BMJ Open

Effectiveness of a projection-based augmented reality exposure system in treating cockroach phobia: study protocol of a randomised controlled trial

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To cite: Grimaldos J, Bretón-López J, Palau-Batet M, *et al*. Effectiveness of a projection-based augmented reality exposure system in treating cockroach phobia: study protocol of a randomised controlled trial. *BMJ Open* 2023;**13**:e069025. doi:10.1136/bmjopen-2022-069025

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-069025).

Received 08 October 2022
Accepted 28 March 2023

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ABSTRACT

Background Despite being the treatment of choice for phobic disorders, in vivo exposure treatment (IVET) presents some important limitations related mainly to low acceptance and high drop-out rates. Augmented reality (AR) technologies can help to overcome these limitations. Evidence supports the use of AR in exposure treatment for small animal phobia. A new projection-based AR exposure treatment system (P-ARET) that offers the possibility of projecting the animals in a natural and non-intrusive environment has been developed. There are no randomised controlled trials (RCTs) available that have tested the efficacy of this system in cockroach phobia. This paper aims to present the protocol of an RCT that evaluates the efficacy of the P-ARET, versus an IVET group and a waiting list control group (WL), in carrying out exposure treatment for cockroach phobia.

Methods/design Participants will be randomly allocated to one of three conditions: (1) P-ARET, (2) IVET and (3) WL. Both treatment conditions will follow the 'one-session treatment' guidelines. As a diagnostic measure, the Anxiety Disorders Interview Schedule for Diagnostic and Statistical Manual for Mental Health Disorders-Version 5 will be used. The Behavioral Avoidance Test will be used as the primary outcome measure. Secondary outcome measures will include an attentional biases task (measured using eye-tracking technology), the Fear of Cockroaches Questionnaire, Cockroach Phobia Beliefs Questionnaire, Fear and Avoidance Scales, Beck Depression Inventory second edition, Disgust Propensity and Sensitivity Scale-Revised-12, State-Trait Anxiety Inventory, Clinician Severity Scale, and Expectation and Satisfaction with the Treatment Scale. The evaluation protocol will include pretreatment and post-treatment evaluations and 1, 6 and 12 months of follow-ups. Intention-to-treat and per-protocol analyses will be performed.

Ethics and dissemination This study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain; 13 December 2019). The results of the presented RCT will be disseminated in presentations at international scientific meetings and peer-reviewed scientific journals.

Trial registration number NCT04563390.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first randomised controlled trial (RCT) designed to test the effectiveness of a projection-based augmented reality exposure treatment for cockroach phobia.
⇒ The intervention is cost-effective as it only requires a single-treatment session.
⇒ The RCT includes an innovative attentional task specifically designed to assess attentional biases based on eye-tracking technology.
⇒ The study includes follow-ups up to 12 months, which can be considered a limitation because the effects of treatment after 1 year are unknown.
⇒ The RCT only includes cockroach phobia; if more animals were added, the system would be more versatile.

INTRODUCTION

Specific phobia (SP) is defined as an extreme and persistent fear of a specific stimulus (object or situation) that is clearly disproportionate to the actual danger or threat posed.[1] SP shows an average cross-national lifetime prevalence of 7.4%, and it is the most prevalent disorder among the anxiety disorders.[2] In addition, SP also shows high rates of comorbidity with other psychological disorders, especially other anxiety and mood disorders,[3] as well as with physical illnesses (eg, cardiac or gastrointestinal problems).[4] Among the different SP subtypes, fear of animals is one of the most prevalent, reaching a lifetime prevalence of 3.8%.[2]

Regarding SP, in vivo exposure is positioned as the gold-standard treatment and has demonstrated its effectiveness in different randomised controlled trials (RCTs) and meta-analyses.[5] However, in vivo exposure has several limitations, such as practical difficulties in its implementation, low acceptance by patients and therapists, and high dropout rates, all of which keep this treatment from

reaching everyone who needs it.[6] In fact, data show that only 7.8% of people suffering from SP seek treatment, 0.8% of whom finally receive specific treatment.[7]

Information and communication technologies can help to overcome these issues, offering new models for the delivery of psychological treatments that can reach a greater number of patients.[8] In this line, a study comparing acceptance and refusal rates reported that 76% of patients with SP preferred virtual reality exposure treatment (VRET) to in vivo exposure treatment (IVET), which was rejected by 25% of patients when they were informed about the procedure.[9] This preference for VRET over IVET could be associated with different barriers inherent to IVET that are not present in VRET, such as the lack of confidentiality (especially when conducted outside the clinic) and limited access to and control of the feared stimulus in the case of animal phobias.[10 11] In contrast, VR and augmented reality (AR) present some benefits in the exposure delivery. Botella *et al*[12] defined the VR system as a stimulating, safe and controlled therapeutic context that offers some advantages, such as (1) exposure to multiple stimuli, (2) offering more situations than reality can provide and (3) giving the therapist full control over the exposed stimulus, all while ensuring privacy and confidentiality without having to leave the clinic. These advantages are shared by both VR and AR, but the latter offers some additional benefits. The main advantage of AR is that the virtual stimulus is introduced in the real world, adding relevant and helpful information, whereas in VR systems, the user is totally immersed in a virtual environment.[13] This particular feature is especially relevant in small animal phobia treatment, where patients can interact with the feared animal in the real world, thus favouring the generalisation of the results to a natural environment.[12]

Preliminary evidence showed that AR can induce anxiety in participants with cockroach phobia, which is an essential requirement when conducting exposure treatment.[14] Based on this evidence, some studies have focused on analysing AR's potential as an alternative way of delivering exposure treatment. A multiple baseline study was conducted that obtained positive results in favour of AR exposure for treating small animal phobias.[13] These results were supported by a later randomised clinical trial that compared IVET with AR exposure therapy (ARET) in cockroach and spider phobias.[15] This study revealed that participants in the ARET condition showed significant reductions in all the fear outcomes that were maintained at the follow-ups.[15]

Although both VR and AR have been found to be effective in treating psychological disorders, and specifically small animal phobias, they have several drawbacks that can be improved. The main issue is that both systems have typically used head-mounted displays (HMDs) to present the virtual objects or virtual environments (in case of VR), thus reducing comfort and communication during the therapy sessions. The frequency of visual contact between patient and therapist during the exposure sessions has been studied, with results showing that visual contact was significantly lower in HMD-based AR than in in vivo sessions,[16] which may affect the results, given the important role of visual awareness in face-to-face communication.[17] A second important issue is that these versions of VR and AR do not allow the patient to interact with the stimulus presented. More realistic behaviour where animals react to the patient's actions (eg, running away when the patient tries to touch them) is related to a greater sense of reality and presence, variables that are implicated in a greater anxiety response when using virtual systems.[18] The third drawback is related to the discomfort produced by the use of HMD during exposure sessions. In the aforementioned RCT, some patients in the ARET group reported dizziness and back pain due to the use of the HMD.[15] In light of these issues, there is a need to continue to improve these systems and make them more natural and user-friendly. In this sense, the development of new systems that use a more comfortable HMD like see-through glasses (such as sunglasses), which allow the patient to fully see the outside world and interact with it, could offer an option to overcome these problems. A pilot parallel RCT has tested the feasibility of an ARET based on an HMD that uses more innovative glasses for the treatment of patients suffering from arachnophobia. The results show that this system is feasible for its implementation in the treatment of arachnophobia, being a system that can be applied in a simple and more friendly way for the user.[19] It should be noted that the efficacy results must be confirmed in further studies.

Our research group developed an AR system for small animal phobias that has been designed with the aim of offering a different AR alternative to the previously mentioned AR systems. This new tool is based on projecting the animals in the real world without having to wear any HMD or device (which facilitates face-to-face communication and eliminates discomfort), and it includes the function of interacting with the animals in a natural and real way (which improves treatment adherence and increases the sense of presence and reality judgement; see Wrzesien *et al*[20] for a detailed description of the system). There is positive evidence of the effectiveness of this projection-based ARET (P-ARET) for cockroach phobia from a single case study.[21] In this study, the results revealed that the P-ARET system was able to induce anxiety in all the participants, and, in general, all of them showed a reduction in most of clinical outcomes used to assess cockroach phobia (ie, avoidance behaviours, fear and catastrophic beliefs).[21] However, this P-ARET system has not been tested in an RCT.

In addition, a limitation of these studies is that most of the outcome measures used to assess the patients' symptoms are based on self-reported measures (such as questionnaires and self-records). There is strong evidence in the field of anxiety disorders that people with anxiety preferentially attend to feared stimuli,[22 23] and this attentional bias plays an important role in the aetiology and maintenance of anxiety disorders.[24] In the case of

SP, thanks to the use of eye-tracking technology, some studies have revealed that individuals with phobia present a hypervigilance–avoidance pattern characterised by accelerated detection of the feared stimulus, followed by rapid and sustained avoidance of it.[23 25 26] In this regard, avoidance behaviour is considered a key component of phobia psychopathology. On the one hand, avoidance allows patients to reduce the anxiety evoked by the feared stimuli;[27] on the other hand, avoidance prevents habituation to the feared stimuli, which is related to the maintenance of the phobic disorder.[28] Therefore, due to the great importance of cognitive processes such as attentional biases in the psychopathology of SP, the inclusion of measures capable of exhaustively evaluating these processes, such as eye-tracking technology, in RCTs would add great value to these studies. This outcome measure would provide not only a more extensive and precise evaluation, but also an additional measure of therapeutic efficacy based on cognitive processes, which would make it possible to evaluate the effects of the treatment on these processes. The available literature on the effects of psychological therapies on reducing attentional biases is still scarce and based on more classic methods of measuring attentional biases (eg, Stroop task). However, some studies suggest that this variable can be sensitive to therapeutic change, showing significant reductions from pretreatment to post-treatment, and so it can be used as a tool for evaluating attentional processes involved in psychological disorders.[29]

The purpose of this work is to present and describe the protocol for an RCT designed to test the efficacy of the P-ARET, compared with IVET and a waiting list control group (WL), for the treatment of cockroach phobia. In this line, the main hypothesis of this study is that both treatment conditions will be more effective in treating cockroach phobia than the control condition. Additionally, secondary hypotheses will be tested, comparing: (1) the efficacy of the two treatment conditions, where we do not expect to find differences; and (2) patients' acceptance in terms of expectations and satisfaction, where we expect participants in the P-ARET condition to show higher and better results.

METHOD

Study design

This study is part of a research project approved by an independent peer review that includes different studies focused on analysing the potential of the application of AR in the treatment of cockroach phobia (Ministerio de Ciencia, Innovación y Universidades (Spain); Programa Estatal I+D+i RTI2018-100993-B-I00). Within this project, two RCTs are included. The first RCT 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 (WL). The second RCT included in the project focuses on analysing the potential of the AR system, evaluating its capacity and efficiency.[30] This second trial compares two treatment groups that both use the AR system to carry out the exposure treatment but varying the number of stimuli presented to the patient (single stimulus vs multiple stimuli). Both studies are completely independent and have separate trial participants.

The first study of the project, a three-armed RCT, is the one described in the present work. This study will be carried out at the Emotional Disorders Clinic, which is attached to the Psychology and Technology Laboratory (LabPsiTec) to which all the authors of this work are linked. This clinic is located at the Jaume I University (Castellón, Spain). Participants will be randomly allocated to three groups: (1) P-ARET for cockroach phobia; (2) IVET and (3) a WL control group. Participants allocated to the control group will be assigned to one of the two treatment conditions after 1 week for ethical reasons. This trial was registered in ClinicalTrials.gov (NCT04563390) and will be conducted following the CONSORT statement (Consolidated Standards Of Reporting Trials, http://www.consort-statement.org)[31 32] and the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials).[33] Participants will be evaluated at pretreatment (prior to the random allocation), post-treatment, and 1, 6 and 12 months of follow-ups. Figure 1 shows the flow chart for the study.

Sample size calculation

Power calculations were performed using Epidat V.4.2 statistical software to estimate the sample size necessary to detect a large standardised mean difference between groups (Cohen's d=0.80) with a power of 0.80 and an alpha of 0.05, based on previous studies using AR systems.[15 21] These calculations were conducted based on the primary outcome: the Behavioral Avoidance Test (BAT), specifically on the 'performance' variable of this test, which is explained below. The minimum sample size for each group was identified as 26 (78 in total), but at least an additional 20% will be recruited to take into account expected follow-up attrition; thus, a minimum total sample of 96 participants (32 per group) is estimated.[15 34]

Eligibility criteria

The study sample will consist of adults 18 years old who meet the diagnostic criteria for specific phobia (animal subtype) of cockroaches, based on the Diagnostic and Statistical Manual for Mental Health Disorders-Version 5 (DSM-5[35]). The inclusion criteria will be: (a) presenting minimum 1-year duration of the phobia, (b) presenting a minimum score of 4 on the Fear and Avoidance Scales of the diagnostic interview administered, (c) willing to follow the study conditions and sign the consent form. Exclusion criteria for the study will include the following: (a) currently receiving treatment for SP; (b) meeting criteria for another severe mental disorder (psychosis, bipolar disorder or severe personality disorder) or having current alcohol or drug dependence or abuse or a severe

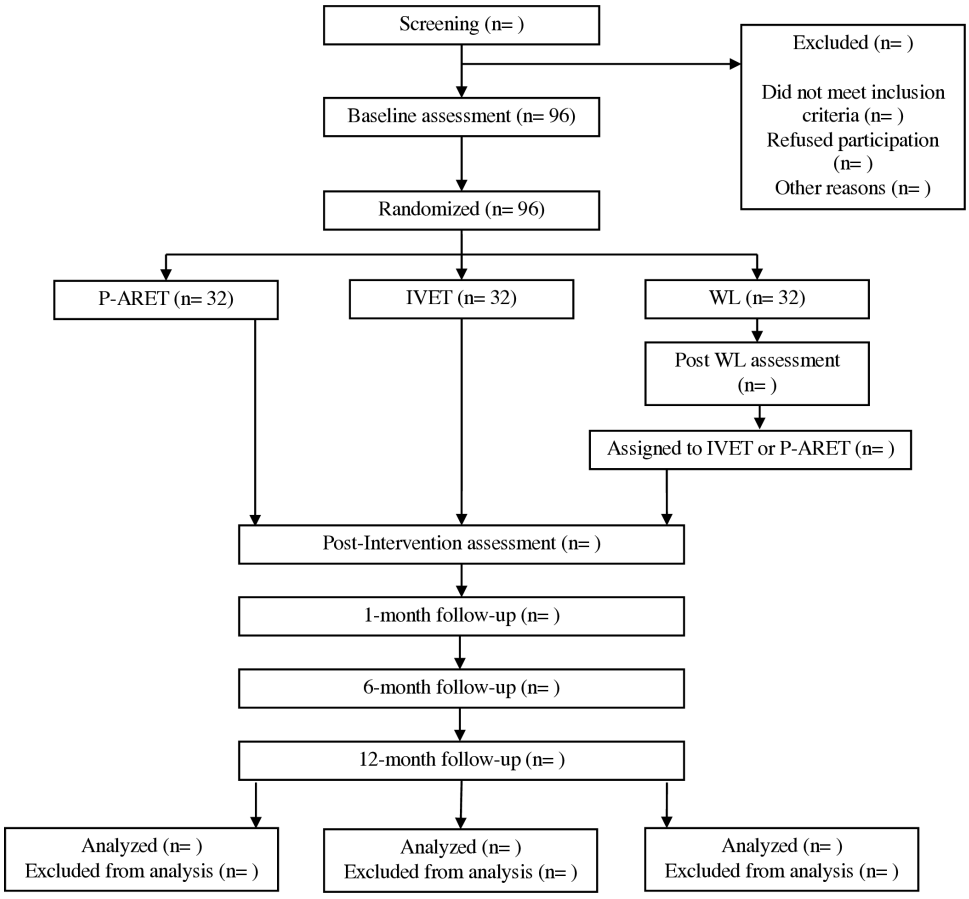

Figure 1 Study flow chart. IVET, in vivo exposure treatment; P-ARET, projection-based augmented reality exposure treatment; WL, waiting list.

organic illness; (c) being capable of inserting their hands in a plastic container containing a cockroach (during the BAT); and (d) in the case of receiving pharmacological treatment, changing the drug or dose during the study (a decrease in the dose is accepted).

The inclusion or exclusion of each case will be assessed by the entire clinical team in order to carry out a more objective and reliable selection process. This team is composed of all the authors of the present work. With the prior agreement of the participant, the audio of the diagnostic interview will be recorded and used to make an independent inter-rater assessment.

Recruitment, randomisation and blinding

The recruitment process will include advertisements via professional websites (ie, LinkedIn), non-professional social networks (ie, Facebook, Twitter and Instagram) and in newspapers. The study will also be offered to people seeking help at the Emotional Disorders Clinic at Universitat Jaume I. An email account will be exclusively dedicated to contacting participants and receiving requests for participation. People interested in participating will receive information about the study and be assessed based on the eligibility criteria.

Regarding the allocation generation process, an independent researcher who is unaware of the characteristics of the study will generate the allocation schedule through randomisation software (Epidat V.4.2). This researcher will keep the allocation schedule and will be the one to assign participants to one of the three conditions following this schedule. In addition, this researcher will assign a sequential code to the participants and will inform the clinician about the code and the assigned group. Participants who meet the inclusion criteria will sign the informed consent form and then be randomly allocated to one of the three experimental conditions. Patients will agree to participate before the random allocation, without knowing the condition to which they will be assigned.

Intervention

Both treatment conditions will follow the same procedure, using the guidelines of the 'one-session treatment' proposed by Öst *et al*.[36] This protocol is based on the use of intensive exposure delivered in only one session lasting up to 3 hours. The protocol includes four parts: (1) exposure to the feared stimulus (cockroach), (2) modelling by the therapist, who interacts with the phobic stimulus and is followed by the patient (if possible), (3) cognitive challenge and (4) reinforcement. The exposure session will be carried out in a gradual, planned and controlled way, and the main purpose of this treatment is for patients to confront their phobic situation in a controlled environment, which allows them to accept and experience

that the negative consequences they fear do not actually occur. The treatment will be applied in the same way in both conditions, except that, in the P-ARET condition, participants will be exposed to virtual cockroaches using the P-ARET system, whereas in the IVET condition, participants will be exposed to real cockroaches. In the WL condition, participants will be assessed at pretreatment and after a 1 week waiting period (the mean time period expected to conduct the one-session treatment and the post-assessment), and then they will be assessed again. For ethical reasons, the patients on the WL will be randomly allocated to one of the two treatment conditions.

Projection-based AR system

The P-ARET system allows patients to directly confront a virtual feared animal (ie, cockroaches) observed in the real environment (virtual animals are projected on a table by a high-resolution projector and ASUS XPro camera). The software for this system allows the therapist to control multiple parameters, such as: the number and size of the animals, the ability to activate their movement or paralyse them, their state (dead or alive), and the ability to make the cockroaches fly or move their wings. All these parameters can be changed by the therapist on a laptop, respecting the natural flow of the exposure session. The system is also developed to detect different objects, such as fingers, hands or any other object placed on the table, which allows the interaction between the person and the animals and multiplies the system's possibilities to generate different exposure situations (eg, chasing or escaping from the animals). The system was programmed in C, using Visual C++ V.9.0 as the development environment, and virtual animals were incorporated with Gamestudio V.8.10. The depth sensor provides images with a resolution of 640×480 pixels, a field of view of approximately 57°×43° (87×67 cm at a distance of 80 cm) and a spatial resolution of 1.3 mm per pixel.[21] Figure 2 shows an example of the P-ARET system.

Instruments

The assessment protocol will include the following measures:

Diagnostic interview

The Anxiety Disorders Interview Schedule for DSM-IV-TR (ADIS-IV)[37] SP section will be used. In addition, DSM-5 criteria will be considered for diagnostic purposes. The ADIS-IV shows adequate psychometric properties and is an excellent interview for assessing anxiety disorders.[38]

Figure 2 Images depicting the projection-based augmented reality exposure treatment system and an example of how the cockroaches look like from the patient's view.

Primary outcomes

The BAT (adapted from Öst *et al*[36]) will be used as a primary outcome. The BAT is an observational test that consists of the participants facing the feared stimulus, measuring the distance at which they are able to approach and to what extent they are able to interact with it, thus providing an objective measure of the behavioural response to the feared stimulus. During this test, a cockroach will be presented inside a closed and transparent container, and the participant will be asked to get as close as possible, open the container and interact with the cockroach using a piece of paper. The researcher will explain to the participant that it is an evaluation test and that they can end the test at any time. This test has been used in previous studies following the same procedure.[13 15] Specifically, 'performance' is the dependent variable of this test. This variable is based on a 12-point scale which is based on the distance that the patient is able to approach (measured in metres marked on the floor) and ultimately interact with the cockroach. This scale ranged from '0', which represents that the participant does not want to enter the room to '12', which represents that the participant is able to interact with the cockroach more than 2 min.

After the therapist has explained the instructions to the participant, he/she will be asked to what extent (from 0 to 10) they believe in the negative thoughts related to cockroaches. Additionally, fear, avoidance and the maximum level of anxiety are also measured during this test on a scale ranging from 0 to 10.

Secondary outcomes

Sociodemographic variables: gender, age, educational level, marital status and work status will be collected as sociodemographic variables.

Cognitive process measure: an eye-tracking attentional task was specifically created for this project. The attentional task was developed by selecting 10 images of cockroaches, spiders, snakes (negative valence images) and cats (positive valence images), and 40 images of butterflies (neutral valence images) from a previously validated image set.[39] The emotional images (positive and negative) were randomly paired with the neutral images, yielding a total of 40 pairs of images. These pairs were duplicated and reversed (if the butterfly was on the left, it was placed on the right) to control possible positioning effects, which resulted in a total of 80 trials. The attentional task was developed in Tobii Pro Lab Software, following the design of other similar studies in this field.[23] We developed an exploratory visual task where participants must freely observe the composition of images. This type of task makes it possible to assess the attentional biases of hypervigilance and avoidance typically associated with SP.[23]

Fear of Cockroaches Questionnaire (FCQ; translated and adapted by Nebot *et al*[40]): this scale is an adaptation of the Fear of Spiders Questionnaire (FSQ)[41] to assess the fear

of cockroaches. This instrument is composed of 18 items that refer to different situations related to cockroaches and is designed to assess the severity of the phobia. Items are rated from 0 ('I strongly disagree') to 7 ('I strongly agree'), and the scores can range from 0 to 126. The original version of the FSQ had excellent psychometric properties.[41] The Spanish adaptation of the FCQ showed two factors: factor 1 ('avoidance/help-seeking') and factor 2 ('vigilance and fear of harm'), which is the same structure as in the original version, with Cronbach's alphas of 0.86 and 0.62 for factors 1 and 2, respectively, in a clinical population.[40] This version of the questionnaire has been used in previous studies by our research group.[13 15]

Cockroach Phobia Beliefs Questionnaire (CBQ; translated and adapted by Nebot *et al*[42]): this scale is an adaptation of the Spider Phobia Beliefs Questionnaire (SBQ).[43] This self-report questionnaire has a total of 78 items divided into two subscales: (1) catastrophic beliefs about cockroaches (CBQ-1) and (2) beliefs about the patient's ability to cope with cockroaches (CBQ-2). All the items are rated from 0 ('I don't believe it at all') to 100 ('I am convinced of it'). The original version of the SBQ showed excellent internal consistency, with a Cronbach's alpha of 0.94 for both subscales. The Spanish adaptation of the SBQ for cockroaches showed excellent internal consistency, with Cronbach's alphas of 0.90 for CBQ-1 and 0.95 for CBQ-2 in a clinical population. This version of the questionnaire was also used in previous studies by our research group.[13 15]

Fear and Avoidance Scales (adapted from Marks and Mathews[44]): on these scales, the patient and therapist together establish the target behaviours related to cockroaches that are causing the main interference in the patient's life (eg, being able to face a cockroach alone at home), rating it in terms of fear (from 0='no fear' to 10='extreme fear') and avoidance (from 0='never avoid' to 10='always avoid'). In addition, negative thoughts related to these situations are registered and rated in terms of the degree of belief, ranging from 0 ('I don't believe that thought at all') to 10 ('I believe the thought is totally true'). The main target behaviour chosen by each participant will be selected to conduct the analyses. This instrument has shown good psychometric properties and is sensitive to change.[44]

Patient's Improvement Scale (adapted from the Clinical Global Impression Scale[45]): this scale is designed to assess the level of improvement achieved by the patient compared with the baseline status. Items are rated from 1 ('much worse') to 7 ('much better') and are answered by the patient.

Other clinical measures

Disgust Propensity and Sensitivity Scale-Revised-12 (DPSS-R-12;[46] adapted and validated in the Spanish population by Sandin *et al*[47]): this is a self-administered questionnaire composed of two subscales that measure the propensity and sensitivity to disgust, respectively. Each scale contains six items that are rated from 1 ('never') to 5 ('always'), resulting in a total score on each scale ranging from 6 to 30. The Spanish version of the DPSS-R-12 showed good psychometric properties in terms of reliability and validity.[47] Mean scores reported in this version were 15.3 (SD=3.5) and 12.2 (SD=4) for the propensity to disgust and sensitivity to disgust scales, respectively.

The *Beck Depression Inventory second edition* (BDI-II;[48] Spanish validation by Sanz *et al*[49]) assesses the presence and severity of symptoms related to the depression diagnosis during the past 2 weeks following DSM-IV criteria. This is a self-administered instrument composed of 21 items rated from 0 to 3, yielding a maximum total score of 63. The Spanish validation of the BDI-II obtained good psychometric properties in terms of reliability and validity, showing high internal consistency (Cronbach's alpha of 0.89).[49]

The *State-Trait Anxiety Inventory*–the trait subscale (adapted from Spielberger *et al*[50]) will be used to assess the trait anxiety of the participants. This scale is composed of 20 items rated from 0 ('nothing/rarely') to 3 ('very much/always'), and it refers to a relatively stable anxious propensity to perceive situations as more or less threatening in general, which directly influences one's immediate state anxiety response. This instrument has shown high internal consistency (Cronbach's alpha of 0.91) and good test–retest reliability (r=0.86).[50]

The *Clinician Severity Scale* (adapted from Brown *et al*[37]) assesses the severity of symptoms on a scale ranging from 0 ('absent') to 8 ('very severe'), evaluated at the discretion of the clinician. This instrument has been used in previous research.[51]

Treatment opinion measures

The Expectation of Treatment Scale and Satisfaction with the Treatment Scale (adapted from Borkovec and Nau[52]) are composed of six items each, rated from 0 ('strongly disagree') to 10 ('strongly agree'), that are designed to assess the extent to which the treatment could satisfy the patient, if it is perceived as logical, if it could be used to treat other psychological problems, if it is useful for the patient's specific problem, if they would recommend it to others and to what extent they perceived the treatment as aversive. The Expectation of Treatment Scale is administered after the intervention has been described, and it measures the patient's subjective expectations after understanding how the treatment session will proceed but without having received it yet. The Satisfaction with the Treatment Scale is administered when the treatment is over, and it assesses the patient's degree of satisfaction with it. These scales have been used in other research studies by our group.[53 54]

Analysis

The IBM SPSS Statistics for Windows (V.28) will be used to carry out the statistical analyses on all the participants' data. Intention-to-treat and per-protocol analyses will be performed. Results will be reported following the CONSORT recommendations[31 32] and SPIRIT

guidelines.[33] Differences in sociodemographic data and baseline clinical measures will be assessed using the X^2 test for categorical variables and analysis of variance (ANOVA) for continuous data. To test the main hypothesis, analyses of post-treatment outcomes on all the clinical measures will be conducted using X^2 tests to assess differences between the groups. Furthermore, to test the secondary hypothesis of efficacy, two-way 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 vs IVET vs WL), and the repeated measures factor will be the measurement time (pretest, post-test, 1-month, 6-month and 12-month follow-ups). To control the type I error rate inflation, Bonferroni correction will be applied for all secondary outcome analyses. To examine group differences at different measurement times, post hoc comparisons will be applied. In addition, a two-way multivariate ANOVA will be performed on all outcomes. Moreover, to assess between-group and within-group changes, effect sizes (Cohen's d) and their CIs will be calculated.[55 56] Missing data will be handled following the authors' recommendations, using the most appropriate method depending on the reasons for the missing data and the sensitivity analysis principles.[57]

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, to which all authors of the present work 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 data collection process, most of the instruments used in the evaluation protocol will be implemented through electronic means (www.qualtrics.com). Patients will receive a personal link in which they will be able to complete the questionnaires. Each participant will be linked to a code and all the data collected on paper (personal data, informed consent form and diagnostic interview) will be stored under key and will only be available to researchers responsible for the study, always protecting the right to privacy. All the clinical data (not personal data as name, telephone, etc) will be transferred to a general database (with password protection) which will contain the corresponding codes of each participant, so that it is impossible to link these data to the participants. The primary use of the data is anonymous.

Ethics and dissemination

The trial will be carried out in compliance with the study protocol and follow the guidelines of the Helsinki Convention and the Madrid Declaration of the World Psychiatric Association and good clinical practice. All participants will be volunteers and give their informed consent to be enrolled in the project once they have been given oral and written information about the study. Participants may withdraw from the study at any time. The selection of the participants will be carried out by qualified personnel using clinical criteria.

This trial has received approval from the Ethics Committee of Universitat Jaume I (Castellón, Spain; 13 December 2019) (number: CD/64/2019). Findings of the RCT will be published in peer-reviewed and open-access scientific journals and presented at international scientific meetings and conferences.

Patient and public involvement

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

DISCUSSION

The present work describes the protocol for an RCT designed to evaluate the effectiveness of a projection-based augmented reality exposure system for cockroach phobia compared with the treatment of choice for SP (ie, in vivo exposure) and a WL control group. In addition, patients' expectations and satisfaction with the treatment will also be assessed and analysed.

The implementation of AR technology in exposure treatments could have important advantages in solving some of the problems associated with more traditional ways of delivering exposure, such as in vivo exposure, highlighting access, acceptance and adherence to the treatment.[9] The appearance of new AR systems has made it possible to overcome some of the problems associated with this type of technology such as dizziness and discomfort caused by intensive use of a traditional HMD.[15] There are already some studies showing the feasibility of new AR systems based on sunglasses-like HMDs that greatly facilitate their use and implementation in exposure treatment, but the efficacy results need to be proven in further studies.[19]

In this study, we present an alternative to HMD-based AR systems with the aim of increasing the availability of evidence-based tools for the treatment of small animal phobia in order to increase versatility and offer more tools that mental health professionals may have and thus be able to better adapt the treatment to each situation and specific case. In this line, the P-ARET offers a natural and friendly environment in which to carry out the treatment, and it is able to present the feared stimuli without the need to wear an HMD. This results in a very generalisable environment in which patients can behave completely naturally since the stimuli are projected on

a physical surface. In addition, the P-ARET offers the possibility of interacting with the animals, which can respond immediately and naturally to the behaviour of the patients, thus increasing the sense of presence and the judgement of reality, important key characteristics of virtual environments.[58]

The promising results of previous studies seem to indicate that the implementation of this system can help to enhance and improve all these aspects of exposure therapy for small animal phobia.[21] Therefore, we expect the P-ARET condition to be more effective for treating cockroach phobia, compared with the control group, and similar results are expected in the in vivo treatment condition, based on results of previous studies.[15] These results are also expected to be maintained over time. In addition, regarding the measures of satisfaction and acceptance of the treatment, the patients in the P-ARET group are expected to report a better experience than the patients in the IVET group. Hence, the implementation of this technology is a way to overcome the problem of low acceptance and, thus, the low rates of access to treatment related to traditional exposure therapy.[6 9]

The strengths of the study are the following: first, this is the first RCT designed to test the effectiveness of a P-ARET for cockroach phobia. Second, the intervention delivered in both treatment conditions is based on the 'one-session treatment' guidelines,[59] whose main characteristic is that the entire treatment is completed in a single session lasting up to 3 hours. This is an important strength to highlight due to the large number of people suffering from anxiety disorders, especially SP.[2] Given these alarming prevalence rates, as Kazdin and Blase[8] and Emmelkamp *et al*[60] proposed, it is increasingly important to develop much more cost-effective treatment programmes to reach larger numbers of people who are in need of psychological treatment. Third, the RCT includes an innovative attentional task specifically designed to assess attentional biases and record attentional scanning patterns using eye-tracking technology. Due to the importance the literature has given to attentional biases in maintaining the phobic disorder, the meticulous and precise study of attentional processes that underlie it is necessary in order to ultimately improve the quality of available treatments. In this line, the measurement of eye movements allows the recording of all the temporal and spatial features of fixation and saccadic movements, which are considered a key part of the attentional mechanisms,[61] and there is strong evidence supporting the use of eye-tracking technology in the study of attentional biases in affective disorders.[62] Specifically, in the small animal phobia research field, studies that evaluated ocular movements during a free exploration task found the hypervigilance–avoidance pattern typically associated with patients with phobia.[23 25 26] In the clinical field, there is a lack of studies assessing the effects of exposure-based treatments on attentional biases. Moreover, the studies in the SP field have used the Stroop task to measure attentional biases, comparing Stroop interference before and after exposure treatment.[63 64] The use of this task has been related to significant methodological limitations in inferring attentional biases.[65] However, a systematic review focused on attentional bias after cognitive–behavioural treatment (CBT)[29] concluded that, in general, attentional biases showed significant reductions after CBT in different populations with anxiety (generalised anxiety disorder, spider phobia, social phobia and obsessive-compulsive disorder). We think the implementation of eye-tracking technology as a measure of attentional biases and treatment effectiveness will help to increase the knowledge in this field.

Finally, some limitations of the present study should be highlighted. First, although the study protocol includes a 12-month follow-up, only the results of the treatments in the short and medium term will be known, but not how they may vary in the long term. Future studies should strive to investigate the long-term effects of the P-ARET system. Second, the RCT focuses on phobia of cockroaches, and so it could be improved if more subtypes of animal phobias were added, such as spiders or rats, which would make the P-ARET system even more versatile.

Acknowledgements The current project was supported by Plan 2021 de Promoción de la Investigación de la Universitat Jaume I (UJI-B2021-47), CIBEROBN, an initiative of the ISCIII (CB06 03/0052), a PhD grant (grant number: PRE2019-087363) funded by MCIN/AEI/10.13039/501100011033 and by 'ESF Investing in your future' and Convocatòria 2023 d'ajudes a grups d'investigació actius en captació de recursos del pla estatal d'I+D+i (reference number: GACUJIMA/2023/05).

Contributors JG drafted the manuscript with important contributions from SQ and JB-L. JG, in collaboration with SQ, JB-L and MP-B, designed the study and participated in each of its phases, with the contribution of LD-S in the recruitment process. All authors participated in the review and different revisions of the manuscript.

Funding Funding for the study was provided by Grant Ministerio de Ciencia, Innovación y Universidades (Spain) (Programa Estatal I+D+I) (grant number: RTI2018-100993-B-100) funded by MCIN/AEI/10.13039/501100011033 and by 'ERDF A way of making Europe', by the European Union.

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 required.

Provenance and peer review Not commissioned; externally peer reviewed.

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