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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

Submission date
22/12/2022

Recruitment status
No longer recruiting

Registration date
30/08/2023

Overall study status
Completed

Last Edited
15/10/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 May 2024

Who is funding the study?
The People of Japan Supplementary funding to UNODC.

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Prevention

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(s)
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

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

Completion date
01/05/2024

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
Instituto 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
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Study participating centre
CFP ENAIP Riva del Garda
Rione Europa, 3, 38066 Riva del Garda TN
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Study participating centre
Istituto Comprensivo Riva 1
Viale Damiano Chiesa, 12, 38066 Riva del Garda TN
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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
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