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The phototherapy light visor: More to it than meets the eye

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Abstract (Document Summary)

A study was conducted to ascertain whether phototherapy light visors provide an effective treatment for seasonal affective disorder. Results suggest that the phototherapy light visor may function as an elaborate placebo.

Full Text (4367 words)

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Seasonal affective disorder is a common illness that affects about 6% of the general population (1, 2). To date, over 20 placebo-controlled studies of light therapy have been conducted to determine efficacy and subject response and tolerance (3, 4). Light therapy was initially administered by having individuals

sit for at least 2 hours per day in front of fluorescent bulb units that delivered 2,500 lux of light head-on at a distance of 3 feet. Light boxes have since been redesigned to deliver an intensity of 10,000 lux at a distance of 12 inches on a downward angle (5). Despite their efficacy in treating symptoms of fall-winter seasonal affective disorder, light boxes are neither portable nor mobile. For these reasons a head-mounted portable light delivery unit, the light visor, was devised (6). The visor provides greater mobility, convenience, and portability and delivers a consistent dose of light because of the fixed relationship between the light source and the eyes.

Two previous studies that examined the efficacy of the light visor have produced unexpected results. In a three-center study, Rosenthal and colleagues compared the efficacy of a bright (6,000-lux) visor with a relatively dim (400-lux) visor in 55 subjects (6). While the bright visor produced a complete clinical response for 26.6% of the subjects, the dimmer unit was nonsignificantly better ($p < 0.07$) and produced complete response for 56% of the patients. Subsequently, Joffe et al. (7) compared three intensities of light visors (60, 600, and 3,500 lux) in a five-center study of 105 patients with seasonal affective disorder. Confounding expectations, all three intensities proved essentially equivalent, with reported response rates of 38%-47%. Such unanticipated findings suggest that the light visor may work in a manner that is qualitatively different from previously evaluated phototherapy units, which calls into question some of the assumptions about the nature of an effective light therapy stimulus. Two possible interpretations exist. First, the light visor, while providing partial or total remission in many patients, may be nothing more than an elaborate placebo treatment. Second, the visor may produce a response at stimulus intensities previously believed to be ineffective. The purpose of this study was to extend the methods of the previous two studies by comparing a visor that emitted a moderately bright light intensity with a visor so dim that we would not have predicted it could be effective by any mechanism other than a placebo effect.

The crucial aspect of this investigation was to devise an inactive control visor that was similar enough to existing devices to remain plausible to subjects as a potentially effective treatment. Dim light has been used as a control in previous light therapy trials (3) and appears to generate equal expectations of improvement on the part of subjects. These expectations have been confirmed in previous treatment studies (6, 7). However, the surprising results of dim light conditions suggest that if the visor is not a placebo treatment, then it may be effective at relatively low intensities. Hence, the placebo needed to be more than just dim. Prior research has suggested that moderately intense red light delivered by a regular light fixture may be ineffective (3) and that bright red light may be less effective than white light (8) or green light (9) in the treatment of seasonal affective disorder. Research has also suggested that brief exposure to moderately intense light is less effective than longer exposure (3). Hence, a placebo visor was designed to incorporate all three factors that would tend to reduce its efficacy. The placebo visor was dim (30 lux), red (> 600 nm), and administered for short durations (30-minute treatment periods). This device was compared to a similar visor that delivered 600 lux of white light during the same exposure period.

METHOD

A blind, random comparison study was conducted at two centers that provide consultation and treatment for patients with seasonal affective disorder. Subjects received 2 weeks of baseline ratings and then 2 weeks of daily light visor treatment, which was followed by 1 week of withdrawal. Those subjects with ophthalmological disorders (other than corrective refractive problems) and serious medical disorders were excluded. Patients currently receiving medications were required to maintain consistent doses during the entire investigation. Those who were on concomitant antidepressant regimens had to have been taking the same dose for at least 4 weeks before the study to be eligible. Each subject was shown the light visor and wore it briefly before treatment to rate his or her expectations of treatment response. Expectations were also rated after the first and second week of visor treatment. Dark wrap-around sunglasses were worn whenever the subjects went out in daylight to minimize possible confound effects of environmental light exposure. Sleep logs were kept during the entire course of the study, and participants were asked to maintain a regular sleep and wake pattern. On the basis of previous studies and initial power analyses, a minimum total group size of 40 patients was estimated to be necessary to detect a difference between an effective visor (an approximate response rate of 40% and more than 50% reduction in mean depression scale score) and a placebo (response rate under 20% and less than 30% reduction in depression scale score) at the $p = 0.05$ level.

Adults of either sex aged 15-71 were recruited for study by clinical or self-referral or by newspaper advertisement. Patients were recruited during one fall-winter season: November through January for the Washington, D.C., site and November through February for the Boston site. Subjects were evaluated by a clinician experienced in the diagnosis and treatment of seasonal affective disorder. After giving informed consent, each subject received the Structured Clinical Interview for DSM-III-R--Patient Version (10) to determine axis I diagnoses. Detailed assessment of their seasonal pattern was collected, and each subject fulfilled Rosenthal-National Institute of Mental Health criteria for seasonal affective disorder (1) and DSM-III-R criteria for either recurrent major depression with seasonal variation or bipolar disorder (depressed or not otherwise specified) with seasonal variation. Separate randomization sequences were applied to premenopausal women and to men and postmenopausal women because of possible differential response rates to antidepressant treatment.

Each subject received 30 minutes of phototherapy daily and used the light visor between the hours of 6:00 a.m. and 9:00 a.m. The visor, a research model supplied by Bio-Brite (6), contained two 2.6-W krypton incandescent bulbs that were powered by a rechargeable battery. Subjects were randomized to treatment with a visor that emitted either 600 lux of white light or 30 lux of red light. The red light visor was constructed by using a number 27 filter that transmitted 4% of the light and excluded light transmission at wavelengths below 600 nm. The intensity of each unit was adjusted to within 10% of specification by positioning the bulbs (which alters the focal length of the device) or by use of neutral density filters, as verified each week with a precision research lux meter.

Each subject received baseline and weekly symptom assessment with the Structured Interview Guide for the Hamilton Depression Rating Scale--Seasonal Affective Disorders Version (11). This instrument is reliable and well-validated and includes items from the 21-item Hamilton Depression Rating Scale along with eight atypical depressive items common to seasonal affective disorder (hypersomnia; carbohydrate craving; increased appetite, eating, and weight; fatigue; social withdrawal; and type B diurnal variation). Subjects with a total score greater than 19 (with a score on the Hamilton depression scale greater than 9) were eligible for inclusion. Raters were blind to the treatment the subjects received. Clinical global improvement was also assessed at the end of treatment; however, the depression scale score was the primary outcome measure. Participants had to complete 2 weeks of baseline evaluation and at least 1 week of phototherapy with depression ratings for inclusion in the analysis. Data were evaluated by using endpoint analyses. We hypothesized, a priori, that the group that received the 600-lux white light visor would 1) show a greater reduction in depression scale scores from baseline, 2) have a greater percentage of subjects with a significant clinical response (at least a 50% reduction in Hamilton depression scale score), and 3) have

greater percentage of subjects experiencing complete recovery (at least a 50% reduction in Hamilton depression scale score and a final score of less than 8).

RESULTS

The 57 individuals who participated in the study were predominantly women (N=48) and had a mean age of 41.5 years (SD=11.6). The randomization sequence resulted in 28 patients (49.1%) receiving the 30-lux red light visor, while 2 patients (50.9%) received the 600-lux white light unit. Table 1 shows the concomitant medications of patients upon entry into the comitant medications of patients upon entry into the study. Medications included antidepressants (19.3%, N=11) and anxiolytics (14.0%, N=8); 40.4% (N=23) were medication free. (Table 1 omitted) There were no significant differences between light visor groups in age, gender, or degree of concurrent medication use. There were also no significant differences between light visor groups or test centers in mean baseline scores on the Hamilton depression scale (F=1.43, df=1, 54, p>0.20) or scores for atypical depressive symptoms (F=0.84, df=1, 54, p>0.30) (table 2). (Table 2 omitted) Similarly, there were no differences between the groups in their degree of initial expectation of effectiveness. Patients assigned to the red light visor expected the device to be, on average, 63.6% effective, and patients assigned to the white light visor expected this device to be 65.2% effective (F=0.19, df=1, 37, p>0.60).

Depression scores were compared between the second baseline week and treatment endpoint. For all but three patients (who terminated the study prematurely after 1 week of visor treatment because of lack of response or worsening condition), endpoint was the second week of treatment. Overall, there was a substantial decline in depression scores during visor treatment. For the entire cohort, Hamilton depression scale scores fell 37.9%, from 16.9 to 10.5 (F=35.9, df=1, 56, p<0.0001), and scores for atypical depressive symptoms fell 47.0%, from 14.9 to 7.9 (F=54.8, df=1, 56, p<0.00001). However, contrary to our expectations, there were no differences in response between patients who received treatment with red or white light (table 2). Mean Hamilton depression scale scores declined by 34.6% for subjects given white light treatment and by 40.9% for subjects given dim red light (F=1.04, df=1, 52, p>0.30). Similarly, scores for atypical depressive symptoms fell by 44.1% for patients assigned bright white light visors and by 49.0% for patients assigned dim red light visors (F=0.71 df=1, 52, p>0.40). Results were comparable between the two centers, since there were no significant main effects of center location or any significant center-by-treatment interactions.

There were also no differences between treatment groups in the percent of patients who had a 50% or greater reduction in scores on the Hamilton depression scale (red light visor: 46.4%, N=13; white light visor: 44.8%, N=13) (p>0.90, Fisher's exact test) or who obtained a final Hamilton depression scale score of less than 8 (red light visor: 46.4%, N=13; white light visor: 44.8%, N=13) (p>0.90, Fisher's exact test). Full clinical remission (operationally defined as at least a 50% reduction in score on the Hamilton depression scale and a final score less than 8) occurred in 39.3% (N=11) of patients who received red light and 41.4% (N=12) of patients who received bright white light (p>0.90, Fisher's exact test). Overall, there were no significant differences in therapeutic outcome between patients treated with red or white light visors.

The only factor that appeared to exert any effect on response was age. Initial scores for atypical depressive symptoms varied across age, declining about two points per decade as age increased ($r=0.43$; $F=12.59$, $df=1, 52$, $p<0.001$). In contrast, scores on the Hamilton depression scale did not vary with age ($F=0.16$, $df=1, 52$, $p>0.60$). The response of atypical depressive symptoms to light therapy was also mildly age dependent ($r=0.28$; $F=6.09$, $df=1, 52$, $p<0.02$). Overall, mean percent improvement in scores for atypical depressive symptoms from baseline to endpoint (regardless of visor color) declined about 10 percentage points per decade as age increased. In contrast, the effect of light treatment on Hamilton depression scale scores was not significantly age dependent ($F=1.40$, $df=1, 52$, $p>0.20$).

A subset of 46 patients (23 from each visor group) were evaluated 1 week after discontinuation of phototherapy to ascertain whether there were group differences in initial relapse rate. In this subgroup there were numerical, but not statistically significant, increases in depression score. Mean scores on the Hamilton depression scale increased from 10.5 to 12.4 ($F=1.42$, $df=1, 43$, $p>0.20$), and scores for atypical depressive symptoms increased from 7.9 to 11.7 ($F=3.24$, $df=1, 43$, $p=0.08$). There were no significant group differences in depression scores during this 1-week withdrawal period (table 2). The number of patients in full clinical remission during the withdrawal period fell from eight to two in the red light visor subgroup and from 11 to five in the white light visor subgroup. Although a greater percentage of patients treated with red light visors appeared to relapse after treatment discontinuation (75.0% versus 54.5%), this difference could have easily occurred by chance ($p>0.74$, Fisher's exact test).

Overall, no statistically significant differences were found between patients assigned to red or white light visors in either their degree of treatment response or withdrawal. These negative findings were based on age-covaried analyses, since age exerted a significant effect on initial scores and degree of response of the scores for atypical depressive symptoms. No differences emerged between groups without age correction or with additional covariates for gender or initial expectation. In short, we could find no evidence for a therapeutic difference between dim red or bright white light visors. Given the group size and variability of the measures, this study had sufficient statistical power (0.80) to detect a difference of 17 points between visor groups in degree of improvement, with $\alpha=0.05$ (12). A priori, we assumed that there would be a 20-25-point difference in percent improvement between an effective treatment and a placebo. Since there was less than a seven-point difference between visor types and it was in the wrong direction (i.e., dim red light showed greater improvement than bright white light), a type II error is unlikely.

DISCUSSION

We sought to ascertain whether the phototherapy light visor was more effective than placebo treatment by using, in our best judgment, a credible placebo that should have exerted no direct therapeutic effect. Thus, the red light visor was designed to be as dim as possible but still perceptible and believable. Evaluation of initial expectancy scores indicated that this was a credible placebo, since patients had the same expectations for therapeutic effect with the red light visor as they did with the brighter white light visor. To our surprise, both visors exerted equal therapeutic effects.

Our findings, which demonstrated comparable efficacy of two phototherapy visors of different intensities, were remarkably similar to previous studies that evaluated the efficacy of phototherapy visors (6, 7). Overall, no significant differences have been found between visors of different intensities and light colors on degree of therapeutic response.

There are three major ways of interpreting this finding. The first hypothesis is that the light visor is nothing more than an elaborate placebo. We cannot reject the null hypothesis, since we have failed, despite our best efforts, to find any association between the intensity or spectral properties of the visor and therapeutic effect. It is well known that the process of adjusting light intensity in the context of a research study exerts beneficial effects on human performance whether the intensity is raised, lowered, or left unchanged—a phenomenon known as the Hawthorne effect (13). This paradigm serves as an important reminder that "placebo" response is not limited to medications or medical treatments, and a Hawthorne effect may well explain the results of the visor studies. The only factor that leads us to entertain possible alternative explanations is the fact that the therapeutic response rate to the placebo condition in this study (39.3%) was substantially greater than what has been found in previous controlled studies. For instance, pharmacological placebos have been used in two published studies (involving 37 patients) that provide individual data (14, 15). Complete recovery rates with drug placebos were only 15.8% and 16.6%, respectively. Dim white light box placebos (5-300 lux) have been used in six studies (66 patients), with average recovery rates of 13.6% (3). Red light treatments have also been used in three studies (37 patients), with average recovery rates of 18.9% (3, 9, 10). Hence, previous placebo-controlled studies have indicated only a modest recovery response rate of 15.7%, versus a 40.4% recovery rate in the present study ($p<0.0005$, Fisher's exact test). It is possible that wearing a light visor might provide a sufficiently novel and interactive experience so as to create a greater placebo effect than seen with light boxes in earlier studies. On balance, response to both red and white light visors was not significantly different than recovery rates after active treatment with 2,500 lux for 2 hours each morning, which produced an average recovery rate of 53% across 17 studies that involved 172

subjects ($p > 0.12$, Fisher's exact test [3]). In short, if the visor is merely a placebo, we need to explain the unusually high response rates.

One possibility is that the placebo response rate may be rising over time as the general population becomes more familiar with the concept of seasonal depression, which is supported by results of the most recent pharmacological studies. Oren et al. (16, 17) observed in two recent double-blind, placebo-controlled trials that five of 12 patients who received placebo in an L-dopa study and four of 13 subjects who received placebo in a trial of cyanocobalamin showed complete clinical recovery (at least a 50% reduction in score on the Hamilton depression scale and a final score of less than 8). Thus, these most recent studies suggest that response of patients with seasonal affective disorder to pharmacological placebo may have increased from about 16% in 1988-1989 (14, 15) to 36% at the present time. If the placebo response rate to sham phototherapy has increased to a similar extent, it is certainly conceivable that the 40.4% recovery rate (for subjects given red and white light visors) observed in the present study is largely a placebo response. It is also possible that other uncontrolled factors (instructions to patients, degree of rapport, presumed reputation of investigators or institutions) may have elevated the placebo response rate in this study.

An alternative hypothesis is that the dim red light visor is a moderately effective treatment for seasonal depression that works through an unusual mechanism. Visor illumination comes in indirectly from above and probably illuminates a narrow region of the retina outside of the fovea. It is conceivable that the visor may be stimulating a portion of the retina most involved in the retinal-hypothalamic pathway. It is also likely that the visor may stimulate a portion of the retina heavily populated by rods that are sensitive to dim red light. The visor differs from the light box in that it maintains a fixed relationship and a fixed proximity to the eyes. Also, use of dim red light in the early morning, shortly after awakening, may allow the treatment to occur while the eyes are still dark adapted. Brighter white light, from visor or light box, probably produces rapid light adaptation. Thus, it is conceivable that dim red light may be effective through a number of retinal mechanisms.

A third alternative is that the light visor may function as a moderately effective treatment for seasonal depression, but its efficacy may have little or nothing to do with its photic properties. Some evidence suggests that light therapy may work by enhancing or entraining circadian rhythms, which may be attenuated (18), phase-delayed (19), or poorly entrained (20) in patients with seasonal depression. Bright white light may be an effective stimulus that corrects these circadian abnormalities. The ritual of donning a light visor, at a fixed time in the early morning, may function as a zeitgeber (time cue) that also affects the circadian clock.

Overall, the efficacy of light visor treatment has been assessed in three controlled trials that involved seven centers and 217 patients. On average, light visors (including placebos) have produced full clinical remission for about 40% of patients. Therapeutic outcome appears to have no direct relationship to intensity (from 30 lux to 6,000 lux), color (red versus white), or duration (30-60 minutes). Visor treatment appears to be better than early placebos (15.7% recovery rate, $N=140$), at least as effective as 30-minute treatment with a 2,500-lux light box (32% recovery rate, $N=65$ [51]), and almost as effective as 2 hours of 2,500-lux morning light (53% recovery rate, $N=172$ [3]). On the other hand, the visor appears to be less effective than 30 minutes of 10,000-lux morning light (79% recovery rate, $N=24$ [5]), and was no more effective than drug placebo used in two recent double-blind studies (36% recovery rate, $N=25$ [16, 17]).

For clinicians who treat patients with seasonal affective disorder, it should be noted that the Bio-Brite light visor sold commercially is structurally different from the research light visor used in the multicenter studies, but there is no reason to believe that its effectiveness would be any different. The limited state of our knowledge indicates that visor treatment is well tolerated (6, 21), and its use is accompanied by a moderate reduction in depression ratings, although this benefit may be largely or entirely a placebo response. The lack of relationship between visor intensity and response rate places the clinician in a bind, since we have no guidelines on how to adjust the light visor to optimize effectiveness. On balance, 30 minutes of 10,000-lux light therapy daily from an angled light fixture appears to be a better first choice for treatment of seasonal affective disorder. Light visors may be useful for patients who travel extensively and require portable treatment. However, we must keep in mind that the results from three multicenter studies provide no scientific evidence that the light visor affords greater therapeutic efficacy than placebo. The light visor appears to function quite differently from the light box, in which there is a direct relationship between intensity and clinical response (3). The 10,000-lux light box produces a twofold greater complete remission rate than the visor (5), and our concerns about the light visor acting as a placebo do not extend to the light box.

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