UMCC 2018.130 NCT03763838

Acupressure for Fatigue in Ovarian Cancer Survivors

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Acupressure for Fatigue in Ovarian Cancer Survivors

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Suzanna M. Zick, ND, MPH, Department of Family Medicine, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to compare acupressure plus normal care, fake (sham) acupressure plus normal care, and normal care alone that you would receive from your health care provider. Acupressure involves applying mild to moderate physical pressure by fingers, hand or a device to specific points on the skin to try to bring about a physiological change in your body, in this case relief from chronic fatigue.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

In order to take part in this study, you must be an adult woman 21 years of age or older with a diagnosis of ovarian cancer, demonstrate feelings of fatigue that started after cancer diagnosis, have initiated cancer treatment (including any maintenance therapies) at least three weeks ago with no progression of disease, and take nothing more than regular medicine for fatigue and plan to take nothing more for fatigue during the course of the study.

You ***cannot*** participate in the study ***if*** you have an untreated mood disorder like bipolar or major depression, have any untreated hypothyroidism, have received acupuncture or acupressure in the last year, have anemia, or have the possibility of becoming pregnant.

3.2 How many people are expected to take part in this study?

Around 150-165 patients will take part in this study (we aim to enroll 50 evaluable participants in each arm).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Once we receive your permission to contact you, we will give you a call to determine your eligibility to be included in the study. If we decide you cannot participate, then you will be done with the study. If you are found eligible, we will ask for your consent to be in the study. Once we have received that consent we will randomize you into one of three groups, one of which will be true acupressure plus usual care, one which will be fake acupressure plus usual care, and one which will be just usual care only. Random means by chance, like rolling dice. You will have a one in three (or 33%) chance of being placed in each group. The usual care group will be the "standard of care" group, which means you will continue to do whatever your health care provider suggests for fatigue management. We will send you a computer tablet with instructions for how to perform acupressure on yourself and an AcuWand with which to do the acupressure (if you are in one of the treatment group). If you are placed in the usual care group you will have the option of receiving the acupressure mobile app on a tablet, and AcuWand pressure device after the completion of the study – yours to keep.

For some research studies, such as the one you are being asked to join, it is important that you do not learn the results of certain tests. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study.

In each of the acupressure groups, you will be given a computer tablet with an app downloaded onto it that will teach you how to perform the acupressure. You will also be offered a tool (AcuWand) which will help you apply the right amount of pressure on the appropriate points on your body.

As a part of this study, you will be asked to answer phone calls or emails, and (if placed in one of the acupressure groups) to perform acupressure daily. Below is an explanation of what will happen at each stage, no matter which group you are placed in.

SCREENING PHASE 1 (one week):

- Discuss interest, eligibility criteria, and study expectations.
- Give informed consent.
- Random assignment to treatment group.
- If you do not have e-mail already, we will help you set up a free e-mail account and let you know how to access wi-fi in the community.

TREATMENT PHASE 2 (six weeks):

- If placed in one of the acupressure groups, you will receive a computer tablet with an app pre-loaded as well as an AcuWand device with which to perform the acupressure. You will watch and use the acupressure app to learn how and when to apply self-acupressure.
- Perform daily acupressure (if in acupressure group).
- We will check in on you every other week by phone or e-mail to make sure all is going well.

- Complete several questionnaires about socio-demographics, other illness you may have, fatigue, general mental health, and your cancer diagnosis, at the end of this period (week 6).
- One of our study team will contact you via Skype to make sure you are doing your acupressure correctly.
- If you are in the treatment group, you will be asked to return the AcuWand in its box with label provided, so that download of your data can be achieved; we will send the AcuWand to you after that for you to keep.

CARRY-OVER PHASE 3: (18 weeks)

- At weeks 12 and 24 of the study we will again ask you to complete the questionnaires as before.
- At week 24, we will ask to complete a short questionnaire evaluating your participation in the study.

After Study Completion

- You will receive a letter letting you know which group you were randomized into and asking if you would like a copy of the study results when they are published.
- The letter will also ask you if you would like to receive the true acupressure app if you were assigned to the sham acupressure group or the usual care group.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your medical information for future research.

If you give us your permission, we will use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your information, we may not be able to take the information out of our research.

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

You will not find out the results of future research. Allowing us to do future research on your medical information will not benefit you directly.

4.2 How much of my time will be needed to take part in this study?
You will be in the study for up to 25 weeks (about 6 months), and will be asked to participate by filling out questionnaires at the beginning of the study and at 6, 12 and 24 weeks after the beginning of the study. Each session of questionnaires is expected to last about 30 minutes. You will be asked (if in one of the acupressure groups) to do acupressure once per day for 6 weeks after the beginning of the study. The acupressure takes about 30 minutes a day to complete.

4.3 When will my participation in the study be over?

Your participation in the study will be over after the week 24 session. This will be about 25 weeks from the initial screening visit.

4.4 What will happen with my information used in this study?
Your collected information may be shared with Ovarian Cancer Research Program administered by the United Stated Department of Defense.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and, after such removal, used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:

- Risk of bruising at points of pressure; there is a very small chance (<1%) of having bruises at points of pressure if you apply too much pressure. This bruising should not continue or get worse. The researchers will try to minimize the risk of bruising by having the acupressure app demonstrate the correct amount of pressure to apply at the start of the study. Additionally, a member of the research team will call you at certain times during the study to evaluate your health and safety. During these conversations we will ask you about any bruising.

- The AcuWand is not FDA approved, nor are we seeking FDA approval for its use. We do not anticipate any problems with the device which would cause injury or harm in any way.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, it is possible that the acupressure treatments could reduce the severity of fatigue you are experiencing. We hope the information learned from this study will benefit other ovarian cancer patients.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

If you chose not to participate in the study you may ask your health care provider if other treatment options, such as over-the-counter (OTC) medications, are options for treating your fatigue. You may also visit www.clinicaltrials.gov to learn of other studies involving fatigue.

You may also wish to pursue acupuncture or acupressure by a licensed practitioner to treat your fatigue if you decide not to participate in this research study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

Your participation is completely voluntary and will not affect your medical treatment now or in the future. You may drop out of the study at any time, after agreeing to become a subject. There is no anticipated harm from stopping the study at any time.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
No. You will not be paid for taking part in this study. You will receive a computer tablet, the acupressure mobile app and the AcuWand device used to perform acupressure for free.

8.3 Who could profit or financially benefit from the study results?
Drs. Zick and Harris, investigators on this study, created the acupressure mobile app. They and the University could benefit financially if the results of this study leads to sales of the acupressure app. Arbor Medical Innovations makes the AcuWand used in this study. If the study leads to more sales of the AcuWand in the future, the company and the University could benefit."

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record. Also, research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. All electronic records will be kept in a password-protected database accessible only to study team members.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

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

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study

- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies; for example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan

- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Suzanna M. Zick, ND, MPH
Department of Family Medicine
Michigan Integrative Medicine

Mailing Address: 1018 Fuller St.
Ann Arbor, MI 48104

Telephone: (855) 504-0120

Study Coordinators: Stephanie Kozar

Mailing Address: 1018 Fuller St.
Ann Arbor, MI 48104

Telephone: (855) 504-0120
Study E-mail: fammed-szickstudy@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

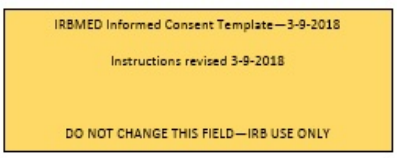
If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:



- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Instruction Sheet included with your computer tablet and AcuWand

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____ of the Zick Study Team. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Use Data From This Study for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my information. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my information for future research.

_____ No, I do not agree to let the study team keep my information for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

PERMISSION TO CONTACT FOR FUTURE STUDIES

Please indicate below if you would like to be contacted by a member of the study team for participation in future studies.

☐ Yes, I would like to be contacted regarding future studies.

☐ No, I would not like to be contacted regarding future studies.

Name (print legal name) _____

Signature of Subject _____

Date of Signature _____

USE OF MOBILE TEXT MESSAGING FOR STUDY-RELATED PURPOSES

Mobile text messaging is not a secure transmission medium. No private information will be sent via text message, but your phone number and the content of the message may be seen by parties outside of the University/study.

You may, at any point, opt out of text messaging by notifying the study coordinator listed above in **section 10.1.**

_____ I consent to the use of text messaging
_____ I do **NOT** consent to the use of text messaging