

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

<b>Submission date</b> 21/10/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/11/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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–Santé (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](mailto:recai.yilmaz@mail.com)
2. Dr Rolando Del Maestro, [rolando.del\\_maestro@mcgill.ca](mailto:rolando.del_maestro@mcgill.ca)

### **Study website**

<https://neurosim.mcgill.ca/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Rolando Del Maestro

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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](mailto:reb.neuro@mcgill.ca)), ref: 2010-270, NEU-09-042

**Study design**

Multicenter interventional four-arm randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/09/2018

**Completion date**

01/11/2020

## Eligibility

**Key inclusion criteria**

Students who are currently enrolled in medical schools.

**Participant type(s)**

Other

**Age group**

Adult

**Sex**

Both

**Target number of participants**

120

**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  
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## Sponsor information

**Organisation**

McGill University

**Sponsor details**

845 Sherbrooke Street West  
Montreal  
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reb.neuro@mcgill.ca

**Sponsor type**

Hospital/treatment centre

**Website**

<https://muhc.ca/>

**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

**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)**

Collège royal des médecins et chirurgiens du Canada, Royal College, The Royal College of Physicians and Surgeons of 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, NRC, CNRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal with a broad audience.

**Intention to publish date**

30/12/2022

**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