Usability of the MeTime MS Acupressure mobile application in adults with MS

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STUDY PROTOCOL

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BACKGROUND AND SPECIFIC AIM

Background: Multiple sclerosis (MS) is an autoimmune disease of the central nervous system that affects approximately one million people in the United States and is the leading cause of non-traumatic disability in young adults[1-4].

Fatigue is the most common symptom experienced by patients with multiple sclerosis (MS)[5-7]. The majority of persons with MS describe fatigue as their most disabling symptom, surpassing pain and even physical impairment. Fatigue impacts activities of daily living, social interactions, and quality of life, and has profound socioeconomic consequences, including loss of occupation[6, 8-13]. Even patients who outwardly appear unaffected by MS may experience severe fatigue that causes significant functional impairment. Fatigue also remains one of the most difficult symptoms to manage, and a critical need exists to find effective alternatives for managing fatigue in MS.

Chronic pain is one of the most common and disabling symptoms in MS[14-25]. Unfortunately, current pain treatments do not provide sufficient or durable pain relief[26, 27]. Given the lack of effectiveness of conventional treatments for chronic pain, there is a dire need for effective alternatives.

Acupuncture is a component of Traditional Chinese Medicine (TCM) where thin needles are inserted at specific points on the body (*acupoints*) to treat disease and alleviate symptoms. Research over the past three decades has shown that acupuncture is effective for the treatment of chronic pain[28]. Acupressure is a related TCM technique wherein pressure is applied with a finger or device to specific *acupoints*. Acupressure is highly scalable and can be taught to patients for self-administration. Research on self-administered acupressure is in its infancy, though promising initial data indicates that self-acupressure is effective for chronic pain[29, 30] and fatigue[31], with one study suggesting that self-acupressure is effective in reducing fatigue in MS[32]. Research has found significant improvements in pain, fatigue, sleep, and depression in breast cancer survivors[33, 34] and improvements in pain intensity in chronic low back pain with self-acupressure[35]. Although there is evidence that acupuncture is effective at alleviating fatigue and pain in MS[36], well-designed studies of self-acupressure for fatigue and pain in MS are needed to better understand the use of this therapy as complementary and integrative treatment for symptom management.

Dr. Kratz adapted the existing MeTime mobile application for self-administered acupressure developed by Dr. Harris and Dr. Zick. The MeTime Acupressure app was originally developed in association with patient focus groups consisting of cancer survivors and the University of Michigan 3D Media Laboratory. The adapted app, MeTime MS, has been tailored to be more relevant to the MS population, including an updated MS-specific introduction video. Before conducting a trial of self-acupressure for pain and fatigue in adults with MS, we aim to first conduct a usability study of the adapted MeTime MS app in a small sample of adults with MS.

Specific Aim: Assess the usability of the MeTime MS mobile application in adults with MS.

METHODS

Study Sample : We will enroll 10 adults with clinically significant pain and fatigue and MS to use the MeTime MS app for 6 weeks and then participate in a focus group or one-one interview to

assess their experience with using the app. Participants in the study must be diagnosed as having MS by a physician; this diagnosis status will be confirmed through medical record review.

Inclusion and exclusion criteria :
Inclusion Criteria

- MS diagnosis (all MS subtypes included)
- Age 18 years or older
- Average Fatigue Severity Scale (FSS) score ≥ 4 at screening coupled with the opinion of the volunteer that the fatigue has interfered with their daily activities for ≥ 3 months
- Presence of chronic pain defined as moderate to severe pain for ≥ 3-month duration that is ≥ 4 on average using a 0-10 numerical rating scale
- Home access to internet via Wi-Fi or cellular data
- Active email account

Exclusion Criteria

- Not fluent in English
- Pregnancy or breast feeding, or anticipate pregnancy in next 6 months
- Inability to use smartphone/tablet and/or MeTime MS mobile app
- Anything at the discretion of the PI or study team that would preclude participation in the study

Participant Recruitment: Participants will be recruited through existing participant registries, including the Kratz Lab registry (HUM00074021), through the University of Michigan Health System clinic-based referrals, in-person recruitment, electronic medical record reviews, through local support groups and informational groups and national and regional chapters of organizations, such as the National Multiple Sclerosis Society. Flyers may be disseminated in community settings and will be advertised on the www.UMHealthResearh.org website.

Study procedures: After obtaining informed consent, participants will be assigned to use one of two versions of the MeTime MS app (N=5 each in the relaxation and stimulating protocols) for 6 weeks. Participants will be provided with their version-specific access code and may use their own smartphones/tablets or receive a loaner device from the study team. Participants will be given a large pencil with eraser or similar tool for stimulating acupressure points; participants may also elect to simply use their fingers/thumb to stimulate acupressure points.

Baseline visits will be scheduled for after the participant receives the study equipment.

The baseline visit will occur online via Zoom (or similar secure Michigan Medicine supported video conferencing system), with the following assessments and procedures completed:

1) Demographic Information (See table 1)
2) Pain and fatigue medication review (See table 1)
3) Brief online questionnaire via REDCap to characterize the sample (See table 1)
4) Orientation and training about acupressure intervention:
    a. Orientation of MeTime-MS mobile application;
    b. Demonstration of the location of all acupoints;

c. Demonstration of the appropriate amount of pressure to apply to the acupoints and the correct stimulating motion.

Participants will be instructed to begin use of the app the day after the baseline visit.

The study team will contact participants weekly to assess for AEs and remain available for participant questions, concerns, and/or issues.

At the end of the 6-week period, participants will complete a usability measure (adapted System Usability Scale) and participate in a focus group or one-on-one interview. In the focus group/interview, participants will be asked about their experience using the MeTime MS app (e.g. ease of use, relevance to MS, etc.)

Participant compensation: Participants will be compensated $25 for the baseline visit and $75 for the focus group/interview.

Primary outcome: The focus groups/interviews will be used to gather MeTime MS app usability data. If the qualitative information collected indicates the need for substantial change to the app, then a second round of focus groups/interviews will be conducted for the original end users to provide feedback on the updated apps. User feedback will inform improvement to the app and the design of a future clinical trial.

Secondary outcome: The System Usability Scale (SUS)[40] adapted for the MeTime MS app will be used to compliment the primary qualitative data on participant perceptions of the app usability. The SUS has 10 items; the total score ranges from 0-40, with higher scores indicating better usability.

Quantitative analyses, including means, standard deviations, and percentages of the demographics and survey data will be conducted to describe the study sample.

Table 1: Study Measures	
Domain	Measure
	Sample Descriptive Measures
Demographics	Age, race, ethnicity, sex, gender, education level, etc.
Disability Level	Patient Determined Disease Steps (PDDS)[37]
Fatigue	PROMIS Fatigue Short Form 7a[38]
Pain	PROMIS Pain Intensity 3a[39]
Medications	Medications for pain and/or fatigue
	Secondary Outcome Measure
Usability	System Usability Scale (SUS)[40] adapted for the MeTime MS app

Data storage: This study will use REDCap, a secure, password protected, and HIPAA compliant web-based data platform hosted by the Michigan Institute for Clinical and Health Research (MICHR) at the UM for data capture and storage. This protected database will be accessed and maintained by study personnel only. This system features both a local and remote web-based interface, secure data transfer, and an Oracle database. Data security, patient privacy, and HIPAA

requirements are a premium consideration for clinical trials research using REDCap. A complete time-stamped audit of all REDCap activity (including which and when study personnel access data) is maintained, adding to the security and fidelity of the data. Study personnel can enter data into the database through administrative access to add to the self-report data provided by participants. For self-report data collection, participants will access individualized study URLs to securely enter data on an internet-connected device of their choosing (for home-based assessments). The study URLs and REDCap surveys are separate from the acupressure app.

ADVERSE EVENT ASSESSMENTS

Adverse events reported by participants that are 1) NOT related to the normal course or chronic symptoms of MS (such as relapses, MRI progression, somatic pain, weakness, numbness, visual disturbances, bladder/bowel symptoms), and 2) NOT events that are expected to occur in the course of daily life or use of disease modifying therapy (injuries, infections, disease modifying therapy infusion reactions, disease modifying therapy injection site reactions, disease modifying therapy-induced lymphopenia.

SAE events will be collected regardless of relatedness to MS or disease modifying therapy use.

AE/SAE Reporting:

Multiple sclerosis is a disease with many disease-related symptoms and complications, and there are many common mild side effects associated with disease modifying therapy use. Due to the patient population and the nature of the disease, as well as the lack of experimental interventions in this study (only standard of care procedures and treatments will be used) we would like to implement the following AE/SAE collection/reporting guidelines:

SAE events that meet all 3 of the following criteria will be collected and submitted to the IRB within 14 days of notification (or 7 days of notification if event is fatal or life-threatening):

- Serious;
- Related (possibly, probably, or definitely); and
- Unexpected

SAEs that are unrelated, regardless of expectedness, will not be reported to the IRB.

In addition, the following AEs will be collected and submitted to the IRB:

- Any related and unexpected AE that results in a change to research or participant's treatments plan.

All other AEs documented during the study will be reported with scheduled continuation review.

SAE Definition:

An adverse event (AE) is any condition which appears or worsens after a participant is enrolled in an investigational study. An AE does not necessarily have a causal relationship with the study agent.

A serious adverse event (SAE) is an adverse experience to acupressure treatment occurring at any timepoint that results in any of the following outcomes:

a) Death
b) A life-threatening adverse treatment experience
c) Inpatient hospitalization or prolongation of existing hospitalization
d) A persistent or significant disability and/or incapacity
e) A congenital anomaly or birth defect

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse treatment experience when, based upon appropriate medical judgement, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. A serious adverse experience includes any experience that is fatal or immediately life-threatening, results in a persistent or significant disability/incapacity, requires or prolongs in-patient hospitalization, or is a congenital anomaly, cancer, or overdose.

Other important medical events that may not result in death, not be life-threatening, or not require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgement, the event may jeopardize the subject/patient and may require medical or surgical intervention to prevent one of the outcomes listed previously.

AE/SAE Relatedness:

Relatedness of an adverse event may be measured by the following definitions:

a) Definitely related: clearly associated with study treatment
b) Probably related: likely associated with study treatment
c) Possibly related: may be associated with study treatment
d) Unlikely to be related, or
e) Definitely not related to the study treatment

For reporting purposes, an AE should be regarded as definitely or probably related to the regimen if the investigator believes that at least one of following criteria are met:

a) There is a clinically plausible time sequence between onset of the AE and the administration of the study treatment.
b) There is a biologically plausible mechanism for the study treatment causing or contributing to the AE.
c) The AE cannot be attributed solely to concurrent/underlying illness, other drugs, or procedures.
d) A potential alternative does not exist.

AE/SAE Expectedness:

Expected adverse events are those adverse events that are listed in the protocol or in the study informed consent document.

Unexpected adverse events are those that:

a) Are not described in the clinical protocol as far as the study treatment is concerned
b) Are not anticipated in the study informed consent. This includes adverse events for which the specificity or severity is not consistent with the description in the informed consent.

Unanticipated problem: Per FDA Procedural Guidance for Clinical Investigators, Sponsors, and IRBs (January 2009), a serious problem that has implications for the conduct of the study (requiring a significant and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent or investigator's brochure).

Unanticipated problem Reporting: Per 21 CFR 312.66, 312.53 (c)(1)(vii), and 56.108(b)(1), should an unanticipated problem occur during the investigation, the investigator will promptly report all unanticipated problems involving risks to human subjects or others to IRBMED and FDA.

AE/SAE Severity:

The severity of an adverse event may be measured using the following definitions:

Mild: Noticeable to the subject, but does not interfere with subject's expected daily activities, and usually does not require additional therapy or intervention, treatment reduction, or discontinuation of the study.

Moderate: Interferes with the subject's expected daily activities, may require some additional therapy or intervention but does not require discontinuation of the study.

Severe: Extremely limits the subject's daily activities and may require discontinuation of study therapy, and/or additional treatment or intervention to resolve.

APPENDICES

Appendix A: Acupressure procedures in MeTime MS app

Participants will be randomized to the relaxation acupressure treatment, stimulating acupressure treatment, or sham acupressure treatment. Acupoints will be stimulated using the thumb, finger, or other tool (such as a pencil eraser; see Figure 1). Each acupoint will be stimulated for 3 continuous minutes, and in the order provided, starting with the head down to the feet. Participants will perform daily acupressure for a total of six weeks.

Figure 1. Large pencil tip eraser for stimulating acupressure points.

The relaxation and stimulating self-acupressure versions of the MeTime MS app will be used (see Figure 2), in addition to the virtual instruction by trained study staff at the baseline visit. Participants will be given the option to (A) download the assigned MeTime MS application onto their personal tablet or smartphone, or (B) use a study-provided device with the assigned MeTime MS application pre-downloaded. Within the MeTime MS app, participants will only have access to their assigned protocol (relaxing or stimulating). Each participant will be provided with a unique identifier that is specific to the assigned protocol: the relaxation group identifier is “blue”; the stimulating group identifier is “yellow”.

Figure 2. Screenshots from the MeTime MS Acupressure App.

Relaxation Acupressure[33-35]

There is a total of 9 acupoints (1 unilateral and 4 bilateral; see Figure 3). Each point will be stimulated for 3 minutes, yielding a total treatment time of 27 minutes each day. The acupoints are:

1. Yin Tang (Unilaterally): Located on the forehead, between the eyebrows.
2. Anmian (Right and Left/bilaterally): Located on the posterior aspect of the neck, in a slight depression along the bone directly behind the ear.
3. Heart 7 (HT7) (Right and Left/bilaterally): Located on the palmer surface of the hands on the wrist crease; in line with the pinky.
4. Spleen 6 (SP6) (Right and Left/bilaterally): Located on the inside of the lower leg, approximately 4 fingers width above the bone of the ankle.
5. Liver 3 (LIV3) (Right and Left/bilaterally): This point is located on the foot, near the big and second toes.

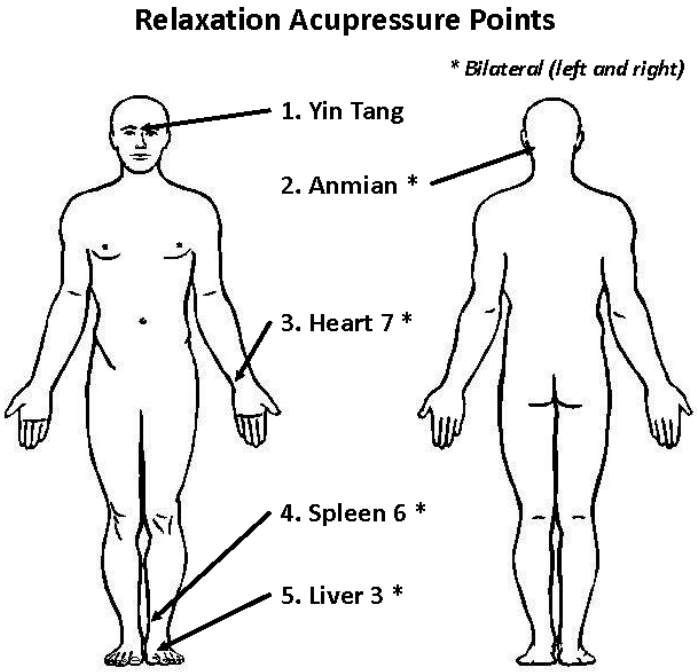

Figure 3. Relaxation Acupressure Points

Stimulating Acupressure[33-35]

There is a total of 10 acupoints (2 unilateral and 4 bilateral; see Figure 4). Each point is stimulated for 3 minutes, yielding a total treatment time of 30 minutes each day. The acupoints are:

1. Du 20 (Unilaterally): Located at the top of the head.
2. Large Intestine 4 (LI4) (Right and Left/bilaterally): Located on the back of the hand, between your thumb and index finger.
3. Conception Vessel 6 (CV6) (Unilaterally): Located two finger widths below the navel on the centerline.
4. Stomach 36 (ST36) (Right and Left/bilaterally): Located on the lower leg below the knee on the outside of the leg.
5. Spleen 6 (SP6) (Right and Left/bilaterally): Located on the inside of the lower leg, approximately 4 fingers width above the bone of the ankle.
6. Kidney 3 (K3) (Right and Left/bilaterally): Located on the inside of the ankle.

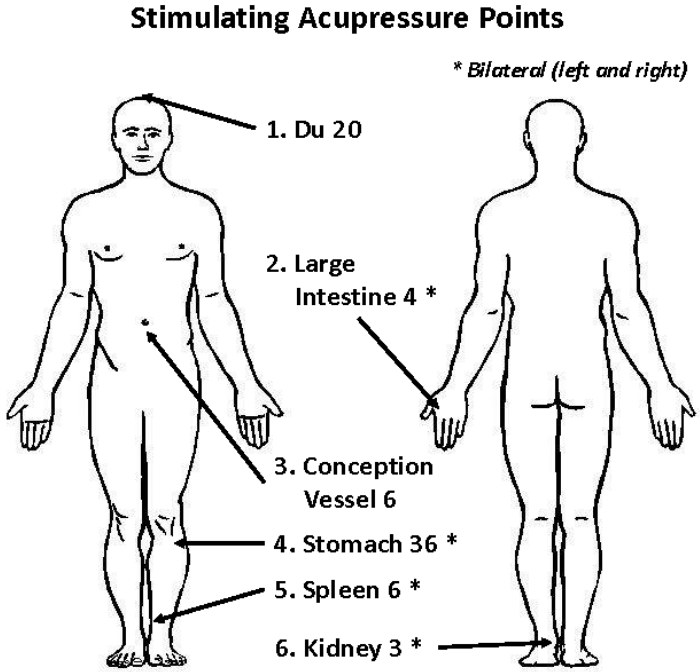

Figure 4. Stimulating Acupressure Points

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