

How early individual characteristics and family environment interact in the development and prevention of externalizing problems across early school years

Submission date 26/08/2016	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 01/09/2016	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/12/2018	Condition category Mental and Behavioural Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Disruptive behaviors such as hyperactivity, aggression, oppositional (challenging) and conduct problems are among the most common behavioral and mental health problems in childhood. These problems are often jointly referred to as externalizing disorders (EDs), the most common of which are such as ADHD and conduct disorder. EDs are widespread, prolonged, and costly to society. If a child is suffering from an ED, then they are more likely to develop mental health problems as an adult, as well as more prone to substance use disorders, school-drop out, crime and violence. It is possible for children to have more than one ED, as they often share common risk factors. Targeting these risk factors therefore could provide an opportunity for prevention. The Community Parent Education Program (COPE) is a new parent training program, designed to help parents develop skills to strengthen their relationships with their children, increase cooperation and solve problems. The aim of this study is to investigate the effectiveness of COPE at preventing disruptive behavior and improving mental health in children.

Who can participate?

Parents of children aged 4 and 5 years who have problems controlling their behaviour, who previously participated in the "Découvrir, Développer, Devenir" (3D) Study.

What does the study involve?

At the start of the study, participants are asked to complete an online questionnaire twice, about 6 months apart, which should take around 90 minutes to complete. Parents and children are also invited to complete a series of computer and other games at home. Each home visit will take 60 minutes maximum. Participants are asked to provide the name and contact details of a person that knows your child well but who does not live with them (e.g. educator, caregiver, extended family member or friend), to invite him/her to complete an online questionnaire about the child's personality and behaviour. Families are then randomly allocated to one of two groups. Those in the first group are invited to participate in a parent-training program (COPE), which consists of 10 weekly two hour group sessions. Each of the 10 weekly sessions of 2 hours

addresses different topics related to early child behaviour and parental problem-solving strategies. Those in the second group continue as normal for the duration of the study. At the end of the study, the questionnaires from the start of the study are repeated to find out if there has been any change to the child's behavior.

What are the possible benefits and risks of participating?

Parents who are allocated to the COPE group benefit from 10 free sessions of a program delivered by trained facilitators that has been shown to be effective in improving parenting skills and reducing behavioural problems and/or attention problems in children 3 to 12 years old. There are no notable risks involved with taking part in this study.

Where is the study run from?

1. Université de Montréal (Canada)
2. Sainte Justine Hospital (Canada)

When is the study starting and how long is it expected to run for?

January 2016 to December 2017

Who is funding the study?

Canadian Institutes of Health Research (Canada)

Who is the main contact?

Dr Natalie Castellanos Ryan

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

MOP – 143049

Study information

Scientific Title

Using a randomized control trial to test developmental models of individual factors by environment interaction in the prediction of externalizing psychopathology across early school years

Acronym

3D Transition RCT

Study objectives

Compared to children of parents randomised to a no-intervention control condition, children of parents randomized to a parent-skills training intervention will have fewer externalising symptoms and diagnoses at post-test (2 months post-intervention).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Le Comité d'éthique de la recherche du CHU Sainte-Justine (Sainte Justine hospital research ethics committee), 09/08/2016, ref: 2016-1143

Primary study design

Interventional

Study design

Single-centre open-label randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Externalising disorders

Interventions

Once parents consent to the study, they will complete a baseline questionnaire and assessment and be randomised to an intervention or control condition (simple randomization, at a ratio of 1:1) using a computer-generated random numbers list.

Intervention arm: Parents will receive the Community Parent Education Program (COPE) delivered at Ste Justine Hospital or other premises of the Université de Montréal. The COPE is manual-based and designed to help parents develop proven skills to strengthen their relationships with their children, increase cooperation and solve problems. COPE is a group-based program of 10-20 parents, who will meet with one or two trained facilitators for 10 weekly 2-hour sessions (so total duration 10 weeks).

Control arm: Parents will not receive any intervention or treatment.

Both groups will be assessed about 6 months post-randomization (roughly 2 months post-intervention for intervention participants).

Intervention Type

Behavioural

Primary outcome(s)

Externalizing symptoms (i.e., conduct disorder, Attentional Deficit and Hyperactivity Disorder (ADHD) and Oppositional Defiance Disorder (ODD) symptoms) are measured using the Strengths and Difficulties Questionnaire (SDQ) and the Social Behavior Questionnaire, rated by the parent and another person “most knowledgeable of the child outside the family” (e.g. teachers) at baseline and 6 months.

Key secondary outcome(s)

1. Child temperament is measured by parent-reported Children’s Behavior Questionnaire at baseline and 6 months
2. Child mental health is measured by parent-reported Child Behavior checklist at baseline and 6 months
3. Response inhibition is assessed by an online version of the Flanker test of the NIH Toolbox (www.nihttoolbox.org) at baseline and 6 months
4. School-engagement and performance is measured using homeroom teacher-reports at baseline and 6 months
5. Parent-child relationship and parenting styles and stress are assessed with the Block Child Rearing Practices Report, the Parenting Stress Index—Short Form and the Perceived Stress Scale at baseline and 6 months

Completion date

31/12/2019

Eligibility**Key inclusion criteria**

1. Parent-child dyads who have taken part in the “Découvrir, Développer, Devenir” (3D) Study (a large pregnancy study that collected data across pregnancy and the first two years of the child’s life of 1594 mothers and their children. IRNPQEO: <http://www.irnpqeo.ca/>)
2. Children who score low on parent-reported self-regulation at 2 years of age (i.e. score below the mean reported in the 3D sample)

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Not meeting inclusion criteria

Date of first enrolment

06/09/2016

Date of final enrolment

01/05/2017

Locations

Countries of recruitment

Canada

Study participating centre**Université de Montréal**

École de Psychoéducation

Pavillon Marie-Victorin

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Study participating centre**Sainte Justine Hospital**

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Sponsor information

Organisation

Canadian Institutes of Health Research

ROR

<https://ror.org/01gavpb45>

Funder(s)

Funder type

Government

Funder Name

Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary