

Research plan, translated from Swedish, including a statistical analysis plan

A controlled study of weighted chain blankets

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Scientific description

Purpose

The primary aim is to investigate whether the nightly use of a weighted chain blanket has a significantly better effect on sleep time, total sleep time and daytime fatigue for patients with sleep disturbance in psychiatric disease compared to a light chain blanket (equivalent to placebo) after four weeks of use. Secondary issues are whether treatment with weighted chain blanket results in a significantly better effect than a light blanket for objectively measured sleep and subjectively assessed anxiety, depression, and pain.

Hypotheses

The use of the weighted chain blanket allows:

1. Sleep time decreases.
2. Sleep stays longer with fewer wake-ups during the night.
3. The sleep becomes calmer
4. The sleep becomes less tense
5. Pain decreases daytime
6. Pain decreases at night
7. Anxiety and anxiety decrease daytime
8. Anxiety and anxiety decrease at night
9. Fatigue decreases daytime
10. Concentration capacity increases daytime

Primary outcome measures

The patient's subjective symptoms of sleep and day fatigue will be evaluated by the Insomnia Sleep Inventory (ISI) and the Fatigue Scale Inventory (FSI) scales. It will also be evaluated by the patient's self-assessed values in the self-assessment rating scale developed by Stockholm Utility for evaluating ball and chain blankets (hereafter referred to as "rating scale for weighted blankets"). Depression and anxiety will be evaluated with the scale Hospital Anxiety and Depression Scale (HAD). Objective sleep parameters will be recorded with actigraphs.

Chief researcher

Responsible for the study of patients with bipolar disorder and/or ADHD is Bodil Ekholm, leg. Occupational Therapist at the Affective Section, Psychiatry Southwest of Stockholm County Council (SLSO) and Mats Adler, Medical Doctor and Chief Physician and Section Manager at the Affective Section, Psychiatry Southwest in Stockholm County Council (SLSO)

Overview

Sleep difficulties are one of the most common reasons for people seeking medical attention. People with sleeping problems often report a great deal of suffering and a negative impact on activity. It has also been found that it increases the risk of other diseases. It also affects the ability to work, which causes high social costs (1-5). Several major studies have shown that between 15 and 50% of the

adult population report that they have sleep disturbances and that it is an increasing problem (1.5.6). Mainly there are sleep difficulties, difficulty in maintaining sleep, as well as nightmares that have been reported. Concerning patients in psychiatry, there is a strong link between sleep disorders and depression/anxiety (7-13). For patients with bipolar disorder, about 70% report that they have sleep disorders (14-15). The traditionally accepted methods of pharmacologically treating these patients and CBT do not always yield success (10, 14). Untreated or ineffective treatment often leads to chronic sleep disorders (1, 9, 10).

Occupational therapists work with activity and activity disorders (16). The condition for being active is that you have a good sleep. Therefore it is natural that occupational therapists also work with sleep disorders.

Prescription of ball and chain blankets is a common occupational therapy intervention (17-21). According to the SBU (22), the purpose of the blankets is to create a sense of security and calmness, but that the scientific evidence is insufficient to assess the effect of weight loss in sleep disorders caused by motor and/or mental anxiety. However, in cost-benefit assessments, cognitive aids and weighted covers for people with mental disabilities have found a clear positive financial outcome for both the user, state, municipality, county council and the general economy (23), due to a decrease in the need for help and the number of sick leave days. People can stay or introduce themselves to work and self-reliance increases.

In summary, the test/prescription of the ball and chain blankets is a promising, relatively new, method for adults with sleep disorders.

Project plan

Patients

Patients with sleep disorders and motor / mental anxiety will be recruited at the Affective section at Psychiatry South West. Patients who are expected to use the chain blankets after assessment by the attending physician will be included after informed consent. All patients who accepted inclusion and who received a chain blanket will be included in the analysis.

Inclusion and exclusion criteria

We intend to recruit patients from Psychiatry Southwest with affective and anxiety diagnoses and/or ADHD, which are simultaneously bothered by sleep disturbance and anxiety/anxiety. Patients are recruited from open and inpatient wards. They should have one of the diagnoses Bipolar Disorder Type I, Type II Bipolar Disorder, Recurrent Depression, Panic Syndrome, Social Phobia, General Anxiety Disorder (GAD) and/or ADHD. They should also have a clinically significant sleep disorder, i.e., a rating of 14 or more on ISI. Exclusion criteria are ongoing drug abuse, consumption of sleep medication beyond recommended levels (> 7.5 mg zopiclone or 10 mg zolpidem) or cognitive problems that make the patient unable to complete the study.

Characteristics of patient material

The examined group will be characterized by age, sex, choice of cover, weight, diagnosis, comorbid diagnosis and duration of disease.

Procedure

After the patient has received oral information and signed a written informed consent, characterization of the patient material will be made. The study will be conducted in four phases. The first week they use their usual blanket (baseline). Sleep, fatigue, anxiety, and depression will be recorded with the scales mentioned above. Then a second part follows four weeks when they use the blanket randomized to (Week 2-5). In the second phase, patients are randomized to either get a 6 or 8 kg lining blanket or a lightweight cover of approximately 1.5 kg of the same appearance in which light plastic chains are sewn in. This cover is of such low weight that it corresponds to a regular blanket and therefore acts as a placebo control. Randomization and instruction, as well as collection of blankets after four weeks of use, will be carried out by a person who does not perform the ratings at inclusion and follow-up. Patients should maintain their medication unchanged during the study period. They are followed up by telephone every week. At the telephone interview information about how they used the blanket will be gathered, and patients will estimate their sleep with the scales mentioned above. After four weeks of use of the blanket, the final visit for the randomized study will be conducted, and data (scales and actigraph) from this visit is the primary outcome of the study.

In the third phase, all patients are offered an open-follow up study in a 4-week (week 6-9) where they can choose freely between ball and chain weighted blankets. After these four weeks, everyone is called for a second visit with new estimates and collection of actigraph data of (week 9). In the fourth phase, patients who wish to continue with one of the weighted blankets will be offered to do so. After 12 months, patients who choose to continue using weighted blankets will be contacted by telephone to check the extent to which they use the blanket and are asked to estimate the same symptoms as before.

Power Calculation

In a previously uncontrolled pilot study of weighted-duty non-control groups, the average sleep time decreased from 98 minutes (SD 69) to 31 minutes (SD 28). Based on these results, calculating the effect of the blanket for a future study where the placebo deck had no effect, and the active blanket would have the same effect as in the pilot study figures would want a power of 0.9 with a significance level of 0.05, only 15 subjects would be required in the study. However, we have no data on the effect of sleep on sleep measured with the ISI scale. Nor is it likely that the placebo blanket would not have any effect at all. However, we expect that patient material of about 100 individuals should be enough to find a significant effect.

Statistical analysis

Comparison between the effect on the groups will be performed after four weeks and eight weeks with conventional methods of statistical significance testing in controlled and randomized studies. All patients who used the blanket for at least one night will be included in the analysis (equivalent to "intention to treat"). Data from patients who discontinue treatment will be asked if they can accept to participate in follow-up in the same way as if they had completed treatment. In these cases, data are included in the analysis as measured. Secondly, Last Observation Carried Forward (LOCF) or other established statistical method is used to handle data from patients who interrupt treatment.

Self-assessed values before, after eight weeks and 12 months will be analyzed with and at eight weeks after with paired t-test for dependent variables. When data distribution does not match normal distribution, the analysis will be supplemented by non-parametric tests.

Timetable

The study will extend over three years.

Safety monitoring

Clinical monitoring will be done by treatment staff on the Affective section in consultation with the patient.

Ethical considerations

Testing/ordination of the chain blanket in sleep disorders, as well as motor anxiety and/or mental anxiety, is a well-known occupational therapy intervention. The method appears effective and has no significant adverse effects. However, the method is not sufficiently illuminated and scientifically tested. The use of the clinical data recorded as part of routine follow-up will be unidentified and therefore does not present a disadvantage to the patient. All procedures will be done with informed consent, data will be processed with confidentiality and unidentified. We believe that the disadvantages of the patients are small.

Possible impact

Sleep disturbances caused by anxiety are one of the common causes of suffering for patients with psychiatric diagnoses. If it is confirmed in this study that the chain blankets can reduce this disorder for the patient group without having any side effects of treatment, it will represent a very big step forward for the treatment of sleep disturbances.

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