Title: FES-Rowing: Preventing the Secondary Conditions of Paralysis Through Vigorous Exercise- A Survey Study of User Needs

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PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

J. Andrew Taylor, Ph.D.

PROTOCOL TITLE

FES-Rowing: Preventing the Secondary Conditions of Paralysis Through Vigorous Exercise - A Survey Study of User Needs

FUNDING

NIH

VERSION DATE

12/14/21

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Primary aim:

1. Collect data pertaining to motivation, preferences and challenges for performing exercise in patients with lower-limb paralysis.
2. Translate responses into design requirements for a new FES-rowing system.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Lack of exercise is a major cause of secondary health conditions, especially for people with paralysis,for whom participation in physical activity is especially difficult. Since the 1980s, functional electrical stimulation (FES) has been used to aid people with paralysis in achieving higher levels of physical activity by activating their paralyzed muscles, enabling exercise with more active muscle mass. Recently, we demonstrated that indoor rowing with FES-assisted leg action (FES-rowing) provides a more robust exercise stimulus for people with paralysis than other options currently available because of the greater active muscle mass and attendant aerobic demand. Several studies have validated that FES-rowing enables even quadriplegics to achieve and sustain activity levels high enough to result in substantial health benefits. Now, FES-rowing is central to our ExPD Program at Spaulding Rehab, which has 60+ active participants with paralysis.

Despite this success, FES-rowing systems have not yet evolved beyond research prototypes, and ours is the only program in the US where FES-rowing is available. A new design is *critically needed* to enable people with paralysis to participate in FES rowing in their own homes, which we believe will maximize both the health and commercial impacts of FES-rowing. Without this, people with paralysis will continue to suffer the high healthcare costs and diminished life expectancy associated with secondary conditions that can be prevented through vigorous exercise.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

The purpose of this study is to begin the process of developing a new, home based FES-rowing system that meets the needs of people with paralysis. We will enroll a total of 20 subjects, male and female, 18 years and older with lower-limb paralysis who use a wheelchair as their primary means of mobility. Ten subjects will be current FES-rowing participants (especially those doing FES-rowing at home) and 10 subjects will be non-participants. To determine user needs we will survey prospective customers to discover their motivations, preferences and challenges pertaining to participation in physical activity in general and FES-rowing. Only the FES-rowing subjects will answer the Quebec User Evaluation of Satisfaction with Assistive Technology (Quest 2.0)

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

The purpose of this observational study is to gain insights into user needs, and market perception of physical activity and FES-rowing to further develop a new, home-based FES-rowing system that meets the needs of people with paralysis. Participants may come to the Cardiovascular Research Laboratory to answer several short questionnaires. Subjects will also be able to answer the questionnaires during a phone interview or zoom teleconference with study staff. We will recruit a total of 20 subjects (10-current FES-row participants and 10 people who have never performed FES-row exercise).

Questionnaires:

Barriers to Physical Activity Questionnaire for People with Mobility Impairments (BPAQ-MI): *measures barriers to physical activity across the intrapersonal, interpersonal, organizational, and community domains.*

Physical Activity and Disability Survey (PADS): *measures physical activity for people with chronic neurological conditions.*

Demographic and Mobility Questionnaire: *Important information to inform on user and design needs and potential market for at home FES-row system.*

Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0)-(FES-row participants only): *measures satisfaction with current FES-row system used in the ExPD Program.*

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

This study offers no treatment to participants.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Risks to participants will be minimized by following the Spaulding Rehabilitation Hospital Policy and Procedure: General Safety Precautions and Procedures for the Conduct of Human Research Guidelines that has been approved by the SRH Professional Staff Executive Committee and the SRH HRC.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Safety during this study will be monitored in several ways: The program director will be responsible for monitoring the completeness of all data and source documents. The Principal Investigator will monitor the informed consent procedures in accordance with the Informed Consent Compliance Checklist of Partners HealthCare Systems HRQIP. The subjects' data/protocol adherence will be monitored by the research coordinator at each step in the study. Checklists and note pages are used to note any deviations or omissions from the protocols.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

Completing questionnaires will take time, though there is no hypothesized risk or major discomfort to the participant. There is a minor risk of loss of confidentiality; however, ID number only will identify all data. Data with ID number only will be kept on a password protected network drive. All paper forms will be de-identified (ID number only) and kept in a locked filing cabinet in a locked office. A master list linking subject information with ID will be kept in a locked filing cabinet in a locked office or in a password protected file and will be accessible to the PI and select trained study staff only.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

There is no direct benefit to subjects participating in this study. However, other with lower-limb paralysis may benefit in the future from the insights gained in this study

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

People with lower-limb paralysis are representative of the population that stands to potentially benefit from this research as we seek to examine: motivation, preferences and challenges pertaining to exercise with the long-term goal of developing a new FES-rowing system. Program exclusion criteria are based mainly on history of lower-limb paralysis and use of a wheelchair as primary means of mobility.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

People who do not speak English will be excluded from participation in this survey study. Participation will be limited to English speakers as the questionnaires are not translated.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Non-English-Speaking-Subjects.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

We will rely mostly on word of mouth and referrals from the spinal cord injury program, the outpatient therapy department and the Exercise for Persons with Disabilities (ExPD) program at SRN to enroll participants in this program. Flyers will be posted at SRH outpatient sites and/or given to potential subjects along with a phone number to call if they are interested in learning more about the study. Our laboratory has been regularly enrolling SCI patients for research from the ExPD program. A phone script will be used for potential subjects that make initial contact via telephone.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Subjects will be compensated $50 for completing this study. The payment will be sent in the form of a check approximately 3-4 weeks after the completion of all the testing for the time-point.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf

Remuneration for Research Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Remuneration-for-Research-Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Eligible participants will be introduced to the study by study staff (i.e., investigator, research coordinator, or research assistant). We will use a verbal consent procedure with waiver of documentation of written informed consent to enroll participants in this study. Study staff will document verbal consent by signing a copy of the information sheet document and with a note to file describing the verbal consent process. Both documents will be placed in the participant's research file. A copy of the information sheet signed by the person who obtained verbal consent will be provided to the participant in-person, via email or regular mail.

The person obtaining consent will discuss the details of the study with the patient using the study information sheet as a guide and will cover all of the required elements of informed consent, including the purpose of the research, the study procedures, risks and benefits associated with participation, and answer study-related questions from the patient. Participants will be advised that their clinical care will not be affected in any way if they decide to participate or decline participation, and that participation can be discontinued at any time. The PI's telephone number and email address will be provided on the information sheet and other study staff will provide their contact information to patients as appropriate. Patients will be given as much time as they need to consider participation. Consent

may be obtained by study staff in person, during a telephone interview or during a zoom teleconference.

We will comply with the MGB policy on email communication with research subjects by using encrypted email ("send secure" function) or non-secure email if requested by the patient and after they acknowledge understanding of, and verbal agreement to accept, the risks as communicated to them. Their agreement to receive non-secure email, including the date of the agreement, will be recorded in the research records.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Informed-Consent-of-Research-Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

Data will be monitored throughout the duration of the program to ensure the safety of subjects. The research coordinator will monitor the weekly data and the principal investigator will review all abnormal findings during the study.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor

safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

Any serious or non-serious adverse event will be recorded in the participant's study folder and adverse event log and reviewed by the PI. Serious and non-serious adverse events will also be reported to the Human Research Committee in accordance with Human Research Committee reporting guidelines, following the timeframes specified by the Partners Investigator's Guidelines.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The research coordinator or research assistant will be responsible for monitoring the completeness of all data and source documents. The Principal Investigator will monitor the informed consent procedures in accordance with the Informed Consent Compliance Checklist of Partners HealthCare Systems HRQIP.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/DSMP-in-Human-Subjects-Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Reporting-Unanticipated-Problems-including-Adverse-Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

Maintaining research volunteers' privacy and keeping personal identifiers confidential is important to the study staff. All research activity including subject data collection will be performed and stored at Spaulding Cambridge. Subject names, contact information, demographic questionnaire, and other information that can be traced back to the subject will be kept separately from data collected for the study. Personal information will be kept in a locked file cabinet or behind the Partners firewall on a password-protected shared file with access by only study staff and away from data. Collected data will have the subject's identification code and some computer software used to collect data will have the date and time marked on the file. Spaulding Hospital certifies key personnel have completed education on the use of human subjects in compliance with NIH regulations.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Specimens/data will not be sent to research collaborators outside of Partners.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Specimens/data will not be stored at collaborating sites outside of Partners for future use not described in the protocol.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Specimens or data collected by research collaborators outside Partners will not be sent to Partners investigators.