



A smartphone-based serious game for depressive symptoms: Protocol for a pilot randomized controlled trial

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ABSTRACT

Background: Depression is the most prevalent mental disorder, with detrimental effects on the patient's well-being, high disability, and a huge associated societal and economic cost. There are evidence-based treatments, but it is difficult to reach all people in need. Internet-based interventions, and more recently smartphone-based interventions, were explored to overcome barriers to access. Evidence shows them to be effective alternatives to traditional treatments. This paper presents the protocol of a pilot study whose primary aim is to investigate the efficacy of a smartphone-based serious game intervention for patients with mild to moderate depressive symptoms.

Methods: This randomized controlled pilot trial protocol foresees two arms design: 1/ smartphone-based serious game intervention (based on Cognitive Behavior Therapy with particular emphasis on Behavioral Activation and Physical Activity), 2/ waiting list control group. The study is expected to recruit 40 participants (18+), which will be randomly assigned to one of the experimental conditions. The duration of the intervention is two months. The primary outcome measure will be depressive symptomatology. Secondary outcomes will include other variables such as physical activity, resilience, anxiety, depression impairment, and positive and negative affect. Treatment expectation, satisfaction, usability, and game playability will also be measured. The data will be analyzed based on the intention-to-treat and per protocol analyses.

Discussion: The study aims to establish initial evidence for the efficacy of a smartphone-based serious game intervention, to serve as input for a larger-scale randomized control trial. The intervention exploits advanced smartphone capabilities, such as the use of a serious game as delivery mode, with the potential benefit of engagement and treatment adherence, and motion sensors to monitor and stimulate physical activity. As a secondary objective, the study aims to gather initial evidence on the user's expectations, satisfaction, usability and playability of the serious game as a treatment.

1. Introduction

Depression affects approximately 280 million people worldwide being the most common mental disorder WHO (2021). It is regarded as one of the leading causes of disability worldwide WHO (2021), and it is the primary cause of suicide deaths. Therefore, where prevention and treatment of depression was already a priority Cuijpers et al. (2012), it has now become more urgent than ever due to the COVID-19 effects Bueno-Notivol et al. (2021). Depression is characterized by intense

sadness, vacuum sensation, despondency, unhappiness or lack of interest APA (2022); NIMH (2022); WHO (2021). There are several evidence-based interventions for depression, both pharmacological and psychotherapy treatments, or a combination of both Cuijpers et al. (2012, 2008). Among evidence-based psychological interventions, we discern Cognitive Behavior Therapy (CBT) Churchill et al. (2001); Cuijpers et al. (2013), behavioral activation (BA) Cuijpers et al. (2008); Ekers et al. (2008), problem-solving therapy Malouff et al. (2007) or interpersonal therapy Cuijpers et al. (2011, 2016). CBT has a multitude of evidence of

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its efficacy Cuijpers et al. (2011, 2008); Thoma et al. (2015). BA, an important component of CBT, has been established as an evidence-based psychological therapy for depression Dimidjian et al. (2011) which can be as effective as the full CBT Jacobson et al. (1996). The main rationale of BA is the reduction of the negative reinforcement, increasing the positive ones (i.e. personal and social pleasant behaviors) Hopko et al. (2003); Lejuez et al. (2001); Richards (2010); Ekers et al. (2014). Furthermore, it shares behavior change techniques Michie et al. (2013) with interventions promoting Physical activity (PA) (i.e. goal setting) Farrand et al. (2014). According to the literature, the relapse rate associated with BA could be reduced with preserved PA, as it intrinsically improves mood and long-term benefits Babyak et al. (2000). Through the rationale treatment delivery of BA, it may be possible to promote PA in people with depression and thus take advantage of the benefits of combining PA with BA. PA has been shown to be effective for depression Cooney et al. (2013); Ekkekakis (2015); Rebar et al. (2015); Mammen and Faulkner (2013), and it is cited by patients as their elected treatment Searle et al. (2011); Ussher et al. (2007). Furthermore, PA helps to prevent relapses Babyak et al. (2000), improves anxiety Stubbs et al. (2017), and helps to prevent problems associated with depression (i.e. diabetes or cardiovascular problems Gibala et al. (2012)). In addition to PA, recent literature shows that positive psychology strategies might also have an impact on increasing well-being and declining clinical symptomatology Ruini (2017); Chaves et al. (2017); Carr et al. (2020); Hendriks et al. (2020); Koydemir et al. (2021). Positive psychology emphasises the importance to treat depression not only by focusing on the reduction of negative symptoms, but also by promoting psychological strengths, building positive emotions and a meaningful life Seligman et al. (2006). Nevertheless, even though there are evidence-based techniques for depression, it is difficult to implement them. Only 13.7 % and 22 % of patients in lower-middle and upper-middle, and 36.8 % in higher-income countries, respectively, receive treatment Evans-Lacko et al. (2018). This is an indication that the dominant model of treatment delivery, namely individual face-to-face therapy, is not sufficient to reach the majority of people in need Kazdin (2015). The reasons behind this are structural, such as economic or availability barriers, or attitudinal, such as low perceived need for treatment, social stigma of mental disorders or the desire to handle the problem by oneself WHO (2021). Removing these barriers and maximizing the dissemination of psychological treatment is an active stream of research, which explores, develops, and validates new ways to deliver psychological interventions Kazdin and Blase (2011); Kazdin (2015).

Technology-based interventions provide a useful way of overcoming these barriers, being cheap, scalable and accessible Kazdin (2015); Kazdin and Blase (2011). Results indicate that Internet-based interventions are effective for the treatment of depression Cuijpers et al. (2011); Taylor et al. (2021); Andrews et al. (2010); Karyotaki et al. (2017), with an efficacy comparable to face-to-face therapies Andrews et al. (2015); Cuijpers et al. (2011). In recent years, research into the use of smartphones as a novel, cost-effective way to deliver mental health therapy dramatically increased, with depression the most targeted disorder - close to 20 % according to a recent, large-scale systematic review Miralles et al. (2020). Only a few of these smartphone apps utilize advanced capabilities of smartphones, such as sensors, gamification techniques or video games. Nevertheless, sensors, such as GPS or accelerometer, could be deployed to detect and stimulate the implication of patients in meaningful activities and to promote PA, which has been shown to be effective in treating and preventing depression Ekkekakis (2015); Mammen and Faulkner (2013); Ekers et al. (2014); Rebar et al. (2015). In addition, serious (video) games Stokes (2005) - of which only 1 study was found according to Miralles et al. (2020) - could provide a number of features which potentially align well with psychological treatment Fleming et al. (2017). Firstly, they have the potential to be engaging and maintain user adherence Eichenberg and Schott (2017); Russoniello et al. (2013) because of their playful nature, safe environments, individual accomplishments, mental distraction,

challenges, and immediate feedback Fleming et al. (2014); Cheek et al. (2015). Emphasis on engagement has been identified as one of the cornerstones to increase the impact of e-therapies Fleming et al. (2016). Secondly, serious games have the potential to be effective, as they offer immersive and positive experiences, and positive emotions might be evoked during gameplay Nah et al. (2014). Finally, serious games provide rich environments for users to train new skills in a safe and reactive way, an essential feature for realizing behavior changes and effective learning Cheek et al. (2015); Fleming et al. (2017).

Recent systematic reviews of video games and gamification for mental health indicate promising results, most importantly towards their effectiveness Eichenberg and Schott (2017); Fleming et al. (2017); Lau et al. (2017); Pine et al. (2020). Based on several literature reviews Fleming et al. (2014); Li et al. (2014); Dias et al. (2018); Eichenberg and Schott (2017); Lau et al. (2017); Fleming et al. (2017); Shah et al. (2018); David et al. (2020), only 10 studies between 2000 and 2018 focus on the assessment of serious games for the treatment of depression in terms of acceptability, user's perception or efficacy Merry et al. (2012); Fleming et al. (2012); Lucassen et al. (2013); Cheek et al. (2015); Shepherd et al. (2015); Poppelaars et al. (2016); Stallard et al. (2011); Stasiak et al. (2012); Carrasco (2016); Lin et al. (2020). Among these studies, 5 different serious games were developed ("SPARX", "Think, Feel, Do", "The Journey", "Maya", "Magical Healing Potion Hunting") and the design of an extension of one of them ("SPARX Rainbow") was defined Lucassen et al. (2013). All these serious games were designed, developed, and tested for/on regular computer platforms. SPARX Fleming et al. (2012); Merry et al. (2012) was migrated to smartphones, yet due to its original design for Personal Computers (PCs), smartphone-specific capabilities - such as the use of sensors, activity data collection, or identification of behavioral patterns - and generally, the anywhere-anytime nature of smartphones, were not taken into account.

Even though studies indicate that serious games are effective as an integral and primary method for treating or preventing depression, larger and more robust trials Fleming et al. (2017); Shah et al. (2018); Eichenberg and Schott (2017); David et al. (2020) and more robust analyses of engagement and continued use are required Fleming et al. (2017); Merry et al. (2012). All of the reviewed studies focused on children, adolescents or young people, thereby not considering the significant market segment of (older) adult video game players, which is nevertheless worth exploring Fleming et al. (2014). The field is relatively new and current literature is limited Lau et al. (2017); Dias et al. (2018). To the best of our knowledge, there are no smartphone-based serious games designed and developed as an intervention for depression.

Taking into consideration the aforementioned gaps in research, we have developed a smartphone-based serious game for depressive symptoms. It is based on CBT, with particular emphasis on BA and PA components, and exploits the smartphone's motion sensor A. Developers (2022) to improve and promote them. The target audience is adults (18+) who suffer mild or moderate depressive symptoms and who have and are able to use a smartphone.

2. Materials and methods

2.1. Aim

The present study aims to (a) investigate the effect of a smartphone-based serious game intervention for individuals with mild to moderate depressive symptoms at post-treatment and follow-ups (3, 6 and 12 months) compared to a waiting list control condition; (b) study the user expectation, user satisfaction, usability, and game playability of this intervention. It is hypothesized that a) the smartphone-based serious game intervention will provide a significant improvement in clinical symptomatology after the treatment compared to the waiting list control group - and the improvement will be maintained in the follow-up and b) the experimental condition will obtain a high expectation, satisfaction, usability and good game playability from the participants.

2.2. Study design

In this study, a two-armed pilot randomized control trial will be conducted. Participants will be randomly assigned to one of two following conditions: a) a smartphone-based serious game condition and b) a waiting list control condition. Randomization will be stratified by levels of depression severity (mild to moderate). This trial was registered on the [ClinicalTrials.gov](https://clinicaltrials.gov) database (NCT04988529) and it follows the CONSORT 2010 statement (Consolidated Standards of Reporting Trials, <http://www.consort-statement.org/>) Moher et al. (2010), CONSORT-EHEALTH Eysenbach et al. (2011) and SPIRIT 2013 guidelines Chan et al. (2013) and has been approved by the Ethics Committee of Universitat Jaume I (Castelló, Spain) on November 22, 2021 (CD/89/2021). Fig. 1 shows the study flowchart.

2.3. Participants and recruitment

The pilot RCT will be carried out at the Emotional Disorder Clinic in Universitat Jaume I. Participants will be adults (18+) who suffer from mild to moderate depressive symptoms. Participants will be volunteers recruited through social media, emails, announcements at the clinic and the university, and a website developed for patient recruitment. Potential participants, who have been assessed by a clinical psychologist, will be informed about all the aspects of the study and all their doubts will be clarified. In addition, informed consent and a consent request for the use of his/her personal data for research purposes in a pseudonymized form must be signed by those who are interested in participating. The confidentiality and security of the data will be ensured following the current legislation and the Declaration of Helsinki. The researcher in charge will evaluate the participants to determine compliance with the

inclusion criteria. The inclusion criteria are: a) be 18 to 65 years old; b) be able to read and understand Spanish; c) be able to use a smartphone; d) have an Android smartphone with an internet connection, and e) suffer from mild to moderate depressive symptoms (from 14 to 28 on the Beck Depression Inventory-II [BDI-II]). Participants are excluded if they a) suffer severe depressive symptoms; b) suffer a severe mental disorder: bipolar disorder, alcohol and/or substance dependence disorder, psychotic disorder, or dementia; c) have a high suicide risk (item 9 of the BDI-II); or d) receive psychological treatment. An alternative treatment will be offered to participants excluded from the study.

Participants who meet the inclusion criteria must agree to participate before finding out to which condition they are assigned. They will then be randomly assigned to one of two experimental conditions by an independent researcher, who will not have information about the study characteristics nor experimental conditions using a weighted random number sequence generated by a computer. The allocation schedule will be communicated to the study researchers. Participants allocated to the experimental group will be contacted by telephone and scheduled to receive a first face-to-face support session to motivate and inform them of the game operation and start psychoeducation. The participants who are assigned to the control condition will have the chance to receive the same experimental treatment when the study finishes. Participants may leave the study at any time.

2.4. Sample size

The sample size in this pilot randomized control trial has been calculated following literature recommendations Whitehead et al. (2016). To ensure scientific validation in the results of pilot studies, at least 15 to 20 participants per condition are required Hertzog (2008).

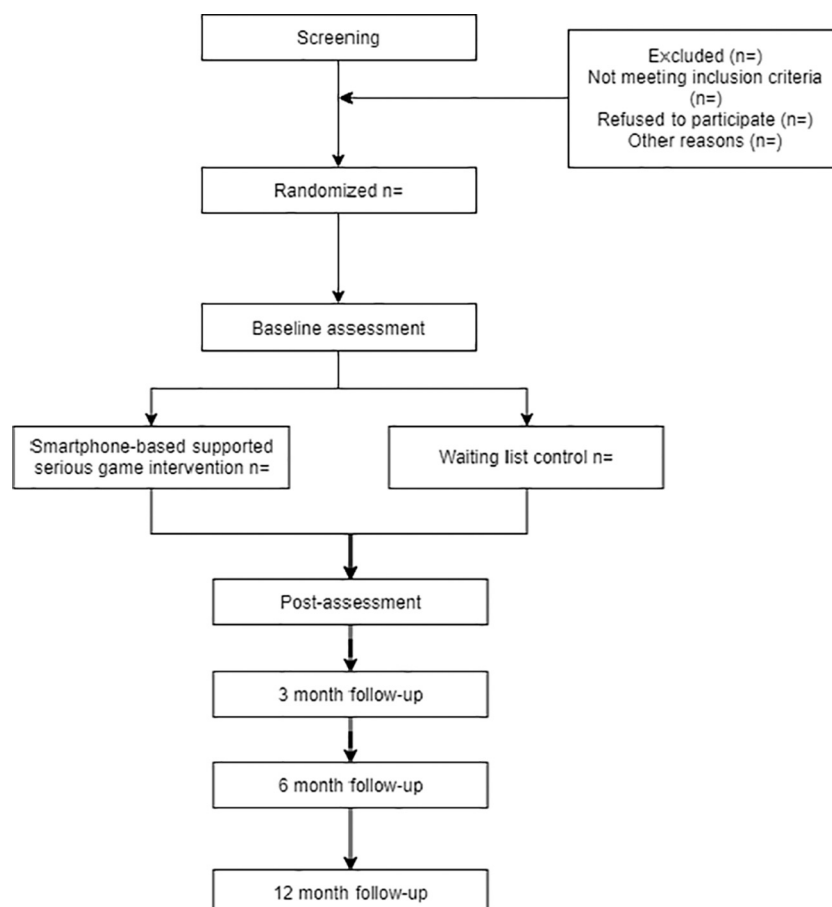


Fig. 1. Study design.

Assuming a significant bilateral level of 5 %, a statistical power of 90 %, and an effect size of moderate magnitude David et al. (2020), a total of 15 participants per condition are needed. Taking into account the drop-outs that could occur in the self-help interventions, a total of 40 participants will be expected.

2.5. Intervention

We developed a smartphone-based serious game intervention called “Horizon: Resilience”. The target audience is adults who suffer from mild to moderate depressive symptoms. The goal of the game is to help them to improve their symptomatology in an accessible and autonomous way.

2.5.1. Psychological content

The psychological content is based on Cognitive Behavior Therapy (CBT). Concretely, the four main CBT techniques for depression, namely Motivation for Change, Cognitive Flexibility, Behavioral Activation (BA) and Physical Activity (PA), and Positive Psychotherapeutic Strategies, are incorporated into the game's mechanics, gameplay and narrative. These psychological components are gradually introduced, through four different levels in the game:

1. Level 1: includes motivation for change and the acceptance of ambivalence in the change process. Specifically, the practiced skills consist of identifying the benefits and costs of the change or status quo and establishing concrete and manageable goals.
2. Level 2: the player learns how to be cognitively flexible while understanding the influence of thought in feelings, learns adaptive ways to deal with stress, and recognizes and balances his/her feelings.
3. Level 3: BA and PA promote meaningful activities, with PA as an important positive influence on our well-being.
4. Level 4: positive psychotherapeutic strategies are added and the player practices all the strategies together.

The following describes the features of the video game in more detail and how the psychological content is incorporated into it.

2.5.2. Serious game concept

“Horizon: Resilience” is a casual serious game (easy-to-use, easy-to-learn, and requires no previous special videogame skills, expertise, or regular time commitment to play) in an isometric top-down perspective. It is a city builder and narrative decision-making game, in which the player acts as the overall manager of a medieval town. The main objective is to make the town thrive through growth and psychological resilience of its inhabitants. The participant (“player” from now) disposes of three main mechanisms to achieve this goal: appropriate management of resources (materials and energy), construction of new buildings, and handling emerging conflicts among inhabitants through interactions with them (see Fig. 2). These three mechanisms are explained in the next subsections.

At the beginning of “Horizon: Resilience”, the player meets the Emory family, who has to deal with the dilemma of continuing to live in their current city, where they are settled but opportunities and prosperity are decreasing, or looking for a new place to live, where resources and opportunities are abundant, but relocating brings new challenges, fears and insecurities. The player takes part in this decision process and then follows the Emory family on their journey. Initially, the place where they settle consists of a few buildings and the local inhabitants, but while helping Earl Emory and interacting with the town inhabitants, the player also assists in making the town and its population grow and prosper. The game scenario is set to mimic typical feelings depressed people struggle with (e.g. hopelessness, lack of energy, etc.), and the game adopts and embeds different psychological strategies as part of game mechanics and gameplay.

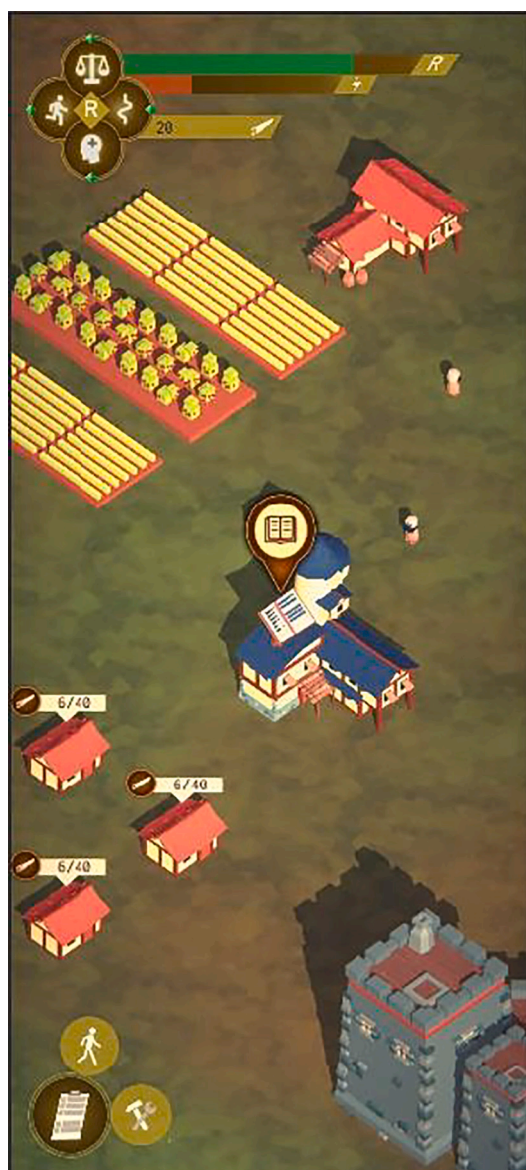


Fig. 2. Game screenshot, with the Library building in the middle of the screen, the Power R and the representation of its components, energy and materials indicators at the top, and the action menu at the bottom.

2.5.3. In-game resources

There are two main resources in the game: materials and energy.

Materials are accumulated in the town's buildings. Each building automatically generates a number of materials over time, depending on the building's size and the population it can sustain. Each building also has a maximum material storage capacity.

Energy is designed to be closely related to the BA and PA psychological components. It is accumulated by different in- and out-of-game actions which stimulate the patient's activation. These are: consulting the therapeutic content related to BA and other psychological techniques (in-game), taking a walk in the player's real life (out-of-game; PA.

- the more PA, the more energy gained), playing daily (in-game; stimulating treatment adherence) and completing a daily questionnaire concerning the player's emotional state (in-game; monitoring depression and anxiety symptoms). Actions are explained in detail in the next subsection. Energy is reset every day, and the player needs to accumulate new energy daily to advance in the game. Energy also unblocks a purely entertaining and engaging feature, namely the possibility to personalize the town (stimulating game engagement).

2.5.4. In-game actions

As town manager, the player has a variety of in-game actions (Table 1) available that allow him/her to control the game's resources (materials and energy) and manage the psychological resilience of the town inhabitants (represented in the game as "Power R", see next subsection). These actions are explained below:

- a) **Constructing buildings:** building is necessary to expand the town, increase material generation and attract more population, which in turn generates new conversations for the player to engage in (see b). There are different types of buildings, which each have different features (cost in materials, size, sustained population, resource generation rate, maximum resource storage) and require a different amount of resources and energy to build.
- b) **Conversing with the town's inhabitant:** Inhabitants are moving around the town and the player can engage in a conversation with some of them. The player is presented with a dialogue and disposes of different predefined answers to select from. These conversations present situations and conflicts that the town's inhabitants experience in their day-to-day lives, and embed psychological strategies. As such, the player helps them to achieve positive change and resilience, while fostering his/her own abilities for behavioral change and cognitive flexibility.
- c) **Walking (in real life):** the player is stimulated through notifications to perform daily PA (walking/running), which corresponds with the BA and PA psychological components. Walking is the main contributor to energy. The activity and its duration are tracked using the smartphone's motion sensors. The player can choose when s/he wants to walk as an option inside the game.
- d) **Visiting the library:** the library is present from the start of the game. Inside, the player finds information about the psychological strategies he/she learned and practices throughout the game (psychoeducation component), under easy-to-understand topics (e.g. How to be more flexible?). Moreover, the relationship between the player's emotional state (obtained through daily questions) and his/her daily PA (energy in the game - BA and PA component) is shown using a graph under the title "My evolution". Consulting library content contributes to the player's energy.
- e) **Answering daily questions:** The PHQ-2 Löwe et al. (2005) questionnaire, to measure the level of depression, and the GAD-2

Table 1
Overview of game actions, their results and underlying psychological components.

Action	Result of the action	Psychological component worked
Constructing buildings	Increases materials generation Increases town population Increases Power R Generates new conversations	Motivation for change
Conversing with town inhabitants	Increases Power R Uses/teaches psychological strategies Generates new conversations	Motivation for Change BA and PA Cognitive flexibility Positive Psychotherapeutic strategies
Walking (in real life)	Increases energy Unblocks options to personalize the town	BA and PA
Visiting the library	Consult psychoeducational content Shows mood – daily activation relationship	Motivation for change Psychoeducation BA and PA Cognitive flexibility Positive Psychotherapeutic strategies
Answering daily questions	Increases energy Monitors player's evolution	Motivation for change BA and PA

questionnaire Kroenke et al. (2007) for anxiety (monitoring) are used (2 questions each, rated from 0 to 3). The resulting scores are shown in a graph in which the player can see the evolution of his/her symptomatology related to energy (BA and PA).

2.5.5. The power R

"The Power R" is an indicator of the town population's psychological resilience. It is composed of four resilient abilities, which correspond with the main psychological techniques for intervention in depression: Motivation for Change, Cognitive Flexibility, BA and PA, and Positive Psychotherapeutic Strategies. The "Power R" is boosted when the player performs actions that work one of these abilities. Concretely, the "Power R" is increased by conversing with inhabitants (solving their conflicts), accumulating energy (visiting the library, physical activity, answering a daily questionnaire, regularly playing), constructing a variety of buildings, and generally, regularly performing actions in the game. The higher the "Power R", the better the resilience of the town's population and the better the town's performance: faster resource generation, higher maximum capacity for storing materials in buildings, and faster energy recovery. In other words, next to experiencing the well-known positive effects of the psychological components practiced throughout the game, the player also observes their positive effects on the town and its inhabitants.

2.5.6. Feedback on the patient's actions in the game

The game provides reinforcing feedback to the player based on his/her actions.

As indicated above, the main contributor to energy is performing (real-life) PA. Once the player performs PA, the game provides feedback when certain established milestones are reached. Feedback is also embedded in the conversations with the town's inhabitants. Depending on the selected action by the player and the flow of the chat, the character's reaction is different. Hereby, the player observes the effect of the selected action and observes what type of strategies are helpful to face specific situations. Finally, feedback about the player's progress (in relation to PA) is visually shown in a graph in the "My evolution" section in the Library building.

2.6. Study support

Participants allocated in the experimental condition will receive various supports during the intervention.

Human support is one part of this reinforcement. At the beginning of the program, each participant will receive a 'welcome' call from the therapist to encourage participation and explain what the game is about. During the course of the 2 month intervention, a research psychologist will make a weekly phone call of approximately two minutes. The content of these calls depends on the participant's progress in the game, his/her adherence to the intervention, and to remind the participant of the importance of accessing the game regularly as to adhere to his/her treatment. The therapist furthermore disposes of an online dashboard where he/she can see the progress of the patient in the game, and he/she can decide to contact the patient additionally if required for adherence to the treatment.

On the other hand, technology-delivered support is offered by push notifications that are sent on the smartphone twice a week to point out the importance of entering the game and being active in the intervention. They also implicitly remind the player that he/she is not alone during the intervention, since his/her participation/progress is monitored. The content of these notifications is personalized and depends on the game's state and the length of the player's absence. Next to this, gameplay has been specifically designed to preserve adherence. For instance, to encourage regularly entering the game, the automatic accumulation of materials is limited so the player needs to return to the game to collect materials and prevent the generation of material from coming to a halt.

3. Measures

Sociodemographic information, such as age, gender, educational level, native country, country of residence, profession, technological literacy w.r.t smartphones, experience with gaming, and base physical activity, is acquired once the participant signs the informed consent form. During the study, various instruments are used to assess primary and secondary outcomes. These instruments and their assessment points are shown in Appendix B.

3.1. Primary outcomes

3.1.1. Beck Depression Inventory (BDI-II)

The BDI-II is widely used to detect and assess the severity of depressive symptoms. The BDI-II consists of 21 multiple-choice items ranging from 0 to 3. It covers the different symptoms of major depressive disorder in the DSM-IV Beck et al. (1996). The BDI-II has high internal consistency (alpha = 0.76 to 0.95) and for the Spanish version (alpha = 0.89) Sanz et al. (2003).

3.2. Secondary outcomes

3.2.1. Measures related to clinical outcomes

3.2.1.1. International Physical Activity Questionnaire (IPAQ). The IPAQ is used to monitor both physical activity and inactivity. It is a validated scale of PA Craig et al. (2003).

3.2.1.2. Connor-Davidson Resilience Scale (CD-RISC). The CD-RISC assesses resilience on a scale with 25 items. Each item is rated from 0 to 4. Higher scores show greater resilience. The CD-RISC has good internal consistency (alpha 0.7) Connor and Davidson (2003) and adequate reliability (alpha = 0.75 to 0.86) is demonstrated in the Spanish version Crespo et al. (2014).

3.2.1.3. Overall Anxiety Severity and Impairment Scale (OASIS). The OASIS is used to assess anxiety symptoms severity and recurrence. Moreover, behavioral avoidance and the interferences provoked by the symptoms in pleasurable activities, social relationships or work are provided by this scale. The OASIS consists of a 5-item rated from 0 to 4. It has demonstrated strong psychometric properties with good internal consistency (alpha = 0.86), as well as test-retest reliability (K = 0.82) and convergent validity Campbell-Sills et al. (2009); Norman et al. (2011). OASIS items have demonstrated good internal consistency (alpha = 0.86) also in the Spanish version González-Robles et al. (2018).

3.2.1.4. Overall Depression Severity and Impairment Scale (ODSIS). The ODSIS is used to assess depressive symptomatology severity and recurrence and the interference in pleasure activities and other aspects of the patient's routine due to the depressive symptomatology. The ODSIS consists of a 5-item self-report measure rated from 0 to 4. It has excellent internal consistency (alpha = 0.92) and it shows good convergent/discriminant validity Bentley et al. (2014). Excellent internal consistency (alpha = 0.93) has been demonstrated in a Spanish clinical sample as well Mira et al. (2019).

3.2.1.5. Positive and negative emotionality Positive and Negative Affect Scale (PANAS). The PANAS is used to measure trait and state affectivity. The PANAS consists of 20 items divided into two independent 10-item dimensions to assess positive affect (PA) and negative affect (NA). Each item is rated on a 5-point Likert-type scale. It has shown excellent internal consistency (alpha = 0.84 to 0.90) and convergent and divergent validity Watson et al. (1988). The Spanish version has also shown high internal consistency (alpha = 0.87 and 0.89 for PA and NA in men; alpha = 0.89 and 0.91 for PA and NA in women, respectively) Díaz-

García et al. (2020).

3.2.1.6. Patient Health Questionnaire-2 (PHQ-2). The PHQ-2 is used as a measure for diagnosing and monitoring depression. The PHQ-2 consists of the first 2 questions of the PHQ-9. Its diagnostic output was comparable to that of the long depression scales. It shows good internal consistency (alpha = 0.83) Löwe et al. (2005).

3.2.1.7. Generalized Anxiety Disorder scale-2 (GAD-2). The GAD-2 is a shorter version (only the first two questions) of the GAD-7, used as a measure for anxiety disorders. Both GAD-7 and GAD-2 perform well as screening tools Kroenke et al. (2007).

3.2.2. Measures related to usability, user expectation, user satisfaction, and playability

3.2.2.1. System Usability Scale (SUS). The SUS is used to measure the usability of software. The SUS is a brief, reliable scale for measuring the usability of a program, consisting of a 10-item questionnaire with 5 response options, from 0 ("strongly disagree") to 4 ("strongly agree") Bangor et al. (2008). Although the validation process of the Spanish version is currently ongoing, it has been used in another Spanish research study Botella et al. (2016).

3.2.2.2. Expectation of treatment scale (ETS) and opinion of treatment scale (OTS), adapted from Borkovec and Nau (1972). These measures were designed to evaluate treatment expectations before the intervention and satisfaction afterwards. Both scales consist of 6 items rated from "0" (not at all) to 10 ("very much"), regarding the logicity of the treatment, the satisfaction with it, if they would recommend it, its usefulness for their problem and other problems, and to what extent it could be or was aversive. The Spanish version has been used in previous studies Botella et al. (2016); Mira et al. (2019).

3.2.2.3. Playability scale. A custom questionnaire based on the Playability model of Sánchez-González et al. (2009) was used (see appendix A). The Playability model consists of 7 attributes, each measurable using characterizing properties. Every model attribute is mapped on a question and quantified using a selection of its positive properties relevant in the game context. One attribute, sociability, was removed due to its irrelevance to the game at hand. Each question is rated from "0" (not at all) to "10" (totally).

3.3. Statistical analysis

Both per protocol and Intention-to-treat (ITT) analyses will be carried out, following CONSORT-eHealth indications Eysenbach et al. (2011). Analysis of variance (ANOVA) will be used for continuous data and chi-square tests (χ^2) for categorical variables to explore between-group differences in baseline socio-demographic and clinical variables. Both normality and multinormality assumptions will be analyzed by applying the Kolmogorov-Smirnov (K-S) test, skewness and kurtosis indexes, and histogram and Q-Q plots. In order to check homoscedasticity assumptions for equality of variances Levene's test will be carried out. Moreover, Mauchly's test will be performed to explore sphericity assumptions. Missing data patterns will be assessed. Whether missing data are missing completely at random (MCAR) will be checked with Little's MCAR test Little (1988). The ITT principle will be carried out in primary and secondary outcomes at post-treatment, and at follow-ups. For this, the maximum likelihood (ML) method using the Expectation Maximization (EM) algorithm will be applied (i.e., Gueorguieva and Krystal (2004); Little and Rubin (2002)). However, we will consider different approaches using sensitivity analyses to apply the most adequate method based on both literature recommendations and missing data patterns (i.e., Salim et al. (2008); Thabane et al. (2013)).

Furthermore, repeated analysis of variance (rm-ANOVA) will be performed to explore the main and interaction effects on primary and secondary variables. The effect sizes (Cohen's *d*) and their respective 95 % confidence intervals (95 % IC) will be calculated by reporting both within- and between-group comparisons Botella and Sánchez-Meca (2015); Cohen (1988); Cumming and Calin-Jageman (2016). Per protocol analyses will be conducted in order to establish conclusions about the efficacy of the intervention in patients who complete the intervention, i.e. play through the complete serious game (completers) Wright and Sim (2003). Separate multivariate analysis of variance (MANOVA) for expectations, satisfaction, usability, and playability measures will be performed, based on patients' completers. All statistical analyses will be performed using IBM SPSS Statistics version 26.0 for Windows.

4. Discussion

This paper presents the protocol for a randomized controlled pilot study of a smartphone-based serious game intervention for adults who suffer mild to moderate depressive symptoms. The main objective of this study is to investigate the smartphone-based serious game's effect on patients' clinical symptoms compared to those not receiving the intervention (waiting list). The secondary objectives are to assess user expectation, satisfaction, usability, and game playability of this intervention. This intervention is based on CBT, a widely applied evidence-based intervention for depression Thoma et al. (2015); López-López et al. (2019), with a focus on one of its most important components: Behavioral Activation (BA). BA is used to stimulate depressed people to reconnect with pleasurable activities Hopko et al. (2003) and it has been shown to be largely effective for reducing depression compared with usual care, waitlist, placebo control conditions, and medication Ekers et al. (2014). BA treatment can combine behavior change techniques with PA promotion. PA has been proven to be beneficial to achieve a healthy mental state Mammen and Faulkner (2013); Cooney et al. (2013); Rebar et al. (2015); Tikka et al. (2021). Combining BA and PA is expected to be particularly effective, as BA can promote PA in depression patients, which in turn may reduce the relapses associated with BA Babyak et al. (2000). Despite the well-known benefits of PA for depression, problems were found when it was implemented into mental health services Farrand et al. (2014); Pentecost et al. (2015), as its efficacy entirely depends on the patient's engagement. Therefore cost-effectively forms to administer PA in order to improve depressive outcomes are needed Rebar et al. (2015). Increasingly, psychological interventions delivered through smartphone apps are becoming a popular method for people suffering from mental illness. Research has shown that the use of smartphones in the treatment makes it more accessible Pham et al. (2016) and often more frequently used than treatment through other means Bush et al. (2015). Technology- and smartphone-based interventions could help to support people with depression by introducing PA as a habit during the treatment Lambert et al. (2018) and to bring the treatment closer to more people in need by reducing the costs Kazdin and Blase (2011); Kazdin (2015). The use of smartphone sensors to detect PA could be a cost-effectively way to improve patient motivation and so to facilitate its prescription. Even though research on smartphone-based interventions is ongoing, the full potential of smartphones – such as the use of sensors and smartphone-based game interventions – is still under-exploited Miralles et al. (2020).

The use of computer games in interventions is expected to maintain patient adherence Shah et al. (2018) and reduce stigma compared to attending conventional therapy. Accessibility to users is a key characteristic to be achieved in therapeutic games Shah et al. (2018). Moreover, it is more attractive than traditional face-to-face interventions and it increases intrinsic motivation (Vázquez et al., 2018). Games have been demonstrated to be potentially beneficial for mental health Eichenberg and Schott (2017); Fleming et al. (2017); Lau et al. (2017); Pine et al. (2020). While several studies have explored the benefits of games for mental health Fleming et al. (2017); Shah et al. (2018); Eichenberg and

Schott (2017); David et al. (2020), more contributions are needed Lau et al. (2017); Dias et al. (2018). In particular, 10 studies focusing on the evaluation of serious games for depression between 2000 and 2018 have been found Merry et al. (2012); Fleming et al. (2012); Lucassen et al. (2013); Cheek et al. (2015); Shepherd et al. (2015); Poppelaars et al. (2016); Stallard et al. (2011); Stasiak et al. (2012); Carrasco (2016); Lin et al. (2020). Nine different serious games are investigated in these studies and all of them were developed to be used on a regular computer, not for a smartphone.

Based on this, the smartphone-based serious game intervention called “Horizon: Resilience” was developed as a casual game taking into account the behavior and mood of people with depressive symptoms. Through this study, we intend to add new proof of the effectiveness of such games to battle depressive symptoms and to analyze the user's expectations and satisfaction of such a smartphone-based serious game intervention. Additionally, we are interested in contributing to the development of new methods to deliver psychological treatment, as to remove barriers and maximize its dissemination Kazdin and Blase (2011); Kazdin (2015) and accessibility Pham et al. (2016). Horizon: Resilience uses the capabilities of smartphones to be reactive to the user's behavior through interactions with the game and to his/her real-life physical activity. The inclusion and promotion of PA as part of game mechanics is in line with the treatment. Psychologists and developers have been jointly working on the design of this intervention, striving for a playable, enjoyable, and engaging game experience, while technically sound and grounded in evidence-supported treatments.

It should be noted that this study has some limitations. Being a technology-based intervention, there is a risk of a high dropout rate. Dropouts are expected but have been minimized as much as possible by using a serious game and engagement mechanisms, as well as providing different types of human and (personalized) technology- delivered support during the intervention. Despite reminders designed into the game for patients to answer the daily questionnaire, recording the evolution of the symptomatology during the intervention depends on the willingness of the player, so missing data is expected. As a technical limitation, the game is designed for the Android operating system, so only participants owning an Android smartphone can participate in the study.

5. Conclusion

This study aims to preliminarily demonstrate a positive effect of the smartphone-based serious game intervention on depressive symptomatology. To the best of our knowledge, to date, this is the first mobile serious game dedicated to providing a CBT intervention for depression and the first to take into account patients' real-world activity. As a secondary objective, the study aims to assess user expectation and satisfaction, usability, and game playability of the intervention. The game was designed by a multidisciplinary team of computer science researchers and psychologists, taking into account both technical and therapeutic best practices. The results of this study could provide initial evidence for the applicability of a new type of intervention delivery, namely through smartphone-based games, possibly improving accessibility and adherence to treatment, and invite further study in the field.

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Ethics approval

This study has been approved by the Ethics Committee of Universitat Jaume I (Castelló, Spain) on November 22, 2021 (CD/89/2021).

CRedit authorship contribution statement

AG-C, SC and AM drafted the manuscript, designed and participated in each phase of the study. JB-L and AG-P participated in the final revision of the manuscript. The final manuscript has been approved by all authors.

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 article.

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Appendix A. Custom playability measure

Custom playability measure based on the Playability model [Sánchez-González et al. \(2009\)](#).

- a) Satisfaction: value from 0 to 10 to which extent you are satisfied with the game, in terms of being entertaining, fun and attractive.
0 (not satisfactory at all) 1 2 3 4 5 6 7 8 9 10 (totally satisfactory)
- b) Learnability: value from 0 to 10 to which extent the game is easy to learn, in terms of required skills, difficulty, speed of learning, and ease of discovery of how to play.
0 (not learnable at all) 1 2 3 4 5 6 7 8 9 10 (totally learnable)
- c) Effectiveness: value from 0 to 10 to which extent the game is effective in providing an entertaining experience, in terms of challenges offered, and time and effort necessary to reach the game's goals.
0 (not effective at all) 1 2 3 4 5 6 7 8 9 10 (totally effective)
- d) Immersion: value from 0 to 10 to which extent you feel immersed in the game, in terms of believability of content, feeling part of the game, and being absorbed in it.
0 (not immersive at all) 1 2 3 4 5 6 7 8 9 10 (totally immersive)
- e) Motivation: value from 0 to 10 to which extent you feel motivated to play the game, in terms of curiosity in how the game continues, wanting to improve in the game, diversity in the game, and confidence to be able to achieve progress in the game.
0 (not motivational at all) 1 2 3 4 5 6 7 8 9 10 (totally motivational)
- f) Emotion: value from 0 to 10 to which extent you feel emotionally involved in the game, in terms of visual or cognitive stimuli being present, player reactions being provoked and emotional responses being triggered.
0 (not emotionally involved at all) 1 2 3 4 5 6 7 8 9 10 (totally emotionally involved)

Appendix B. Overview of measures and time-points

Table 2

Overview of measures and time-points

DI: During Intervention

Post-I: Post Intervention

MFU: Months Follow-Up.

Measure	Screening	Baseline	DI	Post-I	3 MFU	6 MFU	12MFU
Primary outcome measures							
BDI		X		X	X	X	X
Secondary outcome measures							
Measures related to clinical outcomes							
CD-RISC		X		X	X	X	X
IPAQ-SF		X		X			
OASIS		X		X	X	X	X
ODSIS		X		X	X	X	X
PANAS		X		X	X	X	X
PHQ-2		X					
GAD-2		X					
Measures related to usability, user expectation, user satisfaction and game playability outcome measures							

(continued on next page)

Table 2 (continued)

Measure	Screening	Baseline	DI	Post-I	3 MFU	6 MFU	12MFU
SUS				X			
ETS		X					
OTS				X			
Playability Scale				X			

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