

Feasibility study of an integrated parenting intervention

Submission date 04/02/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/04/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A recent report of the United Nations Human Rights Council (2019) estimates that there are currently 70.8 million forcibly displaced people worldwide. As documented by several studies, this group is at great risk of having mental health difficulties. The mental health difficulties of parents not only influence themselves but also children's mental health. The transition of mental health difficulties through harsh parenting highlights the importance of family-level interventions rather than individual-level interventions. Targeting parenting skills might reduce the impact of the displacement on the mental health of children. This study will offer an online group parenting intervention to parent refugees and asylum seekers to improve their parenting satisfaction by addressing mental health difficulties

Who can participate?

Parent refugees and asylum seekers aged over 18 with young children (aged under 3)

What does the study involve?

Participants will attend eight weekly online group parenting intervention and complete several scales to test the feasibility of the intervention. The intervention Learning Through Play (LTP) will be delivered to parent refugees in conjunction with EMDR Group Treatment Protocol (EMDR-GTEP). LTP aims to enable parents to improve their child's psychosocial development by increasing awareness about child development and the importance of play activities.

What are the possible benefits and risks of participating?

Potential benefits to research participants will be improving parenting skills and mental well-being. In addition to that, participants may experience some positive benefits from knowing that they are contributing to the development of new therapies for their communities. Previous research has also shown that taking part in mental health research can have positive effects for participants, including positive feelings of catharsis and being able to help others. Participants will also be reimbursed for their time.

Where is the study run from?

University of Manchester (UK)

When is the study starting and how long is it expected to run for?
February 2021 to March 2022

Who is funding the study?
Turkish Embassy Education Counsellor's Office (UK)

Who is the main contact?
Safa Kemal Kaptan
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
LTP+1

Study information

Scientific Title
Feasibility trial of learning through play parenting intervention integrated with eye movement desensitization and reprocessing group traumatic episode protocol (LTP + EMDR G-TEP)

Acronym
LTP + EMDR G-TEP

Study objectives

To assess the feasibility and acceptability of the group parenting intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/02/2021, The University of Manchester Research Ethics Committee 1 (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; +44 (0)161 275 2206/2674; research.ethics@manchester.ac.uk), ref: 2021-10701-17718

Study design

Online feasibility trial with pre- and post-intervention assessment

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Parenting sense of competence, depression, anxiety, stress

Interventions

LTP+ EMDR G-TEP is a manual assisted integrated parenting psychological intervention. LTP is based on the principles of attachment theory which is integrated with EMDR. The intervention will be delivered in eight sessions over 3 months. The first four sessions are offered weekly and further sessions fortnightly and each session lasting about 60 minutes.

LTP+ EMDR G-TEP has two components:

Component 1 is Learning Through Play (LTP) aims to promote healthy child development by improving parents' mental health and strengthening attachment between parents and their children. The LTP manual covers the physical and psychological development of children and the importance of parent-child play. The key feature of LTP is the pictorial calendar. The calendar contains illustrations of play activities, enables parents to understand how attachment works. LTP is a low-cost intervention since homemade toys and materials are used to keep costs down to the minimum. The program can be easily delivered to disadvantaged groups as it does not require participants to possess formal education.

Component 2 is Eye Movement Desensitization and Reprocessing Group Traumatic Episode Protocol (EMDR G-TEP). EMDR G-TEP is a group psychotherapy intervention. It is aimed at adolescents and adults. The group protocol covers the core principles of standard individual EMDR therapy with special attention to stabilization and positive future resources.

Intervention Type

Behavioural

Primary outcome(s)

Measured at baseline (pre-trial) and post-trial:

1. PTSD assessed using the International Trauma Questionnaire
2. Anxiety assessed using the Generalized Anxiety Disorder 7-item (GAD-7) Scale

3. Depression assessed using the Patient Health Questionnaire-9 (PHQ-9)
4. Parenting skills assessed using the Parenting Sense of Competence Scale

Key secondary outcome(s)

1. Dissociative experiences measured using Dissociative Experiences Scale - II at baseline
2. Participants' satisfaction with the intervention measured using Client Satisfaction Questionnaire (CSQ-8) at post-intervention

Completion date

01/03/2022

Eligibility

Key inclusion criteria

1. Over 18 years old
2. Able to provide informed written consent and to speak English
3. No restriction related to ethnicity, medical conditions will be applied
4. Being a refugee or asylum seeker
5. Being a parent
6. Registered with GP

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Age below 18 years old
2. Not able to provide informed written consent and to speak, read, and understand English
3. Refugees or asylum seekers who are not parents

Date of first enrolment

22/05/2021

Date of final enrolment

01/11/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
The University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
Turkish Embassy Education Counsellor's Office

Funder(s)

Funder type
Government

Funder Name
Turkish Embassy Education Counsellor's Office

Results and Publications

Individual participant data (IPD) sharing plan

The datasets will be available from the corresponding author on reasonable request immediately after publication from Safa Kemal Kaptan (safa.kaptan@manchester.ac.uk).

Type of data: repeated measures data

Data will become available: indefinitely

Data will be shared with researchers for example for meta-analysis purposes or verifying the conducted analyses

Access criteria: upon request

Participants will give informed consent to use the anonymized data for research purposes

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Protocol article](#)

23/12/2021

22/04/2022

Yes

No