ISRCTN98174965 https://doi.org/10.1186/ISRCTN98174965

Can participation in a group program for healthier lifestyle with focus on physical activity and eating habits lead to lower weight among persons with overweight?

Submission date
09/12/2013

Recruitment status
No longer recruiting

Registration date
21/01/2014

Overall study status
Completed

Last Edited
21/01/2014

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In Sweden, the incidence of overweight and obesity is over 46% among the adult population. The largest proportion of overweight and obese people is outside the big cities and in the low socioeconomic population. Overweight and obesity is one of the fastest growing public health problems in the world and also in Sweden, which requires action at both population and individual level. Several methods are available for weight loss and those that lead to the best results (except for surgical reduction of the stomach) are the ones where you not only work with diet change, but where treatment is based on the individuals whole life situation. Methods for improved lifestyle habits such as weight loss often include increased physical activity, which increases the energy consumption and above all improves several metabolic variables such as blood glucose. The aim of the present study is to develop, test and evaluate a method to prevent insufficient physical activity and unhealthy eating habits among overweight and obese people. The method should be applicable in primary health care centers with the resources available within a health care center regardless of size.

Who can participate?
Those who attend health consultations, which are offered by primary health care centers to all people who turn 40 years old in the County Council of Gävleborgand, and who have a Body Mass Index (BMI) between 27 and 32.

What does the study involve?
The study starts with an explorative pilot study which will be followed by a randomized, controlled trial (RCT). The explorative pilot study contains a sample of 12 persons divided into two groups. Both groups will have a district nurse as group leader (of which one of the nurses is a PhD student). The content in the two groups will be the same a group program for healthier lifestyle with focus on physical activity and eating habits. In the pilot study, the key point is to assess and refine all procedures and all data collection methods, to evaluate appropriateness and quality of the instrument and measurement planned for use in the study, and also to

identify confounding variables that may need adjustment before starting the RCT.
A initial small study will be conducted with 12 participants to assess and refine all procedures and all data collection methods before starting a larger study. Participants will be randomly allocated to an intervention group or a control group. The intervention group will receive treatment according to a group program for healthier lifestyle (focus on eating habits and physical activity) and the control group will be offered standard care provided by their primary health care centers. Assessments will be carried out before the start of the study and then at 3, 6, 12, 24 and 48 months. In addition, 30 participants from the intervention group will be selected for group interviews. The selection of the participants will be strategic and participants will be divided according to three possible results (weight reduction, weight stability and weight gain /dissatisfaction with the group program) and the interviews will focus on the participants experience of attending the group program.

What are the possible benefits and risks of participating?
Participating will help to increase our knowledge regarding methods for lifestyle change and weight loss. The intervention can also lead to a healthier lifestyle, reduced weight gain or hopefully weight reduction, and also a possible improvement of metabolic variables and decreased risk of health-/lifestyle-related diseases.
Participating may involve some discomfort associated with the measurement of plasma glucose since it is done by a blood test (finger prick). The other measurements should not involve physical pain or discomfort. Participating also means answering questions, engaging in conversations and contributing to discussions both individual and in group regarding body size and lifestyle habits. Participants will be expected to share their personal experiences in relation to the study content. This can be perceived as insulting and as an invasion of personal privacy. As far as possible, the conversations and discussions about body size and lifestyle habits are to be carried out with the help of clear questions, based on made-up situations and using pre-planned group sessions.

Where is the study run from?
University of Gävle, Sweden and the County Council of Gävleborg, Sweden.

When is the study starting and how long is it expected to run for?
The study is planned to start in early spring (January-March) 2014 and will run for approximately four years. Recruitment for the pilot (initial) study will start in early spring 2014 and the plan is to finish collecting data three months after the start. Recruitment for the larger study will start after data collection is completed for the pilot study.

Who is funding the study?
University of Gävle and County Council of Gävleborg, Sweden.

Who is the main contact?
Jenny Söderberg, PhD student
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A group intervention for healthier lifestyle: a randomized controlled trial in primary health care

Study objectives
Overweight/obese people who participate in a group program for healthier lifestyle in which counselling and advanced counselling is included are more physically active, have healthier eating habits, rate their quality of life higher, experience higher motivation and have lower weight than persons who receive standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Uppsala, 26/06/2013, ref: 2013/238

Study design
Explorative pilot study with experimental before and after design which will be followed by a randomized controlled trial. The study includes a descriptive interview study with a qualitative design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please contact jeyrim@hig.se to request a patient information sheet

Health condition(s) or problem(s) studied
Overweight/obesity in relation with unhealthy eating habits and insufficient physical activity

Interventions
The study starts with an explorative pilot study which will be followed by a randomized, controlled trial (RCT). The explorative pilot study contains a sample of 12 persons divided into two groups. Both groups will have a district nurse as group leader (of which one of the nurses is a PhD student). The content in the two groups will be the same a group program for healthier lifestyle with focus on physical activity and eating habits. In the pilot study, the key point is to assess and refine all procedures and all data collection methods, to evaluate appropriateness and quality of the instrument and measurement planned for use in the study, and also to identify confounding variables that may need adjustment before starting the RCT.

The intervention group will meet at approximately 10 occasions and each session deals with different themes based on the National Guidelines for Methods of Preventing Disease in specific, the guidelines that discuss insufficient physical activity and unhealthy eating habits (published in 2011 by the Swedish National Board of Health and Welfare). The intervention also includes measures according to the described primary and secondary outcome measures below and the use of pedometers and food diaries. Every session will end with 'homework' an assignment that the participant will work with until the next session (for example, try to find a way to increase the number of steps per week by xx number).

The control group will receive standard care as provided by the primary health care centers in the County Council of Gävleborg.

The duration concerning the group sessions will be approximately three months. Measurements will also take place after the end of the group sessions for both study arms. When it comes to 'standard care' it differs some patients receive just one or two counselling sessions, some will be sent to dieticians or other 'specialists'. The standard care takes different 'lines' depending on if the patient is willing to participate, and if the patient has any other health problems (for example, high blood pressure).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Weight (a validated scale)
2. Waist circumference (tape measure in centimetres)
3. BMI (calculated with help of height and weight)
4. Physical activity (activity diary, self-reported and with help from the patients own pedometer)

5. Eating habits (food diary, self-reported)
Concerning the diaries the patients will not need to measure every day during the whole intervention, it will probably be during 5 days at 2-3 occasions allocated during the three months.

Measured at baseline and after 3, 6, 12, 24 and 48 months.

Secondary outcome measures
1. Motivation (validated questionnaires)
2. Quality of life (validated questionnaire)
3. Blood pressure (automatic, validated sphygmomanometer)
4. Plasma glucose

Measured at baseline and 3, 6 and 24 months.

Overall study start date
30/01/2014

Completion date
30/01/2018

Eligibility

Key inclusion criteria
1. Body Mass Index (BMI) 27-32
2. Waist circumference ≥ 80 cm for females and ≥ 94 cm for males
3. Expressed a wish to lose weight
4. Understands Swedish spoken and written

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A total of 220 participants are included in the study (pilot study and RCT). The pilot study includes 12 participants and in the RCT, 208 participants will be recruited and randomized to intervention

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/01/2014

Date of final enrolment
30/01/2018

Locations

Countries of recruitment
Sweden

Study participating centre
University of Gävle
Gävle
Sweden
SE-80176

Sponsor information

Organisation
University of Gävle (Sweden)

Sponsor details
Kungsbäcksvägen 47
Gävle
Sweden
SE-80176

Sponsor type
University/education

Website
http://www.hig.se

ROR
https://ror.org/043fje207

Funder(s)

Funder type
University/education

Funder Name
University of Gävle (Sweden)

Funder Name

County Council of Gävleborg (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration