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Development and performance evaluation of portable light therapy apparatus for improvement of sleep and wakefulness

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This article is dedicated to Prof T Asakura

We have recently developed a portable light therapy apparatus for improvement of sleep quality and wakefulness. To design fundamental specification of this apparatus and evaluate its performance, we conducted some preliminary experiments using a self-made head model for measurement of illumination in eyeball. We also employed iPad-based psychodiagnostic test for evaluating sleep quality. The experimental results demonstrate usefulness of the developed portable light therapy apparatus.

Keywords: Light therapy, Sleep quality, Wakefulness, Blue light

1 Introduction

Due to the advanced sophistication of information and communication technology (ICT), the work contents are complicated and diversified, and an increase in the number of sufferers such as sleeping disorders and depression is a serious social problem with the disturbance of stress and life rhythm. There are reports that light irradiation is effective as a means of treating these diseases [1-3]. High illuminance light therapy is one of the light therapy techniques, in which the eye is illuminated with 10,000 lx of light for 30 minutes after waking up in the morning [4]. This illuminance corresponds to the shade in fine weather and is considered to be effective for the light therapy. On the other hand, some users may get irritated, tired eyes, headache, nausea and other symptoms, but none of them is a serious side effect. Therefore, the light therapy with this illuminance has a potential usefulness as a dairy and easy tool in comparison with medication therapy. Light therapy apparatus is not widely used in Japan except for some specialized medical institutions. Several kinds of products are commercially available overseas, but inconveniences such as a large size of the device and inability to move around during use are practical problems with them. We developed a novel portable light therapy apparatus aiming to solve these problems.

2 Design of the apparatus

2.1 Basic form

Stationary or wearable types are commercially available as a light therapy apparatus, but they are generally large in size. Use of these types causes inconvenience that an user is required to face the apparatus without movement or to maintain less motion of the body during a period of illumination. Moreover, the method in which an user spends his/her time for 30 minutes in the morning only for light therapy is also disadvantageous for popular use. On the other hand, the therapy is expected also for eliminating jet lag, so it is desired that an apparatus can be used in a portable manner. By these reasons, we aimed to develop

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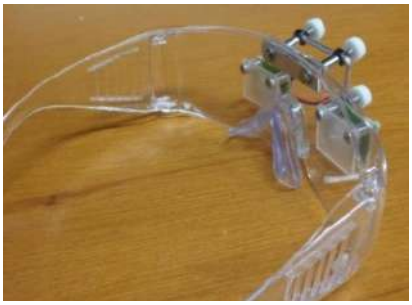
a compact and lightweight portable device. The first prototype device was developed by using a goggle as shown in Fig 1 (a). In comparison with existing commercial products, it became possible to reduce size and weight. But we made further improvement on the overall form, light source specifications, miniaturization, and weight reduction. As a result, we employed a form of glasses as shown in Fig 1 (b).



(a) Goggle type

(b) Glasses type

Fig 1.Two developed types of light therapy apparatus

2.2 Light source

The most important part in this apparatus for development was an appropriate design of light source. For a trial design, we examined and adopted the specifications in the following four points below.

(*a*) *Arrangement of light sources*

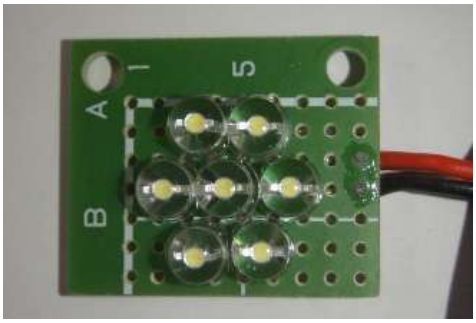
To realize the need of weight reduction and miniaturization of the apparatus, white light LED with high illumination (directivity of 90º and brightness of 1400 mcd) was adopted as the light source which is expected to have less influence in heat generation and to ensure long life. We placed seven LEDs on a substrate in 30 mm × 23 mm as shown in Fig 2 (a) so that an iris portion of the eye could be uniformly irradiated with light of 10,000 ± 100 lx.

(*b) Diffusing plate*

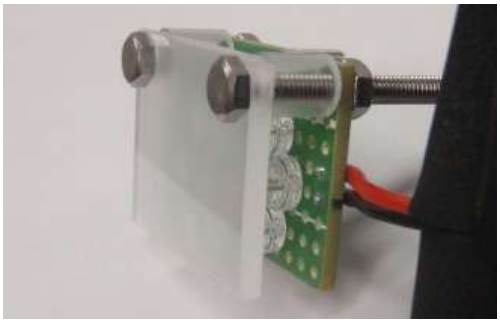
To diffuse rays from seven LEDs and to irradiate uniformly the surface of eyeball, an acrylic plate of the same size as the substrate was placed at a position 7 mm away from the substrate in front of the LED as shown in Fig 2 (b).

(*c*) *Irradiation distance and angle*

To wear the apparatus and to allow user to see the front scene during light irradiation, the light source is located above an angle of 55º obliquely with respect to the line of sight, and is located at a distance of 30 mm from the eye surface. This situation is subject to change due to a shape of face individually. We employed the above-mentioned values as a typical condition for Japanese adult people. This allowed us to be ensured of 10,000 ± 100 lx illuminance on the eyeball.



(a) Alignment of LEDs



(b) Position of diffusing plate

Fig 2. Design of lighting portion.

(*d*) *Spectral characteristics*

The spectral characteristics of the white light LED used in the apparatus consists of two band components of blue and yellow as shown in Fig 3. Blue is an important wavelength component that is expected to be effective in light therapy [5], whereas light component particularly in the shorter wavelength of blue band may have the vicinity of the ultraviolet region, which is harmful to the human body. We made test units having three types of yellow filters with different optical densities placed in front of the diffusing plate. These illumination units have the blue component reduced by 30%, 50%, and 70%. By setting these units to the apparatus, we examined the light therapy effect. We found that the best result was obtained when the apparatus with the blue component cut by 30% was used. In addition, the spectral characteristics of the illuminating light with this condition confirms the safety standards defined in IEC 62471:2006. Therefore, we confirmed that the safety was secured for human eye with the present apparatus.

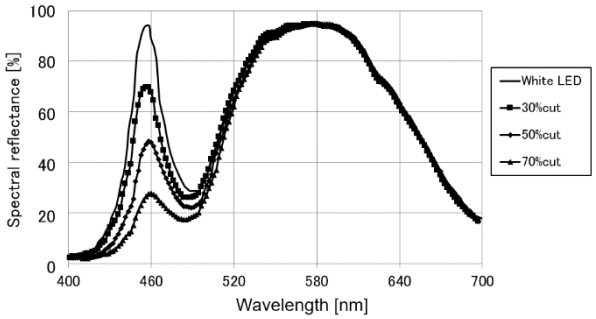
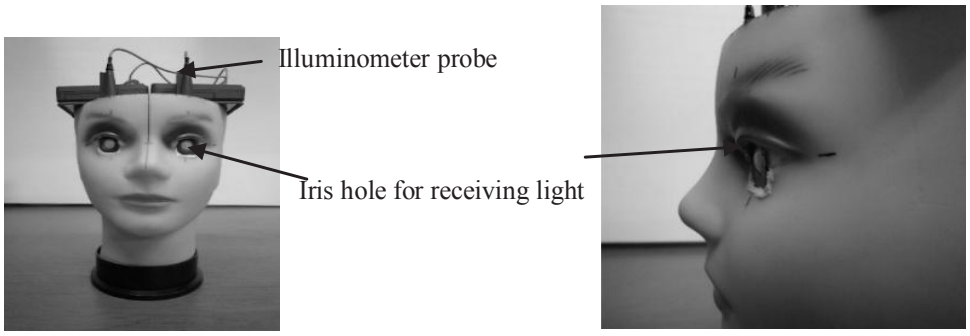


Fig 3. Spectral reflectance of white light LED with different three yellow filters.

3 Methods for evaluation of performance

3.1 Mannequin head-based device for illuminance measurements

To measure illuminance on the eyeball surface with the apparatus being worn on face, an illuminance measuring device shown in Fig 4 was made. We used a commercially available mannequin head filled with a urethane inside, cut the top of a head horizontally, and made a hole so that a probe of an illuminometer (LX 2, Sanwa Co., Japan) could be inserted from the top. Furthermore, we made a hole on the front side of the eyeball so that a light receiving part of the eyeball could coincide with the position of iris, and the illuminometer probe could receive light passing through the iris-like hole. Using this device, we realized a 3-D geometric positioning which is close to the actual situation on face considering the curved skin surface around eye.



(a) Front View (b) Side View

Fig 4. Mannequin head-based device.

3.2 Eyeball model for spectral irradiance measurements

To experimentally estimate the spectral irradiance of light rays from the apparatus to human retina through the pupil, we made an eyeball model shown in Fig 5. Since the average diameter of a human eyeball is about 25 mm, we used two acrylic hemispherical domes with a diameter of 31.8 mm (inner diameter 25.4 mm). A pupil diameter of human changes generally from minimum of 2 mm to maximum of about 8 mm. Since the apparatus irradiates illuminance of 10,000 lx which seems dazzling, the pupil diameter is set to the minimum 2 mm. Also, since the spectral irradiance meter (CL-500A, Konica Minolta, Japan) used for evaluation has the light receiving window with a diameter of 12 mm, we made a hole of the same diameter in the retinal side.

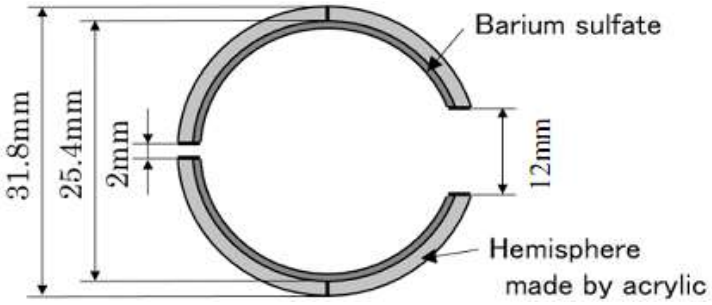


Fig 5. Eyeball model for measurements of spectral irradiance.

Human eyeball is filled with the vitreous humor which is usually almost transparent. We considered that absorption of light in the humor is insignificantly small and did not include any liquid in the eyeball

model. Assuming that the light incident on the pupil is reflected diffusely and relatively uniform on the eyeball and reaches the retina, we applied barium sulfate inside the acrylic hemispherical dome and finished something like a small integrating sphere.

3.3 i Pad-based Kraepelin test

Inspection of Uchida Kraepelin [6] is known as an useful means for evaluating quantitatively the level of human activity, for example, attentiveness and ability of concentration on task, which are generally reduced due to poor sleep quality. Originally this Kraepelin test is carried out by writing results of calculation task directly on a paper sheet on which a large number of figures "1" - "9" are displayed randomly in a matrix manner. To conduct this test and count the result easily and accurately, we developed an application software for i Pad shown in Fig 6.

By conducting this test, we employed the results as an indicator for the degree of waking. It should be noted that there is some learning effects generally in this test. Before the evaluation experiment, we set a preparation step in which subjects practiced this test for 5 min at once, 10 times.

Fig 6. Kraepelin test (Application for i Pad).

3.4 Application software for survey of the feel of sleep and sleepiness

We used "OSA sleep inventory MA version [7]" for survey of feel of sleep. This method is based on psychological measures that investigate sleep introspection in a self-evaluation manner by questionnaire of 16 items at the time of getting up in a clinical situation. On the other hand, for sleepiness, Stanford Sleepiness Scale (SSS) was used [8]. This is a self-assessment measure of sleepiness that has been developed by Stanford University, and evaluates the degree of sleepiness in seven levels, "1" for "no sleepiness" to "7" for "most sleepiness". Normally, both these investigations are made by filling in paper sheets after getting up, but we have also developed an application software for these investigations as well as the Kraepelin test.

3.5 Other additional matters

In the evaluation experiment, we used additionally a thermometer, a body motion monitor, and a sleep meter. Since body temperature generally rises with an increase of an arousal level, we measured body temperature immediately after getting up and in every 10 minutes for 30 minutes. The measurement was made on a portion under a tongue which is regarded as close to the body temperature without being influenced by room temperature. Also, to record changes in the amount of body activity in the whole day, collaborators wore a body motion monitor (Acti sleep+, ActiGraph Inc., USA) on an arm all the time during the evaluation experiments. To analyze sleep quality during sleep, we used a sleep meter (Sleepscan, TANITA, Japan) for collaborators. This study was conducted based on Muroran Institute of Technology ethics rules (approval number H27-04-S04), with the consent of the collaborators.

4 Experimental evaluation of the performance

4.1 Illuminance

To confirm that the illuminating device of the apparatus irradiates the eyeball with appropriate illuminance, we performed measurements of illuminance using the mannequin head-based device as shown in Fig 4. The average value of illumination after measuring 10 times was 10018.8 lx, and the standard deviation was 4.88. From this result, it is found that appropriate illuminance is obtained as designed. In actual situations in use, it is supposed that the illuminance may change from the above value due to individual differences in facial shape, but since the diffusing illumination is used in the device, the influence thereof is considered to be negligible.

4.2 Spectral characteristics and safety

We next investigated compatibility of the apparatus with safety standards as defined in "4.3.4. Retinal blue light hazard exposure limit – small source" based on IEC62471:2006 "Photobiological safety of lamp and lamp systems", by using the eyeball model shown in Fig 5. We confirmed that the illuminance at the retinal position took the average value of 73.96 lx and a standard deviation of 0.51 after measuring 11 times. The spectral radiant intensity curve was obtained as shown in Figure.

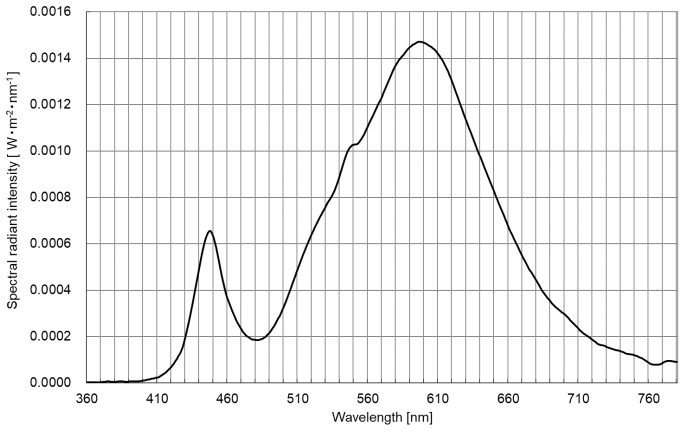


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Fig 7. Spectral radiant intensity with the eyeball model.

Troland (Td) is used as a unit of retinal illuminance that gives brightness of a projected image at the retinal position. When pupil area is 1 mm^2 and illuminance on the eyeball surface is 1 lx, the retinal illuminance E_t becomes 1 Td. Retinal illuminance E in unit of lx is expressed by the following conversion equation (1)[9].

$$E \approx 0.0036 \times \tau \times E_t \tag{1}$$

where τ is transmittance of light inside the eyeball which is known to be about 0.6 - 0.9 when the effects of reflection, absorption, and scattering are taken into account. When illuminance on the eyeball is 10,000 lx, a diameter of a pupil is 2 mm, and the transmittance τ is 0.9, the retinal illuminance E is derived to be 101.79 lx. Since the retinal illuminance measured with the manufactured eyeball model was 73.96 lx as mentioned above, it can be estimated that the eyeball model produced in this study well realizes typical retinal illuminance in human.

When the retina is illuminated with a light source having spectral radiant intensity E (λ), the effective irradiance E_B [W/m^2] which is supposed to cause the retinal injury by the blue light component is specified by IEC 62471:2006 [10] is and expressed by Eq (2),

$$E_B = \sum_{\lambda=300}^{700} E(\lambda)\, B(\lambda)\, \Delta\lambda \tag{2}$$

where $B(\lambda)$ is called the blue light interference function and expresses influence of the blue light to the retina, and $\Delta\lambda$ is a wavelength interval used in measurements (5 nm in this experiment). In this condition, the permissible exposure time t_{max} [s] is obtained by Eq (3),

$$t_{max}\,[\mathrm{s}] = \frac{10^2\,[\mathrm{J/m^2}]}{E_B\,[\mathrm{W/m^2}]} \tag{3}$$

We calculated the effective irradiance E_B for the light irradiated from the present apparatus by using the spectral radiant intensity measured through the eyeball model, and obtained the permissible exposure time t_{max} was to be 4756.2 sec. As will be described later, we designed the present apparatus to use for 30 minutes (1800 seconds) at once which is shorter than t_{max}. According to the safety standard of IEC 62471:2006, the case in which an exposure is permissible for t_{max} = 100 seconds or more is categorized to "risk group 1 (low risk)". Therefore, the use of this apparatus for 30 minutes is considered to be safe in this study.

4.3 Effects for light therapy

4.3.1 Experiment method

To confirm the effectiveness of the apparatus for light therapy, we set up the following experimental protocols and conducted some evaluation experiments. Upon conducting the experiment, we reached to the full understanding about the purpose of this study with six persons who got consent as collaborators. All collaborators are mentally and physically healthy men in their twenties. An experimental process consists of three periods, observation period, rest period, and therapy period. Each period took 7 nights (8 days), with waking up at 7:00 and going to bed at 0:00 both in the observation and therapy periods. A bed was placed in a laboratory room without windows, and the temperature inside the room was set to be 20 ºC by air conditioner. By turning off the room lighting, we prepared nearly darkroom situation. As measurement instruments, we used ActiSleep+ for monitoring activities, Sleepscan (TANITA, Japan) for sleep monitoring, and the sublingual body thermometer after getting up. For inspection, we employed the OSA sleep inventory (OSA) and Stanford Sleepiness Scale (SSS) for sleepiness survey, and the Kraepelin test for wakefulness survey.

4.3.2 Experimental protocol

(1) Phase 1 (Observation period)

(a) On the first day, a subject attaches the body motion monitor to his left arm and, then, he practices the iPad version of Kraepelin test for 5 minutes. He also performs initial setting of his personal data such as name and age in the sleep meter.

(b) The subject measures his sublingual temperature 10 minutes before going to bed and fills in an activity survey form. Then, the subject goes to bed at 0:00 after switch on the sleep meter and gets up at 7:00. Even if he awakes before 7:00, he stays with eye closed until 7:00.

(c) After the subject wakes up, he turns on the room lighting and turns off the sleep meter. Immediately after getting up and every 10 minutes thereafter for 30 minutes, he measures his sublingual temperature, and then reports the results of OSA and SSS inspections on a sleep survey form. Finally, he conducts the Kraepelin test for 5 minutes, and begins his life as usual. In the daytime also, he reports SSS results for comparison .

The aim of setting this observation period is to make it easier to compare various biological data in the therapy period with those in the observation period in which the subject keeps his ordinary life.

(2) Phase 2 (Rest period)

(a) The subject lives his usual life in preparation for the next experiment in Phase 3. It does not matter what time he goes to bed or gets up during this period.

(b) Any measurement and inspection are not made on the subject in this period.

The aim of having the rest period in this step is to reset once the life rhythm that might be made by any influence of the experiments performed in the observation period.

(3) Phase 3 (Therapy period)

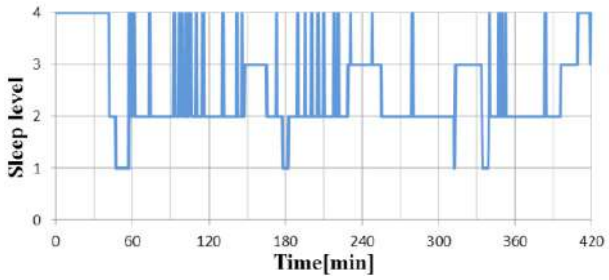
(a) On the first day, the subject is required to practice the Kraepelin test.

(b) The subject measures his sublingual temperature 10 minutes before going to bed and fills in the activity survey form. Then he goes to bed at 0:00 after switch on the sleep meter and gets up at 7:00. Even if he awakes before 7:00, he stays with eye closed until 7:00.

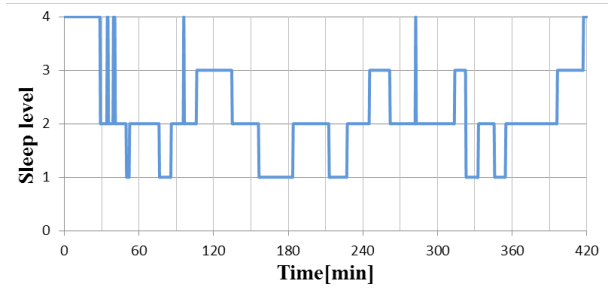
(c) After the subject wakes up, he turns on the room lighting and turns off the sleep meter. He next measures his sublingual temperature, then starts use of the apparatus for 30 minutes. During this use, he continues to measure the sublingual temperature every 10 minutes, until the end of light irradiation with the apparatus. He next reports the results of OSA and SSS inspections on the sleep survey form and conducts the Kraepelin test for 5 minutes. After that, he begins his life as usual. In the day time also, he reports SSS results for comparison.

4.3.3 Results and discussion

In the present experiment, almost similar trends were found for six subjects, so some typical results are shown in this paper. Figures 8 (a) and (b) show measured data of the sleep meter on the 5th day of the observation and therapy periods, respectively. Sleep level "4" means awake, and the smaller number less than "4" indicates the deeper sleeping condition. In the observation period, the subject repeats waking up and sleeping. This result indicates that the subject did not sleep well. On the other hand, the result in the therapy period demonstrates that the number of wakefulness decreases and the deep-sleeping time becomes dominant, which indicates that the subject slept well.



(a) Observation period (5th day)



(b) Therapy period (5th day)

Fig 8. Results of sleep monitoring (Subject 4).

The average value of measured sublingual temperatures for six subjects is shown in Fig 9. Both in the observation and therapy periods, the sublingual temperatures are found to increase slightly with time from waking up. Amount of this increase in 30 minutes is almost the same in both periods. A careful evaluation may indicate that the standard deviation is slightly lower in the therapy period than in the observation period. Since the typical fluctuation of human body temperature is a range of 0.6 - 0.7 ºC [11], the above-mentioned difference in the standard deviation is considered to indicate a promising effect of the apparatus.

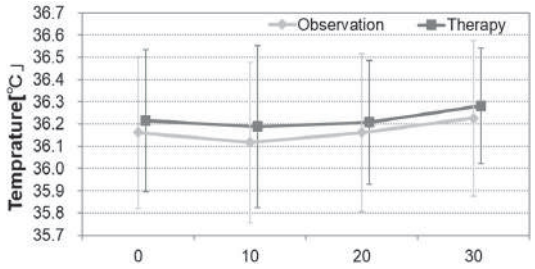


Fig 9. Average of sublingual temperature for six subjects.

Figure 10 shows the average number of correct answers in the Kraepelin test for six subjects. There is almost no difference between the two periods on the first day, but after that, it can be seen that the number of correct answers is larger in the therapy period than in the observation period. This result probably means that the arousal level or activity level increases by use of the light therapy apparatus. Results after summarizing the OSA response for six subjects are shown in Figs 11 (a)-(e) with respect to the first to fifth factors, respectively. The meanings of these factors are as follows; 1st for "sleepiness on rising", 2nd for "initiation and maintenance of sleep", 3rd for "frequent dreaming", 4th for "refreshing", and 5th for "sleep length". In Fig 11, the results of (a),(b),(d) and (e) show that the scores are slightly higher in the therapy period than in the observation period. On the other hand, Fig 11 (c) shows higher score in the observation period than in the therapy period. The analysis of variance gives $P = 0.11$ for the first factor, $P = 0.24$ for the second factor, $P = 0.24$ for the fourth factor, and $P = 0.11$ for the fifth factor. Since we have $P > 0.05$, there was no significant difference between the two periods, and the null hypothesis is adopted and no interaction was observed. It is, however noticed that there are many days with high scores in the therapy period. Figure 12 shows results of SSS indicating the arousal index. Values of the index are in almost the same range for day time both in the therapy and observation periods. However, the values are found to increase in 30 minutes after waking up more in the therapy period than in the observation period, which indicates that the subjects felt more active with the light therapy. The analysis of variance gives $P = 0.054$ and is close to 0.05, which is considered to be of significant reliability.

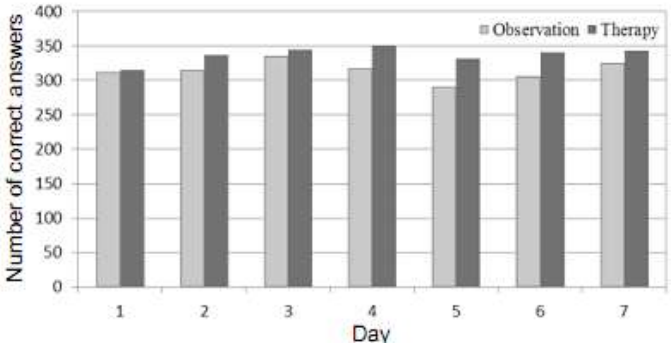
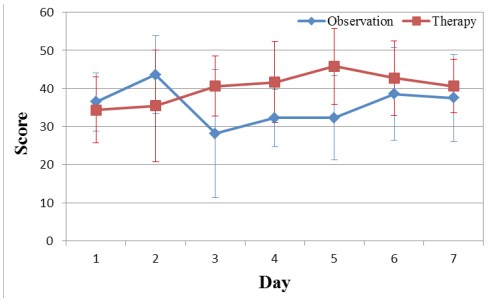
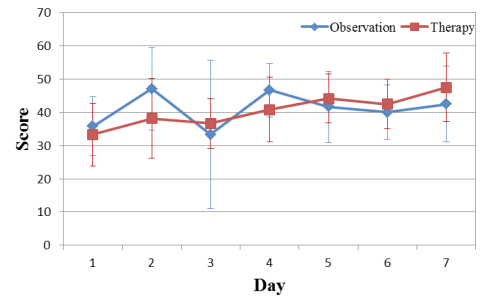


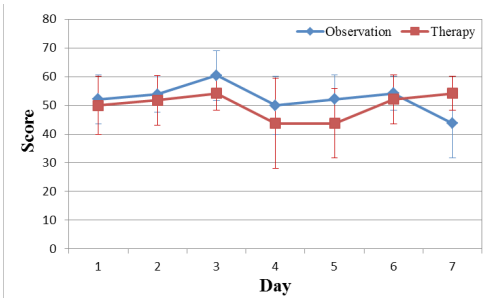
Fig 10. Average of results in the Kraepelin test for six subjects.



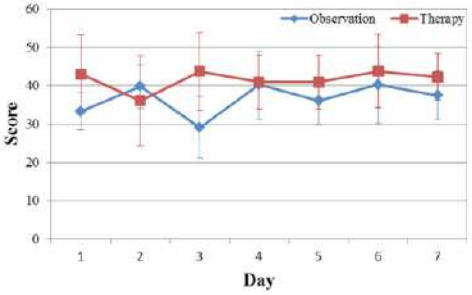
(a) Sleepiness on rising (1st)



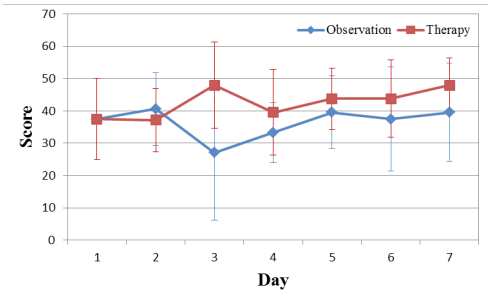
(b) Initiation and maintenance of sleep (2nd)



(c) Frequent dreaming (3rd)



(d) Refreshing (4th)



(e) Sleep length (5th)

Fig11. Results of the OSA response for five factors.

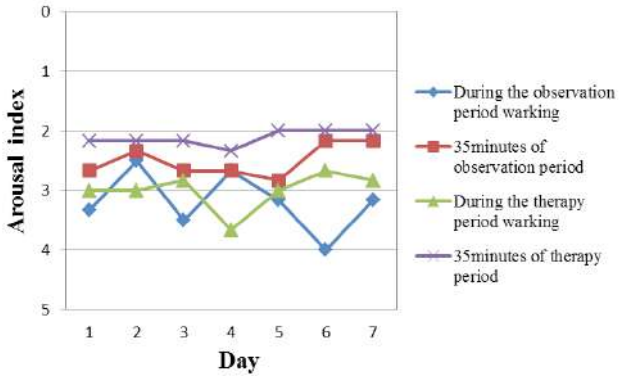


Fig 12. Results of SSS (arousal index of each period and time).

5 Conclusion

In this paper, we described the outline of newly-developed light therapy apparatus and its usefulness. From the results of the evaluation experiments, the light therapy effect of the apparatus can positively be confirmed. Since this kind of experiment is likely to be affected by individual differences, it is necessary to increase the number of subjects in the future and to improve the reliability of results. This apparatus may be widely applied not only to sleep disorder but also for improvement of cases such as depression, shift work, jet lag etc. in the near future.

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