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Improving physical activity and diet in patients with severe mental disorders: Results from the LIFESTYLE multicentric, real-world randomized controlled trial

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ABSTRACT

Aims of the present study are to test the efficacy of a lifestyle group intervention, compared to a brief psycho-educational intervention, on levels of physical activity and dietary habits in a real-world sample of patients with severe mental disorders. The study, funded by the Italian Ministry of Education, has been carried out in six Italian University psychiatric outpatient units. All patients were randomly assigned to the experimental or control group and were assessed through standardized assessment instruments at baseline and six months after randomization. Of the 401 recruited patients, 43.3% had a diagnosis of bipolar disorder, 29.9% of psychosis and 26.9% of major depression. Patients were mainly female (57%), with a mean age of 45.6±11.8 years. Treated patients have almost 8 times the likelihood to show an increase of the total MET (OR: 8.02; $p < .001$) and of the walking MET (OR: 7.68; $p < .001$) and are more likely to increase the weekly consumption of vegetables (OR= 1.98, $p < .05$) and to reduce that of junk food (OR:0.23; $p < .05$). The present study support the notion that patients with severe mental disorders can improve their lifestyle behaviours and that, with appropriate support, they can achieve a healthy living.

1. Introduction

The impact of unhealthy lifestyle behaviours is highly significant in the general population, being associated with a variety of chronic physical conditions, reduced life expectancy and increased healthcare costs (Goldberg et al., 2013). This impact is higher in patients with severe mental disorders (SMD), who have higher rates of obesity, metabolic syndrome, diabetes, cardiovascular diseases (Gaughran et al., 2017; Bartoli et al., 2013), with a reduced life expectancy of about 20-30 years compared to the general population (Taipale et al., 2020; Plana-Ripoll et al., 2020).

The relationship between poor physical health and SMD is complex and multifactorial (Firth et al., 2020), including underlying pathophysiological mechanisms (De Hert et al., 2011), side effects of many psychotropic drugs (Correll et al., 2020; Solmi et al., 2020), and lifestyle-related factors (Bersani et al., 2017), such as sedentary behaviours, poor dietary habits, reduced physical exercise, smoking and alcohol/drug abuse (Luciano et al., 2021; Volkow et al., 2020; Drake et al., 2020; Squeglia, 2020). Among these, patients with a comorbid substance and/or alcohol abuse have more negative outcomes than their counterparts without comorbid disorders, in terms of health status, mortality rates and access to adequate treatments both for physical than for mental disorders (Carrà et al., 2006). Finally, several illness-related factors, including cognitive impairment, reduced psychosocial

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functioning, social isolation and self-stigma (Menon, 2020; Valtorta et al., 2018) can have a significant impact on patients' physical health. In particular, patients with SMD tend to perceive stigmatizing attitudes from their health care providers, and thus are reluctant to seek medical help (Thornicroft, 2011). Internalized stigma causes social withdrawal which may lead to further reduce check-up visits for physical health (Mazzi et al., 2018), and a consequent increase of incidence of cardiovascular diseases (Valtorta et al., 2018) and excess mortality (Holt--Lunstad et al., 2015).

Physical activity and dietary patterns seem to be those lifestyle behaviours which are most amenable to change. The benefits of physical activity on mental health include better quality of life, improved cognitive performance, increased social interactions and longer life expectancy (Alonzo et al., 2022; Menon et al., 2020). Moreover, physical activity significantly reduces stress, anxiety, and depressive symptoms (Hudon et al., 2008). In a large cross-sectional survey (Chekroud et al., 2018), playing team sports significantly improved the mental health of SMD people. Moreover, engaging in physical activities (including mindfulness yoga, walking-exercise) significantly improves affective and anxiety symptoms in patients with chronic physical and mental diseases (Chen et al., 2015; Kwok et al., 2019). Moreover, interventions targeting physical health also improve mental health status, in particular depressive and anxiety symptoms (Gordon et al., 2018), positive and negative psychotic symptoms (Firth et al., 2015), cognitive symptoms (Brondino et al., 2017; Firth et al., 2017) and quality of life (Schuch et al., 2016). In a recent meta-analysis including data from more than 260,000 participants, Schuch et al. (2018) found that individuals with higher levels of physical activity are less likely to develop depression (Maj et al., 2020, 2021). Finally, physical activity interventions are associated with a reduction of body weight (Luciano et al., 2021; McEwen et al., 2020), waist circumference, epicardial adipose tissue, blood triglycerides and total cholesterol (Schuch et al., 2021) in SMD people.

Abnormal dietary patterns are frequently found in patients with severe mental disorders, which further contribute to increase their cardiovascular risk (Firth et al., 2018). In fact, compared with the general population, people with SMD have an excessive caloric intake, low-quality diet, and poor nutritional status (Xu et al., 2022). In particular, patients with schizophrenia and mood disorders are more likely to have higher caloric intake and a dietary pattern mainly constituted by carbohydrates, saturated fat and an excessive use of junk food (e.g., high-fat, high-sugar discretionary foods and takeaways) (Firth et al., 2020). Dietary patters of people with SMD often lead to reduced blood levels of B9 and B12 vitamins, which are often associated with symptom severity (Garcia-Miss et al., 2010; Steardo et al., 2020). Also, blood levels of antioxidant vitamins C and E are reduced in these patients, as a consequence of reduced intake of fresh fruits and vegetables, which contribute to increased oxidative stress (Flatow et al., 2013).

Under these premises, the Italian Ministry of University has recently funded a multicentric collaborative study, coordinated by the Department of Psychiatry of the University of Campania "L. Vanvitelli", to test the efficacy of a new lifestyle group intervention in a real-world sample of patients with SMD. In this paper we report the results of the efficacy of the experimental intervention compared to a psychoeducational group intervention on the levels of physical activity and dietary habits of SMD patients.

2. Methods

The LIFESTYLE study is a multicentric, randomized controlled trial with blinded outcome assessments, carried out in the outpatient units of the Universities of Campania "Luigi Vanvitelli" in Naples, Bari, Genoa, L'Aquila, Pisa, and Rome-Tor Vergata. Each centre was expected to recruit 70 patients, 35 per each arm, with a total sample size of 420. The study has been funded by the Italian Ministry of Education, Universities and Research within the framework of the "Progetti di Rilevante Interesse Nazionale (PRIN)".

Upon recruitment, all patients were asked to provide informed written consent and were randomly allocated to receive the experimental or the control intervention taking into account center, age, gender, and educational level, with a 1:1 ratio. Patients were included in the study if they: (1) were aged between 18 and 65 years; (2) had a primary diagnosis of schizophrenia, schizoaffective disorder, delusional disorder, other psychotic disorders, major depressive disorder, or bipolar disorder according to the DSM-5 and confirmed by the Structured Clinical Interview (2013); (3) provided written informed consent; (4) had a BMI$\geq$ 25.

Patients' exclusion criteria were: (1) inability to perform moderate physical activity (i.e., walking at least 150 min per week, or 75 min of vigorous activity twice a week, according to the guidelines of the Italian Ministry of Health); (2) pregnancy or breast-feeding; (3) intellectual disability or severe cognitive impairment; (4) worsening of psychiatric symptoms or hospital admission in the previous 3 months.

Researchers and statisticians involved in patients' assessments were blinded with respect to patient's allocation.

2.1. Interventions

2.1.1. Experimental intervention: Lifestyle Psychosocial Group Intervention

The experimental intervention was developed using techniques derived from classic psychoeducation (Falloon et al., 1985; Fiorillo et al., 2015), motivational intervention (NICE, 2007; Rogers, 1975; Miller et al., 2009), and cognitive-behavioral therapy (Hofmann et al., 2012), according to the guidelines on the management of physical health in people with mental disorders produced by the World Health Organization (WHO, 2010), the European Association for the Study of Diabetes (Ryden et al., 2013), the European Society of Cardiology (Piepoli et al., 2016), and the European Psychiatric Association (De Hert et al., 2009). The full methodology adopted to develop the intervention is reported in Sampogna et al. (2018).

The experimental intervention lasted 5 months and was administered to groups of 5–10 patients every 7–10 days. The following topics were covered during sessions: (1) healthy diet; (2) physical activity; (3) smoking habits; (4) medication adherence; (5) risky behaviors; (6) circadian rhythms. Each session included the following components: (a) information on risks and benefits of lifestyle behaviours; (b) practical strategies to change unhealthy behaviors; (c) identification of personal life goals; (d) motivation to change; and (e) problem-solving strategies. Sessions were developed in order to stimulate discussion, workgroups and interaction among participants. At the end of each meeting, a 20-min session of moderate physical activity was performed by all participants. During each session, fresh fruits and healthy snacks have been offered to participants.

2.1.2. Control group: brief psychoeducational group intervention

The brief psychoeducational group intervention consisted of 5 weekly sessions administered to groups of 5–10 patients covering information on the following topics: (1) healthy lifestyle; (2) early detection of clinical relapses; (3) effects of pharmacological treatment and management of side effects; (4) stress management techniques; (5) problem-solving techniques.

Manuals were developed for both interventions in order to ensure treatment fidelity among centers.

2.2. Training of mental health professionals

Three mental health professionals per each centre participated in a 5-day training course on the provision of the two interventions. All mental health professionals received constant supervision during the whole study period. A site visit was organized by the coordinating centre in order to guarantee "*in vivo*" supervisions. A separate training course was held on the use of assessment instruments and to test their reliability.

The study was conducted in accordance with globally accepted

standards of good clinical practice, in agreement with the Declaration of Helsinki and with local regulations. The Ethics Committee of the Coordinating Center formally approved the trial in January 2017 (approval number: prot. 64).

2.3. Assessment times and instruments

Researchers were blinded to patients' allocation. All patients were assessed at baseline (T0) and 6 months post-randomization (T1). Patients' main diagnosis was confirmed through the Structured Clinical Interview for DSM-5 (SCID-5).

The following assessment instruments were used to assess patients' psychiatric symptoms, cognitive domains and psychosocial functioning: (a) the Brief Psychiatric Rating Scale (BPRS) (Lukoff et al., 1986), a semi structured interview on psychopathological status. The 24 items of the scale are grouped in four subscales: positive symptoms, negative symptoms, depressive-anxiety symptoms, and manic/hostility symptoms; (b) the Personal and Social Performance Scale (Morosini et al., 2000), a 100-point single-item rating scale, subdivided into 10 equal intervals; (c) the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) Consensus Cognitive Battery (MCCB) – brief version, which includes the MATRICS Consensus Trail Making Test – part A, Brief Assessment of Cognition in Schizophrenia: Symbol Coding, Category Fluency-Animal Naming (Kern et al., 2008; Nuechterlein et al., 2008).

The 18-item International Physical Activity Questionnaire (IPAQ) – short form (Craig et al., 2003) was adopted to assess patients' levels of physical activity. IPAQ scores can be calculated as categorical (resulting in three categories: low, medium and high physical activity) or continuous variables, by calculating METS, which are multiples of estimated resting energy expenditure. IPAQ continuous subscales are total, walking, moderate and vigorous IPAQ. The reliability and validity of the IPAQ for the assessment of physical activity in people with SMD is comparable to that of the general population, with correlation coefficients of .68 for test-retest reliability and .37 for the criterion validity (Faulkner et al., 2006; Bartels et al., 2015).

The 24-items Questionnaire on lifestyle behaviours, developed by the Italian National Institute of Health, was used to explore patients' dietary patterns (e.g., food eaten at lunch or dinner), smoking habits (e.g., number of cigarettes smoked per day; attempts to quit smoking), and physical activity (e.g., time spent in walking per day) (Istituto Superiore di Sanità).

The Cohen's Kappa coefficient was used to assess inter-rater reliability, which was found to be satisfactory for both the PSP (K value=0.918) and the BPRS (K value ranging from 0.835 to 0.972). A 100% agreement rate was found for the SCID-5 diagnoses.

2.4. Statistical analyses

Statistical analyses have been conducted according to the "Intention to Treat" principle. Missing data have been handled using the Last Observation Carried Forward (LOCF). The normal distribution of outcome variables was assessed with the Kolmogorov–Smirnov test. All outcome variables followed a normal distribution, with the exception of IPAQ subscales, which were therefore handled with non-parametric tests. At baseline and at the end of the intervention, descriptive statistics – frequency tables, means (M) and standard deviations (SD), median (MD) and interquartile range (IQR) in case of non- parametric distribution of samples – were calculated for both experimental and control groups. Differences in socio-demographic and clinical characteristics among the two groups at baseline and at the end of the intervention were tested using χ^2 or t-test for independent samples. The impact of the interventions on physical activity and dietary behaviours was explored by the with Wilcoxon test and with χ^2 test, as appropriate.

All variables which showed a statistically significant difference at univariate analyses from baseline to follow-up were entered as dependent variables in a generalized estimating equation models (GEE), which allow estimation of population-averaged models in repeated-measures data. Control vs. intervention interaction terms assessed changes between groups over time; Wald tests determined whether joint effects of time-by-group equaled zero. Age and center were included as time-invariant covariates; time-varying covariates included medications, cognitive functioning, age, gender, type of mental disorder diagnosis. We report covariate-adjusted results using robust estimates of standard errors. All models were adjusted for diagnosis, pharmacological treatment, duration of illness and educational level. Pharmacological treatments and psychiatric diagnoses were included in the regression models as dummy variables (i.e., mood stabilizers, tricyclic antidepressants, new-generation antidepressants, first- and second-generation antipsychotics, depressive disorder, bipolar disorders, psychosis).

3. Results

Forty-hundred and 1 patients agreed to participate in the study and were randomly allocated to receive the experimental or the control intervention (206 in the experimental group and 195 in the control group). Among these, 244 patients (112 in the experimental and 112 in the control group) did not complete the intervention due to: practical difficulties in reaching the study site (27%), not anymore in charge to the local mental health centre (25%), exacerbation of psychiatric symptoms (20%), lack of interest (18%). Therefore, the final sample of patients who have been reassessed at the end of the intervention consists of 177 patients (94 in the experimental and 83 in the control group). No statistically significant differences have been found with respect to socio-demographic and baseline clinical characteristics as well as to baseline anthropometric and metabolic parameters between dropouts and completers.

3.1. Socio-demographic and clinical characteristics

Of the 401 recruited patients, 43.3% had a main diagnosis of bipolar disorder, 29.9% of psychosis and 26.9% of major depression. Patients were mainly female (57%), with a mean age of 45.6±11.8 years and with an educational level of 11.7±2.9 years. 28.6% of patients were married (Table 1). All patients were treated with at least one psychotropic drug: 35% received one pharmacological agent, 39% two, 21% three different drugs and 5% of patients received four different psychotropic drugs. In the global sample, the majority of patients scored "low" at the IPAQ categorical score (56.8%; $N = 227$), 27.3% scored "moderate" ($N = 109$) and 16% ($N = 64$) scored "high" at IPAQ categorical score. There were no significant differences between the two groups with respect to socio-demographic characteristics (Table 1).

3.2. Efficacy of the experimental intervention

At univariate analyses, patients receiving the experimental intervention had an increase from T0 to T1 in Walking (MD=362.0; IQR=1138.5 at T0 vs. MD=594; IQR=1089 at T1; $p < .01$) and total MET (MD=519.5; IQR=1745.2 at T0 vs. MD=693; IQR=1782.02 at T1). There were no statistically significant differences between T0 and T1 in the control group (Table 2).

A general improvement in dietary patterns from T0 to T1 was found in patients receiving the experimental intervention. In particular, we found an increased weekly intake of fish (more than three times per week/daily: 38.4% at T0 vs. 54.4% at T1; $p < .001$), vegetables (more than three times per week/daily: 80.1% at T0 vs 87.9% at T1; $p < .05$) and fresh fruit (more than three times per week/daily: 77.8% at T0 vs 90% at T1; $p < .01$). Moreover, we also found a reduction of junk food (more than three times per week/daily: 23.5% at T0 vs. 15.4% at T1; $p < .05$) and of weekly consumption of cereals (more than three times per week/daily: 35.6% at T0 vs 21.7% at T1; $p < .01$). On the contrary, in the

Table 1
Socio-demographic and clinical characteristics of the sample.

	Experimental group (*N* = 206)	Control group (*N* = 195)
Gender, female, % (N)	55.3 (114)	59 (115)
Age, M (sd)	45.90 (11.58)	45.35 (12.13)
Living situation, with partner yes % (N)	47.1 (97)	48.2 (94)
Years of education, M (sd)	11.70 (2.64)	11.70 (3.14)
Employed, yes, % (N)	37.6 (77)	33.8 (66)
Diagnosis, % (N)		
Bipolar disorder	43.2 (89)	43.6 (85)
Major depression	24.8 (51)	29.2 (57)
Psychotic disorder	32.0 (66)	27.2 (53)
Years in charge to the mental health service, M (sd)	68.68 (81.46)	74.48 (83.98)
Duration of illness, M (sd)	16.20 (11.70)	16.41 (22.36)
Suicide attempts, M (sd)	1.55 (1.20)	1.98 (1.59)
BPRS, Anergia, M (sd)	7.71 (3.06)	7.64 (3.1)
BPRS, Psychotic symptoms, M (sd)	5.26 (1.97)	5.46 (2.11)
BPRS, Depressive/anxiety symptoms, M (sd)	8.66 (3.03)	8.88 (3.2)
BPRS, Hyperactivity sympoms, M (sd)	4.68 (1.94)	4.76 (1.79)
B-MCCB, BACS Symbol coding, M (sd)	34.52 (14.17)	34.52 (13.52)
B-MCCB, Animal naming, M (sd)	18.24 (5.70)	17.53 (5.13)
B-MCCB Trial making test A, M (sd)	52.81 (30.47)	51.90 (26.65)
IPAQ, Low PA, yes % (N)	54.4 (111)	59.1 (114)
IPAQ, Moderate PA, yes % (N)	29.4 (60)	24.9 (48)
IPAQ, High PA, yes % (N)	16.2 (33)	16.1 (31)
PSP, Total score, M (sd)	66.46 (14.85)	64.82 (15.5)

MANSA: Manchester Short Assessment of Quality of Life; ISMI: Internalized Stigma of Mental Illness scale, MMAS: Morisky Medication Adherence Scale; B-MCCB: Brief MATRICS Consensus Cognitive Battery; PSP: Personal and Social Performance Scale; BPRS: Brief Psychiatric Rating Scale; BACS: Brief Assessment of Cognition in Schizophrenia; IPAQ: International Physical Activity Questionnaire; PA: Physical Activity.

Table 2
Changes in physical activity levels between baseline and 6-months follow-up in the two groups.

	Experimental treatment (*N* = 206)		Control group (*N* = 195)	
	Baseline	T1	Baseline	T1
Vigourous METS - minutes/week				
Mean (SD)	280.19 (1195,90)	206,08 (665,24)	367,01 (1228,02)	164,81 (764,74)
Median (IQR)	0 (0)	0 (0)	0 (0)	0 (0)
Moderate METS - minutes/week				
Mean (SD)	238,93 (800,47)	505,65 (1626,91)	248,74 (1184, 12)	247,42 (1065.09)
Median (IQR)	0 (0)	0 (0)	0 (0)	0 (0)
Walking METS - minutes/week				
Mean (SD)	922.39 (1475,66)	1160,56 (1525,79)	719,36 (1325,10)	659,13 (714,17)
Median (IQR)	362 (1138,5)	594.00 (1089.00)*	264,00 (631.13)	552 (808.50)
Physical Activity METS - minutes/week				
Mean (SD)	1335,39 (2449,72)	1672.80 (2487.93)	1141,52 (2195,66)	1370,87 (1973,90)
Median (IQR)	519.5 (1745,2)	693.00 (1782.02)**	541,00 (1745,25)	560 (1345.88)

* $p < .01$; ** $p < .001$.
SD= Standard deviation; IQR= interquartile range; METS= Metabolic Equivalents.

control group we found a worsening of dietary habits with an increase of junk food (more than three times per week/daily: 27.1% at T0 vs. 47% at T1; $p < .01$) and red meat (more than three times per week/daily: 51.6% at T0 vs. 62.4% at T1; $p < .01$) (Table 3).

The GEE analyses confirmed these positive effects of the experimental intervention on lifestyle behaviours (Table 4). In particular, at the end of the intervention, treated patients have almost 8 times the likelihood to show an increase of the IPAQ total MET (OR: 8.02, 95% CI: 6.84-9.42; $p < .001$) and of the IPAQ walking MET (OR: 7.68, 95% CI: 6.17-8.77; $p < .001$). Other factors positively associated with an increase in the IPAQ total MET were younger age (OR: .01; 95% CI: -.02-.02; $p < .05$), reduced BPRS positive symptoms (OR: .08; 95% CI: -.17-.10; $p < .05$) and increased BPRS hyperactivity subscale (OR: .09; 95% CI:-.01-.18).

As regards the other outcome measures, GEE analyses showed a significant effect of the experimental intervention on consumption of

Table 3
Changes of dietary habits between baseline and 6-months follow-up in the two groups.

	Experimental treatment (*N* = 206)		Control group (*N* = 195)	
	Baseline	T1	Baseline	T1
Cereals				
Never/one time per week	64.4 (58)	78.3 (159)	76.6 (147)	72.3 (60)
More than three time per week/daily	35.6 (32)	21.7 (44) **	23.4 (45)	27.7 (23)
Pasta and rice				
Never/one time per week	10.3 (21)	10.0 (9)	9.4 (18)	7.4 (6)
More than three time per week/daily	89.7 (182)	90.0 (81)	90.6 (174)	92.6 (75)
Red meat				
Never/one time per week	42.4 (86)	47.8 (43)	48.4 (93)	47.0 (39)
More than three time per week/daily	57.6 (117)	52.2 (47)	51.6 (99)	62.4 (32) **
Legumes				
Never/one time per week	57.1 (116)	46.7 (42)	53.6 (103)	53.0 (44)
More than three time per week/daily	42.9 (87)	53.3 (48)	46.4 (89)	47.0 (39)
Fish				
Never/one time per week	61.6 (125)	45.6 (41)	67.2 (129)	60.2 (50)
More than three time per week/daily	38.4 (78)	54.4 (49) ***	32.8 (63)	39.8 (33)
Eggs				
Never/one time per week	72.4 (147)	73.3 (66)	68.8 (132)	73.5 (61)
More than three time per week/daily	27,6 (56)	26.7 (24)	31.3 (60)	26.5 (22)
Cured meat				
Never/one time per week	47.1 (97)	46.2 (42)	49.9 (94)	53.0 (44)
More than three time per week/daily	52.2 (106)	53.8 (49)	51.0 (98)	47.0 (39)
Vegetables				
Never/one time per week	18.7 (38)	12.1 (11)	18.2 (35)	13.3 (11)
More than three time per week/daily	80.1 (165)	87.9 (80)*	81.8 (157)	86.7 72)
Fresh fruit				
Never/one time per week	22.2 (45)	18.9 (17)	19.8 (38)	13.3 (11)
More than three time per week/daily	77.8 (158)	90.0 (81) **	80.2 (154)	86.7 (72)
Sweets				
Never/one time per week	55.2 (112)	55.6 (50)	43.2 (83)	51.8 (43)
More than three time per week/daily	44.8 (91)	44.4 (40)	56.8 (109)	48.2 (40)
Junk food				
Never/one time per week	76.5 (156)	84.6 (77)	72.9 (140)	53.0 (44)
More than three time per week/daily	23.5 (143)	15.4 (14)*	27.1 (52)	47.0 (39) **

* $p < .01$; ** $p < .01$; *** $p < .001$.

Table 4
Generalized estimating equation models (GEE).

	IPAQ total MET	IPAQ walking MET	Cereals	Vegetables	Fish	Fresh fruit	Junk food
	OR (95% CI)	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI**
Experimental treatment	8.02 (6.84 to 9.42)***	7.68 (6.17 to 8.77) ***	-2.42 (-4.51 to .34)	1.98 (-1.26 to 3.30)*	.97 (-.82 to 2.76)	.45 (-2.60 to 1.71)	0.23 (-0.73 to .37)*
Gender, female	.20 (-.10 to .51)	.09 (-.23 to 0.41)	.17 (-.35 to .69)	.65 (.08 to 1.21)*	-.12 (-.57 to .32)	.12 (-.41 to .66)	-.46 (-.95 to .04)
Age	-.01 (-.02 to .02)*	-.00 (-.02 to .01)	-.20 (-.04 to .00)	.03 (-.07 to 1.0)**	.00 (-.02 to .02)	.12 (-.41 to .66)	.03 (-.05 to .10) ***
B-MCCB symbol coding	.00 (-.01 to .02)	.95 (.80 to 1.13)	.00 (-.02 to .03)	.04 (.00 to .07)**	-.01 (-.04 to .01)	-.16 (-.40 to .00)	.02 (.00 to .05)*
B-MCCB category fluency: animal naming	.01 (-.03 to .04)	-.00 (-.04 to .33)	-.02 (-.07 to .04)	.00 (-.06 to .07)	-.00 (-.06 to .04)	-.29 (-.06 to .00)	-.00 (-.06 to .05)
B-MCCB trial making test A	.00 (-.01 to .01)	-.00 (-.01 to .00)	.00 (.00 to .01)	.00 (-.01 to .01)	-.01 (-.01 to .00)	.00 (-.02 to .00)	.01 (.00 to .03)*
BPRS depression/anxiety subscale	-0.37 (-.10 to .03)	-.07 (-.13 to .00)	.26 (-.07 to .12)	-.01 (-.12 to .09)	.03 (-.06 to .11)	-.08 (-.02 to .00)	-.03 (-.12 to .07)
BPRS anergia	-.16 (-.08 to 0.05)	.00 (-.06 to .07)	-.05 (-.15 to .12)	.07 (-.05 to .18)	.08 (-.01 to .18)	.00 (-.10 to .10)	-.06 (-.16 to .04)
BPRS psychotic symptoms	.08 (-0.17 to .10)*	.03 (-.06 to .12)	-.02 (-.16 to .12)	-.04 (-.20 to .124)	-.01 (-.13 to .12)	-.05 (-.20 to .09)	-.06 (-.20 to .07)
BPRS hyperactivity symptoms	.09 (-.01 to .18)*	.00 (-.09 to .11)	-.02 (-.17 to .14)	-.12 (-.31 to .07)	-.04 (-.18 to .10)	.10 (-.05 to .26)	-.01 (-.16 to .14)

* $p < .01$;** $p < .01$; *** $p < .001$.
B-MCCB: Brief MATRICS Consensus Cognitive Battery; PSP: Personal and Social Performance; BPRS: Brief Psychiatric Rating Scale.
GEE have been adjusted for diagnosis, pharmacological treatments, duration of illness and years of education.

vegetables and junk food. In fact, receiving the experimental intervention increased the frequency of vegetables consumption (OR= 1.98, 95% CI: 1.26-3.30, $p < .05$) and reduced the likelihood of eating junk food (OR:.23; 95% CI: -1.73-.37; $p < .05$). Other factors influencing vegetables' consumption included male gender (OR=.65; 95% CI: .08-1.21; $p < .05$), older age (OR=-.03; 95% CI: -.07-1.0; $p < .01$) and higher levels of cognitive functioning (B-MCCB symbol coding, OR: .04; 95% CI: .00-0.07, $p < .05$). The consumption of junk food was reduced in older patients (OR= .03, 95% CI: .01-.10, $p < .001$) and in those with better cognitive functioning (B-MCCB symbol coding OR: .03, 95% CI: -.05-.10, $p < .001$; B-MCCB trial making test A OR:.01, 95% CI: .00-.03; $p < .05$). Patients' diagnoses, that were entered as a covariate in all GEE models, did not showed any significant effect on the outcome variables.

4. Discussion

This paper clearly shows the efficacy of a new psychosocial intervention in improving physical activities and dietary habits in a sample of patients with schizophrenia or other primary psychoses, bipolar or unipolar affective disorders. The LIFESTYLE trial represents the first multicentric randomized controlled trial carried out in Italy specifically designed to improve patients' lifestyle behaviours, including physical activity and dietary habits in patients with SMD. In fact, most available studies (Pape et al., 2022) have assessed the efficacy of non-pharmacological interventions on physical health mainly in terms of reduction of body mass index (BMI) and waist circumference, or of improvement of several haematological parameters, such as fasting glucose, total cholesterol and triglycerides.

One of the main findings is the positive effect of the LIFESTYLE intervention on patients' physical activity. In particular, patients receiving the experimental intervention reported an increase in weekly walking hours and in the total weekly physical activity. Other studies carried out with a similar methodology, including the CHANGE, IMPaCT, MOVE and CAPiCOR trials (Jakobsen et al., 2017; Gaughran et al., 2017; Goldberg et al., 2013; Masa-Font et al., 2015), did not found any effect of behavioural interventions on the levels of patients' physical activity. On the contrary, our results are in line with the SHAPE (Bartels et al., 2013), the PHYSICO-DSM-VR trial (Bonfioli et al., 2018), with Xu et al. (2022), Bersani et al. (2017) and Bartels et al. (2015), who found increased time spent in daily walking, improvements of total weekly MET, greater attendance to fitness clubs, increased moderate physical activity levels, or decreased time spent sitting after the provision of a behavioural non-pharmacological intervention. The efficacy of the LIFESTYLE intervention on the levels of physical activities can be due to the inclusion of a motivational component in the intervention, based on the principles of motivational interview developed by Miller and Rollnick (2012). It is likely that this session helped patients to put into practice behavioural changes which are considered important from a theoretical viewpoint, but are considered unfeasible in many patients with rigid cognitive styles. Another factor which can explain the success of our intervention is the inclusion of a walking session at the end of each meeting, in order to stimulate patients to change their behaviours already during the groups, allowing them to share experience, difficulties, and possible solutions toward a more active and healthy living. This approach shows that support from peers and trained professionals are key factors in the delivery of behavioural interventions aimed at promoting physical activity in patients with SMD. However, it has to be said that the comparison with other RCT on the efficacy of non-pharmacological interventions on physical activity is not always possible, since in many studies physical activity has been assessed without reliable questionnaires or by using generic questions, such as attendance to fitness clubs (Sylvia et al., 2019).

The second main finding of our study is that patients receiving the experimental intervention reported an increased intake of vegetables and a reduced weekly consumption of junk food. This finding shows that behavioural interventions, if appropriately delivered according to culture and diet styles (Carmassi et al., 2017), can be useful in improving dietary habits, and contrasts with most available studies, which found no or limited efficacy of non-pharmacological interventions on dietary habits of patients with SMD. Only a few RCTs have found positive results, including reduction of fat consumption in older patients with schizophrenia (McKibbin et al., 2006), increased intake of fruit and vegetables (McCreadie et al., 2005) and better adherence to the Mediterranean diet (Bersani et al., 2017). The interventions provided to improve dietary patterns in people with SMD are highly heterogenous, ranging from the provision of free daily fresh fruits to patients in supported accommodation (McCreadie et al., 2005) to web-based interventions (Looijmans et al., 2019) or to more structured in-person interventions (Masa-Font et al., 2015). The efficacy of our intervention on dietary patterns can be due to the fact that at least 8 out of 20 sessions

of the LIFESTYLE intervention were devoted to changes in dietary patterns, in which the different components of healthy diet were addressed and information on how to balance the different nutrients and how to adhere to the mediterranean diet were provided to participants; during the sessions, post-cards showing the correct dimensions of food portions have been given to patients in order to correct their unhealthy diet habits. Moreover, patients were strongly encouraged to fill weekly dietary sheets for the whole duration of the intervention, that were subsequently discussed during sessions and regular positive feedback on diet was provided by trainers.

The efficacy of the intervention on food consumption and physical activity was influenced by the presence of poor cognitive performance. The impact of cognition in improving lifestyle habits in patient with SMDs has been poorly studied (Ryu et al., 2020; Galderisi et al., 2020; Moritz et al., 2020). It may be that patients with worse cognitive performance have difficulties in the organization of their daily routine, including time for physical activities and cooking healthy food, have problems in understanding the importance of these changes in lifestyle and are less motivated to be actively involved in interventions for the promotion of behavioural changes.

In our sample, at baseline assessment a very small proportion of patients performed adequate levels of physical activity. In fact, more than half of the sample (56.8%) were physically inactive, and only 64 patients out of 402 reported "high" levels of physical activity, which include "vigorous-intensity activity on at least 3 days or of any combination of walking, moderate-intensity or vigorous activity per day". These data, which are in line with available studies, show that SMD patients only rarely perform any type of physical activity (Vancampfort et al., 2019) and highlight the need to improve physical activities in patients with SMD.

It is wort noting that our multivariable models did not report any statistically significant association among diagnostic groups (schizophrenia and other psychotic disorders, depressive and bipolar disorders) and all the considered outcomes. These results is of particular relevance, and support the idea that patients' lifestyle behaviours and their responsiveness to psychosocial interventions are not influenced by any specific psychiatric diagnostic category, but rather by several psychopathological and psychosocial dimensions, according to a transdiagnostic approach to mental disorders (Krueger et al., 2021; Kim et al., 2021; Shah et al., 2020; Barlow et al., 2020), but this finding need to be confirmed by further studies.

Our study presents several strengths which makes the LIFESTYLE intervention particularly innovative and easy to use in routine care of patients with severe mental disorders. These include: (1) the presence of a motivational component, which represents probably the most important strategy to support behavioural changes over time (Sampogna et al., 2018; Zygmut et al., 2002; Rubak et al., 2005); (2) the comprehensive approach to healthy living, targeting almost all components of healthy lifestyle behaviours, such as diet, reduction of sedentary behaviours, promotion of physical exercise, reduction of tobacco use and of risky sexual behaviours, improvement of sleep hygiene, regularization of circadian rhythms and of medication adherence; (3) the need of a relatively brief training course for mental health professionals; (4) the transdiagnostic approach of the intervention, which can be delivered to patients with different psychiatric disorders; (5) the fact that the intervention can be provided by any trained mental health professional, not necessarily sport trainers or nutritionists, which reduces costs associated to its implementation in routine care and increase its scalability in different and heterogeneous settings; (6) the group format, which allowed patients to share experiences and difficulties well beyond those aspect strictly related to the disorders itself (i.e., symptoms and pharmacological adverse events).

Among the study limitations, we acknowledge the high drop-out rate, which reduces the magnitude of our results. However, the final sample size can be considered satisfactory if compared with other available studies, also because there were no differences at baseline between completers and drop-outs. However, this finding is in line with previous trials on behavioural interventions, where attrition rates of up to 40% were reported, even with brief interventions (Speyer et al., 2016, Masa-Font et al., 2015). Several strategies could help to improve rate of participants who complete the psychoeducational intervention and improve the implementation of such interventions in routine care, including electronic reminders (e.g., phone calls, emails, instant messages), availability of dedicated staff members and of rooms/spaces and more time for professionals to run the intervention (Fiorillo et al., 2016). Future implementation strategies should include web-based components with the integration of smartphone apps and wearable devices, for increasing real-time interactions with participants (Hickie, 2020). Another possible limitation is the selection of self-reported assessment instruments to evaluate physical activity and dietary patterns, rather than using more objective measures. If this could have generated a possible recall bias, objective assessment (i.e., ecological momentary assessment) might have significantly reduced the feasibility of the study in a real-world setting. Finally, we recruited patients with a BMI $\geq$ 25, which may have reduced the generalizability of our findings. We recruited overweight or obese patients in order to select those at higher risk of developing comorbidities or with compromised lifestyle behaviours already present at the beginning of the intervention. However, next steps would be to provide the intervention regardless the BMI, in order to test its efficacy as a preventive intervention.

In the last decade the relationship among mental disorders and lifestyle behaviours has become an hot topic in psychiatry, with an increasing number of papers analysing the efficacy of non-pharmacological lifestyle interventions in several aspect of mental health, including the reduction of suicide risk, improvement of global functioning and reduction of symptoms severity (De Rosa et al., 2017), the reduction of feeling of isolation and stigma, the promotion of social relationships, the enhancement of patients' empowerment, self-esteem, sense of belonging, meaning in life and the promotion of patients' engagement in personal goals and adaptive behaviours (Berardelli et al., 2018). However, as happened in the case of physical activity and dietary habits assessed in the present paper, few evidences coming from RCT trials carried out with robust methodology are available and despite the growing interest in the effects of non-pharmacological lifestyle interventions in patients with SMI, still much has to be done.

In conclusion, the LIFESTYLE experimental intervention improves physical activity and dietary patterns in patients with severe mental disorders. Our findings clearly show that patients with SMD can improve their lifestyle behaviours and that, with appropriate support, they can achieve a healthy living. There is the urgent need to implement similar interventions in routine clinical practice if we want to reduce the mortality gap in patients with SMD.

5. Lifestyle working group

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Declaration of Competing Interest

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.

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