Critical appraisal: adjunctive bright light therapy for bipolar depression

Critical Appraisal: Adjunctive Bright Light Therapy for Bipolar Depression : A Randomised Double-Blind Placebo-Controlled Trial

Part 1: Research Question

The Adjunctive Bright Light Therapy for Bipolar Depression Study that was conducted between 2010 and 2014 aimed to investigate the effect of bright light therapy on depressed adults. This was highlighted in the study through the appropriate PICO format. The population was defined as depressed adults with bipolar I or II disorders who were being administered stable doses of antimanic medication. The intervention that was administered to the experimental group was midday bright light therapy (between 12pm and 2: 30pm) of 7, 000-lux bright white light whilst the comparison group received 50-lux dim red light as a placebo. The outcomes that were measured in the study included the remission rate, depression symptom level, rate of mood polarity switch and some exploration of the quality of sleep. [1]

Therefore, the research question can be seen to be very detailed in defining the groups that will be investigated as well as the outcomes that will be measured throughout the study.

Part 2: Previous Research and Contribution to Field

A previous pilot study was conducted by the same authors of this research where they investigated the effects of light therapy for patients who were diagnosed with bipolar disorder and had stable depression. The result from this pilot study showed that morning light therapy induced a complete response in four of the patients and hypomania in the remaining three

participants. [2] Other studies investigated by the researchers showed that in patients with seasonal depression [3-6] or rapid cycling bipolar illness [7] antidepressant effects were observed after midday or evening bright light therapy. These claims are in contrast to an earlier study that administered 8 weeks of morning light therapy with a comparison to a placebo which showed ineffective in improving bipolar depression. [8]

The authors claimed that the differences between these studies may be due to the time of the day that the light therapy was administered as well as the dosage of treatment. The current study began patients on fifteen-minute sessions of their respective therapy and slowly increased the treatment duration by 15 minutes every week to 60 minutes in total by the end of week four or until remission. [1]

Therefore, it can be seen that the author built on their own pilot study and the previous studies conducted by others which provided conflicting results to investigate the effect of midday bright light therapy administered with an increasing dosage over six weeks to ultimately determine the most appropriate treatment for patients with bipolar depression. [1] The study as a result provides a significant contribution to the treatment of bipolar depression by investigating the best therapy options through building on previous studies.

Part 3: The Study Design

The study design that was used for this research question was a randomised controlled trial. Randomised Controlled Trials stand as one of the highest

levels of evidence behind meta-analyses and systematic reviews. [9] The study also adopted a double-blind method whereby the participants as well as the staff interviewing the participants were unaware of the distribution of those in each group. This along with the study design increase the strength of the study as well as the power. [1]

Randomised controlled trials in this context can be seen as appropriate due to the fact that the patients were not being denied treatment with their current medications but the light therapy was just included as a concurrent treatment method with their original treatment plan. [1] As a result, ethical issues were mitigated, care of the patients were taken as a priority above all else and blinding ensured that bias was reduced.

Part 4: Study Participants

Part 4a: The Inclusion Criteria

The inclusion criteria that was defined by the authors was 18-75-year-old patients that were confirmed to be diagnosed with bipolar I or II through the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID) or had a score less than 4 on the Mania Rating Scale. It also included individuals who had a score greater than 20 on the Structured Interview Guide for the Hamilton Depression Rating Scale with Atypical Depression Supplement (SIGH-ADS), meaning they currently had moderate to severe episodes of major depression. The eligible candidates also had to be receiving antimanic medication at stable doses for at least the last four weeks. Pregnant women

were also included in the study as the study designers believed that light therapy would not provide additional harm to the women. [1]

Due to the extensive inclusion criteria that was adopted in this study it can be said that a representative sample was collected. This thereby reduces the likelihood of selection bias to be present.

Part 4b: The Exclusion Criteria

The exclusion criteria for this study included any patients who in the last 6 months had had manic, hypomanic or mixed episodes, those with thoughts of suicide, patients with acute or chronic psychosis or rapid cycling in the past year. [1] Rapid cycling is defined as having at least 4 bipolar mood episodes per year. This includes stages of mania, hypomania or depression occurring within the year. [10] Patients diagnosed with obsessive compulsive disorder, uncontrolled thyroid disease or chronic eye diseases were also excluded. As well as those who had a substance use disorder in the last 6 months, those with a positive urine drug test or those receiving treatment with medication known to have photosensitising properties such as phenothiazine, antimalarial drugs, propranolol, melatonin, Hypericum, stimulants, or chronic non-steroidal anti-inflammatory drugs. [1]

Part 4c: Selection of Participants

The participants for the study were chosen through the WPIC Mood Disorders Program. Written informed consent was received from all participants after the study procedures had been explained to them. 93 potential patients provided informed consent for the study, however after the exclusion criteria

was applied to these participants only 46 participants remained. These patients were then divided evenly into the experimental group and the placebo group each with 23 individuals. The authors stated that there were no significant demographic differences within the two groups. [1]

Part 5: The Study Measures

Part 5a: Study Factors

The study factor that was used was the type and amount of light therapy administered. The 23 participants in the experimental group received 7, 000-lux bright light therapy whilst the placebo group of 23 individuals received 50-lux dim red placebo light. These light therapies were administered through experimental and placebo light boxes that the patients used daily at home or at work and therefore required no further calibration after the first visit. [1]

Part 5b: Outcome Measures

The primary outcome measure that was investigated by the researchers was the remission rate. This was defined as a SIGH-ADS score less than 8 within the four to six-week period. The secondary outcome measures included the response rate to the treatment which was defined as a greater than 50% reduction in the SIGH-ADS score as well as further psychological impacts such as mood polarity switch frequency, occurrence of suicidal thoughts, anxiety symptoms and sleep quality. [1]

The outcome measures that were investigated to increasing the quality of life of patients suffering from bipolar depression as well as increasing the

remission rate. The broad range of outcome measures allows for an understanding of the overall lifestyle impact that bright light therapy had on the participants. As a result, these measures are appropriate in answering the research question due to the fact they are aiming to increase the emotional and mental state of bipolar patients by ascertaining a treatment option with the greatest overall positive impact on their lifestyle.

Part 5c: Measurement Error

Systematic error has likely been reduced or removed due to the study design being a randomized controlled trial. It is further reduced due to the fact that the study was conducted with a double-blind method. Therefore, associations made by the personnel interacting with the patients can be assumed to be true associations that occurred. [1]

Random error may have occurred due to the small sample size of participants that underwent the treatment. [1] This can be reduced in further investigation by increasing the sample size.

Part 6: Bias

Due to the experiment involving light boxes to administer the midday light therapy, participants were advised and agreed not to research information on the design of light boxes. However, it is reasonable to believe that some participants may have searched information even when informed against it. [1] This could lead to performance bias within the results, resulting in an undesirable and biased effect occurring in patients in either group. This

means that the results will not be a true representation of the effect of midday light therapy on bipolar depression.

There were a few people who stopped the study. In the experimental group, only one person was lost whilst in the placebo group five people stopped their participation. However, the authors claim that the early withdrawal rate of 4. 3% in the experimental group and 21. 7% in the placebo group did not result in significant changes in the results. [1] Therefore, attrition bias was accounted for and did not occur to the best of our knowledge.

Furthermore, the information that is asked by the interviewers may be sensitive, such as suicidal thoughts and other psychological symptoms. [1] As a result, this may lead to participants not sharing their true thoughts and information, which is called reporting bias. The results that are then collected by the analysts might therefore be skewed in one direction.

Part 7: Overall Summary

In summary, due to the extensive exclusion criteria and the multitude of outcome measures that were monitored within the study it can be said that the quality of the study is high. This is also increased through the use of adjusted analyses to account for the potential confounding factors such as age, time of enrollment and their SIGH-ADS scores as well as through the use of a double-blind randomized controlled trial to increase the power of the study and rule out further bias. [1]

Although there may be some bias present through reporting and performance and the study also only contained a small sample size, the

researchers aimed to remove as much bias as possible. The study also adds to the field of treatment of bipolar depression and will hopefully lead to further and larger research projects that will further ascertain whether midday bright light therapy is a good treatment option.

Overall, changing practice for patients suffering from bipolar depression in Australia from this single study may be a rash decision and should be considered in the future after further more extensive studies have been conducted that yield similar results.

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