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Peer-led intervention for individuals with major depression: study protocol for a randomized controlled trial (SUPEERMood)

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Abstract

Background Major Depressive Disorder (MDD) is one of the most disabling mental health problems worldwide. The Recovery Model emphasizes peer support to empower individuals with MDD, improve self-management, and patients' quality of life. Despite the demonstrated efficacy of peer-led interventions, further research is needed due to methodological limitations and variability in interventions across studies. Therefore, the objective of this trial is to evaluate the effectiveness of an adjuvant peer-led intervention for the reduction of depressive symptoms in individuals diagnosed with MDD attended in primary care mental health units.

Methods A controlled, parallel, randomized clinical trial will be conducted. The intervention group ($n=35$) will receive 6 weeks of peer-led sessions based on a peer support program drive whilst supervised by nurses, while the control group ($n=35$) will use a mobile Health (mHealth) application for emotional wellness based on CBT for 6 weeks. Measurements will be collected at baseline, at 6 weeks, at 6 and 12 months after the intervention to evaluate post-intervention effects. The primary outcome is the reduction of depressive symptoms through the Beck Depression Inventory (BDI-II) after the intervention. Secondary outcomes will involve measures such as adherence to psychiatric treatment, quality of life, adherence to mediterranean diet, alcohol consumption and physical activity.

Discussion We hypothesize that this peer-led intervention, in contrast to the mHealth, will show improvement in BDI-II score reduction of 6 points after six weeks, 6 and 12 months. Standardized peer-led programs can benefit patients and professionals in terms of efficacy and feasibility of clinical treatment of depression, healthy habits, self-care and quality of life. In addition, they can provide recovery and relapse reduction, improved psychosocial support, minimization of intensive care use, and support for patient autonomy through self-management.

Trial registration The trial protocol is prospectively registered with ClinicalTrials.gov under protocol registration number NCT06398561. Date of registration: May 01, 2024. Recruitment is ongoing.

Highlights

- Peer support programs could be an effective adjuvant treatment of depression.

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• Limited evidence and the lack of standardization of peer support interventions, highlight the need for research in this field.

• Mental health services that foster a sense of recovery identity among patients may have a positive impact on clinical symptoms as well as general wellbeing.

Keywords Peer support, Peer-leader, Depression, Major depression disorder, Depressive disorders, Mental health, Health education, MHealth, Randomized controlled trial

Introduction

Depressive disorders are one of the most prevalent mental health problems in high-income societies affecting over 300 million individuals globally [1]. These disorders represent a major cause of disability, increased risk of premature mortality, decreased quality of life and a significant burden on healthcare systems [1, 2]. Currently, the worldwide prevalence rates are around 5% in adults and 5.7% in individuals aged over 60 [1]. In Spain, according to the latest European Health Survey [3], the depressive disorders' prevalence is 5.7%, with higher rates among women (3.6% in males compared to 7.7% in females). It is of note that the age group with the highest prevalence (at 12%) are those over 75 years old [3].

Major Depressive Disorder (MDD) is the most disabling condition among depressive disorders [4]. MDD frequently appears associated with other health problems, particularly anxiety disorders and substance abuse [4, 5]. Moreover, MDD is associated with a large range of chronic diseases, including cardiovascular, metabolic, neurological, inflammatory, and respiratory disorders [5].

Women aged between 45 and 65 are most affected by MDD [6]. They frequently report persistent feelings of sadness throughout most of the day or a loss of interest and pleasure in activities [6, 7]. This is often accompanied by other symptoms, including insomnia, memory difficulties or negative thoughts including suicidal ideation. Such symptoms severely disrupt their capacity to function effectively in various facets of their life, such as within professional environment, daily routines, social engagements, and personal relationships [8].

First-line treatment for MDD include psychotherapy and antidepressants medications, tailored to the preferences of, with the consent of the individual [9, 10]. There are other second-line neuromodulator antidepressant therapeutic alternatives, but their availability and acceptance by patients vary greatly [10, 11]. Despite these options, a significant number of individuals with MDD have a poor prognosis due to difficulties in diagnosis, limited access to effective treatments, and frequent unsatisfactory responses [12]. Furthermore, around one-third of individuals diagnosed with MDD exhibit non-response to conventional antidepressant interventions, thus manifesting treatment-resistant depression [13].

This, therefore, illustrates the pressing need to explore therapeutic alternatives for the holistic treatment and remission of MDD, which are important issues within the scientific and clinical mental health community [11]. Adjuvant therapies are emerging as a potential solution in this domain. Particularly those focused on educating patients about healthy lifestyles and improving patient autonomy through better self-management of their condition, such as peer support groups and lifestyle interventions [14–16]. Another emerging adjuvant treatment is mobile health (mHealth) [17]. A variety of apps are being developed to mitigate symptoms associated with mental health conditions. These include apps offering mind–body exercises, meditation, and cognitive-behavioural therapy (CBT) specifically tailored for anxiety and depression [18–20]. Some such applications have shown promising outcomes for regular users who have depressive symptoms [19, 20]. However, the validity of these online interventions remains highly restricted, so requires further testing before being considered as an adjuvant treatment method within the healthcare system [21].

Background

The Recovery Model in mental health is a person-centred approach that emphasizes social support, individual responsibility, and empowerment to foster personal strengths and goals to self-management of mental health conditions [22]. Peer support, which involves training individuals who have effectively managed their own disorder to assist others, could play an important role in a recovery-oriented mental health service [23]. Peer support aims to offer positive role modelling to acquire skills and coping strategies to mitigate the symptoms of mental health conditions and integrate them into the community [23, 24].

Peer support programs are increasingly recognized within worldwide healthcare systems as a valuable strategy for managing chronic diseases [25]. A notable example is the Chronic Disease Self-Management Program, an evidence-based program facilitated by trained peer leaders who themselves live with chronic diseases [26]. This program provides participants with the necessary knowledge and skills to effectively manage their conditions,

focusing on symptom management, healthy lifestyle choices, and effective communication with healthcare providers. Participants in the program report improved health outcomes and reduced health service utilization over both six months and two-year period [26, 27]. Additionally, peer support empowers participants to take control of their health, enhancing feelings of self-efficacy and promoting a more active and engaged lifestyles [25].

Peer support programs have expanded to include mental health initiatives, such as Peer Support Project, from Canada [28, 29], which focus on mental health and substance abuse concerns. Comparable initiatives are proliferating in the United States and European countries [30, 31]. Various studies conducted in Germany, revealed that a structured peer support intervention, delivered by trained individuals, resulted in modest improvements in self-efficacy scores at a six-month follow-up [32]. Additionally, a peer-led group program for unemployed individuals significantly improved depressive symptoms through targeted interventions [33]. Similarly, the results of a study conducted in EE. UU has shown benefits in terms of reduction of the usage of healthcare service [34]. Another study carried on UK exposed that structured peer support for depression can enhance student mental wellbeing, though its impact on early and preventive intervention is likely minimal [35].

Multiple systematic reviews underscore the positive impact of mental health peer support on quality of life, social network, empowerment, recovery, satisfaction with services, and workplace environment [30, 31, 36]. However, no significant differences in general psychiatric symptoms, depression and anxiety, inpatient days, and hospitalization were observed [36, 37]. Conversely, a recent review carried out in people with mental health problems show the positive impact of peer support groups in clinical outcomes, including depressive symptoms; self-efficacy, and recovery [30, 38].

The evidence supporting the efficacy of peer support-based programs requires more research due to methodological limitations of previous research, such as small sample sizes, a lack of experimental design, the majority being pilot, feasibility or acceptability studies, as well as brief follow-up period post-intervention [31, 37–41]. Furthermore, the lack of standardized interventions, make the comparison of outcomes across studies difficult [36, 39, 40] The control conditions most frequently used in these studies were: treatment as usual, waiting-list control, or alternative treatments such as clinical groups [30, 42]. This protocol describes a randomized controlled trial (RCT) aimed to assess the effectiveness of a peer-led intervention for individuals with MDD in primary care settings.

Aim of the study

The primary aim is to assess the effectiveness of an adjuvant peer-led intervention for the reduction of depressive symptoms in individuals diagnosed with MDD attending primary care Mental Health Units (MHU), compared with a mHealth intervention based on cognitive-behavioural therapy exercises.

Study objectives

Primary objective

To evaluate the effect of an adjuvant intervention based on a peer support program on reducing of depressive symptoms in individuals with MDD.

The secondary objectives are:

1. To evaluate the effect of the intervention on quality of life of individuals with MDD.
2. To analyse the effect of the intervention on treatment adherence of individuals with MDD.
3. To evaluate the effect of the intervention on related aspects of lifestyle such as: physical activity, adherence to mediterranean diet and risk of alcohol abuse.

Trial design

A controlled, parallel, randomized clinical trial with a follow-up period of 12 months will be conducted. Participants in the intervention group will receive a six-week peer support program, while the control group will use a validated mHealth application, COGITO, which provides information and exercises based on CBT for emotional problems, for the same 6-week period.

Data collection will be carried out at baseline (visit 0), at six weeks (visit 1), at 6 and 12 months (visit 2 and 3) for follow-up. Figure 1 shows study flow diagram.

The development and reporting of the interventions adhere to the Template for Intervention Description and Replication (TIDieR) guidelines [43]. This protocol has been designed in accordance with Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 Statement [44] and adheres to the CONSORT statement recommendations for the reporting of RCTs [45].

Participants

The study will include individuals diagnosed with MDD who are under the care of MHU. Recruitment will be conducted through MHU professionals who will be informed about the study's procedures and objectives. Potential participants that agree to participate will be interviewed to assess their eligibility based on inclusion and exclusion criteria.

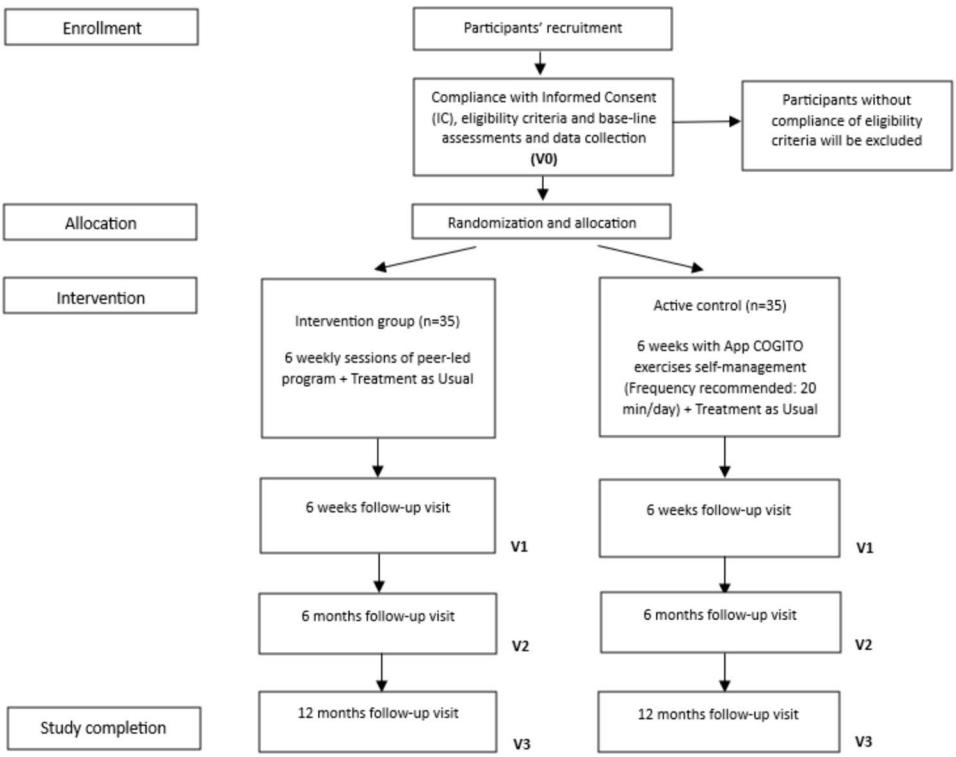

Fig. 1 Study flow diagram

Inclusion and exclusion criteria

Eligible participants will be ≥ 18 years-old, diagnosed with an episode of MDD according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), and the Mini-International Neuropsychiatric Interview (MINI). Additionally, they must have received care from any MHU professional, and possess the adequate physical capacity and cognitive aptitude to understand and engage with the study's requirements.

Individuals will be excluded if they lack competence in Spanish language; have other central nervous system disorders, such as organic brain pathology, traumatic brain injury, or dementia; are experiencing acute episodes of other severe psychiatric disorders as defined by MINI criteria; have serious or uncontrolled medical, infectious, or degenerative conditions that could interfere with affective symptoms; are pregnant or breastfeeding; are at high risk of suicide; have significant travel challenges to the MHU; or have a medical, psychological, or social factors that could substantially block participation in the study.

Sample size calculations

This study aims to assess the effectiveness of the peer-led intervention compared to an m-health intervention facilitated by the COGITO app in reducing depressive symptoms, as well as in improving quality of life and adherence to treatment among participants. Accepting an alpha risk of 0.05 and a beta risk of 0.2, and employing a two-sided test, it is estimated that 35 participants in the intervention group and 35 participants in the control group will be necessary. This calculation is based on the aim to identify a clinically significant difference, remarked by Button et al. [46] of 6 units or more on the Beck Depression Inventory (BDI-II) such as previous related research [47, 48], with an anticipated common standard deviation of 8 units. Anticipating a dropout rate of 20%, as evidenced by previous research [47]. Therefore, the study will require a total sample size of 70 participants.

Randomization and allocation concealment

Concealed block randomization will be used for participant assignment to either the control or intervention groups, with blocks of 4 (1:1 allocation ratio) using Research Electronic Data Capture (REDCap), a web-based application designed to support survey development, electronic data capture, and exportation into statistical software for analysis [49].

The individual responsible for generating the randomization sequence is independent of the research team and the personnel involved in participant recruitment.

Interventions

Description of the intervention group

This intervention comprises two different stages. The initial stage involves the recruitment and training of peer-leaders, who are focused on delivering the peer-led intervention. Further details on these stages are outlined below:

Peer-leaders' training

Prior to the intervention sessions, approximately 5–6 peer leaders will be recruited. These individuals are required to meet the criteria specified in Table 1 and may be sourced from a variety of MHU, including patient and family connections. They will assist as conductors for the intervention sessions.

Upon selection, the peer leaders will complete a 24-h training program. This training consists of six sessions (4 h each). The programme covers health education methodology, peer training techniques and, essential knowledge on managing the disease and potential complications. The peer leaders will act both as conductors and observers within the group. All this content as detailed in Table 2.

Table 1 Description of the reunited characteristics of peer leaders' selection

Characteristics of peer leaders
■ Effective disease management
■ The diagnosis should not be recent; it is recommended that the diagnosis has been established at least one year before or the patient has acquired sufficient knowledge to allow a positive approach to the disease positive approach to the disease
■ Communication skills
■ Skilled in managing emotions and/or working with emotional aspects
■ Motivation and empathy
■ Attitude to learn
■ Commitment to participate in peer training on a voluntary basis

Intervention group based on peer-led sessions

The training will consist of a series of six 2-h workshops, following a model similar to the program protocol but adapted specifically for MDD [50]. Peer leaders, accompanied by mental health professionals acting as facilitators, will conduct these sessions.

Trainers will adhere to a detailed content guide outlining each session's step-by-step structure. This guide will be developed by a multidisciplinary group of mental health experts, including individuals with lived experience of MDD who have successfully managed their condition.

Once the guide is finalized, it will undergo review by national-level experts in depressive disorders to ensure its suitability and effectiveness.

The sessions outlined in Table 3 will serve as a roadmap for developing the MDD workshop.

Table 2 Sessions' content for peer-leaders' training

Session 1. Discovering Health Education
■ Concepts of health, health education, health assets, active patient, self-care and empowerment ■ Human health behaviours and related factors
Session 2. Personal Coping Skills (I)
■ The learning process in individuals ■ Educator's role and observer's role ■ Personal skills, emotions, and positive thinking
Session 3. Personal coping skills (II)
■ Coping with situations and problems ■ Decision making ■ Coping with stress
Session 4. Social skills: communication. Living with the disease
■ The phenomenon of communication ■ The disease: implications in our lives
Session 5. Beyond the health care system: the informal network, patient associations and schools
■ Special situations ■ Patient associations and the informal network to take care of the disease ■ Benefits of patient schools ■ Evaluation of the training and awarding of certificates
Session 6. Working group dynamics
■ Group education. Educational methods: classroom research techniques and analysis techniques ■ Group education. Educational methods: expository techniques and skill development techniques

Table 3 Session's content of peer-led workshop for MDD

Session 1: What do they mean when they talk to me about depression?

- Explaining the concept of depression
- Most prevalent symptoms of MDD
- Causes of why it may appear and risk factors

Session 2: How can I manage the impact of my emotions?

- Identification of my emotions. Emotional intelligence model
- Sources, manifestations, and management of stress
- Coping techniques for life

Session 3: Let's start dealing with depression in the first person

- Use of antidepressant drugs and their effects
- Importance of psychological therapy in the combined treatment
- Knowing and tolerating relapses

Session 4: What can I do to feel better?

- Healthy lifestyles and habits
- The importance of contact with nature and living in the present
- Mindfulness practice
- Self-knowledge and self-care

Session 5: The process of asking for help: An indispensable tool

- Coping with and reasoning about my irrational beliefs. Problem solving workshop
- Social and family support network
- Suicide risk. How to identify it

Session 6: Resources available in my community. Patient associations

- Identification of resources for coping with the health problem
- Presentation of proximity resources. Patients' associations
- Action plan

Description of the active control group based on m-health system (COGITO App)

The control group will be provided with a set of exercise guidelines administered through the COGITO App, which is based on CBT. The duration of app usage will be 6 weeks (as in the intervention group). Participants will be advised to adhere to a daily 20-min exercise regimen to align with the intervention timeframe. The app's use can be tracked through exercise history logs, and alerts will be triggered in instances of low usage. Additionally, participants can activate daily reminders to facilitate adherence.

Participant timeline

Table 4 offers an overview about timeline for participant enrolment, interventions, main study visits, and assessment measures.

Visit 0

At visit 0 (commences 15 days prior to the intervention) the investigators will assess participants' eligibility based on inclusion and exclusion criteria. Upon selection, participants will provide informed consent and complete baseline data along with several questionnaires, including the BDI-II for measuring depressive symptoms, the EuroQoL-5D to evaluate quality of life, the DAI-10 to assess treatment adherence, the PREDIMED for measuring the adherence to Mediterranean diet, the IPAQ for asses the frequency and intensity of physical activity and the AUDIT-C that measures the alcohol consumption. Additionally, during the same visit, randomization will be conducted for each group, and participants will be briefed on the respective procedures to be followed based on the assigned intervention or control group as per the randomization protocol.

Visit 1

At visit 1, which follows one week after the intervention, all participants will undergo individual interviews at the MHU to complete the questionnaires listed in Table 4.

Visit 2 and 3

At visit 2 (scheduled six months after the intervention) and visit 3 (scheduled one year after the intervention) we will re-establish contact with all participants. Phone interviews will be arranged for each participant to administer the questionnaires outlined in Table 4. The third visit will mark the conclusion of the study.

Data collection

Mini international neuropsychiatric interview

The MINI (Mini International Neuropsychiatric Interview) [51] is a structured diagnostic interview used in psychiatry to assess and diagnose major psychiatric

Table 4 Participants' assessment schedules

Evaluations	Intervention group				Control group			
	V0	V1	V2	V3	V0	V1	V2	V3
Time point[a]	-30 d	6 w	6 m	12 m	0 d	6 w	6 m	12 m
Informed consent	X				X			
Inclusion and exclusion criteria	X				X			
Randomization	X				X			
Baseline data[b]	X				X			
End of intervention		X				X		
BDI-II[c]	X	X	X	X	X	X	X	X
EuroQoL-5D[d]	X	X	X	X	X	X	X	X
DAI-10[e]	X	X	X	X	X	X	X	X
AUDIT-C[f]	X	X	X	X	X	X	X	X
PREDIMEDg								
IPAQ[h]	X	X	X	X	X	X	X	X

[a] Time point: d = day; w = week; m = month

[b] Baseline data: Demographics, marital status, diagnostic label related with mental health condition, year of diagnosis, educational level, pharmacological treatment, psychotherapy treatment, PCMHU assigned, profession, comorbidities, current employment status

[c] BDI-II: Beck Depression Inventory-II

[d] EuroQoL-5D: Quality of life questionnaire

[e] DAI-10: Drug Attitude Inventory (10 items)

[f] AUDIT-C: Alcohol Use Disorders Identification Test C

[g] PREDIMED: Adherence to Mediterranean Diet

[h] IPAQ: Physical Activity Questionnaire

disorders according to the DSM criteria. It is designed to be a brief yet comprehensive tool, taking about 15–30 min to administer. The MINI is used by clinicians and researchers to diagnose mental health conditions, aiding quickly and accurately in treatment planning, research studies, and ensuring consistency in psychiatric evaluations. We will use the MINI to ensure compliance with the inclusion criteria.

Sociodemographic data

Furthermore, baseline variables related to sociodemographic data will be recorded. Specifically, the following patient characteristics will be selected for our study: age, gender, marital status, diagnostic label related to mental health condition, year of diagnosis, educational level, pharmacological treatment, psychotherapy treatment, which MHU they are assigned to, profession, comorbidities, and current employment status. These variables will only be required during the initial data collection phase.

All outcomes will be assessed at four different points of time: (1) during the initial interview with participants before the intervention has been started; (2) at the conclusion of the six-week intervention; (3) at a six-month follow-up and (4) at the 12-month follow-up.

Adherence to Mediterranean diet

The dietary assessment tool used comprises of 14 concise questions. These are intended to establish to what extent Mediterranean diet is adhered to. Developed by Spanish researchers, the questions focus on the consumption of essential foods in the Mediterranean diet, with scores categorized into four levels of adherence: high, medium, low, and poor [52].

Physical activity

The International Physical Activity Questionnaire (IPAQ) measures the frequency and intensity of physical activities in contrast to sedentary behaviour undertaken as part of daily life. The aim is to estimate total physical activity in Metabolic Equivalent for Task (MET)/minutes per week as well as time spent sitting [53].

Alcohol use disorders

The Alcohol Use Disorders Identification Test C is a 3-question screening tool for alcohol use that helps detect individuals who engage in risky drinking behaviours or have current alcohol use disorders, such as abuse or dependence. This tool is an abbreviated adaptation of the original 10-item AUDIT questionnaire. That questionnaire was originally developed by the World Health Organization and has been adapted for use in the UK and

deployed across diverse social and healthcare services [54].

Depressive symptoms

The primary outcome will be depressive symptoms measured by Beck Depression Inventory (BDI-II) [55]. This 21-item questionnaire, that ranges from 0 to 63, has satisfactory validity, with a r = 0.66 for people with depressive disorders. It has been validated for the Spanish population and explores different aspects of depressive symptoms, such as: sadness, self-esteem, sleep habits, appetite and concentration, etc.

Adherence to psychiatric treatment

The adherence to treatment will be measured through the Drug Attitude Inventory (DAI). This self-administered questionnaire was created for the purpose of examining therapeutic adherence in the field of psychiatry, focusing on medication-related attitudes and beliefs. Initially, a 30-item questionnaire known as DAI-30 was designed; however, in clinical practice the 10-item version, known as DAI-10, is preferred. The DAI-10 has six positive questions and four negative questions. Participants are asked to rate the statements as true or false, being scored + 1 if correct and -1 if incorrect. The final score varies between -10 and + 10, reflecting a more positive attitude towards psychiatric medication as the score increases. This tool has shown satisfactory validity, accompanied by a test–retest reliability of r = 0.82 [56, 57].

Quality of life

In order to measure the quality of life, the EuroQoL-5D questionnaire will be used. It can be self-administered; however, it is usually carried out via an interview with a professional. The subject evaluates their state by assigning a level of severity to various health dimensions, such as mobility, self-care, activities of daily living, pain/discomfort, and anxiety/depression. An evaluation is subsequently made by means of a visual analogue scale from 0 to 100 points. Construct validity was evaluated within the Spanish population, and results revealed that all contrasts were statistically significant ($P < 0.001$) [58].

Outcome measures

The primary outcome measure will be the depressive symptoms, evaluated with BDI-II at the post-intervention follow-up, at 6 and 12 months. Secondary outcomes to be measured will be quality of life (EuroQol-5D); adherence to psychiatric treatment (DAI-10); adherence to Mediterranean diet (PREDIMED); physical activity (IPAQ) and alcohol use (AUDIT-C).

Data analysis

All statistical analyses will be performed using SPSS version 26 statistical software (SPSS/IBM, Chicago, IL, USA). Intention-to-treat (ITT) analysis will be performed to interpret clinical outcomes.

The effectiveness of the intervention on depressive symptoms (BDI-II) will be assessed using a general linear model (ANOVA) for continuous measures at post-intervention (6 weeks), at 6 and 12 months, adjusted from baseline values.

Multiple imputations will be performed for the main analysis, as this method generally provides less biased one-effect estimates than a full-case analysis. Missing outcomes will be accounted for by multiple imputation with a chained equation [59]. All results will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized clinical trials [45].

Ethical considerations

The present protocol was approved by the Ethical Research Committee (CEI-IB) and the Primary Care Commission of Research for the Balearic Islands (registration number: IB 5356/23 PI; ClinicalTrials.gov: NCT06398561), follows ethical principles from the Declaration of Helsinki. Participants will receive a patient information sheet explaining the research process, risks, and benefits. Participants' written consent will be obtained, and all data collected will be kept anonymous and confidential. Participants can voluntarily withdraw their informed consent at any time during the study. Data will be encrypted, pseudonymized, and protected by the Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights. Results will be published regardless of hypothesis outcomes.

Validity and reliability

The study design was chosen to mitigate the risk of bias, while also minimizing type 1 and type 2 errors related to sample size, by ensuring adequate statistical power. Participants will be carefully selected based on specific criteria to ensure that the intervention's effectiveness measures are appropriate. This selection process will mitigate potential confounding factors, such as differing diagnoses. The intervention is to be established in a program that has had successful outcomes in addressing other health problems. Furthermore, all outcome measures utilized in the study have been previously validated in similar settings.

Discussion

The present study will provide evidence about the effectiveness of a peer-led intervention as an adjuvant treatment for MDD. The proposed intervention could offer significant potential benefits for people with MDD and could contribute to reduce relapses and treatment resistant depression. Among the diverse benefits conferred upon beneficiaries of peer-led intervention are psychosocial support, the acquisition of healthy lifestyle habits, mitigation of social isolation, improved control of self-care skills, guidance in navigating the healthcare system, and access to community-based resources [60–62].

This study has been designed to be applicable to clinical practice and scalable to the MHU. Promoting the recovery and overall quality of life for individuals with mental health problems could ameliorate depressive symptoms, disabilities, and suffering [34, 63]. Peer support and self-management programs are increasingly recognized as valuable recovery-oriented services that not only have the potential to enhance patient well-being and reduce relapse rates but also reduce the pressure on acute care services [30, 62, 64].

Furthermore, peer-led support provides benefits not only for the participants receiving the intervention but also for the peer leaders and mental health professionals involved. Peer leaders may derive a sense of purpose from their role, which can contribute to sustaining their own recovery process and increase their autonomy and self-esteem [65]. Healthcare professionals may also derive indirect benefits when patients develop self-care skills and establish connections with a support system. This all points to the importance of the utilization of relapse prevention strategies and community resources [60, 65].

Incorporating an active control will improve the internal validity of the study. Moreover, an ethical approach is ascertained by ensuring that equal time is allocated to both participant groups, as both will receive additional attention beyond the standard treatment. The mHealth is an accessible tool, like adjuvant treatment, but despite the more than 10,000 apps that exist focused on mental health, only 3–4% are evidence-based [18–20]. In conclusion, high-quality studies evaluating the effectiveness of peer-led interventions in MDD are urgently needed [39, 66].

Limitations

This study presents some limitations due to the nature of the sample and type of intervention. Firstly, a population with depressive symptoms is more likely to present with low adherence to the intervention, resulting in potentially higher than average drop-out rates. This was considered when calculating the sample size.

Secondly, due to the scope of the study and the extensive recruitment requirements, it can be assumed that the recruitment process will be slow, especially when the degree of motivation and affective symptoms of the participants are considered. In accordance with similar interventions, the Clever Hans effect may take place, as it is not possible to perform a triple blind. To remedy this, the external evaluation of the main and secondary outcomes will be blinded about the group assignment.

Abbreviations

MDD	Major Depressive Disorder
mHealth	Mobile Health
MHU	Mental Health Units
CBT	Cognitive-Behavioral Therapy
RCT	Randomized controlled trial
TIDieR	Template for intervention description and replication
SPIRIT	Standard Protocol Items: Recommendations for Intervention Trials
CONSORT	Consolidated Standards of Reporting Trials
DSM-5	Diagnostic and Statistical Manual of Mental Disorders
MINI	Mini-International Neuropsychiatric Interview
BDI-II	Beck Depression Inventory-II
EuroQoL-5D	Quality of life questionnaire
DAI-10	Drug Attitude Inventory (10 items)
AUDIT-C	Alcohol Use Disorders Identification Test C
PREDIMED	Adherence to Mediterranean Diet
IPAQ	Physical Activity Questionnaire
REDCap	Research Electronic Data Capture
ITT	Intention to treat
ANOVA	Analysis of variance
CEI-IB	Research Ethics Committee of the Balearic Islands

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Authors' contributions

Conceptualisation, X.G-G., M.B-V.; M.G-T.; A.M.Y.; methodology, X.G-G., M.B-V.; M.G-T.; A.M.Y.; writing—original draft preparation, X.G-G.; writing—review and editing, X.G-G.;M.L.M-S.; P.R-D.; Y.C-T.; C.G.d.M.; supervision, M.B-V.; A.M.Y, M.G-T.; project administration, M.B-V. All authors have read and agreed to the published version of the manuscript.

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Availability of data and materials

The data presented in this study are available on a reasonable request from the corresponding author. The publication of results will occur regardless of the effectiveness of the experimental intervention. Authorship eligibility will be determined based on the guidelines of the International Committee of Medical Journal Editors (ICMJE).

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The present protocol was approved by the Ethical Research Committee (CEI-IB) and the Primary Care Commission of Research for the Balearic Islands (registration number: IB 5356/23 PI; PI23/41), follows ethical principles from

the Declaration of Helsinki. Participants will receive a patient information sheet explaining the research process, risks, and benefits. Participants' written consent will be obtained, and all data collected will be kept anonymous and confidential. Participants can voluntarily withdraw their informed consent at any time during the study. Data will be encrypted, pseudonymized, and protected by the Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights. Results will be published regardless of hypothesis outcomes.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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