RUTGERS
Cancer Institute
of New Jersey
RUTGERS HEALTH

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681

cinj.org
p. 732-235-2465

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: JourneyAhead: Enhancing Coping and Communication for Women Diagnosed with Gynecological Cancer
Principal Investigator: Sharon Manne, Ph.D.

STUDY SUMMARY: This consent form is part of an informed consent process for a research study. It will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to determine how impactful a new online and virtual coaching program called JourneyAhead is. We hope that going through the session content will benefit you while you are going through your cancer experience and treatment.

The online program has two parts:

1. You will review eight online sessions covering coping with cancer, managing cancer-related stress, getting your support needs met by family and friends, dealing with the medical team, working on accepting challenging emotions, and coping with worries about the future.

2. You will have five 30-45 minute virtual coaching calls with the counselor to review the content and discuss the material with you.

If you take part in this study, you will be asked to:

- Review a consent form and complete a survey.
- Log in to the *JourneyAhead* intervention site and review the content of the 8 sessions. The sessions will be delivered a few days apart so you will not view all 8 at one time. The viewing of the intervention sessions will take place in your own home.
- After sessions 2, 4, 6, 8, and approximately four weeks after session 8 you will be asked to attend a 30-45 minute virtual coaching check-in with the counselor. The goal of the calls is to troubleshoot any problems with learning the coping skills and reviewing important session content.
- After the sessions end, you will be asked to complete a second survey which includes feedback on the session content and virtual coaching.
- After the sessions end you will be asked if you want to participate in a recorded phone or Webex interview with a study staff member to discuss your experience with the program.
- Six months after the first survey, you will be asked to complete a third and final survey.

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681

cinj.org
p. 732-235-2465

Your time in the study will take about 6-7 months. Each survey will take you about 30-45 minutes to complete. Viewing the JourneyAhead intervention sessions will take about 30 minutes and the 5 virtual coaching sessions after Sessions 2,4,6,8 follow up session will take about 30-45 minutes and the phone interview will take approximately 30 to 45 minutes.

Possible harms or burdens of taking part in the study may be:

- Feeling upset by a survey question.
- Feeling upset by looking at information about cancer in the interventions.

Possible benefits of taking part may be:

- Learning information about how to cope with your cancer diagnosis and treatment.

An alternative to taking part in the research study Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study. It will tell you what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them. You should expect to be given answers you completely understand.

After your questions have been answered and you wish to take part in the research study, you will be asked to acknowledge this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by acknowledging this consent form.

Who is conducting this research study and what is it about?

Dr. Sharon Manne is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Sharon Manne may be reached at 732-235-6759. Her mailing address is

Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08901

You will be able to download a copy of the electronic consent form to keep.

Why is this study being done?

The purpose of this study determine how impactful a new online and virtual coaching program called JourneyAhead is. We hope that going through the session content will benefit you while you are going through your cancer experience and treatment.

Who may take part in this study and who may not?

People who meet the following may take part in this study:

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681
cinj.org
p. 732-235-2465

a) Diagnosed with any stage of primary ovarian cancer, primary peritoneal cancer, or primary fallopian tube cancer or experienced a recurrence in the past 5 years;
b) Diagnosed with High Grade Stage 2, any grade Stage 3 or higher endometrial cancer or experienced a recurrence in the past 5 years;
c) Diagnosed with Stage 2 or higher cervical cancer or experienced a recurrence within the past 5 years
d) Diagnosed with any stage Uterine Cancer (both Sarcoma and carcinosarcoma) or experienced a recurrence in the past 5 years;
e) At the time of recruitment the patient has received chemotherapy or radiation in the past 5 years, or is less than 5 years post-cancer surgery;
f) At the time of recruitment, a Karnofsky Performance Status of 80 or above or an Eastern Cooperative Oncology Group (ECOG) (80) score of 0 or 1;
g) 18 years of age or older;
h) English speaking;
i) Has internet access; Able to view the online intervention sessions and attend telephone or video/telehealth chats to discuss the session content and provide feedback.
j) Must give informed consent within 5 years of diagnosis.

Children are not included because the incidence of these cancers in children is rare.

Why have I been asked to take part in this study?
You have been invited to take part in this study because you have been diagnosed with gynecologic cancer.

How long will the study take and how many subjects will take part?
We expect your participation in the study to last approximately 6-7 months because it will take time to get through all 8 sessions, the virtual coaching sessions and complete the follow-up survey. We expect to recruit participants over the course of about 6-8 months.

You will be one of approximately 50 participants in this study. Study staff may contact you via email, mail or phone to discuss the study.

What will I be asked to do if I take part in this study?

The online study has two parts:

1. You will review eight online sessions covering coping with cancer, managing cancer-related stress, getting your support needs met by family and friends, dealing with the medical team, working on accepting challenging emotions, and coping with worries about the future.

2. You will have five 30-45 minute virtual coaching calls with the counselor to review the content and discuss the material with you.

If you take part in this study, you will be asked to:

- Review a consent form and complete a survey.

- Log in to the *JourneyAhead* intervention site and review the content of the 8 sessions. The sessions will be delivered a few days apart so you will not view all 8 at one time. The viewing of the intervention sessions will take place in your own home.

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681
cinj.org
p. 732-235-2465

- After sessions 2, 4, 6, 8 and approximately four weeks after session 8 you will be asked to attend a 30-45 minute virtual coaching check-in with the counselor. The goal of the calls is to troubleshoot any problems with learning the coping skills and reviewing important session content.

- After the sessions end, you will be asked to complete a second survey which includes feedback on the session content and virtual coaching.

- After the sessions end you will be asked if you want to participate in a recorded phone or Webex interview with a study staff member to discuss your experience with the program.

- Six months after the first survey, you will be asked to complete a third and final survey.

We will audio and video record your participation in this study during the interview at the end of the intervention with your permission. You do not have to consent to be audio or video recorded in order to take part in the main research. The recordings will be used to analyze your feedback regarding the intervention and will only be seen by the research team. The recordings may include the following information that can identify you: your face, your voice, any personal information you choose to disclose while being recorded, and the username you use on the Webex program.

What are the risks of harm or discomforts I might experience if I take part in this study?
It is not expected that you will experience any risks or discomforts from taking part in this study. However, potential risks are 1) breach of confidentiality and 2) emotional distress that might come with being asked questions or reading information related to your cancer diagnosis. If you feel uncomfortable with a question, you can skip the question or withdraw from the study altogether. This risk is rare.

If you feel any distress during participation, please let the study team know. An investigator who is trained in psychology and works with cancer patients can give you information about sources of professional help.

As with all research that collects protected health information, there is a risk of breach of confidentiality. This risk is rare.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be:
Learning information about how to cope with your cancer diagnosis and treatment.

However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

There are no alternatives available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681

cinj.org
p. 732-235-2465

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Will there be any cost to me to take Part in this study?

There will be no cost to you to take part in this study.

Will I be paid to take part in this study?

You will receive $ 155 in Amazon e-gift cards for taking part in this study according to the following schedule:
$ 25.00 e-gift card for completing the first survey.
$ 25.00 e-gift card for completing the second survey.
$ 25.00 e-gift card for completing the third survey.
$50.00 e-gift card for participating in the phone interview.
$10.00 e-gift card for each session you view (total of 8 sessions) for a total of $$205 for your participation if you complete all study tasks.

We will not provide any compensation for attending the Phone or video chat (WebEx, FaceTime, Zoom) check-in with the counselor

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

You will be assigned a unique study ID number. All records that contain your name, telephone number, email address or other information that could identify you are kept separate from the survey forms and medical record information. Rutgers Cancer Institute of New Jersey uses username/password security measures to restrict access to only those study team members who are authorized.

We will know your IP address when you respond to the Internet survey. The researchers will see your individual survey responses and the results. These downloaded data will be labeled with participant numbers only. All data on servers are password-protected and limited to authorized research personnel.

We believe that these procedures will be effective in protecting against and minimizing potential risks.

The audio and video recording of your post-program interview will be transcribed and will be used for analysis by the research team. The recording(s) will include your study assigned ID # but not your name. Electronic copies of the recording(s) will be stored on secure servers at Rutgers Cancer Institute of New Jersey. Any hard copy back-ups of audio recordings will be stored in a locked file cabinet and labeled with your study assigned subject ID # on the 5th floor of Rutgers Cancer Institute of New Jersey in the Population Science Department. Any transmission of the audio recordings of the interviews between team members at other participating institutions will be sent via an encrypted email or encrypted hard drive. The audio recording will be retained indefinitely.

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681
cinj.org
p. 732-235-2465

The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

What will happen to my information collected for this research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to: Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08901

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Sharon Manne, Population Sciences department, 732-235-6759.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway HealthSci IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806 or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you acknowledge this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?
Radiology records or images (MRI, CT, PET scans)
Medical history or treatment
Laboratory/diagnostic tests or imaging
Pathology reports, specimen(s) or slide(s)
Operative reports (about a surgery)

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681
cinj.org
p. 732-235-2465

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:
Rutgers University Investigators Involved In the Study
The Rutgers University Institutional Review Board and Compliance Boards
The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
Non-Rutgers investigators on the study team:
Radiant, the Web Development Company who manages the JourneyAhead site
Qualtrics, survey software company

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:
Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08901

How Long Will My Permission Last?
Your permission for the use and sharing of your health information will last until the end of the study. The Rutgers Cancer Institute of New Jersey study team will destroy your identifiable information after study completion.

If you do not wish to take part in the research, close this website address.

If you wish take part in the research, follow the directions below:

Please acknowledge that you have read through this consent form and agree to participate in this study by clicking yes below which will take you to the survey.

If you do not wish to participate, click no and this form will close.

Click on the link that will take you to the [survey or questionnaire.] add LINK here.

Yes No

Rutgers, The State University of New Jersey
195 Little Albany Street
New Brunswick, NJ 08903-2681

cinj.org
p. 732-235-2465

Consent for Audio and Video Recording

Please click 'YES' or 'NO' below to indicate if you agree to the audio and video taping of your post-program invterview You can still participate in the rest of the study without consenting to being recorded

Yes No