

# Evaluation of family check-up and iComet in Gothenburg

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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?

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## Contact information

### Type(s)

Scientific

### Contact name

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## **Additional identifiers**

## **Study information**

### **Scientific Title**

Efficacy of family check-up versus 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

### **Study type(s)**

Other

### **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(s)**

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.

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **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)

**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

## 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?
<a href="#">Results article</a>	results	31/07/2018	29/01/2019	Yes	No