Light therapy for seasonal affective disorder in primary care

Randomised controlled trial

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Background Studies of light therapy have not been conducted previously in primary care.

Aims To evaluate light therapy in primary care.

Method Fifty-seven participants with seasonal affective disorder were randomly allocated to 4 weeks of bright white or dim red light. Baseline expectations for treatment were assessed. Outcome was assessed with the Structured Interview Guide for the Hamilton Depression Scale, Seasonal Affective Disorder Version.

Results Both groups showed decreases in symptom scores of more than 40%. There were no differences in proportions of responders in either group, regardless of the remission criteria applied, with around 60% (74% white light, 57% red light) meeting broad criteria for response and 31% (30% white light, 33% red light) meeting strict criteria. There were no differences in treatment expectations.

Conclusions Primary care patients with seasonal affective disorder improve after light therapy, but bright white light is not associated with greater improvements.

Declaration of interest The study was funded by the Chief Scientist Office of the Scottish Executive Department of Health.

Although three recent trials and a meta-analysis report that bright white light is an effective treatment for seasonal affective disorder (SAD) (Eastman *et al*, 1998; Lewy *et al*, 1998; Terman *et al*, 1998; Thompson *et al*, 1999), research to date has focused upon highly (self-) selected participants, often recruited by advertisement or from specialist referrals (Wirz-Justice, 1998). A trial of light therapy focusing on a relatively unselected patient population has not been undertaken. Our previous work (Eagles *et al*, 1998, 1999*a*,*b*) has demonstrated that community rates of SAD in the north-east of Scotland are of the order of 3.5%, that SAD sufferers consult their general practitioners (GPs) significantly more frequently than controls, and that they consume significantly higher levels of National Health Service (NHS) resources throughout the year. None the less, routine diagnosis and treatment of SAD in primary care is rare, and we hypothesised that there may be large numbers of people who would benefit if light therapy is effective. Thus, we undertook a randomised controlled trial of bright white versus dim red light therapy for SAD patients identified through primary care screening.

METHOD

Study design and selection criteria

During two weeks of January in 1997 and 1998 (as previously described in Eagles *et al*, 1998, 1999*a*), attenders aged 16–64 years at each of 11 large general practices in Grampian were asked to complete the Seasonal Pattern Assessment Questionnaire (SPAQ; Rosenthal *et al*, 1987). Those fulfilling SPAQ criteria for SAD (Kasper *et al*, 1989; Rosen *et al*, 1990; Magnusson & Stefansson, 1993) were invited for interview with a psychiatrist before the end of February. This comprised a clinical assessment to determine whether participants fulfilled DSM–IV criteria for recurrent major depressive episodes with seasonal pattern (American Psychiatric Association, 1994). In addition, to be a 'confirmed case', participants had to score 15 or more on the Structured Interview Guide for the Hamilton Depression Rating Scale, Seasonal Affective Disorder Version (SIGH–SAD) (Terman & Williams, 1994; Williams *et al*, 1994), with a score of at least 6 on the atypical symptoms. Participants satisfying these criteria in the winter of screening were monitored from the following October by weekly completion of the self-rating version of the SIGH–SAD (SIGH–SAD–SR) (Williams *et al*, 1994), which has been shown to produce results consistent with the interview-administered version (Terman *et al*, 1991, 1994). On satisfying the winter 2 criteria for SAD (a minimum total of 18 on the SIGH–SAD, with at least 8 on the atypical items score) and again fulfilling DSM–IV criteria for a major depressive episode, they became eligible for entry to the trial. They were asked to consent to participate in a trial comparing 'two different types of light therapy in order to see if one is more beneficial than the other'. Participants who gave written informed consent were randomly allocated to either bright white light or dim red light, using a minimisation (Pocock, 1983) to ensure balance between the two groups for age, gender and current antidepressant therapy. Participants' GPs were not informed of the group to which each participant was allocated. Nobody was entered into the trial after mid-January, to avoid confusion between treatment effects and natural springtime remission.

Treatments

All participants received light-boxes containing three 36 W bright white series tubes with either a clear filter, giving bright white light at 10 000 lux (bright white group), or a red filter, giving dim-red light at 500 lux (dim red group). Investigation of different parts of the light spectrum suggests that although light at the green/blue end of the spectrum may be effective, red light is not (Oren *et al*, 1991). To determine the correct distance to obtain either 10 000 lux (white) or 500 lux (red), intensities were measured for each light-box using an illuminometer. The distance between the light-box and the participants' eyes was generally around 20 inches. Light-boxes were delivered to and set up for participants, and they were advised that the most beneficial time of use would be mornings, but that use before

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7 p.m. would be acceptable. They were instructed to use the light-box for 30 min a day for the 1st week, 45 min a day for the 2nd week and up to 1 h a day for the remaining 2 weeks of treatment. Boxes were positioned on a flat surface, with the participant at an angle of approximately 30° to the light, with their eyes at mid-fixture level. They were instructed not to stare directly at the light but to gaze across at it once or twice a minute.

Assessment and measures

Participants completed the SIGH–SAD–SR at baseline, weekly during the 4 weeks of treatment, and at 2 and 6 weeks after completion of treatment. During the treatment phase, participants also rated their mood and energy at the end of each day on a scale of −10 to +10 (Eagles, 1994). The mean daily mood and energy levels over each week were used in the analysis.

In order to assess participants' general expectations for light therapy and their specific expectations in respect of their allocated light-box, expectations were measured just before and just after the light-box was set up and switched on, using a four-item expectation questionnaire (Hardy *et al*, 1995). Briefly, participants were asked to rate, on scales of 1–7, how 'logical', 'useful' and 'successful' they thought light treatment would be and whether they would 'recommend' it to a friend.

Statistical analysis

The primary outcome variable was response to treatment at 4 weeks, defined and analysed in three ways: a total SIGH–SAD–SR score of less than or equal to 50% of the baseline total score and a total score of less than or equal to 8 (strict remission criteria); a total SIGH–SAD–SR score of less than 18 and an atypical score of less than 8 (intermediate remission criteria); and a total score less than or equal to 50% of the baseline total (broad remission criteria). The difference in the proportion of responders at week 4 was estimated, together with 95% confidence intervals for the difference.

Differences between the two groups in continuous data were assessed using Student's *t*-test for normally distributed data or the Mann–Whitney test for non-normally distributed data. Categorical response data were analysed using the χ^2-test with Yates correction. The Pearson correlation coefficient was used to measure the relationship between continuous variables, and the Spearman rank correlation was used for non-normally distributed data.

Secondary outcomes included the total SIGH–SAD–SR score at week 4 in an analysis of covariance (ANCOVA) with the baseline SIGH–SAD–SR score as the covariate. A secondary repeated-measures ANCOVA was used to investigate differences between groups in total scores over time (weeks 1–4). Other secondary outcomes included mood and energy levels and expectations.

For the primary outcome, a 5% significance level was used on a two-tailed test, with 95% confidence intervals calculated where appropriate. A 1% significance level on a two-tailed test was used for secondary outcomes. Analysis was by intention to treat. It was estimated that a sample of 41 patients in each group would yield 80% power to detect at the 5% level of significance a 30% difference between the groups in the proportions of responders at 4 weeks.

RESULTS

Of 59 participants who fulfilled inclusion criteria, 57 entered and completed the trial. The remaining two were randomly allocated, one to white and one to red light, but dropped out prior to commencing treatment. The mean (s.d.) age was 41 (10) years (range 24–62). Thirty-two participants (30 women) were randomly allocated to white light and 25 (22 women) to red light (Table 1).

Expectation ratings

Participants' baseline expectations for treatment prior to seeing the allocated light-box were not significantly different between the two groups (Table 1), and were generally high, with the medians all in excess of the mid-point of 4 for all four questions. Expectations after allocated light-boxes were seen and switched on were not significantly different between the two groups (Table 1).

Response to treatment

Table 2 shows the number and per cent of participants who met the specified criteria for response to treatment at 4 weeks. There were no statistically significant differences between the two light treatment groups when analysed using χ^2 tests with Yates correction, regardless of the response criteria employed.

The SIGH–SAD–SR scores

Both groups showed a marked decrease in SIGH–SAD–SR scores, with no clear

Table 1 Description of groups at trial entry

	Randomised treatment	
	White light	Red light
Total number of patients recruited	32	25
Age, mean (s.d.)	42.32 (9.2)	40.56 (10.9)
Gender, *n* (%)		
Male	2 (6.3)	3 (12.0)
Female	30 (93.8)	22 (88.0)
Baseline total SIGH–SAD–SR, mean (s.d.)	34.91 (9.9)	34.69 (7.9)
Baseline expectations, median (IQR)		
Logical	6.0 (5.0, 7.0)	6.0 (5.0, 7.0)
Useful	5.0 (4.0, 7.0)	5.0 (4.8, 7.0)
Successful	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)
Recommend	6.0 (4.0, 6.0)	5.0 (4.0, 7.0)
Post-light-box expectations, median (IQR)		
Logical	6.0 (5.0, 7.0)	6.0 (5.0, 7.0)
Useful	6.0 (5.0, 7.0)	5.0 (4.3, 6.8)
Successful	5.0 (5.0, 6.0)	5.0 (5.0, 6.0)
Recommend	6.0 (5.0, 6.0)	5.0 (4.0, 7.0)

IQR, interquartile range.

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Table 2 Response rates at 4 weeks using strict (a), intermediate (b) and broad (c) remission criteria

	Randomised treatment		Difference in proportions (%) (95% CI)	*P*
	White light (*n*=27)	Red light (*n*=21)		
Response rates, *n* (%)				
(a) Total SIGH–SAD–SR score ⩽50% baseline and ⩽8	8 (29.6)	7 (33.3)	3.7 (−30 to 22)	0.39
(b) Total SIGH–SAD–SR score <18 and atypical <8	17 (63.0)	12 (57.1)	5.8 (−22 to 33)	0.34
(c) Total SIGH–SAD–SR score ⩽50% baseline	20 (74.1)	12 (57.1)	16.9 (−10 to 43)	0.11

differences between the groups (Fig. 1). Both the typical and atypical scores decreased each week by similar magnitudes, regardless of the treatment group. In the ANCOVA of total SIGH–SAD–SR scores at week 4, only those with complete data for all time points were included in the analysis (27 white light and 21 red light, *n*=48) (Table 3). There was no significant difference between the two light treatments in terms of the total SIGH–SAD–SR scores at week 4. However, in a repeated-measures ANCOVA, the differences in SIGH–SAD–SR ratings between weeks in the pairwise comparisons were highly significant (F=20.61, d.f.=3, $P<0.001$), confirming both treatment groups' improvement over the 4 weeks of treatment. The overall decrease from week 1 to week 4, calculated using estimated marginal means, was 48% for white light and 42% for red light. When the same analyses were repeated for all 57 participants' data, by using the method of last value carried forward to substitute for any missing values the results were statistically similar.

There were no significant correlations between participants' expectation ratings and SIGH–SAD–SR scores at each time point in either group. The correlation between the total expectation score (sum of the four expectation ratings after seeing the allocated light-box) and the degree of change in SIGH–SAD–SR scores from weeks 1 to 4 in the white light group was 0.182 (P=0.363) and in the red light group was −0.237 (P=0.3143).

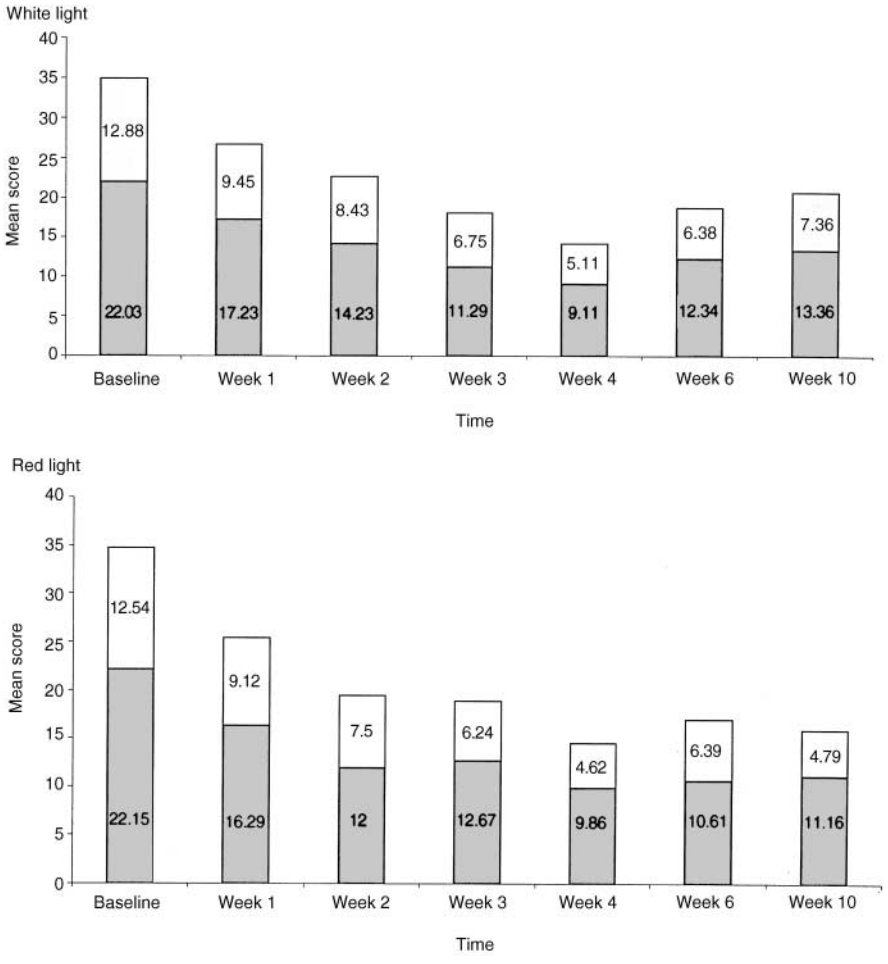

Fig. 1 The SIGH–SAD–SR scores according to typical (▩) and atypical (□) symptoms.

Daily mood and energy ratings

The mean mood and energy ratings, smoothed using a centred moving average measurement, are shown in Fig. 2. Both increased over the 4 weeks for both treatment groups. There was no significant difference between the groups' mean mood or energy levels at week 4. There was a non-significant trend towards higher ratings of mood and energy in participants with red-light-boxes. There were significant inverse correlations between weekly mean mood and energy levels and total SIGH–SAD–SR scores at each time point (ranging from −0.90 to −0.56, $P<0.01$).

DISCUSSION

Main findings

This is the first reported evaluation of light therapy for SAD in a primary care setting. Both bright white and dim red light were associated with clinically significant reductions in SIGH–SAD–SR scores, but with no evidence of any difference between them.

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Table 3 Analysis of total SIGH–SAD–SR score at week 4: results from analysis of covariance

	Mean (s.e.)	*P*	95% CI for estimate
Group difference in SIGH–SAD–SR scores	−0.804 (2.34)	0.73	(−5.53 to 3.92)
		Mean (s.e.)	95% CI for mean
Adjusted means (s.e.)[1]			
White light		13.92 (1.6)	(10.80 to 17.04)
Red light		14.72 (1.8)	(11.18 to 18.26)

1. Adjusted for baseline total SIGH–SAD–SR score.

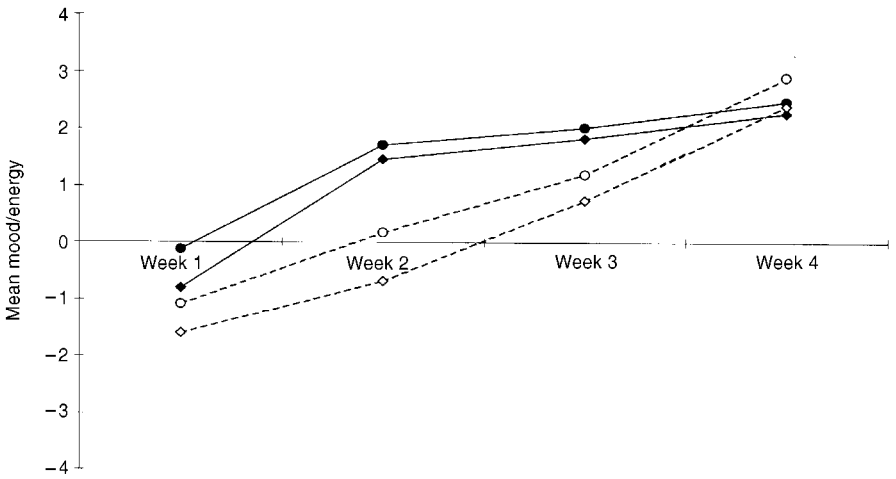

Fig. 2 Mean mood ratings for white light (○) and red light (●) and mean energy ratings for white light (◇) and red light (◆).

Comparisons with previous studies

Comparisons between evaluations of light therapy are complicated by methodological variation, particularly in recruitment methods and eligibility criteria, whether and which control treatments are employed, whether and how treatment expectations are measured and in definitions of response to treatment. None the less, our finding that SIGH–SAD–SR scores at the end of treatment were significantly reduced after light treatment is consistent with previous findings, including the two most recently reported randomised controlled trials (Eastman *et al*, 1998; Terman *et al*, 1998). In addition, the SIGH–SAD–SR scores of both treatment groups in the present study are strikingly similar to those in previous studies.

It is in the lack of a clear difference between treatment and control groups in the proportions of participants defined as responders or remitters that the current study is not consistent with those recent trials, both of which used negative ion generator controls, in one case deactivated. Using relatively broad criteria, the proportion of responders in treatment and control groups in the current study was around 60%. This rate of broadly defined response to a presumed active treatment for SAD is consistent with the literature, whether to bright white light (e.g. Eastman *et al*, 1998; Terman *et al*, 1998) or to fluoxetine (Lam *et al*, 1995). Indeed, when Eastman *et al* also used a broad definition, there was no clear difference between bright white light and dummy negative ion control. The application of more stringent criteria in the current study reduced the response rate to bright light to 33% at week 4, which is no better than the response rate to the red light control or the usual placebo response rates in non-seasonal depression (e.g. Eastman, 1990; Brown, 1994; Moncrieff *et al*, 1998). This is in contrast to the recent (negative ion control) trials where strictly defined response rates to bright light were of the order of 50–65%, which is significantly greater than the control response rates of 30–40%. The current results are more similar to studies of bright light versus dim light controls, often using head-mounted visors, where bright light was not shown to be superior (Joffe *et al*, 1993; Rosenthal *et al*, 1993; Teicher *et al*, 1995; Levitt *et al*, 1996). In the most recent trial of this type (Meesters *et al*, 1999), bright white light and infrared light were equally effective and superior to the no-light control condition.

Choice of control or placebo conditions

A review of studies of light therapy, where the control was usually light of a lower intensity and sometimes a different colour (as in the current study), concluded that although bright light had been shown to be superior to the dim light control, such superiority might be little more than a placebo effect because participants' expectations often predicted response or that responders had a higher expectation than non-responders (Terman *et al*, 1996). In the current study, treatment expectations were not significantly different in the two groups and were not correlated with treatment outcome. Although Eastman *et al* (1998) report no difference in expectations between groups, and Terman *et al* (1998) report no correlation between expectation and response, both papers conclude from these findings that their reported superiority of light therapy is mediated through a specific antidepressant effect beyond its placebo effect. Our own findings are not consistent with that conclusion. However, it may be that dim red light should not be considered as an inactive or inert placebo but as an active placebo (mimicking all the non-specific effects of an active treatment) or as an alternative form of active light treatment. The dummy negative ion generator, with fewer obvious similarities to a light-box, might be considered an inert placebo. An interpretation in terms of an active placebo might help to explain why our findings are consistent with earlier studies using red-light controls and inconsistent with recent studies using negative ion generator controls, particularly in view of our study population. For example, it has been shown that depressed participants

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recruited into trials through advertising (as in both trials using negative ion generator controls) are more likely to be placebo responders than those recruited through routine referral (Miller *et al*, 1997).

Limitations of the study

The study is limited by the small sample size, resulting in low power to detect small differences between the groups. None the less, there was a notable absence of even a non-significant trend towards differences between participants treated with white and red light. A further limitation in this and all other studies evaluating light therapy concerns the choice of an appropriate control, as discussed above. In addition, given the context in which our study was undertaken, with undiagnosed primary care participants not receiving specific treatment for SAD and largely unaware themselves that they had the condition, it can be argued that the appropriate and most pragmatic control is 'treatment as usual'. However, the application of treatment within the current trial was highly pragmatic, with participants supervising their own treatments, as they would in routine clinical practice in primary care. We did not assess compliance systematically, and it might be that it was substantially poorer than in previously reported trials with atypically aware and motivated participants. Thus, despite the fact that many primary care participants with SAD showed considerable improvements in symptom scores after 4 weeks of light therapy, larger open trials with carefully selected control conditions and long-term follow-up are needed to provide further evidence about the effectiveness and efficiency of light therapy for SAD in primary care, and these should include assessments of the impact upon the documented high service use of sufferers.

CLINICAL IMPLICATIONS

- Among patients with seasonal affective disorder (SAD) identified in primary care, we found no difference in treatment responses between those treated with bright white light or with dim red light.
- For both groups of patients, symptom ratings reduced by over 40% during the 4 weeks of the trial.
- These findings do not suggest that patients with SAD in primary care should be identified assertively and treated with bright white light.

LIMITATIONS

- Only 57 patients completed the trial, which may have been statistically underpowered to have detected a clinically significant difference between treatment groups.
- Although treatment expectations were very similar in both groups of patients, dim red light may not be an ideal placebo in that it may not be inactive.
- Patients undertook their light therapy at home and it is possible that their compliance with treatment was inadequate.

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