ActWELL Study Information Sheet (Full)

A randomised control trial to assess the impact of a lifestyle programme (ActWELL) in women attending NHS breast screening clinics.

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PART 1: BACKGROUND TO THE STUDY

Around 75% of Scottish women aged 50 to 70 years attend the NHS breast screening programme with over 160,000 women being seen every year.

We believe that the breast screening clinic provides an excellent opportunity to provide information about how to reduce lifestyle related breast cancer risks. This study will recruit 552 women and aims to test the success of the ActWELL lifestyle programme. We will do this by comparing two groups of women to see whether our programme helps them change their diet, physical activity levels and body weight.

Why am I being given information about this study?

We are letting ALL women who attend for breast cancer screening know about the study.

Why should I read this leaflet?

Before you decide whether to take part, it is important that you understand why we are doing it, and what it involves. You may also want to discuss it with your family and friends. You do not have to make an immediate decision about taking part in the study.

Where is the study being carried out?

This study is being carried out in four NHS areas in Scotland; Glasgow and Clyde, Grampian, Lothian and Tayside.

Who is funding and supporting the study?

The study is funded by the Scottish Government and is supported by the charity Breast Cancer Now. It is supported by the University of Dundee and NHS. The study is being led by the University of Dundee, together with the Universities of Aberdeen, Edinburgh, Glasgow and Stirling.

PART 2: WHAT WILL I HAVE TO DO?

Study Measurements

We will ask everyone to take part in two visits with a research nurse at their local NHS research centre and one phone call.

Visit 1 will be at the start of the study. You be will be asked to complete a consent form to ensure you understand the study and are agreeable to taking part. The research nurse will go through this with you and answer any questions you have. The phone call will take place after 3 months when the nurse will call to ask your weight and repeat some of the study questions.

Visit 2 will take place after 12 months.

At each of the 2 visits the research nurse will:

- Take measurements of your height (visit 1 only), weight, waist circumference and blood pressure
- Take one blood sample
- Ask you some questions about you, your diet, alcohol consumption, activity levels and views on your health

Blood Sample: We will take one blood sample (9mls) at each visit to look for changes in diabetes risk and cardiovascular risk. These samples will be stored then analysed at the end of the study. As they are bloods for research purposes no results will be available to you.

Study Groups

The fairest way of seeing if ActWELL is effective is to allocate people at random (like tossing a coin) to either the ActWELL group or a usual care group.

ActWELL Group

If you are in the ActWELL group you will receive the ActWELL programme over the next 12 months. A lifestyle coach from Breast Cancer Now will contact you to arrange two free, face to face coaching sessions.

The first session will last around 1 hour. The second session, 4-6 weeks later, will take around 45 minutes. These will be held in a community leisure setting. They will be followed by up to 9 telephone contacts. You will also have access to written support materials over the 12 month study period.

A small number of these ActWELL sessions will be recorded for monitoring purposes. Any recordings will be typed up anonymously and the tape will be erased.

Usual Care Group

If you are allocated to the usual care group we will send you a letter to let you know. You will receive the 3 month call from the research nurse and return at 12 months for Visit 2 to repeat the study measurements. You will not see a lifestyle coach during this 12 month period. However, after the study is completed, you will be offered a free lifestyle coaching session. This will take place in a community leisure setting with one of the ActWELL lifestyle coaches.

Activity Monitor Group

Some women within the study (about 1 in 3), from both the ActWELL and usual care group, will be randomly allocated and asked to wear an ActivPAL activity monitor. This provides us with information on your activity levels such as walking and sitting time. You will be given full instructions and asked to wear it for one week. The monitor will be returned in a reply paid envelope. If selected, we will ask you to do this at both the beginning and end of the study.

Feedback on the study

We are also interested in your feedback both during and at the end of the study. At the end of the study, we will give you an anonymous feedback form to complete. We may also ask you to take part in an interview about your experiences. This will be with a separate member of the research team and can be done face to face or by telephone. We would like to record this discussion for later analysis if you allow us. This recording will be typed up anonymously.

PART 3: YOUR SAFETY AND RIGHTS

Do I have to take part?

No. Taking part in this study is completely voluntary. If you do take part, you can withdraw at any time, and do not have to give us a reason. This will not affect any future care you may receive. If you withdraw, all information we have that might identify you will be removed from our files, only your anonymised data will be kept.

Reimbursement of travel expenses

Reasonable travel expenses will be paid to and from the study measurement visits at the NHS research centres. You will also be given a £10 high street shopping voucher for taking part in each of the two measurement visits.

No expenses are available for coaching sessions.

What will happen to the information you collect about me?

All information we collect about you will be kept strictly confidential. At the start of the study you will be assigned an identity (ID) number to protect your anonymity. This will be used on questionnaires, forms and databases.

The Universities of Dundee and Aberdeen are the organisations that are collecting information about you from study visits and telephone conversation.

We may use the information you provide in order to contact you about participating in research we are conducting.

For further information please contact the trial manager or go to ActWELL website.

Any information we report, such as quotes from interviews, will also be kept anonymous. We will inform your GP that you are taking part in case there is any medical reason you are not suitable for the study.

We'd like to follow up how you do in the next few years via electronic records. To allow us to do this we will record your date of birth and hospital identifier number (CHI) with your consent.

We are working in partnership with the charity Breast Cancer Now who are providing the Lifestyle Coaches. We will pass on your contact details so a coach in your area can arrange to meet with you for your coaching sessions. We will also exchange with them some details such as your height and weight and your feedback to the intervention. At the end of the study the coaching session notes will be destroyed.

Confidentiality

Non-identifiable information (using only your ID number) will be kept for a minimum of 5 years on a University of Dundee secure (password protected) server. Any paper documentation will be kept in a locked filing cabinet.

Only members of the study team will have access to the data we collect from you. When the study is complete, the anonymised data may also be shared with others carrying out research into cancer prevention. They will not know who you are.

Are there any risks to me taking part in this study?

The blood test will be taken in the same way as other blood tests using a small needle. It may be uncomfortable but should not be any worse than other blood tests you have had.

There are no known risks to you taking part in the study.

Who has reviewed the study?

The East of Scotland Research Ethics Service which has responsibility for scrutinising proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Dundee and NHS Tayside whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected.

What if something goes wrong?

Complaints, insurance and indemnity

a. Right to raise concerns

If you have any concerns about your participation in the study you have the right to raise your concern with a researcher involved in conducting the study or a doctor involved in your care.

b. Right to make a complaint

If you have a complaint about your participation in the study, you should first talk to a researcher involved in the study. However you have the right to raise a formal complaint. You can make a complaint to a senior member of the research team or to the NHS Complaints Officer for NHS Tayside.

Complaints and Feedback Team
NHS Tayside
Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: feedback.tayside@nhs.net

c. Right to make a claim

In the event that you think you have suffered harm as a result of your participation in the study there are no automatic financial compensation arrangements. However, you may have the right to make a claim for compensation. Where you wish to make a claim, you should consider seeking independent legal advice but you may have to pay for your legal costs.

d. Insurance

The University of Dundee maintains a policy of public liability insurance which provides legal liability cover in respect of damages, costs and expenses arising out of claims. Tayside Health Board is a member of the Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which provides legal liability cover. The local site where you participated in the study also maintain cover via CNORIS.

You may be required to inform insurance companies with whom you intend to purchase life insurance, income protection or travel insurance, about your participation in this study. It is not anticipated that your involvement in the study will adversely affect your ability to purchase insurance but some insurers may use this information to limit the offer of cover, apply exclusions or increase any premium.

PART 4: WHAT HAPPENS NOW?

If you have already left your contact details at your local breast screening clinic one of our research nurses will be in contact with you. Alternatively you can contact us directly by email or telephone as below.

A research nurse will discuss the study with you and provide any further information you may need. They will also check whether you are suitable to take part and make arrangements for your first study visit.

We anticipate that many women will be interested in taking part. If demand is high it may be that not everyone can be offered a place on the study. We also may not be able to contact everyone who expresses an interest.

For more information please call your local number and ask for the ActWELL Research Nurse:

Aberdeen: 01224 554499
Dundee: 01382 632287
Edinburgh:0131 537 3387
Glasgow: 0141 232 7630

Email: actwellstudy@dundee.ac.uk

www.ActWELLstudy.org

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