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BeWEL: the impact of a bodyweight and physical activity intervention on adults at risk of developing colorectal adenomas

Submission date	Recruitment status	[_] Prospectively registered
20/09/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-assess-impact-of-lifestyle-advice-to-people-who-have-had-a-bowel-adenoma-removed-bewel

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2009ON07; G0802030

Study information

Scientific Title
BeWEL: a two-arm multicentre randomised controlled trial of a multiple contact personalised intervention programme versus usual care on weight loss

Acronym
BeWEL

Study objectives
To evaluate the impact of a an intervention programme ("BeWEL") on body weight change, cardiovascular risk factors, diet and physical activity in healthy individuals attending routine NHS clinics who have had pre-cancerous bowel polyps removed but are at risk of developing future cancer and other obesity related conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics B Research Ethics Committee, 23/07/2010, ref: 10/S1402/34

Study design
Two-arm multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer and cardiovascular disease

Interventions
Intervention group (IG):
Receives the "BeWEL" personalised intervention programme, personal body weight scales and

invitations to undertake supervised monthly body weight recordings. The BeWEL personalised, multiple contact, intervention programme will include:
1. Goal-setting for weight, activity, and calorie intake
2. Self-monitoring to achieve these goals
3. Frequent contact to provide accountability and sustain focus
4. Use of problem-solving and other "toolbox" strategies to address goals and potential barriers to achieving them
5. Emphasis on managing individual high-risk situations
The approach will take particular care to emphasise the importance of regular self weighing which is widely associated with greater weight loss and weight prevention (showing a 1 to 3 BMI unit advantage over individuals who do not self weight frequently).

Comparison group (UC):
The usual care (UC) group will be given a general leaflet on healthy lifestyle which is widely available in the NHS setting. This will ensure that all participants receive some lifestyle advice which at the moment is given out on an ad hoc basis.

The total duration of treatment and follow-up is 12 months. Participants will be followed up at 3 months and 12 months post-baseline, and will receive the BeWEL intervention (or usual care) throughout the whole 12 months.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 24/05/2011:
Measured at baseline, 3 months and 12 months:
Body weight (BMI)

Previous primary outcome measures:
Measured at baseline, 3 months and 12 months:
1. Body weight (BMI)
2. Waist circumference

Secondary outcome measures
Measured at baseline, 3 months and 12 months:
1. Waist circumference (Added 24/05/2011)
2. Lipid profile
3. Homeostatic model assessment (HOMA) from fasting insulin and glucose
4. HbA1C
5. Blood pressure
6. Diet
7. Self-assessed health and self-efficacy
8. Objectively measured physical activity levels (from 7 day SenseWear physical activity monitor)
9. Change in primary outcome measures by deprivation
10. Perceived acceptability of the programme (from post-study questionnaires and interviews)
11. Intervention costs

Overall study start date
21/09/2010

Completion date
20/09/2012

Eligibility

Key inclusion criteria
1. Aged 50 to 74 years, either sex
2. Have participated in the NHS Scottish Bowel Screening Programme
3. Had one or more benign adenomas removed
4. Body mass index (BMI) greater than 25 m/kg2
5. Physically able to undertake exercise requirements
6. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
316 participants (158 in each arm)

Total final enrolment
329

Key exclusion criteria
1. Normal colonoscopy
2. Diagnosed with cancer as a result of their colonoscopy
3. Currently suffering from cancer at another site
4. Rely on insulin administration for glucose control
5. BMI less than 25 kg/m2

Date of first enrolment
21/09/2010

Date of final enrolment
20/09/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Dundee
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
c/o Dr Anne Langston
Tayside Academic Health Sciences Centre
Ninewells Hospital & Medical School
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George Pirie Way
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) - National Prevention Research Initiative (NPRI) (UK) (ref: G0802030)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/03/2011		Yes	No
Results article	results	18/12/2013		Yes	No
Results article	results	07/03/2014		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	01/06/2018	08/11/2019	Yes	No
Plain English results			25/10/2022	No	Yes