Title	Symptom Care@Home: Deconstructing an Effective Symptom Management Intervention (SCH)
ClincialTrials.gov ID	NCT02779725
Document	Informed Consent Document
Update/Approval Date	9/17/2019

RESEARCH STUDY SUMMARY

Symptom Care at Home (SCH): Deconstructing an effective, technology-assisted, symptom management intervention

You are being asked to join a research study. This research study is for people who are receiving chemotherapy treatment for their cancer. Before you consider the research, you should be aware of the following information:

- Research is voluntary. You do not have to be in this study.
- You will get standard medical care for your cancer and cancer symptoms even if you decide not to join the study.
- This study uses an automated telephone system for you to call daily to report whether or not you have had common side effects to your chemotherapy treatment. If you report having symptoms the system will ask you further questions about the symptom(s).
- Participants will complete additional monthly surveys about their health and work.
- Some participants will receive automated feedback about the symptoms they told us they had during the daily phone call.
- Some participants will receive follow up with our study nurse practitioners if they report they are having symptoms at a moderate or higher level.
- Everyone in the study gets standard medical treatment from their oncology team for any symptoms they are having while receiving their chemotherapy treatment in addition to receiving either automated feedback from the telephone system or follow-up from a study nurse practitioner.
- Some participants will wear an activity tracker
- The study lasts while you are receiving your chemotherapy treatment for a maximum of 180 days or about 6 months. You will only participate while you are receiving chemotherapy treatment so you will not be on the study if your treatment plan changes or ends prior to 180 days. If you sign up now, you can still take yourself out of the study later on.
- In previous studies of the SCH system, people found that reporting symptoms and receiving care through both the automated messages in the system and the nurse practitioner was helpful in managing their symptoms during treatment. You might benefit from being in the study, but there is no guarantee of benefit.
- The risks of participating are minimal. It may be upsetting to think about your symptoms during your treatment and there is a time commitment to calling into the system every day.
- Please be sure all your questions are answered before you decide to be in the study.
- If you think you want to be in the study, you should read the rest of this document and discuss it with the study team. The document explains what will happen to people in the study.

_____

Participant's initials confirming discussion

Consent and Authorization Document

Research Study Title: Symptom Care at Home (SCH): Deconstructing an effective, technology-assisted, symptom management intervention

BACKGROUND

You are being asked to take part in a research study. If you agree to be in this study, you will need to sign this consent form. This process is known as informed consent. This study is voluntary and it is up to you to decide whether or not you want to participate. Please tell the study staff if you are taking part in another research study.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The research team has designed a system that helps doctors and nurses take care of cancer patients when they are at home. The name of the system is Symptom Care at Home (SCH). When we tested SCH in the past, we found that using the system reduced symptoms for patients. SCH includes three different parts. The first is to have patients call a telephone system daily to tell us about how they are feeling. The second part is to have patients listen to recorded messages during the phone call that will give tips about how to take care of their symptoms while at home. In the past, these calls have taken about 5 minutes. The third part of the system is to have a Nurse Practitioner follow-up with patients who report they aren't feeling well. Now we want to see which parts of SCH work the best to help people feel better. By testing each part we can see what parts are the most useful. We will also evaluate the cost of each part of SCH.

STUDY PROCEDURE

If you choose to sign up for this study, you will participate for a maximum of 180 days (approximately 6 months). You will end your participation at the end of the chemotherapy treatment cycle prior to reaching this maximum time on the study or if your chemotherapy treatment plan is shorter than 180 days, you will participate only during the time you are receiving treatment.

To find out which parts of the SCH system work best, we will have 5 groups which will test different parts of the intervention. If you agree to participate, you will be randomly assigned to one of the five groups. You won't know which group you will be assigned to until after you enroll in the study. At that time we will open the envelope which will tell us what group you are being assigned to for the study.

If you choose to participate, you will be asked to do the following activities while you receive chemotherapy treatment:

- On the first day in the study we will ask you some questions about your health, history, and background information. We will ask you some of the same questions each month that you are in the study and at the end of the study.

- You will call SCH every day to tell us how you have been feeling in the past day. The system will ask questions about some common symptoms or side affects you may have from your treatment or cancer. Once each week SCH will ask you whether you had visits with doctors that you hadn't planned in advance. The average time to complete a call is about 5 minutes.
- If you report that you fell or almost fell or that you had a visit with a doctor that was not planned our research staff will call you. They will call on the next regular work day to ask you some additional questions.
- The study nurse will call some participants when they report their symptoms are bad. The nurses will have access to some participants' daily reports and may summarize the information for their oncology providers. On occasion, the nurse practitioner will ask if he/she can record the call with the patients for quality control purposes. You may refuse the recording at any time. Only study staff and the principal investigator will have access to the recorded phone calls.
- Some participants will receive automated coaching and ideas to help manage symptoms during the daily calls.
- Some participants will wear an activity tracker so we can test whether or not it helps people with cancer be more active. If you are in this group you will be asked wear the tracker every day and to give the study access to your activity information generated by wearing the activity tracker.
- At the end of the study, we will ask you some questions about what you liked or didn't like about the SCH system. We will also ask for your ideas about how we might improve the system.

If you are in a group that is not receiving calls from our study nurse and you report you have had symptoms, it is important for you to know that **none** of the symptom ratings you provide the telephone system are shared with your oncology providers and for you to understand that the information you report daily will **NOT** be seen by anyone until the end of the study. You should always contact your health care provider if you have unrelieved symptoms or concerns. You will be reminded of this each time you complete a call. Everyone who participates in the study will receive the same care from their doctors and nurses as those patients who are not in the study.

RISKS

The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to your cancer. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience you can tell the researcher. She will tell you about resources available to help you deal with your feelings.

BENEFITS

The interventions in this study have helped other people to reduce their symptoms. However we do not know if they will help you. We hope the information we collect during this study may help develop a system to assist health care providers in caring for their cancer patients in between their treatments and clinic visits and decrease symptoms related to treatment.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you feel you have been harmed as a result of the study, you can contact Kathi Mooney, PhD at 801-585-9645 who may be reached from 8:00 a.m. to 5:00 p.m. on weekdays or by email at kathi.mooney@nurs.utah.edu.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with your doctor.

RIGHT OF INVESTIGATOR TO WITHDRAW PARTICIPANTS

The investigator can withdraw you from the study without your approval. Failure to make daily calls over an extended period of time would be one reason the investigator may withdraw you from the study. You will still receive the same care from your doctor. This will not affect your relationship with your doctor.

COSTS

There are no costs to you to participate in this study.

COMPENSATION FOR PARTICIPATION

If you decide to participate in the study, you will be compensated $30 for every month you participate for up to the maximum of 6 months. If you choose to leave the study before the end of your scheduled treatment or before 6 months (whichever occurs first), you will not receive the full amount of compensation. You will receive $30 for each full month you participated in the study and $1 each day for a month where you did not participate until the end of the month (up to $30). If you are assigned to the group that will wear the Garmin Activity Tracker you must return the tracker to receive the compensation.

Since you will be receiving compensation for participating in this study, it is necessary for us to collect your Social Security Number on a Federal W-9 Form. This form is sent to the University of Utah Accounts Payable office. The amount you receive for taking part in this study will be reported to the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study. However, we will not be able to pay you as outlined in this consent form.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address and telephone number, and email address
- Social Security Number to receive compensation payment. If you do not want to release your social security number to us, you can still participate in the study but you will not receive compensation.
- Related medical information about you like your diagnosis, your treatment plan, past treatment, past illnesses or conditions. We will ask you questions but also access your electronic health record.
- All data collected in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- There are some cases in which a researcher is required to report issues, such as serious threats to public health or safety or if you tell us you are considering harming others or yourself.
- A description of this clinical trial will be available on http://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.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team, University of Utah Health Sciences Center, and Huntsman Cancer Institute and Hospital
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights
    - Other academic research centers we are working with: Emory University in Atlanta, Georgia, is helping us with this study and your record may be seen by their research team
    - The National Cancer Institute has provided funding for this study and may audit our research data which could include your information.
    - Datatel Communications, Inc., the company which programs, hosts, and supports the SCH system and databases
    - If you are randomized into a group that will wear an activity tracker, the manufacturer of the device, Garmin, will see your activity information but because we use special coded accounts they will not see your name or personal information.

- If we share your identifying information with groups outside of University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at Huntsman Cancer Hospital.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study.

Please **INITIAL** the appropriate statement to indicate whether or not you give permission for future contact. (Not required to participate in this study)

YES, I give permission to be contacted by the College of Nursing in the future for research purposes. (Please initial) _____

No, I do not give permission to be contacted by the College of Nursing in the future for research purposes (Please initial)_____

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

Yes _____ No _____

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date