

BMJ Open Clinical efficacy of a virtual reality tool for the treatment of obesity: study protocol of a randomised controlled trial

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ABSTRACT

Introduction Previous research has shown that it is feasible to integrate motivational interviewing techniques with behavioural and psychological interventions for the treatment of obesity. Moreover, these combined interventions have the potential to improve health-related outcomes of people living with obesity (PLWO) and to afford maintenance of behavioural changes over time. In addition, the use of virtual reality (VR) embodiment techniques in the treatment of eating disorders and obesity has promising preliminary effectiveness. The objective of this study is to assess the clinical efficacy of a VR intervention that uses embodiment and body-swapping techniques and has been specifically developed to cover the needs of PLWO.

Methods and analysis A randomised control trial will be carried out with an estimated sample of 96 participants with body mass index (BMI) >30. The whole duration of the trial will be 12 months. Participants will be recruited from the external consultations of the Vall d'Hebron University Hospital and be randomly assigned to three groups. The experimental group 1 will engage in a virtual self-conversation using the ConVRself platform, the experimental group 2 will participate in a 'pre-established discourse' provided by the virtual counsellor, who will give psychoeducation advice, and the control group will continue with treatment as usual. Readiness to change, BMI, eating habits and physical activity, psychological well-being, body image satisfaction, quality of life in relation to body image, and weight bias internalisation will be assessed at baseline, post intervention, 1-week and 4-week follow-up. Finally, variables related to adherence and satisfaction with the VR tool will be evaluated for the experimental groups.

Ethics and dissemination This study was approved by the Research Projects Committee of the Vall d'Hebron University Hospital. Findings will be disseminated through peer-reviewed journals, reports to the funding body, conferences and other events for the scientific and clinical community, and the general public.

Trial registration number NCT05094557.

INTRODUCTION

In recent decades, the prevalence of obesity has markedly increased worldwide and has

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The present study is designed as a randomised controlled trial and uses a rigorous methodology containing three (treatment conditions) X 4 (assessments) factors.
- ⇒ Intention-to-treat analyses will be performed using hierarchical linear models to examine the longitudinal changes of participants according to their assigned treatment group.
- ⇒ The sample size was calculated taking into account the low treatment adherence of this population and consequently, the high dropout rates; to deal adequately with this limitation, an extra 20% of patients will be recruited.
- ⇒ This is the first time that people with obesity receive an intensive training on motivational interviewing skills to conduct their own motivational self-conversation using the ConVRself platform. By doing so, we hope to find promising long-term effects in the acquisition and maintenance of healthy lifestyle habits in this population.

nearly tripled since 1975, with 11% of adult men and 15% of adult women being obese.¹ Developing effective treatment approaches for obesity is essential to reduce comorbidities and associated costs, and has been identified as a research and public health priority.^{2,3}

Current guidelines for the treatment of obesity⁴⁻⁶ recommend psychological and behavioural weight management interventions to increase physical activity (or to decrease inactivity), improve eating behaviour and diet quality and reduce energy intake as well as to promote treatment adherence and self-efficacy. These typically include dietary and physical activity-related psychoeducation, prescriptions and behavioural skills, such as self-monitoring, stimulus control, goal setting and problem-solving, in combination with cognitive skills. However, these treatments often fail, and one of the main reasons for

this is the lack of motivation to change among patients or the failure to maintain behavioural change strategies after treatment.⁷ In fact, most patients experience significant weight regain within a year of completing treatment and nearly half of participants return to their original weight within 5 years.^{8,9} A recent study shows that people living with obesity (PLWO) who demonstrated personal motivation to lose weight were more likely to report successful weight loss compared with unmotivated people.¹⁰

Motivational interviewing (MI) is a person-centred approach to counselling in which individuals are encouraged to identify their own goals (and the discrepancies between those goals and their current condition), and to discover a way towards behavioural change with unconditional support by their therapist.¹¹ This strategy follows a non-judgmental style in which ambivalence to change is accepted as normal. The goal is to help the individual, through a collaborative conversation with the therapist, to strengthen motivation and commitment to change in the context of the own desired outcomes.

Research shows that it is feasible to integrate MI techniques with behavioural and psychological interventions for weight loss, including cognitive behavioural therapy (CBT). Interventions combining both MI and CBT have the potential to improve health-related outcomes among PLWO, especially in the long term.¹² A meta-analysis of randomised controlled trials (RCT) using MI techniques for the treatment of overweight and obesity found an enhanced effectiveness when using MI in combination with a behavioural weight management programme.¹³

In addition, the incorporation of new technologies among clinical treatments for obesity has increased steadily in the past few years and has taken on a special relevance during the COVID-19 crisis management.¹⁴ For instance, eHealth interventions have shown promising long-term effects in the improvement of healthy lifestyle among PLWO.¹⁵ Furthermore, virtual reality (VR) has been used in the treatment of eating disorders (EDs) and obesity and has been associated with a reduction in food cravings, improvement in body image and enhancement of emotion regulation skills.^{16–19} However, the studies reporting VR-based treatments are limited because they essentially deliver the same CBT in a safe VR environment without addressing the deep causes of obesity, such as lack of motivation to change or self-stigmatization, key aspects for having long-term effects.

The SOCRATES (Self Conversation in Virtual Reality Embodiment to Enhance Healthier Lifestyles Among Obese People) European project (<https://socratesvr.eu>) aims to use VR from a user-centred perspective focusing on the specific needs of PLWO. For this goal, the SOCRATES project will adapt ConVRself, an existing platform that adopts MI and CBT principles and uses embodiment and body-swapping techniques to promote a self-conversation in VR. While VR embodiment provides a body ownership illusion enabling patients to experience the perceptual illusion that a virtual body is their own,^{20,21} body swapping allows switching between two (or

more) avatars while being immersed in a VR environment, still maintaining embodiment.^{22–24} Thus, by using ConVRself, patients can engage in a self-conversation in which they try solving their problem using their own words by switching between an avatar of themselves and an avatar of a counsellor. During the self-conversation in VR, patients experience two different embodied perspectives of themselves and their problem, a first-person and a second-person perspective. The self-conversation will take place by exposing patients to four VR experiments with ConVRself: ‘embodied discussion about problem and solutions’, ‘overcoming (self-) stigmatisation’, ‘illustrating the possibility of autonomy’ and ‘summing-up’. The tool has shown preliminary effectiveness using the self-conversation technique with samples of university students in terms of greater mood improvement and happiness, and greater perception of change and help for the personal problem after the intervention.^{23,24}

The present study, framed within the SOCRATES project, aims to assess the efficacy of the ConVRself as a therapeutic tool that promotes behavioural change among PLWO. For this, we will conduct an RCT with two experimental groups (experimental group 1 (EG1) and EG2)) and a control group (CG). Each group will receive its assigned intervention during a period of 10 weeks. Participants in the EG1 will receive a combined intervention that includes:

- ▶ Intensive training on basic skills related to MI and CBT (one face-to-face visit and two follow-up phone calls)
- ▶ Psychoeducational advice in video format
- ▶ Multidisciplinary treatment with practical recommendations to achieve a gradual weight loss and engage with physical exercise (treatment as usual (TAU))
- ▶ Body-swapping VR intervention through ConVRself (four face-to-face visits).

The EG2 will receive the following:

- ▶ Psychoeducational advice in video format
- ▶ TAU
- ▶ VR intervention through ConVRself without body swapping (four face-to-face visits).

The CG will receive the following:

- ▶ Psychoeducational advice in video format
- ▶ TAU.

Detailed information regarding each intervention should be found below, in the ‘Interventions’ section.

In particular, we aim to examine whether self-conversation through embodied perspective taking (body swapping) in a VR environment together with the integration of learnt skills on MI and CBT (EG1) might account for helping participants to overcome the obesity-related problems described below, as the first study hypothesis, compared with being embodied in their own virtual representation without using the body-swapping feature (EG2) or compared with standard multidisciplinary treatment for obesity at their hospital (CG).

The implementation of the body-swapping VR intervention proposed for the EG1 is expected to result in a

significant improvement in the primary and secondary outcomes (see below) compared with the treatments proposed for the EG2 and CG. More specifically, we expect that:

- ▶ The combined intervention of the EG1 would lead to significantly greater improvements (differences between baseline and post intervention, which should also be maintained at 1-week and 4-week follow-up) in the primary outcome, that is to say, readiness to engage in healthier lifestyle, and in the secondary outcomes (ie, body mass index (BMI), psychological functioning in terms of symptoms of depression and anxiety, eating behaviours, body satisfaction, weight bias interiorisation, and eating and exercise habits), in comparison to the EG2 and CG interventions.
- ▶ Participants from the EG1 would report greater levels of perceived acceptability and usability of the platform, as well as higher subjective rating of the illusion of body ownership of the virtual avatar(s), compared with EG2.

METHODS AND ANALYSIS

Patient and public involvement

Patients recruited for the RCT will not be directly involved in the design of the platform. However, a previous usability study, which is not described in the present protocol, was conducted with patients with morbid obesity from the Vall d'Hebron University Hospital (Barcelona, Spain). These patients were exposed to one VR session using ConVRself and provided feedback about their experiences and uncovered needs during the virtual experiments. This feedback helped the team to develop an updated version of ConVRself adapted to the specific needs of PLWO.

Design

The study proposes a RCT with three parallel groups (EG1 vs EG2 vs CG) with 1:1:1 allocation. The study design will contain three (treatment conditions) X 4 (assessments) factors. Assessment factors are baseline (T0), post intervention (T1), 1-week (T2) and 4-week follow-up (T3). The design and planning of this study protocol follow the Standard Protocol Items: Recommendations for Interventional Trials 2013 statement (<https://www.spirit-statement.org>).

Sample

The total sample that will be recruited for the RCT will be 96 patients with a BMI between 30 and 45 kg/m² (see 'Sample size calculation' section). The participants will be recruited from the Obesity Unit of the Vall d'Hebron University Hospital and will be patients with obesity receiving regular multidisciplinary treatment at the hospital (see 'Treatment as usual' description below) and willing to improve their obesity-related condition and associated problems.

Inclusion criteria

- ▶ Age between 18 and 65 years
- ▶ BMI ≥ 30 kg/m² and ≤ 55 kg/m²

- ▶ Receiving ambulatory treatment at the Vall d'Hebron University Hospital
- ▶ No concurrent involvement in other treatment related to the obesity condition
- ▶ Minimal digital skills. This refers to being able to use a digital device (smartphone, tablet, computer) to make phone calls and video conversations via the internet, send or receive emails, and search for information about products and (health) service
- ▶ Oral and written understanding of the Spanish language
- ▶ Agreement to sign the informed consent in order to participate.

Exclusion criteria

- ▶ Presence of an ED at least during 2 years
- ▶ Non-stabilised severe mental disorder that could interfere with the successful implementation of the research protocol (ie, psychosis, depression with suicidal risk, alcohol or drug abuse, psychotic or manic symptoms)
- ▶ Auditory or visual complications that may interfere with the correct performance of the virtual experience, such as uncorrected decreased visual or hearing capacity or other conditions that may affect correct perception (including eye diseases that are common among diabetic patients, such as diabetic retinopathy, macular oedema, cataracts, and glaucoma)
- ▶ Intellectual disability or any major illness seriously affecting cognitive performance (ie, neurological disorders)
- ▶ Personal history of epilepsy.

Procedure and randomisation

Healthcare professionals specialised in obesity from the Vall d'Hebron University Hospital will recommend patients potentially suitable to participate in the study. To identify potential candidates for the study, professionals will do a preliminary screening of the patients with obesity currently under care, according to the inclusion and exclusion criteria established for the present study. Individuals will be able to confirm their participation by notifying their interest. A representation of women and men consistent with the actual gender distribution of obesity in Spain²⁵ will be pursued. In specific, according to obesity prevalence data from the Spanish National Institute for Statistics from 2020, 52% of the sample is expected to be male and 48% female. Then, an appointment will be made with a clinical researcher of the SOCRATES team at the Vall d'Hebron Research Institute (VHIR). In this first appointment, participants will be informed about the study, the data confidentiality, and the possibility to withdraw from the study whenever they want without losing any other rights or benefits, and then will be asked to sign the informed consent. Straight after completing and signing these documents, the same clinical researcher will conduct initial clinical interviews with the participants to confirm their eligibility to the

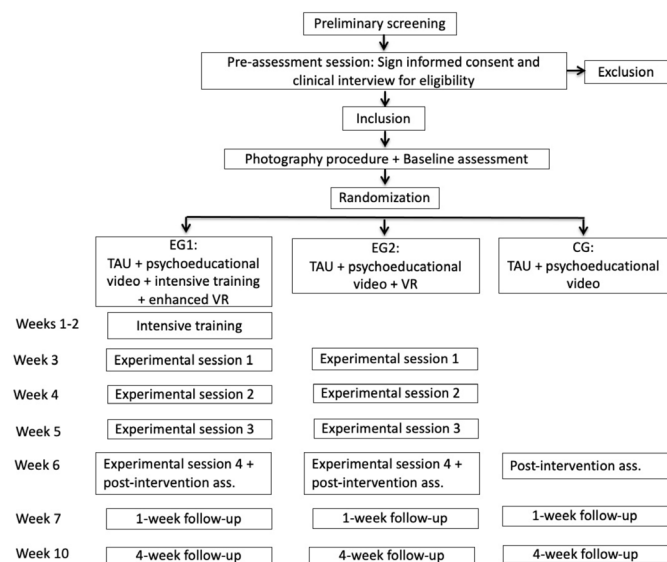


Figure 1 Procedure and timeline of the study. ass., assessment; CG, control group; EG, experimental group; TAU, treatment as usual; VR, virtual reality.

study and evaluate possible comorbidities. At this time, sociodemographic and clinical data of each patient will also be collected. Those who meet the eligibility criteria will follow two procedures. First, they will be invited to complete the ‘baseline assessment’ (self-report questionnaires through paper or online surveys at home). Second, they will have a photography session in which two photographs front and side will be taken for each participant. This photography session before the beginning of the experiment will serve for all patients as a means of observing and comparing their body shapes before and after the intervention. For patients of the experimental groups, these photographs will be used by the team to prepare the participants’ avatars for the VR experience.

After completing the baseline questionnaires, participants will be randomised to one of the three groups (EG1, EG2 or CG). An independent researcher of the SOCRATES team blind to the research questions and treatment conditions will carry out the randomisation through a list of randomly generated numbers using IBM SPSS V.24 software.²⁶ Then, the clinical researcher carrying out the initial interviews will be responsible for communicating the assignment group to the participants, through a phone call, together with the specific identification code for each one of them. Next, the experimental sessions will be carried out, which will last for 6 weeks. It is worth mentioning that a clinical researcher of the VHIR team will always accompany the participants during the VR experiments and guide them on the correct use of the platform.

After the participants’ exposure to their assigned interventions (see ‘Interventions’ section below), the ‘postintervention assessment’ will take place. One week later, the ‘1-week follow-up’ will be conducted, which will include a brief interview with the clinical researcher and several self-report questionnaires. In the same follow-up session,

the clinical researcher will ask the participants of the EG1 and EG2 if they want to receive an extra experimental session. If a participant does not want to receive an extra session, the experimental sessions will finalise for him/her. If a participant wants an extra session, he/she will be exposed again to the final ‘summing-up’ session (see ‘Interventions’ section below) only if he/she meets two or more of the following criteria: (1) scores on any of the readiness rulers below four points; (2) lack of understanding of the virtual MI dialogue (only for the EG1); (3) spontaneous demand for the extra session. Lastly, the ‘4-week follow-up’ will be conducted and include the same self-report questionnaires as the ones delivered at the ‘baseline assessment’.

Right after finalising each of the four experimental sessions, the accompanying clinical researcher will assess if any adverse event occurred. For example, whether participants experience cyber sickness, dizziness, discomfort, nausea, or feel confused or disoriented during their practice with the system. The procedure will stop when the clinical researcher or the participant consider it necessary. Besides, if a significant worsening on the participant’s psychological well-being is identified during the whole procedure, a face-to-face visit with the researcher of the SOCRATES team will be scheduled to assess whether or not he/she will have to discontinue participation in the trial.

Figure 1 presents the study’s procedure and timeline. It is worth mentioning that recruitment started in January 2022 and is expected to be completed by October 2022, while data collection will be completed by January 2023.

Figure 2 describes the procedure for the interventions of EG1 and figure 3 describes the procedure for the intervention of EG2. Finally, table 1 provides a detailed description of the methodology with a definition of the study variables and their assessment tools for each one of the three groups. To optimise participants’ retention and complete follow-up, reminder emails will be sent to all participants at T1, T2 and T3.

Interventions

Intensive training on basic skills related to MI and CBT

Participants assigned to the EG1 will be invited to participate in the 3-day intensive training on basic skills of MI^{11 27} and CBT,^{28–30} which will be carried out by the clinical researchers’ team from VHIR. This intensive training will consist of a 4-hour face-to-face group session in day 1, and 2 individual 30 min telephone coaching sessions in day 2 and day 3. The objective of this training will be to provide patients with specific skills that will enable them to conduct a productive self-conversation in a VR setting. This training is considered a unified intervention with the “Body-swapping VR intervention” (see below). Since EG2 participants will only have a passive role in their VR experiences (not a self-conversation with body swapping), they will not be assigned to the intensive MI and CBT training.

During the day 1 training, participants will learn to better understand their own process of change, be more

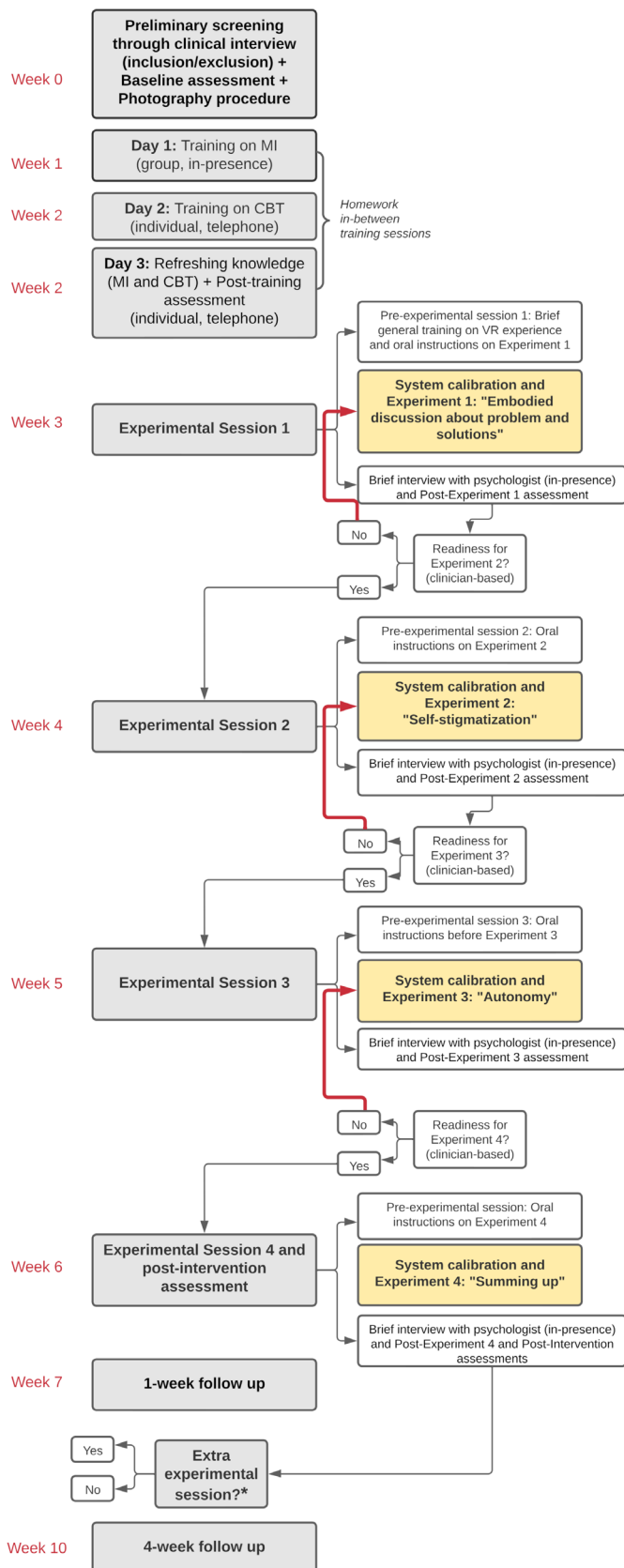


Figure 2 Procedure of the intensive training and experimental sessions for the experimental group 1. * See 'Statistical analysis' section about the inclusion of the number of sessions in the data analyses. CBT, cognitive behavioural therapy; MI, motivational interviewing; VR, virtual reality.

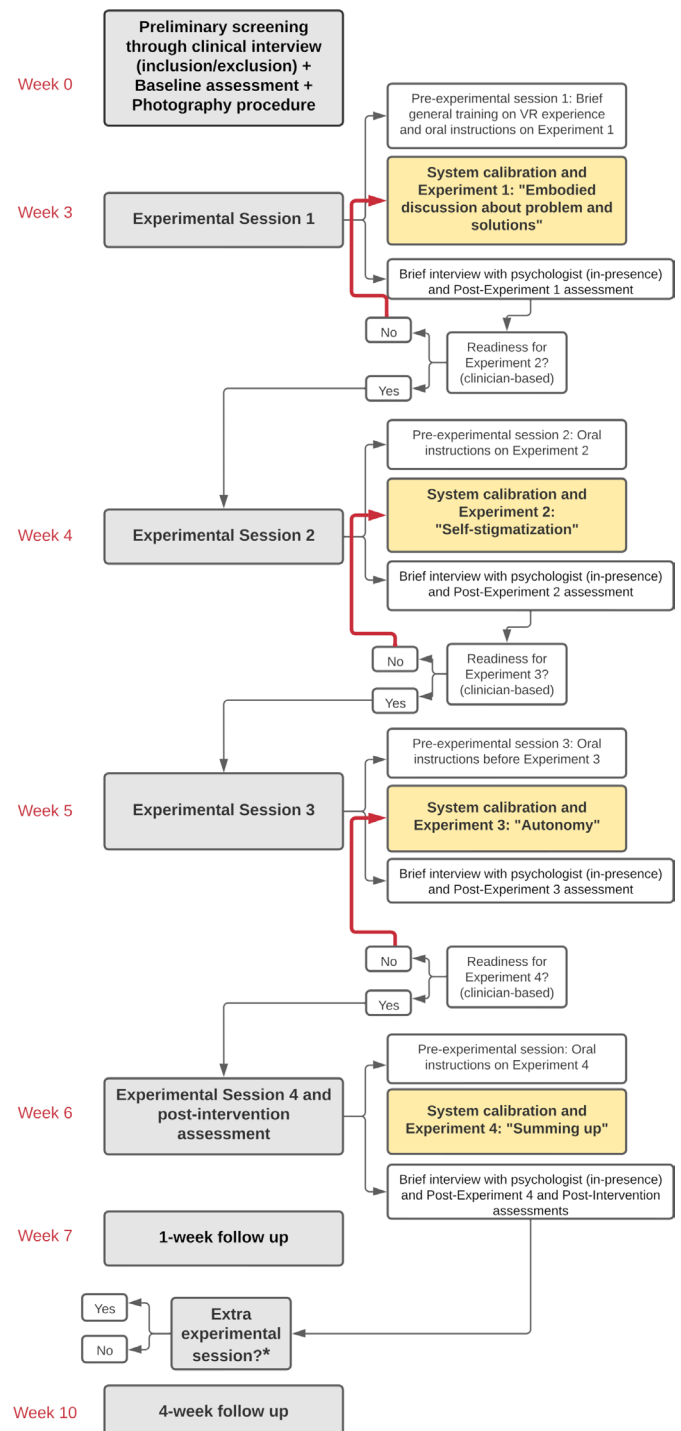


Figure 3 Procedure of the experimental sessions for the experimental group 2. * See 'Statistical analysis' section about the inclusion of the number of sessions in the data analyses VR, virtual reality.

compassionate and empathetic, and thus become better counsellors for themselves. The basic goal of this training is to prepare and instruct participants to organise their self-dialogue better so that they can persuade themselves to change, based on their own values and interests. The session will combine a PowerPoint presentation and videos showing several role-playings among patient/counsellor dyads practicing the skills learnt. The session

Table 1 Study variables and assessment tools for each group

Experimental group 1 and 2						
	Baseline	Post training	Post Exp. 1	Post Exp. 2	Post Exp. 3	Post Exp. 4/ post Interv.
Sociodemographic, clinical variables and body mass index						
1. Sociodemographic data	X					
2. Clinical data related to obesity	X					
3. Medical and psychological antecedents	X					
4. Body mass index	X				X	X
5. Cognitive reserve	X					
Self-report questionnaires for psychological well-being						
1. Readiness rulers	X	X	X	X	X	X
2. Stages and processes of change questionnaires in weight management	X				X	X
3. Three Factor Eating Questionnaire	X				X	X
4. Body Shape Questionnaire	X				X	X
5. Body Image Quality of Life Inventory	X				X	X
6. Modified Weight Bias Internalization Scale	X				X	X
7. Hamilton Anxiety and Depression Scale	X				X	X
8. Lifestyle habits questionnaire	X				X	X
Adherence and satisfaction						
1. Suitability Evaluation Questionnaire		X	X	X	X	X
2a. Body ownership: proper avatar		X	X	X	X	X
2b. Body ownership: avatar of counsellor (only EG1)		X	X	X	X	X
3. Users' experience (interview)		X	X	X	X	X
Knowledge acquisition questionnaires						
1. MI Knowledge Acquisition Questionnaire (only EG1)	X					
2. Cognitive change (only EG1)	X					
Control group						
	Baseline	Post training	Post Exp. 1	Post Exp. 2	Post Exp. 3	Post Exp. 4/ post Interv.
Sociodemographic, clinical variables and body mass index						
1. Sociodemographic data	X					
2. Clinical data related to obesity	X					
3. Medical and psychological antecedents	X					

Continued

Table 1 Continued

Control group		Baseline	Post training	Post Exp. 1	Post Exp. 2	Post Exp. 3	Post Exp. 4/ post Interv.	1-week FU	4-week FU
4. Body mass index		X				X	X	X	X
5. Cognitive reserve		X							
Self-report questionnaires for psychological well-being									
1. Readiness rulers		X				X	X	X	X
2. Stages and processes of change questionnaires in weight management		X				X	X	X	X
3. Three Factor Eating Questionnaire		X				X	X	X	X
4. Body Shape Questionnaire		X				X	X	X	X
5. Body Image Quality of Life Inventory		X				X	X	X	X
6. Modified Weight Bias Internalization Scale		X				X	X	X	X
7. Hamilton Anxiety and Depression Scale		X				X	X	X	X
8. Lifestyle habits questionnaire		X				X	X	X	X
Adherence and satisfaction									
1. Suitability Evaluation Questionnaire									
2a. Body ownership: proper avatar									
2b. Body ownership: avatar of counsellor									
3. Users' experience (interview)									
Knowledge acquisition questionnaires									
1. IMI Knowledge Acquisition Questionnaire									
2. Immediate Cognitive Change									
CI, clinical interview; EG1, experimental group 1; Exp, Experiment; FU, follow-up; Interv, Intervention; MI, motivational interviewing.									

will also give participants the opportunity to practice such skills and receive feedback. Training will be interactive with an open session for questions.

The objective of the day 2 training is to help patients to identify and address obstacles to weight loss (dysfunctional thoughts, emotional and external triggers) and create a personalised case formulation based on CBT principles. At the end of day 2 training, the 'letter to the future exercise' will be sent as a homework to all participants ('Imagine how you would like to be in 2027. Think of a realistic and good situation. From 2027, write a letter to the person you are now in 2022 explaining how you have achieved your goals, the things you have had to change and how you have changed them'), together with a first-aid kit (in PDF format) summarising the most important contents of the training, suggesting questions to ask during the self-dialogue and tips about how to deal with difficult situations related to being with obesity. Homework will be revised and commented with the clinical researcher during the day 3 training. Knowledge acquisition based on the specific learning objectives will be assessed at the end of day 3 training using self-report questionnaires.

Psychoeducational advice in video format

Participants from the three groups will receive psychoeducational advice in video format that will cover the following obesity-related topics: (a) multicausality of obesity; (b) multidimensional effects of obesity; (c) description of obesity-related bias and its potential adverse outcomes; (d) evidence detailing effective treatments for obesity reminding that it is a complex, chronic condition that requires lifelong management and efforts; (e) importance of body respect and acceptance. This 30 min video will be sent to them via email after their first appointment at the hospital (baseline assessment session).

Treatment as usual

TAU will consist of regular medical, nutritional and/or psychiatric follow-ups with the obesity specialists of the Vall d'Hebron University Hospital and standard routine tests. These visits aim to improve patients' health status, provide them with practical recommendations to achieve a gradual weight loss and engage more with physical exercise, and finally, prevent or treat possible clinical conditions requiring weight improvement, such as type 2 diabetes.

Body-swapping VR intervention (EG1)

Participants of the EG1 will engage in a self-conversation through embodied perspective taking (body swapping), according to which they will be embodied alternately in their own virtual representation and in their counsellor's virtual body by means of 4 experiments with ConVRself.

Experiment 1: embodied discussion about problem and solutions

In this experiment, patients will be embodied in their own (self-) avatar and will maintain a conversation with a counsellor's avatar of their choice. Before being exposed

to the VR experience, patients will be able to choose among different gender-matched counsellor's avatar options, including young normal weight, old normal weight, young overweight and old overweight. Once the experiment starts, the patient, embodied in his/her own body, will start describing his/her positive lifestyle change he/she would like to make, in terms of eating healthier or being more physically active. Then, he/she will be body swapped to the counsellor's body and try to respond to the problem just manifested by the patient, inspired by the MI and CBT techniques learnt in the intensive training. The crucial aspect here is that the patient, from the counsellor's viewpoint, will see a representation of his/her real body when looking at the patient's avatar speaking and moving. The counsellor will also be able to give instructions to the patient's avatar (ie, by pressing buttons on a panel in front, within the VR environment) to make the avatar of the person on the other side automatically stand up, turn around and so on.

Experiment 2: overcoming self-stigmatisation

In this second experiment, the patient will maintain a conversation with the same counsellor as the one chosen for the experiment 1. The patient, embodied in his/her own body, will start describing his/her problem in terms of subjective experiences of body size discrimination due to the condition of living with obesity and how different life would be if he/she considered a specific change in his/her life. Then, the participant will be body swapped to the counsellor's avatar and will respond to the problem posed by the participant using MI skills learnt during the training. While interacting with his/her own self-representation from the counsellor's perspective, the patient's avatar will slowly morph between different body shapes, including the real body size and a 'better' one. It is worth mentioning that throughout the whole experiment we will follow the 'Healthy At Every Size' approach,³¹ and encourage the use of the term 'best weight' (ie, the weight that a person can achieve and maintain while living a healthier and happier life). The objective of this session will be to reduce self-weight bias and acknowledge that weight is not a behaviour, encouraging thus body acceptance). The point here is to show that while the body size may change, the underlying person does not change, and that body size should not influence the real essence of that person. This experience will provide an implicit illustration of the fact that body weight and size are independent of the core personality traits and intrinsic values of a person.

Experiment 3: illustrating the possibility of autonomy

In this experiment, the patient embodied in his/her own body will interact with a future and healthier/happier version of himself/herself. Thereby, in this experiment, the patient will not be interacting with the counsellor's avatar as happened in experiments 1 and 2, but with a future self-avatar in 5-year time, a self-avatar who has achieved his/her 'best weight'. Therefore, the patient will

first observe his/her future self in front of him/her and will ask how that healthy condition was achieved and what steps were taken in order to achieve that healthy body weight. Then, the patient, from the embodied perspective of his/her future self, will come up with his/her own ideas about how he/she has achieved those outcomes. Responses will be also encouraged by the MI and CBT skills acquired during the intensive training, in particular the 'letter to the future' exercise.

Experiment 4: summing up

In this last experiment the participant will be embodied in his/her own body and will maintain a conversation with the same counsellor as the one chosen for the experiment 1. The patient will start describing what has been learnt, experienced and changed in his/her lifestyle during the previous experiments. Then, the participant will be body swapped to the counsellor's avatar who will respond to the participants' achievements using MI skills. In addition, patients will be invited to use the self-conversation to address how to adapt the lessons learnt to achieve a healthier lifestyle and sustain their 'best weight' after the treatment is over. When the self-conversation comes to an end, the counsellor will say goodbye and thank the patient for his/her participation.

VR intervention without body swapping (EG2)

Experiment 1: embodied discussion about problem and solutions

As in EG1, participants will be embodied in a self-avatar. In addition, for the counsellor's avatar, participants will be able to choose among different avatar options that will be gender matched (young normal weight, old normal weight, young overweight and old overweight). Once the VR experiment starts, the patient, embodied in his/her own body, will participate in a 'pre-established discourse' provided by the chosen counsellor, who will ask about the perceived barriers for engagement with a healthier lifestyle and will give practical recommendations about how to achieve a healthier and happier life, in terms of healthy eating and physical activity.

Experiment 2: overcoming self-stigmatisation

For experiment 2, the patient, embodied in his/her own body, will participate in a 'pre-established discourse' provided by the chosen counsellor who will ask about subjective experiences of size discrimination due to the condition of living with obesity in daily life and will give practical recommendations about how to achieve body respect and body acceptance.

Experiment 3: illustrating the possibility of autonomy

For experiment 3, the patient, embodied in his/her own body, will continue participating in a 'pre-established discourse' provided by the counsellor of his/her choice. This counsellor will ask about what could happen in the future if the patient continues in his/her current condition and also talk about the physical and psychological consequences of obesity.

Experiment 4: summing up

In this last experiment, the patient, embodied in his/her own body, will participate in a 'pre-established discourse' provided by the chosen counsellor who will make a summary of the main concepts explained during the previous experiments.

Variables and measurements

The primary outcome will be readiness to change habits and secondary outcomes will include BMI, eating habits, general psychological functioning, body satisfaction, weight bias interiorisation, and eating and exercise habits. Besides, sociodemographic and clinical variables as well as variables related to the adoption of the VR tool in terms of perceived usability, user's acceptability, satisfaction and body ownership (for the experimental groups) will also be evaluated. Finally, we will measure knowledge acquisition related to the specific contents of the training during the intensive training of the EG1.

Sociodemographic and clinical variables

Information about participants' age, gender, level of education, marital and employment status as well as clinical information (ie, presence of physical or mental health problems, comorbidities, medication, illness duration, family history of physical or mental health problems) will be collected through a semistructured interview by clinical researchers of the VHIR. The fulfilment of the inclusion criteria will be assessed through the above-mentioned interview and in case of doubt, patients' electronic health records (EHR) will be consulted. Finally, the weight and height of each participant will be measured at the Vall d'Hebron settings. Weight measurements will always be taken by trained staff of the SOCRATES team at the same time of the day and using a digital scale. The patient will be advised to wear light clothing, go barefoot, and adopt a straight body position while being weighed. Height will be obtained by consulting the patients' EHR and taking its most recent measurement. Finally, BMI will be calculated as weight in kilograms divided by height in square metres $W \text{ (kg)}/H^2 \text{ (m}^2\text{)}$.

Readiness to change

Readiness Rulers (RR)

RR¹¹ are Visual Analogue Scales ranging from 1 to 10 that assess 'importance', 'confidence' and 'readiness' to change. For the present study, these three variables will be measured in terms of (a) achieving a healthy weight and (b) exercising more, while the 'readiness' to change scale will be used as critical response primary variable. The advantage of these scales is that they are brief, easy to use, and possess good psychometric properties in addiction studies.³² In addition, through these scales behavioural change is measured as a continuous process rather than a categorical construct that positions each individual in a specific stage of change according to the transtheoretical model.³³ Lower numbers represent 'not willing' to change, 'not confident' and 'not prepared' to change, scores of 4–6 represent ambivalence in terms of

'somewhat willing/confident/prepared to change', and the higher numbers represent 'very willing/confident/prepared to change' or ongoing attempts of changing. It is worth highlighting that high correlations among the three rulers were found in a previous study with outpatients with alcohol abuse disorder.³⁴

- ▶ The importance ruler: It gauges how important change is to a person at the present time, on a scale ranging from 1 (not at all) to 10 (completely). For example, 'on a scale from 1 to 10, with 10 being very important, how important is for you to achieve a healthy weight?'
- ▶ The confidence ruler: It reflects how confident a person is in committing to change at the present time, on a scale from 1 to 10. For example, 'on a scale from 1 to 10, with 10 being completely confident, how confident are you in your ability to achieve a healthy weight?'
- ▶ Readiness to change ruler: The scale evaluates how much prepared to change a person is, in terms of specific actions that reflect commitment, on a scale from 1 to 10. For example, 'on a scale from 1 to 10, with 10 being completely ready to take action, how ready are you to achieve a healthy weight?'

Stages and processes of change questionnaires in weight management (S-Weight and P-Weight)

As a complementary readiness to change measure, the Spanish version of the Stages of Change in Overweight and Obese People (S-Weight) and the Processes of Change in Overweight and Obese People (P-Weight)³⁵ will be used. The S-Weight consists of five mutually exclusive items that allow allocating participants to one of the five stages of change according to the transtheoretical model of change for weight management: precontemplation, contemplation, preparation, action and maintenance. The P-Weight is composed of 34 items for assessing four processes of change in weight management: (1) emotional re-evaluation (13 items), (2) weight management actions (seven items), (3) environmental restructuring (five items), and (4) weight consequences evaluation (nine items). Responses are on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), with none of the items being reverse scored. Total scores for each process of change are obtained by summing the individual items, in which lower scores reflect no use of a given process of change and higher scores reflect the full use of that process. To make scores from the different subscales comparable, these scores are transformed on a scale ranging from 0 to 100. The questionnaire showed adequate internal consistency (Cronbach α ranging from 0.78 to 0.96) and item-total correlations in its Spanish validation,³⁵ and it is a questionnaire highly recommended for the assessment of readiness to change for weight management and control.³⁶

Eating habits

Three Factor Eating Questionnaire-R18 (TFEQ-R18)

The questionnaire³⁷ assesses three different aspects of eating behaviour: (a) cognitive restraint (CR), (b) uncontrolled eating (UE), and (c) emotional eating (EE).

The questionnaire consists of 18 items using a 4-point response scale, which ranges from 1 (definitely true) to 4 (definitely false), and item scores are summated into the three different subscales: CR, UE and EE. Previous studies reported adequate psychometric properties of the instrument³⁷ while the Spanish version³⁸ showed good internal consistency, ranging from 0.75 to 0.87 in a sample of young healthy adults.

Lifestyle Habits Questionnaire

This self-report questionnaire³⁹ has been developed and validated in Spain for the assessment and quantification of lifestyle habits related to overweight and obesity. It consists of 22 items, each one of which is rated using a 5-point Likert scale ranging from 1 (never) to 5 (always), with higher scores indicating better lifestyle habits. The questionnaire assesses five dimensions related to lifestyle habits: diet caloric intake, eating in search of psychological well-being, physical activity, healthy eating, and alcohol intake.

Other psychological variables

Hamilton Anxiety and Depression Scale (HADS)

The questionnaire⁴⁰ consists of 14 items, 7 for anxiety and 7 for depression, and is used to detect the presence and severity of anxiety and depression among people with physical illnesses. The HADS is scored on a 4-point Likert scale ranging from 0 to 3, with the total score ranging from 0 to 42. Higher scores indicate a greater level of distress. Its Spanish validation among outpatients with physical problems and healthy controls⁴¹ demonstrated good psychometric properties with a Cronbach's α of 0.86 for each subscale.

Body Shape Questionnaire (BSQ-10)

The BSQ is a 10-item self-report instrument, derived from the original 34-item version developed by Cooper *et al.*,⁴² which assesses concerns about body shape expressed by clinical and non-clinical samples. It is based on a 6-point Likert scale questions (never, rarely, sometimes, often, very often and always) with higher scores indicating higher body dissatisfaction. The original 34-version has demonstrated adequate psychometric properties among patients with ED⁴² and patients with obesity.⁴³ Its short 10-item version has also been validated among a Spanish-speaking sample of patients with EDs and demonstrated metric invariance and more consistency compared with other short versions.⁴⁴

Body Image Quality of Life Inventory (BIQLI-SP)

The BIQLI⁴⁵ is a 19-item instrument designed to quantify the impact of one's body image experiences on several relevant facets of his/her psychosocial functioning and well-being in everyday life. Participants rate the impact of their own body image on 19 domains or contexts in which body image has been found to be consequential, including day-to-day emotions, self-esteem, sexuality and social relationships, among others. The instrument uses a 7-point bipolar scale ranging from -3 (very negative effect), to 0

(no impact) and to +3 (very positive impact). The BIQLI showed high internal consistency (Cronbach's $\alpha=0.95$) and good test-retest reliability of 0.79. The Spanish validation of the instrument⁴⁶ showed adequate psychometric properties among a sample of healthy Spanish students.

Modified Weight Bias Internalization Scale (WBIS-M)

The WBIS-M⁴⁷ is a self-report 11-item unidimensional scale that is considered one of the most frequently used instruments for assessing internalised weight stigma across different body weight categories, in both clinical and research settings. Each answer is rated using a 7-point scale, ranging from 1 (strongly disagree) to 7 (strongly agree) with higher scores indicating higher internalised weight bias. Items 1 and 9 are reverse scored. The original WBIS-M⁴⁸ demonstrated high internal consistency with a Cronbach's alpha of 0.94, while the Spanish validation showed excellent internal consistency and test-retest reliability.⁴⁷

Cognitive Reserve Questionnaire (CRQ)

The CRQ⁴⁹ is a self-report questionnaire developed and validated in Spanish population, which evaluates the degree of cognitive reserve in healthy controls and in patients with early signs of Alzheimer's disease. The CRQ is composed of eight items that assess aspects generally related to cognitive reserve, such as own and parental educational status, occupational status, the completion of training courses, musical training, and mastery of languages. In addition, the approximate frequency with which cognitively stimulating activities have been carried out throughout life, such as reading and the practice of intellectual games (ie, crossword puzzles and chess) are assessed. The CRQ score ranges from 0 to 25 and is divided into quartiles. In this way, a score equal to or less than 6 points ($\leq Q1$) would show a low cognitive reserve, between 7 and 9 points ($Q1-Q2$) would correspond to a low-medium cognitive reserve, while scores between 10 and 14 ($Q2-Q3$) would show medium-high cognitive reserve. Finally, scores ≥ 15 points would be classified as high cognitive reserve ($Q4$).

Adherence and satisfaction of VR experiments

Suitability Evaluation Questionnaire (SEQ)

The SEQ⁵⁰ is a 14-item questionnaire designed to measure satisfaction, acceptance, and security of use in VR systems and it was specifically designed for rehabilitation systems using VR. Thirteen questions of the SEQ are based on a 5-point Likert scale plus a last open-ended question offering participants the possibility to add comments, if necessary. According to the SEQ structure, the first seven questions measure enjoyment, sense of being in the system, feeling of success and control, realism, easy-to-understand instructions, and general discomfort. Then, four questions measure dizziness or nausea symptoms, eye discomfort, disorientation or confusion symptoms. The last two questions are focused on the difficulty in the engagement with the system. The global score of

SEQ ranges from 13 (poor suitability) to 65 (excellent suitability). Items Q7, Q8, Q9, Q10, Q12 and Q13 are reversed. Finally, given that the questionnaire is composed of different dimensions, it has not been possible to evaluate its internal consistency. For the specific purposes of the present study, the word 'rehabilitation' of Q11 will be replaced by 'obesity treatment'.

Body ownership

At the end of each VR experiment, participants will do a subjective rating of the illusion of body ownership through a 7-point Likert scale, where -3 means 'strongly disagree' and +3 'strongly agree'. The questions that will be asked were taken from a previous study evaluating ConVRself²⁴ and are the following: 'Even though the body I see might not physically look like me, I feel that the virtual body I see when I look down towards myself is my body' (body ownership-look down); 'Even though the body I see might not physically look like me, I feel that the virtual body I see reflected in the mirror is my body' (body ownership-mirror); 'I feel that the movements of the virtual body are caused by my own movements' (body ownership-movements); 'The body I see in the virtual world physically looks like me' (self-recognition). The same questions will be asked for both the patient's self-avatar and the counsellor's avatar.

Users' experience

A brief interview will be carried out after each experiment to assess participants' satisfaction with the VR experience and acceptability of the ConVRself tool, including questions related to their experience using the self-conversation technique, in a VR context, to cope with their condition.

Knowledge acquisition during general training sessions

MI Knowledge Acquisition Questionnaire

The questionnaire was used in the study of Rubak *et al*⁵¹ to evaluate general practitioners' use of MI after having received a training course in MI. For the specific purposes of the present study, only the first four questions of the questionnaire will be used to assess knowledge acquisition of participants from the EG1. The questions reflect the counselling style adopted by the participant in specific patient cases related to using either MI or 'traditional advice giving' (doctor-centred approach). After reversing individual item scores, the total score is calculated and divided by the number of items, thereby generating a mean response for each question.

Immediate Cognitive Change (CC-Immediate Scale)

The CC-Immediate Scale⁵² is a 7-item questionnaire based on a 7-Likert scale that reflects patient's experience of cognitive change and use of cognitive skills after the training sessions. The measure asks the patient to focus on the training session they just concluded and indicate the extent to which he or she agrees with the items of the scale, where lower scores indicate less agreement.

The instrument will be translated into Spanish by the researchers of the SOCRATES team.

Technical features of the VR experiments

The VR system comprises the VR hardware, a tablet or smartphone, and the VR software. As VR hardware, we are going to use the Oculus Quest 2, a standalone headset that consists of the Head-Mounted Display (HMD) that is worn on the participant's head and hand controllers. The HMD has a vision-based inside-out tracking system that enables it to track in real time the participant's head position and orientation in 3D space. In addition, it can track the participant's left and right hand position and orientation through the hand controllers, which are wirelessly connected to the HMD via Bluetooth. The HMD has a powerful built-in processor that allows processing the incoming tracking and audio data and generates images for the left and the right eye (stereoscopic vision) and spatialised audio to the participant's ears. In addition, the ConVRself system, which is built with the Unity3D games engine, animates and displays 3D scenarios and virtual human representations. In addition to delivering real-time images and audio, it can also cast the images from inside VR via WiFi to a smartphone or tablet. If the HMD delivers audio without additional headphones, the audio is also audible by people nearby. That is why we will instruct the participant to wear headphones so that the HMD sound will not overlap with other audio sources (instructions, explanations, advice) from the experience.

To minimise potential COVID-19-related risks during the VR experiments, the research team will follow a safety protocol including the mandatory use of the mask, the disinfection of the hands with hydroalcoholic gel and the cleaning of the Oculus Quest 2 device with the CleanBox (<https://cleanboxtech.com/>) CX1 disinfection system.

The following subsections describe the ConVRself software and how look alike avatars ('self-avatars') will be created.

Software ConVRself

The ConVRself software has three main stages: calibration, tutorial and the experience. The calibration stage captures tracking data from the participant in an upright seated position while participants wear the HMD and hold the VR controllers in their hands. Collected data will allow computing an internal human representation to drive the embodied avatar's movements for the tutorial and experience stage. The tutorial stage has more detailed audio instructions for the participant and prepares the participant to practice the actual experience.

In the tutorial and experience stages, the participant first embodies a seated look alike avatar. The tracking of the participant's upper body movements is mapped to his/her avatar by using inverse kinematics techniques. A virtual mirror which reflects the scene and the participant's virtual body is positioned to the left of the participant (ie, inside the VR environment).

In the EG1, a virtual counsellor previously chosen by the participant appears in front of the participant (experiments 1 and 4). The virtual counsellor can be also an altered representation of the participant's own appearance (experiment 2), or an older and healthier one (experiment 3). Once in the VR environment, pre-recorded audio instructions ask the participant to describe a personal problem to the counsellor in front of him/her. To make the self-conversation possible, while the participant describes this problem, the HMD's microphone is concomitantly recording the participant's voice and the system is tracking the participant's movements and storing them on the HMD memory. While the participant is explaining his/her problem, the avatar of the virtual counsellor in front may perform simple pre-recorded actions such as nodding, clearing the throat, etc. Then, the participant presses a virtual button on the table in front that transforms the participant's perspective to that of the virtual counsellor, which the participant then embodies (ie, body swapping). The participant's upper body movements are now mapped to his/her new body (ie, the virtual counsellor) and the participant thus can see new mirror reflections from this new embodiment perspective. At this point, the participant is able to see his/her look alike avatar in front and can hear herself/himself describing the problem (the one the participant described before). When the description of the problem finishes, the participant embodied as the counsellor can give advice to his/her original avatar. Once completed, the participant as a counsellor can press a button on the virtual table and will then be transformed back to his/her look alike avatar. From this virtual self-representation, the participant can now listen to the advice he/she gave as a virtual counsellor. Applied audio filters change the participant's original voice to that of the counsellor. The participant can then respond and switch perspectives to give advice and to respond as often as he/she likes. In the EG2, there will be no body swapping. Instead the counsellor's avatar will give pre-recorded advice after the participant has described his/her problem. Two additional movie files show in more detail how the first experiment 'embodied discussion about problem and solutions' works for EG1 and EG2 (see online supplemental video 1 and online supplemental video 2).

Creating look alike avatars

To create the look alike avatars, the system needs as input photos of the participant's face, front and side view photos of the participant's whole body, and body weight and height information. In a semiautomatic process, the system deforms a template body mesh to match the weight and height information, and front and side photos. Face and hair will be inferred from the face photo and mapped onto the 3D human model. Body shape will be adapted for altered representations of the participant (such as morphed body sizes or future healthier/happier self in experiments 2 and 3, respectively). We insert a skeleton and blend shapes to the template mesh in order to be

able to move the body, and for mouth and facial expressions. The avatar data resulting from the process will then be loaded onto the VR device's storage system from which the ConVRSelf system will load it.

Sample size calculation

The *a priori* sample size calculation was based on results from a previous study with individuals with an ED, which implemented a 2-week self-compassionate letter-writing intervention using the readiness to change ruler.⁵³ A medium between-group effect size (Cohen's $f=0.28$) is expected. The calculation was conducted using the software programme G*POWER. The primary analysis will concern the hypothesis that the average level of readiness to change ('preparation' to eat healthier and to exercise more domains) at post intervention in the EG1, based on the RR score, will be higher compared with the EG2 and the CG. Assuming an alpha of 0.05 and a power of 0.80 ($\beta=1$) in a two-way repeated measure analysis of variance, a minimum of 27 participants would be required per study arm (three treatment conditions \times four assessment factors). Allowing for a dropout rate of 20% of study participants from baseline, taking the average score of similar previous studies evaluating VR interventions,^{17–19} a total of 96 participants need to be recruited.

Data management

All data in paper form related to the trial, including the clinical researchers' paper notes, self-report questionnaires and informed consent forms, will be securely stored in a key-protected cupboard in the principal investigator's office at VHIR. Regarding online data, these will be saved on an encrypted online database (REDCap) of the VHIR's password-protected servers. Only authorised researchers directly involved in the study will have access to this data. All data will be stored for a minimum of 5 years and be available on request from the corresponding author. All patients' data will be processed in compliance with the Data Protection Impact Assessment (DPIA) document, which has been developed by the clinical researchers of the VHIR team, in collaboration with the Legal and the Informatics departments of the Vall d'Hebron hospital. The DPIA document will be regularly updated to stay on track with the project and inform about any eventual changes.

After obtaining the signed informed consent from participants, a unique alphanumeric code will be allocated to each one of them so that analyses can be conducted anonymously. The database that links participants to their codes will be securely stored on a password-protected server that will only be accessible to the research team.

Statistical analysis

Clinical researchers of the SOCRATES team at the VHIR will conduct statistical analyses. Fisher's exact test for categorical variables and independent samples t-test for continuous variables will be conducted to assess whether there will be significant group differences in any of the

demographic and clinical measures assessed at baseline. Then, intention-to-treat analyses will be performed using hierarchical linear models (HLMs) to test the effect of the three groups (EG1, EG2, CG) on readiness to change (RR scores on 'preparation' to eat healthier and exercise more), BMI, eating behaviours (TFEQ-R18), lifestyle habits (lifestyle habits questionnaire), psychological functioning (HADS), body satisfaction (BSQ-10), quality of life related to body image (BIQLI-SP) and weight bias internalisation (WBIS-M) over time (T0–T3), while effect sizes (Hedges' g) will be reported.

For the two experimental groups, the effect of treatment condition (EG1 and EG2) on adherence, satisfaction with the virtual experiences (SEQ) and body ownership (body ownership questionnaire) over time (post experiment 1–4), will be assessed using also HLM, while examining the influence of age, gender, cognitive reserve and number of experimental sessions in the results since they may condition performance in the virtual experiments.

DISCUSSION

In this article, we describe the protocol of the clinical validation study proposed for the SOCRATES European project, in which we will assess the clinical efficacy of an embodiment body-swapping virtual intervention with ConVRSelf, through an RCT.

The study will provide an important advance in the psychological treatments of obesity, first, by enhancing the effectiveness of those treatments integrating embodiment and body-swapping techniques in a VR context, and second, by addressing the root causes of obesity following the MI theoretical framework¹¹ and the healthy at every size paradigm.³¹ This is the first time that PLWO are properly trained on MI skills to conduct their own motivational self-conversation using the ConVRSelf platform. By doing so, we hope to find promising long-term effects in the acquisition and maintenance of healthy lifestyle habits in this population, in a sustainable way.

Regarding the limitations of the study, the design of the study brings along some methodological difficulties, especially the risk of a high dropout rate over time, also considering the clinical profile of this population that usually shows low treatment adherence. To address this challenge, we include an extra 20% of patients in the trial to ensure that the statistical power will be maintained despite patient attrition.

The age of the participants and their respective digital literacy may condition acceptability of this novel treatment. Besides, participants' cognitive reserve may also condition their performance on the VR experiments. As such, we will control for these variables in data analyses. In addition, the gender effect in the treatment outcomes will be also examined given that the effect of treatment can differ between male and female patients with obesity, as evidenced in previous studies.⁵⁴ Besides, to obtain a homogeneous sample, we have decided to exclude patients with EDs from our sample. Consequently, the

results of the study cannot be generalised to people with obesity and comorbid Binge-Eating Disorder, which is a common comorbidity.⁵⁵ Finally, the questionnaires assessing adherence and satisfaction with the virtual experience, as well as the ones assessing knowledge acquisition, have not been validated, or in some cases translated into the Spanish context, and this may suppose a further limitation of the study.

As a future perspective of the study, in case of results supporting EG1, it would be of scientific interest to carry out a future dismantling study to ascertain the specific contribution of each one of the different ingredients of the intervention. For example, would ConVRself be so efficacious without MI training? Regarding the project's long-term impact, the overall objective is to bring the embodiment body-swapping paradigm treatment into the mainstream and use it for the treatment of a wide range of behavioural disorders by means of a patient-centred intervention. This paradigm, if shown to be feasible, can drastically change how we approach the treatment of several behavioural disorders both as stand-alone therapy and as complementary tool to standard CBT and other available evidence-based treatments.

ETHICS AND DISSEMINATION

Ethical approval of the study protocol and the informed consent forms was received and approved by the Drug Research Ethics Committee and Research Projects Committee of the Vall d'Hebron University Hospital on 3 August 2021 (PR(AG)224/2021). Patients' participation will be with fully informed written consent, which will be revocable at any time. Findings will be disseminated at a national and international level through peer-reviewed journals, reports to the funding body, conferences among the scientific community, events for the general public, the clinical community and the industry and finally, through an active presence on the project's social media platforms.

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Competing interests MS and BS are the founders of the university spin-off company Virtual Bodyworks.

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