WE SURE CAN

Supporting weight loss in
women with breast cancer

NHS

PARTICIPANT INFORMATION SHEET

WE SURE CAN

WEight loss to SUppoRt BrEast CANcer survival

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BREAST CANCER NOW The research & care charity

ctru University of Leeds

Counterweight

UNIVERSITY OF LEEDS

WE SURE CAN

Supporting weight loss in women with breast cancer

We invite you to take part in a weight loss trial.

To help you decide whether you want to take part in this trial, it is important for you to understand why the research is being done, and what it will involve.

Please read this information booklet carefully, and discuss with family or friends if you want to.

If you choose not to take part, your healthcare will not be affected in any way.

If you have any questions, are not clear about anything, or would like more information, please contact us by email: WeSureCan@leeds.ac.uk or by phoning your local research nurse (telephone number on the front page).

Who is organising this research?

This trial is being organised by researchers and staff at the University of Leeds. It is funded by the charity Breast Cancer Now. Research nurses, clinical trial coordinators, and other clinical and research staff at your usual hospital site will be helping us run and manage this trial.

What are the aims of this trial?

We want to find out whether women affected by breast cancer:

- are willing to take part in a weight loss trial
- are able to follow the weight loss programme offered to them as directed
- lose weight during this trial

Our long term aim is to do a much larger trial to find out whether weight loss can improve the chances of surviving breast cancer.

Why is this trial needed?

Women diagnosed with breast cancer who carry excess weight are more likely to be diagnosed with another breast cancer than women with lower body weight.
Excess weight is linked with worse overall health, and poorer quality of life.

There is some evidence that weight loss could improve the chances of surviving breast cancer, but more trials are needed.

Our trial will be the first to test two different weight loss programmes in women with breast cancer. Both programmes have been previously tested in people attending primary care, and both have resulted in weight loss. However, the two programmes are very different, and one is more intensive than the other.

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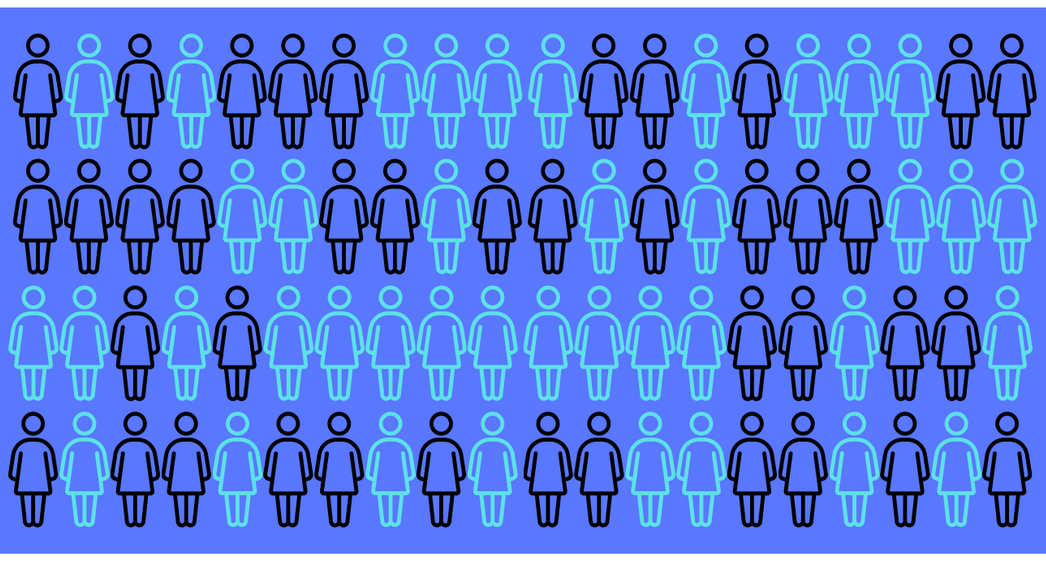
What does taking part in this trial involve?

This is a randomised controlled trial, which means that if you take part, you will be allocated to one of two weight loss programmes. This will be **chosen at random.** You will not be able to choose which group you are put into, and neither will anyone else. Half of all participants will be placed into the meal replacement group, and half will be placed into the weight loss tips group.



44 participants in the meal replacement group

44 participants in the weight loss tips group

Group 1: Meal replacement group

If you are allocated to this group, you will receive a 12 month weight loss programme. This programme is run by an external weight loss company.

This weight loss programme involves three phases, and includes using an app on your mobile:

Phase 1 (12 weeks)

- 3 months of a soups and shakes diet. You will be sent food products (soups, shakes) to eat *instead* of your usual food. This diet reduces calorie intake to 810 calories per day.

Phase 2 (12 weeks)

- The following 3 months involves gradually reintroducing usual food into your diet.

Phase 3 (6 months)

- The following 6 months are a weight maintenance phase, where you will only be using the soups and shakes if you want to, to supplement your usual food intake.

If you regain 2kg or more during phase 3, you will be advised to go back into phase 1 or 2 for a short period of time. Therefore, this intervention could last up to 14 months.

You will have regular phone/video calls with a dietitian throughout this programme.

The dietitian will need to contact your GP to check that this diet is suitable for you. Your GP may need to change your medication doses as a result of this diet. If this happens, you may be asked to have more GP appointments than normal.

You may also be asked by your GP, or the dietitian, to monitor your blood pressure or blood glucose levels, if it is relevant to other conditions you may have (e.g. diabetes, high blood pressure). They will give you instructions on how to do this.

Group 2: Weight loss tips

If you are allocated into this group, instead of the meal replacement programme, you will receive:

A leaflet (emailed to you) containing advice on healthy habits for losing weight.

A 20 minute phone call with a researcher, to discuss the leaflet with you.

What else is involved?

No matter which group you are allocated to, we will ask you to do the following:

Complete a 30-45 minute online questionnaire at the start of the study and at 4, 7, 10, and 13 months later.

Weigh yourself using research standing scales at the start of the trial, and again at 4, 7, 10, 13 months later.

Wear a research watch that tracks your physical activity (movement, e.g. steps, and sleep) for the length of the trial.

We will provide you with the watch and scales for the duration of the trial at no cost to you. We will ask for their (freepost) return at the end of the trial.

You will receive email, SMS and/or phone call reminders throughout the trial to remind you to complete your questionnaires and weigh yourself.

You will **not** be asked to make any additional trips to the hospital.

You might be invited to take part in a phone or video call at 4, 7, 10, or 13 months into the trial. This call will ask you questions about your experience within the trial and will take no more than one hour. This call is **optional.** Even if you say yes to this trial, you can still say no to this additional call. You will receive a separate information sheet and consent form for this, if you are invited.

The trial lasts for **13 months,** from the date that you are allocated a group. However, you may continue in the meal replacement programme for up to 14 months, if required.

Why have I been invited?

You have been identified by staff at the hospital where you received your breast cancer treatment, as someone who may be suitable for this trial.

You **are able** to take part in this trial if you:

- Are 18 years old or over
- Have had a stage II-III breast cancer diagnosis in the previous 14 months
- Have completed your hospital-based treatment
- Have a BMI between 27-45
- Are willing to try meal replacement products for 12 weeks if allocated to this group

You are **not able** to take part in this trial if you:

- Do not have a working email address (this is needed to send trial information to)
- Cannot speak or understand English (this is needed for the appointments with the dietitians)
- Have an eating disorder
- Are lactose intolerant or vegan (some of the food products contain lactose)

There are some additional eligibility criteria related to your diagnosis and other medical conditions you may have. A research nurse (and the dietitian, if you are allocated to the intervention group) will ask you questions over the phone, and look at your medical records, to check that you are suitable.

If you are unsure whether you are able to take part or not, and would like to take part, please contact your research nurse (contact details on the front page).

Do I have to take part if I am suitable?

No. It is completely up to you whether you wish to take part or not.
If you do not wish to take part, your healthcare will not be affected in any way.
If you do decide to take part, you will be asked to read and sign a consent form. Even if you consent to taking part in this trial, you can change your mind leave the study at any time, without giving a reason.

What are some of the benefits of taking part?

- You may lose weight, which can have benefits for your health, and quality of life.
- You may help improve the care of women with breast cancer who have excess weight.
- You will have free use of a watch and scales (for the duration of the study).
- You will receive the intervention food products or leaflet free of charge.

What are some of the risks of taking part?

- There is a time commitment involved of approximately 13 months. Please think carefully about whether you would be able to commit to completing the online questionnaires, wearing a watch, and if in the meal replacement group, following the diet and having regular phone-calls with a dietitian.
- Some of your medications may be stopped, or doses altered, if you are in the meal replacement group and have certain health conditions. However, this will be done by your GP in line with tested protocols, and your health will be monitored by your GP and dietitian.
- If you are in the meal replacement group, you may experience some rare side-effects, such as constipation, dizziness, gallstones, or gout. This will be monitored, and you will be given advice on how to manage these side-effects.

What should I do if I want to take part?

If you would like to join the trial, please phone the research nurse (contact details on the first page) telling them this. They will talk you through the next steps. These include:

- The research nurse checking that you are suitable (if they have not already done so), by asking you a series of questions about your health (e.g. weight, height, history of eating disorders).
- Asking you to complete a consent form indicating that you understand what the trial involves and agree to take part in it. This will either be completed by email, online, or over the phone with the research nurse.
- Asking you to complete a set of online questionnaires. These will ask you questions about your health, breast cancer history, age, mood etc.
- Receiving a set of scales and a watch (that tracks physical activity) to your home address. You will be given written instruction on how to set these up and use them. You will be asked to step on the scales as soon as possible, and to begin wearing your watch straight away.

Once all of these have been completed, you will then be randomised to one of two groups.
You will be phoned by a researcher to inform you of your group allocation.

Please only agree to take part in this study if you are willing to accept allocation to either group. Both programmes are evidence based and can support weight loss, but we do not know how acceptable these programmes are for women affected by breast cancer. Participation in both groups is important to help us design future research and healthcare services.

Flow diagram of order of events

WE SURE CAN

Consent to take part

Receive scales & watch in the post.
Emailed link for questionnaires.

Weigh self. Start wearing watch.
Complete online questionnaires.

Researcher calls – informs you of your group allocation.

Weight loss tips

Receive a leaflet by email

Researcher phones to discuss the leaflet

Meal replacement

A dietitian will call you to ask more questions and discuss the diet

Dietitian communicates with your GP to check suitability

Total Diet Replacement (sent food products) for 12 weeks

Fortnightly calls with dietitian

4 months in
Weigh self
Complete online questionnaires

Food reintroduction (reduction in food products sent to you) for 12 weeks

Fortnightly calls with dietitian

7 months in
Weigh self
Complete online questionnaires

Weight maintenance phase for 6 months

Monthly calls with dietitian

10 months in
Weigh self
Complete online questionnaires

13 months in
Weigh self & complete online questionnaires
Return scales and watch (pre-paid post)
END OF TRIAL

What happens at the end of the trial?

The end of the trial for you is the date that you have:

- completed the 13 month online questionnaire
- stood on the scales for the last time
- worn the watch for the final 7 days

If you take part in the 13 month optional interview, the end of the trial will be after you have also taken part in this.

If you are in the meal replacement group, you may be continuing to use their products, and speak to their dieticians, even after your time in the trial has ended. This will be the case if you have regained some weight, as they will extend the length of the programme for you to help you re-lose the weight and maintain a lower weight.

At the end of the trial, your data will be stored securely and used to answer our research questions. The findings from the trial may be reported at meetings, conferences, and published in journals. More information on the storage and use of your data can be found on the following pages.

You will not be contacted by the research team again, unless you have indicated that you would like to receive the findings from this trial. In which case you will receive these via email in approximately 6-12 months time.

Meal replacement group: you can continue to order products and arrange sessions with the weight loss company if you choose to do so, however it will be at your own expense.

Weight loss tips group: you can continue to access the leaflet and use the tips to help you to maintain a healthy weight.

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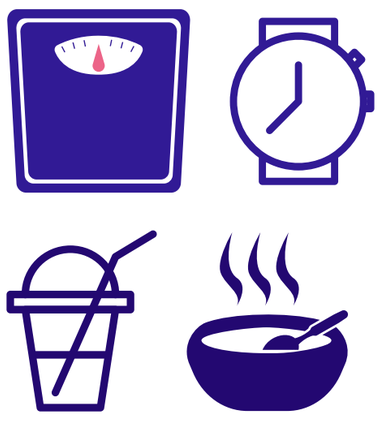
Data and confidentiality

This section outlines how your data will be used, stored, and accessed, during and after the trial.

What data will be collected?

Your NHS number, DOB, contact details. Data from your medical records on your breast cancer diagnosis and treatment, and other medical conditions that you have that are relevant to the trial. For example, we need to know if you have diabetes, to make sure the trial is suitable for you, and to check whether we need to monitor your blood glucose levels.

The online questionnaires will ask about your health, mood, demographics (height, age, etc.), physical activity, sleep, medication taking behaviours, weight management behaviours, use of health services, body image, side-effects, and quality of life.



We will ask you to weigh yourself and wear a watch that tracks your physical activity levels and sleep. This data will be automatically stored and made available to the research team on a secure online database. This data will be anonymous and therefore you cannot be identified by it.

If you are in the meal replacement group, the dietitians will monitor how many food products are sent to you, the number of calls you have with them, any issues you are having with sticking to the programme, and your self-reported weight.

If you take part in the additional phone calls with a researcher, your call will be recorded and typed out.

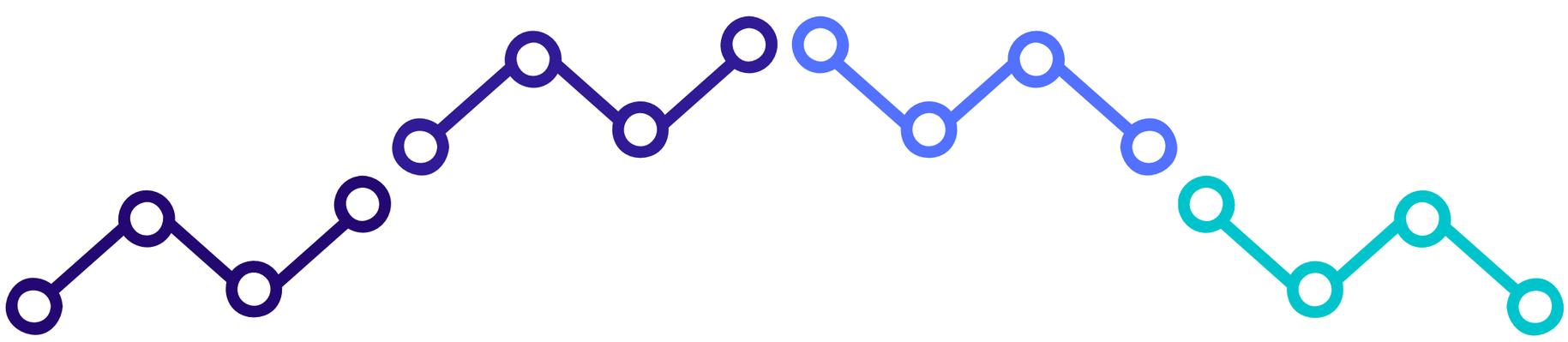
How will my data be stored?

Anonymous data from your scales and watch will be stored on a computer server in France, by the company that makes these products. They will not hold any personal information about you.

The company running the meal replacement programme will store your contact details and the other information they are collecting, in line with their standard data protection processes. Only those who need to use it (e.g. the dietitians) will be able to access it. They will comply with all relevant data storing laws (e.g. GDPR).

The company sending the SMS reminder messages will store your phone numbers for the duration of the trial. They will comply with all relevant data storing laws.

All data collected during this study will be stored in the Clinical Trials Research Unit at the University of Leeds. Only authorised personnel within the research team will have access to your identifiable data.



Who will have access to my data?

Authorised personnel in the research team at the University of Leeds will have access to your identifiable data. The SMS provider company will only have access to your phone numbers.

Other members of the research team, including our independent Trial Steering Committee, can only access your anonymised/pseudonymised data, and will therefore not know who the data belongs to.

The company running the weight loss programme will only have access to the data that they are collecting as part of the study (e.g. your weight, phone number, amount of products sent etc.).

The company that makes the watches and scales will have access to the data saved from these products. However they will not know who this data belongs to, and will not be able to identify or contact you.

The research nurses/team at your hospital will have access to your medical records to make sure you are suitable for this trial.

Stored, anonymised data may be used by other researchers, for future medical and health-related research, if they have relevant ethical approval. This data will be stored for a minimum of 5 years.

External regulatory bodies may access your data, if this trial is audited.

How will my data be used?

The data collected by the weight loss company, research nurse, and scale/watch manufacturers will be sent via secure electronic transfer to the University of Leeds research team for storing and analysing.

Researchers at the University of Leeds will analyse your data, to look at:

- How many women who were offered the trial, took part.
- Whether the interventions resulted in weight loss, and whether more weight was lost in participants in either of the groups.
- Whether participants had any difficulties sticking to the weight loss programmes.
- Whether the trial had any impact on participants' wellbeing.
- Whether it will be feasible to run this trial with a larger number of participants.

Your data will be written up into research papers and published, as well as presented at meetings and conferences. However, it will be kept anonymous.

The University of Leeds is the sponsor for this study.

You can find out more about how we use your information by contacting the University data protection officer on dpo@leeds.ac.uk, and read the University's privacy notice for research participants here: https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf.

Additionally, you can read about how we use your information here:
www.hra.nhs.uk/information-about-patients/
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
or by getting in contact with a member of the research team (contact details on the first page).

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Additional information

What happens if something goes wrong?

The risk of participants suffering harm as a result of taking part is minimal. If you are in the meal replacement group, your dietitian will be monitoring how you respond to the diet. If you have any concerns, please speak to your dietitian about them, or your GP or breast care nurse.

If you have any problems with the scales/watch/online questionnaires during the trial, please email the research team: WeSureCan@leeds.ac.uk

Who do I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team (WeSureCan@leeds.ac.uk).

If you are not happy after that, you can contact the Data Protection Officer on dpo@leeds.ac.uk.

If you are not happy with their response or believe your data is not being processed in a way that is right or lawful, you can complain to the Information Commissioner's Office (ICO) at:
www.ico.org.uk or 0303 123 1113

Who has approved this study?

This research has been reviewed by an independent group of people, called a Research Ethics Committee. All research in the NHS has to be reviewed by this ethics committee, to protect your wellbeing, safety, rights, and dignity. The WALES REC 5 Research Ethics Committee reviewed this study on 15/04/2021, and gave it a favourable review, which means that it is okay for us to proceed with this study.

How do I withdraw from this trial if I want to?

You are free to withdraw from this trial at any time without giving a reason and without this affecting your care in any way, now or in the future. You may do so by talking to the dietitian, research nurse, or research team at any time.

No new information would be collected from you, however we will keep the data you have given up until this point. The same goes for if you lose capacity to continue to participate. We will also still check your medical records for data relating to the safety of this trial (e.g. serious adverse events/hospitalisations). However, your personal information (e.g. contact details) can be removed at your request.

You can also request deletion of your information from the link file (which links your anonymous participant ID code with your real name). This would make your data very unlikely to be linked back to yourself by anyone, including the research team.

For independent advice about participating in research please contact the Patient Advice and Liaison Service for XXXX NHS Trust on:
XXXX XXXXXX
or
PALS@XXX