Official Title	A randomized controlled trial testing the effects of an acupressure intervention on appetite and weight in patients with gastric, esophageal, and pancreatic cancer: a pilot and feasibility study
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Fred Hutchinson Cancer Center

Consent to take part in a research study

Acupressure as a Complementary Therapy for Anorexia in Cancer (the ACT Study)

Principal Investigator: Blake Langley, ND, MS, LAc. Fred Hutchinson Cancer Center. Office: 206-667-3481; mobile: 206-552-0257

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to understand ways to support people with gastric, esophageal, and pancreatic cancer receiving systemic treatments who have low appetite.

If you agree to join this study, you will be asked to complete online questionnaires regarding your symptoms, present to 4 in-person office visits scheduled alongside your regularly scheduled care, apply 4 treatments at home as instructed, keep a record of your activities for the study, and have your body weight measured and blood drawn two (2) times alongside your regularly scheduled care.

This study involves adhering a small bead to specific points on your ear each week and massaging each of these points for 3 minutes every day for 5 days. This study will last for 8 weeks.

We do not know if being in this study will help participants. The study procedures could cause side effects such as local skin irritation or disomfort, as described below in this form.

You do not have to join this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing this study to understand how to create an effective education program for providers and patients to safely and accurately apply ear seeds for managing low appetite. We want to know how ear seeds may support appetite, and symptoms that affect appetite, in patients with gastric, esophageal, and pancreatic cancer.

Since you have stage II-IV gastric, esophageal, or pancreatic cancer and are receiving systemic treatment such as chemotherapy, we would like to ask you to join this research study. We will enroll up to 66 people. While we do not know if this intervention will benefit the appetite, body weight, or other symptoms of participants in this study, we hope the information we learn will help to develop an optimal training and treatment program for people with low appetite due to cancer and its treatment in the future.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

What research tests and procedures are part of this study? / What will happen in this study?

If you decide to join this study, we will do these tests and procedures:

- **Appetite Questionnaires.** These surveys will collect information on appetite and symptoms you may or may not be experiencing that can happen in addition to changes in appetite, including quality of life. This survey has 39 questions and takes 10-15 minutes to complete. You may complete this survey online or over the phone with study staff. The survey may ask questions that are uncomfortable and you may choose to not answer these questions.
- **Pre-Treatment Questionnaire.** This questionnaire has 5 questions and will collect information on what you expect during this trial. This takes less than 5 minutes to complete.
- **Post-Treatment Questionnaire.** The pre-treatment questionnaire will be repeated after your participation in the trial. In addition, a 15-item questionnaire will assess your experience in the trial and takes on average 10 minutes to complete.
- **Blood Draw.** We will assess samples from your blood taken alongside your regular clinical blood draw twice during the trial: one (1) time at the first office visit and one (1) time at the end of the trial after 8 weeks.
- **Body Weight.** We will assess your body weight twice during the trial: one (1) time at the first office visit and one (1) time at the end of the trial after 8 weeks.

After completing the data collection mentioned above, you will be randomized (sorted) into one of two study groups and we will do these procedures:

<u>Waitlist Control Group</u>

- **Standard Care.** We will continue to follow up with you by phone or in-office at your request to ensure you wish to remain in the trial. After 8 weeks during which you are able to continue to receive regular care as directed by your clinician, you will qualify for the same training program and ear seed application regimen described below.

<u>Ear Seed Group</u>

- **In-Clinic Ear Seed Application.** We will apply small, non-latex adhesive patches with an ear seed to 4-6 specific points on each ear. This treatment will be modified according to symptoms you may or may not be experiencing, and may be changed at each visit. The points will be cleaned before placing the adhesive patch and seed. There will be 4 of these visits and each visit will take an estimated 20-30 minutes scheduled alongside your regular office visits at the South Lake Union Campus. The ear seeds will be removed after 5 days.
- **At-Home Ear Seed Application.** We will provide the supplies, training videos, and pamphlets for you to apply new small, non-latex adhesive patches with an ear seed to 4 specific points on each ear. This will happen 2 days after removal of the ear seeds from the previous in-clinic application. This treatment will be the same points for each at-home application. There will be 4 of these applications and we will help correct any incorrect seed placements at your next in-clinic appointment. The ear seeds will be removed after 5 days or at least 2 days before your next in-clinic appointment, whichever is sooner.
- **Ear Seed Photos.** The provider will take a photograph of each ear after ear seed application at your first and third in-office visit. We will ask you to take a photograph of each ear after ear seed application at your first and third at-home application. These photos will be stored on a secured platform and no photos will be stored on any device by study personnel.
- **Acupressure Application and Electronic Diary.** We will ask you to gentle massage each ear seed for 3 minutes, 3 times each day. This may take up 36 minutes each day if ear seeds are massaged on both sides at the same time. We will provide an electronic diary for you to record the self-massage of each acupressure session during the 5-day window after application

How long will I be in this study?

We think you will be in this study for/until about 8-16 weeks. The total time includes 8 weeks of ear seed applications. This will followed by an optional 8-week follow-up questionnaire if you received the treatment group or followed by the same 8-week intervention if you were in the waitlist control group.

The study doctor or your doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest to drop out.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

If you are thinking about dropping out of this study, please let us know.

If you leave the study, your test results and information cannot be removed from the study records.

Risks of being in this study

- **Survey Questionnaires.** You may feel uncomfortable, embarrassed, or self-conscious about answering the study questions. The study staff's questions are to better assist patients and survivors of gastric, esophageal, and pancreatic cancer in the future. You do not have to answer any part of the questionnaires or other assessments; you may ask to skip questions that may make you feel uncomfortable.
- **Loss of confidentiality.** A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We will take measures to try to protect your information, but we can't guarantee privacy. Study staff will also discuss how information will be kept confidential.
- **Discomfort.** There may be some local discomfort, bruising, or bleeding associated with the blood draw. Additionally, ear seeds may cause discomfort during self-massage. We will discuss the appropriate intensity to reduce the likelihood you will experience discomfort from ear seeds.
- **Local skin irritation.** Local irritation may occur due to ear seed adhesive patches or the ear seed pressure. This risk is reduced as we will use non-latex adhesive patches and discussing the recommendations above to reduce discomfort.
- **Weight loss.** The major risks associated with low appetite in cancer is weight loss. We do not know if this treatment will prevent weight loss. This risk will be reduced as you will be able to continue receiving appropriate care as guided by your provider.

What are the benefits?

We do not know if this study will benefit participants. We hope the information we learn will help people with low appetite during cancer treatments in the future. Although the study may not benefit participants directly, we hope the information we learn will improve our understanding of ways to support people experiencing low appetite while receiving systemic treatments for cancer.

You have other choices besides this study.

You do not have to join this study. You are free to say yes or no. Your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

Your other choices may include:

- Another research study.
- Standard nutrition interventions to prevent weight loss.
- Seeking ear seeds or other acupuncture therapy from a Fred Hutch or outside provider.

- No ear seeds or other acupuncture therapy.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

If you decide to join this study, some people or organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- National Center for Complementary and Integrative Health and National Center for Advancing Translational Sciences (the sponsor of the study) and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Center, University of Washington, and Seattle Children's.

We will do our best to keep the personal information in your medical record confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. 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.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study doctor if you have questions about this.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if they believe that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Will you pay me to be in this study?

We will pay you $30 after you complete the baseline study visit, $40 after you complete the third in-clinic visit, and $50 after you complete the final visit. This amounts up to a potential $120 for your partiicpation in this study.

How much will this study cost me?

There are no extra costs for being in this study. You may continue to receive standard clinical care deemed appropriate by your provider and your insurer will be billed for this care.

What if I get sick or hurt after I join this study?

For a life threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Blake Langley at 206-667-3481 (office) or at 206-552-0257 (mobile). He and/or a member of the study team will refer you for appropriate evaluation and treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

Other information.

After about 10 years, your personal information in the database will be destroyed. However, if you choose to donate your samples for future research (see below), your samples and research record will be stored indefinitely.

If you have questions or complaints about this study, please call Dr. Blake Langley at 206-667-3481. If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email irodirector@fredhutch.org.

Your rights

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-667-3481 (office) or 206-552-0257 (mobile) – Dr. Blake Langley
If you get sick or hurt in this study	206-667-3481 (office) or 206-552-0257 (mobile) – Dr. Blake Langley
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)
Your bills and health insurance coverage	(206) 606-6226 – Patient Financial Services, Fred Hutchinson Cancer Center

Emergency number (24 hours): 206-552-0257

What will my information and/or samples be used for?

Your information and tissue samples (such as blood) will be used for the purposes of this study. The application of ear seeds will be tracked to develop and optimize future programs that teach patients how to apply ear seeds on their own.

Your blood samples might help researchers better understand how low appetite occurs in cancer and may change after 8 weeks. This research could be used by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

Will my information and/or tissue samples ever be use for future research?

After we do tests on your blood samples in this study, some sample may be left over. We would like you to donate this leftover sample for future research. This may include genetic research. We also would like to use your information for future research. You do not have to donate your samples or information for future research. You are free to say yes or no. Your regular medical care will not change if you say no.

If you say "no," your samples and information (even if made anonymous) will not be used in future research.

If we want to use your samples and information for other research or share it with other scientists for research, an ethics review committee (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

Your donated samples and information will be stored in a secure location. It will be used for research only. This research may be done by for-profit companies. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. They will not affect your care.

Research on your tissue and information may help develop new products. If these products make money, there is no plan to share the money with you.

If you donate your tissue and information for research, you can change your mind anytime. Just call Dr. Blake Langley at 206-667-3481 and tell us you do not want us to use your samples. There is no penalty for changing your mind. Your regular medical care will not change. However, if you do change your mind, we cannot return donated samples to you or your doctor. We may be able to destroy tissue we know is yours. But if it is stored or shared anonymously (without any label saying who it belongs to), we cannot destroy it. In this case it would still be used for research, but no one would know it was yours.

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to donate your tissue and information to study cancer? (circle one)

YES **NO** Initials: _____ Date: _____

Is it OK if for researchers to keep your name, phone number, and address to contact you to ask you if you would be interested in participating in future research studies? (circle one)

YES **NO** Initials: _____ Date: _____

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant (age 18-65):

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: RG1123492
Current consent version date: 2.0, 12/28/2023
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Copies to: