

Testing the feasibility of a 6:1 intermittent diet breast cancer prevention programme to promote healthy eating and prevent weight gain in women at increased risk of breast cancer

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
30/04/2024	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
03/05/2024	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
04/02/2026	Cancer	<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Weight gain in young women increases the risk of breast cancer and other cancers and conditions. Weight gain occurs in young women attending breast cancer risk clinics and there is an unmet need for effective weight gain prevention interventions for these women. The study is testing whether a novel 6:1 intermittent diet is acceptable and can promote healthy eating and limit weight gain with minimal harms in women at increased risk of breast cancer. Findings in this study will inform whether further research with the 6:1 intermittent diet is warranted

Who can participate?

People who are born female and have not undergone gender reassignment, aged 18-40 years and who are at moderate or high risk of breast cancer and have a healthy BMI (20 - 25 kg/m²).

What does the study involve?

A special diet program aimed at preventing breast cancer. This program lasts for 4 months. We're inviting women from a clinic that focuses on family history and cancer genetics at Manchester University Foundation Trust, as well as those who are at high risk of breast cancer based on a study called BCAN-RAY.

The diet part of the program is called a 6:1 intermittent diet. Basically, for every week, there's one day where you eat fewer calories than usual, and the other six days you eat normally. We're also asking participants to do at least 150 minutes of moderate exercise every week, plus some strength training exercises.

To help you stick to the program, we'll provide support from dietitians through phone calls, video calls, and emails. You'll also have access to group sessions with other participants led by dietitians, and there's a private Facebook group just for this study where you can chat with others for support.

Before and after the program, you'll visit us in person to check your weight, body fat, and muscle. We'll also ask you to fill out some questionnaires about your eating habits, diet, and sleep, and keep a food diary. You'll wear a small device on your wrist to track how active you are throughout the day.

During the program, we'll ask you to keep track of whether you did your low-calorie day each week, and if you experienced any side effects from the diet like headaches, hunger, or feeling tired. We'll also ask for your feedback on how acceptable the diet is through a questionnaire.

What are the potential benefits and risks of taking part?

The diet intervention could help improve diet, weight control and well-being. However, none of these benefits can be guaranteed for the individual participants who take part. The information gained from this study on the safety, acceptability and potential efficacy of a 6:1 diet will help future people who seek advice from healthcare professionals on healthy diets to reduce weight gain and reduce cancer risk.

The health risks of taking part in the study are low as participants will be screened for their suitability prior to taking part. Some people may experience minor symptoms on low-calorie days which may be associated with the diet such as fatigue, irritability (agitation), bad breath, constipation, dizziness, headache, and indigestion. We are recording these as part of the study

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?

November 2023 to January 2026

Who is funding the study?

The National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre (BRC) Prevention and early detection theme (UK)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

343256

ClinicalTrials.gov (NCT)

Nil known

Sponsor reference

G80390

Study information

Scientific Title

The 6:1 intermittent diet breast cancer prevention programme study

Study objectives

Weight gain in young women increases the risk of breast cancer and other cancers and conditions. Weight gain occurs in young women attending high-risk breast cancer prevention clinics and there is an unmet need for effective weight gain prevention interventions. This study is testing if a novel intermittent 6:1 diet is acceptable to women and can promote healthy eating and limit weight gain with minimal harm in women aged 18 - 40 years who are a healthy weight.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 19/11/2024, South Central Berkshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 24/SC/0321

Study design

Single-arm feasibility study

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

The 6:1 diet programme includes an intermittent 6:1 diet which involves one 1000 kcal day per week (to include ~70 g of protein and ~100g carbohydrate) and 6 days per week of healthy eating with a Mediterranean-type diet. It also encourages = or > 150 minutes of moderate-intensity exercise/ week. Participants will follow the programme for 4 months.

Intervention Type

Behavioural

Primary outcome(s)

1. Acceptability of the 6:1 intervention assessed through:

1.1. Uptake: The percentage of patients who are sent the patient information sheet who consent to participate and the percentage of eligible patients who consent to participate.

1.2. Retention to the study: the percentage of patients consented who complete the 4-month review

1.3. Adherence to the low-calorie days will be self-reported as the percentage completion of the potential low-calorie days between randomisation and the 4-month review.

1.4. Patient acceptability of the intervention will be assessed using a validated intervention evaluation questionnaire at the end of the study (Sekhon et al 2022).

2. Preliminary evaluation of any benefits of the diet

2.1. Changes in body weight and body composition (body fat and lean body mass assessed with bioelectrical impedance, waist and hip circumferences) between baseline and 4 months

2.2. Changes in diet quality (Mediterranean diet score) and alcohol intake (7-day recall) and energy and macronutrient intake from 7-day food record (Myfood24 app or 7-day paper food diary) between baseline and 2 and 4 months.

2.3. Changes in physical activity (International Physical Activity Questionnaire IPAQ short form) between baseline and 2 and 4 months and change in activity assessed with an Actigraph between baseline and 4 months i.e. time spent in sleep, sedentary, light, moderate and vigorous activity, total wear time and step count.

3. Preliminary evaluation of any possible harms

3.1. Changes in binge eating between baseline 2 and 4 months assessed with a binge eating questionnaire (Bruce et al J Am Diet Assoc 1996)

3.2. Change in sleep between baseline 2 and 4 months assessed using the Pittsburgh sleep quality index)

3.3. The number of potentially diet-related adverse events including fatigue, constipation, dizziness, headache, irritability (agitation), bad breath indigestion in the month before starting the diet and monthly throughout the intervention at each dietitian review call.

3.4. Mean menstrual cycle length for the month preceding and the 4 months of the programme will be assessed from self- reported diaries.

Key secondary outcome(s)

1. Dietary intake and physical activity during low calorie and the other days of the week measured from 7 day food diaries at 2 and 4 months and actigraph measurements at 4 months

2. Adherence to the 6:1 intermittent diet across the 4 weeks of the menstrual cycle measured using self-report diet adherence and menstrual cycle diaries across each week of the 4-month intervention

Completion date

06/01/2026

Eligibility

Key inclusion criteria

1. Born female and not undergone gender reassignment aged 18-40 years.
2. Moderate or high risk of BC (>17% lifetime risk or >10 year risk of BC of >3% at 40)
3. BMI > or=20 and < or = 25 Kg/m²
4. Able to communicate (written and spoken) in English or other languages
5. Able to attend two face-to-face appointments at MFT at baseline and 4 months
6. Not pregnant or planning to become pregnant: Where appropriate potential participants will have a negative urine pregnancy test at screening and agreement to maintain contraception or abstinence for the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

40 years

Sex

Female

Total final enrolment

30

Key exclusion criteria

1. Previous breast cancer or bilateral preventative mastectomy
2. Currently trying to gain weight
3. Previously had weight loss surgery or taking weight loss medication
4. Have a medical condition that influences diet and weight, for example, diabetes, inflammatory bowel disease or cystic fibrosis.
5. Current diagnosis of a psychiatric disorder, for example bipolar psychotic disorder or current self-harm
6. Substance abuse or harmful alcohol use as indicated by a score of 16 or above on the Alcohol Use Disorders Identification Test (AUDIT)
7. Current or previous diagnosis of an eating disorder
8. Participants with severe binge eating assessed by a score of 27 or more on the Binge Eating Scale (BES)
9. Participants with severe depression assessed by a score of 15 or more on the Patient Health Questionnaire-9 (PHQ-9) questionnaire
10. Participants with severe anxiety assessed by a score of 15 or more on the General Anxiety Disorder (GAD-7) questionnaire.
11. Confirmed pregnant via a pregnancy test, planning pregnancy in the next 4 months, or currently breastfeeding.

Date of first enrolment

17/03/2025

Date of final enrolment

04/08/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Manchester University Hospital Foundation NHS Trust

Nightingale Centre, Wythenshawe Hospital

Wythenshawe

Manchester

England

M23 9LT

Sponsor information

Organisation

Manchester University NHS Foundation Trust

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Manchester NIHR Biomedical Research Centre

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/>

IPD sharing plan summary

Stored in publicly available repository