

Measuring the effects of 3D Immersion Technology (3Scape) on mental health outpatients

Submission date 05/10/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/09/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Glenrose Rehabilitation Hospital has installed a new technology, 3D Immersion Technology (3Scape). This technology screens videos in three dimensions (like watching a movie in a theater). The goal of these videos is to trigger positive memories, engage individuals, and to bring comfort and familiarity. Screening videos using three-dimensional technology may help older adults to reduce social isolation, depression and anxiety. This study aims to test whether watching these videos has a positive effect on social isolation, depression, and anxiety in older adults.

Who can participate?

Older adults aged 65 and older who are clients of the START Psychiatry Day Hospital program at Glenrose Rehabilitation Hospital

What does the study involve?

Older adults will be a part of the study for 6 weeks. All of the activities will take place at Glenrose Rehabilitation Hospital. Older adults will be assigned at random (like flipping a coin) to one of two groups (the Video Group (intervention) or the Healthy Living group (Control)). In the Healthy Living Group, the older adult will receive the standard care on the START program as usual. They will have the chance to have two sessions with the technology at the end of the study (after the last measurements have been taken).

If an older adult is allocated to the Video Group, he/she will be able to watch five 3D videos that will last around 20 minutes each. The older adult will watch five videos over a 6-week time frame. After each video, they discuss the videos in a small group for around 20 minutes. After the discussion, the researchers will ask each participant to fill out two questionnaires, which will also take about 20 minutes. In total, each session will take 1 hour.

At the last meeting, participants complete the same assessments as in the first to assess their quality of life and symptoms of depression and anxiety. This meeting will take around 30 minutes in total.

What are the possible benefits and risks of participating?

The participants' symptoms of depression and anxiety may decrease. The older adults' overall quality of life may improve. However, they may not receive any benefits from being in this study. There will be no cost for participation.

Where is the study run from?

Glenrose Rehabilitation Hospital (Canada)

When is the study starting and how long is it expected to run for?

November 2020 to February 2021

Who is funding the study?

Glenrose Rehabilitation Hospital (Canada)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Pro00093604

Study information

Scientific Title

Measuring the effects of 3D Immersion Technology (3Scape) on mental health outpatients of the START program at Glenrose Rehabilitation Hospital: a feasibility study

Acronym

3ScapeOnSTART

Study objectives

The purpose of this study is to explore the trial design and the effect of 3Scape videos on older adults' depressive and anxiety symptoms and quality of life, the efficacy in terms of caregiver burden of the START Psychiatry Day Hospital program at Glenrose Rehabilitation Hospital (GRH), and to provide data in order to estimate the parameters required to design a definitive Randomized Controlled Trial (RCT)

Research question(s):

1. Is the designed protocol feasible for conducting a future definitive Randomized Controlled Trial (RCT)?
2. Does the 3Scape videos have an effect on the older adults' depressive and anxiety symptoms, mood, and overall quality of life compared with clients who receive the standard care?
3. What is the overall experience, belief and attitudes of older adults and staff while watching the 3Scape videos?
4. Does the 3Scape videos have an effect on the caregiver burden compared with the same caregivers who provide the standard care?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/02/2020, University of Alberta Ethics Committee (308 Campus Tower 8625 - 112 Street Edmonton, Alberta, Canada T6G 1K8; +1 (0)780 492 0459; reoffice@ualberta.ca), ref: Pro00093604

Study design

Pretest-posttest control group 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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Older adults' depressive and anxiety symptoms, mood, overall quality of life, and engagement

Interventions

The random sequence generation will be prepared in advance by a research team member in an Excel file spreadsheet (RAND function) using permuted block randomization with a block size of 4 and a ratio of 1:1.

Control arm: This group will receive the standard care consisting of a) standard psychiatric nursing care (including some individual counselling), b) medication trials or titration (antidepressants, anti-anxiety meds, sleep meds), and c) group therapies (psychoeducation, cognitive behavioral therapy, stress management groups, dialectical behavior therapy, exercise groups, community engagement/wellness groups, leisure groups, grief and loss groups). Every group runs twice a week for 6 weeks (1.5 months). The patients simultaneously attend three therapy groups for 6 weeks. That is, the patients attend three therapy sessions per day, twice a week. Each patient attends every group at some point during their 20-week stay on the program. The group sessions are each one hour long. Therefore, the patients receive 36 hours of standard care every 6 weeks for a total of 108 hours on the START program.

Experimental arm: In the experimental arm, the stress management group therapy (on the START program) will be replaced by five 3D video screenings (the intervention); other than that, they will receive the same standard care. The five 3D video screenings sessions will be delivered as one session per week for 6 weeks. Each session will take approximately 1 hour, consisting of one 20-minute video screening plus a post-video screening discussion. The intervention will be conducted by an occupational therapist on the START program at Glenrose Rehabilitation Hospital (GRH). The videos will be screened in any order. These videos are based on the principles of reminiscence therapy (RT), with each video highlighting a specific topic that is present in society, including animals, music, and nature. The goal of these videos is to trigger positive memories, engage individuals, and to bring comfort and familiarity. The topics of the videos are: (1) The Path; (2) Remembering; (3) The Dance; (4) The Memory Box; and (5) Baby Animals. A sample of the videos can be found via this link: <https://www.3scapesystems.com/library>. The sessions will take place at the Courage Center at GRH. No more than five participants will be present during each video screening session.

Intervention Type

Mixed

Primary outcome measure

1. Depressive and anxiety symptoms assessed using the GAD7 (Generalized Anxiety Disorder – 7 item scale patient self-report tool) and HoNOS symptoms scale (Health of the Nations scale, a clinician rating tool) at baseline (week 0), posttest (week 6), end of the program (week 20)
2. Mood measured using PANAS (The Positive and Negative Affect Schedule, 20-item self-report questionnaire) measured after each video session, weeks 1, 2, 3, 4 and 5
3. Overall quality of life measured using OPQoL-Brief (Older People's Quality of Life Scale – 13 items, self-reported tool) at baseline (week 0), posttest (week 6), end of the program (week 20)

Secondary outcome measures

Engagement while watching the 3Scape videos measured using an engagement scale developed by the team members in a previous study. This is an eight-point Likert scale that has been shown to be understood by older adults even those with mild cognitive impairments. Measured after each video session, weeks 1, 2, 3, 4 and 5

Overall study start date

12/11/2020

Completion date

12/02/2021

Eligibility

Key inclusion criteria

1. Older adults aged 65 years and older
2. Cognitively intact or minimal cognitive impairment, i.e. Montreal Cognitive Assessment (MOCA) ≥ 22
3. Clients of the START Psychiatry Day Hospital program at GRH

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

24 participants in total (12 in each group)

Key exclusion criteria

1. Unable to provide informed consent
2. Unable to communicate in the English language
3. Acute delirium
4. Significant sensory impairment (that would prevent adequate viewing of the 3D videos)
5. A mental health diagnosis with behavioral disturbances such as potential for aggression or severe agitation
6. Aphasia or other diagnosis that would prevent the subject from completing surveys

Date of first enrolment

12/12/2020

Date of final enrolment

12/02/2021

Locations

Countries of recruitment

Canada

Study participating centre

Glenrose Rehabilitation Hospital START program

10230 111 Ave NW

Edmonton

Canada

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Sponsor information

Organisation

Glenrose Rehabilitation Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.albertahealthservices.ca/info/facility.aspx?id=7822>

ROR

<https://ror.org/02n2n9a06>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Glenrose Rehabilitation Hospital

Results and Publications

Publication and dissemination plan

Additional documents such as study protocol, statistical analysis plan etc. will be available. The research team is planning to submit a manuscript to an indexed journal.

The researchers plan to present the interim results to Alberta-based health service organizations (including the Glenrose Rehabilitation), and the final results at provincial, national, and international conferences. They also plan to publish in peer-reviewed journals and grey literature. They will engage with policymakers and support the SME industry partner in commercializing the technology application. They intend to collaborate with occupational therapy education programs, such as the University of Alberta, to incorporate this technology into their curricula.

Intention to publish date

31/07/2021

Individual participant data (IPD) sharing plan

The dataset will not be made available because the researchers do not have permission to do so. Hard copies of consent forms, questionnaires, and study notes will be kept in a locked filing cabinet in the PI's laboratory (1-45) Corbett Hall. All de-identified electronic study documents will be encrypted and stored on a password-protected computer located in the PI's office.

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	protocol	14/09/2021	21/09/2021	Yes	No