

Can yoga reduce the risk of falls and improve mindful eating and quality of life in adults aged 60 years and over?

Submission date 02/12/2019	Recruitment status Suspended	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/02/2021	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The objective of this study is to preliminarily assess the impact of an interprofessional therapeutic yoga program for older adults on falls risk, mindful eating and quality of life. DESIGN--Mixed methods pilot study with pre-post design. Participants in an interprofessional therapeutic yoga program will be assessed for falls risk, mindful eating and self-reported quality of life before and after the program. The yoga program offers gentle yoga as well as education sessions and practices by an occupational therapist, a dietitian and a family physician. SETTING--Assessments will be conducted at the Sunnybrook Academic Family Health Team. Classes are held in a community activity space. PATIENTS-- A total of 12 participants will be recruited. OUTCOME MEASURES--Fullerton Advanced Balance Scale, sit-to-stand test, Falls Efficacy Scale, Mindful Eating Behaviour Scale, 36-Item Short Form Health Survey, focus group.

Background and study aims

Older adults may have difficulty maintaining a healthy lifestyle due to challenges related to mobility and balance, cognition (thinking and memory), eating habits, sleep quality, mood and social isolation. Yoga for older adults has shown to have positive effects on health and quality of life and to support healthy eating behaviours. This study aims to investigate whether a program for older adults including yoga, guidance on healthy eating, mindfulness and general health and wellbeing can reduce the likelihood of a person having a fall, increase their quality of life and improve mindful eating.

Who can participate?

People enrolled in a team-based therapeutic yoga program who are 60 years of age or older. The program is offered in the community and there is no cost to attend.

What does the study involve?

Participants will be assessed for self-reported quality of life, mindful eating and falls risk before and after the program. They will then receive an 8-week course of twice-weekly yoga sessions as well as educational sessions on healthy eating and general health and wellbeing. They will be

assessed again after the end of the program and will also be invited to attend a focus group 4-8 weeks after the end of the program to find out what they thought of the program and what changes they had made to their lifestyle.

What are the possible benefits and risks of participating?

Participants may benefit from learning more about their health through the results of their pre- and post-assessments. They might also benefit if there are improvements to their risk of falling, diet and quality of life as a results of this program.

Anxiety, distress, embarrassment, and/or feelings of sadness may arise from answering questionnaires and interviews about sensitive issues. The Fullerton Advanced Balance scale asks participants to perform various movements that assess static and dynamic balance. As such, there is a small risk of falls and injury. A regulated physiotherapist will be administering this assessment and will administer it in the safest way possible. Participants will be instructed to refrain from any movement they do not feel comfortable with.

Where is the study run from?

Sunnybrook Academic Family Health Team (Canada)

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

July 2019 to October 2022 (updated 12/02/2021, previously: October 2021, updated 18/03/2020, previously: October 2020)

Who is funding the study?

Sunnybrook Academic Family Health Team (Canada)

Who is the main contact?

Ingrid Wirsig, ingrid.wirsig@sunnybrook.ca

Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

253-2019

Study information

Scientific Title

The impact of an interprofessional therapeutic yoga program for older adults on falls risk, mindful eating and quality of life: A pilot study

Study objectives

A twice-weekly, 8-week interprofessional therapeutic yoga program for older adults will have a positive impact on falls prevention, nutrition, and quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/12/2019, Sunnybrook Health Sciences Centre Research Ethics Board (Room C819, 2075 Bayview Ave, Toronto, ON, Canada M4N 3M5; +1 416 480 6100 ext 4276; no email address), ref: 253-2019

Study design

Non-randomized single-arm interventional single-center pilot study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Healthy aging

Interventions

This is a pilot study with pre-post design using mixed methods. Participants will be recruited from among interprofessional therapeutic yoga program participants. The principal investigator (PI) will be the first point of contact. She will confirm interest and ensure study participants meet the inclusion/exclusion criteria. The research assistant (RA) will contact eligible participants, explain the consent process and book an assessment appointment at the Sunnybrook Academic Family Health Team. Participants will be asked to attend two 60-min assessment appointments within the 2-week timeframe before the program begins and the 2-week timeframe after the program ends. During the assessment appointment, participants will be asked to fill out the following assessment questionnaires: Falls Efficacy Scale (FES), Mindful Eating Behaviour Scale (MEBS) and 36-Item Short Form Health Survey (SF-36). In addition, a registered physiotherapist will assess each participant for balance and strength using the Five times Sit to Stand Test (FTSTS) and the Fullerton Advanced Balance (FAB) Scale.

Participants will attend an 8-week interprofessional therapeutic yoga program in the spring of 2020. Classes are held two times a week and are 90 min each. A yoga therapist will lead mindful meditation, gentle movement, breath awareness and relaxation exercises in the yogic tradition. An occupational therapist will lead four 30-min education sessions around falls prevention, home safety, community resources and advanced care planning. A dietitian will lead two 30-min sessions around mindful eating. A family physician will lead one 30-min education session around the benefits of mindfulness and yoga for hypertension prevention and management as well as for overall health and wellness.

Participants will be invited to attend a focus group in the summer of 2020 to share their experiences in the program, what they learned, what they liked best, whether they have changed their habits and how, feasibility of program, opportunities for improving the program.

Intervention Type

Behavioural

Primary outcome(s)

1. Static and dynamic balance assessed using the Fullerton Advanced Balance Scale at pre- and post-intervention
2. Lower limb function and strength assessed using the five-repetition sit-to-stand test (5STS) at pre- and post-intervention
3. Participant's confidence to perform everyday activities without falling assessed using the Falls Efficacy Scale (FES) at pre- and post-intervention
4. Quality of life as measured by the 36-Item Short-Form Health Survey at pre- and post-intervention
5. Mindful eating as measured by the Mindful Eating Behaviour Scale at pre- and post-intervention

Key secondary outcome(s)

1. Additional benefits of intervention assessed using qualitative feedback from a participant focus group after the end of the intervention
2. Suggested improvements to intervention assessed using qualitative feedback from a participant focus group after the end of the intervention
3. Potential barriers to attendance assessed using qualitative feedback from a participant focus group after the end of the intervention
4. Confidence in healthcare system navigation assessed using qualitative feedback from a participant focus group after the end of the intervention
5. Changes in lifestyle as a result of the program assessed using qualitative feedback from a participant focus group after the end of the intervention
6. Whether a regular home practice of yoga has been established assessed using qualitative feedback from a participant focus group after the end of the intervention

Completion date

15/10/2022

Eligibility

Key inclusion criteria

1. Participants in the Sunnybrook Academic Family Health Team interprofessional therapeutic yoga program
2. Aged 60 years or older

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Has participated in a previous yoga program at the Sunnybrook Academic Family Health Team
2. Has participated in a falls prevention program in the past 12 months

Date of first enrolment

01/02/2022

Date of final enrolment

15/03/2022

Locations**Countries of recruitment**

Canada

Study participating centre

Sunnybrook Academic Family Health Team

2075 Bayview Avenue, A120

Toronto

Canada

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Sponsor information**Organisation**

Sunnybrook Academic Family Health Team

ROR

<https://ror.org/03wefcv03>

Funder(s)

Funder type

Not defined

Funder Name

Sunnybrook Academic Family Health Team

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Other