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PROCAS: Lifestyle Breast Cancer Prevention Feasibility Study

Submission date	Recruitment status	[X] Prospectively registered
26/09/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/11/2021	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/trials/a-study-looking-whether-information-about-risk-affects-whether-women-follow-weight-loss-programme-procas-lifestyle-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17480

Study information

Scientific Title
PROCAS: Lifestyle Breast Cancer Prevention Feasibility Study: randomised controlled study

Acronym
PROCAS

Study objectives
Does personalised information about risk of cardiovascular disease and diabetes enhance uptake and adherence to a weight loss programme amongst women who receive breast cancer risk feedback in the NHS Breast Cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull Research Ethics Committee, 09/09/2014, ref: 14/WM/1088

Study design
Randomised; Interventional; Design type: Prevention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

Interventions
172 overweight women currently enrolled on the PROCAS Study will be randomly assigned to a weight loss / lifestyle programme with either:

1. A standard care group (n = 40)
A reminder their individual breast cancer risk and information that weight loss of >5% and lifestyle change can reduce this risk by 25%-30%. They will receive general (not personalised) information on the likely reductions in risk of other diseases with > 5% weight loss/ lifestyle change .

2. An NHS health check group (n = 80)
As above but they will also receive an NHS health check and personalised information on their risk of developing cardiovascular disease and Type 2 diabetes. This group will be informed that weight loss of >5% and lifestyle change can reduce their risk of breast cancer by 25%- 30%, their risk of diabetes by 60% and CVD by 30%.

All participants are seen at baseline, three and six months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight, body fat and fat-free mass are measured at baseline, 3 and 6 months

Secondary outcome measures
1. Biomarkers of CVD (lipids, systolic and diastolic blood pressure), diabetes (HbA1c) are measured at baseline, 3 and 6 months
2. Quality of life is measured using the SF-36 questionnaire at baseline, 3 and 6 months
3. Health status is measured using the EQ-5D questionnaire at baseline, 3 and 6 months

Overall study start date
05/04/2012

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Attending the NHSBSP aged 47 - 74 years and part of the PROCAS study
2. Women who have previously received feedback of their personalised breast cancer risk by phone / face to face / letter
3. BMI ≥25 kg/m2 as breast cancer risk is seen amongst overweight as well as obese women
4. Access to and ability to use a telephone and high/moderate-speed internet
5. Women in the North, Central and South Manchester Clinical Commissioning Groups who are eligible for NHS health check with Public Health Manchester
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 diabetes or high risks of these diseases to receive appropriate follow up tests and medical management.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
172

Total final enrolment
178

Key exclusion criteria
Exclusion criteria as of 03/11/2016:
1. Previous diagnosis of cancer, diabetes, CVD or receiving medication for raised cholesterol. Women with previous non-melanoma skin cancer or cervical intra-epithelial neoplasia will be accepted.
2. Physical or psychiatric condition which precludes suitability or adherence to a home-based diet and exercise programme
3. Current user of hormone replacement therapy (weight affects breast cancer risk amongst non-HRT users only)
4. Advanced renal failure and attending a pre dialysis clinic.
5. Currently successfully following a diet and/or exercise plan and have lost more than 2 lb (1 kg) of weight in the last 2 weeks

Original exclusion criteria:
1. Previous diagnosis of cancer, diabetes, CVD or receiving medication for raised cholesterol
2. Physical or psychiatric condition which precludes suitability or adherence to a home-based diet and exercise programme
3. Current user of hormone replacement therapy (weight affects breast cancer risk amongst non-HRT users only)

Date of first enrolment
01/10/2014

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Nightingale Centre
Southmoor Road
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Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust

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Sponsor type
University/education

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
Prevent Breast Cancer Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	reply to comment	01/03/2020	05/06/2020	Yes	No
Results article	results	04/12/2019	05/06/2020	Yes	No
Plain English results		24/11/2021	24/11/2021	No	Yes
HRA research summary			28/06/2023	No	No