

Piloting of Family UNited in Indonesia and Bangladesh

Submission date 22/09/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/03/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Family is one of the most influential social institutions and caregivers can act as the main protective factors for children's mental health and resilience skills. Family skills programmes support caregivers to be better parents and strengthen positive age-specific and age-appropriate family functioning and interactions. We developed a universal, brief and light family skills programme that is intended for implementation in low-resource settings; the Family UNited programme consists of 12 sessions of 8 hours of contact time over 4 weeks. We conducted a pilot study in Bangladesh and Indonesia to show the feasibility of implementation, replicability and effectiveness of the Family UNited programme in improving family functioning, child behaviour and resilience. The aim of this study is to pilot and evaluate the short-term impact of the Family UNited programme in Bangladesh and Indonesia.

Who can participate?

Caregivers with children aged 8 to 14 years old will be invited through schools in East Java, Indonesia and Dhaka, Bangladesh. Families had to speak Bangla (in Bangladesh) or Bahasa (in Indonesia), be in town for the whole time of the study and measurement meetings and have not participated in any other family skills programme within the last 24 months

What does the study involve?

Families in Indonesia received either the Family UNited programme or could choose to only participate in the data collection meetings, whereas all families in Bangladesh received the Family UNited programme over 4 weeks. Data was collected through paper-based 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 were offered the same intervention (the Family UNited programme) but at different times, unless they clearly stated that they did not want to take part in the programme, but only the data collection. The short-term benefits of the programme were 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 were 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, etc), people were linked to care, and a list of referral centres at the community level was available. Facilitators were 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 (Bangladesh)
3. United Nations Office on Drugs and Crime (Indonesia)

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

May 2019 to May 2020

Who is funding the study?

The People of Japan Supplementary funding to the United Nations Office on Drugs and Crime (UNODC) (Austria)

Who is the main contact?

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Contact information

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

Family UNited: Piloting a new universal United Nations Office on Drugs and Crime (UNODC) family skills programme to improve child mental health, resilience and parenting skills in Indonesia and Bangladesh

Acronym

Family UNited

Study objectives

Family UNited, a brief universal family skills programme, can be implemented in low-resource settings and is effective in increasing child resilience (measured as the capacity to cope with stress), improving child mental health and child behaviour and increasing parenting and family adjustment skills in caregivers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The United Nations Office on Drugs and Crime (UNODC) Drug Prevention and Health Branch in the Headquarters office in Vienna thoroughly reviewed and approved the study protocol. In

addition, the national UNODC field offices in Dhaka, Bangladesh and in Jakarta, Indonesia as well as the associated national ministries (MoE, Ministry of Home Affairs and Ministry of Social Welfare in Bangladesh and the MoE and National Narcotics Board (BNN) in Indonesia), CSOs (DAM in Bangladesh) and a scientific institution (Jakarta State University) in Indonesia acknowledged and supported the programme as an alternative to a formal ethics committee review. After this thorough review, the Family UNited programme has already been integrated into one of the National Narcotics Board programmes. The piloting was performed in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Study design

Multicentre unblinded waitlist-controlled two-arm study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of negative social outcomes

Interventions

In 2018, United Nations Office on Drugs and Crime (UNODC) developed a family skills programme called 'Strong Families', which was tailored for challenged and humanitarian settings (selective level prevention). Building on the positive evidence emerging from Strong Families, UNODC now developed a new family skills programme called "Family UNited". Family UNited is a more comprehensive programme that is suitable for implementation in wider settings (universal level prevention) again targeting particularly families living in low- and middle-income countries.

Family UNited is a group intervention for children and their primary caregivers with sessions attended over 4 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 14 years. Caregivers and children attend group sessions with up to 12 other caregivers and children. Each week the same 12 caregivers attend the programme accompanied by their children for two hours. On arrival, 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 families and facilitators group together in one room for the 'family' session.

The caregiver session in week one focuses on understanding praising and encouraging children. Caregivers learn how attention changes behaviour and how to use rewards, praise and give specific instructions. Children discuss and explore how to develop and practice positive qualities for themselves and begin to think of goals for their future. During the family sessions, children and caregivers come together to discuss what positive qualities they would like for their family and how to implement these in their family's daily life. The caregiver session in week two focuses on encouraging good behaviour and discouraging misbehaviour and strategies to increase their influence as a parent. Caregivers practice skills of giving effective instructions and being clear about rules and expectations. Children in week two 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 learn about each other, practicing positive

communication and stress relief techniques together. In week three, the caregivers practice using both love and limits in interacting with children and the importance of listening and communicating effectively. They learn how to use appropriate consequences with their children when responding to undesirable behaviour. This is achieved through role plays, interactive activities, and group discussions. Children are introduced to discussions on skills to resist peer pressure and during the family session, together with their caregivers, they practice such skills and also take part in fun activities that build on developing family connections. In the final week, week four, caregivers learn and practice strategies to reduce and manage children's aggressive behaviour through setting rules and discussing consequences. Children explore the meaning behind a 'good friend' and continue to practice skills to resist peer pressure. In the family session, families begin with peer pressure resistance practice between children and their caregivers, then take part in fun games that draw the skills they have been learning collectively together as they plan their goals for the future.

Against the background of:

1. UNODC's ongoing programmatic approach focused on strengthening family skills implementation in line with the UNODC WHO International Standards on Drug Use Prevention
2. Lack of open-sourced family skills packages designed and piloted in low- and middle-income countries

3. Interest of local governmental authorities in both Bangladesh and Indonesia including engagement with UNODC

UNODC initiated a pilot of a new family skills tool (Family UNited in both countries). The aim of this study was to assess the effectiveness of Family UNited against its logic model. Accordingly, we conducted a pilot study in Bangladesh and further included a comparison group to an intervention group in Indonesia to measure short-term impacts. We measured child resilience as the increased capacity to cope with stress, child mental health and behaviour and parenting and family adjustment skills in caregivers.

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. Self-reported social-ecological resilience measured from 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, demographic characteristics were collected using a paper-based Family Demographics Questionnaire at baseline

Key secondary outcome(s)

1. Participants with worse scores at baseline (regarded as families with more problems at baseline) were analysed separately for each of the subscales mentioned in the primary outcomes
2. Child mental health and child resilience results were compared by gender of the child before and 2 and 6 weeks after the intervention and compared between the 2 countries, and against the control group.

Completion date

01/05/2020

Eligibility

Key inclusion criteria

1. Primary caregiver with a child aged between 8 and 14 years old
2. Speaking Bangla/Bahasa
3. Willing to take part in the Family UNited programme (or the data collection only in the case of the control group in Indonesia)
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

120

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 from each other

Date of first enrolment

01/07/2019

Date of final enrolment

15/12/2019

Locations

Countries of recruitment

Bangladesh

Indonesia

Study participating centre

Tejgaon High school

Tejgaon

Dhaka

Bangladesh
1215

**Study participating centre
Junior High School**

-
Bandung City
Indonesia
40111

**Study participating centre
Junior High School**

-
Cianjur Regency
Indonesia
43215

**Study participating centre
Junior High School**

-
Cimahi City
Indonesia
40522

**Study participating centre
Junior High School**

-
West Bandung Regency
Indonesia
40553

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 to UNODC)

Results and Publications

Individual participant data (IPD) sharing plan

All datasets generated and analysed during the current pilot study are available publicly and free of cost in the Mendeley Data repository (<https://data.mendeley.com/datasets/krxbjm89zr/1>). All of the individual participant data collected during the trial are being shared within this repository after de-identification. Data will be available for 5 years after the trial, as stated in the consent/assent forms.

The Chief Investigator and the research team assured the confidentiality of participants in accordance with the Data Protection Act 1998. Each participant was assigned a unique identification number to ensure the matching of all questionnaires. All data collected as part of the trial were treated as confidential and were only viewed by members of the trial team; anonymised data were used wherever possible.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2023	18/12/2023	Yes	No