Integrative Medicine Research 9 (2020) 100432

Contents lists available at ScienceDirect

Integrative Medicine Research

journal homepage: www.imr-journal.com

Study protocol

Transcendental Meditation for women affected by domestic violence: Study protocol of a pilot randomised, controlled trial

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ARTICLE INFO

Article history:
Received 30 April 2020
Accepted 18 May 2020
Available online 30 May 2020

Keywords:
Anxiety
Depression
Domestic violence
Meditation
Quality of life

ABSTRACT

Background: Almost one in three women worldwide will be exposed to domestic and family violence some time in their life. This violence can contribute to physical, social, economic and psychological harm. Transcendental Meditation® (TM) may help to lessen the physical and emotional burden of domestic violence.

Methods: The objective of this pilot, parallel-group, randomized controlled trial is to compare the effectiveness of TM to support group control, on quality-of-life, perceived stress and mood in women affected by domestic violence. Women living in Adelaide, South Australia, who have experienced domestic violence in their lifetime, will be randomized to eight weeks of standardised TM training or facilitated group support sessions. Health-related quality of life (AQoL-8D), severity of depression, anxiety and perceived stress (DASS-21), and symptoms of post-traumatic stress disorder (PCL-5) will be self-reported by women at baseline, week 8 (post-intervention) and week 16 (follow-up). Data will be analysed by intention-to-treat using linear mixed-effects models.

Discussion: TM is an effortless, easily practiced and convenient relaxation technique, with reportedly high rates of adherence. While previous studies have shown TM to be effective in improving a range of psychological and behavioural outcomes across different populations, the effects of TM in survivors of domestic violence is largely unknown. If the study described herein is able to demonstrate the benefits of TM in this population, it might offer survivors an accessible, long-term and potentially cost-effective treatment option for domestic violence-induced distress, anxiety and depression.

Trial registration: ACTRN12620000467932.

1. Introduction

Domestic and family violence is a major public health issue. Globally, an estimated thirty percent of women have experienced physical and/or sexual intimate partner violence in their lifetime.[1] In Australia, 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, can affect any member of the household (but predominantly women), and is typically perpetrated by a current or previous cohabiting partner.[2]

The physical, economic and social implications of family, domestic and sexual violence are considerable. In terms of physical consequences, approximately 50,000 women across the globe were intentionally killed by an intimate partner or family member in 2017.[3] Within an Australian context, eight women and two men were hospitalised every day in 2014–2015 due to partner violence,[4] and in 2013–2014, one woman every week and one man every month died as a direct result of partner violence.[5]

Anxiety and depression are common consequences of family, domestic and sexual violence,[6] as is suicide, injury, homelessness, sexually transmitted infections, adverse pregnancy outcomes and alcohol abuse.[4,7] Economically, violence against women and children cost close to AU$22 billion in Australia in 2015–2016.[8] Not surprisingly, family, domestic and sexual violence is a major burden of disease for younger women.

Best practice guidelines for domestic violence typically recommend two broad approaches to managing the consequences of such violence – response and recovery. 'Response' refers to the immedi-

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https://doi.org/10.1016/j.imr.2020.100432

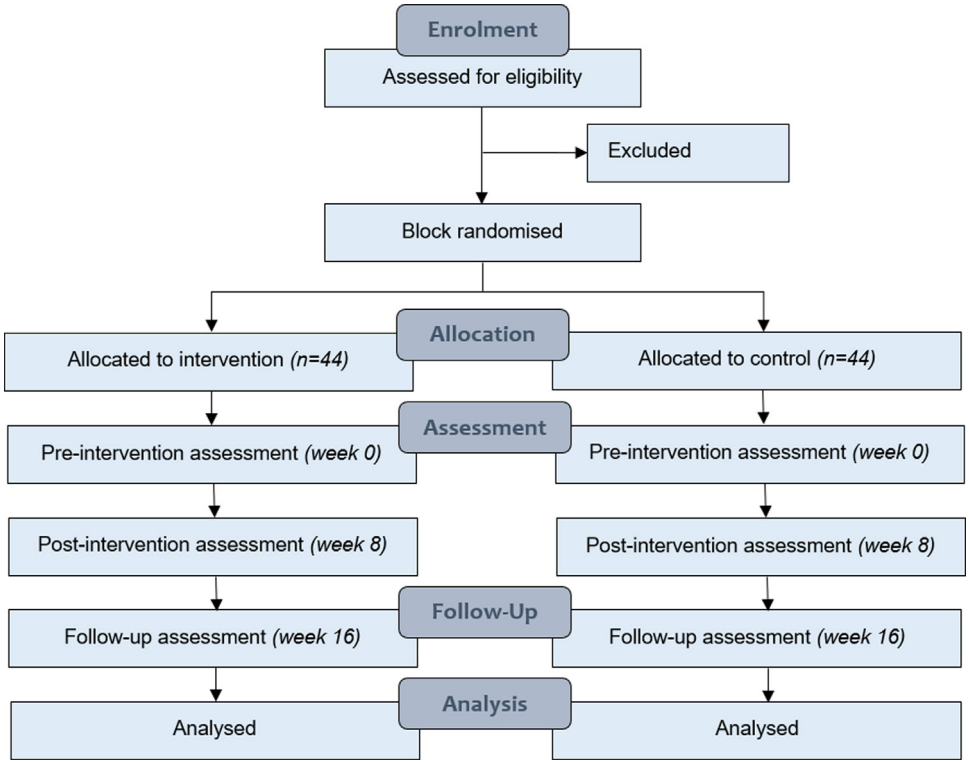

Fig. 1. Study flow chart.

ate management of physical and emotional injuries, preservation of safety (for the survivor and significant others), and referral to appropriate services.[9–12] 'Recovery' relates to the use of appropriate resources and techniques to assist the survivor to heal from their trauma. These strategies vary considerably across clinical guidelines, ranging from psychological treatments such as cognitive behavioral therapy, counselling and group work, to stress reduction techniques such as deep breathing and progressive muscle relaxation.[9–12] While there is some evidence to suggest that these therapies may be effective in improving wellbeing in survivors of domestic violence,[13–15] access to these therapies (in terms of cost, appropriateness and availability) can pose a challenge for some survivors.

Transcendental Meditation® (TM) provides a potential means by which to reduce the physical and emotional burden of family, domestic and sexual violence. This simple, effortless relaxation technique has been demonstrated in a number of studies to be effective in reducing perceived stress, anxiety and depression[16,17], as well as improving self-efficacy and mental and physical well-being.[18] Further research has also shown that TM significantly reduces the severity of trauma symptoms.[19,20]

Building on this body of work, this study sets out to explore whether improvements in quality of life, and perceived stress and mood can be achieved through the use of TM in women exposed to domestic violence.

2. Methods

2.1. Study design

The Strengthening the Inner Woman (SIW) project is a pilot randomized controlled trial with two parallel arms (Fig. 1). The trial aims to compare the effectiveness of the Transcendental Meditation® technique to group support, on the quality of life, perceived stress and mood of women exposed to domestic violence of any type. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR: ACTRN12620000467932).

2.2. Hypotheses

The SIW trial sets out to test the following hypotheses:

2.2.1. Primary hypotheses

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

2.2.2. Secondary hypotheses

1. The Transcendental Meditation® 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 Transcendental Meditation® 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 Transcendental Meditation® technique significantly reduces severity of depression in women exposed to domestic violence, at 8 weeks and 16 weeks post-training, compared to group support.

2.3. Participants

The study selection criteria are outlined below.

2.3.1. Inclusion criteria

Participants who are (a) aged ≥18 years, (b) female, (c) have experienced domestic violence (i.e. emotional, psychological, physical, verbal, social, financial or sexual abuse within the home environment) in their lifetime, (d) are living in metropolitan

Adelaide, South Australia, (e) are able to commit to the intervention/control schedule, (f) are able to speak, read and understand English, and (g) are capable of providing informed consent, will be eligible to participate in the trial.

2.3.2. Exclusion criteria

Women who are in a current violent domestic relationship, have completed training in the Transcendental Meditation® technique, or have a serious psychiatric condition such as bipolar disorder or schizophrenia, will be excluded. Anyone taking psychoactive substances will be asked to abstain from taking these for at least 15 days prior to commencing the trial, and throughout the trial period.

2.3.3. Sample size

Based on an effect size of 0.3 (for the primary outcome, AQoL-8D utility score [as informed by an unpublished quasi-experimental feasibility study of TM for women affected by domestic violence, conducted by the authors in 2017]), and an attrition rate of 10%, a total of 88 participants (44 in each arm) will have 90% power for a linear mixed-effects model (testing for the interaction between time and group) to detect a statistically significant difference in AQoL-8D utility scores with a two-tailed alpha level set at 0.05.

2.4. Setting

The study will be conducted through the Hackham West Children's Centre, a family support facility located in the Southern suburbs of Adelaide, South Australia. The centre is situated in an area affected by considerable intergenerational unemployment and social problems, and is surrounded by a high proportion of government-assisted housing.[21]

2.5. Outcomes

The primary and secondary outcomes of the SIW trial are conceptualised and operationally defined as follows;

2.5.1. Primary outcomes

Health-related quality of life, which denotes a person's sense of wellbeing and an ability to enjoy normal life activities, is shown to be considerably lower in women exposed to domestic violence.[22,23] This outcome will be measured using the 35-item Australian Quality of Life – 8 dimension (AQoL-8D) instrument.[24] This instrument will generate 11 scores, including a utility score, physical and psychosocial super dimension scores, and independent living, senses, pain, mental health, happiness, self-worth, coping and relationship domain scores. The AQoL-8D will be self-administered by participants at baseline, 8 weeks and 16 weeks [primary timepoint].

2.5.2. Secondary outcomes

Severity of perceived stress: Stress is a psychological and physiological reaction to extrinsic or intrinsic events or situations, and is shown to be significantly elevated in women exposed to domestic violence.[25] This outcome will be assessed using the 7-item stress subscale of the 21-item Depression Anxiety Stress Scale (DASS-21).[26] The DASS-21 will be self-administered by participants at baseline, 8 weeks and 16 weeks.

Severity of anxiety: Anxiety is a psychological condition that typically manifests as overwhelming feelings of unease, nervousness, fear and/or apprehension.[27] The condition commonly occurs in people who have experienced domestic violence.[6] Severity of anxiety will be measured using the 7-item anxiety subscale of the 21-item Depression Anxiety Stress Scale (DASS-21).[26] The DASS-21 will be self-administered by participants at baseline, 8 weeks and 16 weeks.

Severity of depression: Depression is a psychological condition characterised by severe and persistent sadness and displeasure in activities.[27] The condition often manifests in individuals that have been exposed to domestic violence.[6] This outcome will be assessed using the 7-item depression subscale of the 21-item Depression Anxiety Stress Scale (DASS-21).[26] The DASS-21 will be self-administered by participants at baseline, 8 weeks and 16 weeks.

Severity of post-traumatic stress disorder (PTSD) symptoms: Studies have consistently demonstrated a significant association between domestic violence exposure and the development of PTSD symptoms.[28] This outcome will be measured using the 20-item PTSD Checklist for DSM-5 (PCL-5).[29] The PCL-5 will be self-administered by participants at baseline, 8 weeks and 16 weeks.

Subjective experience: Participants will be invited to share their experiences of the intervention and control, as well as the trial, through free written text. These experiences will be captured using a customized open-ended question in the data collection form and trial exit form, at 8 weeks and 16 weeks, respectively.

2.6. Recruitment

The study will be promoted using a multi-modal recruitment campaign. Information about the study will be disseminated through flyers (which will be posted throughout the study site, other local community centres, domestic violence services and community health services), broadcast media (i.e. modular advertisements in a free local newspaper), and social media (including a dedicated Facebook page, and Facebook, Twitter and Instagram posts). Media releases also will be distributed to local radio stations, newspapers and television networks to facilitate promotion of the study. Participant recruitment is anticipated to commence in August 2020 and be completed by May 2021.

2.7. Randomization

Participants providing written informed consent will be randomly assigned to the intervention or control group, at a ratio of 1:1. Block randomisation will be used with computer-generated randomly permuted blocks of four in order to approximate equality of sample sizes in each study arm. Randomization codes will be held in sequentially numbered opaque sealed envelopes. This process will be undertaken by a third party not involved in the direct administration of the study. Each envelope will be selected by a member of the research team (who will be unaware of the allocation sequence) in consecutive order at the time of enrolment.

2.8. Interventions

Participants assigned to the intervention group will complete 12 hours (9 face-to-face sessions) of standardised 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 will be delivered using a combination of one-on-one and group-based formats. The training will comprise a 2-hour introductory TM session, four × 1.5-hour sessions to learn TM, and four × 1-hour sessions to refine the technique. The training will be delivered by qualified and experienced instructors of the Transcendental Meditation® technique. In addition to the training, participants will be required to practice TM, 20 minutes twice daily, over the 8-week intervention period. Fidelity to the intervention will be monitored using self-administered daily meditation records, and instructor-administered training attendance/participation records.

Women in the control group will participate in 1.5-hour weekly facilitated group support sessions over a period of 8 weeks. During these group sessions, participants will listen to and share personal experiences and information, and discuss challenges and strategies to improving wellbeing. The support group sessions, and 2-month follow-up session, will be delivered by a qualified and experienced social worker. Fidelity to the control will be measured using facilitator-administered session attendance/participation records.

2.9. Statistical analysis

Study data will be entered onto SPSS (v.25) for data cleaning, coding and analysis. Data will be analysed by intention-to-treat, with per-protocol analyses (i.e. controlling for degree of treatment compliance) performed for hypothesis-generating purposes only. Missing data will be managed using the multiple imputation method. We will report descriptive data using means and standard deviations (where values are normally distributed) and medians and the interquartile range (if data are not normally distributed). Categorical data will be described using frequency distributions and percentages. We will test for baseline differences between groups using independent samples *t*-tests (for means) and independent samples median tests (for medians), where variables are continuous (e.g. age, AQoL-8D index scores, DASS-21 subscores). For categorical variables (e.g. gender, education, employment status), we will use the Fisher's Exact test to measure baseline differences between groups. To estimate the intervention effect for AQoL-8D index scores and subscores, and DASS-21 subscores, we will use Linear mixed-effects models. The models will use restricted maximum likelihood estimation, and include one random effect (i.e. participant ID) to account for subject variation. Fixed effects will include group (intervention and control), time (0, 8 and 16 weeks) and group-by-time interaction. Outcome data not meeting the assumptions of normality and heteroscedasticity will be log-transformed.

2.10. Ethics

2.10 Ethics: The SIW trial has been reviewed and approved by the University of South Australia Human Research Ethics Committee (ID: 202647).

3. Results

Data collection is expected to commence in September 2020. Results are anticipated in late 2021.

4. Discussion

Domestic and family violence is a public health issue of pandemic proportions and with serious biopsychosocial implications, including morbidity, disability and death. Disappointingly, evidence indicates that reports of domestic and family violence are on the rise in many regions.[30–33] If these trends continue, a parallel increase in the adverse consequences of such violence is to be expected.

The prompt and effective management of domestic violence-induced distress, anxiety and depression is critical to reducing the burden of domestic violence, improving the health and wellbeing of survivors, and facilitating recovery. A number of psychological treatments (such as cognitive behavioural therapy and group therapy) may offer some benefit in reducing distress and improving mood in survivors of domestic violence.[13–15,34] However, these treatments may not be suitable or feasible for all survivors of domestic violence due to the high cost, time-commitment and need for specialist providers to deliver these therapies. Adherence to these therapies represents an additional problem, which can in turn adversely impact the effectiveness of these treatments.[34]

Transcendental meditation® (TM) may offer some advantages over traditional psychological treatments. Studies to date have reported high adherence rates with TM,[16,18,35] supporting the view that TM is an effortless and easily practiced therapy.[36] TM is also convenient in that it can be practiced anywhere and anytime; this may be particularly helpful for survivors of domestic violence that have children or are living in unstable environments. Another advantage of TM is that post-training, there are no ongoing costs of therapy, and further, the continuation of TM is not therapist-dependent. These features of TM are likely to be attractive to survivors of domestic violence.

Evidence to date indicates that TM is effective at improving a number of psychobehavioral outcomes (i.e. self-efficacy, stress, burnout, depression, anxiety, quality of life, sleep quality, wellbeing and mental health), across diverse populations.[16–18,35] Notwithstanding, there are no known studies that have explored the impact of TM on these outcomes in survivors of domestic violence. If the proposed study is able to demonstrate the benefits of TM in this population, it could offer survivors an accessible, long-term and potentially cost-effective treatment option for domestic violence-induced distress, anxiety and depression.

Although the proposed study uses a robust study design, and if sufficiently powered, will be able to provide preliminary evidence of the effectiveness of TM (versus group support) for improving quality of life, perceived stress and mood of women exposed to domestic violence, it does have some limitations. For logistical reasons, the study is limited to women living in metropolitan Adelaide, South Australia. As such, the study findings may not translate to non-female survivors of domestic violence, or to those living in rural regions, other states/cities in Australia or international populations. The study also excludes women who are in a current violent domestic relationship. While this criterion serves to protect participants and the research team from perpetrators of the domestic violence, it does mean that the study findings may have limited application to women still living in a violent domestic relationship.

This study will explore, possibly for the first time, the impact of an effortless, easily practiced and convenient relaxation technique (i.e. Transcendental Meditation®) on the quality of life, perceived stress and mood of women affected by domestic and family violence. If the findings support the feasibility of the trial, and provide evidence favoring the effectiveness of TM, this will help justify the conduct of larger, more definitive trials of TM for survivors of domestic violence. The findings of such trials will determine whether TM represents a safe and effective treatment option for domestic violence-induced distress, anxiety and depression.

Author contribution

Conceptualization: HL. Methodology: ML. Writing - Original Draft: ML. Writing - Review & Editing: ML, HL and SN. Funding Acquisition: ML and HL.

Conflict of interest

HL works for GMDO Australia, a not-for-profit educational charity that delivers TM training. The other authors declare no conflict of interest.

Funding

The project has been funded by David Lynch Foundation Australia.

Ethical statement

This research has been approved by the University of South Australia Human Research Ethics Committee (ID: 202647).

Data availability

Not applicable.

References

1. World Health Organisation. *Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence*. Geneva, Switzerland: World Health Organisation; 2013.
2. Australian Bureau of Statistics (ABS). *Personal Safety Survey 2016, ABS cat. no. 4906.0*. Canberra, Australia: ABS; 2017.
3. United Nations Office on Drugs & Crime (UNODC). *Global study on homicide 2018: gender-related killing of women and girls*. Vienna, Austria: UNODC; 2018.
4. Australian Institute of Health & Welfare (AIHW). *Hospitalised assault injuries among women and girls, Cat. no. INJCAT 184*. Canberra, Australia: AIHW; 2017.
5. Bryant W, Bricknell S. *Homicide in Australia 2012–13 to 2013–14: National Homicide Monitoring Program Report*. Canberra, Australia: Australian Institute of Criminology; 2017.
6. Ayre J, Lum On M, Webster K, Gourley M, Moon L. *Examination of the burden of disease of intimate partner violence against women in 2011: final report (ANROWS Horizons, 06/2016)*. Sydney: ANROWS; 2016.
7. Walsh J, Spangaro J, Soldatic K. Global understandings of domestic violence. *Nurs Health Sci* 2015;17:1–4.
8. KPMG. *The cost of violence against women and their children in Australia: final report May 2016*. Canberra, Australia: Department of Social Services; 2016.
9. Benavides MO, Berry OO, Mangus M. *Treating women who have experienced intimate partner violence*. Washington, DC: American Psychiatric Association; 2019.
10. Domestic Violence NSW. *Good practice guidelines for the domestic and family violence sector in NSW*. Redfern, New South Wales: Domestic Violence NSW; 2016.
11. Kenny N, ni Riain NA. *Domestic violence: a guide for general practice*. Dublin, Ireland: Irish College of General Practitioners; 2014.
12. World Health Organization. *Health care for women subjected to intimate partner violence or sexual violence: a clinical handbook*. Geneva, Switzerland: World Health Organization; 2014.
13. Latif M (PhD thesis) *Efficacy of group CBT on anxiety and depressive symptoms of women affected by intimate partner violence*. Karachi: University of Karachi; 2018.
14. Parcesepe AM, Martin SL, Pollock MD, Garcia-Moreno C. The effectiveness of mental health interventions for adult female survivors of sexual assault: a systematic review. *Aggress Violent Behav* 2015;24:15–25.
15. Santos A, Matos M, Machado A. Effectiveness of a group intervention program for female victims of intimate partner violence. *Small Group Res* 2016;48:34–61.
16. Elder C, Nidich S, Moriarty F, Nidich R. Effect of transcendental meditation on employee stress, depression, and burnout: a randomized controlled study. *Perm J* 2014;18:19–23.
17. Orme-Johnson DW, Barnes VA. Effects of the transcendental meditation technique on trait anxiety: a meta-analysis of randomized controlled trials. *J Altern Complement Med* 2014;20:330–41.
18. Goldstein L, Nidich SI, Goodman R, Goodman D. The effect of Transcendental Meditation on self-efficacy, perceived stress, and quality of life in mothers in Uganda. *Health Care Women Int* 2018;1:1–24.
19. Nidich S, Seng A, Compton B, O'Connor T, Salerno J, Nidich R. Reduced trauma symptoms and perceived stress in female prison inmates through the Transcendental Meditation program: a randomized controlled trial. *Perm J* 2017;21:16–7.
20. Nidich S, Mills P, Rainforth R, Heppner P, Schneider RH, Rosenthal NE, et al. Non-trauma-focused meditation versus exposure therapy in veterans with post-traumatic stress disorder: a randomised controlled trial. *Lancet Psychiatry* 2018;5:975–86.
21. Australian Bureau of Statistics. *Hackham West – Huntfield Heights (SA2) (403041079), Canberra, Australia*; 2019. https://itt.abs.gov.au/itt/r.jsp?databyregion&ref=CTA2. Accessed September 27, 2019.
22. Alsaker K, Moen BE, Morken T, Baste V. Intimate partner violence associated with low quality of life – a cross-sectional study. *BMC Womens Health* 2018;18:148.
23. Costa D, Hatzidimitriadou E, Ioannidi-Kapolou E, Lindert J, Soares J, Sundin O, et al. Intimate partner violence and health-related quality of life in European men and women: findings from the DOVE study. *Qual Life Res* 2015;24:463–71.
24. Richardson J, Iezzi A, Khan MA, Maxwell A. Validity and reliability of the Assessment of Quality of Life (AQoL)-8D multi-attribute utility instrument. *Patient* 2014;7:85–96.
25. Boeckel MG, Viola TW, Daruy-Filho L, Martinez M, Grassi-Oliveira R. Intimate partner violence is associated with increased maternal hair cortisol in mother-child dyads. *Compr Psychiatry* 2017;72:18–24.
26. Ng F, Trauer T, Dodd S, Callaly T, Campbell S, Berk M. The validity of the 21-item version of the Depression Anxiety Stress Scales as a routine clinical outcome measure. *Acta Neuropsychiatrica* 2007;19:304–10.
27. Porter RS. *The Merck manual of diagnosis and therapy*. 20th ed. Kenilworth, NJ: Merck Sharp & Dohme Corp; 2018.
28. Lagdon S, Armour C, Stringer M. Adult experience of mental health outcomes as a result of intimate partner violence victimisation: a systematic review. *Eur J Psychotraumatol* 2014;5:1.
29. Blevins C, Weathers F, Davis M, Witte T, Domino J. The posttraumatic stress disorder checklist for DSM-5 (PCL-5): development and initial psychometric evaluation. *J Traumatic Stress* 2015;28:489–98.
30. Australian Bureau of Statistics (ABS). *Recorded crime – victims, Australia, 2018, Cat. No. 4510.0*. Canberra, Australia: ABS; 2018.
31. Chuemchit M, Chernkwanma S, Rugkua R, Daengthern L, Abdullakasim P, Wieringa SE. Prevalence of intimate partner violence in Thailand. *J Fam Violence* 2018;33:315–23.
32. Joseph B, Khalil M, Zangbar B, Kulvatunyou N, Orouji T, Pandit V, et al. Prevalence of domestic violence among trauma patients. *JAMA Surg* 2015;150:1177–83.
33. New Zealand Family Violence Clearinghouse. *Data summary: violence against women: June 2017*. Auckland, New Zealand: University of Auckland; 2017.
34. Warshaw C, Sullivan CM, Rivera EA. *A systematic review of trauma-focused interventions for domestic violence survivors*. Chicago, IL: National Center on Domestic Violence, Trauma & Mental Health; 2013.
35. Nidich S, Nidich RJ, Salerno J, Hadfield B, Elder C. Stress reduction with the transcendental meditation program in caregivers: a pilot study. *Int Arch Nurs Health Care* 2015;1:11.
36. Leach MJ, Francis A, Ziaian T. Transcendental Meditation for the improvement of health and wellbeing in community-dwelling dementia caregivers [TRANSCENDENT]: a randomised wait-list controlled trial. *BMC Complement Altern Med* 2015;15:145.