

Testing a mindfulness intervention for cancer-risk behaviour among youth attending an alternative school

Submission date 26/01/2020	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/01/2020	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/01/2021	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Tobacco use, alcohol use, and sugar-sweetened beverage consumption are each associated with increased cancer risk. Youth attending alternative schools are more likely to engage in these behaviors than other teens. The premise for this study is that mindfulness training may provide a useful tool for youth to cope with stress in their lives, and may reduce their engagement in these cancer-risk behaviours. The primary aim of this study is to evaluate the effect of a school-based mindfulness intervention that includes app-based technology compared to control on tobacco use, alcohol use, and sugar-sweetened beverage consumption among community-based youth attending an alternative high school. Secondary aims are to evaluate the effect of this intervention compared to control on youth mindfulness, self-esteem, emotions, fear, sleep, bullying, school connectedness, and use of mindfulness apps outside the intervention.

Who can participate?

Youth who used tobacco, alcohol, or sugar-sweetened beverages in the past month and are students at Victoria Park High School in Lethbridge, Alberta.

What does the study involve?

School staff at Victoria Park High School will let students know about the program by announcing the information in class. Youth interested will let one of the School Support Staff in their classroom know, who will provide the parent/guardian consent form to take home. Youth in the first group will be asked to take part in an 8-session group mindfulness program delivered twice a week at their school for one month. Those in the second group are asked to take part in this program approximately four months later. Participants are asked to attend a one-on-one appointment in-person to fill out a questionnaire and complete a short audio-recorded interview with a School Support Staff member before the intervention, within one month after it has ended, and again three months after it has ended.

What are the possible benefits and risks of participating?

Direct benefits to those taking part may include engagement in an intervention that strengthens their psychological and social well-being, and may reduce their engagement in health-risk

behaviour. In the longer term, a better understanding of the role that group mindfulness activities may have on cancer-risk behaviour among youth attending alternative schools may increase future student access to these cost-effective interventions. The main risk of participating is answering baseline questions about emotions, bullying, and sense of connection to others at school which may be triggering for some individuals. We have created a document listing all free mental health resources available to youth in the area.

Where is the study run from?

The Social Epidemiology in Action Lab led by Dr. Cheryl Currie in the Faculty of Health Sciences at the University of Lethbridge located in Lethbridge, Alberta, Canada.

When is the study starting and how long is it expected to run for?

The study will begin in March 2020 and is expected to end in early 2021.

Who is funding the study?

The Alberta Cancer Prevention Legacy Fund.

Who is the main contact?

Dr. Cheryl Currie

cheryl.currie@uleth.ca

Contact information

Type(s)

Scientific

Contact name

Dr Cheryl Currie

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

1, January 25, 2020

Study information

Scientific Title

Testing a mindfulness intervention versus wait-listed control for cancer-risk behaviour among youth attending an alternative school: A study protocol

Study objectives

A mindfulness intervention will be superior to wait-listed control on cancer-risk behaviour change among secondary students attending an alternative school.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/01/2020, The Health Research Ethics Board of Alberta (1500, 10104 - 103 Avenue NW, Edmonton, Alberta, T5J 0H8; (780) 423-5727; (780) 429-3509; cancer@hreba.ca), ref: HREBA. CC-18-0350.

Study design

Two-arm wait-listed randomized trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

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

Cancer-risk behaviour

Interventions

This two-arm wait-listed randomized trial will compare two groups on the primary endpoint of cancer-risk behaviour change (smoking, hazardous alcohol use, sugar-sweetened drink consumption) post-intervention.

A total of eight one-hour bi-weekly sessions will be delivered to youth at their school using the Learning to BREATHE program. Sessions will explore the themes of body awareness, thoughts,

emotions, attention, kindness, acceptance, empowerment, and healthy habits. Each session will begin with an invitation to sit on a chair, mat or pillow in a circle within a classroom with two trained mindfulness instructors. A singing bowl will be used to signal the beginning of each session. For the first 5 minutes, facilitators will welcome participants and briefly review ground rules (respect, no interrupting others' practice, safe space in the circle). Next, a mindful transition will be used to help students let go of whatever has happened that day and focus on the session. The transition method used will change session to session (e.g., mindful breath practice, journaling, mindfulness movement practice), and will take 5-10 minutes. For the next 20 minutes, instructors will introduce the theme for the session (e.g., thoughts, emotions) and youth will be invited to talk about the theme or engage in an activity related to the theme (e.g., journal, make a craft). Next, youth will be engaged in a mindfulness practice related to the theme (20 min). This practice will usually be delivered by the instructors, but at times a mindfulness app will be used by the instructor to remind youth that they have access to these practices and can use them outside the intervention. Finally, youth will be invited to reflect on the session and a singing bowl will be used to end the session (5 min). The youth and instructors will then have a meal together before departing.

Randomization process: Unassigned participant IDs will be randomly allocated by a team member (EH) to one of two conditions generated using permuted blocks of two using <https://www.randomizer.org/>. The intervention that an ID was assigned was placed in a sealed envelope and kept in the main study lab at the University of Lethbridge. Participant IDs will be assigned consecutively as youth are enrolled. When the youth leaves the session, they will receive the envelope with information on the intervention they have been assigned including the date, time and location within their school. Assessors will remain blinded to the allocation of the participant during baseline data collection. No school staff or project team members can change the group a participant has been assigned to. Team members performing statistical analysis will also be blinded to the allocation of participants.

Intervention Type

Behavioural

Primary outcome measure

Attempts to reduce one or more cancer-risk behaviours between the baseline data collection and 3-month post-intervention data collection time points

Secondary outcome measures

Between baseline data collection and 3-months post-intervention:

1. Self-esteem measured using a 3-item self-esteem measure used on the national Youth Smoking Survey in Canada
2. Emotions measured using the 18-item Difficulties in Emotion Regulation Scale Short Form (DERS- SF)
3. Fear measured using the 5-item Screen for Child Anxiety Related Emotional Disorders (SCARED)
4. Mindfulness assessed using the 10-item Child and Adolescent Mindfulness Measure (CAMM)
5. Behaviour measured using questions adapted from the Youth Smoking Survey and the Sleep /Wake Problems Behavior Scale
6. Use of mindfulness apps: Four questions will explore the extent to which youth used technology-based mindfulness apps and their reflections on the effectiveness of this tool at enhancing their mindfulness practice

Overall study start date

01/06/2019

Completion date

01/02/2021

Reason abandoned (if study stopped)

Pandemic

Eligibility

Key inclusion criteria

1. Identify as male, female, or gender-diverse
2. Are 19 years of age or younger
3. Currently attend Victoria Park High School
4. Plan to attend Victoria Park High School for the next 12 months
5. Can provide fully informed consent

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

70

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/03/2020

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

Canada

Study participating centre

University of Lethbridge

4401 University Drive

Lethbridge
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Sponsor information

Organisation

University of Lethbridge

Sponsor details

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Sponsor type

University/education

Website

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ROR

<https://ror.org/044j76961>

Funder(s)

Funder type

Government

Funder Name

Alberta Cancer Prevention Legacy Fund

Funder Name

Alberta Innovates

Results and Publications

Publication and dissemination plan

Findings will be disseminated at regional and international conferences, in peer-reviewed journals, and through popular media. The PI will ensure that authors on manuscripts meet authorship criteria as defined by the International Committee of Medical Journal Editors. Professional medical writers will not be used in this study. The protocol will be submitted for publication in February 2020.

Intention to publish date

01/05/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

The anonymized quantitative dataset analyzed during the current study will be available upon reasonable request to Dr. Cheryl Currie (cheryl.currie@uleth.ca) between Jan 1, 2023 and Dec 31, 2025.

IPD sharing plan summary

Not provided at time of registration