FitMi PD: an affordable home therapy device for individuals with Parkinson's disease

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University of Southern California
Division of Biokinesiology and Physical therapy

Study Title: A feasibility study of FitMi PD for unsupervised at-home exercise therapy for individuals with PD

Principal Investigator: Beth E. Fisher, PT, Ph.D., FAPTA

Co-investigator: Giselle Petzinger M.D.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____Time: _____

Signature: _____
(Research Participant)

Signature: _____
(Parent or Legally Authorized Representative)

If signed by other than the research participant, indicate relationship: _____

INFORMED CONSENT FOR RESEARCH

Study Title: A feasibility study of FitMi PD for unsupervised at-home exercise therapy for individuals with PD

Principal Investigator: Beth E. Fisher, PT, PhD, FAPTA

Department: Division of Biokinesiology and Physical Therapy

24-Hour Telephone Number: 323-442-7509

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. If you find any languages difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

KEY INFORMATION

The following is a summary of this study to help you decide whether you should participate. More detailed information is listed later in this form.

1. Being in this research study is voluntary–it is your choice.

2. You are being asked to participate in this study because you are diagnosed with Parkinson's Disease. The purpose of this study is to develop an exercise technology called "FitMi PD" and test its feasibility to promote a safe and feasible home-exercise regime for individuals with Parkinson's Disease. In this study, you will participate in a home-based exercise regime for 3-weeks. You will visit the Neuroplasticity and Imaging Laboratory or your preferred [re+active] Physical Therapy and Wellness Center twice to answer a few questionnaires/surveys and for the training with FitMi PD.

3. There are no major risks from participating in this study. However, if you have not been exercising for a long time, exercise regime can result in mild fatigue and muscle soreness during initial phase of the intervention.

4. You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us to understand the exercise needs for individuals with PD and to develop a safe and feasible way to provide at-home exercise devices specific to individuals with PD.

5. If you decide not to participate in this research, your other choices may include not participating in this study.

DETAILED INFORMATION

PURPOSE

Previous studies have shown the positive effects of exercise therapy on individuals with Parkinson's Disease (PD) to slow their disease progression, improve their motor function, gait, strength, balance and quality of life. However, there is a growing need to promote home therapy options that are optimized to safely promote activity in older individuals with PD. Hence, the purpose of this study is to develop a commercially available exercise technology that is specifically tailored to address the problems faced by individuals with PD.

We hope to develop a device with an in-built library of exercises that could provide a myriad of options similar to a conventional PT regime. You are invited as a possible participant because you are diagnosed with Parkinson's Disease. About 20 participants will take part in the study. This research will be funded by the National Institute of Aging at the National Institute of Health.

PROCEDURES

Screening and Intake Assessment:
If you agree to participate, you will be asked to respond to brief questionnaires about your medical history. You have the right to refuse to answer any question that you may not wish to answer. You will undergo further testing to assess your current physical activity, PD-related functional impairments and quality of life. The results of the screening session will be used only for this research and will not become part of your medical record. The screening and intake assessment duration will be no more than 30 minutes.

You will be excluded from the study if you have a serious medical illness, have a diagnosis other than PD, a history of musculoskeletal injuries that would interfere with exercise regimen, and difficulty understanding the instructions. **You must inform the investigator if any of these situations apply to you**.

Pre-Testing Phase:

Once you finish the interview, you will undergo initial testing and training with the device at one of the following locations of your choice for approximately 3 hours: a) Neuroplasticity and Imaging Laboratory (NAIL) on the USC Health Sciences Campus, b) Rogue Physical Therapy & Wellness at Fountain Valley, CA, [re+active] Physical Therapy and Wellness at 11500 W. Olympic Blvd., #415, Los Angeles, CA or [re+active] Physical Therapy and Wellness at 3848 W. Carson St., Suite 110, Torrance, CA. Initial testing will include testing of cognition level, PD-related functional deficits, and answering a few questionnaires that help to determine your quality of life and daily routine affected by PD.

- PD related functional deficits: Unified Parkinson's Disease Rating Scale (UPDRS)- II & III
- Measuring cognition: Mini-Mental State Examination

Questionnaires
You will be asked to answer various questionnaires at the start of this study. You can opt-out of answering any questions if you are uncomfortable. These include:

- Global Physical Activity Questionnaire (GPAQ)

- Parkinson's Disease Questionnaire (PDQ)
- Parkinson's disease Quality of Life Questionnaire (PDQLQ)

Device information

FitMi consists of two wireless input devices ("Pucks" in yellow and blue) that measure your movement, compression force, & touch events and provide haptic feedback in the form of vibration. These Pucks communicate with the exercise software on a computer or tablet in order to sense and direct exercises. To perform exercises, you will place the Pucks at locations specified by the software or strap them to your body segments, and then manipulate the Pucks or move through a specified range of motion. The software analyzes the sensor inputs in real-time, detecting when you complete an isolated repetition of the target exercise and providing motivating feedback.

Device training

You will be trained to use FitMi PD under supervision by research personnel who will provide initial instruction on how the system works and then guide you through a practice session. You will play through a few exercises in the software until you have demonstrated that you can use the system on your own. After the supervised practice session, you will be invited to take home a FitMi PD system with tablet and exercise software pre-installed. You will also receive a copy of the device information and instruction leaflet along with the device.

Training Phase:

You will exercise for a total of 3 hours/week at the times and durations of your choosing for 3 weeks. A trained therapist will discuss with you some exercise movements that will be appropriate for you from the exercise library installed in the device. The exercise should be performed on a soft stable surface (mat or carpet) and near a table for support whenever required. The mats will be provided to you if you do not have mats or a carpeted floor upon which you need to perform the exercises.

During this period, you can contact the research personnel at this number: (323) 442-1196 (Pooja Iyer, PT, MS)

Follow-up /Post-Testing Phase:

You can do the follow-up/post-testing at either of the two preferred locations of your choice for approximately 3 hours: Neuroplasticity and Imaging Laboratory (NAIL) on the USC Health Sciences Campus,Rogue Physical Therapy & Wellness at Fountain Valley, CA or either of two [re+active] Physical Therapy and Wellness sites (Los Angeles, 90064 or Torrance).
After 3 weeks, you will return for follow-up. At this point, the research personnel will extract the total number of hours of exercise therapy from the tablet. We will also administer questionnaires to get your feedback. The questionnaires will include:

- Confidence in the ability to maintain an exercise program (CONF)
- Exercise control Beliefs (BEL)
- Self-Efficacy for exercise scale (EFFIC)
- Perceived value and usability of the device (IMI)

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- *Risks associated with the device:* There are no risks associated with the device. There is a possibility of difficulty in wearing hip sensors. If this difficulty arises, a Velcro strap will be provided to help the user.

- There are no major risks from participating in this study. However, if you have not been exercising for a long time, exercise regime can result in mild fatigue and muscle soreness during initial phase of the intervention

WHAT ABOUT PREGNANCY?

Your participation will not be affected if you're pregnant as device only collects movement data.

WILL YOUR INFORMATION BE KEPT PRIVATE?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that is made up of professionals and community members who review and monitor research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

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WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You will not benefit directly from participating in this study. However, results from this study may help us to develop strategies for reducing fall risk in older adults with an elevated concern of falling.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to take part in this study.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

The participants will be compensated 150$ after completing the home-based exercise protocol. You will be compensated 150$ regardless of the number of sessions completed by the participants.

WHAT ARE THE COSTS?

There is no cost to you for taking part in this study. The study drug/device will be provided by the sponsor free of charge while you are participating in this study.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You and/or your health plan/insurance will be billed for this treatment. The study sponsor will not pay for this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this information with you. You might change your mind about being in the study based on this information.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled. If withdrawal must be gradual for safety reasons, the PI or the research personnel will tell you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your records. If you agree, this data will be handled the same as the research data. No new information or samples will be collected about you or from you by the study team without your permission.

The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

PARTICIPANT TERMINATION

You may be removed from this study without your consent for any of the following reasons: you do not follow the study investigator's instructions, at the discretion of the investigator or the sponsor, your condition gets worse, or the sponsor closes the study. If this happens, the study investigator will discuss other options with you.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Pooja Iyer, PT, DPT at (323) 442-1196 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact Pooja Iyer at (323) 442-1196 and Beth Fisher at (323) 442-2796. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-442-0114 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Email at irb@usc.edu).

If you have any questions about your rights as a research participant or want to talk to someone independent of the research team, you may contact the USC Institutional Review Board Office at the numbers above or write to the USC Institutional Review Board at 3720 S. Flower St., Suite 325, Los Angeles, CA 90089.
You will get a copy of this consent form.

OPTIONAL VIDEOTAPING:

Please indicate whether or not you agree to be videotaped with a regular digital camera while performing the study task. You do not have to agree to be videotaped in order to take part in the study.
I agree to be videotaped while performing the study task.

☐ YES ☐ NO

STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time*)

Legally Authorized Representative

Name of Legally Authorized Representative	Signature	Date Signed (and Time*)

In case of Pregnant Women (Leave blank if not applicable)

Name of Father of Unborn Child	Father's Signature	Date Signed (and Time*)

Person Obtaining Consent

I have personally explained the research to the participant [and/or the participant's legally authorized representative] using non-technical language. I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)

Name of Witness	Signature	Date Signed

*[**A Witness is Required When**: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.]*