Living Well: A Web Based Program to Improve Quality of Life in Rural and Urban Ovarian Cancer Survivors

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Informed Consent 10/10/2020

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INFORMED CONSENT DOCUMENT

Project Title: **Living Well: A Web-Based Program to Improve Quality of Life in Rural and Urban Ovarian Cancer Survivors**

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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have completed treatment for ovarian cancer within the last 3 years. The purpose of this research study is to compare the effectiveness of two different kinds of intervention programs specifically designed for ovarian cancer survivors to help improve quality of life and well-being, and to decrease distress. The programs will be delivered in a group format using web-conferencing, and participants can access the programs from their homes. We will compare the effects of a stress management and coping program (Mindful Living) with a program promoting healthy lifestyles (Healthy Lifestyles) on quality of life, distress, and well-being. The significance of this research is that we hope it will provide information and effective tools for ovarian cancer survivors to improve quality of life and well-being. Other goals are to increase connectedness and decrease isolation among ovarian cancer survivors.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 100 ovarian cancer survivors will take part in this study conducted by investigators at the University of Iowa. This is a multi-site study, and overall, approximately 300 women will take part in this study nationwide.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 12 months. There will be an introductory phone call (15-30 minutes), a brief practice on use of the study website and web conferencing (15-30 minutes), an orientation session, 10 weekly group sessions, and 2 follow-up group sessions. Each group session will last approximately 1.5 to 2 hours. All sessions will take place in your home or another secure location using web-based conferencing. You will also be asked to complete surveys before and after the 10-week program, and at 6 months and 12 months following the program. Surveys will take approximately 30-45 minutes to complete.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate in this study, you will be randomly assigned to receive either the Mindful living or Healthy Lifestyles study programs. This means that whichever study intervention you receive will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving either of the study intervention programs.

For both programs, your involvement will include

- an introductory phone call to make sure you can operate the web site on the tablet or on your home computer and a follow-up practice with the study website and web conferencing.
- an orientation session to make sure you can connect to the group by web
- group meetings by web for 10 weeks that will take approximately 1½ to 2 hours per week.
- Follow-up group sessions approximately 4.5 months and 9 months after the start of the program (approximately 1-1½ hours)
- Completing surveys on mood, quality of life, coping, and health behaviors before and after the 10-week program, and at 6 months and 12 months after the start of the program.

The *Mindful Living* sessions will involve topics such as coping with ovarian cancer, stress management, maximizing support from friends and family, living with an ovarian cancer diagnosis, relaxation and meditation techniques, spirituality, and imagery.

The *Healthy Lifestyles* sessions will include topics such as exercise, sleep, nutrition, cognitive function, stress management, and survivorship.

If you don't have a laptop or tablet with a camera, we will send you a tablet or webcam by FedEx or UPS. If you do not have internet access at home, we can send you a tablet with internet connectivity. We will also send you a manual with instructions for website use and a workbook for your group. We will give you instructions on how to access the study website, the web conferencing system, and instructions on how to complete questionnaires and play relaxation recordings.

You will have at least one individual practice session with a member of the research team to make sure you feel comfortable using web-conferencing.

Before the program starts, we will schedule a group orientation session so that you can meet the other people in the group and learn exactly what the program will involve. We will schedule the groups to try to be convenient for participant schedules.

In the *Mindful Living* program, in addition to the web sessions, you will be requested to practice the relaxation and meditation techniques that you learn in the program and to keep a short daily record of meaningful moments.

If we send you a tablet or webcam, you will need to return the tablet or webcam to the research team at the University of Iowa by pre-paid FedEx or UPS when the program is finished. If you have an iPad, laptop, or tablet at home, you may be able to use your own device. As with any research, you are free to not answer any questions you would prefer not to answer. By participating in this study, you agree to not download study videos and share them outside the study.

As part of this study, the study team will also be reviewing your medical/survivorship status in the future. This may include contacting you directly, contacting your oncology provider(s) or using publicly available search engines (if we cannot reach you or your oncologist).

Study Timepoints

Activity		ENROLLMENT	Pre-Group	RANDOMIZATION	Week 0	Weeks 1-11	Week 12 (Post)	4.5 mo	6 mo F/U	9-10 mo	12 mo F/U
Screening	X										
Surveys			X				X		X		X
Technical Training			X		X						
Intervention											
						Group orientation & 10 sessions		Follow-up Group session		Follow-up group session	

HIPAA INFORMATION **(See also the WILL MY HEALTH INFORMATION BE USED section):**
We would like to contact your gynecologic oncologist or oncology provider for medical records to verify specific medical information. The information we will request from your oncology provider(s) will include your initial diagnostic and surgical report, pathology report, medical and surgical history, and clinic notes. This consent authorizes us to contact your oncology provider(s) for your medical records. Information from your current medical record, (e.g. your diagnosis, cancer stage, treatment, height, weight, medical history) may be used as part of the study. We may also contact your oncology provider(s) periodically, in the future, to follow up on your medical/survival status (as explained in the previous paragraph). Current and past mental health diagnoses are used as part of the screening for the study but following screening, this information is not used as part of the study. Information from the study other than your participation in the study will not be added to your medical record.

Audiovisual Recording
One aspect of this study involves making audiovisual recordings of the ZOOM group sessions. These are made to evaluate whether the program facilitators are including all the material they need to include. Only members of the study team will have access to these recordings. These recordings will be used while the study is being actively conducted and data is being analyzed after which they will be destroyed.

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over without further consent. Your data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to the purpose of this study.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding ovarian cancer, but it is unlikely that what we learn from these studies will have a direct benefit to you. Your data will not be

used for commercial purposes.

Your data will be stored *with a code which may be linked to* your name. If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact Dr. Susan Lutgendorf, 319-335-2432 or susan-lutgendorf@uiowa.edu. However, if some research with your data has already been completed, the information from that research may still be used.

My data may be stored/shared for future research for any other purpose.

____ Yes ____ No

WILL I BE NOTIFIED IF MY DATA RESULT(S) IN AN UNEXPECTED FINDING?

The results from the data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The data results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. Potential risks of the study include the possibility that you may be uncomfortable answering specific questions on surveys; you may experience minor discomfort from discussing potentially distressing topics in the group, and there is a potential loss of confidentiality from using web conferencing with other cancer survivors. These risks will be minimized by the following procedures: all group members will be instructed on procedures to protect confidentiality at the beginning of the group sessions; you are free to not answer specific questions on study surveys, and you can choose how much information you share about yourself in group discussions.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. Possible benefits include developing skills that will help reduce distress, improve health behaviors, and well-being. We also hope that, in the future, other ovarian cancer survivors might benefit from the interventions being evaluated in this study.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, you may discuss with your doctor other options that are available to you. Instead of being in this study, you could participate in other online stress management or lifestyle studies or programs.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The National Cancer Institute (National Institutes of Health) is funding this research study. This means that the University of Iowa is receiving payments from the National Cancer Institute to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Cancer Institute for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies
- the National Institutes of Health
- auditing departments of the University of Iowa
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will use the following procedures:

- In the orientation session, all participants will be instructed about the importance of confidentiality. Participants will be required to access the web-based intervention in a private location where others could not overhear the group conversation. Additionally, participants can choose to disclose as much or as little personal information as they feel comfortable with in the group session.

To help protect your confidentiality, we will identify your answers to surveys only by code numbers and this information will be kept in a locked file or password protected computer and will not be available to anyone who is not connected with the study. Research data stored electronically is on a password protected server that can only be accessed by approved members of the research team. Study sessions will be conducted via the University of Iowa's Zoom application and although it is not HIPPA compliant, all parties involved will be instructed that information shared needs to remain confidential as noted above. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Certificate of Confidentiality

To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the federal government. This certificate means the researchers cannot be required to tell people who are not connected with the study, including the courts, about your participation, without your written consent. Unless you give permission, the study team can only disclose information about you if you or someone else is in serious danger of harm.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research

team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. A copy of the informed consent document will be available on this website. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your study treatment**.** Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and colleagues at other institutions who are involved in this study.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Susan Lutgendorf, G60 Psychological and Brain Sciences Building, University of Iowa, Iowa City, IA, 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, you are free to do so. We will ask you to let us know that you are leaving the study and to return any study equipment (tablet, webcam, headphones) if you have them. We will also ask you to complete the remaining study surveys if you are willing to do so.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers or NIH might decide to end your participation in this research study earlier than planned. This might happen because the study funding ends.

PARTICIPATION IN FUTURE STUDIES

We would like to be able to contact you for participation in research in the future for follow-up purposes. To do this we will keep your name, phone number, record of your study participation, and information about your diagnosis. Agreeing to be in the current study does not obligate you to participate in a future study and a separate Consent Document would be signed for future studies. You can also consent to be part of this study but decline to be contacted for future studies.

If you are willing to be contacted for future studies please initial here._ _____

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact the Living Well Study at 319-467-0190 or living-well-study@uiowa.edu. If you experience a research-related injury, please contact: Dr. Lutgendorf at 319-335-2432 or the Study coordinator Alyssa Noble at 319-467-0626**.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____

(Signature of Subject) (Date)

Check the method by which consent is being obtained:

□ Consent is being obtained by mail without a discussion between a research team member and the subject. (Research team member does not sign this document)

□ Consent is being obtained in person or by mail or electronically after a discussion between a research team member and the subject. (Research team member signs below.)

Statement of Person Who Obtained Consent

(This line is only to be signed by a research team member after discussion with subject.)

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person Who Obtained Consent) (Date)