

CONSENT FORM FOR PARTICIPANTS IN A RESEARCH STUDY

Universal Sleepwear Design Applications for Post-Mastectomy Women with Lymphedema

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Research Assistant: Kirsten Schaefer, MA Student, Ryerson University, School of Fashion

You are being asked to be part of a research study. Please read the information about the study carefully before you agree to participate. Take as much time as you need to decide. You will read about the study purpose, procedures, benefits, risks, and precautions. You should ask the Principle Investigator to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form.

Participation in this study is voluntary. You have a right to refuse to participate. You may also stop participating in this study at any time. Your choice of participation will not impact on your relationship with your healthcare team or Ryerson University. In order to decide whether you wish to participate in this study, you should understand enough about the risks and benefits to be able to make an informed decision. This is known as the informed consent process. If you wish to participate, please sign at the end of this consent form. Otherwise, just return the form unsigned.

Background

Breast cancer affects approximately 230,000 women in North America each year (Canadian Breast Cancer Foundation, 2010; American Cancer Society, 2010). Surgery to followed by radiation and/or chemotherapy may cure the disease, but it also damages the lymphatic system (Kligman, Wong, Johnston & Laetsch, 2003; Morrell et al., 2005). Lymphedema is a chronic condition that afflicts 35% of women after mastectomy (Dorval et al., 1998); lymph drainage is disrupted, protein and excess fluid accumulate, causing swelling, most often in the arm and hand. The disfigurement caused by surgery and subsequent swelling from lymphedema frequently results in negative body image, decreased self-confidence and quality of life (Woods, 1995; Morgan, Franks and Moffat, 2005).

Functional apparel design prioritizes comfort and serviceability to meet the specific needs of women with mastectomies, while Universal Design aims for designs that are usable by people of all ages and abilities. Relatively little research has been done with post mastectomy sleepwear for women with lymphedema.

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Purpose

The purpose of this study is to determine the sleepwear needs and preferences of breast cancer survivors with lymphedema and to quantify the size difference between affected and unaffected arms in order to develop better fitting garments. This project aims to address the functional, aesthetic and emotional clothing needs of post-mastectomy women with lymphedema by conducting primary research in order to design specialized sleepwear following Universal Design principles.

Procedure

The first part of this study involves participation in a private researcher-participant interview. You will be asked to provide basic demographic information, answering questions like “age” and “marital status”. You will then be asked to discuss and give an opinion on your experience with purchasing and wearing sleepwear as it relates to your lymphedema. This interview will be audio-recorded and transcribed.

The second part of this study involves having your measurements taken using the body scanning technology at Ryerson University.



The [TC]² NX-16 body scanner is a curtained booth similar to a change room, equipped with cameras and light sources. Upon stepping inside, using white light photo technology, it quickly makes a 3D image that can be used for fit analysis and collection of body measurements. This is not an X-ray, there is no radiation. Three-dimensional visual images and numerical data are obtained from the scan using computer software. While the body scanner requires that you to be scanned wearing minimal clothing (i.e. only your undergarments), a private changing area will be provided and you will not be exposed in an undressed state to the researchers at any time.

We anticipate the interview and body scanning procedure to take approximately 90 minutes to complete.

The third part of the study will involve participation in a focus group to view and critique proposed sleepwear design sketches and fabric samples in order to provide feedback to the design team. The interviews, scanning procedure, and focus group will take place at Ryerson University, Kerr Hall, Room KHW 258 “MA Studio”.

Risks

The body scanner is manufactured by Technology/Clothing Corporation; it uses white light photo technology, similar to a flashing camera in a photo booth. The scanner takes multiple photos from different angles, gathering data by recording the measurement where the light bounces off the human body. This is not an X-ray, there is no radiation. The body scanner does create flickering light which may cause seizures in persons with

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photosensitive epilepsy. If you have photosensitive epilepsy, you may choose to participate only in the focus group activities in this study.

Participation in the interviews and focus groups has no known major risks for you. The interview and measurement process will take place in a private design studio at Ryerson University. We will protect the confidentiality of everything you tell us. However, being in this study may make you feel uncomfortable. Discussing your experiences with mastectomy and lymphedema may trigger feelings of sadness, fear or worry. If you feel uncomfortable, you do not need to finish completing the interview or participate in the body scanning procedure.

Benefits

Your contribution to this study will help us understand the challenges you face in finding sleepwear. The measurement data will help us develop a better fitting pattern block which may then be used to develop clothing patterns for women with mastectomies who have lymphedema. Our goal is to design comfortable sleepwear that breast cancer survivors will feel beautiful wearing.

Confidentiality

Quotations and excerpts from interviews and focus groups will be used and labeled with pseudonyms to protect the identity of the participants. Names of participants will not appear in the thesis, reports or conference presentations resulting from this study. Participants will not be identifiable, and only described by gender.

All information collected during this study, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

Representatives of the Ryerson University Ethics Board may look at the study records to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines. No information identifying you will be transferred beyond the investigators in this study, nor to your healthcare team. Paper-based data will be stored in a filing cabinet in a locked office and will only be accessible to members of the research team. This data will be stored for up to seven years and then it will be shredded.

Participation

Your participation in this study is voluntary. You have a choice to not participate in this study. You also have a choice to stop participating in this study at any time. You do not need to give a reason for this. Your choice of participation will not impact future relations with your healthcare team, Wellspring or Ryerson University. Please note that there will be no monetary compensation for taking part in this study.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Sandra Tullio-Pow by phone at 416-979-5000 ext. 6528 or by email at stullio@ryerson.ca

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If you have any questions about your rights as a research participant or have concerns about this study, call the Research Ethics Board (REB) office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

- I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study with the understanding I may withdraw at any time. I will receive a signed copy of this consent form. I voluntarily consent to participate in this study.

Study Subject's Name Signature Date
(Please Print)

- I agree to the audio-taping of the interview and focus group sessions. I understand that all documentation will be kept confidential and will be stored in a secure location and will only be used for review by the research team.

Study Subject's Name Signature Date
(Please Print)

- I agree to participate in the body scanning procedure at Ryerson University.

Study Subject's Name Signature Date
(Please Print)

- If sleepwear prototypes are developed, I would agree to be contacted to participate in field testing.

Signature Contact

Person Obtaining Consent Signature Date