombre	Correo-e	
Dr.		Pablo Jorge Marcos Pardo	pmarcos@ucam.edu	

INFORME DEL COMITÉ

Fecha	29/05/2020
A COMMON	

Tipo de Experimentación

Investigación experimental clínica con seres humanos	
	C. D. Barrison and C. Brand, Str. P.
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	v
en humanos	Λ
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





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	R. A. M.	
Subsanación	19 10 M	
MOTIVACIÓN		
Incrementará conocimientos en su área		

Vº Bº El Presidente,

Mairos

Fdo.: José Alberto Cánovas Sánchez

El Secretario, MITE DE Fdo.: José Alarcón Teruel

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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	1
		abstract	
		(b) Provide in the abstract an informative and balanced summary of what was	1
		done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being	2-3
		reported	
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	3-4
		recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods	3
		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	
		(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	3-4
		effect modifiers. Give diagnostic criteria, if applicable	-
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	3-4
measurement	-	assessment (measurement). Describe comparability of assessment methods if	
		there is more than one group	
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	4-5
		applicable, describe which groupings were chosen and why	
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for	4-5
		confounding	
		(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	4-5
		<i>Case-control study</i> —If applicable, explain how nots to follow-up was addressed	- r -J
		controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking	
		account of sampling strategy	
			1 5
Continued on next page		(\underline{e}) Describe any sensitivity analyses	4-5

Continued on next page

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Results			Pag
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially	3
		eligible, examined for eligibility, confirmed eligible, included in the study, completing	
		follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	3
		(c) Consider use of a flow diagram	3
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and	5
data		information on exposures and potential confounders	
		(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
		<i>Case-control study</i> —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	5
		their precision (eg, 95% confidence interval). Make clear which confounders were	
		adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	5
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a	5
		meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and sensitivity	5
		analyses	
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	8
		imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,	6-7
		multiplicity of analyses, results from similar studies, and other relevant evidence	8
Generalisability	21	Discuss the generalisability (external validity) of the study results	6-7
			8
Other information	on		
Funding	22	Give the source of funding and the role of the funders for the present study and, if	2
-		applicable, for the original study on which the present article is based	

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.