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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	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/08/2016	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Percentage reduction in body fat.

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/03/2002

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Bolton Hospitals NHS Trust (UK)

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