Strengthening the Inner Woman Project

Conducted by Associate Professor Matthew Leach (Southern Cross University) and Mrs Heather Lorenzon (TM for Women)

Approved by the University of South Australia Human Research Ethics Committee [ID: 202647]

Registered with the Australian New Zealand Clinical Trials Registry [ACTRN12620000467932]

Funded by David Lynch Foundation Australia

MARCH 7 2023

Report prepared by:

Associate Professor Matthew Leach RN, BN(Hons), ND, PhD

Southern Cross University

Contents

2
3
4
6
10
11

Background

Family, domestic and sexual violence is a major health and social issue. The Australian Institute of Health and Welfare estimate that family, domestic and sexual violence affects one in six women and one in sixteen men from the age of fifteen years. This violence is often recurrent, and perpetrated by a current or previous cohabiting partner (ABS 2017).

The physical, economic and social implications of family, domestic and sexual violence are considerable. In terms of physical consequences, approximately eight women and two men were hospitalized in Australia every day in 2014-15 due to partner violence (AIHW 2017), and in 2013-14, one woman every week and one man every month died as a direct result of partner violence (Bryant & Bricknell 2017). Anxiety and depression are also frequent consequences of such violence (Ayre et al 2016), as is homelessness (AIHW 2017). Economically, KPMG (2016) estimate that in Australia in 2015-16, violence against women and children cost close to AU\$22 billion. Not surprisingly, family, domestic and sexual violence is a major burden of disease for younger women.

"While many psychological interventions are shown to be relatively effective in improving wellbeing in survivors of domestic violence, these interventions may not be accessible, affordable or acceptable to survivors in many contexts" (Leach & Lorenzon 2023)

Transcendental Meditation™ provides a potential means by which to reduce the physical and emotional burden of family, domestic and sexual violence. This simple, effortless meditation technique has been demonstrated in a number of studies to be effective in reducing perceived stress, anxiety and depression (Elder et al 2014; Orme-Johnson & Barnes 2014), as well as improving self-efficacy and mental and physical well-being (Goldstein et al 2018). However, the effects of TM on women exposed to domestic violence have not been well-explored to date. To address this evidence gap, this study set out to compare the effectiveness of TM to group support, on quality of life, perceived stress and mood in female survivors of domestic violence.

Methods

Study design: Pilot randomised controlled trial with two parallel arms. A detailed description of the study protocol is reported elsewhere (Leach et al 2020).

Hypotheses: The study was designed to test the following hypotheses,

- Primary hypothesis

1. The TM technique significantly improves quality of life in women exposed to domestic violence, at 8 weeks and 16 weeks post-training, compared to group support.

- Secondary hypotheses

- 1. The TM technique significantly reduces severity of perceived stress in women exposed to domestic violence, at 8 weeks and 16 weeks post-training, compared to group support.
- 2. The TM technique significantly reduces severity of anxiety in women exposed to domestic violence, at 8 weeks and 16 weeks post-training, compared to group support.
- 3. The TM technique significantly reduces severity of depression in women exposed to domestic violence, at 8 weeks and 16 weeks post-training, compared to group support.
- 4. The TM technique significantly reduces the severity of post-traumatic stress disorder (PTSD) symptoms in women exposed to domestic violence, at 8 weeks and 16 weeks post-training, compared to group support.

Participants: Selection criteria for the study are outlined below.

- *Inclusion criteria*: Participants who were (a) aged >18 years, (b) female, (c) had experienced domestic violence (i.e. emotional, psychological, physical, verbal, social, financial or sexual abuse within the home environment) in their lifetime, (d) were living in metropolitan Adelaide, South Australia, (e) were able to commit to the intervention/control schedule, (f) were able to speak, read and understand English, and (g) were capable of providing informed consent, were eligible to participate in the trial.
- Exclusion criteria: Women who are in a current violent domestic relationship, had completed training in the Transcendental Meditation® technique, or had a serious psychiatric condition such as bipolar disorder or schizophrenia, were excluded. Anyone taking psychoactive substances were asked to abstain from taking these substances for at least 15 days prior to commencing the trial, and throughout the trial period.

Recruitment: Potentially eligible participants were informed of the study through flyers (which were posted in local community centres across the southern suburbs of Adelaide), a Facebook page, and social media (i.e. Facebook, Twitter, LinkedIn). Media releases were also distributed to local radio stations, newspapers and television networks to facilitate promotion of the study. The recruitment phase of the study was implemented between July 2020 and November 2021.

Randomization: Participants providing written informed consent were randomly assigned to the intervention or control group, at a ratio of 1:1. Block randomization was used with computer-generated randomly permuted

blocks of four in order to approximate equality of sample sizes in each study arm. Randomization codes were held in sequentially numbered opaque sealed envelopes, with each envelope selected by a third party (who was unaware of the allocation sequence) in consecutive order at the time of enrolment.

Intervention: Participants assigned to the intervention group completed 12 hours (9 face-to-face sessions) of standardized training in the Transcendental Meditation® (TM) technique over a period of 8 weeks, with a follow-up session held two months after completion of the training (week 16). Sessions were delivered using a combination of one-on-one and group-based formats. The training comprised a 2-hour introductory TM session and four x 1.5-hour sessions to learn TM, and four x 1-hour sessions to refine the technique. The training was delivered by qualified and experienced instructors of the TM technique. In addition to the training, participants were required to practice TM, 20 minutes twice daily, over the 8-week intervention period.

Comparator: Participants in the control group participated in 1.5-hour weekly facilitated group support sessions over a period of 8 weeks. During these group sessions, participants listened to and shared personal experiences and information, and discussed challenges and strategies to improving wellbeing. The support group sessions, and 2-month follow-up session (week 16), were facilitated by a qualified and experienced social worker.

Outcomes: The outcomes of this study were:

- 1. Health-related quality of life, as measured by the 35-item Australian Quality of Life 8 dimension (AQoL-8D) instrument. The AQoL-8D was self-administered by participants at baseline, week 8 and week 16.
- 2. Depression, as measured using the 21-item Depression Anxiety Stress Scale (DASS-21). The DASS-21 was self-administered by participants at baseline, week 8 and week 16.
- 3. Anxiety, as measured using the DASS-21.
- 4. Stress, as measured using the DASS-21.
- 5. Post-traumatic stress disorder symptoms, as measured using the 20-item PTSD Checklist for DSM-5 (PCL-5). The PCL-5 was self-administered by participants at baseline, week 8 and week 16.
- 6. Subjective experience, as assessed through an open-ended question in the data collection form and trial exit form.

Data analysis: Data were entered into SPSS (v.25) for statistical analysis and analysed by intention-to-treat. Missing data were managed using the multiple imputation method. Measures of central tendency and variability were used for descriptive data where values were normally distributed. Medians and the interquartile range were used to describe data that was not normally distributed. Frequency distributions and percentages were used to describe categorical data. Between-group differences at baseline were analysed using independent samples median tests (for medians), Fisher's Exact tests (for categorical variables), or independent samples t-tests (for means). Linear mixed-effects models were used to test for intervention effects.

Results

Description of sample: Forty-two participants enrolled in the study, of which 21 were assigned to the TM group and 21 were assigned to the support group. The mean age of participants was 47.8 ± 12.3 (SD) years, and all identified as female. Participants were predominantly unemployed/retired (57.1%), single/separated/divorced (64.3%), had rated their overall health status as fair to good (69.0%), and had experienced domestic violence more than 12 months ago (64.3%). Apart from the DASS-21 Stress severity score (which was significantly higher in the TM group, p = .03), there were no statistically significant differences in demographic variables or outcomes between groups at baseline.

Health-related quality of life: AQoL-8D utility score (Figure 1), AQoL-8D superdomain scores and AQoL-8D domain scores (excluding pain and senses domain scores) improved significantly in all participants over the 16 weeks. Accounting for random (subject) effects, participants in the TM group demonstrated a significant increase in AQoL-8D utility scores (time-group interaction, .14; 95% CI .03 to .25; p=.011), AQoL-8D mental superdomain scores (time-group interaction, .10; 95% CI .01 to .20; p=.033), AQoL-8D physical superdomain scores (time-group interaction, .14; 95% CI .03 to .25; p=.015), AQoL-8D coping domain scores (time-group interaction, .15; 95% CI .02 to .27; p=.021), over the 16 weeks when compared with the support group.



Figure 1. Changes in AQoL-8D utility scores over time (n=42)

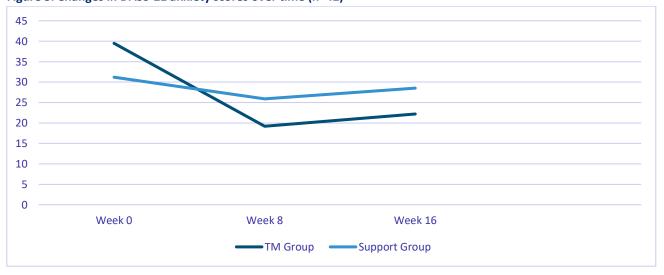
Severity of depression: There was a significant reduction in DASS-21 depression scores in all participants over time (Figure 2). After adjusting for random effects, participants in the TM group showed a significant decrease in DASS-21 depression severity scores (time-group interaction, -10.50; 95% CI -19.88 to -1.11; p=.029) over the 16 weeks when compared with the support group.

Figure 2. Changes in DASS-21 depression scores over time (n=42)



Severity of anxiety: DASS-21 anxiety scores decreased significantly in all participants over time (Figure 3). Accounting for random effects, we found a statistically significant difference in DASS-21 anxiety scores between groups over the 16 weeks, in favour of TM (time-group interaction, -14.32; 95% CI -25.92 to -2.71; p=.017).

Figure 3. Changes in DASS-21 anxiety scores over time (n=42)



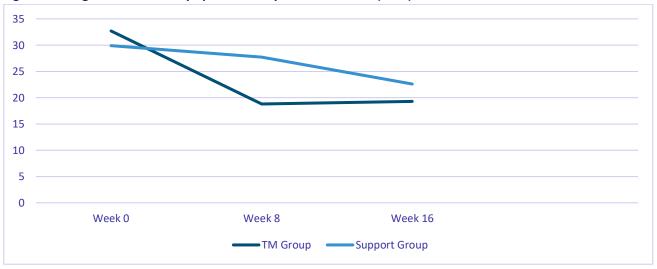
Severity of stress: A significant reduction in DASS-21 anxiety scores was evident across all participants over time (Figure 4). After adjusting for random effects, participants in the TM group showed a significantly greater reduction in DASS-21 stress severity scores over the 16 weeks when compared with the support group (time-group interaction, -12.70; 95% CI -23.43 to -1.98; p=.021).

Figure 4. Changes in DASS-21 stress scores over time (n=42)



Severity of PTSD symptoms: There was a significant reduction in PCL-5 total symptom severity scores in all participants over time (Figure 5). However, when adjusted for random effects, there was no statistically significant difference between groups over the 16 weeks.

Figure 5. Changes in PCL-5 total symptom severity scores over time (n=42)



Adverse events: A total of 12 adverse events were reported by 6 participants in the TM group (i.e. nausea, headache, irritability, weight gain), and 5 adverse events were reported by 5 participants in the support group (i.e. shaking, overwhelm, feeling upset and heart palpitations). There was no statistically significantly difference between groups in the frequency of adverse events.

Subjective experience: Participants in both groups reported an overwhelmingly positive experience of the interventions. For the TM group, participants indicated they were grateful for the experience, found TM easy to learn and practice, the instructors warm and accepting, and the classes enjoyable. Participants reported that TM "provided a lot of benefits", including increased energy levels and confidence to manage life's problems. They

also reported perceived improvements in eyesight, sleep, stress, mental clarity and coping. Two participants indicated that it was challenging to find the time to practice TM twice a day, and for one participant, arranging travel for the classes was difficult.

For the support group, participants indicated the information and techniques were helpful, and the group was "empowering". Participants reported that they enjoyed building connections, sharing experiences, gaining new insights into their own behaviours, and realising that they were not alone. Many indicated the support group was beneficial, with perceived improvements in stress, confidence, wellbeing, anxiety and self-esteem. One participant found it challenging to attend all support group sessions.

Conclusions

This clinical trial set out to compare the effectiveness of TM to group support in female survivors of domestic violence. The findings revealed that TM was significantly more effective than group support in improving health-related quality of life, anxiety, depression and perceived stress, but not PTSD symptoms at 16 weeks. Participants also reported a generally positive experience of TM and group support. These findings suggest that TM may be a plausible treatment option for survivors of domestic violence who are hesitant or unable to partake in group support. TM also could be used as an adjunct to existing programs to foster greater improvements in health outcomes among survivors of domestic violence. An important next step of this research will be to establish the clinical and economic effectiveness of TM in both male and female survivors of domestic violence through larger, more definitive randomised controlled trials.

References

ABS. (2017) Personal Safety Survey 2016. ABS cat. no. 4906.0. Canberra: ABS.

AIHW. (2017) Hospitalised assault injuries among women and girls. Cat. no. INJCAT 184. Canberra: AIHW.

Ayre J, Lum On M, Webster K, Gourley M, Moon L. (2016) Examination of the burden of disease of intimate partner violence against women in 2011: final report (ANROWS Horizons, 06/2016). Sydney: ANROWS.

Bryant W, Bricknell S. (2017) Homicide in Australia 2012–13 to 2013–14: National Homicide Monitoring Program Report. Canberra: AIC.

Elder C, Nidich S, Moriarty F, Nidich R. (2014) Effect of transcendental meditation on employee stress, depression, and burnout: a randomized controlled study. Perm J. 18: 19-23.

Goldstein L, Nidich SI, Goodman R, Goodman D. (2018) The effect of Transcendental Meditation on self-efficacy, perceived stress, and quality of life in mothers in Uganda. Health Care Women Int. 1: 1-24.

KPMG. (2016) The cost of violence against women and their children in Australia: final report May 2016. Canberra: Department of Social Services.

Leach MJ, Lorenzon H, Nidich S. (2020) Transcendental Meditation for women affected by domestic violence: study protocol of a pilot randomised, controlled trial. Integr Med Res. 9: 100432.

Leach MJ. Lorenzon H. (2023) Transcendental Meditation for women affected by domestic violence: a pilot randomized, controlled trial. Unpublished manuscript.

Orme-Johnson DW, Barnes VA. (2014) Effects of the Transcendental Meditation Technique on Trait Anxiety: A Meta-Analysis of Randomized Controlled Trials. J Altern Complement Med. 20: 330-341.