The efficacy and appropriateness of ball blankets on insomnia in depression in outpatient clinics

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Methods
The project comprises three studies.

Study 1 is a systematic integrative review.
Aim: to synthesize the evidence on effects and patient perceived benefits and limitations related to non-pharmacological treatment options for insomnia in depression.
Methods: The design is integrative methodology. Both quantitative and qualitative data will be converted into categories and aggregated into synthesized findings. A systematic literature search will be conducted. Articles will be validated using validated critical appraisal tools from The Joanna Briggs Institute. Data will be analyzed using inductive content analysis.

Study 2 is a randomized crossover study.
Aim: to investigate if the PBB will extend the sleep duration, reduce sleep onset latency, reduce the need for sedatives and hypnotics, improve the quality of sleep and/or reduce the self-reported symptoms of patients with insomnia due to depression.
Methods: The study has a randomized 2-sequence, 2-period, 2-treatment crossover design. The data collection period lasts four weeks. Data will be collected using actigraphy (Micro MotionLogger Watch from Ambulatory Monitory Inc. NY. USA), sleep diaries and six validated questionnaires: The Pittsburg Sleep Quality Index (PSQI), Insomnia Severity Index, Major Depression Inventory (MDI), 6-item Hamilton Rating Scale for Depression (HRSD6), Self Reported Symptoms (SCL-28) and Becks Anxiety Index (BAI) for monitoring sleep quality and self-reported symptoms.

Study 3 is a qualitative study.
Aim: to investigate the patient perceived benefits and limitations of sleeping with ball blankets in order to examine the appropriateness of using ball blankets on insomnia in patients with depression specifically to learn more about the new questions that originates from the results from study 1+2. The aim is to pursue any surprising results or results that need further explanations and to generate new hypotheses.
Methods: Data will be collected using a semi-structured interview guide developed from the results collected in study 1+2. Every interview will last from 30-45 minutes. 10-15 patients will be interviewed. Data will be analyzed using inductive content analysis.

Perspectives
If the PBB reveals an effect on insomnia, it has the potential of becoming an important and innovative non-pharmacological alternative or supplement to the medical treatment of insomnia in patients with depression.

For Protac, scientific and continued research is a key priority. Scientific arguments are crucial for opening new markets and for strengthening the sales in both Denmark and abroad and new results are highly requested. An acknowledgement of the hypothesis in the project is estimated to increase the sales of the PBB considerably and to underline the effect of sensory stimulation as a non-pharmalogical treatment of insomnia among grown-ups.