The Children and Parents in Focus project

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
20/06/2013		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
23/07/2013	Completed	[X] Results	
Last Edited 21/03/2019	Condition category Mental and Behavioural Disorders	☐ 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

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Uppsala Sweden 751 25

Sponsor information

Organisation

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

ROR

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, Vinnovase

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	Yes	No
Protocol article	protocol	16/10/2013	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes