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Implementation of an Internet-based psychological intervention for the treatment of mild depression in primary care: A Hybrid Effectiveness-implementation approach

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Research Article

Keywords: depression, Internet-based interventions, implementation research, primary care

Posted Date: March 8th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-8915542/v1

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Additional Declarations: No competing interests reported.

Version of Record: A version of this preprint was published at BMC Public Health on June 3rd, 2026. See the published version at https://doi.org/10.1186/s12889-026-27573-0.

Abstract

Background

Depression is a significant global challenge. Particularly in Spain, depression in Primary Care (PC) settings is prevalent and inadequately addressed. Online interventions, such as "Smiling is Fun", an online Cognitive Behavioral program, offer promising solutions given its scalability and accessibility. However, successful implementation in real-world settings requires identifying and addressing contextual barriers. This study aims to implement "Smiling is Fun" while assessing its effectiveness and the determinants influencing its implementation.

Methods

The study employed a Hybrid Effectiveness-Implementation Type II approach using a Stepped-Wedge Cluster Randomized-Controlled Trial methodology. Six sites were randomized into three clusters, each undergoing treatment conditions for 16 weeks. Patients were recruited by health professionals in PC settings.

Results

The intervention effectively reduced depressive symptoms and improved positive affect. Participants generally had a positive attitude towards internet interventions, although there was a slight increase in concerns regarding professional contact. Overall satisfaction among participants who completed the intervention was moderately high, but problems with treatment adherence were observed. Professionals demonstrated a willingness to adopt the program, with generally high readiness to implement the intervention. Nevertheless, some important barriers, such as high levels of stress, insufficient learning time, and personnel changes were highlighted.

Discussion

"Smiling is Fun" proved effective in addressing mental health states and depressive symptomatology, with positive perceptions from both professionals and patients. However, barriers need to be addressed, particularly in fostering inclusion in the PC workflow system and promoting patient adherence. Despite limitations, the study underscores the potential of online interventions to improve mental healthcare accessibility.

Trial registration: https://clinicaltrials.gov/study/NCT05294614 (23/03/2022)

Highlights

- In the face of urgent needs of addressing depression, this research demonstrates that even when a psychological intervention has proven its effectiveness and efficacy, numerous challenges can arise in implementing it in everyday settings.

- The inclusion of both participants and professionals implementing the intervention in the research assessment offers an enriched understanding of addressing mental health problems.
- The findings highlight the necessity of spreading awareness of Implementation Research. The lack of understanding exacerbates the effects of contextual factors, impeding the adequate addressing of mental health problems in service settings.

1. Introduction

In today's world, mental health has become a critical concern. Mental health problems show a rising trend and are ranked as leading causes of Disability-Adjusted Life Years (DALYs) worldwide (Murray, 2022). Among these challenges, depression stands out as one of the most significant conditions. It is currently the second leading cause of burden of disease globally and is expected to become the leading cause in 2030 (Malhi & Mann, 2018; WHO, World Health Organization, 2022).

Depression significantly impacts both individuals and their families, with far-reaching consequences not only at a psychological level but also in terms of increasing mortality and morbidity, as well as at economic levels (Duagi et al., 2024). When untreated, the consequences are exacerbated and can have significant implications for public health (Kraus et al., 2019).

In Spain there is a high prevalence of depression, which has been further aggravated by the COVID-19 pandemic (González-Sanguino et al., 2020; Ozamiz-Etxebarria et al., 2020). The annual economic burden associated with depression in Spain is significant and has increased in recent years. The cost of this burden is estimated to be approximately 6.145 million euros, primarily attributed to its chronic nature and associated comorbidities (Vieta et al., 2021).

Primary Care (PC) settings serve as the frontline for detecting and managing most cases of depression (Kroenke, 2018). In fact, depression is the most prevalent disorders seen in this setting in Spain (Roca et al., 2009).

Evidence-Based Psychological Practices (EBPP) for treating depression are available in various formats, and their effectiveness has been demonstrated (Cuijpers et al., 2023). However, as highlighted in a recent systematic review, there is a significant global gap in effectively addressing depression (Cuijpers et al., 2023). In high-income countries like Spain, only around 23% of individuals with depression receive minimally adequate treatment (Moitra et al., 2022). Although this issue has been previously highlighted in Spain (Latorre Postigo et al., 2012), satisfactory solutions have not yet been found. Consequently, there is an urgent need to explore interventions aimed at addressing depression within health settings, particularly considering the unmet needs that have been identified (Chisholm et al., 2016).

One potential solution to the presented problem, promoting scalability and accessibility to intervention, is through online interventions (Cuijpers et al., 2023). Internet interventions are presented as a cost-effective and alternative solution to address the challenges associated with traditional psychotherapy (Karyotaki et al., 2017). Specifically, online interventions are proposed as a solution to address this issue

in PC in Spain (Barcelo-Soler et al., 2019), with the program “Smiling is fun” (in Spanish: “*Sonreír es divertido”*).

"Smiling is Fun" is an online self-guided intervention designed to address low to moderate depression, backed by substantial evidence (Mira, Bretón-López, et al., 2018; Mira et al., 2019). The results of these studies indicate that it is a promising candidate, showing positive effects not only on psychological symptoms but also at an economic level by promoting its scalability in an online format (Romero-Sanchiz et al., 2017).

We have accumulated evidence from various Randomized Controlled Trials (RCT) of the Smiling is Fun program in different parts of Spain. Nevertheless, to meet the needs of the population, further steps are required to understand how this intervention functions in daily clinical settings and how it can become a standard treatment, going beyond randomized clinical trials with researchers’ support and resources (Bauer & Kirchner, 2020). In line with this objective, a specific study has been conducted in PC in Spain in three different Autonomous Communities (AC) to identify the factors influencing the use of the intervention and to promote its implementation to address the problem of depression.

In alignment with our objectives, the study was conducted based on Implementation Research (IR) (Bauer & Kirchner, 2020). Specifically, IR provided the methodological framework to comprehend the adoption of Evidence-Based Practices (EBP) into real-world settings, examining the determinants that impact the uptake process. This research not only focuses on the effectiveness of the innovation but also delves into the barriers and facilitators that enable its implementation in a specific context. Consequently, its primary focus lies in identifying barriers and designing strategies to promote the uptake of a specific innovation within a particular context, aiming to integrate it as a routine service (Curran, 2020; Massey & Vroom, 2020).

While the determinants need further investigation and to be specified within this context, prior literature has provided valuable guidance for implementing proactive strategies. A comprehensive set of 13 strategies has been identified for application in the ongoing study. These strategies were selected following Powell's compilation of 68 strategies (Powell et al., 2012), prioritizing Proctor's recommendations (Proctor et al., 2013) and emphasizing Fixsen's core components (Fixsen et al., 2005). The strategies were outlined in detail in the published protocol (Lorente-Català et al., 2022) including identifying and preparing champions, conducting educational meetings, etc. Throughout the study, careful consideration has been given to these strategies, with adaptations made as necessary to suit the specific context.

The translation and implementation of this program must be context-specific and consider the specific contextual barriers and facilitators. Some of the key factors that need to be addressed include the professionals involved, the beliefs about online interventions, the acceptance from patients, etc. (Titzler et al., 2018; Vis et al., 2018). Furthermore, it is essential to identify determinant factors and barriers in order to successfully implement the program and maintain its effectiveness (Damschroder, 2020).

With the aim of addressing various research questions encompassing effectiveness and implementation outcomes, a Hybrid-effectiveness implementation study was conducted (Curran et al., 2012; Landes et al., 2019). The protocol of this study was extensively described in a previous publication (Lorente-Català et al., 2022).

This study addressed four main aspects:

- Identifying barriers and strategies influencing the implementation process.
- Evaluating implementation outcomes related to the implementation including acceptability, appropriateness, feasibility, fidelity, penetration, and sustainability.
- Assessing the effectiveness of Smiling is Fun in addressing depression in PC.
- Conducting an economic assessment.

It is important to note that the economic results are not presented in this study.

In summary, this study aims to address population needs in real attentional settings. We do have adequate interventions, although their benefits are not yet reaching the population. There is a crucial need to explore how these interventions operate within a specific context and to identify the barriers that hinder their implementation. Additionally, it is essential to identify and promote strategies that facilitate successful implementation outcomes while preserving the effectiveness of the intervention.

2. Methods

2.1 Study design

A Hybrid Effectiveness-Implementation Type II approach was employed in PC facilities in Spain to address various research inquiries concerning both implementation and effectiveness issues in addressing depression (Landes et al., 2019).

This approach utilized a Stepped Wedge Cluster Randomized Controlled Trial (SW-CRT) methodology (Hemming et al., 2018). Three distinct sequences were established, randomized across six implementation sites grouped into three clusters. Subsequently, within each sequence, two PC facilities were randomly allocated. Each sequence consisted of eight clusters of the treatment condition (16 weeks) with a previous control condition of varying duration for each sequence. Control conditions comprised one cluster (two weeks), two clusters (four weeks), and three clusters (six weeks) for each variation of the sequence.

The detailed rationale and graphical representation of this design are comprehensively explained in the protocol study (Lorente-Català et al., 2022). See the section of SW design in Figure 1 for a brief description of the design and procedure.

The trial has been registered at ClinicalTrials.gov (NCT05294614). The study is reported following Standards for Reporting Implementation Studies Statement (StaRI) (Pinnock et al., 2017) regarding implementation and effectiveness outcomes.

2.2 Participants, recruitment, and eligibility criteria

The study population is outlined in cluster and participant levels (Hemming et al., 2018). Information regarding all levels, settings, eligibility criteria, recruitment, and procedures is visually reflected in Figure 1, with further detailed explanations available in the protocol (Lorente-Català et al., 2022).

At the cluster level, six implementation sites were predetermined, encompassing two PC settings (one rural and one urban) from each AC, including Andalusia, Aragon, and the Balearic Islands. Each PC was randomly assigned to one of the sequences established according to the SW-CRT. All health professionals attending PC were included as cluster-level participants. They provided informed consent. These professionals served as implementers in real-world settings and were responsible for patient recruitment.

At the participant level, inclusion and exclusion criteria for patients were established (refer to Figure 2). Patients were recruited by health professionals, and after receiving study explanations and providing consent, they were assigned to one of the three conditions.

2.3 Intervention

The applied innovation is "Smiling is Fun," which is a structured online intervention based on Cognitive Behavioral Therapy (CBT) designed to address depression disorders (Mira et al., 2019). This intervention comprises six therapeutic components, including transdiagnostic components, cognitive behavioral therapy, and positive psychology (see Figure 3). It consists of nine interactive modules and two preliminary modules, presented sequentially. The modules are as follows: 1. Motivation for change; 2. Understanding emotional problems; 3. Sleep and medication management; 4. Learning to move; 5. Learning to be flexible; 6. Learning to enjoy; 7. Learning to live; 8. Living and learning; 9. From now on, what else…? The intervention is estimated to last eight to sixteen weeks. Upon completion of a module, the platform includes a review section to revisit the completed modules. For detailed information about the modules, including objectives, contents, and exercises, refer to Table A.1. of the protocol (Lorente-Català et al., 2022).

Each module provides psychoeducational information along with practical exercises, combining text with multimedia elements such as videos, audios, and images. Additionally, the intervention offers three tools: (1) a calendar for tracking the frequency of program use, completed and pending tasks; (2) a guided diary for participants to focus on the topics covered in the modules; and (3) a "How I am?" section graphically displaying the relationship between mood state and completed program tasks.

2.4 Measures

The outcomes included in the study address effectiveness and implementation outcomes related to the implemented innovation. Detailed information is included in the protocol (Lorente-Català et al., 2022).

For the effectiveness outcomes, patients receiving the intervention were assessed on severity of depressive symtoms (Patient Health Questionnaire- 9; PHQ-9) (Diez-Quevedo et al., 2001; Kroenke et al., 2001), the presence and valence of emotional affect (Positive and Negative Affect Schedule; PANAS-SF) (Díaz-García et al., 2020; Watson et al., 1988) and the severity on mobility, self-care, usual activities, pain/discomfort, anxiety and depression (EuroQol-5D-5L) (Ramos-Goñi et al., 2018).

Regarding the implementation outcomes, all level participants were considered including patients and implementers (professionals and managers). Here is a coherent English paragraph that summarizes and describes all the measures you listed:

The study employed a comprehensive set of implementation measures across several domains. Feasibility was assessed using the Feasibility of Intervention Measure (FIM) (Weiner et al., 2017), which evaluates the extent to which the intervention can be successfully used. Acceptability was examined through multiple tools, including the Acceptability of Intervention Measure (AIM) (Weiner et al., 2017), the Attitudes towards Psychological Online Interventions (APOI) (Schröder et al., 2015), the Evidence-Based Practice Attitude Scale (EBPAS) (Aarons, 2004; Padmanabhanunni, 2018), and the Client Satisfaction Questionnaire (Boß et al., 2016), all aimed at capturing participants' perceptions, attitudes, and satisfaction with the intervention. Appropriateness was measured with the Normalization MeAsure Development Questionnaire (NoMAD) (Finch et al., 2018; Rapley et al., 2018), which assesses the extent to which the intervention becomes integrated into routine practice, and the Intervention Appropriateness Measure (IAM) (Weiner et al., 2017), which evaluates perceived suitability of the intervention. Fidelity was indexed by the number of completed modules, while penetration was reflected in the number of providers or managers who delivered the online intervention, indicating its integration within the service. Finally, sustainability was explored using the Barriers and Facilitators of Implementation (FBI) tool (Bach-Mortensen et al., 2018; Lorente-Català et al., 2022), the Implementation Climate Scale (ICS) (Ehrhart et al., 2014), and the Implementation Leadership Scale (ILS) (Aarons et al., 2014), which together capture the contextual factors, strategic climate, and leadership supporting the long-term implementation of evidence-based practices.

Other measures included patients' socio-demographic characteristics including gender, age, marital status, educational level, employment status, and income level. Demographics were also gathered from professionals: gender, age, qualifications, professional experience, time working in the department, time spent attending to patients, internet use and abilities, and expertise regarding online interventions.

2.5 Sample size

The total sample size established in the protocol was 420 patients, with 140 designated for each AC. The calculation was performed based on SW designs, assuming a conservative effect size (0.25), a power of 0.80, and an alpha of 0.05. Following adjustment with a correction factor (DEsw) and accounting for an assumed experimental loss of 20%, it was determined that recruiting 70 participants per center would be required. Detailed explanations regarding the considerations made during the sample size calculation can be found in the study protocol (Lorente-Català et al., 2022).

2.6 Data analysis

Analyses were conducted using the statistical package SPSS Statistics v.28. Descriptive analyses were performed to describe the sample characteristics, including sociodemographic variables, for the population assessed and included in the study.

In the protocol, ANOVA analyses were initially planned. However, normality has been tested using the Kolmogorov-Smirnov and it was found that the data were non-normally distributed for some variables. In such cases, it was established in the protocol to use non-parametric tests, specifically the Kruskal-Wallis test. Nonetheless, due to the significantly smaller sample size than expected, more robust methods were considered necessary. As a result, linear mixed models were employed with time as a factor, incorporating Bonferroni adjustments. Magnitude effect was reported according to Cohens' d Effect Size.

Furthermore, non-parametric tests using Kruskal-Wallis test for all data except for PHQ-9, where the Friedman test was utilized, were conducted to confirm the findings.

3. Results

3.1 Patients

A total sample of 186 people were recruited, out of which 57 did not meet the criteria or declined to participate. Of these 57 participants; 27 did not meet the criteria established by PHQ-9, 11 did not answer after several attempts, 9 did not present diagnosis for depression, 7 of them finally were not interested in participating, and 3 lacked an appropriate internet device. Consequently, 129 participants were recruited and met the criteria. The mean age of the sample was 43.16 (SD=11.79). Most of the sample were women (N=99, 76.7%) compared to a smaller number of men (N=30; 23.3%). The majority were married or in a relationship (N=60; 46.5%) and were living in their own house with their partner and/or children (N=53; 41.1%). The majority had completed secondary education (N=59; 45.7%) or university studies (N=51; 39.5%). Only 28.7% of the sample was actively working (N=7). Most of them were unemployed (N=72, 55.8%) and only 13.2% were receiving subsidies. The majority were in the first range of the minimum salary stipulated (N=42; 32.6%). Detailed characteristics of the patients recruited are reflected in Table 1.

The effectiveness of the intervention was assessed by observing the depressive symptomatology with the PHQ-9 scale at three distinct points in time: initially when accessing the platform (PRE-1), after the control period (PRE-2), and upon intervention completion (POST). Specifically, a significant decrease of the depressive symptomatology was observed across all three time points ($F_{(2,112)}$=44.47; p=<.001). Furthermore, there was a low to moderate effect size observed between PRE-1 and PRE-2 (d=0.34), a moderate to large effect size between time PRE-2 and POST (d=0.62), and a large effect size between PRE-1 and POST (d=0.87).

Through PANAS, both positive affect and negative affect improvement were observed. Specifically, there was an increase in positive affect ($F_{(1,48)}$=40.12; p<.001) and a decrease in negative affect ($F_{(1,52)}$=29.51; p<0.001), being both statistically significant.

Based on the EQ-5D, the general health status of the patients was assessed. This scale indicates three levels based on the severity of issues; no problem (level 1), some problem (level 2) and a lot of problems (level 3). Regarding the various subscales, mobility ($F_{(1,52)}$=0.20; p=0.88) and looking after myself ($F_{(1,56)}$=2.26; p=0.14) did not show significant variations, indicating no problems in these areas.

Significant improvements were observed in all other subscales. Specifically, there was a significant decrease in reported problems with usual activities ($F_{(1,47)}$=6.23; p=0.01), having pain or discomfort ($F_{(1,33)}$=6.82; p=0.01), and feeling worried and sad or unhappy ($F_{(1,53)}$=31.5; p<.001). Finally, a significant overall improvement was observed in the general health perceived by the patient on the day of the assessment ($F_{(1,52)}$=12.28; p<.001).

Regarding the perception of the intervention (AIM, IAM and FIM), there was a non-significant decrease observed in the acceptability (AIM) of the intervention ($F_{(1,51)}$=0.51; p=0.47). The appropriateness (IAM) was assessed in the same measure ($F_{(1,57)}$=0.001; p=0.97). Finally, a non-significant increase was observed in the feasibility (FIM) of the intervention ($F_{(1,35)}$=2.48; p=0.124).

The APOI was used to assess attitudes toward internet interventions. A non-significance decrease was observed in negative attitudes toward the efficacy and security of the intervention (Skepticism and Perception of Risk-SKE) ($F_{(1,64)}$=0.04; p=0.82), positive attitudes regarding the utility and credibility of the intervention (Confidence in Effectiveness-CON) ($F_{(1,72)}$=0.21; p=0.64), and positive attitudes related to the privacy gained through online interventions (Anonymity Benefits-ABE) ($F_{(1,51)}$=1.09; p=0.30). A significant increase was observed in relation to concerns about the lack of professional contact (Technologization Threat-TET) ($F_{(1,51)}$=7.45; p=0.009). Overall, there was a non-significant increase in the total score of the APOI, reflecting the general acceptance of online interventions ($F_{(1,56)}$=0.03; p=0.86).

Considering the satisfaction of those who completed all the intervention, an average mean of 23.14 (Range=8-32; SD=8.76) was obtained in the CSQ-I questionnaire.

The results obtained are reflected in Table 2.

3.2 Professionals

Of the 86 recruited professionals (Balearic Island=28; Andalusia=34; Aragon=24), only 57 (Balearic Island=25; Andalusia=18; Aragon=14) were successfully contacted for a telephone interview and provided access to online intervention. Among them, 45 were women (78.9%) and 12 were men (21.1%) with an average age of 45.58 (SD=11.29; range 25-65). Of the recruited professionals, 36 were medical doctors (63.2%) and 11 nurses (19.3%), while information regarding the professional background of 10 individuals was not available. The characteristics of the professionals are reflected in Table 3.

Most of the professionals had extensive experience, with over fifteen years in the profession (N=37; 64.9%). However, their time in the department was shorter, with most having been in their current department for 3 to 5 years (N=15; 26.3%), followed by 13 with less than 1 year and 11 with between 1 and 2 years.

Regarding the affluence of patients, the majority claimed to see fewer than 20 new patients per month (N=28; 49.1%). In terms of attendance, professionals estimated a mean of 13.16 minutes per patients (SD=10.53; range 6 –60).

Regarding internet usage, the majority reported using it every day (N=51;89.5%) and expressed either good or average abilities in using the internet (in both cases N=22;38.6%). The internet abilities are in congruence with the technological profile assessment, where they got a mean of 2.15 (SD=0.54), being 2 categorized as normal. However, regarding internet interventions, most of them had not seen (N=47; 82.5%), received training, or used an online intervention (in both cases N=53; 93%).

Professionals' willingness to adopt innovations on EBP (EBPAS) was demonstrated with a mean score of 3.77 out of 5 (Range=2.38-4.38; SD=0.39; N=38).

Regarding the climate for implementing (ICS) the intervention Smiling is Fun, the highest score was observed in the team's focus on EBP with a mean of 3.09 (Range=1-4; SD=0.74). Other factors included providing educational support for implementation (Mean=2.71; Range=0.33-4; SD=0.92), recognition of mental health workers for implementing the program (Mean=2.47; Range=0.67-3.67; SD=0.81) and selecting mental health professionals for their openness (Mean=2.33; Range=0-4; SD=1.2). The lowest ranked factors were selecting based solely on prior experience in the program or similar ones (Mean=1.63; Range=0-4; SD=1.3) and offering rewards to professionals for program implementation (Mean=0.91; Range=0-3; SD=1.07). The overall mean score for the scale was 2.19 (Range=0.44-3.44; SD=0.78). Additionally, the readiness of the professionals within PC settings to implement the intervention was assessed using the ORIC scale, yielding an average of 4.07 (range=1.5-5; SD=0.87).

Leadership style was also assessed using the ILS scale, with the highest mean observed in the Supportive attitudes at 3.02 (Range=1-4; SD=0.74). This was followed sequentially by Knowledgeable (Mean=2.80; Range=0.67-4; SD=0.80), Perseverant (Mean=2.76; Range=0.75-4; SD=0.84), and Proactive

(Mean=2.45; Range=0-4; SD=1.94). The average total score for the scale was 2.76 (Range=0.75-4; SD=0.76).

Based on the list of barriers and facilitators (Appendix 2; Table 4; List of barriers and facilitators) listed in the FBI questionnaire, professionals reported prior to implementation which aspects they believed could hinder or facilitate the progress of implementing the intervention “Smiling is Fun,” even if only to a small extent. Once the intervention was implemented, professionals were asked again which aspects finally interfered with or facilitated the process. The option “other” was offered in case professionals were uncertain or preferred not to answer.

Barriers more frequently pointed out before implementation included frequent changes in staff (N=32; 86.5%), insufficient time provided for learning and implementing the new program (N=29; 78.4%), and high levels of stress (N=28; 75.7%). After implementation, high levels of stress (N=19; 70.4%), lack of integration of the program into medical records (N=19; 70.4%), and a gap between professionals who attended the training and those who did not (N=18; 66.7%) were identified as prominent barriers.

As for facilitators highlighted before implementation, they included leader support for the intervention (N=34; 91.9%), organizational capacity (N=33; 89.2%), and reporting on patient outcomes and progress (N=33; 89.2%). After implementation, the most valued facilitators were the intervention’s alignment with the target population (N=22; 81.5%), perceived effectiveness of the intervention (N=21; 77.8%) and reporting on patient outcomes and progress (N=21; 77.8%). The complete list of frequencies of barriers and facilitators is provided in Appendix 1.

Based on the set of scales AIM, IAM and FIM, a decrease on the acceptability, appropriateness, and the feasibility of the intervention perceived by professionals was observed. Nevertheless, in neither case was this significant; acceptability ($F_{(1,43)}$= 2.44; p=0.126; N_{PRE}=4.45, SE_{PRE}=0.01; N_{POST}=4.22, SE_{POST}=0.11), appropriateness ($F_{(1,34)}$=7.8; p=0.08; N_{PRE}=4.56, SE_{PRE}=0.11; N_{POST}=4.20, SE_{POST}=0.11) and feasibility ($F_{(1,44)}$=3,49; p=0.68; N_{PRE}=4.22, SE_{PRE}=0.11; N_{POST}=3.91, SE_{POST}=0.12).

4. Discussion

Depression needs to be addressed, and PC, which is established as the first step in public healthcare to receive assistance, offers the opportunity to tackle this issue in Spain (Kringos et al., 2015). With the primary objective of enhancing the population’s accessibility to EBPP, a Hybrid Effectiveness-Implementation Type II using SW-RCT approach was conducted. The study aimed to implement the program ‘Smiling is Fun’ to address mild to moderate depression.

One of the goals of the study was to evaluate the effectiveness of Smiling is Fun in addressing depression among participants. The findings indicate a significant reduction in depressive symptomatology with a large effect size. The observed decrease in depressive symptoms aligns with existing literature highlighting the effectiveness of Smiling is Fun (Mira et al., 2016, 2019) and other CBT online interventions in reducing depression (Karyotaki et al., 2017, 2018).

In addition to reductions in depressive symptoms, our findings also revealed significant improvements in positive affect and reductions in negative affect. This dual effect on affective states is consistent with the broader goal of promoting overall well-being and emotional resilience. By targeting both depressive symptoms and affective states, online interventions have the potential to offer comprehensive support for individuals experiencing mental health challenges (Fadipe et al., 2023). The effects of Smiling is Fun are consistent with previous studies that focus on the effects of positive psychology components that build the intervention (Mira, Bretón-López, et al., 2018).

Furthermore, a general improvement in the health status of the participants was observed. Specifically, the EQ-5D revealed a decrease in problematic areas related to depression symptomatology, including not doing the daily activities, having pain or discomfort, and having emotional problems related to worry, saddens or unhappiness.

Consistent with previous research (Andersson, 2018; Cuijpers et al., 2023), our findings suggest that online platforms can effectively deliver EBPP, underscoring the potential of online interventions as a viable approach for addressing depression and general mental health, particularly considering the convenience and accessibility they offer to individuals seeking support (Mohr et al., 2017).

Once the effectiveness of the intervention was established, a parallel objective was to assess implementation outcomes influencing this process.

The evaluation of participants' perceptions including professionals and patients regarding the online intervention provided valuable insights into its acceptability, appropriateness, feasibility, fidelity, attitudes toward internet interventions, and overall satisfaction with the program.

Regarding the acceptability, appropriateness, and feasibility, both patients and professionals perceived it as moderately to highly favorable. These perceptions remained relatively stable throughout the implementation process. The lack of significant changes in acceptability, appropriateness, and feasibility suggests that participants' overall perceptions of the intervention remained steady. Despite not experiencing a significant increase, and rather observing a non-significant decrease in most cases, this consistency implies that the intervention maintained its perceived value and relevance.

Examining attitudes toward internet interventions using the APOI revealed a broader perspective. Although skepticism and perceived risk and confidence in effectiveness were moderate, participants also demonstrated moderate levels on finding anonymity beneficial. While there were no significant changes, there were indications of pre-established attitudes that could hinder implementation. Addressing these hesitations is crucial for enhancing acceptance and uptake of internet interventions.

A notable concern was the lack of professional contact, evident from the significant increase in the Technologization Threat. This emphasizes the need to balance accessibility and the provision of direct interaction with healthcare professionals. This observation aligns with the existing literature, which suggests that interventions with minimal professional enrolment may lead to higher rates of adherence

and effectiveness by addressing these beliefs (Andersson et al., 2019). Despite these perceptions, participants who completed the intervention reported high levels of satisfaction.

Fidelity of the implementation was determined by the number of modules completed. It is important to note that there is a need for further development to address this concern, as not all participants completed the entire intervention. Once more, the literature underscores lower rates of adherence in self-applied interventions, often attributed to participants' perceived lack of time to engage fully in the intervention themselves (Grant et al., 2023). This constraint can significantly impact module completion rates.

Regarding sustainability, the climate for implementation using the ICS scale revealed several key factors influencing professionals' readiness to implement the intervention. The emphasis on the team's focus on EBPP suggests a supportive organizational culture for innovation and change. However, areas for improvement include providing educational support for implementation and recognizing mental health workers for their efforts, which can enhance motivation and engagement in the implementation process.

The readiness of professionals within PC settings to implement the intervention, as measured by the ORIC scale, indicates a high level of readiness overall. This suggests that professionals perceive themselves as capable and prepared to integrate the intervention into their practice, which is essential for successful implementation and sustainability.

The leadership style exhibited by professionals, as measured by the ILS scale, reflects a predominantly supportive approach, followed by knowledgeable, perseverant, and proactive attitudes. A supportive leadership style is essential to foster a positive organizational climate and facilitate the implementation process by providing guidance, encouragement, and resources to support staff members. The relatively high scores across all leadership dimensions indicate a favorable leadership context for implementing the intervention.

So it seems that PC settings could offer an adequate context to implement the intervention (Vis et al., 2022). Nevertheless, more precise information is necessary, such as identifying barriers and facilitators for implementation which is essential to understand the contextual factors that can hinder or support the successful adoption of new interventions. Before implementation, professionals identified frequent changes in staff, insufficient time for learning and implementation, and high levels of stress as prominent barriers. Other barriers included lack of personnel and difficulties in following the process of implementation as established. These factors highlight the challenges inherent in introducing new interventions within dynamic and demanding healthcare environments.

After implementation, high levels of stress, lack of integration of the program into medical records, and disparities between trained and untrained professionals emerged as persistent barriers. These findings underscore the importance of ongoing support and resources to address stressors and promote the integration of interventions into existing workflows.

On the other hand, leader support for the intervention, organizational capacity, and reporting on patient outcomes and progress were identified as significant facilitators before implementation. These factors emphasize the critical role of leadership in championing the intervention, fostering a supportive organizational culture, and promoting accountability and transparency in implementation efforts.

Following implementation, the intervention's alignment with the target population, perceived effectiveness, and continued reporting on patient outcomes emerged as key facilitators. These findings highlight the importance of maintaining alignment with organizational goals and priorities, demonstrating the intervention's effectiveness, and monitoring progress to sustain engagement and momentum over time.

Overall, the findings highlight the multifaceted nature of implementation processes within PC settings, where leadership style, organizational factors, and contextual barriers and facilitators intersect to shape the success of intervention efforts. By addressing identified barriers and leveraging facilitators, healthcare organizations can optimize their capacity to effectively implement and sustain interventions like Smiling is Fun, ultimately enhancing the delivery of mental healthcare within primary care settings.

In order to address some of the detected main barriers, new strategies need to be developed and tested such as the incorporation of online educational resources for professionals or addressing stress levels of health professionals (Powell et al., 2015).

Prior to implementation, a set of 13 strategies were designed and described (Lorente-Català et al., 2022). However, during the implementation process, some difficulties arose, resulting in the partial or non-execution of certain strategies. For instance, financial strategies involving economic reinforcement per patient for professionals to promote adoption and penetration were hindered by the funder.

Another pre-established strategy that faced challenges was reminding clinicians about the recruitment and the study itself. Promotion of the implementation was hindered because physical visits to PC settings by local researchers made it difficult to contact professionals. However, midway through the implementation process, the identified health professional champions were called and interviewed. One significant barrier they identified was the overload of studies being conducted in the different centers, causing them to forget this particular one. In fact, when contacting professionals to conduct post-questionnaires, a notable percentage did not remember the project. Strategies in this regard need refinement and adaptation to the specific situation.

Additionally, another partially implemented strategy involved using advisory and work groups to qualitatively assess professionals. As mentioned earlier, champions of each PC center were assessed once. However, further assessment is needed, including a broader profile of professionals.

While this study presents several advantages, it should be interpreted within the context of its limitations. First, the small sample size and the recruitment problems restrict the generalizability of its findings. Consequently, testing hypothesis should be viewed as preliminary and interpreted cautiously.

Adherence issues were observed throughout the study, which may have impacted the consistency and reliability of the results. Additionally, the absence of recorded technical support hinders the assessment of the resources required for implementation and is especially related to economical and personal costs.

The study encountered significant challenges during its execution due to the unforeseen onset of the COVID-19 pandemic. This global health crisis resulted in substantial disruptions, particularly in the overload experienced by professionals and service attendance. Therefore, any adaptations or repetitions of this study should account for these unique circumstances.

Moreover, the absence of follow-up due to insufficient data hampers our ability to assess the sustainability of the observed changes over time.

5. Conclusion

In conclusion, while the study demonstrates promising outcomes regarding the effectiveness of the 'Smiling is Fun' intervention in addressing depression and enhancing overall well-being, it is essential to acknowledge the complexity of implementing such interventions within PC settings. The identified barriers and facilitators underscore the need for ongoing refinement and adaptation of strategies to optimize implementation success. Despite its limitations, this study contributes valuable insights into the potential of online interventions to augment mental health care accessibility and delivery. Moving forward, continued research and development efforts are warranted to address challenges and ensure the sustained impact of interventions like 'Smiling is Fun' in real-world healthcare contexts.

Declarations

Ethics approval and consent to participate

The study Ethics Committee was approved by all Autonomous Communities including 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 accordance with the guidelines of the Helsinki and Tokyo Declaration.

All participants were informed about the study and provided consent to participate.

Trial registration: https://clinicaltrials.gov/study/NCT05294614

Consent for publication

The consent of publication was given by all participants.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author.

Funding

Coordinated project grant from Ministerio de Ciencia, Innovación y Universidades (Spain). Instituto de Salud Carlos III. Convocatoria de Ayudas a la acción estratégica de salud. Reference: P19/00723. Fondo Europeo de Desarrollo Regional (FEDER).

R.L.-C. holds a PhD grant from “Consellería de Innovación, Universidades, Ciencia y Sociedad Digital, Generalitat Valencia (Spain). Subvenciones para la contratación de personal investigador de carácter predoctoral (ACIF/2020)”. Reference: ACIF/2020/332.

Authors’ contributions

AGP, JGC, FMC, YLDH and MG developed the project, won the grant, and supervised the entire implementation process. AC, SFM, EVM, GGP, and IFR were the researchers in each Autonomous Community, leading professional recruitment and implementation. RLC was the coordinator of the local researchers and the major contributor in analyzing the data and writing the manuscript. All authors read and approved the final manuscript.

Conflict statement

The authors declare that they have no conflicts of interest.

Acknowledgements.

We would like to express our gratitude to all the health professionals in Primary Care who are committed to mental health and have facilitated the implementation of this intervention.

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Tables

Table 1. Characteristics of recruited patients.

	Total N	%		Total N	%
Marital stage			**Employment status**		
Married or in a relationship	60	46.5%	Student	5	3,9%
Single	41	31.8%	Homemaker	4	3.1%
Separated or divorced	25	19.4%	Unemployed with benefits	17	13.12%
Widowed	3	2.3%	Unemployed without benefits	55	42.6%
N total	129	100%	Employed	37	28.7%
Living			Employed but on sick leave	7	5.4%
Own residence alone	14	10.9%	Retired	3	2.3%
Own residence with partner	15	11.6%	Permanently disabled	1	0.8%
Own residence with partner and/or children	53	41.1%	**N total**	129	100%
Family home	33	25.6%	**Income level**		
Other	14	10.9%	<MIS	9	7%
N Total	129	100%	1-2 MIS	42	32.6%
Educational level			2-4 MIS	8	32.6%
Not completed studies but knows how to read and write	3	2.3%	>4 MIS	3	2.3%
Secondary school graduate	16	12.4%	N total	62	48.1%
Secondary studies	59	45.7%	**Reasons for abandonment**		
University studies	51	30.5%	Not need it	4	17.4%
N total	129	100%	Does not believe in its usefulness	1	4.3%
			Lack of time	6	26.1%
			Not comfortable with the program's interface	2	8.7%
			Prefers personal interaction	2	8.7%
			Other	8	34.8%
			N total	23	100%

N=sample size; SD=Standard Deviation; MIS= Minimum Interprofessional salary (<MIS= 900 euros; 1-2 MIS= 901 to 1800 euros; 2-4 MIS=1801 to 3600; >4MIS= more than 3601 euros).

Table 2. Patient outcomes

	Pre		Post	Pre-Post				
				F	P	D		
PHQ9	14.71 (0.69)	12.20 (0.69)	6.06 (0.90)	44.47	**<.001**	$0.34_{PRE1-PRE2}$	$0.62_{PRE2-POST}$	$0.87_{PRE-POST}$
PANAS-PA	17.69 (0.77)		26.31 (1.31)	40.12	**<.001**	0.91		
PANAS-NA	29.52 (0.95)		19.41 (1.69)	29.51	**<.001**	0.75		
AIM	4.20 (0.08)		4.09 (0.14)	0.515	0.47	0.10		
IAM	4.30 (0.08)		4.31 (0.14)	0.001	0.97	0.004		
FIM	4,21 (0.07)		4.41 (0.12)	2.48	0.12	0.26		
APOI SKE	2.32 (0.08)		2.28 (0.14)	0.04	0.82	0.02		
APOI CON	2.15 (0.09)		2.05 (0.17)	0.21	0.64	0.05		
APOI TET	3.20 (0.07)		3.57 (0.12)	7.45	**0.009**	0.38		
APOI ABE	3.06 (0.10)		2.86 (0.17)	1.09	0.30	0.14		
APOI total	42.94 (0.83)		43.20 (1.44)	0.03	0.86	0.02		
EUROQOL mobility	1.25 (0.05)		1.26 (0.09)	0.02	0.88	0.01		
EUROQOL looking after myself	1.29 (0.05)		1.13 (0.09)	2.25	0.13	0.19		
EUROQOL doing usual activities	1.83 (0.06)		1.54 (0.11)	6.23	**0.01**	0.36		
EUROQOL having pain or discomfort	1.84 (0.07)		1.51 (0.12)	6.82	**0.01**	0.45		
EUROQOL feeling worried sad or unhappy	2.31 (0.06)		1.62 (0.11)	31.54	**<.001**	0.77		

EUROQOL today	45.77 (2.19)	59.95 (3.81)	12.27	**<.001**	0.48

ABE= Anonymity Benefits; AIM= Acceptability of Intervention Measure; APOI= Attitudes towards Psychological Online Interventions; CON= Confidence in Effectiveness; FIM= Feasibility of Intervention Measure; IAM= Intervention Appropriateness Measure; PANAS-NA= Positive and Negative Affect Schedule-Negative Affect; PANAS-PA= Positive and Negative Affect Schedule-Positive Affect; PHQ-9= Patient Health Questionnaire- 9; SKE= Skepticism and Perception of Risk; TET= Technologization Threat.

Table 3. Professionals' information

	N	%(N)		N	% (N)
Qualification			**New patients**		
Bachelor's degree	1	1.8	<20	28	49.1
Degree	12	21.1	20-30	15	26.3
Master	6	10.5	30-40	7	12.3
PhD	3	5.3	>40	5	8.8
Specialization	30	52.6	N total	55	96.5
N total	52	91.2	**Internet use**		
Profession			Mostly every day	51	89.5
Doctor	36	63.2	Several times per week	5	8.8
Nurse	11	19.3	N total	56	98.2
N total	47	82.5	**Internet abilities**		
Experience			Really good	7	12.3
1-2 years	1	1.8	Good	22	38.6
3-5 years	8	14	Half	22	38.6
6-10 years	6	10.5	Poor	6	10.5
11-15 years	4	7	N total	57	
>15 years	37	64.9	**Seen online interventions**		
N total	56	98.2	Yes	9	15.8
Time department			No	47	82.5
<1 year	13	22.8	Do not know	1	1.8
1-2 years	11	19.3	N total	57	
3-5 years	15	26.3	**Trained to apply online intervention**		
6-10 years	7	12.3	Yes	4	7
11-15 years	3	5.3	No	53	93
>15 years	8	14	N total	57	
N total	57	100	**Used online intervention**		
			Yes	4	7
			No	53	93

N total	57

Figures

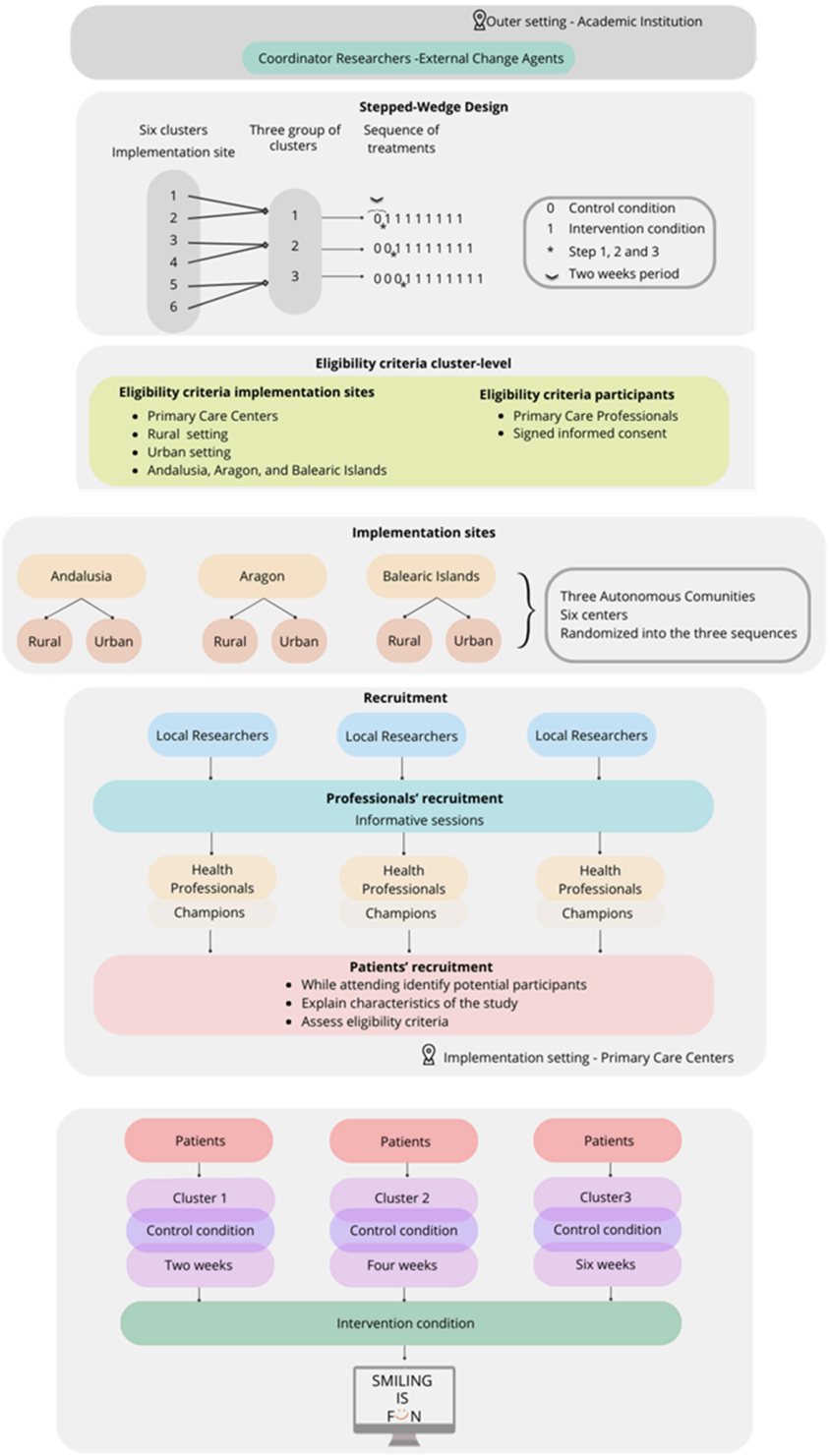


Figure 1

Design, eligibility criteria cluster-level, recruitment, and procedure.

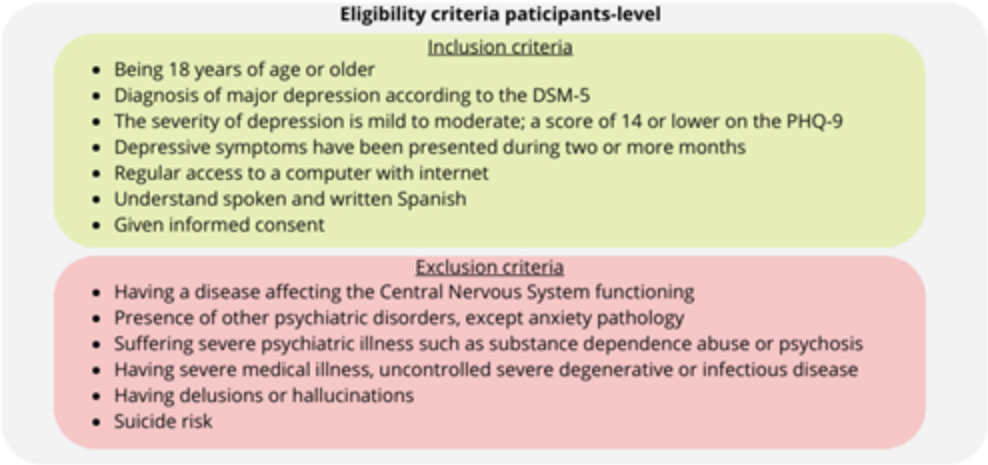


Figure 2

Eligibility criteria participants-level



Figure 3

Smiling is Fun components.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1.StaRiChecklist.pdf
- Appendix2.pdf

- CONSORT2010Checklist.pdf