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Feasibility study of an integrated parenting intervention

Submission date
04/02/2021

Recruitment status
No longer recruiting

Registration date
11/03/2021

Overall study status
Completed

Last Edited
22/04/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Safa.kaptan@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Safa Kemal Kaptan

ORCID ID
https://orcid.org/0000-0002-4709-6543

Contact details
Global Mental Health and Cultural Psychiatry Research Group
Complex Trauma and Resilience Research Unit
Division of Psychology and Mental Health
University of Manchester
Jean Macfarlane Building, 3.306
Manchester
United Kingdom
M13 9PY
+44 (0)7404791100
safa.kaptan@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
04/02/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
8-10

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
England

United Kingdom

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

Sponsor information

Organisation
Turkish Embassy Education Counsellor's Office

Sponsor details
First Floor
5-15 Cromer St
London
United Kingdom
WC1H 8LS
+44 (0)20 3875 9551
burslu_londra@meb.gov.tr

Sponsor type
Government

Website
http://londra.meb.gov.tr/

Funder(s)

Funder type
Government

Funder Name
Turkish Embassy Education Counsellor's Office

Results and Publications

Publication and dissemination plan
Once the study receives ethical approval the protocol will be published in a peer-review journal. Findings will also be submitted to a peer-review journal and relevant conferences. Finally, the study will form a chapter in the PhD thesis.

Intention to publish date
01/01/2022

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?
Protocol article		23/12/2021	22/04/2022	Yes	No