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TITLE: Physical Telerehabilitation in Patients with Multiple Sclerosis with Significant Mobility Impairment

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CONTRACTING ORGANIZATION: TRUSTEES OF COLUMBIA UNIVERSITY
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Purpose: Previous studies clearly established clinical benefits of physical rehabilitation in patients with multiple sclerosis with significant mobility impairment (PwMSMI). The purpose of this project is to conduct a pilot clinical trial aimed at establishing the extent of impact of the proposed patient-centered physical telerehabilitation model on functional and symptom outcomes in PwMSMI. Scope: This report covers activities carried out during the Year 1 of the project. The major tasks during the reporting period comprised Task 1 (Prepare Regulatory Documents and Finalize Research Protocol during Months 1–6), Task 2 (Identify and Enroll Eligible Study Subjects during Months 7–27); and Task 3 (Conduct Randomized Controlled Trial during Months 7–27). Major findings: The Task 1 has been successfully completed. The Tasks 2 and 3 are being implemented as planned. Overall, 31 potentially eligible patients have been screened, out of whom 2 refused, 17 were not interested at the time of recruitment, and 12 patients were consented and enrolled into the study.

15. SUBJECT TERMS

rehabilitation, multiple sclerosis, mobility impairment, telemedicine

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1. Introduction

Previous studies clearly established clinical benefits of physical rehabilitation in patients with multiple sclerosis with significant mobility impairment (PwMSMI). However, multiple barriers limit introduction of rehabilitation in these patients. Telemedicine approaches have potential to significantly improve access of PwMSMI to rehabilitation services but their efficacy has not been evaluated systematically. The purpose of this project is to conduct a pilot clinical trial aimed at establishing the extent of impact of the proposed patient-centered physical telerehabilitation model on functional and symptom outcomes in PwMSMI. The scope of work includes enrollment of 58 PwMSMI who are randomly assigned to telerehabilitation and control groups and followed for six months.

2. Keywords

- Rehabilitation
- Multiple Sclerosis
- Mobility Impairment
- Telemedicine

3. Accomplishments

What were the major goals of the project?
The major goal of the project is to determine the effect of physical telerehabilitation on functional outcomes in PwMSMI with significant mobility impairment in a pilot randomized controlled trial. This report covers activities carried out during the Year 1 of the project. The major tasks during the reporting period comprised Task 1 (Prepare Regulatory Documents and Finalize Research Protocol during Months 1-6), Task 2 (Identify and Enroll Eligible Study Subjects during Months 7-27); and Task 3 (Conduct Randomized Controlled Trial during Months 7-27).

What was accomplished under these goals?
The Task 1 has been successfully completed by Month 6 in compliance with the Scope of Work. It included refinement of eligibility criteria, exclusion criteria, and screening protocol; finalization of consent form & human subject protocol; submission of IRB protocol for Columbia University IRB review; submission of IRB protocol for Military 2nd level IRB review; and submission of annual IRB report for continuing review. The Tasks 2 and 3 are being implemented as planned. Patient recruitment workflow has been successfully established and enrollment into the clinical trial is being carried out according to the enrollment plan. Overall, 31 potentially eligible patients have been screened, out of whom 2 refused, 17 were not interested at the time of recruitment, and 12 patients were consented and enrolled into the study. According to the Projected Quarterly Enrollment plan in the Scope of Work, overall 4 subjects were supposed to be enrolled by the end of the Year 1. As our total enrollment is 12 subjects, the enrollment plan is carried out successfully.

What opportunities for training and professional development has the project provided?
Sinan Zhu, PhD, the study coordinator for this project, completed Clinical Site Coordinator training provided by the Society of Clinical Research Associates (SOCRA).

How were the results disseminated to communities of interest?
Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
During the next reporting period we will continue carrying out comprehensive set of procedures to identify and enroll eligible patients including distribution of recruitment flyers, query preparation and execution for identifying eligible patients in Clinical Data Warehouse, sending invitation letters to potentially eligible participants and following up with subject consenting and recruitment. We are encouraged by high interest of patients with multiple sclerosis and their providers in this study and we will continue working with providers who are treating these patients on reaching out potential study participants.

4. Impact

What was the impact on the development of the principal discipline(s) of the project?
Given the greater mobility disability and greater difficulty with transport that is typically seen in PwMSMI, this home-based telerehabilitation program is expected to have the greatest impact on this group of individuals. The proposed pilot clinical trial will have a major impact on multiple sclerosis treatment by providing evidence on feasibility and clinical impact of innovative model of home-based rehabilitation in PwMSMI.

What was the impact on other disciplines?
Nothing to Report.

What was the impact on technology transfer?
Nothing to Report.

What was the impact on society beyond science and technology?
The results from this project are likely to make a significant impact on modern approaches for providing rehabilitation services to people with significant mobility impairment. This project paves way for utilizing information technology to improve functional status and quality of life for people who has mobility disability and limited access to life-long rehabilitation services.

5. Changes/Problems

Nothing to Report.

6. Products

Publications, conference papers, and presentations
Other publications, conference papers, and presentations: Wood J, Finkelstein J. Telerehabilitation System to Support Multipronged Exercise in Patients with Multiple Sclerosis. Accepted for presentation at the IEEE International Conference on Bioinformatics and Biomedicine (BIBM), Kansas, MO, November 13-16, 2017.

7. Participants & Other Collaborating Organizations

What individuals have worked on the project?

Name: Dr. Joseph Finkelstein
Project Role: PI
Researcher Identifier (e.g. ORCID ID): orcid.org/0000-0002-8084-7441
Nearest person month worked: 5 calendar months
Contribution to Project: Dr. Finkelstein is the PI to oversee the overall project.

Name: Dr. Joel Stein
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 calendar months
Contribution to Project: Dr. Stein provides guidance on optimal approaches for rehabilitation in patients with severe mobility impairments due to multiple sclerosis.

Name: Dr. Ying Wei
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 calendar months
Contribution to Project: Dr. Wei provides data analysis and interpretation of the study results and oversees data collection and study fidelity

Name: Jeffrey Wood
Project Role: Technical Analyst
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4 calendar months
Contribution to Project: Mr. Wood is responsible for maintaining study databases and for providing technical assistance to the study subjects.

Name: Adam Blanchard
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3 calendar months
Contribution to Project: Mr. Blanchard conducts blinded research evaluation of all study subjects using the assessment tools.

Name: Lauri Bishop
Project Role: PT-clinical eval. and Research Physical Therapist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 calendar months
Contribution to Project: Dr. Bishop conducts clinical evaluation of all study subjects and prescribe individual exercise plan based on patient evaluation, as well as follows the patients throughout duration of the study, review system alerts and respond correspondingly.

Name: Sinan Zhu
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 calendar months
Contribution to Project: Dr. Zhu works with PI on submitting IRB protocols and developing the study manual, and oversee patient enrollment and follow-up on a daily

8. Special Reporting Requirements

N/A

9. Appendices

N/A