

Anti Aging Bed Pilot Study Report



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Anti Aging Bed - Pilot Study Report

Version 1. November 2023

Disclaimer

This Pilot Study report presented here is intended for informational purposes only. The present report consists of statistical analysis performed on the data obtained by a pilot study. The data and any conclusions drawn from it are subject to limitations and assumptions that should be considered. Scientifica Consulting does not take any responsibility and accepts no liability for any loss or damage of any kind arising out of the use, misuse, or reliance upon, the material presented herein. Information contained in this document cannot be used for any purpose that is unlawful or prohibited. This document may contain material for the sole use of the intended recipient. Any review, copying, or distribution of this document without prior consent of Scientifica Consulting and Anti Aging Bed is strictly prohibited.

Institutional review board approval

The study protocol was approved by the QuietMind Foundation Institutional Review Board prior to execution (Annex I).

1. Proposed title

Effect of the Anti Aging Bed Cover on Quality of Sleep, Recovery, Stress and Mood.

2. Objective

Investigate the effect of the Anti Aging Bed Cover on Quality of Sleep, Recovery, Stress and Mood.

3. Outcomes

3.1. Primary Outcomes

- Quality of Sleep, assessed through the Fitbit Inspire 2 actigraphy band. Parameters collected were:
 - Recovery: Resting heart rate, Overall sleep score, revitalization score
 - Quality of sleep: Restlessness, minutes asleep, number of awakenings, minutes awake
 - Sleep stages: time in bed, minutes in REM sleep, minutes in light sleep, and in deep sleep
 - Quality of Sleep, assessed through the Pittsburgh Quality of Sleep Index, The Epworth Sleepiness Scale, and the Insomnia Severity Index

3.2. Secondary outcomes

- Self-assessed questions on quality of sleep, mood, energy level and stress (0-10 rating scale)
- Emotional states of depression, anxiety and stress (DASS21)
- Mood, though the Profile of Mood States (POMS)

4. Study Design

4.1. Study Type

Pre post interventional trial.

4.2. Study Outline

- Participants were screened and asked to sign an Informed Consent Form
- 30 participants were selected and underwent baseline evaluations: complete the evaluation questionnaires and provide sleep data for 2 weeks
- Participants received an Anti Aging Bed Cover and were asked to use it on their beds for 6 weeks
- After intervention period participants were asked to remove the cover from their beds for 2 weeks wash-off period
- Participants were re-evaluated at the end of the intervention period.
- Actigraphy data was collected as well during the 2-week wash-off period

5. Population

Adults with poor quality of sleep.

5.1. Inclusion Criteria

- Ages 18 and over,
- Willingness to participate in the study
- Poor Quality of Sleep (Indicated by the Pittsburgh Quality of Sleep Index over 5)

5.2. Exclusion Criteria

- Previous use of the Anti Aging Bed Cover,
- Constant use of sleep aids,
- Present injuries that may hinder the participation in the study.

6. Sample size

30 participants.

7. Statistical Analysis

Data analysis was conducted using Graph Pad Prism® (version 8.0). For the analysis of questionnaire responses, the Shapiro-Wilk test to assess data normality was applied. In cases of normal distribution, a paired T-test was utilized. Alternatively, for non-normal distributions, the Wilcoxon Test was employed.

Regarding the actigraphy data, the mean values were calculated over the 2-week baseline, six-week intervention period and wash-off period. Like the questionnaire analysis, the data was first subjected to the Shapiro-Wilk normality test. For data adhering to normal distribution, an Ordinary One-way ANOVA, complemented by Tukey's multiple comparison test, and an unpaired T-test were performed. In instances of non-normal distribution, the Kruskal-Wallis test followed by Dunn's multiple comparison test and a Mann-Whitney test were applied.

Results are presented as mean \pm standard error of the mean (SEM) for each group. A p-value of less than 0.05 was considered statistically significant by the researchers. Percentage differences were calculated using Microsoft Excel®.

8. Results

8.1. Self-assessed questions on quality of sleep, mood, energy level and stress

In the Self-assessed questions (as shown in Figure 1), statistically significant differences were found between the baseline and post intervention in the items "overall quality of sleep" ($p = 0.0001$) and an overall stress levels" ($p = 0.0071$). Results also indicate a positive effect on mood and energy levels, although data was not statistically significant.

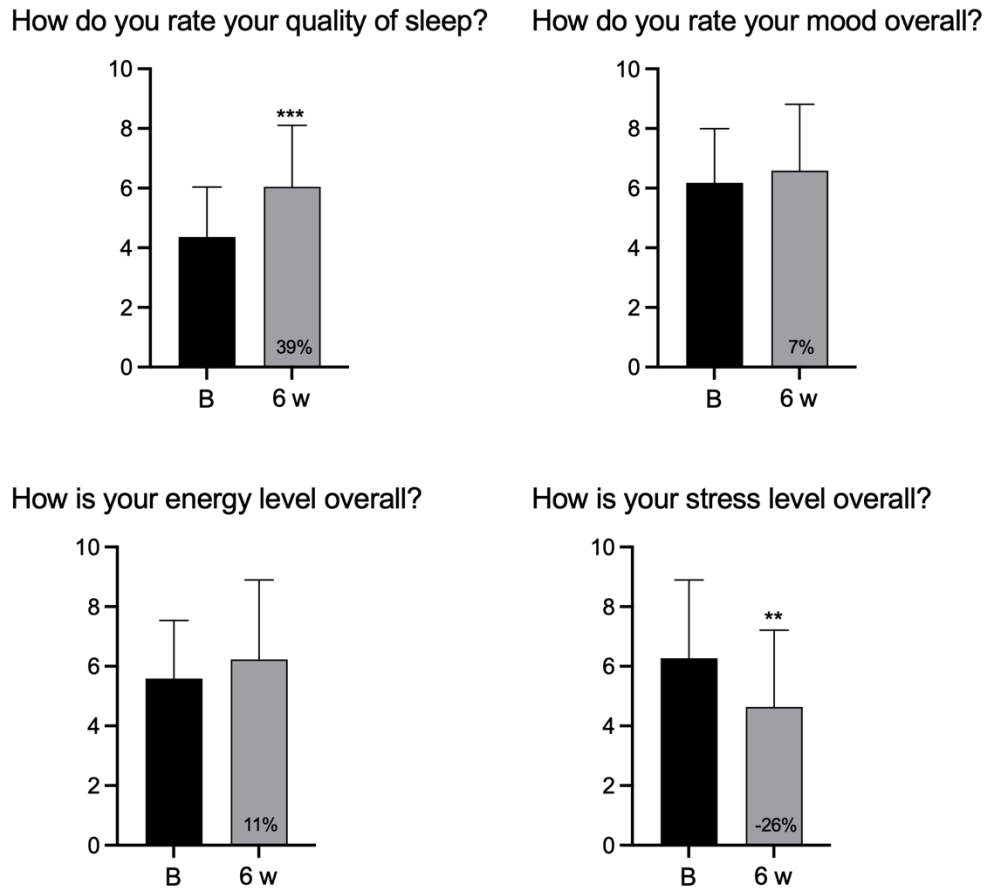


Figure 1. Self-assessed questions on quality of sleep, mood, energy level and stress. There was a statistically significant increase in quality of sleep and a reduction in stress level. Each point represents the mean of participants and vertical lines show the SEM. The Symbol * denotes a significant difference of $*P < 0.05$ when compared to Baseline. The % value is in relation to the Baseline questionnaire. Quality of sleep and stress data passed the Shapiro Wilk normality Test, and a paired T Test was performed. Mood and energy level data did not pass the Shapiro Wilk normality Test and a Wilcoxon Test was performed. B: baseline questionnaire; 6 w: 6 weeks questionnaire.

8.2. Emotional states of depression, anxiety and stress (DASS21)

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) is a set of three self-report scales designed to measure the emotional states of depression, anxiety, and stress. In Figure 2 it is possible to observe that there was a statistically significant reduction in the Depression ($p=0.0010$), Anxiety ($p=0.0002$) and Stress ($p<0.0001$) subscales.

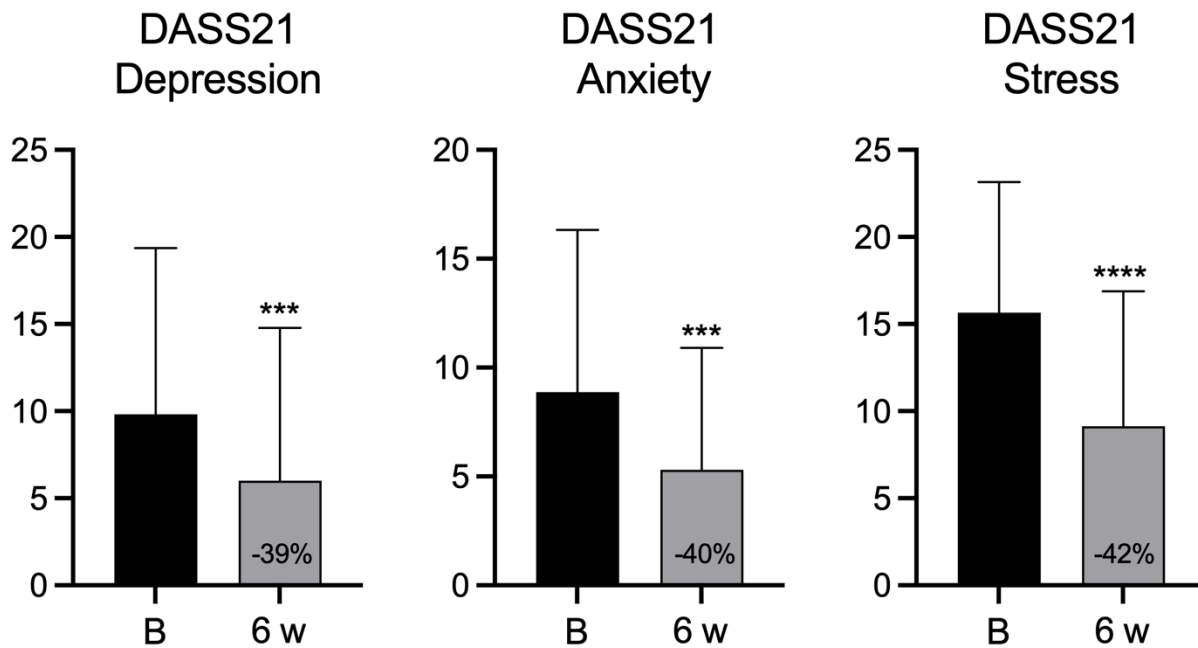


Figure 2. The DASS21 Questionnaire. There was a statistically significant reduction in Depression, Anxiety and Stress. Each point represents the mean of participants and vertical lines show the SEM. The Symbol * denotes a significant difference of $*P<0.05$ when compared to Baseline. The % value is in relation to the Baseline questionnaire. Data did not pass the Shapiro Wilk normality Test and a Wilcoxon Test was performed. B: baseline questionnaire; 6 w: 6 weeks questionnaire.

8.3. Mood, though the Profile of Mood States (POMS)

Lower scores indicate more stable mood profiles in The Profile of Mood States (POMS). It is Possible to observe in Figure 3 that there was a statistically significant reduction in Tension ($p= 0.0002$), Depression ($p=0.0010$), Anger ($p=0.0022$), Fatigue ($p=0.0007$), Confusion ($p<0.0001$), and Total Mood Disturbance ($p<0.0001$). There was also a significant increase in Vigor ($p=0.0259$).

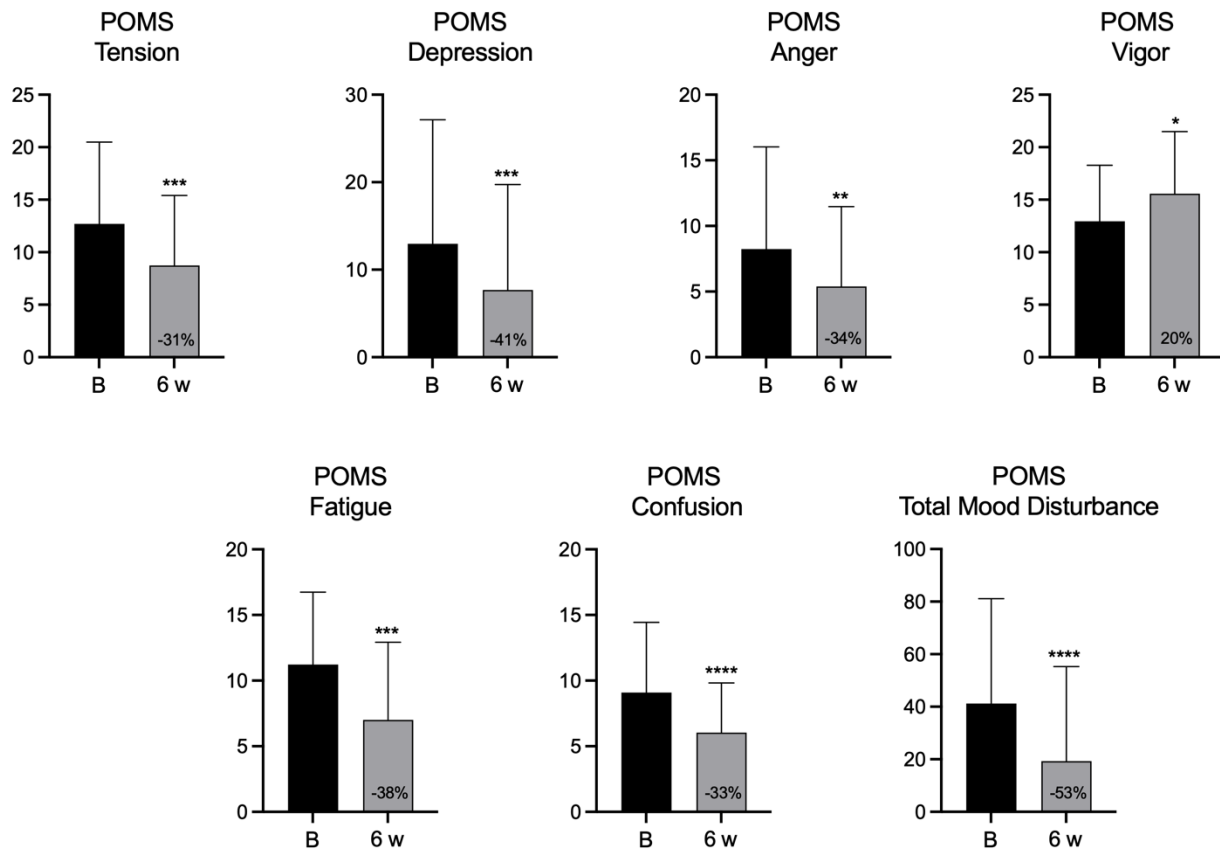


Figure 3. The POMS Questionnaire. There was statistically significant differences. Each point represents the mean of participants and vertical lines show the SEM. The Symbol * denotes a significant difference of $*P<0.05$ when compared to Baseline. The % value is in relation to the Baseline questionnaire. Data did not pass the Shapiro Wilk normality Test and a Wilcoxon Test was performed. The Vigor data passed the Shapiro Wilk normality Test, and a paired T Test was performed. B: baseline questionnaire; 6 w: 6 weeks questionnaire.

8.4. Quality of Sleep - Questionnaire-based

Three different quality of sleep questionnaires were utilized. Analysis of the Epworth Sleepiness Scale (Figure 4) revealed no statistically significant changes between the pre and post intervention. It is important to note that higher scores on this scale indicate greater levels of excessive sleepiness.

In contrast, the Insomnia Severity Index (ISI - Figure 4) demonstrated a statistically significant reduction in scores at the 6-week mark ($p = 0.0020$), indicating an improvement in insomnia symptoms.

Furthermore, the Pittsburgh Sleep Quality Index (PSQI) was employed, where higher scores signify poorer sleep quality. Figure 5 depicts statistically significant reductions in several PSQI components: Subjective Sleep Quality ($p = 0.0137$), Sleep Latency ($p = 0.0002$), Sleep Efficiency ($p = 0.0103$), Sleep Disturbance ($p = 0.0039$), as well as in the Global Score ($p = 0.0003$). These results indicate overall improvements in various aspects of sleep quality.

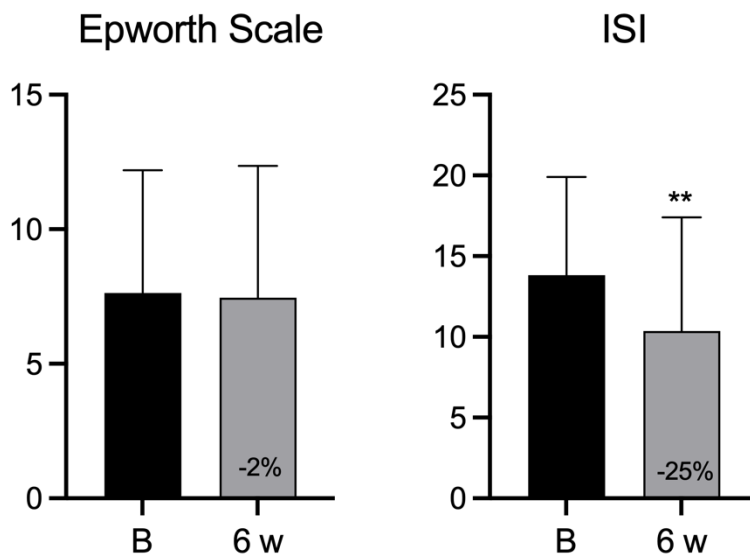


Figure 4. The Epworth Sleepiness Scale and the Insomnia Severity Index (ISI). The Symbol * denotes a significant difference of $*P < 0.05$ when compared to Pre evaluation. Each point represents the mean of participants and vertical lines show the SEM. The % value is in relation to the Baseline questionnaire. The data passed the Shapiro Wilk normality Test, and a paired T Test was performed. B: baseline questionnaire; 6 w: 6 weeks questionnaire.

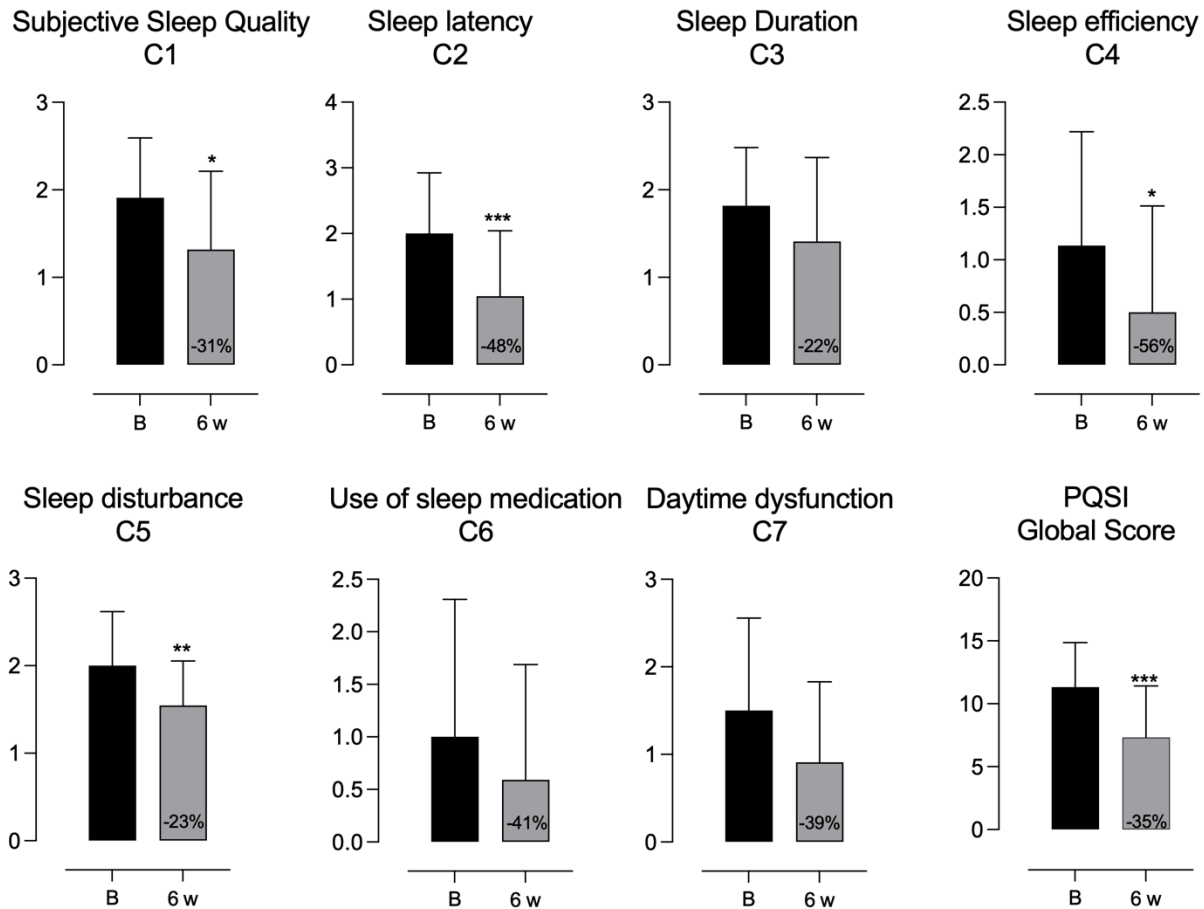


Figure 5. The PQSI. There was a statistically significant reduction in the 6 weeks questionnaire. Each point represents the mean of participants and vertical lines show the SEM. The Symbol * denotes a significant difference of $*P < 0.05$ when compared to Baseline. The % value is in relation to the Baseline questionnaire. Data did not pass the Shapiro Wilk normality Test and a Wilcoxon Test was performed. The Global score data passed the Shapiro Wilk normality Test, and a paired T Test was performed. B: baseline questionnaire; 6 w-6 weeks questionnaire.

8.5. Quality of Sleep - Actigraphy data

Data registered on the participants' Fitbit device was extracted. Comparisons between baseline, intervention period, and two weeks post intervention were made. There weren't any statistically significant differences, as it can be observed in Figures 6, 7 and 8.

It is noteworthy that during the intervention and wash-off phases, overall time in bed, minutes asleep, minutes in REM and Light sleep decreased in comparison to baseline, and minutes in deep sleep increased, particularly during the intervention phase (9%), although the differences were not statistically significant (Figure 8).

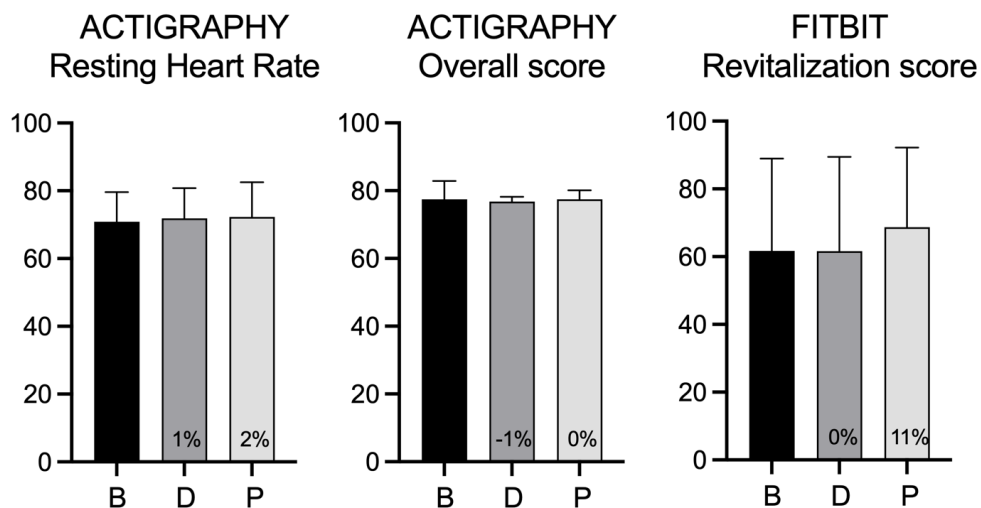


Figure 6. Actigraphy sleep data. No statistically significant differences were found. Each point represents the mean of participants and vertical lines show the SEM. The % value is in relation to the Baseline questionnaire. Data did not pass the Shapiro Wilk normality Test and a Mann-Whitney test was performed, except for the Overall Score data. B: Baseline; D: during intervention; Post: 2 weeks post.

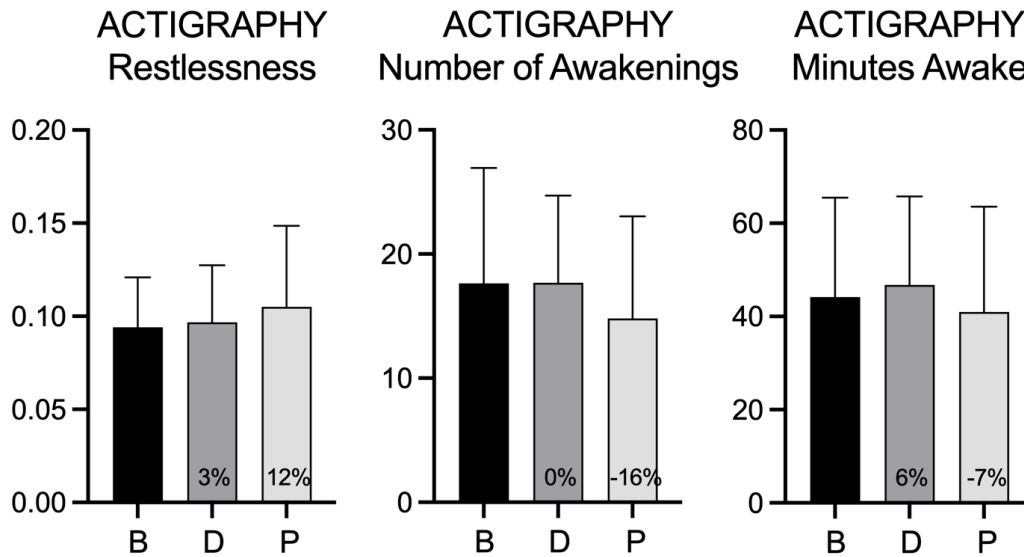


Figure 7. Actigraphy sleep data. No statistically significant differences were found. Each point represents the mean of participants and vertical lines show the SEM. The % value is in relation to the Baseline questionnaire. Data passed the Shapiro Wilk normality Test and an Unpaired T Test was performed, except for the Number of Awakenings data. B: Baseline; D: during intervention; Post: 2 weeks post.

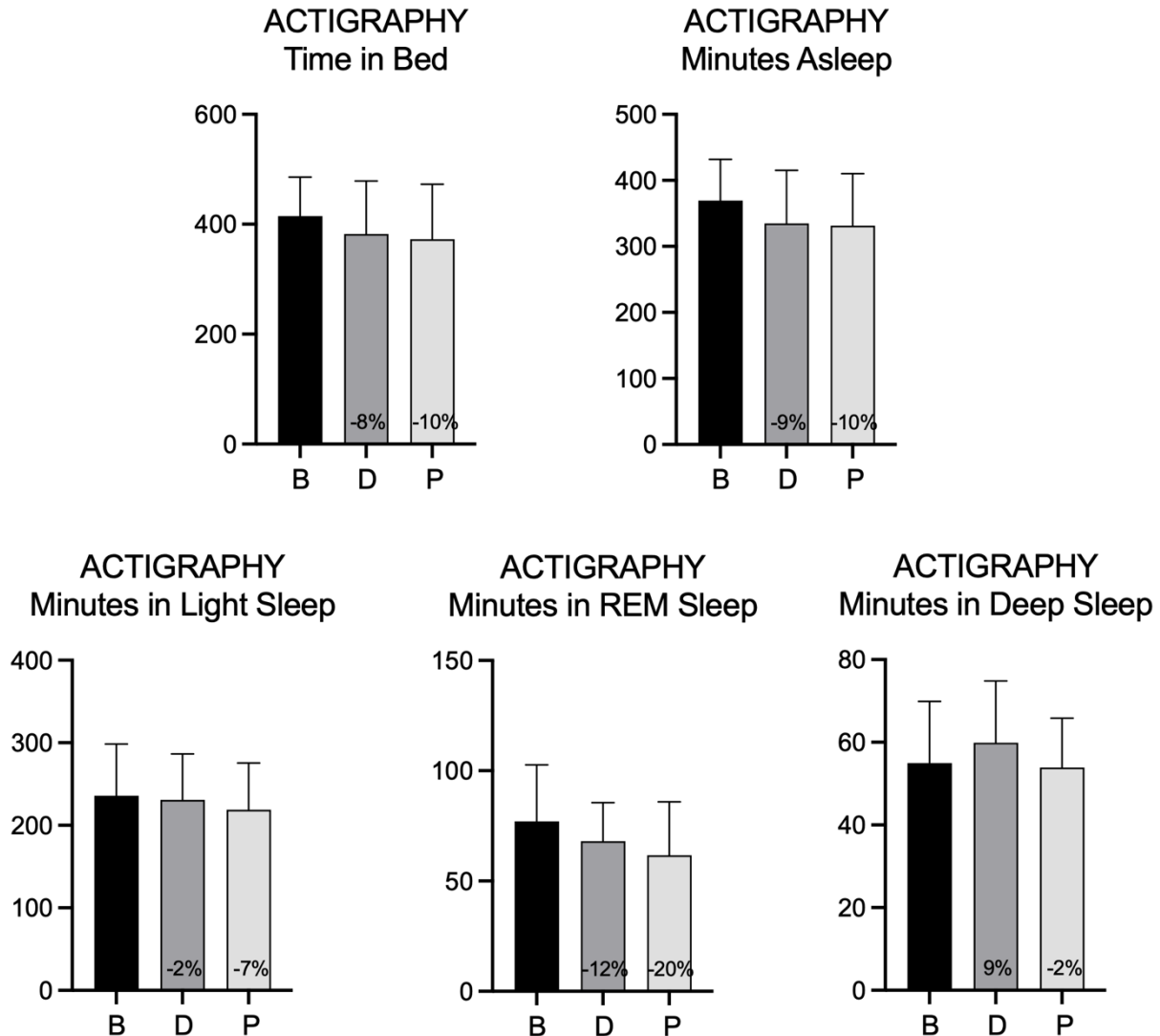


Figure 8. Actigraphy sleep data. No statistically significant differences were found. Each point represents the mean of participants and vertical lines show the SEM. The % value is in relation to the Baseline questionnaire. Data passed the Shapiro Wilk normality Test and an Unpaired T Test was performed. B: Baseline; D: during intervention; Post: 2 weeks post.

9. Conclusions

This study aimed to investigate the impact of the Anti Aging Bed Cover on sleep quality, recovery, stress, and mood in adults with poor sleep quality. The primary outcomes included various parameters of sleep quality measured through actigraphy data (Fitbit Inspire 2) and validated sleep questionnaires. Secondary outcomes focused on self-assessed sleep quality, mood, energy level, stress, and emotional states.

The key findings from the study are as follows:

A. Self-Assessed Outcomes:

- Participants reported improvements in overall sleep quality and a reduction in stress levels. However, changes in mood and energy levels, while positive, did not reach statistical significance.

B. Mood and Emotional States:

- The results from the Profile of Mood States (POMS) and the Depression, Anxiety, and Stress Scale (DASS-21) showed statistically significant improvements in emotional states. Participants reported reductions in tension, depression, anger, fatigue, and confusion, alongside an increase in vigor. These findings suggest an overall positive effect on mood and emotional well-being.

C. Sleep Quality - Questionnaire-based:

- The analysis of the Pittsburgh Sleep Quality Index (PSQI) and the Insomnia Severity Index (ISI) showed statistically significant improvements in subjective sleep quality, sleep latency, sleep efficiency, and overall sleep disturbance. These improvements suggest that the Anti Aging Bed Cover positively affects various aspects of sleep quality.
- However, the Epworth Sleepiness Scale did not show significant changes, indicating that the intervention may not influence daytime sleepiness levels.

Sleep Quality - Actigraphy Data:

- The actigraphy data did not show statistically significant changes across the intervention and post-intervention phases. This finding suggests that the subjective improvements in sleep quality and emotional states were not fully captured by actigraphy measures.
- An interesting observation from the study was the change in sleep patterns during the intervention and wash-off phases. Specifically, there was a decrease in the overall time spent in bed and minutes asleep, and a reduction in the duration of REM and Light sleep stages when compared to the baseline. Conversely, the time spent in deep sleep showed an increase, notably during the intervention phase with a rise of 9%. However, it's important to note that these differences did not reach statistical significance, as detailed in Figure 8.

In conclusion, the use of the Anti Aging Bed Cover appears to have a beneficial effect on sleep quality and emotional well-being in adults with poor sleep quality. These improvements were particularly evident in subjective measures of sleep quality and stress levels. While the actigraphy data did not show significant changes, this might be due to the limitations of the measurement tool or the complexity of sleep as a multifaceted phenomenon. Future research could focus on exploring the mechanisms behind these improvements and assessing the long-term effects of using the Anti Aging Bed Cover.

10. Limitations

A. Sample Size and Diversity:

- The study involved 30 participants, which is a relatively small sample size. This limitation may affect the generalizability of the findings. Additionally, the study did not specify the demographic diversity of the participants, which could influence the outcomes, particularly in terms of different sleep patterns and responses to the intervention.

B. Subjective vs. Objective Measures:

- While subjective sleep quality and emotional well-being improved, these findings were not fully corroborated by the objective actigraphy data from the Fitbit device. This discrepancy raises questions about the sensitivity and specificity of wearable technology in capturing subtle changes in sleep quality.

C. Short-Term Study Duration:

- The six-week intervention period, followed by a two-week wash-off period, provides only a short-term view. Longer-term effects and sustainability of the benefits are not addressed in this study.

D. Lack of Control Group:

- The study design did not include a control group. The absence of a comparison group using a standard bed cover limits the ability to attribute observed improvements solely to the Anti Aging Bed Cover.

E. Self-Reported Measures:

- The reliance on self-reported questionnaires can introduce bias, as participants' responses may be influenced by their expectations or perceptions of the intervention.

11. Future Research Suggestions

A. Longer-Term Studies with Larger and More Diverse Samples:

- Future studies should consider a larger and more diverse participant pool over a longer duration to validate and expand upon these findings.

B. Incorporation of a Control Group:

- Including a control group using standard bedding would provide a stronger basis for comparison and help isolate the effects of the Anti Aging Bed Cover.

C. Exploration of Mechanisms:

- Investigating the physiological or psychological mechanisms behind the observed improvements would offer deeper insights into how the Anti Aging Bed Cover impacts sleep and emotional well-being.

D. Integration of Additional Objective Measures:

- Utilizing more comprehensive objective measures, such as polysomnography, could provide a more detailed understanding of sleep architecture and quality.

E. Long-term Follow-up:

- Conducting follow-up assessments months or even years after the intervention would help determine the long-term sustainability of the benefits observed.

F. Expanded Focus:

- Research could also explore the impact of the Anti Aging Bed Cover on other related aspects such as daytime functioning, cognitive performance, and overall quality of life.

By addressing these limitations and suggestions, future research can provide a more robust understanding of the benefits and mechanisms of the Anti Aging Bed Cover, thereby contributing to the broader field of sleep quality improvement strategies.



Institutional Review Board

Allan Lundy, PhD, Chairperson

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Francisco Cidral, PhD
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May 12, 2023

Dear Dr. Cidral,

I am pleased to inform you that your application titled “Effect of the Anti-Aging Bed Cover on Quality of Sleep, Recovery, Stress and Mood” has been approved as an expedited review by the Quietmind Foundation Institutional Review Board. This approval is valid for one year, through May 11, 2024. If there is to be any contact with participants after that date (for follow-up, for example), you must ask for an extension (which is normally a very quick process). If there are to be any significant changes to the protocol or informed consent, you must request an amended approval, which is also usually very quick.

While not required, we would be interested in receiving a report of the study’s results (e.g., a paper presentation delivered at a conference). We wish you the very best with your research and your practice!

Sincerely,

Allan Lundy, PhD

Allan Lundy, PhD
QMF IRB Chairperson
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ANNEX II: ABSTRACT FOR CONGRESS SUBMISSION

Background: Sleep quality is a crucial aspect of overall health and well-being. Innovations in bedding, such as the Anti Aging Bed Cover, promise to enhance sleep quality, but empirical evidence is needed to support these claims.

Objective: This study aimed to investigate the effects of the Anti Aging Bed Cover on sleep quality, recovery, stress, and mood in adults with poor sleep quality.

Methods: Thirty participants were enrolled in a pre-post interventional trial. Participants utilized the Anti Aging Bed Cover for six weeks and were evaluated using various measures, including the Pittsburgh Sleep Quality Index, the Epworth Sleepiness Scale, the Insomnia Severity Index, and the Depression, Anxiety, and Stress Scale (DASS-21). Fitbit Inspire 2 actigraphy bands were used to collect objective sleep data. Statistical analyses were performed using Graph Pad Prism® (version 8.0).

Results: The study found significant improvements in the Insomnia Severity Index and various components of the Pittsburgh Sleep Quality Index, indicating enhanced sleep quality. Participants also reported reductions in stress and improvements in mood. However, the Epworth Sleepiness Scale did not show significant changes. Objective sleep data from the actigraphy device did not demonstrate statistically significant differences. During the intervention and wash-off phases of the study, notable changes in sleep patterns were observed. The overall time in bed and minutes asleep, and the duration of REM and Light sleep decreased, while deep sleep increased, especially during the intervention phase with a 9% rise. However, these changes were not statistically significant.

Conclusion: The Anti Aging Bed Cover may positively influence sleep quality and emotional well-being in adults with poor sleep quality. While subjective measures indicated improvements, these were not fully captured by objective actigraphy data, highlighting the need for further research with more comprehensive methodologies. Notably, the study lacked a control group and had a relatively small sample size.

Keywords: Sleep quality, bedding, actigraphy, mood, stress, interventional study.