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Family History Lifestyle Study

Family History Lifestyle (FHL) Study

Participant information sheet

Randomised comparison of two remotely delivered diet and physical activity weight loss programmes vs written diet and physical activity advice amongst overweight women at increased risk of breast cancer attending Family History Clinics

We would like to invite you to take part in a research study that aims to help overweight women with an increased risk of breast cancer lose weight and reduce their chances of developing breast cancer and other diseases. This leaflet gives you more information about the study – **please read it carefully before deciding whether to take part.**

- If you decide to take part in the study you will be asked to attend three assessment appointments at your recruiting hospital.
- You will be randomly allocated to one of three weight loss programmes with the aim of losing weight and reducing your risk of breast cancer and other diseases.
- If you are interested in taking part please visit the study website and answer a short eligibility questionnaire online:

  www.websiteaddress.co.uk
  When prompted please enter the passcode: FHLSH

- If you have any questions about the study or would like to join but do not have internet access, please call centre contact name on the telephone number above.

This study is being carried out by a team of UK researchers under the supervision of Dr. Michelle Harvie at the Wythenshawe hospital (University Hospital of South Manchester, UHSM).

Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take your time to read the following information carefully. Discuss it with your friends, relatives, or GP if you wish, before you make a decision to be involved. Take time to consider whether or not you wish to take part.

Please ring the research team on the number at the top of the first page if there is anything that is not clear, or if you would like more information.

Your participation in the study is entirely voluntary so you don't have to take part if you do not want to and you can opt out of the study at any time without giving a reason. Thank you for reading this information; we hope this research will be of interest to you.

Why are we doing this research

Being overweight and not having a healthy lifestyle increases the risk of breast cancer, ten other cancers and other diseases including heart disease, stroke, diabetes and dementia.

Experts estimate that around 30% of breast cancers in the UK could be prevented by lifestyle change (weight control, physical activity, reduced alcohol). This means potentially 15,000 fewer women being diagnosed with breast cancer each year.

Women at high risk of breast cancer can reduce their risk with lifestyle change. We have found that losing 5% of your weight at any age (and keeping it off) can significantly reduce the risk of developing breast cancer. Weight loss also reduces the risk of diabetes by up to 60%, and improves cholesterol levels and blood pressure giving good reductions in the risk of heart disease, stroke and dementia.

Breast cancer Family History Clinics in the UK do not routinely offer weight loss / lifestyle services to reduce risk of breast cancer. In this study we are interested to find out whether we can engage women in Family History Clinics with a weight reduction and healthy lifestyle programme, and whether there is a difference in effectiveness between different types of programme.

What is the purpose of this research?

The FHL study will compare three groups of women; one group will receive detailed written diet and physical activity information for weight loss and healthy living, and the other two groups will receive this written information in addition to phone and email support from a dietitian. One of these groups will also receive information on their risk of heart disease,

stroke and diabetes. We will look at the impact of the support from the dietitian compared to the written advice only, and the impact of receiving the additional risk information.

Why have I been asked to take part?

You have been invited to take part in the FHL study because you are at increased risk of breast cancer, and you are registered with a breast cancer Family History Clinic.

What happens if I agree to take part?

If you agree to take part you will be randomly allocated to one of three groups for 12 months. You cannot choose which group you enter.

The three groups are:

Group 1: Written advice programme

You will be reminded of your personal breast cancer risk by phone, and given detailed written diet and physical activity advice for weight loss.

Group 2: Standard phone and e mail programme

You will be reminded of your personal breast cancer risk and have one-to-one diet and physical activity advice from a dietitian by phone. You will be encouraged to use a website to monitor your progress for 12 months. You will be supported by the dietitian by phone and e-mail during the first 6 months, and e-mail only during the second six months.

Group 3: Enhanced phone and e mail programme

You will have a finger prick blood test to measure your cholesterol and HbA1c (a marker of diabetes risk) at your initial assessment appointment. You will be reminded of your personal breast cancer risk, and also your cholesterol, HbA1c and blood pressure results and your risk of developing heart disease, stroke and diabetes. You will have one-to-one diet and physical activity advice from a dietitian by phone. You will be encouraged to use a website to monitor your progress for 12 months. You will be supported by the dietitian by phone and e-mail during the first 6 months, and e-mail only during the second six months.

All groups will be encouraged to lose approximately 1-2 lb (½-1 kg) per week by following either of our two recommended diets and building up to a minimum of 30 minutes of moderate intensity physical activity (e.g. brisk walking) for 5 days a week.

The 2 recommended diets

- The 2 Day Diet which includes two low calorie, low carbohydrate days and 5 days of healthy Mediterranean eating.

- A Mediterranean calorie controlled diet seven days a week.

Mediterranean healthy eating includes lower fat meats, fish, fruit and vegetables, wholegrain starchy foods (e.g. wholegrain bread and cereals), beans and pulses, low fat dairy products and healthy fats found in foods like nuts, seeds and olive/rapeseed oil.

What appointments do I need to attend?

The FHL study involves three appointments at your local hospital; an initial screening and assessment appointment when we will confirm if you meet the eligibility for the trial and assessment appointments at six and 12 months. These appointments will take between one and two hours and will include:

- Assessment of your height and your weight and body fat using a special pair of scales.
- Your waist, hip and bust and below bust (back) measurements.
- Completion of some questionnaires.
- Measurement of your blood pressure
- If you are in Group 3 you will have the finger prick blood test for cholesterol and HbA1c described above at your initial and 12 month appointments. If you are in Groups 1 and 2 you will be offered these optional blood tests at your 12 month appointment.
- You will be asked to complete some on line/ postal questionnaires at 3 months

Optional sub-studies

The FHL study has three sub-studies which you can join if you wish:

Sub-study 1: Breast density

Breast density is a measure of the amount of fat and gland tissue in the breast which is strongly related to risk. This sub-study will assess changes in breast density between your mammogram when you join the study and your 12 month mammogram to look at the effect of weight loss on breast density.
If you are in this sub-study your mammogram will be read and reported in the normal way by the hospital radiologists.

Sub-study 2: Breast proteins

Cells within the breasts release proteins into the blood, and a number of these proteins have been linked to breast cancer risk. We will look at the effect of weight loss on the amount of these proteins in your blood Sub-study 2 involves a blood test from your arm at your baseline

and 12 month appointments. The amount of blood taken is less than one teaspoon and you will not need to fast for this blood test.

Sub-study 3: Interview study

If you are in Groups 2 or 3 and based in Greater Manchester you may be invited to take part in an interview at the end of the 12 month programme. You will be asked about your views on the telephone/web-based programme and the impact of the advice you received. This interview can be arranged at a time that suits you, either at The Nightingale Centre or at you home.

Involvement of the General Practitioner/Family doctor (GP)

We will inform your GP of your participation in the trial. If the FHL study team need to confirm that it is safe for you to do more physical activity, we will ask you to seek approval from your GP. Results from the study assessments, e.g. weight, blood pressure, cholesterol and HbA1c levels will be fed back to your GP with your consent. You are unable to take part in the trial if you do not agree that your GP can be informed of your participation.

Frequently asked questions

Do I have to take part?

No, you do not have to take part if you do not wish to and your decision will not affect any standard of care you receive at your Family History Clinic.

What happens if I change my mind?

It is OK if you agree to take part in the study but later change your mind. You do not need to give a reason and it will not affect the standard of care you receive at your Family History Clinic. The FHL study team may also choose to withdraw you if it is necessary for your health or safety due to unexpected findings during the study. If you decide to withdraw from the study, or the study is stopped for any reason, we will use the data that may have already been collected, unless you request otherwise.

Are there any benefits from taking part?

There are no guaranteed benefits to you taking part in the study. All participants will receive detailed diet and physical activity advice for weight loss and healthy living which is aimed at reducing your risk of breast cancer, many other cancers, diabetes, heart disease, stroke and dementia.

The blood tests in the study will tell you about your risk of heart disease, stroke and diabetes, both of which are common diseases in the UK and the cause of much ill health.

You will be contributing to scientific knowledge about the benefits of diet, physical activity and a healthy lifestyle to reduce risk of breast cancer and other diseases in women. The study will help us to develop a well-researched lifestyle programme which can be included in the NHS care of all patients within breast cancer Family History Clinics in the UK.

Are there any risks from taking part?

You will be asked to follow a diet and physical activity plan and complete some trial paperwork which requires some time and commitment. Some women may be disappointed if they do not achieve the weight loss they hoped for, or if they are not able to adhere fully to their diet and physical activity plan.

You will have your usual mammograms whilst on the study. These carry a small risk of radiation-induced cancer developing later in life, due to exposure to x-rays. The benefits of mammogram screening at your usual frequency outweigh the risks involved. The mammograms you have as part of this study are what you would experience as standard care and as such there is no additional radiation risk involved by taking part in this study.

The blood tests involve a finger prick. You could experience brief pain when the lancet goes into your finger. There is a small chance that this could develop into a bruise or be sore to the touch for a short period of time afterwards.

If you take part in sub-study 2 you will have blood samples taken from your arm which could result in slight discomfort or bruising.

If you take part in sub-study 3 it is possible that talking about your experiences and feelings will be upsetting. If you decide not to continue with the interview, we will respect this.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the lead researcher who will do their best to answer your questions (**Dr Michelle Harvie, 0161 291 4410**). If you remain unhappy and wish to complain formally, you can do so through the NHS complaints procedure. Details can be obtained from:

- The Nightingale Centre at UHSM: Patient Experience Service, 0161 291 2033
- University Hospital Southampton: Patient Support Services, 023 8120 6325
- Tameside Hospital: Patient Advice and Liaison Service**,** 0161 922 4466

The Family History Clinics are insured to carry out clinical research. If something did go wrong and you were harmed or suffered deterioration in your health as a result of taking part in this study then you may have grounds for legal action or compensation.

Additional information about the study

Expenses

We are able to offer reimbursement for reasonable travel expenses (car, bus or tram) linked to visits for this study including standard car park fees. There are no other payments for taking part.

Will my details be kept confidential?

Yes. The study team and any associated regulatory authorities follow strict ethical and legal guidance regarding participant confidentiality. Any information we have about you will be handled in confidence and will only be used for the purposes of this study. All data recorded will be coded and your name will remain anonymous.

If you join the study, some relevant parts of your medical records may be looked at by authorised personnel from UHSM or your recruiting NHS Trust. These records may also be looked at by an independent auditing body and regulatory authorities to check that the study is being carried out correctly. We will only access parts of your medical records that are relevant to this research and all information accessed will be kept strictly confidential.

Women in sub-study 1 who are recruited at University Hospital Southampton or Tameside will have their mammogram data transferred securely to researchers at University Hospital of South Manchester via a secure NHS system.

If you are in Groups 2 or 3 you will use the study website which will be just for women on the study and you will log in using a username and password. Your weight and physical activity details will remain secure and are not shared with other participants. Your e-mail address will not be used for any other purpose or passed on to any third party.

With your consent we may wish to use the blood samples you have given for future research, they will be stored in an anonymised form and therefore they cannot be linked back to you. Your anonymised samples will be used mainly by local researchers (if applicable), but ethically approved research projects may take place in hospitals, universities, non-profit institutions or laboratories worldwide.

Will my insurance be affected if I take part in this study?

It is unlikely that your insurance premiums will be affected by participation in this study as the study has the potential to reduce your risk of ill health. However, if you are at all concerned, then we advise that you contact your insurers and seek expert advice before agreeing to participate.

Who has reviewed this study?

Research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is made up of experts, non-experts and members of the general public. Together they review research applications to ensure your safety, rights, wellbeing and dignity are protected at all times. This study has been reviewed and given favourable opinion by the North West - Preston Research Ethics Committee.

What will happen to the study results?

The results of this study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research has shown. This means our study information is double-checked by other professionals in research and healthcare. There is a possibility that the study and its results may be publicised for example on radio, television, magazines, books and websites. **You will not be identified in any publicity, reports or publication arising from this study.** You will be offered a summary of the results of the study which are expected by the end of 2019.

Who is organising and funding the research?

Researchers from UHSM are organising the FHL Study. The study is funded by the charity Prevent Breast Cancer Ltd, registered charity number 1109839.

Further information and contact details

For further information about this study, please contact:

Centre contact name
The Nightingale Centre
Manchester University NHS Foundation Trust
Wythenshawe Hospital
Southmoor road
Manchester
M23 9LT

Thank you for taking the time to read this information sheet.
We hope it has been of interest to you.