Back Breast & Bra Study

Curtin University

Information Sheet & Consent Form

Study 3

HREC Project Number:	*RDHS-267-15*
Project Title:	*Back, breast & bra study. Study 3.*
Principal Investigator:	*Associate Professor Kathy Briffa*
Version Number:	*1*
Version Date:	*04/10/2015*

The Project

Upper back pain is a common complaint affecting many women. Women with large breasts often show changes in their posture which often leads them to seek treatment for upper back pain. Breast size, is one factor among many that may affect posture and contribute to the pain felt in the upper back. In addition to breast size there are a number of other physical and psychological factors that may contribute to pain. Whether a woman's breast size is more or less important than these other factors is unknown. This study aims to explore the relationship between upper back pain and the breast.

The Research Team

The project is being conducted by Linda Spencer who is a Musculoskeletal Physiotherapist completing a Doctor of Philosophy at Curtin University. Associate Professor Kathy Briffa, Dr Robyn Fary and Dr Leanda McKenna offer substantial experience in research and are supervising Linda with the project.

The Search for Volunteers

We are looking for healthy women to participate in this study. You have been asked to take part because you are awaiting breast reduction surgery. Initially you will be asked to complete a series of questionnaires and then invited to participate further where physical measures of your back pain, posture, breasts and bra will be taken. There will be no cost to you for taking part in this research.

Taking part in a research project is voluntary. If you decide to take part and then change your mind, you can withdraw from the project. If you chose not to take part or start and then stop the study, it will not affect your relationship with the University or Breast Clinic; their staff or colleagues.

The Role of the Volunteer

Before your surgery and as a participant in this study you will be asked to:

Initially:

1. Complete a number of questionnaires (paper copies or online) about your health, back pain, breast symptoms; bras and medications. This is likely to take approximately 30 mins.

Then:
Having completed the questionnaire pack you will be invited to participate in the study further. This will include two visits (one before and one after your surgery) to Curtin Interprofessional Health & Wellness Centre at Curtin University. Here you will have a bone density scan and other physical measures of your back movement, back strength, upper back pain, breast size and posture (see below). This is likely to take 1 hour.

The Details:

You will be asked to make your own travel arrangements to attend appointments. You will be provided with free parking at all appointments.

- **The Curtin Interprofessional Health and Wellness Centre appointment:**

Before your scheduled session at Curtin Interprofessional Health and Wellness Centre you will be asked to avoid any unaccustomed activity in the preceding 48 hours that may induce temporary muscle or joint soreness. You will be asked to bring details of all current medications and asked to attend in loose fitting attire, wearing the bra you find most comfortable.

You will be asked to attend Curtin Interprofessional Health & Wellness Clinic at a time that is convenient to you. An appointment time will be prearranged with you. Upon arrival you will have all the procedures explained to you. The tests will take place in a single room within the clinic that is locked when all tests are taking place. Only you and a member of the research team will be in the room. The following tests will be completed:

Bone density scan: You will be asked to lay on your back for around 15mins for the bone density scan to be completed. You will be provided with a gown for this procedure and asked to remove any metal from your clothing/body. The scan will be completed by Linda Spencer or research supervisor.

Back movement test: You will be asked to stand with your shirt removed (bra on) for this measure. Adhesive markers will be placed on your upper spine. A photograph will be taken at the start. You will then be asked to arch your back whilst a second photograph is taken. The amount of movement you have will be measured from the photographs.

Posture assessment: You will be asked to sit with you shirt removed (bra on) for this measure. Adhesive markers will be placed on your spine and shoulder. Sitting comfortably a photograph will be taken from the side. The photograph will be used to measure your posture.

Breast measures: Several measures of your breast will be made using a tape measure. You will be asked to remove your bra for these measures.

Bra size measures: You will be asked to stand with your bra removed for this measure. A tape measure will be used to measure around your chest at points over and under your bust to determine you bra size.

Bra strap pressure: You will be asked to stand with your bra on for this measure. Small sensors will be placed under the straps of your bra at various points to measure the pressure under the strap. The sensors will be connected to a computer via wires to retrieve this information electronically.

Back strength measures: You will lay on your stomach on a bed with your clothes on for this measure. You will be asked to lift your chest off of the bed and hold for as long as you can. The amount of time that you can hold this position will be recorded.

Back pain measures: You will be asked to sit and/or lay on your stomach. A handheld device will be placed at various points on your back (spine) and upper body (muscles). You will be asked to indicate if and when the points become painful as pressure is applied to them using the device.

As a participant undergoing breast reduction surgery we are interested to see if any of these measures change as a result. Therefore you will be asked to attend at any stage prior to your surgery and then again at least three months following your surgery when it is comfortable for you to move and lay on your stomach. The same measures will be taken at both sessions. You will be asked to provide details of your surgery (e.g. how much breast tissue was removed and the type of incision made on your breast) and will be asked to complete a surgery satisfaction questionnaire at the second session.

The Benefits

As a participant in this study you will incur the following benefits:

1. A printed copy of your bone mineral density results that you can take to your GP to discuss.
2. Information on how to correctly fit your bra.

Your Privacy:

The session held at Curtin Interprofessional Health and Wellness Centre will involve a number of procedures where you will be asked to undress to expose your back or breasts to permit measures to be taken. You will be provided with a gown and ample draping to ensure your comfort throughout the session. The procedures will take place in a private and secured room with only a member of the research team present.

Photographic images will be taken as part of some of the procedures. These images will exclude facial features and any identifying marks (birth marks or tattoos) will be pixelated. The images will be coded to carefully ensure anonymity.

All of your personal details, data and images will be de-identified, coded, protected and stored securely. The study has to adhere to strict guidelines which will ensure confidentiality. The data will only be accessible to the research team and used for research purposes only. The Curtin Ethics Office may access the data for audit purposes.

The information we collect in this study will be kept under secure conditions at Curtin University for 7 years after the research has ended and then it will be destroyed.

The results of this research may be presented at conferences or published in professional journals. You will not be identified in any results that are published or presented.

The Risks

The procedures will require you to sit, stand and lay in a variety of positions (including laying on your stomach). If you have difficulty with changing position or feel unable to maintain a position for long you must inform the research team prior to attending.

The procedure which measures upper back pain will induce temporary discomfort. A small handheld device will be pressed on your back joints and muscles to assess how sensitive they are. You will be asked to indicate when pressure becomes discomfort. At this point the device will be withdrawn from contact with your back. Any ongoing pain following the session should be reported to the research team.

One procedure involved in this study will expose you to a very small dose of radiation (bone mineral density scan). The total amount of radiation that you will receive has been verified by the Curtin Radiation Safety Officer. The test involves the use of a low dose x-rays about equal to one thousandth of the background radiation you would receive in one year living in Perth. The total background radiation in Western Australia is about 2000 µSv per year. The radiation dose from cosmic rays from flying in a jet from Perth to London is approximately 100 µSv.

During this research we may find a result that has implications for your health. You will be notified of this and advised to contact your GP at your earliest convenience.

The Contact Details

Contact Linda Spencer if you would like to discuss any aspect of the study or would like to volunteer to participate. Email: **Linda.spencer@postgrad.curtin.edu.au** or Telephone**: 9266 4644**

If you decide to take part in this research we will ask you to sign the consent form. Signing the consent indicates that you have understood the information provided in this document and agree to be in the research project. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the unsigned consent form to keep.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number RDHS-267-15). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.

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- I have read, *{or had read to me in my first language – delete if not appropriate},* the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I consent to the collection and secure storage of images of myself as part of my involvement in this project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by Curtin University Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – updated March 2014.
- I understand I will receive an unsigned copy of this Information Statement and Consent Form.

Participant Name	
Participant Signature	
Date	

Declaration by researcher: I have supplied an Information Letter and Consent Form to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

Researcher Name	
Researcher Signature	
Date	

Note: All parties signing the Consent Form must date their own signature.

Please return this completed form to:

Mail: Linda Spencer (PhD Candidate)
C/o Associate Professor Kathy Briffa.
School of Physiotherapy & Exercise Science
Curtin University
Kent Street
Bentley WA.

Email: Linda.spencer@postgrad.curtin.edu.au