New York State Psychiatric Institute

Institutional Review Board

November 5, 2021

To: Dr. Brian Fallon

From: Dr. Edward Nunes, Co-Chair
Dr. Agnes Whitaker, Co-Chair

Subject: Approval Notice: Continuation Expedited per 45CFR46.110(b)(1)(f)(7)

Your protocol # **6927** entitled: **MEDITATION AND STRETCHING FOR POST TREATMENT LYME DISEASE SYNDROME** Protocol version date 11/05/2021 has been approved by the New York State Psychiatric Institute - Columbia University Department of Psychiatry Institutional Review Board from **November 7, 2021 to November 6, 2022.**

Consent requirements:
√ Not applicable: Data Analysis Only
☐ 45CFR46.116 (f)(3) waiver of consent for closed record/chart review
☐ Signature by the person(s) obtaining consent is required to document the consent process
☐ Documentation of an independent assessment of the participant's capacity to consent is also required.

Approved for recruitment of subjects who lack capacity to consent: ☐ No ☐ Yes

Field Monitoring Requirements: ☐ Routine ☐ Special: _____

✓ Only copies of consent documents that are currently approved by the IRB may be used to obtain consent for participation in this study.
✓ A progress report and application for continuing review is required 2 months prior to the expiration date of IRB approval.
✓ Changes to this research may not be initiated without the review and approval of the IRB except when necessary to eliminate immediate hazards to participants.
✓ All serious and/or unanticipated problems or events involving risks to subjects or others must be reported immediately to the IRB. Please refer to the PI-IRB website at http://irb.nyspi.org for Adverse Event Reporting Procedures and additional reporting requirements.

EN/AHW/alw

Signed copy on file at IRB

Protocol Title:
Meditation and Stretching for Post Treatment Lyme Disease Syndrome

Version Date:
11/05/2021

Protocol Number:
6927

First Approval:
11/07/2014

Expiration Date:
11/06/2022

Contact Principal Investigator:
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Co-Investigator(s):
Charles Alexander

Research Chief:
Helen Simpson, MD

Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am submitting an annual continuation without modifications

Department & Unaffiliated Personnel

Department

What Department does the PI belong to?
Clinical Therapeutics
Within the department, what Center or group are you affiliated with, if any?
Center for the Study of Neuroinflammatory Disorders & Biobehavioral Medicine

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.
Dr. Charles Alexander, MD (Private Practice, Southport CT)

Application for Continuation of Research

Status

Current Status of Study:
All research interventions were completed. Only data analysis is ongoing.

Summary of Experiences to Date

Please provide a summary of scientific progress of the study and the experience of research participants, to date. This requirement is designed to allow for the investigator and the IRB to reassess the study's risks and benefits in terms of developments in the field, changing practice patterns, and new IRB policies and procedures.

The data analysis has been finished. Our analysis is nearly completed. An article titled "Kundalini yoga for post-treatment Lyme disease: A randomized controlled pilot study" currently is being prepared for submission.

Funding

Have there been any changes in funding status since the prior approval?
No
Have the principal investigator and other investigators made all required disclosures of financial interest in the study sponsor/product?
Yes

Summary

Have there been any study findings, recent literature, or untoward events occuring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?
No
Have there been any serious adverse events (serious and/or unanticipated problems involving risks to subjects or others at this site which occured in the past year)?
No
Have all study staff with a significant role in the design or implementation of the human subject components of this study received required training in human research subject protections?
Yes
Is the study covered by a certificate of confidentiality?
No

Overall Progress

Approved sample size

40
Total number of participants enrolled to date
26
Number of participants who have completed the study to date
23
Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates?
No
Comments / additional information

Sample Demographics

Specify population
40
Total number of participants enrolled from this population to date
26
Gender, Racial and Ethnic Breakdown
Sex:
Male, n = 12 (46.2%)
Female, n = 13 (50.0%)
Missing, n = 1 (3.8%)

Ethnicity:
White (non-Hispanic), n = 19 (73.1%)
Black (non-Hispanic), n = 1 (3.8%)
Hispanic, n = 1 (3.8%)
Missing, n = 5 (19.2%)

Summary of Current Year's Enrollment and Drop-out

Number of participants who signed consent in the past year
0
Did the investigator withdraw participants from the study?
No
Did participants decide to discontinue study involvement?
No

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures
✓ Psychiatric Assessment
✓ Psychotherapy Trial

✓ Internet-based Data Collection or Transmission

Population

Indicate which of the following populations will be included in this research
✓ Medically Ill Subjects
✓ Adults
✓ Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
No

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
This protocol describes research conducted by the PI at other facilities/locations
Yes
✓ Community Sources

Community Sources

Type in location(s)
The oversight, screening, preliminary consent review, data entry, research file monitoring and preparation, data management, and analysis will take place at the NYSPI. The actual in-person final signing of consent and conduct of therapy with study participants will be conducted in the private practice office of Dr. Charles Alexander in Southport Connecticut.

Lay Summary of Proposed Research

Lay Summary of Proposed Research
The CDC reports that approximately 10-20% of patients treated for Lyme disease with the recommended 2-4 week course of antibiotics will continue to have symptoms of fatigue, pain, or joint and muscle aches despite prior antibiotic treatment. The symptoms can last up to months or even years after treatment. The medical community officially calls this condition “Post-treatment Lyme disease Syndrome” (PTLDS) but some have called it “chronic Lyme disease” **(CLD)**. **High clinical suspicion of Chronic Lyme Disease**

may even be found in patients that do not meet meet the criteria of a CDC based diagnosis; that is, having a positive blood test, rash, or characteristic symptoms. The exact cause of these symptoms is unknown; the IDSA has concluded that the symptoms are likely lingering effects of the previous infection and that further antibiotic therapy is unwarranted. Despite the IDSA's recommendations, many patients choose to receive additional courses of antibiotic therapy. Some of these patients continue to experience symptoms despite the additional antibiotic therapy; persistent symptoms among many within this subgroup of post-treatment patients are more likely due to a post-infectious process and for these patients new treatment approaches are needed. The common symptoms of post-treatment Lyme disease include muscle and joint pains, memory problems, sleep disturbance, cognitive problems ("brain fog"), and fatigue.

Alternative treatments that can assuage fatigue, muscle and joint pains, and improve cognitive function are urgently needed. Recent studies indicate that meditation can be a helpful strategy in reducing muscle pain and improving energy among patients with other chronic musculoskeletal disorders, such as fibromyalgia. We wish to conduct a preliminary study to examine the efficacy of meditation among patients with PTLDS and **CLD**. Specifically, we will use the breathing, meditation, and stretching techniques common to Kundalini Yoga practice. We plan to assess the degree in which this practice can reduce Post-Treatment Lyme Disease and **Chronic Lyme Disease symptoms**. Because fatigue and pain are so common among patients with PTLDS or **CLD**, the primary focus of this study will be fatigue and pain. Secondary outcomes will include cognitive complaints, physical and mental functioning, medical utilization, somatic symptoms, and psychopathology.
During this study, patients will be screened intially over the telephone to assess eligibility, sign consent with the study treating psychiatrist, and complete self-report questionnaires. Forty patients will be enrolled. Of these, 20 will be randomly assigned to meditation group therapy and 20 will be assigned to a wait-list. Assessments will be conducted prior to treatment, at 4 weeks and at 8 weeks. There will also be a 6 month follow-up by questionnaire and telephone interview. Study participants randomized to the wait-list control group will then be offered, after 8 weeks, the option of joining a meditation group for 8 weeks. Each meditation group will be composed of 6-8 subjects. Should this study find evidence suggesting that meditation therapy is helpful in reducing the symptoms of PTLDS, this would be a valuable finding that would lead to a larger study as it has important public health implications for many individuals now quite disabled with these chronic symptoms.

Background, Significance and Rationale

Background, Significance and Rationale

The proposed study seeks to evaluate the efficacy of meditation among patients previously treated for Lyme disease but continuing to experience prominent symptoms of fatigue and/or pain. Study participants will have an established diagnosis of Lyme disease, prior treatment for the disease, and persistent impairment or distress that could reasonably be attributed to Lyme disease, as measured by self-report questionnaires.

The usefulness of meditation in patients with Post-Treatment Lyme Disease and Chronic Lyme Disease is uncertain. However, previous research has demonstrated the value of mindfulness and meditation in the alleviation of physical symptoms of chronic disease in other patient populations. Specifically, these practices have demonstrated benefit in the areas of fatigue, affect, and pain management.

Meditation involves a combination of muscular activity, directed focus on the self, breathing and energy

(Collins C, 1998). This mind-body fitness has been found to foster physical, mental and emotional health through the use of stretching, breathing practices, concentration and meditation (Ross & Thompson, 2010). Mindfulness, the practice of maintaining moment-to-moment awareness and accepting experiences as they are without judgment or reactivity, is at the heart of most meditation practice and the center of many alternative clinical interventions (Carlson & Garland, 2005) .

The benefits of mindfulness and meditation have been demonstrated in multiple patient groups. Carlson and Garland (2005) found significant reductions in fatigue, sleep disturbances, stress and mood disturbances as well as significant increases in sleep quality in a population of cancer patients who completed an 8-week course in Mindfulness-Based Stress Reduction (MBSR). A similar trend was noted in the application of mindfulness-based cognitive therapy for a group of cancer survivors; 30% of the treatment group showed clinical improvement in levels of fatigue versus just 4% of the control group. Furthermore, the treatment effect was still present at a six month follow-up (van der Lee & Garssen, 2010). The effect of mindfulness training on patients suffering from Multiple Sclerosis has also been investigated; levels of fatigue, depression and quality of life were all shown to improve following an 8 week mindfulness training course (Grossman et al. 2010). “Distressed individuals” (as measured by self-report answers to the question “how often do you feel distressed?”) have also been shown to benefit from mindfulness-based interventions, as an eight week course in MBSR resulted in statistically significant decreases in fatigue and perceived stress accompanied by increases in quality of life, positive affect and mindfulness for such a population (Nyklíček & Kuijpers, 2008).

New research suggests that meditation techniques suppress the hypothalamic-pituitary-adrenal axis and the sympathetic nervous system, which usually up regulate cortisol and catecholamines, perpetuating the body’s stress response. Studies also suggest that meditation can boost the immune system by increasing levels of IgA antibodies and natural killer immune cells while decreasing markers such as inflammatory cytokines and C reactive protein. Furthermore, neuroimaging research demonstrates that mindfulness meditation can induce “neuroplastic changes” in several areas of the brain including the anterior cingulate cortex, insula, tempro-parietal junction, and fronto-limbic network. These changes are associated with the reduction of stress-related symptoms in part through enhanced immune function. (Purdy, 2013)

Kundalini Yoga incorporates mindfulness practice with a triad of stretching, breathing, and meditation. The KY practice to be used in this study was promulgated and disseminated by one of best known teachers of KY in the Western Hemisphere, **Guruchan Singh Khalsa**. Dr. Alexander who is a certified instructor in this method has had over 500 hours of training in KY.

Given the neurological changes and clinical improvements associated with meditation and mindfulness, we are hopeful that the proposed study will demonstrate a decrease of fatigue, pain, and other symptoms of Post-Treatment Lyme Disease.

Our goal in this study is to assess the efficacy of meditation and stretching in patients with chronic Lyme disease symptoms. Positive results from this study could provide patients with an alternative therapeutic modality when standard treatments are no longer working. The three components of treatment consist of a weekly group therapy consisting of 10 minutes of muscular relaxation/stretching exercises and a meditation period characterized by a directed breathing exercise followed by a guided meditation.

In this study, patients are randomly assigned either to 8 weeks of active treatment or an 8 week wait-list. The wait-list group will not take part in study treatment (daily meditation or stretching) during the study wait of 8 weeks in order for us to compare change related to the study intervention to change associated with no active treatment (treatment-as-usual). These patients however will be offered the opportunity to receive 8 weeks of treatment in the next group that starts after the 8 weeks of waiting has ended.

Specific Aims and Hypotheses

Specific Aims and Hypotheses
Primary Study Goals/Aims
1. To assess whether people with PTLDS self-report greater change in core symptom of fatigue and pain, and satisfaction with global health after receiving study treatment for 8 weeks than people with PTLDS who do not receive such treatment.

Secondary Study Goals/Aims
1. To assess whether people with PTLDS self-report greater change in secondary outcome measures (physical & social functioning, multisystemic symptoms, anxiety, depression) after receiving study treatment for 8 weeks than people with PTLDS who do not receive such treatment

2. To assess the compliance of patients with weekly group meditation/stretching therapy and (based on self-report) the daily meditation therapy.

3. To assess at 6 month follow-up whether patients have continued with the medication practice, whether gains observed at week 8 have been sustained, and the medical utilization over the prior 3 month period compared to the pre-study medical utilization.

4. To assess whether the pre-treatment measures of stress, trauma history, illness perception, intolerance of uncertainty, and pain catastrophizing are variables that are related to 8 week and 6 month outcome.

Our overall hypothesis is that participants in the experimental group who perform meditation and stretching exercises daily in addition to educational seminars will improve to a greater extent (measured by self-report questionnaires of symptoms, functioning, and health satisfaction at baseline, mid-way and 8 weeks) compared to the control group.

Description of Subject Population

Sample #1

Specify subject population
40
Number of completers required to accomplish study aims
34
Projected number of subjects who will be enrolled to obtain required number of completers
40
Age range of subject population
18-65

Gender, Racial and Ethnic Breakdown
Based on prior studies of individuals with Lyme disease, we anticipate the following gender and racial/ethnic group representation
Gender: 60% women, 40% men
Racial/ethnic: 90% Caucasian, 10% other
(The racial/ethnic mix reflects the demographics of heavily Lyme endemic regions which tend to be rural or suburban areas as opposed to urban cities)
Description of subject population
40 individuals with previously diagnosed and treated Lyme disease, male and female, all ethnicities, age 18-65.

Recruitment Procedures

Describe settings where recruitment will occur
1. Notices will be placed on the Columbia Lyme center website, the Holistic Center "The Aquarian Path" website, and in Dr. Charles Alexander's office in Fairfield, CT
2. Flyers will be posted in public locations in Fairfield, CT (e.g, library, yoga studio)
3. Flyers will posted in the offices of doctors in the region.
4. As of April 2018, we want to add information regarding this study on the Columbia Recruit Me website- https://recruit.cumc.columbia.edu/

How and by whom will subjects be approached and/or recruited?
1. Subjects will be recruited by media advertisements (website, newspapers), by Dr. Charles Alexander in his clinical practice.
   a. Prior to posting ads in newspapers and online, the notice will be submitted to the IRB for approval
   b. Information about the study will be made available to patients by Dr. Charles Alexander and by Dr. Brian Fallon in their routine encounter with patients.
2. Information about the study will be publicized in Fairfield, CT and through newspapers and online sources.
3. Patients will be recruited directly from Dr. Charles Alexander or in response to media advertisements (e.g., web, newspapers).
4. Fliers with a cover letter will be sent to clinicians in the area of the study for referral of patients to the Columbia Lyme Service for recruitment.
   a. Prior to sending fliers and cover letters to clinicians, the notice will be submitted to the IRB for approval.

How will the study be advertised/publicized?
1. Information about the study will be publicized in Fairfield, CT and through newspapers and online sources.
2. Patients will be recruited directly from Dr. Charles Alexander or Dr. Brian Fallon in response to media advertisements (e.g., web, newspapers).
3. Fliers with a cover letter about the study will be sent to clinicians with practices in the region of the study so that they may distribute it to their patients.

4. **As of April 2018, we want to add information regarding this study on the Columbia Recruit Me website- https://recruit.cumc.columbia.edu/**

Do you have ads/recruitment material requiring review at this time?
Yes
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
NCT02344537

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
No

Inclusion/Exclusion Criteria

Name the subject group/sub sample
Experimental and Treatment as Usual Groups
Create or insert table to describe the inclusion criteria and methods to ascertain them

Criterion	Method of Ascertainment
History of prior diagnosis of Lyme Disease by health care provider at least 6 months prior to assessment	**Documentation/records of diagnosis made by physician**
Previously treated for Lyme Disease	Documentation of prior treatment for Lyme Disease that meets IDSA recommended standards for the stage of illness;
Current symptoms of PTLDS started within 6 months after getting Lyme disease	Self-report and review of medical records if available
Current symptoms have persisted for at least the last 6 months.	Self-report and review of medical records if available
Between the ages of 18 and 65, male or female	Self-report
English speaking	Phone screening and self-report

Primary complaint of fatigue or pain	-If fatigue, the severity score on the Promis Fatigue measure is 60 or higher (T-score); - If pain, the severity score on the VAS (0-10) Pain is at least 4
Individuals whose medical and/or psychiatric treatment has been stable for the prior 8 weeks	Self-report
Individuals who agree to not start a new treatment for PTLS during the course of the study- this applies to both those assigned to the control wait list group and those assigned to the experimental group	Self-report

Create or insert table to describe the exclusion criteria and methods to ascertain them

Criterion	Method of Ascertainment
Individual with another reasonable medical explanation (other than Lyme) that might better account for current fatigue or pain (e.g., Thyroid Disease, Anemia, Rheumatoid Arthritis)	Self-report and review of medical records if available
Individual with a major psychiatric diagnosis that might make study participation difficult (e.g, Dissociative Identity Disorder, Psychosis, Post Traumatic Stress Disorder, Substance abuse with the prior 6 months, Pain Disorder treated with opiate-based medication)	MINI Mental State Assessment and Self-Report
Individuals with severe depression	Phone interview and a T-score of 70 and above PROMIS Depression- Short Form (8 item version).
Individuals with Physical disability that might make study participation difficult	Self-report and review of medical records if available
Individuals whose current medical status is so severe or unstable that participation in the study (and not receiving new treatments from other providers) would be difficult.	Phone interview and self-report
Unwillingness to complete questionnaires, speak with study research assistant, or dedicate twenty minutes daily to meditation and stretching	Self-report

Suicidal attempts within the last 6 months or current suicidal thoughts	Phone interview and the "suicidality item" on the Beck Depression Inventory is a score of "2 or more"
Individuals unwilling to delay starting optional treatment for Lyme disease for the duration of the study	Self-report
Individuals with a prior lifetime practice of at least one month of daily practice of Kundalini yoga or those who currently practice daily meditation or yoga	Self-report

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
Yes
Waiver of documentation of consent
No
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
No
Describe procedures used to obtain consent during the screening process
1. Patients will be screened over the telephone by the study research assistant (RA) for possible enrollment.
2. If patient's self-report suggests eligibility, a copy of the consent form will be sent to the patient for review.
3. The patient will be asked to fax records of treatment history and prior blood tests for Lyme. The RA will then review Lyme disease/treatment documents.
Describe Study Consent Procedures

1. After patients are screened and records are reviewed to confirm the inclusion/exclusion criteria are met, patients will be invited to attend an introductory session with Dr. Charles Alexander. At this introductory meeting, the consent form will be reviewed with the participant by Dr. Charles Alexander including the study purpose, alternatives, risks and benefits. After the participant signs consent, Dr. Charles Alexander

will mail, fax, or scan/efax the form back to us; we do have a HIPAA secure efax. We will then sign the consent on our end and file this in the participant's chart. Once signed consent is obtained, the participant will be randomly assigned to either wait-list control or experimental group.

2. Should a patient articulate suicidal ideation voluntarily or select a score on item 9 of 2 or more on the Beck Depression Inventory, then the study RA will notify the study principal investigator in order for him to follow-up with the patient.

Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form

Justification for Waiver or Alteration of Consent

Waiver of consent is requested for the following
Partial Waiver for telephone screens.
Explain why your research can not be practicably carried out without the waiver or alteration
The initial phone screen is done in order to establish the participants Lyme history. It is difficult to get participants in without initial contact over the phone and without having some background of their Lyme history.
Describe whether and how subjects will be provided with additional pertinent information after participation
Participants will receive a copy if the consent form and the notices of privacy practice form for their records.

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Doshi, Shreya, MA
Fallon, Brian, MD
Type in the name(s) not found in the above list

Dr. Charles Alexander, MD

Study Procedures

Describe the procedures required for this study
Recruitment
1. Interested participants will respond to flyer advertisements or hear about this meditation study in the context of talks given by Dr. Fallon or Dr. Alexander. Interested individuals will be guided to contact the screening study coordinator directly to be evaluated further and to learn more about the study. Dr.

Alexander will not actively recruit study participants directly from his own private practice, although a flyer will be available in his office. Interested individuals from his practice would similarly be told to contact the study coordinator to learn more.

Screening
2a. Participants will be screened over the phone following a screening questionnaire to ensure they meet the inclusion criteria and do not have any exclusion conditions. A brief medical and psychiatric history will be obtained. A question has been added to the screening questionnaire that confirm that if the potential study participant is a current patient of Dr. Alexander that he has not previously discussed the study with him/her.
2b. If information obtained during the telephone screen indicates that the patient is or may be suicidal, the principal investigator (Dr. Fallon) will be notified immediately. Dr. Fallon will then talk with the patient to assess further; the subsequent action would be according to risk: i) providing a referral to a psychiatrist or mental health clinic in the patient's geographic area if the risk is deemed low; or ii) if the risk is deemed moderate or high, advising the patient to come directly to the NYSPI for an in-person evaluation by Dr. Fallon or go to the local emergency room for immediate in-person evaluation.

Consent Procedures
3. Once potentially eligible participants have been screened and eligibility confirmed, a member of our research team will send them a consent form either electronically or by mail. The consent form will be reviewed with the participant over the telephone by a research assistant, including the study purpose, risks and benefits. The subject will then be assigned an introductory meeting date. At the meeting, Dr. Charles Alexander will again review the consent form and **b**oth Dr. Alexander and the subject will sign consent in person. Dr. Charles Alexander will then fax or efax the signed consent form back to us (& keep the original in a locked file in his office for our later pick-up). Once signed consent is obtained by us from Dr. Alexander and once patients have returned the baseline self-assessment forms to us, the participant will be randomly assigned to either the control or experimental group by us.

Study Procedures

4. Participants will be randomly assigned to the control or experimental group.
a. Controls will be on a wait-list in which they will complete self-report questionnaires at baseline, 4 weeks and eight weeks.
b. The experimental group will be told that a start-date will be provided once a certain number of people have been found eligible to start. Groups of 6-8 participants will run concurrently.

5. After consent is signed, for a baseline evaluation, self-report questionnaires will be given to the patient by Dr. Alexander or sent to the participant electronically. The self-report questionnaires will consist of questions regarding the participant’s current clinical status.

6. The experimental group will attend an introductory meeting to be taught the meditation and stretching protocol. It will be a guided meditation in which Dr. Alexander will speak over a foundational sound for about eleven minutes. The narrative will provide a focus for the mind to induce a focused awareness. The spoken narrative is about focusing, expanding and refining the participants’ perception. Each participant in the experimental group will receive a copy of the guided meditation to listen to every day. The stretching

protocol will consist of simple postures and stretches that will last for about 10 minutes. Participants will receive a handout of the different postures that are to be completed each day along with the meditation.

7, The first part of the guided meditation will last about 8 minutes. It is a directed breath. Sitting comfortably with a straight spine in a chair or on the floor as desired, the subject is instructed to perform a short repetitive breath named Breath of Fire. Breath of Fire is characterized as an active exhale, a pulse of the abdomen in towards the spine, which forces air from the lungs. This is than followed by a relaxation of the abdominal muscles and diaphragm. As the abdomen and diaphragm relax air enters back into the lungs only to be exhaled again by the pulse of the abdominal muscles. This progresses at an approximate rate of one breath per second but when done correctly it does not lead to hyperventilation and, in fact, it can be preformed for extended periods of time. In this study, the breath is performed with the thumb tip touching first the tip of the index finger while the hands are rotating at the wrists. The rotation is a small movement such that the right hand is rotating clockwise while the left rotates counter clockwise. This causes the hands to approach each other at the bottom of the rotation and to depart from each other at the top of the rotation. If there is too much pain in the wrist joints to do this comfortably, the hand rotation can be done as a visualization. After one and a half minutes, while continuing the hand rotation, the thumb is switched so as to touch the tip of the middle finger for a minute and a half than, sequentially, the other fingers until all have spent an equal amount of time touching the thumb tip. When all this is completed, the hands are cupped and brought together such that the finger tips of one hand are in contact with the same fingertip of the opposite hand. After one minute the two cupped hands are separated so as to create a space of about 6 inches between the tips of the fingers. After one minute more the subjects move on to the guided meditation.

The second part, a Guided Meditation, will last 11 minutes. It is composed of words spoken over a musical background. In this meditation the subjects are guided to picture a healing force or light, a positive energy field, circulating around and within and through themselves. When this force comes in contact with areas that are troubled or painful, subjects are instructed to visualize the distress as being transformed such that healing takes place.

8. Participants in the experimental group will be asked to maintain a meditation log throughout the 8 weeks. They will be asked to record the number of minutes of meditation and stretching as well as any discomfort they experienced.

9. Weekly sessions will be offered at a time that is most suitable for the group of 6-8 members. At each session. the experimental group will practice meditation and stretching as a group as well as have the opportunity to ask any questions about their daily practice.

10. When control participants have completed their eight week wait time and their final self-report questionnaires and they wish to learn the meditation approach provided by this study, they will be offered an 8 week no-cost treatment by Dr. Alexander as part of a separate treatment group of “treatment as usual” randomized subjects.

11. All participants will be evaluated by self-report questionnaire and telephone follow-up by our research coordinator 6-months after starting the meditation therapy or the wait-list assignment.

12. For clinical emergencies, Dr. Alexander and Dr. Fallon will provide their cell phone numbers to study participants for use as needed.

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation

Participants will be dropped from the study if they meet either of the following criteria:
a) suicidal ideation emerges during the study as self-reported by the individual or as assessed by a BDI Item-9 score of 2 or more at week 4;
or
b) depression worsens significantly - this will be operationalized as:
i. BDI score worsening by more than 5 points from the prior assessment;
and ii. the score falls into the severe range (value 29-63) on the BDI-II at week 4 and remains elevated at a repeat assessment at week 5.

Participants who meet either of the above will meet with Dr. Alexander who will evaluate the individual psychiatrically and refer him/her for appropriate care. That individual will no longer be in the study.

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment

Primary Measures

Measure Title	# of items	Baseline	Week 4	Week 8	6Months
Promis 43 Panel- Pain Interference	6	x	x	x	x
Brief Pain Inventory VAS	9	x	x	x	x
Promis Fatigue 1.0	7	x	x	x	x
Global Health Satisfaction	9	x	x	x	x

Secondary Measures

Measure Title	# of Items	Baseline	Week4	Week 8	6months
Mindful Attention Scale	15	x		x	

Multisystem Symptom Questionnaire	34	x	x	x	x
Promis 43 Sleep, Depression, Anxiety,Physical Function	24	x	x	x	x
Promis Social Satisfaction	8	x	x	x	x
Beck Depression Inventory	21	x	x	x	x
Daily Meditation Record		x	x	x	
Intolerance of Uncertainty	7	x			
Applied Cognition (NIH toolbox)	8	x	x	x	x
Pain Catastrophizing	6	x			
Life Events History Scale	16	x			
Perceived Stress Scale	4	x			
CD-RISC	2	x			
Brief Illness Perception	8	x	x	x	
Whiteley Index	7	x	x	x	x
Medical Utilization Questionnaire	6	x			x

Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
Yes
Maximum duration of delay to any treatment
Participants randomized to “treatment as usual” will have to wait a minimum of 8 weeks to start active treatment with meditation. These individuals will have fulfilled their agreement with our study and would no longer be asked to avoid starting treatments. Should they wish to receive the 4 weeks of offered group meditation therapy, the next “TAU” meditation group would be expected to start within 4-6 weeks of their study completion.

Participants randomized to “meditation/stretching” may have to wait 4-8 weeks until a group of 6-7 eligible participants are identified who have been randomized to meditation. Groups of 6-7 eligible participants will run concurrently to minimize the wait time for participants.
All participants in this study will be able to continue during the study with whatever treatment they had been receiving prior to the start of this study. They will only be asked not to start new treatments, unless it is medically or psychiatrically recommended by their doctor. If they need to start a new treatment during the study, we will ask them to complete self-report questionnaires prior to starting the new treatment and then notify Dr. Charles Alexander and Rachel Goldman so we can make note of it in their research record.
Maximum duration of delay to standard care or treatment of known efficacy
8 weeks

Treatment to be provided at the end of the study
No

Clinical Treatment Alternatives

Clinical treatment alternatives
Individuals do not have to participate in this study in order to obtain guidance in meditation or yoga stretching. Both therapeutic modalities are available elsewhere. Individuals who wish to receive private treatment will be advised to consult with practitioners in their area.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
1. Quiet Meditation can sometimes lead to distress among individuals with a prior trauma history as they may re-visualize or remember the trauma during the quiet meditation.
2.The self-report questionnaires may lead to psychological distress among some individuals.
3. Stretching or postures may lead to discomfort.
4. Individuals are asked to not start new treatments during the course of this study. For patients who may wish to start an optional treatment, the 8-12 week delay in starting a new treatment may result in delay in receiving a potentially beneficial optional treatment.

Describe procedures for minimizing risks
1. Patients can stop the self-report questionnaires, postures or meditation at any point or if distress is excessive
2. Participants who have indicated suicidal thoughts on item 9 of the BDI (score of 2 or more) will be evaluated further and referred to a local mental health provider as needed
3. Dr. Charles Alexander and Dr. Brian Fallon will be reachable by phone in the case of an emergency throughout the study
4. If discomfort arises during stretching or postures, patients will be told they can stop at any point
5. If a treatment is recommended by a physician as medically necessary, then that treatment is allowed - the participant merely needs to notify us of this change.

Methods to Protect Confidentiality

Describe methods to protect confidentiality

All of the patients' paper-based self-report questionnaires and research data will be stored in locked filing cabinets and will be kept confidential to the extent permitted by law. Research binders will be available only to research staff and Federal, State and Institutional personnel as part of routine audits. There are legal advocacy organizations that have the authority under State law to access otherwise confidential subject

records, but they cannot re-disclose this information without the patient's consent. Any research data transmitted or stored electronically will use a subject ID number, not the patient's name.
Self-report questionnaires and research data that are collected electronically will be collected via REDCap (Research Electronic Data Capture), hosted at Columbia University. REDCap is a secure web application for building and managing online surveys and databases that complies with HIPAA requirements for a secure database.

Will the study be conducted under a certificate of confidentiality?
No

Direct Benefits to Subjects

Direct Benefits to Subjects
This study may or may not directly benefit participants, however participation will contribute to the evaluation of a potentially beneficial treatment for the symptoms that persist among many patients with a history of Lyme disease. It is hoped that the knowledge gained in this study will be of benefit to patients suffering from Lyme disease in the future.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
No

References

References

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Uploads

Upload copy(ies) of unbolded Consent Form(s)
Upload copy(ies) of bolded Consent Form(s)
Upload copy(ies) of recruitment materials/ads to be reviewed
Upload copy(ies) of the HIPAA form
HIPPA_6927_SD_10_13_2015.pdf
Waiver_Meditation_Study_10212016.pdf
Upload any additional documents that may be related to this study

New York State Psychiatric Institute (NYSPI)
Authorization to Use or Disclose Health Information during a Research Study

Protocol Number: 6927 **Principal Investigator:** Brian Fallon, MD

Name of Study: Meditation and Stretching for Post Treatment Lyme Disease Syndrome

Before researchers can use or share any identifiable health information ("Health Information") about you as part of the above study (the "Research"), the New York State Psychiatric Institute (NYSPI) is required to obtain your authorization. You agree to allow the following individuals and entities to use and disclose Health Information about you as described below:

- New York State Psychiatric Institute (NYSPI), your doctors and other health care providers, if any, and
- The Principal Investigator and his/her staff (together "Researchers"). Researchers may include staff of NYSPI, the New York State Office of Mental Health (OMH), Research Foundation for Mental Hygiene, Inc. (RFMH), and Columbia University (CU), provided such staff is a part of the study, and
- Providers of services for the Research at CU, NYSPI and/or RFMH, such as MRI or PET, or Central Reference Laboratories (NKI), if indicated in the consent form**.**

1. The Health Information that may be used and/or disclosed for this Research includes:

☑ All information collected during the Research as told to you in the Informed Consent Form.
☑ Health Information in your clinical research record which includes the results of physical exams, medical and psychiatric history, laboratory or diagnostic tests, or Health Information relating to a particular condition that is related to the Research.
☐ Additional information may include:

2. **The Health Information listed above may be disclosed to:**

☑ Researchers and their staff at the following organizations involved with this Research:
Lyme and Tick-borne Diseases Research Center at Columbia & Center for Biobehavioral Medicine at NYSPI

☐ The Sponsor of the Research,

and its agents and contractors (together, "Sponsor"); and

☑ Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research.
☐ Private laboratories and other persons and organizations that analyze your health information in connection with this study

☐ Other (family members or significant others, study buddies, outside agencies etc.) Specify:

3. By giving permission to release your Health Information as described above, you understand that your Health Information may be disclosed to individuals or entities which are not required to comply with the federal and state privacy laws which govern the use and disclosure of personal Health Information by NYSPI. This means that once your Health

Information has been disclosed to a third party which does not have to follow these laws (e.g., a drug company or the Sponsor of the Research), it may no longer be protected under the HIPAA or NYS Mental Hygiene Law requirements but is subject to the terms of the consent form and may be subject to other state or federal privacy laws or regulations.

4. Please note that:

- You do not have to sign this Authorization form, but if you do not, you may not be able to participate in the study or receive study related care. You may change your mind at any time and for any reason. If you do so, you may no longer be allowed to participate in the study. If you withdraw this Authorization the research staff and the Sponsor, if this is sponsored research, may still use or disclose Health Information containing identifying information they already have collected about you as needed to maintain the reliability of the research. Any request to withdraw this Authorization must be made in writing to (enter name and contact information below):

  Brian A. Fallon, MD, Columbia University Medical Center, Lyme Center, 1051 Riverside Drive, Unit 69, NYC, NY 10032

- While the Research is going on, you may not be allowed to review the Health Information in your clinical research record that has been created or collected by NYSPI. When this research has been completed you may be allowed to see this information. If it is needed for your care, your Health Information will be given to you or your Doctor.

5. This Authorization does not have an end date.

6. You will be given a copy of this form after you have signed it.

I agree to the use and disclosure of Health Information about me as described above:

_____ _____

Signature of Participant/ Legal Representative Date

_____

Printed Name of Participant

_____

Relationship of Legal Representative to Participant (if applicable)

We also ask you or your legal representative to initial the statements below:

☐ **I have received a copy of the NYSPI/OMH Notice of Privacy Practices.**

New York State Psychiatric Institute Institutional Review Board
Request for HIPAA Waiver of Authorization and/or Waiver of Consent

Use this form if you are requesting to waive or alter <u>some or all</u> of the elements of consent and/or of HIPAA authorization requirements.

IRB Protocol Number: 7537 Name of Principal Investigator: Brian Fallon, MD

Title of Study: Evaluation of patients with Lyme Disease and Healthy Controls – An Umbrella Screening Protocol for Individuals Interested in Lyme Research

Please indicate and explain nature of request below:

- ☑ Partial Waiver for telephone screens.
- ☐ Partial Waiver for internet survey research.
- ☐ Full Waiver for the purpose of accessing an existing database or records (paper or electronic) to identify potential subject or to conduct above research.

Describe the identifiable information that you will be collecting or accessing under this waiver (Be specific to allow the IRB to determine whether the information includes any of the 18 HIPAA identifiers or any other method of identifying the individuals): Name, Telephone Number, Email, Lyme Medical Records- especially, the following-

Curr Lyme C6
Curr Lyme C6+
Curr Lyme IgM
Curr Ly IgM Non-sp
Curr Ly IgM +
Curr Lyme IgG
Curr Ly IgG Nonsp
Curr Ly IgG+
Past Ly C6/ELISA +
Past Ly IgG+
Past Ly IgM+
Past Classic EM Rash
Past Ly Arthritis
Past Ly Facial Palsy
Past Ly Meningitis
Notes
Medications at Visit

The study, or phase of the study for which the waiver is being sought, should present no more than minimal risk to the subject, including risk to their confidentiality. Please explain how your study, or the phase of the study for which the waiver is being sought, meets the following criteria:

1. **Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects.** The only possible risk of doing the phone screen is that the participants may find some of the screening questions distressing because

it asks about their medical history. If this happens, they can choose not to answer specific questions.

2. **Explain why is it not practical to obtain consent and/or authorization from subjects?** The initial phone screen is done in order to get the participants in for a more detailed evaluation under the Meditation and Yoga for Patients with Post-treatment Lyme protocol. It is difficult to get participants in without initial contact over the phone and without having some background of their Lyme history.

3. **Can the research practicably be conducted without access to, and use of, the individually identifiable information? If not, why?** No. It is imperative that we collect certain PHI and ask participants to send us Medical Records for us to review since it is the only way we can ascertain if they have Lyme disease. Also, name, telephone number and email address are needed because we need to get in touch with them.

4. **Indicate how you plan to protect the identifiers from improper use and disclosure.**
   Check all that apply:
   - ☑ Electronic safeguards where only study staff has access and the database meets all security requirements as outlined in the NYSPI Security Plan (e.g. password protection, data encryption, firewall, no outside transmission of data, restricted access etc).
   - ☑ Physical safeguards where only study staff has access to areas with study information and NYSPI recommendations for physical security are in place (locked cabinets, locked filing room, restricted access etc).
   - ☐ No identifiers, links or codes will be retained that permit data to be identified.
   - ☐ Other:

5. Describe your plan to destroy the identifiers at the earliest opportunity:
   - ☑ Identifiers will be destroyed if the patient does not meet criteria for admission to the study
   - ☑ Identifiers will be retained until potential subjects sign consent and authorization and complete the study. Destruction of all identifiers will be consistent with federal, state and Institute policies, and or other contractual agreements.
   - ☐ N/A as I will not record identifiers or create links or codes to connect the data

6. **Where applicable: Describe how subjects will be provided with additional pertinent information after participation.**
   Participants will receive a copy if the consent form and the notices of privacy practice form for their records.

By submitting this application you are certifying that the protected health information or other identifiable information will not be reused or disclosed except as required by law, for authorized oversight of the research, or for other research that has been reviewed and approved by the IRB with specific approval regarding access to this protected health information.

☑ Agree ☐ Do not agree

FOR THOSE REQUESTING ACCESS TO MEDICAL RECORDS MAINTAINED AT NYSPI

Please also complete the following to describe selection criteria for your request:

Selection Criteria for records required (e.g. diagnosis, age, date of admission)

Dates of required records: from / / through / /

Anticipated sources of information (check all that apply)

☐ Paper medical records, Owner

☐ OMH EMR and/or DUKE EMR

☐ Other (describe)

Number of records needed: Number _____ ☐ ≥ 50 ☐ < 50
