Whittom & Boucher
Promotion de la Santé inc.

PILOT STUDY REPORT
ON
BRIGHTWAVES

Denis Boucher, Ph.D.

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1100, boul. de la Rive-Sud, suite 120
St-Romuald (Quebec) G6W 5M6
Tel.: 418-834-1177 Fax : 418-834-5596

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1. Introduction

Midi-Plus Consultants Inc. gave our company, Whittom & Boucher Promotion de la Santé inc., the mandate to develop a research protocol with the objective of evaluating the influence of BrightWaves - a process generating infra sounds that correspond to brain waves - on the sleep quality of people with sleep disorders.

Midi-Plus Consultants Inc. first used the protocol in the framework of a pilot study. The personnel of Midi-Plus Consultants directed the collection of data for this pilot study and our company acted as advisors throughout the study. Whittom & Boucher Promotion de la Santé Inc. also carried out a statistical analysis of the collected data and wrote the present report.

It is also important to emphasize that in order to respect the intellectual property of our client, we cannot divulge the nature of the product, BrightWaves, in detail in this report.

1.1 Objectives of the pilot study

This pilot study consisted of two objectives:

1) To evaluate the influence of BrightWaves on the sleep quality of people with sleep disorders.
2) To determine if it would be useful to proceed with an experimental study of this product.

2. Methodology

2.1 The subjects

The subjects were recruited through an advertisement, which appeared in the Journal de Quebec on May 22, 2000, and a through a television report on the program «Vision Québec» on TQS.

Thirty-four people in all (16 men and 18 women) showed an interest in participating in the study by contacting the Midi-Plus Consultants inc. team. All of these people were accepted and became part of the study. Three people (three women) dropped out of the study before the experimental phase began. One of them had not been able to obtain a CD player, another moved without informing the Midi-Plus Consultants team, and one person found the procedure too complex.

Therefore, thirty people began the study; however, five people (four men and one woman) abandoned the study during the pretest phase. Three of them did not return any of the documents and two people had variable schedules (day, evening and night), making it impossible for them to follow the required procedure. Also, six people (four men and two women) withdrew as soon as the treatment phase began. Two of these people mentioned that they were too busy to complete the study, one person stated problems with his sound system, one person had an accident, one person withdrew because of illness and one person withdrew

following the death of a loved one. Finally, one person's (a woman's) data was sent by mail as requested, but did not reach the Midi-Plus Consultants team.

Thus, the analysis of the data was based on 19 subjects (8 men and 11 women). The subjects were not remunerated for participating in this study.

2.2 Progress of the Pilot Study

The study took place from May 25 to mid-July of the year 2000. Following the advertisement for the study, the people who called the Midi-Plus Consultants team were given information on the study at the time of this first contact by telephone.

Subsequently, a package was sent to each subject, containing information and documents related to the pre-test phase such as: a letter explaining the procedure to follow, an agreement of non-disclosure, a consent form, a general information form, a pre-stamped envelope, questionnaires related to the evaluation of sleep quality and sleep problems, and the sleep diary. The sleep diary covered a two-week period. The subjects were asked to fill out and return the group of documents as soon as possible, with the exception of the sleep diary, using the pre-stamped envelope provided in the package. In the days preceding the end of the two-week pre-test period corresponding to the sleep diary, the subjects received a new package containing: a new sleep diary, the CD BrightWaves, a letter explaining the procedure to follow (in which the subjects were invited to return their first sleep diary as soon as possible), as well as a pre-stamped envelope. The subjects were asked to use the compact disc for a period of one month, following the instructions provided with the CD. A few days before the end of the treatment phase, the subjects received a final package, which included the questionnaires to fill out, a letter explaining the procedure to follow and a pre-stamped envelope in which to return the documents.

The pre-test period lasted for two weeks. From the beginning, the subjects were asked to fill out the following questionnaires: Index of Sleep Quality, Beliefs and Attitudes about Sleep, and the Sleep Impairment Index. As well, for a period of two full weeks, the subjects were asked to fill out their sleep diaries.

Once the pre-test period was completed, the experimental treatment phase began. Subjects were to listen to the laser disc BrightWaves each night for the whole night for a period of one month. During this period, the subjects were to fill out their sleep diaries. At the end of the experimental period, the subjects were asked to fill out the questionnaires again: Sleep Quality Index, Beliefs and Attitudes about Sleep, and the Sleep Impairment Index.

For the duration of the pilot study, the experimenters had no voluntary contact with the subjects, so as not to influence the results of the study. However, they had to remain available to the subjects in order to answer their questions if necessary.

2.3 Selection Criteria

No selection criteria were used for the purposes of this pilot study. Thus, the subjects were accepted independently of age, medical status, medications consumed and the perception of the product.

2.4 Measurements

With regard to this pilot study, the measurement instruments used were those most currently employed in the study of sleep disorders. However, it must be noted that no physiological measurements were taken, nor were any diagnoses made regarding the nature of any sleep disorders.

A) The Sleep Diary

Given the subjective nature of the experience of insomnia, the representation and the description of it by the person who lives through the experience are considered to be very important measurements for evaluating the changes in sleep that occur over a specific period of time. This instrument is presented in the form of a grid to fill out daily upon waking, and it provides a subjective estimation of sleep parameters. A two-week basic data recording period is suggested in order to obtain a valid and reliable profile of sleep problems and to minimize reactivity effects related to the self-evaluation method (Lacks & Morin, 1992). The grid allows the collection of the following information:

1) Nap,
2) Medication,
3) Bed time,
4) Sleep onset time,
5) Number of night awakenings,
6) Duration of night awakenings,
7) Wake time,
8) Rise time,
9) Physical state upon rising
10) Sleep quality

The form used was that of Morin (1997).

B) Sleep Impairment Index (SII)

This questionnaire is composed of 7 items which are used to evaluate quantitatively how much the person is affected by insomnia and to judge the results of a treatment (Morin & Azrin, 1985, cited in Mimeault, 1997). The subject responds to the questionnaire with the help of a Likert-type scale (0=None to 4=Extreme) for the following components:

1) Severity of delayed sleep onset,
2) Satisfaction with actual sleep,
3) Interference of insomnia with daytime functioning ,
4) Perception of the consequences of insomnia
5) Level of distress caused by insomnia.

This information is significant in terms of the person's perception of his sleep difficulties. The total score falls between 0 and 28, for which a high score indicates an elevated perception of the sleep impairment. The French version of the Sleep Impairment Index (Blais, Gendron, Mimeault & Morin, 1996, cited in Mimeault, 1997) offers good internal consistence with a Cronbach alpha coefficient of 0.88 and a test-retest fidelity coefficient of 0.65 for a two-week interval.

C) Beliefs and Attitudes About Sleep (BAS)

This 30 statement questionnaire evaluates perceptions about sleep (Morin, 1993). Five theoretic constructions concerning strategies favoring sleep are studied:

1) Attribution error and amplification of the consequences of insomnia,
2) Control and predictability of sleep,
3) Unrealistic expectations about sleep requirements,
4) Preconceived ideas about the causes of sleep and
5) Mistaken concepts on ways of promoting sleep.

For each statement, the person evaluates how much he agrees or disagrees with the help of an analogic scale (0=stongly disagree to 10= strongly agree). A high score on this questionnaire is associated with a high level of dysfunctional beliefs. The French version of the instrument offers very good internal consistence (0.90 alpha) and test-retest reliability of 0.72 for a two-week period.

D) Pittsburgh Sleep Quality Index (PSQI)

This index (Buysse, Reynolds, Monk, Berman & Kupfer, 1989, cited in Mimeault, 1997) evaluates the quality of sleep and its disturbances in the course of the past month. It consists of 19 self-evaluation questions, measuring seven components:

1) Subjective sleep quality,
2) Sleep latency,
3) Sleep duration,
4) Habitual sleep efficiency,
5) Sleep disturbances,
6) Use of sleeping medications,
7) Daytime dysfunction.

The quotation takes place on a scale of 4 points (0 = no difficulty to 3 = severe difficulties). The seven components of the score add up to give a score varying between 0 and 21 points. A result of more than 5 indicates that the subject suffers from severe sleep difficulties for at least two of the seven components or that he experiences moderate difficulties in more than three. The psychometric data of the French version demonstrates an acceptable internal homogeneity (alpha = 0.88) and a test-retest reliability of 0.62 (Blais et al., 1996).

3. Description of the Results

The objectives of this pilot study were:

1) To evaluate the influence of BrightWaves on the sleep quality of people with sleep disorders.
2) To determine if it would be useful to proceed with an experimental study of this product.

3.1 The subjects

The analysis of the results was based on 19 subjects (8 men and 11 women) aged between 24 and 74 years old, the average age being 45.1 years old (± 11.2).

3.2 Medication taken

Eight people took medication during the progress of this study. Table 1 shows the number of people using a particular medication during the pre-test period and during the period using BrightWaves.

Table 1 Medication taken

Medication taken	Number of people taking medication during the pre-test phase	Number of people taking medication during the treatment phase
Empracet	1	0
Duricef	1	1
Antibiotic (name of the medication unknown)	0	1
Provera	1	1
Premarin	2	2
Zithromax	0	1
Serax	1	1
Gen-Temazepam	1	1
Syntroid	1	1
Percocet	1	0
Tegretol	1	1
Zocor	1	1
Lectopam	1	1
Wellbutrin	1	1
Actifed	0	1

3.3 Sleep diary

The different variables of the sleep diary were analyzed through a Student t-test or sign test, according to the norms of the test, thus comparing the results obtained in the pre-test phase to those obtained after the last two weeks of the post-test phase (use of BrightWaves).

3.3.1 Total nap time

The results of the analyses demonstrated that the use of BrightWaves did not influence total naptime in a significant way ($p > 0.05$). Thus, naptime remained similar for all of the subjects throughout the experiment. Table 2 presents the means and standard deviations of total naptime.

Table 2 Means and standard deviations of total naptime

Variable	Pre-test (minutes per day)	Post-test (minutes per day)
Total nap time	8.20±12.90	10.24±23.73

3.3.2 Time period between going to bed and turning out the lights

The analysis of the results based on the period of time between going to bed and turning out the lights revealed the use of BrightWaves brought about no significant change ($p > 0.05$) in this respect. Table 3 presents the means and standard deviations of the time periods before turning out the lights in the pre-test and post-test phases.

Table 3 Means and standard deviations of the time period before turning out the lights

Variable	Pre-test (minutes)	Post-test (minutes)
Time period between going to bed and turning out the lights	20.29±34.47	7.30±10.72

3.3.3 Time period between the last awakening and rising

The results of the analyses on the time period between the last awakening and rising did not allow the demonstration of a significant influence ($p > 0.05$) after the use of BrightWaves. So, the time period between the last awakening and rising remained unchanged. To this effect, Table 4 presents the means and standard deviations of the pre-test and post-test results for this variable.

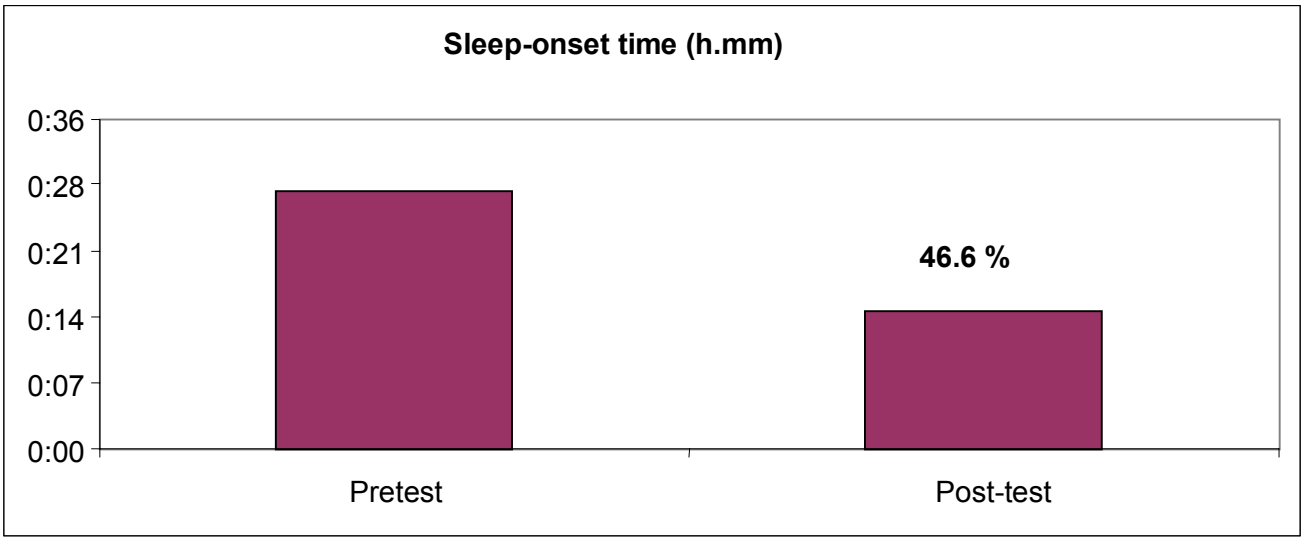
Table 4 Means and standard deviations of the time period between the last awakening and rising

Variable	Pre-test (minutes)	Post-test (minutes)
Time between the last awakening and rising	32.37±39	33.37±37

3.3.4 Sleep- onset time

The results of the analysis based on sleep-onset time demonstrated that after using BrightWaves, the subjects reported taking less time to fall asleep, thus going from an average falling asleep period of 27.95 (±21.80) minutes in the pre-test phase to 14.93 (±9.02) minutes in the post-test phase ($p < 0.002$). This represents a significant decrease of 46.6% in sleep-onset time. Figure 1 presents the evolution of sleep onset time in the pretest and post-test phases.

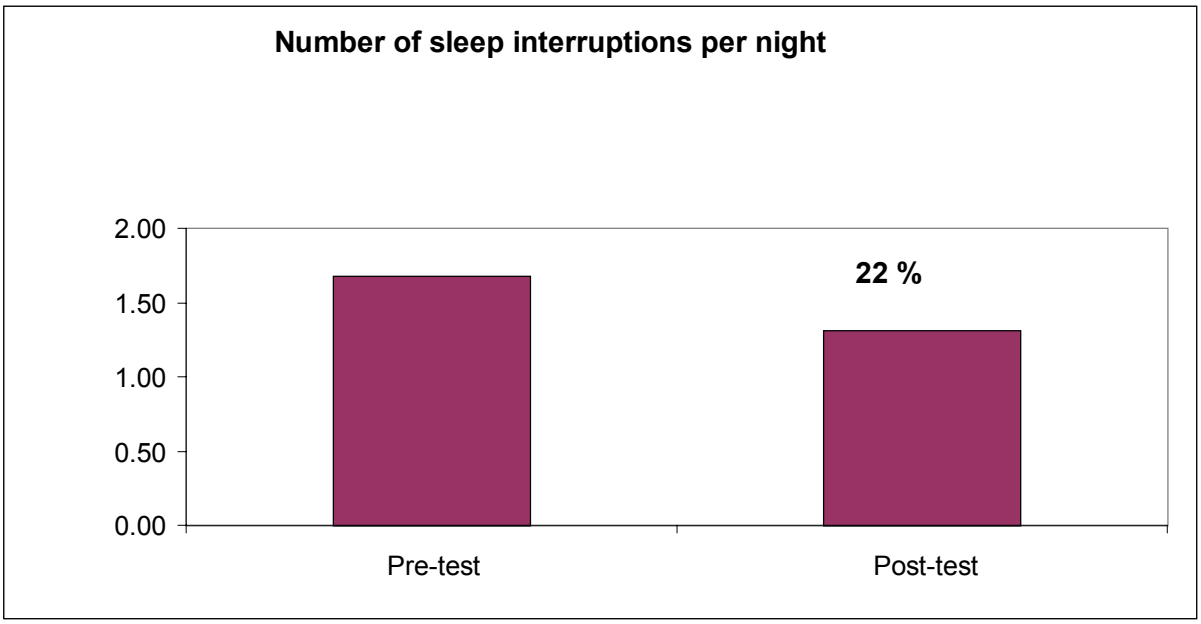
Figure 1 Evolution of sleep-onset time



3.3.5 Number of sleep interruptions

The analysis of the results related to the number of sleep interruptions revealed that the use of BrightWaves produced a significant decrease ($p < 0.03$) of the number of sleep interruptions per night, thus going from 1.68 (±0.89) interruption before using BrightWaves to 1.31 (±0.91) interruption after using it. This corresponds to a reduction in sleep interruptions in the order of 22%. Figure 2 presents the evolution of this variable over time.

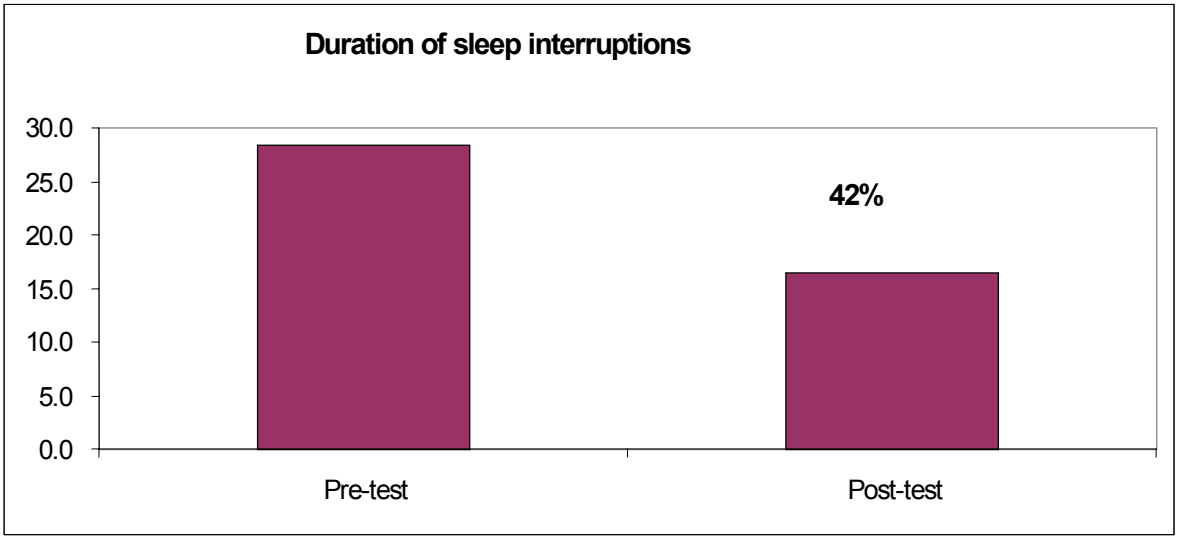
Figure 2 Number of sleep interruptions per night



3.3.6 Duration of sleep interruptions

The analysis of the results also showed a significant decrease ($p < 0.002$) in the duration of sleep interruptions per night after using BrightWaves. The duration of the interruptions went from an average of 28.32 (±21.69) minutes before the use of BrightWaves (pre-test phase) to an average of 16.46 (±13.36) minutes following its use, corresponding to a decrease of close to 42%. Figure 3 shows the evolution of the duration of sleep interruptions over time.

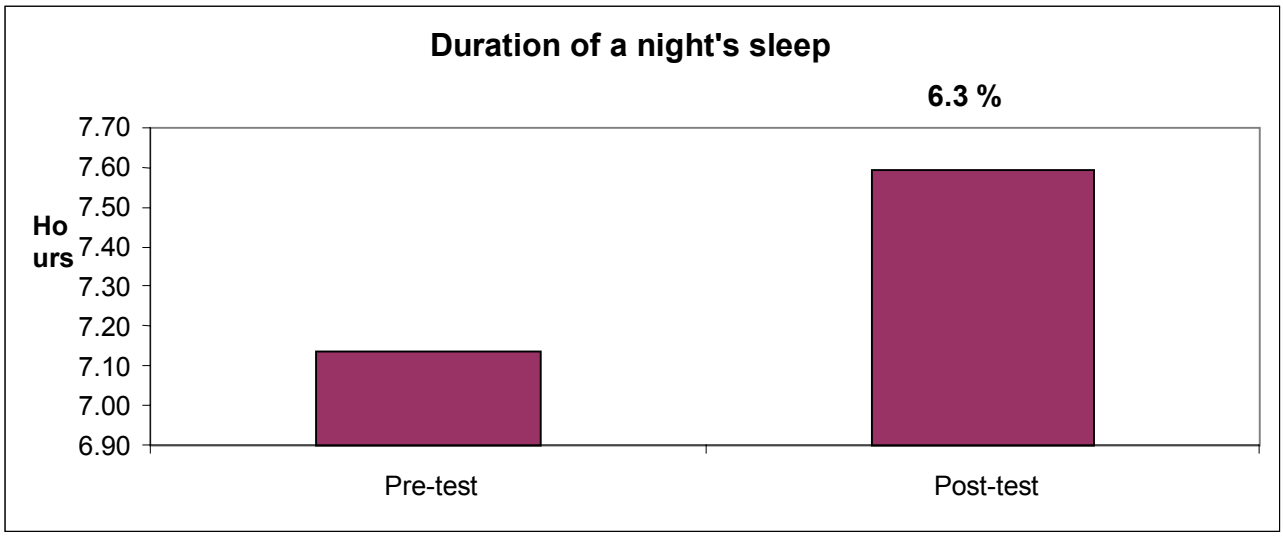
Figure 3 Duration of sleep interruptions per night



3.3.7 Sleep duration

The analysis of the results based on the duration of a night's sleep revealed a significant improvement ($p < 0.03$) in the amount of sleep per night following the use of BrightWaves, going from 7.14 (± 1.09) hours per night in the pre-test phase to 7.59 (±1.16) hours per night. This represents and improvement of 6.3% for sleep duration. Figure 4 shows the change observed in the duration of a night's sleep.

Figure 4 Duration of a night's sleep



3.3.8 Feeling rested upon rising

According to a Likert-type scale ranging from 1 (exhausted) to 5 (rested), the subjects evaluated how rested they felt upon rising. The analysis of the results demonstrated a significant improvement ($p < 0.002$) in the feeling of being rested upon rising, going from an average of 2.94 in the pre-test phase to 3.30 in the post-test phase, which corresponds to a 12.2% improvement. Table 5 shows the means and standard deviations of the feeling of being rested upon rising in the pre-test and post-test phases.

Tableau 5 Feeling rested upon rising

Variable	Pre-test	Post-test
Feeling rested upon rising	2.94±0.60	3.30±0.69

3.3.9 Sleep evaluation

The subjects' evaluation of their own sleep was made by means of a Likert-type scale ranging from 1 (very agitated) to 5(very deep). The analysis of the results showed a significant improvement in terms of the perception of the preceding night's depth of sleep. This value went from 3.10 in the pre-test phase to 3.41 following the use of BrightWaves, thus

corresponding to an improvement of 10%. Table 6 shows the means and standard deviations for this variable for the pre-test and post-test phases.

Table6 Means and standard deviations for sleep evaluation

Variable	Pre-test	Post-test
Evaluation of the preceding night's sleep	3.10±0.61	3.41±0.76

3.4 Sleep Impairment Index

The analysis of the results obtained from the questionnaire *Sleep Impairment Index* were analyzed by means of a Student t-test (paired sample), comparing the pre-test results with those obtained in the post-test phase, after the use of BrightWaves. The analysis of the results revealed a tendency for change ($p = 0.057$) in terms of the perception of sleep imapirment after the treatment phase. However, this change cannot be considered a significant improvement. Having a greater number of subjects may have allowed a significant change to take place. Table 6 shows the means and standard deviations of the results obtained in the pre-test and post-test.

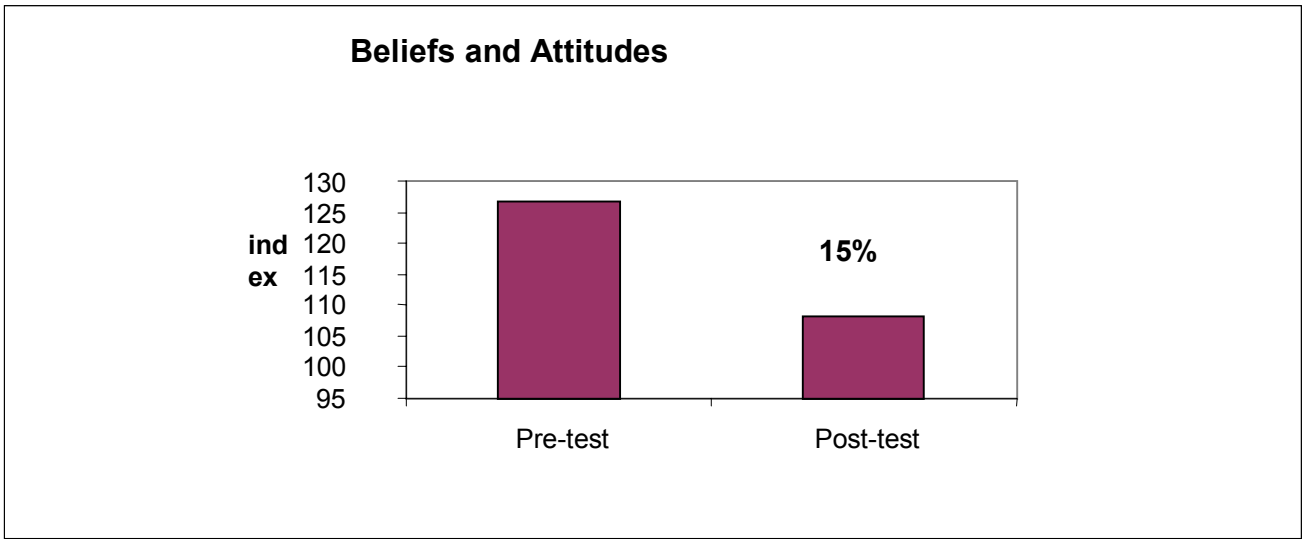
Table 7 Means and standard deviations for the Sleep Impairment Index

Variable	Pre-test (minutes)	Post-test (minutes)
Sleep Impairment Index	14.39±3.29	12.66±4.56

3.5 Dysfunctional Beliefs and Attitudes about Sleep

The results obtained from the questionnaire, *Beliefs and attitudes about sleep* were analyzed by the means of a Student t-test (paired sample), once more comparing the results obtained in the pre-test phase with those obtained in the post-test phase. The analysis of the results revealed a significant improvement in the subjects' beliefs and attitudes about sleep ($p< 0.009$). The use of BrightWaves thus gave rise to a positive change in terms of dysfunctional beliefs and attitudes, going from a score of 127 (±41.57) in pre-test to 108,2 (±38,93) in post-test, which represents an improvement of 14.8%. Figure 5 shows the evolution of the subjects' beliefs and attitudes over time.

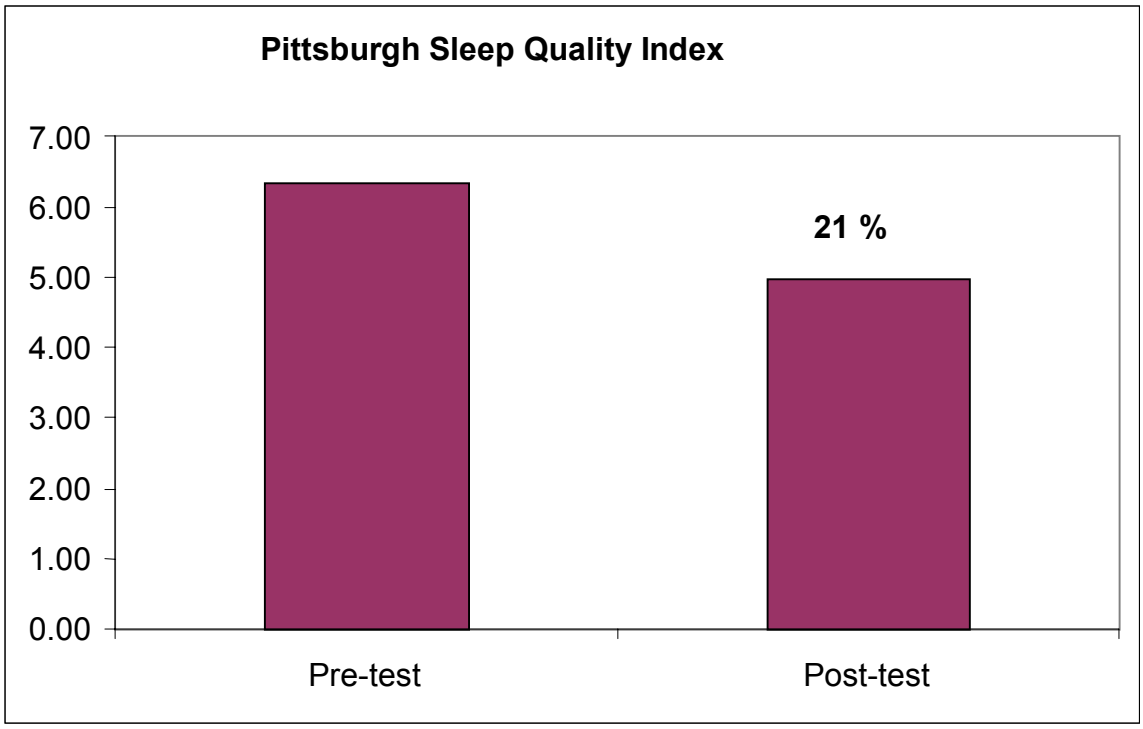
Figure 5 Evolution of subjects' beliefs and attitudes



3.6 Pittsburgh Sleep Quality Index (PSQI)

The results of the questionnaire *Pittsburgh Sleep Quality Index* were analyzed through a Student t-test (paired sample), comparing the results obtained in the pre-test phase to those obtained after the treatment phase. The analysis of the results demonstrated a significant improvement in sleep quality ($p < 0.04$). These results highlight the fact that the subjects noted better sleep quality following the period using BrightWaves, going from an average score of 6.34 (±2.42) in pretest to 4.99 (±2.81) in post-test, thus implying an improvement of 21.3%. Figure 6 highlights the evolution of perceived sleep quality over time.

Figure 6 Perceived evolution of sleep quality



4. Interpretation of the results

This pilot study had two objectives:

1) To evaluate the influence of BrightWaves on the sleep quality of people with sleep disorders.
2) To determine if it would be useful to proceed with an experimental study of this product.

The results of this study showed that the use of BrightWaves did not influence the variables: total nap time, time between going to bed and turning out the lights and the time between waking and rising, indicating that these sleep habits stayed the same throughout the experiment.

However, the analyses demonstrated that the use of BrightWaves gave rise to a decrease in the time it took to fall asleep, a decrease in the number of sleep interruptions and in the duration of these interruptions, an increase in sleep duration, an improvement in the feeling of being rested upon waking and in the perception of a deeper sleep. Therefore, these results indicate that BrightWaves modified important aspects influencing sleep quality.

The use of BrightWaves also brought about a positive change in dysfunctional beliefs and attitudes subjects may have had in terms of sleep. Although BrightWaves does not act directly on peoples' beliefs and attitudes, it is possible to consider that its influence on other sleep parameters has an indirect positive effect on these beliefs and attitudes. However, this hypothesis could only be confirmed through a clinical experimental study with the use of a

control group. In addition, the use of BrightWaves seemed to bring about an improved perception of sleep quality in the subjects.

However, the results demonstrated that despite a positive influence the use of BrightWaves had on several of the preceding variables, the perception of sleep impairment was not modified, even though a tendency for change must be noted. Therefore, this leaves room to consider the fact that a longer exposure to BrightWaves and/or a greater number of subjects would be necessary for the changes engendered by BrightWaves to bring about a modification of perceived sleep impairment in the subjects.

In conclusion, the results demonstrated that BrightWaves positively influenced several sleep parameters, although it must be noted that certain parameters were not modified: total nap time, time between going to bed and turning out the lights, time between waking and rising and the ability to positively influence perceived sleep impairment. However, apart from the latter, these variables do not seem to have as fundamental an influence as the variables that were positively modified following the use of BrightWaves.

- sleep-onset time;
- number of sleep interruptions;
- duration of the interruptions;
- sleep duration;
- feeling rested upon waking;
- perception of a deeper sleep;
- beliefs and attitudes;
- sleep quality.

These results have therefore provided a response to the objectives of the study, thus determining that BrightWaves can positively influence certain important parameters affecting sleep quality and justifying the passage to the next step: an experimental study

However, it must be specified that this pilot study has certain limitations. It does not constitute an experimental research design with the presence of a control group and random assignment of subjects. Because of this, it was impossible to control the placebo effect or to compare the efficiency of BrightWaves with any other treatment. Moreover, it would be important during an experimental study to make a diagnosis and/or classification of the severity of the sleep disorders affecting the subjects in order to determine, if there are significant changes, to what extent BrightWaves influences people suffering from severe and chronic disorders.

In addition, even though the use of BrightWaves gave rise to positive changes in terms of several parameters influencing the quality of sleep, it is presently impossible to predict the clinical impact of BrightWaves. It must also be taken into account that no physiological variables were evaluated. Therefore, it is impossible to know at this time if BrightWaves modifies the brain waves of its subjects, thus acting according to the mechanism proposed by its creator.

This pilot study was, therefore, an essential step in determining the potential clinical impact of BrightWaves. Since the results suggest a very interesting efficiency on the part of the product, it is now a matter of proceeding to an experimental study that will investigate not only the psychological aspect, but also the physiological variables (brain waves) in order to

confirm the effectiveness and the clinical interest of this product. This experimental study will compare BrightWaves to a placebo treatment and, ideally, a placebo treatment and a known treatment. At that time, more precise and complete conclusions could be drawn.

Denis Boucher, Ph.D.

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