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Real time assessment of patients' and healthcare professionals' reactions during educational training sessions using a simplified electroencephalography and an eye tracking device: a feasibility study

Submission date
26/04/2017

Recruitment status
No longer recruiting

Registration date
16/05/2017

Overall study status
Completed

Last Edited
09/03/2018

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tailoring an educational training session to a learner's reactions in real time leads to a better learning experience. Capturing these reactions is now possible using two devices: a headset allowing a reading of brain activity (simplified electroencephalography (EEG)) and glasses that follow the learner's gaze (eye tracking device). These devices can provide new insights about the nature of the learner's reactions (stress, excitement, engagement, focus, interest and relaxation), the moment at which they are experienced and the effect of the different components of the educational training session. However, the feasibility and acceptability of using these devices still need to be assessed in face-to-face and online educational training sessions. The main aim of this study is to assess the acceptability and feasibility of using a simplified EEG (EMOTIV's EPOC+ ©) and an eye tracking device (Pupil © Headset) to measure patients' and health professionals' reactions. The secondary aims are: to obtain information about emotive and cognitive reactions measured by the EEG (stress, excitement, engagement, focus, interest and relaxation), gaze measured by the eye tracking device, and the comfort of wearing these devices; to establish a process to transfer data from these devices to a database and to produce statistics; to compare the data obtained by EEG with visual scales assessing the same reactions.

Who can participate?
Healthcare professionals (nurses working in the coronary care unit and cardiology residents) and patients in the coronary care unit who are either close to being discharged home or have an altered state of consciousness (delirium).

What does the study involve?
The nurses are asked to wear both devices for 30 minutes during an online educational training session. The cardiology residents are asked to wear the EEG device for 60 minutes during a face-

to-face educational training session. The patients close to being discharged are asked to wear both devices for 30 minutes during an educational training session. The patients with an altered state of consciousness wear the EEG device for about 10 minutes. The following measurements are taken: the time needed by the research team to set up each device; the number of measurements obtained by each device versus the number expected; the difficulties encountered setting up the devices; the signal quality of the EEG; and the comfort of the participants while wearing the devices. All measurements are taken by the research nurse and recorded in a database except for the measurements related to the comfort of the participants which are measured using a visual scale. The measurements taken by the simplified EEG (stress, excitement, engagement, focus, interest, and relaxation) are continuously and automatically recorded by the device software. These scores are compared with the ones reported by the patient after the training program using visual scales. The participant's gaze is also measured using the eye tracking device.

What are the possible benefits and risks of participating?
The results of this study may be used to improve educational training sessions for patients and healthcare professionals. No risks are anticipated. No inconvenience is anticipated except for the time needed to participate.

Where is the study run from?
Montreal Heart Institute Research Center (Canada)

When is the study starting and how long is it expected to run for?
September 2016 to March 2018

Who is funding the study?
1. Montreal Heart Institute Foundation (Canada)
2. The funding of Sylvie Cossette's laboratory (Canada)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
#2016-2134

Study information

Scientific Title
Assessment of emotional-cognitive reactions in patients and health professionals volunteers during educational training sessions using a 14-channel electroencephalography and eye tracking: a feasibility study

Acronym
RECORD

Study objectives
No hypothesis was formulated.

The main aim of this pilot study is to assess the acceptability and feasibility of using a 14-channel electroencephalography (EMOTIV's EPOC+ ©) and an eye tracking device (Pupil © Headset) to measure patients' and health professionals' emotive and cognitive reactions during educational training sessions.

The secondary aims are:
1. To obtain information about the standard deviations of the 6 variables measured by the 14-channel electroencephalography (stress, excitement, engagement, focus, interest, and relaxation), the variable by the eye tracking device (spatial, temporal and frequencies measures of the), and the comfort of participants wearing these devices
2. Establish a process to transfer data from these devices to an Excel database. Produce some preliminary statistics
3. Compare the data obtained on the variables measured by the 14-channel EEG device with visual analog scale assessing the same constructs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Montreal Heart Institute, 23/03/2017, ref: #2016-2134 – RECORD

Study design
Single-centre non-randomized pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cardiologic care

Interventions
Participants will be asked to wear the 14-channel electroencephalography and/or the eye tracking device for about 15 minutes while they realize either a pre-existing online or face-to-face educational training session.

Regarding the feasibility arm of the study, the following variables will be measured:
1. Time needed by the research team to install and calibrate each device
2. Number of measures obtained by each device versus the number expected
2. Difficulties encountered in the installation of the devices
3. Signal quality of the 14-channel electroencephalography

Regarding the acceptability arm of the study, the following variable will be measured:
1. Comfort of the participants while wearing the devices

Intervention Type
Device

Primary outcome measure
1. Acceptability of using the 14-channel electroencephalography and the eye tracking device, measured by using the visual analogue scale right at the end of the educational training session
2. Feasibility of using the 14-channel electroencephalography and the eye tracking device, measured by recording the following variables during the experiment:
2.1. Time needed by the research team to install and calibrate each device
2.2. Number of measures obtained by each device versus the number expected
2.3. Difficulties encountered in the installation of the devices
2.4. Signal quality of the simplified electroencephalography. Regarding the acceptability arm of the study, the comfort of the participants while wearing the devices will be measured
3. Emotive and cognitive reactions (stress, excitement, engagement, focus, interest, and relaxation): continuously and automatically interpreted by the MyEmotiv software (produced by the EMOTIV EPOC+ © manufacturer) which provides a score between 0 and 100 for each measure; a higher score indicates a more intense reaction. These scores will be compared with the ones reported by the patient right after the training program by using visual scales

Secondary outcome measures
No secondary outcome measures

Overall study start date
22/09/2016

Completion date
23/03/2018

Eligibility

Key inclusion criteria
All participants must be aged 18 or over and be able to speak and read French

Patients
1. Non-hospitalised:
1.1. Completing an online educational training session (TAVIE@COEUR)
2. Hospitalised at the coronary care unit and close to be discharged:
2.1. Hospitalized at the coronary care unit
2.2. Identified by the assistant-chief nurse as potentially being discharged in the next 48 hours
2.3. Completing an online educational training session (TAVIE@COEUR)
3. Hospitalised at the coronary care unit and presenting an altered state of consciousness:
3.1. Hospitalized at the coronary care unit
3.2. Identified by the assistant-chief nurse as having score ≥ 5 at the Ramsay Coma Scale OR as having received a delirium diagnostic
3.3. Have a family member available to consent for the patient

Healthcare professionals
1. Residents: Attending a cardiac-related educational training session provided to a group of medical trainees
2. Coronary care unit nurse: Completing an online educational training session (MOTIV@COEUR)

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 participants; 10 healthcare professionals and 10 patients

Key exclusion criteria

Participants will be excluded if they wear an implantable medical device (e.g. pacemaker, defibrillator, mechanical heart) as radio emissions may interfere with appliances, medical equipment, and automated medical dosimetry systems

Date of first enrolment
23/03/2017

Date of final enrolment
23/03/2018

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Heart Institute
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Sponsor information

Organisation
Montreal Heart Institute Reasearch Center

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Sponsor type
Research organisation

Website
http://www.icm-mhi.org/en/index.html

ROR

https://ror.org/03vs03g62

Funder(s)

Funder type
Charity

Funder Name
Montreal Heart Institute Foundation

Funder Name
The funding of Sylvie Cossette's laboratory

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal for Fall 2017

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository "Centre de recherche de l'Institut de Cardiologie de Montréal". No weblink is available.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No