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.

**Purpose**

- **Primary Outcome Measures:**
  - Child Behavior Checklist (to measure change from baseline) (Time Frame: Measure change from baseline to 6 & 12 months) [Designated as safety issue: No]
  - Measure of child behavior change from baseline to 6 & 12 months

- **Secondary Outcome Measures:**
  - Depression Anxiety and Stress Scale Short Form (DASS-21) (Fin-Can) (Time Frame: Baseline, 6 & 12 months) [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: Measure change from baseline to 6 & 12 months post randomization) [Designated as safety issue: No]
  - Measure parent's parenting practice changes from baseline
  - Barkley's Guide-Score: 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 parent ADHD symptom changes from 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 behavior changes at discharge 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
  - Strength & Difficulties Questionnaire (Screening Tool) (Time Frame: Screening) [Designated as safety issue: No]
  - Questions 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 interpersonal 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 Primary Completion Date:** December 2015 (Final data collection date for primary outcome measure)

**Annex:**

- **No Intervention:** Usual care (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**
  - **Strengthen Families Intervention**
    - **Behavioral: Strongest Families**

**Detailed Description:**

- This project will have two phases, described below. The first part will be the 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:**

- Strongest Families program provides evidence-based psychological and behavioral interventions to families with children with child 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 the handbook. The preliminary analysis of a Strongest Families effectiveness trial based at the sickKids Children's Hospital's Research Institute (RKHC) Health Centre (Projects K234 and K405A) and effect size reports from the RKHC strengthened 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, collaboratively 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 the individual child training parent training.

- The benefit of 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. The 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 components 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 evaluate 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, it is a personalized website that tracks and save 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 added 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 the sickKids. Third, parents, using pseudonyms, will participate in a discussion based 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 behavioral 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.

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 behavioral challenges for the last 6 months
- Parent/guardian 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
  - Friedreich’s Ataxia
  - 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**

Crossing 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

**Publications:**


**Health Authority:**

Canada: Institutional Review Board
Finland: Ethics Committee

**ClinicalTrials.gov Identifier:** NCT01750996

**History of Changes**

Other Study ID Numbers: CIHR# 103146

Study First Received: November 14, 2011

Last Updated: July 23, 2015

**Additional relevant MeSH terms:**

Attention Deficit and Disruptive Behavior Disorders
Mental Disorders
Mental Disorders Diagnosed in Childhood

**ClinicalTrials.gov processed this record on January 24, 2016**