

Patient invite to referral & programme

STUDY: EXpanding into communities to imProve physical activity sSupport foR womEn after breast cancer (PURE-EX)



PURE-EX

***Supporting women to be active
after breast cancer***

You are being invited to take part in our study

Please take time to read the following information carefully. Please ask us if there is anything that is not clear, or if you would like more information.

What is the PURE-EX study about?

We have developed a support package to help women recover from breast cancer.

We know that breast cancer treatment can leave women feeling tired, weaker and often frustrated that they are unable to do what they did before cancer. We also know that recovery from breast cancer is not a straightforward process but includes ups and downs and times when you may be unsure how much/how little you should be doing, what could help you recover, and whether other women are going through the same as you.

The PURE-EX support package uses movement to help women to regain their confidence and strength after breast cancer. Movement is one of the best things people can do to lower fatigue and reduce the risk of cancer coming back.

We developed PURE-EX in collaboration with women who have had breast cancer, breast care teams and exercise professionals.

We are now inviting women to take part in the support programme and let us know what they think.

Why have I been invited?

You have been invited to take part because you were diagnosed with breast cancer and have now completed your surgery.

Do I have to take part?

No. It is entirely up to you whether you want to take part or not.

Deciding not to take part, or to withdraw from the study, will not change the standard of treatment or care you receive from your breast care team.

What will I be asked to do if take part?

We are asking your permission for a member of your breast care team to talk to you about physical activity and movement during a routine consultation.

- With your permission, they may ask to audio-record this part of your consultation – this would then be listened to by the research team for quality control purposes.
- If appropriate, the member of your breast care team will also offer some brief advice and offer a referral to the PURE-EX programme (which you can choose to accept or refuse – it is entirely up to you).
- If you decline the referral, you may be asked if you are happy to give a reason why – you don't not have to do this, but it would be helpful for us to know why women may decline the referral.
- If you do accept the referral, a member of your breast care team will then sit with you to give you more information about the PURE-EX programme and what it involves.

At this point you can either decide to go ahead with accepting the referral to the PURE-EX programme or not.

- You can also ask to have more time to consider your decision, and a member of the team will make contact with you a couple of days later by phone, to see whether you would like to go ahead with the referral or not.

After your consultation, you may also be invited to take part in an interview with a researcher from Newcastle University.

- At this interview you will be asked about your experiences and views of being given the offer of the referral from your breast care team. Again, you will be invited to share why you decided to accept or decline the offer of the referral. However, you don't have to share your reason if you would prefer not to, but it would be helpful for us to know why women accept or decline the referral to the PURE-EX programme.
- There are more details about the interviews further on in the leaflet.

What will I be asked to do if I decide to take part in the PURE-EX programme?

If you choose to accept this referral, the programme will involve:

A trained exercise instructor contacting you by phone or email (depending on your preference).

- The instructor is trained in supporting women to be active after breast cancer. They are employed by Healthworks, a local community-based charity in Newcastle upon Tyne.
- The instructor will give you more information and answer any questions you have.

The instructor will invite you to come for a one-to-one review at the Healthworks Resource Centre (located in Benwell, NE4 8BE) at a time which suits you.

- At this one-to-one review, the instructor will collect information on your personal background and medical history. Some of these details will already have been provided by your breast care team.
- The instructor will talk with you about your recovery after surgery and about being active after breast cancer. They will show you some of the movements and exercises which will feature in the classes – this is so you will know what to expect and the instructor can learn more about what you are comfortable with.
- They will then carry out some basic strength and movements tests, such as standing balance and grip strength.
- They will also ask if you would be happy to wear an activity sensor (a small device you wear on your wrist like a watch) which measures how active you are for 7 days. After the 7 days you would be asked to post the device back to Healthworks – you will be provided with a pre-paid envelope to do this.
- You will also be given some questionnaires to take home, complete and return, again with pre-paid envelopes.
- You will be asked if you would like to ‘buddy-up’ with another woman who will be attending the classes. To do this, your contact details will be shared with another woman who, like you, will be attending the classes for the first time.

You will be invited to attend a programme of movement classes at the Healthworks Centre in Benwell.

- You will be invited to attend 12 movement classes in total – one a week for a period of 12-16 weeks. You will have a period of 16 weeks to attend all 12 classes, should there be some weeks you cannot attend.
- The classes will be attended by up to 12 women who have had breast cancer.
- The classes will be in a private space, last around 50 minutes, and involve a gentle warm-up followed by a mixture of aerobic, strength, and balance exercises, and then a gentle cool-down.
- Please be assured that these classes are for everyone. For all exercises there will be options to for all abilities – including seated exercises.
- The instructor will also offer you personalised advice and support for physical activity.

What will happen once I have taken part in the programme?

Once you have attended all 12 classes, you will be invited back to Healthworks for a second one-to-one review with the instructor.

- Just like at the first one-to-one review, the instructor will carry out some basic strength and movement tests, such as standing balance and grip strength.
- They will also ask if you would be happy to wear an activity sensor again for 7 days, before posting it back (with a pre-paid envelope).
- You will also be given some questionnaires to take home, complete and return, again with pre-paid envelopes.
- All these measures will help us to understand if the movement classes were beneficial to you.
- You will be asked if you would like to receive personalised feedback on what these measures told us.
- The instructor will also offer you personalised advice and support for continuing physical activity now the programme has ended.
- You will also receive a £25 shopping voucher as a thank you for taking part in the programme.

After this second one-to-one review you may be invited to take part in an interview with a researcher from Newcastle University.

- At this interview, you would be asked about your views and experiences of the programme. This is so we can understand what women think of it, what they liked about it, if they felt it helped them, and also if there is anything that should be done differently.
- Any interview you choose to take part in can be done online, on the phone or in person if you prefer and will last approximately 60 minutes, or as long as you like. We will ask your permission to audio-record the interview.
- The audio-recording of the interview will be typed-up (transcribed) and anonymised so that the transcript does not contain your name and personal details, and you will not be identifiable by anything you have said.
- Anonymised quotes from interviews may be used in publications.
- Please note, you do not have to take part in any interviews if you do not wish to.

Please note, that with your permission, we will inform your GP you have taken part in the PURE-EX study.

What do I need to be able to take part in the programme?

- As the movement classes will be held in Benwell, you will need to be able to travel to and from the classes.
- You can wear whatever you like to the classes, so long as you are comfortable and safe. We recommend wearing comfortable, breathable clothing and flat trainers (no heels).
- You may wish to wear a comfortable mastectomy sports bra.
- Please bring a drinks bottle with you.
- Movement is for everyone. It doesn't matter if you've never exercised before, or whether you've always been very active - this programme is for women of all abilities.

What if I decide I don't want to be involved in the study anymore?

We expect that taking part in this study will last approximately 20 weeks (from referral, from attending a one-to-one review, taking part in the programme, attending the second one-to-one review and taking part in an interview (if you chose to). After giving your consent to take part, you are still free to withdraw from the study at any time without needing to give a reason. You can do this by contacting the study's lead researcher, Dr Morven Brown (contact details below). during the study. However, any information you provide us up until that point may still be used in the study.

Who is organising and conducting the study?

Newcastle University is the sponsor for this study.

The study team are from Newcastle University. They are working with researchers and healthcare professionals from across several universities and NHS Trusts in England.

The movement classes will be provided by trained exercise instructors from Healthworks a local community-based charity in Newcastle upon Tyne. You can find out more about Healthworks here: <https://www.healthworksne.org.uk/>

Dr Sam Orange and Professor Bernard Corfe from Newcastle University are leading the study.

The Principal Investigator responsible for the study at your hospital is [INSERT PI NAME]. [PI name] and their colleagues are inviting their patients to take part in PURE-EX.

Who has approved and funded this study?



This study has been approved by an NHS Research Ethics Committee (REC reference: 25/WA/0330)

The study has been funded by a grant from Breast Cancer Now.

How can I get more information or who can I talk to if I have some questions?

You can contact Morven Brown who is the lead researcher for the study at Newcastle University:



Phone or text:
07874 637 239



Email:
morven.brown@newcastle.ac.uk

If you prefer, you can also ask someone in your hospital team to pass your contact details on to us, and we will contact you.

What happens with the information I give to you?

Only fully trained and delegated members of the research team will have access to your information.

Your personal details including name, telephone number, postal address and email address will be held on a secure Newcastle University database only accessible to authorised personnel. The research team, including the Healthworks instructors, will be able to access these to send you questionnaires and contact you about PURE-EX.

We may ask to audio-record consultations and any interviews. The recordings of interviews will be transcribed (typed out) either by research staff at Newcastle University or by an external company that we work with. These transcripts will be anonymised – that means they will not contain your name or personal details, and no-one will be able to identify you, or anyone else, from anything that you have said. We will also not tell your healthcare team anything that you have said to us.

All information collected about you will be kept strictly confidential and we will only collect and keep information necessary for the study (such as your age, when you were diagnosed with breast cancer, and breast cancer treatments you have received). This information as well as questionnaires, any recordings, and transcripts, will be stored using a study ID number and not under your name.

Your personal details will be securely stored (on a Newcastle University secure server) and destroyed after we have completed the study and sent you a summary of the study findings (if you would like to receive this).

Any audio-recordings will be stored separately on the secure server and will be deleted when the anonymised transcripts have been analysed. Anonymised data (e.g., from interviews or questionnaires) will be held for a maximum of 10 years after the end of the study.

What will happen with the results of the study?

We will collate all feedback from women about the PURE-EX programme. We will also seek feedback from healthcare professionals and the programme instructors regarding the study. This information will help us to know what people thought about PURE-EX and what could be changed to make it as useful and helpful as it can be for women.

The results will be presented at conferences, published in a medical journal (no-one will be able to identify you in any of these presentations or reports).

We may also use the data from this study in student projects or share them with researchers working with us. However, you will not be identifiable in anything we share.

What are the benefits of taking part?

Personally, you may find taking part in this research helpful as you will be provided with additional information and support regarding being physically active after breast cancer. You may find it rewarding or interesting that you will be contributing to research which aims to help women who have had breast cancer.

Are there any disadvantages of taking part?

All forms of movement come with a small risk of complications, such as chest pain or muscle injury. However, this risk is very low, and it is widely accepted that **the benefits of regular movement far outweigh any risks**. We will minimise this risk further by performing a health screen (during the one-to-one review) and taking you through a gentle warm-up at the start of the movement class.

You will not be expected to do any movement or exercise that you are not comfortable with. If you find taking part raises issues, questions or concerns for you at any point, we will provide you with details of who you can contact for help or information.

What if I have concerns or want to make a complaint about the study?



If at any time, you are concerned about any aspect of this study, you should speak to the researcher directly, or contact the study lead using the details provided in this leaflet.

If you were approached to take part in the study by your cancer team, you may contact one of your doctors or nurses to discuss this and you may also complain formally about the study, through the Patient Advice and Liaison Service (PALS). Freephone: XXXXXX, Website: XXXXX, Email: XXXXXX

What if I have questions after I take part in the study?

If you have questions about the study, please contact the researcher, Morven Brown. If you have questions about your breast care, please contact your clinical team. If you have questions about your general health, you can contact your GP. If you would like more information, advice and support about breast cancer you could contact Breast Cancer Now (website: <https://breastcancernow.org/>).

**Thank you for taking the time to read this information sheet.
Please read on if you would like further details on how we will use the
information about you.**

How will we use information about you?

We (Newcastle University – the Sponsor for the study) will need to use information from your medical records for this research project. This information will include your:

- name
- date of birth
- contact details/address
- diagnosis
- date of diagnosis
- treatment received/receiving
- date of treatment

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data (e.g., questionnaire, interview transcript) will have a study ID number on it instead.

Newcastle university is responsible for looking after your information.

We will keep all information about you safe and secure by: storing data on a secure part of the Newcastle University network; using secure NHS.net email to communicate with the NHS and Healthworks about the study.

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- ☐ at www.hra.nhs.uk/patientdataandresearch
- ☐ by asking one of the research team
- ☐ by emailing the Data Protection Officer for Newcastle University at rec-man@newcastle.ac.uk