

Virtual nature exposure with hypnosis for hematology patients receiving cellular therapy

Submission date 06/11/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/11/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/11/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

Contact name

Dr Valentyn Fournier

ORCID ID

<https://orcid.org/0000-0002-1289-8968>

Contact details

Hôpital Maisonneuve-Rosemont
5415, boulevard de l'Assomption
Montréal
Canada
H1T 2M4
+1 (0)4387385583
valentyn.fournier@umontreal.ca

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@sss.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 permuted 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 between 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
5415, boulevard de l'Assomption
Montréal
Canada
H1T 2M4

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 - Santé, Fonds de la recherche en santé du Québec, 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