

RESEARCH PROTOCOL

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

Full/Long Title of the Trial

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

Short Trial Title/Acronym

BREAST cancer risk reduction through FAMily-based lifestyle change (B-FAM)

Protocol Version Number and Date

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Amendment History

Amendment No.	Protocol Version and date	Details of Changes Made

Research Reference Numbers

IRAS Number	364154
Sponsor Reference	NHS00231
Funder Reference	This trial is funded by the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC) (NIHR203308).

This protocol has regard for the HRA guidance

This project will be conducted in accordance with the trial protocol and the ethical principles outlined by Good Clinical Practice (GCP) and the Declaration of Helsinki in its most current version.

Signature Page

The sponsor signature on the IRAS form, acts as documented acceptance that the sponsor approves the protocol.

The Chief Investigator should sign below to confirm the following:

The Chief Investigator confirms the protocol has been agreed and accepted and agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

Chief Investigator:

Signature:

Date:



15/12/25

Name: (please print):

Michelle Harvie

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Key Trial Contacts

Chief Investigator (main supervisor)	Professor Michelle Harvie Address: Research Dietitians First Floor, Education & Research Centre, Manchester University NHS Foundation Trust, Wythenshawe, Manchester, M23 9LT Phone: 0161 291 5815 Email: michelle.harvie@manchester.ac.uk
Co-investigator and trial Contact for Enquiries (student)	Mai Haiba Division of Cancer Sciences School of Medical Sciences Faculty of Biology, Medicine and Health University of Manchester Phone: 0161 306 9740 Email: mai.haiba@postgrad.manchester.ac.uk
Co- Investigator (co-supervisor)	Professor David French Division of Psychology and Mental Health, School of Health Sciences, Faculty of Biology, Medicine and Health, Phone: 0161 275 2605 Email: david.french@manchester.ac.uk
Co-investigator (co-supervisor)	Dr Nia Coupe Division of Medical Education School of Medical Sciences Faculty of Biology, Medicine and Health University of Manchester Phone: 0161 306 9033 Email: nia.coupe@manchester.ac.uk
Co-investigator	Dr Sacha Howell Division of Cancer Sciences, Faculty of Biology Medicine and Health The University of Manchester

	Oglesby Cancer Research Centre, 555 Wilmslow Road, Manchester M20 4GJ Phone: 0161 446 8347 Email: sacha.howell@christie.nhs.uk
Public contributors	Jennifer Rodgers Sarah McGillvray
Trial dietitian	Cheryl Lombardelli Research Dietitians First Floor Education and Research Centre, Manchester University NHS Foundation Trust Wythenshawe, Manchester, M23 9LT Phone: 0161 291 5815 Emails: cheryl.lombardelli@mft.nhs.uk
Trial dietitian	Heather Spilsbury Research Dietitians First Floor Education and Research Centre, Manchester University NHS Foundation Trust Wythenshawe, Manchester, M23 9LT Phone: 0161 291 5815 Email: Heather.Spilsbury@mft.nhs.uk
Sponsor	Mrs Stacey Body University of Manchester Faculty of Biology Medicine and Health Oxford road Manchester M13 9PL
Funder(s)	This trial is funded by the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC) (NIHR203308).
Key Protocol Contributors	Mai Haiba, Professor Michelle Harvie, Professor David French, Dr Nia Coupe
Committees	Trial management group

Trial Summary

Trial Design	Single-arm feasibility trial
Trial Participants	Mothers ≥ 18 years with overweight/obesity identified by the Family History Clinic as having moderate or high risk of

	breast cancer and have children living within the same household ≤ 17 years
Planned Size of Sample	15-20 mothers
Recruitment Period	2-3 months
Follow Up Period	3 months
Overall, Trial Duration	6 months
Research Question/Aim(s)	An intervention feasibility trial to assess acceptability and engagement to a family-based weight loss intervention for breast cancer risk reduction amongst mothers identified at increased risk of breast cancer.
Trial objectives	Co-primary feasibility objectives are: • Uptake and retention to the intervention, including demographics of mothers recruited and reasons for non-eligibility • Feedback of acceptability from participating mothers with a validated acceptability questionnaire. • Engagement with different elements of the programme for mothers and their families • Quantify dietitian time required per mother for delivery of the intervention. Secondary objectives • Preliminary evaluation of any benefits of the intervention 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.
Primary Outcome Measure	Co-Primary Endpoint • Numbers invited and consented to the trial. • Numbers consented who complete the trial. • Demographics of subjects recruited • Acceptability questionnaire • The number of mothers engaging with each online session and engagement of their families with the family challenges • Dietitian time for programme delivery per mother in the trial
Secondary Outcome Measure(s)	Secondary Endpoint(s) for participating mothers not for other family members

	• Measured maternal weight and body composition; body fat and lean mass (assessed with bioelectrical impedance), waist, hip circumference. • 7-day paper food diary • Mediterranean diet score • International Physical activity questionnaire (IPAQ) short form. • Alcohol and smoking intake Family endpoints (completed by the mother): • Family functioning measured using the general functioning subscale of the McMaster Family Assessment Device • Family nutrition and physical activity questionnaire (FNPA).
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Funding and Support

Funder(s)	This trial is funded by the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC) (NIHR203308).
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Role of Trial Sponsor and Funder

The University of Manchester is acting as sponsor for this trial and is assuming overall responsibility for the initiation and management of the trial. The University will provide permission to conduct the research and monitor the progress of that research. The sponsor has influence over all aspects of the trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results which are the responsibility of the research team.

The trial is funded by NIHR Manchester BRC. The funder is financing the project and has no role in the trial design.

Roles and Responsibilities of Trial Management Committees/Groups & Individuals

Trial Steering Groups

The trial has a Trial Management Group (TMG). The TMG will review recruitment/ retention/ completeness of data and new safety information. The TMG includes the following members:

- Chair: Professor Michelle Harvie
- Team involved in the day to day running of the Trial: Mai Haiba, Cheryl Lombardelli
- Co applicants to provide expertise on behaviour change, Psychology and well-being: Prof David French, Dr Nia Coupe
- 2 public contributors: Jennifer Rodger, Sarah McGillvray

- Dr Sacha Howell – medical oncologist and clinical lead for the MFT family history clinic

Key Words:

Family intervention, weight; breast cancer; health behaviour; acceptability; feasibility.

Abbreviations

Abbreviation	Definition
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AE	Adverse Event
AFT	Association for Family Therapy and Systemic Practice
AUDIT	Alcohol Use Disorders Identification Test
BC	Breast Cancer
BES	Binge Eating Scale
BMI	Body Mass Index
BRC	Biomedical Research Centre
BCT	Behaviour Change Technique
CI	Chief Investigator
CRF	Case Report Form
eCRF	Electronic Case Report Form
FAD	Family Assessment Device
B-FAM	BREAST cancer risk reduction through FAMily-based lifestyle change
FBBT	Family-Based Behavioural Treatment
FHC	Family History Clinic
FNPA	Family Nutrition and Physical Activity questionnaire
FST	Family Systems Theory
GAD-7	Generalised Anxiety Disorder-7 scale
GCP	Good Clinical Practice
GF	General Functioning subscale
GLP-1	Glucagon-Like Peptide-1
GIP	Glucose-Dependent Insulinotropic Polypeptide
GP	General Practitioner
HRA	Health Research Authority
HCP	Health Care Professional
IRAS	Integrated Research Application System
IPAQ	International Physical Activity Questionnaire
IT	Information Technology
MFT	Manchester University NHS Foundation Trust

NHS	National Health Service
NIHR	National Institute for Health and Care Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
PA	Physical Activity
PAR-Q	Physical Activity Readiness Questionnaire
PHQ-9	Patient Health Questionnaire-9
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMG	Trial Management Group
TMF	Trial Master File
UoM	University of Manchester
WHO	World Health Organization
MFT	Manchester University NHS Foundation Trust
REC	Research Ethics Committee
TMF	Trial Master File
PPIE	Patient and Public Involvement and Engagement

1. Background

In the United Kingdom, 1 in 10 women will develop breast cancer before the age of 75 years and 1.5% of women in this age group will die from breast cancer(1). Postmenopausal breast cancer risk is linked to risk factors including excess body weight, sedentariness, smoking and alcohol. The World Cancer Research Fund estimates that up to one-third of cases could be preventable through these potentially modifiable behaviours(2). Excess body weight (BMI) has demonstrated a dose-response relationship with post-menopausal breast cancer risk(3-5). Evidence from large cohort studies have also demonstrated that maintained weight loss of 5-10% is associated with reduced risk(6).

Weight loss interventions targeting women vary in their components and success rates, including those aiming at cancer prevention. Studies have shown modest weight reductions and improved diet and physical activity among women attending the national breast screening service or those identified at high breast cancer risk through family history clinics(7-9). In the wider weight management setting, factors influencing success of weight loss include intervention-related factors like behaviour change techniques and personalized approaches, and psychosocial aspects including motivation, body image, and support structures(10, 11). Tailored interventions, especially those incorporating behaviour change theories(12) and technological support(13) generally yield better outcomes. However, barriers such as low motivation, time constraints, and lack of personalization can impede success(14).

Women generally face greater challenges when losing weight and trying to maintain a healthy weight than men, particularly those with childcare responsibilities(15). At this stage of their lives, women navigate various challenges such as pregnancy, breastfeeding, caring for children, and managing full-time work or education(16). These responsibilities make it difficult to maintain healthy dietary and exercise habits. Additionally, the home food environment, influenced by the dietary needs and preferences of their partner and children, adds another layer of complexity(17).

Involving family members in weight loss interventions has the potential to be beneficial for parents and children, though effectiveness varies based on relationship dynamics and the type of support provided(18). To date most family-based interventions have focussed on managing weight in children and adolescents. Family-based interventions for obesity leverage complex family dynamics to promote health behaviour changes across all age groups in the family(19, 20). Drawing from theories like Ecological Systems Theory and Social Cognitive Theory, these interventions target family interactions which influence diet, physical activity, and sedentary behaviours(21, 22). Findings from family weight control interventions which focus on children suggest involving the entire family can improve family roles, communication, and lifestyle choices, benefiting obesity management and overall health across the whole family(23, 24).

Adult weight loss interventions involving partners highlight the role of spousal relationships(24-27). Supportive behaviours, autonomy support, and positive spouse relationship quality enhance weight loss outcomes, particularly when criticism is avoided. Family-based approaches show promise, with evidence indicating better outcomes when interventions aim to target spouses or family members compared to individual-focused approaches.(28-30) Thus, a family intervention may help the mother overcome some of their barriers for behaviour change. An additional benefit relevant to families with genetic conditions as studied herein is the potential that family interventions can have a positive influence on health behaviours on the whole family, including the children who may have inherited the mother's disease risks. Mothers often play a crucial role through role modelling, support, and education in a family which can have a positive impact on children's health behaviours. Effective

family dynamics with clear rules and boundaries correlate with healthier outcomes, including lower BMI in children and adolescents. Family interventions often focus on weight loss in an index case, but there is often a ripple effect where untreated partners or family members may benefit indirectly from changes in the home food environment and supportive behaviours(18, 31-33).

The design and evaluation of this intervention follows the updated MRC Framework for Developing and Evaluating Complex Interventions(34), ensuring that the B-FAM programme is developed systematically, theoretically informed, and embedded within real-world implementation contexts

In this feasibility trial (aligning with the feasibility/piloting phase of the MRC framework), mothers at increased risk of breast cancer with overweight/ obesity will receive a 12-week family-based weight loss intervention. The intervention has been developed using evidence from multiple sources (MRC development phase) and includes behaviour change techniques (BCTs) identified in: 1. A systematic review of randomized controlled trials of family weight loss interventions, 2. qualitative interviews with mothers with overweight / obesity and healthcare professionals, and 3. insights from patient and public involvement and engagement (PPIE) sessions. BCTs utilised in the intervention were mapped across 8 trials in the systematic review which demonstrated significant maternal weight loss outcome (defined as >1.5 kg or >0.5 kg/m² or $>2\%$ weight loss) and with low or minimal concerns risk of bias either overall and across domain 2 (deviations from the intended intervention) and domain 3 (missing outcome data). BCTs utilised were also extracted from 10 semi-structured interviews with mothers with overweight/obesity and at high risk of breast cancer as well as 3 semi structured interviews with health care professionals (research dietitians) with experience in weight management for breast cancer risk reduction.

A family systems theory informed approach will be utilised based on the algorithm by Pratt and Skelton(35)(detailed in appendix 1) and the intervention is tailored to the family's level of functioning. A simple assessment of Family functioning will be performed at baseline using the general functioning (GF) subscale of the McMaster family assessment device (FAD)(36). The GF subscale has been tested for validity and reliability and can be utilised as a screening tool to assess family functioning. The GF subscale is brief and has a high correlation with the other 6 subscales of the FAD which renders it practical and deductive within the context of the B-FAM trial.

Families identified with greater communication or relationship challenges at baseline will receive enhanced relational support aligning with family system theory principles relating to FST concepts including structure, rules, communication, responsiveness, involvement and strengths (which are further explained in table 2). Families identified with better functioning will be asked to focus on shared health goals and joint activities through a Family Based Behavioural Treatment (FBBT) aligned approach (focusing on self-monitoring, goal setting, problem solving, behavioural contracting, relapse and prevention). Each weekly session includes a specific theme—such as nutrition skills, emotional eating strategies, or problem-solving barriers. This family-centred, theory-informed approach aims to create a supportive environment for sustainable lifestyle changes for the mother and her family.

The 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.

2. Research Question/Aim(s)

An intervention feasibility trial to assess the uptake, retention, engagement (mothers and family) and acceptability of a family-based weight loss intervention aiming at cancer prevention through weight loss for mothers with overweight/obesity identified at risk of breast cancer

2.1 Objectives

Co- primary feasibility objectives are:

- Uptake and /retention to the intervention, including demographics of the mother recruited and reasons for non-eligibility
- Engagement with different elements of the programme for mothers and families
- Feedback of acceptability of the participating mothers with a validated acceptability questionnaire.
- Quantify dietitian time required per mother for delivery of the family intervention.

Secondary objectives

Preliminary evaluation of any effects of the programme for the mother; body weight healthy eating, physical activity as well as diet and physical activity behaviours for participating family members or any changes in family relationships.

2.2 Outcomes

Co-primary Outcome Measures:

- Numbers invited and consented to the trial.
- Numbers consented who complete the trial.
- Demographics of subjects recruited
- Acceptability questionnaire(37).
- The number of mothers engaging with each online session and engagement of their families with the family challenges
- Dietitian time for programme delivery per mother

Secondary Outcome Measures:

Maternal measures:

- Measured maternal weight and body composition; body fat and lean mass (assessed with bioelectrical impedance, Tanita 980 which were calibrated in April 2024 and will be

calibrated during the course of the trial, calibration certificate would be provided separately) waist, hip circumference.

- 7-day paper food diary.
- Mediterranean diet score(38).1
- International Physical activity questionnaire (IPAQ) short form(39)

Family endpoints (completed by the mother):

- Family functioning measured using the general functioning subscale of the McMaster Family Assessment Device(40).
- Family nutrition and physical activity questionnaire (FNPA)(41).

3. Trial Design and Methods of Data Collection

3.1 Trial Design: *A single-arm feasibility trial*

12-week Family-based weight loss intervention

The intervention comprises 3 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

A detailed fortnightly session structure is reported in Table (1). The sessions **directly involve the mother** (not the family) and aim to support the mother to make personal changes and also to implement health behaviour change across her family.

Each session has a maternal component as well as a family component based primarily on FBBT concepts.

A family systems theory toolbox would inform optional add-on intervention components targeting family functioning challenges identified during the baseline assessment and baseline diet and exercise call as well as during the intervention follow-up sessions. This suggested toolbox would target family functionality for more dysfunctional families through structure, rules, communication, responsiveness, involvement and strengths (examples in table 2). This would follow the suggested algorithm of Pratt and Skelton originally developed for childhood obesity management being adapted to maternal obesity for this trial (35). Their suggested algorithm is in Appendix 1. However, on the occasions when family dysfunction is beyond the scope of practice of the dietitian, alternative supportive measures would be discussed with the mother (i.e. seeking support for the weight loss intervention from other family members outside of the nuclear family or from friends) and she will be signposted to psychological/family therapy services (more details on this in section 6.1, Management of identified family dysfunction).

Table 1: Fortnightly session structure of the 12-week family-based weight loss intervention

Session (Week)	Objective	In-session activities	Between-session reinforcement	Behaviour change techniques (BCTs) as per Michie's Taxonomy(42)
1 (W0)	Rationale, SMART goal setting, start baseline family assessment	-Personal weight loss goals (pros and cons) -Breast cancer-obesity link -Discuss family health goals based on FNPA* assessment -1 goal each (PA**, diet, home food environment)	-Weekly Action Plan (personal, family & home food environment) -Optional weekly weight -Pantry Reset checklist & shopping list -Assign personal meal plans -Optional family challenge	5.1 Information about health consequences of overweight/ obesity 12.1 Restructuring the physical environment 3.2 Social support (practical) 3.3 Social support (emotional) 13.1 Identification of self as a role model
2 (W2)	Master self-monitoring; stimulus control	-Suggest ways for self-monitoring (app/ food diary/ reminders/probes) -Set new goals or re-enforce previous goals (self and family for PA**, diet and food environment)	-Weekly Action Plan (personal, family & home food environment) -Optional weekly weight -Optional family challenge	4.1 Instructions on how to perform the behaviour 12.3 Avoidance/reducing exposure to cues of behaviour 1.2 Problem solving
3 (W4)	Address events affecting diet and PA**	-Discuss possible events that impede health goals -Explore problem solving skills (identify, understand, list possible solutions, pros and	-Weekly Action Plan (personal, family & home food environment) -Optional weekly weight -Optional family challenge	1.2 Problem solving 1.4 Action planning 4.1 Instructions on how to perform the behaviour

Session (Week)	Objective	In-session activities	Between-session reinforcement	Behaviour change techniques (BCTs) as per Michie's Taxonomy(42)
		cons, choose solution, review) -Review personal and family goals (diet, PA** and home environment) either re-enforce or identify new goals		12.2 Restructuring the social environment
4 (W6)	Address factors affecting eating and PA**	-Explore eating stimuli (food/non-food) and ways to address them -Explore barriers to PA** and ways to overcome them -Review personal and family goals (diet, PA** and home environment) either re-enforce or identify new goals	-Come up with list of things to say/do to overcome triggers and boost PA motivation -Weekly Action Plan (personal, family & home food environment) -Optional weekly weight -Optional family challenge	1.4 Action planning 15.4 Self talk 15.3 Focus on past success 11.2 Reduce negative emotions 8.3 Habit formation, 8.4 Habit reversal 12.1 Restructuring the physical environment 12.2 Restructuring the social environment
5 (W8)	Motivation refresh; role- model identity; food as a reward	-Review "what's working" -Role-model reflection -Explore if patient uses food as a reward or relief of emotional stress -Review personal and family goals (diet, PA** and home environment) either re-enforce or identify new goals	-Come-up with list of enjoyable activities/non-food rewards -Weekly Action Plan (personal, family & home food environment) -Optional weekly weight -Optional family challenge	5.1 Information about health consequences 15.1 Verbal persuasion about capability 13.1 Identification of self as a role model 10.4 Social reward 3.3 Social support (emotional)

Session (Week)	Objective	In-session activities	Between-session reinforcement	Behaviour change techniques (BCTs) as per Michie's Taxonomy(42)
6 (W10)	Outcome feedback; relapse prevention	-Review outcomes and progress -Reflect on personal/family behaviour change -Identify potential relapse triggers and prevention strategies -Review personal and family goals (diet, PA** and home environment) & either re-enforce or identify new goals	- Draft Personalised Maintenance Plan - Continue weekly Action Plan and optional weight tracking - Prepare for final review -Optional family challenge	2.7 Feedback on outcome(s) of behaviour 12.1 Restructuring the physical environment 12.2 Restructuring the social environment 15.3 Focus on past success
7 (W12)	Final diet call and long-term maintenance	- Review 12-week progress (dietary, behavioural, family) - Finalise maintenance strategies - Reinforce relapse prevention and self-monitoring - Celebrate achievements	- Implement finalised Personal Maintenance Plan -Optional family challenge	1.4 Action planning 2.3 Self-monitoring of behaviour 2.7 Feedback on outcome(s) of behaviour 15.3 Focus on past success 8.3 Habit formation
Optional on each session: family challenge reward chart (family to choose from family meals/ family PA**/ cooking together/shopping together)				

*FNPA: family nutrition and physical activity questionnaire, **PA: physical activity

Table 2: A family systems theory toolbox (FST) aligning with Pratt and Skelton algorithm adapted to maternal weight loss context

FST Concepts	Health-specific (Maternal Weight-loss Context)
Structure	Adults (especially mothers) provide structure for family meals, food purchasing, and physical activity routines that support the mother's weight-loss and overall family health.
Rules	Rules for eating, snacking, and family activity are clearly defined (e.g., limiting high-calorie snacks, screen time during meals) and support the mother's and family's healthy-living goals.
Communication	Communication about food, body image, and health focuses on shared goals, encouragement, and problem-solving rather than criticism or weight-focused talk.
Behavioural Control	Implementation and reinforcement of agreed-upon family health routines (e.g., grocery planning, shared family activities) to maintain consistency and accountability for behaviour change.
Responsiveness	Family members show understanding and flexibility toward the mother's dietary and physical-activity goals (e.g., offering support during social meals or busy family schedules).
Involvement	Partner and children are involved in meal planning, cooking, and shared physical activities that align with the mother's weight-management plan.
Strengths	Prior successes or shared values (e.g., family unity, perseverance) are leveraged to support sustained lifestyle change and create a positive home food and activity environment.
Barriers to Change	Competing demands (e.g., childcare, work stress, time pressure) or household barriers (e.g., partner resistance, limited time for meal prep) are identified and problem-solved collaboratively.

Dietary and physical activity recommendations

The mother would be asked to follow a prescribed energy-reduced Mediterranean type diet with the aim of achieving weight loss. The whole family would be encouraged to follow a general dietary approach aligned with the Mediterranean diet recommendations.

The Mediterranean diet is rich in vegetables, fruits, wholegrains, and legumes, with moderate amounts of nuts and seeds. Fish and poultry will be encouraged as preferred animal protein sources, while intake of red meat will be limited and processed meat avoided. Sugar-sweetened drinks and alcohol will be discouraged. Olive oil and other monounsaturated fats may be used as

the main added fats. Mediterranean diet guidance would be tailored for each family taking into account ethnic or cultural differences as well as differences in food budgeting across families.

Energy target: 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(43), which applies the validated dynamic model of energy balance developed by Hall et al(44). This model integrates age, sex, height, weight, and physical activity level to account for metabolic adaptations and changes in energy expenditure and body composition during weight loss. Based on the model output, an individualized daily energy prescription will be generated for each mother to achieve a gradual weight loss of approximately 0.5–2.0 kg per week, while maintaining a minimum energy intake of $\geq 1,200$ kcal/day.

Macronutrient composition the diet aims to include protein 1.2 g/kg body weight (to support satiety and preserve lean mass), fat 25–35% of total energy (emphasising unsaturated sources), ~ 25% energy from protein and the remainder from complex carbohydrates (wholegrains, legumes, vegetables). Fibre intake will be encouraged at ≥ 30 g/day, and free sugars kept below 5–10% of total energy. Alcohol would be recommended to be less than 10 units/week.

Physical activity 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(45). Mothers who are less active at baseline will be supported to gradually increase activity, with the aim of reducing sedentary time and incorporating movement into daily family routines. In addition to individual physical activity recommendations for the mother, the whole family would be encouraged to increase their activity level and to undertake shared physical activities as deemed appropriate.

Participating mothers will receive their initial advice to follow the diet and engage in physical activity by phone / video call after completion of baseline assessments. They will be offered dietetic support via phone call / video call (MS teams) / email reviews with their allocated trial dietitians at week 0, 2, 4, 6, 8, 10 and 12 after starting the programme and receive exit diet and physical activity advice after their 3-month review. They would also be provided with a Mediterranean diet booklet and Family challenges and activities booklet to supplement the dietetic advice provided during the dietetic support calls.

Suitability and safety to undertake an unsupervised home based physical activity programme will be assessed using the Physical Activity Readiness questionnaire (PAR-Q) (46). This will be completed during the baseline assessments. If mothers answer yes to one or more of the seven physical activity screening questions, with their permission we will send a letter to their GP to ask if they can verify whether the participant is safe to undertake the home-based exercise programme. A GP letter of authorisation will need to be completed as appropriate before any trial related physical activity can commence. They can still join the study and take part in weight loss intervention if they are not able to do this.

3.2 Methods of Data Collection

Whilst it is a family-based intervention, we are **only** collecting trial outcome data from mothers.

Participating mothers will be asked to:

- Attend a face-to-face baseline appointment for assessment of weight, body composition and completion of the demographic / diet history questionnaire and all other trial questionnaires using Qualtrics. Mothers will be asked not to eat or drink for 90 minutes before the appointment (to minimise error with the bioelectrical impedance measurement) and will be offered a complimentary drink and snack at Wythenshawe Hospital after their appointment.
- Record a 7-day food record using a paper food diary for a week following their baseline appointment before starting the fortnightly dietetic follow up sessions.
- Repeat the food diary and questionnaires (using Qualtrics/ or emailed / posted paper versions) after 6 and 12 weeks in the programme
- Repeat the questionnaires (using Qualtrics/ or emailed / posted paper versions) after 6 and 12 weeks in the programme, including updating any demographic information.
- Attend a 12-week face-to-face review to repeat all of the baseline measures and complete the Intervention evaluation and acceptability feedback questionnaire.
- Feedback on engagement of their family members from mothers and any changes in family diet and health behaviours using the FNPA questionnaire

3.3 Schedule of Procedures

Procedures	Screening/ baseline	Week 0	Week 2	Week 4	Week 6 (+/- 7days)	Week 8	Week 10	Week 12 (+/- 7days)
Informed consent	x							
Screening for eligibility	x							
GAD (anxiety) PHQ (depression)	x							
Binge eating questionnaire (BES)	x							
AUDIT, (alcohol dependency)	x							
Pregnancy test where appropriate	x							
Medical history	x							Update any changes
Demographic / diet history questionnaire	x							

PAR-Q readiness to exercise questionnaire	x							
Alcohol intake (7-day recall), smoking and vaping questionnaire	x				x			x
Physical activity (IPAQ short form)	x				x			x
7-days food diary (paper)	x				x			x
Body weight, body fat and lean body mass (impedance), Waist/ hip circumference	x							x
Mediterranean diet score	x				x			x
Family functioning (general functioning subscale of the McMaster Family Assessment Device)	x				x			x
Family nutrition and physical activity questionnaire (FNPA)	x				x			x
Intervention evaluation questionnaire and self-reported acceptability data**								x
Dietitian review call / video call/ email		x	x	x	x	x	x	x
Assessment of dietitian time spent delivering the intervention		x	x	x	x	x	x	x
Assessment of engagement of mother with dietitian calls / and whether family engaged with the intervention			x	x	x	x	x	x
Optional home weight recording and reporting to								

trial team (not mandatory)			x	x	x	x	x	
Optional anonymous NIHR demographic questionnaire	x							

- Maternal weight and body composition, body fat and lean mass, waist and hip circumference will be assessed with bioelectrical impedance, Tanita 980 scales which were calibrated in April 2024 and will be calibrated during the course of the trial, calibration certificate would be provided separately.

4 Trial Sample and Recruitment

4.1 Eligibility Criteria

Inclusion Criteria

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

Exclusion Criteria

- Previous cancer diagnosis with the exception of previous non-melanoma skin cancer or cervical epithelial neoplasia
- Currently pregnant or breastfeeding
- Current GLP-1/GIP agonist use, other anti-obesity meds, or prior bariatric surgery
- Medical/psychiatric conditions in the views of the study clinician making participation inappropriate or unsafe.
- Inability to consent
- Inability to attend face to face and/or remote sessions.
- Current participation in other weight loss programmes/trials
- Substance abuse or harmful alcohol use as indicated by a score of 16 or above on the Alcohol Use Disorders Identification Test (AUDIT).
- Current or previous diagnosis of an eating disorder.

- Participants with severe binge eating assessed by a score of 27 or more on the Binge Eating Scale (BES).
- Participants with severe depression assessed by a score of 15 or more on the Patient Health Questionnaire-9 (PHQ-9) questionnaire.
- Participants with severe anxiety assessed by a score of 15 or more on the General Anxiety Disorder (GAD-7) questionnaire.

All individuals will be considered for inclusion in this trial regardless of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, and sexual orientation except where the trial inclusion and exclusion criteria EXPLICITLY state otherwise.

4.2 Trial Setting and Sample Identification

Identification of potential mothers within the MFT Family History Clinic, Wythenshawe, Cancer Genetics Clinic, St Mary's Hospital (MFT) and North Manchester General Hospital family history clinic (MFT). Baseline and final trial assessments at clinical research facility at Wythenshawe Hospital. MFT will act as research site for the trial.

4.3 Sampling

4.3.1 Size of Sample

This is a pragmatic single-arm intervention feasibility trial where the co-primary objectives is to assess the acceptability of the intervention overall and the different elements of the intervention not hypothesis testing the intervention for efficacy(47).

A sample of **15-20** is justified to provide a range of views on acceptability and feasibility of the intervention. A sample size of 20 will enable recruitment rates in the region of 25% to be estimated with an error of +/-16% at most; also, a retention rate in the region of 85% will be estimated with error of +/-16% at most. (<https://goodcalculators.com/sample-size-calculator/>)

4.4 Recruitment

Potential mothers at >17% lifetime risk or with 10-year risk of BC >3% at 40 and aged ≥18 years from the MFT Family History Clinic and from the Cancer Genetics Clinic, St Mary's Hospital and North Manchester General Hospital family history clinic (MFT) will be made aware of the trial in three ways:

1. Invited by health care professionals in the clinic during consultations and provided a patient information sheet.
2. Mailed a patient information sheet.
3. Recruited via a poster displayed in the clinic and / or promoted via Prevent Breast cancer website / newsletter or on other websites and social media platforms such as Facebook ® and X®. These mothers will have their attendance at the Wythenshawe/ St Mary's/ North Manchester General Hospital family history clinic (MFT) verified by a member of the relevant clinical teams.

Interested mothers will be asked to contact the B-FAM trial research team on a trial phone or trial specific email address who will provide more information about the trial and complete preliminary screening questions.

Those made aware of the trial via social media will have their attendance at MFT high-risk clinics confirmed with clinical teams in these clinics and then sent a copy of the patient information sheet.

Interested people who contact the team will be asked if they have read and understood the participant information sheet (PIS). There will be ample opportunity within this call for potential participants to ask questions. They will complete a preliminary eligibility screening proforma with one of the research team using an assigned screening number. The screening proforma will not contain identifiable data on the potential participant. The screening log which contains their name and contact details will be stored separately in an encrypted screening log on the recruiting site (MFT) server. An anonymised version of the log will be stored on the University server as a record of total numbers of people approached, recruited, declined.

In order to report uptake to the trial and reasons for screen fail, we will ask ineligible people if we can keep their answers, they have given to the eligibility questions and record their verbal consent. With their consent we will complete all the eligibility questions with them. By doing this we will identify and report multiple reasons for screen failure. We will not keep their name so that the information is anonymised. If they do not consent to us keeping this anonymous information we will destroy it.

Full eligibility for the trial will be assessed at a face-to-face screening / baseline appointment at Wythenshawe hospital which will check weight and height and BMI, pregnancy status, and their binge eating, anxiety and depression scores and AUDIT alcohol dependency scores. We will record screen fails and reasons for this.

Screening visit

Eligible and interested mothers will be booked a face-to-face screening/ baseline appointment at MFT. They will be asked to refrain from food or drink for 90 minutes before the appointment to ensure accuracy of the bioelectrical impedance measurement.

This appointment will include:

1. Signed informed consent form.
2. Medical history and recording their previously communicated estimated breast cancer risk.
3. Measure height, weight and calculate BMI, waist and hip measurements.
4. Eligibility screening questionnaires:
 - a. Generalised Anxiety Disorder scale (GAD-7).

- b. Patient Health Questionnaire-9 (PHQ-9).
 - c. Binge Eating Scale (BES) [37].
 - d. Alcohol Use Disorders Identification Test (AUDIT) (48).
5. Exclusion of pregnancy, confirmed with pregnancy test where relevant. A pregnancy test is not required if the mother meets the following NICE criteria for excluding pregnancy (negative predictive value of 99-100%) (<https://cks.nice.org.uk/topics/contraception-assessment/management/assessment-for-contraception/>):
- Is within the first 5 days of the onset of a normal (natural) menstrual period.
 - Has not had sexual intercourse since the start of last normal menses.
 - Has been correctly and consistently using a reliable method of contraception.
6. Confirmation of eligibility.
7. Remainder of baseline assessments including the PAR-Q readiness to exercise questionnaire (see Table. 1 Schedule of procedures).

Baseline run in week:

We wish to assess habitual dietary intake and levels of physical activity before starting the programme. Participants will be asked to record a 7-day food record using a paper food diary.

4.5 Consent

Potential mothers who express interest in participating and who appear to meet the inclusion criteria will be asked to provide written informed consent to enter the trial. Informed consent will be sought after they have had adequate time to understand the information given to them in the PIS and we have answered their questions. The person taking consent must be satisfied that the mother understands the information given to them, the demands of the trial including the risks and benefits involved, and only then can they seek consent from the mother.

Consent will be taken by a member of the trial team who is Good Clinical Practice (GCP) trained, experienced, and who has been delegated by the CI to undertake this activity in the delegation log.

4.6 Participant Compensation

Mothers will be offered reasonable travel expenses for any trial visits which are made in addition to normal care.

5 Statistics and Analysis

Co – primary feasibility outcomes will be measured as follows:

Uptake rate will be measured for the whole trial and within each of the recruiting populations i.e. the family history clinic (FHC) at Wythenshawe, St Mary's and North Manchester General Hospital family history clinic (MFT):

- The percentage of patients who are sent the patient information sheet who consent to participate.
- The percentage of eligible patients who consent to participate.
- Key characteristics (ethnicity, breast cancer risk, deprivation index, BMI, smoking behaviour) of mothers recruited vs the overall population in this age group in the MFT family history clinic.
- The number of mothers recruited via the clinic poster and the Prevent website.
- The proportion of mothers who were screened who did not meet the eligibility criteria and the number of mothers who did not give consent to take part will also be recorded and where possible reasons for this.

Retention to the trial

- This is reported as the percentage of mothers consented who complete the 3-month review.
- Report key characteristics (i.e. ethnicity, age, breast cancer risk, deprivation index, BMI) of mothers completing vs those who withdraw or are lost to follow up.

Patient acceptability

Self-reported acceptability data will be assessed using a validated intervention evaluation questionnaire assessed at 12 weeks (20), or at the time of withdrawal from the study where mothers are happy to do this.

Number of participants engaging with each online session and family challenges

Engagement with the programme will be recorded by the dietitian by capturing the following data on the case report forms during the fortnightly diet reviews: mothers' attendance at fortnightly dietitian calls, extent of family engagement as reflected by the number and nature of shared family activities.

Dietitian time for intervention delivery per mother

Dietitian time will be recorded for each diet call with mothers

Preliminary evaluation of any benefits of the diet

- Changes in body weight and body composition (body fat and lean body mass assessed with bioelectrical impedance, waist and hip circumferences) for mothers between baseline and 12 weeks.
- Changes in diet quality assessed through Mediterranean diet score and food diary for mothers between baseline, 6 weeks and 12 weeks. (Patients will fill in a paper food diary & research dietitians manually enter on my food 24 web-based programme to estimate caloric and macronutrients intake. Participants will be identified with a study ID, and no identifiable info will be entered)
- Changes in physical activity (International Physical Activity Questionnaire IPAQ short form) for mothers between baseline, 6 and 12 weeks.
- Change in alcohol consumption, smoking status, and vaping behaviour, measured using a validated self-reported alcohol, smoking and vaping questionnaire at baseline, 6 and 12 weeks
- Family functioning measured using the general functioning subscale of the McMaster Family Assessment Device(40) reported by mothers at baseline, 6 and 12 weeks.
- Family nutrition and physical activity questionnaire (FNPA).(41) reported by mothers at baseline, 6 and 12 weeks.

Preliminary evaluation of any possible harms

- Assessment of Family functioning measured using the general functioning subscale of the McMaster Family Assessment Device could highlight any positive or negative changes in family relationships and functioning as a result of taking part in the trial.

Time for delivery of the programme

The dietitian time required for delivery of the intervention dietitian calls will be recorded and totalled across the 12-week intervention.

End of the trial:

The end of study is the point at which all data have been collected for the study and contact with participants completed. This corresponds to the end of follow up of participants and completion of all face-to-face visits at Wythenshawe Hospital as well as the final diet call and completion of study questionnaires and food diaries.

6. Ethical and Regulatory Considerations

6.1 Risks and Burdens to Mothers

This feasibility trial is low risk as the intervention is based on the NHS and Mediterranean diet recommendations for healthy diet and lifestyle. However, it is anticipated that participating mothers and families might encounter some issues detailed below:

- **Psychological:** some mothers might experience distress when discussing weight, body image, family dynamics and breast cancer risk. Also guilt or frustration might be encountered when not achieving weight loss goals. The trial is minimising the risk of exacerbating existing disordered eating by excluding people with a history of eating disorders and high scores for binge-eating, anxiety and depression at baseline.
- **Time/inconvenience:** Mothers are asked to attend two face-to-face visits at MFT, complete baseline and follow-up assessments, and participate in online/telephone sessions with the dietitian. This may cause burden alongside daily family responsibilities.
- **Behavioural change:** Adjusting diet and activity patterns within a family context may be challenging and could temporarily disrupt household routines. Children may express resistance to changes in home food availability or physical activity.

Psychological scores:

The binge eating and anxiety and depression questionnaires at baseline and discussions with the trial dietitians may highlight psychological issues. Potential participants who are excluded from the trial at baseline due to high psychological scores will be provided guidance for who they can contact for further support and advised to self-refer to relevant support services including NHS Talking Therapies

<https://www.nhs.uk/mental-health/talking-therapies-medicine-treatments/talking-therapies-and-counselling/nhs-talking-therapies/>

or <https://www.beateatingdisorders.org.uk> [beateatingdisorders.org.uk]

or <https://www.gmmh.nhs.uk/eating-disorder-service> [gmmh.nhs.uk]

or <https://hsm.manchester.gov.uk/kb5/manchester/directory/service.page?id=2XcrkYV3p1A> [hsm.manchester.gov.uk]

or <https://www.samaritans.org> [samaritans.org]

We will seek the participant's permission to inform their GP of these findings and our recommendation to seek Manchester Psychological Wellbeing Service support.

Those identified with moderate psychology scores i.e. Patient Health Questionnaire-9 (PHQ-9) score of 10-14 (moderate depression), GAD-7 score of 10 –14 (moderate anxiety), Binge Eating Scale (BES) scores of 18-26 (moderate binge-eating), AUDIT-C scores of 8-15 (increasing risk of drinking disorder) will be asked the history of this and whether they are currently receiving support / treatment and what this entails. Those not currently receiving treatment will be provided guidance for who they can contact for further support and signposted to appropriate local services, and we will seek permission to copy this information to their GP.

Trial questionnaires completed at baseline and during the trial will be reviewed when completed and mothers contacted and triaged to the appropriate services as outline above.

Management of Identified Family Dysfunction

As part of the trial, family functioning will be assessed using the General Functioning (GF) subscale of the McMaster Family Assessment Device (FAD). A mean score of ≥ 2.0 indicates potential family dysfunction. Where participating families score ≥ 2.0 , the trial dietitian will discuss the finding sensitively with the mother and explain that this may reflect communication or relationship challenges that could affect lifestyle change. Where deemed appropriate mothers will be signposted to appropriate professional family therapy services for further support.

Mothers will be provided with information on how to locate qualified systemic or family therapists through the Association for Family Therapy and Systemic Practice (AFT) public directory (<https://www.aft.org.uk/page/findatherapist>). The directory lists accredited therapists across the United Kingdom, allowing families to access local NHS or private services. The research team will not make formal referrals but will advise mothers to self-refer or discuss options with their general practitioner if they wish to pursue structured family therapy.

This approach ensures that any psychosocial issues identified during the trial are appropriately addressed while maintaining mother confidentiality and staying within the professional remit of the trial dietitians.

6.2 Research Ethics Committee (REC) and Other Regulatory Review & Reports

NHS Research Ethics Committee and HRA approval will be obtained before commencing research.

The trial will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

Withdrawal of patients / stopping rules

The possible reasons for withdrawal of participating mothers include:

1. Pregnancy during the trial.
2. Following safety review by the trial management group (TMG).
3. Increased level of risk of deterioration of mental state.
4. Unplanned loss of contact for ≥ 6 weeks.
5. Development of medical condition where weight control and diet and physical activity are no longer feasible or appropriate.

Participant choice to withdraw.

The right of the participant to refuse to continue in the trial without giving reason(s) will be respected. All participants are free to withdraw at any time. We will not recruit additional participants to replace those who withdraw. Data from participants who withdraw from the trial will be retained for use.

The trial may be prematurely discontinued by the Sponsor, CI or TMG on the basis of new safety information or for other reasons given by Regional Ethics Committee (REC). If the trial is prematurely discontinued, active participants will be informed, and no further participant data will be collected. The Competent Authority and REC will be informed within 15 days of the early termination of the trial.

6.3 Amendments

The chief investigator is responsible for ensuring that any subsequent amendments gain the necessary approvals before implementation. Any amendments to the trial will be reviewed by the Sponsorship Team prior to submission. Any non-substantial amendments shall be notified to the HRA and any substantial amendments, along with amended documentation, shall be approved by the REC, and HRA, prior to implementation as per nationally agreed guidelines. The Chief Investigator or designee will work with the University and the MFT research site to put the necessary arrangements in place to implement the amendment and to confirm their support for the trial as amended.

6.4 Peer Review

This protocol is for a PhD (Mai Haiba). It has been reviewed by all co-investigators. The co-investigators bring complementary clinical and research expertise spanning behavioural psychology (Prof David French), qualitative research and implementation science (Dr Nia Coupe), and research dietetics and cancer prevention (Prof Michelle Harvie). All co-investigators hold substantive or honorary appointments within the University of Manchester and Manchester University NHS Foundation Trust.

6.5 Patient & Public Involvement

Two patient representatives are involved in the TMG. The patient representative role is to review the study design and the patient burden of participating in the study, patient materials (recruitment information, diet resources). Also, to work with researchers to help collate free text feedback from mothers from the acceptability questionnaire of what mothers liked / did not like about the diet programme and to advise on best routes of research dissemination to reach the target audience.

A series of PPIE activities have informed this protocol:

- 1- A session with mothers through VOCALS (Aug 2024).
- 2- A session with children through VOCALS Voice up (Nov 2024).
- 3-Feedback on qualitative interview schedules has been obtained from 2 public advisors (Nov-Dec 2024).
- 4-An intervention design workshop has been held with 2 public advisors (June 2025).

5- A PPIE session with a woman with lived experience of obesity during the annual ASO meeting on the 10th of September 2025: discussed the proposed intervention sessions outlines and aims.

6 -A written feedback has been received by 2 public contributors on paperwork (PIS, recruitment poster and email, diet booklet, family challenges and activities booklet): November/December 2025

6.6 Timeline of the trial: 8 months:

Months of trial	1	2	3	4	5	6	7
Recruitment							
Follow up of participants							
Analysis & dissemination							

The end of the study is defined as the last point of data collection from participants

6.7 Protocol Compliance

- The research team will be vigilant in protocol deviations and will record them on a trial specific deviation log which will be regularly assessed by the CI.
- Deviations that may affect the safety, physical or mental integrity of participants or scientific value of the trial will be reported to the trial sponsor via UoMRGT@manchester.ac.uk by the research team.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach and should also be reported to the sponsor without delay.

6.8 Data Protection and Participant Confidentiality

All investigators and trial site staff will comply with the requirements of the **UK Data Protection Act 2018** and the **UK General Data Protection Regulation (UK GDPR)** with regard to the collection, storage, processing, and disclosure of personal information. The trial will also adhere to the University of Manchester's *Data Protection Policy and Records Retention Schedule (v1.5, 2023)* and to the Sponsor's Information Governance procedures.

Collection and coding of data:

Personal identifiable information (name, date of birth, contact details, NHS number) will be collected only where necessary for screening, scheduling visits, and remote follow-up by the research dietitians conducting the trial. Once consented, each mother will be assigned a **unique trial ID**. This ID will be used on all trial documentation and datasets. A separate

linking file connecting the mother's personal identifiers with the trial ID will be stored in an encrypted, password-protected folder accessible only to authorised members of the research team until data analysis has been completed after-which it would be deleted.

Participating mothers will fill in paper food diaries and research dietitians will manually enter the food diaries on my food 24 web-based programme to estimate caloric and macronutrient intake. Participants will be identified with a study ID, and no identifiable info will be entered.

Storage and security:

- Electronic data (including eCRFs and questionnaires) will be collected through **Qualtrics**, a GDPR-compliant, University-approved secure web platform. Data are stored on university servers backed up daily by IT Services.
- Clinical measurements recorded on the eCRFs and correspondence within MFT will be recorded in **Hive**, the Trust's secure electronic health-record system.
- All electronic trial folders will be held on the University's secure research drive with encryption, password protection, and daily backup.
- We anticipate that the majority of questionnaires will be completed online using Qualtrics. Paper questionnaires and paper food diaries will be stored securely in a locked filing cabinet in the research dietitian's office and scanned and transferred securely at the end of the study to be stored on in secure research storage at the University of Manchester
- Participants being reimbursed for travel will have their bank details retained by the university finance department to align with their records retention policy

Access control:

Access to identifiable data will be limited to the minimum number of authorised individuals necessary for trial delivery, quality control, monitoring, or audit by the Sponsor, University, NHS regulators, or REC. Data transmitted between MFT and the University of Manchester will be pseudonymised and transferred using secure, encrypted channels (e.g. University-approved file-transfer systems).

Confidentiality during data sharing:

Copies of scanned consent forms will need to be transferred between the recruiting site MFT and the university researchers leading this study using approved secure transfer systems. The consent will need to be stored on the University secure research storage. Any paper food diaries or paper questionnaires transferred will be coded (pseudonymised).

Hard copies of the consent forms will be stored at MFT in a locked cabinet

Data retention and destruction:

Anonymised research data will be stored on the secure, backed-up University of Manchester research drive for **five years after publication**, in accordance with the University's *Records Retention Schedule (v1.5, 2023)* and *Research Data Management Policy*. [Records Retention Schedule - V1.5 041223.docx](#)

Identifiable data (postcode) will be removed following derivation of area-level variables (ie: deprivation score).

If potential participants were not eligible at the eligibility pre-screening call, all identifiable data collected will be destroyed in line with the University's guidelines [Disposal of confidential material \(shredding\) | Information Governance Office | StaffNet | The University of Manchester](#). However, if people provide verbal consent, we will keep de-identified information of record reasons for screen fail.

We will retain patient contact details for 3-6 months after the end of the study for those who wished to be sent a lay summary of the findings of the study

Since the patients will be recruited from MFT. A permanent record of their interest and reasons for non- eligibility will be recorded on their electronic patient records (HIVE) at MFT

Consent forms:

Copies of signed paper consent forms will be stored securely at the study research site at MFT (in a locked cabinet in a locked office). A copy of the scanned consent form will be uploaded to the participant medical records (HIVE). Consent forms will be retained for **seven years** post-study completion, consistent with the University retention period for *consent forms for interventional studies concerning adults*. Hard copies will be kept at MFT and scanned copies to be kept on secure research storage at the University of Manchester. After these periods, all identifiable data will be securely destroyed.

After data analysis is complete, a **fully anonymised dataset** will be deposited in the University of Manchester's open research repository (*Figshare*) for long-term archiving and sharing, where it will be stored indefinitely in line with University Library *Research Data Management and Sharing* guidance.

All electronic data will be held on secure, access-controlled University systems with encryption, password protection, and daily backup, and will be permanently deleted from internal servers at the end of the stated retention period.

Data custodian:

The **Chief Investigator (Michelle Harvie)** will act as the **Data Custodian** for the duration of the trial.

Table 3. Source data and data handling and processing for trial data		
Trial Data	Source data	Data handling / processing
Recruitment data	Screening Proforma	Screening Proformas will be completed directly on to Hive

	E-mails from interested mothers to secure trial specific shared university email.	By research dietitians @ MFT E-mails will be kept on the secure server until recruitment data is entered for full reporting of trial recruitment data. E-mails to the shared UoM e-mail address are stored on UoM servers.
Body weight/ body fat and lean body mass.	Entered directly to Qualtrics	Data will be downloaded from Qualtrics in anonymous form and stored on secure University of Manchester one drive. Would also be copied onto Hive (electronic patient record at MFT) By research dietitians @ MFT
Questionnaires	Questionnaires completed by mother via Qualtrics,	Data will be downloaded from Qualtrics in anonymous form and stored on secure University of Manchester servers by Mai Haiba (PhD student)
Food diaries	Paper food diaries to be filled in by participating mothers	Participating mothers will fill in paper food diaries and research dietitians will manually enter the food diaries on my food 24 web-based programme to estimate caloric and macronutrient intake. Participants will be identified with a study ID, and no identifiable info will be entered. By research dietitians @ MFT
Case report form from baseline diet advice and fortnightly calls Self-report monthly weights.	Entered directly to Qualtrics	Data will be downloaded from Qualtrics in anonymous form and stored on secure University of Manchester servers. Summary of diet advice recorded on Hive (electronic patient record at MFT) By research dietitians @ MFT
Engagement with the dietitian calls/ emails and dietitian time for	Clinical summary of trial visits & dietitian reviews	Data will be downloaded from Qualtrics in anonymous form and stored on

delivering the intervention.	will be recorded on Qualtrics. Clinical summary of trial visits is copied into Hive (electronic patient record at MFT)	secure University of Manchester servers. By Mai Haiba (PhD student)
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6.9 Indemnity

The UoM indemnity scheme will apply to this trial to ensure it meets the potential legal liability of the sponsor, equipment, employer, and investigators for harm to mothers arising from the management, design and conduct of the research. In the unlikely event that something does go wrong, and participants are harmed during the trial, they may have grounds for a legal action for compensation against the University of Manchester, but they may have to pay their legal costs.

6.10 Monitoring

The trial will be subject to the audit and monitoring regime of UoM in line with applicable UoM SOPs and policies.

The Trial Management Group (Section 1) is responsible for ensuring the appropriate, effective and timely implementation of the trial including monitoring adherence to protocol. The day-to-day operational management of the trial is co-ordinated by Mai Haiba who reports weekly to Prof Michelle Harvie. The TMG meets every 2 months.

The day-to-day operational management of the feasibility trial is co-ordinated by the CI and research dietitians (MH and CL) who meets fortnightly to monitor progress and any issues which may need relaying to the TMG

7. Safety Reporting

- The trial is non-CTIMP and will only report any Serious Adverse Events (SAEs)
- An SAE is defined as an untoward occurrence that: (a) results in death; (b) is life-threatening; (c) requires hospitalisation or prolongation of existing hospitalisation; (d) results in persistent or significant disability or incapacity; (e) consists of a congenital anomaly or birth defect; or (f) is otherwise considered medically significant by the investigator

The CI must send details of the SAE to FBMHethics@manchester.ac.uk within one working day of being notified of the SAE.

- An SAE occurring to a research participant should be reported to the REC where in

the opinion of the Chief Investigator the event was:

- “Related” – that is, it resulted from administration of any of the research procedures, and
- “Unexpected” – that is, the type of event is not listed in the protocol as an expected occurrence.

Any SAEs that are considered related to a study intervention/procedure and unexpected (i.e. an unexpected SAR) must be reported to the REC within 15 days of the CI first becoming aware of the event. This means the REC should be notified based on the initial report, even if the final report is pending.

The CI is responsible for:

- Receiving and assessing serious adverse events as per the protocol
- Reporting SAEs and urgent safety measures to the sponsor and REC as per the requirements of the Research Ethics Service

8. Dissemination

8.1 Dissemination Policy

Following completion of the trial, data will be analysed and results published in a peer-reviewed journal. If mothers have given consent to be contacted with a summary of the results, they will receive this after publication.

We will ask trial participating mothers if they would like a summary of the results of the trial and send a lay summary of the findings at the end of the trial. Findings will also be shared with cancer prevention charitable bodies and organisations in the UK, such as Prevent Breast Cancer.

As this trial is part of a PhD project, B-FAM trial results would be published within the thesis of this PhD.

The trial is registered on ISRCTN trial registry: ISRCTN10436313 and results of the study will be uploaded to this when available

9. Archiving

The end of the trial is defined by the final clinical review of the last participating mother. We will then enter a period of data validation quality control checks. The electronic records will be archived on the UoM server. Hard copies of paper consent forms, PAR-Q forms, and any paper questionnaires completed will be archived at MFT once the sponsor has authorised archiving.

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11. Appendices:

Appendix 1:

Suggested algorithm by Pratt and Skelton for the management of childhood obesity which has been adapted for maternal weight loss in the current trial.

