Randomized Controlled Trial of Comet Via the Internet or in Group Format.

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03465384

Recruitment Status: Recruiting
First Posted: March 14, 2018
Last Update Posted: March 14, 2018
See Contacts and Locations

Sponsor: Karolinska Institutet
Collaborator: Stockholm County Council, Sweden
Information provided by (Responsible Party): Martin Forster, Karolinska Institutet

Study Description

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Brief Summary: The Comet-program is a Swedish parent training program developed to target externalizing behaviors in children between 3-11 years. The program is normally delivered in group format in primary and specialized care and has already been evaluated in several studies. The internet-based version of the program has also been evaluated separately, but in this study the two formats will be directly compared in a randomized non-inferiority study. Parent ratings, child ratings as well as blinded clinical assessments will be conducted before the interventions, after the interventions (2-3 month after start of intervention), and at follow-up (12 mont after first assessment). The primary research question is: Will the internet-based format of Comet be at least as effective as the group format in reducing externalizing behaviors? Secondary research questions concern possible differential effects of the two formats on cost-effectiveness, parenting behaviors, parent mental health, applicability and consumer satisfaction, and the children's quality of life.

Study Design

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Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 134 participants
Allocation: Randomized
Intervention Model: Parallel Assignment

Intervention Model Description: Participants are randomized to the standard intervention (Parent training in group format) or the experimental condition (Internet-based parent training).

Masking: Single (Outcomes Assessor)

Masking Description: Independent clinicians will perform diagnostic assessments at pre and post measurements. The clinicians will be blind to the experimental condition the participants they assess.

Primary Purpose: Treatment

Official Title: Parent Training Targeting Externalizing Behaviors in Children in Primary Care: A Randomized Non-inferiority Study of the Comet-program Delivered Via the Internet or in Group Format.

Anticipated Study Start Date: March 2018

Estimated Primary Completion Date: July 2020

Estimated Study Completion Date: July 2020

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
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<tbody>
<tr>
<td>Active Comparator: Comet in group format The standard format of the intervention that is well established in primary and specialized care in Sweden. Parents receive the education/training in small groups led by two group leaders.</td>
<td>Behavioral: Comet The intervention is a behaviorally based and manualized parent training program.</td>
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<tr>
<td>Experimental: Internet-based Comet The same content as the group format of Comet, but delivered mainly as online self-help.</td>
<td>Behavioral: Comet The intervention is a behaviorally based and manualized parent training program.</td>
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Outcome Measures

Primary Outcome Measures:

1. Eyberg Child Behavior Inventory (change in externalizing behaviors) [ Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month) ]

   A rating scale completed by parents measuring externalizing behaviors in children. The scale contains two subscales which both will be reported independently as outcomes in this study: The intensity scale (range 36-252) and the problem scale (range 0-36). In both cases higher values indicate more externalizing behaviors.

2. Strengths and Difficulties Questionnaire - subscale hyperactivity/inattention (change) [ Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month) ]

   A rating scale completed by parents measuring both externalizing and internalizing behaviors in children, as well as the impact of such behaviors. The subscale of hyperactivity/attention problems will
be used as a primary outcome in this study (range 0-10, where higher values represent more hyperactivity/inattention).

3. Mini International Neuropsychiatric Interview (change in diagnostic status) [ Time Frame: Pre (0 month) and Post (4 month) ]

   A structured diagnostic interview conducted by clinicians with parents and (if possible) the child. Only the sections for ADHD and ODD will be used in the present study. Outcomes that will be reported are diagnostic status of both ADHD and ODD (yes/no), the number of symptoms (range 0-20 for ADHD and 0-9 for ODD), and the clinician rated severity (range 0-8 for each diagnosis, where higher value represents more severe problems).

Secondary Outcome Measures :

1. Parenting Young Children (change in parenting strategies) [ Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month) ]

   A rating scale completed by parents measuring parenting behaviors and strategies. The parents both rate the frequency of different activities (range 21-105 - higher values represent better outcome) and indicate if they find the activity/strategy problematic (range 0-21 - higher values represent worse outcome).

2. Adult-Child Relationship Scale (change in quality of relationship) [ Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month) ]

   A rating scale completed by parents measuring the level of warmth and conflict in the relationship between the parent and child. There is one subscale for each of these constructs which will be reported separately. Warmth in the relationship has a range of 5-25, where higher values represent warmer relationship. Conflict has a range of 4-28, where higher values represent more conflicts.

3. Perceived Stress Scale (change in stress) [ Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month) ]

   A rating scale completed by parents measuring (own) perceived stress. The range of the scale is 0 to 40, with higher values representing more stress.

4. Patient Health Questionnaire (change in depressive symptoms) [ Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month) ]

   A rating scale completed by parents measuring (own) depression. The range of the scale is 0 to 27, with higher values representing more depressive symptoms.

5. Kiddy-KINDL Interview (change in quality of life) [ Time Frame: Pre (0 month) and Post (4 month) ]
A structures interview that a clinician conducts with a child, measuring the experienced quality of life. The subscales pertaining relationship to parents (range 0-14, high values representing better relationship) and own wellbeing (range 0-12, higher values representing more wellbeing) will be used in the present study.

6. Strengths and Difficulties Questionnaire - emotional/peer problems (change) [Time Frame: Pre (0 month), Post (4 month) and Follow-up (12 month)]

A rating scale completed by parents measuring both externalizing and internalizing behaviors in children, as well as the impact of such behaviors. The subscales related to child well-being (emotional problems and peer problems) will be used as a secondary outcome in this study. The range of both subscales are 0 to 10, where higher values represent more problems.

7. Client Satisfaction Questionnaire [Time Frame: Post (4 month)]

A rating scale completed by parents measuring the satisfaction with the offered intervention - range 8 to 32, where higher values represent higher satisfaction.

8. Interview with clinicians about applicability of treatment [Time Frame: Post (4 month)]

A structured interview will be conducted with a selection of the clinicians about their experience with the interventions in the study, in terms of satisfaction and applicability.

Other Outcome Measures:

1. Strengths and Difficulties Questionnaire - impact (change across intervention) [Time Frame: Week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 11.]

The parents will each week throughout the intervention rate the present impact of their child's externalizing behaviors by completing the impact subscale of the Strengths and Difficulties Questionnaire (range 0-15, where higher values indicate more severe impact of the externalizing behaviors).

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 3 Years to 11 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Criteria

Inclusion Criteria:

- Primary reason for contact with health care is child externalizing behaviors.

Exclusion Criteria:

- Not sufficiently fluent in written Swedish to be able to take part in an internet-based (text-based) intervention.
- No access to computer/ipad/phone
- Social problems that makes investigation or intervention from the social services necessary.

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03465384

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Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided
Plan Description: This has not yet been decided by the research team, but the information will be updated as soon as a decision has been reached.

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Martin Forster, Karolinska Institutet:
Parent-Child relations Externalizing behaviors
Parenting Randomized controlled trial
Non-inferiority trial Cost-effectiveness

Additional relevant MeSH terms:
Disease Pathologic Processes
Attention Deficit Disorder with Hyperactivity Neurodevelopmental Disorders
Attention Deficit and Disruptive Behavior Disorders Mental Disorders