



Impact of manual diaphragm release on respiratory performance and sleep quality in pregnant women with sleep apnea: a randomized controlled trial

Impacto de la liberación manual del diafragma en el rendimiento respiratorio y la calidad del sueño en mujeres embarazadas con apnea del sueño: un ensayo controlado aleatorizado

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Abstract

Introduction: Obstructive sleep apnea (OSA) in pregnancy presents significant health hazards to both mothers and their babies. Current OSA treatments are often uncomfortable or not well accepted by pregnant women.

Objectives: This study evaluates the effectiveness of the Manual Diaphragm Release Technique (MDRT) in improving sleep quality, diaphragmatic excursion, and sleep duration among pregnant women with OSA.

Methodology:

This randomized, controlled trial included 39 pregnant women in their third trimester diagnosed with OSA. Participants were randomly allocated into the experimental group (12 sessions of MDRT over four weeks plus positioning education) or the control group (positioning education). Outcomes measured were the Pittsburgh Sleep Quality Index (PSQI), diaphragmatic excursion, and sleep duration.

Results

The experimental group indicated significant improvements in all measured outcomes: PSQI ($p=0.008$), diaphragmatic excursion ($p=0.001$), and sleep duration ($p=0.001$).

Conclusion

These findings suggest that MDRT is a promising, non-invasive intervention for improving diaphragmatic excursion, sleep quality, and duration in pregnant women with OSA. However, additional research with larger sample sizes and longer follow-up is necessary.

Keywords

Obstructive sleep apnea, pregnancy, sleep quality, diaphragmatic excursion, non-invasive treatment.

Resumen

Introducción: La apnea obstructiva del sueño (AOS) durante el embarazo presenta riesgos significativos para la salud tanto de la madre como de su bebé. Los tratamientos actuales para la AOS suelen ser incómodos o no son bien aceptados por las mujeres embarazadas.

Objetivos: Este estudio evalúa la eficacia de la Técnica de Liberación Manual del Diafragma (MDRT) para mejorar la calidad, la excursión diafragmática y la duración del sueño en mujeres embarazadas con AOS.

Metodología:

Este ensayo clínico aleatorizado y controlado incluyó a 39 mujeres embarazadas en el tercer trimestre diagnosticadas con AOS. Las participantes fueron asignadas aleatoriamente al grupo experimental (12 sesiones de MDRT durante cuatro semanas, más educación sobre el posicionamiento) o al grupo control (educación sobre el posicionamiento). Los resultados medidos fueron el Índice de Calidad del Sueño de Pittsburgh (PSQI), la excursión diafragmática y la duración del sueño.

Resultados

El grupo experimental mostró mejoras significativas en todos los resultados medidos: PSQI ($p = 0,008$), excursión diafragmática ($p = 0,001$) y duración del sueño ($p = 0,001$).

Conclusión Estos hallazgos sugieren que la MDRT es una intervención prometedora y no invasiva para mejorar la excursión diafragmática, la calidad y la duración del sueño en mujeres embarazadas con AOS. Sin embargo, se necesitan más investigaciones con muestras más grandes y un seguimiento más prolongado.

Palabras clave

Apnea obstructiva del sueño, embarazo, calidad del sueño, excursión diafragmática, tratamiento no invasivo.

Introduction

Obstructive sleep apnea (OSA) affects 3- 8% of pregnant women (Dominguez& Habib, 2022), and is related with critical maternal and fetal health risks, including preeclampsia, gestational diabetes, restricted intrauterine growth, preterm labor, and raised probability of cesarean delivery (Silvestri & Aricò, 2019; Liu et al., 2019). Approximately 15% to 30% of high-risk pregnancies can suffer from sleep-disordered breathing, according to recent reviews, while clinically significant OSA is more common in the third trimester due to progressive physiological and mechanical changes associated with gestation (Maniaci et al., 2024). Sleep disturbances during pregnancy have received increasing clinical attention during the last five years due to its implications for fetal well-being and Maternal morbidity (Pamidi & Ayappa, 2024).

OSA is represented by repeated episodes of upper airway obstruction, either partial or total, that often cause sleep disturbances, diminished oxygen saturation, and impaired cognitive and emotional well-being as a result of chronic sleep deprivation (Maniaci et al., 2024). Five or more episodes of apnea or hypopnea per hour of sleep, along with symptoms such excessive daytime sleepiness, exhaustion, and inadequate cognition, are used to confirm the diagnosis. Effective therapy is essential for pregnant women with OSA due to the possibility of long-term health implications. However, due to discomfort, difficulty in usage, and worries about safety during pregnancy, conventional methods like continuous positive airway pressure (CPAP) are frequently poorly tolerated (Mone et al., 2022)

The diaphragm is the primary inspiratory muscle responsible for tidal breathing, thoracoabdominal coordination, and producing pressure during inspiration. Restricting diaphragmatic excursion can lower inspiratory efficiency, resulting in shallow breathing, increased activation of auxiliary muscles, and reduced ventilatory stability. Restricted diaphragmatic mobility may have an indirect influence on upper airway function as well. Adequate diaphragmatic contraction produces effective airflow and negative intrathoracic pressure; however, if respiratory mechanics are compromised, the balance between inspiratory suction forces and pharyngeal dilator muscle activity may be disrupted, increasing the risk of upper airway collapse during sleep, especially when neuromuscular tone is physiologically reduced (Lessa et al., 2016; Molnár et al., 2022). Thus, impaired diaphragmatic kinematics may contribute not only to decreased ventilation but also to increased nocturnal respiratory instability in pregnant women with OSA.

The Manual Diaphragm Release Technique (MDRT) is a promising manual therapy that targets myofascial restrictions in the diaphragm to improve respiratory mechanics and diaphragmatic mobility. MDRT can enhance diaphragmatic excursion, increase ventilation, and minimize respiratory effort, each of which may help people with OSA avoid airway collapse (Nair et al., 2019). Although the procedure has been used for respiratory dysfunction, its impact on OSA, especially in pregnant women, has not yet been studied. Improving the diaphragm's function might decrease the severity of sleep deprivation symptoms because it is essential to respiratory mechanics (Rocha et al., 2015).

Positional therapy is a conservative technique that is widely utilized in patients whose OSA worsens while lying supine. It can reduce airway obstruction in some individuals, but it does not address defective respiratory muscle mechanics or restricted diaphragmatic movement (Omobomi & Quan, 2018). Positional therapy could be done by techniques such as the tennis ball method, which involves attaching a tennis ball to the backside of a pajama shirt to keep from supine resting, have successfully reduced apnea frequency and improved overall sleep quality in positional OSA cases (Srijithesh et al., 2019). As a result, combining positional guidance with an intervention to improve diaphragmatic function may provide additional benefits in pregnant women with OSA.

Despite the potential of both MDRT and positional therapy, there is limited evidence assessing their combined effects, especially in pregnant women with OSA. This research was intended to fill this gap in the literature by evaluating the effects of a combined intervention involving MDRT and positioning education on sleep quality, diaphragmatic excursion, and sleep duration in pregnant women with OSA. It is hypothesized that MDRT improves diaphragmatic excursion, which indirectly impacts sleep quality in pregnant women with OSA.



Method

Study design

A randomized controlled study was conducted to assess the effects of MDRT on pregnant women with sleep apnea. The experimental group received 12 MDRT sessions over four weeks, as well as positioning education, while the control group received only positioning education. Outcomes were assessed before and after the intervention. The interventions lasted from 1/11/2023 to 1/3/2024. The study also has a clinical-trials.gov registry (NCT06273787) and accepted by the ethical committee of Faculty of Physical Therapy Cairo University (Approval Number: P.T.REC/012/004857).

Sample size

G*Power software (version 3.1) was utilized to calculate the a priori sample size for a repeated-measures design with two groups and two time points. The Pittsburgh Sleep Quality Index (PSQI), the main outcome measure, was used in the calculations, with an expected effect size of 0.46, an alpha cutoff of 0.05, and statistical power of 80%. To detect a statistically significant group-by-time interaction, each group needed at least 18 participants. The target recruiting sample increased to 40 participants to account for an expected attrition rate of about 10%.

Participants

Forty pregnant women were recruited from outpatient obstetric and physical therapy settings (Figure 1). Women were eligible if they met the following criteria: (1) third-trimester pregnancy, (2) age between 30 and 40 years, (3) singleton pregnancy, (4) physician-confirmed diagnosis of obstructive sleep apnea with sleeping for less than seven hours, and (5) medical clearance from their obstetrician to participate in the study

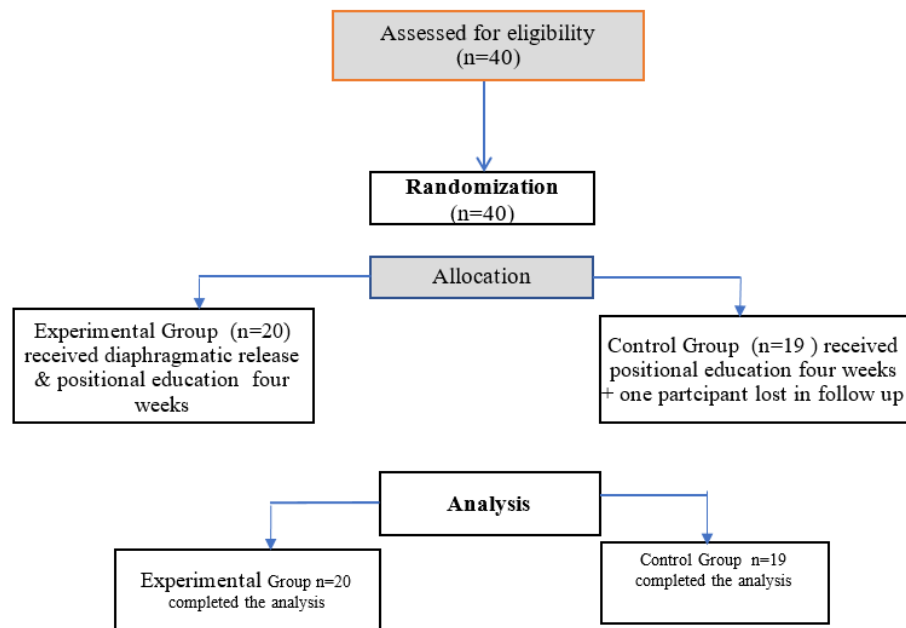
Participants were excluded if they were smokers; had a history of pulmonary surgery; had chronic respiratory disease, including asthma; had high-risk pregnancy conditions that might limit safe participation; had neuromuscular, musculoskeletal, or neurological disorders affecting respiratory mechanics or another active treatment for OSA; had contraindications to manual therapy; or were unable to understand study instructions or complete outcome assessments. All participants provided written informed consent before enrollment.

Randomization, allocation concealment, and blinding

Following the baseline evaluation, eligible individuals were randomly assigned to one of two study groups using a computer-generated randomization schedule created by an independent research assistant who had no involvement in recruitment, treatment administration, or outcome assessment. Allocation concealment was achieved by using sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope held the group assignment and was only opened until baseline measures were completed and eligibility was confirmed.

Because of the nature of the intervention, participant and therapist blindness was not possible. However, the assessor in charge of outcome measurement and the statistician in charge of data analysis were not aware of the group allocation.

Figure 1. Consort flow chart



Outcome measures

Assessments were conducted at baseline and after the 4-week intervention period.

Primary outcome

Sleep quality was evaluated using the Pittsburgh Sleep Quality Index (PSQI). Subjective sleep quality, sleep latency, sleep length, habitual sleep efficiency, sleep disruptions, sleep medication use, and daytime dysfunction are the seven categories of this validated self-report questionnaire, which consists of 19 items. Higher scores on the PSQI scale, which goes from 0 to 21, indicate lower sleep quality (Nishiyama et al., 2014). Poor sleep quality is indicated by a score higher than five.

Secondary outcomes

Diaphragmatic excursion was assessed using B-mode and M-mode ultrasonography by an experienced assessor. Participants were assessed in a standardized semi-recumbent position for ensuring comfort and safety during late pregnancy. A low-frequency curvi-linear transducer was inserted in the right sub-costal area along the midclavicular or anterior axillary line to observe the posterior third of the right hemidiaphragm through the liver's acoustic window. Following quiet tidal breathing, individuals were encouraged to take a deep breath from their functional residual capacity. Diaphragmatic movement was recorded in M-mode, with excursion defined as the vertical displacement of the diaphragmatic dome from end-expiration to maximal inspiration, measured in cm. Three technically acceptable trials were recorded, and the average value was chosen for analysis (Figure 2a&b).

Figure 2a. Shows the diaphragm identified by ultrasound at the end of a quiet expiration, deep within the ribs and intercostal muscle layer.

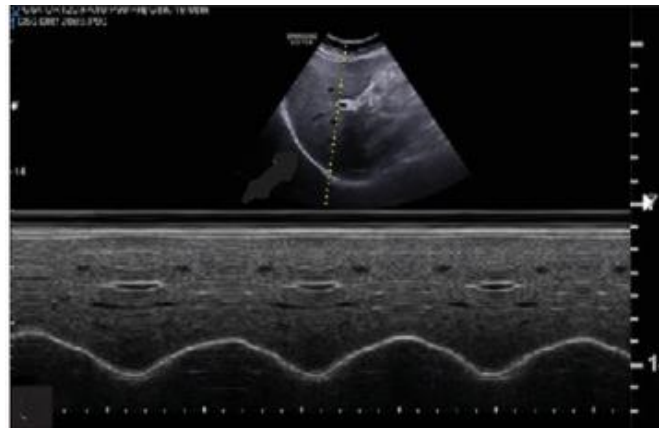


Figure 2b. The diaphragm is identified by ultrasonography near the end of silent inspiration, deep within the intercostal muscle layer and ribs



Sleep duration

Sleep Duration: all participants were asked to give answers to the closed-ended question "What is your average daily sleeping hour number?" by indicating how many hours they slept. it was categorized sleep duration into three categories based on previous research: less than seven, seven to nine, and more than nine hours per day. Sleeping for less than seven hours was considered insufficient. Seven to nine hours of sleep was regarded as appropriate (Chaput et al., 2020).

Intervention

Diaphragmatic Release

Participants in the experimental group got a combined intervention that included diaphragmatic release and positional education for obstructive sleep apnea. The intervention was delivered over four weeks, with a total of 12 sessions administered three times each week (Nair et al., 2019). All sessions were supervised by the same licensed physical therapist, who was trained in women's health physical therapy and manual therapy techniques. The therapeutic rationale for MDRT was to enhance diaphragmatic mobility and optimize thoracoabdominal mechanics by reducing myofascial restrictions at the diaphragmatic attachments and lower rib cage, thereby potentially improving ventilation and sleep-related breathing function (Rocha et al., 2015).

Participants were positioned in a semi- reclined position with enough external support to maximize comfort throughout late pregnancy (Jensen et al., 2007). The therapist placed the pisiform, hypothenar eminence, and lateral surface of both hands' final three fingers bilaterally beneath the costal cartilages of the seventh to tenth ribs. During inspiration, mild cranial and lateral traction were used to help with rib elevation and lower thoracic cage expansion. During expiration, the therapist maintained manual contact with the interior costal margin, moving inward and superiorly, gradually intensifying the contact

within the participant's tolerance. Throughout the technique, the manual contact was recorded to correspond with the participant's breathing cycle. Each treatment session consisted of two sets of 10 deep breathing cycles, separated by approximately 1 minute of rest. Manual pressure was applied progressively and cautiously, with continuous adjustment according to participant tolerance (Rocha et al., 2015; Thali & Ganesh, 2023).

Positioning education

all Participants in the two groups just received positioning education, which was a conservative, non-invasive technique for managing positional OSA. Education focused on avoiding the supine sleeping posture, as upper airway obstruction can exacerbate in susceptible persons (Omobomi & Quan, 2018; Srijithesh et al., 2019). At baseline, each participant was individually educated on how to adopt a positional approach that involved wearing a garment with a tennis ball positioned posteriorly to inhibit supine sleep at night. Participants were told to sleep mostly in a lateral posture, avoid extended supine positioning, and utilize the positional device nightly throughout the 4-week study period. These instructions were reinforced during follow-up communication.

Throughout the trial, all participants were followed for adverse symptoms or clinical intolerance, such as discomfort, dizziness, dyspnea, uterine irritability, pain, or any obstetric or respiratory incident that may exclude continued therapy. If any concerning symptoms had arisen, the therapy session would have been ended immediately and the participant directed for appropriate medical evaluation. There were no significant intervention-related adverse events recorded during the trial.

Data analysis

Mean \pm standard deviation (SD) was used to illustrate the data. An unpaired t-test was employed to compare the subjects' characteristics. The data were examined for the presence of extreme scores, homogeneity of variance, and the normality assumption. The Shapiro-Wilk test for data normality revealed that the assessed variables (U.S. diaphragm excursion, PSQI, and sleep duration recommendation) were normally distributed.

The effects of the assessed variables were compared within and between groups using MANOVA, which was utilized to determine the impact of the MDRT on the combined set of PSQI, Diaphragmatic Excursion Assessment, and Sleep Duration Recommendations. The Statistical Package for the Social Sciences (SPSS Inc., Chicago, Illinois, USA) version 20 for Windows was utilized to analyze the data. A significant P value was defined as less than or equal to 0.05.

Results

Subject demographic details

Table (1) illustrates no significant variation between the subject characteristics' mean values of age, BMI, and gestational age of the two groups ($p = 0.83, 0.86,$ and 0.42), respectively.

Table 1. Demographic characteristics of participants data of experimental and control group

Demographic data	Experimental group (n=20)	Control group (n=19)	t-value	p-value
Age (years)	35.4 \pm 3.3	35.2 \pm 3	0.22	0.83
BMI (kg/m ²)	27.1 \pm 1.3	27.2 \pm 1.4	-0.17	0.86
Gestational age (years)	26.4 \pm 1.4	26 \pm 1.4	0.82	0.42

Data was expressed as mean \pm SD, p- value: significance level ≤ 0.05

Primary outcome analysis indicated a statistically significant variation in the mean value of PSQI post-treatment across both groups ($p=0.008$). A significant reduction was indicated in PSQI in both groups after treatment when compared with the baseline values ($p=0.001$).

The secondary outcome analysis showed a statistically significant change in the mean values of U.S. diaphragm excursion after treatment across both groups ($p=0.014$), with the superiority of the experimental group. Regarding within-group comparison, there was a statistically significant increase in the U.S.



of diaphragm excursion in the experimental group after treatment when compared with the baseline values ($p=0.001$), while there was no statistically significant change in the control group.

The tertiary outcome was sleep duration. There was a statistically significant increase in sleep duration in both groups after treatment when compared with the baseline values ($p=0.001$), in favor of the experimental group, as displayed in Table (2).

Table 2. US, PSQI and sleep duration during RCT of participants for measured variables of both groups.

Outcome variables	Experimental (n= 20)	Control (n=19)	MD (95% CI)	P-value
U.S of diaphragm excursion (cm)				
Baseline	1.85 ± 0.34	1.77 ± 0.49	0.08 (-0.19, 0.34)	0.538
Post-intervention	2.27 ± 0.69	1.79 ± 0.44	0.48 (-0.85, -0.1)	0.014*
P-value	0.001*	0.779		
PSQI				
Baseline	8.67 ± 1.47	8.42 ± 1.34	0.25 (-0.66, 1.17)	0.557
Post-intervention	5.08 ± 1.64	7.22 ± 1.56	-2.44 (-2.14, -0.39)	0.008*
P-value	0.001*	0.001*		
Sleep duration (hours)				
Baseline	6.55 ± 1.1	6.26 ± 1	0.29 (-0.39, 0.97)	0.388
Post-intervention	7.7 ± 1	6.79 ± 0.62	0.91 (0.38, 1.44)	0.001*
P-value	0.001*	0.001*		

Data was expressed as mean ± SD, US: ultrasound, PSQI: Pittsburgh sleep quality index, MD (95% CI): mean difference (95% confidence interval for difference), *: significant p-value ≤ 0.05

Two-way mixed design MANOVA was employed to ascertain how the two groups differed in their scores on the combined parametric variables (PSQI, diaphragmatic excursion assessment, and sleep duration recommendations). There was a significant multivariate effect for the groups, Wilk's A = 0.052; F = 210, P = 0.001, partial eta squared (η^2) = 0.95; for time, Wilk's A = 0.032; F = 351, P < 0.001, η^2 = 0.97; and for the interaction of groups and time, Wilk's A = 0.14; F = 71.4, P < 0.001, η^2 = 0.86.

Discussion

This research aimed to evaluate the efficacy of the MDRT in alleviating sleep apnea among pregnant women, specifically comparing it to the commonly used positioning education to avoid supine sleeping. Sleep apnea throughout pregnancy poses considerable maternal and fetal health risks. Given these risks, finding effective and non-invasive treatment methods is crucial.

Our study holds particular significance because, despite the known benefits of the MDRT in improving diaphragmatic mobility and respiratory function in patients with COPD (Rocha et al., 2015), its effects had not been previously explored in the context of pregnant women having sleep apnea. This research aimed to fill this gap by investigating whether MDRT could offer a viable alternative or complement to existing treatment strategies for sleep apnea in pregnancy.

The results of our study demonstrated a significant improvement in all assessed variables for the group receiving the MDRT. Specifically, the experimental group experienced a marked increase in diaphragmatic excursion post-treatment, surpassing that of the control group. This result suggests that the MDRT effectively enhances the mechanical function of the diaphragm, potentially reducing the frequency and intensity of apnea attacks by maintaining better airway patency throughout sleeping.

In line with our findings, a randomized crossover study on COPD patients examined the impact of the MDRT on diaphragmatic excursion. The study revealed a statistically significant enhancement of diaphragmatic excursion following the intervention. The study also indicated that the MDRT was not inferior to the diaphragmatic stretch technique (Nair et al., 2019). Also, recent research conducted on COPD demonstrated the efficacy of MDRT in improving diaphragmatic excursion among COPD patients (Leóns-Macías et al., 2018).

The most notable structural alterations include weight gain (about 20% greater than pre-pregnant weight) and uterine volume, which affects diaphragm elevation and hinders breathing (Atef, 2020). However, the parasympathetic system was activated by MDRT, which enhanced oxygen saturation and



reduced respiratory rate, bronchospasm, and dyspnea or difficulty in breathing. (Ghallab et al., 2024). The manual diaphragm release (DR) approach improves exercise capacity, breathing efficiency, dyspnea, and diaphragmatic contraction (Silvestri & Aricò, 2019).

Another recent study found that the MDRT when combined with traditional breathing exercises, could enhance pulmonary function outcomes, which are directly linked to improving diaphragmatic excursion among patients with COVID-19 (Ghallab et al., 2024).

The present study demonstrated significant improvement in PSQI after applying the MDRT; the PSQI scores indicated a significant improvement in sleep quality for the experimental group. This improvement is clinically meaningful as inadequate sleep during pregnancy is associated with various adverse consequences, including elevated stress levels, reduced immune function, and a higher risk of postpartum depression (Polo-Kantola et al., 2017). By improving sleep quality, the MDRT may contribute to better overall maternal health and well-being.

In addition to sleep quality, we observed a significant increase in sleep duration for the group receiving the MDRT. Adequate sleep duration is vital for pregnant women, as it affects fetal development and maternal health (Sedov et al., 2018). The increase in sleep duration observed in our study highlights the potential of the MDRT to provide comprehensive benefits in managing sleep apnea and improving sleep patterns throughout pregnancy.

In concordance with our findings, a two-month regimen of the MDRT, performed three times per week, improved PSQI scores, diaphragmatic excursion, and diaphragmatic thickness fraction in patients with gastro-esophageal reflux disease (GERD) (Facco et al., 2017).

These findings align with the theoretical understanding of how diaphragmatic function impacts respiratory health. By directly manipulating the diaphragm muscle, the MDRT likely enhances its strength and flexibility, leading to better respiratory mechanics and reduced upper airway resistance (Sherif et al., 2024; Lessa et al., 2016). This mechanism can be particularly beneficial in pregnancy, where physiological changes often compromise respiratory function.

Supporting this proposal, a pilot randomized trial on asthmatic patients evaluated the effectiveness of the manual technique on respiratory pressures and chest mobility. The study demonstrated improvements in maximum inspiratory pressures and the flexibility of the rib cage (McKenzie et al., 2009).

Our research adds to the growing body of evidence that suggest non-invasive interventions for managing sleep apnea in pregnant women. The significant improvements in diaphragmatic excursion, sleep quality, and sleep duration observed with the MDRT underscore its potential as a valuable addition to the therapeutic options available for this population. Moreover, the simplicity and non-invasiveness of the MDRT make it an attractive option for pregnant women seeking to manage sleep apnea without pharmacological interventions or surgical procedures.

Limitations: The study had several limitations. The sample size recruited was relatively small. Additionally, the intervention's effectiveness could be influenced by individual variations in manual technique application. Also, reliance on subjective assessment of sleep via the sleep diary could be biased due to individual perceptions. Larger sample sizes, longer follow-up times, and standardized protocols to validate these results and determine the sustained advantages of MDRT in pregnant women with sleep apnea should be considered in future research. Second, blinding was inherently limited by the nature of the intervention. Because MDRT is a manual, therapist-delivered treatment, neither the therapist nor the participants could be fully blinded to group allocation. This introduces the possibility of performance and expectation bias, particularly in outcomes related to perceived sleep quality. Although assessor blinding may reduce some measurement bias, the absence of full blinding remains an important methodological limitation.

Conclusions

MDRT appears to be a feasible and potentially beneficial adjunctive intervention for improving diaphragmatic excursion and selected sleep-related outcomes in pregnant women with OSA. However, given



the methodological limitations of the present study, these findings should be interpreted cautiously and confirmed in larger, rigorously designed trials before broad clinical implementation is recommended.

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Conflicts of interest

No competing interests were declared by the authors.

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