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Evaluation of family check-up and iComet in Gothenburg

Submission date
30/11/2012

Recruitment status
No longer recruiting

Registration date
04/01/2013

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
More than a hundred different parenting programs are currently being used in Sweden with barely a handful number of programs showing some scientific evidence of good outcome. In the present study, we will be evaluating the outcome (efficacy) of two parenting programs that are designed to help parents of children with conduct problems or disruptive behavior. The programs are the Family check-up (FCU) and a more established parenting program in Sweden called Comet. Comet will be delivered via Internet (therefore called iComet).
We want to answer the following questions:
1. What are the norms from the general population of parents of children aged 10 to 13 years regarding questionnaires measuring conduct problems, disruptive behavior, parenting style and other relevant factors?
2. Which effects do these programs have on children's and adolescents' conduct problems, parents' style of parenting, children's general psychological health, social adaptation, and relation to peers and parents?
3. How large is the attrition, completion and adherence to each programs?
4. Which variables predict or explain the outcome in each parenting program?
5. Do children at risk of psychological problems show a risk profile with regard to tooth health and dental hygiene, and would these interventions (program) positively affect children's dental hygiene?

Who can participate?
Parents interested in participating will be asked to respond to questionnaires regarding the problems they experience with their child, and those scoring above a certain cut-off would be eligible for participations. However, parents of children who are already in a treatment program for conduct problems, as well as those who are in need of other service due to mental retardation or autism spectrum disorder will not be eligible for participation.

What does the study involve?
After receiving informed consent and initial inclusion, parents and their child, as well as child's main teacher at school will be asked to respond to some questionnaires. In addition, parents and their child will be asked to discuss a set of five questions (scenarios) while being filmed as part of the evaluation for the parenting programs.

All the parents will then be randomized to either FCU or iComet. Parents in the iComet condition will receive guidance from a family guide once a week for 10 weeks, while those who have been assigned to FCU will meet with a family guide for 1 to 3 sessions to make a further assessment of needs and resources. The family guide then presents a final analysis and in agreement with parents they start a program that is adapted to each family's need and circumstances. The FCU is also characterized by using available resources within and around each family, which in certain cases means use of other treatment options that are available.
Ten weeks after the start of each parenting program, a new assessment will take place and parents will be reassessed 1 and 2 years after the end of the intervention. In the FCU, families receive a new check-up just before each yearly follow-up assessment to ascertain whether the family might need any booster sessions or further help.

What are the possible benefits and risks of participating?
Both interventions among the few parental strategies for conduct problems have been shown to lead to favorable outcome for a substantial portion of participants in previous trials.
No risks have been identified related to the psychosocial treatments that are delivered within this trial.

Where is the study run from?
Only parents in schools within participating municipalities in Gothenburg (i.e., Ösra Göteborg, Angered, Centrum, Askim-Frölunda-Högsbo, Västra Göteborg and Lundby) will be the target of information and recruitment.

When is the study starting and how long is it expected to run for?
Recruitment of families to the intervention study started in January 2011. We will be recruiting families until the end of spring of 2013. The duration of the intervention is 10 weeks. All the included families will be followed-up for 2 years after the end of the treatment. The study in terms of data collection will be completed by the end of June 2015.

Who is funding the study?
Swedish National Board of Health and Welfare

Who is the main contact?
Ata Ghaderi, PhD
ata.ghaderi@psyk.uu.se

Contact information

Type(s)
Scientific

Contact name
Prof Ata Ghaderi

ORCID ID
http://orcid.org/0000-0001-8483-7964

Contact details
Karolinska Institutet
Department of Clinical Neuroscience
Division of Psychology

Stockholm
Sweden
17177
+46 (0)8 524 832 48
ata.ghaderi@ki.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of family check-up verus iComet for early prevention of conduct problems

Study objectives
1. What effects do these programs have on children's and adolescents' conduct problems, parents' style of parenting, children's general psychological health, social adaptation, and relation to peers and parents?
2. How large is the attrition from each parenting program, percentage of parents completing the programs and adherence to each program?
3. Which variables predict (moderators), or explain (mediators) the outcome in each parenting program?
4. Do children at risk of psychological problems show a risk profile with regard to tooth health and dental hygiene, and would these interventions positively affect children's dental hygiene?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethical committee at Uppsala University, 14/04/2010, ref: Dnr. 2010/119

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Conduct disorder

Interventions
Parents will be randomized to either FCU or iComet.

The iComet is a 10-week long intervention, delivered through Internet. Parents are provided with simple and concrete principles of effective parenting, using attention, encouragement, limit setting, joint play, and everyday principle of reinforcement to help their children increase the frequency of adequate and functional behaviors which in turn decreased the space for less desirable behaviors.

The FCU might be just 3-4 sessions ending with a feedback, or resulting in a program focusing on relevant aspects of parenting or other interventions that according to the analysis are crucial for good outcome.

In both condition a post-intervention assessment is made after 10 weeks. One and two years after the end of the treatment yearly follow-ups will be done. If funding is available, our aim is to do three year follow-up as well.

Intervention Type
Behavioural

Primary outcome measure
1. The Strengths and Difficulties Questionnaire (Goodman & Scott, 1999)
2. The Disruptive Behavior Disorders (DBD) Rating scale (Pelham et al., 1992)
3. Risk taking behavior and depression

A post-intervention assessment is made after 10 weeks. One and two years after the end of the treatment yearly follow-ups will be done.

Secondary outcome measures
1. Warmth and conflict in the family
2. Parental level of depressive symptoms and anxiety
3. Parental emotions regulation, parenting style (use of harsh discipline and in consequent parenting)

A post-intervention assessment is made after 10 weeks. One and two years after the end of the treatment yearly follow-ups will be done.

Overall study start date
01/08/2010

Completion date
30/05/2015

Eligibility

Key inclusion criteria
Families with children with significant difficulties according to Eyberg Child Behavior Inventory

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
280

Key exclusion criteria
Concurrent treatment program for conduct problems, as well as need of other service due to mental retardation, autism spectrum disorder or other severe mental disorders.

Date of first enrolment
01/01/2011

Date of final enrolment
30/05/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
Uppsala
Sweden
75142

Sponsor information

Organisation
Swedish National Board of Health and Welfare (Sweden)

Sponsor details

Rålambsvägen 3
Stockholm
Sweden
106 30
+46 (0)75 247 30 00
socialstyrelsen@socialstyrelsen.se

Sponsor type
Government

Website
http://www.socialstyrelsen.se/english/

ROR
https://ror.org/01v4pc162

Funder(s)

Funder type
Government

Funder Name
Socialstyrelsen

Alternative Name(s)
National Board of Health and Welfare

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Publication and dissemination plan
Intent to publish a couple of papers based on data from this trial during 2016.

Intention to publish date
31/07/2016

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	31/07/2018	29/01/2019	Yes	No