ISRCTN17590019 https://doi.org/10.1186/ISRCTN17590019

A comparison of digital, visual, and visuospatial automated feedback systems in simulated bimanual surgical skills training

Submission date
21/10/2022

Recruitment status
No longer recruiting

Registration date
01/11/2022

Overall study status
Completed

Last Edited
01/11/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Virtual reality simulation training platforms provide realistically simulated operative procedures, objective computer-assisted performance assessment, and tailored feedback. Trainees enhance their skills by practising risk-free realistically simulated operative procedures. This study explores the efficiency of feedback in technical skills learning by comparing digital, visual, and visuospatial feedback protocols to practice alone without feedback.

Who can participate?
Students who are currently enrolled in medical schools

What does the study involve?
Participants do a total of six tumor resection tasks with and without feedback depending on their group allocation.

What are the possible benefits and risks of participating?
The study allows students to practice their surgical bimanual skills using a cutting-edge simulation technology with haptic feedback, the NeuroVR neurosurgical simulator. The study involves no risks to participants.

Where is the study run from?
The Neurosurgical Simulation and Artificial Intelligence Learning Centre, McGill University which is located at the Montreal Neurological Institute and Hospital (Canada)

When is the study starting and how long is it expected to run for?
September 2018 to November 2020

Who is funding the study?
1. Brain Tumour Foundation of Canada (Canada)
2. Royal College of Physicians and Surgeons of Canada (Canada)
3. Franco Di Giovanni Foundation (Canada)

4. Montreal Neurological Institute and Hospital (Canada)
5. Fonds de recherche du Quebec–Sante (Canada)
6. McGill University Internal Studentships (Canada)
7. National Research Council of Canada (Canada)

Who is the main contact?
1. Dr Recai Yilmaz, recai.yilmaz@mail.com
2. Dr Rolando Del Maestro, rolando.del_maestro@mcgill.ca

Contact information

Type(s)
Principal investigator

Contact name
Prof Rolando Del Maestro

ORCID ID
https://orcid.org/0000-0003-3733-8921

Contact details
300 Leo Pariseau, Suite 2210
Montreal
Canada
H2X 4B3
+1 (0)519 708 0346
rolando.del_maestro@mcgill.ca

Type(s)
Scientific

Contact name
Dr Recai Yilmaz

ORCID ID
https://orcid.org/0000-0003-0521-3227

Contact details
300 Leo Pariseau, Suite 2210
Montreal
Canada
H2X 4B3
+1 (0)438 979 1299
recai.yilmaz@mail.com

Type(s)
Public

Contact name
Dr Recai Yilmaz

ORCID ID
https://orcid.org/0000-0003-0521-3227

Contact details
300 Leo Pariseau, Suite 2210
Montreal
Canada
H2X 4B3
+1 (0)438 979 1299
recai.yilmaz@mail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of feedback modality on simulated surgical skills learning using automated educational systems

Acronym
FeedbackEffect

Study objectives
1. Students who are provided with feedback information will achieve a higher learning rate in simulated bimanual surgical skills learning than students who practice without feedback
2. Visual and visuospatial feedback will achieve a higher learning rate than providing feedback without visual and visuospatial information

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2021, McGill University Health Centre Research Ethics Board (Neurosciences-Psychiatry, 3801 University Street, #686, Montreal, Quebec, H3A 2B4, Canada; +1 (0)514 398 1046; reb.neuro@mcgill.ca), ref: 2010-270, NEU-09-042

Study design
Multicenter interventional four-arm randomized controlled trial

Primary study design

Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Training bimanual surgical skills of medical students using virtual reality simulation and feedback

Interventions
This is a four-arm randomized controlled trial. Google online random number generator is used to determine participant group allocation between the four groups. Participants perform six simulated tumor resections, a practice subpial tumor resection five times, and a complex realistic brain tumor resection once. The first group acts as the control group that is doing the tasks without any feedback. The participants in the remaining groups receive digital, visual, and visuospatial feedback after completing each task based on their group allocation in three feedback groups. Each session of the simulation trial takes an hour and a half, and data are collected in a single session with no follow-up.

Intervention Type
Other

Primary outcome(s)
Learning measured using the total number of expert benchmarks achieved on previously validated 14 performance metrics with expert-level benchmarks, on a scale of 1 to 14, across five repetitions of the simulated task, assessed after the completion of each task

Key secondary outcome(s))
Performance improvement measured using participant scores, across the five repetitions of the simulated task, on the 14 performance metrics, assessed after the completion of each task:
1. Brain volume removed (cc)
2. Amount of blood loss (cc)
3. Maximum force applied with the dominant hand (Newton)
4. Maximum force applied with a non-dominant hand (Newton)
5. Sum of forces applied with the dominant hand (Newton)
6. Sum of forces applied with a non-dominant hand (Newton)
7. Tumour percentage removed (%)
8. Total tip path length dominant hand (mm)
9. Total tip path length non-dominant hand (mm)
10. Path length index
11. Efficiency index
12. Average instrument tips separation distance (mm)
13. Coordination index
14. Bimanual forces ratio

Completion date
01/11/2020

Eligibility

Key inclusion criteria

Students who are currently enrolled in medical schools.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
120

Key exclusion criteria
There are no exclusion criteria

Date of first enrolment
01/07/2019

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Canada

Study participating centre
McGill University
Neurosurgical Simulation and Artificial Intelligence Learning Centre
Montreal Neurological Institute
3801 University Street
Room E2.89
Montreal
Canada
H3A 2B4

Sponsor information

Organisation
McGill University

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Charity

Funder Name
Brain Tumour Foundation of Canada

Alternative Name(s)
Fondation canadienne des tumeurs cérébrales, BTFC, BrainTumourFdn, The Brain Tumour Foundation of Canada (BTFC), BTFC

Funding Body Type
Private sector organisation

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

Location
Canada

Funder Name
Royal College of Physicians and Surgeons of Canada

Alternative Name(s)
Royal College, The Royal College of Physicians and Surgeons of Canada, Collège Royal, Collège royal des médecins et chirurgiens du Canada, Le Collège royal des médecins et chirurgiens du Canada, RCPSC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Funder Name
Franco Di Giovanni Foundation

Funder Name
Montreal Neurological Institute and Hospital

Alternative Name(s)
Institut et Hôpital Neurologiques de Montréal, Neuro, Montreal Neurological Institute-Hospital, Montreal Neuro, The Neuro, MNI

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Canada

Funder Name
Quebec Health Research Fund

Funder Name
McGill University

Alternative Name(s)
McGill, Université McGill, Universitas McGill, MGU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Funder Name
National Research Council Canada

Alternative Name(s)
Conseil national de recherches Canada, ResearchCouncilCan, NRC, CNRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Canada

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 Dr Recai Yilmaz (recai.yilmaz@mail.com), Dr Rolando Del Maestro (rolando.del_maestro@mcgill.ca). Institution: Neurosurgical Simulation and Artificial Intelligence Learning Centre, McGill University, 300 Rue Léo Pariseau, Suite 2210, H2X 4B3, Montreal, Quebec, Canada, neurosimlab@gmail.com.

The raw simulation performance dataset collected in this study is available from the contact people on a reasonable request. With the approval of both Dr Recai Yilmaz and Dr Rolando Del Maestro, this dataset or any data derived from the raw simulation performance data can be made available to a researcher or a research group that works or will work in collaboration with the research group at the Neurosurgical Simulation and Artificial Intelligence Learning Centre. Data would become available during this time of collaboration and may be used only for scientific research purposes. Participant consent was obtained to use this data for scientific research purposes. Participant data were anonymized, and the data was stored using participant ID numbers without any personal information. Participant re-identification is not allowed.

IPD sharing plan summary
Available on request

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes