NCT02750865

Computer Health Agent for Responsive Medical Services (CHARMS)

Consent Form

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BOSTON MEDICAL CENTER AND THE
BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH AND DENTAL MEDICINE

RESEARCH CONSENT FORM

Basic Information

Title of Project: Computer Health Agent for Responsive Medical Services (CHARMS)

IRB Number: H-34877 **NCT02750865**

Sponsor: National Institute for Nursing Research/NIH

Principal Investigator: Michael Paasche-Orlow
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Boston, MA 02118

Study Phone Number: 617-414-6668

Background

Having a serious illness can affect your life in many different ways. A new computer system is being developed to offer help and support to people who have serious medical problems. In this research study, we will ask you to help us find out if this system can be helpful to people with chronic disease. You are being asked to be in this study because you are an adult patient at Boston Medical Center. Your participation in this research study will last about 2 hours today, then there will be a 30-minute phone call once per month for the next 5 months, then a final study visit in 6 months that will take about 2 hours.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose

In this project, we will create and test a computer-generated character who can educate and counsel patients about their health conditions, in order to improve the quality of life for adults living with chronic conditions.

What Will Happen in This Research Study

If you decide to be in this study, we will ask you to come to Boston Medical Center for a first study visit that will take about two hours. During that visit we will ask you questions about your quality of life and

your attitudes about your health and happiness. At the end of the visit, we will randomly, like the flip of a coin, assign you to be in one of two study groups.

STUDY GROUP ONE
We will call you on the phone once per month for the next 5 months to ask you a few questions about how you are doing.

STUDY GROUP TWO
We will teach you how to use a small touch-screen tablet computer that you will take home with you for as long as you are in the study (up to 6 months). On the tablet, you can talk, by using buttons on the touch screen, to an animated character who will ask you questions about how you are doing and how you are feeling. The tablet can then send any information you give it back to our study team. A nurse who is part of our study team will review the information, and contact your doctor when needed. We will ask that you spend 10-15 minutes each day using the tablet, or as much as you are comfortable doing. If we see that your tablet has not uploaded any data in 7 days, we will call you to make sure it is still working. After 4 weekly reminder calls, if you still have not used the tablet at least once in 30 days, you will be terminated from the study. We will ask you to complete the exit interview at that time.

If your tablet stops working, you should call us as soon as possible. If we can't fix it over the phone, you will need to bring the tablet to us so that we can fix it in our office, or give you a new one if we can't fix it. If your tablet is damaged (cracked screen, broken case, etc) and needs to be replaced, we will replace it for you one time. If you report a second tablet broken, you will be terminated from the study, and at that time we will ask you to complete the exit interview.

At the end of the study, we would like to ask you some questions about your impression of the character and the tablet system. This part of the survey would be audio-taped. We will ask you some more questions about your quality of life and your attitudes about your health and happiness. You can choose not to be audio-taped if you wish. Please check the appropriate box below, and initial your choice. You can still be in the study if you choose not to be audio-taped.

I agree to have a portion of my interview audio-recorded: ☐ YES _____ (Initial)
☐ NO_____ (Initial)

Once your enrollment in the study is complete, you will return the tablet to the study team.

BOTH STUDY GROUPS
We will ask you to come back to BMC at 6 months for a final study visit. This visit will also last about two hours.

We will also ask you to choose a close friend or family member who knows about your health. We would like to interview this person, and also have your permission to contact him/her in case we can't reach you for any of the monthly phone calls. If at any time while you are in the study you become unable to answer questions, you give this surrogate permission to answer questions and make decisions about your ongoing participation in this study on your behalf.

"If I become unable to answer questions, I authorize this surrogate to answer questions and make decisions about my ongoing participation in this study on my behalf."

(initials)

While you are in this study, you change your mind about who this person should be, you can let us know who the new caregiver should be so we can contact that person.

After your exit interview is completed, we would like to review your BMC medical record and record the number of times you were in contact with the primary care clinic while you were in the study, and if you were admitted to the hospital while you were in the study, as well as the reasons for these visits. We will only record this information for the time period in which you were in this study.

You will be one of approximately 800 subjects who will to be asked to be in the study.

Risks and Discomforts

There are very few risks to you if you are in this study. One risk is that some of the questions we ask may make you uncomfortable. You can skip any questions that make you uncomfortable. Another small risk is a loss of confidentiality, or that your private health information will be seen by people who would not normally be able to see it. We are very careful to keep all your information private. The only people allowed to see your answers will be the people working on the study and people who make sure we run our study the right way. Your answers and a copy of this document will be locked in our files. Nothing will be put in your medical record. When we report the results of the study, we will not include your name. No one will know you were a part of the study or which answers are yours.

Potential Benefits

The benefits of being in this study may be: you will have an improved quality of life while you are in this study. However, you may not receive any benefit. Your being in the study may help the investigators learn ways to improve the quality of life for patients with chronic health conditions.

The following alternative procedures or treatments are available if you choose not to be in this study: you may speak to your doctor, nurse, or social worker about ways to get support for your serious medical condition.

Costs

There are no costs to you for being in this research study.

Payment

You will receive $75 for the initial study visit, $10 for each monthly phone call, and $75 for the final study visit. If you need to come in for a tablet problem, you will receive $20 for that unscheduled visit.

Confidentiality

We will do our best to keep your information safe. However, we cannot guarantee confidentiality. Federal and state agencies, if they are required by law or are involved in research oversight, may access information about you from this study including your health information. Such agencies may include theU.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.

We will protect your information by assigning a random study id that will be used instead of your name on all study documents. We will store your data on our secure computers, and only people working on this study will be able to see it. We will keep your data for a set period of time after the study is complete, as we are required to do.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. We will record information from this study in your medical record, such as information related to your medical care. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways. 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.

Use and Disclosure of Your Health Information

Boston Medical Center wants to use and/or share your health information as part of this research study. The law requires Boston Medical Center to get your authorization (permission) to do so.

Health information that might be used or given out during this research includes:

- Information from your hospital or office health records at Boston Medical Center or elsewhere. This applies to information that is reasonably related to the aims, conduct, and oversight of the research study. If health information is needed from your doctors or hospitals outside of Boston Medical Center, you will be asked to give permission for these records to be sent to the researcher.
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or given out to others are:

- To do the research described here
- To make sure we do the research according to certain standards set by ethics, law, and quality groups or otherwise as required by law

The people and groups that may use or give out your health information are:

- Researchers involved in this research study from Boston Medical Center
- Researchers from other institutions or organizations that are involved in this research study
- Other people at Boston Medical Center who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operationsPeople or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee

research information and the safety of the study

- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research

Some people or groups who get your health information might not be obligated to follow the same privacy laws that we follow. We ask anyone who gets your health information from us to protect the privacy of your information. However, after your information has been shared with others, we cannot promise that it will be kept private.

The time period for using or giving out your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and give out your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not

affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact the study team at 617-414-6937. Also call if you need to report an injury while being in this research

You may also call 617-638-7207 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject:

Printed name of subject

By signing this consent form, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research and authorize the use and release of your Protected Health Information.

Signature of subject Date

Researcher: _____

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that s/he understands what is involved in the study and freely agrees to participate.

_____

Signature of person conducting consent discussion Date

This consent form was read to and apparently understood by the subject in my presence.

_____

Printed name of witness (a person not otherwise associated with the study)

_____ _____

Signature of witness Date