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Controlled longitudinal evaluation of a school based program to prevent adolescent dating violence and related risk behaviours

Submission date	Recruitment status	[ ] Prospectively registered
26/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/08/2009	Mental and Behavioural Disorders	

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
MCT-66913

Study information

Scientific Title
Controlled longitudinal evaluation of a school based program to prevent adolescent dating violence and related risk behaviours: a randomised controlled trial

Study objectives
This trial will evaluate a school-based intervention designed to address the problems of dating violence, substance abuse, and high-risk sexual behaviour as they emerge in the context of relationships over the course of high school transitions (grades 9 - 11). We hypothesise that youths receiving the Comprehensive School-Based Intervention (CSBI), relative to standard-intervention controls, will show less abusive and more positive behaviour with dating partners and peers over time. Intervention youth will also demonstrate safer choices with respect to sexual behaviour and substance use as measured by our risk index. Risk behaviours will be measured by a Comprehensive Adolescent Risk Index reflecting violence toward dating partners, violence towards peers, unsafe sexual behaviour, and substance use. Secondary aims of the study include higher levels of school connectedness among students, and positive perceptions of teachers and parents on the impact of the intervention on students.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Centre for Addiction and Mental Health Research Ethics Board approved on the 19th April 2004

Study design
Randomised 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
Dating violence and related risk behaviours

Interventions
Intervention (Comprehensive School Based Intervention)/Control (standard health curricula). CSBI involves a whole school approach with extensive teacher training, parent education, and

schoolwide events. The cornerstone of the intervention is an intensive 21-session classroom curriculum. The curriculum emphasises skill-building exercises, and expands this approach in an integrated manner to prevention of violence in relationships and unsafe sexual behaviours. The curriculum is embedded within a comprehensive and ongoing initiative that includes: schoolwide activities to promote positive relationships and prevent violence and abuse; information sharing with parents to encourage positive adolescent choices in these areas; exposure to community resources that promote healthy adolescent choices; school-wide campaigns related to substance use, sexual behaviour and violence; and training for all school personnel. In addition, a student-led Social Action Committee will be formed at each CSBI school.

School-level interventions will include yearly teacher awareness education for the entire staff, information for all staff on the fundamentals of the program, and supplementary activities, such as theatre presentations and guest panels for all grades. Parents will be provided with information about the program during Grade 9 orientation; written information about the program and about developmental changes during adolescence; and suggested parenting strategies and community resources for parents with teens.

The control condition involves existing curricula. Based on a sample of questionnaires collected from teachers and interviews with key stakeholders, the status quo condition involved less class time (particularly in the area of violence prevention), and didactic information delivery, with minimal skill-building, school, parent, or community components.

Trial details received: 12 Sept 2005.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Students scores on the Comprehensive Adolescent Risk Index (CARI), a self-report behavioural risk index that was developed and validated during the pilot phase of this program. The CARI is generated by classifying students into low, medium and high risk groups in the areas of dating violence, peer violence, substance use, and sexual behaviour. The scores in each domain (0, 1 or 2) are added to generate the CARI score, which ranges from 0 - 8. The primary outcomes were measured at the beginning and end of Grade 9 (2004/2005) and will be measured again two years later, at the end of Grade 11 (2007).

Secondary outcome measures
The secondary outcomes were measured at the beginning and end of Grade 9 (2004/2005) and will be measured again two years later, at the end of Grade 11 (2007). Secondary outcomes that will be evaluated on an exploratory basis include acquisition of interpersonal relationship skills, school connectedness, and official school record indicators. Acquisition of interpersonal skills will be assessed with a behavioural analog paradigm at the end of Grade 9, with a random subsample of students drawn from some of the schools. The analog will involve role-playing a conflict scenario with an older, opposite-sex student who has been trained by the researchers. The scenarios will be similar to those included in the curriculum, and will represent typical adolescent interpersonal conflicts related to triad behaviours (sex, substance use, and violence). The role plays will be videotaped and participants interaction will be coded. School connectedness will be measured with a 5-item self-report scale that was developed for the US

National Adolescent Health Survey. Official school indicators of incident reports and suspension records will also be obtained.

Overall study start date
01/09/2004

Completion date
30/06/2009

Eligibility

Key inclusion criteria
School eligibility includes a willingness:
1. To be involved in teacher training, curriculum delivery, and school-wide implementation over 4 years (if required)
2. To facilitate the evaluation of all components of the study over 4 years
3. To participate in a randomised trial
To be eligible, the school also has to provide faculty and principal approval of the curriculum and evaluation, and to agree not to introduce other related programs during the 4-year study.

There are no eligibility requirements at the individual student level because all Grade 9 students attending a demonstration school will receive the intervention (Physical Health and Education is mandatory). Participants will be adolescents, aged 15 - 16 years old (grade nine), either sex.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
1507 (1722 in final sample as of 16/05/08)

Key exclusion criteria
A school is ineligible for the trial if it was involved in the pilot phase of the program or has implemented similar curricula.

Date of first enrolment
01/09/2004

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Canada

Study participating centre
CAMH Centre for Prevention Science
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Sponsor information

Organisation
Centre for Addiction and Mental Health (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.camh.net/

ROR
https://ror.org/03e71c577

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-66913)

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	01/08/2009		Yes	No