

INTRODUCTION

- Up to 80% of women suffer from sleep disruption due to hot flashes during menopause and perimenopause.
- This study evaluated the effectiveness of the BedJet System as a non-hormonal and easy-to-use treatment in a population of menopausal and perimenopausal women experiencing hot flashes and/or night sweats and sleep disturbances. Effectiveness was measured using a validated sleep, menopausal symptom, and quality of life questionnaire.
- The current solutions for relieving menopausal sleep disturbances and associated symptoms during sleep are limited. If available, they either have unpleasant and possibly detrimental side effects, are not conclusive in their effectiveness, or are difficult treatments to adopt and comply with.
- Considering the known impact of poor sleep on overall health and mood, and the prevalence of menopausal women, there is an urgent need for a treatment that can effectively address the problem. This is the first study evaluating the efficacy of the BedJet System for treatment of hot flashes and poor quality of sleep in menopausal women.

OBJECTIVES

- Evaluate the clinical efficacy of the BedJet Climate System in **relieving poor sleep quality** for menopausal and perimenopausal women.
- Determine the clinical efficacy of the BedJet Climate System in **reducing hot flashes and night sweats** for menopausal and perimenopausal women.
- Evaluate the clinical efficacy of the BedJet Climate System in **improving daytime functioning** for menopausal and perimenopausal women.
- Evaluate the clinical efficacy of the BedJet Climate System in **improving mood** for menopausal and perimenopausal women.
- Add to the current knowledge base of **non-pharmacological treatments for vasomotor symptoms and sleep disturbances**.
- Add to the current knowledge base of **technology based treatments for sleep disturbances** in menopausal and perimenopausal women.

STUDY POPULATION

- This prospective study consisted of 46 female patients with an average age of 50 who reported hot flashes, night sweats, and sleep disturbances.
- 38 women completed the protocol.
- The patients were recruited by South Shore Women's Health in Weymouth, MA and by the BlueSleep Sleep Apnea and Snoring Center in New York City, NY.
- IRB approval was obtained for the study.

MATERIALS & METHODS

- We evaluated the BedJet's (fig 1-4) efficacy using four validated pre- and post-treatment surveys: the Functional Outcome of Sleep Questionnaire (FOSQ) (table 1), the Pittsburgh Sleep Quality Index (PSQI) (table 2), the Insomnia Severity Index (ISI) (table 3), and the Greene Climate™ Scale.
- We examined the data collected from the FOSQ, PSQI, and ISI for 38 of the subjects who completed the study, and the Greene Climate™ Scale for 24 of the 38 subjects.
- The subjects used the BedJet System for a period of at least 3 weeks. Answers to the questionnaires were obtained before and after treatment using the BedJet system.

FIG 2: UNDER-BED PLACEMENT



FIG 4: BEDJET UNIT



FIG 1: COOLING & WARMING



FIG 3: BEDJET INFRARED

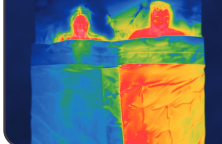


FIG 4: BEDJET UNIT

- Cooling, heating, and climate comfort system for beds.
- Silky quiet operation, low power consumption.
- Fits on any size bed with any type of mattress.
- Paired with special bed sheet accessory for improved air distribution.

TABLE 1: FOSQ QUESTIONNAIRE

Functional Outcome of Sleep (FOSQ)
(rating: 1 = yes, extremely; 2 = yes, moderate; 3 = yes, a little; 4 = no)
Perfect daytime score = 40 (no sleepiness)
Perfect daytime score = 20 (most sleep)

- Do you have difficulty concentrating on things you do because you are sleepy or tired?
- Do you generally have difficulty remembering things because you are sleepy or tired?
- Do you have difficulty operating a motor vehicle for short distances because you are sleepy?
- Do you have difficulty operating a motor vehicle for long distances because you are sleepy?
- Do you have difficulty visiting your family or friends in their home because you are sleepy?
- Has your relationship with family, friends or colleagues been affected because you are sleepy?
- Do you have difficulty watching a movie or video because you become sleepy or tired?
- Do you have difficulty being as active as you want in the evening because you are sleepy?
- Do you have difficulty being active in the morning because you are sleepy or tired?
- Has your mood been affected because you are sleepy or tired?

TABLE 2: PSQI QUESTIONNAIRE

Pittsburgh Sleep Quality Index (PSQI)
(complex scoring; score of 5 or greater indicates poor sleep quality)

In the past month:

- When have you usually gone to bed?
- How long has it taken you to fall asleep each night?
- What time have you usually gotten up in the morning?
- How many hours did you usually sleep at night? How many hours were you in bed?
- How often have you had trouble sleeping because you (a) cannot get to sleep within 30 minutes; (b) wake up in the middle of the night; (c) have to get up to use the bathroom; (d) cannot breathe comfortably (so short or so long bouts); (e) feel like you had too hot; (f) have had too many; (g) have pain; (h) other reason.
- How often have you taken medicine to help you sleep (except for OTC)?
- How often have you had trouble staying awake while driving, eating meals, or in social settings?
- How much of a problem has it been for you to keep up with your normal daytime activities?
- How would you rate your sleep quality overall?

TABLE 3: INSOMNIA SCALE (7Qs)

Insomnia Severity Index (ISI)
(rating: 0 = no insomnia; 8 = mild-to-moderate insomnia; 15-21 = moderate-to-severe insomnia)

Rate the questions/statements below using the following scale:
0 = never, 1 = rarely, 2 = moderately, 3 = somewhat, 4 = very often

- Difficulty falling asleep?
- Difficulty staying asleep?
- Problem waking up because?
- How satisfied or dissatisfied are you with your sleep?
- How noticeable is your sleep problem compared to others?
- How worried are you about your current sleep problem?
- How much does your current sleep problem interfere with your daily life (e.g., mood, work, concentration, memory)?

RESULTS

SLEEP QUALITY, DAYTIME FUNCTION, INSOMNIA, AND MENOPAUSAL SYMPTOMS ALL IMPROVED AFTER USE OF THE BEDJET CLIMATE SYSTEM.

All results were statistically significant (p < 0.001).

Percent of subjects reporting improvement:

- ISI: 94%
- Greene Scale: 85%
- FOSQ: 89%
- PSQI: 83%

Patient Overall Outcomes

Test	Initial Score (Pre)	Final Score (Post)	t	p	Notes
Greene	25.22	16.35	11.670	< .001	good menopausal symptoms
ISI	15.19	8.01	11.597	< .001	significant clinical insomnia
FOSQ	27.78	35.67	11.635	< .001	higher score = better function
PSQI	11.08	5.89	11.138	< .001	indicator of poor sleep

Details of signs and symptoms which improved significantly and those that did not change significantly during treatment:

Green Scale significantly improved symptoms:
Hot flashes, night sweats, anxiety/panic, lack of energy, irritability, muscle and joint pain

ISI significantly improved symptoms:
Falling asleep, staying asleep, waking up too early

FOSQ significantly improved symptoms:
Improved mood, effect of poor sleep on work/home relationships

Symptoms that did not change significantly:
Social interest, feelings of unhappiness or depression

DISCUSSION

- In our study, BedJet, a new non-invasive treatment for menopausal symptoms during sleep, has been shown to be effective for improving nocturnal hot flashes and night sweats, insomnia, quality of sleep, and daytime functioning, with reducing common daytime symptoms of menopause in 85% of subjects.
- The greatest impact of the BedJet use was on the Greene Climate™ score. Although 84% of subjects also had improvement in their insomnia.
- Hormone therapy has been found to modestly improve subjective sleep quality during menopause. Unfortunately, CBT for sleep, acupuncture, and yoga have also been shown to have modest effects on sleep during the climacteric.
- Overlapping sleep disturbances in women during middle include insomnia and sleep apnea. In our study, the insomnia index also significantly improved, suggesting that the poor sleep caused by hot flashes and night sweats may be a risk factor for middle depression.

CONCLUSIONS

- The BedJet System is a new, safe, and effective sleep technology which has been shown to be clinically effective for the treatment of nocturnal hot flashes and night sweats in a group of menopausal women.
- Over the past 30 years, consumer technology has been useful means to raise awareness about sleep disturbances. Most connected activity devices today collect sleep data to help users make informed changes in their sleep habits.
- Unfortunately, while activity trackers and connected devices can monitor activity and make inferential judgments regarding duration and quality of sleep, they cannot treat sleep disorders, and rarely influence the quality of sleep.
- There is an urgent need for better ways to diagnose and treat sleep disorders given the known impact of poor quality on health and the multi-billion dollar burden on the US economy related to poor sleep (\$400 billion/year according to the Rand Corporation).
- Each available sleep technology capable of identifying sleep problems is a first step in assessing diagnosis of sleep disorders on a global scale.

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