AWARD NUMBER: W81XWH-17-1-0367

TITLE: Development of a Web-Based Symptom Self-Management Program for Individuals with Multiple Sclerosis

PRINCIPAL INVESTIGATOR: Anna Kratz, PhD

CONTRACTING ORGANIZATION: University of Michigan
Ann Arbor, MI 48109

REPORT DATE: OCTOBER 2019

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2019	Annual Report	15SEP2018 - 14SEP2019

4. TITLE AND SUBTITLE

Development of a Web-Based Symptom Self-Management Program for Individuals with Multiple Sclerosis

5a. CONTRACT NUMBER
W81XWH-17-1-0367

5b. GRANT NUMBER
GRANT12236951

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Anna Kratz, PhD

E-Mail: alkratz@med.umich.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Michigan
Physical Medicine & Rehabilitation
2800 Plymouth Rd NCRC B16 #G031N
Ann Arbor MI 48108-2800

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

This is a revised Annual Report. The original Annual Report, submitted 10/14/2019 was rejected because Specific Aim 3 noted in this report was not called out in the approved SOW with a header/title. A new SOW with the header was submitted.

14. ABSTRACT

The primary objective of the proposed research is to improve management of pain, fatigue, and depressed mood through an online platform that provides education, guidance, and skills-building exercises that are specifically tailored for people with multiple sclerosis (MS). Access to rehabilitation care that focuses on symptom self-management is seriously limited for many individuals with MS due to geographical location, limited resources (e.g. financial, transportation), and/or disability. The objective of this proposal is to expand access to symptom self-management care to all patients with MS, with particular focus on those under-served patients with limited access to symptom management care by developing and pilot-testing a web-based symptom self-management program, called "my MS Toolkit."

15. SUBJECT TERMS

Multiple sclerosis; pain; fatigue; depression; self-management; web-based intervention; pilot study

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	11	USAMRMC

TABLE OF CONTENTS

1. INTRODUCTION

Individuals with multiple sclerosis (MS) frequently suffer from a constellation of co-occurring symptoms that are associated with poorer health, functioning, and quality of life. Three symptoms – pain, fatigue, and depression – are especially common and frequently co-occur in MS. Current standard of care guidelines indicate that providers should offer individually-tailored multidisciplinary outpatient rehabilitation for MS symptoms, including medical management, therapies, and/or behavioral health (e.g., self-management) interventions; and, research indicates that symptom self-management interventions are effective at treating the impact of symptoms in those with MS. However, the vast majority of patients with MS are unable to access such MS specialty care and rehabilitation to help with symptom management. Fortunately, web-based self-management interventions (WEB-SM) have the potential to improve the reach of behavioral health interventions into more of the population via remote delivery and scalability to essentially "meet patients where they are." The primary objective of the proposed research is to improve management of pain, fatigue, and depressed mood through development of a web-based platform (*"My MS Toolkit"*) that provides education, guidance, and skills-building exercises that are specifically tailored for people with MS and build upon existing evidence-based self-management strategies.

The goals of this study to develop and test the feasibility and generate initial effect sizes of a web-based self-management intervention to manage fatigue, pain, and depressed mood in persons with MS, will be achieved through by addressing the following aims: Specific Aim 1: To develop an MS-specific web-based program for self-management of fatigue, pain, and depressed mood symptoms. Specific Aim 2: To examine the feasibility, acceptability and treatment satisfaction of this novel, internet-based symptom self-management intervention for individuals with MS who experience pain, fatigue, and/or depressed mood. Specific Aim 3: To evaluate the impact of *My MS Toolkit* examining self-efficacy and global perceptions of change and treatment response rates from pre- to post- *My MS Toolkit* intervention. This 18-month study will be conducted in two phases. During Phase 1 (months 1-9) the research team will develop a web-based self-management program for MS symptoms, called *My MS Toolkit.* A stakeholder panel of individuals with MS (n=5) will be consulted during the developmental phase to ensure the usability/accessibility and relevance of *My MS Toolkit* to those with MS. During Phase 2 the newly developed *My MS Toolkit* will be pilot tested in a group of 20 people with MS who report clinically significant pain, fatigue, and/or depressive symptoms. Pilot study participants will complete a battery of pre-treatment outcome measures, followed by 12 weeks of intervention (use of *My MS Toolkit*), and then a battery of post-treatment outcome measures. To evaluate the acceptability and feasibility of *My MS Toolkit,* participant responses to a feasibility/acceptability question and program compliance will be examined. To evaluate the impact of *My MS Toolkit,* pre- to post-treatment improvements in self-efficacy to manage symptoms, pain interference, fatigue impact, depressive symptoms, and post-treatment global impressions of change will be examined.

2. KEYWORDS

Multiple sclerosis; pain; fatigue; depression; self-management; web-based intervention; pilot study

3. ACCOMPLISHMENTS

What were the major goals of the study?

The goals of the study were to: 1) develop an MS-specific web-based program for self-management of fatigue, pain, and depressed mood symptoms (Specific Aim 1); 2) examine the feasibility, acceptability and treatment satisfaction of this novel, internet-based symptom self-management intervention for individuals with MS who experience pain, fatigue, and/or depressed mood (Specific Aim 2); and 3) evaluate the impact of My MS Toolkit examining self-efficacy and global perceptions of change and treatment response rates from pre- to post- My MS Toolkit intervention (Specific Aim 3; Note that there was no header for this Aim in the approved Revised_SOW dated May 2017. A re-revised SOW was submitted with this heading "Specific Aim 3: To evaluate the impact of the web-based program on self-efficacy, global perceptions of change, and treatment response rates pre- to post-intervention" added to call out the tasks related to the third aim, accompany this revised final report).

What was accomplished under these goals?

Specific Aim 1: Develop MS-specific web-based program for self-management of symptoms.

We have successfully achieved all milestones related to the first aim of this study. We developed content for the web-based program and worked with a web-development team to produce text, audio, video, and photo content for the website. The website has been fully programmed and beta-tested. Stakeholder input, from a panel of 5 persons with MS (3 women, 2 men), was solicited and informed the development of the website. We conducted two in-person stakeholder meetings, one at the beginning of the study, and one after the website was programmed. We also solicited stakeholder feedback throughout the process through emails and phone calls to stakeholders.

We are currently working with the web development team who created My MS Toolkit to collect web analytic data from during the pilot trial study phase. Once that work is complete, the website will be released to the public (it is currently password protected until web analytic data can be collected).

Specific Aim 2: Pilot test the feasibility, acceptability, and treatment satisfaction of the web-based program.

We just recently finished data collection from N=20 participants to address this specific aim (final study participant completed on 09/25/2019). We are in the process of cleaning and analyzing the data for this aim.

Specific Aim 3: Pilot test the impact of My MS Toolkit in terms of self-efficacy and global perceptions of change and treatment response rates from pre- to post- intervention.

We just recently finished data collection from N=20 participants to address this specific aim (final study participant completed on 09/25/2019). We are in the process of cleaning and analyzing the data for this aim.

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

Nothing to report.

How were these results disseminated to communities of interest?

We are currently working with the web development team who created My MS Toolkit to collect web analytic data for the trial phase of the study (to assess usage of the site during the pilot trial). After that data collection is finished, the website will be released to the public. Our intent is to disseminate news about the *My MS Toolkit* website after the pilot study is completed. We plan to leverage the dissemination capabilities of organizations, such as the national and local (Michigan, Washington) chapters of the National MS Society to disseminate news to MS communities of interest (e.g., patients, caregivers, families, friends, health care providers). We will also engage with the communications office at Michigan Medicine to produce a press release about the website.

What do you plan to do during the next reporting period to accomplish the goals?

We plan to complete data cleaning and analysis related to Specific Aims 2 and 3 and disseminate those findings in a scientific presentation and peer-reviewed publication. The team has submitted a Podium Presentation proposal for the Annual Scientific Meeting of the American Psychological Association Division 22 (Rehabilitation Psychology) to present the data from this study in February 2020 (invitation decision pending). After web analytic data is collected, we will make the website public and advertise the availability of the website, which will be freely and easily accessible to anyone with access to an internet connected device.

4. IMPACT

What was the impact of the development of the principal disciplines of the project?

Given that neither the product of this work (the My MS Toolkit website) nor the findings from the pilot study have yet been disseminated to communities of interest, there has been no measurable impact of this work to date. However, we expect there to be immediate impact on professions

related to MS rehabilitation and health care, people with MS, and the scientific community once this work is disseminated.

What was the impact on other disciplines?

None to report.

What was the impact on technology transfer?

None to report.

What was the impact on society beyond science and technology?

None to report.

5. CHANGES/PROBLEMS

Changes in approach and reasons for change

None to report.

Actual or anticipated problems or delays and actions or plans to resolve them

We have no substantial problems or delays to report. We are slightly behind schedule in terms of the second aim, but have plans to accelerate recruitment and are confident we can catch up to our original timeline.

Changes that had a significant impact on expenditures

None to report.

Significant changes in use or care of human subjects

None to report.

6. PRODUCTS, INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Publications, conference papers, and presentations

- ***Journal publications:***

  None to report. We anticipate publishing empirical findings from Phase 2 data, when complete.
- ***Books or other non-periodical, one-time publications:***

  None to report.
- ***Other publications, conference papers, and presentations:***

  The study team (led by Dr. Kratz) has submitted a Podium Presentation proposal for the Annual Scientific Meeting of the American Psychological Association Division 22 (Rehabilitation Psychology) to present the data from this study in February 2020 (invitation decision pending).

  Websites:

  Work related to Specific Aim 1 has resulted in the creation of a website (www.mymstoolkit.com/)
- ***Technologies or techniques***

  None to report.
- ***Inventions, patent applications, licenses***

  None to report.
- ***Other Products***

  None to report.

7. PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name	Anna Kratz
Project Role	Project Director/Principal Investigator
Research Identifier	0000-0002-3664-3898
Nearest person month worked	1
Contribution to Project	Dr. Kratz has performed work in the area of: Overseeing all aspects of the study, including developing the website content, working directly with web development team to program treatment website, overseeing study personnel, leading team of investigators, developing study protocol for Phase II of the study, assisting staff with regulatory aspects of the study, working with study stakeholders to incorporate patient feedback.
Funding Support	University of Michigan Department of Physical Medicine and Rehabilitation is cost-sharing a portion of Dr. Kratz's salary for this project.

Name	David Williams
Project Role	Co-Investigator
Research Identifier	0000-0002-5052-4895
Nearest person month worked	1
Contribution to Project	Dr. Williams has performed work in the area of: Assisting with developing website content and format, participating in stakeholder meetings, working to incorporate stakeholder feedback.
Funding Support	Not Applicable

Name	Shubhangi Kulkarni
Project Role	Research Coordinator
Research Identifier	Not Applicable
Nearest person month worked	1
Contribution to Project	Ms. Kulkarni has performed work in the area of: Providing scientific and administrative support for website development and programming, organizing, planning, and overseeing stakeholder meetings, recruiting stakeholders, compensating stakeholders, overseeing (with support from PI) all regulatory aspects of the study, collating and summarizing stakeholder feedback.
Funding Support	Not Applicable

Name	Kristen Pickup
Project Role	Research Coordinator

Research Identifier	Not Applicable
Nearest person month worked	1
Contribution to Project	Ms. Pickup has performed work in the area of: Providing scientific and administrative support for website development and programming, organizing, planning, and overseeing stakeholder meetings, recruiting stakeholders, compensating stakeholders, overseeing (with support from PI) all regulatory aspects of the study, collating and summarizing stakeholder feedback. Programming data collection websites, recruiting, enrolling, and collecting data from pilot trial participants. Compensating participants and assisting with data cleaning.
Funding Support	Not Applicable

Name	Dawn Ehde
Project Role	Co-I
Research Identifier	Not available
Nearest person month worked	1
Contribution to Project	Dr. Ehde has performed work in the area of: Assisting with developing website content and format, participating in stakeholder meetings, working to incorporate stakeholder feedback.
Funding Support	Not Applicable

Name	Kevin Alschuler
Project Role	Co-I
Research Identifier	Not available
Nearest person month worked	1
Contribution to Project	Work performed has been: Assisting with developing website content and format, participating in stakeholder meetings, working to incorporate stakeholder feedback.
Funding Support	Not Applicable

Has there been a change in the active other support of the PD/PI or senior/key personnel since the last reporting period?

Anna Kratz

Active			
Project Number:	90ARCP0003-01-00	**Dates of Project:**	09/01/2019 – 08/31/2024
Role	Principal Investigator	**Annual Direct Costs:**	$166,891
Funding Source:	Health and Human Services, Department	**Calendar Months**	0.90 CM

	of-Administration for Community Living, National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)		
Title of Project (or Subproject): University of Michigan Advanced Rehabilitation Research Training Program in Community Living and Participation			
Specific Aims: This proposed 5-year, University of Michigan Advanced Rehabilitation Research Training Program in Community Living and Participation (ARRTP-CP) will train postdoctoral fellows to advance the rehabilitation field by embracing community-based and person-centered research methods. This program is a collaboration between academic researchers at the University of Michigan(U-M) School of Public Health (SPH), Institute for Healthcare Policy and Innovation (IHPI) and the Departments of Physical Medicine and Rehabilitation (PM&R) and Internal Medicine –Divisions of Rheumatology and Anesthesiology, and their community partners. The U-M ARRTP-CP is guided by the principles of competency-based education and assessment in furtherance of individualized training plans that promote achievement of core research competencies.			
Agency Contact:	Mr. Timothy Beatty, 330 C Street, Room 1305, Administration for Community Living, Washington, DC 20202, Phone: 202-795-7306		
Completed			
Project Number:	5K01AR064275-05	**Dates of Project:**	09/01/2013 – 06/30/2019
Role	Principal Investigator	**Annual Direct Costs:**	$130,958
Funding Source:	NIH	**Calendar Months**	9.0 CM
Title of Project (or Subproject): Characteristics and Mechanisms of Cognitive Problems in Fibromyalgia			
Specific Aims: The scientific objectives of this application are to methodically describe the phenotypic nature of fibrofog, examine the neurological processes underlying these cognitive problems, and test the utility of cognitive measures in fibrofog.			
Agency Contact:	Lucas, Butch: Email: blucas@mail.nih.gov		
Project Number:	RG 4986A1/1/UWSC7531	**Dates of Project:**	04/01/2014 – 09/30/2019
Role	Principal Investigator	**Annual Direct Costs:**	$15,717
Funding Source:	University of Washington/NMSS	**Calendar Months**	1.20 CM

Title of Project (or Subproject): Life after MS diagnosis: a biopsychosocial assessment of symptom trajectory	
Specific Aims: Year 1: Dr. Kratz will provide the PI consultation on the selection and administration of outcomes measures and study design. She will establish data collection and data monitoring protocols and will see to it that research staff are following protocols. Once data collection has begun, she will conduct monthly data quality checks for the first three months of the study to assure adherence to study data collection protocols. Years 2 and 3: Dr. Kratz will conduct quarterly data quality checks and troubleshoot problems with data collection and/or entry. She will also conduct quarterly data analyses to ensure that study recruitment is meeting sample requirements in terms of participant demographic and clinical characteristics (e.g. to assure that appropriate numbers of racial minority participants are being recruited) and advise the research team for the need for targeted recruitment efforts. Year 4: Dr. Kratz will ensure that all data are adequately cleaned and conduct standard data integrity analyses. She will complete all primary study statistical analyses (to test the primary aim hypotheses) and will disseminate study findings through peer-reviewed manuscripts and scientific conference presentations.	
Agency Contact:	Christine Krauss; ckrauss@u.washington.edu

What other organizations were involved as partners?

- **Organization Name:** University of Washington
- **Location of Organization:** Seattle, Washington
- **Partner's contribution to the projec**t
  - **Financial support:** None;
  - **In-kind support:** None;
  - **Facilities:** Project collaborators use the partner's facilities for project activities;
  - **Collaboration:** Project collaborators (Co-Investigators) work with the collaborators at University of Michigan (Primary site) on the project;
  - **Personnel exchanges***:* None; and
  - **Other:** None

8. SPECIAL REPORTING REQUIREMENTS

Collaborative Awards

None to report.

Quad Charts

None to report.

9. APPENDICES

None to report.