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

NCT05815017

6.24.24

INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  YOOMI: Effect of Gamified Physical Therapy Exercise Software on Inpatient Mobility

- **Principal Investigator Name**
  Jay Naik, MD

- **Principal Investigator Div. & Dept.**
  Robert Wood Johnson Division of General Internal Medicine, Department of Medicine

- **Principal Investigator Contact Info:**
  naikjh@rwjms.rutgers.edu
  125 Paterson Street, Suite 2300
  New Brunswick, NJ 08901
  732-235-7122

- **Protocol Version and Date:**
  V1 6.24.24

RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

Table of Contents

Skip To Section: Hold **CTRL** + **Click (Below)** To Follow Link in **Blue**

1.0	Research Design
1.1	Purpose/Specific Aims
1.2	Research Significance
1.3	Research Design and Methods
1.4	Preliminary Data
1.5	Sample Size Justification
1.6	Study Variables
1.7	Drugs/Devices/Biologics
1.8	Specimen Collection
1.9	Data Collection
1.10	Timetable/Schedule of Events
2.0	Project Management
2.1	Research Staff and Qualifications
2.2	Research Staff Training
2.3	Other Resources
2.4	Research Sites
3.0	Multi-Center Research
4.0	Subject Considerations
4.1	Subject Selection and Enrollment Considerations
4.2	Obtaining Identifiable Information About Non-Subjects
4.3	Number of Subjects
4.4	Consent Procedures
4.5	Special Consent Populations
4.6	Economic Burden and/or Compensation For Subjects
4.7	Risks of Harm/Potential for Benefits to Subjects
5.0	Special Considerations
5.1	Health Insurance Portability and Accountability Act (HIPAA)
5.2	Family Educational Rights and Privacy Act (FERPA)
5.3	Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
5.4	General Data Protection Regulation (GDPR)
5.5	NJ Access to Medical Research Act (Surrogate Consent)
6.0	Data Management Plan
6.1	Data Analysis
6.2	Data Security
6.3	Data Safety And Monitoring
6.4	Reporting Results
6.5	Secondary Use of Data
7.0	Research Repositories – Specimens and/or Data
8.0	Approvals/Authorizations
9.0	Bibliography

1.0 Research Design

1.1 Purpose/Specific Aims

The primary aim of this pilot/proof of concept study is to determine whether gamified physical therapy software can help inpatients exercise within the safety of their own beds and preserve pre-hospitalization function.

A. Objectives

Determine how much inpatients use gamified physical therapy exercise software in terms of utilization time and percentage of exercise repetitions completed, as well as post-exercise patient satisfaction with the software and self-performance assessments. Determine the change in AMPAC (Activity Measure For Post Acute Care) scores, length of hospitalization, rates of discharge to home, home with physical therapy, subacute rehabilitation, and acute rehabilitation in the gamified physical therapy exercise software intervention plus usual care group to the usual care group.

B. Hypotheses / Research Question(s)

The investigators hypothesize that the use of gamified physical therapy exercise software to mobilize inpatients in their beds will be feasible with greater than 30 min daily utilization times, greater than 50% of exercise repetition completion, and have a high degree of patient satisfaction with an improvement in self-performance assessments. Additionally, the investigators hypothesize that using this software will lead to preserved AMPAC scores, decreased length of hospitalization, and decrease post-acute care needs without any adverse effect on safety.

1.2 Research Significance

At least 30% of adults over the age of 70 who are hospitalized for a medical illness develop a new impairment in an “Activity of Daily Living” (ADL) during their hospital stay. Deconditioning and activity restrictions play an important role in the functional decline of the hospitalized older adult. Resulting ADL impairments may include basic life activities such as bathing, dressing, or walking, and oftentimes affect a patient’s life far more than the initial ailment that brought the patient into the hospital. Patients often require post-acute care services to address ADL impairments and improve function, though many may still become newly and permanently dependent for ADLs. In 2013, nearly 8 million inpatients were discharged to post-acute care settings for rehabilitation, accounting for 22% of all hospital discharges, and an additional 59 billion dollars in cost. Patients discharged to post-acute care settings had a length of stay that was 3.4 days longer and $8,600 more expensive than patients discharged home. A major opportunity exists in preventing the functional decline of inpatients and reducing the cost and burden of post-acute care needs.

Bed rest interferes with the function of major body organs with adults losing greater than 1% of lean muscle mass per day of hospitalization, or 12% per week. There are many hospital protocols to help reduce atrophy and improve mobilization, such as initiatives to get patients to sit in a chair or ambulating patients with assistance. At Robert Wood Johnson University Hospital, The Early Mobilization Program aims to keep older patients physically moving while they are in the hospital. Those patients able to walk receive assistance three times a day, and those unable to walk receive coaching to complete simple active range of motion exercises three times daily. Early mobility for the older patient is key to maintaining independence and preventing complications such as pneumonia, weakness, balance problems and clots. The goal of Hospital Elder Life Program (HELP) is to get patients up and walking 3 times a day but if there is some medical indication why this cannot happen, active range of motion

exercises in bed becomes very crucial to the patients well being. However, there are many barriers to adhering to these initiatives regularly primarily because of limited nursing and physical therapy staff and time constraints as well as concerns about patient safety and risk of falls. Mobilizing patients in the inpatient setting is challenging given the limitations in staff and safety barriers.

Prior research has shown that mobilizing hospitalized patients reduces functional decline. In the outpatient setting, physical therapy exercise software with real-time feedback has shown to improve patient depression, anxiety, musculoskeletal pain, and function. No such research has yet been done in the inpatient setting to see how a staff independent gamified physical therapy exercise software used while in bed would affect a patient's satisfaction and function. We propose an exploratory pilot trial to evaluate the feasibility, patient satisfaction, and effect on AMPAC scores, length of hospitalization, and post-acute care needs of such software on inpatients.

1.3 Research Design and Methods

We will conduct a prospective, randomized-controlled pilot trial to test the above aims on patients aged 65 and older who have been admitted to the Medical Teaching Service (MTS) or Non-Teaching Service (NTS) in Robert Wood Johnson University Hospital (New Brunswick) (RWJUH-NB) and enrolled in the HELP program. The study will consist of two groups: gamified physical therapy exercise software intervention group plus usual care or usual care alone. We will recruit up to 80 participants on an ongoing basis, for a total of 40 participants in each group of the study.

Participants recruited for the study will need to meet inclusion/exclusion criteria ("Table 1," below). All potential participants will have capacity to consent. If consent is obtained, the study will proceed as outlined in section 1.7 and 1.9.

A. Research Procedures

1. All participants will be recruited daily from inpatients on the Medical Teaching Service or Non-teaching Service in the HELP program who meet eligibility criteria. After obtaining consent to approach the patient from the attending physicians (all of the participants will be from the PI's own division of physicians) and from the patient to participate, eligible patients will be asked screening questions before being randomized into the intervention group or control group. Participants randomized to the intervention group will be asked each day by a volunteer whether they would like to use the gamified physical therapy exercise software while in their beds. Participants willing to exercise will have the device set up for them to participate by a volunteer and the software will begin with a tutorial video for different exercises and then ask patients to perform in sequence with prompting and motion tracking. Exercises include Frontal Bicep Curls, Arm Crosses, Press Ups, Arm Rotations, and Basketball Shots. Participants in both the intervention and control groups will complete a mobility self-assessment survey.

Table 1. Subject Criteria

Inclusion	***Exclusion***
≥65 years of age	Unstable psychiatric illness
English-fluency in reading and speaking	Unstable/critically ill patients requiring ICU-level care
Capacity to consent	Surgical tube present (e.g. JP drains)
Enrolled in HELP program	Surgery during the hospitalization
Attending physician confirms there are no medical contraindication to in bed exercises	Bed Rest Activity Order

Study participants will be contacted again one month after discharge via phone call to assess their functional level through self-assessed AMPAC score and independence in ADLs/iADLs. There will be two research coordinator (Dr. Lawrence and Dr. Naik), one volunteer coordinator (Ms. Dhyana Velez) and at least one volunteer present daily to set up device and administer surveys (10-15 volunteers in total).

B. Data Points

We will collect participant demographics (intervention and control groups, available in EMR), AMPAC scores (intervention and control groups, available in EMR), 3DCAM Delirium Scale (intervention and control groups, available in EMR), patient satisfaction scores (intervention group only), patient mobility self-assessments (intervention and control groups, administered by research staff), software utilization time (intervention group only), percentage of exercise repetitions performed (intervention group only). All data points will be collected daily throughout the course of hospitalization until discharge once enrolled into the study.

C. Study Duration

Study will accrue participants until 80 patients are recruited, and individual participants will be followed for a total of 1 month after discharge.

D. Endpoints

The primary endpoints will be software utilization time (intervention group only), percentage of exercise repetitions performed (intervention group only), change in AMPAC scores (intervention vs control groups). Secondary endpoints include patient satisfaction scores (intervention group only), patient self-assessments (intervention vs control groups), length of hospital stay (intervention vs control groups), 3DCAM Delirium Scale (intervention vs control groups), post-discharge care needs (intervention vs control groups), and 1-month post-discharge self-assessed AMPAC score (intervention vs control groups) and ADL/iADL independence (intervention vs control groups).

1.4 Preliminary Data

None

1.5 Sample Size Justification

At this time, there is no data on how gamified physical therapy exercise software use in the inpatient setting. The study team is unable to estimate a sample size sufficient to detect a pre-specified difference in outcomes. There are approximately 40 patients participating in the HELP program on any given day with most patients being admitted to the Medical Teaching Service or Non-Teaching Service. Assuming 3-4 of these patients will be eligible and consent to participation in the trial per week, we will need 26 weeks to recruit 80 patients. This trial is a pilot study that will gather data to be used for future trial designs, including realistic estimates of a sample size needed to detect clinically significant differences.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The experimental intervention will be the gamified physical therapy exercise software that will be provided for patients in the intervention group. Both groups will receive standard of care interventions including nursing driven initiatives, physical therapy, and mobilization as part of the HELP program.

B. Dependent Variables or Outcome Measures

Dependent variables include

- Change in AMPAC scores (Intervention and control groups)
- 3DCAM Delirium Scale (Intervention and control groups)
- Patient satisfaction score (Intervention group only)
- Patient self-assessments (Intervention and control groups)

- Software utilization time (Intervention group only)
- Percentage of exercise repetitions completed (Intervention group only)
- Length of hospital stay (Intervention and control groups)
- Post-discharge care needs (Intervention and control groups)
- Post-discharge self-assessed AMPAC score and ADL/iADL independence

1.7 Drugs/Devices/Biologics

A. Schedule and Administration

The gamified physical therapy exercise software provides video and audio cues through patient motion tracking to assist in communicating the proper motion of an exercise. These exercises have been gamified by adding goals and which are tracked and scored. Each day, volunteers will ask participants in the intervention group if they would like to use gamified physical therapy exercise software. Their most recent vital signs will be confirmed to have a BP < 180/100 mmHg and HR < 120 bpm with the nurse taking care of the patient. If vital signs are greater than these values, then the participants will be revisited at a later time for reconsideration as time permits. Participants with vital signs within the parameters who wish to participate will have the software set up for them. Participants will choose how long they would like to exercise and will exercise at their own pace and can choose to stop at any time. Recommended exercise time will be about 30 min and comprise of 5 exercises 3 sets of 10 repetitions each. The software will adjust the number of repetitions based on the patient's engagement and ability level, e.g. it will increase number of repetitions requested by 2 for patients who are able to complete them and decrease the requested repetitions by 2 for patients who are unable to complete them.

B. Drug/Device Accountability and Storage Methods

The gamified physical therapy software ("Yoomi") will run via a computer and monitor mounted on a portable rod with wheels that can be wheeled into a patient's room. There will be a camera on the device which will track patient exercises and form. The device will be stored in the Clinical Academic Building when not in use.

1.8 Specimen Collection

A. Primary Specimen Collection

None

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Processing**: N/A
- **Storage**: N/A
- **Disposition**: N/A

B. Secondary Specimen Collection

None

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Storage**: N/A
- **Disposition**: N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: Data collection will occur in two primary sites: RWJUH-NB and the Clinical Academic Building (CAB). No special permissions to collect information will be required (besides an Institutional Review Committee form for access to the medical chart)
- **Process of Data Collection**: Data will be collected by participating physicians/co-investigators/volunteers. In the hospital, participants in both groups will be asked to complete a self-assessment survey each day ("Self-assessment Survey," attached). Participants in the intervention group who used the gamified physical therapy exercise software will be asked to complete a patient satisfaction survey after use ("Patient satisfaction survey," attached). Daily AMPAC scores, 3DCAM delirium scale, Length of hospital stay, and post-discharge care needs will be collected from the participant's electronic medical record.

  Participants will be contacted by phone 30 days after discharge to gather self-assessed AMPAC scores and ADL/iADLs independence ("Follow-up Script," attached).

  The PI will check in with the co-investigators who are acquiring this information during monthly meetings in order to oversee the process

- **Timing and Frequency**: Patients will be contacted daily while in the hospital to complete surveys and once 30 days post-discharge.
- **Procedures for Audio/Visual Recording**: There will be no audio/visual recording.
- **Study Instruments**: We will use a patient satisfaction survey which takes 2 minutes to complete daily ("Patient Satisfaction Survey," attached), patient self-assessment survey which takes 5 min to complete daily, ("Self-Assessment Survey," attached). Other data will be collected from the EMR including daily 3DCAM scale (charted by nurses as part of HELP program), daily AMPAC scores (charted by nurses as part of HELP program), length of hospital stay, post discharge care needs (Recorded as home with no needs, home services e.g. home PT/Home Health Aide/Visiting Nursing services, Subacute rehabilitation, Acute Rehabilitation, or Long Term Care facility). The gamified physical therapy exercise software will record utilization time in minutes and record percentage of exercise repetitions completed which will both be tied to a user ID. The user ID will be tied to an MRN number which will be kept by the PI with lock and key in the office.
- **Ethnographic Studies, Interviews, Or Observation**: See "Process of Data Collection"
- **Subject Identifiers**: After enrollment in the study, research staff will record each participant's full name, date of birth, home address, e-mail address, telephone number, and demographics. Each study participant will have a research ID number assigned to link study data with their demographic data. The link between study ID and participant information will be kept separately in a locked cabinet in the PI's office.

B. Secondary Data Collection

Data from the Epic electronic medical record (EMR) will be used to gather AMPAC scores, 3DCAM delirium scale, length of hospital stay, post-discharge care needs, and demographic information.

- **Type of Records**: Epic EMR will be accessed for each participant in the study and notes will be reviewed for AMPAC scores, 3DCAM delirium scale, length of hospital stay, post-discharge care needs, and demographic information.
- **Location**: The data noted above exists in Epic EMR; permission from RWJUH-NB's Institutional Review Committee is required and has been obtained. Information from the chart will be abstracted in the CAB.
- **Inclusion/Exclusion**: We will access the Epic EMR charts only for participants in the study. Information from the chart will be abstracted in the CAB.
- **Data Abstraction Form(s):** "Epic Chart Data," attached.

1.10 Timetable/Schedule of Events

N/A

2.0 Project Management

2.1 Research Staff and Qualifications

Dr Jay Naik, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will act as the Principal Investigator and provide project management support

Dr Ibiyonu Lawrence, MD, is an Associate Professor of Medicine in the Division of General Internal Medicine and Chief of Geriatrics, Robert Wood Johnson Medical School. She will provide project management support

Dr Michael Steinberg, MD, MPH, is the Division Chief of General Internal Medicine, Robert Wood Johnson Medical School and Vice Chair for Research in the Department of Internal Medicine

Dr Karthik Kota, MD, MPH, Research Staff, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Renu George, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Catherine Chen, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Raman Bhalla, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Payal Parikh, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Sheetal Patel, MD, is an Associate Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr James Prister, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Daniel Schaer, MD, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Christina Theodorou-Ross, MD, is an Instructor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Sofiul Noman, MD, is an Instructor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Andrew Azab, MD, is an Instructor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Stephen Priest, MD, is an Instructor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support

Dr Payal Dave, MD, is an Assistant Program Director and Assistant Professor of Medicine in the Division of Education, Department of Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Sarang Kim, MD, is an Assistant Program Director and Associate Professor of Medicine in the Division of Education, Department of Internal Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Deborah Kim, MD, is an Assistant Professor of Medicine in the Division of Pulmonary And Critical Care Medicine, Robert Wood Johnson Medical School. She will provide project management support

Dr Rohan Shah, MD MS, is an Assistant Professor of Medicine in the Division of General Internal Medicine, Robert Wood Johnson Medical School. He will provide project management support.

Dhyana Velez, BSN RN-BC GRN, is the coordinator of the Hospital Elder Life Program at Robert Wood Johnson University Hospital. She will provide project management support

Samantha Spinelli, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Laura Perez, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Kavya Kadabageri, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Rena Chaiklin, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Briana Hernandez, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Randy Luna, is a volunteer for the Hospital Elder Life Program. He will help in the setting up of physical therapy software device and taking patient surveys

Kellsey Church, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Dylan Wilde, is a volunteer for the Hospital Elder Life Program. He will help in the setting up of physical therapy software device and taking patient surveys

Simran Patel, is a volunteer for the Hospital Elder Life Program. She will help in the setting up of physical therapy software device and taking patient surveys

Sachit Sudharshan, is a volunteer for the Hospital Elder Life Program. He will help in the setting up of physical therapy software device and taking patient surveys

2.2 Research Staff Training

All research staff will be provided with a copy of the protocol and be on-boarded to the project by Dr Naik

2.3 Other Resources

Data collection will take place at CAB 2300 (Division of General Internal Medicine), 125 Paterson Street, New Brunswick, NJ 08901; at this location, sufficient workspace and access to research materials is available to research staff

2.3 Research Sites

Robert Wood Johnson University Hospital and CAB 5100, 125 Paterson Street, New Brunswick, NJ 08901

3.0 Multi-Center Research

N/A

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Patients age 65 or older, admitted to the medical teaching services or non-teaching services at Robert Wood Johnson University Hospital and enrolled in the HELP program.

B. Recruitment Details

Potential study participants will be identified by the attending physicians in charge of their care. Once identified, attending physicians or their designees will read through the consent for the trial (as their question is part of usual intake/care). If patients decline, the attending or their designee will proceed with care as customary

Patients who are approached by the study team but are unable to talk at the moment due to whatever reason (needing to go for testing, feeling poorly but wanting the study team to return) or who feel that they need more time to think about participation in the study will be left a copy of the consent form and a flyer (entitled “Yoomi Consent”)

C. Subject Screening

Potential participants will be screened in person

- **Inclusion Criteria**
  Please refer to Table 1
- **Exclusion Criteria**
  Please refer to Table 1

D. Privacy Protections

Prospective subjects will be identified by only Dr Naik or Dr Lawrence by screening patients enrolled in the HELP program.

4.2 Obtaining Identifiable Information About Non-Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

We will recruit 80 participants.

B. Total Number of Subjects If Multicenter Study

N/A.

C. Feasibility

Assuming 3-4 of these patients will be eligible and consent to participation in the trial per week, we will need 26 weeks to recruit 80 patients.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  Consent will take place at Robert Wood Johnson University Hospital in the participant's hospital room
- **Ongoing Consent**
  N/A
- **Individual Roles for Researchers Involved in Consent**
  The individuals listed in this application drafted the consent document, and will ensure all subjects provide informed consent before proceeding with the rest of the study
- **Consent Discussion Duration**
  Consent discussions will take approximately 5-10 minutes to complete
- **Coercion or Undue Influence**
  As part of the consent process, participants will be assured they may withdraw from the study at any time without penalty
- **Subject Understanding**
  The consent form (to be provided to the participant) will be written at a fifth-grade education level to provide ease of comprehension. After participants have read the form, the research staff member will go over the major components of the study, review any sections that the participant finds unclear, and answer any questions the participant may have. Once this process is complete, participants will be asked to sign the consent
- **Protecting Privacy**
  Family members will be asked to leave the room during consent unless patient would like family member present.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  N/A
- **Destruction of Identifiers**
  Personally identifying information will be destroyed 6 years after study completion as per standard practice (the PI will dispose of paper forms with patient identifiers in patient shredding bins and delete the REDCap file with patients' names and contact information)
- **Use of Deception/Concealment**
  N/A
  a. **Minimal Risk Justification**
     N/A
  b. **Alternatives**
     N/A
  c. **Subject Debriefing**
     N/A

C. Documentation of Consent

- **Documenting Consent**
  Patients will be asked to sign the consent form
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  N/A

4.5 Special Consent Populations

N/A

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  N/A

- **Non-Parental Permission**
  N/A
- **Assent Process**
  N/A
- **Documentation of Assent**
  N/A.
- **Reaching Age of Majority During Study**
  N/A

B. Enrolling Wards of the State
N/A
- **Research Outside of NJ Involving Minors**
  N/A

C. Enrolling Non-English-Speaking Subjects
N/A
- **Process for Non-English-Speaking Subjects**
  N/A
- **Short Form Consent for Non-English Speakers**
  N/A

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)
N/A
- **Assessing Adult Capacity to Consent**
  N/A
- **Selecting a Surrogate & Consent Process**
  N/A
- **Subject Assent**
  N/A
- **Selecting a Witness to the Surrogate Consent Process**
  N/A
- **Removing a Subject**
  N/A

E. Special Consent Considerations
N/A

4.6 Economic Burden and/or Compensation for Subjects

Item	Price	Number Needed	Total Cost
Patient Incentive	$0	80 participants	$0
Principal Investigator	$0	1 person	$0
Co-Investigators	$0	1 people	$0
Yoomi Software and Device	Provided by Yoomi	2 Devices	$0
Grand Total			$0

A. Expenses
N/A

B. Compensation/Incentives

N/A

C Compensation Documentation
N/A

.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  There is concern that a patient may not be able to exercise due to a medical condition. This risk be mitigated by confirming with the attending physician caring for the participant that they do not have a condition that would be a contraindication to exercise. There is concern that exercising in a patient's bed may dislodge a patient's surgical tubes. This risk will be mitigated by excluding patients with surgical tubes or recent surgery. The only other risk of harm to the patient is breach of patient confidentiality (see"4.7E" for how this will be addressed)
- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  See section "Reasonably Foreseeable Risks of Harm"
- **Other Foreseeable Risks of Harm**
  N/A
- **Observation and Sensitive Information**
  N/A

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
N/A

E. Minimizing Risks of Harm
See section "Reasonably Foreseeable Risks of Harm"
.

- **Certificate of Confidentiality**
  N/A
- **Provisions to Protect the Privacy Interests of Subjects**
  Participants are free to withdraw from the study at any time they choose, at which point their data will be linked by the study through their research ID and their personally identifying information will be destroyed. Since there are multiple researchers involved in this process, the number of study staff who will be involved in converting raw data to identifier-free data will be limited by the PI

F. Potential Direct Benefits to Subjects
Patients may benefit as exercising in bed may prevent hospitalization related muscle atrophy and functional decline as well as reduce length of hospitalization and post-acute care needs.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
N/A

5.2 Family Educational Rights and Privacy Act (FERPA)
N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

N/A

A. Special Populations

- N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

The pilot study will describe the usability of the *Yoomi* gamified physical therapy software in the hospital setting in terms of total utilization time and measure engagement by quantifying total number of prescribed exercises that were actually performed. The study will also look at key dependent variables including AMPAC score assessment, 3DCAM scale, length of hospital stay, post discharge care needs and compare these between the two groups. Chi square analyses will be used to compare categorical data between arms and t-tests will be used to compare continuous data.

6.2 Data Security

Data will be protected by being kept under lock and key in the PI's office (for physical data) and within a secure, password protected folder on the University's HIPAA-compliant cloud services (for electronic data). All research staff will have completed appropriate training for handling patient information, and have access to dedicated workstations from which they can securely access data and analyze it using appropriate software. The workstations described are all computers authenticated on the Rutgers Barnabas Health System network and password-protected. The numeric identifiers assigned for patient data will be used for all transcription purposes.

Electronic data will be stored on Amazon Web Services S3. Data that will be stored includes de-identified key exercise pose data in the form of x,y coordinates per frame (this is used for AI algorithm to motion track and evaluate performance on exercises), software utilization minutes, and percentage of exercise repetitions completed.

Once all data is collected, entered, and analyzed, the PI will destroy all private/identifying information, leaving only the numeric identifiers linking the data collected

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

Data/Safety Monitoring plan is not necessary as the gamified physical therapy software in bed exercises pose minimal risk to patients. Similar exercise programs without gamification and real-time feedback already exist on patient entertainment monitors and can be accessed by patients, these have not shown any risk to patient safety.

B. Data/Safety Monitoring Board Details

Since the intervention poses minimal risk to patients, a data safety monitoring board is not needed.

6.4 Reporting Results

A. Individual Subjects' Results
N/A

B. Aggregate Results
After the study is completed, and after any embargo period for publication, information about the study's effect will be published.

C. Professional Reporting
We will attempt to publish both the study design and the study results in the scientific literature and at conferences depending on interest and trial results

D. Clinical Trials Registration, Results Reporting and Consent Posting
This research qualifies as a clinical trial and will be registered pending approval by the RWJMS IRB

6.5 Secondary Use of the Data
N/A

7.0 Research Repositories – Specimens and/or Data

N/A

8.0 Approvals/Authorizations

N/A

9.0 Bibliography

Greysen SR, Stijacic Cenzer I, Boscardin WJ, Covinsky KE. Functional Impairment: An UnmeasuredMarker of Medicare Costs for Postacute Care of Older Adults. J Am Geriatr Soc. 2017 Sep;65(9):1996-2002. doi: 10.1111/jgs.14955. Epub 2017 Jun 21. PMID: 28636200; PMCID: PMC5603365.

Covinsky KE, Pierluissi E, Johnston CB. Hospitalization-Associated Disability: "She Was Probably Able to Ambulate, but I'm Not Sure". *JAMA.* 2011;306(16):1782–1793. doi:10.1001/jama.2011.1556

Wen Tian, Ph.D., M.D. An All-Payer View of Hospital Discharge to Postacute Care, 2013. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp

Kojaie-Bidgoli, A., Sharifi, F., Maghsoud, F. et al. The Modified Hospital Elder Life Program (HELP) in geriatric hospitalized patients in internal wards: A double-blind randomized control trial. BMC Geriatr 21, 599 (2021). https://doi.org/10.1186/s12877-021-02520-3

Sarah Richardson, MBBS, James Murray, MSc, Daniel Davis, PhD, Blossom C M Stephan, PhD, Louise Robinson, PhD, Carol Brayne, MD, Linda Barnes, Stuart Parker, MD, Avan A Sayer, PhD, Richard M Dodds, PhD, Louise Allan, PhD, Delirium and Delirium Severity Predict the Trajectory of the Hierarchical Assessment of Balance and Mobility in Hospitalized Older People: Findings From the DECIDE Study, The Journals of Gerontology: Series A, Volume 77, Issue 3, March 2022, Pages 531–535, https://doi.org/10.1093/gerona/glab081

Bertelsen AS, Storm A, Minet L, Ryg J. Use of robot technology in passive mobilization of acute hospitalized geriatric medicine patients: a pilot test and feasibility study. Pilot Feasibility Stud. 2020 Jan 6;6:1. doi: 10.1186/s40814-019-0545-z. PMID: 31921434; PMCID: PMC6943926.

Kim CM, van der Heide EM, van Rompay TJL, Verkerke GJ, Ludden GDS
Overview and Strategy Analysis of Technology-Based Nonpharmacological Interventions for In-Hospital Delirium Prevention and Reduction: Systematic Scoping Review
J Med Internet Res 2021;23(8):e26079
doi: 10.2196/26079

Lohse, Keith PhD; Shirzad, Navid MASc; Verster, Alida; Hodges, Nicola PhD; Van der Loos, H. F. Machiel PhD. Video Games and Rehabilitation: Using Design Principles to Enhance Engagement in Physical Therapy. Journal of Neurologic Physical Therapy 37(4):p 166-175, December 2013. | DOI: 10.1097/NPT.0000000000000017

Valiani, V., Lauzé, M., Martel, D. et al. A new adaptive home-based exercise technology among older adults living in nursing home: A pilot study on feasibility, acceptability and physical performance. J Nutr Health Aging 21, 819–824 (2017). https://doi.org/10.1007/s12603-016-0820-0

Wang, G., Yang, M., Hong, M. et al. Clinical outcomes one year after a digital musculoskeletal (MSK) program: an observational, longitudinal study with nonparticipant comparison group. BMC Musculoskelet Disord 23, 237 (2022). https://doi.org/10.1186/s12891-022-05188-x