FitMi Plus: Smart Functional Modules for Practicing Activities of Daily Living after Stroke

ClinicalTrials.gov Identifier: NCT03935425

Date: 04/20/2021

UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

FitMi Plus: Smart Functional Modules for Practicing Activities of Daily Living
Phase 2

Lead Researcher
David J. Reinkensmeyer, Ph.D.

Department of Mechanical and Aerospace Engineering

(949) 824-5218

24-Hour Telephone Number: (949) 910-7903

STUDY LOCATION(S):
Gross Hall, UCI main campus

Hewitt Hall, UCI main campus

Acute Rehabilitation Unit, UCI Douglas Hospital

STUDY SPONSOR(S):
National Institutes of Health

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose

The purpose of this research study is to evaluate two different methods for performing arm and hand exercises at home after stroke. Both methods of home exercise will involve a technology called “FitMi”, which consists of two devices that look like hockey pucks and can sense movement and force. FitMi connects to a computer that displays how to do the exercises and keeps count of how many exercises you do. One exercise method will use exercises designed by rehabilitation therapists with the FitMi pucks. The other exercise method will use exercises designed by rehabilitation therapists with the FitMi pucks plus add-on exercises that simulate activities of daily living like turning a door knob or zipping a zipper. You will be randomized to one of the exercise groups.

Study Procedures
In this study, you will be asked to perform a series of assessments to determine your eligibility to participate in this study and to determine your movement abilities. If eligible, you will then be asked to take the FitMi exercise tool home for three weeks in order to do exercises at home. You will be asked to return after three weeks and then again one month after that to perform additional assessments to assess any changes in your movement abilities over time.

Expected Duration
Participation will last a total of two months, consisting of an initial, 1-2 hour clinic visit, a training visit within 7 days after the initial visit, three weeks of exercise at home with a target of 3 hours of exercise per week, a second 1-2 hour clinic visit after the three weeks of home exercise, and a final 1-2 hour clinic visit one month after that. A total of 4 visits for the study.

Risks of Participation
If you participate, there is a small risk of fatigue or muscle soreness from the exercise. There is also a slight risk that your private medical information could be shared with individuals who are not members of the study team. You may also be asked to wear a wearable sensor called a manumeter that has additional risks since it includes wearing a magnet worn on the finger.

Benefits to Participants
Taking part in this study may or may not make your health better. While researchers hope that the exercises you perform in this study will improve your movement ability, and previous similar studies suggest this is likely to be true, there is no direct proof of this yet.

Benefits to Others or Society

This study will help researchers learn more about the best way to do rehabilitation exercise after a stroke and it is hoped that this information will help in the treatment of future patients with similar conditions.

Alternative Procedures or Treatments
There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to evaluate and improve a device called FitMi for performing exercises after a stroke.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 50 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be

determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you are between 18 and 85 years of age, and had a stroke over 6 months ago.

Exclusion Requirements
You cannot participate in this study if you have too much or too little impairment in your hand or arm, severe pain in your and or arm, severe visual deficits, or severe neglect of one side of your body. You cannot participate in this study if you are currently enrolled in another rehabilitation therapy study.

HOW LONG WILL THE STUDY GO ON?

This study will last two months. First, you will undergo an initial baseline assessment to ensure you meet the eligibility criteria for the study, which will take place during a 1-2 hour clinic visit. If you are eligible to participate, you will receive 30 minutes of training with the FitMi exercise device, and then you will be asked to take FitMi home and use it to perform at least 3 hours of exercise per week for three weeks. After this three-week exercise period, you will be invited back to the clinic for follow up assessments, which will last approximately 1-2 hours. Finally, you will be asked to return for a final 1-2 hour clinic visit one month after that in order to repeat the assessments.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include:

- You will be asked questions about your current health, medical history and use of medications (if any).
- To further help understand your background, you will also be asked permission for the researchers to obtain information about your stroke from your medical records.
- The examiner will perform a brief assessment to ensure that you can move your arm and hand enough to take part in this study and will perform a brief clinical assessment of your ability to move your hand and arm.

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done.

During the main part of the study...
First, you will report to Hewitt Haall or Gross Hall on the UCI main campus or the Acute Rehabilitation Unit at the UCI Medical Center. An examiner may perform additional assessments to better assess your ability to move your hand and arm and to determine how much you are using your hand and arm at home.

Then, you will be given a FitMi device with a touchscreen tablet that has the FitMi software pre-installed. You will receive a 30-minute training session on how to setup and use the device, and a therapist will assign you exercises to perform with the device at home. At this time, you may also be asked to wear a device called the Manumeter, or Migo,for 24 hours, and then mail it back to the research team. The Manumeter is a device that includes a wrist-watch and a ring in order to measure how much you are using your hand at home. Return postage will be provided.

Next, you will take the FitMi device home, where you will be instructed to perform at least three hours of exercise per week for three weeks. During this time, you may receive periodic phone calls from the study therapist to ensure you are not having any difficulties with the device or experiencing any pain.

After the three-week exercise period, you will be asked to return to Gross Hall or Hewitt Hall on the UCI main campus. At this point, you will return the FitMi device, and an examiner will repeat the assessments that were performed at the beginning of the study. You may also be asked to wear the Manumeter for 24 hours again.

Finally, you will be asked to return to Gross Hall or Hewitt Hall one month later. At this visit, the examiner will again repeat the assessments that were performed at the beginning of the study. You may also be asked to wear the Manumeter for 24 hours again.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious.

Known risks and side effects related to the study include a small of muscle fatigue, muscle soreness, or joint pain due to increased physical activity. Should any of these risks arise or persist, you will be instructed to cease therapy until the problem has been resolved. At this point, the staff research therapists/physicians will evaluate you and provide a recommended course of action.

If you are asked to wear the Manumeter, there are other risks, including:

- The ring or watch could irritate the skin of the finger or wrist.
- The ring may stick to a metal object if it is placed against it. This risk is more serious if that metal object is sharp or hot (e.g. a knife or a pot on the stove). However, the magnet is not very strong, so it would be unlikely to pull your finger towards a metal object unintentionally.
- If you were to fail to remove the ring during an MRI scan, then the ring could move quickly toward the MRI magnet, injuring you. This is a normal risk associated with wearing any ferromagnetic jewelry and MRI.
- The magnetic ring could interfere with a pacemaker. Therefore, if you use a pacemaker, you will be excluded from using the Manumeter.

Randomization:

In this study, you will be assigned to perform certain types of exercises with FitMi by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less effective or to have more side effects than the other study group(s), or than standard treatments available for your condition.

Psychological discomforts:
Some of the procedures may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop.

Unknown risks:
There may be risks related to the research that we don't know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly-identified risks.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation
You will be paid $40 in cash at the end of each study visit, for a maximum of $ 160 for the four visits. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits and/or procedures that you have completed.

Reimbursement
You will be refunded for the following expenses that you incur:

- Parking fees
- Transportation fees if you need to take a ride service
- $20 if you use your own vehicle for transportation

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for participation in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California, the study sponsor Flint Rehabilitation Devices, LLC, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for a final close-out visit.

If you elect to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
All identifiable information that will be collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data in case we need to confirm results that are still be generated by ongoing analysis, or in case we decide to do a long-term follow-up of the benefits of the training.

Data Storage

All research data will be maintained in paper format in a secure location at UCI. Only authorized individuals will have access to it. Research data will be stored electronically on a secure computer in an encrypted file with password protection. The video recordings will also be stored in a secure location; then transcribed and erased at the end of the study.

Data Retention

In accordance with UC Office of the President policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, the study sponsor, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ClinicalTrials.gov

ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Investigator Financial Conflict of Interest

Dr. Reinkensmeyer has financial interests in Flint Rehabilitation Devices, a company with interests related to this study. Flint manufacturers the FitMi pucks. Dr. Reinkensmeyer is a co-founder of Flint Rehabilitation Devices and member of the board of managers. Dr. Reinkensmeyer also owns stock and received consulting income, which is in addition to his salary from the University of California, Irvine.

The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee (COIOC). The COIOC has determined that the researcher's financial interests are appropriately managed as to avoid compromising the quality or reliability of the study and furthermore, the UCI Institutional Review Board has determined that appropriate safeguards are in place to avoid adversely affecting your safety and welfare.

Photo Release

I authorize the University of California Irvine Biorobotics Laboratory to photograph or permit other persons to photograph me while participating in a research study, and agree that the negatives, prints, or digital files may be used for such purposes and in such manner as may be deemed necessary.

I agree to hold harmless the University of California, its officers, agents and employees from any liability resulting from or arising in connection with the taking, publication, and release of photographs of the participant pursuant to this agreement.

☐Yes
☐No

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact the UCI Institutional Review Board by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

_____ _____

Subject Signature **Date**

_____

Printed Name of Subject

_____ _____

Signature of Person Obtaining Informed Consent **Date**

(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

_____

Printed Name of Person Obtaining Informed Consent

A witness signature is required on this consent form only if: ***(Researchers: check which one applies)***

IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive
research procedures).

For the witness:

I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____

Witness Signature **Date**

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____

Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.