Investigational sleep pad device increases deep sleep of midlife adults with insomnia symptoms: A randomized clinical trial

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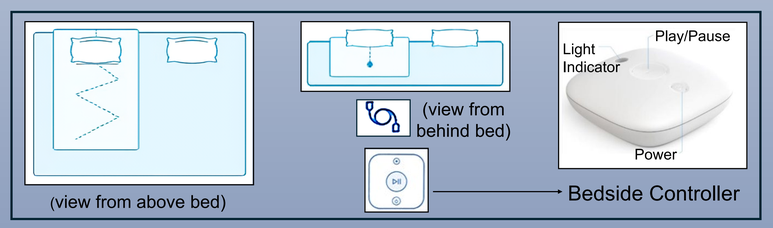
Background

- At least 34M adults in the US have insomnia.
- There is a need for nonpharmacologic, accessible insomnia treatments.
- This Proof-of-Concept pilot (NCT #05908344) evaluated a consumer-grade technology for effects on sleep and insomnia symptoms.

Sleep Pad System

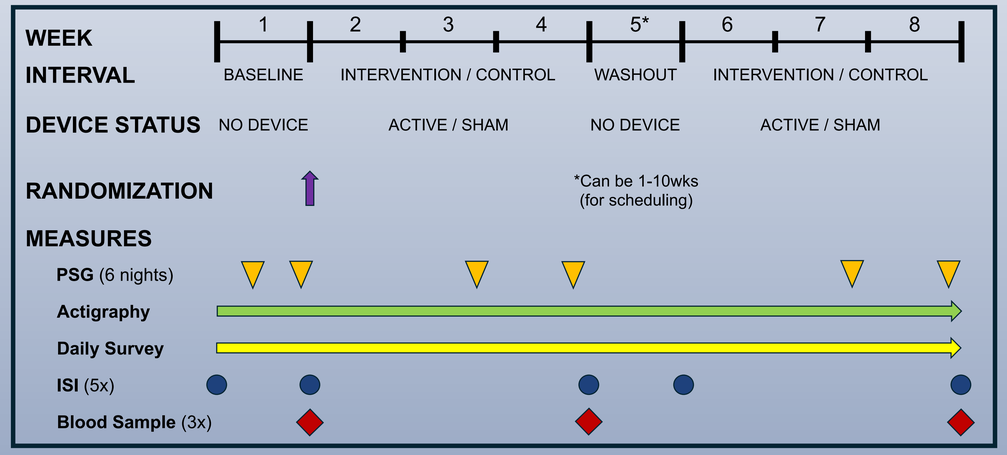


- US Patent #11147942 (Issued 10/19/2021)
- Fabric pad with embedded conductive wire that emits a radiofrequency gradient

Methods

- Ten participants (40-65 years) with an ISI ≥ 8 provided data Sept 2023 – March 2024.
- **Primary Outcomes:**
  - Insomnia Severity Index [ISI]
  - Subjective Sleep Onset Latency [OL]
  - Polysomnography [PSG]
    - Total Sleep Time [TST]
    - Sleep Quality [WASO]
    - Slow-Wave Sleep [NREM 3]
- Data collection for the primary outcomes occurred in participants' homes.
- Sham devices were identical to active devices except for emission of radiofrequency gradient.

Randomized Double-Blind Crossover Protocol



Results

Active sleep pad improved NREM3 sleep relative to Sham

LMEM Comparisons

Outcome	Effect	Est.~	SE	df	t	*p*
ISI^	Treatment	0.13	0.86	13	0.15	.887
	Order	0.50	0.86	13	0.58	.571
OL	Treatment	3.43	2.52	9	1.36	.207
	Order	-0.13	2.80	8	-0.04	.966
TST	Treatment	0.01	0.12	9	0.08	.941
	Order	-0.003	0.23	8	-0.01	.992
WASO#	Treatment	1.05	1.19	17	0.28	.781
	Order	2.34	1.19	17	-2.29	**.035**
NREM3						
Mins	Treatment	5.60	2.0	9	2.80	**.021**
	Order	-3.30	7.1	8	-0.46	.655
%	Treatment	0.01	0.005	9	2.78	**.021**
	Order	-0.01	0.02	8	-0.45	.660
Continuity	Treatment	-4.11	1.54	9	-2.67	**.026**
	Order	1.49	1.75	8	0.85	.420

Treatment: Active (vs. Sham) sleep pad use
Order: Randomized to Active first (vs. Sham first)

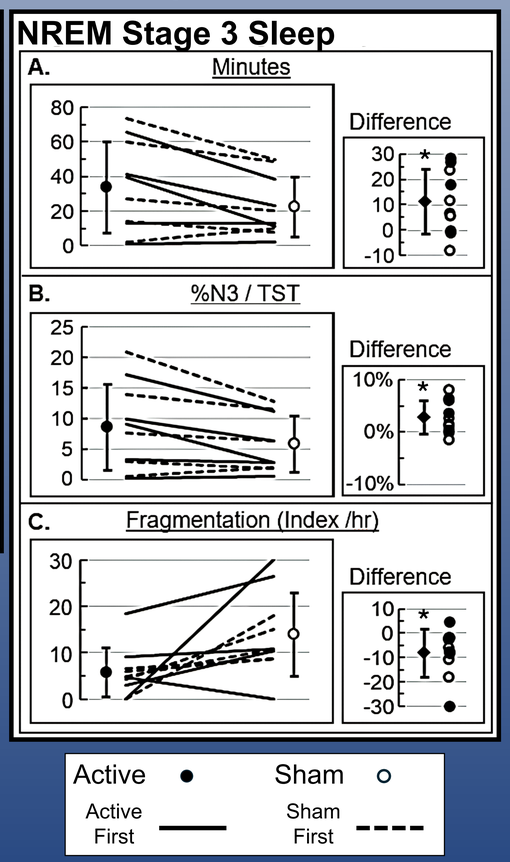
Bold *p*-values reflect significance (2-tailed; $p<.05$).

~Estimates account for random intercepts, except where the random effect could not be estimated.

^Two participants missing ISI data were excluded.

#WASO data transformed (ln) for heteroscedasticity; reported table estimates were back-transformed.

NREM Stage 3 Sleep



Sample Characteristics

Demographic, Screening, and Baseline Data

			All	Randomization Order	
			M(SD)	*Active - Sham*	*Sham - Active*
		n	or %	M(SD)	M(SD)
Socio-demographics	Age (yrs)	10	55.2 (6.0)	-	-
	Sex (%F)	10	80%	-	-
	Race (%White)	10	90%	-	-
	Ethnicity (%Non-Hispanic)	10	100%	-	-
Screening Data	Insomnia Symptoms	8	13.3 (6.4)	-	-
Baseline Data	Insomnia Symptoms	8	10.9 (4.9)	8.8 (5.6)	13.0 (3.5)
	Polysomnography				
	TST (hrs)	10	6.6 (0.8)	6.2 (0.9)	6.9 (0.7)
	WASO (mins)	10	44.2 (29.0)	48.8 (38.4)	39.6 (19.1)
	NREM3 (mins)	10	24.7 (25.8)	20.2 (22.2)	29.1 (30.9)
	NREM3 %	10	6.21 (6.26)	5.2 (5.4)	7.2 (7.5)
	Sleep Diary				
	OL (mins)	10	20.3 (14.9)	15.7 (12.6)	24.9 (17.0)

Baseline Randomization Order comparisons were *ns.* No participants withdrew.

Methods (cont'd.)

- ISI and OL were averaged within each segment and change from BL or WO was computed.
- PSG was scored by a blinded RPSGT, with Sleep Onset defined by Edinger et al. 2013[1]. One night from each segment was compared.
- Linear Mixed Effects Models (LMEM) with random intercepts estimated differences in outcomes between Active or Sham sleep pads.

Conclusions

- NREM3 sleep was improved with Active sleep pad use relative to Sham, across 3 metrics:
  - A 36% increase in total minutes
  - A 42% increase in proportion of total sleep
  - A 72% decrease in the disruptions per hour
- No significant difference in insomnia symptoms
- The sleep pad may have implications for health outcomes associated with slow-wave sleep.

References and Support

[1]Edinger J.D., Ulmer C.S., & Means M.K. (2013). *JCSM 9(5):481-91.*

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