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Family History Lifestyle Study

Submission date 20/11/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 30/11/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/03/2024	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-healthy-eating-exercise-women-increased-risk-breast-cancer-the-family-history-lifestyle-study

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35447

Study information

Scientific Title
Randomised comparison of two remotely delivered diet and physical activity weight loss programmes vs written diet and physical activity advice amongst overweight women attending a Family History Clinic at increased risk of breast cancer: a phase 3 efficacy study

Study objectives
This study is an individually randomised trial to test the efficacy for weight loss over 12 months of two different remotely delivered diet and physical activity weight loss programmes compared to only receiving written diet and physical activity information amongst 209 overweight/obese women in UK Family History Clinics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 21/08/2017, ref: 17.NW.0440

Study design
Randomised; Interventional; Design type: Prevention, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Breast cancer

Interventions
209 overweight/obese women in 3 UK NHS family history clinics are randomly assigned to one of 2 different 12 month weight loss/lifestyle programmes or a group receiving written advice:
1. A written advice group (n=35): Women receive their personal breast cancer risk and are given written diet and physical advice for weight loss.
2. A breast cancer prevention programme (n=87): Women receive their personal breast cancer and a 6 month health care professional supported telephone, web based and e-mail programme followed by 6 months of web support.

3. A multiple disease prevention programme(n=87): Women receive their personal risks of breast cancer , heart disease stroke , from an NHS health check followed by a 6 month health care professional supported telephone, web based and e-mail programme followed by 6 months of web support.

All participants have their weight and diet and physical activity behaviours assessed at baseline, 6 and 12 months.

Intervention Type
Other

Primary outcome measure
Percentage weight loss is measured using Tanita 180 bioelectrical impedance scales at baseline, 6 months and 12 months

Secondary outcome measures
1. Health behaviours is measured using the questionnaire “Mediterranean diet score” “IPAQ” and “Alcohol and Smoking” at baseline, 3 months, 6 months and 12 months and an optional physical activity monitor an baseline and 12 months
2. Change in body composition is measured using Tanita 180 bioelectrical impedance scales at baseline, 6 months and 12 months
3. Blood pressure is measured using a blood pressure monitor at baseline, 6 months and 12 months
4. Diet behaviour is measured using the questionnaire “Mediterranean diet score” at baseline, 3 months, 6 months and 12 months
5. Physical Activity is measured using the questionnaire “IPAQ” at baseline, 3 months, 6 months and 12 months and an optional physical activity monitor an baseline and 12 months
6. Quality of life is measured using the questionnaire “EQ-5D-5L”, ICE-CAP-A” and “health Resource Use” at baseline, 6 months and 12 months
7. Disease Risk perception is measured using the questionnaire “Study beliefs and Behaviours” at baseline, 6 months and 12 months
8. The impact of the three interventions on Health status and well-being is measured using the questionnaire “EQ-5D-5L” and ICE-CAP-A”” at baseline, 6 months and 12 months
9. Use of healthcare resources is measured using the questionnaire “health Resource Use” at baseline, 6 months and 12 months
10. The fidelity of the delivery of the Breast Cancer Prevention Programme and Multiple Disease Prevention Programme programmes is measured using the study phone call and email CRF
11. Behaviour change is measured using the questionnaire “Study beliefs and Behaviours” at baseline, 6 months and 12 months
12. Mammographic density is measured using automated volumetric and area based density analysis and visual assessment by a consultant radiologist at baseline and 12 months
13. The views of women using the programmes is measured using qualitative thematic analysis of a semi structured interview after 12 months

Overall study start date
01/05/2017

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Receiving annual or 18 monthly mammograms in the FHC (aged > 30 years)), or as part of a mammographic surveillance programme for increased familial risk of BC
2. Have previously received information on their risk of developing BC within the FHC
2. Overweight / obese (BMI ≥ 25 kg/m2)
3. Access to the internet and telephone
4. Ability to understand English and complete trial paperwork as successful participation requires engagement with weekly tailored e-mails and an interactive patient forum
5. Participants must be willing to follow a diet and physical activity plan with the aim of losing weight
6. Agree that results of any NHS Health Checks conducted in the study can be communicated back to their GP. This is a requirement of NHS Health Checks to allow patients with undiagnosed CVD or T2DM or high risks of these diseases to receive appropriate follow up tests and medical management.
7. Assessed as safe to undertake a home based moderate intensity physical activity programme according to the physical activity readiness questionnaire (PAR-Q) +/- clearance from GP where appropriate
8. Women taking chemoprevention for BC, e.g. tamoxifen, raloxifine or aromatase inhibitors are eligible to join the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 209; UK Sample Size: 209

Total final enrolment
210

Key exclusion criteria
1. Only one woman per family is able to join the study to avoid contamination between the groups
2. Previous diagnosis of cancer with the exception of previous non-melanoma skin cancer or cervical intra-epithelial neoplasia
3. Previous diagnosis of cardiovascular disease i.e. stroke, transient ischaemic attack (TIA), angina, heart attack, heart failure or ventricular or aortic aneurysm
4. Currently prescribed statins for raised cholesterol
5. Current diagnosis of T2DM
6. Current physical co-morbidity or hypertension which makes the patients unsuitable for a home based moderate physical activity programme as assessed with a positive PAR-Q score and opinion of the patients general practitioner for example; unstable angina, resting systolic BP >

160 resting diastolic BP > 100 mmHg with or without medication, a significant drop in blood pressure during physical activity, uncontrolled tachycardia> 100 bpm at rest, uncontrolled arrhythmia
7. Previous diagnosis of borderline personality disorder, bipolar psychotic disorder, or self-harm.
8. Currently prescribed antipsychotics i.e. Aripiprazole, Clozapine, Olanzapine, Quetiapine, Risperidone as these can cause excessive weight gain
9. Current alcohol or drug dependency
10. People requiring highly specialist medical diets which cannot be adjusted to fit with a weight loss diet i.e. phenylketonuria, maple syrup urine disease, glycogen storage diseases, and urea cycle disorders advanced kidney disease, advanced liver disease
11. Currently pregnant, breast feeding or planning pregnancy in the next 12 months
12. Patients who are currently on treatment with Orlistat for weight loss or who have previously had bariatric surgery for weight loss including gastric bypass and sleeve gastrectomy
13. Current diagnosis of kidney disease
14. Patients with a diagnosis of an eating disorder (e.g. binge eating or bulimia)
15. Currently successfully following a diet and/or physical activity plan and have lost more than 2 lb (1 kg) of weight in the last 2 weeks
16. Currently or previously on the PROCAS (Predicting Risk of Breast Cancer at Screening) Study

Date of first enrolment
29/11/2017

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Tameside General Hospital
Fountain Street
Ashton-under-Lyne
United Kingdom
OL6 9RW

Study participating centre
Southampton General Hospital
Tremona Road
Hampshire
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SO16 6YD

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust

Sponsor details
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
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M23 9LT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
Prevent Breast Cancer Limited

Results and Publications

Publication and dissemination plan

The data from the trial will be owned by the sponsor. Trial results will be written as a final report for the funding body and disseminated at national/international scientific conferences and peer reviewed scientific papers and a number of web sites which for example may include Prevent Breast Cancer, the Manchester Breast Centre, Manchester Biomedical Research Centre Cancer Prevention and Early Detection, University of Manchester Women's Cancer. Outputs from the trial will be written up jointly by the Chief Investigator and all co-applicants.

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan
All datasets used and analysed during the current study and the trial protocol are available from the corresponding author (Dr Michelle Harvie, michelle.harvie@manchester.ac.uk) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.1	30/08/2017	30/11/2017	No	Yes
Protocol file	version 2.0	14/01/2018	18/08/2022	No	No
Results article		25/02/2023	27/02/2023	Yes	No
Plain English results			07/03/2024	No	Yes