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Reducing violence and victimization in at-risk adolescent girls and boys

Submission date	Recruitment status	[X] Prospectively registered
22/12/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/06/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effectiveness of a relational intervention in reducing violence and victimization in at-risk adolescent girls and boys

Study objectives

1. Adolescents whose caregivers participate in the intervention will engage in lower levels of aggressive behaviour and will experience lower levels of victimization at the end of the intervention and at regular follow-up assessmentts compared to youth whose caregivers did not participate in the intervention.
2. Parent-adolescent attachment security will increase from pre- to post-intervention and at regular follow-ups for those who complete the intervention program, compared to parents and adolescents in the no-intervention comparison condition.
3. Puberty onset will moderate intervention outcomes such that reductions in aggression, violence, and victimization will be greatest for girls and boys with earlier puberty. In addition, we predict that intervention outcomes will be even more pronounced for girls with earlier puberty than for boys with earlier puberty.
4. Among adolescents whose parents receive intervention, youth with specific genetic markers will show greater reductions in aggression compared to youth without these genetic markers. Conversely, among adolescents whose parents do not receive intervention, those with particular genetic markers will show greater increases in aggression and compared with youth without them.
5. Changes in parent-adolescent attachment security from pre- to post-intervention will mediate reductions in violence and victimization immediately post-intervention and at regular follow-ups.
6. Gender differences in the attachment processes that underlie intervention outcomes will be explored based on evidence that girls reductions in aggressive and violent behaviour are related to a reduction in attachment anxiety, while boys reductions in aggressive behaviour are related to a reduction in attachment avoidance.
7. Adolescents prior exposure to stress exposure will be associated with blunted cortisol responses at pre-intervention.
8. Normalization of stress reactivity will mediate reductions in aggressive behaviour from pre- to post-intervention and at regular follow-ups.
9. There will be reduced activity in ventral PFC in response to emotional stimuli among youth of parents in the intervention condition, compared to no change in the comparison condition.
10. Reduced activity in ventral PFC will mediate intervention reductions in aggressive behaviour as measured immediately following intervention and at regular follow-ups.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
At risk for aggression, violence and poor mental health

Interventions
1. A 10-week attachment-focused intervention program (Connect) for parents or parental surrogates of teens who engage in aggressive, violent, and antisocial behaviour.
2. Following completion of informed consent by parents and assent by youth, parents will complete screening (described below) to determine eligibility.
3. During the screening and enrolment period, participants in the community will be identified and recruited in a multi-stage screening process conducted across three cohorts of youth over three consecutive school years. Primary schools within a large urban area will participate to ensure the required screening sample of N=7,000. Adolescents who self-identify and are identified by parents or alternate caregivers as highly aggressive will be invited to participate in screening. Those who score in the top 40% of the screening measure will be eligible for the Stage 2 screen. The Stage 2 screen will consist of having primary caregivers complete the self-report of the Problem Frequency Behaviour Frequency Scale-Aggression, rating their adolescent. A final risk score will be obtained by standardizing scores on the youth- and parent-report screens within sex, and then combining the two scores. We will invite approximately the top 14-16% of these youth and their families to participate in the RCT phase of the project. During the enrolment period, parents of eligible youth indicating interest in participating will be provided with information about the program and invited to participate. This information will be presented in evening group sessions at local schools, and with individual follow-up sessions as needed.
4. Eligible parent-youth dyads will be randomly assigned to either the intervention, a 10 week manualized parent-teen attachment intervention - Connect, or a no-intervention comparison condition.
5. Parents and youth will complete measures prior to and following treatment, and three sessions afterwards at six-month intervals post-treatment.
6. Each 1 hour intervention session will address an attachment principle that captures key aspects of the parent-teen relationship and common parenting challenges.
7. The objective of the intervention is to enhance skills related to:
7.1. Secure attachment
7.2. Parental sensitivity
7.3. Partnership and mutuality
7.4. Dyadic affect regulation

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The Comprehensive Adolescent-Parent Attachment Inventory Parent Version (CAPAI-P)
2. The Comprehensive Adolescent-Parent Inventory Youth Version (CAPAI-Y)
3. The Childrens Report of Parenting Behaviors Inventory (CRPBI)
4. The Caregiver Strain Questionnaire (CGSQ)
5. Parental Support for Fighting Scale (PSFS)
6. Problem Behavior Frequency Scale Aggression and Victimization (Youth report)
7. The Conflict Tactics Scale Perpetrator subscale (CTS; youth and parent report)
8. The Affect Regulation Checklist (ARC; parent and youth report)
9. Youth Self-Report (YSR) Externalizing scale
10. Normative Beliefs About Aggression Scale
11. Attitudes Towards Aggression in Dating Situations Scale
12. Child Behavior Checklist (CBCL) Externalizing and Internalizing scales (Parent report about adolescent)

Secondary outcome measures
1. The Parenting Representations Interview
2. Youth biological stress reactivity (salivary cortisol)
3. Genotype moderation (DRD4)
4. Grade point average

Overall study start date
01/09/2012

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. English speaking
2. Parent-youth dyads of adolescents (community sample) at risk for significantly elevated levels of aggression and violence
3. Available to attend all intervention program components and follow-ups

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
700

Key exclusion criteria
Imminent risk of suicide will be ineligible and referred for immediate mental health services

Date of first enrolment
01/09/2012

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Canada

Study participating centre
Simon Fraser University
Burnaby, B.C.
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Sponsor information

Organisation
Simon Fraser University (Canada)

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Sponsor type
University/education

Website
http://www.sfu.ca/

ROR
https://ror.org/0213rcc28

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) (ref: 251560)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration