ISRCTN10436313 https://doi.org/10.1186/ISRCTN10436313

Breast cancer risk reduction through family-based lifestyle change

Submission date
20/11/2025

Recruitment status
Recruiting

Registration date
27/11/2025

Overall study status
Ongoing

Last Edited
27/11/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the most common cancer in women in the UK and living with overweight/obesity increases the risk. Research shows that losing even 5-10% of body weight can reduce breast cancer risk. However, many women and especially mothers find it difficult to lose weight while balancing family, work and childcare. Family dynamics, routines and the home food environment can strongly influence the women's success in achieving a healthy weight.
This study aims to test whether a family based weight loss programme is acceptable and practical for mothers with overweight or obesity who are identified as having increased breast cancer risk through NHS family history clinic/genetic clinics. The B-FAM programme (BREAST cancer risk reduction through FAMily-based lifestyle change) encourage mothers to lose weight through changes in diet andphysical activity using strategies such as self-monitoring, meal planning and building family support. Findings in this study will inform whether further research of the family-based weight loss programme is warranted.

Who can participate?
This single centre single-arm feasibility study in Manchester will recruit 15-20 mothers at increased risk of breast cancer living with overweight/obesity aged 18 years or older who live with children 17 years or under to take part.

What does the study involve?
A participating mother would be invited to take part in a 12-week family-based weight loss programme supported by a research dietitian. Mothers will be asked to attend a face to face visit before the start and at the end of the programme to assess weight, body fat and muscle (using special scales). They will also complete questionnaires to assess their eating behaviour, dietary intake, physical activity and alcohol intake and complete a 7 day food diary
The 12-week programme includes personalised diet and physical activity advice based on cancer-prevention guidance to support weight loss of approximately 0.5–1 kg (1–2 lb) per week, supported by fortnightly phone/ video call or email contact with their designated trial dietitian covering topics including meal planning, emotional eating, problem-solving, The mother would be encouraged to involve her family in healthy eating and physical activity at home, although the weight-loss focus remains on the mother.

What are the possible benefits and risks of participating?
Direct health benefits cannot be promised. Some women may experience improvements in weight, fitness, or family support, but this cannot be guaranteed. By taking part, a participating mother may have the opportunity to receive personalised dietetic support, learn practical skills for healthy eating and physical activity, and involve her partner and children in positive lifestyle changes. The broader benefit is that her involvement will help inform the development of future NHS services for women at increased risk of breast cancer.
The study is considered low risk and follows NHS healthy eating and lifestyle recommendations, but some participants may experience some emotional distress when discussing weight, body image, family relationships, or breast cancer risk. If a participating mother becomes distressed, she may pause, stop a session, or withdraw from the trial at any time without giving a reason. If questionnaire scores suggest family communication or relationship difficulties, the dietitian will discuss this sensitively and provide information on how mothers can find a qualified family therapist through the Association for Family Therapy and Systemic Practice directory. The mother may also choose to speak with her GP or access local NHS family support services. The research team will not make any formal referrals.

Where is the study run from?
Manchester University Hospital Foundation NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2026 to September 2026

Who is funding the study?
This trial is funded by the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC) (NIHR203308).

Who is the main contact?
Mai Haiba, mai.haiba@postgrad.manchester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Michelle Harvie

ORCID ID
https://orcid.org/0000-0001-9761-3089

Contact details
First Floor Education and Research Centre
Manchester University Hospital Foundation NHS Trust
Wythenshawe
Manchester
United Kingdom
M23 9LT
+44 161 291 5815
michelle.harvie@manchester.ac.uk

Type(s)
Public, Scientific

Contact name
Ms Mai Haiba

Contact details
Division of cancer sciences
School of Medical sciences
Faculty of Biology, Medicine and Health
University of Manchester
Manchester
United Kingdom
M13 9NT
+44 161 291 5815
mai.haiba@postgrad.manchester.ac.uk

Additional identifiers

National Institute for Health and Care Research (NIHR)
203308

Integrated Research Application System (IRAS)
364154

Study information

Scientific Title
Intervention feasibility trial of a family-based weight loss programme for mothers with overweight or obesity identified at increased risk of breast cancer

Acronym
B-FAM

Study objectives
Co-primary feasibility objectives are:
1. Uptake and retention to the programme, including demographics of mothers recruited and reasons for non-eligibility
2. Feedback of acceptability from participating mothers with a validated acceptability questionnaire.
3. Engagement with different elements of the programme for mothers and their families
4. Quantify dietitian time required per mother for delivery of the programme.
Secondary objective:
1. Preliminary evaluation of any effects of the programme for the mother; body weight, healthy eating, physical activity and any changes in health behaviour of participating family members or any changes in family relationships.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Single-arm feasibility trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of breast cancer in women at increased risk

Interventions
A 12-week family-based behavioural weight-loss programme (B-FAM) delivered by a research dietitian. The programme provides:
- Personalised energy-reduced Mediterranean-style diet: Individual energy requirements for each participating mother will be estimated using the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Body Weight Planner online calculator
- Physical activity guidance per WHO 2020 recommendations: Participating mothers will be encouraged to achieve at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic activity per week, or an equivalent combination and muscle-strengthening exercises on two or more days
- The fortnightly intervention sessions are structured to involve only the mothers which would provide more opportunity to focus on her own health goals while equipping her with tools to enhance the home food environment and help her create a more supportive family atmosphere. Enhancing family support would occur via providing tailored educational materials that re-enforces the diet and physical activity guidance of our trial in a way that suits her partner and children. There would also be reward charts to encourage family participation in shared health goals via family exercise or cooking challenges.
- Family-based components using Family Systems Theory and Family-Based Behavioural Treatment principles
- Fortnightly remote dietitian follow-up (weeks 0, 2, 4, 6, 8, 10, 12) plus structured between-session action plans

Intervention phases:
- Phase 1: Acquire new skills (weeks 0-4): Learn new skills around diet, physical activity and home environment set-up
- Phase 2: Consolidate skills (weeks 4-8): establish new routines and teach coping skills
- Phase 3: Maintain changes: (weeks 8-12): reinforce newly acquired routines and behaviours, address expected barriers for sustainability

Duration of intervention: 12 weeks
Follow-up timepoints: Fortnightly diet and exercise review
Face-to-face assessments: Baseline and week 12 reviews

Intervention Type
Behavioural

Primary outcome(s)
1. Numbers invited and consented to the trial , measured using screening logs and consent logs at baseline
2. Numbers consented who complete the trial, measured using retention logs at week 12
3. Demographics of recruited mothers, measured using a demographic and diet-history questionnaire at baseline on Qualtrics (or paper forms)
4. Acceptability, measured using the validated intervention acceptability questionnaire (Sekhon et al., 2022) at week 12 on Qualtrics (or paper forms)
5. Engagement with sessions and family challenges, measured using dietitian CRFs documenting attendance at fortnightly calls and mother-reported family engagement across weeks 0–12
6. Dietitian time required per mother, measured using structured dietitian time-tracking forms completed at every dietitian contact point (weeks 0–12)

Key secondary outcome(s))
For participating mothers not for other family members:
1. Measured maternal weight and body composition; body fat and lean mass (assessed with bioelectrical impedance(Tanita 980 BIA)), waist, hip circumference measured by research dietitians measured at baseline and week 12.
2. Dietary intake, measured using a 7-day food diary via MyFood24® or paper diary at baseline, week 6, and week 12.
3. Mediterranean Diet Score, measured using the validated 14-item questionnaire at baseline, week 6, and week 12.
4. Physical activity, measured using IPAQ-Short Form at baseline, week 6, and week 12.

Family endpoints (completed by the mother):
5. Family functioning, measured using the General Functioning subscale (GF) of the McMaster Family Assessment Device at baseline, week 6, and week 12.
6. Family Nutrition and Physical Activity (FNPA) questionnaire, measured at baseline, week 6, and week 12.

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Born female, no gender reassignment
2. Age ≥18 years
3. Moderate/high BC risk (≥17% lifetime or ≥3% 10year risk at age 40) per clinic assessment
4. BMI ≥25.0 kg/m² (≥23.5 for ethnic minority groups)
5. Communicates in English/other supported language and has phone access
6. Can attend 2 facetoface visits at MFT
7. Not pregnant/planning pregnancy in next 3 months; negative pregnancy test if indicated; agrees to contraception/abstinence
8. Family participation (potential willingness of the family members to take part as reported by the mother)
9. Coresident dependent children aged 17 years or under

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Previous cancer diagnosis with exception of non-melanoma skin cancer or cervical intra-epithelial neoplasia
2. Currently pregnant or breastfeeding
3. Current GLP1/GIP agonist use, other antiobesity medications, or prior bariatric surgery
4. Medical/psychiatric conditions, in the view of the study clinician, making participation inappropriate or unsafe
5. Inability to consent
6. Inability to attend face-to-face and/or remote sessions
7. Current participation in other weight loss programmes/trials
8. Substance abuse or harmful alcohol use as indicated by a score of 16 or above on the Alcohol Use Disorders Identification Test (AUDIT)
9. Current or previous diagnosis of an eating disorder
10. Participants with severe binge eating assessed by a score of 27 or more on the Binge Eating Scale (BES)
11. Participants with severe depression assessed by a score of 15 or more on the Patient Health Questionnaire-9 (PHQ-9) questionnaire
12. Participants with severe anxiety assessed by a score of 15 or more on the General Anxiety Disorder (GAD-7) questionnaire

Date of first enrolment
01/02/2026

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

An anonymised dataset will be uploaded at the end of the study onto a data-sharing repository i.e. Figshare in accordance with FAIR principles for data sharing: https://figshare.manchester.ac.uk/ at the end of the stated retention period.

IPD sharing plan summary

Stored in publicly available repository