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Testing the effectiveness and acceptability of Strong Families – Iran

Submission date
18/08/2021

Recruitment status
No longer recruiting

Registration date
20/08/2021

Overall study status
Completed

Last Edited
28/09/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Caregivers have a key role in protecting children's wellbeing, and with appropriate skills can prevent a number of negative social outcomes, including drug use, child maltreatment, poor mental health and reduce childhood aggression. The role of caregivers is particularly important in challenged or humanitarian settings. Interventions encouraging safe and nurturing relationships between caregivers and their children can therefore prevent these negative social outcomes. The United Nations Office on Drugs and Crime (UNODC) has been implementing a global initiative on prevention that has been piloting evidence-based family skills prevention in low- and middle-income countries globally. The Strong Families programme was designed as a light touch family skills programme with a focus on supporting caregiving particularly during stressful situations. The aim of this study is to evaluate the short-term impact of the Strong Families programme in Iran.

Who can participate?
Caregivers with children aged 8-12 years who speak Farsi, are in town for the whole time of the study and measurement meetings, and have not participated in another family skills programme within the last 24 months

What does the study involve?
Participants are randomly allocated to either receive the Strong Families programme over 3 weeks (one session of 1-2 hours per week) or to receive services-as-usual, and only receive the Strong Families programme after the completion of all data collection. Data is collected through questionnaires assessing changes in parenting skills and family adjustment in caregivers, children's behaviour, and children's resilience capacities.

What are the possible benefits and risks of participating?
All participants receive the same intervention (the Strong Families programme) but at different times. The short-term benefits of the programme 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, and improved mental health outcomes in children and parents. Although not assessed through this study per se, the intended long-term benefits are reduction in violence, reduction in substance abuse, reduction

in risky behaviours and 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 of 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 Headquarters (Austria)
2. United Nations Office on Drugs and Crime (Iran)
3. Participant recruitment in Iran

When is the study starting and how long is it expected to run for?
September 2019 to December 2021

Who is funding the study?
This research was funded by Japan Supplementary funding 2019-20 to UNODC, grant number S1-32ADK-000093. The Strong Families Programme was developed and tested in Afghanistan thanks to the generous support of the US-INL (Bureau of International Narcotics and Law Enforcement Affairs). The researchers would also like to acknowledge the contribution of the government of France and Sweden for their support for the programme.

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Type(s)
Scientific

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Study information

Scientific Title
Impact of a brief family skills training programme (Strong Families) on child mental health, resilience and parenting skills in Iran: a multisite randomized controlled trial

Study objectives
The Strong Families programme is a group intervention for children and their primary caregivers with sessions attended over 3 weeks (one session per week). Up to two parents or main caregivers attend with a maximum of two children under their care aged eight to 12 years.

The main aim of the current study was to expand the experience with Strong Families, which had so far tested on its feasibility and effectiveness with one arm research modality through a two-arm intervention/control trial that would further assess its impact on different domains of its logical framework. The dimensions of impact to be evaluated were namely on child mental health, parenting and family adjustment skills and child resilience. Furthermore, such an impact would be assessed by different family characteristics, namely by including a sub-analysis of the “most-at-risk” families at baseline.

The secondary objective was to also assess the replicability of the previous single-arm pilot study in a new country. Coincidentally and while not originally intended, one further objective of this study was to compare the effect of the programme on different ethnicities (cultural background) within Iran by stratifying the analysis of results for families from Iran and those who have migrated from Afghanistan to Iran in the past. This last objective would help assess the replicability component regardless of cultural background.

From their partner organisations, the researchers had knowledge that families with Afghan origin had more children and that these children would also often be enrolled at a later age into school and hence would be older when recruiting children from the same grade into our study. To test for this hypothesis, they included an analysis to see if a higher number of children within a family which could potentially be a more stressful situation within the home, or children with an older age would cause higher scores at baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2019, the Institutional Review Board of the Iranian Drug Control Headquarters (DCHQ; Above Poonak Square, After Hoveizeh Recreation Complex, No 20, Presidential Anti-Narcotics Headquarters, Tehran; Tel: not available; public_relations@dhcq.ir), ref: 12/2583429

Primary study design
Interventional

Study design
Multisite non-blinded time-convenience randomized trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Prevention of negative social outcomes, including drug use, child maltreatment, poor mental health and childhood aggression in families living in Iran

Interventions

The Strong Families programme is a group intervention for children and their primary caregivers with sessions attended over 3 weeks (one session per week). Up to two parents or main caregivers attend with a maximum of two children under their care aged eight to 12 years. During week one, caregivers attend a group session with up to 12 other caregivers for one hour. This is the caregiver pre-session, it deals with normalizing the challenges caregivers may be facing while also teaching effective stress management techniques. During weeks two and three, the same 12 caregivers attend the programme accompanied by their children for two hours. Children and caregivers from each family split into two separate rooms for the first hour and take part in group 'child' or 'caregiver' sessions. Then, during the immediate second hour, all participants group together in one room for a 'family' session'.

The caregiver session in week two focuses on practising using both love and limits in interacting with children and the importance of listening and communicating effectively. This is achieved through role-plays, interactive activities and group discussions. In week two, children explore what 'stress' means and begin to normalize feelings they may experience when stressed. They also learn stress management techniques. During the family session caregivers and children come together and take part in activities that provide an opportunity to practice positive communication, understanding the sources of challenges in each other's lives and practise stress relief techniques together.

In week three, caregivers practice strategies to increase their influence as a parent, such as encouraging good behaviour and discouraging misbehaviour. They also learn about using directed praise and using appropriate consequences with their children. Children explore rules and responsibilities and are guided to begin thinking about setting future goals and how they might achieve these. They are also supported to think about the important roles their caregivers play in their lives. In the final family session, caregivers and children take part in activities that promote exploring family values and what actions they might take to show these in their daily lives. They also spend time practising communicating appreciation for each other.

The cultural adaptation of the Strong Families programme to the context of Iran was assured through seven technical sessions from April to June 2019, with representatives from the Drug Prevention Department of the Iranian Drug Control Headquarters (DCHQ), Ministry of Education (MOH), Ministry of Health and Medical Education (MOHME), State Welfare Organisation (SWO) and three civil society organisations: The Iranian Life Quality Advancement Institute (ILIA), Society for Recovery Support (SRS) and the Toloo Sobh Khorshid Institute, and UNODC. Further to adding the cultural adaptation in the Iranian context UNODC held an advocacy meeting with the different national counterparts responsible for drug use prevention as well as the family skills trainers on the added value and experience of Strong Families to facilitate endorsement at the political level. The translation of the training materials and questionnaires into Farsi was conducted by a translator selected from the roster of the UN translators, and reviewed and edited by UNODC staff.

To evaluate the programme, the researchers conducted a multisite non-blinded time-convenience randomized trial with two arms to assess effectiveness:
1. Intervention group: receiving the Strong Families programme
2. Control/waitlist group: receiving services-as-usual, and only receiving the Strong Families programme after the completion of all data collection points

The researchers prospectively collected outcome data assessing changes in parenting skills and family adjustment in caregivers, children's behaviour, and children's resilience capacities. To assess feasibility and acceptability in the Iranian context, they additionally included an embedded process evaluation.

Sampling utilised an opportunistic 'universal' approach, in which research assistants recruited families from the general population, without targeting any particular risk group. Clinical diagnoses were not assessed in participants, however, during the first session, caregivers were provided with leaflets with information on where they might access help in case they observe severe stress reactions, or other physical, mental or sexual health concerns they might have for themselves or their children. Inclusion criteria in the programme and the study included speaking Farsi, being willing to take part in the programme and being in the town for the duration of the whole study and measurement meetings. Families were excluded from the study if they had taken part in any other family skills training programme during the last 24 months or if the caregiver and child lived separately. Non-biased allocation to the intervention or control group was done only after the first data collection by convenience, i.e. availability of families. Participants in the intervention group were then told to attend the first programme session on the same day, whereas families in the control group were informed to attend the next data collection point 5 weeks later (2 weeks after the intervention group had completed the programme).

Ten centers were nominated for the implementation of the programme in Tehran and Karaj in Iran. The ten centers were: two schools selected by the Ministry of Education (MoE), two community centers selected by the State Welfare Organisation (SWO), two community primary health care centers selected by the Ministry of Health (MoH) and four centers from non-governmental organisations (NGOs). The two schools included in the trial were the Aeme Athar elementary school for boys and Efaf elementary school for girls, both located in district 15 of Tehran, a known low-income urban area. Moreover, two centres from ILIA NGO were chosen, that routinely provide educational services for children of Afghan refugees and Iranian citizens, as does SRS. The remaining centres were the Akbari Health Centre (MoH), the Hakimieh Health Centre (MoH), Ghasedak (SWO), Ghoncheh (SWO) and Toloo e Sobh e Khorshid (NGO). Overall, centres were selected based on the main criteria of having access to families and the provision of two rooms for the programme to run and were not segregated based on gender.

Facilitators were selected based on their previous experience in school-based prevention activities, such as SFP 10-14 and FAST or those who were familiar with prevention activities, like SRS and ILIA who have launched life skills programmes earlier in Iran. Facilitators were frequently staff of the centers to ensure sustainability and continuation after termination of the study. Most of the facilitators nominated by the MOH had no previous experience facilitating prevention programmes. In addition, DCHQ requested to select facilitators that have at least 10-15 years left until their retirement and separation from the institution, to ensure retainment of knowledge and skills. In November 2019, 41 facilitators (37 females and 4 males) from all 10 centers were trained on the Strong Families programme in Tehran by two international trainers. In addition, 26 research assistants (23 female and 3 male) from all 10 centers were trained by local UNODC staff (also previously trained by the same international trainers) in a 2-day training. This 2-day session covered recruitment of participants, data collection and acquaintance with the data collection tools.

Immediately after completion of the training, research assistants distributed brochures containing information to caregivers of all children aged eight to 12 years within the reach of

their respective centers. Further, they were provided with posters and banners of Strong Families to hang up on the walls of the centers to attract interested families. For the formal schools however, two entire classes were chosen for programme implementation.

Caregivers were invited via a self-referral process to attend an information session where they were given further verbal and written information and questions were answered. Although centers were instructed on random allocation of participants through sealed envelopes, none of them complied with this. The usual practice was that after caregivers were introduced to the programme, the centers presented them with the timelines of the three cycles of the programme and caregivers could register based on their availability. Once families agreed to take part in the study, they attended a baseline measurement session in which written informed consent was obtained prior to data collection. Children completed assent forms, and caregivers consent forms. These forms recognized that all participants had an opportunity to ask any questions about the study they might have, did not feel any pressure to take part, and that they accepted that the data collected would be anonymized and used in scientific publications.

Families were enrolled on the study between 18 November 2019, and 7 December 2019 and subsequently the programme was delivered in all 10 centers. The first measurement meetings took place in November/December 2019 in all study sites and in late December/January 2020 for the control group. All families in the intervention group took the programme in December or January 2019, whereas families in the control group were told to come back only for the second measurement meeting 5 weeks later (which is 2 weeks after the completion of the intervention group). Initial plans were for the waitlist (i.e. control) group to receive the intervention in March 2020, after all data collection was completed. However, programme delivery in almost all centers was postponed due to COVID-19 lockdown measures. At the time of writing this application for registration, Iran is still experiencing lockdown restrictions. While the commitment to avail Strong Families to all families on the waiting list will materialize as soon as the measures will ease, UNODC availed, in interim, a booklet and leaflet containing information regarding parenting under COVID-19 to all families.

Intervention Type
Behavioural

Primary outcome(s)
1. Child mental health 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 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. Social-ecological resilience self-reported through children through the paper-based Child and Youth Resilience Measure (CYRM-R) at baseline (1 week before the start of the intervention), at 2 weeks after programme completion and then 6 weeks post-intervention
4. For stratification, baseline characteristics were collected using a paper-based Family Demographics Questionnaire at baseline

Key secondary outcome(s)
Implementation process evaluated based on the number of sessions provided by coordinators in the field, and information on fidelity, dose received, reach and inputs provided by facilitators and independent observers at the end of each session of the Strong Families programme (after completion of each of the three sessions with families during the actual intervention period)

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Primary caregiver with a child between 8 and 12 years
2. Speaking Farsi
3. Willing to take part in the Strong Families programme
4. Being in the town for the duration of the whole study and measurement meetings

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
377

Key exclusion criteria
1. Having taken part in any other family skills training programme during the last 24 months
2. The primary caregiver and child lived separately

Date of first enrolment
18/11/2019

Date of final enrolment
07/12/2019

Locations

Countries of recruitment
Iran

Study participating centre
Aeme Athar elementary school
Iran
-

Study participating centre
Efaf elementary school
Iran
-

Study participating centre
Akbari Health Centre
Iran
-

Study participating centre
Hakimieh Health Centre
Iran
-

Study participating centre
Ghasedak
Iran
-

Study participating centre
Ghoncheh
Iran
-

Study participating centre
Toloo e Sobh e Khorshid
Iran
-

Study participating centre
ILIA (Iranian Life Quality Advancement Institute) Shahr e Rey
Iran
-

Study participating centre

ILIA (Iranian Life Quality Advancement Institute) Karaj
Iran
-

Study participating centre
Society for Recovery Support (SRS)
Iran
-

Sponsor information

Organisation
United Nations Office on Drugs and Crime

ROR
https://ror.org/04567sh69

Funder(s)

Funder type
Government

Funder Name
The People of Japan (Japan Supplementary funding 2019-20 to UNODC, grant number S1-32ADK-000093)

Results and Publications

Individual participant data (IPD) sharing plan
All datasets generated and analysed during the current pilot study are already available publicly and free of cost in the Mendeley Data repository: https://data.mendeley.com/datasets/yfmp8n2n4p/draft?a=2c4cb928-70f4-46d2-8fbd-f742bd384219. All of the individual participant data collected during the trial are being shared within this repository after deidentification. Data are already available and will be available for 5 years after the trial, as stated in the consent/assent forms.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/10/2021	06/09/2023	Yes	No
Dataset		23/03/2021	28/09/2026	No	No