

# Assessing the efficacy of a brief universal family skills programme (Family UNited) on violence and substance use indicators in youth in Trentino and Parma, Italy

<b>Submission date</b> 22/12/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/08/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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. The current study aims to evaluate the short-term impact of improving family skills outcomes and caregiver and child mental health using Family UNited with families in Trentino and Parma, Italy.

### Who can participate?

Caregivers with children aged between 8 and 15 years old residing in Parma and Trentino, Italy

### What does the study involve?

Families in the intervention group will receive the Family UNited programme over 4 weeks, while waitlist/control group families will receive the Family UNited programme after the completion of all data collection points. Data will be collected through questionnaires assessing changes in parenting skills and family adjustment in caregivers, children's behaviour, children's resilience capacities and attitude towards peer violence.

### What are the possible benefits and risks of participating?

All participants will be offered the same intervention (the Family UNited programme) but at different times, unless they clearly state that they do not want to take part in the programme, but only the data collections. The programme is expected to provide short-term benefits of 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 a 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. However, should a situation arise through the discussion of a sensitive topic (for example violence in the family, severe mental trauma, etc), people will be linked to care, and a list of referral centres at the community level is available. Facilitators will be 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. University of Trento, Italy
3. University of Parma, Italy

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

December 2021 to September 2023

Who is funding the study?

The People of Japan Supplementary funding to UNODC.

Who is the main contact?

Dr Wadih Maalouf, wadih.maalouf@unodc.org

## Contact information

### Type(s)

Scientific

### Contact name

Dr Karin Haar

### ORCID ID

<https://orcid.org/0000-0001-7833-5976>

### Contact details

Prevention, Treatment and Rehabilitation Section  
Drugs, Laboratory and Scientific Services Branch  
Division for Policy Analysis and Public Affairs  
United Nations Office on Drugs and Crime  
Vienna  
Austria  
1400  
+43 1 26060 5182  
karin.haar@un.org

### Type(s)

Principal Investigator

### Contact name

Dr Wadih Maalouf

**ORCID ID**

<https://orcid.org/0000-0003-1820-3693>

**Contact details**

Prevention, Treatment and Rehabilitation Section  
Drugs, Laboratory and Scientific Services Branch  
Division for Policy Analysis and Public Affairs  
United Nations Office on Drugs and Crime  
Vienna  
Austria  
1400  
+43 1 26060 5182  
wadih.maalouf@un.org

**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

0238338

**Study information****Scientific Title**

Assessing the efficacy of a brief universal family skills programme on violence and substance use indicators in youth in Trentino and Parma, Italy through a multi-centre, non-blinded, cluster-randomised controlled trial (cRCT) of Family UNited

**Acronym**

Family UNited

**Study objectives**

The current study aims to explore the efficacy, fidelity, and acceptability of this universal prevention programme with families in Trentino and Parma, Italy, and the feasibility of delivering the programme.

The primary objective (impact evaluation) will be to test the efficacy of the Family UNited programme in improving family skills outcomes and caregiver and child mental health and resilience, as reported by caregivers and children, when implemented in Trentino and Parma, Italy. According to the logic model of Family UNited, the short-term participant and family impact will be measured and compared against a waitlist/control group.

The secondary objective (process evaluation) will be to calculate the extent of families' attendance of Family UNited sessions, to evaluate the completeness of programme delivery.

Further, the fidelity will be assessed to ensure facilitator compliance with the programme as trained.

The tertiary objective will be to explore the cultural and contextual acceptability of the Family UNited program for families in Trentino and Parma, Italy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/09/2022, Research Ethics Board of the University of Parma (Piazzale le San Francesco 3 PARMA, 43121, Italy; +39 0521 034643; protocollo@unipr.it), ref: 31-2022-N

### **Study design**

Multisite non-blinded two-arm cluster-randomized controlled trial with embedded process evaluation

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **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 negative social outcomes

### **Interventions**

In 2018, 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.

Participants will be parents or caregivers and one child under their care aged between eight and 15 years. Sampling will be opportunistic, using a 'universal' approach, in which facilitators will recruit families from the general population, not targeting specifically those with particular difficulties or risks. Inclusion criteria are caregivers who speak Italian and have at least one child under their care aged eight to 15 years, willing to take part in the programme and being in the area for the duration of the whole study. Families who took part in any other family skills

training programme in the past 24 months or where the caregiver lives separately from the child or does not have a constant relationship of attendance with the child (i.e. less than half of the time in case of shared custody) will be excluded from the study.

Family UNited will be delivered to families in groups of approximately 12 families (depending on COVID-19 physical distancing measures, this might need to be reduced down to a minimum of five families). Only one or two parents or main caregivers will be invited to attend with a maximum of two children under their care aged eight to 15 years.

The programme consists of four meetings spread over four weeks. In the first hour each week, two facilitators will work with caregivers in one room, whereas the other two facilitators work with the children in a separate room. In the second hour of the meeting, all four facilitators and all caregivers and children come together in one room for the joint family session.

During the Caregiver Sessions, caregivers learn about children's behaviour and how caregiver attention changes children's behaviour. They learn techniques to make the behaviour they want to see more likely to happen. They practice how to communicate with their children in a way that is healthy and promotes listening. They are also shown ways to make sure their children know that they are loved, and at the same time, how to set limits that help the children stay safe and feel secure.

During the Child Sessions, children learn about some good ways to deal with stress and the importance of talking to trusted adults about their feelings. They think about their caregiver's responsibilities and have discussions about the positive qualities they want to develop and use as adults. In addition, children learn and practice ways to deal with peer pressure situations, increasing the likelihood that they will stay healthy and safe.

In the Family Sessions, caregivers and their children come together to practice positive and respectful communication. Together, they play games and participate in activities that encourage positive relationships and build trust. The children enjoy one-to-one time with their caregivers while talking about the strengths and qualities they share as families and the things they can do together to demonstrate their family values.

Based on the process evaluation, we will monitor participants' attendance at each of the sessions and calculate the "Reach" and "Dose received".

During the trial period, participants will be requested not to take part in any other family skills programme, nor will any other contacts be made with the families, apart from the scheduled sessions of the Family UNited programme.

Facilitators in both Trentino and Parma have been trained on Family UNited through a 3 full-day in-person workshop in December 2021. They reached pilot families in March/April 2022 and implemented the programme. The same facilitators will implement Family UNited during the planned cluster-randomized controlled trial.

The primary outcome of this trial is to assess the efficacy of Family UNited in improving family skills outcomes and family mental health, by assessing caregivers parenting skills, parental confidence and mental health, as well as children's behavioural and mental health outcomes and resilience capacities and aggression and hostile behaviour as short-term impacts, as described in the logic model. To assess this, caregivers and children will complete a battery of questionnaires, right before the intervention (Time 1), two weeks post-intervention (Time 2) and six weeks post-intervention (Time 3) and mean/median scores will be compared.

In addition, semi-structured interviews will be conducted with a select group of caregivers that have completed the Family UNited programme and facilitators to include experiences and recommendations through a qualitative perspective.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Child mental health measured using 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 using 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 by children measured using 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. To measure youth's opinions or feelings about fighting (defined as physical fights, with pushing and hitting), not just arguments, measured using the "Attitude Toward Interpersonal Peer Violence" (ATIPV) at baseline (1 week before the start of the intervention), at 2 weeks after programme completion and then 6 weeks post-intervention
5. For stratification, demographic characteristics measured using a paper-based Family Demographics Questionnaire at baseline

## **Secondary outcome measures**

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 Family UNited programme (after completion of each of the three sessions with families during the actual intervention period)

## **Overall study start date**

01/12/2021

## **Completion date**

01/09/2023

# **Eligibility**

## **Key inclusion criteria**

1. Primary caregiver with a child aged between 8 and 15 years old
2. Speaking Italian
3. Willing to take part in the Family UNited programme and the data collection
4. Being in the area for the duration of the whole study and measurement meetings

## **Participant type(s)**

Healthy volunteer

## **Age group**

Mixed

**Sex**

Both

**Target number of participants**

160 (8 clusters with 20 families each)

**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**

15/02/2023

**Date of final enrolment**

15/04/2023

**Locations****Countries of recruitment**

Italy

**Study participating centre****Fra' Salimbene**

Piazzale Santafiora

Parma

Italy

43100

**Study participating centre****Scuola primaria Adorni**

Via Paciaudi Paolo Maria 1/A

Parma

Italy

43121

**Study participating centre****IC Giuseppe Verdi**

Via Langhirano 454/A 43124

Corcagnano (PR)

Parma

Italy

43124

**Study participating centre****Istituto Guatelli**

Via San Prospero 11 – 43044 Collecchio

Parma

Italy

43044

**Study participating centre****IPSIA - Istituto Professionale Statale per Industria ed Artigianato**

Piazzale Sicilia 5, 43100 PARMA (PR)

Parma

Italy

43100

**Study participating centre****CFP ENAIP Borgo Valsugana**

Via Giamaolle, 15, 38051 Borgo Valsugana TN

Borgo Valsugana

Italy

38051

**Study participating centre****CFP ENAIP Riva del Garda**

Rione Europa, 3, 38066 Riva del Garda TN

Riva del Garda

Italy

38066

**Study participating centre****Istituto Comprensivo Riva 1**

Viale Damiano Chiesa, 12, 38066 Riva del Garda TN

Riva del Garda

Italy

38066

**Sponsor information****Organisation**

United Nations Office on Drugs and Crime



**Sponsor details**

PO Box 500  
Vienna  
Austria  
1400  
+43 (0)1260605182  
wadih.maalouf@un.org

**Sponsor type**

Government

**Website**

<https://www.unodc.org/>

**ROR**

<https://ror.org/04567sh69>

**Funder(s)****Funder type**

Government

**Funder Name**

The People of Japan (Japan Supplementary funding to UNODC)

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. The study protocol including participant information sheets and all evaluation tools is being submitted for peer-reviewed publication before the start of the trial. Subsequently, the statistical analysis plan, clinical study report and analytic code can be shared upon request by any researcher or another interested party. Other documents will be shared with anyone who provides a methodologically sound proposal for non-commercial businesses to achieve the aims in the approved proposal. Proposals should be directed to Dr Wadih Maalouf (wadih.maalouf@un.org).

**Intention to publish date**

31/12/2023

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository, such as the Mendeley Data repository. 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 will assure the confidentiality of

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

**IPD sharing plan summary**

Stored in publicly available repository