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Trauma-informed interventions for cancer-risk behaviours among adults

Submission date 31/12/2018	**Recruitment status** Stopped	[ ] Prospectively registered [X] Protocol
Registration date 21/08/2019	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 18/01/2021	**Condition category** Other	[ ] Individual participant data [ ] 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. The premise for this study is that psychological trauma is a common experience and a key driver of these behaviours among community-based adults. Most trauma occurs in the context of interpersonal experiences in childhood (e.g., child abuse) and adulthood (e.g., domestic violence). Research tells us that people will habitually use tobacco, alcohol, and excessive sugar consumption to cope with these experiences, as well as triggers that remind them of these experiences later in life. Engaging in trauma-informed therapies that help people deal with the emotions and physical sensations they have when triggered may reduce their reliance on tobacco, alcohol and sugar to quell these sensations. The primary aim of this study is to evaluate the effect of trauma-informed group yoga, group drumming, and group psychoeducation compared to control on tobacco use, alcohol use, and sugar-sweetened beverage consumption among community-based adults. Secondary aims are to evaluate the effect of these three interventions compared to control on psychological and physiological stress symptomology, social connections, and coping behaviour.

Who can participate?

Adults who used tobacco, alcohol, or sugar-sweetened beverages in the past month and live in Lethbridge, Alberta.

What does the study involve?

Participants are recruited using ads placed in public areas and randomly allocated to one of four groups. Those in the first group are asked to take part in a 12-session group yoga class. Those in the second group are asked to take part in a 12-session group drumming class. Those in the third group are asked to take part in a 12-session psychoeducation class. Those in the fourth group will not receive an intervention. Participants are asked to attend a one-on-one appointment in-person to fill out a questionnaire package, provide a saliva sample, and complete physical measures at the beginning and end of the intervention, and again 6 months after the intervention.

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 wellbeing. In the longer term, a better understanding of the role that trauma-informed group activities may have on cancer-risk behaviour among community-based adults may increase future public access to these cost-effective interventions. The main risk of participating is answering baseline questions about past traumatic experiences which may be triggering for some individuals. We have created a document listing all free mental health resources available to participants community, and sharing this with each person at their baseline data collection appointment.

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?
April 2018 to February 2021
(updated 10/07/2020, previously: The study started in April 2019 and is expected to end in late 2021.)

Who is funding the study?
The Alberta Cancer Legacy Fund.

Who is the main contact?
Dr. Cheryl Currie: cheryl.currie@uleth.ca

Contact information

Type(s)
Scientific

Contact name
Dr Cheryl Currie

Contact details
M3083 4401 University Drive
Lethbridge
Canada
T1K3M4

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
A randomised controlled trial of trauma-informed interventions versus control for cancer-risk behaviours among adults

Acronym
CRIS

Study objectives
Trauma-informed interventions will be superior to control for cancer-risk behaviour change.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/01/2019, 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-18-0467.

Study design
Interventional, randomised superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Cancer-risk behaviours

Interventions
Participants will engage in one of four conditions. Each intervention session and each pre and post-intervention assessment will take approximately 90 minutes. All spaces selected for interventions are comparable in terms of room accessibility, size, natural light, and configuration.

Group yoga
Trauma-informed yoga will be delivered once a week for 12 weeks by two licensed yoga instructors who have completed training in trauma-informed yoga delivery (approximately 25 participants per class). Each session will begin with an invitation to sit in a semi-circle facing the

instructors on a yoga mat or chair placed behind a mat arranged. Participants can engage in the class from the mat or chair or move between them as the class unfolds. One instructor will lead the class from the mat, while the second will silently demonstrate the same practice using the chair. The instructor will begin the class by introducing the theme for that week (e.g., grounding and safety, centering, non-attachment, imprints of the past, connection to nature) (10 min). This will be followed by a breath practice (10 min), a yoga practice (50 min), and a meditation practice (10 min), and closing words from the instructors and class (10 min).

Group drumming
Group drumming will be delivered once a week for 12 weeks by two instructors certified to deliver the Integrative Drum Circles (IDC) method (approximately 25 participants per class) [55,56]. Each session will begin with an invitation to sit on a chair beside a drum of their choice arranged in a semi-circle facing the instructors. One instructor will lead the class, while the second instructor will silently demonstrate the same practice for participants. An instructor will begin the class by introducing the theme for that week (e.g., respect, gratefulness, gentleness) (10 min). This will be followed by a drum practice using the IDC method (70 min) and closing words from the instructors and class (10 min).

Group psychoeducation
Group psychoeducation will be delivered once a week for 12 weeks by two licensed and experienced counselors (approximately 12-13 participants per class, with two separate sessions running each week as 25 is too many to accommodate at one time for this intervention). Each session will begin with an invitation to sit on a chair arranged in a semi-circle facing the facilitators. One facilitator will lead the session each week. The facilitator will begin the class by introducing the theme for that week (e.g., setting goals, being mindfulness) (10 min). This will be followed by a lecture and activities to integrate the learning (e.g., group discussion, journaling) (70 min), and closing words from the instructors and class (10 min).

Control
The control group will not receive an intervention.

Unassigned participant IDs were randomly allocated by two team members to one of four conditions generated using permuted blocks of four generated on https://www.randomizer.org/. The intervention that an ID was assigned was placed in a sealed and kept in the main study lab. Participant IDs are assigned consecutively as participants are enrolled. When the participant leaves the session, they receive the envelope with information on the intervention they have been assigned including the date, time and location; and contact information for the coordinator leading the intervention they have been assigned to, who will send them a reminder before the intervention begins. Assessors remain blinded to the allocation of the participant during baseline data collection. Participants are asked not to communicate with the assessors about the intervention received. At the two remaining data collection timepoints, we will examine the success of assessor blinding by asking whether the assessor thought the participant had been allocated to a specific arm of the trial, including the percentage of certainty. (i.e., 50% would be interpreted as a pure guess). No project team member 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

1. Smoking is measured using 4 items and salivary cotinine concentration at baseline, 1-month follow-up and 6-month follow-up.
2. Hazardous alcohol use is measured using AUDIT at baseline, 1-month follow-up and 6-month follow-up.
3. Sugar-sweetened beverage consumption is measured using 3 items at baseline, 1-month follow-up and 6-month follow-up.

Secondary outcome measures

Psychological stress symptomology
1. PTSD is measured using PTSD Checklist at baseline, 1-month follow-up and 6-month follow-up.
2. Dissociative experiences is measured using BDE-S at baseline, 1-month follow-up and 6-month follow-up.
3. Depression is measured using 2 items at baseline, 1-month follow-up and 6-month follow-up.
4. Suicide is measured using 2 items at baseline, 1-month follow-up and 6-month follow-up.
5. Complicated grief is measured using BGQ at baseline, 1-month follow-up and 6-month follow-up.
6. Self-esteem is measured using RSES at baseline, 1-month follow-up and 6-month follow-up.
7. Self-compassion is measured using SCS-SF at baseline, 1-month follow-up and 6-month follow-up.
8. Resilience is measured using CD- at baseline, 1-month follow-up and 6-month follow-up.

Physiologic stress symptomology
1. Neuroendocrine is measured using Salivary DHEA-S at baseline, 1-month follow-up and 6-month follow-up.
2. Metabolic is measured using BMI, waist circumference at baseline, 1-month follow-up and 6-month follow-up.
3. Cardiovascular is measured using Blood pressure, heart rate, uric acid at baseline, 1-month follow-up and 6-month follow-up.
4. Immune is measured using Secretory IgA, CRP, Interleukins IL-1β, IL-6, IL-8, TNF-α at baseline, 1-month follow-up and 6-month follow-up.
5. General health is measured using 14 items at 1-month follow-up and 6-month follow-up.

Social dislocation
1. Social Support is measured using SSQ at baseline, 1-month follow-up and 6-month follow-up.
2. Social Support is measured using VI at baseline, 1-month follow-up and 6-month follow-up.

Coping behaviour
1. Physical activity is measured using IPAQ at baseline, 1-month follow-up and 6-month follow-up.
2. Sedentary behaviour is measured using IPAQ at 1-month follow-up and 6-month follow-up.
3. Sleep behaviour is measured using PSQI at baseline, 1-month follow-up and 6-month follow-up.
4. Eating habits is measured using 7 items at baseline, 1-month follow-up and 6-month follow-up.
5. Drug use /dependence is measured using DUDIT at baseline, 1-month follow-up and 6-month follow-up.

Overall study start date

01/01/2018

Completion date

11/02/2020

Reason abandoned (if study stopped)
Pandemic

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/07/2020:
1. 18 years and older
2. Currently live at a permanent residential address in Lethbridge, AB
3. Plan to live in Lethbridge for the next 12 months
4. Smoked, consumed alcohol, or consumed sugar-sweetened beverages at least once in the past month

Previous inclusion criteria:
1. Identify as First Nations, Métis, Inuit or Indigenous
2. 18 years and older
3. Currently live at a permanent residential address in Lethbridge, AB
4. Plan to live in Lethbridge for the next 12 months
5. Smoke (any amount), consume 4 or more drinks at least once in past month, or consumed sugar-sweetened beverages at least once in the past week.
6. Experienced a psychologically traumatizing event in their lives

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
N/A

Date of first enrolment
11/03/2019

Date of final enrolment
12/03/2020

Locations

Countries of recruitment
Canada

Study participating centre
University of Lethbridge
M3083 4401 University Drive
Lethbridge
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T1K3M4

Sponsor information

Organisation
Faculty of Health Sciences, University of Lethbridge

Sponsor details
M3083 4401 University Drive
Lethbridge
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Sponsor type
University/education

ROR
https://ror.org/044j76961

Funder(s)

Funder type
Government

Funder Name
Alberta Cancer Legacy Fund

Results and Publications

Publication and dissemination plan
Findings will be disseminated at regional and international conferences, in peer-reviewed journals, and through popular media.

Intention to publish date

Individual participant data (IPD) sharing plan

The anonymised quantitative dataset analysed 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

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2019	27/01/2020	Yes	No