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The Aberdeen Behaviour Change (ABC) Weight Loss Study

Submission date	Recruitment status	[_] Prospectively registered
17/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/01/2012	Nutritional, Metabolic, Endocrine	

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
V2 30 June 2009

Study information

Scientific Title
Feasibility study for a randomised controlled trial of a behavioural intervention to reduce weight in obese adults with additional risk factors for chronic disease

Acronym
ABC weight loss study

Study objectives
The purpose of the proposed study is to test the feasibility and acceptability of the intervention, measurement and trial procedures for a Randomised Controlled Trial (RCT) of a newly developed behaviour change intervention in a sample of obese adults with additional risk factors for disease recruited from GP practice lists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by North of Scotland Research Ethical Committee (REC) (ref: 09/S0801/54)

Study design
Pilot single centre single-blinded randomised active controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Obesity with additional risk factors

Interventions
Participants will be randomised to a group based manual based intervention or a leaflet control condition in accordance to a 2:1 allocation ratio.

1. Intervention group (Nurse-led 6 session group intervention):
The group intervention focuses on changing activity and dietary behaviours, and in turn weight and waist/hip ratio, in a sample of obese participants with additional risk factors. It is based on a comprehensive systematic review and a systematic intervention development process.
An experienced nurse will deliver six group sessions (five weekly sessions in the beginning of the intervention and a refresher session 3 weeks after session 5). The nurse will be trained and instructed in delivering the intervention in accordance with a detailed manual consisting of behaviour change techniques that have been identified as successful in terms of weight loss in our systematic review. Groups will include up to ten participants. The introduction of behaviour change techniques will follow a logical pattern with the introduction of action planning and self–monitoring in the first few sessions, followed by the introduction of subsequent techniques on a weekly basis concluding with relapse prevention towards the end of the intervention.
In addition, participants in the intervention group will receive brief encouraging letters if they miss sessions, offering to send additional study materials (e.g. self-monitoring or goal setting sheets) and the leaflets 'So you want to lose weight... for good - A guide to losing weight for men and women' and 'Get Active' issued by the British Heart Foundation.
Intervention sessions will be recorded and anonymously transcribed.

2. Control group (standard care plus written information from the British Heart Foundation):
Participants in the control group will receive the leaflets 'So you want to lose weight... for good - A guide to losing weight for men and women' and 'Get Active' issued by the British Heart Foundation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Acceptability and feasibility for the pilot trial

Key secondary outcome(s))
1. Changes in physical activity, diet (kcal/fat intake) and weight at 3 and 6 months (these will be primary outcomes for the main trial)
2. Changes in psychological predictors of physical activity and dietary behaviours

Completion date
30/08/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/04/2011:
1. Adult patients from the lists of GP practices in Grampian
2. BMI ≥ 30
3. Co-morbidities such as type 2 diabetes, impaired glucose tolerance or hypertension.

Previous inclusion criteria:
1. Adult patients from the lists of GP practices in Grampian
2. BMI ≥ 35
3. Co-morbidities such as type 2 diabetes, impaired glucose tolerance or hypertension.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Insufficient knowledge of the English language to take part in group interventions and use written materials
2. Conditions preventing participants from engagement in mild-moderate physical activities such as walking

Date of first enrolment
15/09/2009

Date of final enrolment
30/08/2010

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB24 2UB

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Scottish Government, Chief Scientist Office (UK) (Ref: CZG/2/390)

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?
Results article	results	01/01/2011		Yes	No