**Study title: PROMOTE - Exploratory research into the PeRceptions Of cancer and clinical trials amongst Muslim wOmen with breasT cancEr.**

Hello, my name is Lorraine Turner, I am a Consultant Advanced Nurse Practitioner at The Christie Hospital and PhD student at the University of Manchester and I am leading this study.

You are being invited to take part in this research study to better understand the perceptions of breast cancer and clinical trials of women of Muslim faith and their families. Your participation will help co-develop an intervention that meet the needs of Muslim women to help increase participation in cancer clinical trials. This study is part of a PhD. Taking part is completely voluntary. Before you decide whether to take part, it is important you know why this research is needed and what it will involve.

Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. If you struggle to read or understand this information, please speak with a member of your medical team or the researcher who will help you. We will arrange for an interpreter in your preferred language if needed. Thank you for taking the time to read this.

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**Participant information sheet**

**What is the purpose of the research?**

It is essential to have a wide range of people from different communities take part in cancer clinical trials to help understand how biological variations can contribute to cancer occurrence, experience of cancer and effectiveness of treatments. It promotes equal opportunities in accessing treatment options so advances in medicine and healthcare fairly benefits all people affected by cancer. However, in Greater Manchester (GM) very few people from ethnic communities take part in clinical trials. Over a quarter of GM’s residents are from an ethnic community, with the majority describing themselves as Muslim. You have been chosen because we feel it’s important to understand what women of Muslim faith and their families feel and understand about cancer and clinical trials so that culturally sensitive recruitment methods can be developed to meet the needs of Muslim women and improve clinical trial participation.

This study involves 3 phases. Phases 1 (interviews) & 3 (workshops) will invite breast cancer patients of Muslim faith to take part. Patient’s immediate family member or primary caregiver will also be invited to take part if you agree. Phase 2 will involve a survey for health care professionals. The findings from phase 1 & 2 will be used to help structure phase 3. Phase 3 will involve 4 consecutive workshops with the aim to co-design a faith-based intervention that will support Muslim women’s awareness, understanding and participation of cancer clinical trials.

We want to ensure Muslim women feel well informed about cancer clinical trials and feel empowered to participate. This information sheet will give you information about phase 1 of the study. If you agree to take part in phase 1 you will be asked if you would like to be contacted about phase 3. Taking part in phase 1 does not mean you have to continue to take part in phase 3.

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**Who has reviewed the research project?**

The research project has been reviewed by experts who have knowledge and experience in this subject area and who are of Muslim faith. The study was reviewed & approved by South West Frenchay Research Ethics Committee 3rd October 2024 and the Health Regulatory Authority & Health and Care Research Wales 9th October 2024. Reference: IRAS 343703.

**Will the outcomes of the research be published?**

The results of the study will be available after the study has finished and will be written up as part of the researchers PhD project. The study will be summarised and published as research articles in relevant journals. They may also be used in presentations at conferences. All the data used in publications / conferences including any quotes of my responses will be in anonymous form. This means that the results will not contain any information that could be used to identify you.

We will write an easy-to-read summary to share with participants who took part. You can request a summary of the results by providing your email address on the consent form.

**Who will carry out the research?**

Lorraine Turner from the school of Nursing, Midwifery and Social Work, University of Manchester and the Christie NHS Foundation Trust is carrying out the study as part of a PhD programme. The research team includes Professor Janelle Yorke (Honorary Professor of Cancer Nursing at The University of Manchester), Dr Sally Taylor (The Christie Hospital and The University of Manchester), Professor Fiona Thistlethwaite (Honorary Professor at The University of Manchester and The Christie Hospital) and Professor Jo Dumville (Professor of Applied Health Research at The University of Manchester). The research study is endorsed by the Manchester Biomedical Research Centre.

**Am I suitable to take part?**

* We are inviting women aged 18 years and over who have breast cancer (any type) and who identify themselves as Muslim.
* Those who are receiving treatment for their breast cancer and those who have finished treatment.
* Those who have taken part in clinical trials and those who have not taken part.
* Immediate family member such as spouse, child (by blood, adoption, or marriage), brother, sister, father, mother, grandparent or primary caregiver is also invited to take part if you agree.



**What are the benefits if I take part?**

There are no direct benefits of taking part in this study.

We hope you will enjoy sharing your experiences with us. Your participation in this research project will help us develop a meaningful and relevant intervention that meets the needs of Muslim women and help increase awareness, understanding and participation in cancer clinical trials.

**What would I be asked to do if I took part?**

If you complete the consent to contact form which your clinical care team or community representative has given you, the researcher will contact you to discuss the study further and answer any questions. If needed, we can arrange for an interpreter so that we can discuss the study and answer any questions in your preferred language. If you decide to take part, you will be given this information sheet to keep.

We aim to invite 12-15 women to take part in an interview, which will last approximately 45-60 minutes. The interviews can be carried out in a location that is convenient for you such as your home, private space in a community centre or hospital which you attend or virtually using the University of Manchester’s approved on-line platform MS 365 Teams.

**Before the start of the interview:**

* The researcher will contact you regarding possible dates, times and locations for the interview. A date, time and location will be chosen that is convenient for you.
* You will be asked to sign the consent form if you agree to take part. We can arrange an audio recording of your consent if you struggle to read or write. Both of which will be securely stored and only accessible by the research team.
* If you cannot speak English or would prefer to have an interpreter for your preferred language, then please let the researcher know so she can arrange for one.
* If you would like to have a member of your family or primary caregiver with you during the interview for support, that is absolutely fine.
* We are keen to hear the views and experiences of patient’s immediate family members such as spouse, child, brother, sister, father, mother, grandparent, or primary caregiver. If you agree, we will also invite them to take part in the interview.
* If a family member / caregiver wishes to take part, they will be asked to sign a separate consent form on the day of the interview.
* We will ask you to complete a paper questionnaire which includes demographic & personal characteristics. This will take around 5 minutes to complete.

We appreciate it’s a huge commitment to take part in an interview and we will do our best to make the interview as convenient and accessible as possible.

**During the interview:**

* This will involve one interview with the researcher and if available a research ambassador (a community representative recruited by the research team who is female and of Muslim faith).
* The interviews will be recorded using secure audio recording equipment. If the interview is done virtually then the interview will be audio recorded only, with no video recording.
* It is essential for the study that the interview is recorded, and we will only use the information recorded with your consent. You will not be able to decide which parts of the interview can and can’t be used.
* If you agree to be recorded, you should be comfortable with the recording process at all times.
* The researcher will ask you about your experience of breast cancer and how it’s affected you and your family. We will also ask about your experience of the care received for your cancer and your thoughts and feelings around cancer treatment including clinical trials and research.
* Due to the nature of the questions, it might make you think about emotions or difficult situations that you find upsetting. Your wellbeing is important, so if at any time during the interview you feel uncomfortable, or it’s causing you distress then you may stop the interview.
* If you need support, we can help sign post you to the appropriate services.

**Will I be compensated for taking part?**

Travel expenses will be covered if you need to travel to a location to take part in the interview.

In the unlikely event that something does go wrong, and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**What happens if I do not want to take part, or if I change my mind?**

It is up to you to decide whether or not to take part. You will receive the same care whether you join the research study or not. The researcher will only contact you if you complete the consent to contact form given to you. If you decide to take part, you will be given this information sheet to keep and asked to tick a box on the consent form to confirm consent or provide verbal consent which will be audio recorded.

If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights.

It is essential for the study that the interview is recorded so it is important that you are comfortable with the recording process at all times, but you are free to stop recording at any time.

If you decide not to take part, you do not need to do anything further.

* If at any time during the interview you feel uncomfortable with the recording, you are free to ask the researcher to stop recording.
* You will be able to withdraw from the study at any time without giving reason and your care will not be affected. Any recording already collected before withdrawing from the study will be used in the study.
* The researcher will be there to answer any concerns that you may have throughout the interview.

**After the interview:**

* If you consent to receiving information regarding the third phase of this study, the researcher will contact you around 6 weeks prior to starting phase 3 to discuss what is involved and send you a participant information sheet.
* If you do not want to receive the information about phase 3 or a summary of the findings from this study when completed, then your contact details will be securely destroyed.
* There may be little direct benefit to you from taking part in this research. However, with your participation in this study you will help us develop a meaningful and relevant intervention that meets the needs of Muslim women and will help increase awareness, understanding and participation of cancer clinical trials.

**Data Protection and Confidentiality**

**What information will you collect about me?**

In order to participate in this research project, we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

* Age
* Place / Country of birth
* Place of residency (including postcode)
* Number of years lived in the UK if not born in the UK & first, second or third generation.
* Ethnicity
* Religion
* First language & preferred language
* Marital status
* Dependents i.e., children or care for relatives
* Education status
* Income
* Family history of cancer (any type of cancer)
* Year of breast cancer diagnosis
* Name of Clinical care team and Hospital you are receiving care from (if applicable)
* The interview recordings will consist of voice only and recorded using a University of Manchester encrypted audio recorder device or via the University’s approved virtual platform MS 365 Teams
* Audio recordings will be transcribed by the researcher, which means writing out the conversation we had during the interview. Any identifiable information will be removed at this point and participants given a unique ID number, known only to the research team so data is not identifiable (transcripts will be pseudonymised). Once interviews have been transcribed the audio files will be securely deleted.

**Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

**What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recording.

Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095) (https://documents.manchester.ac.uk/display.aspx?DocID=37095).

**Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

* All personal identifiable data collected will be assigned an ID number (not your name, date of birth or hospital number for example) only known to the research team (known as pseudonymised). These will be stored in a password protected file on a secure Research Data Storage server at the University of Manchester. The pseudonymisation key for linking your ID number to your identity will be accessible only to the research team and stored separately from all collected data in a separate file on the University’s SharePoint drive.
* Consent to contact forms containing personal information will be stored by the researcher in a secure locked cabinet, in a locked room accessible only to members of the research team. These will be destroyed when no longer needed or by the end of phase 1 (or phase 3 if you consent to be contacted for phase 3).
* Consent forms containing personal details will be stored in a locked filing cabinet in a locked room accessible only by the research team. They will be retained for a period of 5 years following the end of the study for audit purposes and then securely destroyed.
* Contact details given to receive information regarding phase 3 of the study and / or receive a summary of the study findings will be stored in electronic format and saved in a separate file on the University’s Research Data Storage service. This will be securely deleted when the study findings have been sent to you. If you change your mind, then please just contact the researcher. Your details can then be securely deleted.
* Recorded audio consents will be pseudonymised and stored separately to any personal identifiable data. They will be retained for a period of 5 years following the end of the study for audit purposes and then securely deleted by the University’s ResearchIT.
* Interviews will be audio recorded using a University of Manchester encrypted recording device and will be separate from the audio consent. Recordings will be transferred from the audio recorded device to secure University Research Data Storage server. As soon as the recording is checked once transferred, it will be deleted from the audio recording device.
* If interviews are done virtually then your participation in this study will be recorded using a separate audio recording device or the recording function on MS 365 Teams. If audio recorded using Teams, your personal data will be processed by Microsoft. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of Interview.
* We will use the recording of the interview to make a transcript.
* Transcripts will be assigned an ID number only known to the research team (known as pseudonymised). These will be stored in a password protected file on a secure server at the University of Manchester. The researcher and an additional member of the research team will transcribe audio recordings. However, we may have to use University of Manchester approved transcriptionists. For participants of non-English speaking an approved University of Manchester translation / transcription service will be used to translate and transcribe the interviews into English. All approved external transcriptionists are required to sign service level agreement and client confidentiality agreements.
* Encrypted audio files will be uploaded to the approved transcription / translation service through the University’s secure encrypted portal.
* Once transcriptions have been received by the researcher and checked against the audio-recording, the audio recording will be deleted by the University’s ResearchIT.
* Once all the data has been analysed by the end of the study, we will destroy the pseudonymisation key, anonymising your data (i.e., the link will be broken between ID number and your name). Hence you can request to withdraw your data any time prior to data being anonymised.
* Data will not be kept for future studies and any digital files will be destroyed 5 years after the end of the study by the University’s ResearchIT, in line with the University’s Records Retention Schedule.

Please also note that individuals from The University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data, but all individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

**Potential Disclosures**

If, during the study, we have concerns about your safety or the safety of others, we will inform the relevant authority. If it’s related to your health, we will inform your breast cancer care team and / or immediate family member / primary caregiver. If during the study, you disclose information about misconduct / poor practice during the care you have received, we have a professional obligation to report this and will therefore need to inform the relevant authorities.

If you would like more general information on how researchers use data about patients, please visit: [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

**What if I have a complaint?**

If you have a complaint that you wish to direct to members of the research team, please contact:

**Professor Fiona Thistlethwaite**

Fiona.thistlethwaite@manchester.ac.uk

Telephone: 0161 918 2325

Formal Complaints *-* If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:

**The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:** **research.complaints@manchester.ac.uk** **or by telephoning 0161 306 8089.**

If you wish to contact us about your data protection rights, please email **dataprotection@manchester.ac.uk** or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information. Tel: **0303 123 1113.**

Website:<https://ico.org.uk/make-a-complaint/data-protection-complaints/data-protection-complaints/>

**Contact details?**

If you have any queries about the study, would like more information about the study or if you would like to take part, please contact:

**Lorraine Turner** Email: Lorraine.turner-5@postgrad.manchester.ac.uk

Work telephone: 0161 918 2446.