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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

Registration date
01/09/2016

Overall study status
Completed

Last Edited
12/12/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Single-centre open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 measure
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.

Secondary outcome measures
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.nihtoolbox.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

Overall study start date
01/01/2016

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)

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
250

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
90, av. Vincent-d'Indy
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Study participating centre
Sainte Justine Hospital
3175 Chemin de la Côte-Sainte-Catherine
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H3T 1C4

Sponsor information

Organisation
Canadian Institutes of Health Research

Sponsor details
Room 97
160 Elgin Street
Ottawa
Canada
K1A 0W9

Sponsor type
Government

Website
www.cihr-irsc.gc.ca

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, 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
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository