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

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14. ABSTRACT Purpose: The clinical benefits of physical rehabilitation in patients with multiple sclerosis with significant mobility impairment (PwMSMI) have been well documented. However multiple barriers limit ability of these patients to continuously participate in rehabilitation programs. 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 2 of the project. The major tasks during the reporting period comprised 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 2 was successfully completed. The Task 3 has been implemented as planned. Overall, 91 potentially eligible patients were recruited, 74 patients were screened, and 58 patients were consented and enrolled into the study.					
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1. Introduction

The clinical benefits of physical rehabilitation in patients with multiple sclerosis with significant mobility impairment (PwMSMI) have been well documented. Life-long engagement in physical rehabilitation is required in these patients to reduce functional decline. However multiple barriers limit ability of these patients to continuously participate in rehabilitation programs. 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 2 of the project. The objectives during the reporting period comprised the Major Task 2 (Identify and Enroll Eligible Study Subjects during Months 7-27); and the Major Task 3 (Conduct Randomized Controlled Trial during Months 7-27).

What was accomplished under these goals?

The Tasks 2 and 3 have been implemented as planned. Patient recruitment workflow has been successfully established and enrollment into the clinical trial and patient follow-up are being carried out according to the enrollment plan. The patient enrollment target (N=58) for this study has been successfully reached. Overall, 91 potentially eligible patients have been recruited, 74 patients were screened, and 58 patients were consented and enrolled into the study. We believe that our strategy of reaching out to multiple sclerosis centers located in our geographical area and engaging neurologists in referring MS patients with severe mobility impairment for potential participation in our study resulted in successful patient enrollment on a timely basis.

Initial descriptive analysis demonstrated that there was no difference in major patient characteristics between the control (C) and intervention (I) groups: Age (C: 54±12, I: 55±12), Years with MS (C: 19±13, I: 20±12), Years of education (C: 15±3, I: 15±3), Annual relapse number (C: 0.6±1.42, I: 0.7±1.96), ER visits in the last 3 months at the baseline (C: 0.2±0.43, I: 0.3±0.58). There was no difference between the study groups (C vs. I) in the distribution of the following sociodemographic parameters: Gender (C: 73-27, I: 77-23, F-M), Ethnicity (C: 14-86, I: 12-88, Hispanic: yes-no), Born in US (C: 18-82, I: 21-79, no-yes), Internet use (C: 87-13, I: 84-16, once a day vs. less than once a day).

A comparison of functional outcomes at baseline and 3-month using paired t-test identified statistically significant improvement only in the intervention group whereas changes in the control group did not

reach statistical significance. Preliminary analysis in the intervention group demonstrated positive statistically significant changes in Multiple Sclerosis Impact Scale (MSIS) ($t=2.714$, $p=0.013$), Modified Ashworth Scale ($t=2.760$, $p=0.015$), and Berg Balance Scale ($t=-2.950$, $p=0.021$). No significant differences were found in these parameters in the control group.

What opportunities for training and professional development has the project provided?

Good Clinical Practice (GCP) training has been completed by all project members.

How were the results disseminated to communities of interest?

The results of this project were presented at the 7th International Conference on the Global Telehealth (GT2018) conducted by the International Medical Informatics Association (IMIA).

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 follow up patients according to the study protocol. The Major Task #3 (Conduct Randomized Controlled Trial) will be completed by the Month 27 of the study. The major Task #4 (Data Analysis) will commence on the Month 28 and will be completed by the Month 36 of the study.

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

Dr. Joel Stein assumed the responsibilities of the study PI effective 07/01/18.

6. Products

Publications, conference papers, and presentations

Other publications, conference papers, and presentations: Finkelstein J, Liu J. Designing Telerehabilitation System for Multipronged Exercise in Patients with Multiple Sclerosis. Stud Health Technol Inform. 2018;254:16-23. PMID: 30306953.

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:	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 basis

8. Special Reporting Requirements

N/A

9. Appendices

N/A