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Mindfulness virtual community

Submission date
07/12/2016

Recruitment status
No longer recruiting

Registration date
20/12/2016

Overall study status
Completed

Last Edited
03/12/2020

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
Diagnosable mental illnesses are becoming increasingly common on North American university campuses. Meanwhile the Canadian health care system confronts serious service challenges, which means long waiting times for mental health care. This is of particular concern for youth entering higher education under an economic downturn, affected by immediate and long term financial stressors and insecure futures. These stressors are often amplified for youth from vulnerable poor and ethnic minority communities. The goal of the present research is to help students adopt mental health-promoting behaviours that may reduce their needs to access psychiatric and/or clinical counselling services. Mindfulness is a technique which involves learning to become more aware of the self and the present moment. Mindfulness-based programs have been found to have a positive effect on the mental and physical health. At York University, the mindfulness-based Healthy Student Initiative (HSI) program has developed 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 the innovative of 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 investigate the effectiveness of the Mindfulness Virtual Community.

Who can participate?
Adults who are undergraduate students at York University (Toronto, Keele campus).

What does the study involve?
Participants are randomly allocated to one of four groups. Those in the first group take part in the Mindfulness Virtual Community (MVC). This consists of interactive, online activities for 4 weeks: general and youth-specific mental health education and mindfulness modules delivered via audio and video recordings and made available three times a week, for four weeks (total of 12 modules); anonymous, asynchronous peer-to-peer discussion boards; and anonymous, 20-minute synchronous video conferences (group-based) led by a psychologist. Those in the second group receive Mindfulness Cognitive-Behavioural Therapy (CBT-M). This consists of one-hour sessions each week for 8 weeks, including mental health education and guided mindfulness exercises run by a psychologist or an advance-level psychology trainee. Those in the third group

are placed on a waiting list to take part in the therapy and are given access to a list of available resources to support mental health. Those in the fourth group are also placed on a waiting list and given access to resources as well as access to the online mental health education modules. At the start of the study and then again after four and eight weeks, participants in all groups complete a number of questionnaires designed to assess their mental wellbeing and stress levels.

What are the possible benefits and risks of participating?
The focus of this research is mental health and the development of a mindfulness practice. All participants in this study will have the direct opportunity to benefit from online materials on common mental health challenges and practices of mindfulness The focus of this research is mental health and the development of a mindfulness practice. Some participants will have the opportunity to join face-to-face or virtual group-based sessions on mindfulness. All participants will have earn either course credit (2%) or a cash honorarium ($50). We do not anticipate that participation in the study will cause any extreme distress. Nonetheless, all participants will be provided with a Resource List on available services in the community and on campus. There are no notable risks involved with participating.

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

When is the study starting and how long is it expected to run for?
January 2016 to March 2017

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

Who is the main contact?
1. Professor Christo El Morr (scientific)
elmorr@yorku.ca
2. Professor Farah Ahmad (scientific)
farahmad@yorku.ca
3. Professor Paul Ritvo (scientific)

Study website
www.studentsmentalhealth.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
York University REB Protocol #1470

Study information

Scientific Title
Mindfulness virtual and face-to-face approaches for student mental health: A randomized controlled trial

Acronym
MVC

Study objectives

Current study hypothesis as of 05/12/2019:
Primary:
1. Symptom scores for stress, depression and anxiety at T3 will be significantly better in the MVC intervention group when compared with wait-list control group
2. Quality of life scores and program satisfaction at T3 will be significantly better for the MVC intervention group when compared with the wait-list group
3. Rates of classroom absenteeism and self-reported disability days at T3 will be significantly lower for the MVC intervention group when compared with the wait-list group.

Secondary:
1. Symptom scores for stress, depression and anxiety at T2 compared to T1 will be significantly reduced for the two intervention groups (MVC and CBT-M) when compared with the wait-list group
2. Symptom scores for stress, depression and anxiety at T2 compared to T1 will not be significantly different when MVC and CBT-M intervention groups are compared
3. Level of mindfulness will be significantly higher at T2 compared to T1 for the MVC and CBT-M intervention groups
4. Quality of life scores at T2 compared to T1 will be significantly higher in the MVC and CBT-M intervention groups when compared with the wait-list control group
5. Quality of life scores and program satisfaction at T2 will not be significantly different when MVC and CBT-M intervention groups are compared
6. Student engagement and experience will overall be significantly better for the MVC and CBT-M intervention groups when compared to the wait-list control.
7. Rates of classroom absenteeism and self-reported disability days at T2 compared to T1 will be significantly lower for the MVC and CBT-M intervention groups when compared to the wait-list group
8. Rates of class absenteeism and self-reported disability days at T2 will not be significantly different between MVC and CBT-M intervention groups

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Previous study hypothesis:
Primary:
1. Symptom scores for stress, depression and anxiety at T2 will be significantly better in the MVC intervention group when compared with wait-list control group
2. Quality of life scores and program satisfaction at T2 will be significantly better for the MVC intervention group when compared with the wait-list group
3. 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 group.

Secondary:
1. Symptom scores for stress, depression and anxiety at T2 compared to T1 will be significantly reduced for the two intervention groups (MVC and CBT-M) when compared with the wait-list group
2. Symptom scores for stress, depression and anxiety at T2 compared to T1 will not be significantly different when MVC and CBT-M intervention groups are compared
3. Level of mindfulness will be significantly higher at T2 compared to T1 for the MVC and CBT-M intervention groups
4. Quality of life scores at T2 compared to T1 will be significantly higher in the MVC and CBT-M intervention groups when compared with the wait-list control group
5. Quality of life scores and program satisfaction at T2 will not be significantly different when

MVC and CBT-M intervention groups are compared
6. Student engagement and experience will overall be significantly better for the MVC and CBT-M intervention groups when compared to the wait-list control.
7. Rates of classroom absenteeism and self-reported disability days at T2 compared to T1 will be significantly lower for the MVC and CBT-M intervention groups when compared to the wait-list group
8. Rates of class absenteeism and self-reported disability days at T2 will not be significantly different between MVC and CBT-M intervention groups

Ethics approval required
Old ethics approval format

Ethics approval(s)
York University Office of Research Ethics, Human Participants Review Sub-Committee (HPRC), 03/11/2016, ref: #e2016-345

Study design
Single-centre randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format; please use contact details to request a Participant Information Sheet and Consent Form.

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

Interventions
Current interventions as of 05/12/2019:
Participants will complete an Informed Consent and then will then be randomly assigned to one of four arms in a 1:1:1:1 ratio by opening a sequentially numbered envelope containing a randomly-generated allocation by an off-site biostatistician.

Group 1 (Waitlist): Students randomized to this arm will complete baseline and follow-up (at 4 and 8 weeks) assessments and will be offered a list of available resources to support mental health.

Group 2 (Partial-MVC): Students randomized to this arm will complete baseline and follow-up (at 4 and 8 weeks) assessments and will be offered access to the online mental health education modules and a list of available resources to support mental health.

Group 3 (Group-based face-to-face Cognitive Behaviour Therapy-Mindfulness (CBT-M) program modeled on the Healthy Student Initiative (HSI), a successful in-person mindfulness program running at York University): Students randomized to this arm will complete baseline and follow-up (4- and 8-week) assessments and will receive the same list of resources, but additionally will participate in regularly scheduled, in-person CBT-M group meetings of 1 hour per week for a duration of 8 weeks; during these sessions they will receive mental health education and will engage in guided mindfulness exercises. The groups will be led by graduate students under the remote supervision of a registered clinical psychologist.

Group 4 (Novel Mindfulness Virtual Community (Full-MVC) intervention): Students randomized to this arm will complete baseline and follow-up (4- and 8-week) assessments and receive the list of resources, and will also participate in a series of interactive, online activities: general and youth-specific mental health education and mindfulness modules drawing from CBT principles, delivered via audio and video recordings, and that participants may watch on their computers or phones at their own convenience; anonymous, asynchronous discussion boards pertaining to mental health and mindfulness practice; and anonymous, 20-minute synchronous video conferences (group-based) led by a mental health professional, scheduled on alternate days, during which participating students can engage with the professional on topics of covered in the accompanying module. Total duration of Full-MVC intervention is 8-weeks: participants receive access to 3 components of intervention in the first 4-week period and then only modules in second 4-week period.

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Previous interventions:
Participants will complete an Informed Consent and then will then be randomly assigned to one of four arms in a 1:1:1:1 ratio by opening a sequentially numbered envelope containing a randomly-generated allocation by an off-site biostatistician.

Group 1 (Waitlist A): Students randomized to this arm will complete baseline and follow-up (at 4 and 8 weeks) assessments and will be offered a list of available resources to support mental health.

Group 2 (Waitlist B): Students randomized to this arm will complete baseline and follow-up (at 4 and 8 weeks) assessments and will be offered access to the online mental health education modules and a list of available resources to support mental health.

Group 3 (Group-based face-to-face Cognitive Behaviour Therapy-Mindfulness (CBT-M) program modeled on the Healthy Student Initiative (HSI), a successful in-person mindfulness program running at York University): Students randomized to this arm will complete baseline and follow-up (4- and 8-week) assessments and will receive the same list of resources, but additionally will participate in regularly scheduled, in-person CBT-M group meetings of 1 hour per week for a duration of 8 weeks; during these sessions they will receive mental health education and will engage in guided mindfulness exercises. The groups will be led by graduate students under the remote supervision of a registered clinical psychologist.

Group 4 (Novel Mindfulness Virtual Community (MVC) intervention): Students randomized to this arm will complete baseline and follow-up (4- and 8-week) assessments and receive the list of resources, and will also participate in a series of interactive, online activities: general and youth-specific mental health education and mindfulness modules drawing from CBT principles, delivered via audio and video recordings, and that participants may watch on their computers or phones at their own convenience; anonymous, asynchronous discussion boards pertaining to

mental health and mindfulness practice; and anonymous, 20-minute synchronous video conferences (group-based) led by a mental health professional, scheduled on alternate days, during which participating students can engage with the professional on topics of covered in the accompanying module.

Intervention Type
Behavioural

Primary outcome measure
1. Depression is measured using the Patient Health Questionnaire (PHQ-9) at baseline, 4 and 8 weeks
2. Anxiety is measured using the Beck Anxiety Inventory (BAI) at baseline, 4 and 8 weeks
3. Stress is measured using the Perceived Stress Scale (PSS) at baseline, 4 and 8 weeks

Secondary outcome measures
1. Quality of life is measured using the Quality of Life Scale (QOLS) at baseline, 4 and 8 weeks
2. Life satisfaction is measured using the Brief Multi-Dimensional Students' Life Satisfaction Scale (BMSLSS) at baseline, 4 and 8 weeks
3. Mindfulness is measured using the Brief Five Facet Mindfulness Questionnaire (BFFMQ) at baseline, 4 and 8 weeks

Overall study start date
01/01/2016

Completion date
20/03/2017

Eligibility

Key inclusion criteria
1. Aged 18 years 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. Fluent in reading, writing and conversing in English
4. Willing to be randomized into an intervention which may require up to 4 hours per week of their time

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

This is a pilot RCT that will enrol 120 participants for the full intervention; a total of 160 participants will be targeted for recruitment, to allow for ~ 25% attrition.

Total final enrolment
148

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

Date of first enrolment
06/12/2016

Date of final enrolment
20/01/2017

Locations

Countries of recruitment
Canada

Study participating centre
York University
4700 Keele Street
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Sponsor information

Organisation
York University

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Sponsor type

University/education

Website
http://research.info.yorku.ca/

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, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Intent to publish in high impact peer-reviewed journals within an year after completion of all data.

Intention to publish date
20/03/2018

Individual participant data (IPD) sharing plan
All data will be held by the Nominated Principal Applicant (PI), Dr. El Morr at York University. Upon receiving a request for release of data, the three PIs will make a joint decision.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	survey results	26/03/2019	10/04/2019	Yes	No
Results article	results	18/02/2020	24/02/2020	Yes	No
Results article	observational results	11/01/2021	03/12/2020	Yes	No