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Exploring the effects of yoga therapy on heart rate and other patient-reported outcomes after cancer treatment

Submission date
06/12/2021

Recruitment status
No longer recruiting

Registration date
08/12/2021

Overall study status
Completed

Last Edited
23/02/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims:
After cancer treatment, many adults report unwanted side-effects such as anxiety, stress, depression, fatigue, and challenges with cognitive function. These patient-reported outcomes are associated with a disruption in breathing and heart rate, measured by heart rate variability. Patient-reported outcomes and heart rate variability have been associated with poor health outcomes and mortality rates. Therefore, interventions to improve heart rate variability and patient-reported outcomes among adults following cancer treatment are needed. Yoga therapy is an intervention that can improve heart rate variability and patient-reported outcomes. This study investigated the effects of a 7-week yoga therapy program on heart rate variability and specific patient-reported outcomes (i.e., cancer-related fatigue, anxiety, cognitive function, depression, stress, quality of life) in adults treated for cancer.

Who can participate?
Participants were adults who completed cancer treatment recruited from the Ottawa Integrative Cancer Centre. Recruitment for this study is closed.

What does the study involve?
Participants received one 1:1 yoga therapy session (i.e., one participant, one yoga therapist) and six weekly group-based yoga therapy sessions (i.e., 2-3 participants, one yoga therapist). During these sessions, participants wore a Hexoskin Smart Shirt to measure their heart rate variability. Participants completed questionnaires at seven time points: three times before the program (i.e., -6 weeks, -3 weeks, immediately before the 1:1 yoga therapy session), immediately after the 1:1 yoga therapy session, before the first group-based yoga therapy session, after the last group-based yoga therapy session, and during a 6-week follow-up.

What are the possible risks and benefits of participating?
Yoga therapy has been shown to improve psychosocial outcomes such as anxiety and stress, enhance heart rate variability and reduce cardiovascular disease risk. There are no known risks associated with participating in this study.

Where is the study run from?
This study is run by the University of Ottawa and at the Canadian College of Naturopathic Medicine.

When is the study starting and how long is it expected to run for?
March 2017 to January 2020

Who is funding the study?
The Canadian CAM Research Fund.

Who is the main contact?
Dr Jennifer Brunet, Principle Investigator
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Exploring the effects of yoga therapy on heart rate variability and patient-reported outcomes after cancer treatment: a single-subject experimental study protocol

Study objectives
Yoga therapy (YT) will lead to improvements in heart rate variability (HRV), and furthermore that YT will lead to reduced cancer-related fatigue, anxiety, depression, and stress, improved cognitive function, and improved QoL. Changes in slopes for HRV and specific PROs across the transition from one phase to another phase (i.e., when 1:1 YT is introduced, when group-based YT is introduced, and when the YT program is completed) will also be examined to determine if there is a difference in level of change across phases. We have no hypothesis for this aim given its exploratory nature.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2017, University of Ottawa Social Sciences and Humanities Research Ethics Boards (Tabaret Hall, 550 Cumberland S, Room 15, Ottawa, ON, Canada, K1N 6N5; +1 (613) 5625387; ethics@uottawa.ca), ref: H01-17-04

Study design
Single-centre experimental exploratory single-subject

Primary study design
Interventional

Secondary study design
Single-subject

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied
Effects of Yoga Therapy (YT) on heart rate variability (HRV) of adults with a history of cancer

Interventions
Each participant received a 1:1 YT session (i.e., one participant, one Yoga Therapist; intervention phase 1) and 6 weeks of group-based YT (i.e., 2-3 participants, one Yoga Therapist; intervention phase 2), and repeated assessments were conducted before, during, and after the YT program to assess if changes in outcomes occurred.

Intervention Type
Behavioural

Primary outcome measure
HRV is measured using a Hexoskin Smart Shirt at all 7 assessment periods (1 = 6 weeks prior to the one-on-one yoga therapy (1:1 YT) session, 2 = 3 weeks prior to the 1:1 YT session, 3 = immediately prior to the 1:1 YT session, 4 = immediately following the 1:1 YT session, 5 = prior to the first group-based YT session, 6 = after the last group-based YT session, 7 = 6 week follow-up) and continuously between assessment 3 and 4 (i.e., throughout the 1:1 YT session).

Secondary outcome measures
1. General state of regulation for different autonomic functions, namely orthostatic-circulatory, rest/activity, and digestive regulation measured using the Trait and State Autonomic Regulation (aR) scales at assessment periods 1, 2, 3, 5, 6, and 7.
2. Fatigue and its influence on global quality of life over a 7-day period measured using Functional Assessment of Cancer Therapy-Fatigue Scale (FACT-F) at assessment periods 1, 2, 3, 5, 6, and 7.
3. Impairment of cognitive abilities and its impact on quality of life during the past 7 days measured using Functional Assessment of Cancer Therapy-Cognitive Function Version 3 (FACT-Cog-Version 3) at assessment periods 1, 2, 3, 5, 6, and 7.
4. Depressive symptomatology during the past week measured using The Center for Epidemiologic Studies Depression (CES-D) short-form Scale at assessment periods 1, 2, 3, 5, 6, and 7.
5. Stress was measured using the Perceived Stress Scale (PSS; 10-item version) at assessment periods 1, 2, 3, 5, 6, and 7.
6. Subjective level of anxiety in specific situations and in general situations measured using The State-Trait Anxiety Inventory (STAI) at assessment periods 1, 2, 3, 4, 5, 6, and 7.
7. Health-related QoL (physical, social, emotional and functional well-being) measured using The Functional Assessment of Cancer Therapy General version 4 (FACT-G-Version 4) at assessment periods 1, 2, 3, 5, 6, and 7.
8. Sense of belonging to the group and sense of commonality with in-group members measured using The Group Identification Scale (GIS) at assessment periods 6 and 7.

Overall study start date
14/03/2017

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. ≥18 years of age
2. Received a diagnosis of cancer (regardless of time since diagnosis);
3. Not undergone conventional cancer treatments (chemotherapy, radiotherapy, surgery) within the past 3 months and had none scheduled for the next 5 months;
4. Not currently on any cardiac medication;
5. Self-reported no YT practice since their cancer diagnosis;
6. Cleared for physical activity as indicated by physical activity readiness questions, and;
7. Willing and able to provide informed consent in English.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Total final enrolment
25

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2017

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
Canada

Study participating centre
Ottawa Integrative Cancer Centre
429 MacLaren St.
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Sponsor information

Organisation
University of Ottawa

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Sponsor type
University/education

Website
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ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian CAM Research Fund

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan

The data cannot be shared as participants were assured that their data would be kept private and confidential to the extent permitted by law and that only the research team would have access to the data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/04/2022	11/04/2022	Yes	No
Results article		22/02/2024	23/02/2024	Yes	No