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Tele-rehabilitation and radiation for patients with gliomas

Submission date
06/11/2025

Recruitment status
Recruiting

Registration date
07/11/2025

Overall study status
Ongoing

Last Edited
11/11/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Primary brain tumours (or tumours that start in the brain) are becoming more common and can lead to serious long-term challenges such as difficulty walking, thinking and talking. Treatments like radiation therapy can help people live longer, but often with significant changes to how they function. Rehabilitation can help improve these changes and enhance the quality of life of people living with primary brain tumours; however, it is almost always in-person and starts after radiation therapy, when many difficulties have already set in.

This study proposes to start rehabilitation at the same time as radiation therapy and deliver it through telerehabilitation. This is therapy provided through video calls and other communication technologies. Telerehabilitation is an effective way to provide therapy to patients with brain tumours at home; however, little is known about how feasible, safe or beneficial it is when started at the same time as radiation therapy.

The goal of this study is to understand if it is feasible for adults who have been recently diagnosed with a primary brain tumour to participate in telerehabilitation during their radiation therapy. It aims to answer whether 1) it is safe and beneficial to deliver an 8-week telerehabilitation program while a person is also receiving radiation therapy; 2) what questionnaires and physical and cognitive tests are feasible for participants to complete, and how often; and 3) what are the experiences of participants with their telerehabilitation.

Who can participate?
Adults 18 years of age or older who have been diagnosed with a primary brain tumour of any grade, and are planning to start their first course of radiation therapy. Participants must also have had brain surgery within the past 12 weeks and have a support person available to provide physical assistance during the study.

What does the study involve?
Participants will be randomly assigned to one of two groups for 8 weeks, starting at the same time as their radiation therapy:
• Active Care Group: Participants will receive telerehabilitation from a physiotherapist, occupational therapist, and/or speech-language pathologist twice a week for up to 8 weeks.

• Usual Care Group: Participants will receive a home exercise program to help build strength and fitness, along with access to BrainHQ, an online program designed to improve thinking and memory.

All participants will complete questionnaires and tests of their physical and thinking abilities every 4 weeks for 12 weeks (a total of 4 times), and again at 26 weeks. At the end of the study, those in the Active Care group will be invited to share their experiences about telerehabilitation in a one-on-one interview.

What are the possible benefits and risks of participating?
Possible benefits: People participating in this study may receive rehabilitation earlier in their disease course, which could help improve their function sooner. Therapy is delivered remotely, so participants can do it from the comfort of their home. Those in the Usual Care group will receive physical and thinking exercises that they can do on their own.

Possible risks: Physical exercise can sometimes lead to muscle soreness, fatigue, falls or injury. In rare cases, it may also lead to heart problems, such chest discomfort or an irregular heartbeat. Participants will be asked to complete questionnaires about their well-being, which may make some people feel uncomfortable.

Where is the study run from?
This study takes place at Toronto Rehab - University Health Network in Toronto, Ontario, Canada

When is the study starting and how long is it expected to run for?
April 2025 to July 2027. The study starts enrolling in June 2025 and is expected to run for 1 year or until recruitment is complete.

Who is funding the study?
1. The University Health Network Foundation, Canada
2. Princess Margaret Cancer Foundation, Canada

Who is the main contact?
Dr Meiqi Guo, Meiqi.Guo@uhn.ca
Physiatrist and Brain Rehabilitation Program Medical Director, Toronto Rehab

Contact information

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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
24-5893

Study information

Scientific Title
Concurrent teleRehabilitation and Radiation (CoRR) for patients with gliomas

Acronym
CoRR

Study objectives
This study has three main objectives:
1) To evaluate the feasibility (recruitment, retention, protocol adherence), safety (adverse events), and preliminary efficacy (cognitive, physical, quality of life outcomes) of an interprofessional, synchronous telerehabilitation program consisting of individualized PT, OT, and/or SLP sessions, compared with usual care among individuals concurrently undergoing radiotherapy for intracranial glioma.

2) To evaluate the feasibility of administering cognitive and physical functioning outcome measures, and to assess quality of life and cancer survival for a future, larger-scale study.

3) To understand patients' and caregivers' telerehabilitation experiences, including their perceived barriers and facilitators to participation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/04/2025, University Health Network Research Ethics Board (LuCliff Place 700 Bay Street, 17th Floor, Suite 1700-01, Toronto, Ontario, M5G 1Z6, Canada; +1 416 581 7849; reb@uhnresearch.ca), ref: 24-5893

Study design
Pilot interventional single-blinded randomized controlled trial with embedded qualitative component

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Feasibility and safety of delivering telerehabilitation early and concurrently with radiation therapy for individuals with primary brain tumours

Interventions
Current interventions as of 10/11/2025:
Intervention arm: Active Rehab
Participants in this arm receive outpatient rehabilitation delivered via synchronous, video-based telerehabilitation concurrent to their radiation therapy by a physiotherapist, occupational therapist, and/or speech language pathologist for up to 8 weeks.

Active Comparator: Usual Care
Participants in this arm receive generic, seated aerobic and strength training exercise instructions, and an online subscription to BrainHQ (exercises for memory, attention and decision-making).

Eligible participants will be stratified for glioma grade (grade ≤3, grade=4) and then randomly assigned to either the active care or usual care group using a 1:1 allocation ratio block design. The schedule will be randomly generated by our biostatistician using the PLAN procedure (SAS 9.4, SAS Institute, Inc., USA).

Previous interventions:
Intervention arm: Active Rehab
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Active Comparator: Usual Care
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instructions, and an online subscription to BrainHQ (exercises for memory, attention and decision-making).

Eligible participants will be stratified for glioma grade (grade ≤3, grade=4) and then randomly assigned to either the active care or usual care group using a 1:1 allocation ratio block design.

Intervention Type
Behavioural

Primary outcome(s)
The percentage of participants who complete the intervention measured using study data from enrollment to the end of the intervention (outpatient telerehabilitation) at 8 weeks

Key secondary outcome(s))
1. Recruitment of participants, measured by the percentage of eligible patients who consent to the trial at the point of initial recruitment contact.
2. Telerehab session attendance (Active Rehab group), measured by percentage of telerehabilitation sessions attended, from enrollment to the end of treatment at week 8.
3. BrainHQ/exercise program usage (Usual Care group), measured by percentage of participants engaging with BrainHQ and/or exercise programs, from enrollment to the end of treatment at week 8.
4. Retention – time needed for data collection, measured by minutes required to complete questionnaires and physical/cognitive assessments, from enrollment to the end of treatment at week 8 and at week 26.
5. Participant experience, measured by semi-structured qualitative interviews exploring perceptions of the telerehabilitation intervention, at week 26.
6. Percentage and type of adverse events (AE) among participants who experienced an AE, measured by distribution and relatedness of event types, from enrollment to the end of treatment at week 8.
7. Change from baseline in the Fatigue Severity Scale, measured by 9-item scale scores ranging from 1 to 7, at 0, 4, 8, 12, and 26 weeks.
8. Overall survival, measured by time from intervention start until death from any cause, at 4, 8, 12, and 26 weeks.
9. Progression-free survival, measured by time from treatment start until disease progression or death, at 4, 8, 12, and 26 weeks.
10. Change from baseline in the EuroQol-5 Dimension 5 Level (EQ-5D-5L), measured by self-report scores across five domains, at 0, 4, 8, 12, and 26 weeks.
11. Change from baseline in the Perceived Medical Condition Self-Management Scale, measured by 8-item self-efficacy scores ranging from 8 to 40, at 0, 4, 8, 12, and 26 weeks.
12. Change from baseline in the Berg Balance Scale, measured by 14-item scores ranging from 0 to 56, at 0, 4, 8, 12, and 26 weeks.
13. Change from baseline in the Timed Up and Go, measured by time in seconds to complete a mobility task, at 0, 4, 8, 12, and 26 weeks.
14. Change from baseline in the Arm Capacity and Movement Test (ArmCAM), measured by 10-item scores ranging from 0 to 100, at 0, 4, 8, 12, and 26 weeks.
15. Change from baseline in the 30 Second Chair Stand, measured by the number of sit-to-stand repetitions in 30 seconds, at 0, 4, 8, 12, and 26 weeks.
16. Change from baseline in the Brief Visuospatial Memory Test - Revised (BVMT), measured by recall scores ranging from 0 to 36, at 0, 4, 8, 12, and 26 weeks.
17. Change from baseline in the Rey Auditory Verbal Learning Test (RAVLT), measured by total recall scores ranging from 0 to 75, at 0, 4, 8, 12, and 26 weeks.

18. Change from baseline in the Sustained Attention to Response Test (SART), measured by errors of commission and omission, at 0, 4, 8, 12, and 26 weeks.
19. Change from baseline in the Digit Span Forward and Backwards Tests, measured by length of digit sequences recalled, at 0, 4, 8, 12, and 26 weeks.
20. Change from baseline in the Wechsler Test of Adult Reading (WTAR), measured by standardised word reading scores, at 0, 4, 8, 12, and 26 weeks.
21. Optional cognitive assessment – Red/Green Test, measured by accuracy and reaction time to red and green stimuli, at 0, 4, 8, 12, and 26 weeks.
22. Optional cognitive assessment – Backwards Counting, measured by the number of correct backward counts within a time limit, at 0, 4, 8, 12, and 26 weeks.
23. Optional cognitive assessment – Number Series Test, measured by the number of correct numerical pattern completions, at 0, 4, 8, 12, and 26 weeks.
24. Optional cognitive assessment – Phonemic and Semantic Verbal Fluency, measured by the number of unique items named in 60 seconds, at 0, 4, 8, 12, and 26 weeks.

Completion date
01/07/2026

Eligibility

Key inclusion criteria
1. 18 years of age of older
2. Planned to undergo an initial course of radiation for a diagnosis of intracranial glioma (any grade)
3. Recent brain surgery (within 12 weeks)
4. Eastern Cooperative Oncology Group (ECOG) performance status greater than (>) 1 at time of enrollment
5. Have a caregiver, friend, or family member available to provide physical support during the initial assessment session and Active Rehab sessions
6. Eligible to be prescribed Brain HQ and home exercises
7. Have an email address, or caregiver, friend or family member has an email address
8. Have cognitive-communicative ability to participate as per clinical judgement
9. Able to provide informed consent, or if not, have a legal decision maker
10. Access to a space with necessary therapy requirements (e.g. must have sturdy chair with armrests; if the room is carpeted, must be low-pile)
11. Able to understand English to the point that they are able to follow instructions and express levels of exertion, pain, distress, etc, as determined by the study team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

120 years

Sex
All

Key exclusion criteria
1. Undergoing a repeat course of in-field irradiation for a recurrent brain tumour
2. Spinal glioma
3. Currently receiving inpatient or outpatient rehabilitation
4. Living in long-term care
5. Severe vision or hearing loss impacting ability to participate actively in rehabilitation
6. Planned surgery that would preclude or affect participation in the protocol
7. Contraindications to radiation therapy (e.g. pregnancy, or trying to conceive)

Date of first enrolment
13/06/2025

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
Canada

Study participating centre
University Health Network - Toronto Rehab
550 University Avenue
Toronto, Ontario
Canada
M5G 2A2

Sponsor information

Organisation
University Health Network

ROR
https://ror.org/042xt5161

Funder(s)

Funder type

Research organisation

Funder Name
University Health Network Foundation

Alternative Name(s)
UHN Foundation, UHNF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Funder Name
Princess Margaret Cancer Foundation

Alternative Name(s)
PMCF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Meiqi Guo, Co-Principal Investigator, meiqi.guo@uhn.ca

The data sets generated and/or analysed during the current study will also be published as a supplement to the results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	15/08/2025	10/11/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.2	07/03/2025	11/11/2025	No	No