ISRCTN21831510 https://doi.org/10.1186/ISRCTN21831510

Can we use virtual reality-assisted cognitive behavioral therapy with Inuit in Quebec?

Submission date
26/04/2022

Recruitment status
No longer recruiting

Registration date
29/04/2022

Overall study status
Completed

Last Edited
08/04/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Virtual reality (VR) is an interactive, computer-generated three-dimensional world of images, videos and sounds accessed through a VR headset/system. VR-assisted interventions effectively increase mental well-being, such as building the ability to regulate emotions. In a VR environment, an individual can learn skills for healthy control of emotions either as self-management with a recorded guided relaxation or with a psychotherapist being present. In the current study, we will compare home-environment self-management to at-clinic therapist-guided psychotherapy.

Who can participate?
The treatment is provided for Inuit living in the Greater Montreal Area, between the ages of 14 and 60. If successful, this project will improve access to culturally safe and validated psychotherapy for Inuit living in Quebec, independent of their geographical location.

What does the study involve?
The study involves doing one of two mental health programs for 10 weeks and doing some tests and questionnaires. Both programs involve mental health resources given, in part, with virtual reality (VR).

What are the possible benefits and risks of participating?
When filling out the questionnaires and during and after the psychotherapy session, possible disadvantages include fatigue, discomfort, anxiety, stress or frustration. The questionnaires include questions that can cause mild psychological stress or anxiety. Wearing the VR headset can cause nausea and dizziness. It is temporary and its use will be interrupted immediately. The time the study takes, including travel may be inconvenient.

The research team believes that participating in this research project carries little risk to you. Some people may experience increases in anxiety, unhealthy coping or suicidal ideation through the course of the research project. Wearing the VR headset can sometimes cause epileptic seizures. This risk is minimized using the exclusion criteria for those factors that could predict severe risk.

You may be getting a personal benefit from your participation in this research project, but we cannot assure you of that. Furthermore, we hope the results obtained will contribute to the advancement of scientific knowledge in this area of research, as well as validate new treatments that are culturally safe.

Where is the study run from?
Douglas Mental Health University Institute, Verdun, Quebec (Canada)

When is the study starting and how long is it expected to run for?
January 2019 to December 2024

Who is funding the study?
The study is funded by MEDTEQ FSISSS and Health Brains Healthy Lives (HBHL) grants (Canada)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05631743

Secondary identifying numbers
IUSMD 21-52

Study information

Scientific Title
A virtual reality-assisted cognitive behavioral therapy (VR-CBT) for and with Inuit in Quebec - a proof-of-concept randomized controlled trial

Study objectives
We expect to see preliminary evidence that our VR-CBT can be more successful than guided VR relaxation with Calm Place (self-management) decreasing difficulties in emotion regulation, psychiatry symptoms, increasing well-being, and normalizing responses to stressful stimuli (reactivity).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/10/2021, CIUSSS de l'Ouest-de-l'Ile-de-Montreal Research Ethics Board (Biomedical subcommittee, 6875, boulevard LaSalle, FBC 1116, Montréal, Québec, H4H 1R3, Canada; +1 514 761-6131 poste 2708; cer.reb@douglas.mcgill.ca), ref: IUSMD 21-52

Study design
Single centre proof-of-concept interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Emotion regulation/dysregulation

Interventions
The study design is a two-arm randomized controlled pilot trial (simple 1:1 randomization using a random number generator, unblinded).
We will recruit Inuit in Quebec and randomly assign them to two treatment groups (n=20 each). The active psychotherapy group will receive a ten-week manualized virtual reality (VR) assisted cognitive-behavioral psychotherapy (VR-CBT) at the clinic and guided by a psychotherapist. The VR-CBT will aim at improving emotion regulation.
The comparison group will use a VR self-management program, Calm Place, for building emotion regulation through guided relaxation during ten weeks at home. To evaluate outcome in both groups, we will measure self-reports of emotion regulation, affect, distress and well-being throughout, as well as a psychophysiological reactivity paradigm pre-post treatment.

Intervention Type
Behavioural

Primary outcome measure
Emotion regulation is measured using the Difficulties in Emotion Regulation Scale-16 item (a short, valid measure of emotion regulation) at pre-intervention, during (every two weeks) and post-intervention.

Secondary outcome measures
1. Reactivity to stress via subjective and objective markers is measured during a psychophysiological reactivity testing paradigm. We measure psychophysiology, such as heart rate, heart rate variability, and skin conductance during a baseline and height exposure in VR. The paradigm testing will be done during the initial visit and the last visit after the end of the VR

intervention (minimum of seven and maximum of ten weeks). Visual analogue scales for anxiety, emotional arousal, and emotional valence (VAS-A, EA, EV) are given during each segment of this test as well. We measure changes in reactivity and resting level responses as compared from relaxed (forest walk) to height exposure, expecting lower resting levels of heart rate and increased heart rate variability and decreased skin conductance response. Time Frame: Approximately 1-hour testing session, administered twice.
2. Psychiatric Symptoms (anxiety, depression, PTSD, substance use disorders) will be monitored for change in symptom severity and any loss/gain of probable psychiatric diagnosis (for screening measures). The measures are Generalized Anxiety Disorder Scale-7 item, Patient Health Questionnaire - 9 item, Primary Care Screen for PTSD DSM-5 item (PC-PTSD-5), Alcohol Use Disorders Identification Test- version C, and Drug Abuse Screening Test-10 item, given on at both baselines (pre-post) and every 2-4 weeks during the intervention.
3. We will monitor any change in psychological distress and well-being, Clinical outcome in routine evaluation outcome measure and 10 item (CORE- OM/10) and Short/ Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS/WEMWBS) at baselines (pre-post) and every 2-4 weeks during the intervention.
4. Feasibility of interventions is assessed by the number (percentages) of sessions attended (or completed at home), treatment completion/drop-out, use of the at-home VR program over 10 weeks of the intervention period (researcher recorded)]

Overall study start date
01/01/2019

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Self-identify as Inuk
2. Live in Montreal
3. Between 14 to 60 years of age
4. Proficient in English or French
5. No history of cardiac conditions
6. No history of epilepsy
7. Can provide an emergency contact
8. Tolerance of VR headset
9. Tolerance of sensors
10. Has no current suicidal or homicidal risk
11. No history of psychosis or schizophrenia
12. Current stable mood
13. Is generally mentally stable (no current suicidality, need for hospitalization, etc)
14. Score less than 8 on the Alcohol Use Disorders Identification Test C
15. Score less than 3 on the Drug Abuse Screen Test (10 item version)
16. Not have had any change in psychoactive medications during 4 weeks preceding screening and inclusion in the study

Participant type(s)
Patient

Age group

Mixed

Lower age limit
14 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Does not identify as Inuk
2. Youth below the age of 14 and adults above the age of 60.
3. Self-reported history of psychosis or schizophrenia
4. Current substance abuse, as measured by two screens (AUDIT-C, DAST-10)
5. Other mental or physical condition that might preclude them from the trial (i.e. pre-existing heart conditions, convulsions, acute mental health risk).

Date of first enrolment
30/06/2022

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Canada

Study participating centre
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/05dk2r620

Funder(s)

Funder type
Charity

Funder Name
MEDTEQ

Funder Name
McGill University

Alternative Name(s)
McGill, Université McGill, Universitas McGill, MGU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality of participants and cultural sensitivity.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/05/2023	25/05/2023	Yes	No