Promoting the Psychological Health of Women With SCI: A Virtual World Intervention

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University of Texas Health Science Center at Houston/Memorial Hermann Healthcare System
INFORMED CONSENT FORM TO TAKE PART IN RESEARCH
Promoting the Psychological Health of Women with SCI: A Virtual World Intervention
HSC-MS-17-0474
Adult

INVITATION TO TAKE PART

Summary

You are invited to take part in a research study. The study will test a group program designed to enhance the psychological health of women with spinal cord injury (SCI). Participants will be randomized (like flipping a coin) to either the Zest program or a control group. If you are in the Zest program, you will create avatars to represent yourself and will participate in group sessions in the online virtual world of Second Life. The sessions (or meetings) will be held once a week, for 10 weeks, for 2 hours each time. If you are in the control group, you will receive program materials at the end of the study but will not participate in the weekly group sessions.

All participants will complete questionnaires online at three time points: right before the program starts, right after the program ends, and again at 6 months. Participants will receive a small payment for completing the online questionnaires.

There are no serious risks to taking part in this study other than potential minor discomfort from learning Second Life, answering survey questions about your psychological health, and sharing personal information with other women in the group. You may benefit by feeling good about being part of a research study that could lead to better well-being for women with SCI. If you are in the intervention group, you may learn new information about psychological health and gain new skills (such as communication, relaxation, and self-care skills) to help you make positive changes in your life. You also may benefit from the sharing with other women with similar life experiences. However, y You may not receive any specific benefit from taking part in this study.

If you are interested in learning more about this study, I will continue reading the information below.

Full Consent

You are invited to take part in a research project called, *Promoting the Psychological Health of Women with SCI: A Virtual World Intervention*, conducted by Dr. Susan Robinson-Whelen, of TIRR Memorial Hermann and the University of Texas Health Science Center at Houston (UTHealth). For this research project, she will be called the Principal Investigator or PI.

The purpose of this project is to test an internet-based psychological health promotion program for women with spinal cord injury (SCI). You may be selected to join a group of women with SCI to go through this program using the online virtual world of Second Life. This study will help us understand how this intervention may help women with SCI improve their psychological health.

Once a group of women has been enrolled in the study, you will be sent a link to an online survey, or questionnaire. The questionnaire will include questions about you (such as your years of education), your spinal cord injury (such as your

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age at injury), and other disability-related questions (such as your primary way of ambulating or getting around) and questions about your thoughts, feelings, and mood. After enough people have completed the survey or questionnaire, you will be randomized, like pulling names out a hat, and placed in one of two groups, either the intervention group or control group.

If you are assigned to the intervention group, you will need to learn to use Second Life. Second Life is an online 3D virtual world in which the psychological health program will be offered. You will be sent Second Life training documents electronically and will be offered Second Life training sessions. You will be contacted by either study staff or Erin Porcher, an outside consultant with whom we have contracted to provide SL training, to schedule these training sessions.

Once trained you will begin the 10 session psychological health program in Second Life. Each session occurs once a week for 2 hours, for a total of ten weeks. As part of the intervention group, you will be asked to complete a brief survey after each session to give us feedback and suggestions for improvement. After completing the 10 sessions you will be asked to complete a set of evaluation questions about the intervention, as well as the post-test, which will ask similar questions as the first questionnaire or survey. Finally, you will be asked to complete a final follow-up questionnaire 6 months after the intervention ends.

If you are assigned to the control group, you will be asked to complete the set of questions online at the beginning of the project, about 10 weeks later, and again at the 6 month follow-up. After you complete the 6-month questionnaire, you will be given a copy of all psychological health promotion intervention materials.

There are no serious risks to taking part in this study. If you are in the group that gets the program, your risks may include some minor stress from learning to use a new program on your computer. You could also have minor stress from sharing personal information with others in the group. Please keep in mind, however, that you will not have to share anything you are not comfortable sharing. You will be able to decide what and how much you share.

The information you share with study personnel will be held confidential “unless otherwise required by law” …such exceptions include plans to hurt yourself or others or reportable disclosures of abuse. We cannot guarantee that fellow group members will keep your information private and confidential. However, people in the group will know each other only by their avatar name. This means that other group members will not know your real name unless you tell them. Group discussions are held in a private location in Second Life. Only people invited by the study staff will have access to the private site. People in both groups may also have some minor stress or discomfort from answering personal questions as part of the questionnaires or surveys. People in the control group may feel disappointed in the group assignment. All control group participants will be given program materials after the 6-month follow-up.

You may not receive any specific benefit from taking part in this study. However, you may learn new information and gain more awareness about psychological health, particularly as it relates to women with SCI. You may also gain new skills in the areas of communication, relaxation, and self-care. You may also learn new skills to help you make positive changes in your life. If you are in the intervention group, you may also benefit from the sharing with other women with similar life experiences. Participants of both groups may also benefit by feeling good about being part of a research study that could lead to better well-being for women with SCI.

Your decision to take part is voluntary. You may refuse to take part or choose to stop taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you. You may refuse to answer any questions asked at any time.

The program being tested is free to participants. People in the study must have a computer that they can use, high speed internet access, an email account, and a phone to be in the study. There are no additional costs to be in the study. You will be paid a total of $100 after you complete your participation in this study ($25 after the pre-test, $25 after the post-test, and $50 after completing the 6-month follow-up).

This research project has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston as HSC-MS-17-0474.

If you have questions at any time about this research study, please feel free to contact the research office at 713-797-7572. You may also call Dr. Susan Robinson-Whelen at the number listed above or [redacted] after hours. Dr. Robinson-Whelen is in charge of the study.

You may change your mind and revoke (take back) this Authorization at any time. To revoke this Authorization, you must write to:

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CPHS STATEMENT: This study (HSC-MS-17-0474) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at (713) 500-7943.