1. **Title:** Treatment of Sleep Disturbances in Trauma-affected Refugees – A Randomised Controlled Trial (PTF5)

2. **Status of the project:** Application for funding and approval by the Danish Data Protection Agency, the Danish Ethical Committee of Science and the Danish Health and Medicines Authority

3. **Project period:** 01.01.16 – 31.12.18

4. **Investigator:** Hinuga Sandahl, MD

5. **Supervisors and collaborative partners**

   **Supervisors:**
   - Principal supervisor; Associate Professor Jessica Carlsson Lohmann, CTP.
   - Co-supervisor; Professor Poul Jennum, Danish Center for Sleep medicine.
   - Co-supervisor; Lone Baandrup, Mental Health Center Glostrup.

   **Collaborative partners:**
   - Stig Bernt Poulsen, Department of Psychology, University of Copenhagen.
   - Barry Krakow, Sleep & Human Health Institute, Medical Director & Principal Investigator, Albuquerque, NM.
   - Annette van Schagen, psychologist, Foundation Centrum ’45, Holland. PhD student at Utrecht University.

6. **Background**

   Sleep disturbances are often referred to as a hallmark and a core symptom of PTSD (1–5). In a sample of 832 trauma-affected refugees undergoing psychiatric treatment at Competence Centre for Transcultural Psychiatry (CTP) in the period 2008-2012 98.9% reported sleep disturbances and 98.5% reported recurrent nightmares (6). Studies on treatment of sleep disturbances in refugees suffering from PTSD are scarce. The lack of studies concerning psychoeducation, psychotherapy, as well as pharmacological treatment leaves clinicians without validated clinical guidelines for treatment of sleep disturbances (6).

7. **Aims**

   The overall aim of this study is to examine sleep enhancing treatment in refugees with PTSD in a randomized controlled trial.

   The objectives are

   1. To estimate treatment effects of Imagery Rehearsal therapy (IRT) and mianserine on sleep quality, sleep length and nightmares compared to treatment as usual (TAU) in CTP
   2. To study the relation between enhanced sleep, PTSD-symptoms, observer rated functioning and self-rated quality of life
   3. To examine predictors for positive outcome of treatment

8. **Methods**

   The study is a pragmatic randomized controlled trial, performed in a clinical setting in a psychiatric outpatient clinic, over a two year period.

   The design has a 2x2 factorial design. The allocation ratio to the four groups is 1:1:1:1.

   **8.1 Number of participants (N):** 230 participants
8.2 Population: Trauma-affected refugees fulfilling the criteria for Posttraumatic Stress Disorder and referred for treatment at CTP

8.3 Description of data and data collection
The study will include patients from February 2016 to autumn 2017. Patients will be randomised to one of four treatment groups: 1) Treatment as usual (TAU) in CTP (manual-based Cognitive Behavioural Therapy, medicine according to algorithm and psychoeducation). 2) TAU and add-on treatment with mianserine. 3) TAU and add-on treatment with IRT. 4) TAU and add-on treatment with mianserine and IRT. The primary outcome in this trial is sleep disturbances measured on Pittsburgh Sleep Quality Index (PSQI) (7,8).

8.4 Application/acceptance from the Danish Data Protection Agency, the National Committee on Health Research Ethics: Applications sent autumn 2015.

8.5 Analysis
Primary and secondary outcome variable will be analysed with ANOVA or linear regression analyses of differences between pre-treatment and post-treatment scores. Linear regression will be used to analyse pre-treatment scores as predictor of post-treatment scores. Effect size will be measured with Cohens d.

9. Expected results: The study is expected to add new knowledge on treatment of sleep disturbances in trauma-affected refugees.

10. Dissemination of results
The results will be presented at international conferences, in other settings relevant to professionals working with trauma-affected refugees and in peer-reviewed scientific journals. Three papers are planned for:
   A. Treatment effect on sleep disturbances of TAU compared to add-on treatment with mianserine, IRT or a combination of both
   B. The relation between enhanced sleep, PTSD-symptoms, physician evaluated functioning and patient evaluated quality of life
   C. Prediction of outcome of treatment depending on severity of sleep disturbances

11. References


