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Mindfulness virtual community

Submission date	Recruitment status	[X] Prospectively registered
19/06/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/06/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2025	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The prevalence of diagnosable mental illnesses is increasing on North American university campuses. The Canadian health care system faces serious service challenges that result in long wait-times for mental health care. This is of particular concern for youth entering post-secondary education and affected by immediate and long term financial stressors and insecure futures. These stressors are often worse for youth from vulnerable socioeconomic and ethnic minority communities. Mindfulness-based programmes have been found to positively impact psychological and physical health with multiple meta-analyses demonstrating positive impacts in clinical and non-clinical populations. At York University, the mindfulness-based Healthy Student Initiative (HSI) programme has evolved over five years, offering group-based mindfulness meditation training to students throughout the school year. Despite assessed benefits, the ongoing question has been how to scale-up the HSI program to reach more students. This led to combining mindfulness-based self-help modules with an online community platform. The Mindfulness Virtual Community for students includes the three core elements: mindfulness-based self-help modules, online group meetings moderated by a psychologist (synchronous) and peer-to-peer discussion boards moderated by a psychologist (asynchronous). The aim of this study is to help students adopt mental health-promoting behaviours that may reduce their needs to access counselling services.

Who can participate?
Students aged 18 and older who are currently enrolled at York University (Canada).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive an online programme to complete which includes mental health education, discussion boards, video conferences/messaging with counselling psychologists, and email reminders. Those in the second group are placed on the wait list where they have access to the programme at the end of the study. Participants are followed up at the end of the study to compare their anxiety levels, stress and overall health to prior to the programme.

What are the possible benefits and risks of participating?
Participants may benefit from the materials on common mental health challenges and practices

of mindfulness, which can improve their overall quality of life, satisfaction and can enhance academic performance. There are no notable risks however, participants are provided with a resource list with available services in the community and on campus.

Where is the study run from?
York University (Canada)

When is the study starting and how long is it expected to run for?
June 2015 to December 2018

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
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Additional identifiers

Protocol serial number
York University REB Certificate #: e2017 - 181

Study information

Scientific Title
Mindfulness Virtual approaches for students' wellbeing on Campus: A randomised controlled trial

Acronym
MVC

Study objectives
Primary hypotheses:
1. Symptom scores for stress, depression and anxiety at T2 will be significantly better in the
2. Mindfulness virtual community (MVC) intervention group when compared with wait-list control group
3. Quality of life scores and program satisfaction at T2 will be significantly better for the MVC intervention group when compared with the wait-list control group
4. Rates of classroom absenteeism and self-reported disability days at T2 will be significantly lower for the MVC intervention group when compared with the wait-list control group

Secondary hypotheses:
1. Symptom scores for stress, depression and anxiety at T2 compared to T1 will be significantly

reduced for MVC intervention group when compared with the wait-list control group
2. Level of mindfulness will be significantly higher at T2 compared to T1 for the MVC intervention group when compared with the wait-list control group
3. Quality of life scores at T2 compared to T1 will be significantly higher in the MVC intervention group when compared with the wait-list control group
4. Student engagement and experience will overall be significantly better for the MVC intervention group when compared to the wait-list control group
5. Rates of classroom absenteeism and self-reported disability days at T2 compared to T1 will be significantly lower for the MVC when compared to the wait-list control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
York University Office of Research Ethics, Human Participants Review Sub-Committee (HPRC), 02 /06/2017, ref: #e2017- 181

Study design
Double blind single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mental health including stress, anxiety and depression

Interventions
Participants complete an informed consent form and are randomly assigned to one of two study arms. Allocation is done by opening a sequentially numbered envelope containing a randomly-generated allocation by an off-site biostatistician.

Study arm 1 Wait List: This is a control arm for the study. Participants randomised to this arm are asked to complete two assessments over the period of the study (8 weeks). These assessments include a baseline and follow-up assessments (at baseline and week 8). Participants will be offered a list of available resources to support mental health. After 8 weeks, participants in this arm have an opportunity to access the mindfulness videos and exercises.

Study arm 2 Mindfulness Virtual Community (MVC) online intervention: Participants allocated to this arm complete baseline and follow-up (baseline and week 8) assessments, receive the list of resources, and also participate in a series of interactive, online activities. These activities include:
1. Mental health education (general and youth-specific) and mindfulness meditation practice, drawing from CBT principles, delivered as 12 audio-video recorded modules that will be released gradually at about 1-2 modules per week that participants may watch on their computers, tablets or phones at their own convenience
2. Anonymous, asynchronous peer-to-peer discussion boards (moderated by a counselling psychologist) pertaining to mental health and mindfulness practice
3. Anonymous, 20- minute synchronous video conferences (group-based) led by a counselling psychologist, scheduled 1-2 days a week, to engage participants on topics covered in the 12

modules
4. Direct messaging with the counselling psychologist
5. Email reminders from project staff when new modules and video conference sessions become available.

Participants are followed up at the end of the study with online surveys to be assessed for their anxiety levels, stress and health.

Intervention Type
Behavioural

Primary outcome(s)
1. Depression level is measured using Patient Health Questionnaire (PHQ-9) using a self-administered online survey at baseline and week eight
2. Anxiety level is measured using Beck Anxiety Inventory (BAI) using a self-administered online survey at baseline and week eight
3. Stress level is measured using Perceived Stress Scale (PSS) using a self-administered online survey at baseline and week eight

Key secondary outcome(s))
1. Quality of Life is measured using Quality of Life Scale (QOLS) using a self-administered online survey at baseline and week eight
2. Student Satisfaction is measured using Brief Multi-Dimensional Students' Life Satisfaction Scale (BMSLSS) using a self-administered online survey at baseline and week eight
3. Mindfulness level measured using Brief Five Facet Mindfulness Questionnaire (BFFMQ) using a self-administered online survey at baseline and week eight

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Currently enrolled as an undergraduate student at York University (Toronto, Keele campus) and planning to remain so for the coming semester
3. Reading, writing and conversing in English
4. Willing to be randomised into an intervention which may require up to 2 hours per week of their time

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
160

Key exclusion criteria
1. Cannot meet the time commitments of the trial
2. Not comfortable in reading, writing and speaking English
3. Self-reported symptoms of psychosis (e.g. hallucinations, hearing voices) in last 30 days
4. Self-report dependencies on alcohol, illicit drugs, or prescription drugs used for non-medical reasons in last 30 days

Date of first enrolment
23/06/2017

Date of final enrolment
20/12/2018

Locations

Countries of recruitment
Canada

Study participating centre
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Sponsor information

Organisation
York University

ROR
https://ror.org/05fq50484

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

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 is not expected to be made available due to the data set containing sensitive mental health participant data and, hence, not available publicly. All dataset will be held by the Nominated Principal Applicant (PI), Dr. El Morr at York University. On receiving a request for release of data, the three PIs will make a joint decision.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/07/2020	26/11/2020	Yes	No
Results article		04/07/2023	04/07/2023	Yes	No
Results article	Secondary analysis predicting effectiveness	13/04/2024	30/06/2025	Yes	No
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