

## Correspondence

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### Reply to critics of research on Transcendental Meditation in the prevention and control of hypertension

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This commentary addresses a Review [1] and Editorial Comment [2] in the *Journal of Hypertension* on the effects of Maharishi's Transcendental Meditation (TM) program on blood pressure, both of which contain many errors and omissions. This research originated in the 1970s at independent universities, including Harvard Medical School [3], the University of Chicago [4], the University of Cincinnati [5] and the Medical College of Allahabad, India [6]. No religious institutions promote TM. Multiple baseline measures on hypertensive adults found that, after a mean of 6.1 months, systolic blood pressure (SBP) and diastolic blood pressure (DBP) decreased by a mean of  $-12.6$  and  $-8.8$  mmHg, respectively. All comments below are based only on the versions of the six RCTs published in the referenced peer-reviewed journals.

The six RCTs were co-authored by 10 independent collaborators from Harvard University and the University of Maryland [7], West Oakland Health Center, University of Arkansas, and the Haight-Ashbury Free Clinic [8,12], University of Iowa Hospitals and Clinics [9], and the Georgia Institute for Prevention of Human Disease and the Medical College of Georgia [10,11]. Blood pressure data were collected blind by personnel at independent institutions. The collaborators did not have any particular commitment to TM or the TM organization and none would gain financially from the research results. The studies were funded by grants from the National Institute of Mental Health [7], the National Institutes of Health, including the National Heart, Lung and Blood Institute [8–12], the Retirement Research Foundation [8], and the American Heart Association [10,11]. Grant proposals from these agencies are subject to stringent peer review under highly competitive conditions, and

only those proposals with the best research designs conducted under the most objective conditions are funded.

The meta-analysis on hypertension [13], as cited in the commentary [2], did not refute the effect of TM on blood pressure because it did not include TM. TM reduces blood pressure significantly more than a relaxation technique modelled after TM [7] or Progressive Muscle Relaxation (PMR) [8,14]. The effects of TM cannot be attributed to 'slowing breathing' because TM does not involve voluntary breath control.

In the first RCT [7], performed on 80-year-olds, post-test levels of SBP (mmHg), adjusting for pretest levels by analysis of covariance (ANCOVA), were TM = 125.4, mindfulness = 130.3, relaxation = 145.0, and no-treatment = 135.3, and are clinically meaningful differences. Planned contrasts showed that TM reduced SBP more than the three other groups ( $P < 0.01$ ). This is a more powerful statistical technique than pairwise comparisons, because it pools data for all subjects in the study. The most important pairwise comparison, between TM and mental relaxation (an active control closely modelled after TM), was significant ( $P < 0.01$ ).

The second RCT [8] found that TM reduced SBP/DBP by  $-10.4/-5.7$  mmHg in hypertensive adults after 3 months, significantly more than PMR or Health Education (HE). ANCOVAs showed that sex, weight and medication status were not confounds. Subgroup analyses reported in a second study [15] found that TM reduced blood pressure for both genders, as well as for patients in both high and low risk categories for six hypertension-related measures of risk: obesity, alcohol use, psychosocial stress, dietary sodium-potassium ratio, physical inactivity and presence of multiple risks.

The third RCT [9] only found decreased blood pressure in subjects who practiced TM regularly, raising the question of which patients are willing to learn the technique and continue practicing it. However, five other RCTs [7,8,10,11,14] have demonstrated that TM has a causal role in reducing blood pressure, including two controlling for subject attrition by intent-to-treat analysis [8,14].

The fourth RCT on pre-hypertensive adolescents [10] did not exaggerate the effect by using a single-day baseline because the estimate of adaptation (change in the control) did not decrease. Moreover, the study found reduced SBP, cardiac output and heart rate reactivity to stressors, which should have been reviewed [1]

because exaggerated cardiovascular reactivity is known to contribute to hypertension and coronary heart disease.

The fifth RCT, an unpublished doctoral dissertation [12], should not have been considered by the review [1] because of lack of sufficient available information. These subjects were a subset of a recently published RCT [14] of 150 hypertensive African-American adults, which found significant reductions in DBP and antihypertensive medication use over 1 year in the TM group compared to PMR and HE controls, replicating the previous 3-month study [8] and extending it to 1 year.

The sixth RCT [11] used state-of-the-art ambulatory blood pressure monitoring, which has been shown to be a better predictor of hypertension than resting clinical pressure, relatively free of placebo effects, free from assessor blinding issues, highly reproducible and sensitive to small changes in average blood pressure. TM significantly decreased SBP in pre-hypertensive adolescents compared to controls by approximately 4 mmHg over a 4-month period, with a similar effect on DBP.

This school-based study necessitated group randomization, which is considered the 'gold standard' for such designs [16]. Moreover, 'School' was included as a random effect in the analysis to test that the test for treatment by time effect was free from random 'School' variations. Group randomization tends to reduce the effective sample size of a study, reducing power to detect a significant difference. Because a significant difference between the TM and control was reported, such power considerations are irrelevant.

The review [1] dismisses three of the RCTs on TM as being irrelevant to diagnosed hypertension because they examined normotensive young adults [9] or pre-hypertensive adolescents [10,11]. However, in view of the recommendation of JNC-7 that health-promoting lifestyle modifications be implemented well before blood pressure reaches the 'hypertensive' range, these studies are highly relevant.

Contrary to the conclusions of the review [1] or comment [2], the RCTs on TM and blood pressure were well-controlled and objectively conducted. We note that the authors of the review [1] sit on the editorial board of *Focus on Alternative and Complementary Therapies (FACT)*, a journal that is published by Pharmaceutical Press and associated with the Royal Pharmaceutical Society of Great Britain, supported by the multi-billion dollar anti-hypertensive medication industry.

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## Reply

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We would like to make the following reply to the correspondence from Orme-Johnson *et al.* [1]. Regarding the scientific content of our systematic review of studies of Transcendental Meditation (TM) for hypertension, we are content to let readers examine the original papers, our review, the comments made by Orme-Johnson *et al.* [1] and draw their own conclusions. However, we would like readers to note that our review is based only upon the peer-reviewed versions of articles and not the modified

versions that sometimes appear in the collected scientific papers published by the TM organization.

The affiliation of authors to the Maharishi University of Management (MUM) or the Maharishi International University is explicitly stated in three of the six studies included in our review [2]. As described, affiliations with the TM organization are easily detected for lead authors of the other three studies included. Orme-Johnson *et al.* [1] have similar associations. Orme-Johnson explicitly describes himself as retired Dean of Research at MUM and is also an editor of two of the collected volumes [3,4] of scientific research on TM published by the TM organization (mainly papers published without peer review). As stated in our review, Barnes is a long-standing TM teacher. An internet search reveals that a certain Alex M. Hankey taught at MUM in the 1970s and Roger Chalmers was, in 1990, an editor of another volume of TM research [5] in which he is described as vice-chancellor of the Maharishi European Research University.

The TM organization does not describe itself as a religion but it does have several hallmarks of a cult, including a charismatic leader, multi-million dollar institutions, a hierarchy, and some unusual views, including the idea that achieving a critical mass of meditators will bring about world peace. The publication of positive research regarding TM will certainly not hamper recruitment of new meditators who pay handsomely for the privilege of learning the technique. This only underlines the importance of independent assessments of TM research and of independent clinical trials of TM in indications where the treatment appears to be promising. Ours is the only independent review of TM for hypertension. We hope that much needed independent research does take place and that it does eventually demonstrate the efficacy of TM in hypertension.

As for the implication that we are somehow serving the pharmaceutical industry, perhaps readers would like to examine the publication list of our research group (<http://www.pms.ac.uk/compmed/research.html>) where they can see that we have a 10-year history of carrying out trials and systematic reviews of all types of complementary medicine, many of which have reached positive conclusions. Many of these studies have concerned herbal extracts which, when the evidence merits it, we have not hesitated to compare favourably with standard pharmaceutical treatments. *Focus on Alternative and Complementary Therapies (FACT)* is an independent evidence-based review journal reporting developments in the field of complementary medicine (<http://www.ex.ac.uk/FACT>). Its content is not influenced in any way by the pharmaceutical industry. Our editorial positions with FACT are voluntary and unpaid, and we have never received funds from the pharmaceutical industry.

Pharmaceutical Press, the publisher of FACT, is part of the Royal Pharmaceutical Society of Great Britain, the regulatory and professional body for pharmacists in the UK.

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## Facts and fiction of poor compliance as a cause of inadequate blood pressure control

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The recent review article by Wetzels *et al.* [1] investigated the interesting relationship between blood pressure control and compliance. In the included articles under review, compliance was measured with electronic monitors which are considered as the 'gold standard' method. However, every generally used measurement method of compliance has its own severe limitations. Although the electronic monitors have certain benefits compared to some other methods [2], they do not provide evidence that the patient has really taken the dose. Accordingly, none of these methods are really the 'gold standard' method.

It appears that many patients try to hide their non-compliance. The finding of a clinical trial of chronic obstructive pulmonary disease treatment is worth mentioning [3]. Thirty percent of study participants, who thought that the inhalator measures only the number of used dosages, used the inhalator over a hundred times within a few hours, and a majority of these emptyings happened just before a follow-up visit. How the patients try to hide their non-compliance probably may depend on how they think a certain device functions.

So, how much of compliance is attributable to white-coat compliance [4], or just playing the role of a compliant patient, which, in the case of hypertensive patients,

means removing a tablet from the electronic monitor without swallowing the tablet? Furthermore, how many patients who are unaware of monitoring are actually suspicious of being monitored? Wetzels *et al.* [1] also found a decrease in compliance over time in studies with a longer monitoring period. How much of this is a real decrease in compliance and how much of it is a decrease in playing the role of a compliant patient? These are questions that remain to be answered in future studies.

The study by Wetzels *et al.* [1] shows that the relationship between compliance and blood pressure control is very difficult to establish. Of course, that does not mean that there is no relationship because antihypertensive medicines would be shown as being ineffective. The authors set many relevant challenges for future studies. Furthermore, the editorial comment concerning better compliance with a once-a-day regimen, but possibly better drug coverage with a twice-a-day regimen [5], suggests a contradictory, but relevant research question. When compliance is not perfect, what are the situations where poorer compliance will cause a better drug coverage and better clinical outcome?

There are many methodological questions, as well as the need for a more profound understanding of compliance phenomenon, before we can take at least some kind of step towards the practical 'gold standard' method. Thus, as it is written in the Bible 'For we know in part' (*I Corinthians 13:9*), so it is also in the compliance field. Obviously, there is a lot of work to be done before additional benefits are achieved with respect to antihypertensive treatments.

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## Reply

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In reply to the letter of Jokisalo [1], we wish to make a few remarks. Jokisalo argues that electronic monitoring of

patient compliance cannot be considered as a 'gold standard'. We agree with the arguments. Measuring patient compliance is notoriously difficult. The minimum requirements for a gold standard for compliance measurements would be validity and reliability. The method should prove ingestion of the medication and provide information about the timing of ingestion. In addition, the patient should not be aware of the compliance measurements and should not be able to consciously influence the results [2,3].

Unfortunately, at present, there is no instrument available that combines all of these properties. Electronic monitoring offers a very precise dosing history but does not prove ingestion of the medication. However, because the monitoring device registers the time of medication intake, it is very hard for a patient to deliberately fake taking medication at regular intervals because this would require opening the bottle every day at the same time for a long period.

It appears more plausible that a patient would be prompted to be more compliant (white-coat compliance) if he or she were aware, or had a suspicion, of being monitored. Several uncontrolled studies have indeed shown that a short period of monitoring is followed by normalization of blood pressure in a considerable part of patients who, before monitoring, did not respond to antihypertensive medication. The better response to medication is probably caused by improved compliance [4,5].

Treating physicians can take advantage of this phenomenon in clinical practice. Electronic monitoring allows the treating physician to determine what blood pressure control can be obtained when a patient is taking his medication as prescribed. Therefore, electronic monitoring makes it possible to discriminate between non-compliers and non-responders. In this way, electronic monitoring can be used as a tool to manage compliance problems.

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