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Does an adolescent programme delivered to teenagers who took part in a mother-infant intervention reduce interpersonal violence?

Submission date
16/04/2018

Recruitment status
No longer recruiting

Registration date
10/05/2018

Overall study status
Completed

Last Edited
01/04/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study is proposed to evaluate the effect of a second-wave intervention to prevent violence, delivered to adolescents who had participated as infants, along with their mothers, in a home-based maternal child attachment intervention (the Thula Sana Mother-Infant Intervention). This study continues the aims to investigate strategies to reduce levels of interpersonal violence, victimization, and aggression, and improves attitudes, knowledge, and belief systems about violence, compared with no intervention.

Who can participate?
Children of mothers who took place in the original Thula Sana trial, who are now 16-19 years old.

What does the study involve?
Participants are randomly allocated to one of four groups:
i. Thula Sana + Zifune (i.e., includes participants who received the early intervention and will now receive the adolescent intervention)
ii. Thula Sana only (i.e., includes participants who only received the early intervention)
iii. Zifune only (i.e., includes participants who did not receive the early intervention, but will now receive the adolescent intervention)
iv. No-Intervention Control (i.e., includes participants who did not receive the early intervention, and will also not receive the adolescent intervention)

The intervention consists of a three day workshop followed by five fortnightly sessions, delivered to groups of 20 adolescents at a time by trained and supervised community health workers. The intervention uses a collaborative approach to help adolescents think about their behaviour and their relationships, and to explore and plan for their future, with a focus on skills to reduce interpersonal violence.
All participants (index and control) are assessed before the intervention starts and after 3 months using questionnaires.

What are the possible benefits and risks of participating?
There are number of potential benefits to the study. Participants in the intervention are very likely to benefit in terms of improvements if the intervention is successful. There are no immediate benefits to participants in the control group participating in this study. The potential benefit to society is substantial. Should this study achieve its aims, it will produce a community-based intervention, which is deliverable in LMIC contexts, for the improvement of adolescent health and well-being living in multi-risk environments. It will also provide much needed information about the potential benefit of a second wave psychosocial intervention for adolescents living in poverty.

The potential risks include psychological distress, as a result of exposure to violence, abuse, HIV and other content and questions in the intervention sessions and assessments. In the event that participants show signs of extreme distress, community workers facilitate referral to local counselling and health services, under the guidance of the Principal Investigator and Project Manager. A further risk relates to staff safety during the study. The study ensures that all research assistants and fieldwork staff are trained in awareness and safety measures. Staff do not undertake assessments in any situation in which they feel uncomfortable or unsafe, and are encouraged to travel in pairs in any areas which are less safe.

Where is the study run from?
Masiphulisane Research Centre (South Africa)

When is the study starting and how long is it expected to run for?
September 2017 to August 2019

Who is funding the study?
Wellspring Philanthropic Fund (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N1710094

Study information

Scientific Title
The Zifune Project: Does a second wave adolescent intervention improve gains and reduce interpersonal violence for recipients of a mother-infant attachment intervention?

Study objectives
1. Participation in an early intervention to promote early mother-infant relationships during the perinatal period in addition to a later intervention to promote adolescent well-being reduces levels of interpersonal violence, victimization, and aggression, and improves attitudes, knowledge, and belief systems about violence, compared with those who participate in either the early or adolescent intervention, or no intervention.
2. Participation in either an early intervention to promote early mother-infant relationships during the perinatal period or later intervention to promote adolescent well-being reduces levels of interpersonal violence, victimization, and aggression, and improves attitudes, knowledge, and belief systems about violence, compared with no intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stellenbosch University Health Research Ethics Committee, 29/11/2017, ref: N1710094

Study design
Randomised controlled trial with re-randomised sample for second RCT

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Interpersonal violence

Interventions
Participants who previously participated in the Thula Sana randomised controlled trial, who are now adolescents aged 16-19 years, are re-enrolled into a new intervention called Zifune. These participants are re-randomised into two new groups, meaning that that the original Thula Sana sample will now consist of four groups:
1. Thula Sana + Zifune (includes participants who received the early intervention and will now receive the adolescent intervention)
2. Thula Sana only (includes participants who only received the early intervention)
3. Zifune only (includes participants who did not receive the early intervention, but will now receive the adolescent intervention)
4. No-Intervention Control (includes participants who did not receive the early intervention, and will also not receive the adolescent intervention)

Subjects are randomised separately by whether they originally received the Thula Sana infant intervention or were allocated to the control condition. Each group of subjects are sorted by increasing age (measured in days) and randomised in consecutive blocks of sizes either 4 or 6. The size of blocks are determined by independent coin tosses. Within a block, subjects are randomised in a balanced fashion to treatment or control. The treatment and control group each have 210 patients.
The Zifune programme is a community-based group programme delivered by trained and supervised lay community health workers. It is delivered through an initial 3 day workshop, followed by five fortnightly sessions at a centrally-situated community centre, delivered over three months. Each group is mixed gender and consists of approximately 20 participants. The intervention uses a collaborative intervention approach to help adolescents think about their behaviour and their relationships, and to explore and plan for their future, with a focus on skills to reduce interpersonal violence. The goal of the programme is to provide a space where adolescents have time to reflect on their current situation, plan a future that is meaningful and exciting to them, and then apply the skills and plans into their everyday lives. The four main content areas are tracking the life journey of the participant (including the development of a clear, explicit and measurable vision of the future, what is required to reach this goal, overcoming challenges to reaching this goal (such as drugs and alcohol, unsafe sex, violence), and making linkages with support structures and informal or formal mentors. Each participant is assigned a facilitator/life coach who continually engages with their allocated participants and their parents or guardians were applicable over the intervention period.
All participants (index and control) are assessed 3 months after their baseline assessment (an immediate post-intervention follow-up).

Intervention Type
Behavioural

Primary outcome measure
1. Perpetration of interpersonal violence is measured using a self-report questionnaire from the WHO multi-country study on women's health and domestic violence against women (WHO Core Questionnaire) at baseline and immediate post-intervention follow-up.
2. Levels of victimization of interpersonal violence are assessed using a self-report questionnaire from the WHO multi-country study on women's health and domestic violence against women

(WHO Core Questionnaire) at baseline and immediate post-intervention follow-up.
3. Aggression is measured using self-report questionnaires (Buss-Perry Aggression Questionnaire and the Youth Self-Report Questionnaire's Aggressive Behaviour subscale) at baseline and immediate post-intervention follow-up.
4. Attitudes, knowledge and belief systems with regards to gender relations and interpersonal violence are assessed using self-report questionnaires (the Attitudes about Intimate Partner Violence questionnaire and the Gender Equitable Men Scale) at baseline and immediate post-intervention follow-up.

Secondary outcome measures
1. Substance use is assessed using self-report questionnaire (the Alcohol Use Disorders Identification Test (AUDIT)) and self-report questions related to tobacco and other drug use at baseline and immediate post-intervention follow-up.
2. Family relationships are assessed using a self-report questionnaire (Family Assessment Device) at baseline and immediate post-intervention follow-up.
3. Mental health and behavioural outcomes are assessed using self-report questionnaires (Youth Self-Report, Strengths and Difficulties Questionnaire; Rosenburg Self-Esteem scale, the Columbia-Suicide Severity Rating Scale) at baseline and immediate post-intervention follow-up.
4. School retention for participants enrolled in school is assessed through participant self-report at baseline and immediate post-intervention follow-up.

Overall study start date
22/09/2017

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Children who were enrolled with their mothers in the Thula Sana trial between 1999 and 2003 (n=449). Thula Sana was an early parenting intervention project in South Africa, which improved mother-infant interaction and infant functioning.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
In the original trial there were 449 mothers and their infants participating. Since then, 27 children have died and 2 refused to continue to participate. We aim to re-enrol 420 participants (children) and their carers.

Key exclusion criteria
1. Children whose mothers were not participants in the original study.

Date of first enrolment
05/02/2018

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
South Africa

Study participating centre
Masiphulisane Research Centre
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Sponsor information

Organisation
Wellspring Philanthropic Fund

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Sponsor type
Charity

Funder(s)

Funder type
Charity

Funder Name
Wellspring Philanthropic Fund

Results and Publications

Publication and dissemination plan
Intended publication of least 4 peer reviewed publications from the trial. We will also publish a policy brief. Findings will be presented at local and international conferences.

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	27/04/2018	01/04/2019	No	Yes