Coping power program and parent management training for families with children with conduct problems

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/10/2014		[_] Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/12/2015	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/01/2023	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

A common reason for referral to psychiatric treatment among school-aged children and adolescents is aggressive behavior and other conduct problems. Oppositional Defiant Disorder (ODD) describes emotional and behavioral problems when a child often loses temper, is angry, argues with adults, whereas Conduct Disorder (CD) includes more severe behaviors such as fighting, lying, stealing and playing truant from school. Children with ODD or CD are at higher risk than average of continued behavior problems. Parent management training (PMT) programs aim at helping parents develop strategies to manage their child's behavioral problems at home and at school. PMT programs have been shown to reduce the frequency and severity of behavior problems. Children with CD or ODD are at a higher risk than average of being antisocial as adults and developing psychiatric diseases. Parent Management Training (PMT) programs have been developed to train parents to manage their child's behavioural problems at home and at school. These have been shown to reduce the risk of the child continuing to be antisocial as an adult. However, some risk factors may not be addressed by a PMT program. These include hostility towards others, difficulties in problem solving and not being able to control feelings of anger. The Coping Power Program (CPP), which involves structured group and individual cognitive behaviour sessions for children and their parents, aims to address these risk factors. Here, we want to compare the performance and cost-effectiveness of a combined PMT program (a Swedish version called Komet) and CPP treatment, with that of the PMT (Comet) program on its own.

Who can participate?

Families with children aged 8 and 12 years old with behavioural problems, which have resulted in being referred to Stockholm child and adolescent psychiatric units. The child is typically diagnosed with CD or ODD.

What does the study involve?

The families are randomly allocated into one of two groups. Those in group 1 receive the PMT (Komet)/child CBT (Coping Power Program) treatment. Those in group 2 receive only the PMT (Komet) program. The families and teachers fill in questionnaires developed to monitor progress

before treatment begins, just after the treatment ends, every third week during the treatment period and then 12 and 24 months after the treatment ends. The children's level of intelligence is assessed before treatment begins.

What are the possible benefits and risks of participating? Benefits of participating include the possibility of an improvement to the children's behaviour. There are no notable risks of participating.

Where is the study run from? Child and Adolescent Psychiatric clinics in Sweden.

When is the study starting and how long is it expected to run? February 2013 to December 2018

Who is funding the study? 1. Söderström-Königska Foundation (Sweden) 2. Stockholm Child and Adolescent Psychiatry (Sweden)

Who is the main contact? Pia Enebrink pia.enebrink@ki.se

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Randomized controlled trial of the Parent-Management Training program and the Coping Power Program. Komet: Effects and costs of two treatments for children with conduct problems

Acronym

PMT-CPP

Study objectives

The combined treatment (CPP and PMT) will result in significantly less conduct problems, improved child social skills and problem-solving skills, than the treatment targeting parents only (PMT).

Ethics approval required

Old ethics approval format

Ethics approval(s) The regional ethical committee in Stockholm, refs 2011/1587-31; 2013/1555-32; 2014/1507-32

Study design Multi-centre randomized controlled trial

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet Patient information is in Swedish and available upon request

Health condition(s) or problem(s) studied

- 1. Oppositional Defiant Disorder
- 2. Conduct Disorder

Interventions

Families are randomized to one of two groups.

Intervention group: Participants take part in both the Coping Power Program (CPP) and Parent Management Treatment (PMT).

Control group: Participants take part in the Parent Management Treatment (PMT) alone.

The Coping Power Program (CPP) is an intervention developed for children with aggressive behavior. In the present study, the child component of the intervention is used. The treatment is conducted in a group with other children, and includes emotion awareness components as well as anger management, perspective taking and social problem solving.

The Parent Management Treatment (PMT) in the present study is based on the Swedish groupbased PMT-program Komet. The Komet-program aims at helping parents develop and use parenting skills for handling their children's conduct problem behaviors.

The families participate in the interventions during 3 months. Data is collected at baseline, during the intervention (short questionnaire), after the intervention 3 months after baseline, as well as 12- and 24 months after treatment.

Intervention Type

Behavioural

Primary outcome measure

Conduct problems measured using the Disruptive Behaviour Disorders (DBD) questionnaire, the Strengths and Difficulties Questionnaire (SDQ), the conduct problems scale and presence of ODD/CD symptoms after treatment and at 12 and 24 months.

Secondary outcome measures

Parents/teachers:

1. Child friendships and emotional well-being, measured using the Strengths and Difficulties Questionnaire (SDQ) and teacher evaluation at baseline, after treatment, 12 and 24 months 2. Child social competence and self-control, measured using the Social competence scale – parent, a modified version of the Social Skills Rating System (SSRS) and teacher evaluation at baseline, after treatment, 12 and 24 months

3. Child callous-unemotional traits are measured using the Antisocial Processing Screening Device, with one sub-scale measuring callous unemotional (CU) traits at baseline, after treatment, 12 and 24 months

4. Parent strategies measured using three sub-scales (appropriate discipline, harsh and inconsistent

discipline, praise and incentives) of the Parenting Practices Interview, at baseline, during treatment, after treatment, 12 and 24 months

5. Parent stress measured through Perceived Stress Scale (PSS) also filled in at baseline, during treatment, after treatment, 12 and 24 months

6. Parental self-efficacy and satisfaction through Parenting sense of competence scale at at baseline, after treatment, 12 and 24 months

7. Treatment alliance recorded during and after treatment

Children:

1. Child social competence and social skills measured using a modified version of the Social Skills Rating System (SSRS) at baseline and after treatment

2. Child attitude and problem-solving strategies measured using the Problem-solving measure for conflict outcome expectations questionnaire and a home interview with the child at baseline and after treatment

3. Child friendships and emotional well-being, measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline and after treatment

4. Treatment alliance is measured by a 10-graded scale after the treatment

Therapist/research assistant-rated variables:

 Therapists register participation in treatment sessions, number of home-work completed during treatment, costs and amount of time associated with treatment
Risk factors are determined using the Early Assessment Risk List for Boys (EARL-20B) and Early Assessment Risk List for Girls (EARL-21G) tools at baseline and after treatment

Overall study start date

01/02/2013

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Children aged between 8 and 12 years

- 2. Diagnosis of Oppositional Defiant Disorder, Conduct Disorder or Disruptive Behavior NOS
- 3. Referred to child and adolescent psychiatry in Stockholm, Sweden

Participant type(s)

Patient

Age group Other

Sex

Both

Target number of participants 150 families

Total final enrolment

120

Key exclusion criteria

- 1. Severe depression
- 2. Self-harming behaviors
- 3. Autism spectrum disorder
- 4. Psychosis
- 5. Cognitive retardation
- 6. Presence of violence or severe substance abuse in the family

Date of first enrolment

01/01/2014

Date of final enrolment 01/03/2016

Locations

Countries of recruitment Sweden

Study participating centre Karolinska Institute Division of Psychology Nobels väg 9 Solna Sweden 171 65

Sponsor information

Organisation

Söderström-Königska Foundation (Sweden)

Sponsor details

Box 738 101 35 Stockholm Stockholm Sweden 101 35

Sponsor type

Charity

Funder(s)

Funder type Research organisation

Funder Name Söderström-Königska Foundation

Funder Name Stockholm Child and Adolescent Psychiatry

Results and Publications

Publication and dissemination plan

Planned publication of five articles aimed at international researchers, clinicians, policy makers.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/04/2018	08/04/2020	Yes	No
<u>Results article</u>	results	01/09/2020	15/09/2020	Yes	No
<u>Results article</u>	2-Year Follow-Up	28/01/2022	04/01/2023	Yes	No