

Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

eTable 1: Dates of Study Participation by Cohort: Recruitment, Classes, and Study Visits

Cohort	Dates of Recruitment ^a		Dates of Intervention ^b	Dates of Follow-Up Study Visits ^c		
	Phone Screens	Screening Visits	MBSR & HA Education Classes	12 Week Study Visit	24 Week Study Visit	36 Week Study Visit
1	07/29/16-09/11/16	8/26/16-9/12/16	Mondays 10/17/16-12/12/16	Dec-Jan 2016	March 2017	June 2017
2	01/13/17-02/21/17	02/01/17-02/24/17	Mondays 3/27/17-5/22/17	May-June 2017	Sept 2017	Dec 2017
3	04/01/17-06/28/17	06/05/17-06/29/17	Thursdays 7/27/17-9/21/17	Sept-Oct 2017	Dec 2017	March 2018
4	06/01/17-09/07/17	08/7/17-09/8/17	Mondays 10/9/17-11/27/17	Dec 2017	March 2018	June 2018
5	01/05/18-02/20/18	02/05/18-02/21/18	Thursdays 03/22/18-05/17/18	May-June 2017	August 2018	Dec 2018
6	04/01/18-06/24/18	05/10/18-06/25/18	Thursdays 06/26/18-09/20/18	Sept-Oct 2018	Dec 2018	Feb-March 2019
7	07/01/18-09/30/18	08/28/18-10/01/18	Mondays 10/29/17-12/17/17	Dec-Jan 2018	Feb-March 2019	May-June 2019

a-Recruitment continued until enough participants were available for each cohort (~16), so some participants maintained baseline headache logs for > 4 weeks until start of classes; data were only analyzed from 1st 4 weeks of entries.

b-The day of the week varied by cohorts in an effort to increase participant availability; Wednesdays were avoided due to church activities; Instructor(s) had conflicts on Tuesdays; weekends were avoided.

c-The timing of follow-up study visits were based on the dates of the intervention, +/- 2-4 weeks

eTable 2, Eligibility Criteria and Justification

Inclusion Criteria	Justification
Diagnosis of Migraine by ICHD-2 ^a criteria	<ul style="list-style-type: none"> • ICHD-2^a was the edition in effect at study onset • ICHD criteria is standard headache research diagnostic criteria
4 to 20 migraines/month	<ul style="list-style-type: none"> • Targeting episodic migraine (4-14 headaches/mo) and including those with 15-20 headaches/month given month-month headache variability⁸⁰ while excluding medication overuse headache
≥1 year of migraine	<ul style="list-style-type: none"> • Ensures migraine stability and diagnosis
≥ 18 years	<ul style="list-style-type: none"> • Given group-based classes, aids in group cohesion and participation
Available for 8 weekly in-person classes	<ul style="list-style-type: none"> • Ensures ability to participate in study interventions
Exclusion Criteria	Justification
Regular mind-body practice	<ul style="list-style-type: none"> • Those already practicing intervention may not experience additional benefit
Unstable medical/psychiatric condition	<ul style="list-style-type: none"> • Ensure participant safety and engagement with study
Severe clinical depression (with Patient Health Questionnaire PHQ-9 >20)	<ul style="list-style-type: none"> • Participants with severe clinical depression may need a more comprehensive treatment approach than provided through this study • Rare cases of psychosis have been reported with mind-body practices, and often occur in those with history of significant psychiatric disease
Non-migraine chronic pain	<ul style="list-style-type: none"> • Since quantitative sensory testing (QST) was being conducted at every study visit, chronic pain could interfere with QST results
Active medication overuse headache (MOH) ^b	<ul style="list-style-type: none"> • MOH is often refractory until treated (e.g., offending medication withdrawn)⁸³
Current/planned pregnancy	<ul style="list-style-type: none"> • Delivery/newborn life could interfere in study participation • Fluctuations of headache frequency that typically occur with hormonal fluctuations during pregnancy could impact our primary outcome assessment (i.e., headache frequency)
New migraine medication within 4 weeks	<ul style="list-style-type: none"> • Ensure stability of current headache treatments
Unable to maintain stable medications for study duration	<ul style="list-style-type: none"> • Ensure stability of treatment options for study duration (participants are able to stay on current acute/preventive migraine treatment options)
Failure to complete baseline headache logs	<ul style="list-style-type: none"> • Ensure ability to complete study procedures
Absence of pain ratings to noxious (49°C) stimuli	<ul style="list-style-type: none"> • Ensure participants have responses to pain measures to prevent floor effect

a-International Classification of Headache Disorders (ICHD)-2 diagnostic criteria for migraine without aura: at least 5 attacks with: headache lasting 4-72 hours (untreated or unsuccessfully treated); 2+ features of: unilateral/pulsating/moderate-severe intensity/worsening with routine activity; 1+ features of: nausea and/or vomiting/photophobia and phonophobia; not attributed to another diagnosis

b-ICHD-2 criteria for Medication Overuse Headache (MOH): headache occurring on 15+ days/month in patient with pre-existing headache disorder; regular overuse for > 3 months of acute/symptomatic headache treatment; not attributed to another diagnosis.

eTable 3: Course Content of MBSR and Headache (HA) Education Interventions

	MBSR	Headache (HA) Education
Course Overview^{a, b}		
	<ul style="list-style-type: none"> • Met weekly for 8 weeks for 2 hour classes, plus a 1 day optional “retreat.” • Mindfulness is experientially cultivated through sitting and walking meditation, body scan (sequential attention to parts of the body), and mindful movement (bodily awareness during gentle stretching, based on hatha yoga). By repeatedly bringing attention back to the natural rhythm of the breath, participants are encouraged to build their capacity to attend to physical and mental perceptions. • Participants share their mindfulness experiences with others. • The instructor also gives information about stress and stress relief, teaching participants to use MBSR skills to reduce negative effects of stress reactivity and develop better ways of responding positively to stress. • In addition to practicing the formal practices of mindfulness meditation, participants are advised to incorporate mindfulness into their daily lives so that routine activities (e.g., brushing teeth, taking a shower, etc.) can become a meditative practice, developing a more flexible capacity to utilize mindfulness in everyday situations. • Each participant was given the same standard guided electronic audio recordings and encouraged to practice at home for 30 minutes per day, at least 5 additional days per week. 	<ul style="list-style-type: none"> • Met weekly for 8 weeks for 2 hour classes, plus a 1 day optional learning “retreat” session. Content included education about migraine pathophysiology, headache triggers, stress. Time for questions, answers, and discussion was provided during each class.
Weekly Curriculum Content		
Week 1	<p>Introduction, Mind-body and participatory medicine discussion & explanation of mindful awareness</p> <p><u>Experiential practices:</u> mindfulness of breathing, mindful eating, and the body scan</p> <p><u>Dialogue:</u> “letting go”</p>	<p>Introduction, Types of Headaches, Migraine Symptoms & Prevalence</p>
Week 2	<p><u>Discussion</u> of role of perception in the appraisal of stress, pleasant events calendar.</p> <p><u>Experiential practices:</u> sitting meditation, mindful hatha yoga, body scan</p> <p><u>Dialogue:</u> perception, non-judging awareness</p>	<p>PowerPoint Presentation & Discussion on Migraine pathophysiology, triggers and Migraine myths/facts.</p>
Week 3	<p><u>Discussion</u> of challenges and insights from present moment awareness in daily life, awareness of pleasant and unpleasant events calendar</p> <p><u>Experiential practices:</u> mindful hatha yoga, sitting meditation, walking meditation</p> <p><u>Dialogue:</u> Triangle of awareness, acceptance, encouraging to share with others</p>	<p>PowerPoint Presentation & Discussion on Migraine treatment options.</p>
Week 4	<p><u>Discussion</u> and presentation on stress, stress reactivity, and habitual reactive patterns; discussion on systematic expansion of field of awareness</p> <p><u>Experiential practices:</u> mindful hatha yoga, sitting meditation, <u>body scan</u></p> <p><u>Dialogue:</u> stress reactivity, trusting</p>	<p>PowerPoint Presentation & Discussion on secondary headaches and Medication Overuse headache.</p>

	MBSR	Headache (HA) Education
Weekly Curriculum Content		
Week 5	<u>Discussion</u> on capacity to adapt to everyday challenges and stressors; awareness of responding vs. reacting; awareness of habitual patterns of behavior <u>Experiential practices:</u> mindful hatha, yoga, sitting meditation, body scan <u>Dialogue:</u> responding vs. reactivity, wise attention without	PowerPoint Presentation & Discussion on lifestyle and Migraine and the impact of diet, exercise, sleep.
Week 6	<u>Discussion</u> of transformational coping strategies to develop stress hardiness/resilience with the development of inner resources; discussion of challenging interpersonal communications <u>Experiential practices:</u> mindful hatha yoga, sitting meditation <u>Dialogue:</u> Communication styles, equanimity, non-striving	PowerPoint Presentation & Discussion on Migraine and hormonal influences.
Optional retreat day	The retreat includes elements of all the mindfulness practices and is conducted in silence: mindful hatha yoga, sitting meditation, body scan, walking meditation, mountain/lake meditation, eating meditation, lovingkindness meditation	The retreat includes an overview of previously discussed sessions, questions, guidelines for effective group meetings, a video series and personal reflections.
Week 7	<u>Discussion & awareness</u> of communication patterns; personal daily practice <u>Experiential practices:</u> sitting meditation, mindful hatha yoga, walking mediation, lovingkindness <u>Dialogue:</u> communication skills, patience	PowerPoint Presentation & Discussion on Migraine and Wellbeing as well as the impact of stress, depression, anxiety
Week 8	Summary of course content, closure <u>Experiential practices:</u> body scan, mindful hatha yoga, sitting meditation <u>Dialogue/questions:</u> wise attention and acceptance to present moment; how to apply to daily life, how to maintain and deepen daily practice beyond 8 weeks	PowerPoint Presentation & Discussion on Migraine and its impact on family, work, and relationships.

a-Each participant received a binder at the beginning of each course for educational materials. The MBSR binder contained all learning and educational materials at course onset. The HA education binder was provided at course onset, and each week students received the PowerPoint slides via handouts, plus additional handouts/learning materials pertinent to that week's session.

b-The MBSR course was led by the same instructor for all cohorts. The HA Education course was led by the same instructor for 6/7 of the cohorts; a 2nd instructor led the 7th cohort. Analyses from Patient Centered Communication skills, Working Alliance Inventory, and Client Satisfaction Questionnaire, did not demonstrate any cohort effects. Further, participant feedback across cohorts provided during qualitative interviews (to be reported in detail elsewhere) also did not suggest significant impact of having a different instructor during the 7th cohort.

eTable 4: Treatment Fidelity Plan & Delivery

Aspect of Treatment Fidelity ⁴⁰	Strategies & Assessments
Study Design	<p>Both intervention and control groups received the same “dose” of 8 weekly 2-hour classes, plus one optional “retreat” day.</p> <p>Both instructors followed detailed manuals for conducting their intervention. The MBSR intervention was conducted according to the standard MBSR curriculum and standards of practice,^{39,85} without modifications.</p>
Provider Training	<p>Each intervention was led by the same instructor across all 7 cohorts for each intervention.^a The two interventions required instructors with different expertise and could not be the same person.</p> <p>The MBSR instructor has been trained in the structured protocol created by Dr. Kabat-Zinn⁸⁶; has taught over 25 MBSR courses; and followed the standardized protocol without modifications for migraine. The Headache education instructor was a doctorate-level instructor with significant headache expertise who helped organize the content for the course.</p>
Treatment Delivery	<p>Both instructors had a standard expected check-list of both critical and minimal intervention components for each session’s requirements and goals, respectively, and completed it at the end of each session; these checklists were reviewed by assessors to confirm treatment delivery during the Fidelity Review Assessment (see eMethods 3).</p> <p>Classes were audio-recorded and 27% (15 of 56) of the 8 MBSR classes across 7 cohorts were pseudo-randomly selected to ensure representation across cohorts and class sessions. Four undergraduate students not involved in treatment delivery were trained^b on the intervention, standardized protocol, instructor checklists (see eMethods 4), and assessments with discussion of three separate classes across three cohorts. Each class was evaluated^c by at least two assessors independently using both the instructor checklist (see eMethods 4), and the curriculum guide on 3 factors: content-adherence (extent to which therapist provided the intervention per protocol); content-appropriateness (extent to which therapist provided the intervention in a manner which addressed patient’s questions); content-quality (overall skill with which the therapist provided the intervention), modified from the MBCT Adherence, Appropriateness, and Quality Scale.⁸⁷ Scores from 0-3 were given for each factor (0: not at all; 1: weak/poor; 2: Good/Acceptable; 3: Excellent). The dose (duration of recording or presence of missing recording) was tracked for each class. Each assessor also rated consistency across cohorts and commented on any differences or discrepancies between recordings of different cohorts (see eMethods 3). Of the 41 class assessments completed, inter-rater reliability was excellent, adherence intra-class correlation = 0.93 ; appropriateness intra-class correlation = 1.0; quality intra-class correlation = 1.0. Assessment of therapist fidelity to the treatment protocol demonstrated excellent adherence, appropriateness, and quality (average scores from 0-3 of 2.9 (0.3); 3 (0); and 3 (0), respectively).</p> <p>For the HA Education recordings, 2 team members conducted all the analyses using the instructor checklists. Due to equipment failure, not all HA Education classes were audiotaped and so 100% of the available classes were reviewed.</p> <p>Both the MBSR and HA Education classes were taught on the same day/time for each cohort; class days/times varied by cohort to increase participation.</p>
	<p><u>Therapeutic Relationship</u></p> <ul style="list-style-type: none"> • The instructors for both groups were chosen specifically with similar interpersonal skills and levels of compassion with patient interactions. • The quality of the therapeutic relationship between participant and instructor was measured with both the Patient Centered Communication Skills⁴⁷ (at 12 weeks) and the Working Alliance Inventory (after 2nd class and at 12 weeks).
Treatment Receipt	<p>Class attendance was monitored by the instructor at each class across all cohorts.</p>
Enactment of Treatment skills	<p>Participants kept daily logs to track MBSR home activities via REDCap up to 36 week study visit.</p>

- a- The HA Education course was led by the same instructor for 6/7 of the cohorts; a 2nd Masters-level instructor led the 7th cohort. Analyses from Patient Centered Communication Skills surveys did not show variability across cohorts; additional participant feedback provided during qualitative interviews (to be reported in detail elsewhere) do not suggest significant impact of having a different instructor during the 7th cohort.
- b- Reviewers were educated about the MBSR curriculum and the Headache Education curriculum by becoming familiar with 1) the Authorized MBSR Curriculum Guide developed by the Center for Mindfulness³⁹; 2) instructor checklists for each of the 8 weekly classes for both the MBSR and HA Education courses (**see eMethods 4**); 3) all the binder materials provided to participants (handouts, readings, PowerPoint slides provided to participants throughout both courses); 4) The Book/Manual: *Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness* by Jon Kabat-Zinn.⁸⁸ After multiple discussions among each other and alongside a certified MBSR trained instructor about MBSR and the tenets of mindfulness, students began analyzing the audio-recorded MBSR classes and HA Education classes for treatment fidelity. For the MBSR classes, all 4 team members first listened to two classes to confirm consistency, protocol for analyses, and to resolve any discrepancies before continuing.
- c- Students conducted several assessments at a time and met weekly during the process to confirm consistency among team members before proceeding to further analyses to prevent rater drift. At the weekly meetings, all the reviewers announced their independently obtained scores, then a discussion was held on why they chose that score.

eTable 5 Reasons and Time Points for Exclusion

Exclusion/Reason Unable to Participate	Time Point of Exclusion, Drop-out or Study Withdrawal (n)				
	Screening Time Point			After Randomization	
	Phone Screen	Baseline Visit	During HA log	Drop out	With-drew
Lack of availability/interest in 8 weekly in-person classes	656		5		
Did not meet eligibility criteria	426	18	15		
No show/cancellation of baseline visit/unable to contact	129		3		
Unknown/no reason	323				
No pain ratings to noxious stimuli		7			
Did not complete headache logs			13		
TOTALS	1534	25	36		
REASONS DID NOT MEET ELIGIBILITY CRITERIA					
< 4 migraines/ month	104		8		
>20 migraines/ month	86	6	1		
Non-migraine chronic pain	68	2			
Medication overuse headache (by ICHD-2 criteria)	50	4	4		
Current mind-body practice	28	1			
Inability to participate in study visits	22				
New medication started within 4 weeks	16		1		
<1 year of migraine	11				
Current/planned pregnancy/ breastfeeding	9				
Non-migraine headache diagnosis (by ICHD-2 criteria)	6	3			
Severe clinical depression/anxiety	6				
Did not speak English	6				
Unable to maintain stable medications	6				
Unstable medical/psychiatric condition	5	1	1		
No pain ratings to noxious stimuli	2				
<18 years	1				
Unable to commit to classes		1			
TOTALS	426	18	15		

eTable 6 Reasons and Time Points for Withdrawal and Lost to Follow-Up

GROUP	Time Point of Withdrawal				Time Point of Lost to Follow-up			
	After Randomi- zation	Prior to 12 weeks	Prior to 24 weeks	Prior to 36 weeks	After Randomi- zation	Prior to 12 weeks	Prior to 24 weeks	Prior to 36 weeks
MBSR	3	4	1	0	1	4	2	1
HA Education	3	1	4	1	0	2	2	2
REASONS								
Lack of availability/interest in 8 weekly in- person classes	2	5	5	1				
Unstable medical/psychiatric condition	2							
Unable to contact								
Travel: difficulty finding study location/ parking/ commute too long	2							
TOTALS	6	5	5	1	1	6	4	3

eMethods 1. Recruitment Strategies

Patients and providers at Wake Forest Baptist Health (WFBH) were recruited through flyers, brochures, “provider pocket cards,” and presentations, focusing on the Wake Forest Baptist Health (WFBH) Comprehensive Headache Program and departments of Neurology, Family Medicine, Internal Medicine, and Emergency medicine. Prior headache research participants who previously gave consent for future contact were notified. The WFBH electronic medical record (EMR) system was utilized; providers were notified of the study when in a patient’s chart with a migraine diagnosis. Key community advertising efforts focusing on the Winston-Salem area (due to the weekly in-person study time commitment) included social media campaigns (Facebook and Twitter), Facebook live videos, search engine marketing through Google, and local advertisements (restaurant bathrooms, electronic billboards, newspapers, television, magazines, email listservs, bus tails). A variety of methods were utilized to target diverse populations. Electronic advertising methods brought participants to an online database of institutional research (WFBH BeInvolved) which provided study details. Advertisements were broadly spread across the local community to increase recruitment of diverse populations, and WFBH Maya Angelou Center for Health Equity offered financial support for those with transportation needs. Participants contacted study staff via a dedicated study cell phone, study email, the link on the BeInvolved website, or direct EMR provider messaging.

eMethods 2. Phone Screen

INITIAL PHONE CALL & SCREENING FORM

Participant Name: _____

Date: _____

Time: _____

Screened by: _____

Call initiated by _____

Screened in

Screened out (circle): **Declined?** **Ineligible?**

Reason:

Future research agreement YES NO

This is ____ from Wake Forest Baptist Medical Center Department of Neurology. I am calling about our Research Study for adults with Migraines. Thank you so much for your interest in our study. We are following up to see if you may be eligible. How did you hear about our study?

Advertisement

- TV Interview Dr. Wells, WXII _____
 - Facebook tv interview link _____
- Bus-tail ad _____
- Billboard- Stratford Road _____
- Flyer (location? elevator?) _____
- Natural Triad Magazine, where _____
- Newspaper (WF Undergrad?) _____
- Google Ad (SEM)
- TV Ad (in the past) _____
- Vital Newsletter _____

Online

- Facebook _____
 - Facebook Live? _____
 - Video with people? _____
 - Video with word images? _____
- Be Involved Wake Forest research website
- Wake Forest undergrad newspaper online website
- Clinicaltrials.gov
- MyWakeHealth
- Twitter _____

Email (Natural Triad OR Winston-Salem Journal OR

Center for Integrative Medicine Newsletter)

- Recommendation
 - Family/friend (how did THEY hear about study?)
 - Provider referral (who?) _____
 - Letter in the mail (BPA)
 - Other/More details _____
-

2-We also need to have your contact information:

Mailing Address:

Email: _____

Best Phone number(s) better to reach you? _____

Date of Birth: _____

- How old are you? If <18, STOP
- May we contact you in the future about future headache research studies? Yes/NO
 - Give ALL patients our contact information: Phone: XXX, Email: XXX
- We are studying the effects of non-drug treatment options for adults with migraines. Specifically, we are studying the effect of 8 weekly classes where adults with migraines will learn more information that may help your migraines. You will discuss and learn drug-free ways to better handle your headaches. The classes will be run in groups with other adults with migraines. You may continue taking your migraine medications during the study. **Does this sound like something you would be interested in?**
-
- The next round of classes will be held ...{ }**
- We'll go through the full details about the study, but first let's see if you are eligible to participate. I will ask you some questions about your health & background to help determine if you may be eligible for this study.**

SCREENING – Inclusions / Exclusions

- Do you have any other active pain conditions that you are treating (such as chronic low back pain, fibromyalgia, or any other chronic pain conditions?) If yes to these TWO questions: STOP
 - If yes: do you have pain from this condition every day?
 - If yes: do you take medication every day to treat it?
- Do you have a condition or injury that impacts your ability to feel temperature or pain in your arms or legs?
 - If yes, clarify if would prevent ability to feel heat with heat pain testing (and if so, ineligible)
- Do you currently practice meditation, acupuncture, or biofeedback? (IF they CURRENTLY practice daily meditation, STOP) Description: _____
- Has a doctor told you that you have migraines? (just helpful to know, not a requirement)
- How long have you had headaches? (must be at least ONE year)
- How many days/ month do you have headaches of ANY type? (<20, ideally <15)
 - _____ days/mo with ANY type of headache
- How many days/month do you have MIGRAINE headaches? (Ideally at least 4)
 - _____ days/mo with MIGRAINE headache
- Do you have a headache every day? (If yes, exclude)
- CONFIRM: 4-20 headaches/mo with at least 1+ “migraine”
- How long do your headaches typically last if untreated: _____ (must be 4-72 hrs)
- With your headaches (Must have 2):
 - Where on your head are your headaches—one side or both?
 - What does the pain of your headache feel like? (Pulsating, throbbing, _____)

- Are they typically moderate or severe in intensity?
- Does activity make them worse (do you avoid routine physical activity- like walking up stairs with a headache?)
- During your headaches: (Must have 1)
 - Do you have nausea and/or vomiting
 - Are you sensitive to light? Sensitive to Noise?
- Has anyone told you that you have another problem that is causing your headaches? (if yes, STOP)
- What medications do you currently take to treat your headaches? (include **all** over the counter and prescription medications & supplements) **STOP if could diagnose Medication Overuse Headaches (≥15 days/month of headaches, and 2+ days/week use of abortive medication)**

NAME/dose/frequency—to STOP headache (prn)	NAME/dose/frequency-to PREVENT headache (daily)
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Do you use any treatments that are not medicines to treat your headaches? If yes, what are they?

NAME of treatment	Any comments they may add
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Do you have any other major medical of psychiatric conditions? IF Yes—what are they?
 - If DEPRESSION/ANXIETY: Do you feel that your depression is under control?
 - Consider stopping if they have a disease that would interfere with the study (i.e. Chronic Kidney disease, requiring hemodialysis, epilepsy, Parkinson’s disease, MS, depression with suicidality etc.)
 Please list on the next page

Past Medical/Psychiatric History	Any details they may add (when, severity, hospitalizations, etc)
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

OTHER

- Have you started a new headache medicine in the last month?
- Do you think you will start a new headache medicine in the next 9 months?
- Are you currently participating in any drug trial or a clinical study?

FOR WOMEN (*If pregnant, breastfeeding, planning either, or not using reliable birth control method, STOP

- Are you currently pregnant or breastfeeding?
- Are you planning on becoming pregnant in the next 4-6 months

- How are you preventing pregnancy? (If still menstruating & sexually active, must be on some form of birth control, such as abstinence, oral contraceptives, IUD intrauterine device, DepoProvera, tubal ligation, vasectomy of partner, condoms, sponge).

STUDY PARTICIPATION

- Are you able *and* willing to attend 8 weekly classes, lasting 2 hours each? [Dates of classes: xxx].
- Are you able to come in for 4 study visits (lasting, 1-2.5 hrs)? [occur during the day]
- During the trial you can stay on any medications that you are currently taking to treat your headaches. We ask that during the trial you do not change your headache medicines (in other words, you do not start a new medicine or change the dose of your current medicines). Would you be able to do that?
- Would you be able and willing to keep track of all your headaches in a daily headache log (for 9 months)?

We are very excited--you may be eligible for participation in our trial! You now MAY have the opportunity to participate in our trial that involves 8 weekly classes where you will learn more information that may help your headaches. You will discuss and learn drug-free ways to better handle your headaches. Typically, these classes are expensive, but they would be free to you. In fact, as a sign of our appreciation, you will receive \$80 for the full completion of the study. Specifically—you will receive Visa Gift cards in these amounts at each visit:

- \$10 at the First Visit
- \$15 at the 8 weekly classes after the Initial Follow-up Visit
- \$20 at the 3 month Follow-up Visit
- \$35 at the 6 month Follow-up Visit

All of your parking expenses will be covered. There should be no out-of-pocket costs for you. During the program and after it ends, we will contact you to see how you are doing

Let's go over some of the logistics of the study:

Prior to the classes, you would be evaluated to see if you are eligible for the study, and this would involve a study visit at Wake Forest Baptist Medical Center with a physician. At that visit, you would also answer some questionnaires. Additionally, you will be introduced to a heat stimulus paradigm that may produce the feeling of pain. We will stimulate your forearm and the back of your leg. We apply heat, and some people may interpret it as painful. We've done this on hundreds of participants and most tolerate it well. We are trying to understand the mechanism for how this type of intervention may be helpful. At that point, if you qualify for the study, then you will be given a headache log to track your headaches for 4 weeks.

After you track your headaches for 4 weeks, if you qualify for the study, then you would be randomized into one of the two groups. The way randomization works is: you will have equal chance of being involved in either group, like flipping a coin. You will not be able to choose which group you are in, nor would we be able to.

You would then begin the classes, once/week for 8 weeks, lasting 2 hours each. The classes will be held at Wake Forest Baptist Medical Center in the evenings from 6-8pm. The next round of classes will be on MONDAYS FROM 6-8PM, October 22nd-December 10th.

After the 8 weekly classes, you will return to Wake Forest Baptist Medical Center for 3 additional visits: initially after the 8 week class, and again 3 months later and 6 months later. At the first FOLLOW-UP visit, you will have the opportunity to tell us about your experience in the study with an interview. At each visit, you will also complete the same set of questionnaires as baseline as well as the heat stimulus paradigm. You will continue to keep a headache log during this time. So, you will track your headaches for about a month prior to the classes, for the duration of the classes and for 6 months after the class ends, so the entire study lasts about 9 months.

From here:

- 1--We will now EMAIL YOU A BROCHURE WITH all these details in writing so that you feel comfortable understanding the study
- 2--Call or tell will call to schedule 1st visit:

DETAILS OF FIRST VISIT:

- It is important that you are headache free during the heat assessment part of the visit and NO pain-relieving medications within 12 hours of the visit, including tylenol, ibuprofen, triptans, narcotics, etc. If you do have a headache **the day of the visit**, or take pain-relieving medication within 12 hrs of the visit, you have 2 options:
 - A-reschedule the entire visit; please call us so that we can re-schedule your visit. 336-705-2396.
 - B-Come into the visit if you are able; and we will complete some of the visit, then at that time we will set up another time to complete the final initial screen
- Confirm have Date of Birth: _____
- For the heat pain testing, we will be doing this on your arms and legs, so please wear clothing to have access to your arms and legs
- This will be the longest visit of the study—lasting 2-2.5 hours
- All study visits take place in the CLINICAL RESEARCH UNIT of Wake Forest Baptist. **Please come 15 min prior to your visit. Please sign in at the front desk when you arrive.**
- We can also send you the informed consent form if you would like it; we will go over this in detail at the 1st visit. Would you like this in advance of the 1st visit?

IMPORTANT:

- If you change your mind about your participation in the study, please let us know.
- Please let us know ASAP if you are not able to make the visit for any reason.
- We are very excited about your participation in our study and look forward to seeing you at your visit!
- Contact information to reach us if you have any questions:
 - Phone:336-705-2396
 - Email: help4migraines@wakehealth.edu
- Do you have any questions?

For YOU (phone screener) to do now

- Interviewer (your) Name _____
- Date _____
- Time _____
- Complete all information on top of Page 1 (e.g., Screened in/out? Reason?)
- EMAIL PARTICIPANT THE STUDY BROCHURE
- CHANGE COLOR ON ISHARE
- IF SCHEDULE VISIT: SCHEDULE WITH CRU TOO

Comments: _____

If SCREENS OUT or says “not interested” at any time:

- Thank you very much for your interest and consideration of our study. Unfortunately, you are not eligible to participate in **the 8 weekly classes**.
 - However, we will be doing future studies for adults with headaches, can we contact you in the future?
Yes No
 - If you are interested in seeing one of our excellent headache doctors at the Headache Program at Wake Forest Baptist, you can call 336-716-4101.
 - If something changes and you think you may be eligible for future classes, please contact us at phone 336-705-2396 OR email us at help4migraines@wakehealth.edu

eMethods 3: MBSR Treatment Fidelity Review Assessment

Reviewer (Your) Name: _____

Date of Review: _____

How long did it take you to complete this review? _____

Cohort of Review: _____

Class of Review: _____

Date of Class: _____

ASSESSMENT OF TREATMENT FIDELITY		
DOSE		
	Answer/Comments	
Duration of recording		
Was any of the recording missing?		
CONTENT-ADHERENCE		
<i>Extent to which therapist provided the intervention per protocol</i>		
	Rating	Comments
Did instructor complete the key items on checklist we gave them?	<input type="radio"/> 3-Yes, Excellent <input type="radio"/> 2-Yes, Good/Acceptable <input type="radio"/> 1-No, Weak/Poor <input type="radio"/> 0-No, Not at all	
Did instructor complete the key items from manual?	<input type="radio"/> 3-Yes, Excellent <input type="radio"/> 2-Yes, Good/Acceptable <input type="radio"/> 1-No, Weak/Poor <input type="radio"/> 0-No, Not at all	
CONTENT-APPROPRIATENESS		
<i>Extent to which therapist provided intervention in a manner that was appropriate for participants</i>		
	Rating	Comments
Did the instructor provide the intervention in a manner which was appropriate for patients (addressed patient questions, commented when appropriate to meet needs of patients)?	<input type="radio"/> 3-Yes, Excellent <input type="radio"/> 2-Yes, Good/Acceptable <input type="radio"/> 1-No, Weak/Poor <input type="radio"/> 0-No, Not at all	
CONTENT-QUALITY		
<i>Overall skill with which the therapist provided the intervention</i>		
	Rating	Comments
What was the overall skill with which the instructor provided the intervention?	<input type="radio"/> 3-Excellent <input type="radio"/> 2-Good/Acceptable <input type="radio"/> 1-Weak/Poor <input type="radio"/> 0-Unacceptable	

Have you listened to the same class for another cohort?

- Yes
- No

If yes, please describe

- Cohorts: _____
- Classes: _____

If yes, were the sessions consistent across the different cohorts?

- 3-Yes, Excellent
- 2-Yes, Good/Acceptable
- 1-No, Weak/Poor
- 0-No, Not at all

Please describe any major differences or discrepancies between the 2 (or more) sessions:

Any other comments, notes, or thoughts about this recording? (e.g., interruptions that occurred—please describe; a particular participant being disruptive or interfering with the session, etc.)

ADDENDUM: Scale Considerations

3 points (Excellent):

- Effective performance.
- Meets all major / essential / core criteria or acceptable equivalents and met three or more additional criteria.
- Significant evidence that skill is present.
- Truly excellent.
- Fully meets competency requirement.

2 points (Good/Acceptable/Satisfactory/Average)

- Adequate for effective performance.
- Meets most but not all major / essential / core criteria
- Some deficiencies exist in the areas assessed but none of major concern.
- Satisfactory evidence that skill is present.
- Competent – solid and steady in essential aspects but could be improved.
- Meets enough of the competency requirement to adequately perform the task.

1 point (Weak/Poor/Much less than Acceptable)

- Insufficient or significantly below criteria required for successful job performance.
- Many deficiencies.
- A major problem exists.
- Describes / demonstrates insufficient range of skills appropriate for handling of situation.
- Describes / demonstrates plausible but inappropriate behaviours for handling the situation and/or the outcome if not obtained.
- Describes / demonstrates counter-productive behaviours that have negative outcomes or consequences (make the situation worse)

0 points (Unacceptable):

- No evidence that skills are present OR evidence that the skill is not present
- No answer or inappropriate answer.
- Not competent

eMethods 4: Instructor Curriculum Checklists

- Utilized by Instructor each class
- Utilized by Assessors in reviewing treatment fidelity:

MBSR Curriculum: Instructor Checklist

Week 1:

At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Agreement with the patient on participation
 - Come if able even if have headache
 - Explain retreat day
- Experiential: mindfulness, mindful eating, body scan
- Dialogue: “letting go”

At the end of class:

- Explain daily assignments
 - Give daily assignments: body scan, 9 dots, mindful eating
 - CDs distributed, explain dropbox
- Explain: start new daily headache log TODAY
- Explain: will also have link to keep track of daily home practice

Week 2:

At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: body scan, sitting meditation
- Dialogue: perception, non-judging awareness
- Video: gorilla-perception

At the end of class:

- Daily assignment: pleasant events calendar, body scan daily, plus begin sitting, informal practice
- Explain: Will have extra link for a few surveys to complete electronically with headache log
- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities

Week 3:

At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: mindful movement introduced, sitting meditation
- Dialogue: Triangle of awareness, acceptance, encouraging to share with others

At the end of class:

- Daily assignment: unpleasant events calendar, alternate body scan with mindful movement, plus sitting, informal practice
- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities

Week 4:At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: sitting meditation, mindful movement, body scan
- Dialogue: stress reactivity, trusting

At the end of class:

- Daily assignment: alternate body scan with mindful movement, plus sitting, informal practice
- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities

Week 5:At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: sitting, mindful movement, walking mindfulness
- Dialogue: responding vs. reactivity, wise attention without judgment

At the end of class:

- Daily assignment: stressful communication calendar, alternate sitting with body scan/mindful movement, informal practice
- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities

Week 6:At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: mindful movement, sitting
- Dialogue: Communication styles, equanimity, non-striving

At the end of class:

- Daily assignment: alternate sitting with body scan/mindful movement, informal practice
- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities

RETREAT DAY:At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Silent retreat day
- Bringing in elements of all that have learned

At the end of class:

- Recommend: continue daily headache log

- Recommend: continue tracking home practice activities

Week 7:

At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: mountain meditation, walking meditation
- Dialogue: communication skills, patience

At the end of class:

- Daily assignment: practice without audio recording
- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities

Week 8:

At the beginning of class:

- Turn on recorder
- Take class attendance

During class:

- Experiential: body scan, mindful movement, walking
- Letter to oneself
- Dialogue/questions: wise attention and acceptance to present moment; how to apply to daily life, how to maintain and deepen daily practice beyond 8 weeks

At the end of class:

- Recommend: continue daily headache log
- Recommend: continue tracking home practice activities
- Continue daily practice at home
- Keep follow-up appointments (this week, again in 3 months, and again in 6 months)

Headache Education Curriculum: Instructor Checklist

Session 1:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

- Introduction and Welcome to the Program
 - Welcome/Overview of sessions and weekly schedule
 - In this session we will cover...
 - Handout notebooks and first handouts
 - What if you miss a class?
- Agreement with the patient on participation
 - Come if able even if have headache**
 - Explain retreat day
 - Questions before getting started
 - Guidelines for effective group meetings
 - Getting to Know You (introductions)
 - Types of headache
 - Primary and secondary headaches

- Primary headaches: Sinus, cluster, tension, migraine
- Migraine or a headache, what's the difference?
- What is Migraine?
 - Who gets migraine?
 - What are the symptoms and stages of migraine?
 - What is aura?
 - Can migraine get worse over time?
- Progression of episodic to chronic migraine

At the end of class:

- Go over handouts
- Explain: start new daily headache log TODAY—should have NEW link—make this link a new “favorite” on your browser, to replace old link

Session 2:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

What causes migraine?

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- Migraine Pathophysiology
 - What are the causes of migraine
 - Neurologic (happens in the brain)not vascular
 - Biologic not psychiatric/psychologic
 - Genetics/Inherited
 - Migraine: Gender and lifespan (image)
- Migraine Triggers
 - What are the triggers that can cause migraine?
 - Environmental
 - Behavioral
- Migraine Myths and facts
 - Not a vascular condition
 - Its not “all in your head”
 - Inherited but not transmitted

At the end of class:

- Explain: Will have extra link for a few surveys to complete electronically with headache log (on survey queue with headache log)
- Recommend: continue daily headache log
- Give out handouts

Session 3:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

Migraine treatments

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- What treatments are available for migraine?

- Drug
 - Abortives
 - Palliative
 - Preventives
- Non-drug
 - Physical therapies & Complementary medicine
 - Behavioral
- What to expect in an evaluation
- Talking to a doctor
- When to go to the Emergency Department
 - What to expect from the ED

At the end of class:

- Recommend: continue daily headache log
- Give out handouts

Session 4:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

Secondary headaches

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- What are secondary headaches?
 - What are types of secondary headaches?
 - Differences between migraine and secondary headache
- Medication Overuse Headache
 - What is MOH?
 - What triggers it/brings it on?
 - How to avoid it

At the end of class:

- Recommend: continue daily headache log
- Give out handouts

Session 5:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

Lifestyle and migraine

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- Revisit triggers
 - Sleep
 - Diet
 - Exercise, sex and exertion
- Stress and Migraine

At the end of class:

- Recommend: continue daily headache log
- Give out handouts

Session 6:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

Women and Migraine

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- Incidence and prevalence
- Hormones
 - Menstruation
 - Menopause
 - Birth control
- Other biological factors
- Social factors

At the end of class:

- Recommend: continue daily headache log
- Give out handouts

Retreat:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- Video series
- Personal reflections

At the end of class:

- Recommend: continue daily headache log
- Give out handouts

Session 7:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

Migraine and other aspects of Well Being

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- Review events from Retreat Day
- Psychiatric comorbidities
 - How to recognize them
 - What to do about it
- Stroke
- Cardiovascular disease

At the end of class:

- Recommend: continue daily headache log
- Give out handouts

Session 8:

At the beginning of class:

- Turn on recorder
- Take class attendance

Class Content

Impact of Migraine

- Overview of sessions and weekly schedule
- Questions before getting started
- Guidelines for effective group meetings
- Impact of Migraine on Relationships and Responsibilities
 - Family and parenting
 - Marital
 - Social Relationships
 - Work life
- Wrap Up & review

At the end of class:

- Recommend: continue daily headache log
- Give out handouts
- Keep follow-up appointments (this week, again in 3 months, and again in 6 months)