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Virtual nature exposure with hypnosis for hematology patients receiving cellular therapy

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
06/11/2025

Overall study status
Ongoing

Last Edited
06/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Hematopoietic cell transplant (HCT) is a cornerstone treatment for blood cancers but often causes serious side effects that affect physical and psychological well-being. One major challenge is the mandatory protective isolation that exacerbates anxiodepressive symptoms. Nature exposure is known to improve psychological wellbeing, but the patients' immunodeficiency prevents contact with real natural settings during HCT. Virtual reality (VR) can reproduce immersive high-intensity natural environments inside the hospital. Coupling nature exposure with VR and hypnosis may increase the benefits of virtual nature exposure. The aim of this study is to determine whether a combined virtual nature exposure and hypnosis intervention improves psychological outcomes (quality of life, anxiety and depression symptoms, pain, fatigue) in patients compared with standard treatment.

Who can participate?
Patients aged over 18 years old who are undergoing autologous or allogeneic HCT for a hematologic malignancy and are sufficiently fluent in French to fully understand the recorded hypnosis sessions.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the experimental group will receive an intervention consisting of virtual exposure sessions to nature environments (forest or beach) combined with hypnosis, each lasting 30 minutes and delivered over a 2-week period. The control group won't have any intervention.

What are the possible benefits and risks of participating?
No direct benefit is known for the moment given the study's aim to evaluate the effect of the intervention. A minor risk of cybersickness during the intervention could occur.

Where is the study run from?
This study is led at Hôpital Maisonneuve-Rosemont (Montréal, Québec, Canada).

When is the study starting and how long is it expected to run for?
November 2025 to March 2027

Who is funding the study?
This work is supported by the Université de Montréal Maryse and William Brock Chair for clinical research into stem cell transplantation and the Fonds de Recherche du Québec - Oncopole.

Who is the main contact?
Valentyn Fournier, valentyn.fournier@umontreal.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of combining virtual nature exposure and hypnosis on quality of life in patients with hematologic malignancies undergoing hematopoietic cell transplant: a randomized controlled trial

Acronym
RVH003

Study objectives

The aim of this study is to determine whether an intervention combining virtual nature exposure and hypnosis improves psychological outcomes (quality of life, anxiety and depressive symptoms, pain, and fatigue) in patients with a hematological malignancy treated with hematopoietic cell transplantation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/09/2025, Research Ethics Committee of Hôpital Maisonneuve-Rosemont (5415, boulevard de l'Assomption, Montréal, H1T 2M4, Canada; +1 (0)5142523400; bcrc.cemtl@ssss.gouv.qc.ca), ref: H1T 2M4

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Psychological outcomes (quality of life, anxiety and depressive symptoms, pain, and fatigue) in patients with a hematological malignancy treated with hematopoietic cell transplantation

Interventions
After providing informed consent, participants will be randomly assigned to either the experimental group receiving the intervention or the control group. Allocation will be done following a permutated blocks randomization (blocks size of 4, 6, or 8, randomly fixed) to ensure a global balance and limit predictability of allocation procedure. Allocation list was generated before the beginning of inclusions using the blockrand package (Snow, 2020) for R version 4.5.1. Allocation concealment is ensured by keeping sequence secure and only accessible to the person responsible for inclusions.

Participants in the experimental group will receive an intervention consisting of virtual exposure sessions to nature environments (forest or beach) combined with hypnosis, each lasting 30 minutes and delivered over a 2-week period. It will be delivered via a Meta Quest 3 Pro headset. The virtual nature exposure is accompanied by a pre-recorded hypnotic communication played simultaneously .

The control group won't have any intervention.

Intervention Type
Behavioural

Primary outcome(s)
Quality of life measured by the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) questionnaire at pre-transplant (T0: baseline), before the

intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.

Key secondary outcome(s))

1. Quality of life Social/Family subscale scores measured by the specific subscale of the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
2. Quality of life Emotional subscale scores measured by the specific subscale of the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) questionnaire at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
3. Quality of life Functional subscale scores measured by the specific subscale of the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) questionnaire at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
4. Quality of life Transplant-Specific subscale scores measured by the specific subscale of the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT) questionnaire at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
5. Anxiety and depressive symptoms measured by the Hospital Anxiety and Depression Scale (HADS) at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
6. Subjective pain measured by the Brief Pain Inventory – Short Form (BPI-SF) at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
7. Fatigue measured by the Multidimensional Fatigue Inventory – 10 Items (MFI) at pre-transplant (T0: baseline), before the intervention (T1: day +7 ± 1 day post-transplant), after the intervention (T2: day +21 ± 1 day post-transplant), and at 1 month (T3: day +28 ± 2 days) and 3 months (T4: day +100 ±10 days) post-HCT.
8. Cybersickness measured with the Simulator Sickness Questionnaire (SSQ) after each use of the intervention 6 times during 2 weeks betweem T1 (day +7 ± 1 day post-transplant) and T2 (day +21 ± 1 day post-transplant)

Completion date

15/03/2027

Eligibility

Key inclusion criteria

1. Over 18 years old
2. Undergoing autologous or allogeneic HCT for a hematologic malignancy
3. Sufficiently fluent in French to fully understand the recorded hypnosis sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Being treated with a HCT at home
2. Received HCT previously
3. Significant cognitive or psychiatric disorders impairing communication with others
4. Sensory impairments (deafness, blindness) that impact participation in the study

Date of first enrolment
01/11/2025

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
Canada

Study participating centre
Hôpital Maisonneuve-Rosemont
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Sponsor information

Organisation
Hôpital Maisonneuve-Rosemont

ROR

https://ror.org/03rdc4968

Funder(s)

Funder type
University/education

Funder Name
Université de Montréal

Alternative Name(s)
University of Montreal, UDEM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Funder Name
Santé

Alternative Name(s)
Fonds de Recherche du Québec - Sante, Fonds de la recherche en sante du Quebec, Fonds de Recherche du Québec - Santé, Fonds de Recherche du Québec - Santé (FRQS), SciChefQC, FRQS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository on OSF

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes