NET Trial Protocol

1. Referrals

NET trial participation was offered to clients at the organisation as well as for those who were referred to the organisation, but were not accepted as clients due to the limited capacity of the organization at the time of referral. Potential participants were informed about the study by an organisational staff member in the course of routine attendance at appointments, or referred by their legal representatives.

Individuals and referrers were sent an information sheet regarding the trial highlighting that potential participants must meet the following criteria to be eligible for the trial: 1) Be over the age of 18; 2) Have a history of being trafficked; 3) Meet diagnostic criteria for PTSD; 4) Be willing and able to have a course of psychological treatment that involves talking about past traumas in detail. 5) Be psychologically stable enough for this treatment (no recent suicide attempts or self-harm, able to care for self; 6) Be practically stable enough (i.e. is reasonably safe - not street homeless, not destitute, not at imminent risk of removal, not currently in a situation of abuse or exploitation); 7) Be willing to be randomised for the purposes of the research trial to either receive treatment immediately or to wait for approximately six months before receiving treatment; 8) Be able to attend weekly 90 minute appointments at the organisation's offices; and 9) Should not have had a full-course of previous trauma-focused therapy.

NET trial recruitment closed as of October 2018.

2. Assessment + letter

Appointed clinicians assessed potential participants for NET over one or two sessions to determine suitability and readiness against the participation criteria and to obtain consent for the trial. Consent forms consisted of the organisation's general safeguarding form, audio consent for CAPS recordings, and consent to participate in the trial.

Inclusion criteria are a PTSD diagnosis according to DSM 5, a history of human trafficking or other human rights abuses, and informed consent. Exclusion criteria are any internal or external factors that indicate the person is not stable enough for trauma-focused treatment to be appropriate (in accordance with NICE Guidelines for PTSD, 2005). This will include comorbid psychosis, substance misuse and high risk of suicide and/or self-harm, as well as destitution, street homelessness, risk of imminent removal from the UK and the inability of parents to organise childcare due to safeguarding and attendance issues.

A letter to the participant, their GP and their solicitor (if required) should be sent, explaining the participant is currently being assessed for the NET trial. A second letter should be sent once the participant has either been accepted or not onto the trial.

If the participant is not accepted on the trial the letter should explain the reasons why and a phone call should also be made explain the reasons and manage any distress.

3. CAPS and measures

Symptoms of post-traumatic stress disorder, depression, dissociation, additional clinical measures and a measure of daily functioning are assessed at baseline, mid-way through treatment (after 10 sessions), after 16 sessions, at the end of treatment (if this is more than 16 sessions), and at three,

six and twelve month follow-up. Blinded assessments are conducted by raters unaware of treatment condition and clients are instructed not to reveal treatment conditions if possible (though this has had little success).

We will collect data relating to participants' demographics, their mental health symptoms, and overall daily functioning. The measures we aim to use to measure dimensions of change are the Clinician-administered PTSD Scale (Weathers et al., 2015) and Post-traumatic Stress Disorder Checklist (Weathers et al., 2013) to assess symptoms of PTSD; Patient Health Questionnaire (Kroenke, Spitzer & Williams, 2001) and the Generalised Anxiety Disorder Scale (Spitzer, Kroenke, Williams & Lowe, 2006) to assess symptoms of anxiety and depression; the Shutdown Dissociation Scale (Schauer, Schalinski & Elbert, 2010) to assess symptoms of dissociation; the Clinical Outcomes in Routine Evaluation scale (Evans et al., 2009) to assess levels of generalized distress; the Perseverative Thinking Questionnaire (Ehrling et al., 2011) to assess rumination; the Rosenberg Self-Esteem Scale to assess self-esteem (Rosenberg, 1965); the Self-Compassion Scale short form (Raes, 2010) and the Self-Critical Rumination Scale (Smart, 2013) to monitor any changes in levels of self-compassion, blame and self-criticism common to the participant group; and the Work and Social Adjustment Scale (Marks, 1986) to assess general daily functioning and satisfaction.

Additionally, we collect demographic information on participants. This included their age, gender, nationality, country of origin, ethnicity, nature and severity of trauma, diagnosis(es), immigration status, level of English, marital status, years of education and any prescribed psychotropic medication.

The scores from the measures need to be input into the NET Measures data spreadsheet.

4. Randomisation

After informed consent is obtained, participants are randomized to either the NET condition (receiving treatment straight away) or the waitlist control condition (receiving treatment approximately 6 months later). Participants are randomised to each condition by the toss of a virtual coin (http://virtualcointoss.com/). Up to 20 sessions of NET are offered (anticipated average 16). We will also allow for additional time for participants needing an interpreter, and allow for additional sessions, if NET needs to be paused or if other issues come up during the course of treatment that need more urgent attention (such as concerns about legal or practical matters, as is common with this client group). Any additional sessions used for non-NET purposes are noted, and the content will be documented.

Once the client has finished the assessment phase and has completed the consent forms, baseline measures and baseline CAPS, they can be randomised using the virtual coin toss. Details of the condition they have been randomised to needs to be completed on the participant spreadsheet, and a therapist needs to ideally be identified if the participant has been allocated to the NET immediately condition. A phone call should be made to the participant to explain the condition they have been randomised to and what to expect next. Check if an interpreter is needed for the phone call. This phone call should also be logged as an interaction.

5. Stabilisation

Participants receive three sessions of stabilisation work irrespective of being allocated to the NET or the waitlist condition. This is to ensure that all participants receive similar levels of stabilisation work before they enter the trial. The aims are to: Help the participant to become aware of and understand

their symptoms in a psychological way; develop some coping strategies to manage their symptoms; and prepare them for trauma-focused therapy. An outline of the three sessions is as follows:

- Session 1: What is PTSD, and what will treatment involve? Dissociation and flashbacks and techniques to manage them, such as relaxation techniques.
- Session 2: How does fear affect the body? What happens to the brain during a traumatic event? And reclaiming your life activities – introduce activity scheduling.
- Session 3: Sleep hygiene. Grounding techniques recap. Review progress of activities. Staying well plan – summary of what helps and crisis plan.

In order to arrange stabilisation, an Assistant Psychologist (AP) needs to be identified and the participant should be called and booked in for the first stabilisation appointment. The details of the upcoming appointment should be recorded on the participant spreadsheet along with the name of the AP who is facilitating stabilisation. Check if an interpreter is needed for the appointments. For NET immediately clients, it is good to keep the NET therapist updated on progress and give an estimated time frame for them to start therapy with the participant.

6. Post-stabilisation measures

Once stabilisation has been completed the participant needs to complete all measures again.

A letter to the participant, their GP and their solicitor (if required) should be sent, with their progress through the NET trial.

Hopefully the same Assistant Psychologist that saw the participant for stabilisation can book a follow up session to do post-stabilisation measures. Please document all the dates for measures and the name of the AP who delivered the measures on the participant spreadsheet. Check if an interpreter is needed for the measures. The scores from the measures need to be input into the NET Measures data spreadsheet.

7. Therapy or Waitlist (WL)

The participant now either begins NET therapy with up to 20 sessions offered (anticipated average 16) or enters the wait list period. At session 8 of NET mid-treatment measures need to be completed; and after approximately 10 weeks on the wait list mid-waitlist measures need to be completed. There is a two-week cut off window for collecting mid-treatment/waitlist measures, however often it is good to collect the data even out of window – but just make a note that it is out of window and a brief reason why data collection fell out of window.

Please keep track of the session number each participant is currently at, so you have a good idea when mid-treatment occurs and when the participant is coming to the end of NET therapy. The therapist name needs to be documented on the participant spreadsheet. Please ask the therapist to keep a record of how many NET sessions each of their participants had, how many times they DNA'd and how many non-NET sessions they received. With non-NET sessions it is also important to keep a record of the general reason the NET session was not able to go ahead and what they needed to talk about instead. Plan ahead of waitlist participants and identify potential therapist

8. End of Therapy or WL

Once participants have completed their time on the WL, their therapist needs to be updated and NET sessions organised as promptly as possible. Once NET therapy has been completed a letter

written by the NET therapist to the participant, their GP and their solicitor (if required) should be sent. Blind End of treatment/WL measures and CAPS need to be administered. There is a four-week cut off window for collecting end of treatment/WL measures and CAPS, however often it is good to collect the data even out of window – but just make a note that it is out of window and a brief reason why data collection fell out of window.

Please record the date of the last NET session on the Participant Spreadsheet. A therapist other than the participant's NET therapist needs to be identified to do the blind End of Treatment CAPS. An AP needs to be found to do the blind End of Treatment measures. A blind therapist should also do the End of Waitlist CAPS and again a blind AP to do the End of Waitlist measures. Before a CAPS appointment please add a post it note to the CAPS form (and hand this to the therapist) with a brief description of the main traumas experienced by the individual. This means the therapist knows a little about the history before the session as they are unable to look the client up without becoming unblinded. A therapist needs to then be identified (if not already) for the End of Waitlist participant so they can start NET treatment ASAP then refer back to point number 7. All the CAPS and measures scores need to be labelled correctly and recorded in the appropriate place (see point 6 for details).

8. Follow Up – 3, 6 and 12 month

Three month follow up is measures only, six and twelve month follow ups are for both measures and CAPS.

There is a six-week cut off window for collecting follow up measures and CAPS, however often it is good to collect the data even out of window – but just make a note that it is out of window and a brief reason why data collection fell out of window.

Book all follow up measures appointments with an Assistant Psychologist, and the CAPS with an appropriate therapist. Before a CAPS appointment please add a post it note to the CAPS form (and hand this to the therapist) with a brief description of the main traumas experienced by the individual. This means the therapist knows a little about the history before the session as they are unable to look the client up without becoming unblinded. Please document all the dates for measures on the participant spreadsheet. Check if an interpreter is needed for the measures.

NET trial flowchart