

# The Children and Parents in Focus project

<b>Submission date</b> 20/06/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/07/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/03/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many studies have shown that parenting support programs are effective in reducing behavioural and emotional problems in children. However, resources are limited and there is a debate about which program should be made available to parents. Triple P - Positive Parenting Program is an evidence-based program that is currently available in Sweden. Triple P level 2 is a low-cost program that consists of three large group seminars. Triple P level 3 and 4 are more intensive, with level 3 being delivered in one-to-one sessions and level 4 being delivered in small groups. In this study, we examine whether combining the three levels of Triple P is more effective than offering Triple P level 2 alone.

### Who can participate?

All families with a child aged 3 to 5 in participating preschools in Uppsala, Sweden who can speak Swedish, Arabic, Somali, Persian, Sorani or English.

### What does the study involve?

Participants will be asked to complete a set of questionnaires annually until the child is 5. Participating preschools will be randomly divided into three conditions: Universal, Universal Plus and Services as Usual. Families in the Universal and Universal Plus preschools will be invited to participate in a series of parenting seminars run by trained preschool teachers or community workers. These are Triple P seminars and provide practical advice on how to raise healthier and more competent children. Families in the Universal Plus preschools will receive additional parenting support by attending one-to-one or group sessions (Triple P primary Care or Group). These programs have a greater focus on parenting strategies that help to prevent behavioural problems. All three programs will be available throughout the project and parents can attend any time that is convenient for them.

### What are the possible benefits and risks of participating?

Parents participating in one or more of the Triple P sessions may benefit from improved parenting skills, child behaviour and mental health. We do not expect any risks to be associated with participation.

### Where is the study run from?

Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden

When is the study starting and how long is it expected to run for?  
Recruitment is expected to start in August 2013 and end in July 2017

Who is funding the study?  
Joint grant FORMAS (Sweden)

Who is the main contact?  
Associate Professor Anna Sarkadi  
anna.sarkadi@kbh.uu.se

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Anna Sarkadi

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
The Children and Parents in Focus project: a population-based cluster randomised controlled trial to prevent behavioural and emotional problems in children

**Study objectives**  
The aim of this population-based cluster randomised controlled trial is to prevent behavioural and emotional problems in pre-school children. The study has three arms:  
1. Universal approach  
2. Universal plus (universal and targeted) approach

### 3. Services-as-usual

The trialists hypothesise that compared to the services as usual, universal approach and the universal plus approach will have greater population reach and be more effective.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Regional Ethics Committee in Uppsala, 14/11/2012, ref: 2012/437

### **Study design**

Cluster randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

Other

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

Prevention

### **Participant information sheet**

Not available in web format, please contact Ms Anna Backman ([anna.backman@kbh.uu.se](mailto:anna.backman@kbh.uu.se)) to request a patient information sheet.

### **Health condition(s) or problem(s) studied**

Child behaviour and emotional problems

### **Interventions**

Universal arm: All families in this condition will be offered a light parenting program. The program includes 3 stand alone parenting seminars (Triple P level 2) and will be offered periodically throughout the implementation phase (August 2014 - July 2017). Parents are free to attend at any time.

Universal plus arm: All families in this condition will be offered the light parenting program described above as well as some extra support namely Triple P level 3 which consists of up to 4 brief individual sessions and Triple P level 4 which is an 8-session group program. All the three programs would be available throughout the implementation phase. Parents are free to attend at any time.

Services-as-usual arm: Families in this condition will only be offered the services as usual in their child health centre and preschool.

### **Intervention Type**

Other

### **Phase**

Not Applicable

**Primary outcome measure**

Child externalising and internalising symptoms at ages 3, 4 and 5 measured by Strengths and Difficulties Questionnaires (SDQ)

**Secondary outcome measures**

1. Parenting practices
2. Parent mental health
3. Economic evaluation

**Overall study start date**

01/08/2013

**Completion date**

31/07/2018

## Eligibility

**Key inclusion criteria**

All parents with a 3, 4, or 5-year-old child enrolled in the participating preschools in the municipality of Uppsala

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Target sample size is 3000

**Key exclusion criteria**

The study main language is Swedish. Study information and questionnaires are also available in the five most common languages in the immigrant community in Uppsala: Arabic, Somali, Persian, Sorani, and English. Parents will not be able to participate in the study if they neither understand Swedish nor any of the above languages.

**Date of first enrolment**

01/08/2013

**Date of final enrolment**

31/07/2017

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**  
**Uppsala University**  
Uppsala  
Sweden  
751 25

## **Sponsor information**

### **Organisation**

The Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (Formas) (Sweden)

### **Sponsor details**

Kungsbron 21  
Box 1206  
Stockholm  
Sweden  
11182  
+46 (0)8-775 40 00  
registrator@formas.se

### **Sponsor type**

Research council

### **Website**

<http://www.formas.se>

### **ROR**

<https://ror.org/03pjs1y45>

## **Funder(s)**

### **Funder type**

Research council

### **Funder Name**

Svenska Forskningsrådet Formas

### **Alternative Name(s)**

Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning, Swedish Research Council Formas, Formas

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

VINNOVA

**Alternative Name(s)**

Swedish Governmental Agency for Innovation Systems

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

Forskningsrådet för Arbetsliv och Socialvetenskap

**Alternative Name(s)**

Swedish Council for Working Life and Social Research, FAS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Sweden

**Funder Name**

Vetenskapsrådet

**Alternative Name(s)**

Swedish Research Council, VR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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="#">Protocol article</a>	protocol	16/10/2013		Yes	No
<a href="#">Results article</a>	results	01/01/2019		Yes	No