ISRCTN43629398 https://doi.org/10.1186/ISRCTN43629398

The impact of technology supported mindfulness training on attention and emotion

Submission date
15/06/2016

Recruitment status
No longer recruiting

Registration date
16/06/2016

Overall study status
Completed

Last Edited
01/12/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mindfulness refers to a mental state achieved by becoming aware of the present moment, while recognizing one's thoughts, feelings and bodily sensations. Mindfulness training (MT) programs are becoming more common in the treatment of a range of mental health conditions, as well as improving attention and lowering stress. Research support for MT is currently mainly based on weekly instructor-led group sessions. It is unknown whether patients may benefit from technology-supported MT (tsMT), in which meditation is delivered individually, without the need for a facilitator, travel to a training site, or the presence of a supportive group environment. The aim of this study is to find out whether tsMT could help improve attention and feelings of wellbeing more effectively than algebra training.

Who can participate?
Healthy adults with good eyesight who are fluent in English.

What does the study involve?
After learning about the study and agreeing to take part, participants are first asked to complete some questionnaires to measure their mood and sense of well-being, and also to perform a task that involved naming colour words that were sometimes presented in a different colour (Stroop test), in order to measure attention. Participants are then randomly assigned to one or two groups. Those in the first group practice meditation using a brain feedback headband (which provides sounds that reflect the brain's state, such as beach waves and wind) and iPad for 10 minutes a day for six weeks. Those in the second group practice algebra on an online training program for 10 minutes every day for six weeks. After each practice session, participants fill out a brief survey to confirm their practice and rate their experience. Participants are required to practice on at least 75% of these days to stay in the study. At the end of the 6 weeks, participants return to the study centre and repeat questionnaires and colour naming task.

What are the possible benefits and risks of participating?
There are no known benefits of participating, although there is a possibility that taking part in the mindfulness training could promote a greater sense of wellbeing. There are no risks involved with participating in this study.

Where is the study run from?
Baycrest Health Sciences Centre (Canada)

When is the study starting and how long is it expected to run for?
March 2014 to December 2015

Who is funding the study?
Ontario Centre for Excellence Voucher for Innovation Program (Canada)

Who is the main contact?
Professor Norman Farb
norman.farb@utoronto.ca

Contact information

Type(s)
Public

Contact name
Prof Norman Farb

ORCID ID
http://orcid.org/0000-0002-8407-2938

Contact details
University of Toronto Mississauga
3359 Mississauga Road
Dept of Psychology - Deerfield
Mississauga
Canada
L5L 1C6
+1 905 828 3859
norman.farb@utoronto.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32099

Study information

Scientific Title
Attentional and Affective Consequences of technology supported Mindfulness Training

Acronym
AACtsMT

Study objectives
Technology-supported mindfulness training will produce greater improvements to attention and subjective well-being than an active control training condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Clinical Ethics Committee Baycrest Health Sciences Centre, 21/11/2014, ref: 12-54
2. University of Toronto Research Ethics Committee, 24/04/2015, ref: 31579

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
General affective health

Interventions
Following initial telephone screening interviews, participants sre invited to attend assessment sessions at the Rotman Research Institute at Baycrest Health Centre in Toronto, Canada, a Health Centre fully affiliated with the University of Toronto. Participants complete a short battery of attention and executive control tasks, and self-report measures of well-being. Participants are blind to experimental condition while completing the baseline assessment battery, before being informed of their group assignment to the mindfulness training or active control conditions. Randomization is carried out using a random number generator in the MATLAB computing environment, which randomly assigns sub-blocks of 4 participants to ensure even recruitment throughout the study, i.e. within each sub-block, 2 participants are assigned to the mindfulness training group and 2 are assigned to the control group. Randomization is performed by the study PI and communicated to the research assistants upon participant booking without any direct contact between the PI and participants.

Mindfulness Training: To deliver the technology supported MT intervention, Interaxon Inc.'s Muse is employed, a wireless EEG headset and accompanying mobile device software application. Participants are provided with a Muse headset, iPod with the pre-installed Calm App, charging cables and headphones. Participants are taught to set up the Muse headset and associated software application, which delivers a guided-meditation application focusing attention on the breath, a core introductory meditation practice in mindfulness training. The application provides step-by-step instructions on operating the headset and guides participants through MT sessions. Users begin a mediation session by clicking on an icon and are lead through the exercise by a voice recording. The Muse headset collects data and transmits the information to the application that provides real-time auditory feedback during the meditation session. In a virtual beach environment, the auditory feedback consists of beach waves and wind sounds that reflect the brain's state, allowing the trainee to gauge their performance in attaining a meditative state. A calm score is calculated at the end of the session, which reports the length of time the brain was calm during the session.

Active Control Training: Participants are enrolled in a free, online, high school level algebra class (Khan Academy), in which they are presented with a mixture of brief lectures and math problems. Daily training consists of completing 10 minutes of course material. The program allows participants to learn concepts through feedback/hints, and watching videos demonstrating how to solve similar problems. At the end of learning each concept, participants receive a score of correct responses and are awarded a mastery level to move on to the next concept.

The daily training lasts for 6 weeks (42 days). Participants are required to complete at least 32 /42 (75%) sessions over the six weeks of training. A successful training session consists of completing either a 10-minute meditation session with the Muse or completing 10 minutes of algebra practice problems on Khan Academy. Following the 6 week training period, participants attend a post-intervention assessment. There is no subsequent follow-up period.

Intervention Type
Behavioural

Primary outcome measure
1. Affective symptom severity is measured using the Public Health Questionnaire (PHQ-SADS) at baseline and 6 weeks
2. Attention is measured using reaction time on a behavioural Stroop Task at baseline and 6 weeks

Secondary outcome measures
1. Dispositional mindfulness is measured using the Freiburg Mindfulness Inventory (FMI) at baseline and 6 weeks
2. Current emotional state is measured using the Positive and Negative Affective Schedule (PANAS) at baseline and 6 weeks
3. Well-being (physical, psychological, social, and environmental) is measured using the brief version of the World Health Organization Quality of Life scale (WHOQOL-BREF) at baseline and 6 weeks
4. Personality trait impact on intervention responsiveness is measured using the Big Five Inventory (BFI) personality checklist at baseline and 6 weeks

Overall study start date
01/03/2014

Completion date
15/12/2015

Eligibility

Key inclusion criteria
1. Fluency in English
2. Normal or corrected to normal vision
3. Aged 18 and over

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Presence of any neuropsychological or psychiatric condition that may influence the functioning of the nervous system
2. History of head injury
3. Prior meditation experience

Date of first enrolment
05/01/2015

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Canada

Study participating centre
Baycrest Health Sciences Centre
3560 Bathurst Street
Toronto
Canada
M6A 2E1

Sponsor information

Organisation
Ontario Centres for Excellence (OCE)

Sponsor details
156 Front Street West
Suite 200
Toronto
Canada
M5J 2L6
+1 416 861 1092
Martin.Lord@oce-ontario.org

Sponsor type
Government

Website
http://www.oce-ontario.org/

ROR
https://ror.org/01t8nk565

Funder(s)

Funder type
Government

Funder Name
Ontario Centre for Excellence Voucher for Innovation Program

Results and Publications

Publication and dissemination plan
Planned submission to peer reviewed, open source journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/11/2016		Yes	No