Effectiveness of focused meditation for patients with chronic low back pain —a randomized controlled clinical trial

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Effectiveness of focused meditation for patients with chronic low back pain—A randomized controlled clinical trial☆

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1. Introduction

Low back pain is a major public health problem, with more than 70% of the population in Western societies experiencing low back pain in a given year.[1] Chronic low back pain can seriously affect quality of life and has a high comorbidity with impaired psychological well-being and depression. Furthermore, it is the most costly ailment of working age with an estimated € 10 billion spent annually on medical cost in Germany and more than 30 billion USD spent in the USA.[2,3] A wide variety of treatments for back pain exist including education, analgesic and anti-inflammatory medication, exercise, injections, manual therapies, acupuncture and further complementary therapies, surgery and minimally invasive treatments. However, there is still unsatisfactory evidence to support most of these treatments. Because patients with low back pain are frequently dissatisfied with their medical care, they commonly seek out Complementary and Alternative Medicine (CAM) methods for treatment.[4,5] Several methods of Mind-Body Medicine have found to be effective in chronic pain conditions. For example, Hatha Yoga in low back and neck pain[6–8] and Tai chi in fibromyalgia[9] have demonstrated clinically relevant effects in randomized trials.

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Meditation has been increasingly used in the adjunctive treatment of chronic disease conditions. Several experimental studies revealed decreased central pain responsiveness in long-term meditation practitioners, and, meditation as a neuromodulatory interventions may modify cortical structures and processes involved in attention and the emotional responding to.[10]

Programs of eight-week mindfulness meditation or mindfulness-based stress reduction (MBSR) have been introduced for early supportive treatment of chronic pain patients.[11–13] Mindfulness meditation has demonstrated beneficial clinical effects for various health problems, including anxiety disorders,[14] mood and quality of life in cancer patients,[15] and the prevention of relapse of depression[16] among others. However, to date, only a few controlled studies investigating chronic pain patients [17–19] and two RCTs investigating the effects of a meditation program in a population of elderly patients with chronic back pain exist to.[20,21]

In this study, we aimed to evaluate the effectiveness of meditation in patients with low back pain by means of a randomized trial.

2. Methods

This study was designed as a randomized controlled clinical trial. All study participants gave their informed consent. The study protocol was reviewed and approved by the Ethics committee of the Charité-University Medical Center, Berlin, Germany. Patients were enrolled between October 2009 and June 2010; interventions and follow-up were completed by February, 2011. All study procedures and data collection were carried out at the outpatient department of the Immanuel Krankenhaus Berlin, Department of Internal and Complementary Medicine.

2.1. Study procedures

We recruited participants by means of press releases offering cost-free participation in a study for chronic low back pain. Potential participants were screened for eligibility by telephone interview, and eligible candidates were scheduled for an enrolment appointment. A study physician performed the candidates' physical examinations. Thereafter, each eligible participant was randomly assigned to either an 8-week meditation group or a home-based exercise program with an additional offer to join a meditation class after 8 weeks without further evaluation (wait list offer). The written and personal study information emphasized that both treatments might be useful for the treatment of chronic back pain.

2.2. Study participants

Patients of both sexes were eligible if they were between the ages of 18 and 75 and suffered from low back pain for at least three months with a self-rated minimum intensity >40 mm on the 100 mm VAS on more than 5 days a week in the preceding 3 months. Any regular analgetic medication should not have been changed in the preceding 6 weeks. Rescue medication was allowed and patients were asked to document any intake in a diary. Participants should have had no previous experience in meditation. We excluded subjects if they either had undergone invasive treatment within the last 6 weeks or had treatment planned within the next 10 weeks. We also excluded subjects whose back pain was complicated (spinal stenosis, herniated vertebral disk) or was attributable to specific underlying diseases (for example congenital anomalies in the cervical spine area, fractured bones). Subjects with manifest osteoporosis, spondylolisthesis, or other coexisting serious comorbidity as well as subjects participating in another study were also excluded. Diagnosis of unspecific low back pain had to be confirmed by a board certified orthopaedic physician, rheumatologist, neurosurgeon or a pain specialist.

2.3. Randomization

Patients were randomly allocated to a treatment group by a non-stratified block-randomization with varying block lengths and by preparing sealed, sequentially numbered opaque envelopes containing the treatment assignments. Randomization was based on the "ranuni" pseudo-random number generator of the SAS/Base® statistical software (SAS Inc., Cary NC, USA), and the envelopes were prepared by the study biostatistician. When a patient fulfilled all enrolment criteria, the study physician opened the lowest numbered envelope to reveal that patient's assignment.

2.4. Interventions

Subjects were asked to participate in a weekly 90-min group meditation class over an 8-week period, or to adhere to a standardized home-based exercise program after initially receiving personal information by a physician.

2.4.1. Meditation

Subjects were taught a focused meditation technique (jyoti meditation).[22] Jyoti meditation is a technique for controlling and directing attention away from the physical body and sensations, from the emotions and thoughts to a place of relaxation or peace within the organism. To handle potential ruminative and distractive thoughts, participants were recommended to repeat a silent mantra of individual choice. The individually chosen mantra should have a pleasant connotation or meaning with regards to the general personal or spiritual background. When repeating the mantra the subjects were asked to close the eyes and to withdraw attention from thoughts and focus it at the still point between the eyes. The technique of jyoti meditation was chosen as it is easy to learn and can be performed without further physical requirements.

The meditation teachers had longstanding experience with the method. During the weekly meditation class, participants practiced the method initially for 15 min with stepwise prolongation to 30 min. Thereafter, they had the possibility to exchange opinions and speak about the experiences with the meditation technique. Patients were encouraged to practice at home for 20–30 min every day.

2.4.2. Exercise

For specific exercise and chronic low back education, participants in the exercise group received an established and previously used self-care manual developed by a large statutory German health care insurance company. A total of 15 exercises were described focusing on muscle stretching, strengthening and joint mobility with proper posture depiction. Patients were encouraged to practice these exercises for at least 20 min daily.

2.5. Outcomes

All subjects were asked to complete standardized questionnaires at the outset of the study (baseline, day 0), after 4 weeks (day 28 ± 5) and after 8 weeks (day 56 ± 5). The first questionnaire was filled out at the study site; all subsequent questionnaires were sent to participants by mail and brought back to the study site at a fixed date.

2.5.1. Primary outcome

The primary outcome was the mean group difference of average back pain intensity change at rest during the last 7 days from

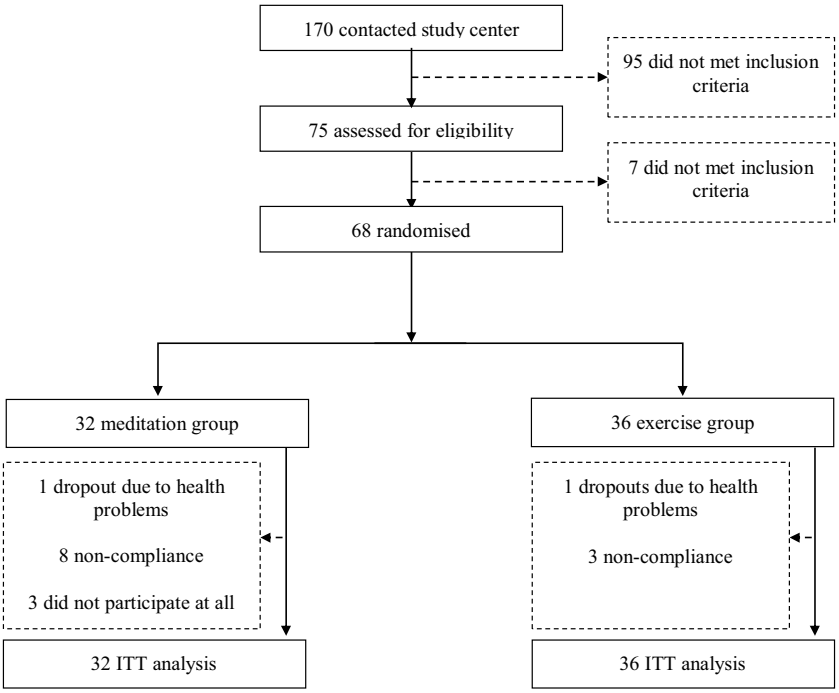

Fig. 1. Trial flow chart.

baseline to week 8. As assessed by VAS (0 = no pain and 100 = worst imaginable pain).

2.5.2. Secondary outcomes

Secondary outcomes included the VAS for pain-related bothersomeness and the scores of Roland Morris Disability Index (RMDQ),[23] the Cohen Perceived Stress scale (PSS),[24] the Hospital Anxiety Depression Scale (HADS).[25] Quality-of-life (QOL) was measured by the Medical Outcomes Study 36-Item-Short-Form (SF-36).[26, 27]

To control non-specific treatment effects, outcome expectation was rated by all patients on a 5-point Likert scale ranging from 4 (expecting considerable pain relief) to 0 (expecting no pain relief) immediately after they had been informed of their randomly assigned treatment. Patients' global rating of the subjective effectiveness of the received intervention was additionally assessed by 5-point Likert scales at the end of the study.

Adverse effects were assessed by pre-specified lists to be filled in by the study physician during the final study interview. Additionally, subjects were asked to keep a diary to record any adverse effects of their treatment, as well as any use of oral rescue medication. Trained, blinded research assistants collected patient-reported data, and research personnel blinded to group allocation entered and monitored the data.

2.6. Sample size determination and statistical analysis

There were no data with a similar study population to be used for calculation of the effect and sample effect size. In a *meta*-analysis on the effects of mindfulness meditation in different disease conditions, a mean effect size of d = 0.5 was found.[28] In a study on meditation in elderly patients with chronic back pain, an effect size of d = 0.83 for acceptance of pain was found.[20] In assuming an effect size of 0.55–0.60 for pain relief by meditation, we calculated to include n = 50 patients. This would ensure detection of a standardized effect size (Cohen's d) of 0.57 with a power of ß = 80% by means of a two-sided level $\alpha = 5\%$ *t*-test. To account for a 10% drop out rate, we decided to include a minimum of 56 patients. After recruitment of 40 patients, an unanticipated higher early dropout rate occurred. We therefore increased the sample size to at least 68 patients to ensure sufficient statistical power of the study.

All outcome criteria were analyzed by intention-to-treat, including all randomized subjects, irrespective of whether or not they adhered to the protocol, or gave a full set of data. For each outcome, we fitted a GEE (Generalized Estimation Equation) ANCOVA (analysis of covariance) which included treatment group (binary covariate), the respective baseline value (linear covariate), the patients expectation (linear covariate) and time (repeated measurement factor) as independent variables. The GEE technique considers the structure of missing values implicitely. Treatment effects were estimated within these models and reported as adjusted group differences, including respective 95% confidence intervals (CI) and p-values. In a second step, we analyzed the data for the per-protocol population similarly using a GEE ANCOVA.

3. Results

Telephone screening yielded 170 calls from subjects interested in study participation. After enrolling the first 40 patients in the study, the drop-out rate was higher than anticipated and the sample size was increased to 68 study patients. Of the 68 enrolled patients, 32 patients were randomly allocated to the meditation group, and 36 to the exercise group. 16 subjects withdrew from the study over the 8 week period, resulting in completed data sets for 20 patients in the meditation group and 32 patients in the exercise group. Reasons for discontinuation are summarized in Fig. 1 with the most frequent given reason being the lack of time for further study participation. 12 subjects in the meditation group and 4 subjects in the exercise group did not complete the study. 3 subjects in the meditation group stopped study participation before the first intervention (perceived lack of time), 8 participants in the meditation group and 3 participants in the exercise group did not further adhere to the study within the first 4 study weeks due to personal reasons or perceived lack of time, and did not want to complete the post-intervention assessment. One subject in each group withdrew due to health problems not related to the intervention.

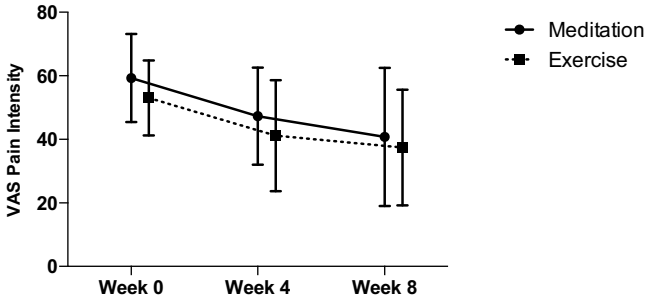

Fig. 2. Primary outcome—back pain at rest (VAS).

3.1. Baseline data

Subject's age mean age was 55 ± 10 years. Mean duration of low back pain was 11 years. Baseline characteristics were balanced between groups with exception of a higher proportion of women compared to men in the exercise group and higher pain intensity in the meditation group at baseline. Treatment outcome expectation was comparable in both groups (Table 1).

About 50% of the meditation group attended at least 6 of the 8 meditation classes. The majority of participants did not practice meditation at home for the recommend amount of time. All participants in the exercise group reported having read the book. About 60% reported practicing the suggested low back pain exercise techniques at least several times a week.

3.2.1. Primary outcome

In the meditation program, mean back pain within the last 7 days decreased from 59.3 ± 13.9 mm to 47.3 ± 15.3 mm after four weeks and 40.8 ± 21.8 mm after eight weeks. In the exercise group, mean back pain was 52.9 ± 11.8 mm at baseline and decreased to 41.0 ± 17.5 mm after four weeks and 37.3 ± 18.2 mm after eight weeks. A mean baseline adjusted group difference of −1.4 (95%CI −11.6 to 8.8; p = 0.78) resulted after eight weeks (Fig. 2). Results did not change relevantly when calculating outcomes for the per-protocol population, with a mean back pain reduction from 57.1 ± 12.7 mm to 37.8 ± 19.4 mm in the meditation group and 52.7 ± 11.7 to 36.9 ± 18.5 mm after eight weeks in the exercise group. This resulted in an adjusted group difference of −2.1 (95%CI: −12.8 to 8.6; p = 0.695).

3.2.2. Secondary outcomes

For pain-related bothersomeness, the Roland Morris function score, and the depression and anxiety scores comparable improvements in both groups were also observed. Although the meditation group consistently showed somewhat greater improvement than the control group, differences did not reach statistical significance (Table 2).

Perceived stress as assessed by PSS was significantly greater reduced by meditation compared to exercise. QOL as assessed by SF-36 did improve in both groups to a comparable extent (Table 2).

3.2.3. Additional results

The use of rescue medication was reduced in 5 subjects of the mediation group and none of exercise group.

3.4. Safety

There were no serious adverse events in either group. Two subjects reported an increase of an already existing tinnitus during the first weeks of meditation. One patient reported slightly increased dizziness and headache during the meditation. None of the patients in either group reported any other complaints directly related to the study interventions.

4. Discussion

This study compared the effects of an 8-week meditation course to a self-care exercise program in patients with chronic low back pain by means of a randomized clinical trial. We found comparable pain reduction in both groups. We also found comparable improvements in pain-related bothersomeness, function and quality of life in both groups. Although the improvements in the meditation group were consistently greater than in the exercise group, the differences did not reach statistical significance. Meditation did significantly reduce the level of perceived stress, however, this had no clear impact on the other outcomes within the eight-week study period.

Our study has some important limitations. First, the drop-out rate was largely higher than anticipated. Reasons for drop-out were not related to study intervention, but especially in the meditation group participants reported time constraints to fulfill the required meditation practice. Also, a number of patients expected rapid pain relief through meditation and experienced loss of motivation when rapid pain relief did not emerge within several weeks. Most of the participants in the meditation group found the practice of meditation more difficult than expected. Only few participants practiced meditation according to the recommended 30 min daily. However, patients who managed to implement regular meditation practice reported health improvements in other areas such as gastrointestinal complaints or sleep. Second, in our sample size calculation we did focus on anticipated changes with meditation over time and the improvements with exercise appear to have been underestimated. Thus, in addition with the reduced number of participants due to drop-outs our study seems underpowered. For future studies a larger sample size is needed to detect a difference between meditation and exercise on pain relief. Third, we found ongoing improvements of pain and other outcomes between weeks 4 and 8 when the trial was designed to end. Thus, our trial may have had a too short intervention period. A further important limitation is that the time spent in meditation intervention was not matched to the exercise group time and that an instructor facilitated the meditation intervention weekly while the control group was left to administer exercise on their own. Thus, it is possible that the slight advantage for the meditation group is attributable to the effects of attention.

Strengths of our study include the rigorous randomization procedure, our use of recommended and validated assessment tools and outcome measures, well-defined inclusion and exclusion criteria and a control group practicing exercise as an evidence-based intervention.

Of note, most participants rated the effectiveness of meditation in the final interview as "good". We cannot clearly explain this mismatch with the other results.

Only a few minor adverse events possibly associated with the meditation practice were described. Meditation as therapeutic method can be regarded as safe.

In view of our results and the preexisting research on meditation in patients with low back pain, a clear conclusion seems difficult. Compared to programs of MBSR our focused jyoti meditation program consisted of reduced practice and attention time. It might be that the practice time recommended in our trial was not long enough to induce sustainable effects. Furthermore, our course did not offer a retreat or additional exercises like yoga postures and body scan techniques as commonly used in mindfulness programs. Most likely, the practice of focused meditation may reduce rumination and distraction; the induced relaxation response may further

Table 1
Baseline characteristics of study patients.

	Meditation (n = 32)	Exercise (n = 36)	p-value
General characteristics			
Age (Mean ± SD)	55.5 ± 10.6	54.8 ± 10.6	0.946
Sex (n)			
Female	90.6	63.9	0.009
Male	9.4	36.1	
Employment status (%)			
Working	46.9	41.7	0.736
Unable to work	6.3	8.3	
Unemployed	12.5	19.4	
Retired	34.4	33.3	
Back pain characteristics			
Duration of back pain (y; Mean ± SD)	10.1 ± 7.7	12.7 ± 11.6	0.525
Pain at rest (VAS 100 mm; Mean ± SD)	59.3 ± 13.9	52.9 ± 11.8	0.042
Pain bothersomeness (VAS 100 mm; Mean ± SD)	54.8 ± 20.7	53.7 ± 17.7	0.990
Further Baseline characteristics			
Roland Morris	9.0 ± 4.0	8.8 ± 3.3	0.415
PSS Score	31.3 ± 7.7	28.8 ± 8.2	0.194
SF-36—Mental Component Score	37.8 ± 11.4	40.8 ± 11.7	0.350
SF-36—Physical Component Score	38.7 ± 8.2	40.4 ± 5.9	0.308
HADS Anxiety	10.3 ± 3.9	8.9 ± 3.0	0.073
HADS Depression	7.8 ± 4.2	6.9 ± 3.6	0.339
Expected effectiveness			
ineffective	6.3	8.3	0.415
less effective	37.5	27.8	
effective	50.0	55.6	
very effective	6.3	8.3	
not specified	0.0	0.0	

Table 2
Means and standard deviations (unadjusted values) for all outcome parameters with mean group differences and 95% CI for change on treatment (baseline adjusted values).

	Baseline	Week 4	Week 8
Pain at rest (VAS)			
Meditation (Mean ± SD)	59.3 ± 13.9	47.3 ± 15.3	40.8 ± 21.8
Exercise (Mean ± SD)	52.9 ± 11.8	41.0 ± 17.5	37.3 ± 18.2
Group difference (95% CI); p-value		−2.5 (−12.5; 7.6); 0.625	−1.4 (−11.6; 8.8); 0.758
Pain Bothersomeness (VAS)			
Meditation (Mean ± SD)	54.8 ± 20.7	40.9 ± 17.0	38.9 ± 23.4
Exercise (Mean ± SD)	53.7 ± 17.7	40.2 ± 17.9	32.9 ± 19.4
Group difference (95% CI) p-value		−1.8 (−12.3; 8.8); 0.741	5.8 (−5.2; 16.9); 0.3
Roland Morris			
Meditation (Mean ± SD)	9.0 ± 4.0	5.1 ± 5.6	5.3 ± 4.5
Exercise (Mean ± SD)	8.8 ± 3.3	5.5 ± 4.8	6.4 ± 4.9
Group difference (95% CI); p-value		−0.6 (−2.5; 1.3); 0.53	−1.3 (−3.1; 0.5); 0152
PSS Score (0–56)			
Meditation (Mean ± SD)	31.3 ± 7.7	29.4 ± 8.4	28.4 ± 9.1
Exercise (Mean ± SD)	28.8 ± 8.2	27.8 ± 8.4	28.7± 8.7
Group difference (95% CI); p-value		−2.0 (−5.4; 1.3); 0.237	−3.2 (−6.1;-0.3); 0.032
SF-36—Mental Component Score			
Meditation (Mean ± SD)	37.8 ± 11.4	40.8 ± 12.3	40.7 ± 12.5
Exercise (Mean ± SD)	40.8 ± 11.7	40.2 ± 12.1	40.1 ± 12.5
Group difference (95% CI); p-value		0.9 (−5.1; 7.0); 0.763	2.1 (−3.2; 7.4); 0.44
SF-36—Physical Component Score			
Meditation (Mean ± SD)	38.7 ± 8.2	35.3 ± 9.3	42.5 ± 10.6
Exercise (Mean ± SD)	40.4 ± 5.9	44.7 ± 7.3	44.5 ± 8.4
Group difference (95% CI); p-value		−3.7 (−7.3; −0.0); 0.049	0.4 (−3.5; 4.4); 0.831
HADS Anxiety			
Meditation (Mean ± SD)	10.3 ± 3.9	9.8 ± 4.9	8.8 ± 4.7
Exercise (Mean ± SD)	8.9 ± 3.0	8.6 ± 3.4	8.3 ± 3.9
Group difference (95% CI); p-value		−0.4 (−2.0; 1.2); 0.609	−1.1 (−2.8; 0.5); 0.188
HADS Depression			
Meditation (Mean ± SD)	7.8 ± 4.2	8.4 ± 4.5	7.5 ± 4.5
Exercise (Mean ± SD)	6.9 ± 3.6	7.3 ± 3.6	7.0 ± 3.9
Group difference (95% CI); p-value		−0.7 (−2.3; 1.0); 0.442	−0.8 (−2.3; 0.7); 0.306

PSS = Cohen Perceived Stress Scale, HADS = Hospital Anxiety and Depression scale, SF-36 = 36 Item Short Form Health Survey, VAS = Visual Analog Scale.

reduce stress as observed in our study. In contrast, mindfulness programs put a strong impact on developing a mindful and acceptance attitude and to apply this to any experience and to disease conditions.

In view of the fact that many patients dropped out of meditation and that few people adhered to most classes our data suggest that meditation is likely to appeal to only a subset of patients. Yet, it has to be considered as an option, while other options include other types of meditation, yoga, standard exercise, medications and spontaneous improvement over time.

Our results have to be compared with previous studies on meditation and chronic pain and low back pain. Wong et al. [18] conducted a randomized controlled trial on 99 community dwelling adults to compare the effects of MBSR with a multidisciplinary intervention program on general chronic pain. For both groups similar improvements of pain intensity and pain-related distress with no significant differences between groups at 6 months after intervention were found. Mindfulness meditation was also not superior to the control intervention for mood, anxiety and depression. The authors argued that the participants of the MBSR group did not practice regularly and that the therapists had limited experience in treating chronic pain patients. A recent randomized trial investigating MBSR in fibromyalgia[19] also found no significant group differences in pain, mood, stress, depression and anxiety compared to active controls. A recent systematic review on MBSR in chronic low back pain found three randomized trials with a total of 117 included patients. Results showed only inconclusive evidence for pain reduction through mindfulness meditation but limited evidence of improved pain acceptance.[17] Two of the three studies investigated low back pain in older adults (>65 years). In the first study with 37 patients, mindfulness meditation was compared to a wait-list control and modest but significant improvements in pain acceptance were found.[20] In the second study with 40 patients, mindfulness meditation was compared to a health education program.[21] No significant differences between both groups were found. A further study tested an 8-week loving-kindness program for chronic low back pain patients. Post and follow-up analyses showed significant improvements in pain and psychological distress in the loving-kindness group, but no changes in the control group.[29] Thus, it might be that meditation is not highly effective in chronic low back pain or that the meditation programs have to be more and specifically adapted to this disease condition.

In conclusion, an 8-week focused meditation program or a self-care exercise program led to comparable pain relief in patients with chronic low-back pain. Only meditation reduced perceived stress while function, QOL and psychological well-being improved comparably in both groups. Further studies should be designed with longer-term observation periods and use adapted meditation programs that enhance adherence and specific needs of chronic back pain patients. Furthermore, randomized trials comparing focused meditation with mindfulness meditation or other forms of mediation and exercise seem warranted.

Conflict of interest

There are no conflicts of interest related to the study for all authors.

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