Assessing the efficacy of a structured stress management program in reducing stress and climacteric symptoms in peri- and postmenopausal women

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Abstract
To evaluate the effectiveness of a structured education program on lifestyle habits, which is also incorporating teaching on deep breathing, progressive muscle relaxation, and guided visualization, in the control of various components of the climacteric symptomatology in peri- and postmenopausal women. Sixty-one women aged 40–65 years with varying climacteric and stress symptoms were included in this study. Women were randomly assigned to the intervention group (31) or the control group (30). The intervention group followed an 8-week stress management program. The following parameters were assessed at baseline and at the end of the 8-week follow-up period in both groups: climacteric symptoms (Green Climacteric Scale (GCS)), sleep quality (Pittsburg Sleep Quality Index (PSQI)), mood status (Depression-Anxiety-Stress Scale), self-esteem (Rosenberg Self-esteem Scale), and health-related control (health locus of control (HLC)). A mixed-model ANOVA showed significant time × group × GCS interaction (within subjects: $F_{187} = 23.830$, $p$ value<0.001; between subjects: $F_{371} = 3.9078$, $p$ value<0.001). With regard to HLC, there was a non-significant between subjects but a significant within-subjects effect (HLC × group × time, $F_{497} = 3.848$, $p$ value = 0.024). Regarding DASS scores, there was a significant between-subjects effect ($F_{394} = 10.258$, $p$ value = 0.003) but a non-significant within-subjects effect. With regard to PSQI, the analysis showed significant within-subjects effects (PSQI × group × time: $F_{74} = 4.691$, $p$ value = 0.003) and non-significant between-subjects’ effects ($F_{0.022} = 0.883$). Finally, regarding RSS, there was a significant within-subjects’ (RSS × group × time, $F_{4.183} = 4.183$, $p$ value = 0.029) but non-significant between-subjects’ effect ($F_{1.582} = 1.582$, $p$ value = 0.213). Stress management may offer an alternative approach to the management of climacteric symptoms.

Keywords Stress · Depression · Anxiety · Menopause · Relaxation therapy · Climacteric symptoms

Introduction
Ovarian senescence and the ensuing fluctuation in levels of estrogen is accompanied by hormonal, physical, and psychological changes, which adversely affect quality of life (Woods et al. 2009). As reported in a recent cross-sectional analysis, higher levels of circulating interleukin 8 and tumor necrosis factor alpha are associated with the severity of hot flushes in healthy young postmenopausal women (Huang et al. 2017). Most importantly, the perimenopausal fluctuation of sex hormones seems to interact with the mechanisms of stress (Woods et al. 2009; Huang et al. 2017).

The definition of the reproductive milestones of women has been described in the criteria set out by the Stages of Reproductive Aging workshop +10 (Harlow et al. 2012). Accordingly, “perimenopause” as a term that refers to women...
with elevated levels of follicle-stimulated hormone (FSH) and amenorrhea of various intervals, lasting for at least 60 days. Menopause was defined as cessation of menses for at least 12 months, as well as serum estradiol levels less than 50 pg/mL and FSH > 25 mIU/mL (Harlow et al. 2012). These subgroups of patients are assessed together, considering the development of climacteric symptoms, as they are the most commonly affected (Harlow et al. 2012; Davis et al. 2015).

The hypothalamic-pituitary-ovarian axis, the hypothalamic-pituitary-adrenal axis, and the autonomic nervous system affect significantly the intensity of menopausal symptoms (Fang et al. 2014). It has to be noted here that climacteric symptoms include a variety of complaints, from sweating and hot flashes up to depression and anxiety, while they occur more frequently in women around the time of the menopausal transition, so perimenopause and in the first few years after the cessation of menses (Davis et al. 2015). Chronic stress may disrupt the “stress adaptation system” which, in turn, may affect the intensity of menopausal symptoms (Albert and Newhouse 2019). In a study conducted in women with a history of chronic stress, circulating norepinephrine was positively associated with the severity of climacteric symptoms (Fang et al. 2014; Albert and Newhouse 2019). The individual perception of menopausal symptoms may depend on pre-existing stress levels (Ayers et al. 2010; Nosek et al. 2010). Stress during the menopausal transition exacerbates climacteric symptoms, which in turn increase stress levels; this vicious cycle may render women dysfunctional in their daily lives (Nosek et al. 2010). Depression occurs more frequently within the first 24 months after the last period. Particularly affected are women with a history of negative stressful life events during their reproductive years or negative perceptions about their future health in the postreproductive period (Zhou et al. 2012; Cohen et al. 2006). Stress management, therefore, may contribute to the reduction of menopausal symptoms.

Although menopausal hormone therapy is the treatment of choice for climacteric symptoms, the fear of breast cancer and thrombosis makes often physicians and patients reluctant to use it (Armeni et al. 2016). Alternative approaches in the management of climacteric complaints are of particular interest for the middle-aged woman. Adaptation of a middle-aged woman to the physiological reproductive changes and the ensuing short- or long-term problems is largely associated with her overall self-esteem. A recent study has shown that resilience could determine the ability to cope with the changes that develop around the time of the menopausal transition (Süss et al. 2020). Finally, health cognition, determined by personality, personal experiences, the social environment, and emotions, may also affect the sense of well-being and the perception of climacteric disturbances (Smith and Ruiz 2008).

Evidence supports that a combination of psychological techniques and educational sessions is associated with reductions of stress in women with intimate partner violence (Kokka et al. 2019), with pathologic gambling (Linardatou et al. 2014) and with chronic neck pain (Metikairidis et al. 2017). Therefore, we postulated that a structured education program on lifestyle habits, which also incorporates teaching on stress-management techniques of diaphragmatic breathing (DB), progressive muscle relaxation (PMR), and guided visualization, will be efficient in the control of various components of the climacteric symptomatology in peri- and postmenopausal women, including self-esteem and health-related control.

### Materials and methods

#### Subjects

This was a randomized intervention pilot study, which aimed to assess possible causal relationships between psychological interventions and psychometric/climacteric scores, in a sample of middle-aged women. After power analysis, we initially included 70 women, aged between 40 and 65 years old who were peri- and/or postmenopausal with bothersome climacteric symptoms. Sample size was calculated using an online calculator. Accordingly, a sample of 28 participants in every group would provide enough power to detect a difference of \( \pm 0.12 \pm 1.82 \) in the scores of the Greene climacteric scale, between the intervention and the control group (alpha error level 0.10, power 80%).

The study was conducted at the Menopause Clinic, 2nd Department of Obstetrics and Gynecology, Aretaieio Hospital. This clinic offers both primary prevention practices, as well as advice to peri- and young postmenopausal women seeking guidance on dealing with disturbing climacteric symptoms. Before recruitment, all women were subjected to a routine assessment program including breast mammography, evaluation of kidney/liver function, and assessment of thyroid status, as well as gynecological examination and Papanicolaou smear. During the first and every annual or biannual appointment in the Menopause Clinic, a detailed personal and gynecological history is obtained by a trained medical professional, and the details are subsequently coded and stored in an electronic database for future reference.

Inclusion criteria were as follows: age between 40 and 65 years old, perimenopausal or postmenopausal status, last menstrual period <10 years at inclusion, Greek as primary language or adequate ability to read and write in Greek, absence of neurologic disorders, severe psychiatric diseases (e.g., psychosis, bipolar disorder, major depression), chronic organic disorders, perimenopausal, and particularly young postmenopausal women present with the same extent of climacteric symptoms, hence the rational of their combined assessment (Harlow et al. 2012; Davis et al. 2015). Exclusion criteria were as follows: current intake of menopausal...
hormone therapy or treatment during the last 6 months, current or previous psychotherapy or psychological counseling, current use of antidepressants, anxiolytics or sleeping pills, psychoactive substances, or alcohol. All participants signed an informed consent to participate in the study, which was approved by the Local Ethical Committee and was conducted according to the Declaration of Helsinki and its later amendments.

All women who attended the Menopause Clinic between the year of 2015 until the year of 2017 were initially screened for inclusion in the study. Following application of the previously mentioned exclusion criteria, a total of 7 women were excluded. Sixty-three women who met the above inclusion/exclusion criteria were randomized into two groups (i.e. 33 women in the intervention group and 30 women in the control group) according to a random number generated by online random number generator based on cosmic radiation (random.org). Both groups were informed about the purpose of the program in the same way. During the first session, two women of the intervention group dropped out the study and were not included in either the pre- or post-intervention analysis; the first one left the study due to unexpected travel, and the second one could not continue due to heavy workload.

The intervention group was invited to attend a stress management program for 8 weeks, which consisted of one weekly session on the benefits of regular exercise, healthy diet, cognitive restructuring, and positive thinking, and learning relaxation techniques such as diaphragmatic breathing, progressive neuromuscular relaxation, and guided visualization (Kokka et al. 2019; Linardatou et al. 2014; Metikaridis et al. 2017). The control group did not attend a stress management program, but received only verbal advice on diet, exercise, and relaxation, and we also had a weekly phone call follow-up with them.

The intervention group was invited to visit the clinic in a weekly basis, while the control group visited the clinic only in the first and eighth week. All participants were asked to complete the questionnaires only at the beginning and at the end of the study.

During the first session, we provided the same information about stress and its implications on health to all participants. The intervention group received training on the techniques of DB and PMR, provided via an audio CD (total duration of 25 min, 10 min DB, and 15 min PMR). The technique of guided imagery was explained to the participants of the intervention group at the fourth session. The DB technique involves diaphragmatic deep breathing followed by slow and prolonged exhalations. The manipulation of the respiratory motion is known to contribute to a physiological response, including decreased oxygen consumption and heart rate as well as increased parasympathetic activity. The PMR technique reduces anxiety and stress by coordinating relaxation periods and muscle contractions. This technique is effective in reducing anxiety and perceived stress and increasing sense of control. Finally, the guided imagery technique involves encouragement to imaging a place where there is a feeling of comfort and safety. This approach stimulates the four senses in an attempt to induce a physiological relaxation response.

Participants of the intervention group were encouraged in weekly meetings to practice the techniques twice per day and to use a diary to record their daily practice (up to 112 sessions). Further instructions were also provided with regard to managing the association between stress and personality as well as gender-related stress factors.

Participants of the control group were provided with the audio CDs as well as with instructions on the aforementioned relaxation techniques at the end of the 8th week.

**Measurements-measuring tools**

The following measurements were obtained in both groups at baseline and after 8 weeks:

- Climacteric symptoms were assessed via the Green Climacteric Scale (GCS) (Greene 1976). The symptoms were evaluated in four domains, namely vasomotor, psychological, sexual, and psychosomatic. The severity of symptoms was rated on a Likert scale. We obtained a total score separately for every category of climacteric symptoms. For the psychological domain, the Cronbach’s a coefficient was 0.703 (initial) and 0.878 (final). For the vasomotor domain, the Cronbach’s a coefficient was 0.881 (initial) and 0.874 (final). For the somatic domain, the Cronbach’s a coefficient was 0.493 (initial) and 0.659 (final).
- Sleep quality was assessed via the Pittsburg Questionnaire (PQ) (Perantoni et al. 2012), validated in the Greek language. This 19-item questionnaire consists of self-report questions reflecting attitude in seven clinically derived domains, namely sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medications, daytime dysfunction, and subjective sleep quality. Reliability analysis was performed estimating Cronbach’s a coefficient which was 0.619 (initial) and 0.650 (final).
- Self-esteem levels were assessed via the Rosenberg Self-esteem Scale (RSS), validated in Greek language (Galanou et al. 2014). This questionnaire consists of ten questions, which are rated on a Likert scale. Reliability analysis was assessed using Cronbach’s a coefficient, which was 0.405 (initial) and 0.586 (final).
- Depression, stress, and anxiety symptoms were assessed with the Depression, Anxiety, Stress Scale (DASS-21), validated in the Greek language (Lyarakos et al. 2011). This self-report questionnaire consists of three individual subscales, for assessment of anxiety, depression, and
stress, which are comprised of seven questions rated on Likert response scale. Responses are estimated with a score from 0 up to 3, which corresponds to answers of “did not apply to me at all” up to “applied to me very much” or “applied to me most of the time.” Higher level of severity in each dimension is indicated by higher scores. Reliability analysis was done by estimating Cronbach’s a coefficient which was estimated as 0.841 (initial) and 0.823 (final).

• Health-related control was assessed via the Health Locus of Control Questionnaire (HLCQ) (Karademas 2009; Wallston et al. 1978), validated in the Greek language. This questionnaire consists of 18 questions, which are rated on a Likert scale. The responses are coded as follows: “very strongly disagree” scores 1; “disagree to some extent” scores 2; “slightly disagree” scores 3; “agree slightly” scores 4; “agree to some degree” scores 5; “agree very much” scores 6. The questionnaire is divided into three subclasses, which are independent to each other: internal, change, and personal others. Reliability analysis was performed using Cronbach’s a coefficient, which was estimated as follows: HLC internal 0.773 (initial) and 0.761 (final), HLC change 0.835 (initial) and 0.827 (final), HLC personal 0.464 (initial) and 0.615 (final).

### Statistical analysis

All data analyses were conducted using the IBM SPSS Statistics, version 20. Demographic and psychometric data are presented using frequency and descriptive statistics (mean ± standard deviation). All continuous variables were examined for normality of the distribution at each time point. To evaluate the effect of intervention on psychometric variables, we used a model of mixed design analysis of variance (ANOVA), according to the type of questionnaire used and the time, taking also into account the classification into the intervention group or the control group. The results are presented as within-subjects effect, between-subjects effect (intervention vs control), and interaction effect (main outcome of the questionnaire used, main effect of time, interaction between the results of the questionnaire and time). We also evaluated for time simple effects for each group using paired t tests for pre- and post-intervention scores in each group. The level of statistical significance was set at \( p < 0.05 \), with Bonferroni correction for multiple comparisons.

### Results

Sixty-one women were entered into the final analysis. Between-group comparison at baseline (Table 1) on demographics, BMI, and years of menopause did not reveal significant differences \( (p > 0.05, \text{ns}) \).

Table 1. Basic demographic data, BMI, and menopause duration of the intervention and control group at baseline.

| Variables                  | Groups       |
|----------------------------|--------------|
|                            | Intervention | Control      |
| Age (years)                | 57.70 (6.89) | 56.52 (4.73) |
| Education (years)          | 4.67 (1.39)  | 4.52 (1.35)  |
| BMI                        | 27.87 (4.38) | 26.71 (5.48) |
| Menopause duration (years) | 6.80 (1.46)  | 6.94 (3.07)  |

With regard to GCS, the analysis showed significant within-subjects effect, namely GCS × group × time, with \( F = 23.830, p \text{ value} < 0.001 \). Between-subjects’ effects were also significant with \( F = 39.078, p \text{ value} < 0.001 \). There was significant interaction effect with regard to time × GCS \( (F = 163.143, p \text{ value} < 0.001) \), but also independently for time and GCS.

With regard to RSS, the analysis showed significant within-subjects’ effect \( \text{RSS × group × time}, F = 4.183, p \text{ value} = 0.029 \). Between-subjects’ effects were not significant \( (F = 1.582, p \text{ value} = 0.213) \). There was a significant effect of time × RSS \( (F = 16.343, p \text{ value} < 0.001) \), and also independently for time and RSS.

With regard to HLC, there was a non-significant between-subjects effect \( (F = 2.441, p \text{ value} = 0.124) \) but a significant within-subjects effect \( \text{HLC × group × time}, F = 3.848, p \text{ value} = 0.024 \). The interaction effect of time was not significant \( (F = 0.746, p \text{ value} = 0.391) \), the interaction effect of HLC was significant \( (F = 33.490, p \text{ value} < 0.001) \), while the time × HLC effect was not significant \( (F = 1.796, p \text{ value} = 0.185) \).

With regard to DASS, there was a significant between-subjects effect \( (F = 10.258, p \text{ value} = \)
0.003). The within-subjects effect was not significant (DASS × group × time, $F = 0.292, p$ value = 0.747). Finally, significant interaction effects were observed for time ($F = 7.306, p$ value = 0.010), DASS ($F = 5.232, p$ value = 0.022), but a non-significant interaction of time × DASS ($F = 0.209, p$ value = 0.650).

With regard to PSQI questionnaire (combined outcome of all 7 subdomains), the analysis showed significant within-subjects’ effects (PSQI × group × time, $F = 4.691, p$ value = 0.003). The between-subject effect was not significant ($F = 0.022, p$ value = 0.883). Time showed a significant interaction effect ($F = 10.343, p$ value = 0.003) and also PSQI results showed significant interaction effects ($F = 39.851, p$ value<< 0.001). However, time × PSQI interaction was not significant ($F = 1.109, p$ value = 0.300).

**Discussion**

This study aimed to assess the efficacy of a structured education program on lifestyle habits, which also incorporates teaching on stress-management techniques of diaphragmatic breathing, progressive muscle relaxation, and guided visualization, with regard to the control of climacteric symptomatology in peri- and postmenopausal women, including anxiety,
stress, self-esteem, and health-related control. Our findings support the superiority of the applied intervention over a non-specialized one that was applied on the control group and highlight the importance of stress reduction for the management of climacteric symptoms, particularly regarding their severity. The health-related control, sleep quality, and self-esteem showed an improvement over time which however was not significantly different between the intervention and control group. Finally, the intervention had an inconsistent effect on measures of depression and anxiety at the end of the 8 weeks.

Climacteric symptoms may be successfully managed by opting for either pharmacological or alternatively non-pharmacological approaches (Davis et al. 2015). Women are increasingly using alternative treatments to alleviate the symptoms of menopause and stress, such as exercise, selective nutrition, various relaxation, and stress management techniques like DB, PMR, and guided visualization (Chaudhuri et al. 2015; Vélez Toral et al. 2014; Woods et al. 2014; Yazdkhasti et al. 2015). Previous reports in perimenopausal women described the efficacy of implementing relaxation techniques to reduce stress and climacteric symptoms (Ayers et al. 2010; Nosek et al. 2010). The effect of independent psychological interventions or health education programs has been evaluated by a few studies, which showed controversial outcomes. A recent randomized controlled trial (RCT) showed reduction in scores of anxiety and depression, following mindfulness-based stress reduction techniques (Wong et al. 2018). In a lifestyle education study (Rathnayake et al. 2019), young postmenopausal women showed improved climacteric symptoms scores following completion of an 8-week health educational program, as opposed to control women.

On the contrary, other studies show no effects of relaxation techniques or exercise with regard to managing stress or climacteric symptoms. A recent Cochrane review study, evaluating five RCTs with a total of 733 women, reported inconclusive results regarding the efficacy of exercise in controlling vasomotor symptoms, irrespectively of the use of menopausal hormone therapy (Daley et al. 2014). Another Cochrane review (Saensak et al. 2014), including four RCTs and 281 participants, reported that the evidence concerning the efficacy of PMR on the intensity of menopausal symptoms remains inconclusive (Saensak et al. 2014).

Non-pharmacological therapies for the management of symptoms related to estrogen deficiency are particularly beneficial for women with a history of breast cancer. So far, the existing literature examined the effects of behavioral interventions on specific components of menopausal symptomatology. As demonstrated in a randomized phase II clinical trial in 68 women, paced breathing at 6 breaths per minute seems to be an effective behavioral intervention for regulation of hot flash score and frequency (Sood et al. 2013), which is in agreement with our findings. As reported in a recent review, cognitive behavioral therapy, hypnosis, acupuncture, exercise and yoga, and dietary advice have been shown to be beneficial for the management of vasomotor symptoms in women with a history of breast cancer (Szabo et al. 2019). Earlier evidence on mindful therapies and relaxation techniques has been proven insufficient for effective management of vasomotor symptoms (Saensak et al. 2014). Furthermore, another systematic review found no association between relaxation techniques or mindfulness interventions on the severity of vasomotor symptoms (Goldstein et al. 2017).

The main strength of this study is the fact that we assessed the efficacy of a combined intervention program consisting of both education on healthy lifestyle and three individual relaxation techniques. Moreover, by using the Greene scale, we aimed on the assessment of all symptoms related to the climacterium, namely psychological, psychosomatic, vasomotor, and sexual. On the contrary, previous studies assessed the efficacy of one technique on vasomotor symptoms particularly; hence, our results are not directly comparable. The non-constant associations between the intervention and
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Table 2  Mixed ANOVA for the effectiveness of Greene scale (GCS), Rosenberg self-esteem scale (RSS), health-related control (HLC), Depression anxiety stress scale (DASS), and PSQI (Pittsburg Sleep Quality Index) between the intervention group and control, during the intervention period of 8 weeks

|                          | F     | p value | η²   |
|--------------------------|-------|---------|------|
| Greene scale             |       |         |      |
| Between-subjects’ effects|       |         |      |
| Grouping                 | 39.078| <0.001  | 0.398|
| Within-subjects’ effects|       |         |      |
| o GCS × group × time     | 23.830| <0.001  | 0.288|
| Interaction effects      |       |         |      |
| • Time                   | 259.508| <0.001  | 0.815|
| • RSS                    | 205.796| <0.001  | 0.777|
| • Time × GCS             | 163.143| <0.001  | 0.734|
| RSS                      |       |         |      |
| Between-subjects’ effects|       |         |      |
| • Grouping               | 1.582 | 0.213   | 0.026|
| Within-subjects’ effects|       |         |      |
| o RSS × group × time     | 4.183 | 0.029   | 0.066|
| Interaction effects      |       |         |      |
| • Time                   | 10.322| 0.022   | 0.149|
| • RSS                    | 11.567| 0.001   | 0.164|
| • Time × RSS             | 16.343| <0.001  | 0.217|
| Health-related control   |       |         |      |
| Between-subjects’ effect |       |         |      |
| Grouping                 | 2.441 | 0.124   | 0.040|
| Within-subjects’ effects|       |         |      |
| Health-related control × group × time | 3.848 | 0.024 | 0.061 |
| Interaction effects      |       |         |      |
| • Time                   | 0.746 | 0.391   | 0.012|
| • Health-related control | 33.490| <0.001  | 0.693|
| • Time × health-related control | 1.796 | 0.185 | 0.030 |
| DASS                     |       |         |      |
| Between-subjects’ effects|       |         |      |
| Grouping                 | 10.258| 0.003   | 0.186|
| Within-subjects’ effects|       |         |      |
| DASS × group × time      | 0.292 | 0.747   | 0.006|
| Interaction effects      |       |         |      |
| • Time                   | 7.306 | 0.010   | 0.140|
| • DASS                   | 5.232 | 0.022   | 0.111|
| • Time × DASS            | 0.209 | 0.650   | 0.005|
| PSQI                     |       |         |      |
| Between-subjects’ effects|       |         |      |
| Grouping                 | 0.022 | 0.883   | 0.001|
| Within-subjects’ effects|       |         |      |
| PSQI × group × time      | 4.691 | 0.003   | 0.121|
| Interaction effects      |       |         |      |
| • Time                   | 10.343| 0.003   | 0.233|
| • PSQI                   | 39.851| <0.001  | 0.540|
| • Time × PSQI            | 1.109 | 0.300   | 0.032|

The outcomes in the remaining assessed questionnaires might be explained by the fact that they are not specifically designed for menopausal women. Our results are of clinical significance for women who have contraindications or are not willing to receive menopausal hormone therapy for their symptoms.

Limitations of our study need to be documented. First, the sample size was relatively small. Second, the sample was retrieved from a Menopause Clinic, so it mainly consists of women with greater awareness of health issues arising at mid-life but also of women with higher rates of climacteric symptoms; thus, the results should not be extrapolated to the general population. The Greene Climacteric Scale has been translated but not validated in the Greek language. Finally, the 8 weeks duration of the intervention is relatively small, in order to ensure that the participants gained the required experience in managing menopause-related stress conditions in the future. However, the observed efficacy of this intervention program provides relative reassurance regarding acquiring abilities to cope with stress, at least in short term.

In conclusion, our study shows that the intervention of an 8-week program for stress management helped women to adjust to a healthy lifestyle in terms of healthy nutrition, regular exercise, and sleep and to implement a combination of relaxation and stress management techniques, cognitive restructuring, and self-awareness. The intervention reduced significantly both stress and climacteric symptoms. Larger randomized and prospective studies with a wider combination of relaxation techniques are needed to corroborate our results.

Availability of data and material  Upon request

Author contributions  AA, manuscript drafting and data collection
AP, data collection, conduction of psychological interventions studies
FC, conduction of psychological intervention studies, statistical analysis
EA, manuscript drafting
AS, data collection
KP, data collection
GC, coordination of psychological interventions and interpretation of statistical analysis
IZ, coordination of psychological interventions studies
IL, overall supervision of data collection, intervention studies, statistical analysis, and manuscript proof editing

Conflict of interest  The authors declare no competing interests.

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