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The effects of a 12-week exercise intervention on respiratory exchange ratio, body composition, thyroid function and lipid metabolism in hypothyroid, obese women

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
08/08/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
M0010111344

Study information

Scientific Title
The effects of a 12-week exercise intervention on respiratory exchange ratio, body composition, thyroid function and lipid metabolism in hypothyroid, obese women

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Obesity

Interventions
Patients who appear eligible to the inclusion criteria will be selected from among those having their thyroid function checked, and will be sent a letter via their GP. This letter invites the patient to give consent for the investigator to gain access to her address. If consent is given, the investigator will contact the patient by letter, inviting her to a meeting to discuss the study. Enclosed with this letter will be a patient information sheet and an informed consent form, which the patient will be invited to complete at or within 24 h after the end of the meeting. After recruitment patients randomised to the intervention group will receive a 12-week structured exercise program, supervised by the investigator. Patients in the control group will receive information on 'underactive thyroid' and will have their opportunity to participate in exercise delayed for 12 weeks. Before and after this period, all subjects will undergo: echocardiography and near infra-red spectrometry, respiratory exchange ratio (RER) rest and exercise, body composition analysis and serum lipid profile and thyroid function measurement. After the second (post-intervention) measurements, all subjects will receive a 3-month membership to the Bolton Excel Cardiogym, where they will have the opportunity to complete an exercise program under qualified gym supervision.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Percentage reduction in body fat.

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/09/2003

Eligibility

Key inclusion criteria

1. Obese (Body Mass Index [BMI] =30.1-40, American College of Sports Medicine [ACSM])
2. Female
3. Sedentary (>90min of moderate physical activity per week)
4. Age 40-50
5. Subclinical hypothyroidism ('mild hypothyroidism'): elevated thyroid stimulating hormone (TSH) 4-10 mU/l but within-normal-range serum and T4 levels (>8 pmol/l)
6. Able to attend exercise sessions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

11/03/2002

Date of final enrolment

01/09/2003

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Consultant in Clinical Chemistry
Bolton
United Kingdom
BL4 0JR

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Bolton Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration