IRB APPROVED
AS MODIFIED
Jul 25, 2024

Department of Medicine
Division of Hematology Oncology

UPMC Cancer Pavilion, Fifth Floor
5150 Centre Avenue
Pittsburgh, PA 15232
412-648-6575
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CONSENT FOR RESEARCH
University of Pittsburgh/UPMC

TITLE:	Nurse AMIE (Addressing Malignancies in Individuals Everyday)
PROTOCOL NO.:	R01-CA254659 WCG IRB Protocol #20216947 91727 PittPRO# STUDY22090133
SPONSOR:	NIH NCI
PRINCIPAL INVESTIGATOR:	Kathryn Schmitz, PhD, MPH Department: Medicine, Division of Hematology Oncology The Assembly 5051 Centre Ave, Suite 5000 Pittsburgh, PA 15213 412-623-6216 E-mail Address: schmitzk@upmc.edu
STUDY-RELATED PHONE NUMBER(S):	Weekdays: 8:00 a.m. to 5:00 p m. (412)-623-6216. After hours, call (412)641-5411 and ask for the oncologic doctor on 24-hour call.

Subject's Printed Name: _____

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because you have been diagnosed with advanced cancer and live in a rural area.

What is the purpose of this research study?

The purpose of this voluntary research study is to determine if a tablet-based computer supportive care program improves overall survival and symptoms after two years in people living with advanced cancer in rural areas.

People living with advanced cancer often return for medical care as often as one time per week. The focus of these appointments includes ongoing cancer treatments and acute medical care, leaving little time to talk about other chronic issues such as pain, fatigue, mental health concerns (like distress), or other quality of life-related concerns (like not being able to sleep).

We have developed a tablet-based computer supportive care program to address this issue and provide high quality care without the necessity for extra in-person doctor visits.

How long will the research study last?

If you agree to participate in this research, you will be in the study for two years.

What will I need to do?

If you take part in this research, your major responsibilities are:

- Follow instructions from the research staff and Nurse AMIE
- Participate in the study visits
  - Four in-office visits (one at the start of the study, and follow-ups at months 6, 12, and 24)
  - Four at-home visits (follow-ups at months 1, 3, 9, and 18)

- Complete surveys (occurs during all visits)
- Complete physical function measurements (occurs during in-office visits only)
- Be randomized into one of two groups: Nurse AMIE or usual standard of care. If randomized into the Nurse AMIE group, use the tablet-based computer at home daily.
- Wear a device that measures your physical activity or a week at 12 months and at 24 months.

What are the main risks of taking part in the study?

For this study, the main risks to know about are:

- Exercising can lead to muscle soreness or injury, dehydration, fatigue, shortness of breath, or fainting.
- Some of the survey questions may make you feel sad or uncomfortable. You may skip those questions and still participate in this study.
- There is always a risk of loss of confidentiality from participating in research. We take many steps to keep your information private.
- Risk of randomization: you may not like your randomly assigned group assignment. The research group has no control over group assignment and cannot change it.
- You may experience skin irritation with wearing the physical activity measuring device.

What are the possible benefits to me that may reasonably be expected from being in the research?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from taking part in this research include decreasing your risk for chronic diseases and improving your quality of life through exercising and addressing cancer-related fatigue, distress, pain, and loss of sleep.

Results of this study may benefit other people in the future by helping us learn more about how a tablet-based computer supportive care program can aid in the support of patients with advanced cancer living in rural areas.

What happens if I do not want to be in this research?

Participation in this research is completely voluntary. You can decide to participate or not to participate. Instead of being in this research study, you may choose to take part in a different research study, if one is available, or you may choose not to take part in any research study.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?

This research is being done to find out if a tablet-based computer supportive care program improves overall survival and symptoms after two years in people living with advanced cancer in rural areas.

People living with advanced cancer often return for medical care as often as one time per week. The focus of these appointments includes ongoing cancer treatments and acute medical care, leaving little time to talk about other chronic issues such as pain, fatigue, mental health concerns (like distress), or other quality of life-related concerns (like not being able to sleep).

Previous research with advanced cancer patients who live in cities says that asking patients about their symptoms and offering interventions for those symptoms leads to longer survival. We have developed an investigational tablet-based computer supportive care program to look at this issue and provide high quality care without the necessity for extra in-person doctor visits. This study focuses on participants like you, who have advanced cancer and live in rural areas.

Approximately 344 people will take part in this research in rural areas.

2. What will happen in this research study?

If you agree to participate in this research, you will first review, understand, and sign this consent document before any study-related activities are done.

This study is a randomized control trial with two groups: one group will receive the Nurse AMIE supportive care intervention and the other group will receive the usual standard of care. The chances of ending up in either group is the same as flipping a coin (50%).

- The Nurse AMIE group will be provided a tablet-based computer and cellular data to use the program. The Nurse AMIE program on the tablet-based computer will be used daily for the entire duration of the study (two years).
    - Each day, you will be asked about your symptoms (pain, fatigue, sleep, distress)
    - Based on your answer, you will be asked to complete a task called an intervention. Interventions include listening to soothing music, following along with a guided relaxation, watching a video on managing your symptoms, taking a walk, or doing exercises that focus on balance, stretching, or strengthening your muscles.
    - Once a week, you will be asked more in-depth questions about your symptoms.
- Participants in the usual standard of care group will receive a binder with supportive care information. This includes information and resources about symptom management, exercise handouts, soothing music, meditation and relaxation and recipes.

Regardless of which group you are in, you will be asked to fill out surveys, do physical function measurements, and wear a physical activity measuring device:

- Surveys will be done at the beginning of the study and after 1 month, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months.
- Physical function measurements will be done at the beginning of the study and after 6 months, 12 months, and 24 months.
- Wear a physical activity measuring device for one week at 12 months and at 24 months.

Visits at the beginning of the study, and at 6 months, 12 months, and 24 months will take about 1 hour each and occur on-site. Visits at 1 month, 3 months, 9 months, and 18 months will take about 15 minutes each and occur at your home.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- Follow instructions from the research staff and Nurse AMIE
- Participate in the study visits
  - Four in-office visits (one at the start of the study, and follow-ups at 6 months, 12 months, and 24 months)
  - Four at-home visits (follow-ups at months 1 month, 3 months, 9 months, and 18 months)
- Complete surveys (occurs during all visits)
- Complete physical function measurements (occurs during in-office visits)
- Be randomized into one of two groups: Nurse AMIE or usual standard of care. If randomized into the Nurse AMIE group, use the tablet-based computer at home daily and do not alter the existing security settings on the device.

3. What are the risks and possible discomforts from being in this research study?

Physical Risks
While on this study, you are at risk for side effects. You may experience none, some, or all of those listed below as a result of exercising or physical function measurements:

Likely
Muscle soreness and injury from the exercise training program. The muscle soreness may last several days after each exercise, but it is not likely to be severe enough to limit any usual daily activities. There is also a risk of muscle injury from the exercise program, such as a muscle sprain, strain, or excessive muscle soreness. It is estimated that over any given month, 4% of adults who walk for exercise on a regular basis will get an injury severe enough to cause a change in activities of daily living for a week or more and that requires medical attention.

Less Likely
Individuals who do high doses of exercise (higher than what is prescribed in this study) can experience dehydration, overexertion, shortness of breath, and fainting. Note that risks associated with exercise may be made worse by ongoing chemotherapy treatments.

There are no other risks associated with an exercise program of this nature in this population. Moderate intensity exercise does not pose a risk to the heart (cardiovascular system). In fact, NOT exercising poses more risk to the cardiovascular system than moderate intensity exercise.

Completing Surveys
You may get tired or bored when we are asking you questions or while you are completing the surveys. You do not have to answer any question you do not want to answer. Some of the questions will be about your feelings, such as sadness and anxiety. You may skip the questions that make you feel sad or uncomfortable.

Randomization
The chances of being randomized to either group is the same as flipping a coin (50%). You may not like your randomly assigned group assignment. The research group has no control over group assignment and cannot change it.

Loss of Confidentiality
There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the researchers, but steps will be taken to prevent this from happening. The privacy of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Changing or tampering with the existing security settings on the tablet-based computer device could increase the loss of confidentiality and impact your participation in this study. Absolute confidentiality cannot be guaranteed. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Skin Irritation
There is a risk that you will have some skin irritation because of the device we are asking you to wear to measure your physical activity (an accelerometer). You may wear a thin layer of clothing under the accelerometer if you prefer.

4. What are the possible benefits from being in this research study?
4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research.

If you are assigned to the Nurse AMIE group, you may enjoy the physical and psychological benefits of the Nurse AMIE program. These benefits may include decreasing your risk for chronic diseases and improving your quality of life through exercising and addressing cancer-related fatigue, distress, pain, and loss of sleep.

If you are assigned to the usual standard of care group, you may benefit from the resources in the binder that will be provided to you.

4b. What are the possible benefits to others?

The results of this research may benefit others in the future by helping us learn more about how a tablet-based computer supportive care program can aid in the treatment and recovery of advanced cancer patients living in rural areas.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study. Since it is investigational, the tablet-based computer supportive care program offered in this research is only available to you if you take part in the research study. The resources in the binder for supportive care are available to you outside of this research.

Interventions including listening to soothing music, guided relaxation, relaxation techniques and exercise and dietary programs are available outside of the research.

6. How long will I take part in this research study?

If you agree to take part in this research, it will take you about two years to complete this research study. You will be asked to visit the research site 4 times.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?
7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files, we will include these identifiers: your name, address, date of birth, telephone number, email address, medical record number, and a study code number.

- A list that matches your name with your study code number will be kept in a locked file in Dr. Schmitz's office.
- Your research records will be labeled with your study code number and will be kept in a safe area in Dr. Schmitz's research office.
- A copy of this signed consent form may be included in your medical record. This means that other healthcare providers may know you are in this study.
- You will not be recorded by the tablet-based computer device.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. For additional information ask the principal investigator or a member of the study team or contact the University of Pittsburgh Office of Research Protections at (412) 383-1480.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. What will happen to my research information and/or samples after the study is completed?

Research records will be maintained for at least 7 years following final reporting or publication of a project. We may use your research information in future studies or may share your information with

other investigators for future research without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity.

7c. How will my identifiable health information be used?

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

As part of this research study, we are asking your permission to use your medical records to see if you are eligible to be in this study, confirm diagnosis dates and treatment plans and to assess health care utilization. This permission does not expire. We will collect the following information: your diagnosis, age, past medical history, tests that were done to diagnose your condition, and results of any tissue biopsies or blood tests that were already done as part of your standard medical care.

We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study including from your medical records once people outside UPMC or the University have viewed it.

You can withdraw your permission to allow the research to team use your information from your medical records. You can do this by sending a request in writing to Dr. Schmitz listed on the first page. If you do so, you will be withdrawn from this study since your medical information is a critical part. The research team will continue to use information collected from you or your records up to that point.

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders made by the investigators for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

In addition, the following people/groups may see, use, and share your identifiable health information:

- Research staff involved in this study
- Non-research staff within Pitt/UPMC who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research

- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- WCG IRB
- A group that oversees the data (study information) and safety of this research

These groups may also review and/or copy your original Pitt/UPMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable health information may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law.

If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

If you test positive for certain diseases, we are required to report to the Pennsylvania Department of Health.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.

- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?
8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- Examples of research-related tests and procedures that may be provided at no cost to you may include: visits to the study site, functional tests, and/or questionnaires. Talk to the study team about which items and procedures this includes.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company may be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company may be billed for the costs of these routine tests and procedures in the usual manner.
- You may be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research, you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be billed for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

9. Will I be paid to take part in this research study?

If you are randomized to the Nurse AMIE group, you will be provided a step counter called a pedometer ($20 value), a resistance band ($15), and a tablet-based computer ($250). You may keep these items after completing the study.

You will receive $15 for each in-office visit for your participation in this research study, no matter which group you are in, for a total of $60. These visits occur at the beginning of the study, at 6 months, at 12 months, and at 24 months. If you do not complete the study for any reason, you will be paid for the visits you have completed.

You will receive $15 per day for each day you wear the accelerometer, up to a maximum of 7 days, for a total of $105 per visit at 12 months and at 24 months. If the accelerometer is worn at both of these visits, you may receive up to a possible total of $210 over the course of the study for wearing the accelerometer.

UPMC utilizes an electronic payment card as a secure payment method to disburse research study compensation and/or expense reimbursements. The electronic payment card is administered by Vincent™ (formerly WePay). The study staff will discuss the use of the electronic payment card with you and answer any questions you may have about the reimbursements. You can also learn more about Vincent™ by visiting its website: http://vincentpay.com/

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding'; thus you would only receive 76% of the expected payment.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institutes of Health to support this research.

It is possible that your research information and/or specimens (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you decide to leave the research, **you will need to return the** tablet-based computer **we have loaned to you for the purposes of this research study.**

Your research doctor or the principal investigator may take you out of the research study without your permission.

- Some possible reasons for this are: continuing the research would be harmful to you, your condition has become worse, you did not follow the instructions of the study doctor, you experience serious side effects, you meet exclusion criteria, or you tamper with the security settings on the tablet-based computer device.

During the course of the research, you will be provided with any new information that may affect your health, welfare, or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Kathryn Schmitz at 412-623-6216 or 412-641-5411 (24 hours) if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the University of Pittsburgh Human Research Protection Advocate at 1-866-212-2668 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the University of Pittsburgh Human Research Protection Office (HRPO) web site at https://www.hrpo.pitt.edu for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and

- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HRP at 1-866-212-2668

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

A description of this clinical trial will be available on https://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.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was started until after this consent form was signed.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study and provide authorization to use and share my medical records. A copy of this consent form will be given to me.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name