TITLE:	FitMi AD: a safe and motivating computer-guided exercise system for individuals with MCI or mild dementia due to Alzheimer's disease
PROTOCOL NO.:	2R44AG063651-02
SPONSOR:	National Institutes of Health; Flint Rehabilitation Devices, LLC
SITE INVESTIGATOR:	John De Beixedon MD
STUDY-RELATED PHONE NUMBER(S):	626-395-7732

Subject's Name: _____ **Date**: _____

PLEASE READ THIS CONSENT CAREFULLY

This consent form contains important information that will help you decide if you want to participate in this research study. Please ask the study doctor or the study staff to explain any words or information not clear to you.

Read this consent form carefully before making any decisions. The study staff is available to answer ANY questions about anything that is not clear. You may take home an unsigned copy of this consent form to think about and discuss with family and friends. You will get a copy of the signed consent form if you choose to participate in the study.

INFORMED CONSENT FORM

KEY INFORMATION

The following is a short, concise summary of this study and to help you decide if you should participate. If you are interested in participating, more detailed information is included later on in this form.

1. Participation in this research study is voluntary. It is your choice.

2. You are being asked to take part in a research study because you have a diagnosis of mild cognitive impairment or mild dementia due to Alzheimer's Disease. The purpose of this research study is to evaluate a new exercise program for individuals with mild cognitive impairment or mild dementia to perform home-based exercises. Your participation will last a total of three months, consisting of an initial clinic visit, three months of exercise at home, a 6-week (mid-point) clinic visit, and a follow-up clinic visit after the 3 months of home exercise. We will perform a series of assessments to determine your eligibility to participate in this study and to determine your movement abilities. You will be asked to perform guided exercises with a therapist or to take an FDA-listed exercise tool home for three months in order to do exercises at home. At the end of 3 months, you will be asked to return to the clinic to assess any changes in your movement abilities over time. More detailed information about the study procedures can be found under the "Procedures" section.

3. There are risks from participating in this study. The most common risks are fatigue or muscle soreness from the exercise. There is also a small risk that your private medical information could be shared with individuals who are not members of the study team. More detailed information about the risks of this study can be found under the "Risks and Discomforts" section.

4. 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.

5. If you decide not to join this study, your only alternative is not to participate in this study.

DETAILED CONSENT INFORMATION

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to evaluate and improve a device called FitMi AD for performing exercises at home in individuals with MCI or mild dementia due to AD.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 15 participants will take part in this study. Subjects will be enrolled at Havana Research Institute (HRI).

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 older than 50 years of age, have MCI or mild dementia due to AD (i.e. Clinical Dementia Rating (CDR) score 1 for mild dementia or 0.5 for MCI); are able to clearly see the screen and hear the audio instructions from the FitMi AD tablet; have a family member or friend who can answer questions about the your daily living skills; and are willing to participate in a research study.

Exclusion Requirements
The principal investigator may choose to exclude you from participating due to other medical conditions. You cannot participate in this study if use a wheelchair as a primary mobility device (use of a cane or walker is permitted); if you have other neurologic conditions such as movement disorders or history of stroke; and other severe concurrent medical conditions that may prevent you from completing the 3-month study. You will not be prevented from engaging in any additional exercise activities or rehabilitation that you may receive for normal care.

HOW LONG WILL THE STUDY GO ON?
This study will last a total of three 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 be assigned to either an intervention or a conventional therapy group, where you will be asked to perform at least 30 minutes of exercise each day for three months. You will be invited back to the clinic for an assessment, lasting about 1-2 hours, after 6-weeks (midway) and three months (follow up). Assessments may be spread out over two days or conducted over the phone.

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 and supplements (if any).
- To further help understand your background, we will ask for your permission to allow us to obtain information about your AD diagnosis from your medical records.
- The examiner will perform a brief assessment to ensure that you can move your arms and legs enough to take part in this study.

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 additional procedures and tests done.

During the main part of the study...
At the baseline evaluation, you will be asked to perform several functional assessments. For these assessments, a research therapist will instruct you to perform a motion, like standing up from a chair

or walking a short distance, then will score how many repetitions, how fast, or how well you do the movement. The therapist will also take your blood pressure and heart rate. Here is a list of the assessments you may be asked to do:

- Clinical Dementia Rating (CDR) – assesses cognitive impairment
- Functional Reach Test (FRT) – how far can you reach while standing in a fixed position
- Timed UP and Go Test (TUG) – you stand up from a chair and walk a short distance and the therapist times you
- 30 second chair stand test (30CST) – stand up as many times as you can in 30 seconds
- Intrinsic Motivation Inventory – you rate how motivated you are on a scale
- Global Physical Activity Questionnaire (GPAQ) -- assesses physical activity habits
- Geriatric Depression Scale (GDS15) -- evaluates depression in elderly individuals
- Pittsburgh Sleep Quality Index (PSQI) -- measures quality and patterns of sleep in adults
- Visual analog pain scale -- indicate your perceived pain intensity
- Heart rate and blood pressure – the therapist measures these with a blood pressure cuff
- AD Assessment – you will perform specific exercises with the FitMi AD pucks under therapist supervision

If you are eligible to continue after the baseline evaluation, you will be randomly assigned into either the FitMi AD therapy or conventional therapy groups based on drawing a number from a bag. There is 50% chance you will be in the FitMi AD group and a 50% chance you will be in the tried-and-true conventional therapy group.

If you are randomized into the FitMi AD group, you will be given a FitMi device with a touchscreen tablet that has the FitMi AD software pre-installed. The FitMi device is listed with the FDA as a Class I exercise device, and it complies with all regulatory requirements. 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 MiGo on each wrist for 24 hours, and then mail it back to the research team. The MiGo is a wrist-watch with sensors inside to measure how much you are using your hands and arms at home. Return postage will be provided.

Next, you will take the FitMi AD device home, where you will be instructed to perform at least 30 minutes of exercise each day for three months. During this time, you will receive periodic phone calls from the study therapist to ensure you are not having any difficulties with the device or experiencing any pain.

If you are randomized into the conventional therapy group, you will receive a notebook with a printed sheet of exercises. The exercise options and recommended dosage will be the same for both groups. After 6 weeks, you will be asked to return to RRI to repeat the assessments that were performed at the beginning of the study. You will be asked to return one more time for assessment after the three-month exercise period is complete. You may also be asked to wear the MiGos for 24 hours again. At this point, you will also return the FitMi AD device if you were given one.

WHAT ARE THE POSSIBLE BENEFITS TO PARTICIPATING IN THE STUDY?

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.

This study will help researchers learn more about the best way to facilitate exercise at home in individuals with MCI or mild dementia due to AD and it is hoped that this information will help future patients with similar conditions.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

You may have side effects while in 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 possibility 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 a female, you must not get pregnant while in this study. If you are a woman of child-bearing potential, you will be given a urine pregnancy test before you begin the study to make sure that you are not pregnant. The effect of the study device on the developing fetus during pregnancy and the risk of birth defects are unknown or may be unforeseeable.

Randomization:

In this study, you will be assigned to perform certain types of exercises with FitMi AD 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.

Breach of confidentiality:

There is a small risk that people who are not connected with this study will learn your identity or your personal information.

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.

WHAT ARE THE ALTERNATIVES TO NON-PARTICIPATION?

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

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

The maximum total payment for participation in this study is $270. You will be paid $50 after each in-person evaluation visit at baseline, 6-weeks, and at the end of the three-month exercise period.

Twelve follow-up phone calls will take place during the study. You will be paid $10 for completing each of those phone calls. 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.

Payments will be provided as a check. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

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?
Emergency medical care will be made available at Havana Research Institute if you are here undergoing care. Otherwise, you should use your usual medical resources (i.e., paramedics, emergency room, etc.).

If you become ill or get an injury as a result of this study, you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

If the illness or injury is the result of participation in the therapy sessions or functional evaluations in this study, payment for the treatment will be your responsibility. If you have an injury or illness from use of the investigational device (FitMi AD) required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the study doctor and study sponsor have decided that the injury or illness is directly related to the investigational device and is not the result of the therapy, functional evaluations, a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
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. You are not waiving any of your legal rights by signing this consent form. Your decision will not affect your future relationship with Havana Research Institute or your quality of care at Havana Research Institute. 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.

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?

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 being 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 HRI. 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.

Data Retention
The researchers intend to keep the research data for approximately 6 years.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized Havana Research Institute (HRI) personnel, Rancho Research Institute, the study sponsor, and the Rancho Research Institute Institutional Review Board (a committee that reviews and approves research studies to protect your rights) may inspect and copy records pertaining to this research. Other regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) may also access your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-RRI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information about you.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA Authorization document. You will be asked to sign a separate HIPAA Authorization for Research form authorizing the access, use, creation, and disclosure of your health information.

IRB NUMBER: IRB #501
IRB APPROVAL DATE: 10/19/2023
IRB EXPIRATION DATE: 09/17/2024

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.

ClinicalTrials.gov is a Website 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 Website 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.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions, complaints or concerns or believe you may have developed an injury related to this research, contact the Principal Investigator, John De Beixedon MD at telephone number 626-395-7732.

If you have questions regarding your rights as a research participant, you may contact the Havana Research Institute at 626-395-7732 and/or the Rancho Research Institute Institutional Review Board at 562-385-6299.

You can contact a 24-hour number (626-395-7732) to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

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.

You will be given a copy of this signed and dated consent form to keep.

SUBJECT'S CONSENT

I have read this consent form. My questions have been answered and I will receive a copy of this consent form to keep. I voluntarily consent to participate in this study involving the procedures stated above, with an understanding of the known possible risks that might occur and with an understanding that not all such risks may be completely known. I am aware that I may not benefit directly from my participation in this study. I am authorizing the use and disclosure of my personal health information. I understand that I cannot participate in this research study without this authorization. If I refuse to give my authorization, my medical care will not be affected.

By signing this consent form, I am not giving up any legal rights. I also understand that nothing in this consent form is intended to change any applicable federal, state or local laws regarding informed consent.

This consent form has been fully explained to me and I want to participate in this study.

Subject's Signature	Subject's Printed Name	Date

PERSON OBTAINING INFORMED CONSENT

I certify that I have reviewed the contents of this form with the person signing above, who, in my opinion, understood the explanation. I have explained the known risks and benefits of the research.

Person Obtaining Consent's Signature	Person Obtaining Consent's Printed Name	Date

This consent form will be used only for English speaking persons.

You will get a copy of this form after it is signed

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