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ORIGINAL ARTICLE

Preliminary assessment on the effectiveness of the Luminette® in adolescents with a delayed sleep phase syndrome (DSPS): Randomized single blind placebo-controlled study

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Summary The aim of this pilot study was to test the effectiveness of a light therapy device (the Luminette®) on the delayed sleep phase syndrome (DSPS) in a group of adolescents (n = 10) between 15 and 18 years old (three girls and seven boys, average age 16.3 years old) affected by this syndrome. This study was conducted using an experimental single blind placebo-controlled design. The diagnosis of the DSPS among participants was established based on the criteria specified in the International Classification of Sleep Disorders — Second Edition (ICSD-2). The data were collected using two questionnaires: (1) Teen Sleep Diary (TSD) and (2) the Pediatric Daytime Sleepiness Scale (PDSS). The results indicated significant improvements in the experimental group (users of the real Luminette®) compared to the control group (users of the placebo Luminette®) with respect to the delay of sleep onset, the quality and the daytime sleepiness. This study underlines the importance of conducting further research on the Luminette® with a larger sample of adolescents with DSPS: quicker to fall asleep, longer sleep duration, improved sleep quality and reduced daytime sleepiness level. This study highlights the relevance to undertake later research on treatment using the Luminette® with a larger sample of adolescents who have DSPS.

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Introduction

Delayed sleep-phase syndrome (DSPS), a disruption of the circadian rhythm, is understood as a delay in the main sleeping period and by the inability to fall asleep at a conventional time or to wake up at a time that is socially acceptable [1—3]. DSPS may affect between 7 and16% of adolescents and certain biological and psychological factors may be involved [4, 5]. With regard to biological factors, among other things, researchers mention appearance during puberty which may lead to a disruption of circadian rhythm especially due to a low sensitivity to light in the morning and hypersensitivity of light at night, which delays the secretions of melatonin at bedtime and maintains a high level of melatonin when waking up [6—9]. These two phenomena may partially explain why some adolescents go to bed late and suffer the consequences during the daytime such as having a hard time getting up, not getting enough sleep, feeling sleepy, attention and vigilance problems, lowered school performance and a difficult mood (irritability, anxiety and depression). It is also important to emphasize a risk of obesity due to a lack of sleep caused by delays in falling asleep observed with adolescents [10—13]. Many different psychosocial factors may also promote the onset of DSPS, including a reduction of parental monitoring, the increase of extracurricular activities, part-time jobs, a excess of television and computer consumption in the evening [14—16].

Besides taking sleeping pills, which is not advised during adolescences because of a risk of addiction, young people who wish to reduce their DSPS have access to different treatments, namely healthy sleep programs, taking melatonin at bedtime and using light therapy when they wake up [17, 18]. Even though light therapy may be effective with adults afflicted with DSPS, it entails constraints that make it difficult to apply to adolescents. First of all, treatment needs to take place at a certain time in the day, which requires measuring the initial circadian phase constantly (without disrupting sleep) [19]. This procedure requires repeated measurements of body temperature rectally and of the level of melatonin in the blood by saliva sampling between one and six o'clock in the morning. Unless the circadian phase is identified beforehand, a aggravation of DSPS may occur, hence the interest of applying this protocol [20, 21]. Another considerable obstacle makes treatment difficult: classical light therapy devices are stationary require the subject to be exposed to bright light during a time varying between 60 and 120 minutes upon waking up. In our opinion, this alone is enough to discourage many adolescents.

Throughout our research, we discovered a wearable light therapy device that may better meet these adolescents' lifestyles. This is the "Luminette®" which unlike classical devices, helps to maintain proper vision of the environment. In other words, adolescents may go about their morning activities while receiving the light therapy treatment. Even though the Luminette® seems perfectly able to treat DSPS in adolescents, we cannot find any study assessing its effectiveness and this is precisely what justifies this exploratory pilot study. We should still mention that this exploratory pilot study carried out in a natural setting, we did not apply the protocol of physiological measurements (body temperature and melatonin levels) which would identify the initial circadian phase in the subjects.

Objective and hypothesis of the study

The objective of this study consisted of assessing the effects of the Luminette® on DSPS in a group of adolescents. Three hypotheses define this objective: compared with the adolescents in the control group, the subject undergoing light therapy treatment using the Luminette® , starting during the second week of treatment, should:

- (H1) fall asleep earlier and sleep longer throughout the week;
- (H2) enjoy higher quality sleep during the same period;
- (H3) be less sleepy during the daytime.

Method

Experimental protocol and participants

We used a single blind placebo-controlled randomized trial experimental protocol. This protocol, on the one hand, involved light therapy treatment using the Luminette® and on the other hand, light therapy treatment using a placebo device. It was not possible to use a double-blind trial because of a different between the two types of Luminette: unlike the genuine Luminette® which produces white light and a light spectrum ($400 < X < 750$ nm), the placebo Luminette® diffuses orange light and light spectrum ($560 < X < 650$ nm): this particularity is identified by researchers by was unknown to participants. The participants followed the treatment at home during the wintertime, in December 2012. They had to meet the four diagnostic criteria mentioned in the International Classification of Sleep Disorders — Second Edition (ICSD-2) [4] (Table 1).

Participant recruitment took place between August 15 and October 15, 2012 via posters and flyers distributed at the community center "La Cité Francophone", located in Edmonton (Alberta, Canada). This center includes a medical clinic, a school of adolescents who have problems adapting to school and a job search office. In order to eliminate as many variables possible which might bias the results related to light therapy treatment, we applied certain exclusionary criteria as recommended by Sack et al. [5].

Table 1 The four diagnostic criteria for DSPS as specified in ICSD-2.

A delay of the main sleep phase with relation to the requirements of societal life; regular complaints of falling asleep at conventional times and inability to wake up at a determined morning hour.
If the person can set his own hours, sleep is without anomaly and the normal duration for his age.
The sleep phase is delayed over 24 hours but is stable
The use of a sleep diary or an actigraph for at least 7 days indicates a constant delay of the sleep period
Symptoms cannot be better explained by another disorder

Following a structured interview and after keeping a sleep diary over seven consecutive days, those subjects were excluded who did not meet the diagnostic criteria of ICSD-2 [4] with relation to DSPS as well as those who showed ophthalmological or mental health problems according to the results of the structured interview: retinopathy, attention deficit hyperactivity disorder (ADHD) or mood swings. Subjects were also excluded who used sleep aids, melatonin or any other product which may influence sleep (cigarettes, coffee, cola, energy drinks, etc.). Finally, considering that light stimulates wakefulness [16, 22], adolescents who refused to eliminate sources of light (computers, television, etc.) in their bedrooms after 9 p.m. were also removed. Out of the 31 adolescents who volunteered to participate in the study, only ten adolescents aged 15 to 18 (three girls and seven boys, average age of 16.3 years) were selected. They were randomly split into two groups of 5 participants. Randomization was achieved by a person who did not know about the study; the participants were called to draw a card at random featuring either the number 1 (experimental group) or the number 2 (control group). For three consecutive weeks, the first group received light therapy treatment using the Luminette® at a rate of 45 minutes every morning, as soon as possible after waking up. The second group received placebo light therapy treatment during the same period and under the same conditions (Fig. 1 summarizes this information).

The participants had to record any relevant information about their sleep experience daily in a special diary. The information gathered on the first day helped set a data baseline. At the same time, the participants had to fill out a questionnaire about their sleepiness on day 1 and day 22 of the experiment. Our protocol did not include any prior identification of the subjects' circadian phase (body temperature and melatonin level) because of the nature of the study. However, even though most researchers do gather this type of data, the American Academy of Sleep Medicine (AASM) indicates that this prior gathering of information is not necessary [23].

Equipment

Light therapy treatment

As mentioned above, this study was meant to verify the effects of the light therapy device known as the Luminette® on DSPS. The light source of this device is comprised of miniature light-emitting diodes (LEDs) distributed on the upper part of each lens, outside of the user's view. The diodes reflect the light into the eye using a diffractive lens. This technology precisely focuses the light rays onto the lower half of the retina no matter the incline angle of the eye (Fig. 2). The intensity of 2000 lux should be sufficiently powerful to inhibit the secretion of melatonin and to reset the circadian clock of those subject to the treament [24].

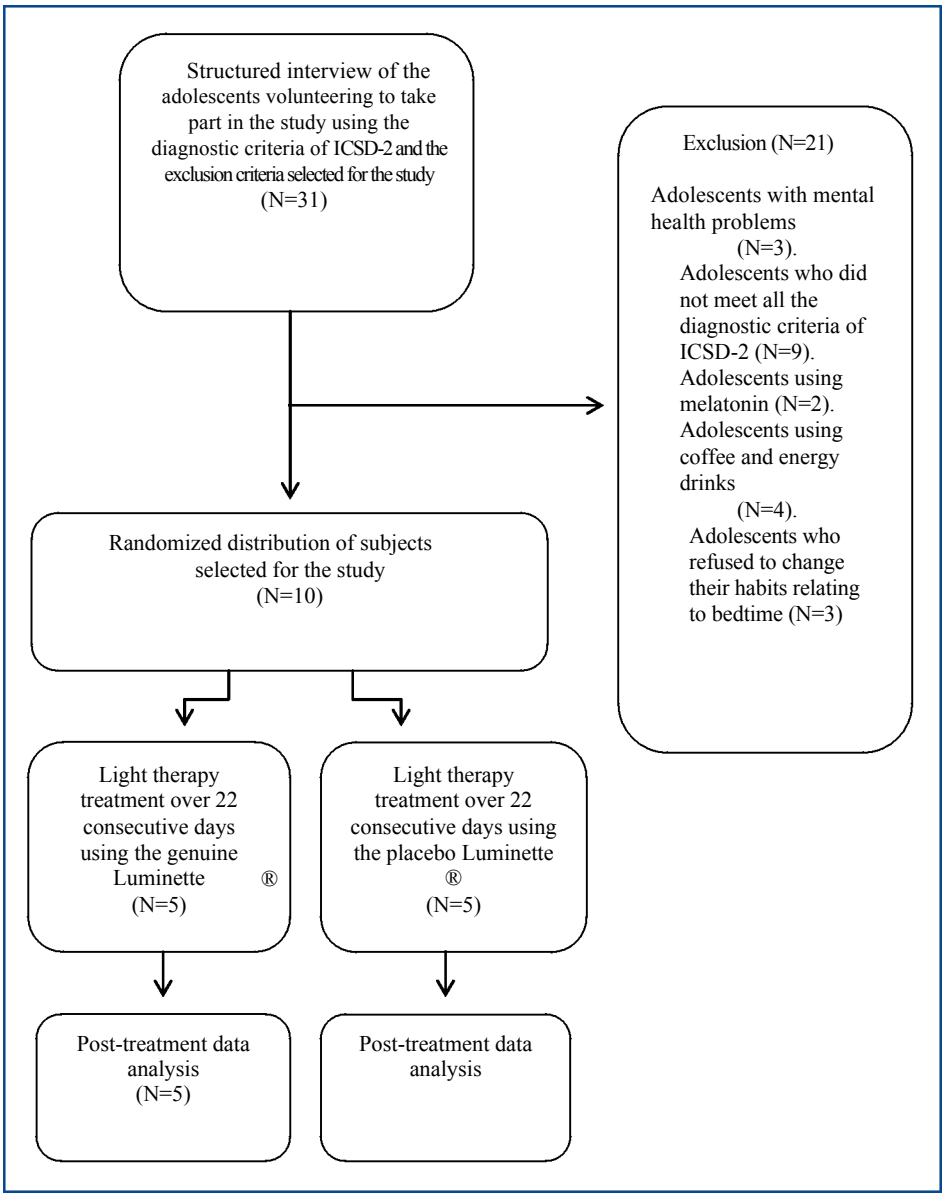

Figure 1. Exclusion criteria and randomized controlled procedure relating to the participants in the study of light therapy using the genuine Luminette® and the placebo Luminette®.

Placebo treatment

To aid this research, the Lucimed Company developed the placebo Luminette® used in our study. Both devices are identical except for the color of the light diffused. As mentioned, the genuine Luminette® emits white light and the placebo Luminette® emits an orange light resulting from an inactivation of the blue LEDs.

Sleep habits

To assess the participants' sleep habit, we used the Teen Sleep Diary (TSD) from the National Sleep Foundation [25]. Throughout the entire period of experimentation, i.e. during 22 consecutive days (from December 1 through 22, 2012), all the participants had to indicate in the TSD:

- the time they went to bed;
- the time they fell asleep;
- they time they woke up;
- the quality of their sleep.

This information was gathered every morning when the participants work up. The quality of the sleep was assessed using a Likert-type 5-point scale included in the TSD (1 "I had a poor night's sleep" to 5 "I had an excellent night of sleep").

Table 2 Weekly averages (and standard deviations) of hours of sleep and the duration of sleep of both groups.

	Experimental group (n = 5)	Control group (n = 5)
Hours of sleep Week 1	0:40 (15)	0:23 (10)
Hours of sleep Week 2	23:07 (23)	24:07 (16)
Hours of sleep Week 3	22:41 (8)	24:14 (10)
Duration of sleep Week 1 (in minutes)	364 (24)	381 (23)
Duration of sleep Week 2 (in minutes)	457 (43)	395 (17)
Duration of sleep Week 3 (in minutes)	487 (19)	391 (25)

Levels of sleepiness

The level of the participants' sleepiness was measured using the Pediatric Daytime Sleepiness Scale (PDSS) [26]. This test includes eight items relating to the states of the adolescents' sleepiness during the daytime (How many times do you fall asleep during the day? Are you sleepy during class time?). The adolescents had to indicate their level of sleepiness on a Likert-type 5-point scale (0=never, 4=always). The internal coherence of the PDSS is 0.78 (Cronbach's alpha) [26].

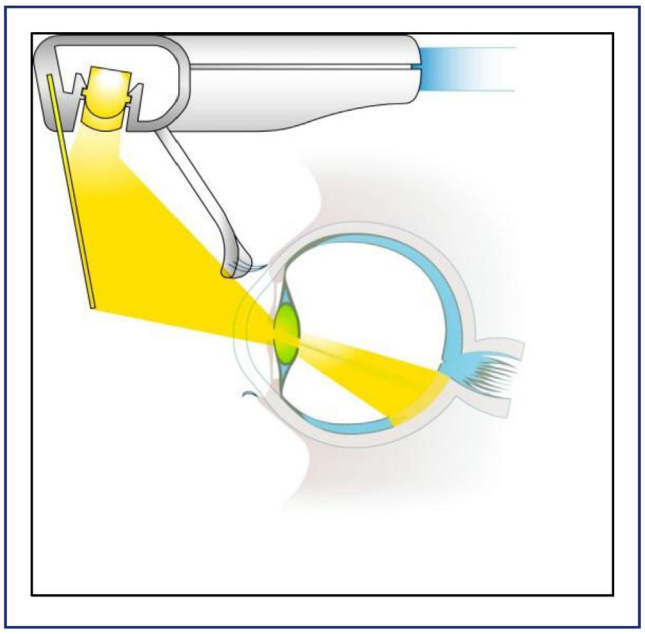

Figure 2. Diagram showing the angle the Luminette® uses to emit light toward the retina.

Results

Using the data gathered (Table 2), the average hours of sleepiness and the average duration of sleep per week were calculated over the three weeks of experimentation. Considering the permissiveness the adolescents generally enjoy with regard to bedtimes on weekends, we excluded data relating to Friday night, Saturday morning and Saturday night. Nonparametric Mann-Witney U tests were applied to compare the effect of the treatment on both groups considering the limited size of the sample.

Throughout Week 1, statistical analyses revealed a tendency to delay the time of falling asleep ($Z = -1.915$, $p = 0.056$) in the adolescents in the experimental group compared with the control group. Throughout Weeks 2 and 3, we observed significant changes in the time of falling asleep in the experimental compared with the control group, which advanced, and in the duration of sleep, which increased (respectively in Week 2: $Z = -2.627$, $p = 0.008$ and $Z = -2.312$, $p = 0.016$; for Week 3: $Z = -2.627$, $p = 0.008$ and $Z = -2.611$, $p = 0.008$).

The statistical analysis of the participants' sleep quality relied on their own assessment (Table 3).

Table 3 Weekly averages (and standard deviations) of the quality of sleep in both groups.

	Experimental group (n = 5)	Control group (n = 5)
Sleep quality Week 1	2.04 (0.17)	2.22 (0.23)
Sleep quality Week 2	3.44 (0.17)	2.44 (0.26)
Sleep quality Week 3	3.40 (0.14)	2.64 (0.26)

The nonparametric Mann-Whitney U tests reveal significant differences between the results of both groups. Throughout the first week, the sleep quality in the control group is significantly higher than in the experimental group ($Z = -2.447$, $p = 0.016$), but the trend reversed throughout the second and third weeks: the experimental group showed better sleep quality than the control group (respectively, $Z = -2.635$, $p = 0.008$ and $Z = -2.677$, $p = 0.008$).

Finally, a variance analysis with two factors (the "Group X" factor and the "Execution Time" factor) with measurements repeated on the last factor applying to the results obtained on the daytime sleepiness scale (PDSS). Through pretesting before the light therapy treatment, the average of the experimental group was 23 (out of 32, standard deviation: 2) and in the control group at 23.4 (standard deviation: 2.3). In post-testing, i.e. at the end of light therapy treatment, the average of the experimental group is 14.8 (standard deviation: 1.79) and in the control group at 22 (standard deviation: 4.25). The statistical analysis highlights an Execution Time effect (F (1.8) = 153.6, $p = 0.000$, $\eta^2_p = 0.950$) as well as an effect of Group (F (1.8) = 9.03, $p = 0.017$, $\eta^2_p = 0{,}530$). These results mean that the scores on the daytime sleepiness scale reduce significantly between the pretest and the post-test and differ significantly between the control group and the experimental group. An interaction of Execution Time x Group (F (1.8) = 77.07, $p = 0.000$, $\eta^2_p = 0.906$) was also revealed in these analyses.

Discussion

This pilot study was meant to test the effectiveness of the Luminette® in treating DSPS in adolescents. The results indicate that the average hours of sleep in the adolescents using the genuine Luminette® are significantly earlier and their average sleep durations are significantly higher than those in adolescents subject to placebo treatment, throughout the second and third weeks of treatment. These results confirm the first hypothesis of our study and support the results of light therapy treatment carried out over six consecutive days with 25 young adults with sleep phase delay syndrome [27]. Furthermore, the data reveals that the adolescents in the experimental group had the subjective quality of their sleep improve significantly during the second and third weeks using the Luminette® compared with the adolescents in the control group. This corroborates the second hypothesis of our study. Finally, the last results presented above demonstrate that the adolescents in the experimental group were less affected by daytime sleepiness throughout Weeks 2 and 3 than the subjects in the control group, which confirms our third hypothesis.

The results of this pilot study suggest that light therapy using the Luminette® advances the time of falling asleep and increases the duration of sleep reported in the diary. However, the limitations of this work should be emphasized. First of all, the small number of subjects and the absence of information about their chronotype. In fact, using questionnaires to assess the choronotype of the adolescents who have DSPS would help to better appreciate the severity of the phase delay and to better determine the appropriate time for light therapy [28, 29]. Then, the fact that the measurements gathered throughout the experiment was subjective (sleep diary, self-assessment of the quality of sleep and daytime sleepiness). To make up for these weak methodological areas, it would be interested to carry out new research of larger magnitude in this domain by using more objective measurements such as actimetrics, which is recommended to appreciate the effect of light therapy treatment for circadian rhythm problems [30]. Furthermore, our study only lasted three weeks, which is a period so short that the hours of sleep during weekends were not considered. A more long-term treatment applied to a larger sample, accounting for all hours of sleep would help verify if the beneficial effects of the Luminette® on DSPS in adolescents would last or fade away over time. We also think that it would be relevant to compare the respective effectiveness of treatment with melatonin and Luminette® light therapy. The results of such an investigation would inform clinical workers who have to recommend a treatment or a combination of treatments to adolescents affected with this syndrome.

Finally, despite the methodological limitations of this pilot study, for the first time, we have demonstrated the effectiveness of the Luminette® in treating DSPS with adolescents. Our results favor the development of similar research, given the magnitude DSPS has taken in recent years with young people [31, 32].

Statement of interest

The authors state that they have no conflict of interest with relation to this article.

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