1. **Title:** Treatment of traumatised refugees: the effect of Basic Body Awareness Therapy versus mixed physical activity as add-on treatment – A Randomised Controlled Trial (PTF4)

2. **Status of the project:** In the process of including patients and collecting data.

3. **Project period:** The inclusion period has taken place since September 2013 and is expected to be complete by autumn 2015.

4. **Investigator:** Maja Sticker Nordbrandt, MD, PhD student

5. **Supervisors and collaborative partners**

   - Senior Consultant Jessica Carlsson, PhD (CTP) (primary supervisor).
   - Professor Erik Lykke Mortensen, University of Copenhagen (supervisor).
   - Associate Professor Jonna Anne Jensen, Metropolitan University College, Denmark (collaborative partner).
   - Professor Derrick Silove, Psychiatry Research & Teaching Unit, Liverpool Hospital, University of New South Wales, Australia (collaborative partner).
   - Executive director Jorge Aroche, The New South Wales Service for the Treatment and Rehabilitation of Torture and Trauma Survivors (STARTTS), Australia (collaborative partner).

6. **Background**

   Chronic pain is commonly comorbid to PTSD(1–5). According to the well-established “Mutual Maintenance Theory” there is a mutual maintenance of PTSD and chronic pain, and the treatment of chronic pain plays a central role in improving the treatment and wellbeing of patients with PTSD(3). Nevertheless, there is a lack of knowledge about how to treat chronic pain in trauma-affected refugee populations. The project is motivated by this important gap.

   The effects of physical activity on other psychiatric illnesses than PTSD have been examined(6–13). Regarding depression, which is often comorbid to PTSD(14–19), the evidence suggests small or moderate effects of physical activity(16,20,21). Importantly, positive effects of physical activity have also been seen for chronic pain(22–30). However, scientific knowledge about physical activity as part of the treatment for traumatised refugees is rather limited and no national or international guidelines exist on this topic(31–33). Despite this gap, different types of physical activity are often used as part of the treatment for this group of patients.

   There are a few randomised controlled trials on traumatised refugees with PTSD, which had physical activity as the intervention. Among these, one small randomised controlled trial from 2011 by Liedl et al., suggesting specifically that physical activity adds value to pain management for traumatised refugees (34). Another type of physical activity which has been studied as intervention in a number of trials on other illnesses such as chronic pain, fibromyalgia, schizophrenia, personality disorders and non-specific musculoskeletal disorders is Basic Body Awareness Therapy (BBAT) (9,11,24–26,35). In order to test the feasibility of BBAT on a group of traumatised refugees, a pilot study was conducted in 2012 (36) at the Competence Centre for Transcultural Psychiatry (CTP). The participants showed high acceptability, compliance and satisfaction with BBAT (36).

   The present study has been inspired by the preliminary results of these two abovementioned studies.
As in the case of depression, the working mechanisms behind the effect of physical activity on PTSD symptoms are unclear. The Cochrane review; “Sports & Games for post-traumatic stress disorder” from 2010 concludes: “Randomised controlled trials assessing the effect of sport and game interventions are needed to inform the current practice of using sports and games to improve symptoms of PTSD”. In line with this, there is a need for more systematic research examining a number of unsolved issues: 1) the effectiveness of physical activity as a remedy for symptoms of PTSD and chronic pain; 2) the relative benefits of different types of physical activity; 3) whether group or individual physical activity is the most efficient; 4) the optimum duration and intensity of physical activity.

7. Aims

1) To examine whether physical activity as an add-on treatment to psychiatric treatment as usual, gives an increased effect compared to psychiatric treatment as usual in mental symptoms (PTSD, depression and anxiety), quality of life, functional capacity, coping with pain and body awareness.

2) To examine, whether an increase in physiological parameters such as strength, endurance, balance and coordination correlates with an improvement of PTSD, anxiety, depression, coping with pain, quality of life, functional capacity as well as body awareness.

3) To examine if the number of hours spent on home exercises in the specific assigned physical activity is a positive predictor of the treatment effect.

4) To examine if Basic Body Awareness Therapy (BBAT) has a higher impact on mental symptoms (PTSD, depression, anxiety), coping with pain, quality of life, functional capacity, and body awareness, compared to mixed physical activity.

8. Methods

8.1 Number of participants (N)

288 (min. 200 are expected to complete the trial in accordance with the protocol).

8.2 Population

Patients referred to treatment for PTSD at CTP from September 2013 to August 2015; aged 18 or older; refugee or family reunified with a refugee; diagnosed with PTSD pursuant to the ICD-10 research criteria; psychological trauma in the anamnesis; estimated by a medical doctor to be motivated for treatment; provide written informed consent.

8.3 Description of data and data collection

The patients are randomised into three groups. All three groups receive psychiatric treatment as usual (TAU). TAU consists of 6-7 months of medical treatment according to best clinical practice in the field and manual-based Cognitive Behavioural Therapy. While one of the three groups is a control group and solely receives TAU, the two other groups receive add-on treatment with physical activity. One of the groups is assigned to Basic Body Awareness Therapy (BBAT) (a method focusing on breathing, posture and body awareness) while the other group is assigned to mixed physical activity (MPA), which focuses on exercises of strength, endurance, balance and coordination. For all three groups the treatment period is around 6-7 months.

The patients will fill out self-administered ratings three times during the treatment period: one at the pre-treatment consultation (baseline), one halfway through the treatment (before the first psychotherapy session) and one just after completing the treatment. Furthermore, there
are ratings and tests specifically related to the physical activity at the beginning and at the end of the treatment programme. Trained medical students carry out blinded observer-ratings of depression and anxiety at the start and at the end of the treatment programme. The primary endpoint of the study will be symptoms of PTSD, and secondary endpoints will be symptoms of depression, anxiety, and quality of life, functional capacity, coping with pain, body awareness and physical fitness.

8.4 Application/acceptance from the Danish Data Protection Agency, the National Committee on Health Research Ethics
Consent for the study has been given both from the Danish Data Protection Agency and the National Committee on Health Research Ethics.

8.5 Analysis
Drop-out analysis is based on the patients who show up at the initial referral interview. The patients in the programme will be compared with the patients who were excluded at the referral interview in order to identify possible systematic selection bias. Furthermore, the group of patients included in the trial, but who eventually drop out and do not complete the trial will be analysed. In addition to completer analysis, intention-to-treat analyses will be carried out.

9. Expected results
The results of this trial are expected to improve treatment for the individual patient and to stimulate further research within a relatively short time. In the long term, results are expected to be applied in reference programmes and clinical guidelines. This will ensure high quality evidence-based treatment as well as ease the work of practitioners with respect to identifying the appropriate type of treatment for the patient. Furthermore, the trial is expected to generate a socio-economic gain as ineffective treatment programmes are prevented.

10. Dissemination of results
Positive as well as inconclusive or negative results will be published. After completion of data analysis, three publications are planned regarding the following aspects of the study:
- The effect of physical activity as an add-on treatment to psychiatric treatment as usual for traumatised refugees.
- The mental health benefits of a focus on body awareness when treating traumatised refugees with physical activity.
- The mental health benefits of improvement of parameters of fitness when treating traumatised refugees with PTSD.

The results are planned to be presented on national as well as international meetings and conferences of psychiatry.

11. References
2. Olsen DR, Montgomery E, Bøjholm S, Foldsang A. Prevalence of pain in the head, back and feet in refugees previously exposed to torture: a ten-year follow-up study. Disabil Rehabil


36. Stade K, Skammeritz S, Hjortkjaer C, Carlsson J. “After all the traumas my body has been through, I feel good that it is still working.” –Basic Body Awareness Therapy for traumatised refugees. Torture. 2015;In press.