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Improving the efficacy of exposure therapy using projection-based augmented reality for the treatment of cockroach phobia: a randomised clinical trial protocol

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ABSTRACT

Introduction In vivo exposure is the treatment of choice for specific phobia (SP), but this technique presents limitations related to access and acceptability. Augmented reality (AR) offers advantages like maximising strategies such as 'variability' (varying stimuli, durations, levels of intensity or the order of the items), control by the therapist, or 'exposure to multiple contexts', which can produce positive effects in terms of fear renewal and generalisation of the results. The aim of this study is to test the efficacy of varying the phobic stimuli during treatment with AR: using multiple stimuli (MS) versus a single stimulus (SS) in participants with SP.

Methods and analysis Participants (N=80) with a diagnosis of an SP of cockroaches will be randomised into two conditions: (1) projection-based AR exposure therapy with MS (P-ARET MS); (2) P-ARET with an SS (P-ARET SS). The measures are related to the efficacy results (fear, avoidance and negative thoughts, performance on the behavioural avoidance test (BAT) and preferences). The primary outcome measure is the BAT, and the secondary outcome measures are the BAT through AR, Fear of Cockroaches Questionnaire, Cockroach Phobia Beliefs Questionnaire, Fear and Avoidance Scales Patient's Improvement Scale, and Beck Depression Inventory Second Edition. Five evaluation moments will be included: preintervention, postintervention, and 1-month, 6-month, and 12-month follow-ups. The treatment will follow the guidelines of the 'one-session treatment'. Student's t-tests to compare the two groups on the post-test will be applied. In addition, two-way analysis of variances with repeated measures in one of the two factors (pretest, post-test and follow-ups) will be carried out to compare intragroup differences.

Ethics and dissemination The Universitat Jaume I Ethics Committee (Castellón, Spain) granted approval for the study (CD/64/2019). Dissemination will include publications and presentations at national and international conferences.

Trial registration number NCT04563403.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The exposure therapy session lasts a maximum of 3 hours and is done in a single day, which facilitates the application of the treatment and accelerates the therapeutic results.
⇒ There are no devices that interfere between the participant and the therapist during the exposure session, such as a helmet or augmented reality glasses.
⇒ Short-term and long-term follow-ups will be carried out (1, 6 and 12 months).
⇒ No control group was included in the design of this study.
⇒ The treatment is carried out only for participants with a cockroach phobia and not with other types of phobias.

INTRODUCTION

Specific phobia (SP) is the most prevalent anxiety disorder, and it has a high rate of comorbidity with other mental disorders and different physical diseases such as cardiac or gastrointestinal problems.[1] Although it is sometimes considered a less serious problem than other psychological disorders, people who suffer from it report severe deterioration in different areas of their lives[2] Regarding the SP, animal fear is one of the most prevalent subtypes of SP (3.8%).[3]

Among the evidence-based psychological treatments, in vivo exposure is the treatment of choice for this problem, and it has been supported by several randomised controlled trials (RCTs) and meta-analyses.[4] Nevertheless, only 7.8% out of people suffering from SP seek treatment, only 0.8% of these patients receive a specific treatment for their problem and only 23% report receiving helpful treatment for SP from the first professional seen.[5 6] Some reasons for this situation are that this technique presents limitations related to access and acceptability (low acceptance by patients and therapists, high drop-out rates, limited access to the treatment and difficulties applying it in the clinical context).[7] Regarding therapists' acceptance, studies suggest that clinicians may consider in vivo

exposure therapy (IVET) cruel, and they may be uncomfortable with some ethical considerations.[8] Moreover, other barriers are lack of confidentiality and high associated costs when IVET is conducted outside the therapist's office, as well as having limited access to the feared stimulus in the case of small animal phobias (spiders or cockroaches).[8–11]

These limitations can be improved thanks to technological advances such as the use of virtual reality (VR) and augmented reality (AR). In this regard, many studies have shown comparable results with VR exposure treatment (VRET) and IVET.[9 12] Garcia-Palacios *et al*[13] results support the use of VRET to improve the acceptability of IVET. They found that 76% of people with a diagnosis of SP choose VRET over in vivo exposure, and around 25% reject IVET when they are informed about the procedure, or they drop-out during treatment. Regarding AR, Suso-Ribera *et al*[14] data show that the AR exposure therapy (ARET), in addition to VRET, is a useful alternative to IVET treatments for small animal phobia. Moreover, the use of AR offers important advantages in exposure therapy for SP compared with VRET and IVET, especially access and acceptability: (1) exposure to multiple virtual stimuli, (2) going beyond reality and (3) having complete control over the situation[15 16]

In the study by Botella *et al*[16] using AR for small phobias, all the observed gains were maintained in the follow-ups, and the results showed that one of the advantages of AR is that it allows users to see the real world while virtual objects merge with real ones in a composite image. Furthermore, Botella *et al*[17] data reveal that participants considered the ARET treatment less aversive than IVET for the treatment of animal phobia. However, these studies used a head-mounted display for AR, which can limit communication between the patient and the therapist. Therefore, our group developed a display to provide projection-based ARET (P-ARET) for small phobias.[18] The P-ARET can improve these limitations because it is an innovative AR system that allows the patient to confront the animal directly without intrusive hardware, it promotes a more natural interaction with the environment and provides more comfort to the patient, and it improves adherence to the treatment by including games in the system.

Preliminary and encouraging feasibility results of the P-ARET system were found in a single case study.[19] The results indicated that the feasibility of the P-ARET system for small animal phobia treatment was comparable to what was achieved by other traditional treatments in other similar studies. Despite these good results, it is important to keep in mind that this is a preliminary study and more research is needed in this line.

The advantages offered by technologies such as VR and AR can also help to improve the effectiveness of exposure therapy. Some studies have examined the mechanisms involved in improving the effectiveness of exposure in phobias.[20 21] Craske *et al*[20] reported some strategies that can maximise the effectiveness of IVET. These strategies are: 'variability' (varying stimuli, durations, levels of intensity or the order of the hierarchy items), greater control by the therapists or 'exposure to multiple contexts' (MC), which can produce a positive effect in terms of fear renewal and generalisation of the results.

Regarding the exposure to MC, some studies found that VRET with MC produced a positive effect in terms of fear renewal and generalisation of the results in people with spider phobias.[22 23] In a later study, Shiban *et al*[24] conducted a treatment analogue study to investigate whether VR exposure to multiple stimuli (MS) and a combination of both MS and MC would further improve treatment efficacy. They found that MC during exposure therapy reduced the return of the fear at post-treatment, but not at follow-up, whereas MS (different spiders) during treatment seemed to have beneficial effects on efficacy at post-treatment and at follow-up.

In addition, studies have emphasised the relevance of overlearning when applying exposure, following the guidelines developed for 'intensive one-session treatment' (OST).[25 26]

Our study follows this line of research, and we intend to go a step further and explore ways of optimising exposure therapy based on the inhibitory learning approach using P-ARET. Therefore, the aim of this study is to describe the protocol for an RCT that will test the efficacy of varying the phobic stimuli during ARET: using MS (P-ARET MS) versus a single stimulus (P-ARET SS) in participants with cockroach phobia.

The main hypothesis of the protocol is that the P-ARET MS group will have better results than the P-ARET SS group after treatment. Additionally, the MS group will also have better results during the follow-ups.

METHOD

Study design

This work is part of a research project (Ministerio de Ciencia, Innovación y Universidades (Spain) (Programa Estatal I+D+i RTI2018-100993-B-I00) composed by two RCTs. The first RCT study in the project focuses on analysing the effectiveness of the exposure treatment using AR compared with the treatment of choice for SP (in vivo exposure) and with a control group (waiting list).[27] The study presented in this manuscript is focused on analysing the potential of the AR system, evaluating its efficacy and feasibility, and comparing two treatment groups that use the AR exposure treatment, but varying the number of stimuli presented to the patient (one SS vs MS). Both studies are completely independent and have separate trial participants.

The proposed study is a randomised, parallel-group, two-arm, clinical trial. Eligible participants will be randomly allocated to two experimental conditions: P-ARET MS or P-ARET SS.

There will be five assessment points (pretreatment, post-treatment, and 1-month, 6-month, and 12-month follow-ups), in order to provide data about the intervention and the maintenance of the improvements.

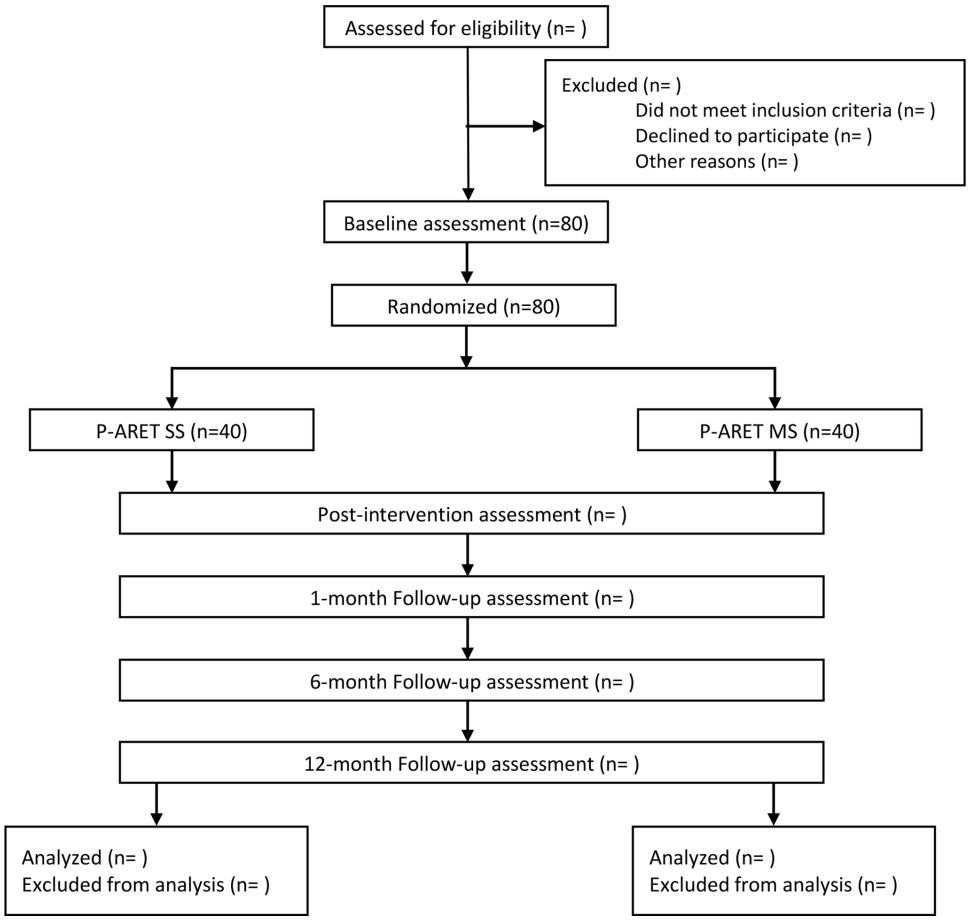

Figure 1 Study flow chart.

To promote the retention of participants, they will be contacted by phone or mail in order to get them to attend the follow-ups and that they will be explained that it is something that will help them because it is somewhat complicated to have the opportunity to face a real cockroach in daily life. If any participant does not attend one follow-up, we will try to get them to attend the next one. All the postintervention data will be collected as well as the follow-ups that have been completed.

The RCT is registered on the ClinicalTrials.gov database (NCT04563403) and the report will follow the CONSORT 2010 (Consolidated Standards of Reporting Trials: http://www.consort-statement.org)[28] and SPIRIT guidelines (Standard Protocol Items: Recommendations for intervention Trials).[29] Figure 1 shows the flow diagram of the study design.

Participants

Eligibility criteria

Inclusion criteria include: being at least 18 years old, meeting the diagnostic criteria of The Diagnostic and Statistical Manual of Mental Illnesses-5 edition (DSM-5) of the American Psychiatric Association's (APA, 2013) for SP (animal subtype) of cockroaches, having the phobia for a minimum 6 months, signing an informed consent and presenting a score of 4 or more on the fear and avoidance scales of the Anxiety Disorders Interview Schedule for DSM-IV-TR (ADIS-IV).[30]

Exclusion criteria include: presence of another severe mental disorder that requires immediate attention, current alcohol or drug dependence or abuse, psychosis or severe organic illness, currently being treated in a similar treatment programme, being capable of inserting their hands in a plastic container with a cockroach (during the behavioural test), receiving other psychological treatment during the study on cockroach phobia and starting to receive pharmacological treatment during the study (or in case of already receiving it, changing the drug or dose).

Diagnostic interviews will be recorded, with the participant's permission, to carry out an independent inter-rater assessment.

Sample size calculations

Power calculations were carried out using the statistical software Epidat V.4.2. to estimate the necessary sample size to detect a moderate between-group standardised mean difference (Cohen's d=0.70) with a power of 0.80 and an alpha set at 0.05, based on a similar study comparing MS and SS exposure.[24] This size calculation is based on the main result, which is the 'performance'

variable of the behavioural avoidance test (BAT) with a real cockroach.

The minimum sample size for each group was identified as 33 (66 in all), but at least an additional 20% will be recruited to allow for expected follow-up attrition, with an estimated minimum total sample of 80 participants (40 per group).[17]

Recruitment, randomisation and blinding

Participants will be recruited online through advertisements in professional (ie, LinkedIn) and non-professional social networks (ie, Facebook, Twitter or Instagram), and in newspapers. Moreover, the study will be offered to people who seek help at the Emotional Disorders Clinic at Universitat Jaume I. Participants interested in participating will receive information about the study and be assessed for eligibility criteria. Participants who meet the inclusion criteria will sign the informed consent form. Regarding the mechanism of implementing the allocation sequence, once the online informed consent is signed, an independent researcher will generate the allocation schedule through a computer randomisation software (Epidat V.4.2). The independent researcher is a member of the LabPsiTec laboratory but does not belong to the submitted study and does not have any information about the study participants. This researcher will assign a sequential code to the participants and will inform the clinician about the code and the assigned condition.

Patients will agree to participate before the random allocation and without knowing to which treatment they will be assigned, like the therapist, who will not know the group of participants before the treatment. Due to the nature of the intervention, it will not be possible to mask the participants or the clinicians who administer the intervention.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Intervention

The treatment will follow the guidelines of the 'OST' proposed by Öst *et al*.[25] The protocol involves the use of intensive exposure carried out in one session lasting up to 3 hours and individually implemented. It is composed of four parts: exposure to the feared object (cockroach), modelling (the therapist will interact with the phobic stimulus first and, if possible, the patient will follow the same steps), cognitive challenge and reinforcement. Following the instructions recommended by Öst *et al*,[25] the exposure session will be completed in a gradual, planned and controlled way. The purpose is for patients to confront their phobic situation in a controlled manner, allowing them to accept that the negative consequences they fear do not actually occur.

In this study, both treatment conditions will be applied using the P-ARET system. However, in one condition (P-ARET MS) the variability of the stimuli available in the system (cockroaches different in colour, size or number) will be used. In contrast, in the P-ARET SS condition, only one cockroach will be used and always of the same type (one similar to the cockroaches that participants can find outside the study). The two treatment conditions can be seen in figure 2.

Figure 2 The image shows the MS condition on the left and the SS condition on the right. MS, multiple stimuli; SS, single stimulus.

Before starting the exposure process, an exposure hierarchy will be created together with each participant. The participants will evaluate the different possible steps according to their level of anxiety from 0 to 10.

If the participant is in the SS condition, there is only one cockroach during the entire process, but the size of the cockroach and the distance the participant approaches (from far, close to the cockroach, the touch…) can be varied. In addition, the programme allows you to interact with the cockroach (to chase you, flee, kill it and fly). Depending on the anxiety that each of these steps produces, the exposure will always start with items producing moderate levels of anxiety (4–5), and little by little it will increase.

For participants in the MS condition, the number of cockroaches and the colour of the cockroaches (black, brown, reddish…) will also be considered. Otherwise, it is similar to the other condition. From the computer, the therapist can control all the movements of the cockroach (stay still, walk, turn around, fly or die).

Instruments

The evaluations will be performed at screening, pretreatment, post-treatment, and 1-month, 6-month, and 12-month follow-ups.

Diagnostic Interview

The ADIS for DSM-IV-TR (ADIS-IV)[30] is a specific diagnostic semistructured interview for SP based on DSM-IV-TR criteria. This interview will help to make a differential diagnosis of other phobias or anxiety-related disorders. It includes other measures, such as interference and distress perceived by the participant, rated on a scale from 0 to 8 (0='not at all' and 8='very severe'), and the clinician's severity rating using a scale from 0 to 8 (0='absent/none' and 8='very severely disturbing/disabling').

This interview has shown adequate psychometric properties and good to excellent reliability for the majority of the anxiety disorders.[31]

Primary outcome measures

BAT (adapted from Öst *et al*[25]) is a behavioural test where the patients will be presented with a real cockroach and encouraged to get closer and interact with the stimulus as much as they can. The cockroach is in a closed, transparent plastic terrarium. The dependent variable for this test is the 'performance'. It is used a 12-point system based on the distance and level of interaction with the animal 0 (the participant does not enter the room) to 12 (the participant interacts with the cockroach) during the test to assess this variable.

Also, before performing the task, the clinician evaluates the patient's degree of anxiety, avoidance and belief in the thoughts they fear related to the animal (0–10). Results of this BAT for Spanish participants with various small animal phobias can be found in Botella *et al*.[17]

Secondary outcome measures

BAT through AR (adapted from Öst *et al*[25]). Patients will be presented with a novel projected cockroach (not used before in either of the two treatment conditions), and they will be encouraged to get closer and interact with the stimulus as much as they can. The anxiety level (0–10), distance and level of interaction with the animal will be registered by the experimenter and evaluated on a scale ranging from 0 (the participant does not enter the room) to 12 (the participant interacts with the cockroach). This test aims to evaluate whether there are differences in performance between the participants in the SS and MS conditions, given that the latter will confront animals of different colours, sizes and shapes during the treatment, whereas the participants in the SS condition will not. The cockroach used in this BAT will not be used during the exposure treatment in either of the two conditions.

Fear of Cockroaches Questionnaire (FCQ; adapted from the Fear of Spiders Questionnaire, FSQ[32]). This questionnaire assesses the level of fear of cockroaches. It contains 18 items about cockroaches that are designed to evaluate the severity of the cockroach phobia on a scale ranging from 0 ('I strongly disagree') to 7 ('I strongly agree'), and the scores can range from 0 to 126. The FSQ has shown excellent psychometric properties. An RCT focused on comparing different exposure treatment versions for small animal phobia (cockroaches and spiders) used both versions (FCQ and FSQ) in the Spanish population[17] and showed that the mean scores in phobic patients before and after treatment were 95.81 (SD=13.96) and 44.47 (SD=21.38), respectively.

Cockroach Phobia Beliefs Questionnaire (adapted from the Spider Phobia Beliefs Questionnaire SBQ[33]). This questionnaire assesses two different constructs, namely, catastrophic beliefs about cockroaches and beliefs about the patient's ability to cope with a cockroach. It contains 78 items rated on a scale ranging from 0 ('I don't believe so') to 100 ('I'm convinced of it'). This adaptation has been used for cockroaches and spiders.[17]

Fear and Avoidance Scales (adapted from Marks and Mathews[34]). This instrument assesses the level of fear and avoidance of the feared stimulus (ie, cockroaches) on a scale ranging from 0 (none) to 10 (very much). It evaluates target behaviour, negative thoughts and modulators. This scale has shown good reliability and sensitivity to change.[34]

Patient's Improvement Scale (adapted from the Clinical Global Impression scale).[35] This instrument evaluates the degree of improvement in the patient's symptoms after the treatment compared with before it. Scores range from 1 (much worse) to 7 (much better). This scale is answered by the patient.

Beck Depression Inventory Second Edition (BDI-II).[36] Spanish validation from Sanz.[37] This instrument assesses the existence and severity of depression symptoms in the past 2 weeks, based on DSM-IV criteria. It is a self-report instrument that contains 21 items rated on a Likert scale ranging from 0 to 3. The BDI-II total score can be obtained by adding up the answers, from a minimum of 0 to a maximum of 63 points. The instrument shows adequate internal consistency (Cronbach's alphas ranging from 0.76 to 0.96) and good test–retest reliability (0.80). The psychometric properties of the Spanish adaptation also show high internal consistency.[37]

Other prespecified outcome measures

Disgust Propensity and Sensitivity Scale-Revised-12 (DPSS-R-12).[38] This scale includes two subscales that measure propensity to disgust (six items) and sensitivity to disgust (six items). The 12 items are rated on a scale ranging from 1 ('never') to 5 ('always'), and the total score on each subscale can range from 6 to 30. Regarding the psychometric properties reported in the Spanish adaptation,[38] the DPSS-R-12 showed good reliability (internal consistency) and validity (convergent, divergent and predictive) results. Mean scores reported in normative values were 15.3 (SD=3.5) for the propensity to disgust subscale and 12.2 (SD=4.0) for the sensitivity to disgust subscale.

The Clinician Severity Scale (adapted from Brown *et al*[30]). The clinician rates the severity of the patient's symptomatology on a scale from 0 to 8, where 0 is symptom-free and 8 is extremely severe. This scale will be completed by the clinician before the treatment and after the treatment is over. This scale has been used in previous studies.[39–41]

Treatment opinion measures

Expectations Scale and Satisfaction Scale (adapted from Borkovec and Nau[42]). This self-report inventory measures the participants' expectations before they start the treatment, and it assesses satisfaction after they finish it. It includes six items rated on a scale ranging from 0 ('not at all') to 10 ('highly'), and the items provide information about the extent to which: (1) the treatment is perceived as logical; (2) patients are satisfied with the treatment; (3) they would recommend the treatment to others; (4) the treatment would be useful to treat other psychological problems; (5) participants perceive the treatment as useful for their particular problem and (6) the treatment

Table 1 Overview of measures and time points

Measures	Screening	Post-treatment	1-month follow up	6-month follow up	12-month follow up
ADIS-IV	X	X	X	X	X
BAT	X	X	X	X	X
BAT AR	X	X	X	X	X
FCQ	X	X	X	X	X
CBQ	X	X	X	X	X
Fear and Avoidance Scales	X	X	X	X	X
PIS		X	X	X	X
BDI-II	X	X	X	X	X
STAI	X	X	X	X	X
DPSS-R-12	X	X	X	X	X
Expectations Scale and Satisfaction Scale	X	X	X	X	X
The Clinician Severity Scale	X	X	X	X	X

ADIS-IV, Anxiety Disorders Interview Schedule for Diagnostic and Statistical Manual of Mental Illnesses-IV Edition (DSM-IV); AR, augmented reality; BAT, Behavioural Avoidance Test; BDI-II, Beck Depression Inventory Second Edition; CBQ, Cockroach Phobia Beliefs Questionnaire; DPSS-R-12, Disgust Propensity and Sensitivity Scale-Revised-12; FCQ, Fear of Cockroaches Questionnaire; PIS, Patient's Improvement Scale; STAI, State-Trait Anxiety Inventory.

is perceived as aversive. These scales have been used in previous studies[13 17]

Preferences about treatment condition. Preferences about the treatment condition (MS vs SS) were assessed with a questionnaire composed of the following items: Item 1 'If you could choose between the two types of exposure sessions, which one would you choose?'; Item 2 'Which of these two ways of applying the exposure session do you consider to be more effective in helping you overcome your problem?'; Item 3 'Which of these two ways of applying the exposure session do you consider more aversive?' and Item 4 'Which of these two ways to apply the exposure session would you recommend to a friend who had the same problem?'

All study variables and assessment periods can be found in table 1.

Statistical analysis

Data from all the participants will be entered into the IBM SPSS Statistics for Windows (V.28) to perform the statistical analyses. Baseline differences in sociodemographic and clinical variables will be assessed by using χ^2 tests for categorical variables and Student's t-test for continuous data. Intention-to-treat and per-protocol analyses will follow the CONSORT recommendations, and SPIRIT guidelines will be followed in reporting the results.[28 29]

In order to test the hypothesis of efficacy, the main test carried out will be a Student's t-test to compare the efficacy of the two groups on the post-test. To test the secondary hypotheses, two-way analysis of variance (ANOVAs) with repeated measures in one factor will be carried out for each primary and secondary outcome. The between-group factor will be the type of treatment (P-ARET MS vs P-ARET SS), and the repeated-measures factor will be the measurement time (pretest, post-test, 1-motnh, 6-motnh, and 12-motnh follow-up). To control type I error rate inflation due to multiple statistical testing, significance tests for the secondary outcomes will be corrected by applying Bonferroni method. In order to examine group differences through different measurement times, post hoc comparisons will be performed. In addition, a two-way multivariate ANOVA will be conducted for all the outcomes.

Effect sizes (Cohen's d) and their CIs will be calculated to assess between-group and within-group changes.[43 44]

Missing data will be handled according to the most appropriate method, depending on the reasons for missingness, following the authors' recommendations and sensitivity analysis principles.[45]

Data collection and management

Regarding data protection, this trial will comply with the existing guidelines in Spain and the European Union for the protection of patients in clinical trials. All the data collected from the evaluation interviews and the instruments included in the evaluation protocol of all the studies considered in this project will be kept under the data security conditions of the Emotional Disorders Clinic attached to Labpsitec. All the authors of this study are linked as part of the research team.

This clinic is governed by international and national ethical guidelines related to the practice and research in Clinical Psychology (64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013; Code of Ethics of the Official College of Psychologists, 1987).

For ensuring the data collection process, most of the instruments used in the assessment protocol will be implemented through electronic means (www.qualtrics.

com). Patients will receive a personal link to fill out the questionnaires. The data collected on paper from each participant (personal data, informed consent form and diagnostic interview) will be stored under a password and will only be available to the researchers responsible for the study, always safeguarding the right to privacy. In addition, each participant will be linked to a code.

Clinical data (not personal data) will be transferred to a general database with a password that will contain the corresponding codes of each participant in such a way that it is impossible to link this data to the participants. Therefore, the use of the data is anonymous.

Ethics and dissemination

The study procedures were approved by the Research Ethics Committee of Universitat Jaume I (Castellón, Spain) on 13 December 2019 (CD/64/2019). The study will be conducted following The Helsinki Convention and the Madrid Declaration of the World Psychiatric Association. Participation will be completely voluntary, and participants will have to provide written informed consent. Online informed consent will be obtained on Qualtrics. The selection of the participants will be carried out by qualified personnel using clinical criteria. All eligible participants will be given oral and written information about the study, and they may leave the research at any time.

Dissemination will include publications and presentations at national and international conferences.

DISCUSSION

The aim of this work is to describe the protocol for an RCT that will examine the efficacy of exposure therapy for participants with cockroach phobia administered in two ways: using P-ARET MS versus a P-ARET SS.

Previous studies have supported the efficacy of varying the stimuli during exposure interventions.[20 46 47] Therefore, it is expected that the two treatment conditions will be effective, but the P-ARET MS condition will show a greater generalisation of the results and their maintenance in the follow-up periods. This study makes it possible to offer treatment alternatives that reduce the limitations of other previous treatments, through the use of P-ARET. The study also has a controlled design, something that has not been done with this technology until now.[7 16]

This study has some strengths. As mentioned above, this is the first study to explore the efficacy of varying the stimuli during exposure therapy with the P-ARET system in an RCT for SP. We expect that these advances in the optimisation of exposure therapy for SP will also provide knowledge that can be generalised to the optimisation of exposure therapy, not only in SP, but also in other anxiety disorders, given that it is the technique of choice to treat avoidance behaviours. In this regard, it would also be interesting to carry out studies using stimulation variability in other types of SP and anxiety problems.

One of the novel contributions of this study is that it includes the BAT administered through AR. This test aims to evaluate whether there are differences in the performance of the participants in the SS and MS conditions,[24] and it allows greater access to the feared stimuli in situations where it is difficult to carry out a BAT in vivo or in situations that are not very accessible (as occurs in flying phobia). Our proposal can also be a contribution to this study.

As mentioned above, P-ARET can also improve the acceptability of exposure-based treatments (the main limitation of the exposure technique), which in other conditions can be, as mentioned in the literature, 'the cruellest cure'[7] and it can facilitate the use of exposure for SP and other problems.

From a technological point of view, P-ARET would provide mental health professionals with innovative tools such as the use of AR. Moreover, these advances would result in the immediate application of variations and innovations in the intervention protocols, which could help a large number of people, facilitate the work of professionals in the field of psychological interventions for SP and be extrapolated to other anxiety disorders.

Finally, the intervention is based on the 'OST' guidelines,[48] so that the entire treatment is carried out in a single session lasting a maximum of 3 hours, which allows patients to be attended to in a short time, thus reducing travel and associated costs. Moreover, if we also optimise the exposure technique, we will be able to care for more patients in less time and with better results.

Nevertheless, this study also has some limitations. The first limitation is the lack of a waiting list group control. Second, our study includes follow-ups at 1, 6 and 12 months. However, if sustained effects are observed at the 3-month, 6-month, and 12-month follow-ups, future research could include assessments at 24 months.

Finally, this study focuses only on cockroach phobia, so it would be interesting to add other types of animal phobias, such as spider phobia. It would also be interesting to extend this study to other SP that are not related to animals.

Despite these deficiencies, the study has several strengths and could be beneficial for people with a diagnosis of SP and other anxiety disorders and help to better understand the implications of stimulation variability during exposure techniques through technologies.

This study is designed to make some contributions to this line of research. On the one hand, we aim to improve the efficiency of exposure therapy by overcoming the main limitation of in vivo exposure, that is, its low acceptability. On the other hand, we aim to optimise exposure therapy by using the variability of the stimuli available in the projection-based AR system. These results can contribute to improving exposure therapy for other anxiety problems, making it possible to enhance the quality of treatments. The project findings will be relevant not only for the treatment of SP, but also for the treatment of other anxiety disorders.

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Contributors SQ, JB-L, MP-B, JG and LD-S contributed to the planning of the RCT as well as the development of the intervention protocol for the two augmented reality exposure therapy conditions. MP-B, SQ and JB-L carried out all stages of the trial and wrote the main manuscript text. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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