Strongest Families Finland Canada: Family-based Prevention and Treatment Program of Early Childhood Disruptive Behavior (Fin-Can)

This study is ongoing, but not recruiting participants.

Sponsor:
IWK Health Centre

Collaborator:
Canadian Institutes of Health Research (CIHR)

Information provided by (Responsible Party):
IWK Health Centre

ClinicalTrials.gov Identifier:
NCT01750996

First received: November 14, 2011
Last updated: July 23, 2015
Last verified: July 2015
History of Changes

Purpose

The goal of the Strongest Families Finland Canada project is to help parents develop skills to strengthen their families and reduce disruptive behavior in their 4 year old children.

Condition	Intervention	Phase
Disruptive Behavior Disorder	Behavioral: Strongest Families	Phase 1 Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Prevention

Official Title: Strongest Families Finland Canada: Family-based Prevention and Treatment Program of Early Childhood Disruptive Behavior

Resource links provided by NLM:

MedlinePlus related topics: Parenting

U.S. FDA Resources

Further study details as provided by IWK Health Centre:

Primary Outcome Measures:

- CHild Behaviour Checklist (to measure change from baseline) [Time Frame: Measure change from baseline at 6 & 12 months] [Designated as safety issue: No]
  Measure of child behavioural change from baseline to 6 & 12 months

Secondary Outcome Measures:

- Depression Anxiety and Stress Scale Short Form (DASS-21)- Finnish [Time Frame: Baseline, 6 & 12months] [Designated as safety issue: No]
  Parental stress changes from baseline will be measured over time
- The Parenting Scale (To measure change from baseline to 6 & 21 months) [Time Frame: To measure change from baseline to 6 & 12 months post randomization] [Designated as safety issue: No]
  Measure parental parenting practice changes from baseline
- Barkley's Quick-Screen: The Barkley Adult ADHD Rating Scale IV (to measure change from baseline) [Time Frame: Measure change from baseline to 6&12 months] [Designated as safety issue: No]
  To measure parental ADHD symptom changes form baseline
- Child Behaviour Checklist- Teacher version (to measure change since baseline) [Time Frame: Measure change from Baseline to 6 & 12 months] [Designated as safety issue: No]
  To measure child behaviour changes at daycare from baseline to 6 & 12 months post randomization
- Satisfaction measure: Researcher designed for the Intervention group [Time Frame: End of intervention and 12 months] [Designated as safety issue: No]
  To measure satisfaction with Intervention and website information
- Strengths & Difficulties Questionnaire (Screening Tool) [Time Frame: Screening] [Designated as safety issue: No]
  Screening tool used to identify high risk 4 year olds
- The Parent Problem Checklist [Time Frame: Measure change from Baseline to 6 & 12 months] [Designated as safety issue: No]
  To measure interparental conflict
- The Sense of Coherence Scale (SOC-13) [Time Frame: Measure change from Baseline to 6 & 12 months] [Designated as safety issue: No]
  To measure parent's sense of coherence (i.e., global view of the world, and individual environment as comprehensible, manageable and meaningful)
- The Inventory of Callous-Unemotional Traits [Time Frame: Measure change from Baseline to 6 & 12 months] [Designated as safety issue: No]
  To measure child empathy

Estimated Enrollment: 500
Study Start Date: November 2011
Estimated Study Completion Date: December 2015
Estimated Primary Completion Date: December 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
No Intervention: Usual Care control (Parenting tips) Participants randomized to usual care will have access to a brief information website containing brief parenting tips but will not receive Strongest Families Intervention	
Experimental: Strongest Families Strongest Families intervention	Behavioral: Strongest Families Behavioural intervention

Hide Detailed Description

Detailed Description:

This project will have two phases, described below. The first part will be development of the web based program, the second part will be the implementation of the program in Finland. All participants will be recruited in Finland and all research activities will take place in Finland, by the Finnish Consortium. The Canadian Consortium will assist in funding and provide expert support.

Part 1: Website development:

The Strongest families program provides evidence based psychological and behavioural interventions to families with children with mild to moderate mental health problems. Parents work through a handbook with exercises, watch instructional videos and participate in weekly phone calls from a trained 'coach' (paraprofessional) to provide support, respond to parents' questions and highlight the skills included in a handbook. The preliminary analysis of a Strongest Families effectiveness trial based at the Izaak Walton Killam Children's Hospital (IWK) Health Centre (Projects #2234, and #2654) and effect size reports from the IWK Strongest families Service Program suggest that Strongest Families is an effective treatment for Oppositional Defiant Disorder (ODD).

Strongest Families is an adaptation of the COPE program. COPE is a large-group parent training program (average 25 families per group) that has been evaluated and used in many centres across Canada, the United States and Europe. It was developed at McMaster University by a team led by Dr. Charles Cunningham (one of the investigators on this submission). The groups use a coping modelling problem solving approach to skill acquisition which encourages parents to discuss the solution to common problems, collaborate in the formulation of child management strategies, share successes, and provide supportive feedback. Large group discussions may also provide more information regarding normal child development and a greater perspective on common child management difficulties than clinic/individual parent training .

The benefits for parents participating in COPE group sessions are many, but the burden of traveling to receive services can impede attendance, especially for families in rural areas. One solution to this issue would be to adapt individualized Strongest Families to a more accessible mode.

We propose to develop a web-based version of Strongest Families in preparation for a Randomized Control Trial (RCT) in Finland. All components of web site will be developed using a collaborative approach with active participation by all members of the research team. We will review each of the component as it is developed. We estimate a minimum of three rounds of testing for each component. The program will be evaluated using the user-interface so that we review the website and all its various features in a manner that simulates the actual parent experience. No qualitative or quantitative data will be recorded for this phase of the project. No participants will be recruited for this phase of the trial.

The web version of Strongest Families will have two components. First, is a personalized website that tracks and uses all activities and interactions to modify the Strongest Families intervention as the user progresses through the sessions. Interactions include questions, surveys, and polls which will be asked periodically throughout the program (for examples see Appendix A). Second, the parenting skills curriculum will be based on our Strongest Families program, an approach derived from programs developed by members of this team18,19. Third, parents , using pseudonyms, will participate in a discussion board/blog to exchange ideas. Pseudonyms will be chosen by the participant, but will not include any identifying elements.

Part 2: Randomized trial (Conducted in Finland, no Canadian recruitment)

The centerpiece project will be a population-based RCT of high risk 4 year olds attending well-child clinics in Turku and environs. Families of children with behavioural challenges fort he last six months, scoring 5 points or more on the Conduct subscale

of the Strengths and Difficulties Questionnaire (SDQ) and with some perceived problems by the parent in the impact section of the SDQ will be offered participation in a 2 arm trial. All data will be collected in Finland and stored at the University of Turku. All forms/scripts/ measures will be administered in Finnish or Swedish. This project has been approved by the Intermunicipal Hospital District of Southwest Finland. The Canadian team will provide expert and financial support.

Treatment Group: Families randomized to Web-Enhanced Strongest Families (described above) will receive the website program described above.

Control Group: Families randomized to Educational Control will receive access to a static website with parenting tips as well as a 45 coaching call to review the parenting tips.

Randomization: (1:1 treatment: control; stratified by sex). Randomization sequences were generated by a qualified expert at arms length to the trial using a random permuted block sequence generator then concealed the placements using a double envelop system labeled with sequential numbers. Study staff were blinded to placements until randomization was completed by a study staff delegate.

Eligibility

Ages Eligible for Study: 4 Years to 5 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Child is 4 years old at time of recruitment
- Parent/guardian has access to a computer and the internet
- Parent/guardian is comfortable reading at a Grade 5 level
- Child meets screening criteria (SDQ score of 4 or more with some problems per impact score)
  - Child has had behavioural challenges for the last 6 months
  - Parent has access to phone in home
  - Parent speaks/writes Finnish

Exclusion Criteria:

- - Has received or is receiving behavioral treatment (parent training) before
- Diagnosis of:
  - Autism or a Pervasive development disorder (PDD)
  - Down's syndrome
  - Fetal Alcohol Syndrome
  - Mental retardation
  - Genetic diagnosis that will lead to mental retardation
  - Major mental health disorder (e.g., depression, psychosis)
- Child is not speaking using a sentence
- Child is deaf or blind

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01750996

Locations

Finland

University of Turku, Finland
TUrku, Finland

Sponsors and Collaborators

IWK Health Centre

Canadian Institutes of Health Research (CIHR)

Investigators

Principal Investigator: Patrick J McGrath, PhD IWK Health Centre

More Information

Publications:

McGrath PJ, Sourander A, Lingley-Pottie P, Ristkari T, Cunningham C, Huttunen J, Filbert K, Aromaa M, Corkum P, Hinkka-Yli-Salomäki S, Kinnunen M, Lampi K, Penttinen A, Sinokki A, Unruh A, Vuorio J, Watters C. Remote population-based intervention for disruptive behavior at age four: study protocol for a randomized trial of Internet-assisted parent training (Strongest Families Finland-Canada). BMC Public Health. 2013 Oct 21;13:985. doi: 10.1186/1471-2458-13-985.

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Health Authority: Canada: Institutional Review Board
Finland: Ethics Committee

Additional relevant MeSH terms:
Attention Deficit and Disruptive Behavior Disorders
Mental Disorders
Mental Disorders Diagnosed in Childhood

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