Journal of Affective Disorders 332 (2023) 231–237

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research paper

One-year follow-up of the effectiveness of a lifestyle modification programme as an adjuvant treatment of depression in primary care: A randomised clinical trial

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ARTICLE INFO

Keywords:
Depression
Lifestyle modification
Diet
Physical exercise
Sleep quality
Primary care

ABSTRACT

Background: An estimated 280 million individuals suffer from depression. Brief group interventions in Primary Healthcare Centres (PHCs) are recommended. One goal of these interventions is to educate people about healthy lifestyle habits, as they prevent the development of depression. This study aims to analyse the one-year follow-up results about the effectiveness of a Lifestyle Modification Programme (LMP) and an LMP plus Information and Communication Technologies (LMP + ICTs) when compared to Treatment as Usual (TAU).

Methods: We conducted an open-label, multicentre, pragmatic, randomised clinical trial. A total of 188 individuals that visited a general practitioner and met the inclusion criteria were randomised. LMP consisted of six weekly 90-minute group sessions focusing on lifestyle improvement. LMP + ICTs was a hybrid of the LMP format with the inclusion of a wearable smartwatch. We used linear mixed models (with a random intercept and an unstructured covariance) to evaluate the effectiveness of the interventions, and an intention-to-treat analysis and Multiple Imputation technique for handling missing data.

Results: LMP + ICTs showed a statistically significant reduction on depressive symptoms ($b = -2.68$, 95 % CI = [−4.239, −1.133] $p = .001$) and sedentarism (b = −37.38, 95 % CI [−62.930, −11.833], $p = .004$) compared to TAU.

Limitations: Most of the dropouts were due to time restrictions.

Conclusions: In long-term, LMPs plus ICTs administered in PHCs to people suffering from depression were effective in reducing depressive symptomatology and sedentarism comparing to TAU. More research is needed to enhance adherence to lifestyle recommendations. These promising programmes could be easily implemented in PHCs.

Trial registration number: ClinicalTrials.gov Registry (NCT03951350).

1. Introduction

Depression is the second most prevalent cause of disability globally (World Health Organization (WHO), 2017), and it is a serious public health problem that affects an estimated 280 million people of all ages (World Health Organization (WHO), 2021). Depression management at Primary Healthcare Centres (PHCs) is encouraged due to its high incidence (World Health Organization, 2016), as one out of every ten patients at that level of care exhibits depressed symptoms (Malhi and Mann, 2018).

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https://doi.org/10.1016/j.jad.2023.04.007
Received 13 June 2022; Received in revised form 20 March 2023; Accepted 7 April 2023
Available online 11 April 2023

Brief group interventions have various advantages in PHCs, for example, they can be offered by either trained mental health professionals or experienced non-mental health caregivers (Nieuwsma et al., 2012). One of the aims of these interventions is to educate individuals about healthy living habits (Malhi et al., 2018) since Lifestyle Modification Programmes (LMPs) are considered a beneficial therapeutic strategy to prevent the development of depression (Aguilar-Latorre et al., 2022b; Forsyth et al., 2015; García-Toro et al., 2012; Lopresti et al., 2013).

In terms of particular lifestyle variables, interventions that support healthier dietary practices may contribute to reducing depressive symptoms (Opie et al., 2021). In particular, the Mediterranean diet has been associated with improved symptoms of depression (Pano et al., 2021), and beyond that, there is evidence that the Mediterranean lifestyle may be a more effective prevention strategy for depression (Hershey et al., 2022). Regarding physical activity, there is a negative relationship between regular exercise and depressive symptoms (Kim, 2022). Moreover, including exercise in antidepressant drug treatment may offer significant advantages over affective symptoms of depression (Murri et al., 2018). In this line, sedentary behaviour and short sleep duration in older adults are associated with depressive symptoms (Luo et al., 2022). Furthermore, there is a higher risk of depression among older people with sleep problems than without them (Hill et al., 2022; Zhang et al., 2022).

Besides that, previous research has suggested that monitoring of everyday behaviors promotes lifestyle modifications in depressed primary care patients (Olivan-Blázquez et al., 2018; Serrano-Ripoll et al., 2015). Therefore, the use of Information and Communication Technologies (ICT), such as wearable devices, is recommended to improve adherence (NICE, 2014).

This study aims to analyse the one-year follow-up results about the effectiveness of an LMP and an LMP plus Information and Communication Technologies (LMP + ICTs) when compared to Treatment as Usual (TAU).

2. Methods and analysis

2.1. Study design

An open-label, multicentre, pragmatic, randomised clinical trial (RCT) in three parallel groups (TAU as a control group, and LMP and LMP + ICTs as intervention groups) was carried out in several PHCs. Trial registration number: NCT03951350.

2.2. Sample size

A Spanish study with primary care patients was used as a proxy reference to determine the sample size for this research. Serrano-Ripoll et al. (2015) reported an average BDI-II score (Beck et al., 1996) of 24.5 points (SD 7.84) (Serrano-Ripoll et al., 2015). We determined that a decrease of at least 4.28 points would be clinically significant and beneficial for people in Spain, based on Button et al. (2015) (Button et al., 2015) proposal of considering a 17.5 % reduction in the BDI-II as clinically relevant. Accepting a risk of 0.05 and a risk of 0.20 in a bilateral contrast, each treatment group required 35 participants. With a hypothetical 20 % withdrawal rate, a final sample size of 42 participants per group was considered. A total sample size of 126 participants was required.

2.3. Recruitment and participants

Participants were selected from individuals who saw a general practitioner (GP) at one of the participating PHCs for any reason and satisfied the inclusion criteria outlined below.

By the end of the study, 188 patients had been recruited from PHCs in two sites in Spain (Zaragoza and Mallorca). The PHCs were chosen by convenience sampling (i.e., the PHCs where we had easy access and where we were able to make a first dissemination of the study were chosen) (Galloway, 2005). In Spain, PHCs are centres where the basic and initial level of care is provided, and global care and continuity are guaranteed throughout the patient's life, acting as case manager and flow coordinator and regulator. It includes activities for health promotion, health education, disease prevention, health care, health maintenance and recovery, as well as physical rehabilitation and social work (Ministerio de Sanidad, 2023).

The inclusion criteria were the following: individuals with depression (scoring 10 to 30 points on the BDI-II) (Beck et al., 1996), of both sexes over the age of 18, with a duration of depression symptoms extending over at least two months, and who understood written and spoken Spanish. The exclusion criteria were the following: suffering from another disease affecting the central nervous system (organic brain pathology or having suffered a traumatic brain injury of any severity, dementia) determined by people self-report; having another psychiatric diagnosis or psychiatric severe illness (substance dependence or abuse, history of schizophrenia or other psychotic disorders, eating disorders) with the exception of anxious pathology or personality disorders (collected through a medical history); the presence of a severe or uncontrolled medical, infectious or degenerative illness that may have interfered with the affective symptoms; the presence of delirium or hallucinations, risk of suicide, pregnancy or lactation; patients who had participated in another clinical trial during the previous 6 months or who were in psychotherapy at the time of the study; those who practiced mindfulness, yoga, meditation or similar practices during the previous 6 months, engaging in formal training at least once a week; and the presence of any medical, psychological or social problem that could have seriously interfered with the patient's participation in the study.

An independent researcher assigned participants using a computer-generated random number (Kim and Shin, 2014). Patients were randomly assigned to one of three conditions at each PHC. Because they were informed of the intervention, participants were not blinded to their allocation. Data from participants was entered and coded by a blinded Research Assistant (RA). Another blinded RA assessed the outcomes and analysed the data. All information gathered was handled in compliance with current personal data protection rules.

2.4. Intervention development and evaluation

GPs provided general medical care (TAU) to all participants (Cuijpers et al., 2019; Ministry of Health Social Services and Equality, 2014).

Those assigned to LMP had a 90-min session each week for six weeks, which was complemented with PowerPoint presentations. The following subjects were addressed: 1) Psychoeducation on depression; 2) Behaviour activation; 3) Sleep hygiene habits and careful exposure to sunlight; 4) Physical activity; 5) Adherence to the Mediterranean diet; and 6) Summary of previous sessions. LMP + ICTs reproduced the LMP format, with the addition of participants receiving a wearable wristwatch and being asked to use it to track daily minutes walked and sleep habits. Participants who were not assigned to any of the two interventions were part of the TAU group. The published protocol provides further information (Aguilar-Latorre et al., 2020).

At baseline (T0), immediately following the intervention (T1), six-month follow-up (T2), and twelve-month follow-up (T3), patient data was gathered by a blinded RA.

2.5. Outcomes and measures

Gender, age, marital status, level of education, occupation, and economic level were collected.

The BDI-II was used to assess the severity of depression symptoms as the primary outcome. It is made up of 21 questions, with higher scores indicating more severe depression symptoms (Sanz et al., 2005). At baseline, the internal consistency of the BDI-II in our sample was

acceptable (α = 0.71).

Secondary outcomes:

The International Physical Activity Questionnaire-Short Form (IPAQ-SF) (Kim et al., 2013) was used to assess the physical activity over the last seven days (Roman-Viñas et al., 2010). It contains seven items and has good reliability for vigorous physical activity and sitting hours, poor validity for moderate activity and moderate reliability for walking (Kurtze et al., 2008). The minutes walked per week and the minutes sat per day were use in the present study.

The 14-item Mediterranean Diet Adherence Screener (MEDAS), developed by the PREDIMED study group (Martínez-González et al., 2010), was used to assess food intake and consumption patterns related to the Mediterranean diet. A higher score indicates a higher level of adherence (Schröder et al., 2011).

The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) was used to assess sleep quality and sleep patterns. It contains 19 items. Higher scores indicate worse sleep quality (Royuela-Rico and Macías-Fernández, 1997). The internal consistency of the PSQI in our sample was acceptable at baseline (α = 0.75).

2.6. Statistical analysis

Firstly, a descriptive analysis (frequencies for categorical variables; means and standard deviation for continuous variables) and a univariate analysis (one-way ANOVA for age, BDI-II, IPAQ-SF, PSQI, and MEDAS, and Chi-Square test for the remaining variables) were used to examine the data and determined whether there were baseline differences between groups after randomisation. Secondly, to answer the main objective – whether there were differences between treatment groups regarding their effectiveness in reducing depression – we used Linear Mixed-Effects Models (LMEMs) (Singer and Willett, 2003). We specified a model with a random intercept and unstructured covariance. The parameter of interest was the interaction effect of treatment and time in a model that also included age as a covariate because it was the only baseline variable that was significantly different between groups. Cohen's d (*d*) is calculated from the estimated mean values of BDI-II and its standard deviations (SD) at baseline (Mcgough and Faraone, 2009).

Moreover, to answer the second question – whether there were differences between treatment groups with respect to the improvement of lifestyle variables – we used LMEMs with the same previous components.

The results from the trial were presented as a regression coefficient for predicting change in primary and secondary outcomes with 95 % confidence intervals. LMEMs were tested against a Bonferroni-adjusted alpha level of 0.01 (0.05/5) (Haynes, 2013). We used an intention-to-treat analysis (ITT) (McCoy, 2017) and Multiple Imputation technique (MI) for handling missing data. The statistical analyses were performed using the SPSS software (version 25.0) (IBM Corp., 2017) and the imputations were performed using the "mice" package (van Buuren and Groothuis-Oudshoorn, 2011), freely available in the Comprehensive R Archive Network (CRAN-R) of the R statistical software environment (version 3.6.2) (R Core Team, 2019).

3. Ethics approval

Ethics approval was granted by the Research Ethics Committee of Aragón (CEICA, PI18/286) and the Research Ethics Committee of the Balearic Islands (IB3950/19 PI). The study was developed following the Helsinki Declaration. All of the subjects signed an informed consent form; their data were anonymised and were only used for the purposes of the study.

4. Results

A total of 246 participants were evaluated for eligibility, with 14 of them failing to meet the inclusion criteria, 6 declining to participate because they were not interested, and 38 declining to participate because they had time incompatibility. Of the 246 initial participants, 58 (23.58 %) did not participate. Finally, 188 participants were included (Fig. 1) (Moher et al., 2001).

Firstly, the descriptive analysis showed that of the 188 participants, 162 were female and 26 were male, and all participants were between 20 and 83 years old (mean age = 53.32, SD = 13.07) at T0. The univariate analysis subsequently revealed significant differences between the groups ($p = .014$) regarding age, specifically between the TAU and LMP + ICTs groups ($p = .018$), with the LMP + ICT participants being older. However, no significant differences were found between the groups in the other variables (Table 1).

Secondly, the LMEM evidenced that there was a significant effect on BDI-II in the LMP + ICTs (LMP + ICTs vs. TAU slope difference, $b = -2.68$, 95 % CI = [−4.239, −1.133] $p = .001$) (Table 2). That reduction in BDI-II implies a moderate effect size in the LMP + ICTs ($d = 0.519$).

Moreover, LMEMs showed that the variables that measure lifestyle (IPAQ-SF-Walking, IPAQ-SF-Sedentarism, PSQI and MEDAS) changed differently when comparing TAU to the intervention group. Specifically, regarding IPAQ-SF-Sedentarism, there was a significant decrease in the LMP + ICTs group (LMP + ICTs vs. TAU slope difference, b = −37.38, 95 % CI [−62.930, −11.833], $p = .004$) (Supplementary Table 1). That decrease in IPAQ-SF-Sedentarism implies a small effect size in the LMP + ICTs ($d = 0.198$). Regarding IPAQ-SF-Walking, PSQI and MEDAS there were no significant changes in any group (Supplementary Tables 3, 4 and 5).

5. Discussion

The findings of this study indicate that over 12 months, LMP + ICTs were effective in decreasing depressive symptoms. Also, LMP + ICTs helped in the reduction of minutes seated per day.

These results are in line with other studies. For example, a smartphone-delivered multicomponent lifestyle medicine intervention revealed significant improvements in depressive symptoms (Wong et al., 2021). Regarding changes on lifestyle, reflecting a long-lasting effect of the intervention, people receiving the LMP + ICTs group significantly decreased their total daily minutes seated (approximately, three quarters of an hour) when compared to TAU. Sedentary lifestyle were associated with higher likelihood of having depressive symptoms (Mamplekou et al., 2010; Werneck et al., 2022; Zhai et al., 2015). Moreover, a study evaluating sitting time using a wearable device found that total and prolonged sitting time was associated with depression (Biddle et al., 2021). So, counteracting the sedentarism may restore mental health (Mohammed Ali and Kunugi, 2020).

The differences found between both interventions (LMP and LMP + ICTs) could be due to the use of the wearable smartwatch for monitoring. Some of the advantages of this use have been reported in our study. Firstly, the patients from the LMP + ICTs group had significant reduction in their depression. Secondly, these patients had significantly decreased the minutes sitting per day. So, as reported in other studies, ICT-based health solutions could facilitate health promotion and disease prevention (Haluza and Jungwirth, 2015).

The beneficial results could also have been due to the group format of the interventions, since social support is associated with a lower risk of depressive symptoms (Du et al., 2022).

Concerning the study's strengths, the first strength was that the research findings were easily transferrable to practise because it was conducted in primary care settings and any health practitioner could carry out the intervention. Furthermore, and as a novel feature, a variety of components of healthy lifestyles were addressed combined, with no observed harmful effects from the treatments. Finally, the participants of the intervention have been able to be evaluated for one year, allowing the present analysis of long-term results.

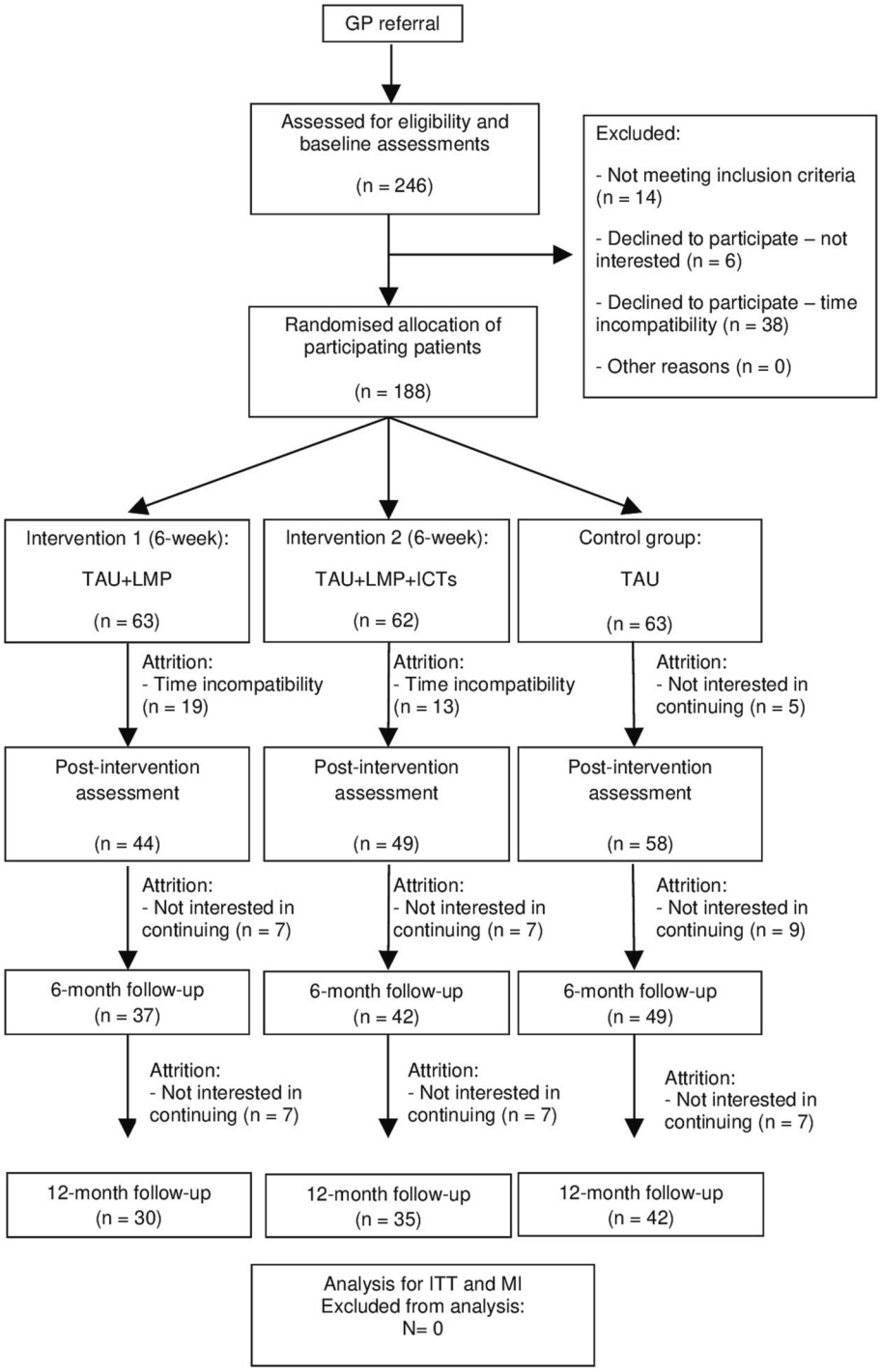

Fig. 1. Flowchart of the study: randomisation, sampling and monitoring of patients.
GP, General Practitioner; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies; ITT, Intention-to-treat; MI, Multiple Imputation Technique.

6. Limitations

One limitation was the overlap with COVID-19, which might have made it difficult for participants to fully implement the lifestyle recommendations during this time period because they couldn't go out to do their normal routines (Aguilar-Latorre et al., 2022a). Another concern was the dropout rate, which was mostly due to time constraints or a lack of interest in responding questionnaires throughout the follow-up period. This limitation was addressed by employing the multiple imputation technique for missing data. In addition, as a control group we have used a wait list control group. That group received the intervention after the active treatment group. When it would be unethical to deny participants access to treatment, wait list control groups are frequently used, as long as the wait is still shorter than that for routine services (Elliott and Brown, 2002). However, wait list control groups may artificially inflate estimates of intervention effect (Cunningham et al., 2013). Finally, future trials could consider adherence strategies for avoiding drop-out. Also, analyzing the effectiveness of LMPs for different sociodemographic factors might be planned for future trials with larger sample sizes.

Table 1
Sociodemographic and clinical characteristics of the sample.

Variables	Total (*n* = 188)	TAU (n = 63)	LMP (*n* = 63)	LMP + ICTs (*n* = 62)	*F or* X^2
Age, *M* (*SD*)	53.32 (13.07)	49.54 (13.50)	54.35 (12.97)	56.11 (11.99)	4.399*
Gender, *female n (%)*	162 (86.2)	52 (82.5)	54 (85.7)	56 (90.3)	1.60
Education					
None or primary, *n (%)*	72 (38.3)	21 (33.3)	22 (34.9)	29 (46.8)	2.84
Secondary or tertiary, *n (%)*	116 (61.7)	42 (66.7)	41 (65.1)	33 (53.2)	
Occupation					
Working, *n (%)*	53 (28.2)	23 (36.5)	17 (27)	13 (21)	3.79
Not working, *n (%)*	135 (71.8)	40 (63.5)	46 (73)	49 (79)	
Marital status					
With a partner, *n (%)*	105 (54.4)	32 (50.8)	34 (54)	37 (59.7)	1.02
Without a partner, *n (%)*	88 (45.6)	31 (49.2)	29 (46)	25 (40.3)	
Economic level					
< IMW to 2 IMW, *n (%)*	164 (87.2)	57 (90.5)	51 (81)	56 (90.3)	3.35
>2 IMW, *n (%)*	24 (12.8)	6 (9.5)	12 (19)	6 (9.7)	
Taking antidepressants, *yes n (%)*	132 (71.3)	45 (71.4)	46 (73)	43 (69.4)	.39
BDI-II, *M* (*SD*)	24.90 (5.11)	24.13 (5.05)	25.00 (4.94)	25.58 (5.29)	1.28
Number of sessions attended**, *M* (*SD*)	4.98 (1.09)	–	5.07 (1.02)	4.90 (1.15)	.57
IPAQ-SF-Walking, *M* (*SD*)	206.46 (273.95)	208.25 (324.92)	233.25 (261.87)	177.42 (226.87)	.64
IPAQ-SF-Sedentarism, *M* (*SD*)	289.97 (186.24)	256.75 (212.23)	306.67 (180.20)	306.77 (160.72)	1.51
PSQI, *M* (*SD*)	11.66 (4.64)	11.57 (4.91)	12.11 (4.34)	11.29 (4.69)	.50
MEDAS, *M* (*SD*)	6.47 (1.86)	6.41 (1.81)	6.54 (2.08)	6.45 (1.70)	.07

Note. IMW, Interprofessional Minimum Wage. one-way ANOVA for age, BDI-II, IPAQ-SF, PSQI, and MEDAS, and Chi-Square test for the remaining variables. BDI-II, Beck II Self-Applied Depression Inventory; IPAQ-SF, Physical Activity Questionnaire-Short Form; PSQI, Pittsburgh Sleep Quality Index; MEDAS, Mediterranean Diet Adherence Screener; TAU, Treatment as Usual; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

* $p < .05$.

** Only patients in the intervention group who did not drop out were included.

Table 2
Estimates of Fixed Effects in BDI-II.

Parameter	Estimate	*SE*	t	*p*	95 % CI for estimated
Intercept	25.497	1.257	20.283	<.001	[23.027, 27.967]
Time	−0.749	0.556	−1.345	.179	[−1.843, 0.344]
Age	−0.079	0.042	−1.893	.060	[−0.162, 0.003]
LMP + ICTs	−0.299	1.792	−0.167	.868	[−3.820, 3.221]
LMP	−1.116	1.775	−0.629	.529	[−4.604, 2.370]
LMP + ICTs * Time	**−2.686**	0.790	−3.397	**.001**	[−4.239, −1.133]
LMP * Time	−1.015	0.787	−1.290	.198	[−2.562, 0.531]

Note. Significant differences ($p \leq .01$) are highlighted in bold. CI, confidence interval; LMP, Lifestyle Modification Programme; ICTs, Information and Communication Technologies.

7. Conclusion

In long-term, LMPs+ICTs administered in PHCs to people suffering from depression were effective in reducing depressive symptomatology and sedentarism comparing to TAU. More research is needed to enhance adherence to lifestyle recommendations. These promising programmes could be easily implemented in PHCs.

Funding

This work was supported by Carlos III Health Institute grant number PI18/01336 and the University of Zaragoza. The funders have no role in study design, data collection and analysis, decision to publish or manuscript preparation. The funding organization will audit trial conduct once a year.

CRediT authorship contribution statement

Alejandra Aguilar-Latorre: Data curation, Formal analysis, Investigation, Methodology, Software, Visualization, Writing – original draft. **Bárbara Oliván-Blázquez:** Conceptualization, Funding acquisition, Investigation, Project administration, Supervision, Validation, Writing – original draft. **Guillermo Pérez Algorta:** Formal analysis, Methodology, Writing – review & editing. **Maria J. Serrano-Ripoll:** Conceptualization, Investigation, Supervision, Writing – review & editing. **Linda E. Olszewski:** Formal analysis, Writing – review & editing. **Alberto Turón-Lanuza:** Formal analysis, Methodology, Writing – review & editing.

Conflict of interest

None.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Acknowledgements

We wish to thank the Aragonese Primary Care Research Group (GAIAP, B21_20R) that is part of the Department of Innovation, Research and University at the Government of Aragón (Spain) and the Institute for Health Research Aragón (IIS Aragón); the Research Network on Chronicity, Primary Care and Health Promotion (RICAPPS, RD21/0016/0005) that is part of the Results-Oriented Cooperative Research Networks in Health (RICORS) (Carlos III Health Institute); Feder Funds "Another way to make Europe", NextGenerationEU funds and the University of Zaragoza. This research has been developed during a short-research term of AAL at Lancaster University supported by *Campus de Excelencia Internacional del Valle del Ebro* (Campus Iberus), "Convenio de subvención Erasmus+ Educación Superior para prácticas Consorcio Iberus+", and *Universidad de Zaragoza*, *Fundación Bancaria Ibercaja y Fundación CAI* "Programa Ibercaja-CAI de Estancias de Investigación", grant number CM 9/21.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jad.2023.04.007.

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