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Can virtual reality-based meditation help reduce anxiety and depression in patients newly diagnosed with acute leukemia?

Submission date
14/05/2022

Recruitment status
No longer recruiting

Registration date
06/06/2022

Overall study status
Completed

Last Edited
02/05/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In contrast to other cancer therapy stages, the initial stage of therapy (induction chemotherapy) causes the highest level of anxiety and depression among newly diagnosed patients with the blood cancer acute leukemia. Heightened anxiety and depression can lead patients to avoid medical messages to reduce the psychological stimulation caused by their disease.

According to previous studies, exercise therapy, cognitive behavioural therapy, mindfulness and meditation have successfully been used to reduce anxiety and depression during the induction chemotherapy period. However, due to cancer-related symptoms (fatigue, pain, emesis) and complications (anemia, bleeding, infection), exercise therapy could actually make a patient's condition worse.

Mindfulness and meditation have been shown to reduce anxiety, depression and negative emotions effectively. However, continual medical treatments and the noisy ward environment can readily interrupt the meditation process. The aim of this study is to see if virtual reality can improve the meditation intervention procedure to reduce anxiety and depression in patients with acute leukemia at the beginning of their treatment.

Who can participate?
Adults newly diagnosed with acute leukemia

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the intervention group receive conventional care plus an immersive experience from a virtual reality device delivering meditation guidance, peaceful background music, and images. Patients in the control group receive conventional care only.

What are the possible benefits and risks of participating?
Benefits not provided at time of registration
Participation in the intervention group is associated with a risk of developing virtual reality-

related symptoms, including general symptoms (dizziness, difficulty concentrating, nausea, drowsiness, fatigue, headache, boredom) and eye-related symptoms (blurred vision, tired eyes, difficulty focusing, sore/aching eyes). Once participants report severe symptoms, the intervention is suspended and participants would be required to quit the study.

Where is the study run from?
Second Affiliated Hospital of Guangzhou University of Chinese Medicine

When is the study starting and how long is it expected to run for?
January 2021 to February 2022

Who is funding the study?
Investigator funded (China)

Who is the main contact?
Bixia Zhang
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Effect of virtual reality combined with meditation on alleviating anxiety and depression among acute leukemia patients during induction chemotherapy

Study objectives
Virtual reality combined with meditation can effectively alleviate anxiety and depression among acute leukemia patients during induction chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2021, Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine (111 Dade Road, Yuexiu District, Guangzhou, Guangdong, 510030, China; +86 20 8188 7233 (35943); llbgs@gzucm.edu.cn), ref: YE2021-020-01.

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of anxiety and depression during induction chemotherapy in previously untreated patients newly diagnosed with acute leukemia

Interventions
Randomization:
Random assignment to the intervention group and control group will be performed by SPSS 24.0 at a proportion of 1:1. The 70 generated codes will be written on the same sized paper and the paper will be placed in opaque, sealed, and sequentially numbered envelopes. A participant receives a numbered envelope after the qualified initial assessment. The paper showing “1” means that the participant is assigned to the control group, and “2” means that the participant is assigned to the intervention group.

Control group:
The control group will receive conventional care alone, including general care, psychological care, and health education. General care: limiting activity depending on patients condition to prevent bleeding, preventing blocking and infection from a peripherally inserted central catheter, protective quarantine used to prevent infection in patients, oxygen inhalation to prevent symptoms caused by anemia, adequate nutrition intake, monitoring changes of patients' vital signs and side-effect caused by chemotherapy. Psychological care: developing a good relationship with patients, identifying patients' negative emotions, and enlightening them. Health education: assisting patients to build up to perception and cognition of disease through imparting knowledge.

Intervention group:
In addition to conventional care, the VR combined with meditation intervention is offered to patients in the intervention group. During the intervention, patients experience a sense of immersion through a VR device delivering meditation guidance, background music, and images. We selected 14 different VR 3D videos (about 20 minutes) which are freely downloaded from the Internet, mixing peaceful background music and meditation guidance referenced by a specialist. An immersive effect is experienced from the natural environment. Patients feel as if they are sitting in a forest or by a beach and are able to meditate following the meditation guidance, listening to authentic natural sounds and peaceful background music to keep a peaceful mind. The intervention procedure will be given once a day for 14 days.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety is measured using State Anxiety Inventory at baseline and post-intervention (2 weeks)
2. Depression is measured using the Center for Epidemiological Studies Depression Scale at baseline and post-intervention (2 weeks)

Key secondary outcome(s))
Quality of life is measured using The Functional Assessment of Cancer Therapy-Leukemia Questionnaire at baseline and post-intervention (2 weeks).

Completion date
12/02/2022

Eligibility

Key inclusion criteria
1. Newly diagnosed with acute leukemia, including acute myeloid leukemia and acute lymphocytic leukemia
2. No relevant previous treatment
3. Aged 18 years and over
4. Normal cognition and comprehension
5. Karnofsky Performance Status 60

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
63

Key exclusion criteria
1. Aggravation in related symptoms, such as severe infection, bleeding, or anemia
2. Complicated with other neoplastic diagnoses
3. In a critical condition
4. Accompanied eye-related diseases
5. Refused participation or participating in other studies

Date of first enrolment
13/01/2021

Date of final enrolment
12/01/2022

Locations

Countries of recruitment
China

Study participating centre
Second Affiliated Hospital of Guangzhou University of Chinese Medicine
111 Dade Road, Yuexiu District, Guangzhou, Guangdong Province, China
Guangzhou
China
510030

Sponsor information

Organisation
Guangdong Provincial Hospital of Traditional Chinese Medicine

ROR
https://ror.org/01gb3y148

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Bixia Zhang, 20192110640@stu.gzucm.edu.cn, the type of data is the original data. After the submission of the paper to a journal, data will become available and will be available for 1 year. Data will be shared with researchers who are specialists in Artificial Intelligence. The type of analysis is Meta-analysis. Consent from participants was obtained and participants were assured anonymity and confidentiality of the information.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2023	02/05/2023	Yes	No