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Original article

The effectiveness of a program of physical activity and diet to modify cardiovascular risk factors in patients with severe mental illness after 3-month follow-up: CAPiCOR randomized clinical trial

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ABSTRACT

Background: The aim of this randomized clinical trial follow-up at three months was to evaluate the effectiveness of an educational intervention with a focus on diet and physical activity (PA) to change the amount of PA, body mass index (BMI) and the waist circumference (WC) in patients with severe mental illness.

Methods: We recruited 332 outpatients with severe mental disorders undergoing treatment with antipsychotic medication from Mental Healthcare Centers of Barcelona. They were randomly assigned to an intervention or a control group. The patients in the intervention group participated in a group PA and diet educational program. The blinded measurements at 0 and 3 months were: the level of PA (IPAQ questionnaire), BMI, WC, blood pressure, dietary habits (PREDIMED questionnaire), quality of life (SF-36 questionnaire) and laboratory parameters (cholesterol, triglycerides, glucose).

Results: The average age was 46.7 years and 55% were males. Schizophrenia had been diagnosed in 67.1% of them. At 3 months, the average weekly walking METs rose significantly in the IG 266.05 METs (95%CI: 16.86 to 515.25; $P = 0.036$). The total MET average also rose although not significantly: 191.38 METs (95%CI: 1.38 to 381.38; $P = 0.086$). However, the BMI decreased significantly more in the CG, by 0.26 kg/m^2 (95%CI: 0.02 to 0.51; $P = 0.038$), than in the IG. There were no significant differences in the WC.

Conclusions: The short-term results suggest that the intervention increases the level of PA, but does not improve physical or laboratory parameters.

Trial registration: Clinicaltrials.gov NCT01729650 (effectiveness of a physical activity and diet program in patients with psychotic disorder [CAPiCOR]).

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1. Introduction

Patients with a severe mental disorder (SMD), such as schizophrenia, schizoaffective and bipolar disorders, have a significantly higher presence of cardiovascular risk factors (CVRF) [5,28]. They also present with a decreased life expectancy of between 10 and 25 years despite being a predominantly young population [21].

This increased risk is due to the interaction of multiple etiological factors [6]: genetic predisposition [3], environmental factors due to unhealthy lifestyles [8] and the increasingly evident contribution of antipsychotic drugs to metabolic disorders [2].

The role of obesity and sedentarism relative to cardiovascular risks has been well documented (Framingham Heart Study) [29]. Obesity, predominately abdominal type obesity, and being overweight are two to three times more prevalent in patients with psychotic disorders [4,28].

Interventions that have proven effective in patients with psychosis have been carried out to decrease the cardiovascular risk, but those that aimed at reducing body weight or increasing the level of PA are less conclusive due to the small number of studies included, the small sample size or the heterogeneity of the variables collected [12,19,36]. Nevertheless, all these reviews suggested some benefit from these interventions.

Daumit et al. recently conducted an intervention with almost 300 SMD patients, which revealed a significant decrease in weight at 18 months in the intervention group [10]. Moreover, Fernández-San-Martín et al. presented the results of a meta-analysis that included 20 studies. It demonstrated that interventions to modify lifestyles improve anthropometric and clinical parameters at 3 months. At 6 and 12 months, the difference measurements between the control and intervention groups were maintained although it was with greater variability [14]. Firth et al. has just published a meta-analysis that included a total of 17 trials that evaluated the effect of exercise on physical and mental variables. This review concluded that although there were no reductions in body weight or BMI, moderate to vigorous exercise can improve other CVRF parameters, physical fitness and psychiatric symptoms [15].

The collaboration of the Primary Care Team (PCT) and Mental Health Team (MHT) is essential to developing physical care activities and health promotion programs as well as to improving on caregiving for patients with psychosis [39]. The recommendations in the literature contemplate improved CVRF monitoring in these patients and establishing channels of close collaboration between mental health professionals and the PCT as the primary aims [30,32]. Our group initiated a collaborative study between seven PCT and three reference MHT outpatient centers from which a joint protocol for monitoring CVRF emerged [38].

An interest in improving the physical health of patients with psychosis has led to the present randomized clinical trial. The main objective is to evaluate the effectiveness of an intervention based on a program of PA and diet, coordinated between PCT and MHT, to change the weekly PA level, BMI and WC in patients with schizophrenia and schizoaffective or bipolar disorders.

The secondary objective is to evaluate the effectiveness of this intervention in modifying blood pressure, dietary habits, quality of life as well as plasma cholesterol and blood sugar levels. We present the results at 3 months from a randomized clinical trial that will last one year.

2. Methods

2.1. Study oversight

The project was assessed and approved by the CEIC, the ethical committee of the Primary Healthcare-University Research Institute IDIAP Jordi Gol, with registration number P11/64. All the enrolled patients were informed verbally and in writing of the objectives, methodology, tests and interventions that they would receive if they participated in the study. In case of disability, it was signed by the legal guardian of the patient.

All the authors participated in the conception and design of the study as well as in revising the article and the final report.

The study was conducted in accordance with the study protocol [27].

2.2. Setting and study population

We conducted a randomized clinical trial (RCT) with a control group with one-year follow-up. The 3-month results, which are compared to baseline measurements in the intervention group (IG) and control group (CG), are presented in this paper.

A total of 332 patients (18–65 years of age), who had signed informed consent, were recruited from 10 public MHTs. Those teams provide mental health care to a population of about 415,000 inhabitants in the metropolitan area of Barcelona. The patients had been diagnosed with a schizophrenic, schizoaffective or bipolar disorder and had been undergoing treatment with an antipsychotic drug for at least 3 months prior to enrollment. They also had low PA levels (short version of the International Physical Activity Questionnaire, IPAQ) [9], BMI values equal to or greater than 25 (it includes overweight and obese patients) [33], have resided in the reference area for a minimum of one year and have a knowledge of the Spanish language.

Those patients who had any contraindication for PA (a severe acute physical illness) [23], an episode of acute mania or a psychotic state one month before enrollment, a drug dependence with active consumption (except nicotine) were excluded. Pregnancy or breastfeeding and those not seen by the MHT or by the PCT in the year prior to inclusion in the study were also excluded.

The professionals from each MHT recruited participants from among those visited in their centers over a 2 to 4 months period (according to the center). The recruitment was carried out at regular scheduled visits. The MHTs started participating at different times. The first MHT started in March, 2012 and the last in March, 2014. The assessment criteria for inclusion/exclusion was confirmed by the patients' psychiatrists. The distribution was randomized by a computer program run by a researcher external to the professional recruiters. Half of the patients in each center were assigned to the IG and the other half to the CG. Recruitment was discontinued when 30 patients had been enrolled.

The sample size for each of the main measurements was calculated and the one resulting in the largest sample size (the BMI) was chosen. Accepting an alpha risk of 0.05 and a beta risk of 0.20 in a bilateral contrast, it would be necessary to study 478 subjects (239 subjects in the IG and 239 in the CG) to detect a difference equal to or greater than 1.16 kg/m^2 in the BMI [31]. It was assumed that the common standard deviation would be 6.2. A loss rate of 30% at follow-up was estimated.

2.3. Control group

The subjects assigned to the CG followed the usual program of regular check-ups with their reference psychiatrist (usually every two months, if no decompensation was observed) and continued the treatment prescribed for their disease.

2.4. Intervention group

The IG subjects went through an educational program and followed a PA program based on different stages as well as dietary

intervention in groups with a maximum of 15 people. The intervention was designed by mental health and primary care nurses and physicians.

All the professional participants and evaluators received training beforehand. Professionals who carried out the intervention also worked on motivation in terms of both physical activity and diet to achieve the desired changes and objectives.

The PA intervention consisted of 24 sessions (twice weekly) carried out over 3 months in different periods of the year, depending on the center. However, it was never done in summer so as to avoid the heat. The first 8 sessions (40 minutes) were carried out in the MHC and consisted of making first contact with PA (intensity, recommendations for safe practices, etc.) and pedometers. Those sessions were conducted by mental health nurses. The aim of the other 16 sessions (60 minutes), which were done in the streets around the MHC, was to increase the number of daily steps taken to reach 10,000 steps per day on routes adapted to the physical condition of the subjects and guided by the MHT. At the end of the intervention, pedometers, routes and recommendations and strategies to continue maintaining the total number of steps taken were handed out to the patients.

The dietary intervention consisted of 16 sessions (twice weekly) of 20 minutes duration to provide basic knowledge on healthy dietary habits (based on a traditional Mediterranean diet for cardiovascular protection). This was done by the nurses from the MHT or PCT centers. A diary of foods consumed in the prior 24 hours was reviewed to determine the knowledge acquired in each session by the patients.

All the subjects, in both the IG and CG, kept up their usual visits with their reference mental health professional and continued the usual treatment for their disease.

2.5. Data collection and follow-up

The randomized assignment and the collection of information by interviewers (psychologists and mental health nurses) were carried out blind. The evaluation of the response variable was done blind at 0 and 3 months. At three months, the intervention ended and its effect up to that point was evaluated.

The anthropometric measures were the BMI in kg/m^2 (a quantitative variable and a qualitative variable of two categories: $\geq$30 and the others [33]), the waist circumference in cm (considering pathological values: >101 cm in men and >87 cm in women) and blood pressure. The laboratory parameters were glucose, triglycerides and cholesterol (mg/dl). For lifestyle characteristics, we used the International Physical Activity Questionnaire (IPAQ) adapted to Spanish [9] for the assessment of PA as a continuous variable by calculating metabolic equivalent units (METs) expended per week and as a categorical variable. The subjects were classified according to their PA level as either low, moderate or high (in this variable, we differentiate the total weekly METs and the walking weekly METs). The PREDIMED questionnaire, a 14-item Mediterranean diet fulfillment questionnaire [26], was used for dietary habits. It scores from 0 to 14 points from minimum to maximum compliance and considers 9 as the cutoff point [11]. Quality of life was evaluated with the SF-36, a 36 item questionnaire that detects states of positive and negative health and explores physical and mental health with eight dimensions of the health status as well as the variables of the physical and mental composite summaries [37]. We also used the Clinical Global Impression Scale to measure the severity of and change in symptoms due to therapeutic interventions [17].

2.6. Statistical analysis

Analyses were conducted according to the intention to treat principle. Missing data was replaced by using the Last Observation Carried Forward (LOCF). All patients who signed informed consent as well as those who did the initial assessment were included.

Primary outcomes were: the PA level (assessed with the IPAQ [9]), BMI and the WC. The secondary outcomes were blood pressure, glucose, triglycerides and total cholesterol along with the PREDIMED and SF-36 questionnaires [26,37].

Descriptive statistics were calculated for the dependent, confounding and general variables for both the IG and the CG. The homogeneity of the two groups for these variables at baseline was also checked. In all cases, a bilateral alpha of 0.05 was considered an error and confidence intervals were calculated at 95%. An outcome variable was calculated for 3 months, which is the difference between the result of all the variables at each cutoff and the initial value for each individual. The differences between groups were evaluated and the 95% confidence interval of the difference was calculated.

For the comparison of differences between the groups' variables, the Student-t test was used. In the event that the variables did not follow a normal distribution, we applied the Mann-Whitney test. The effect size was evaluated with the standardized effect size (SES) [20]. The SES is calculated as the mean difference between the intervention and the control groups, divided by the standard deviation (SD) of the control group change. The SES is a standardized measure of change that allows for a comparison between groups, between measures in the same study and between different studies. The interpretation of the SES is as follows: Values 0.2–0.5 represent small changes, 0.5–0.8 moderate changes and >0.8 big changes.

3. Results

3.1. Study participants

The flow of participants is shown in Fig. 1. Nearly 50% of patients declined to participate. Almost 87% maintained their participation at 3 months, 84% in the IG and 89% in the CG.

We included 332 participants in the study. Patients were randomized either to the IG (n = 169) or CG (n = 163). Tables 1 and 2 show the baseline IG and CG characteristics. These two groups were similar at baseline in terms of demographic and clinical characteristics except for the marital status. There were twice the number of divorced patients in the IG than in CG (P = 0.05). The average age of the participants was 46.7 years and 55% were males. Approximately two thirds of participants had been diagnosed with schizophrenia. Over 65% met the criteria for obesity and almost 85% had a high WC. Basal adherence to the Mediterranean diet was low in 85% of the participants.

3.2. Changes at 3 months

Some 49% of patients attended at least 60% of the sessions (Table 3). A total of 21 patients (6.3%) did not attend any session, while 3 patients attended all the sessions. Attendance in sessions in the center (including the focus on diet and the exercises inside the center) was 58.0%. On the other hand, attendance in walking sessions outside the center was 42.6% (P = 0.006).

Table 4 shows the changes in the results of the baseline and three month variables, within and between the IG and the CG. With regard to the primary outcomes, what stands out is a statistically significant increase in the IG walking METs (P = 0.036). At 3 months, those increase on average 186.34 METs (95%CI: 14.80 to 357.88),

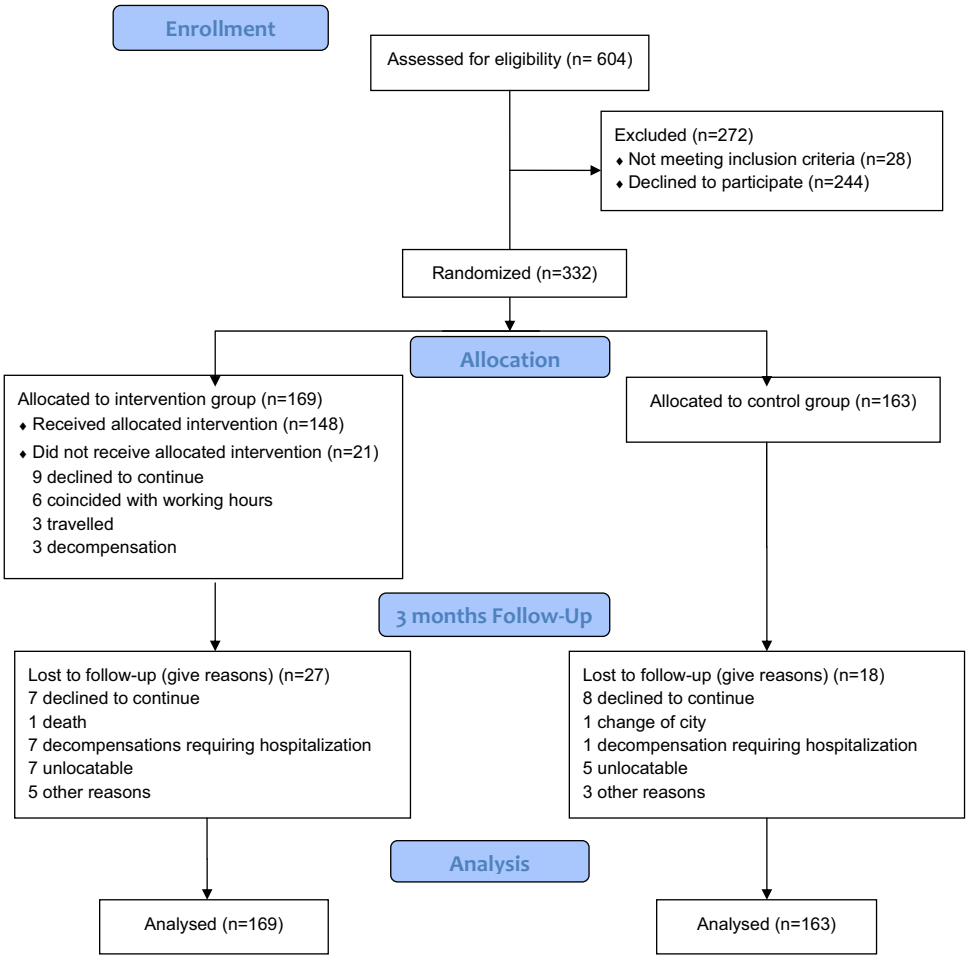

Fig. 1. Flow chart of participants.

while the CG METs decreased −79.71 (95%CI: −262.02 to 102.60). Although the difference is not statistically significant ($P = 0.086$), the total METs also increased more in the IG (mean METs: 191.38; 95%CI: 1.38 to 381.38) than in the CG (mean METs: −48.09; 95%CI: −246.46 to 150.29). These results were also analyzed depending on whether patients came to roughly 60% of sessions (14/24), but neither were these differences statistically significant. The average increase in walking METs in those who attended less than 60% of the sessions was 126.24 METs (SD: 920.64) and almost double in patients who attended more than 60% of the sessions with 250.15 METs (SD: 1306.60). However, it was not significant ($P = 0.201$). The MET total rose an average 115.40 METs (SD: 1091.62) in those who attended less than 60% of the sessions and more than double in those who attended more than 60% with 271.11 (SD: 1380.78). This was not statistically significant ($P = 0.176$), either.

The BMI decreased more and in a statistically significant manner in the CG (−0.23 kg/m^2; 95%CI: −0.39 to −0.07) than in the IG (0.04 kg/m^2; 95%CI: −0.15 to 0.22). There were no significant differences in the median change of the BMI in the IG relative to session attendance ($P = 0.18$): −0.09 (95%CI: −0.31 to −0.13) in those who attended less than 60% and 0.16 (95%CI: 0.15 to 0.48) in those who attended 60% or more of the sessions.

No significant differences were found in the WC or the Mediterranean diet adherence score (PREDIMED) although both groups saw an increase in the latter.

Of the analytical parameters, there was only a statistically significant decrease in the average CG glucose (CG: −2.43 mg/dl; 95%CI: −4.68 to −0.18 and IG: 1.36 mg/dl; 95%CI: −1.35 to 4.06).

The clinical evaluation of the mental state of the patients, measured with the CGI, was not modified in either of the two groups. The median change in the CGI score was −0.16 (−0.32 to −0.01) in the CG and −0.06 (−0.19 to 0.07) in the IG.

Table 5 shows the changes in quality of life. Of the 8 dimensions that the SF-36 analyzes, significant differences in favor of IG in the average physical function score were found (IG: 3.39; 95%CI: 1.29 to 5.50 and CG: 0.43; 95%CI: −1.46 to 2.32). The social function (IG: 0.82; 95%CI: −3.22 to 4.86 and CG: 7.29; 95%CI: 3.26 to 11.31) and the emotional role (IG: −0.05; 95%CI: −3.78 to 3.68 and CG: 6.39; 95%CI: 2.14 to 10.65) saw a score increase in the CG. The physical component significantly improves in the IG (IG: 1.83; 95%CI: 0.70 to 2.95 and CG: 0.24; 95%CI: −0.74 To 1.22) and the mental component in the CG (IG: −0.39; 95%CI: −1.97 to 1.19 and CG: 2.19; 95%CI: 0.58 to 3.81) in the variables summary.

4. Discussion

The SMD patients who participated in a program of PA and diet coordinated between the PCT and MHT to improve cardiovascular risk factors saw a significant increase in their level of weekly physical activity. Despite this, the increase of PA did not translate into an improvement in the physical and analytical parameters.

The increase in PA related to walking was the parameter that showed a greater difference, increasing almost 190 METs in the IG. However, it declined by nearly 80 METs in the CG with respect to baseline. This demonstrates the effectiveness of the intervention to enhance PA in SMD patients although the effect size was small.

Table 1
Socio-demographic and clinical baseline characteristics of the study participants[a].

	Intervention group ($n=169$)	Control group ($n=163$)
Socio-demographic characteristics		
Age (years), mean (SD), $n=332$	46.3 ± 8.9	47.1 ± 9.9
Sex, *n* (%)		
Female	76 (45.0)	74 (45.4)
Male	93 (55.0)	89 (54.6)
Marital status, *n* (%)*		
Never married	100 (59.1)	105 (64.4)
Married or with a partner	28 (16.6)	34 (20.9)
Widower/widow	5 (3.0)	7 (4.3)
Divorced or separated	36 (21.3)	17 (10.4)
Educational level, *n* (%)		
Illiterate + can read	8 (4.8)	9 (5.5)
Primary studies	60 (36.4)	61 (37.7)
Secondary studies	82 (49.7)	68 (42.0)
Universitary education	15 (9.1)	24 (14.8)
Property type, *n* (%)		
Own home	50 (30.1)	46 (28.8)
Family home	92 (55.4)	89 (55.6)
Residential program or guardianship	24 (14.5)	26 (15.6)
Employment status, *n* (%)		
Able to work	27 (16.0)	32 (19.6)
Unable to work	142 (84.0)	131 (80.4)
Country of origin, *n* (%)		
Spain	157 (95.2)	155 (96.3)
Others	8 (4.8)	6 (3.7)
Clinical characteristics		
Psychiatric diagnosis, *n* (%)		
Schizophrenia	111 (65.6)	112 (68.7)
Schizoaffective disorder	28 (16.6)	29 (17.8)
Bipolar disorder	30 (17.8)	22 (13.5)
Hospitalizations (last year)		
No	142 (84.0)	143 (87.7)
One or more	27 (16.0)	20 (12.3)
CGI, mean (SD), $n=329$	3.9 ± 1.1	4.1 ± 1.1
CGI, *n* (%)		
Mild	55 (32.7)	45 (28.0)
Moderate	46 (27.4)	51 (31.7)
Serious	67 (39.9)	65 (40.3)
Number of visits by PCT (last year), mean (SD), $n=329$	11.2 ± 11.4	9.9 ± 9.8
Number of visits by MHT (last year), mean (SD), $n=332$	19.8 ± 13.9	18.5 ± 12.6

SD: standard deviation; CGI: Clinical Global Impression Scale; PCT: Primary Care Team; MHT: Mental Health Team. The percentages of each variable are calculated with all patients with information for that variable, not the total number of participants.
[a] Plus-minus values are means ± SD.
* *P*-value significant ($P=0.05$).

Table 2
Baseline outcome variables of the study participants[a].

	Intervention group ($n=169$)	Control group ($n=163$)
Lifestyle characteristics		
Smokers, *n* (%)		
Yes	109 (64.5)	93 (57.1)
No	60 (35.5)	70 (42.9)
Alcohol consumption, *n* (%)		
Daily	2 (1.2)	6 (3.7)
Sporadic	46 (27.3)	47 (28.8)
No consumption	121 (71.5)	110 (67.5)
Cannabis consumption, *n* (%)		
Daily	2 (1.2)	1 (0.6)
Sporadic	6 (3.5)	1 (0.6)
No consumption	161 (95.3)	160 (98.8)
PREDIMED		
Low adherence (<9)	147 (87.0%)	135 (82.8)
High adherence (≥9)	22 (13.0%)	28 (17.2)
Total METs (weekly), mean (SD), $n=326$	1340.6 ± 1508.4	1453.5 ± 1460.6
Walking METs (weekly), mean (SD), $n=328$	1208.0 + 1471.3	1278.0 + 1281.3
Physical parameters		
BMI, *n* (%)		
<30	61 (36.1)	50 (30.7)
≥30	108 (63.9)	113 (69.3)
Waist circumference, *n* (%)		
≤87 women and ≤101 men	30 (17.9)	21 (12.9)
>87 women and >101 men	138 (82.1)	142 (87.1)
Systolic/diastolic blood pressure, *n* (%)		
<140/90	117 (70.1)	116 (71.6)
≥140/90	50 (29.9)	46 (28.4)
Laboratory parameters		
Glucose, *n* (%)		
<126	138 (90.8)	131 (89.7)
≥126	14 (9.2)	15 (10.3)
Triglycerides, *n* (%)		
<150	77 (52.7)	81 (55.9)
≥150	69 (47.3)	64 (44.1)
Total cholesterol, *n* (%)		
<240	128 (84.8)	132 (88.6)
≥240	23 (15.2)	17 (11.4)

SD: standard deviation; MET: metabolic equivalent units (from International Physical Activity Questionnaire); BMI: body mass index. The percentages of each variable are calculated with all patients with information for that variable, not the total number of participants.
[a] Plus-minus values are means ± SD.

Although the IPAQ questionnaire is validated for patients with schizophrenia [13], there are few clinical trials that use this population so as to compare those results with ours. If we compare our results with other RCTs in overweight or obese people without mental pathology [16], we found increases of up to 1000 METs post-intervention (no significant differences between the IG and CG). It might be that these interventions are more complex in patients with mental illness. However, it is important to keep the type of intervention in mind. For Fuller et al., the intervention lasts 12 months, while this one is approximately 80 minutes per week for 12 weeks. One could conclude that our intervention is of low intensity and short duration, which makes it difficult to find more consistent results. In this sense, Ter Meulen published a systematic review of patients with schizophrenia in 2012 that concluded that the most successful exercise-promoting interventions are those of moderate to high intensity [35]. On the other hand, planning early interventions, interventions from the start of treatment with anti-psychotics, to increase the effectiveness of the interventions and prevent weight increase might be the way forward so as to forestall the complications of treatment. However, the INTERACT study did not find a significant decrease in the BMI at 12 months in the patients who had received an early intervention in comparison to the CG [24]. The recently published HELPER program, applied to patients with an incipient diagnosis did not find significant reductions in the BMI in the subprogram "Encourage activity, Improve Diet, and Reduce Weight Gain [25]".

Still, the increase in PA was not reflected in other physical or analytical parameters. Some parameters even improved in the CG.

Table 3
Attended sessions for the intervention group.

Cutoff 60% assistance	*n*	%
0 to 13 sessions	86	50.9
14 to 24 sessions	83	49.1
Median	Percentile 25	Percentile 75
13	5	20

Table 4
Changes in outcomes within in each group and between the intervention and control group.

	Intervention group			Control group			Difference (95%CI) between groups (intervention group – control group)		
Characteristics	*n*	Mean (SD)	Difference (95%CI)	*n*	Mean (SD)	Difference (95%CI)	Difference (95%CI)	*P*-value	SES
Body mass index	169			163					
Pre-intervention		32.34 (6.17)			32.57 (5.35)				
3 (post-intervention)		32.38 (6.19)	0.04 (−0.15 to 0.22)		32.34 (5.44)	−0.23 (−0.39 to −0.07)	0.26 (0.02 to 0.51)	0.038	0.25
Waist circumference	168			163					
Pre-intervention		108.20 (14.38)			109.26 (12.69)				
3 (post-intervention)		109.17 (14.74)	0.98 (0.01 to 1.95)		109.25 (13.15)	−0.018 (−0.88 to 0.85)	0.99 (−0.31 to 2.30)	0.133	0.18
PREDIMED	169			163					
Pre-intervention		6.02 (2.25)			6.31 (2.26)				
3 (post-intervention)		6.75 (2.28)	0.72 (0.43 to 1.02)		6.79 (2.19)	0.47 (0.16 to 0.79)	0.25 (−0.18 to 0.68)	0.256	0.12
Total METs (weekly)	166			160					
Pre-intervention		1340.63 (1508.35)			1453.45 (1460.56)				
3 (post-intervention)		1532.01 (1539.60)	191.38 (1.38 to 381.38)		1405.36 (12431.93)	−48.09 (−246.46 to 150.29)	239.47 (−34.07 to 512.99)	0.086	0.19
Walking METs (weekly)	167			161					
Pre-intervention		1207.96 (1471.26)			1277.96 (1281.30)				
3 (post-intervention)		1394.30 (1505.37)	186.34 (14.80 to 357.88)		1198.25 (1047.73)	−79.71 (−262.02 to 102.60)	266.05 (16.86 to 515.25)	0.036	0.23
Systolic blood pressure	167			162					
Pre-intervention		125.27 (18.86)			125.76 (20.19)				
3 (post-intervention)		123.13 (16.82)	−2.14 (−4.47 to 0.18)		123.54 (18.49)	−2.22 (−4.69 to 0.24)	0.08 (−3.30 to 3.45)	0.964	0.01
Diastolic blood pressure	167			162					
Pre-intervention		80.71 (12.34)			80.99 (12.32)				
3 (post-intervention)		80.47 (10.52)	−0.25 (−2.04 to 1.55)		79.71 (11.11)	−1.28 (−2.98 to 0.41)	1.04 (−1.42 to 3.50)	0.407	0.10
Total cholesterol	151			149					
Pre-intervention		201.80 (36.75)			199.99 (38.95)				
3 (post-intervention)		202.24 (36.66)	0.44 (−3.55 to 4.43)		200.16 (36.00)	0.17 (−3.39 to 3.73)	0.27 (−5.06 to 5.60)	0.922	0.01
Glucose	152			146					
Pre-intervention		100.49 (28.19)			102.77 (28.74)				
3 (post-intervention)		101.84 (33.83)	1.36 (−1.35 to 4.06)		100.34 (26.85)	−2.43 (−4.68 to −0.18)	3.79 (0.27 to 7.30)	0.035	0.28
Triglycerides	146			145					
Pre-intervention		173.55 (158.52)			167.63 (106.81)				
3 (post-intervention)		174.53 (160.02)	0.99 (−7.93 to 9.90)		163.83 (107.67)	−3.81 (−11.22 to 3.60)	4.79 (−6.76 to 16.34)	0.415	0.11
CGI	168			161					
Pre-intervention		3.99 (1.11)			4.06 (1.07)				
3 (post-intervention)		3.93 (1.18)	−0.06 (−0.19 to 0.07)		3.89 (1.29)	−0.16 (−0.32 to −0.01)	−0.11 (−0.31 to 0.10)	0.312	−0.11

SD: standard deviation; CI: confidence interval; MET: metabolic equivalent units (from International Physical Activity Questionnaire); SES: standardized effect size.

Table 5
Changes in quality of life within each group and between the intervention and control group.

	Intervention group			Control group			Difference (95%CI) between groups (intervention group – control group)		
Characteristics	*n*	Mean (SD)	Difference (95%CI)	*n*	Mean (SD)	Difference (95%CI)	Difference (95%CI)	*P*-value	SES
Physical function	168			163					
Pre-intervention		76.88 (18.33)			77.87 (17.56)				
3 (post-intervention)		80.15 (17.73)	3.39 (1.29 to 5.50)		78.30 (16.99)	0.43 (−1.46 to 2.32)	2. 96 (0.14 to 5.78)	0.011	0.243
Role-physical	168			163					
Pre-intervention		84.18 (23.88)			83.13 (24.47)				
3 (post-intervention)		87.46 (20.88)	3.21 (−0.65 to 7.07)		86.66 (23.99)	3.53 (0.37 to 6.69)	−0.32 (−5.30 to 4.67)	0.427	−0.016
Bodily pain	168			163					
Pre-intervention		71.16 (28.48)			74.34 (25.58)				
3 (post-intervention)		74.73 (28.17)	3.60 (−0.87 to 8.06)		76.40 (27.19)	2.06 (−2.10 to 6.21)	1.54 (−4.55 to 7.63)	0.445	0.057
General health	168			163					
Pre-intervention		52.46 (23.02)			53.34 (23.07)				
3 (post-intervention)		55.63 (21.88)	3.19 (0.57 to 5.81)		56.59 (22.17)	3.25 (0.22 to 6.28)	−0.06 (−4.05 to 3.92)	0.815	−0.003
Vitality	168			162					
Pre-intervention		49.67 (24.73)			51.20 (21.65)				
3 (post-intervention)		50.56 (22.51)	0.89 (−2.09 to 3.87)		52.71 (22.68)	1.42 (−1.93 to 4.76)	−0.52 (−4.98 to 3.93)	0.565	−0.024
Social function	168			163					
Pre-intervention		82.29 (26.89)			78.30 (27.39)				
3 (post-intervention)		83.21 (24.70)	0.82 (−3.22 to 4.86)		85.58 (24.56)	7.29 (3.26 to 11.31)	−6.47 (−12.15 to 0.78)	0.022	−0.249
Role-emotional	168			163					
Pre-intervention		81.80 (26.83)			78.32 (27.15)				
3 (post-intervention)		81.61 (24.82)	−0.05 (−3.78 to 3.68)		84.71 (24.10)	6.39 (2.14 to 10.65)	−6.44 (−12.07 to −0.81)	0.050	−0.234
Mental health	168			162					
Pre-intervention		61.88 (21.94)			61.72 (22.11)				
3 (post-intervention)		62.60 (21.48)	0.71 (−2.15 to 3.58)		63.34 (22.87)	1.52 (−1.09 to 4.13)	−0.81 (−4.68 to 3.07)	0.997	−0.048
Standardized Physical Component Scale	168			162					
Pre-intervention		48.89 (7.56)			49.80 (7.76)				
3 (post-intervention)		50.71 (7.54)	1.83 (0.70 to 2.95)		50.08 (7.89)	0.24 (−0.74 to 1.22)	1.59 (0.09 to 3.08)	0.018	0.251
Standardized Mental Component Scale	168			162					
Pre-intervention		44.71 (12.66)			43.46 (12.14)				
3 (post-intervention)		44.32 (12.31)	−0.39 (−1.97 to 1.19)		45.71 (12.04)	2.19 (0.58 to 3.81)	−2.59 (−4.84 to −0.34)	0.007	−0.249

SD: standard deviation; CI: confidence interval; Standardized Physical Component Scale: a physical composite summary; Standardized Mental Component Scale: a mental composite summary; SES: standardized effect size.

For example, the BMI, which saw a slight improvement in the CG (−0.23 kg/m^2) remained unchanged in the IG (0.04 kg/m^2). Blood sugar, which declined in the CG (−2.43 mg/dl), increased slightly in the IG (1.36 mg/dl). Although those differences are statistically significant, we believe that a decrease of approximately 0.2 kg/m^2 in the BMI or of about 2 mg/dl in glucose has little clinical relevance in our daily practice.

There were no significant effects on body weight or BMI found in the systematic review published by Firth et al. [15].

Neither was a significant improvement in terms of adherence to the Mediterranean diet observed although both groups showed a trend toward improvement.

These results are for the 3 months just after the start of the intervention, which is a randomized clinical trial that evaluates of one year. It is hoped that these results will improve in the coming months, depending on whether the participants are able to integrate the knowledge acquired during the intervention and to implement lifestyle changes. For example, the intervention carried out by Daumit et al. (patients with a SMD participating in psychiatric rehabilitation programs) at 6 months revealed a mean net weight change (IG minus CG) of −1.5 kg, but at 18 months the difference increased to −3.2 kg. In the same study, the net difference in BMI at 18 months is −1.1 kg in favor of the IG [10].

Analyzing the results of the SF-36, an improvement in the physical parameters (physical function and physical composite summary Variable) was seen in the IG, which seems logical if we consider the increase in PA that they experienced at the end of the intervention. An improvement in mental parameters (social function, emotional role and mental composite variable summary) was seen in the CG. That this latter finding may be related to the participation of patients in the CG in other community programs cannot be ruled out, a fact that might influence the outcome. It may also be due to natural variations in the course of mental illnesses. Heggelund also used the SF-36 scale to assess changes in the quality of life in schizophrenic patients undergoing maximal strength training (IG) versus playing computer games (CG), but no differences in either physical or mental variables were observed [18]. Casañas et al. instead used the EQ-5D quality of life scale on patients with depression and saw an improvement in the IG at 3 months, but not at 6 and 9 months [7]. It is important to look to the work done by Leese et al. which concludes that the SF-36 is applicable and reliable in schizophrenia patients although the 8 dimensions score is preferable to that of the physical and mental composite summary variables for these patients [22].

One problem encountered was the modest adherence to attending sessions, especially in terms of PA sessions. It may be simply a matter of timetables, of leaving the center where the diet training was taking place, etc. However, if you look at the attendance at meetings in Daumit's work, average attendance in the first six months stood at 56% (which coincides with ours of almost 55%), while it went down to 19% in the second six months. It is associated with decompensations and to the social problems of SMD patients [10]. Despite this, attendance at the follow-up interview at 3 months was 87%. An effort was made to ensure patient adherence through telephone locating (at least three attempts per appointment, if the patient has stated that he/she wanted to participate) when any scheduled visits and intervention sessions were missed.

In this regard, the Scheewe's RCT published in 2013 on aerobic exercise in schizophrenia patients concluded that significant improvements in fitness, psychiatric symptoms and overall functioning only occurred in participants who attended ≥50% of the exercise sessions [34], which might explain the low consistency of some findings in our study. Therefore, a subanalysis was conducted depending on whether the patients had come to roughly 60% of the sessions. Despite not finding statistically significant differences in either the mean of the variable walking METs or the total METs, the METs are doubled in the group with the highest rate of meeting attendance.

Another problem is that the expected sample size was not reached. A total of 332 patients of the 478 projected in the initial calculations were recruited. This is due to several factors, among them was that the recruitment was slower than expected and the percentage of patients who agreed to participate in the study was lower than expected. It is also necessary to keep the characteristics of these patients and their reluctance to participate in projects in mind [1]. In spite of having a smaller than expected sample, the lack of statistical significance does not appear to be due to that, but to there simply not being any variation. For example, the BMI does not change at all in the IG and we believe that it would hardly vary by increasing the sample.

We must take into account that the average age of the disease in the participants is 14.10 years, similar in both groups. If we add the fact that 69% of patients scored the CGI values of moderate or severe symptoms, we find ourselves with a type of chronic patient very rooted in their previous life styles. That fact brings an added difficulty to modifying lifestyles and the parameters studied in these patients in comparison to a healthy population.

Due to the multicentric nature of the study, centralized training of all participants in the study by the principal investigator was necessary.

5. Conclusions

In conclusion, our preliminary results suggest that an educational program intervention, which focuses on diet and PA, increases the level of PA, but does not improve physical or laboratory parameters. We will have to wait for the 12-month results to demonstrate whether the intervention is effective at long-term or not.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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