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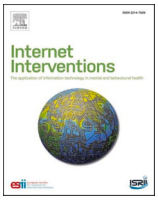

Telephone support vs. self-guidance in an Internet-based self-administered psychological program for the treatment of depression: Protocol for a hybrid type 1 effectiveness-implementation randomized controlled trial

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ABSTRACT

Background: Depression is already the leading psychological disability around the world, impairing daily life, well-being, and social functioning and leading to personal and social costs. Despite the effectiveness of Evidence-Based Psychological Practices (EBPP), a significant percentage of depressive individuals remain untreated, especially in Primary Care (PC) settings in Spain. There are numerous barriers that limit access to EBPPs, including high costs, professional training, and adherence problems. Information and Communication Technologies (ICTs) offer a cost-effective way to disseminate and scale EBPPs to address these barriers. The iCBT program Smiling is Fun has been demonstrated to be a cost-effective treatment for depression in various Randomized Control Trials. However, adherence and implementation problems in real-world settings need to be addressed. Implementation research can help evaluate these challenges by identifying facilitators and barriers to the implementation process in PC. In this regard, including human support has been pointed out as a possible key factor in addressing the population's mental health needs and promoting treatment adherence.
Objective: The current study aims to examine the effectiveness, adherence rates, and implementation process of Smiling is Fun to address depression in a PC setting considering the influence of telephone support vs no support.
Methods: The proposed research is a Hybrid Effectiveness-Implementation Type I study, with a two-armed randomized controlled design, which will test a clinical intervention for major depressive disorder while gathering information on its implementation in a real-world setting. The study will include adult patients with mild to moderate symptoms of depression. Participants will be randomly assigned to one of two groups: self-applied psychotherapy or self-applied psychotherapy with psychotherapeutic telephone support. The trial will recruit 110 patient participants, with a loss-to-follow-up rate of 30 %.
Discussion: A study protocol for a hybrid effectiveness-implementation study is presented with the aim to assess the implementation of Smiling is Fun for the treatment of depression in PC. The study evaluates the influence of telephone support during a self-administered intervention compared to unguided self-administration. The main goal is to address the barriers and facilitators of the implementation process and to promote treatment adherence. Ultimately, the results of the study could help in the uptake of sustainable resources so that the population could gain better access to psychological interventions in mental health services.
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1. Introduction

Depression can lead to a severe impairment in daily life, well-being, and social functioning (Zuelke et al., 2018) and is expected to be the primary cause of burden worldwide (World Health Organization, 2022). In addition, it presents high comorbidity rates with other mental disorders, chronic physical illnesses, and neurological diseases (Gili et al., 2013; Kang et al., 2015; Rey et al., 2015). Even though the treatment of depression is essential to prevent the chronification and worsening of the symptomatology (Baader et al., 2012; Wardenaar et al., 2014), 75 % of people with depression remain untreated (World Health Organization, 2022).

In Spain, this situation is especially dramatic in Primary Care (PC) settings, where depression is the most prevalent mental disorder (13.9–29 %), leading to high annual economic costs (5.348 million euros) as well as personal and social costs (National Health Survey, 2017; Roca et al., 2009a, 2009b; Salvador-Carulla et al., 2011; Serrano-Blanco et al., 2010; Vindel et al., 2012).

Despite the proven effectiveness of psychological and pharmacological treatment (or the combination of both) in addressing depression (Cuijpers and Gentili, 2017), Evidence-Based Treatments (EBT) do not reach the population (Kazdin and Blase, 2011; Morris et al., 2011).

In Spain, specifically at the PC level, despite the high prevalence of depressive patients and their preference for psychotherapy (Rodgers et al., 2012), the high dropout rates associated with pharmacological treatments (Martínez et al., 2014), and the recommendation of the National Institute for Health and Clinical Excellence (NICE, 2020) to apply Evidence-Based Psychological Treatments (EBPT) to address depression, the treatment of choice is still medication (Pinto-Meza et al., 2008), with a growing tendency to over-prescribe antidepressants (Codony et al., 2007; González-López et al., 2015). However, psychotherapy is in demand by patients and has been shown to reduce the number of medical consultations and hospitalization days, and achieve better results in terms of adherence, relapse prevention, and reduction of chronicity (Huhn et al., 2014a, 2014b).

In light of this situation, addressing depression adequately and finding a way to establish it in the mental health system becomes imperative.

Some of the barriers preventing the adequate treatment of the population are the high cost of face-to-face treatment, the professional training, long waiting lists, adherence problems, and the time required to apply interventions (Fernández et al., 2010; Webb et al., 2017). Information and Communication Technologies (ICTs) offer a cost-effective way to address some of these barriers, promoting the dissemination, accessibility, and scalability of the EBPT (Ebert et al., 2018; Kazdin and Rabbitt, 2013; Titov, 2011). Systematic reviews and meta-analysis have provided evidence supporting the effectiveness and acceptability of using Internet-Based Treatments (IBT) to address depression (Karyotaki et al., 2017, 2021; Richards and Richardson, 2012a, 2012b; Sander et al., 2016), with results being comparable to face-to-face treatment (Carlbring et al., 2018; Cuijpers et al., 2019). Furthermore, regarding the context of interest (PC), a recent systematic review supported the use of Internet Cognitive-Behavioral Treatments (iCBT) to increase the number of people receiving mental health care, highlighting the importance of the implementation of interventions already proven in Randomized Controlled Trials (RCTs) (Etzelmueller et al., 2020).

According to the literature, the use of validated iCBT is presented as a tool to address the population's mental health needs (Karyotaki et al., 2018). The research group LabPsiTec has developed a Spanish iCBT called Smiling is Fun (“Sonreír es Divertido”) which includes psychological strategies to address depression. Through diverse RCTs, the intervention has demonstrated efficacy and effectiveness in the prevention and treatment of depression (e.g., Botella et al., 2016; Mira et al., 2019; Mira et al., 2016). Smiling is Fun is not only effective at reducing depressive symptomatology and increasing the positive affect but has also been demonstrated to be cost-effective (Botella et al., 2015a, 2015b; Romero-Sanchiz et al., 2017a, 2017b). The clinical benefits of Smiling is Fun, along with its cost-effective appropriateness, suggest that this EBPT intervention could be used to cover the needs of PC settings.

Although these findings are promising, it is still necessary to consider the naturalistic character of this study which is focused on a specific daily setting, PC in Spain. In real settings, one of the main problems is the know-do gap, which is understood as a temporal gap of 17 to 20 years for the population to benefit from scientific advances (Morris et al., 2011; Van Den Driessen Mareeuw et al., 2015). The obstacles associated with EBT uptake are mainly due to the differences between laboratory and real settings, as in daily settings there is a lower level of control, lower economical and personal resources, less level of specialization, low rates of motivation, etc. (Bauer and Kirchner, 2020).

Faced with this problem, Implementation Research (IR) establishes a methodology to assess the facilitators and impeding factors of the implementation process in a specific context and population (Bauer and Kirchner, 2020; Grol et al., 2007). Implementation designs offer us the methodology and information to promote access to EBPT in healthcare systems by detecting the factors influencing it and offering strategies to implement the intervention while maintaining its validity (King et al., 2019).

One of the proposed designs are the hybrids ones. Hybrid models allow the dual assessment of the clinical intervention's effectiveness and the implementation process to different degrees (Curran et al., 2012). In terms of the assessment target, three different types of hybrid designs are established varying in their focus and the amount of emphasis on effectiveness versus implementation outcomes. The Hybrid Type I model focuses on testing the clinical intervention's effectiveness while collecting information on the potential for implementation in real-world settings. This type of design is recommended when there is some evidence about the effectiveness of the intervention and extra information regarding the implementation process in a context is necessary. The Hybrid Type I model is especially indicated when the aim is to test the clinical effectiveness in a specific context and population, especially when stakeholders have an impact on the implementation process (Green et al., 2019).

Given that a classical RCT design could lead to an overestimation of the uptake of the intervention in PC, a hybrid type I model is considered a more appropriate design for the purpose of this study, offering valuable information about the implementation process (Singal et al., 2014).

With all this in mind, the Smiling is Fun program and the hybrid type I design seem to be appropriate for the implementation in PC. However, an important question remains unanswered regarding possible barriers in the implementation process. One of the repeated findings in iCBT is that, despite its effectiveness, there is a high number of patients that drop out. In this regard, an important factor influencing the outcome of iCBT for depression is the degree of professional support or guidance received throughout the treatment. In the review conducted by Andersson et al. (2019), it was concluded that self-guided iCBTs tend to be less effective than therapist-guided iCBTs and that the latter modality tends to be as effective as face-to-face CBT, maintaining outcomes over time. The effect size of the intervention has been observed to increase with professional contact, showing a higher increase if the contact was done before and during the treatment (Johansson and Andersson, 2012). As a result, one of the strategies proposed is to combine online care with brief telephone contacts to increase adherence and reduce dropout rates. Furthermore, the practical and technical support and the software application have been determined to be key factors for implementation success together with therapeutic aspects, such as alliance and bonding, empathy and validation, or self-revealing responses (Andersson et al., 2019).

Given that in this context the attendance time of professionals is usually very limited, it is essential to carry out studies that provide us with more detailed knowledge about the role of the contact between clinician and patient, the attendance frequency or the type of support offered by clinicians (Botella et al., 2015a, 2015b).

Accordingly, our research aims to investigate the potential of additional telephone contact to enhance the implementation process and contribute to improved intervention effectiveness and patient adherence. To this end, we have formulated the following hypotheses. Our primary hypothesis posits that providing guidance through scheduled calls will enhance the efficacy of treating mild and moderate depression when compared to non-telephonic support condition. Specifically, we expect patients in the human support group to demonstrate a significantly greater reduction in depression severity, as assessed by the Beck Depression Inventory (BDI-II), when comparing pre and post-treatment assessment.

The secondary hypotheses encompass: (2) greater patient adherence in the human support group compared to the unguided group, measured by the number of completed modules; (3) the human support group will experience a more substantial improvement in quality of life compared to the unguided group, as evidenced by superior outcomes on the European Quality of Life 5D (EUROQOL); (4) the implementation process will exhibit higher success in the human support group demonstrating higher levels of feasibility measured by Feasibility of Intervention Measure (FIM), greater levels of acceptance according to Acceptability of Intervention Measure (AIM) and enhanced appropriateness on the Intervention Appropriateness Measure (IAM) of patient at post-treatment and follow-ups, as well as for stakeholders at post-implementation stage of the intervention.

All in all, the current implementation research aims to conduct a Hybrid Type I study with a two-armed randomized controlled design to examine the effectiveness and implementation factors of the Smiling is Fun program in the context of depression in Primary Care settings. The study will compare two conditions: one with telephone support and one without. The objective is to evaluate the effectiveness of Smiling is Fun at reducing depression symptoms, as well as to identify the impact of support on adherence and to detect the implementation factors that may influence its sustainability.

2. Methods

2.1. Design

The proposed study follows a Hybrid Effectiveness-Implementation Type I model with a two-armed randomized controlled design (Green et al., 2019).

The study will test the clinical intervention while gathering information on its delivery during the effective trial and on its potential for implementation in a real-world situation (Curran et al., 2012).

All participants who meet the eligibility criteria will receive the intervention and will be randomly assigned to one of the two groups: (1) self-applied psychotherapy through the Internet and (2) self-applied psychotherapy with psychotherapeutic telephone support.

The study protocol will be developed following the Consolidated Standards of Reporting Trials (CONSORT; Chan et al., 2013) and the guidance for reporting intervention development studies in health research (GUIDED; Duncan et al., 2020). The trial is registered at ClinicalTrials.gov as NCT06230237.

2.2. Study population, recruitment, and eligibility criteria

2.2.1. Study population

According to the established design, Hybrid Effectiveness-Implementation I, the population of interest is not limited to the patients. In this case, the target of the study will be the stakeholders directly involved in the process, the patients and the health professionals. The patients will be part of the general population attending PC settings and will be the target that receives the intervention. The health professionals will be recruited by researchers to implement the intervention and conduct the recruitment of patients all in PC settings.

2.2.2. Patients

The study sample will consist of adults aged over 18 years and up to 65, who meet the Diagnostic and Statistical Manual for Mental Health Disorders-Version 5 (DSM-5; APA, 2013) criteria for major depressive disorder and who meet the eligibility criteria recruited in Primary Care settings.

2.2.3. Health professionals

The health professional sample will consist of clinicians working in PC in the Gandia Health Department (Valencia, Spain). They will be responsible for the recruitment and implementation work. No exclusion criteria are established.

2.2.4. Patient eligibility criteria

Participants will be included if they meet the following criteria; (1) age 18 to 65 years; (2) ability to understand and read Spanish; (3) meeting diagnostic criteria for major depressive disorder (DSM-5); (4) mild or moderate symptoms of the Spanish version of the Beck Depression Inventory-II (BDI-II; 14–19: mild depression; 20–28: moderate depression); (5) internet access at home and an email account.

Participants will be excluded if they: (1) present any illness that affects the Central Nervous System (CNS) (i.e., Parkinson's disease or Alzheimer's disease); (2) have a severe mental disorder (e.g., alcohol abuse and dependence, psychosis, eating disorders, etc.); (3) have a presence of hallucinations or delirium; (4) are at risk of suicide or (5) are already receiving psychotherapy.

Participants with comorbid and related disorders will be included when depression is the primary diagnosis. Furthermore, to not neglect the needs of the population, candidates who do not meet the inclusion criteria will be derived to treatment alternatives better suited to their specific needs. Patients who take antidepressant or anxiolytic medication will be included in the study if it has been three months since the onset of pharmacological therapy.

2.3. Sample size

The total sample size of the study was calculated using version 3.1 of G*Power (Faul et al., 2007). A priori analysis was conducted for sample estimation, considering two groups (telephone support vs. self-guidance) and two measurement points (pre-treatment and post-treatment assessments). An alpha risk of 0.05, a beta risk of 0.2, and a small effect size of 0.15 were determined, resulting in a total sample size of 148 participants. Based on previous studies (Mira et al., 2017, 2019) a loss-to-follow-up rate of 30 % was anticipated on post-treatment assessment. Therefore, the sample size was increased to 194 participants, who will be randomly allocated to either the telephone support condition ($n = 97$) or the condition without telephone support ($n = 97$).

2.4. Study procedure

The implementation setting will be PC at health centers which are part of the *Gandia* Health Department in the Valencian Community (Spain) (Fig. 1).

Health professionals will be recruited by local researchers through talks held at their workplace. The professionals will recruit the patients. Primary care physicians will receive instructions about participants' profiles to identify the patients who fit properly and to refer them to the researchers. Then, the diagnosis will be confirmed through a non-standardized semi-structured interview following the DSM-5 criteria. This interview will be conducted by a psychologist with a master's degree and training in structured interviews such as the MINI, specifically hired for the purpose of conducting these interviews. In the course of the interview, the evaluation of suicide risk will be conducted using the Beck Suicidal Intent Scale (SIS) (Beck et al., 1979) in the Spanish validated version (de Rivera, 2000). In the suicide risk assessment, no cut-off is established, as any indication of the presence of suicidal ideation should

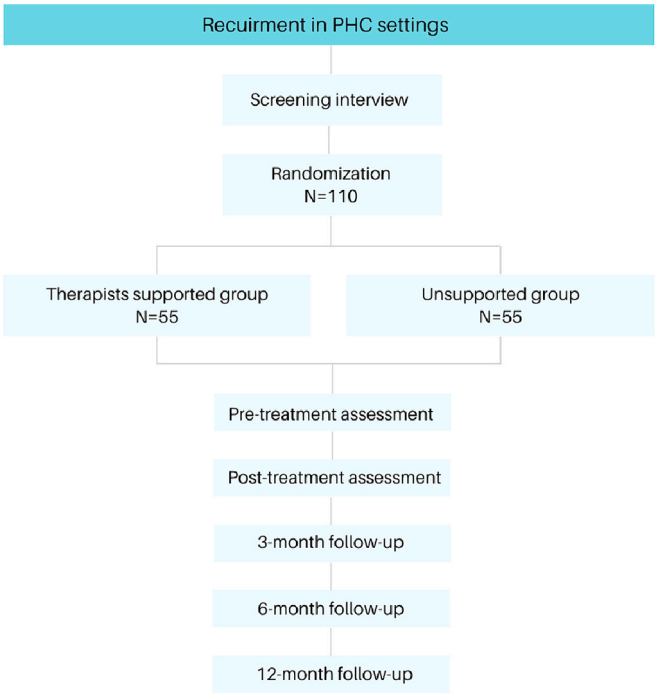

Fig. 1. Study of patients' procedure.

be considered (Brown et al., 2000). Higher punctuation will indicate higher risk of suicide. Psychologists should consider initiating established protocols in accordance with PC settings to address the situation effectively when the risk of suicide is identified.

The patients who meet these criteria will be assigned to one of both experimental conditions. The informed consent form will be signed before randomization to one of the two conditions.

Participants allocated to the unguided condition will only communicate with researchers in case of technical issues. Participants allocated to the therapist support condition will receive 6 supportive phone calls from researchers, a phone call will be made every 2 weeks. Phone calls will not last more than 20 min and will be structured following a pre-established outline. These will be made by local researchers and the content will depend on how many modules participants have completed since the last phone call. The different pre-established phone actions are described in Fig. 2.

In the event of adverse events, the intervention provides a designated system for response. At the beginning of each module, participants undergo an evaluation of risk factors, including assessments for suicide risk and depressive symptomatology. Responding to these questions is mandatory to progress through the intervention. If elevated scores on these questionnaires suggest a moderate or higher risk, researchers promptly receive an alert. Subsequently, these incidents are communicated and collaboratively addressed with the Primary Care professionals.

3. Measures description

The assessment protocol is outlined in Table 1.

3.1. Primary outcomes

3.1.1. Depressive symptoms

The Beck Depression Inventory-II (BDI II; Beck et al., 1996) is a 21-item self-report test that aims to screen depression and the severity of a range of symptoms linked to depression. Items are presented on a 4-point Likert scale in which 0 is the absence of symptoms and 3 is maximum intensity during the last two weeks. Results indicate minimal depression (0–13), mild (14–19), moderate (20–28), and severe (29–63) depression. The Spanish adaptation has shown excellent psychometric properties showing high internal consistency ($\alpha = 0.88$) (Sanz et al., 2003; Sanz et al., 2005).

3.2. Secondary outcomes

3.2.1. Effectiveness outcomes

3.2.1.1. Quality of life. The EuroQol 5-Dimensions (EQ-5D; Herdman et al., 2001) is a self-report questionnaire that measures health-related quality of life. It is composed of 6 items, the first 5 items assess the following dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The scoring of these dimensions ranges from 1 to 3 (1 with no problems and 3 with a lot of problems).

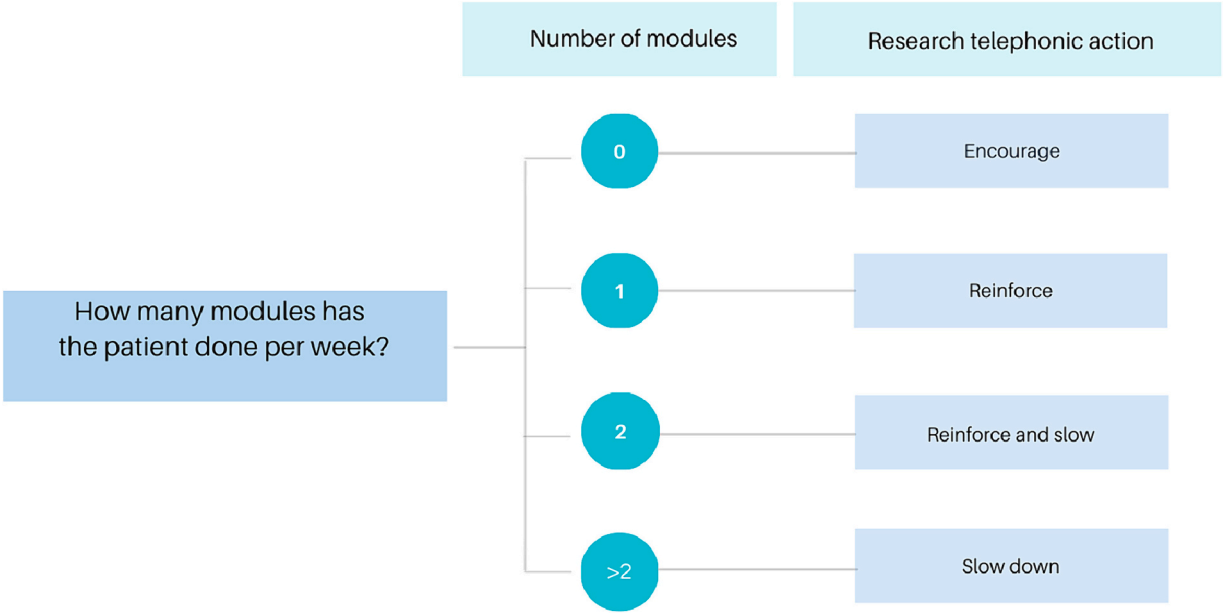

Fig. 2. Telephone support action according to the patient's performance.

Table 1
Assessment protocol.

Outcome	Instrument	Assessment target	Patients Time of assessment			Health professionals Time of assessment
			Pre-treatment	Post-treatment	Follow-up	Post-participation
Effectiveness	Beck Depression Inventory II (BDI II)	Severity of depression	X	X	X	
	European Quality of Life (EUROQOL 5D)	Quality of life related to health	X	X	X	
	12-Item Short Form Health Survey (SF-12)	Physical and mental health	X	X	X	
	Positive and Negative Affect Schedule-Trait (PANAS-R)	Positive and negative affect	X	X	X	
Implementation	Feasibility of Intervention Measure (FIM)	Feasibility of the intervention	X	X	X	X
	System Usability Scale (SUS)	Perceived ease of use of the platform	X	X		
	Acceptability of Intervention Measure (AIM)	Acceptability of the intervention	X	x	x	X
	Attitudes towards Psychological Online Interventions (APOI)	Attitudes towards the implemented intervention	X	X	X	X
	Normalization MeAsure Development Questionnaire (NoMAD)	Normalization process of the intervention				X
	Intervention Appropriateness Measure (IAM)	Perceived appropriateness of the intervention	X	X	X	X
	Barriers and facilitators of the implementation (FBI)	Barriers and facilitator of the implementation process	X	x	X	X
	Client Satisfaction Questionnaire adapted to Internet-Based interventions (CSQ-I)	General satisfaction of the intervention			X	

The following item measures the current health status through a vertical Visual Analogue Scale (VAS), ranging from 0 (worst imaginable health) to 100 (best imaginable health). This questionnaire was validated in the Spanish population using values of EUROQOL as dependent variables of health and sociodemographic variables from the Spanish sample, and a coefficient of determination of 0.45 for tariff values and 0.81 for the VAS scale was obtained (Ramos-Goñi et al., 2018).

3.2.1.2. Positive affect and negative affect. The Positive and Negative Affect Schedule-Trait (PANAS-R) is a 10-item self-report questionnaire that assesses positive and negative affect, both as independent dimensions (Watson et al., 1988). This 6-point Likert scale (from 0 = very slightly or not at all to 5 extremely) asks about the frequency of the items during the last week. The score of both scales goes from 0 (lower affect) to 50 (more presence of the specific affect). The alpha coefficient for the positive affect is 0.92 and 0.88 for the negative affect in its Spanish adaptation (López-Gómez et al., 2015).

3.2.2. Implementation outcomes

Regarding the implementation outcomes, we will assess the extent to which Smiling is Fun can be successfully implemented in PC (feasibility), the perceived usefulness and satisfaction of the intervention for the health professionals (acceptability), the perceived fit, relevance, or compatibility (appropriateness), and the maintenance of the intervention in PC (sustainability).

3.2.2.1. Feasibility. Feasibility of Intervention Measure (FIM) (Weiner et al., 2017a, 2017b). A four items scale on a 5-point Likert (from 1 = completely disagree to 5 = completely agree) scale assess the feasibility of an intervention in a specific context. The FIM showed high levels of internal consistency ($\alpha = 0.89$) and test-retest reliability coefficients ($\alpha = 0.88$).

3.2.2.2. Acceptability. System Usability Scale (SUS; Bangor et al., 2008; Brooke, 1996). This scale assesses the usability being qualitatively related to the quality and acceptance of the platform by the facility of use perceived through 10 items on a 5-point Likert scale (from 1 = strongly agree to 5 = strongly disagree). The SUS will be applied using the Spanish version by Castilla et al. (2023).

Acceptability of Intervention Measure (AIM; Weiner et al., 2017a, 2017b). A 4-item scale (from 1 = completely disagree to 5 = completely agree) that assesses the perception of the stakeholders about the agreeableness of treatment in a specific context. *The construct has shown good psychometric properties with high levels of internal consistency* ($\alpha = 0.89$) *and test-retest reliability* ($\alpha = 0.83$).

Attitudes towards Psychological Online Interventions (APOI; Schröder et al., 2015). A 16-item questionnaire, with a 5-point Likert scale (from 1 = totally agree to 5 = totally disagree), assesses attitudes towards IBT. The APOI explores four dimensions; "Skepticism and Perception of Risks", "Confidence in Effectiveness", "Technologization Threat" and "Anonymity Benefits". The scale has shown acceptable to good internal consistency ($\alpha = 0.77$) (Schröder et al., 2015).

3.2.2.3. Appropriateness. Normalization MeAsure Development Questionnaire (NoMAD; Finch et al., 2018). Based on the Normalization Process Theory, the NoMAD, a questionnaire of 13 items 5-Likert scale (from strongly agree to strongly disagree), has been developed to assess the process of normalization (May et al., 2009; Rapley et al., 2018). The NoMAD focuses on four dimensions: coherence, cognitive participation, collective action, and reflexive monitoring. This questionnaire has demonstrated high levels of internal consistency along the four dimensions (20 items) (alpha = 0.89).

Intervention Appropriateness Measure (IAM; Weiner et al., 2017a, 2017b). A 4-item scale (from 1 = completely disagree to 5 = completely agree) that measures the appropriateness of the intervention. The scale has shown good psychometric properties with high levels of internal consistency ($\alpha = 0.87$) and test-retest reliability ($\alpha = 0.87$).

3.2.2.4. Sustainability. Barriers and facilitators of the implementation (FBI). The FBI is a questionnaire with dichotomic items (yes/no) specifically developed for this study and the study conducted by Lorente-Català et al. (2022). The questionnaire was created following the systematic review on EBT implementation barriers and facilitators among third sector organizations (Bach-Mortensen et al., 2018). As a result, 28 items assess the possible barriers, and 15 items evaluate the facilitators.

3.2.2.5. Satisfaction with IBI. Client Satisfaction Questionnaire adapted to Internet-Based Interventions (CSQ-I; Boß et al., 2016). This 9-item questionnaire assesses participants' satisfaction with IBI. Items are presented on a 1 to 4 Likert scale in which 1 "does not apply to me" and 4 "does apply to me". The total score ranges from 8 to 32. It has adequate psychometric properties, Boß et al. (2016) rate Omega = 0.93 and 0.95

in two different samples.

4. Intervention

"Smiling is Fun" is a self-administered cognitive behavioral internet-based intervention program for the treatment of depression. The intervention includes six components: the transdiagnostic components (motivation, psychoeducation, cognitive therapy, and relapse prevention) (Barlow et al., 2016), behavioral activation (Lejuez et al., 2001), and the components of positive psychology to offer strategies that promote and enhance positive moods (Algoe and Fredrickson, 2011; Sin and Lyubomirsky, 2009).

The program consists of nine therapy modules covering different psychological techniques to cope with depression and everyday problems; (0) Welcome module; (1) Motivation to change (motivation); (2) Understanding emotional problems (psychoeducation I); (3) Sleep hygiene and managing medication (psychoeducation II); (4) Learning to get going (behavioral activation); (5) Learning to be flexible (cognitive therapy); (6) Learning to enjoy (positive psychology I), (7) Learning to live: The importance of values (positive psychology II), (8) Living and learning (positive psychology III), and (9) What next? (relapse prevention). For complete information about the intervention, see the following references (Botella et al., 2012; Botella et al., 2016; Mira et al., 2017; Lorente-Català et al., 2022).

All the modules share a similar structure: first, questions related to the previous module are posed, the contents of the module are explained, exercises are proposed, and self-testing questions are presented. Subsequently, the tasks that the patients must perform to practice what they have learned in the module are indicated. The modules are sequential, and it is recommended to work on each one at least once a week. The duration of the program may vary among users, but it is estimated that the duration for most people will be 3 months. The program sends an email to the users and the clinician if more than two weeks pass without connecting to the program. In this message, the patient is encouraged to continue so that they can benefit from the program.

5. Data analysis

Variables will be described using descriptive statistics (means and 95 % confidence intervals in the case of quantitative variables with a normal distribution and medians and interquartile ranges in the case of quantitative variables with non-normal distributions). For the analysis of treatment efficacy and implementation process, the pertinent normality and homoscedasticity data check will be carried out before the inferential analyses using the Shapiro-Wilk and Levene tests, respectively. To confirm the main hypothesis, contrasts of means in the dependent variables will be carried out according to groups through Student *t*-tests and repeated measures ANOVAs. Stepwise multiple regressions will also be applied to search for explanatory factors of the variance observed in the dependent variables. These analyses will be conducted for the patients who have completed the protocol (70 % of the treatment). According to the CONSORT recommendations for the analysis of RCTs, an intention-to-treat analysis will be used. Missing data will be addressed through a multiple imputation process. Data will be analyzed with the IBM SPSS Statistics 20.0 statistical package.

6. Ethics

The study will be conducted following the guidelines of the Helsinki and Tokyo Declaration (World Medical Association, 2013, 1975). All participants will be volunteers (patients and health professionals) and no compensation will be received for their participation. To participate, signing the informed consent will be required. Withdrawal at any time will be possible without consequences and without the need to justify it.

The study has been approved by the Research, Teaching and Ethics Committee of the Hospital's Mental Health Unit of *Francesc de Borja* Hospital (Gandia, Spain) with reference UGP-21-143.

All the data used will follow the Spanish Organic Law 3/2018, of December 5, on the Protection of Personal Data (LOPD) guidelines to guarantee digital rights, which adapts Spanish legislation to the General Regulation of Data Protection of the European Union (GRDP).

A specific security plan has been established that guarantees the safety of the data when using the platform. Two completely separate systems will store the data and there will be independent access to each database. These systems were developed to ensure that the personal data and clinical data of the patients are stored separately. Consequently, two different servers will be used; clinical data will be stored on server 1 and personal data on server 2, doubling all the security.

7. Discussion

This paper outlines a hybrid type 1 effectiveness-implementation study protocol for Smiling is Fun, an EBPP for depression. The study is part of a broader line of research aimed at improving access to treatment and promoting adherence to IBIs (Andersson et al., 2019). To counteract the high proportion of patients with depression that are not receiving psychological treatment (Thornicroft et al., 2017), IBI has proven to be a cost-effective alternative (Karyotaki et al., 2021). Smiling is Fun has been considered a promising solution that has already demonstrated its efficacy in previous RCTs in the reduction of depressive symptomatology and the increase of positive affect (Botella et al., 2016; Etzelmueller et al., 2020; Mira et al., 2019, 2018, 2017; Montero-Marín et al., 2016a, 2016b).

Even though adherence is a key aspect of the translation process of EBPT to the population, this study aims to go further, considering its naturalistic character and the uptake of the intervention in the mental health system. In this regard, IR is established as the scientific framework to address the existing gap and promote the implementation of Smiling is Fun in PC.

If our hypotheses are confirmed, the implementation of Smiling is Fun with phone support will obtain higher levels of efficacy and higher rates of adherence compared to the unguided condition. Furthermore, the implementation process will be more successful for the human support group in terms of the feasibility, acceptance, and appropriateness perceived by patients and professionals.

In conclusion, this study offers a promising approach to addressing the alarming situation of depression in primary care. By evaluating the factors that facilitate adherence to IBIs and those that influence the implementation process, the study seeks to identify sustainable resources that will enable the population to access psychological interventions in mental health services. By listening to patients' preferences and adhering to NICE recommendations, the study aims to improve the uptake of evidence-based IBIs (NICE, 2020; Rodgers et al., 2012), such as Smiling is Fun, and ultimately contribute to the development of effective and scalable interventions for depression.

Ethics

This trial received approval from the Ethics Committee of Hospital Francesc de Borja (Gandia, Spain) (21 May 2021).

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Declaration of competing interest

The authors declare that they have no conflict of interest.

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