ORIGINAL PAPER

THE TRAGER APPROACH IN THE TREATMENT OF CHRONIC HEADACHE: A PILOT STUDY

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Context • *Although the traditional treatment of headache has been pharmacological, there have been many attempts to treat headaches with other methods with mixed levels of success.*
Objective • *To obtain preliminary data on the efficacy of the Trager approach in the treatment of chronic headache.*
Design • *Small-scale randomized controlled clinical trial.*
Setting • *University-based clinic.*
Patients • *Thirty-three volunteers with a self-reported history of chronic headache with at least one headache per week for at least 6 months.*
Interventions • *Medication only control group, medication and attention control group, and medication and Trager treatment group.*
Main Outcome Measures • *Self-reported frequency, duration, and intensity of headache, medication usage and headache quality of life (HQOL) obtained at baseline and after a 6-week treatment period.*
Results • *Analyses of variance demonstrated significant improvement in HQOL for the Trager and attention control groups, and reduction in medication usage for the Trager group ($P < 0.05$). Within-group analyses revealed that participants randomized to Trager demonstrated a significant decrease in the frequency of headaches ($P = 0.045$), improvement in HQOL ($P = 0.045$), and a 44% decrease in medication usage ($P = 0.03$). Participants randomized to the attention control group demonstrated a significant improvement in HQOL ($P = 0.035$) and a 19% decrease in medication usage ($P = 0.15$). Participants randomized to the no-treatment control group revealed a significant increase in headache duration ($P = 0.025$) and intensity ($P = 0.025$), and a declination in HQOL ($P = 0.035$).*
Conclusions • *The Trager approach decreased headache frequency and medication usage. Trager and physician attention improved HQOL. A larger, multi-site study is recommended.*
(Altern Ther Health Med, 2004;10(5):40-46.)

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Headache has long been a highly prevalent and often long-standing problem with severe consequences on those stricken.[1-7] Although traditionally the treatment of headache has been pharmacological, there have been many attempts to treat headache with other therapies. These other therapies used either alone or in combination with medication have demonstrated mixed levels of success. In a randomized controlled trial, spinal manipulation in the treatment of tension type headache produced reductions in both total headache hours and use of analgesics.[8] Mobilization of the upper cervical spine in ten participants reduced frequency, duration, and intensity of headache.[9] A physical therapy pro-

gram likewise produced improvement in muscle contraction headache in 20 participants.[10] A number of studies have shown improvement in headache following various forms of relaxation training.[2, 11-13] While alternative therapies of many kinds have been used and proposed as approaches to the treatment of headache,[14,15] few randomized control trials have been conducted to evaluate their efficacy.

The Trager approach combines the benefits of manipulative therapy and relaxation training. Because studies have found increased effectiveness through combined therapies,[1] the Trager approach has potential to be effective in the treatment of chronic headache. A review of the medical literature revealed lack of information regarding the Trager method in the treatment of chronic headache. The objective of this small-scale randomized controlled clinical trial was to provide pilot data on the efficacy of Trager in the treatment of chronic headache and assess the feasibility of a larger, phase III multi-site trial. In addition to the implementation of the "gold standard" design for the evaluation of the benefits of the Trager intervention, an additional design feature of this study is the utilization of two control groups, a "usual care" control group and an "attention" control group.

METHODS

Participants

Participants were recruited from the practices of Family Medicine at the Keck School of Medicine at the University of Southern California. Eligibility criteria included: a) 18 to 65 years; b) self-reported history of chronic headache (>1 headache/week for >6 months); c) diagnosis by physician of migraine, tension-type, and/or cluster-type headache; and d) typical headache intensity between 25 and 85 on a visual analog scale from 0 to 100. Exclusion criteria included: a) potentially life-threatening etiology of the chronic headache; b) contraindications to Trager approach and manipulation; and c) prior exposure to Trager approach. In order to obtain preliminary data regarding treatment outcomes, sample size goals were to recruit a minimum of 30 participants, and randomize across treatments within strata defined by the type of headache (migraine, tension, cluster).

Study Design

The Institutional Review Board at the University of Southern California approved the study protocol. All study procedures adhere to the Declaration of Helsinki for research involving human subjects. Participants were pre-screened for eligibility and explained the purpose of the trial by telephone interview. Potentially eligible participants were then invited to a Screening Examination at the USC Family Medicine Clinic where informed consent was obtained, a headache history (including medications) was taken, and a physical examination was performed to exclude brain-mass related headache, trauma-related headache, unstable spine, and severe carotid artery stenosis. The attending physician confirmed headache diagnosis and participant eligibility.

Baseline data were then obtained on eligible participants, and included a two-week Headache Diary of daily headache frequency, duration and intensity, and headache-related medication usage. Because of the wide variety of treatments, it was the physical act of taking medication, not an evaluation of the medication itself that was measured. In addition, each participant completed a Headache Quality of Life (HQOL) instrument. The Clinical Coordinator trained the participant in the completion of the Headache Diary and the HQOL and reviewed the baseline diary for completeness.

Participants were then randomly assigned to one of the three treatment groups: a) medication only *no-treatment control* group, b) medication and *attention control group*, and c) medication and Trager treatment group. Participants were randomized with strata defined by type of headache. The treatment phase was six weeks in duration. During the treatment period, participants were asked to complete the Headache Diary daily and turn them in on a weekly basis. In the no-treatment and Trager groups, medication usage was not discussed with the participants during the baseline or treatment phase. In the attention group, the physician discussed medication usage with the participants during the treatment phase. The Headache Diary was returned weekly to the Clinic and was reviewed by the Clinical Coordinator for completeness. At the end of the six-week treatment period, the Clinical Coordinator administered the HQOL instrument.

Trager Treatment Group

Participants in the Trager group were treated by the Trager practitioner in the Family Practice Clinic once a week for six weeks. The Trager approach is a movement-based educational process designed to help patients increase their body awareness, learn relaxation skills, and practice pain-free, balanced movement. Trager seeks to increase body awareness through this process, which encourages the patient to alter tension, relaxation, and movement patterns. It can be understood in part as a manual approach and in part as a cognitive/behavioral approach that emphasizes mind/body interactions.

A typical one-hour Trager session has three components. First, a brief current history is taken. Next, the participant lies on a padded table while the practitioner gently touches the soft tissue and gently mobilizes the joint areas in order to impart the feel of relaxed, properly toned tissue and the feel of unrestricted movement. Movements are slow and rhythmic. The practitioner works within the participant's unrestricted range of motion and does not push past resistance, instead extending the range of motion only when the participant's increasing relaxation permits it and always staying within normal physiological joint range of motion. In the case of treatment for chronic headache, the practitioner addresses areas of tension and restricted motion, in affected areas such as, but not limited to, the head, neck, upper back, and shoulders, in order to encourage site-specific as well as general relaxation. Third, to increase somatic awareness, the practitioner teaches the participant simple movements designed to

assist in recall and re-creation of the relaxed, unrestricted movement achieved during the tablework portion of the session. The practitioner encourages the participant to practice these movements between sessions; however, there is no fixed assignment of homework for the participant.

Attention Treatment Control Group

Participants in the attention group also came into the Family Practice Clinic once a week during the six-week treatment period. The physician discussed the previous week's headaches and asked about medication intake, overall perception of well being, changes in headaches, and if the participant had any questions or concerns at the time. The physician did a physical exam of the head and neck and described any pertinent findings or changes. The interaction between physician and participant was 15-20 minutes for each appointment.

No-Treatment Control Group

Participants in the no-treatment group did not have any scheduled visits with a healthcare provider during the six-week treatment period.

Headache Quality of Life Instrument

The HQOL instrument was adapted from the Migraine-specific Quality of Life Questionnaire (MSQOL).[16] Modifications of the MSQOL included: a) using 4 (out of 5) subscales, b) using 12 (out of 15 items), c) reducing the number of response choices from 7 to 5, d) replacing text referring to "migraine headache" to "headache", and e) targeting a "past 4-week period" instead of a "24-hour period." In addition to the reported psychometric properties of the MSQOL, construct validity of the revised MSQOL was evaluated by correlating the baseline HQOL scores with the baseline self-reported characteristics from the Headache Diary. We found a statistically significant correlation between the HQOL score with headache intensity ($r = -0.54$, $P = 0.004$) and headache frequency ($r = -0.45$, $P < 0.02$).

Statistical Analysis

Study endpoints included a) headache frequency, intensity and duration, b) medication usage, and c) self-reported HQOL. Baseline headache characteristics were computed as the average of the weekly diary data obtained two weeks pre-treatment. Outcome headache characteristics were computed as the average of the 4th, 5th, and 6th weeks of treatment. Medication usage was measured by the total number of pills taken biweekly during the baseline phase and during the treatment phase.

Demographic factors, headache history, and baseline headache frequency, intensity and duration were contrasted across the three randomized groups utilizing analysis of variance for continuous variables and chi-square analyses for discrete variables. Factors resulting in an imbalance across treatment groups were used as covariates in the outcome analyses. Treatment outcomes and changes from baseline were compared across the three treatment groups using the analysis of (co)variance (intent-to-treat analysis). When significant differences were found, pairwise comparisons were conducted utilizing the Tukey multiple comparison procedure. In addition, six-week outcomes and changes from baseline were analyzed within each treatment group using a paired t-test (planned secondary analysis). All statistical testing was conducted at the 0.05 level and utilized SAS (Cary, NC).

RESULTS

A total of 49 participants with chronic headache were potentially eligible based on the telephone pre-screen. Of these, 33 (67%) signed the informed consent, were evaluated as eligible, and were randomized (14, 7, and 12 in the Trager, attention and no-treatment groups, respectively). Four participants (3, 1, and 0 in the Trager, attention and no-treatment groups) withdrew from the study prior to completing the 6-week treatment period resulting in 29 evaluable participants who completed the study (11, 6, and 12 in the Trager, attention, and no-treatment groups, respectively). Reasons for dropout included moving out of the area (n=1), onset of headache during the first treatment session (n=1), and unknown (n=2). No between-group differences for gender, age, headache type, length or intensity were found between the 29 evaluable vs. the 4 participants that were randomized, but did not complete the study.

Baseline Characteristics

The average (SD) age for the evaluable participants was 29.9 (13.1) years; the majority of participants (n=25, 86%) were female. The average (SD) headache length and intensity (measured on a 0-100 scale) were 17.4 (12.3) years and 59.7 (17.5), respectively.

Table 1 summarizes the baseline characteristics and headache history stratified by randomized treatment group assignment. No significant differences across treatment groups were found for age, gender, use of caffeine, history of injury, attitudes towards complementary or alternative medicine, the type of headache, headache length, intensity or location, as well as the prevalence of nausea, and light sensitivity. In contrast, proportionately more participants randomized to the attention group experienced occasional auras (P=0.006).

Table 2 summarizes baseline values for the study endpoints. No significant differences were found at baseline across treatment groups in headache frequency or intensity, and quality of life. Because participants randomized to the Trager group tended to have longer lasting headaches at baseline (P=0.07), headache duration was included as a covariate in the analyses of changes in duration.

Treatment Outcomes

Analyses of variance demonstrated no significant differences in post-treatment outcomes or changes from baseline for each of the Headache Diary endpoints (Table 2). However, compared to the control group, both the Trager and the attention

TABLE 1 Baseline Demographic and Headache History Characteristics

Characteristic	Trager (n = 11)	Attention (n = 6)	Control (n = 12)	*P*-Value‡
Age (years)	35.4 ± 13.8*	48.2 ± 12.7	39.9 ± 11.2	0.16
Gender: Female	11 (100%)†	5 (83%)	10 (83%)	0.36
Headache Type				
Migraine	0 (0%)	1 (17%)	2 (17%)	0.49
Migraine with Tension	7 (64%)	5 (83%)	7 (58%)	
Tension	3 (27%)	0 (0%)	3 (25%)	
Cluster	1 (9%)	0 (0%)	0 (0%)	
Headache Length (years)	15.0 ± 11.4	18.0 ± 17.7	19.5 ± 10.5	0.69
Headache Intensity (0 to 100)	58.5 ± 18.3	65.0 ± 23.5	58.0 ± 13.9	0.72
Use of massage for healthcare	7 (64%)	4 (67%)	5 (42%)	0.47
Location of typical headache				
Always same place	3 (27%)	3 (50%)	4 (40%)	0.44
Different each time	4 (36%)	3 (50%)	4 (40%)	
Moves throughout duration/vague	4 (36%)	0 (0%)	2 (20%)	
Nausea				
Often	3 (27%)	0 (0%)	2 (18%)	0.25
Occasionally	6 (55%)	5 (100%)	5 (45%)	
No	2 (18%)	0 (0.0%)	4 (36%)	
Light Sensitive				
Often	5 (45%)	3 (50%)	4 (36%)	0.26
Occasionally	6 (55%)	3 (50%)	4 (36%)	
No	0 (0%)	0 (0%)	3 (27%)	
Aura				
Often	5 (46%)	0 (0%)	0 (0%)	0.006
Occasionally	3 (27%)	5 (100%)	5 (45%)	
No	3 (27%)	0 (0%)	6 (55%)	
Injury	1 (10%)	0 (0%)	1 (9%)	0.73
Caffeine	8 (73%)	5 (83%)	8 (73%)	0.87
Belief that CAM might be helpful	10 (91%)	5 (83%)	11 (92%)	0.85

Note: CAM = complementary/alternative medicine;
* Mean (SD); † Frequency (percent)
‡ Analysis of variance across the three treatment groups.

groups had a significant mean (±SD) decrease in headache duration (1.8±2.7 versus –0.6±3.6 and –0.3±1.6 hours, respectively, $P<0.05$). Further, there was an apparent trend for a greater reduction in the number of headache episodes per week in the Trager group (27.5% reduction) as compared to the attention group (3.7% reduction) and the no-treatment control group (13.5% increase). Marginally or statistically significant differences across the treatment groups were found in post-treatment HQOL ($P = 0.06$) and changes in HQOL ($P = 0.001$). Multiple comparisons revealed significant differences between the Trager vs. the no-treatment control group, and the attention vs. the no-treatment control groups (both $P < 0.05$). Finally, analyses of variance demonstrated statistically significant differences in medication usage across the treatment groups ($P = 0.04$), attributed to differences between the Trager vs. the no-treatment control group ($P < 0.05$).

TABLE 2 Baseline and Treatment Outcomes

	Trager (n = 11)	Attention (n = 6)	Control (n = 12)	*P*-Value*
Frequency (per wk)				
Baseline	9.1 ± 2.8	8.2 ± 4.7	9.6 ± 3.7	0.73
Treatment	6.5 ± 5.4	7.8 ± 7.3	10.9 ± 5.9	0.22
Change	-2.5 ± 4.6	-0.3 ± 9.7	1.3 ± 5.4	0.34
P-value (1-sided)	0.045	0.47	0.21	
Duration (hours)				
Baseline	8.1 ± 1.8	5.8 ± 3.7	5.6 ± 2.6	0.07
Treatment	7.4 ± 3.5	6.3 ± 4.3	7.3 ± 4.1	0.19
Change	-0.6 ± 3.6	-0.3 ± 1.6	1.8 ± 2.7	0.19
P-value (1-sided)	0.29	0.35	0.025	
Intensity (0 to 100)				
Baseline	43.1 ± 13.6	43.8 ± 8.6	42.2 ± 15.9	0.97
Treatment	43.4 ± 17.1	39.7 ± 21.6	48.8 ± 19.7	0.61
Change	0.3 ± 20.1	-4.2 ± 20.6	6.6 ± 10.4	0.41
P-value (1-sided)	0.48	0.32	0.025	
Headache QOL				
Baseline	3.0 ± 0.7	2.9 ± 0.8	3.1 ± 0.9	0.82
Treatment	3.4 ± 0.7	3.6 ± 0.6	2.6 ± 1.1	0.06
Change	0.4 ± 0.8a	0.8 ± 0.8a	-0.5 ± 0.7b	0.001
P-value (1-sided)	0.045	0.035	0.035	
Biweekly Total Medication Usage				
Baseline	15.1 ± 12.1	19.7 ± 21.3	24.1 ± 16.6	0.45
Treatment	8.5 ± 7.0a	16.0 ± 24.8	30.2 ± 22.1b	0.04
Change	- 6.7 ± 9.2	-3.8 ± 7.9	6.2 ± 18.6	0.10
P-value (1-sided)	0.03	0.15	0.20	

* Analysis of covariance for headache duration outcomes (adjusting for baseline duration). Analysis of variance for all other endpoints. Comparisons significant at the 0.05 level using the Tukey procedure are indicated by different letters (a, b).
† Paired t-test.

As an additional validation of the HQOL, we found that the HQOL score was significantly related to the self-reported headache frequency during the treatment period ($r = -0.45$, $P < 0.02$).

Treatment Outcomes Within Study Groups

Within-group treatment results demonstrated participants randomized to the Trager treatment group showed a statistically significant decrease in the frequency of headaches ($P = 0.045$) and improvement in HQOL ($P = 0.045$). In addition, within-group treatment results demonstrated that during the treatment phase the mean medication usage for participants in the Trager group significantly decreased by 44% ($P = 0.03$).

No significant within-group changes were noted in headache frequency, duration or intensity for the attention control group. However, as in the case of the Trager group, participants randomized to the attention control group demonstrated a significant improvement in HQOL ($P = 0.035$). Medication usage by participants in the attention group decreased by 19% ($P = 0.15$).

Participants randomized to the no-treatment control group showed a statistically significant increase in the average headache duration ($P = 0.025$) and intensity ($P = 0.025$), a declination in HQOL ($P = 0.035$), and a 25% increase in medication use ($P > 0.2$).

DISCUSSION

Trager Outcomes

Although case studies of the successful amelioration of joint pain through the Trager technique have been reported,[17] this is the first study to apply Trager to the treatment of headache. The results of this small-scale randomized clinical trial indicate that Trager is effective in decreasing the frequency of headache, decreasing medication intake and improving quality of life in headache patients. DeBruijn-Kofman et al[2] also found a decrease in frequency (but less influence on intensity) when they studied behavioral intervention, suggesting a preventive effect of treatment.

Ramsey[17] described part of the physiological reasons for pain reduction via Trager as: "The end result of Trager work is lasting neuromuscular re-education for the client with a sense of integration and effortlessness of movement. Several mechanisms can explain Trager's effectiveness. Trager work is an effective tool for overall relaxation. Through the rhythmic rocking of the joints, the vestibular and activating systems are stimulated, producing an overall calming effect on the nervous system secondary to the inhibition of sympathetic discharge and facilitation of parasympathetic discharge. The central nervous system communicates the lengthening of the muscle tissue during Trager to the brain via Type Ia and Type II afferent neurons of muscle spindles, resulting in reduction of the tone maintained. Stimulation of the nerve endings in the joints reduces the perception of pain and influences muscle tone."

The improvements seen in this study support the potential efficacy of Trager in treating chronic headache. Trager at this time can only be compared with other approaches that emphasize training in awareness through relaxation, movement, and manual methods. Holroyd et al[18] raised the possibility that improvements in migraine patients achieved with non-pharmacological treatment are more likely to be maintained without additional treatment than are similar improvements achieved with abortive pharmacological treatment. Trager and similar approaches are further supported by studies[14, 19] which found that patients who improved were more likely to have had a better understanding of their headaches. Launso et al[14] indicate that patients who improved were those who believed that their headaches could be controlled through the integration of mind and body.

Attention Group Outcomes

As with the Trager group, the attention control group showed a significant improvement in headache quality of life. Four of six participants in the attention group had changes made in their care including a work-up for a shoulder problem (radiograph and Trigger-point therapy) and changes in medication. While these changes are within the treatment guidelines that a physician might use in standard treatment, they may in part explain the improvements in the attention control group. This finding suggests that patients are more likely to benefit from more focused awareness on the part of patients, physicians and physician-extenders. If they, like Trager practitioners, could increase the patient's awareness, they might also increase their patient's improvement.

Control Group Outcomes

Although there was no significant decrease in headache duration or intensity for either of the treatment groups, there was a significant increase in duration and intensity in the control group. Compared to the control group, participants randomized to the Trager or the attention groups demonstrated a significant mean decrease in headache duration and intensity. It should be noted that "duration" and "intensity" are conditional, subjective measurements and that "frequency" is an unconditional, objective measurement. Therefore, a decrease in the frequency of headaches is not reflected in a decrease in intensity or duration of headache. Subjectively, fewer numbers of headaches may translate into fewer days or hours lost from work, regardless of the duration or intensity.

Headache Quality of Life

Similar to subjects treated with guided imagery in a study by Mannix et al[15] participants randomized to the Trager group showed a significant improvement in HQOL. This is encouraging, as headache and migraine sufferers have lower health-related quality of life than those without headache,[20] and quality of life is impaired not just during, but also between headache attacks.[21] Although the improvement in HQOL was not significantly different between the Trager and the attention groups, improvements for each of these groups were significantly better than the control group.

Bove and Nilsson[8] point out that it is important to consider the level of personal attention given during any particular treatment, and in that regard, both the Trager and attention control groups benefited in HQOL through their interaction with their individual practitioner. Similarly, Holroyd et al[18] suggest that brief educational interventions designed to address the problem of patient self-management may yield significant improvements in standard therapies, and Mannix et al[22] found that a concise educational program can significantly improve health-related quality of life, decrease headache-related disability, and promote the use of self-management techniques.

Medication Usage

Headache, in the medical model, is treated primarily through medication. Even though all participants had a history and current usage of medication, they were still having frequent headaches on entry to the study. Medication overuse and rebound can even be a cause for headache in patients suffering

from migraine, tension-type headache, or combined headache.[23] Medication usage decreased significantly in the Trager group and nominally in the attention group, while increasing in the control group. Clearly, there would be a substantial economic and clinical value to decreasing the amounts of medications taken by headache patients.

Five of the Trager participants were taking migraine-specific medications, including 5HT agonists. In the experience of the Trager practitioner involved in this study (JL), patients diagnosed with migraine and those diagnosed with tension headache have similar muscle tension patterns, particularly in the neck and upper back, and both kinds of patient respond similarly to treatment. This also supports the findings of deBruijn-Kofman et al[2] whose study of behavioral treatment indicated that the classification into migraine and tension-type headache might be of little value. Several studies support the "spectrum" or "continuum" concept[24-27] where tension-type headaches are the beginning stage and severe migraine headaches are the end of a continuum of severity. Couch et al[28] emphasizes the idea of "a final common pathway" especially when observing the syndrome of chronic daily headache, even in the face of multiple etiologies. Silberstein et al[29] suggests that "among migraine sufferers, individual attacks of migraine and tension-type headache may be part of a spectrum of severity." Although there is some disagreement as to whether headaches can be defined empirically to distinguish between tension and migraine, it is likely that we would expect similar results if patients with only migraine were treated with Trager.

Study Limitations

As a pilot study designed to give preliminary data, the numbers of participants recruited and randomized was small, and that the sample may not be representative. However, our sample was gender-representative in that women have more chronic headaches than men. Further, although the HQOL was adapted from a valid instrument (the MSQOL), analyses of the psychometric properties of the HQOL were limited. Further exploration with larger sample sizes is needed.

Attrition should be particularly anticipated when studying the headache population. This study had an attrition rate of 12% (4 out of 33 randomized subjects), but other studies have had severe dropout rates, losing up to 50% of their population.[1, 15,19, 22] The relatively high attrition rate of this population should be taken into consideration when planning future studies. Other studies have listed "lack of time" as a primary reason for dropout.[30] Finally, in the ideal situation, the medication used by all participants would be the same pharmaceutical preparation, and a clearly defined increase or decrease of specific drug type would be measured. A larger study is needed to evaluate the types of medications taken and examine this component more carefully while addressing drug-induced headache and the troubles of withdrawal.

Summary and Conclusions

In this first randomized trial evaluating the efficacy of Trager in treating chronic headache, we have demonstrated that the Trager approach decreased both headache frequency and medication usage, and that both Trager and physician attention improved the HQOL measurements in chronic headache patients. That there were improvements in the attention group, implies that the close attention and education probably had positive effects on the patient. However, the patient improvement in frequency, HQOL, and medication usage while under the care of the Trager practitioner implies that properly focused attention, combined with Trager's manual approaches, is an effective and promising treatment for chronic headache. In addition, the Trager approach has potential to be efficacious when applied to other conditions in which tension may be ameliorated through self-awareness and relaxation.

Many determination of efficacy of alternative/complementary therapies is made by case studies at best, and anecdotal reports at the least. Further, many alternative practitioners defend the lack of outcomes research by explaining that alternative research does not lend itself to the standard scientific method. Demonstration of equivalence between the Trager method and the attention control group in a randomized, controlled, pilot study, such as this, is the first step in scientifically assessing the efficacy of alternative treatments. Thus, this pilot study has provided data for the design feasibility of a larger, phase III multi-site trial.

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