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A family skills training programme for challenged and humanitarian settings introduced in Afghanistan

Submission date
05/03/2020

Recruitment status
No longer recruiting

Registration date
09/03/2020

Overall study status
Completed

Last Edited
26/08/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Children living in challenged humanitarian settings (including those in rural/underserved areas, the displaced, refugees, in conflict/post-conflict situations) are at greater risk of mental health difficulties or behavioural problems, with caregivers acting as their main protective factors. While many family skills programmes exist, very few were developed for, or piloted in, low resource settings (settings with limited infrastructure, typical of humanitarian settings). The researchers, therefore, designed a brief and light programme; the Strong Families (SF) programme, consisting of 5 hours contact time over 3 weeks. The researchers will conduct a pilot study with the aim to test the feasibility of implementation, and a preliminary look at the effectiveness of SF, in improving child behaviour and family functioning in families living in Afghanistan.

Who can participate?
Female caregiver to a child between the age of 8-12 years.

What does the study involve?
Families will be recruited via two high schools and one 100 beds Drug Treatment Centre (DTC) for women and children in Kabul, a 150 beds drug demand reduction (DDR) hospital in Balkh and a women DTC in Herat. The schools will be selected by the Ministry of Education based on the main criteria of having easy access of the families to the school and the provision of two class rooms for the programme to run. Caregiver information sheets will be distributed to all children aged eight to 12, who attend the participating schools, to take home to their caregivers. Female caregivers will be invited via a self-referral process to attend an information session where they will be given further verbal and written information and questions will be answered. Caregivers will be asked to phone the school within the next 4 days if they want to participate. The first to call the school will be invited to take part in the pilot study and attend a baseline measurement session the following week in which written informed consent will be obtained prior to data collection.
The Strong Families (SF) programme, consists of 5 hours contact time over 3 weeks. Demographic data, emotional and behavioural difficulties of children and parental skills and

family adjustment measures will be collected from caregivers before, 2 and 6 weeks after the intervention.

What are the possible benefits and risks of participating?
The anticipated short-term benefits are:
• Improved caregiver confidence in family management skills
• Improved caregiving in parenting skills
• Improved child behaviour
• Reduced aggressive and hostile behaviours
• Increased capacity to cope with stress
• Improved mental health outcomes in children and parents
Although not assessed through this study per se, the intended long-term benefits are as described in the logic framework (https://www.unodc.org/documents/drug-prevention-and-treatment/Strong_families_Brochure.pdf)
• Reduction in violence
• Reduction in substance abuse
• Reduction in risky behaviours
• Improved mental health for caregivers and children
No direct risks resulting from the programme or the evaluation of the programme per se are anticipated. In general, however, the programme is not thought as an intervention to cure severe trauma. Should however a situation arise through the discussion in regards to a sensitive topic (for example violence in the family, severe mental trauma through war exposure, etc.), people will be linked to care, and a list of referral centres available at the community level is available. Facilitators are prepared to refer people with problems that are beyond the scope of the programme to the respective dedicated sites.

Where is the study run from?
1. United Nations Office on Drugs and Crime (Austria)
2. Participant recruitment in Afghanistan

When is the study starting and how long is it expected to run for?
July 2018 to October 2018

Who is funding the study?
US-INL (Bureau of International Narcotics and Law Enforcement Affairs) (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DRKS00020791

Study information

Scientific Title
Strong Families: A new family skills training programme for challenged and humanitarian settings: a single-arm intervention tested in Afghanistan

Study objectives
The primary objective was to test the effectiveness of the Strong Families program in improving family skills outcomes and caregiver and child mental health, as reported by caregivers and children, when implemented in schools and the social and health care settings in Afghanistan.
The secondary objective was to assess the implementation process of Strong Families in preparation for a Randomised Controlled Trial (RCT) in Afghanistan.
The tertiary objective was to explore the cultural acceptability of the Strong Families program for families, practitioners and policymakers in Afghanistan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by:
1. UNODC Drug Prevention and Health Branch in the Headquarters office of Vienna
2. UNODC national field office in Kabul
3. Afghan Ministry of Counter Narcotics
4. Ministry of Public Health

5. Ministry of Labour and Social Affairs
6. Ministry of Education
7. Ministry of Women Affairs and Ministry of Health
8. NGOs that supported the programme
as an alternative to ethics committee review. The Strong Families programme has been thoroughly analysed and, after approval, has been integrated in the National Drug Demand Reduction policy 2019-2023 for Afghanistan, as well as the National Drug Demand Reduction Strategy 2018-2022. Further, the donor to the programme development and implementation, US-INL (Bureau of International Narcotics and Law Enforcement Affairs) under the U.S. Department of State, had reviewed and approved the proposal before initiating the trial.

Study design
Open multicentre pilot interventional single-arm (uncontrolled) study feasibility and acceptability trial with an embedded effectiveness evaluation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Prevention

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
Prevention of mental health disorders
Prevention of drug use disorders
Improvement of parenting skills

Interventions
All families receive the Strong Families programme, which is a training programme delivered through three sessions (7 components requiring 5 h of invested time by the families in total). This group intervention is attended by children and their primary caregivers over a time span of 3 weeks (one session per week). In week one, a group of 12 caregivers meet for the 1-h caregiver pre-session. In weeks two and three, the same 12 caregivers meet again in one room, and their 12 children meet in parallel in another room for the child sessions. After these 1-h parallel sessions, all caregivers and children immediately meet in one room for another1-h for a joint family session.

The session of week one (caregiver pre-session) explores parents challenges and develops ways to better deal with stress. In week two, caregivers discuss the means of showing love while at the same time having and enforcing limits and listening to children, while the children learn how to deal with stress. During the family session they practice positive communication and are encouraged to practice stress relief techniques together. In week three, parents learn to

encourage good behaviour and discourage misbehaviour, while children explore rules and responsibilities and think about future goals in addition to the important roles their caregivers play in their lives. In the final family session, caregivers and children learn about family values and practice sharing appreciation to each other.

Data on demographics, emotional and behavioural difficulties of children and parental skills and family adjustment measures are collected from all caregivers through self-administered questionnaires.
Two outcome measures are completed by participants at baseline (i.e. 1 week before intervention delivery) (t1) and 2 weeks (t2) and 6 weeks (t3) after intervention delivery. These are the paper-based Strengths and Difficulties Questionnaire (SDQ) and a Parenting and Family Adjustment Scales (PAFAS). A standardized Family Background Questionnaire (FBQ) is completed at t1 to collect demographic characteristics.

Intervention Type
Behavioural

Primary outcome measure
1. Child mental health was measured through a paper-based questionnaire, Strengths and Difficulties Questionnaire (SDQ) at baseline (1 week before the start of the intervention), at 2 weeks after programme completion and then 6 weeks post-intervention
2. Parenting skills were measured through a paper-based questionnaire, Parenting and family adjustment scales (PAFAS) at baseline (1 week before the start of the intervention), at 2 weeks after programme completion and then 6 weeks post-intervention.
3. For stratification, a paper-based Family Demographics Questionnaire was filled in at baseline

Secondary outcome measures
1. Fidelity and completeness of programme delivery was assessed through interviews with facilitators and researchers, and interviews with managers and co-ordinators after the completion of the trial, independent observer questionnaires and completion of self-assessment tools through facilitators after each training session delivered to families.
2. Families' rates of recruitment, attendance to programme, provision and quality of intended inputs, such as suitability of transport, venues, refreshment were measured through the independent observer questionnaires (supported by research team members to track attendance for every session) and completion of self-assessment tools through facilitators after each training session delivered to families

Overall study start date
15/02/2018

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Female caregiver to a child between the age of 8-12 years
2. Speaks Dari
3. Willing to take part in the programme
4. In the town for the duration of the whole intervention and the measurement meetings

Participant type(s)
Other

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. Already taken part in another family skills training programme in the past 6 months
2. Caregiver lives separately from the child

Date of first enrolment
01/07/2018

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
Afghanistan

Study participating centre
Zarghona High School
Kabul
Afghanistan
1007

Study participating centre

Bibi Mahro High School
Kabul
Afghanistan
1011

Study participating centre
Khushal Mena Drug Treatment Centre (DTC)
Kabul
Afghanistan
1003

Study participating centre
Drug demand reduction (DDR) hospital
Balkh
Afghanistan
1751

Study participating centre
Women Drug Treatment Centre (DTC)
Herat
Afghanistan
3001

Sponsor information

Organisation
United Nations Office on Drugs and Crime

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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
US-INL (Bureau of International Narcotics and Law Enforcement Affairs)

Results and Publications

Publication and dissemination plan
All datasets generated and analysed during the current pilot study, as well as all questionnaires used are already publicly and free of cost available in the Mendeley Data repository, http://dx.doi.org/10.17632/v5dryspfy4.1.
Further, all results will be published in a peer-reviewed journal (BMC Public Health acceptance pending clinical trial registration number).
The study protocol and analysis plan can be shared any time upon request by any researcher or another interested party. They have already been freely and broadly been shared with the respective Ministries in Afghanistan, as well as all counterparts involved, NGOs, facilitators, UNODC Headquarter and Field offices.

Intention to publish date
01/04/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/05/2020	26/08/2020	Yes	No