UCL Ethics Project ID: 8133/002

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**Treating Post-traumatic Stress Disorder in Victims of Trafficking and other Forced Migrants using Narrative Exposure Therapy: A Pilot Randomized Controlled Trial**

We would like to invite you to take part in a research project looking at how well Narrative Exposure Therapy, a specialised form of talking therapy, works in victims of trafficking and other human rights abuses who experience Post-traumatic Stress Disorder (PTSD). In this information sheet we have explained why the research is being done and what it would involve for you. Please read this information carefully before making a decision about whether to take part, and discuss it with others if you wish. Please also feel free to ask questions if anything is unclear or you would like more information. Please note, taking part will not influence your asylum seeking process.

**What is the purpose of the project?**

In our work at the Helen Bamber Foundation, we routinely offer a talking therapy called Narrative Exposure Therapy to people with symptoms of post-traumatic stress disorder (PTSD) who have experienced many different types of trauma. There is good evidence for the use of Narrative Exposure Therapy within war zones, yet only a small amount of research has explored whether it works well in people who have left their countries of origin. Therefore, we are hoping to evaluate how well our therapy works for different groups of people who have all experienced multiple traumas, and to make sure they are treated in the most efficient and effective way. To make sure it works effectively, we have to compare Narrative Exposure Therapy to something else. Therefore, we will be comparing it to people who are waiting to receive therapy.

**What will happen if I decide to take part?**

If you decide to take part, you will be given this information sheet to keep and asked to sign a consent form. When you enter, you will randomly be allocated to either start therapy straight away, or placed into the ‘waiting list’ group to start therapy about six months later. If you are allocated to the waiting list group, however, you will still have the same access to any other services offered by the Helen Bamber Foundation. If you are placed in the waiting list group, you will be given a review appointment before you start therapy to make sure that it is still the right type of help for you at that time.

Throughout the duration of the research study, you will routinely be asked to fill out questions about your mental health and well-being. This will include questions about particular symptoms you are having such as “Have you been having bad dreams or nightmares about the trauma?” and asking you to rate statements such as “Worrying thoughts go through my mind”. You will also be asked questions relating to your day-to-day life. These questionnaires will take to a total of about 20-30 minutes to fill in. If you need an interpreter, one will be arranged for you. We will ask you the same set of questions again three, six and twelve months after you have finished therapy. This is so we can see how things change for you over time.

**Are there any risks to me if I take part?**

This study has been approved by the UCL Ethics Committee who have assessed the risks to anyone taking part. We do not anticipate you will experience any negative effects of participating in this study, and you are free to withdraw at any time and do not have to give a reason. Deciding not to take part or to withdraw will not affect the other help and support you receive from the Helen Bamber Foundation. However, if at any point you feel that the therapy is not helping you, you can talk to your therapist. They will be able to arrange any support you might need.

**Will my taking part in this study be kept confidential?**

Your answers to the questionnaires will be ‘anonymised’. This means that none of your personal information (for example your name) will be linked to your responses. Instead your responses will be given a unique code that we use during our data analysis. The results from this study may be published in future. You will not be identified personally in anything that is published. Once the study is finished, we will contact you with a summary of the findings.

All the information you provide will be strictly confidential so that only the research team have access to them. The questionnaire data will be entered into an electronic database and stored securely for the duration of the project so they can only be accessed by the researchers working on this project. All data will be collected and stored in accordance with the Data Protection Act 1998.

**Who is organising the research?**

The research project has been reviewed and approved by the Research Ethics Committee at UCL. The research is being supervised and carried out by clinicians and researchers at the Helen Bamber Foundation.

**Will withdrawing from the study affect my treatment or activities at the Helen Bamber Foundation?**

Participation in the study is entirely voluntary and you do not have to take part. You can change your mind and withdraw your consent to participate at any time, without giving any reason for doing so. If you decide not to participate in the study, or decide to leave the study, this will not in any way affect the support or therapy you are receiving (or may receive in future) from the Helen Bamber Foundation.

Please discuss the information above with others if you wish, or ask us if there is anything that you would like more information about before deciding to take part.

**What do I do if I need help with my problems?**

If you need any help with ongoing problems, please speak to your therapist.

**What are the possible benefits of taking part?**

We hope that the information we get from this study will help us find out how well Narrative Exposure Therapy works. This will help us make sure that symptoms of PTSD are treated in the most effective way. This will also allow us to share this information with other people and organisations (such as charities, practitioners, and researchers) to make sure we are helping people as effectively as possible during this time.

**Research Team:**

Professor Cornelius Katona, Consultant Psychiatrist, Helen Bamber Foundation and Honorary Professor, Division of Psychiatry, UCL

Dr Katy Robjant, Consultant Clinical Psychologist, Helen Bamber Foundation

Dr Francesca Brady, Clinical Psychologist, Helen Bamber Foundation

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Contact the team on 0203 058 2020 or reception@helenbamber.org with any queries.