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Weight loss in obese women with Polycystic Ovary Syndrome (PCOS)

Submission date
24/03/2011

Recruitment status
No longer recruiting

Registration date
13/04/2011

Overall study status
Completed

Last Edited
21/12/2017

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
Polycystic Ovary Syndrome (PCOS) is one of the most common female endocrine disorders, affecting 10 to 26% of women of reproductive age in the UK. There is considerable debate as to the optimal treatment for PCOS. The majority of scientific papers suggest that diet and lifestyle interventions should be the first line treatment for PCOS, especially for obese women. This can be attributed to the fact that even a modest weight loss of 2-5% total body weight can restore ovulation in overweight women with PCOS as well as achieving a reduction of central fat and an improvement in insulin sensitivity. Also, both insulin sensitivity and androgen concentrations are likely to improve in patients with a weight loss of 5% of their initial weight. We aim to examine two dietary treatments to determine their success in terms of weight reduction and ovulation. We also aim to compare changes in insulin sensitivity and other metabolic parameters.

Who can participate?
Women who are obese, aged 20-40 years old, who wish to conceive and have PCOS.

What does the study involve?
The study lasts for 12 months and will involve 66 patients. If you agree to take part, you will be asked to provided informed consent. You will then undergo a period of 6 months of dietary intervention and 6 months of follow up. You will be randomly allocated to either a 600-calorie deficit diet (CDD) (low fat, reduced calorie diet) or a nutritionally balanced commercial very-low-calorie diet (VLCD) (LighterLife). Both diets will be accompanied with weekly counseling group sessions. Each counseling session will be 2 hours long. At the end of this 6 month period, counseling and dietary interventions will stop and participants will have a further 6 months follow up with the dieticians at the fertility clinic. A final review will be arranged at the end of the 12 month period. The CDD is based on a healthy eating approach for 6 months, and you will be given advice on food shopping choices, portion sizes, food preparation and given recipes to make it easier to adhere to the diet. The VLCD (LighterLife) is a nutritionally balanced commercial meal replacement programme, where solely shakes, soups and bars are consumed for 3 months, followed by 3 months of gradual reintroduction to conventional food choices. You will be invited to undergo a series of standard measurements. For the initial screening, you will be asked to fast from 8pm the prior evening and you will undergo the following tests: blood sampling for lipids, sugar levels, thyroid function, liver and kidney tests and levels of hormones

and other parameters that may affect your ability to conceive. If you meet the inclusion criteria for the study, the following tests will be carried out: body composition, blood pressure, waist circumference, questionnaires, ovulation diary, oral glucose tolerance test (OGTT) which is a test of how well your body processes sugar. You will then be randomly allocated to one of the two dietary treatments. All measurements will be repeated at 6 months. If you become pregnant you will be asked to stop any intervention and leave the study. If you are on the 12 week VLCD weight loss stage, you will be commenced on a standardised protocol for reintroduction of food during which monitoring will continue. Once you are established on a normal diet, you will leave the study.

What are the possible benefits and risks of participating?
If you follow either of the diets thoroughly, you may lose weight. However, this cannot be guaranteed. The information from this study may provide us with a better understanding of the mechanisms that are involved in PCOS, fertility and obesity and the development of more effective weight loss strategies for this specific syndrome. In addition, taking part in this study will allow you to get dietary and counseling advice on a weekly basis. For the VLCD which we will be using in this study, the main side effects are short-term/temporary and these include: constipation, diarrhoea, nausea, cramps, fatigue, feeling cold, hunger, headaches, feeling lightheaded, hair shedding, hallitosis, gallstones, gout, hypotension. There are no perceived risks to the unborn child from participating in either dietary interventions.

Where is the study run from?
The study will be run from the Department of Obstetrics and Gynaecology and Rosehill Annexe at Aberdeen Royal Infirmary. The lead centre for this study is Robert Gordon University.

When is the study starting and how long is it expected to run for?
The study will be starting in November 2011. You will be enrolled in the study for 12 months. Recruitment for the study will continue until approximately April 2012 and we foresee the study to finish in April 2013.

Who is funding the study?
The research is being funded by LighterLife (www.lighterlife.co.uk) and organized by members of the Robert Gordon University and NHS Grampian.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PCOS

Study information

Scientific Title
Weight loss in obese women with Polycystic Ovary Syndrome (PCOS): a randomised controlled trial

Acronym
PCOS

Study objectives
The use of a very low calorie diet could be a useful alternative to the 600 calorie deficient diet for reducing weight and improving ovulation in obese women with polycystic ovarian syndrome

2010 review in http://www.ncbi.nlm.nih.gov/pubmed/21151687

Please note, as of 14/11/2011 the overall trial start and end dates were updated. The previous dates were as follows:
Original start date: 01/05/2011
Original end date: 01/12/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee, 24/03/2011, ref. 11/AL/0066

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity, polycystic ovarian syndrome/weight loss, fertility

Interventions

1. If the patient successfully meets the eligibility criteria all will be invited to undergo an oral glucose tolerance test (OGTT)
2. Patients will be randomised
3. Every patient will be assigned to either of the two dietary interventions
4. All of the above measurements will be repeated at the 24 week visit
5. Only weight and blood pressure will be assessed in the interim weekly visits
6. At 12 months, weight will be assessed, the questionnaires will be repeated and the record of menses will be collected
7. 600kcal deficient diet (low fat, reduced calorie)
8. Using the Schofield and the Harris Benedict Equations 600 kcals will be removed from the patient's estimated daily energy intake
9. The amount of energy allowed will be broken into portions of different food groups
10. Portion sizes will be explained to the patients and written information will also be provided
11. The patients will follow this weight loss period for 24 weeks and will attend weekly group sessions based on the principles of cognitive behavioural therapy and transactional analysis
12. Very low calorie diet programme (VLCD)
13. The LighterLife (LL) Programme will be administered:
13.1. This commercial diet is nutritionally balanced but calorie deficient
13.2. It is comprised of soups, shakes and bars to replace conventional food and provide a daily average of 550 kcal (36% carbohydrate, 36% protein and 28% fat and at least 100% of the recommended dietary allowance (RDA) for vitamins and minerals)
14. Patients are advised to stay adequately hydrated while on the programme.
15. LL has two distinctive stages:
15.1. Weight loss
15.2. Ongoing weight management
15.3. During each stage, patients attend weekly group meetings of 4-12 people delivered by a trained LL counsellor, enabling active management of motivation and compliance, utilising group support and counselling to encourage long term behavioural modification and weight management
16. The active weight loss period lasts for 12 weeks where patients will only consume the meal replacements that will be provided to them at their weekly group sessions
17. Following the weight loss period, patients are gradually reintroduced to solid food following a standardised protocol where food packs are gradually decreased while the consumption of conventional food is increased, while still receiving counselling and support
18. All subjects will receive initial instructions on how to follow their randomly assigned diet.
19. They will be given assistance by phone or email between the visits
20. The behavioural therapy will remain separate for the two dietary interventions, but will be delivered by the same counsellor
21. After the period of 6 months, patients will be sent back to the dietitian at the Department of Obstetrics and Gynaecology and will be followed up after a further 6 month period where weight, questionnaires and menstrual pattern will be assessed
22. Participants will visit the study centre (at Rosehill Annex, Forsterhill) on a weekly basis for the group meetings during the first six months of the study
23. The duration of every meeting will be approximately 2 hours
24. During the final 6 months of the study 'drop in' sessions will be available
25. Behaviour modification:
26.1. During each stage, patients attend weekly group meetings of 4-12 people delivered by a group facilitator, enabling active management of motivation and compliance, utilising group support and counselling informed by the principles used in cognitive behaviour therapy and transactional analysis.
26.2. The behavioural therapy will remain separate for the two dietary interventions due to the two very different dietary approaches and will be provided by the appropriately trained PhD

student.
26.3. However, the same behaviour change techniques will be applied to both groups resulting in the delivery of the same support
26.4. This will be achieved by distributing the same materials to both groups except where the behaviour is treatment specific, where the material will be adapted to the different dietary interventions.
26.5. The same amount of time will be devoted to each meeting group.
26.6. The same group facilitator will run all the group sessions for the whole duration of the study.
26.7. Blinding the facilitator to the treatment group while advantageous, is not possible, given the requirement for tailoring aspects of the behaviour change techniques to either the VLCD or 600 kcal diet.
26. The group modification sessions will involve a group agreement, so that the group establishes a feeling of a safe and confidential space within which emotional exploration, personal growth, introspection and sharing may be possible
27. The behaviour modification will borrow elements from either Cognitive Behavioural Therapy or Transactional Analysis
28. At the beginning of every meeting, there will be some time for reviewing and sharing newly gained insights or discussing any problem that appeared the last week
29. Participants are then given a chance to explore and learn something new by interactive learning
30. At the end of each session, participants are prompted to do some further reading or promoting self thinking through some 'homework'
31. Overall, the sessions will aim to develop participant's self awareness and insight into thoughts, learn how these affect their feelings and behaviour
32. They will learn to develop new strategies for dealing with problems, without using food 33. Participants will also practice on setting realistic goals and putting them into action, increase their confidence in their ability to make changes, identifying patterns or unhelpful behaviour and discover how they break out of them (drama triangle).
34. Through tentative challenging, and by exploring the power of thought, the patients will investigate the links between thoughts, feelings and behaviours, identify the pros and cons of the challenging process of change, work towards ways to test their ways of thinking and practice towards more balanced ways of thinking and consequently eating.
35. The groups will look further into the roles that have played in their families where food is concerned and investigate how this might link to weight gain
36. At the last meeting the progress will be acknowledged and the groups will be informed that for the next 6 months they can pop in during the drop-in sessions

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Weight loss-will be measured with subjects wearing light clothing and no shoes, on a calibrated digital scale (Tanita Body Composition Analyzer, type BC 410 MA III)
2. Ovulation-A calendar will be provided for the patients to keep track of their menses for the 12 month duration of the study

Key secondary outcome(s))
1. Changes in hirsutism evaluated using the Ferriman Gallwey questionnaire
2. Changes in quality of life evalusated using theObesity-Related Well-Being (ORWELL 97) questionnaire
3. Changes in activity levels: a questionnaire adapted from the Framingham study, will be administered to the patients
4. Changes in body composition: For ensuring accuracy it will be determined by both air-displacement method (Bod Pod, Life Measurement Inc, USA) and whole body impendance analysis (Body Composition Analyzer BC-418MA, Tanita Corporation of America Inc., USA
5. Changes in androgen levels-Blood samples will be drawn and analysed for levels of testosterone, androstenedione, dehydroepiandrosterone sulfate (DHEAS), 17-alpha-hydroxyprogesterone (17-OHP)
6. Changes in lipid profile-Blood samples will be drawn and analysed for levels of low density lipoprotein (LDL), high density lipoprotein Level (HDL), total cholesterol levels and triglycerides
7. Changes in ACTH, cortisol
8. Changes in glycaemia and insulin sensitivity
9. Changes in levels of prolactin, progesterone, luteinising hormone (LH), follicle stimulating hormone (FSH), sex hormone binding globulin (SHBG) evaluated by blood tests

Measured at at baseline, 6 and 12 months.

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Obese women body mass index (BMI) > 30 kg/m2
2. Aged between 20-40 years old who wish to conceive and have polycystic ovary syndrome (PCOS) as defined by the Rotterdam criteria, (2003)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Previously diagnosed diabetics (both types 1 and 2)
2. History of renal disorder, hepatic disease, thyroid disease or cancer
3. Eating disorders
4. Weight altering medication
5. Weight loss > 2% in the last 3 months
6. Major cardiovascular or cerebrovascular event in the last 6 months

7. Pregnancy or lactation
8. Miscarriage in the last 3 months
9. Following contraception methods
10. Cardiac dysrhythmia
11. Porphyria (disorder of certain enzymes in the haeme biosynthetic pathway)
12. Thrombosis
13. Total lactose intolerance
14. Convulsions, seizures, epilepsy
15. Major depressive episodes, psychotic episodes, schizophrenia
16. Serious illness, injury or trauma/surgery in the last 3 months or due to undergo surgery

Date of first enrolment
01/11/2011

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Robert Gordon University
Aberdeen
United Kingdom
AB25 1HG

Sponsor information

Organisation
Robert Gordon University (UK)

ROR
https://ror.org/04f0qj703

Funder(s)

Funder type
Industry

Funder Name
LighterLife

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes