

Headed paper

Participant information sheet

Study title:

The experience of spiritual healing in women with breast cancer who are receiving long term hormonal therapy

Invitation to participate in the study:

You are invited to participate in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything you do not understand, or if you have any questions, please feel free to contact me, Fiona Barlow, you will find my contact details at the end of this information sheet.

Thank you for reading this.

What is the purpose of the study?

The aim of this research is to find out if one-to-one healing can offer any benefits for people who are receiving long term medical treatments such as the hormone therapy that you are currently receiving. Healing is sometimes referred to as the laying on of hands, although it does not necessarily involve direct touch. Whilst it is often referred to as 'spiritual' healing, it is available to people with any religious belief and to those with no belief. Healers aim to care for the patient and do not claim to cure cancer. At present we don't really know if it works or how it works and we want to investigate these issues in some depth.

Why have I been chosen?

You have been chosen because you are currently receiving hormone therapy following initial treatment for breast cancer and have reported some unpleasant or unwanted symptoms. Because we are not sure how long the effects of healing last, we will not wish to include you in this study if you have received one-to-one or distant healing since the start of your cancer journey. Also we will not include those who are healers themselves.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, please keep this information sheet. You will be asked to sign a consent form before you start the research. If you decide to take part you are free to withdraw at any time without giving a reason. Your decision not to participate or to withdraw will not affect any aspect of the care you receive. If you do decide to withdraw, you may request that any or all of the information already collected be destroyed or withheld.

What will happen if I decide to take part?

If you return the enclosed reply slip, I will contact you to talk through all aspects of the study and answer any questions you have.

I will then arrange to meet you at the Wellcome Trust Clinical Research Facility at Southampton General Hospital where the study will take place. At this visit, the details of the study will be explained again and you will see where healing will take place. You will be asked to sign a consent form and complete a checklist of your current symptoms.

You will be able to book up to 10 sessions of healing, free of charge. These will take place at the Wellcome unit, with a trained healer from the Harry Edwards Healing Sanctuary near Guilford, who may be a man or a woman. Each session will last approximately 40 minutes. Healers place their hands on or near your body (depending on your wishes), starting at the head and working down to your feet. Each session will be video-recorded to provide an exact record of the healer's actions for our analysis. You will be able to view this if you wish. If you are not happy with the idea of recording, a chaperone will attend each session. I will attend some sessions to record my own observations.

At the end each session, I may invite you to spend a little time talking about your experience and impressions of the session. I would like to tape-record this conversation for analysis, if you are happy for me to do so. I will also give you a daily log for you to jot down any thoughts, sensations and feelings you have between healing sessions. These will help to document any physical or mental changes that take place over time.

After the final session, I will arrange to interview you in your home, at the Wellcome Facility, or at another convenient private location to tape-record your reflections on the experience of receiving healing. I will collect your diary and ask you to fill in another symptom checklist to compare with the one you filled in at the beginning. This interview will normally last 1 to 2 hours, depending on your wishes. All of the information collected will be analysed to identify common threads in responses to healing that will help us to understand what is happening and the affects of healing for individuals

A few weeks later, I will send you a copy of the preliminary analysis of the information we have collected from you and about your healing experience and invite you to comment on their accuracy. You will also be invited to attend a small group meeting at the Wellcome unit with up to five other people who have taken part in this study. This will enable myself and my supervisors to gain important feedback on our initial findings. I would also like you, with the group, to share your thoughts and feelings on the usefulness of questionnaires that that are commonly used to evaluate the outcomes of medical treatments and offer suggestions for improvement.

What are the benefits of taking part?

We are unable to predict if you are likely to benefit in any way from taking part in this study. We emphasise that healers make no claim to cure cancer.

Are there any disadvantages to taking part?

Taking part in the study will take up your valuable time. The study may cause you to reflect on experiences that you find upsetting. If this does happen, I will do my best to ensure that you are properly supported and given information that will provide you with long term help and support if you need it. We do not anticipate any adverse responses to healing, but if you experience any unpleasant or worrying symptoms or feelings at any stage, please draw these to the attention of myself and the healer and report them to your GP or hospital consultant.

Will the information I provide be kept confidential?

We will ask for your permission to let your general practitioner (GP) know that you have agreed to take part in the study, just in case he or she is aware of any reasons why this might not be medically appropriate, and in case there are any changes during the study that affect your health. For the same reason, we will let your hospital consultant know that you have agreed to participate. We will not examine your medical records.

The video-tapes of the healing sessions will be viewed in private only by myself and members of my supervisory team for the purposes of the analysis. The audiotapes will be transcribed into a written form, either by myself or by a member of the research team who fully appreciates their confidential nature and who has given an undertaking not to disclose any information.

All information in the form of tapes and transcripts collected as part of this study will be seen only by myself and my supervisors and, if requested, university research auditors. All of the tapes and information will be coded (referred to only by a number) and kept in a locked cabinet in my office. The code-breaker will be kept locked separately. After the study is finished, all of this material will be locked securely in the research office for 10 years (we are not allowed to destroy the data in case there are any future queries about the conduct of the research).

As we sift and analyse your information, we will take steps to protect your identity by changing names, locations and other significant information. This will ensure that any direct quotations or observations published as part of the research findings cannot be traced back to you.

I recognise that this study will generate a lot of information (video, audio and written) that I may not be able to fully analyse as part of my PhD. At the end of the study, I will ask for your consent to share this with other academics for research purposes.

When I come to present the study to a wider audience, for example at conferences, it may be helpful to support the research findings with personally identifiable video images and/or audio extracts. I will ask you for your consent for this at the end of the study, once you are fully aware of the content. Please be reassured that I will not release any personal information without your signed consent, which you will be under no pressure or obligation to give.

What will happen to the results of the research study?

I will write up the findings in my PhD thesis as well as for publication in medical journals and journals that specialise in complementary therapies. The information gathered from you and the other participants in this study will also contribute to a larger study to test the effects of spiritual healing.

Who is funding the research?

The research is funded by The Harry Edwards Healing Sanctuary. Healing is provided free of charge and the study is conducted independently by Fiona Barlow and her supervisors.

Who has reviewed the study?

This study has been reviewed by academics from the National Cancer Research Institute, the University of Southampton Cancer Science Protocol Review Committee, and the Central Office for Research at Southampton University Hospital's Trust.

Contact for further information

If you have any further questions, please contact Fiona Barlow on [telephone number to be confirmed]

Thank you for reading this information sheet.