

Short report

RETRACTED – A training programme involving automatic self-transcending meditation in late-life depression: preliminary analysis of an ongoing randomised controlled trial

Akshya Vasudev, Amanda Arena, Amer M. Burhan, Emily Ionson, Hussein Hirjee, Pramudith Maldeniya, Stephen Wetmore and Ronnie I. Newman

Late-life depression affects 2–6% of seniors aged 60 years and above. Patients are increasingly embracing non-pharmacological therapies, many of which have not been scientifically evaluated. This study aimed to evaluate a category of meditation, automatic self-transcending meditation (ASTM), in alleviating symptoms of depression when augmenting treatment as usual (NCT02149810). The preliminary results of an ongoing single-blind randomised controlled trial comparing a training programme involving ASTM with a wait-list control indicate that a 12-week ASTM programme may lead to significantly greater reductions in depression and anxiety severity. As such, ASTM may be an effective adjunctive therapy in the treatment of late-life depression.

Declaration of interest

R.I.N. is Director of Research and Health Promotion for the Art of Living Foundation, Canada and supervised the staff providing ASTM training.

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Major depressive disorder in seniors, described as late-life depression, is a disabling condition afflicting 2–6% of the population over age 60.¹ Late-life depression leads to substantial health and economic costs associated with elevated mortality rates caused by cardiovascular episodes and high risk of suicide.^{1–2} Although antidepressants are the mainstay of treatment, the response rate is only 30–40%,³ necessitating research on additional non-pharmacological therapies. Automatic self-transcending meditation (ASTM), a class of meditation, warrants further scientific evaluation. ASTM draws attention inward to quiet the mind, and induces physiological and mental relaxation. The practice involves relaxed attention to a specific sound value (mantra); this permits the mind to experience a restful but alert state of consciousness.^{4–6}

The aim of this ongoing study is to evaluate the effectiveness of ASTM in alleviating cardiovascular and mood-related symptoms of late-life depression (see Amtul *et al*⁷ for the complete study protocol). This report presents the preliminary results of adding ASTM to treatment-as-usual (TAU) on affective symptoms of late-life depression; an analysis of cardiovascular and affective symptoms post-ASTM training will be available upon study completion.

Method

Fifty-one participants 60–85 years of age enrolled in the study (Fig. 1). This ongoing single-blind (assessor-blind) RCT compares the addition of a 12-week training programme of ASTM to a TAU wait-list group.

In our evaluation of ASTM for alleviating affective symptoms of depression, the Hamilton Depression Rating Scale 17-item version (HAM-D17)⁸ was set as the primary outcome measure. Geriatric Depression Scale (GDS),⁹ Geriatric Anxiety Inventory (GAI),¹⁰ Clinical Global Impression (CGI),¹¹ Quality of Life Profile Seniors Version (QOLSV),¹² Toronto Side Effects Scale

(TSES)¹³ and the Physical Activity Scale for the Elderly (PASE)¹⁴ scores were considered secondary measures. Participants were recruited from primary and secondary health centres in London, Ontario, Canada; additionally, advertisements were placed in community centres. Individuals interested in the study were screened as per inclusion and exclusion criteria (see below). Referring physicians were masked to treatment allocations to minimise bias. Experimental methods were approved by the University of Western Ontario's Research Ethics Board.

Inclusion and exclusion criteria

Potential participants completed an eligibility assessment upon which the following criteria were met: participants were 60–85 years of age with a diagnosis of mild-to-moderate MDD due to either unipolar depression or bipolar disorder; participant had a current HAMD-17 score of 8–22; of good general physical health; able to sit comfortably for 30–45 min without any major pain or discomfort; have sufficient hearing to follow verbal instructions when the eyes are closed; and willing to attend 75% of follow-up appointments as an out-patient.

The following were exclusion criteria for the study: a diagnosis of stroke, transient ischaemic attack, heart disease or a seizure in the past year; head injury within the past 6 months; score less than 24 on the Mini-Mental State Examination; experiencing thoughts of suicide at any stage of the study; other significant mental health diagnoses. Additionally, individuals who practised any type of meditation, mindfulness or breathing techniques regularly or who were participating in similar studies did not qualify.

Treatment allocation and assessments

Participants were allocated with equal probability to the ASTM or TAU study arms using online randomisation software.¹⁵ The randomisation list was secured by a technician not directly involved in the research, ensuring concealment of allocation from assessors. The ASTM programme provided Sahaj Samadhi

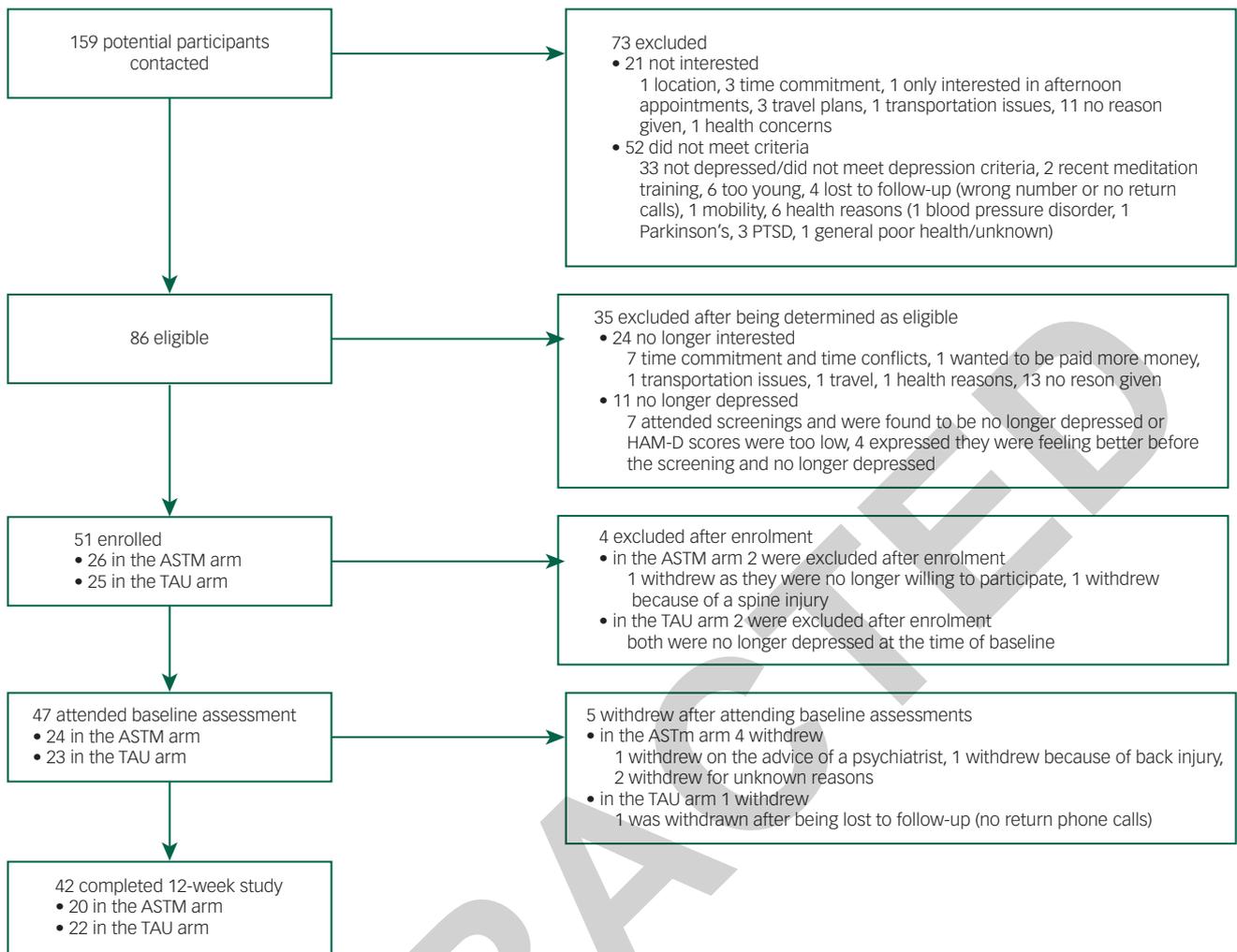


Fig. 1 CONSORT diagram.

Meditation, taught by a certified instructor from the Art of Living Foundation. It took place in groups of 3–8 participants on 4 consecutive days (2 h/day), followed by 11 one-hour weekly ‘reinforcement’ sessions. Participants were asked to independently practise ASTM 20 min twice a day and to attend 75% of reinforcement sessions.

Individuals in the TAU arm continued their existing treatments, including antidepressants and/or psychotherapy, and were offered the 4-day meditation training 12 weeks after the inclusion.

All participants attended monthly assessments during the study, where the aforementioned scales were administered by a trained rater, and any change in medication was documented.

	ASTM	TAU	<i>P</i>
Age (s.d.)	68.33 (6.12)	66.95 (6.31)	0.471
Gender			
Female	14	18	0.058
Male	11	4	

Demographic data were collected for all participants who completed baseline. The mean age between treatment arms was not significantly different as assessed by a two-tailed *t*-test $\alpha=0.05$. The gender distribution was not significantly different between treatment arms as assessed by a chi-square test $\alpha=0.05$.

Results

Data are available from 47 participants (4 were excluded after baseline data collection and last observation was carried forward for all analyses). Participant demographics are presented in Table 1.

Figure 2a presents mean HAM-D17 scores for each study arm. Baseline HAM-D scores were comparable between the groups (ASTM mean HAM-D score=14.5, s.d.=4.3; TAU mean HAM-D score=15.7, s.d.=4.2). In the first 4 weeks, HAM-D scores on average decreased by 3.3 points and 1.2 points in the ASTM and TAU groups, respectively. At the end of 12 weeks, 50% of ASTM participants achieved remission (defined as HAM-D17 score <8, ASTM mean HAM-D=9.2, s.d.=4.3); only 9% of TAU participants achieved remission (TAU mean HAM-D score=14.5, s.d.=4.8).

A 2x4 repeated-measures ANOVA with a Greenhouse–Geisser correction identified significant changes in HAM-D17 score over the 12-week period ($F(2.489, 112.027)=14.986, P<0.001, \eta_p^2=0.250$). Importantly, there was a significant interaction between HAM-D score and condition, with ASTM participants demonstrating the largest reductions in depression severity over time ($F(2.489, 112.027)=5.178, P<0.05, \eta_p^2=0.103$). There was also a significant main effect of condition, $F(1, 45)=8.240, P<0.05, \eta_p^2=0.155$.

Figures 2b and 2c show scores on the GDS and GAI findings respectively. For both scales, 2x4 repeated-measures ANOVA identified significant changes in score over time (GDS: $F(2.507,$

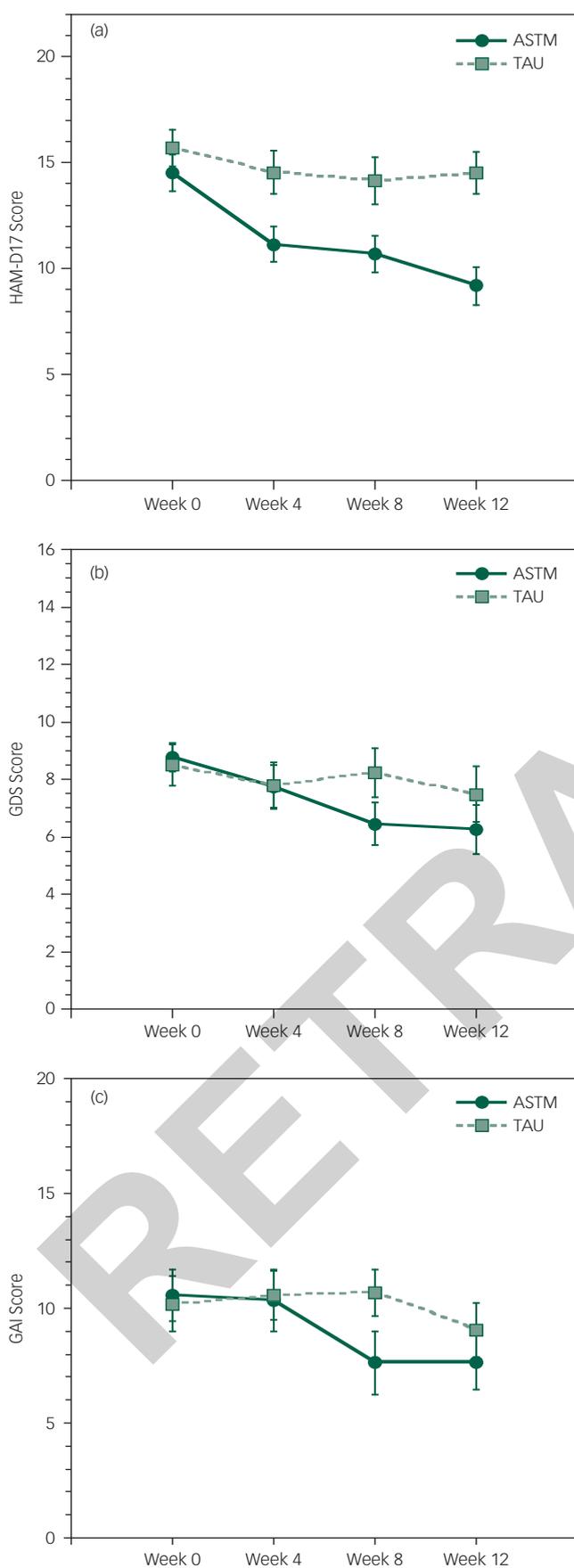


Fig. 2 (a) Mean HAM-D17 score for ASTM and TAU study arms presented at each assessment interval. (b) Mean self-rated GDS score. (c) Mean self-rated GAI score. Error bars represent ± 1 s.e.m.

112.834)=7.073, $P=0.001$, $\eta_p^2=0.136$; GAI: $F(2.414, 108.614)=5.413$, $P<0.05$, $\eta_p^2=0.107$), as well as interactions between score and condition (GDS: $F(2.507, 112.834)=2.970$, $P<0.05$, $\eta_p^2=0.062$; GAI: $F(2.414, 108.614)=2.946$, $P<0.05$, $\eta_p^2=0.061$).

The CGI-I scale indicated a significant effect of study arm, with ASTM participants improving through the study ($F(1, 45)=8.137$, $P<0.001$, $\eta_p^2=0.153$). There was also a significant score over time ($F(2.218, 99.797)=123.924$, $P<0.001$, $\eta_p^2=0.734$) and a CGI-I score \times condition interaction ($F(1, 45)=19.422$, $P<0.001$, $\eta_p^2=0.153$).

QOLSV scores improved over time ($F(3, 135)=4.032$, $P<0.05$, $\eta_p^2=0.082$), regardless of treatment arm, with no significant between-subjects differences.

There were no demonstrable physical activity level changes or perceived side-effects as measured by PASE and TSES, respectively.

Discussion

Preliminary results suggest that ASTM *in addition* to existing treatments reduces depression and anxiety severity, compared with treatment with antidepressants and/or psychotherapies only. This study is ongoing, and completion is expected in 2016.

Late-life depression-specific standardised and validated observer-rated and self-rated outcome measures ensured reliability and generalisability of our data. Preliminary results suggest physical activity level did not mediate ASTM group improvement. Consonant with numerous studies of ASTM in both psychiatric^{16–19} and non-clinical populations,^{20,21} neither the frequency nor the severity of potential adverse events, measured by the TSES, suggests ASTM was unsafe. Like previous ASTM studies,²² compliance was high, and the mean dropout rate was 17.6% (22.2% in ASTM arm and 12.5% in TAU), with no dropouts related to adverse events (see Fig. 1).

Clinicians should remain cognisant of meditation categories (e.g. concentration, open monitoring and ASTM) and their indications for specific mental health conditions. Of these, mindfulness has been found effective for relapse prevention in populations with depression;²³ its efficacy as a treatment for depression remains equivocal.²⁴ The present study provides insight into the applicability of a less frequently utilised, yet highly promising meditation category for the treatment of late-life depression.

A study limitation is the comparison of the ASTM training programme with a wait-list control. Ideally, ASTM would be compared with an active control that is similar in format (i.e. group setting, regular contact with a trainer) and time commitment. However this study's aim was to assess whether this technique and associated programme provided any additional benefit compared with TAU. We took measures to reduce risk of bias in this study: assessors were masked to allocation; intention-to-treat analysis was used; the results for all mental health measures have been reported. This study is not free of selection or performance biases, and such biases are difficult to reduce in such an RCT. Future research should focus on comparing this technique with active controls such as mindfulness meditation and cognitive behavioural therapy, so as to disentangle the potential confounding effects of social inclusion or performance bias from any specific benefits of the ASTM technique itself.

These preliminary results demonstrate that an ASTM training programme shows great promise as an adjunctive treatment for late-life depression.

Akshya Vasudev, MBBS, MD, MRCPsych, Divisions of Geriatric Psychiatry and Clinical Pharmacology, Departments of Psychiatry and Medicine, Western University, London, Ontario, Canada; **Amanda Arena**, PhD, Division of Geriatric Psychiatry, Department of Psychiatry, Western University, London, Ontario, Canada; **Amer M. Burhan**, MD, Division of Geriatric Psychiatry, Department of Psychiatry, Western University, London, Ontario, Canada; **Emily Ianson**, HBSc, DCTM, Division of Geriatric Psychiatry, Department of Psychiatry, Western University, London, Ontario, Canada; **Hussein Hirjee**, MMath, Division of Geriatric Psychiatry, Department of Psychiatry, Western University, London, Ontario, Canada; **Pramudith Maldeniya**, MD, Division of Geriatric Psychiatry, Department of Psychiatry, Western University, London, Ontario, Canada; **Stephen Wetmore**, MD, Department of Family Medicine, University of Western Ontario, London, Ontario, Canada; **Ronnie I. Newman**, EdM, CAS, Art of Living Foundation, Canada; Nova Southeastern University Lifelong Learning Institute, Davie, FL, USA

Correspondence: Dr Akshya Vasudev, Division of Geriatric Psychiatry, Department of Psychiatry, Western University, #A2-607, Victoria Hospital, 800 Commissioners Road East, London, Ontario, Canada N6A 5W9. Email: akshya.vasudev@uwu.ca

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