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Original research

Efficacy of vibrotactile positional therapy devices on patients with positional obstructive sleep apnoea: a systematic review and meta-analysis

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ABSTRACT

Introduction Vibrotactile positional therapy (PT) devices are a new treatment modality for positional obstructive sleep apnoea (POSA). This review aimed to determine the effect of vibrotactile PT on the Apnoea Hypopnoea Index (AHI) and the percentage of time spent in the supine position (%Tsupine) in patients with POSA, compared with baseline. Secondary aims were to investigate the effect on daytime sleepiness, quality of life and sleep quality.

Methods A systematic review and meta-analysis was performed of randomised controlled trials (RCTs) and cohort studies that investigated the effect of vibrotactile PT in POSA patients. Searches were performed via MEDLINE, CENTRAL and Embase up to 29 October 2022.

Results 1119 studies were identified, 18 studies met the inclusion criteria (10 RCTs, 8 cohort studies). The use of vibrotactile PT significantly reduced the AHI at follow-up compared with baseline (mean difference (95% CI) −9.19 events/hour (−11.68 to −6.70); p<0.00001). The mean %Tsupine was also significantly reduced (mean difference (95% CI) −32.79% (−38.75% to −26.83%); p<0.00001). The percentage changes in the AHI and %Tsupine were 43% and 70%, respectively. Secondary outcomes were daytime sleepiness, quality of life and sleep indices. These showed minimal change, although follow-up was short.

Conclusion Vibrotactile PT devices are effective in treating POSA; reducing both AHI and %Tsupine. The effect on sleep quality, daytime sleepiness and disease-specific quality of life was minimal. However, there were limited data and follow-up was often brief, meaning that further research is needed to determine the effect of vibrotactile PT on patient-centred outcomes.

PROSPERO registration number CRD42020188617.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Vibrotactile positional therapy is a new treatment modality for patients with positional sleep apnoea, which reduces time in the supine position. It may also reduce the severity of obstructive sleep apnoea (OSA), thereby improving patient-centred outcomes.

WHAT THIS STUDY ADDS

⇒ Vibrotactile positional therapy was effective in reducing time spent in the supine position and the severity of OSA, plus daytime sleepiness; however, this latter finding did not reach a clinically meaningful difference.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study highlighted a lack of patient-centred outcomes beyond daytime sleepiness, such as daytime functioning and sleep quality indices, therefore, well-designed clinical trials are required to fill these evidence gaps.

INTRODUCTION

Obstructive sleep apnoea (OSA) is a common sleep disorder with nearly 1 billion people estimated to have OSA worldwide.[1 2] The supine sleep position is a risk factor for OSA,[3] and those with OSA that occurs predominantly or exclusively in the supine position are referred to as patients with positional OSA (POSA).[4] The exact definition of POSA varies[3–8] but it is often defined as an Apnoea Hypopnoea Index (AHI) in the supine position that is twice that of the non-supine AHI, with an overall AHI>5 events/hour.[3]

More than 50% of patients, diagnosed with OSA, have POSA.[9–12] Patients with POSA are more likely to be male,[13] younger,[14] have a lower body mass index (BMI),[12] smaller neck and waist circumferences, and lower Mallampati scores,[2] than those with non-POSA. OSA severity in patients with POSA tends to be milder, with a prevalence of POSA of 80% in mild-to-moderate OSA, compared with 40% in severe OSA.[12]

In patients with POSA, positional therapy (PT) has been proposed as a treatment option. Recent guidelines recommend that it is considered in those with POSA in whom other treatments such as continuous positive airway pressure (CPAP) are unsuitable or not tolerated.[15] PT is any technique that prevents patients sleeping in the supine position.[2] Traditional PT techniques use mechanical avoidance of the supine position and include the use of a bulky object (eg, a tennis ball attached to the back of nightwear or a wedge-shaped pillow). These techniques are efficacious but are poorly tolerated,[16–18] with low long-term compliance rates (10%).[16] Traditional PT techniques, therefore, have not succeeded as a satisfactory routine treatment for POSA patients.

Vibrotactile PT devices are a relatively new development for the treatment of POSA. These light-weight devices contain position sensors to determine the body position. They also contain

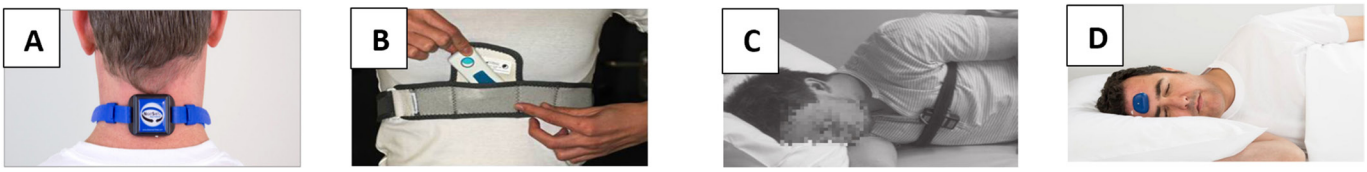

Figure 1 Vibrotactile PT devices on different body sites. Figures showing different positional therapy devices worn on different bodily sites: (A) The Night Shift™ Sleep Positioner (Advanced Brain Monitoring Inc., California, USA) is typically worn on the back of the neck; (B) The Night Balance™ Sleep Positioner Trainer (Den Haag, The Netherlands), is worn around the chest; (C) The BuzzPOD Body Position Orientation Device (Gorman ProMed Pty Ltd, Victoria, Australia), is worn around the chest; (D)The Somnibel™ Positional Therapy System (Sibel, Barcelona, Spain) device, secured on the forehead. Pictures are modified with permission recieved from Bignold *et al*,[7] Oksenberg *et al*,[18] van Maanen *et al*,[20] Sterne *et al*.[26] PT, positional therapy.

small haptic motors (similar to those found in a smartphone) which produce an incremental vibratory stimulus in response to movement into the supine position, thus encouraging a position change. Additionally, all devices are capable of objectively monitoring usage and adherence data. Vibrotactile PT devices can be positioned at different sites on the body; back of the neck,[19] chest[7 20] or the forehead[21] (see figure 1).

The primary aim of this systematic review and meta-analysis was to investigate the effect of vibrotactile PT devices on the AHI and the percentage time spent supine (%Tsupine) in patients with POSA, in comparison to baseline. A secondary aim was to investigate the effect of vibrotactile PT devices on daytime sleepiness, daytime functioning, quality of life, sleep efficiency and arousal from sleep.

METHODS

This systematic review was performed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocol (PRISMA-P) and was registered on PROSPERO (CRD42020188617).

Inclusion criteria

1. Study type: randomised parallel controlled and cross-over trials and prospective cohort studies.
2. Population: studies that involved adult participants diagnosed with POSA.
3. Type of intervention: studies that used vibrotactile PT devices.
4. Type of outcome: primary outcomes were the AHI and %Tsupine. Both variables were measured objectively either by polygraphy or polysomnography (PSG) at a follow-up visit compared with baseline. In addition, the following secondary outcomes that assessed daytime functioning and quality of life outcomes, compared with baseline, were extracted: Epworth Sleepiness Scale (ESS) scores,[22] Functional Outcomes of Sleep Questionnaire (FOSQ) global score,[23] The 36-Item Short Form Health Survey (SF-36) scores.[24] Other secondary outcome measures included objectively measured sleep quality outcomes (sleep efficiency and arousal index).

Exclusion criteria

1. Studies that were not in the English language.
2. Studies that involved animals.
3. Studies that used diagnostic modalities other than polygraphy or PSG.

Search strategy

To identify relevant research articles, an electronic search of the following databases was performed: Medline (Ovid), Embase, Cochrane Library (CENTRAL). The search strategy was developed in consultation with an expert librarian. The following Medical Subject Headings (MeSH) terms, keywords and combinations were used: obstructive sleep apnoea, obstructive sleep apnoea, obstructive sleep apnoea hypopnoea syndrome, obstructive sleep apnoea hypopnoea syndrome, OSA, OSAHS, POSA, ePOSA; positional, position, posture, supine, supine-isolated, supine-predominant, supine-exclusive, dorsal, lateral; treatment, therapy, device, trainer. The search strategy for all the electronic databases is included in online supplemental, section 1.1, pg 2.

Search procedures

Searches were performed by two authors (ASA and JLK). All identified articles were imported into the COVIDENCE website (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia) and duplicates were removed. For the assessment of eligibility, both reviewers (ASA and JLK) screened titles and abstracts of all identified research articles; ineligible articles were excluded. An additional manual search of the reference lists of the eligible articles as well as relevant systematic reviews was performed to capture articles that were not identified in the original electronic search. A search for ongoing clinical trials was also performed in the databases. Full-text review of all the eligible articles was performed by two reviewers (ASA and JLK). Disagreement was resolved through discussion until a consensus was reached. Where consensus could not be reached, the decision of a third reviewer (CDT) was sought.

Data extraction

From each research article, the following details were extracted and checked by two reviewers (ASA and JLK): research study characteristics, participant characteristics, intervention and comparator characteristics. A standardised Microsoft Excel data extraction form was used. In case of missing data, the corresponding author was contacted by email. If data could not be obtained from the authors, calculation methods were used to determine the mean and SD.[25] If data could neither be sourced from the authors or calculated by a standard method, then the data were not included in the quantitative meta-analysis. If both per-protocol and intention-to-treat data were available, then the more conservative intention-to-treat data were used. Two reviewers (ASA and JLK) independently judged each risk of bias item for all the included clinical trials. Disagreement was resolved through discussion until a consensus was reached. If consensus could not be reached, the decision of a third reviewer (CDT) was sought. The 'Risk of Bias' tool in the Cochrane Collaboration RevMan V.5.4 software (Review Manager (RevMan) software, The Cochrane Collaboration, Copenhagen) was used for randomised studies and the Risk Of Bias In Non-Randomized

Studies-of Interventions (ROBINS-I) tool was used for cohort studies.[26]

Data analysis

Synthesis of the results was aimed at clinically relevant outcomes including polygraphy or PSG-measured variables and daytime functioning measures. A meta-analysis was performed using RevMan V.5.4 software (Review Manager (RevMan) software, The Cochrane Collaboration, Copenhagen). Results of continuous outcomes were expressed as mean difference and 95% CI. A random-effect model was used for the analysis of the effect of the vibrotactile PT at follow-up, compared with the baseline. Heterogeneity among the included studies was assessed using prediction interval, I^2 statistics and p value. Subgroup meta-analyses based on the level of OSA severity, type of study design and the bodily location where vibrotactile PT device was worn were performed if I^2 was ≥50% and p<0.1.

RESULTS

This systematic search revealed 1119 articles, of which 374 were duplicates. After title and abstract screening, 25 articles were assessed for eligibility for full-text reading. After exclusions, 18 studies were included in this review, of which 10 were clinical trials (five parallel randomised controlled trials (RCTs) and five cross-over trials) and eight were cohort studies. The results of the search procedure are presented in a PRISMA flow chart (online supplemental figure S1, online supplemental file, pg 4). This search also identified four ongoing registered clinical trials which are available in online supplemental section 1.2, pg 2–3.

Of the included studies, participant age (mean±SD) ranged from 44±11.2 to 64.8±9.5 years. In all studies, the average BMI fell into the overweight category that is, BMI 25–30 kg/m^2. The studies tended to include participants across the OSA disease spectrum with no study limiting participants to a single OSA severity. Therefore, the level of OSA severity for each study was based on the mean baseline AHI of that study: mild (four studies: two clinical trials and two cohort study), moderate (12 studies: seven clinical trials and five cohort studies) and severe (two studies: one clinical trial and 1 cohort study).

The majority of studies used chest-worn PT devices (six clinical trials and six cohort studies), three used neck-worn devices (two clinical trials and one cohort study), two studies used a forehead-secured PT device (one clinical trial and one cohort study) and one study (one clinical trial) used a prototype.

Across the 10 clinical trials, the control group varied between inactive PT treatment (two studies), no treatment (one study), mandibular advancement device (MAD) (two studies), tennis ball technique (TBT) (one study) and auto-titrated positive airway pressure (APAP) (two studies). One study used two different comparisons (MAD only, and combined MAD and PT). One study used two comparisons (no treatment and inactive PT treatment).

The duration of follow-up was different between the studies. In three studies, the follow-up duration was less than 1 week (two clinical trials, one cohort study). In six studies, the follow-up durations were between 1 week and a month (two clinical trials and four cohort studies). In the remaining nine studies, the follow-up durations were between 1 and 3 months (four clinical trials and three cohort studies). These studies are summarised in table 1 and table 2 for clinical trials and cohort studies, respectively.

Primary outcomes

AHI with vibrotactile PT at follow-up compared with baseline

Eighteen studies measured the total AHI at follow-up (with vibrotactile PT) compared with baseline (no vibrotactile PT). One study[27] was excluded as mean (SD) data could not be calculated. Pooled analysis of 17 studies (n=700) showed a statistically significant reduction in the total AHI at follow-up compared with baseline (mean difference (95% CI) –9.19 of events/hour (–11.68 to –6.70); p<0.00001) (online supplemental figure S2, online supplemental file, pg 5). The analysis based on the

Table 1 Summary of the baseline characteristics of the included clinical trials

Authors and year	Type of sleep study	Design	Sample size	Intervention	Location and name of device	Control	Follow-up/wash-out
Bignold *et al*, 2011[7]	Polygraphy	Randomised cross-over trial	n=15	PT	Chest; BuzzPOD	Inactive treatment	3 weeks/1 week wash-out
van Maanen *et al*, 2012[36]	PSG	Randomised cross-over trial	n=30	PT	Neck, prototype	Inactive treatment	1 night with device on and 1 night off/1–2 weeks wash-out
Dieltjens *et al*, 2015[37]	PSG	Randomised cross-over trial	n=20	PT	Chest, Night Balance	MAD only, PT+MAD	1 night intervention/no wash-out
Eijsvogel *et al*, 2015[38]	PSG	Parallel RCT	n=55	PT	Chest, Night Balance	TBT	1 month
Benoist *et al*, 2017[39]	PSG	Multicentre parallel RCT	n=99	PT	Chest, Night Balance	MAD	3 months
Laub *et al*, 2017[40]	Polygraphy	Parallel RCT	n=101	PT	Chest, Night Balance	No treatment	2 months
Berry *et al*, 2019[41]	PSG	Multicentre randomised cross-over trial	n=117	PT	Chest, Night Balance	APAP	6 weeks/no wash-out
Mok *et al*, 2020[42]	PSG	Randomised cross-over trial	n=40	PT	Neck, Night Shift	APAP	8 weeks/1 week wash-out
Hidalgo Armas *et al*, 2021[43]	PSG	Parallel RCT	n=128	PT	Forehead, Somnibel	No treatment, Inactive treatment	12 weeks
Suzuki *et al*, 2021[44]	PSG	Parallel RCT	n=160	PT	Neck, Night Shift	MAD	8 weeks

For more information on the location and the names of the device, see figure 1.
APAP, auto-adjusting positive airway pressure; MAD, mandibular advancement device; n, sample size; PSG, polysomnography; PT, positional therapy; RCT, randomised controlled trials; TBT, tennis-ball technique.

Table 2 Summary of the baseline characteristics of the included cohort studies

Authors and year	Type of sleep study	Design	Sample size	Intervention	Location and name of device	Follow-up
van Maanen *et al*, 2013[20]	PSG	Cohort study	n=31	PT	Chest, Night Balance	1 month
van Maanen and de Vries, 2014[27]	Polygraphy	Multicentre cohort study	n=106	PT	Chest, Night Balance	6 months
Levendowski *et al*, 2014[19]	PSG	Cohort study	n=30	PT	Chest, Night Balance	1 month
Scarlata *et al*, 2016[45]	PSG	Cohort study	n=20	PT	Neck, Night Shift	3 days
Beyers *et al*, 2018[46]	PSG	Cohort study	n=79	PT	Chest, Night Balance	1 month
de Ruiter *et al*, 2018[47]	PSG	Cohort study	n=99	PT	Chest, Night Balance	12 months
Hidalgo Armas *et al*, 2019[21]	PSG	Cohort study	n=12	PT	Forehead, Somnibel	4 weeks
Beyers *et al*, 2019[48]	PSG	Cohort study	n=36	PT	Chest, Night Balance	12 months

For more information on the location and the names of the device, see figure 1.
n, sample size; PSG, polysomnography; PT, positional therapy.

study design, indicated a more conservative reduction of AHI in the RCTs, compared with the cross-over or cohort studies (figure 2). Pooled analysis of five parallel RCTs (n=250) showed a statistically significant reduction in the total AHI at follow-up compared with baseline (mean difference (95% CI) –5.09 of events/hour (−7.37 to –2.81); p<0.0001). Five studies were cross-over randomised trials (n=215). The pooled subgroup analysis showed a larger and statistically significant effect size (mean difference (95% CI) –13.74 of events/hour (–15.49 to –11.99); p<0.00001). The pooled subgroup analysis of the seven cohort studies (n=235) showed a statistically significant reduction in the total AHI at follow-up compared with baseline (mean difference (95% CI) –9.69 of events/hour (–13.24 to –6.14); p<0.00001).

Percentage of time spent in the supine position (%Tsupine) with vibrotactile PT at follow-up compared with baseline

Pooling of the results from 17 studies (n=700) that compared mean %Tsupine at follow-up compared with baseline showed a significant reduction in the mean %Tsupine (mean difference (95% CI) −32.79% (–38.75% to –26.83%); p<0.00001) (online supplemental figure S3, online supplemental file, pg 5). The analysis based on the study design, included parallel RCTs, cross-over randomised trials and cohort studies (figure 3). Five studies were parallel RCTs (n=247) and showed statistically significant reduction in the mean %Tsupine at follow-up, compared with baseline (mean difference (95% CI) −30.62% (–49.32% to –11.93%), p=0.001). The pooled analysis of five cross-over randomised trials (n=218) also showed significant reduction in the mean %Tsupine at follow-up compared with baseline (mean difference (95% CI) −35.10% (–42.71% to –27.48%), p=0.00001). As did the pooled subgroup analysis of the seven cohort studies (n=235), which showed significant reduction in the mean %Tsupine at follow-up compared with baseline (mean difference (95% CI) −33.71% (–39.83% to –27.58%), p=0.00001).

Secondary outcomes

Epworth Sleepiness Scale

ESS data were available from nine studies (n=411). There was a significant reduction in the mean ESS score at follow-up

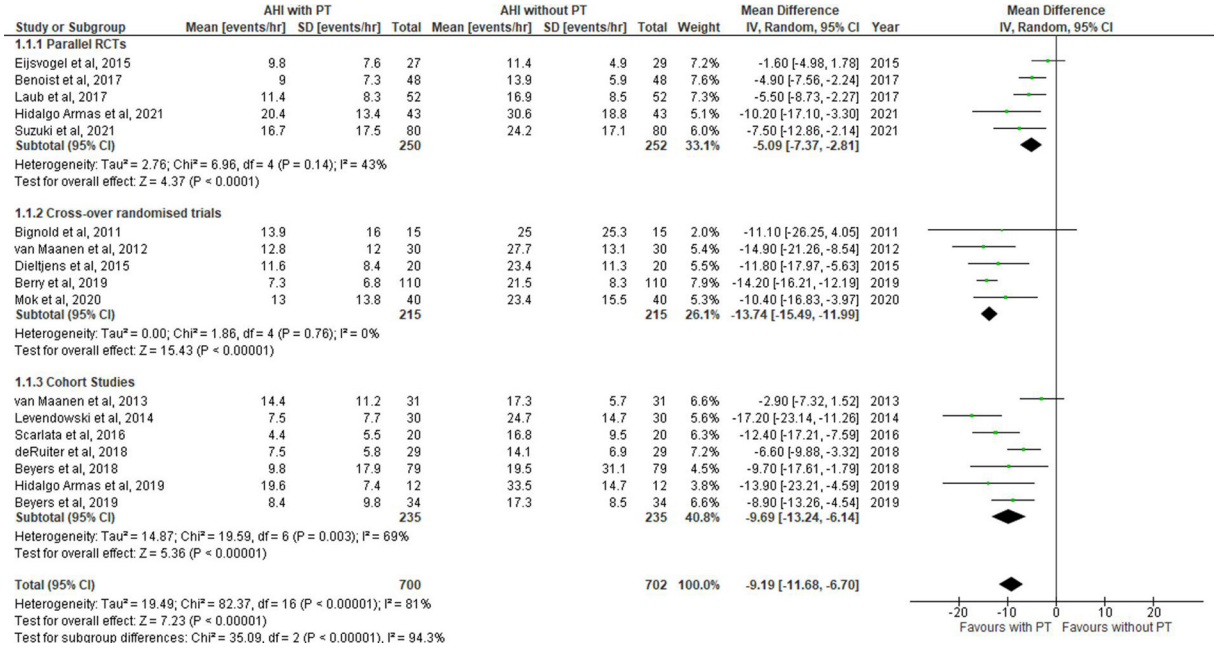

Figure 2 Forest plot comparing total AHI with and without vibrotactile PT (baseline) based on study design. AHI, Apnoea Hypopnoea Index; IV, inverse variance; PT, positional therapy; RCT, randomised controlled trial.

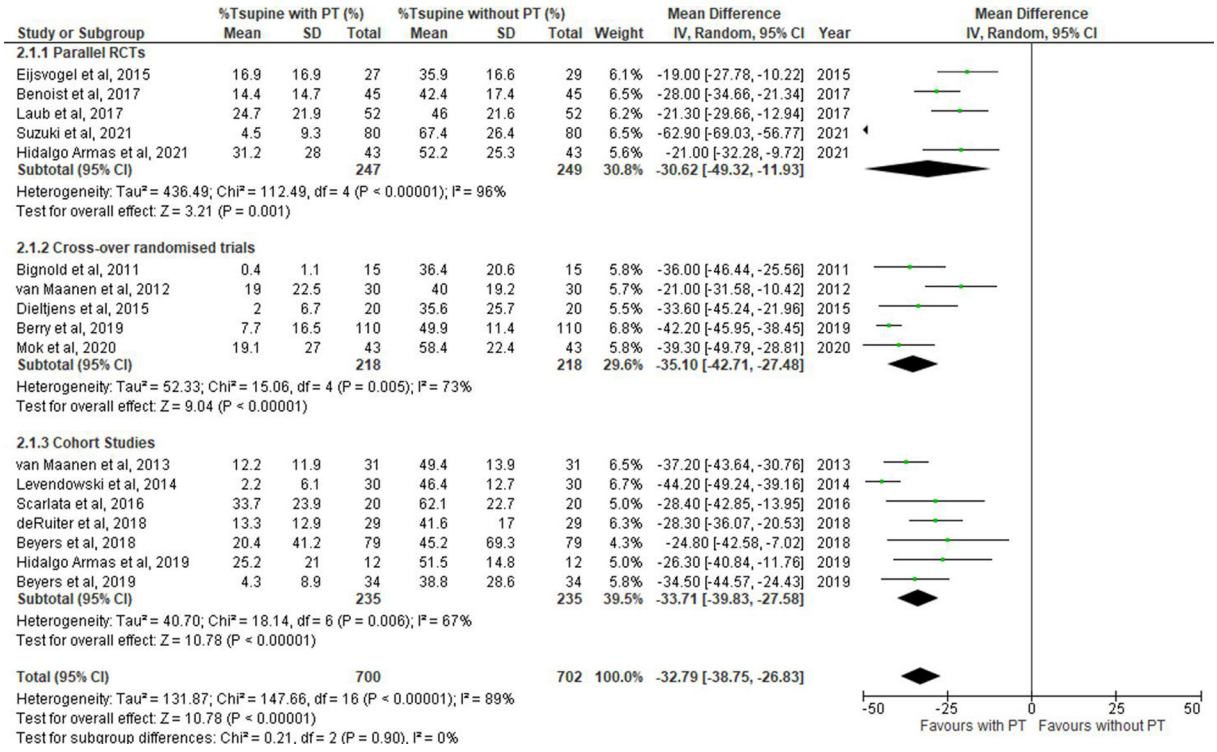

Figure 3 Forest plot comparing percentage of time spent in supine position with and without vibrotactile PT (baseline) based on study design. %Tsupine, percentage of time spent in supine position; IV, inverse variance; PT, positional therapy; RCT, randomised controlled trial.

compared with baseline by a mean difference of −1.17 (95% CI −1.75 to –0.58) (p<0.0001) (figure 4).

Quality of life (FOSQ global score and SF-36 vitality score)

FOSQ data were only available from four studies (n=224). One other study[27] was excluded as they used a different FOSQ version with a different FOSQ global score. The use of vibrotactile PT resulted in a significant increase in the mean global FOSQ score by a mean difference of +0.56 (95% CI +0.12 to +1.00) (p=0.01) (online supplemental figure S4, online supplemental file, pg 6).

SF-36 vitality score data were available from only two studies (n=150). The use of vibrotactile PT resulted in a significant increase in the mean vitality score by a mean difference of +6.72 (95% CI +2.52 to +10.92) (p=0.002) (online supplemental figure S5, online supplemental file, pg 6).

Sleep efficiency

Sleep efficiency data were available from 11 studies (n=417). The use of vibrotactile PT did not result in a statistically significant difference in the mean sleep efficiency with mean difference of +0.74 (95% CI −0.63 to +2.11) (p=0.29) (online supplemental figure S6, online supplemental file, pg 6).

Arousal index

The arousal index data were available from 10 studies (n=372). Pooling of these data showed that the use of vibrotactile PT resulted in a small significant reduction in the mean arousal index; mean difference of −3.11 (95% CI −6.00 to –0.21) (p=0.04) (online supplemental figure S7, online supplemental file, pg 7).

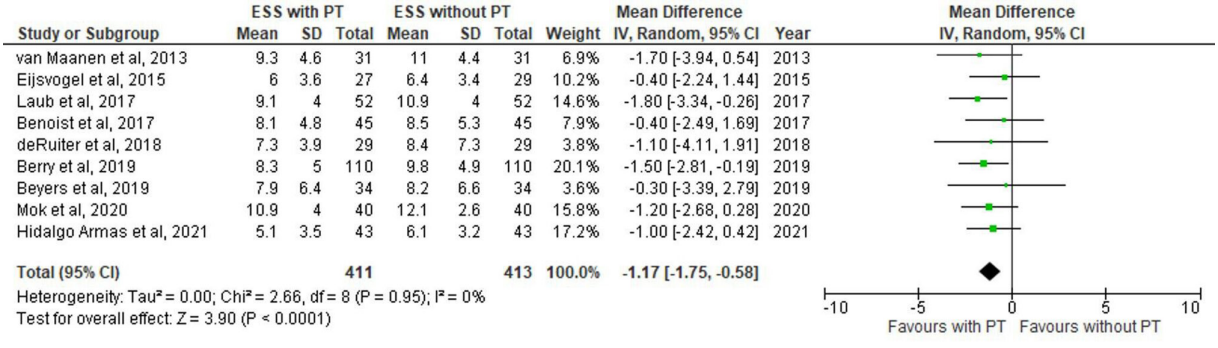

Figure 4 Forest plot of clinical trials and cohort studies comparing Epworth Sleepiness Scale (ESS) with and without vibrotactile PT (baseline). IV, inverse variance; PT, positional therapy.

Sensitivity analyses

Because of the statistically significant heterogeneity that was found in most of the results, subgroup analyses were performed for the primary outcome variables.

AHI with and without vibrotactile PT

The result of the random-effects model of the AHI with and without PT showed that the heterogeneity was statistically significant with $p<0.00001$ and I^2 statistics of 81%. Therefore, predetermined subgroup analyses were done based on the type of study design (outlined in the primary outcomes results), OSA severity and the bodily location where vibrotactile PT device was worn.

For the subgroup analysis based on OSA severity, the level of OSA severity was determined based on the average baseline value of the AHI in each included study (online supplemental figure S8, online supplemental file, pg 7).

Mild OSA

Three studies included 104 participants with mild OSA (ie, average baseline AHI<15 events/hour). Pooling of the results showed reduction in the AHI at follow-up compared with baseline (mean difference (95% CI) −4.42 events/hour (−7.10 to −1.75), p=0.001) (online supplemental figure S8, online supplemental file, pg 7). This equated to a 34% reduction in AHI. The I^2 statistic in this model was higher, which might be explained by the presence of other factors that contributed to heterogeneity such as duration of follow-up.

Moderate and severe OSA

Fourteen studies included 596 participants with moderate and severe OSA (ie, average baseline AHI≥15 events/hour). The results showed that there was a significant reduction in the AHI at follow-up compared with baseline (mean difference (95% CI) −10.50 events/hour (−13.01 to −7.99), p<0.00001) (online supplemental figure S8, online supplemental file, pg 7). This equated to a 46% reduction in AHI.

A further subgroup analysis was completed based on the location on body where the vibrotactile PT device was worn (chest-worn PT device vs neck-worn PT device) (online supplemental figure S9, online supplemental file, pg 8). However, we were not able to complete subgroup analysis on studies that used forehead-secured devices because of the insufficient number of studies.

Chest-worn device

Pooled subgroup analysis of ten studies that used a chest-worn device (n=475) showed a statistically significant reduction in the total AHI at follow-up compared with baseline (mean difference (95% CI) −8.19 of events/hour (−11.46 to −4.92); p<0.00001).

Neck-worn device

Pooled analysis of four studies that used a neck-worn device (n=170) showed a statistically significant reduction in the total AHI at follow-up compared with baseline (mean difference (95% CI) −11.17 of events/hour (−14.19 to −8.16); p<0.00001).

Percentage of time spent in the supine position

Heterogeneity results of the %Tsupine model were statistically significant with $p<0.00001$ and I^2 statistics of 88%. Subgroup analyses were performed, as for AHI, based on the type of study design (outlined in the primary outcome results), OSA level of severity and the body location where vibrotactile PT device was worn.

Mild OSA

Three studies included 101 participants with mild OSA and compared mean %Tsupine with and without vibrotactile PT. There was a significant reduction in the mean %Tsupine at follow-up compared with baseline (mean difference (95% CI) −25.60% (−31.13 to −20.07) (p<0.00001) (online supplemental figure S10, online supplemental file, pg 8). The calculated percentage of change was 64%.

Moderate and severe OSA

Fourteen studies included 599 participants with moderate and severe OSA and compared mean %Tsupine with and without vibrotactile PT. There was a significant reduction in the mean %Tsupine at follow-up compared with baseline (mean difference (95% CI) (−34.58% (−41.08% to −28.08%) (p<0.00001) (online supplemental figure S10, online supplemental file, pg 8). The calculated percentage of change was 71%.

A further subgroup analysis based on the location on body where the vibrotactile PT device was worn (chest-worn PT device neck-worn PT device) (online supplemental figure S11, online supplemental file, pg 9). However, we were not able to complete subgroup analysis on studies that used forehead-secured devices because of the insufficient number of studies.

Chest-worn device

Pooled subgroup analysis of 10 studies that used chest-worn device (n=472) showed a statistically significant reduction in mean %Tsupine at follow-up compared with baseline (mean difference (95% CI) (−32.35% (−37.80% to −26.91%) (p<0.00001)

Neck-worn device

Pooled analysis of four studies that used neck-worn device (n=173) showed a statistically significant reduction in mean %Tsupine at follow-up compared with baseline (mean difference (95% CI) (−38.28% (−59.79% to −16.78%) (p=0.0005).

Risk of bias and evidence quality assessment

The main reason for increased risk of bias in the included randomised studies is the difficulty to blind participants from different interventions (APAP, MAD, TBT or no device) (online supplemental figure S12, online supplemental file, pg 9). The main reasons for risk of bias in cohort studies were moderate risk of bias due to confounding (online supplemental figure S13, online supplemental file, pg 10). Grading Recommendations, Assessment, Development and Evaluations (GRADE) approach to quality of evidence is presented in table 3 for our three most important outcomes (AHI, %Tsupine and ESS). Evidence was similar from subgroups of RCTs, cross-over and cohort studies, representing a high quality of evidence; risk of bias was not sufficiently large to decrease confidence in the estimated treatment effect and no studies were excluded due to risk of bias. Our Funnel plot (online supplemental figure S14, online supplemental file, pg 10), showed some points outside the funnel and an absence of smaller studies, suggestive of publication bias meaning evidence was downgraded by one point. For AHI and %Tsupine, imprecision was not highly evident in this review

Table 3 Grading Recommendations, Assessment, Development and Evaluations (GRADE) quality of evidence assessment for the most important outcomes

Outcome	No of participants (studies)	GRADE assessment
AHI	700 participants (17 studies)	⊕⊕⊕O Moderate ► Reduced by one for risk of publication bias
Percentage time supine	700 participants (17 studies)	⊕⊕⊕O Moderate ► Reduced by one for risk of publication bias
ESS	411 participants (9 studies)	⊕⊕OO Low ► Reduced by one for risk of publication bias ► Reduced by one for imprecision

AHI, Apnoea Hypopnoea Index; ESS, Epworth Sleepiness Scale.

because of the large sample size (n=700) and the clinical decision would not be different if the true effect was at either side of the 95% CI. Moreover, the studies in this review showed consistent effect with overlap of the CIs. However, for the ESS estimates were at risk of imprecision with the lower limit of the 95% CI well below the minimal important difference of 2,[28] meaning evidence was downgraded by one point for this outcome. Finally, all studies directly compared the intervention of interest (vibrotactile PT) in the population of interest (POSA) and all reported the AHI and %Tsupine, with most (nine studies) reporting the ESS. Therefore, according to the Grading Recommendations, Assessment, Development and Evaluations (GRADE) approach, the quality of evidence to recommend the use of vibrotactile PT in patients with POSA to reduce the AHI and %Tsupine is moderate, while evidence for a reduction in ESS is low.

DISCUSSION

The main findings of this systematic review and meta-analysis showed that vibrotactile PT is effective in reducing AHI and time spent in the supine position in patients with POSA. Pooled data also showed a reduction in daytime sleepiness and a disease-specific quality of life score (FOSQ), but these secondary findings did not reach a clinically meaningful difference. Additionally, there were minimal improvements in sleep efficiency and arousal index. However, there were insufficient data to determine the effect of these vibrotactile PT devices on overall quality of life using generic questionnaires such as the SF-36.

Reductions observed in the primary outcomes—AHI and %Tsupine—are in keeping with previous data. The recently published UK National Institute for Health and Care Excellence (NICE) guidelines (NG202) investigated a combined analysis of traditional and vibrotactile PT, stratified by disease severity and concluded that they can be effective in reducing time spent in the supine position in mild and moderate OSA.[29] These guidelines recommend consideration of PT in patients with POSA in whom other treatments are not suitable or are not tolerated. In addition, the consensus opinion was that PT offers potential cost savings for the NHS, compared with other available treatment options.[29] From an earlier meta-analysis, that included seven studies using specifically vibrotactile PT devices (four clinical trials and three cohort studies), the reductions in the AHI and the time spent in the supine position were 54% and 84%, respectively.[30] In the current review, the reductions were 43% and 70%, respectively. The slightly lower efficacy observed in these findings may be attributed to the inclusion of more recent studies, which tested the effect of vibrotactile PT on participants with higher baseline AHI.

The use of vibrotactile stimuli to encourage a position change from supine may be expected to cause arousal or awakening and thus lead to sleep fragmentation. However, sleep efficiency and arousal index did not change with the use of the vibrotactile PT. Future physiological studies might be useful to determine phenotypic arousal responses to the vibrotactile stimuli produced by the PT device.

Although there is convincing evidence that vibrotactile PT significantly reduces objective supine sleep, and therefore, the severity of sleep apnoea in patients with POSA, there is less subjective data that describes the effect on quality of life. This is due in part to the variety of follow-up durations and differing quality of life measures used across the studies. In this review, the most frequently measured patient-reported outcome was the ESS (reported in nine studies). While the self-reported ESS was reduced with PT treatment, the reduction did not meet the clinically important difference of between 2 and 3, meaning that there may not be a meaningful change in daytime sleepiness.[31] Additionally, the FOSQ, a disease specific quality of life questionnaire to determine the impact of a sleep disorder on activities of everyday living, was used as a measure of quality of life in three studies, and again there was improvement observed with treatment but it did not reach the minimal clinically important difference of 1.8.[32] However, the follow-up in some studies was short, and therefore, may have missed important clinical changes in patient-centred outcomes.

The quality of life measure which has proven to be most sensitive to the impact of OSA and to its treatment is the Vitality score of the SF-36 questionnaire.[33 34] Only two of the studies included in the present review used the SF-36 in their assessment; however, there was an increase in vitality observed with PT treatment in the pooled analysis of these studies. Future trials focused on sensitive patient-reported quality of life outcomes are needed. One such trial, the POSA trial (NCT04153240) is ongoing and specifically addresses this point.

The current review and meta-analysis is the largest of its type to date; 18 studies were included (10 clinical trials and 8 cohort studies) with over 700 patients. In a field progressing quickly, these results provide a timely update on a previous meta-analysis focused specifically on vibrotactile devices which included seven studies.[30] Moreover, in comparison to the recent NICE review,[29] which compared both traditional and vibrotactile PT modalities to other available treatment options, the current review used baseline and post-PT data, irrespective of the comparator, thus enabling pooling of more data for analysis.

Limitations

In the current review, there are several points to consider in the interpretation of the results. The first is the heterogeneity in the definitions of POSA, the PT devices used, as well as the differences between the control arms of the included clinical trials. Two studies used inactive vibrotactile PT treatment, one study used no treatment, one study used MAD, one study used TBT and two studies used APAP. The remaining two studies used multiple comparators or combined therapy as control. Therefore, pooling of the results was only possible with vibrotactile PT at follow-up, compared with baseline. However, with this approach, we were able to include the large number of studies reported on.

In most of the studies, the follow-up times were short (3 months or less), and therefore, were not able to investigate the

long-term effect of the vibrotactile PT. This highlights the need for large blinded RCTs powered to look at changes in patient-centred outcomes over longer follow-up periods.

In addition, adherence rates were defined differently between different studies, and therefore, data were unable to be pooled. Future trials should also report the adherence with therapy, as this is likely to be a key determinant of therapy efficacy. When comparing to other treatment options such as CPAP and surgical approaches, the combination of adherence data and reduction in AHI on therapy should be considered.[35]

A further limitation was that our review excluded non-English language studies.

CONCLUSION

There is evidence that vibrotactile PT reduces the time spent in the supine position and AHI in patients with POSA, however, the effect on self-reported daytime sleepiness does not reach clinical significance and evidence on the longer-term effect of PT is lacking. Other, more targeted outcomes for OSA, such as vitality, have limited data and follow-up periods were often short. Therefore, well-designed clinical trials are required to fill these evidence gaps.

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Contributors ASA developed the project, designed the study protocol and wrote the search strategy, plus the first protocol. ASA and JLK extracted the data. ASA planned and performed statistical analysis. ASA wrote the first manuscript draft. JLK, MJM and CDT provided critical insights and supervision. All authors contributed to and approved the final written manuscript. JLK is the guarantor and accepts full responsibility for the work.

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