

CO-VENTURE PROJECT: A CLUSTER RANDOMIZED TRIAL INVESTIGATING THE EFFECTS OF DELAYING THE ONSET OF SUBSTANCE USE ON ADOLESCENT COGNITIVE DEVELOPMENT



The **Coventure project** provides a unique opportunity to examine the beneficial effects of early intervention on cognitive development and future addiction, while controlling for neuropsychological factors implicated in the predisposition to early drinking and drug abuse.

The **Prevention Program** is a school-based alcohol and drug prevention program proven to prevent onset and growth in alcohol and substance misuse in youth. This selected personality-targeted approach is based on a psychosocial model and targets four personality-specific motivational pathways to substance misuse.

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PROBLEM BEING INVESTIGATED

Adolescent onset alcohol and illicit drug use are associated with a myriad of immediate and long-term negative consequences. Onset of alcohol use at or before 14 years of age is strongly associated with increased risk of developing alcohol use disorders, with rates of adult alcohol dependence in this group estimated at 40%. Adolescent substance use is also associated with greater risk for mental health problems, suicidal behavior, other drug use, poor academic performance, school drop-out, risky sexual behaviours, poor physical health, and injuries.

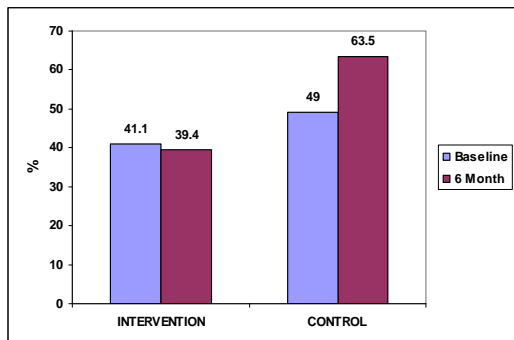
Our research team has now repeatedly and consistently shown that psychological interventions targeting personality risk factors for substance misuse are highly effective in preventing and reducing alcohol and drug use in adolescents. Beneficial effects of the Prevention program on substance use outcomes have been replicated in three separate trials in Canada and the United Kingdom, showing 30%-80% reductions in drinking, binge drinking and illicit drug use, and onset of problem symptoms over a two-year period.

What is the Prevention program? Brief, school-based coping skills interventions targeting personality risk factors for adolescent substance misuse with effects which have been shown to last for up to two years in two separate randomized trials. **The Prevention program** has proven both feasible and effective when delivered by trained school-staff, and thus can operate within an implementation model that has a higher likelihood of being

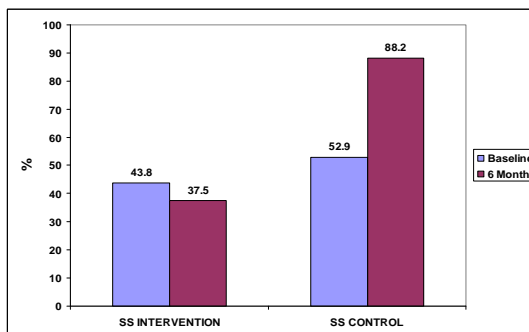
Quebec Statistics: 26.8% of 7th Grade students report having used alcohol in the past year, 48.3% have engaged in binge drinking during this period. By grade 8, 46.8% of students have consumed alcohol. These results suggest that Quebec youth may initiate drinking earlier and show an accelerated growth in alcohol use, such that by the end of high school, 85.6% of Quebec students report alcohol use in the past year, 79.8% of whom binge drink. Illicit substance use is also very common amongst Quebec students (50%) and co-occurs with alcohol use.

adopted by schools in a sustainable manner. We now aim to show the impact of the program on socially and clinically significant outcomes.

RESULTS FROM THE PREVENTURE TRIAL IN 2006



Binge drinking in drinkers was significantly reduced at 6 month follow up across all intervention group.



Binge drinking in student drinkers who participated in the SS intervention was significantly reduced at 6 month follow up. We found that for every 2 who participated in the session, **1 case of binge drinking was prevented.**

RESEARCH DESIGN OF CO-VENTURE TRIAL

This is a cluster randomized design in which 32 high schools across Montreal will be randomly assigned to receive training and to deliver the Preventure programme to one cohort of Grade 7 students (intervention group) or to be trained and assisted in delivering the programme to a future Year 7 cohort (control group). Evaluations of students will occur annually from September to December until the end of high school. Student will be assessed on personality, substance use, mental health and cognitive measures.

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OBJECTIVES

Primary: to examine how this evidence-based intervention can reduce the onset of substance use disorders in young people and related secondary mental health, academic and cognitive outcomes through longer-term trial of this intervention strategy.

Secondary: to use sensitive neuropsychological measures to examine how this evidence-based intervention can positively impact on cognitive development over the course of adolescence.

The Preventure program involves delivering specialized coping skills group workshops to students when they are in the 7th or 8th grade. Only about 45% of students in a given grade will be invited to participate in the workshops. The workshops focus on motivating adolescents to understand how their personality style leads to certain emotional and behavioural reactions. Four different workshops will be run, focusing either on managing impulsivity, thrill seeking, anxiety sensitivity or negative thinking. The students will first be asked to participate in a survey asking them about their personality, their strengths and weaknesses, their risk-taking behaviour and their learning style. Then, if their school has been trained to deliver the program, they might be invited to participate in two 90-minute workshops, delivered at school during class time or lunch hour. All children who agree to participate in the study will be invited to complete the same survey in each subsequent academic year for four years.

DATA COLLECTION PROCEDURES

PROJECT TO COMMENCE IN SCHOOLS:	Fall 2012 <ol style="list-style-type: none"> 1. Introduction meeting with project coordinator and school administrator and Staff (60 minutes) 2. Research agreement is signed, project can begin
NUMBER OF STUDENTS REQUIRED:	<ul style="list-style-type: none"> • 100 -150 Grade 7 (and Grade 8 depending on the school) in 2012-2013 • Same cohort of student followed for the next 5 years
SCHOOL STAFF INVOLVEMENT:	<ol style="list-style-type: none"> 1. Minimum 3 experienced counselors, educators, or teachers; 2. Staff will be trained and supervised to implement the Preventure programme; 3. 1 staff member will serve as liaison agent between the research team and school; 4. 18 hours of coping skills workshop training + 3 hours of supervision.
RANDOMIZATION PARTICIPATION DATES:	<p>One (1) baseline assessment in 2012 and four (4) annual follow-ups till 2017.</p> <ol style="list-style-type: none"> 1. Assessment periods: September to January for ALL schools and ALL 2012-2013 Grade 7 students; 2. Intervention group workshops ONLY in 2012-2013: October 2012 to February 2013; 3. Control group workshops AFTER 2014; 4. 4 workshops, <u>minimum 8</u> 90 minute sessions (4-8 students per workshop).
TIME REQUIRED WITH STUDENTS:	<ol style="list-style-type: none"> 1. 60 minutes EVERY YEAR, ONCE YEAR for the annual assessment for ALL and SAME 2012-2013 Grade 7 students till 2017; 2. 2 X 90 minutes sessions=interventions (workshops) for 45% of the students (Year 1 in Intervention group and AFTER Year 3 in Control group)
COSTS TO SCHOOL	NONE. Training and workshop material provided by research team.
DATE OF COMPLETION OF RESEARCH REPORT	Winter – Spring 2017

ADVANTAGES

Participating in this project will allow your school to receive training and intervention tools, material relevant to the Preventure program and method at no costs to your administration. The technique can be applied to Secondary students of subsequent years long after the project is complete. This initiative will contribute to your schools drug and alcohol prevention measures. As an academic institution there is much to gain in contributing to this research project, particularly when drug and alcohol use has detrimental effects on the cognitive development and academic performance of adolescents.

ETHICS, CONSENT AND CONFIDENTIALITY

The Co-venture project has been approved by the CHU Ste Justine Research Center Ethics Committee. The committee recognised the negligible potential harm (no harm apparent from 3 previous randomised trials), and as such, does not constitute experimental research. The Coventure project has been approved by Several Montreal School boards including the Lester B Pearson and English Montreal for implementation in eligible secondary schools.

This study will require written informed assent by students, where their confidentiality will be assured and their data will not be shared with the school or their parents unless they indicate serious and imminent risk of harm. Schools will have the option to allow parents to actively consent (provide written consent) or passively consent to their child's participation.

Based on our experience conducting four separate randomized trials with adolescents, we believe it is important to allow parents to opt out and to allow eligible and interested adolescents to actively assent to participate. In previous trials in Canada, the United Kingdom and The Netherlands, active consent by parents led to approximately 50% attrition of eligible students, despite the fact that 85% of these children expressed interest in participating in this programme voluntarily. We also have data indicating that eligibility for the intervention programme is associated with greater drop-out as a result of written parental consent. Nevertheless, we will allow school administrators to decide whether they will use an opt-out or an active written parental consent procedure. Both consent procedures were approved by the CHU Ste-Justine Ethics committee and School Board.

Interventions will not be video or tape recorded. All data collected is to be kept confidential and stored securely.

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FOR MORE INFORMATION

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Principal investigator agrees to share all relevant research data that is compiled in reports or published with school authorities. LOGO:
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