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Strengthening parent-teen relationships to reduce risk and enhance healthy development

Submission date	Recruitment status	[X] Prospectively registered
20/06/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/09/2018	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The social and economic costs of teen violence and aggression are substantial and rising. Despite recent progress, further research is needed to develop interventions for pre-teens and adolescents, particularly those at the highest level of risk. Few programs have addressed the relevance of gender differences, and important questions remain regarding the need for 'gender sensitive', 'gender tailored' or 'gender specific' programming. Programs that promote and strengthen relationships between youth and their parents may enhance healthy development and reduce violence, aggression and related mental health and social problems. We have developed an intervention to strengthen parent-teen relationships. The aim of this study is to evaluate the short- and long-term effectiveness of this program for girls and boys at high risk for aggression, violence and poor social and mental health.

What does the study involve?
Youth (aged 13 -16 years of age) with serious conduct problems and their caregivers (biological, adoptive and stable surrogate parents)

What does the study involve?
Parent and youth pairs are randomly allocated to receive either treatment as usual or a 10-week parent-teen attachment intervention. The effectiveness of the intervention, compared with treatment as usual, is assessed at 6-month intervals over a one-year period.

What are the possible benefits and risks of participating?
Caregivers or youth may sometimes feel a little upset when talking about problems, but other than this there are no other risks we can foresee.

Where does the study take place?
Simon Fraser University (Canada)

When is the study starting and how long is it expected to run for?
September 2011 to June 2014

Who is funding the project?
Canadian Institutes for Health Research (Canada)

Who is the main contact?
Dr Marlene Moretti

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Strengthening parent-teen relationships to reduce risk and enhance healthy development: a sex and gender framework in translating research into practice

Study objectives
1. Evaluate the effectiveness of a parent-teen attachment based intervention for girls and boys compared to treatment usual using a randomized control design, with a one year follow-up period
2. Examine the role of sex and gender in relation to factors that mediate therapeutic gains (attachment security) and moderate treatment outcome (genetic markers)
3. Investigate sex and gender in relation to mechanisms that underlie treatment change: shifts in parenting representations and adolescent stress reactivity

Ethics approval required
Old ethics approval format

Ethics approval(s)

Simon Fraser Research Ethics Board, submitted June 2011

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
High risk for aggression, violence and poor social and mental health

Interventions
1. A 10-week attachment-focused intervention program for parents or parental surrogates of teens who engage in aggressive, violent, and antisocial behaviour
2. During the enrolment period, all parents seeking clinical services at designated mental health facilities will be provided with information about the trial and invited to participate
3. Following completion of informed consent by parents and assent by youth, parents will complete screening to determine eligibility
4. Eligible parent-youth dyads will be randomly assigned to either the intervention, a 10 week manualized parent-teen attachment intervention - Connect, or treatment as usual (TAU)
5. Parents and youth will complete measures prior to and following treatment, and twice afterwards at six-month intervals post-treatment
6. Caregivers allocated to the intervention arm will attend a 10-week, manualized, attachment-focused parent group
7. Each 1 hour session will Address an attachment principle that captures key aspects of the parent-teen relationship and common parenting challenges
8. The objective of the intervention is to enhance skills related to:
8.1. Secure attachment
8.2. Parental sensitivity
8.3. Partnership and mutuality
8.4. Dyadic affect regulation
9. Treatment as Usual (TAU) Characteristics: Clinics included in the trial also offer an array of services for families, parents and teens
10. TAU is available at each participating mental health centre and will include other forms of parenting groups, family therapy, parent or youth cognitive therapy or supportive counselling
11. Treatment duration is typically short (3-4 months)

12. We will code treatment dose in both treatment conditions in terms of total number of sessions attended, total weeks of treatment, average length of sessions, and total hours in treatment

Intervention Type
Behavioural

Primary outcome measure
1. Parent report: Brief Child and Family Phone Interview (BCFPI)
2. Three measures of parenting: The Parenting Sense of Competence Scale (PSOC)
3. The Childrens Report of Parenting Behaviors Inventory (CRPBI)
4. The Caregiver Strain Questionnaire (CGSQ) which measures: the Comprehensive Adolescent-Parent Attachment Inventory Parent Version (CAPAI-P)
5. You report: BCFPI
6. The Self Report of Offending-Revised (SRO-R)
7. The Conflict Tactics Scale Perpetrator subscale (CTS)
8. The Affect Regulation Checklist (ARC): The Comprehensive Adolescent-Parent Inventory Youth Version (CAPAI-Y)

Secondary outcome measures
1. Parent report: The Parenting Representations Interview Adolescence version
2. Youth biological stress reactivity (salivary cortisol)
3. Genotype moderation (DRD4)
4. Official arrest data
5. Grade point average and absenteeism
6. Other services received

Overall study start date
01/09/2011

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. English-speaking
2. Parent-youth dyads of youth diagnosed with conduct disorder (t-score of ≥ 65, BCFPI)
3. Available (i.e. no anticipated extended absences)

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants

400

Key exclusion criteria
1. Cases that are positive for acute psychosis
2. Imminent risk of suicide will be ineligible and will be referred for immediate alternative services

Date of first enrolment
01/09/2011

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Canada

Study participating centre
Simon Fraser University
Burnaby
Canada
V5A1S6

Sponsor information

Organisation
Simon Fraser University (Canada)

Sponsor details
8888 University Drive
Burnaby
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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No