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Implementation of a psychological online intervention for low to moderate depression in primary care: study protocol

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ABSTRACT

Background: Depression affects millions of people all over the world and implies a great socioeconomic burden. Despite there are different effective evidence-based interventions for treating depression, only a small proportion of these patients receives an appropriate treatment. In this regard, information and communication technologies (ICTs) can be used with therapeutic aims and this can contribute to make interventions more accessible. One example is "Smiling is fun", an internet-based treatment which has proved to be effective and cost-effective for treating depression in Spanish Primary Care (PC). However, the "know-do gap" between research and clinical settings implies that the actual implementation of such interventions could last up to 20 years. To overcome this obstacle, the implementation research establishes the methodology to implement the advances developed in the laboratories to the health care services maintaining the validity of the intervention and offering specific strategies for the implementation process.

Objective: This is the protocol of an implementation study for the Internet-based program "Smiling is fun", which will be conducted on patients with mild-to-moderate depression of Spanish PC settings. In the implementation study, the feasibility, efficacy, cost-efficacy, acceptability, adoption, appropriateness, fidelity, penetration, normalization, and sustainability will be assessed.

Methods: The current investigation is a Hybrid Effectiveness-Implementation Type II design. A Stepped Wedge randomized controlled trial design will be used, with a cohort of 420 adults diagnosed with depression (mild-to-moderate) who will undergo a first control phase (no treatment) followed by the intervention, which will last 16 weeks, and finishing with an optional use of the intervention. All patients will be assessed at baseline, during the treatment, and at post-treatment. The study will be conducted in three Spanish regions: Andalusia, Aragon, and the Balearic Islands. Two primary care centers of each region will participate, one located in the urban setting and the other in the rural setting. The primary outcome will be implementation success of the intervention assessing the reach, clinical effect, acceptability, appropriateness, adoption, feasibility, fidelity, penetration, implementation costs and sustainability services.

Discussion: "Smiling is Fun", which has already been established as effective and cost-effective, will be adapted according to users' experiences and opinions, and the efficacy and cost-efficacy of the program will again be assessed. The study will point out barriers and facilitators to consider in the implementation process of internet-based psychological interventions in health services. The ultimate goal is to break the research-to-practice split, which would undoubtedly contribute to reduce the high burden of depression in our society.

Trial registration: ClinicalTrials.gov, Identifier: NCT05294614.

1. Introduction

Depression is one of the most prevalent disabling psychological disorders with significant personal and social costs. In fact, it is the second cause of disability and is expected that in 2030 will be the first cause of disease burden worldwide (Mathers and Loncar, 2006; Ferrari et al., 2013; Haro et al., 2014). Specifically, in Spain, the annual cost of depressive disorders is estimated to be 5.348 million of euros and the lifetime prevalence rate in the general population in Spain is estimated at 10.55 (Salvador-Carulla et al., 2011). Moreover, the prevalence rate is specially problematic in Primary Care (PC) (13.9–29 %), being the most prevalent mental disorder in this setting (Roca et al., 2009).

Pharmacological and psychological interventions (or the combination of both) are effective in the treatment of depression (Cuijpers et al., 2011; Cuijpers and Gentili, 2017). Furthermore, Evidence-Based Psychological Treatments (EBPT) such as Cognitive Behavior Therapy (CBT) or Behavioral Activation are recommended to address depressive symptomatology (Nathan and Gorman, 2015). Despite the fact that there are effective treatments for depression, access to these treatments is limited (Kazdin and Blase, 2011). Less than half of depressed people is treated by a professional and only a quarter receive an appropriate treatment. Elevated costs of face-to-face treatment, the required time for

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the application of the intervention, adherence problems, or the lack of well-trained professionals are some of the causes of this situation (Fernández et al., 2010). In PC settings in Spain, this problem is specially dramatic, not only because of the high rate of prevalence, but also for the lack of accessibility to psychological treatment (Aragonès et al., 2004; Gabilondo et al., 2011; Serrano-Blanco et al., 2010).

Traditional psychological face-to-face therapy is not responding to the population's mental health needs, underlying the necessity of alternative cost-effective ways of administering interventions. Information and Communication Technologies (ICTs) offer cost-effective and accessible resources to address mental health needs (Titov, 2011; Kazdin and Rabbitt, 2013). Systematic reviews and meta-analysis have supported the effectiveness and acceptability of Internet-based treatments (IBT) for depression (Karyotaki et al., 2018; Kaltenthaler et al., 2008; Cuijpers et al., 2009; Andrews et al., 2010; Andersson and Cuijpers, 2009; Karyotaki et al., 2017; Richards and Richardson, 2012). Furthermore, ICT tools are pointed as a solution to address dissemination, accessibility, and delivery problems of psychological interventions (Kazdin and Rabbitt, 2013).

Our research group has developed an Internet-delivered CBT (ICBT) ("Smiling is Fun"), that has shown efficacy in different RCTs (i.e., Botella et al., 2016; Mira et al., 2019, 2018, 2017). The results showed a significant reduction of depressive symptoms and an increase in positive affect (Mira et al., 2019). Furthermore, the intervention was cost-effective, highlighting the economical appropriateness of it in Spanish PC settings along with its clinical benefits (Romero-Sanchiz et al., 2017).

However, although "Smiling is Fun" has demonstrated efficacy and cost-effectiveness, there is still a way to go until a program like this is implemented and used in routine PC. In this sense, it is necessary to take into account the know-do gap between the scientific world and the clinical settings, which is translated into 17 to 20 years for the population to benefit from the advantages of psychological research (Van Den Driessen Mareeuw et al., 2015; Pakenham-Walsh, 2004; Morris et al., 2011). Implementation Research (IR) was developed to address this issue, studying the strategies and factors that affect the translation process of evidence based treatments to the daily routine (Bauer and Kirchner, 2020). One of the essentials aspects of IR is his interaction with the context. Despite a growing body of literature on the therapeutic changes experienced by the population with different mental disorders (Grol et al., 2007), almost no research attempts to understand the dynamic interactions between individuals and the context where they receive the treatment, and how these interactions may influence individual improvement (Kazdin, 2008). Unlike laboratory simulations conducted far from clinical settings, implementation studies are context specific. These studies focus on determining the reasons for the effectiveness of a treatment and the factors influencing it considering the uniqueness of the implementation settings (May et al., 2016). Therefore, the main objective is to determine the barriers and facilitators in each context and develop specific implementation strategies for the desired intervention. Consequently, IR establishes the methodology and the scientific approaches to implement the advances from the laboratories to the health care services maintaining the validity of the intervention (King et al., 2019).

Fixsen and their colleagues elaborated a synthesis of the IR literature determining the core components for implementation practice (Fixsen et al., 2005). These components, which act in an interactive and compensatory way, included *preservice and inservice training, consultant/support, staff evaluation, facilitative administration and systems intervention.* Although these components might be considered to drive an implementation study, as IR is context-specific, in our case a review of the related literature for PC settings, depressed population, and internet interventions is needed.

Vis et al., identified 37 determinants clustered in six groups in the implementation process of eMental Health (eMH) interventions to address mood disorders in routine practice using the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance) (Vis et al., 2018). The determinants were grouped as (1) the acceptance of the intervention perceived by different agents involved, including determinants such as expectations and preferences or technical aspects (ex. Technical support, complexity of the platform), (2) the appropriateness of the intervention including determinants such as the professional-patient interaction, the patients' needs and characteristics, (3) the participants' engagement considering the organization, policies, leadership, collaboration etc., (4) the resources for the implementation including personnel, funds and the infrastructure, (5) work processes comprising primary and facilitating processes and (6) the leadership in the implementation process attaching the management, strategies, etc. Another results from a review focusing on the implementation components on Internet intervention for depression through the Active Implementation Framework (AIF) show congruency with the determined factors (Drozd et al., 2016).

In congruence, other studies also underline the importance of the professional's role. It has been observed that the general motivation and beliefs about the intervention and ICTs act as mediators on the implementation process (Titzler et al., 2018). Although these characteristics act as facilitators, the lack of time, the negative beliefs about the intervention and ICT, and the lack of knowledge are some of the observed barriers (Folker et al., 2018; Vis et al., 2018; Wilhelmsen et al., 2014).

Albeit these results may shed light on the factors influencing the implementation of interventions in daily settings, not all factors and strategies are significant in all contexts. In fact, the current knowledge about the implementation process to address depression is scare stunning the translation process of an intervention to daily practice (Drozd et al., 2016). Therefore, it is necessary to explore the factors related to the implementation process in the specific real-world setting (PC settings in Spain), the implementation costs, and the necessary strategies to implement the specific intervention (Smiling is fun).

In view of the above, there is a need to determine the barriers and strategies that may help in implementation process of the intervention Smiling is Fun. The present work describes the protocol of a Hybrid-effectiveness implementation study of the IBT "Smiling is Fun" to address mild-to-moderate depression in Spanish PC settings.

The protocol will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) adapted for Stepped Wedge Trials (SWT) corresponding to the selected design for the study (Hemming et al., 2018).

In particular, the main research question of the study is:

- Which are the barriers impeding the implementation process in PC of a psychological intervention applied through ICTs to address mild to moderate depression and which strategies are useful to overcome these barriers and promote the implementation?

Furthermore, the following specific aims are stablished:

- To assess the implementation results considering the dimensions of acceptability, adoption, appropriateness, feasibility, fidelity, penetration, and sustainability, perceived and experienced by the different agents involved.
- To assess the efficacy of the intervention.
- To assess the implementation results based on an economic evaluation.

2. Methods

2.1. Hypothesis

According to the literature and the established objectives the following hypotheses are determined:

Implementation:

- Regarding barriers and facilitators of the implementation process, no specific hypotheses are established. Although there is some literature that could lead to some hypotheses, considering the context specificity of the study, a more constructivist and unbiased understanding will be developed.
- The data on the use of the platform and the questionnaire Feasibility of Intervention Measure (FIM) will demonstrate that the intervention is adopted, feasible, and has high fidelity.
- The intervention will show high acceptability measured by the System Usability Scale (SUS).
- The perceived appropriateness of the intervention will be high according to the Intervention Appropriateness Measure (IAM).
- There will be preliminary indicators of sustainability of the intervention measured by the Program Sustainability Assessment (PASAT) and the barriers and facilitators questionnaire.
- The implementation of the intervention will be successful, understanding that Smiling is fun will be normalized in the Primary Care settings assessed through the Normalization MeAsure Development Questionnaire (NoMAD).

Efficacy and cost-effectiveness.

- The intervention will be effective in reducing depression symptoms severity measured by the Patient Health Questionnaire (PHQ9) and improving Quality of Life (EuroQuol-5D-5L)
- The psychological intervention applied through ICTs will be cost-effective.

2.2. Design

The current investigation is a Hybrid Effectiveness-Implementation Type II design, which allow the dual assessment of the clinical intervention's effectiveness and the implementation process in different degrees, adopting two co-primary aims (Green et al., 2019).

A Stepped Wedge Randomized controlled trial (SWT) design will be used. SWT represent a variation of the clinical trials randomized by clusters. The clusters are the unit of randomization which are defined into different sequences that determine the order to switch to the intervention condition from the control condition. In SW all the groups receive the treatment (intervention condition) with an initial period with no exposure to the intervention (control condition), followed by the application in a randomized order of the treatment in a staggered and sequential way. Fig. 1 shows the schema of the design that will be followed in this study (Copas et al., 2015; Hemming et al., 2018). Specifically, three sequences will be applied into 6 implementation sites. The assignment of the six clusters (two centers for each region in Spain participating in the study) to one of the three sequences will be randomly performed (Thompson et al., 2017). In these sequences, three steps or crossover can be differentiated. A step is defined as the change from the control condition to the intervention condition, which in this study will be done at 2, 4 and 6 weeks with no transition period established. In the three sequences each cluster-period (b) (*a group of observations by time of measurement and cluster*) will have an extension of two weeks leading to 30 weeks of duration of the trial (15 clusters × 2 weeks cluster period). Within these 30 weeks, participants will be 16 weeks under the treatment condition. In this case, the measurement points (Tx) will be linked to trial steps, therefore the individuals will be assessed each two weeks.

These designs are especially recommended when there is evidence that a treatment produces beneficial effects or it is difficult to cause harm (Hemming et al., 2015). SWT has the advantage that it does not require the use of control groups, such us clusters act as own controls (Beard et al., 2015).

Considering the previous evidence about the efficacy and effectiveness of the implemented intervention (Mira et al., 2019), ethical benefits are found as control group receive also the intervention. Addressing depression in PC is an imperative urgency (Haro et al., 2014), therefore preventing a group of people from receiving a beneficial evidence-based intervention would be unethical (Prost et al., 2015). Furthermore, SWT prevent dropping out and promote higher motivation to participate as all participants benefit from the intervention (Beard et al., 2015). Besides promoting a greater willingness to participate, it offers more information about the effectiveness of the intervention due to all clusters participate.

Despite all the enumerates advantages, SWT designs present also some limitations that need to be considered in the study development. Due to the control condition they present longer durations which can lead to an increase on the drop-out rates or the loss of motivation (Dreischulte et al., 2013). However, some strategies could be implemented to prevent it, such as professional contact in the step between conditions (Prost et al., 2015).

These designs are also influenced by temporal trends, within-cluster contamination and contextual and policy changes (Hemming et al., 2018). One example of these contextual factors that could influence the study is the COVID-19 pandemic (Thome et al., 2021). These designs are context-specific in a real-setting, which leads to a more complexity

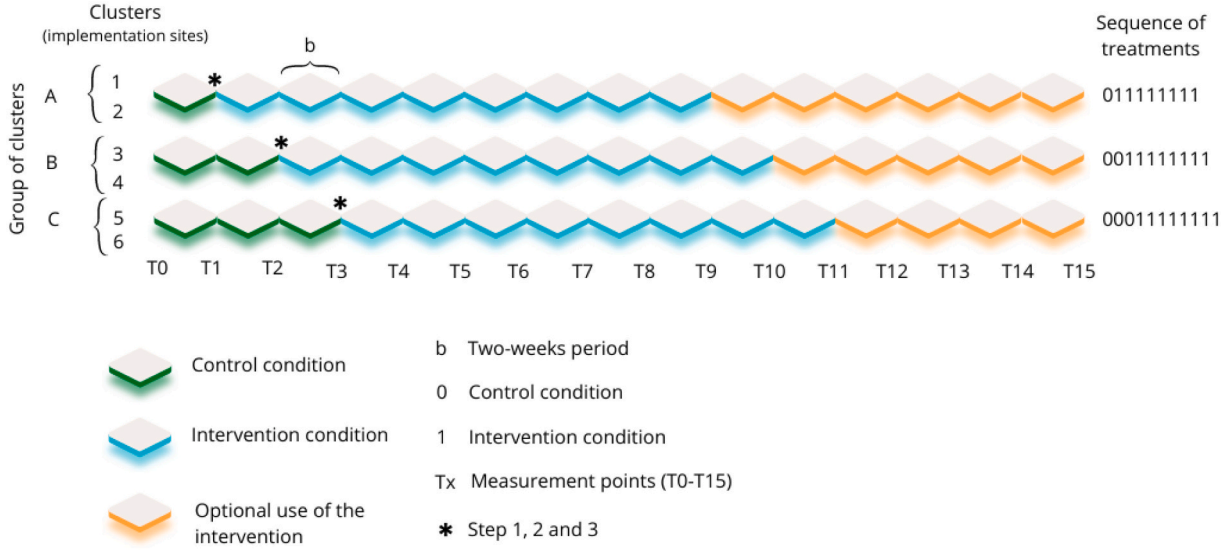

Fig. 1. Design of the study; stepped wedge cluster randomized trial design.

needing more coordination at logistical level and higher level of adaptation. Although one of the benefits of SWT is the continuous learning along the process and the consequent adjustments (Beard et al., 2015), these continuous adaptations can undermine the standardization of application and the replicability of the study. To overcome this limitation and promote long-term sustainability, it is necessary to register and protocolize all the actions performed during the study (Hemming et al., 2018; Prost et al., 2015).

2.2.1. Implementation model

The implementation model of the study will have an especial focus to the Hermes et al. (2019) recommendations which are focused on psychological interventions supported by ICTs.

Hermes and colleagues adapted the taxonomy of outcomes of Proctor (E. Proctor et al., 2011) to the field of psychological interventions supported by ICTs (Hermes et al., 2019). The Proctor's taxonomy highlighted the following outcomes for the implementation process: acceptability, adoption, appropriateness, feasibility, fidelity, implementation costs, penetration, and sustainability. However, Hermes et al. (2019) pointed out the lack of successful implementation of Behavioral Intervention Technologies, defined as those electronic devices and services developed to address behaviors, cognitions, and emotional states. Consequently, in order to promote their use in care settings they developed a specific theoretical framework and measurement tool for e-health services implementation. In this study we will follow these recommendations.

2.3. Study population, recruitment, and eligibility criteria

According to the CONSORT guidelines, eligibility criteria for clusters (implementations sites) and participants need to be reported (item 4a) (Hemming et al., 2018).

- Clusters level

At cluster level the implementation sites and the cluster-level participants are differentiated. In Fig. 2 the eligibility criteria for this study and the interaction with the designed SWT are offered. Specifically, implementation sites focus on PC settings of three pre-determined Autonomous Communities (Andalusia, Aragon and Balearic Islands) at urban and rural settings. The cluster-level participants are composed by the different professionals of PC such as doctors, nurses and administrators that will be responsible for the local implementation work. All implementers will give the informed consent to participate considering the protection of privacy, voluntary participation, and the right to withdraw from the study at any given time. There are not exclusion criteria for the cluster-level participants.

- Participants level

At individual-level participants specific inclusion and exclusion criteria are established. Participants (patients) will be included in the study in case of (1) being 18 year of age or older, (2) with an established diagnosis of major depression according to the Diagnostic and Statistical Manual of Mental Disorder (DSM-5), (3) the severity of the depression is mild to moderate with a punctuation of 14 and lower on the PHQ-9, (4)

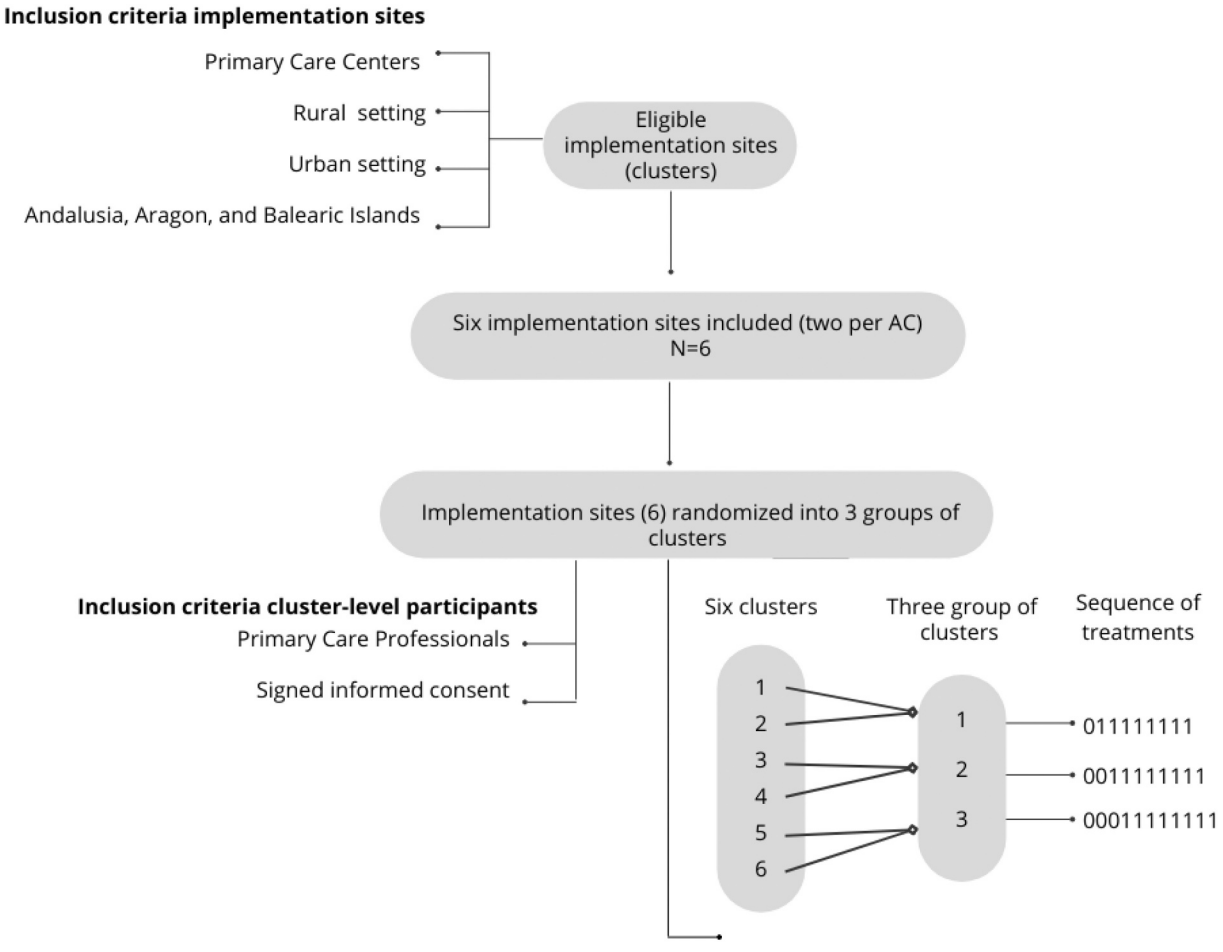

Fig. 2. Cluster level eligibility process.

the depressive symptomatology has been present during two or more months, (5) had regular access to computer with Internet connection (6) understand spoken and written Spanish and (7) the participant has given the informed consent.

Participants will be excluded if they (1) present a disease affecting the Central Nervous System functioning, (2) suffer other psychiatric diagnosis with the exception of anxiety pathology, or suffer severe psychiatric illnesses (substance dependence and abuse, psychosis, eating disorders, etc.), (3) presence of severe medical illness, uncontrolled severe degenerative or infectious disease that could interfere with the administration of the psychological treatment, (4) presence of delusions or hallucinations in the time of study and (5) presence of risk of suicide.

Regarding professionals the inclusion criteria were being health professionals in the primary care centers included in the study, accepting to participate and signing a consent form. We did not include any exclusion criteria.

Regarding managers, the inclusion criteria were being the manager of the primary care centers and accepting to participate in the study and signing a consent form. No exclusion criteria were established.

2.4. Recruitment

The patients will be recruited by the participating professionals in the PC settings. Health professionals will identify potential participants within their patients and will explain the characteristics of the study. Any questions will be addressed in order to ensure that they have understood everything correctly and the patients interested in participating will sign the informed consent. The health professional will assess if the potential participants meet the inclusion criteria.

Regarding the recruitment of the implicated agents in the implementation process; health professionals, managers, and the investigators in each region will conduct this process. For the recruitment a specific session with information about the intervention and the study will be held in each PC center to ask for participation.

2.5. Sample size

Participants will be 420 (140 in each region AC) patients with low to moderate depression. Required sample size was calculated following recommendations for SW designs (Hemming and Taljaard, 2016). First, it is needed to calculate the sample size required in case of an individual randomization. In our case, with a conservative effect size of 0.25 on the continuous variable, a statistical power of 80 % and an alpha of 0.05, the necessary size calculated with the Student's *t*-test would be N1 = 506 participants (394 per experimental condition). Secondly, a correction factor (DEsw) or design effect needs to be calculated, which is multiplied by the sample size obtained in case of individual randomization, to obtain the sample size necessary for the study using the following formula:

$$N1\ DEsw = m(t+1)k$$

In the formula, *m* is the necessary sample for each cluster and for each assessment moment (variable to determine), *t* is the number of sequences (in this case: 3), and *k* is the number of groups or clusters (in this case: 6).

$$DESW = 3(t+1)(1-\rho)[1+\rho(tm+m-1)]/2(t-1/t)[1+p(tm/2+m-1)$$

Considering the described formula for Desw, ρ is the expected correlation between the measurements, which in this study is expected to be between moderate and large (ρ = 0'25). It is possible to determine the numbers of clusters of each sequence (m) isolating the equation as follows:

$$m = (-b \pm \sqrt{(b2-4ac)})/2a, \text{where :}$$

$$a = -2k^*(t-1/t)^*\rho^*(1+t/2)$$

$$b = 3N1^*(1-\rho)^*\rho(1+t) - 2k^*(t-1/t)^*(1-\rho)$$

$$c = 3N1^*(1-\rho)2$$

In this study a sample *m* is obtained for each cluster and each moment of evaluation of 57 participants. Assuming an experimental loss of 20 %, it will be necessary to recruit 70 participants per each center and maintain at least 57 of them throughout the study. Consequently, it is needed a sample of 140 participants per region and 420 participants in total.

2.6. Ethics

The study will be conducted following the guidelines of the Helsinki and Tokyo Declaration (World Medical Association, 1975, 2013). The participation will be completely voluntary, and the participants will not receive any compensation for their participation. Participants will be informed about the possibility of withdrawal with no consequences. The informed consent will be signed once the participants have all the information about the study.

The study has been approved by the Ethics Committee of the Investigation of Balearic Islands (CEI), Ethics Committee of Investigation of the Autonomous Community of Aragon (CEICA) and the Ethics Committee of Investigation of Malaga and Northeast. In addition, the trial is registered at ClinicalTrials.gov as NCT05294614.

The implementation study will be conducted and reported according to the Standards for Reporting Implementation Studies Statement (StaRI) (Pinnock et al., 2017).

2.7. Intervention

"Smiling is Fun" ("*Sonreír es divertido*" in Spanish) is a manualized intervention protocol of ICBT using multimedia material in an interactive and self-administered way for the prevention and treatment of depression and adjustment disorders (Botella et al., 2016). "Smiling is Fun" is made up around six main components including some transdiagnostic components (motivation, psychoeducation, cognitive therapy and relapse prevention) (Barlow et al., 2016), behavioral activation (Lejuez et al., 2001), and positive psychology to offer strategies to promote and enhance positive mood (Algoe and Fredrickson, 2011; Sin and Lyubomirsky, 2009). The program is composed of the most effective psychological techniques for stress management, to promote coping, emotion regulation, and resilience to learn to deal with depressive symptoms and daily problems.

The program consists of nine interactive modules and two initial modules that are presented in a pre-established sequential way and has an estimated duration between of 8 and 16 weeks. The information about the objective, contents and exercises of each module are reflected in Table A.1.

2.8. Implementation study procedure

As implementation strategies are one of the main focus of this study, priori battery of implementation strategies has been established according to the detected barriers by the literature (explained below). However, prior to define the implementation strategies for this study, is necessary to establish the different agents in the implementation process.

Following the CONSORT guide the cluster and participants levels have been defined. However, as this is a hybrid-implementation study different role of implementers have been determined with different levels of interaction. Fig. 3, reflect the multiple levels of implementation influences and implications and the interaction between the involved

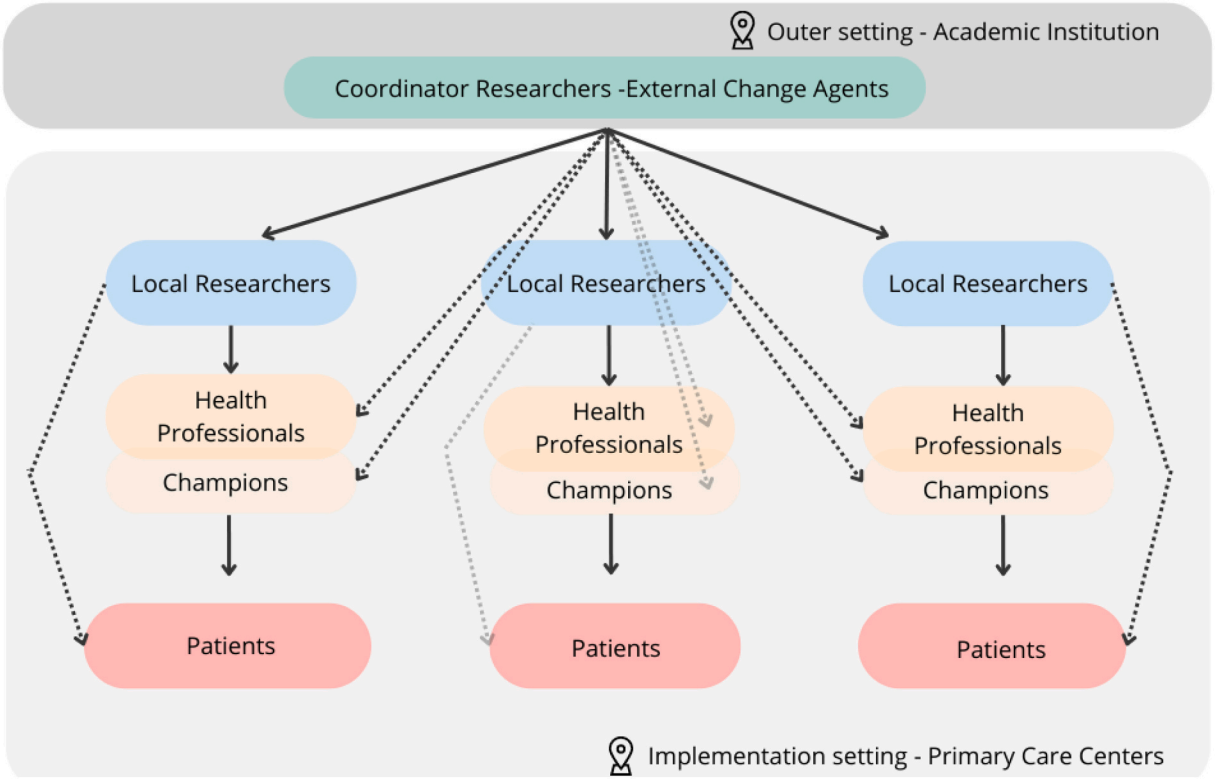

Fig. 3. Implementation influences flowchart.
Notes: The arrows in the flow chart establish the level of intensity in the implementation of the strategies and the interaction between the agents involved. Specifically, the continuous arrows mark a greater interaction and the dashed arrows a more punctual or secondary interaction.

agents in inner and outer settings.

In the outer settings, the external change agents affiliated to the academic institution facilitate the implementation process by coordinating the study (Damschroder et al., 2009). The main coordination tasks are conducting with the local researchers, although there is punctual contact with health professionals to conduct the qualitative and quantitative assessment as to offer general training.

In the implementation setting, the local researchers and the health professionals are the main implementers and the patients are those who receive the implemented intervention.

Local researchers have the greater weight in the implementation of strategies. They are responsible of the recruitment of mental health professional and the dissemination tasks of the study. On a second level, they also assess the recruited patients by health professionals and in case that they met the established criteria, local researchers give access to patient to the platform. Furthermore, local researchers will select the champions between health professionals.

Champions are the professionals that will act as a defenders and supporters of the study. They will be selected according to the beliefs and behaviors demonstrated towards the intervention (Damschroder et al., 2009).

Finally, the health professionals are those that will implement the intervention and will have the higher impact on the normalization process of the intervention. Most of the implementation strategies will be directed to impact on them (for example: attitudes, incentives, training, technical support, etc.) and therefore promote the implementation process.

The literature has determined some factors impeding and promoting the implementation process, for example, support staff, acceptance, technical support, perceived patient's needs, leadership, policies, etc. In accordance, different strategies have been established in order to overcome and promote the different factors. In IR implementation strategies are pre-established actions and methods used to enhance the adoption, implementation, and sustainability of EBT in a specific setting (Proctor et al., 2013).

The implementation strategies that will be applied in this study are reported following Proctor et al. (2013) recommendations: (Proctor et al., 2013) and focus on the core components for implementation process determined by Fixsen et al. (2005).

According to the barriers determined by the literature in these contexts, target and settings a total of 13 strategies, addressing one or several determinants will be implemented. These strategies has been determined following the compilation of 68 implementation strategies grouped in six key processes (*planning, educating, financing, restructuring, managing quality and attending to policy context*) developed by Powell and colleagues for clinical innovations in health (Powell et al., 2012).

It should be mentioned that the strategies can suffer variation along the implementation process based on health professionals' feedback from qualitative interviews. The possible adaptations will be reported and protocolized (Hemming et al., 2018; Prost et al., 2015).

The package of the strategies designed for this study include the components in Table A.2.

2.9. Assessment plan

2.9.1. Efficacy and cost effectiveness

Patient Health Questionnnaire-9 (PHQ-9) (Kroenke et al., 2001). The PHQ-9 is a 9-item self-report scale questionnaire to assess the severity of depressive symptoms. The Spanish version will be used as a primary outcome, this presents comparable diagnostic validity to the original version, with levels of 88 % of sensitivity and 88 % of specificity (Diez-Quevedo et al., 2001).

EuroQol-5D-5L (Ramos-Goñi et al., 2018). This questionnaire describes health status in terms of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) according to five levels of severity.

Client Service Receipt Inventory (CSRI) (Beecham and Knapp, 2001). The CSRI is a questionnaire to collect retrospective information about the use of the healthcare resources and variables related with the indirect impact. The applied version is designed to collect retrospectively the data of the use of services during the previous six months (Vázquez-Barquero et al., 1997).

2.9.2. Implementation outcome measures

Feasibility: defined as the extent to which a new treatment can be successfully used or carried out within a given agency or setting.

Feasibility of Intervention Measure (FIM) (Weiner et al., 2017). This scale includes four items designed to measure feasibility of the intervention. The scale has shown good psychometric properties with high levels of internal consistency (alpha from 0.85 to 0.91) and test-retest reliability coefficients ranged from 0.73 to 0.88.
Feasibility will be also measured with passive data gathered by the online platform about use of the program, specifically the frequency of use during the study.

Acceptability: defined as the perception among implementation stakeholders that the intervention is useful or satisfactory. The instruments to assess acceptability are:

System Usability Scale (SUS) (Bangor et al., 2008). The SUS is a 10-item questionnaire to measure the usability which qualitatively is related with the quality and acceptability of the system. The usability is defined as the facility of use perceived by the users of the implemented technology.
Acceptability of Intervention Measure (AIM) (Weiner et al., 2017). This measure is composed by 12 items that measure three implementation constructs; acceptability, the appropriateness, and the feasibility of the intervention. The three constructs have shown good psychometric properties with high levels of internal consistency (alpha from 0.85 to 0.91) and test-retest reliability coefficients ranged from 0.73 to 0.88.
Client Satisfaction Questionnaire adapted to Internet-Based interventions (CSQ-I) (Boß et al., 2016). The CSQ-I is an 8-item questionnaire that assesses the general satisfaction of the participants regarding the received intervention. The internet version has shown excellent reliability (Omega = 0.93 and 0.95) (Boß et al., 2016).

Appropriateness: This construct is defined as perceived fit, relevance or compatibility of the EBP for a given practice setting. We will use the following measures:

Normalization MeAsure Development Questionnaire (NoMAD) (Rapley et al., 2018; Finch et al., 2018). NoMAD is a 23-items questionnaire that assess the process of normalization of an intervention according to the Normalization Process Theory (May et al., 2009) focusing on four dimensions: coherence, cognitive participation, collective action and reflexive monitoring. The NoMAD has shown good psychometric properties, showing high levels of internal consistency along the four dimensions (20 items) (alpha = 0.89).
Intervention Appropriateness Measure (IAM) (Weiner et al., 2017). The IAM measure appropriateness of the intervention. The scale has shown good psychometric properties with high levels of internal consistency (alpha from 0.85 to 0.91) and test-retest reliability coefficients ranged from 0.73 to 0.88.

Adoption: Defined as the intention, initial decision or action to try or employ an EBP. Adoption will be measure by the number of participants who accepted to use the program and actually accessed the online program. We will gather this information from passive data from the online platform.

Fidelity: In the context of internet interventions, fidelity is defined by the expected use of clinically meaningful use. This dimension will be measured with passive data from the online platform; number of modules completed, and number of tasks completed.

Penetration: Following Hermes et al., we will measure this dimension with the number of managers who actually delivered the IBT and the number of patients who accepted to use the internet intervention and completed at least 80 % of the program.

Sustainability: This dimension is defined by the extent to which a new intervention is maintained.

Program Sustainability Assessment Tool (PASAT) (Luke et al., 2014). The PASAT assess the capacity for a program sustainability in public health during the implementation process. The test has shown excellent psychometric properties with high internal consistency (alpha = 0.70 to 0.92).
Barriers and facilitators of the implementation (FBI). The FBI is a questionnaire developed specifically for this study according to the systematic review about the barriers and facilitators in the process implementation of evidence based intervention among the third sector (Bach-Mortensen et al., 2018). According to this review, 28 items were established to address the construct of barriers and 15 items to address the facilitators.

The study variables assessed, and the instruments used are summarized in Table A.2.

2.10. Data analysis

2.10.1. Efficacy

For the analysis of treatment efficacy, both an intention-to-treat analysis and an analysis for the patients that have completed the protocol (80 % of the treatment) will be conducted. The analysis will include the description and elementary head-to-head comparisons across time. Specifically, the 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). To confirm the main hypothesis, all the variables (t0-tk) will be used for the ANOVA test with the appropriate post-hoc contrasts if we compare variables with a normal distribution, or using the Kruskal-Wallis H test if variables are not normally-distributed. Finally, multivariate analyses including multi-level regression will be performed incorporating measures such as patients and time, if necessary.

2.10.2. Economic evaluation

The economic evaluation will be carried out following the recommendations of the Spanish guideline for economic evaluation of health technologies (López Bastida et al., 2010). The economic evaluation will be conducted in terms of a Cost-Effectiveness Analysis (CEA) and Cost-Utility Analysis (CUA), and a societal perspective will be adopted. For the CEA, the effectiveness of the intervention will be estimated as improvement of the depression, measured with the PHQ-9. Results of the CEA will be expressed in terms of the incremental cost-effectiveness ratio (ICER), calculated by dividing the difference in total costs through the Client Service Receipt Inventory (CSRI) between the treatment phase and the control phase by the difference in PHQ-9 scores between both phases. For the CUA, the effectiveness of the intervention will be estimated as Quality-Adjusted Life Years (QALYs). Results of the CUA will be expressed in terms of the Incremental Cost-Utility Ratio (ICUR), calculated by dividing the difference in total costs between the treatment phase and the control phase by the difference in QALYs between both phases. To analyze the uncertainty of the ICER and ICUR results, we will perform sensitivity analyses.

2.10.3. Implementation study

One of the main focus of this study are the implementation results, which are understood as the effects of the implementation strategies to translate the intervention in the specific context (Proctor et al., 2011). As a consequence, the implementation data of the study will be analyzed in order to understand the specific barriers and strategies for this context. Different outcomes will be considered for implementation analyses according to the adopted model (Hermes et al., 2019; Proctor et al., 2011). The analysis of the passive data will consist of objective and direct counts (e.g., logins, frequency of use, modules completed, task completed, etc.). The self-report questionnaires will be scored according to the questionnaires' instructions. Qualitatively data will be recorded through interviews with the different health professional. These interviews will pretend to identify the difficulties, facilities and opinions of the implementers. The interviews will be conducted using brainstorming and focus group method in order to detect determinants of practice. Due to the changing nature of the context qualitative data will be assessed in different moments of the implementation process and reported in a specific protocol (Hemming et al., 2018).

3. Discussion

Mental health needs of the population are not being adequately addressed due to the gap between research and practice and the lack of financial and personal resources (Bauer and Kirchner, 2020). In Spain, this is specially problematic in PC, where it is the most prevalent disorder (Roca et al., 2009; Serrano-Blanco et al., 2010) leading to important personal and economical costs (Ferrari et al., 2013; Salvador-Carulla et al., 2011).

IR focuses on the development of implementation studies to address the know-do gap and bring the scientific advances to health services. These studies are context-specific and focus on the barriers and facilitators of the implementation process (Bauer and Kirchner, 2020). Consequently, implementation studies offer the theoretical framework to specifically address the problem found in PC, facilitating the factors and strategies to focus on bringing EBPT to this setting and population (King et al., 2019).

Consequently, the intervention "Smiling is Fun" developed to address depressive symptomatology (Mira et al., 2019) is presented as an opportunity to increase the number of people receiving treatment for depression. As its efficacy and cost-effectiveness have been already proven in PC, the following step is to succeed in the implementation of this intervention in routine practice.

The advantages of IBT such as Smiling is fun have been widely demonstrated. Nevertheless, it is necessary to answer the question how; How to translate them to daily care settings? How to get the implementation in public services?

In the study protocol, we describe a hybrid type II effectiveness-implementation study with a SW randomized controlled trial design to assess the implementation of an ICBT ("Smiling is Fun") to address mild to moderate depression in PC in Spain.

The implementation study will be conducted in order to assess the impact of the intervention in participants' depressive symptomatology, the direct and indirect costs of the intervention and the different factors (barriers and facilitators) influencing the implementation process. Note that the main goal of the study is not to prove the effectiveness of the intervention, as it has already been proven (Mira et al., 2019). The ultimate goal is to break the research-practice split (Kazdin, 2008), implementing an EBPT to address the depressive symptomatology in PC settings and determining the factors influencing in this process. In order to assess the implementation, process the different moderator factors (acceptability, appropriateness, adoption, feasibility, fidelity, penetration and sustainability), the implementation strategies designed and the specific contextual factors will be assessed.

If our hypothesis is confirmed, the designed implementation strategies will facilitate the implementation process and the barriers to deal in the future will be determined. In congruency, our findings will support the efficacy of Smiling is Fun for reducing depressive symptomatology and the intervention will be successfully normalized in Spanish PC settings, being the implementation process successful. Furthermore, our results will provide information about the potential use of ICTs related to the cost-effectiveness of online-based psychological interventions. The study will show how implementation studies are useful to establish the framework to address the barriers and promote the facilitators to promote the acceptability, appropriateness, adoption, feasibility, fidelity, penetration, and sustainability of internet psychological interventions in health services.

To sum up, the present investigation could establish the first step to promote the use of ICBT in PC in Spain and improve the access of the population to EBPT for depression. The final goal is to reduce the high burden of this important health problem, seeking the integration of an EBPT into actual care setting. This study will help to understand the factors impeding and promoting the gap between the EBPT and the implementation of these into routine practice.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2022.100581.

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