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RESEARCH PROTOCOL

**Evaluating the acceptability, adherence, and efficacy of an innovative mixed reality experience to deliver exposure therapy for contamination-related obsessive-compulsive disorder in adults**

**Lay title: Designing and piloting an innovative mixed reality experience to deliver exposure therapy for contamination-related obsessive-compulsive disorder**

Prepared by Kelvin Wong and Chernyse Wong

Trial is registered with ANZCTR (ACTRN12624000881538p)

Version 2.2, 6-8-2024

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# Administrative Information

## Protocol version history

|  |  |
| --- | --- |
| **Protocol version number** | **Version date** |
| 1.1 | 17/5/2024 |
| 1.2 | 4/6/2024 |
| 1.3 | 25/6/2024 |
| 2.1 | 16/7/2024 |
| 2.2 | 6/8/2024 |
|  |  |

## Principal investigator

|  |  |  |  |
| --- | --- | --- | --- |
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## Other study investigators

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Email** | **Affiliation** | **Comments** |
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| Ms. Chernyse Wei Ren Wong | 104233444@student.swin.edu.au | Swinburne University of Technology | Student investigator (Masters) |

## Study sponsor

|  |  |
| --- | --- |
| **Name** | Swinburne University of Technology |
| **Address** | John Street,  Hawthorn, VIC 3122 |
| **Contact** | kelvinwong@swin.edu.au |

## Funding and resources

Swinburne University School of Health Sciences Small Research Grants (11.2711.33215).

## Study sites

|  |  |
| --- | --- |
| **Site name** | **Site address** |
| Testing Rooms 344, Clinical Trials Research Centre | Level 3, Advanced Technologies Centre, Burwood Rd, Hawthorn, VIC 3122 |

## Independent and/or study safety individuals or committees

The following investigator is responsible for notifying HREC of any concerns relating to safety during this study:

|  |  |  |
| --- | --- | --- |
| **Title** | **Name** | **Email** |
| Dr. | Kelvin Wong | kelvinwong@swin.edu.au |

## Insurance

This trial is covered by Swinburne’s Medical Malpractice insurance.

# Introduction

## Background and rationale

Obsessive compulsive disorder (OCD) is characterised by obsessions – intrusive and persistent thoughts, urges or images that cause significant anxiety

or distress; and compulsions – which are repetitive behaviours or mental acts the individual feels they must perform to alleviate the anxiety or distress (American Psychiatric Association, 2022; APA). It has a lifetime prevalence rate of approximately 2% in adults (Skapinakis et al., 2016) and is associated with decreased quality of life for the individual, their family and/or carers (Macy et al., 2013), as well as significant impairments in social and occupational functioning (APA, 2022). Contamination-related OCD (C-OCD) is one of the most common OCD subtypes (Markarian et al., 2010), where individuals have an overwhelming concern about being in contact with contaminants (e.g., bodily fluids, germs, disease, dirt) and perform compulsions like repeated handwashing.

The recommended first-line treatment for OCD is cognitive-behavioural therapy incorporating exposure and response prevention (ERP; Australian Psychological Society, 2018; APS; National Institute for Health and Care Excellence, 2005). In ERP, individuals are gradually exposed to feared stimuli or situations in vivo and encouraged to resist engaging in compulsive behaviours, with the objective of reducing distress and fear associated with the stimuli. ERP has shown moderate effectiveness in reducing OCD symptoms (Öst et al., 2015). However, in vivo ERP has a dropout rate of 18.7% (Ong et al., 2016). One of these reasons is because patients tend to find confrontation with their greatest fears to be highly aversive. Furthermore, therapists are reluctant to administer ERP for a myriad of reasons: lack of confidence in their competence, patients’ readiness for exposure work, and fear of harming their patients (Law & Boisseau, 2019). Given this poor response to ERP, solutions must be devised to increase its uptake.

To address the aversiveness of in vivo ERP, virtual reality-based ERP (VERP) has gained popularity as a more acceptable alternative for anxiety and related disorders (Carl et al., 2019). A pilot study of VERP for C-OCD demonstrated that it was able to induce anxiety and disgust in participants, but only reduced compulsive and not obsessive symptoms (Miegel et al., 2022). The authors attributed this weaker effect to the moderate sense of immersion that participants reported, and suggested for future research to optimise participants’ immersion in VERP to improve its efficacy.

One way to increase the level of immersion is to use mixed reality. Mixed reality overcomes the limitations of virtual reality as it does not require a virtual world to be constructed – instead it projects virtual stimuli onto the real-world environment, which potentially increases immersion.

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Skapinakis, P., Caldwell, D., Welton, N., Hollingworth, W., Kessler, D., & Baxter, H. (2016). A systematic review of the clinical effectiveness and cost-effectiveness of pharmacological and psychological interventions for the management of obsessive-compulsive disorder in children/adolescents and adults. *Health Technology Assessment, 20*(43). https://doi.org/10.3310/hta20430

## Study objectives or hypotheses

The aim of this study is to develop a MERP experience that targets contamination fears and to assess its feasibility and acceptability in a clinical OCD sample. A secondary aim of this study is to explore whether MERP increases the acceptability of in vivo ERP. We hypothesise that participants will find MERP acceptable, immersive, and able to elicit contamination fears (i.e., feasible). We also hypothesise that acceptability of MERP is positively associated with the acceptability of in vivo ERP.

## Study design

This protocol describes a single-arm pilot study.

# Methods

## Study setting

The setting for this study is Testing Room 344 in the Clinical Trials Research Centre located on Level 3 of the Advanced Technologies Centre (Swinburne University of Technology, Hawthorn Campus).

## Eligibility criteria

Participants will be included in the study if they are aged 18 years or over; meet current DSM-5 diagnostic criteria for OCD with one of their concerns being related to contamination; have the ability to provide written, informed consent; and are fluent in English. Exclusion criteria include a past or present diagnosis of schizophrenia-spectrum or bipolar disorder; a present substance use disorder; acute suicidality; have a cardiac pacemaker or other implanted medical device; have any serious pre-existing health conditions including heart conditions, traumatic brain injury, neck or spinal injury, cognitive impairment; a history of migraines, epilepsy, seizures or other epilepsy-like symptoms; impaired stereo-depth perception, uncorrected astigmatism, or other uncorrected binocular vision abnormalities; or are pregnant.

## Interventions

The MERP experience was designed by Liminal VR. It will be deployed on the Meta Quest 3, a mixed reality headset that superimposes computer-generated imagery on a real-world view. Within the program, participants will be exposed to and asked to interact with virtual contaminants projected onto a real table which are intended to trigger their C-OCD concerns. Participants will use their own hands to manipulate the virtual objects. There are three experiences in the exposure – abstract, realistic, and hyper-realistic. The abstract and hyper-realistic experiences will respectively use a half-eaten burger or a half-eaten mouldy burger as the contaminant, while the realistic experience will have a mouldy burger sealed in a plastic box as the contaminant. The order of experiences will be randomised for each participant.

After putting on the headset, at the start of each experience, participants will see virtual objects projected onto the table. This includes a virtual partition dividing the table into halves – on the left will be the contaminant (burger) with a blue block placed on top of it and a grey block on the table next to it; the right side will have four differently coloured blocks. Participants will be instructed to place their phone on the bottom right corner of the table. They will then be guided to look at the contaminant and to move the grey block to the right side of the table. Then, they will be prompted to move the blue block to the right side of the table and build a tower with all the blocks. Finally, they will be prompted to interact with their phone on the table by unlocking it and finding a photo that makes them feel neutral. Then the experience will end. The table will be cleaned prior to starting the ambiguous experience.

The student investigator will monitor participant adherence to the MERP experience, which will be accomplished by mirroring what the participant sees through their headset onto the student investigator’s phone using the Meta Quest application.

**Visual Analogue Scale.** A visual analogue scale will be used to measure participants’ state levels of anxiety and disgust before, during, and after each experience. The scale ranges from 0 (no anxiety/disgust) to 100 (extreme anxiety/disgust).

**Filler task.** There will be a 5-minute break between each experience where participants will be asked to engage in a neutral filler task (spot the difference puzzles) while still wearing the headset.

## Outcomes

Primary, secondary, and other outcomes – include, analysis metric, explanation of clinical relevance of efficacy and harm outcomes is strongly recommended

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outcomes** | **Screening** | **Baseline** | **Intervention** | **Post-Intervention** |
| Diagnostic Interview for Anxiety, Mood, and OCD, and Related Neuropsychiatric Disorders – select questions from OCD module (DIAMOND; Tolin et al.,2013) | **x** |  |  |  |
| Diagnostic Interview for Anxiety, Mood, and OCD, and Related Neuropsychiatric Disorders – select modules (DIAMOND; Tolin et al.,2013) |  | **x** |  |  |
| Yale-Brown Obsessive Compulsive Scale (Y-BOCS; Goodman et al., 1989) |  | **x** |  |  |
| Vancouver Obsessional Compulsive Inventory II – Mental Contamination Subscale (VOCI-II MCS; Radomsky et al., under review) |  | **x** |  |  |
| Obsessive-Compulsive Inventory – 12 (OCD-12; Abramovitch et al., 2021) |  | **x** |  |  |
| Disgust Propensity and Sensitivity Scale – Revised (DPSS-R; van Overveld et al., 2006) |  | **x** |  |  |
| Treatment Acceptability/Adherence Scale – modified for MERP (TAAS-M; Milosevic et al., 2015) |  | **x** |  | **x** |
| Treatment Acceptability/Adherence Scale – modified for ERP (TAAS-E; Milosevic et al., 2015) |  | **x** |  | **x** |
| Depression Anxiety Stress Scales – 21 (DASS-21; Lovibond & Lovibond, 1995) |  | **x** |  |  |
| Acceptance and Action Questionnaire for Obsessive Compulsive Disorder (AAQ-OC; Jacoby et al., 2018) |  | **x** |  | **x** |
| Visual Analogue Scale |  |  | **x** |  |
| Modified Temple Presence Inventory (TPI; Lohse et al.,2023) |  |  |  | **x** |
| Questions prompting participant feedback on the intervention |  |  |  | **x** |

Note. Primary outcomes are highlighted.

## Participant timeline

Participants will be recruited via psychology clinics in Melbourne (e.g. Swinburne Psychology Clinic), community flyers, and via the principal and co-investigators’ social media accounts and community networks. Potential participants will be phone screened for their study eligibility. Participants who are eligible will be booked in for a single 3-hour session to complete the baseline and intervention phases. At the session, participant consent will first be provided by signing the consent instrument via Qualtrics. The student investigator, who is a provisional psychologist, will then conduct clinical interviews with the participant to determine a current diagnosis of OCD (DIAMOND) and the presence of contamination-concerns (Y-BOCS). A registered clinical psychologist will be available to provide supervision around diagnosis. Participants will then complete the baseline questionnaires via Qualtrics (VOCI-II MCS, OCI-12, DPSS-R, TAAS-M, TAAS-E, DASS-21, AAQ-OC). The student investigator will then guide participants through the MERP experience. Following this, participants will complete the post-intervention questionnaires (TAAS-M, TAAS-E, AAQ-OC, TPI) and be asked to provide qualitative feedback regarding the MERP experience. Participants will be reimbursed with a $30 Woolworths gift voucher for their time.

## Sample size

The study aims to recruit 20 participants. A power analysis is not required for a pilot study.

## Recruitment strategy

Participants will be recruited via psychology clinics in Melbourne (Swinburne Psychology Clinic), community flyers, and via the principal and co-investigators’ social media accounts and community networks. Participants will be reimbursed with a $30 Woolworths gift voucher for their time.

## Allocation of participants

Not applicable.

## Blinding

Not applicable.

## Data collection methods

These are listed in 3.4 and provided in the ‘Materials and measures’ document.

## Data management

All data will be handled in accordance with the Privacy and Data Protection Act 2014 (Vic), with any health information collected handled in accordance with the Health Records Act 2001 (Vic). Specifically, all interview and questionnaire data will be de-identified to maintain confidentiality and anonymity, as well as password protected and stored securely in the Principal Investigator’s OneDrive for Business within Swinburne University’s IT system. The Qualtrics software will collect, and thus store, participants’ responses on the interview and questionnaires. Please see the Qualtrics privacy statement for more information: https://www.qualtrics.com/privacy-statement/. Storage of the data collected will adhere to university regulations (https://www.swinburne.edu.au/privacy/). De-identified data will be accessible to and analysed by the research team, and may be stored indefinitely and shared with other researchers on data sharing platforms (e.g., the Open Science Framework) and/or shared with colleagues for research purposes (e.g., meta-analyses).

The anonymous findings of this study may be submitted for publication in professional publications, academic journals, or conferences. Participants will not be named or identified in any reports or publications arising from this research. If participants want to receive a summary of the findings, they will be able to contact the Principal Investigator via email after data collection is completed by December 2025.

## Statistical/data analysis methods

Jamovi will be used to analyse the data. To assess feasibility and acceptability of the study (Hypothesis 1), descriptive statistics of scores on the TPI and post-intervention TAAS-M will be reviewed. In addition, paired samples t-tests will compare pre- and post-MERP scores on the anxiety and disgust VAS. To assess whether acceptability of MERP is positively associated with acceptability of in vivo ERP (Hypothesis 2), linear mixed effects modelling will be used to predict pre to post changes in TAAS-E from pre to post TAAS-M. We will also conduct a qualitative analysis on participant feedback on the intervention.

## Data monitoring

Not applicable.

## Harms

Safety reports will be assessed on the seriousness, causality, and expectedness of the event to the trial treatment(s), intervention(s), investigational medical product(s), investigational medical device(s). The following are known and expected adverse effects, harms, risks or discomforts associated with trial procedures, treatments, or interventions.

1. Known adverse effects:
   1. Nil known adverse effects are expected to occur following the MERP experience.
2. Known harms, risks, or discomforts:
   1. Risks related to interview and questionnaires. It is possible that participants may experience some discomfort or distress when answering questions about sensitive topics (e.g., OCD symptoms). To mitigate the risk of participants becoming distressed during or after the data collection procedure, we will take the following steps:
      1. Advising participants in all relevant documentation that participation is voluntary (i.e., they can leave any response blank), all information provided is confidential, and that participants are free to withdraw from the research project at any time.
      2. All consent and debriefing documentation to include contact details of the researchers and support services/procedures:

* Contact Dr. Kelvin Wong at [kelvinwong@swin.edu.au](mailto:kelvinwong@swin.edu.au).
* If you are a current student at Swinburne University, contact the free student counselling services on **(03) 9214 8483**, or the after-hours support line on **1300 854 144**.
* Call Lifeline anytime on **131 114**. Lifeline provides anonymous 24-hour counselling assistance. In case of an emergency, dial **000**.
* Contact your local community health centre (which you can find listed in your white pages), or public hospital, and ask to see a Psychologist in the Outpatient clinic.
* Call and arrange an appointment with a psychologist at the Swinburne University Psychology Clinic on **(03) 9214 8653**. This is a low-cost service that is accessible by the community.
* Contact your General Practitioner, ask for a Mental Health plan (under the Better Access to Mental Health Scheme), and ask for a referral to a Psychologist or Clinical Psychologist that they recommend. You can also find professional help using the Australian Psychological Society Find a Psychologist tool ([https://psychology.org.au/find-a-psychologist](https://psychology.org.au/find-a-psychologist%22%20/t%20%22_blank)).
  + 1. Ensuring that all questionnaires request, rather than force, a response.
    2. The student investigator will be trained in progressive muscle relaxation and will apply this to distressed participants. They will also provide participants with contact details for support services/procedures (see above).
  1. Risks related to MERP experience. It is possible that participants may experience physical discomfort such as eye strain, nausea, dizziness, and headaches. Participants may also experience emotional distress during the MERP experience. To mitigate these during or after the intervention:
     1. Participants will be informed about the potential risks in the recruitment material, phone screening, consent form, and right before the intervention.
     2. Participants will be encouraged to remain in the clinic for 15 minutes after the intervention before leaving the premises.
     3. We will advise participants that they are free to stop the intervention at any time.
     4. We will monitor participants for signs of sweating or paleness during the intervention.
     5. A clinical nurse will be on-site to monitor and review participants if required.
     6. The principal investigator is a clinical psychologist and will be on-site to provide support to participants and the student investigator at all times.
     7. The student investigator will be trained in progressive muscle relaxation and will apply this to distressed participants. They will also provide participants with contact details for support services/procedures (see above).

|  |  |
| --- | --- |
| **Adverse Event (AE)** | Any untoward occurrence in a clinical trial participant administered the intervention and that does not necessarily have a causal relationship with this intervention.  *Reporting*   * A record of all adverse event reports will be recorded by the research team and reported to SUHREC via the Adverse Event reporting pathway in ERM. |
| **Serious Adverse Event (SAE)** | Any adverse event that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.  *Reporting*   * Any serious adverse events will be reported to SUHREC via the Adverse Event reporting pathway in ERM. |
| **Significant Safety Issue (SSI)** | A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the study.  *Reporting*  Urgent safety measure   * Reports defined as an **urgent safety measure** that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial will be reported to SUHREC via the Adverse Event reporting pathway in ERM **within 72 hours.** * Reports defined as significant safety issues should be reported to SUHREC via the Adverse Event reporting pathway in ERM **within 15 calendar days** of the research team becoming aware of the issue. |
| **Suspected Unexpected Serious Adverse Reaction (SUSAR)** | An adverse reaction that is both serious and unexpected.  *Reporting*   * All **suspected unexpected serious adverse reactions** occurring in participants will be reported to SUHREC via the Adverse Event reporting pathway in ERM within **15 calendar days** of becoming aware of the case. * All fatal or life threatening Australian **suspected unexpected serious adverse reactions** will be immediately reported to SUHREC via the Adverse Event reporting pathway in ERM, but no later than **7 calendar days** after being made aware of the case, with any follow-up information within a further 8 calendar days. |

## Auditing

Not applicable.

## Research ethics approval

Human research ethics (HREC) approval sought before the commencement of the project.

|  |  |  |  |
| --- | --- | --- | --- |
| **HREC Name** | **Ethics Reference and Project ID** | **Ethics approval date** | **Ethics expiration date** |
| Swinburne University of Technology HREC (SUHREC) | 20247996-19317 | 09/08/2024 | 09/02/2026 |

## Protocol amendments

Protocol modifications will be communicated to SUHREC via ERM.

## Consent or assent

Informed consent will be obtained from all participants.

## Confidentiality

See 3.11.

## Declaration of interests

None.

## Access to data

See 3.11.

## Ancillary and post-study care

See 3.14.

## Dissemination policy

See 3.11.

# Appendices: Study Documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **Document** | **Version #** | **Version date** | **Appendix #** |
| Explanatory statement and consent instrument | 3 | 6/8/24 |  |
| Debriefing script | 1 | 18/6/24 |  |
| Materials and measures | 2 | 16/7/24 |  |
| Recruitment materials (flyer) | 3 | 6/8/24 |  |
| Draft clinical trial registration | 1 | 18/6/24 |  |
| Clinical trial notification |  |  |  |