1. Title: The effect of the treatment of traumatised refugees with trauma-focused cognitive behavioural therapy (TFCBT) and medical treatment including antidepressants – a randomised controlled clinical study (PTF1)

(This project is linked to Traumatised refugees in treatment – description of psychiatric diagnoses and full symptom picture using systematic SCAN interviews)

2. Status of the project: Data collection has been completed. Data analysis is ongoing and the first paper is in press (please see below Dissemination).

3. Project period: 15 June 2009 – mid-June 2011 (inclusion of participants)

4. Investigator: Cæcilie Buhmann, MD, PhD

5. Population: Adult trauma-affected refugees referred to treatment at CTP

6. Number of participants: 200

7. Aims and description

- To examine the efficacy of medical treatment consisting of antidepressants and psychoeducation, in patients with PTSD and/or depression as a result of trauma e.g. persecution, torture, war or civil war.
- To examine the efficacy of TFCBT in patients with PTSD and/or depression as a result of above-mentioned traumas.
- To examine the treatment effect of combined medical treatment and TFCBT in patients with PTSD and/or depression as a result of above-mentioned traumas.
- To examine whether patients’ condition is improved, unchanged or worsened 6 and 18 months after completing the treatment.
- To examine the predictive factors for treatment effect including differences in treatment response between patients who have been subjected to torture, and patients who have suffered other traumas.
- To examine the acceptability of pharmacological and psychotherapeutic treatment for traumatised refugees with PTSD and/or depression.

Follow-up interviews, including ratings, are conducted with all patients from PTF1 6 and 18 months after treatment. At the interview, the same parameters as during treatment (quality of life, functional level, symptoms and pain) are assessed in addition to an assessment of stressful events in the patient’s life since completing the treatment. The first interview is expected to take place in June 2010 and the last interview in late 2013. The project will shed light on whether the long-term effect is different depending on whether patients have been treated with psychotherapy or medication. Furthermore, it could shed light on whether the patients continue with the prescribed medication after completing the treatment, and whether the patients have received additional treatment for mental or physical illness after completing the course of treatment at CTP.

All patients who complete a minimum of 2 months of treatment fill out questionnaires concerning patient satisfaction. Moreover, patients are asked about the experienced disadvantages of psychotherapy and medical treatment respectively. This data can be compared with the ratings
carried out as part of the clinical trial, in order to assess whether the treatment is acceptable and whether there is a relationship between treatment outcome and satisfaction.

8. Dissemination of results
One paper has been finalised and is currently in press:

*The effect of flexible cognitive behavioral therapy and medical treatment, including antidepressants on PTSD and depression in traumatized refugees – a pragmatic randomized controlled clinical trial*

Further planned scientific articles:

- *Satisfaction and acceptability of pharmacological treatment and TFKAT in traumatised refugees*
- *Long-term effects of treatment with pharmacological and psychotherapeutic treatment of traumatised refugees – a follow-up study*
- *Predictive factors for treatment effect in the pharmacological and psychotherapeutic treatment of traumatised refugees*