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Protecting youth from interpersonal violence via implementation of the Strengthening Families Programme 10-14 in Panama

Submission date
02/07/2017

Recruitment status
Stopped

Registration date
13/07/2017

Overall study status
Stopped

Last Edited
23/01/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

In Central America, interpersonal violence can significantly reduce adolescents' opportunities for becoming happy and healthy adults. It is estimated that an adolescent is involved in 82% of all homicides in Central America. Interpersonal violence not only puts their lives at risk, it also affects their health and their academic performance. Research suggests that healthy family functioning is one of the most important factors that can protect adolescents from violence. For this reason, for over 5 years the United Nations Office on Drugs and Crime (UNODC) has invested in implementing the Strengthening Families Programme for adolescents 10 to 14 years old (SFP 10-14) in several countries across Central America as a prevention strategy. The Spanish version of SFP 10-14 is known as Familias Fuertes. SFP 10-14 is delivered in seven group sessions in which both the adolescent and their parents take part in workshops and activities to build family strengths such as communication and assertive discipline. Research suggests that building these skills before problems occur protects adolescents from engaging in risky behaviour, and thus from difficulties later in life. The hub of UNODC's efforts in the last 5 years has been Panama, with close working relationships established between NGOs, education, health and policy. Moreover, members of the research team have conducted a series of prevention studies in Panama. These include conducting early studies of the use of SPF 10-14 in Panama to assess the acceptability of the intervention in this setting. The aim of this study is to build on previous efforts and test the use of SFP 10-14 widely across high-risk townships in Panama. Panama has been chosen due to its strong governmental support, its existing hub for SPF 10-14, and a local investigator with expertise in the topic. Panama's growing rates of interpersonal violence make this issue a pressing local policy priority, with 1 in 3 deaths of those between 10-14 years old due to interpersonal violence. This study tests whether SPF 10-14 leads to a reduction in indicators of risk for families that take part, compared to those who simply receive usual care provided in their communities.

Who can participate?

Families with an adolescent aged between 10 and 14 recruited from those who access services from the site or widely from the community.

What does the study involve?
There are 28 participating groups (i.e., schools or clinics) and 30 families are recruited per group. The groups are randomly allocated to either attend SFP 10-14 (Familias Fuertes) sessions or to receive the usual services. SFP 10-14 (Familias Fuertes) is delivered in groups of about 10 families (a minimum of 6 and a maximum of 16 families). The programme comprises 7 weekly sessions of two hours each. Parent and adolescent sessions are conducted separately in the first hour, followed by a second hour together as a family. The first hour focuses on skills, with the second hour designed to recognise family strengths and practice skills covered in the first hour. The intervention addresses three broad areas: family functioning, including communication between parents and children; strengthening parental skills; and helping young people to develop new skills in relation to resisting peer pressure, stress management, and goal setting. Problem behaviours, family functioning, parental discipline, parental stress, quality of life, substance misuse, gang involvement and delinquency are all assessed at different timepoints at the start of the study (T0) and at 2 (T1), 6 (T2) and 12 months (T3) follow-up. The primary endpoint will be assessed at 12 months (T3).

What are the possible benefits and risks of participating?
The results have the potential to impact policies beyond Panama given that UNODC has strong and well-established links in this region. This study will directly influence the lives of 420 families and adolescents from those sites allocated to the SFP 10-14 group. All families in this group have free access; no other family skills training programme is currently available locally. Community advisory forums are also set up to strengthen community networks, and advice /engagement will be sought from other members of townships where the intervention will be introduced (e.g., political societies, NGOs). Participants in the control group are offered the intervention once the study is over, if it is found to be effective. In terms of risks, no direct risks are foreseen. Families have to complete questionnaires that might be distressing. If needed, they are referred to specialist services.

Where is the study run from?
1. Torrijos Carter MINSA Clinic
2. San Isidro MINSA Clinic
3. Samaria Sinai School
4. Felipillo MINSA Clinic
5. Arabe de Libia School
6. Republica de Haiti School
7. Simon Bolivar School
8. Republica de Brazil School
9. Arias Paredes School
10. Republica de Honduras School
11. Justo Arosemena School
12. Jose Artiga School
13. Sta Librada Rural School
14. Belisario Porras School
15. Nvo Veranillo Clinic
16. Valle de Urraca School
17. Nueve de Enero School
18. Republica de Alemania School
19. Juan Diaz Clinic
20. Ascanio Villalaz School
21. Genesis School
22. La Siesta School
23. Manuel Amador Guerrero School

24. Union Panamericana School
25. Sta Rita School
26. Jose del C. Echevers
27. Climaco Delgado School
28. Curundu Clinic

When is the study starting and how long is it expected to run for?
July 2017 to March 2020

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
R120374

Study information

Scientific Title
PRO YOUTH trial: protecting youth from interpersonal violence via implementation of the Strengthening Families Programme 10-14 in Panama: a cluster randomized controlled trial

Acronym
PRO YOUTH

Study objectives
Primary objective
The primary objective will be to test the effectiveness of SFP 10-14 (Familias Fuertes) in reducing youth aggressive and hostile behaviour, as reported by parents and adolescents, when implemented via health and educational sites in Panama.

Secondary objective
The secondary objective will be to assess the implementation process of SFP 10-14 (Familias Fuertes) in order to optimize its scaling up and sustainability, should the intervention be shown to be effective.

Tertiary objective
The tertiary objective will be to assess the cost-effectiveness of SFP 10-14 (Familias Fuertes) in Panama.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Manchester Research Ethics Committee 1 (UK), 16/05/2017, ref: 2017-0717-2872
2. Research Ethics Committee from Punta Pacifica Hospital (Panama), 23/03/2017, ref: 28

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Interpersonal violence in adolescents 10-14 years old

Interventions
There are 28 clusters (i.e., schools or clinics) and 30 families are recruited per cluster. Clusters (i. e., clinics or schools) will be randomized to:
1. Implementation of Familias Fuertes in health and educational services (clinics and schools)
2. Services-as-usual (control)
A minimization algorithm will be used to ensure equivalency across arms in terms of: (i) the population size of townships where the clinic/school is located, (ii) homicide rates per 10,000 inhabitants in townships, and (iii) type of site (e.g. clinic or school). Sites will be allocated using online software (www.sealedenvelope.com). Given that this is a real-world implementation trial that involves training a limited number of staff embedded in selected clusters, these need to be randomized before families are recruited into the study. The trialists are aware that randomization of clusters before recruiting participants can influence recruitment and dropout in the control arm. To minimize these issues, the trialists have included costs for compensating families for participation and will instruct staff not to reveal site allocation until families have agreed to take part and before signing informed consent.

SFP 10-14 (Familias Fuertes) will be delivered in groups of approximately 10 families (a minimum of 6 and a maximum of 16 families). The programme comprises 7 weekly sessions of two hours each. Parent and adolescent sessions are conducted separately in the first hour, followed by a second hour together as a family. The first hour focuses on skills, with the second hour designed to recognise family strengths and practice skills covered in the first hour. The intervention addresses three broad areas: family functioning, including communication between parents and children; strengthening parental skills; and helping young people to develop new skills in relation to resisting peer pressure, stress management, and goal setting.

Evaluations in the United States suggest medium to high effect sizes of the programme on adolescent exposure to illicit substance use and young adult lifetime substance use (e.g. d = 0.40 – 0.50). However, there is only one trial evaluating effects of the programme on aggressive and hostile behaviours of adolescents. This trial suggests significant improvements in observer ratings of adolescent aggressive and hostile behaviours in adolescent-parent interactions, in family-member report of aggressive and hostile behaviours in those interactions, and in adolescent self-report of aggressive and destructive conduct across settings at 1.5, 2.5, and 4 years follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 05/06/2018:
Problem behaviours, measured with the Externalizing subscale of the Child Behaviour Checklist (Parent Version) for children 6 to 18 years that measures rule-breaking and aggressive behaviour. This scale consists of 35 items responded by parents using a scale from 0 to 2, being 0 = not true, 1 = somewhat or sometimes true, and 2 = very true or often true. The questionnaire takes 10 minutes to complete. Measured at baseline (T0), 2 (T1), 6 (T2) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
All outcomes will be assessed via face-to-face sessions in schools or clinics, via telephone interviews or through delivery/pick up of questionnaires to family homes. Format of assessment will depend on family's individual preferences.

Previous primary outcome measures:
Problem behaviours, measured with the Externalizing subscale of the Child Behaviour Checklist (Parent Version) for children 6 to 18 years that measures rule-breaking and aggressive behaviour. This scale consists of 35 items responded by parents using a scale from 0 to 2, being 0 = not true, 1 = somewhat or sometimes true, and 2 = very true or often true. The questionnaire takes 10 minutes to complete. Measured at baseline, 2, 6 and 12 months follow-up

Key secondary outcome(s))

Current secondary outcome measures as of 05/06/2018:
Parent reported:
1. Family functioning, measured with the Family Relationship Index (FRI). The FRI is a 27-item uni-dimensional measurement of the quality of social relationships in the family environment as determined by cohesion, expressiveness and conflict. Participants respond True or False to each item. Measured at baseline (T0), 2 (T1), 6 (T2) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
2. Parental discipline, measured with the Parenting Scale (PS). The PS is a 7-point Likert-scale 30-item questionnaire that measures parenting practices in three subscales: laxness, over-reactivity and hostile parenting. Laxness refers to a parent's inconsistency or permissive parenting, while over-reactivity refers to a parent's harsh or punitive parenting. Hostile parenting refers to the extent to which a parent hits, curses or insults their child. Measured at baseline (T0), 2 (T1), 6 (T2) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
3. Parental stress, measured with the Depression-Anxiety-Stress Scale 21 (DASS-21). DASS-21 is a 21 self-report questionnaire designed to measure the severity of a range of symptoms common to both Depression and Anxiety. The individual is required to indicate the presence of a symptom over the previous week. Each item is scored from 0 (did not apply to me at all over the last week) to 3 (applied to me very much or most of the time over the past week). Measured at baseline (T0), 2 (T1) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
4. Quality of life, measured with the ED-5D-5L, which assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The respondent is asked to indicate his/her health state by ticking in the box against the most appropriate statement in each of the 5 dimensions. The validated Spanish version provided by EuroQoL is used. Measured at baseline (T0), 2 (T1), 6 (T2) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.

Adolescent reported
1. Problem behaviours, measured with the Externalizing Subscale of the Youth Self-Report CBCL (YSR). It is composed of 32 items that are responded on a 0 to 2 scale, being 0 = not true, 1 = somewhat or sometimes true, and 2 = very true or often true. As in the parent-reported version of the CBCL, the YSR assesses rule-breaking and aggressive behaviour. Measured at baseline (T0), 2 (T1), 6 (T2) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
2. Family functioning, measured with the Family Relationship Index. Measured at baseline, 2, 6 and 12 months follow-up
3. Parental discipline, measured with the Children's Report of Parent Behaviour Inventory. This instrument has 52 items to evaluate the relationship of the child with his/her mother and 52 items to evaluate relationship with his/her father. Items are responded in a 1-3 scale, being 1 = never, 2 = sometimes and 3 = often. Measured at baseline (T0), 2 (T1) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
4. Quality of life, measured with the Child Health Utility 9 Dimensions, which is a paediatric

generic preference based measure of health related quality of life. It allows the calculation of quality adjusted life years (QALYs) for use in cost utility analysis. It assesses 9 dimensions with 5 response options each. The validated Spanish version provided by Scharr at the University of Sheffield will be used. Measured at baseline (T0), 2 (T1), 6 (T2) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
5. Substance misuse, measured with 10 items from the Health Behaviour for School-Aged Children Questionnaire (HBSC). These items measure frequency of smoking cigarettes and e-cigarettes, frequency of use of different types of alcoholic drinks, age of initiation of alcohol use and smoking, marijuana intake and use of other drugs. Measured at baseline (T0), 2 (T1) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
6. Gang involvement, measured with the Jamaica Survey of Gang Involvement from the Jamaica Youth Survey. While the full survey is 107 items to measure five core competencies, for this study only 4 items that measure previous gang history are used. Measured at baseline (T0) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.
7. Delinquency, measured with the Self-Report Delinquency Scale. This instrument has 39 items in which adolescents respond how many times in the last 6 months have they engaged in delinquent and criminal activities. They are able to choose from (a) once a month, (b) once every 2-3 weeks, (c) once a week, (d) 2-3 times a week, (e) once a day, to (f) 2-3 times a day. Measured at baseline (T0) and 12 months follow-up (T3). The primary endpoint is at 12 months follow-up or T3.

Previous secondary outcome measures:
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2. Parental discipline, measured with the Parenting Scale (PS). The PS is a 7-point Likert-scale 30-item questionnaire that measures parenting practices in three subscales: laxness, over-reactivity and hostile parenting. Laxness refers to a parent's inconsistency or permissive parenting, while over-reactivity refers to a parent's harsh or punitive parenting. Hostile parenting refers to the extent to which a parent hits, curses or insults their child. Measured at baseline, 2, 6 and 12 months follow-up
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4. Quality of life, measured with the ED-5D-5L, which assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The respondent is asked to indicate his/her health state by ticking in the box against the most appropriate statement in each of the 5 dimensions. The validated Spanish version provided by EuroQoL is used. Measured at baseline, 2, 6 and 12 months follow-up

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4. Quality of life, measured with the Child Health Utility 9 Dimensions, which is a paediatric generic preference based measure of health related quality of life. It allows the calculation of quality adjusted life years (QALYs) for use in cost utility analysis. It assesses 9 dimensions with 5 response options each. The validated Spanish version provided by Scharr at the University of Sheffield will be used. Measured at baseline, 2, 6 and 12 months follow-up
5. Substance misuse, measured with 10 items from the Health Behaviour for School-Aged Children Questionnaire (HBSC). These items measure frequency of smoking cigarettes and e-cigarettes, frequency of use of different types of alcoholic drinks, age of initiation of alcohol use and smoking, marijuana intake and use of other drugs. Measured at baseline, 2 and 12 months follow-up
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7. Delinquency, measured with the Self-Report Delinquency Scale. This instrument has 39 items in which adolescents respond how many times in the last 6 months have they engaged in delinquent and criminal activities. They are able to choose from (a) once a month, (b) once every 2-3 weeks, (c) once a week, (d) 2-3 times a week, (e) once a day, to (f) 2-3 times a day. Measured at baseline and 12 months follow-up

Completion date
01/03/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/06/2018:
1. Families with a male or female adolescent between 10 and 14 years old
2. At least one primary caregiver and one child 10-14 are willing to attend the programme together within a fixed time period if a place is offered
3. The ability to speak Spanish (literacy aid will be provided to parents or children who cannot read or write)
4. Families can be recruited from those who access services from the centres or widely from the community

Previous inclusion criteria:
1. Families with a male or female adolescent between 10 and 14 years old
2. At least one primary caregiver and one child 10-14 are willing to attend the programme together within a fixed time period if a place is offered
3. The ability to speak Spanish (literacy aid will be provided to parents or children who cannot read or write)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Families in which children and parents live separately (e.g., the child is in care)
2. Families that have participated in SFP 10-14 (Familias Fuertes) previously
3. Families that have taken part in any other family-based intervention in the last 12 months

Date of first enrolment
01/07/2017

Date of final enrolment
24/07/2018

Locations

Countries of recruitment
Panama

Study participating centre
Torrijos Carter MINSA Clinic
Panama
0000

Study participating centre
San Isidro MINSA Clinic
Panama
0000

Study participating centre
Samaria Sinai School
Panama
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Study participating centre

Felipillo MINSA Clinic
Panama
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Study participating centre
Arabe de Libia School
Panama
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Study participating centre
Republica de Haiti School
Panama
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Study participating centre
Simon Bolivar School
Panama
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Study participating centre
Republica de Brazil School
Panama
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Study participating centre
Arias Paredes School
Panama
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Panama
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Study participating centre

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Study participating centre
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Study participating centre
Belisario Porras School
Panama
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Study participating centre
Nvo Veranillo Clinic
Panama
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Study participating centre
Valle de Urraca School
Panama
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Study participating centre
Nueve de Enero School
Panama
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Study participating centre

Republica de Alemania School
Panama
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Study participating centre
Juan Diaz Clinic
Panama
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Study participating centre
Ascanio Villalaz School
Panama
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Study participating centre
Genesis School
Panama
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Study participating centre
La Siesta School
Panama
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Study participating centre
Manuel Amador Guerrero School
Panama
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Study participating centre
Union Panamericana School
Panama
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Study participating centre

Sta Rita School
Panama
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Study participating centre
Jose del C. Echevers
Panama
0000

Study participating centre
Climaco Delgado School
Panama
0000

Study participating centre
Curundu Clinic
Panama
0000

Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Following MRC's policies on data sharing, only anonymised data from this trial will be suitable for sharing.
1. Discovery by potential users of the research data: Data will be made available through the University of Manchester institutional data repository and UK Data Archive, together with appropriate metadata in line with MRC policy to support the understanding and re-use by other researchers, and will be allocated a Digital Object Identifier to reference the data in publications
2. Governance of access: Third party rules on sharing will be adhered to (e.g. UK Data Service) and when appropriate, data sharing agreements will be established with all partners. Requests for access to the data will be directed to PIs. This is in line with the University of Manchester Research Data Management Policy. Only anonymised data will be suitable for sharing
3. The study team's exclusive use of the data: Participant information sheets and consent forms will include information on plans for data sharing and enable participants to give their explicit and informed consent to such data sharing
4. Restrictions or delays to sharing, with planned actions to limit such restrictions: Strategies to limit sharing restrictions will include data being anonymised. Data will not be made available to other researchers until primary outputs are published/impact reached. The study team will endeavour to produce primary outputs without delay. Thus, the trialists foresee that our anonymised data will be ready for sharing 3 years after completion of the study
5. Regulation of responsibilities of users: the trialists will implement Data-sharing Agreements with new users. Agreements will prohibit any attempt to identify study participants, breach confidentiality or make unapproved contact with them

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/06/2018		Yes	No