Letter of Information

TITLE: **Automatic Self Transcending Meditation (ASTM) versus Treatment As Usual (TAU) in patients with Late Life Depression (LLD): a single blind randomized controlled longitudinal study.**

Principal Investigators: Dr. Akshya Vasudev

Co-investigators: Ronnie Newman, Dr. Pramudith Maldeniya, Dr. Amer Burhan, Dr. Stephen Wetmore

INTRODUCTION AND PURPOSE

Depression affects people across all ages. In the elderly, depression is also known as late life depression (LLD). LLD is relatively common, with a prevalence rate ranging between 2 to 6%. In patients with LLD, antidepressant medications are currently the "gold standard" for treatment. However, only 30-40% of patients respond adequately to antidepressant medication. Therefore, it is important to explore additional and complementary treatment options.

We also know that an episode of depression by itself can negatively affect the state of heart health, but our understanding of the mechanisms by which this occurs is limited. Therefore, our overall goal of this study is to examine two things. First, whether a category of meditation called Automatic Self Transcending Meditation (ASTM) is helpful in reducing symptoms of depression. Second, we aim to determine whether ASTM provides any beneficial effect on heart health among those suffering from late life depression.

How will you measure heart health?

One commonly used measure of heart health is known as Heart Rate Variability (HRV). HRV can be calculated by measuring changes in your heart rate on a beat-to-beat basis with an electrocardiogram (ECG) machine. Research has shown that reduced HRV can put people at increased risk for various heart diseases like heart attacks. Recently it has also been found that older adults with an episode of depression may have reduced HRV. While it would be beneficial to provide routine ways of improving HRV in people suffering from LLD, there are currently no readily available therapies.

What is Automatic Self-Transcending Meditation (ASTM)?

ASTM is a class of meditation that allows the mind to become quiet and promotes physical and mental relaxation. ASTM practice involves sitting comfortably with the eyes closed and utilizes a

specific sound value commonly referred to as a '*mantra'*. The goal of ASTM is to draw our attention inwards and allow our mind to be in a restful yet alert state. This meditation technique is taught by certified instructors and has been learned by more than one million people of all ages and health status' worldwide. Some research has shown that this form of meditation reduces the effects of stress as well as improves heart function in healthy adults. However, its effects on HRV and depressive symptoms in people with late life depression, has not yet been adequately studied.

PARTICIPANT INCLUSION/EXCLUSION CRITERIA

In order to take part in this research study the following criteria have to be met:

- Participants must be between the ages of 60 and 85 years and should be suffering from a major depressive episode due to either unipolar depression or a bipolar disorder, as diagnosed by the treating physician or a psychiatrist
- Must be able to sit comfortably for 30-45 minutes without any major pain or discomfort, be able to hear well enough to follow verbal instructions when the eyes are closed, and be in good general physical health.
- Participants should be willing to attend 75% of follow up appointments as an outpatient.

The following are exclusion criteria for the study. If you know or think you have any of the following conditions please let the study team or psychiatrist know:

- A diagnosis of a brain condition like seizures, strokes, mini-strokes/TIAs, or heart disease over the last year
- A head injury in the past 6 months
- Experiencing thoughts of suicide at any stage of the study
- A history of any of the following mental health conditions: psychosis over the past year; dependence on alcohol or recreational drugs, post traumatic stress disorder (PTSD), dissociative disorder, obsessive compulsive disorder (OCD), panic disorder, personality disorder, or any neurocognitive disorder including dementia.
- Also, if you have been practicing any types of meditation, mindfulness, or breathing techniques regularly, or are participating in other similar studies, you would not qualify for our study.

What happens when you are eligible and agree to participate?

If you are interested, able, and agree to participate in this study then you will be asked to visit us for a screening assessment with our research team. This involves completing a one-to-one interview and completing some standardised questionnaires. It should take around an hour and a half or less to complete this screening assessment. At the end of the screening we will be able to let you know if you qualify to participate in this study.

Once you are successfully screened you will be enrolled into the study. This next step involves randomly placing you in one of two groups, that is either the ASTM group (also called ASTM arm), or a treatment as usual (TAU) arm. We will use a computer program to randomly assign you (also called allocation) into one of the above two groups. Essentially your group allocation will be based on chance. One way of thinking about this is like flipping a coin. There is a 1 in 2

chance you will be in either group. In total, we plan to have 96 participants; 48 in the ASTM arm and 48 in the TAU arm. Participants in both arms will be able to continue to receive their usual antidepressant medications and/or psychotherapies if they are on such treatments through the period of the study. The ASTM group will learn the meditation technique first while the TAU group participants will be offered the meditation technique shortly after the 12-week study period.

What happens before and after the study period?

Interviews and questionnaires assessing depression diagnosis will be completed first by a trained rater and then confirmed by a psychiatrist. This will take place at the Geriatric Mental Health Program at Victoria Hospital, LHSC.

Likely on a different scheduled day, you will be requested to arrive at Room 402, Neurovascular Research Laboratory also called the Laboratory for Brain and Heart Health, Labatt Health Sciences Building, Western University campus for a cardiovascular health assessment. At the scheduled appointment, your height and weight will be measured, as will your blood pressure, breathing and heart rate variability.

Heart rate variability will be measured by using an electrocardiogram (ECG) machine. We will measure your blood pressure with a cuff around your finger, and also with a larger cuff placed around the upper part of your arm, just like it is done in a doctor's office. The arm cuff will be inflated with air for about 30 seconds to measure your blood pressure. Your rate and depth of breathing will be measured by placing a respiratory belt made of soft cloth around your ribcage.

All of the above testing is expected to take around half an hour.

As a part of the study protocol we would request you to attend additional laboratory visits at week twelve (12) for both groups and at twenty four (24) weeks for the ASTM arm using the same procedures.

What happens during the study period?

After you have been randomised to one of the two arms you could have one of the following procedures offered to you:

1. ASTM arm: If you are randomized to the ASTM arm you will continue to receive your antidepressant medications and/or any psychotherapy, **IF** you are on such therapy/ies. ASTM is being offered in addition to such therapy/ies. If you are randomized to this arm of the study you will initially undergo training on this technique at a room in Victoria Hospital, LHSC or at the Lawson Building on 750 Baseline Road East by certified teachers of the Art of Living Foundation. You will be asked to wear comfortable clothes and bring along a bottle of water. The training sessions will occur on four consecutive days. The first part of your training will be individual and you will continue your training with at least 3-4 other people who have also been randomized to this arm. Each training session will be 90-120 minutes long. You will then be asked to attend 45-60 minute follow up sessions once weekly for 12 weeks. We shall also be asking you to practice ASTM at home for 20 minutes twice daily over these 12 weeks

and to record the ASTM practice times at your home, and any other noteworthy observations in a log sheet that shall be provided to you.

2. TAU arm: If you are randomized to the TAU arm you will continue to receive your antidepressant medications and/or any psychotherapy, **IF** you are on such therapy/ies. After a period of 12 weeks you will also be offered the four-day ASTM training course. Effectively after week 12 you will complete your participation in the study and no further assessments will need to be completed.

We will also ask that all study participants attend 3 or 4 appointments at the Geriatric Mental Health Program, Victoria Hospital, LHSC for follow up. We will use clinical questionnaires that are commonly used in research and ask questions related to your mood. We will also ask you about your antidepressant use and other medications which you are taking. We shall arrange follow up visits at weeks 4, 8, 12, and 24 of the study (only participants in the ASTM arm will be asked to attend follow up appointments at 24 weeks). Each visit should take approximately 45 minutes.

Please note that there is no obligation to start an antidepressant and/or psychotherapy, if you are not on such treatments, as a part of your involvement in this study. However, we would encourage you to consider these treatments as they are well proven for the treatment of depression and can be further discussed with your treating physician and/or psychiatrist.

Masking

This study is a single blind study meaning that the investigators and assessors will not know to which group participants belong. This will help in preventing any sort of bias when participants are assessed. It will not be possible to blind participants or the staff providing treatment as to which group participants have been assigned. Therefore we ask participants not to discuss their group allocations with the investigators and their research team.

Benefits

Your participation will help to improve the understanding of treatments that might be helpful in reducing LLD and its' accompanying biological changes among seniors. You may experience reduction in depressive symptoms and improved cardiovascular health. There is also the possibility that you will receive no personal benefit from this study.

Risks

Even though there are no known direct risks of ASTM, some common side effects reported include mild anxiety caused by the relaxation itself. Other experienced side effects include boredom, feeling addicted to the technique, and feeling mildly detached from your surroundings. However, such effects have been found mostly in individuals who practice such techniques for several years; no other short-term side effects have been reported.

The electrodes used to measure your heart rate are placed on your chest using a sticky adhesive that may lead to temporary redness of the skin on your chest.

There are no known harmful effects with blood pressure measures as we plan to take them in the study.

Your participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care.

If you are participating in another study at this time, please inform the study coordinator right away to determine if it is appropriate for you to participate in this study.

In the event of a study-related injury, you will receive care and you do not at any point waive any legal rights by signing the consent form.

Representatives of the Western University Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research team.

Confidentiality

Your research records will be stored in a secure office for up to a period of 10 years. To further protect your confidentiality, your name will be replaced with a participant ID number on all documents. The master list linking your identity and participant ID number will be stored separately in a secure office. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published. Your results will remain anonymous and will be combined with those of other participants. No information that could reveal your identity will be released to anyone with the exception of your Family Doctor if you give permission for this.

The rare exception to guaranteeing confidentiality is in cases where you indicate you may harm yourself or someone else. Then we are required to disclose information by law.

You have the right to request the withdrawal of your data at any point during or after the study. Upon receipt of such a request, we will make every effort for data withdrawal and furthermore, all physical and electronic data shall be securely shredded.

Alternatives to study participation

You may choose not to participate in this study.

Reimbursement

We shall reimburse your travel, parking and out-of-pocket costs to a maximum of $150. You can choose to have this paid to you at week 12 or at week 24 of the study.

Contact persons

If you have any questions about the study please contact:

Principal Investigator:
Dr Akshya Vasudev (519) 685 8500 ext 58807
Or send an email to akshya.vasudev@lhsc.on.ca
(Please note that email is not entirely a secure form of communication and caution is recommended with information included to protect your privacy)

If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute (519) 667-6649.

Please visit our website:

astmstudy.com

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CONSENT

I have read the letter of information, had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction. Furthermore, I consent to my family doctor or medical clinic being allowed to release my medical information as needed for the purposes of this study.

SIGNATURES

_____

Name of Family Doctor or Clinic

I agree _____ (initial) OR I disagree _____ (initial)

_____ _____

Signature of Participant Date

_____

Print

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Print