My MS Toolkit: A Symptom Self-Management Program for Multiple Sclerosis

Informed Consent Document

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Informed Consent

This study is being conducted at the University of Michigan and Dr. Anna Kratz is in charge of the study. The study is funded by the Department of Defense (DoD).

We're doing this research study to learn if the newly developed web-based program My *MS Toolkit* is helpful to improve the symptom self-management in persons with multiple sclerosis (MS). This study will include a group of 20 individuals with Multiple Sclerosis who report clinically-significant pain, fatigue and/or depressed mood.

You will simply be encouraged to explore all aspects of the website, following prompts and guides built into the program, with no additional contact from study professionals during the 12-week study period. My MS Toolkit include text for each of the 8 modules that describes effective symptom selfmanagement strategies, as well as video and/or audio content for particularly crucial information, worksheets for content-specific activities, and summary sheets for you to use as resources. You are recommended to practice and apply the behavioral skills on a regular basis and to revisit the My MS Toolkit site on at least a weekly basis and more frequently when new issues arise.

During the 12-week study period, you will complete brief survey every two weeks (total = 5 surveys) about the program usage. Additionally, you will be asked to complete a survey in the beginning and at the end of 12 weeks period (after the study is concluded). We expect it to take about 20-25 minutes to complete the baseline as well as follow-up survey. The surveys you take every two weeks will take about 5 minutes to complete.

Participating in this study is voluntary. You don't have to participate if you'd rather not. You can skip any survey questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in "Contact Information".

The known or expected risks to you related to the surveys and assessing the website are minimal.

Web-based MS self-management program: It is possible that you may become frustrated/fatigued while exploring all of the aspects of the website or find it difficult or uncomfortable to practice some of the skills. You can stop using the web-based program at any time and can skip any modules that you would like. Additionally, you will be asked at each web-based survey during the study if you experience any negative effects from using the website. You will also receive the contact info for the study staff whom you can contact if you feel uncomfortable from using the website or any of the modules.

Study Questionnaires: Risks of study questionnaire completion include discomfort, frustration, or boredom. You choose not to answer any questions that make you frustrated or uncomfortable and may take breaks as needed when completing the survey questions. You will complete all the questionnaires from your home at your convenience.

Confidentiality: There may be a risk of loss to confidentiality or privacy. To keep your information confidential, we will use a number instead of your name on the study documents and store all of your information in a locked cabinet and/or in password protected files. Although we'll keep a list of all the people who assessed the website and/or answered our survey, no one outside our study team will be able to figure out who answered the survey or which people gave which answers. We plan to publish what we learn from this study, but we won't include any personal information that could reveal who participated in this study.

As with any research study, there may be additional risks that are unknown or unexpected.

You may not receive any personal benefits from being in this study, but, information from this study may benefit other people now or in the future. It's possible that you may see an improvement in your self-management skills to address various MS symptoms as a result of being in this study.

Representatives from the DoD will have access to the records from this study.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

There will be no cost to you for being in this study. To thank you for taking part in our study, we'll send you $20 for completing the initial survey and $30 for completing the last survey at the end of the 12 weeks period. Additionally, you will receive $10 for each survey completed during the intervention (total = $50 for 5 surveys). The University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.

A description of this clinical trial may be available on www.ClinicalTrials.gov. This website will not include information that can identify you. You can search this website at any time.

Contact Information

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Dr. Anna Kratz	Study Coordinator: Shubha Kulkarni
Mailing Address:	Mailing Address:
Department of Physical Medicine and Rehabilitation, University of Michigan Medical School, North Campus Research Complex, 2800 Plymouth Rd., Building NCRC B16, Room G031N	Department of Physical Medicine and Rehabilitation, University of Michigan Medical School, North Campus Research Complex, 2800 Plymouth Rd., Building NCRC B16, G000N-21
Telephone: (734) 647-5982	Telephone: (734) 615-3330
Email: alkratz@med.umich.edu	Email: shubhak@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)

2800 Plymouth Road
Building 520, Room 3214

Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

Phone Consent

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Participant Name

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Name of interviewer/consenter Signature of interviewer/consenter Date