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Body Acupuncture, Scalp Acupuncture, and Ear Acupressure as Adjuncts to Trazodone for Primary Insomnia: A Randomized Controlled Trial

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Abstract

Background: Trazodone is widely prescribed for primary insomnia, yet several recent appraisals have questioned its suitability as first-line therapy. Acupuncture is increasingly used as an adjunct, but head-to-head comparisons of different acupuncture and acupressure modalities added to pharmacotherapy remain scarce.

Objectives: To compare the effectiveness of body acupuncture, scalp acupuncture, and ear acupressure, each added to trazodone, against trazodone alone in adults with primary insomnia.

Methods: In this single-blind (outcome assessor and statistician), parallel-group, superiority randomized controlled trial, 99 adults with DSM-5–defined primary insomnia (Pittsburgh Sleep Quality Index [PSQI] ≥ 6) were block-randomized (1:1:1:1) to body acupuncture, scalp acupuncture, ear acupressure, or trazodone alone; all groups received trazodone 50 mg nightly. Acupuncture groups received 12 sessions over 4 weeks (ear acupressure: 4 sessions/month). Outcomes—sleep duration (primary), PSQI, and quality of life (WHOQOL-BREF)—were assessed at baseline, week 4, and week 12. Between-group differences were estimated both as raw change-from-baseline scores and as baseline- and age-adjusted mean differences (ANCOVA), each with 95% confidence intervals; standardized effect sizes are additionally reported as Cohen's.

Results: All four groups improved significantly from baseline across all outcomes. Body acupuncture produced the largest and most consistent added benefit. After adjustment for baseline score and age, body acupuncture exceeded trazodone alone at week 4 and week 12 for sleep duration (adjusted mean difference +0.81 h [95% CI 0.53, 1.08] and +1.14 h [0.73, 1.56]), PSQI (−4.41 points [−539, −3.44] and −4.46 [−5.42, −3.50]), and quality of life (+13.3 points [12.4, 14.2] and +8.4 [4.6, 12.2]; all $p < 0.001$). Scalp acupuncture exceeded trazodone alone for PSQI and quality of life from week 4, and for sleep duration by week 12. Ear acupressure exceeded trazodone alone for PSQI at both time points but not for sleep duration or quality of life. The very large standardized effects (e.g., Cohen's d = 6.68 for quality of life) reflected small within-group standard deviations rather than implausibly large raw differences, and findings were consistent across change-score and adjusted analyses.

Conclusions: Adding body or scalp acupuncture to trazodone produced clinically meaningful improvements in sleep duration, sleep quality, and quality of life beyond trazodone alone in adults with primary insomnia; ear acupressure conferred a more limited, PSQI-specific benefit.

Trial registration: Iranian Registry of Clinical Trials, IRCT20230626058585N2 (registered 2023-06-26; irct.behdasht.gov.ir).

Keywords: Acupuncture; Acupressure; *Insomnia; Sleep Initiation and Maintenance Disorders; Trazodone; Quality of Life; Randomized Controlled Trial*

1. Background

Insomnia is among the most prevalent sleep disorders, affecting an estimated 10–20% of adults when defined by diagnostic criteria and up to one-third of the general population when milder complaints are included (1,2). Beyond its direct burden on daytime functioning and quality of life, insomnia is increasingly recognized as a risk factor for cardiometabolic, neurocognitive, and psychiatric morbidity, and its prevalence continues to rise across most world regions (2,3). Expert and pan-European appraisals have repeatedly identified chronic insomnia as an under-recognized and under-treated

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condition, with substantial unmet need for accessible, effective management strategies beyond first-line recommendations (3-5). The hyperarousal model, encompassing cognitive, emotional, and physiological over-activation that impairs sleep initiation and maintenance, remains the most widely supported pathophysiological framework (6).

Pharmacotherapy remains the most common management strategy, and trazodone in particular is one of the most frequently prescribed agents for insomnia worldwide (7), despite not holding a formal insomnia indication in most jurisdictions. A systematic review of its evidence base found support for a modest hypnotic effect with a comparatively favorable short-term safety profile (7), yet a network meta-analysis of pharmacological treatments for insomnia disorder did not identify trazodone among the more favorable options for either acute or long-term management (8). A subsequent clinical suitability appraisal explicitly posed the question of whether trazodone should be considered first-line therapy for insomnia (9), and the American Academy of Sleep Medicine's clinical practice guideline assigns trazodone only a weak recommendation against its use for sleep-onset or sleep-maintenance insomnia, reflecting low confidence in the balance of benefit and harm (10). This uncertainty around monotherapy has motivated growing interest in adjunctive, non-pharmacological approaches that might augment the benefit of standard drug treatment.

Acupuncture is among the most widely studied complementary interventions for insomnia. A systematic review and meta-analysis reported that patients receiving acupuncture for more than three weeks experienced significantly greater symptomatic improvement than those receiving pharmacological treatment alone (11); a further systematic review and meta-analysis extended this benefit to cancer-related insomnia (12); and a comprehensive review of clinical and preclinical evidence described consistent benefits on subjective sleep quality as well as objective sleep architecture, including increased slow-wave and REM sleep and reduced sleep-onset latency, albeit with methodological heterogeneity across the underlying trials (13). However, acupuncture is not a single, uniform intervention: body acupuncture, scalp acupuncture, and auricular (ear) stimulation rest on distinct point-selection systems and are typically studied in isolation. Moreover, auricular stimulation may be delivered either by needling or, as in the present trial, by acupressure with seed pellets. Scalp acupuncture, developed from clinical experience treating a range of cerebral conditions (14), has shown favorable effects on sleep quality and sleep architecture in randomized and meta-analytic evidence (15-17), whereas the evidence base for auricular approaches is comparatively limited and inconsistent, with two independent systematic reviews concluding that the quantity and quality of available trials were insufficient to support firm conclusions (18,19), and a randomized trial finding no additional benefit from augmenting body acupuncture with ear stimulation (20). Electroacupuncture added to standard care has also shown durable benefit for sleep quality in a comorbid psychiatric population, with effects sustained to 32 weeks (21).

2. Objectives

To our knowledge, no randomized trial has directly compared body acupuncture, scalp acupuncture, and ear acupressure, each added to a common pharmacological background, against pharmacotherapy alone within a single primary-insomnia population. Clarifying the relative and incremental value of each modality is clinically relevant for selecting an adjunctive approach that balances effectiveness against the practical

burden of treatment. We therefore conducted a four-arm randomized controlled trial to compare the effectiveness of body acupuncture, scalp acupuncture, and ear acupressure, each added to trazodone, against trazodone alone, on sleep duration, sleep quality, and quality of life in adults with primary insomnia.

3. Methods

3.1. Trial design

This was a single-blind (outcome assessor and statistician), four-arm, parallel-group, superiority randomized controlled trial, approved by the Ethics Committee of Mashhad University of Medical Sciences (approval code IR.MUMS.REC.1405.109; research project No. 4011325, 12 April 2023) and registered with the Iranian Registry of Clinical Trials (IRCT20230626058585N2, registered 26 June 2023). The trial is reported in accordance with the CONSORT 2010 statement (22).

3.2. Participants

Adults presenting with sleep complaints were identified through a neurology clinic, community health centers, and social-media outreach, and underwent a six-step screening process. All candidates first completed the validated Persian version of the Pittsburgh Sleep Quality Index (PSQI) (23); a cut-off of ≥ 6 was used, corresponding to the best balance of sensitivity (85%) and specificity (84%) reported for this version. Patients scoring at or above this threshold were then evaluated by an experienced neurologist to confirm a diagnosis of primary insomnia according to DSM-5 criteria and to exclude other sleep disorders, including obstructive sleep apnea (STOP-BANG score ≥ 3), restless legs syndrome (International Restless Legs Syndrome Study Group criteria), periodic limb movement disorder, circadian rhythm disorders, and parasomnias. This rigorous, structured six-step screening sequence, and particularly the 4-week washout period free of any pharmacological or non-pharmacological insomnia treatment that preceded baseline assessment, was designed to minimize carry-over and confounding and to establish a clean, common baseline across groups. After the washout, baseline PSQI and WHOQOL-BREF questionnaires were re-administered to establish a common baseline across groups. Written informed consent was obtained from all participants before randomization.

3.3. Randomization and blinding

Eligible participants were allocated 1:1:1:1 to the four study groups using block randomization (block size of 8) generated with an online randomization tool. Allocations were placed in sequentially numbered, sealed, opaque envelopes prepared by a research team member not involved in outcome assessment; envelopes were opened in order as participants were enrolled. Given the physical nature of the acupuncture and acupressure interventions, treating practitioners and participants could not be blinded; the outcome assessor and the statistician performing the analysis were blinded to group allocation.

3.4. Interventions

All four groups continued a standardized pharmacological background of trazodone 50 mg orally, once nightly, 30 minutes before bedtime, for 4 weeks, allowing evaluation of the additive effect of each acupuncture or acupressure modality over pharmacotherapy alone.

Body acupuncture: Twelve sessions of manual body acupuncture (3 sessions/week for 4 weeks; 30 minutes/session) at points selected according to a standard traditional Chinese medicine protocol for insomnia, using 0.25 × 40 mm needles.

Scalp acupuncture: Twelve sessions (3 sessions/week for 4 weeks; 15 minutes/session) based on the Jiao scalp acupuncture system, targeting sensorimotor

and sleep-regulation-related areas, with needles inserted at a 15° angle.

Ear acupressure: Auricular acupressure was delivered using Vaccaria (Vaccaria segetalis) seeds fixed with adhesive tape; needles were not used. Seeds were applied bilaterally to the auricular Shenmen, subcortex, heart, and sedative (sympathetic) points, selected for their traditional role in calming shen and promoting sleep. Participants were instructed to self-stimulate each seed by applying firm, steady pressure with the thumb and index finger until a mild sensation of warmth, soreness, or distension (deqi) was felt, for approximately 1–2 minutes per point, three times daily and additionally before sleep. Seeds were replaced once weekly over four weekly sessions (one month). Adherence to the self-stimulation schedule was monitored at each weekly visit through a patient-completed pressure diary and direct questioning, and seeds were re-checked and re-affixed as needed.

Trazodone alone: Trazodone 50 mg nightly with no adjunctive acupuncture or acupressure.

3.5. Outcomes

The primary outcome was nightly sleep duration (hours). Secondary outcomes were sleep quality, measured with the total PSQI score, and quality of life, measured with the WHOQOL-BREF questionnaire (24). All outcomes were assessed at baseline (T0), week 4 (T4, end of the active intervention period), and week 12 (T12).

3.6. Sample size

Sample size was calculated for the PSQI outcome using a between-group difference of 2.5 points, a pooled standard deviation of 2.8 (25), two-sided $\alpha = 0.05$, and 80% power, yielding 21 participants per group; allowing for 10% attrition, a target of 22–23 participants per group (90 total) was set. Ninety-nine participants were ultimately enrolled and analyzed (25, 25, 24, and 25 in the ear, body, scalp, and drug-alone groups, respectively).

3.7. Statistical analysis

Continuous variables are reported as mean ± SD; categorical variables as n (%). Baseline comparability across the four groups was assessed with one-way ANOVA for continuous variables and the χ^2 test for categorical variables. For each outcome, between-group and within-group change over the three time points was analyzed with two-way mixed-design repeated-measures ANOVA (between-subject factor: group; within-subject factor: time), with Greenhouse-Geisser correction applied when Mauchly's test indicated a violation of sphericity; results were corroborated with a linear mixed-effects model (random intercept per participant, maximum-likelihood estimation), which additionally accommodated the small amount of missing follow-up data without imputation. To address the observed baseline imbalance in age and in baseline PSQI directly, the primary between-group comparisons versus the drug-alone group were pre-specified as adjusted analyses: for each outcome and at each follow-up (week 4 and week 12), an analysis of covariance (ANCOVA) modelled the follow-up score as a function of treatment group with the corresponding baseline score and age as covariates, and adjusted mean differences versus the drug-alone group were reported with 95% confidence intervals. As a complementary analysis robust to baseline imbalance, raw change-from-baseline scores were computed for each participant and compared between groups (difference in mean change versus drug-alone, with 95% confidence intervals). Pairwise between-group comparisons at each time point were also performed with independent-samples t tests, Bonferroni-corrected for multiplicity, with standardized effect sizes reported as Cohen's d and 95% confidence intervals. Within-group change across time points was

assessed with paired t tests, similarly Bonferroni-corrected. Distributions of all outcomes were inspected for outliers using the 1.5 × IQR rule and for floor and ceiling effects at each time point. A two-sided $p < 0.05$ was considered statistically significant throughout. Analyses were performed in Python (pandas, SciPy, pingouin, and statsmodels libraries).

4. Results

Ninety-nine participants were randomized and analyzed (ear acupressure, n = 25; body acupuncture, n = 25; scalp acupuncture, n = 24; trazodone alone, n = 25); one participant in the drug-alone group had incomplete follow-up data. The four groups were comparable at baseline for sex, education, night-shift work, and baseline sleep-disturbance pattern (all $p > 0.05$); a significant between-group difference in age was observed ($p = 0.046$, partial $\eta^2 = 0.081$) (Table 1). Baseline PSQI also differed across groups, being lower (better) in the ear and body groups than in the drug-alone group (Table 1). Both age and baseline score were therefore carried as covariates in the adjusted analyses described below.

Table 1. Baseline demographic and clinical characteristics

Characteristic	Ear (n=25)	Body (n=25)	Scalp (n=24)	Drug (n=25)	p
Age (years), mean±SD	38.5±5.0	37.9±5.2	39.5±5.2	41.8±5.4	0.046
Female sex, n (%)	15 (60)	14 (56)	13 (54)	15 (60)	0.967
Bachelor's degree or higher, n (%)	11 (44)	11 (44)	11 (46)	11 (44)	0.999
Night-shift work, n (%)	4 (16)	5 (20)	6 (25)	5 (20)	0.892
Sleep duration, h, mean±SD	4.01±0.37	4.19±0.43	3.75±0.59	3.84±0.49	0.004
PSQI, mean±SD	16.7±1.7	16.4±2.2	17.7±2.3	18.6±1.8	<0.001
Quality of life (WHOQOL-BREF), mean±SD	35.0±1.4	34.0±1.6	34.2±2.0	33.9±0.9	0.052

Values are mean ± SD or n (%). p-values from one-way ANOVA (continuous) or χ^2 test (categorical). Baseline values for the three outcomes (shaded) are shown here and repeated at T0 in Table 2; baseline PSQI and sleep duration differed across groups and were adjusted for in the ANCOVA analyses (Tables 4–5).

For all three outcomes, the main effects of time and group, and the group × time interaction, were statistically significant in both the repeated-measures ANOVA and the linear mixed-effects model (all $p < 0.001$; Table 2), indicating that the trajectory of improvement differed by treatment group.

Table 2. Outcome scores by group and time point, with group×time interaction

Outcome / Time	Ear	Body	Scalp	Drug	Group×Time
Sleep duration, h — T0	4.01±0.37	4.19±0.43	3.75±0.59	3.84±0.49	F=9.29, p<0.001, η^2p=0.227
T4	6.30±0.25	7.42±0.64	6.54±0.44	6.54±0.43	
T12	5.40±0.50	6.54±0.93	6.17±0.73	5.38±0.48	
PSQI, T0	16.7±1.7	16.4±2.2	17.7±2.3	18.6±1.8	F=8.77, p<0.001, η^2p=0.217
T4	6.6±1.6	4.2±1.5	7.5±1.9	9.5±1.9	
T12	5.1±1.6	3.4±0.8	6.5±1.9	8.5±1.9	
Quality of life, T0	35.0±1.4	34.0±1.6	34.2±2.0	33.9±0.9	F=23.40, p<0.001, η^2p=0.425
T4	60.7±1.8	73.4±2.4	64.3±2.5	60.0±1.5	
T12	53.7±4.1	60.8±10.3	61.1±5.2	52.0±5.2	

Values are mean ± SD. η^2p, partial eta-squared. Greenhouse-Geisser-corrected F-tests are shown where sphericity was violated (all three outcomes).

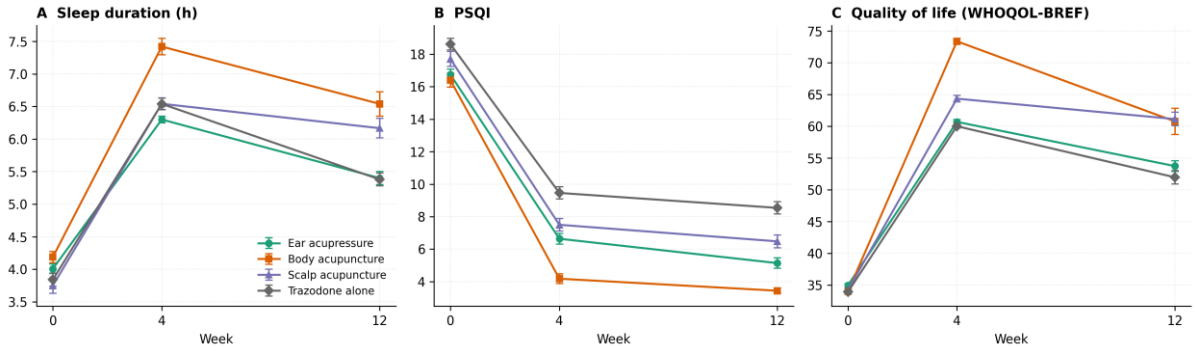


Figure 1. Mean (± SE) trajectories for (A) sleep duration, (B) PSQI, and (C) quality-of-life score, by group, over 12 weeks.

4.1. Sleep duration

At week 4, body acupuncture exceeded trazodone alone (Cohen's d = 1.61, 95% CI 0.97–2.25; Table 3); this advantage persisted at week 12 (d = 1.56). Scalp acupuncture did not differ from trazodone alone at week 4 but exceeded it by week 12 (d = 1.27). Ear acupressure did not exceed trazodone alone at either time point. Within-group, all four groups improved significantly from baseline at both follow-ups ($p < 0.001$). The adjusted and change-score analyses were concordant: the baseline- and age-adjusted mean difference versus trazodone alone for body acupuncture was +0.81 h (95% CI 0.53, 1.08) at week 4 and +1.14 h (0.73, 1.56) at week 12, and the corresponding differences in raw change were +0.53 h (0.21, 0.86) and +0.81 h (0.39, 1.24) (Tables 4–5).

4.2. Sleep quality (PSQI)

All three intervention modalities produced significantly lower (better) PSQI scores than trazodone alone at both week 4 and week 12 (Table 3), with the largest effect for body acupuncture (d = −3.11 and −3.51 at weeks 4 and 12, respectively), followed by ear acupressure (d = −1.60 and −1.93) and scalp acupuncture (d = −1.04 and −1.09). Baseline PSQI was already lower in the ear and body groups than in the drug-alone group (d = −1.06 and −1.11, respectively). The baseline- and age-adjusted mean difference versus trazodone alone for body acupuncture was −4.41 points (95% CI −5.39, −3.44) at week 4 and −4.46 (−5.42, −3.50) at week 12; for ear acupressure, −2.09 (−3.04, −1.14) and −2.86 (−3.79, −1.92); and for scalp acupuncture, −1.61 (−2.52, −0.70) and −1.79 (−2.69, −0.90) (Table 5). The change-score analysis showed the same ordering (Table 4).

4.3. Quality of life

Body and scalp acupuncture exceeded trazodone alone from week 4 onward (Cohen's d = 6.68 and 2.11, respectively) and remained superior at week 12 (d = 1.08 and 1.76). Ear acupressure did not differ significantly from trazodone alone at either time point. The baseline- and age-adjusted mean difference versus trazodone alone for body acupuncture was +13.3 points (95% CI 12.4, 14.2) at week 4 and +8.4 (4.6, 12.2) at week 12, and for scalp acupuncture +4.0 (3.2, 4.9) and +8.6 (4.8, 12.3); the change-score analysis was concordant (Table 4). As detailed below, the exceptionally large standardized effect at week 4 (d = 6.68) is attributable to the small within-group standard deviations (≈ 2 points on the 0–100 scale) rather than to an implausibly large raw difference of 13 points.

Table 3. Between-group standardized effect sizes (Cohen's d [95% CI]) versus trazodone alone

Outcome	Time	Ear vs Drug	Body vs Drug	Scalp vs Drug
Sleep duration	T4	−0.68 [−1.25, −0.11]	1.61 [0.97, 2.25]#	0.00 [−0.56, 0.56]
	T12	0.04 [−0.51, 0.60]	1.56 [0.93, 2.19]#	1.27 [0.66, 1.89]#
PSQI	T4	−1.60 [−2.24, −0.97]#	−3.11 [−3.93, −2.29]#	−1.04 [−1.63, −0.44]*
	T12	−1.93 [−2.61, −1.26]#	−3.51 [−4.39, −2.62]#	−1.09 [−1.69, −0.49]*
Quality of life	T4	0.42 [−0.14, 0.98]	6.68 [5.26, 8.11]#	2.11 [1.42, 2.81]#
	T12	0.37 [−0.18, 0.93]	1.08 [0.48, 1.67]*	1.76 [1.10, 2.42]#

*# p<0.001, * p<0.05, Bonferroni-corrected. Unmarked comparisons were not statistically significant. Standardized effect sizes should be interpreted alongside the raw change scores (Table 4) and baseline- and age-adjusted mean differences (Table 5); the largest Cohen's d values reflect small within-group standard deviations rather than unusually large raw differences (see Discussion).*

Table 4. Raw change-from-baseline scores by group, and difference in mean change versus trazodone alone (95% CI)

Outcome	Time	Ear	Body	Scalp	Drug	Body−Drug (95% CI)
Sleep duration, h	T4	+2.29	+3.23	+2.79	+2.70	+0.53 (0.21, 0.86)*
	T12	+1.39	+2.35	+2.42	+1.54	+0.81 (0.39, 1.24)#
PSQI	T4	−10.10	−12.22	−10.21	−9.16	−3.06 (−4.15, −1.97)#
	T12	−11.60	−12.96	−11.23	−10.08	−2.88 (−4.05, −1.71)#
Quality of life	T4	+25.72	+39.36	+30.08	+26.08	+13.28 (12.67, 13.89)#
	T12	+18.76	+26.76	+26.88	+18.04	+8.72 (4.30, 13.14)#

*Values are mean within-group change from baseline. The final column shows the between-group difference in mean change (body acupuncture minus trazodone alone) with 95% CI, from independent-samples t tests; the ear- and scalp-vs-drug differences in change are reported in the text. # p<0.001, * p<0.05. This change-from-baseline analysis is robust to the baseline imbalance and confirms that the body- and scalp-acupuncture advantages are not artefacts of better baseline status.*

Table 5. Baseline- and age-adjusted mean differences versus trazodone alone (ANCOVA; 95% CI)

Outcome	Time	Ear vs Drug	Body vs Drug	Scalp vs Drug
Sleep duration, h	T4	−0.28 (−0.55, −0.02)*	+0.81 (0.53, 1.08)#	0.00 (−0.26, 0.27)
	T12	+0.01 (−0.39, 0.41)	+1.14 (0.73, 1.56)#	+0.79 (0.39, 1.19)#
PSQI	T4	−2.09 (−3.04, −1.14)#	−4.41 (−5.39, −3.44)#	−1.61 (−2.52, −0.70)#
	T12	−2.86 (−3.79, −1.92)#	−4.46 (−5.42, −3.50)#	−1.79 (−2.69, −0.90)#
Quality of life	T4	−0.31 (−1.20, 0.57)	+13.29 (12.43, 14.15)#	+4.02 (3.17, 4.87)#
	T12	+0.18 (−3.71, 4.06)	+8.41 (4.63, 12.18)#	+8.57 (4.84, 12.31)#

*Adjusted mean difference versus trazodone alone from ANCOVA with the baseline value of the outcome and age as covariates (drug-alone group as reference); positive values favour the intervention for sleep duration and quality of life, negative values favour the intervention for PSQI (lower = better). # p<0.001, * p<0.05. The body- and scalp-acupuncture advantages persist after adjustment for the baseline imbalance and age.*

5. Discussion

In this randomized trial, adding body or scalp acupuncture to trazodone produced significantly greater improvement than trazodone alone across sleep duration, sleep quality, and quality of life, with body acupuncture showing the largest and most consistent benefit at both week 4 and week 12. Ear acupressure produced an added benefit specific to sleep quality (PSQI) but not to sleep duration or quality of life. All four groups, including trazodone alone,

improved significantly from their own baseline, indicating that the acupuncture and acupressure modalities augmented rather than replaced a genuine pharmacological effect. Importantly, the between-group advantages were confirmed in two analyses robust to the baseline imbalance, raw change-from-baseline scores and baseline- and age-adjusted ANCOVA, so the superiority of body and scalp acupuncture is unlikely to be an artefact of their more favourable baseline status or of regression to the mean.

The standardized effect sizes in this trial are larger than those typically reported in acupuncture-for-insomnia meta-analyses, moderate standardized mean differences (26). Three considerations bear on their interpretation. First, the largest values are driven by unusually small within-group standard deviations rather than by implausibly large raw differences. For quality of life at week 4, for example, the body-acupuncture and drug-alone groups differed by 13.4 points on the 0–100 WHOQOL-BREF scale—a clinically meaningful but not extreme difference—yet the pooled standard deviation was only about 2 points, which inflates Cohen's d to 6.68; the corresponding change-score difference (+13.3 points) and adjusted difference (+13.3 points) convey the effect on the original, clinically interpretable scale. Second, we verified that these small standard deviations were not produced by outliers or by floor/ceiling effects: no values fell outside the 1.5 × IQR fences for any outcome at any time point (other than the expected clustering of week-4 sleep duration near its attainable maximum), and WHOQOL-BREF scores ranged from 32 to 77, far from the 0 and 100 bounds. Third, the pattern and direction of effects were preserved across the unadjusted, change-score, and baseline- and age-adjusted analyses (Tables 3–5), which argues against residual baseline imbalance or selective reporting as explanations. Nevertheless, because participants and practitioners were unblinded and all outcomes were self-reported, we cannot exclude that expectancy contributed to the magnitude of the effects, and the absolute sizes should be interpreted with caution and confirmed in blinded, multicentre trials.

The superiority of body acupuncture is consistent with a meta-analysis reporting significantly greater symptomatic improvement with acupuncture beyond three weeks of treatment compared with pharmacotherapy alone (11), and with mechanistic evidence linking acupuncture to measurable changes in sleep architecture, including increased slow-wave and REM sleep (13), which may plausibly underlie the concurrent gains we observed in both sleep duration and subjective quality. The durability of this advantage to week 12 also parallels a trial of electroacupuncture in a comorbid psychiatric population, in which sleep-quality improvement remained significant 32 weeks after treatment initiation (21).

The delayed but sustained emergence of benefit for scalp acupuncture—evident for quality of life from week 4 but for sleep duration only by week 12—mirrors prior randomized and meta-analytic evidence that scalp acupuncture favorably affects both sleep quality and sleep architecture (15-17), and suggests a treatment effect that may consolidate after the active intervention period ends.

The more limited benefit observed for ear acupressure is in keeping with the literature's persistent uncertainty about auricular approaches specifically: two independent systematic reviews concluded that the quantity and quality of trials were insufficient to support firm conclusions about auricular acupuncture and acupressure for insomnia (18,19), and a randomized trial found no incremental benefit from augmenting body acupuncture with ear stimulation (20). That ear acupressure nonetheless produced a

significant improvement in PSQI in the present trial—while not extending to sleep duration or quality of life—suggests a real but outcome-specific effect that may reflect the multidimensional nature of the PSQI (encompassing latency, efficiency, disturbances, and daytime dysfunction) rather than a uniformly weaker intervention. It is also consistent with the lower-intensity, patient-administered nature of acupressure relative to needle acupuncture.

The comparatively modest improvement in the trazodone-alone group, despite being statistically significant relative to its own baseline, is consistent with recent appraisals questioning trazodone's suitability as a first-line insomnia therapy (8,9) and with the American Academy of Sleep Medicine's weak recommendation against its use for this indication (10). Our findings extend this literature by showing that, when trazodone is retained as a common background therapy, adding acupuncture—particularly body acupuncture—can meaningfully improve outcomes beyond what pharmacotherapy achieves alone.

5.1. Strengths and limitations

Strengths of this trial include block randomization with sequentially numbered sealed envelopes, a rigorous six-step screening process with neurologist-confirmed DSM-5 diagnosis and active exclusion of competing sleep disorders (obstructive sleep apnea, restless legs syndrome, periodic limb movement disorder, circadian rhythm disorders, and parasomnias), and, importantly, a 4-week washout period before baseline assessment that reduced carry-over from prior treatment and helped establish a clean, common baseline. Several limitations should be considered. First, and most importantly, the nature of the interventions precluded blinding of participants and treating practitioners, and all three outcomes (sleep duration, PSQI, and WHOQOL-BREF) were self-reported; outcome expectancy may therefore have inflated the magnitude of the observed improvements, an effect that is plausibly greatest for the global quality-of-life ratings and for body acupuncture, which involved the most intensive practitioner contact (twelve 30-minute needling sessions). The large quality-of-life effect for body acupuncture in particular should be interpreted in this light. A significant baseline age imbalance and a baseline PSQI imbalance were present across groups; although results were robust to both change-score and baseline- and age-adjusted analyses (Tables 4–5), residual confounding cannot be fully excluded. Outcomes relied on validated self-report instruments rather than objective measures such as actigraphy or polysomnography. Follow-up was limited to 12 weeks, precluding conclusions about longer-term durability. The single-centre design and the reliance on acupressure (rather than needle acupuncture) for the auricular arm further limit generalizability of the ear-intervention findings. Finally, because all groups received background trazodone, these findings characterize the incremental value of acupuncture and acupressure as an adjunct rather than their effect as a stand-alone therapy.

6. Conclusions

In adults with primary insomnia receiving trazodone, adding body or scalp acupuncture produced clinically meaningful, statistically significant improvements in sleep duration, sleep quality, and quality of life beyond trazodone alone over 12 weeks that persisted after adjustment for baseline imbalance and age; ear acupressure produced a more limited benefit confined to sleep quality. These findings support body acupuncture, and to a lesser extent scalp acupuncture, as effective adjuncts to standard pharmacotherapy for primary insomnia, while highlighting the need for blinded, longer-term, multicenter trials

incorporating objective sleep measures and sham controls to confirm and extend these results.

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