YOOMI: Effect of Gamified Physical Therapy Exercise Software on Inpatient Mobility

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: YOOMI: Effect of Gamified Physical Therapy Exercise Software on Inpatient Mobility
Principal Investigator: Jay Naik MD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to: test the feasibility using gamified physical therapy exercise software for inpatients and measure its effect on mobility in participants. Participants will be randomized into two groups: intervention plus usual care group or the usual care group.

If you are in the intervention group plus usual care group, you will also be asked to use gamified physical therapy exercise software each day and complete post-exercise satisfaction survey, and daily mobility self-assessment form. The gamified physical therapy software is experimental and will ask you to perform a series of exercises while playing games. The software will give you real-time feedback regarding the exercises you perform and guide you. We hypothesize that it may help to improve mobility and maintain function at the time of discharge. Your time in the study will take 5 minutes to complete the self-assessment forms daily, 15-30 minute of exercise with the gamified physical therapy software daily as tolerated, and 2 minutes to complete a post-exercise satisfaction survey after each exercise session. You will also be called 30 days after discharge to complete another self-mobility assessment.

If you are in the usual care group, you will be asked to complete a daily mobility self-assessment form which will take about 5 minutes each day that you are hospitalized. You will also be called 30 days after discharge to complete another self-mobility assessment.

Possible harms or burdens of taking part in the study may be harms associated with exercising and developing an exercise associated injury. Possible benefits of taking part may be maintaining and improving mobility during hospitalization from exercising daily while here.

An alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Jay Naik MD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Jay Naik MD may be reached at 732-235-7122, 125 Paterson Street, Suite 2300 New Brunswick, NJ 08901

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
Patients admitted to the hospital often develop functional impairments due to being in bed most of the day. Each day of bedrest leads to significant muscle loss. As a result, many patients become dependent on others or require rehabilitation at a facility to improve mobility and function prior to returning home. Staff in the hospital is limited and often unable to mobilize patients every day while hospitalized. We are testing a new experimental gamified physical therapy exercise software to see if it can be a fun, enjoyable way to help mobilize patients without the assistance of staff.

Who may take part in this study and who may not?
Patients aged 65 and older, who can speak English, have capacity to consent, and are enrolled in the Hospitalized Elderly Life Program (HELP) can participate in the study. The primary physician caring for the patient will also be contacted to confirm that there are no contraindications to exercise.

Patients with unstable psychiatric illness, critical illness, surgical tubes/drains, surgery during this hospitalization, or a bed rest recommendation by their primary physician may not participate.

Why have I been asked to take part in this study?
You are being asked to participate because you are age 65 and older and enrolled in the HELP program.

How long will the study take and how many subjects will take part?
In total, 80 patients will participate in this study. The study will continue for the duration that you are hospitalized and you will also receive one 10 minute phone call 30 days after discharge.

What will I be asked to do if I take part in this study?
Participants will be randomized into two groups: intervention plus usual care group or the usual care group.

If you are in the intervention group plus usual care group, you will also be asked to use gamified physical therapy exercise software each day and complete post-exercise satisfaction survey, and daily mobility self-assessment form. The gamified physical therapy software is experimental and will ask you to perform a series of exercises while playing games. The software will give you real-time feedback regarding the exercises you perform and guide you using a camera that interprets your motions. There will be no audio or visual recording by the camera. We hypothesize that it may help to improve mobility and maintain function at the time of discharge. Your time in the study will take 5 minutes to complete the self-assessment forms daily, 15-30 minute of exercise with the gamified physical therapy software daily as tolerated, and 2 minutes to complete a post-exercise satisfaction survey after each exercise session. You will also be called 30 days after discharge to complete another self-mobility assessment.

If you are in the usual care group, you will be asked to complete a daily mobility self-assessment form which will take about 5 minutes each day that you are hospitalized. You will also be called 30 days after discharge to complete another self-mobility assessment.

What are the risks of harm or discomforts I might experience if I take part in this study?

The risks of harm of discomforts will be limited to the risks or harms of performing in bed light to moderate exercise.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be improved mobility and reduced risk of hospitalization. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take Part in this study?
There is no cost to participate in the study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. To reduce the risk of breaching patient confidentiality, the study team will enact several safeguards. First, only those approved by Rutgers University's Institutional Review Board (a committee that regulates research activity) will have access to the underlying data in the research study. Data will be collected using REDCap; notably, this software will keep track of everyone who accesses this data, and when. Only two members of the research team (the Principal Investigator and one additional investigator) will have access to information that links your personal identity to your medical history and demographic information; the master link between these two sets of data will be kept for 6 years beyond study completion, and then destroyed as per standard practice. All paper forms used during the trial will be kept under lock and key in the PI's office.

The research team may use or share your information collected or created for this study with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The Food and Drug Administration

A description of this clinical trial will be available on 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.

What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the study is over? The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to

Jay Naik MD
Division of General Internal Medicine
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New Brunswick, NJ 08901
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Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

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Division of General Internal Medicine
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If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- Length of Stay

- AMPAC scores
- 3DCAM Delirium Scale
- Post-discharge care needs
- Demographic information
- Medical history

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary For Clinical Care:
    - Robert Wood Johnson University Hospital
- The Food and Drug Administration

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

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How Long Will My Permission Last?
Your permission for the use and sharing of your health information will last until the end of the research study.

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AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____