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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
30/04/2024

Recruitment status
No longer recruiting

Registration date
03/05/2024

Overall study status
Ongoing

Last Edited
16/09/2024

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
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 July 2025

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?
Dr Michelle Harvie, michelle.harvie@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr 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

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)
Not yet submitted

Study design
Single-arm feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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 measure
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. Tthe 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.

Secondary outcome measures
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

Overall study start date
01/11/2023

Completion date
31/08/2025

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
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
01/01/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University Hospital Foundation NHS Trust
Nightingale Centre, Wythenshawe Hospital
Wythenshawe
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Research Office
1st floor, The Nowgen Centre
29 Grafton Street
Manchester
England
United Kingdom
M13 9WU
+44 161 276 4125
Lynne.Webster@mft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://mft.nhs.uk/research/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Manchester NIHR Biomedical Research Centre

Results and Publications

Publication and dissemination plan
Plan to publish protocol paper and publication of the results in a high-impact peer-reviewed journal

Intention to publish date
01/11/2025

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