ISRCTN87234794 https://doi.org/10.1186/ISRCTN87234794

Preventing overweight and obesity in women through mindful eating, dance and yoga exercises

Submission date
27/02/2023

Recruitment status
No longer recruiting

Registration date
27/02/2023

Overall study status
Completed

Last Edited
30/03/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Many current treatment options for managing overweight and obesity consist of rather strict diet and exercise regimes that are difficult to implement as a lifelong routine. Therefore, alternative initiatives such as mindful eating and pleasure-oriented physical activity with more focus on implementation and enjoyment are needed to reverse the obesity epidemic. Mindful eating is an approach focusing on inner hunger and satiety (fullness) signals. YogaDance is a new exercise approach combining elements of yoga and dance. The aim of this study is to investigate the individual and combined effects of mindful eating and YogaDance.

Who can participate?
Healthy, inactive women with overweight or obesity

What does the study involve?
Participants were randomly allocated to one of four groups for 8 weeks: mindful eating alone, YogaDance alone, the combination of mindful eating and YogaDance, or control. The combined mindful eating and YogaDance intervention group followed three weekly YogaDance classes and a mindful eating workshop every second week (in total four workshops) for a total period of 8 weeks. The mindful eating intervention group only attended the four mindful eating workshops and the YogaDance intervention group only followed the three weekly YogaDance classes. The control group did not participate in the YogaDance classes nor the mindful eating workshops. Fat mass, body weight, waist circumference, other physiological outcomes, behavioral and quality of life are measured.

What are the possible benefits and risks of participating?
Benefits include weight loss as well as improved eating behavior and quality of life.

Where is the study run from?
University of Copenhagen (Denmark)

When is the study starting and how long is it expected to run for?
February 2021 to April 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Christian Ritz, ritz@sdu.dk

Contact information

Type(s)
Scientific

Contact name
Prof Christian Ritz

ORCID ID
https://orcid.org/0000-0002-5095-0624

Contact details
National Institute of Public Health
Studiestraede 6
Copenhagen K
Denmark
DK-1455
+45 (0)65509696
ritz@sdu.dk

Additional identifiers

Protocol serial number
YDME

Study information

Scientific Title
Effects of mindful eating and YogaDance among overweight and obese women – an exploratory randomized controlled trial

Study objectives
The aim of this study was to explore the effect of combining mindful eating and the novel YogaDance approach in overweight and obese women. The hypothesis was that the combination would lead to a reduction in total body fat mass (compared to a control group).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/07/2021, Ethics Committee of the capital region of Denmark (De Videnskabsetiske Komiteer, Region Hovedstaden, Borgervaenget 3, st., 2100 Copenhagen OE, Denmark; +45 (0)38 66 63 95; vek@regionh.dk), ref: H-21013705

Primary study design
Interventional

Study design
Parallel-arm open-label randomized controlled superiority trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of overweight and obesity in women

Interventions
Participants were allocated by block randomization to one of three intervention groups (mindful eating alone, YogaDance alone, or mindful eating and YogaDance combined) or the control group in a 1:1:1:1 ratio. This trial design enabled the assessment of the two approaches mindful eating and YogaDance separately as well as jointly. The combined mindful eating and YogaDance intervention group followed three weekly YogaDance classes and a mindful eating workshop every second week (in total four workshops) for a total period of 8 weeks. This training intensity was selected to ensure participant adherence and meet the recommendations by WHO for physical activity for adults (i.e., 150 minutes at moderate intensity or 75 minutes at high intensity per week). The mindful eating intervention group only attended the four mindful eating workshops and the YogaDance intervention group only followed the three weekly YogaDance classes. The control group did not participate in the YogaDance classes nor the mindful eating workshops.

Intervention Type
Other

Primary outcome(s)
Fat mass is measured using a dual-energy x-ray absorptiometry (DXA) scanner (Lunar iDXA with CoreScan module, GE Healthcare, Denmark) at baseline and again at end of the study after 8 weeks

Key secondary outcome(s)
Measured at baseline and after the intervention was completed (at 8 weeks):
1. Body weight measured using a calibrated digital scale (Tanita WB-110MA)
2. BMI defined as body weight divided by height squared
3. Waist circumference measured using a non-elastic band
4. Fat percent measured using a DXA scanner
5. Fat-free mass measured using a DXA scanner
6. Visceral fat measured using a DXA scanner
7. Bone mineral density measured using a DXA scanner
8. Blood pressure measured using a validated automatic blood pressure monitor (UA-787 Plus)
9. Quality of life measured using the WHO-QOL-100 questionnaire

10. Eating behavior measured using a Danish version of the IES-2 questionnaire
11. Energy intake measured using 3-day dietary records
12. Physical activity measured using the International Physical Activity Questionnaires (IPAQ)

Completion date
10/04/2022

Eligibility

Key inclusion criteria
1. Women between 18 and 65 years of age
2. Body mass index (BMI) between 25-35 kg/m² and/or a waist circumference of ≥80 cm
3. Healthy
4. Have an inactive lifestyle, defined as <2.5 hours of light physical activity per week or <1 hour of moderate to hard physical activity per week

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
61

Key exclusion criteria
1. Pregnant, breastfeeding or plan to become pregnant within the study period
2. Self-reported severe disease (including cancer, cardiovascular disease [CVD], type 1 or 2 diabetes, osteoporosis)
3. Self-reported eating disorder (e.g., anorexia, bulimia, orthorexia, binge eating disorder)
4. Following a very restrictive diet (i.e. excluding several food items)
5. Participation in other studies

Date of first enrolment
01/11/2021

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
Denmark

Study participating centre
University of Copenhagen
Department of Nutrition and Exercise
Rolighedsvej 26
Frederiksberg C
Denmark
DK-1958

Sponsor information

Organisation
University of Copenhagen

ROR
https://ror.org/035b05819

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sofie Hauerberg Henninger (sofiehenninger@gmail.com) and Anna Yde Fibieger (annafibieger@gmail.com). Pseudo-anonymized individual-level data will be available upon presenting of a statistical analysis plan or study protocol.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/03/2023	30/03/2023	Yes	No