

Early Initiatives for Children at Risk (TIBIR) an evaluation of the intervention modules: Teacher Consultation (Tidlig Innsats for Barn i Risiko)

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|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| Submission date 09/04/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 30/05/2013 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 30/05/2013 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

This study aims to test how well Teacher Consultation (TC), one of six modules in the program Early Intervention for Children at Risk (TIBIR in Norwegian), works. TIBIR is a program developed by the Norwegian Center for Child Behavioural Development to prevent and treat behavioral problems and strengthen social competence in children. TC consists of six to eight consultations, and focuses on designing and performing classroom and individual techniques for stopping or reducing conduct problems and at promoting behaviour that benefits others.

The aims of the present study are:

To compare the effects of TC to regular services given to prevent and treat children identified as having behavioral problems at school or kindergarten.

To determine whether some children benefit more from TC than others?

How can TC be improved?

Who can participate?

In total, 200 children, from various sites/areas in Norway, between the age of 3 to 12 years, having behavioral problems at school or kindergarten, can participate in this study. The consultation will be offered to the classroom and preschool teachers working with these children.

What does the study involve?

In this study, participants are randomly allocated to one of two groups, TC or regular services. They will receive the respective service. Questionnaires are filled by the childrens parents, classroom or preschool teachers and the consultants. Parents and teachers are asked to report on the childs behavior before, after, and 6 months after the consultation. Consultants and teachers are asked to fill the forms during the consultation.

What are the possible benefits and risks of participating?

All participants will receive well-known consultations carried out in the centres where the study will be conducted. There are no known risks in participating in this study.

Where is the study run from?

The Norwegian Center for Child Behavioral Development, University of Oslo, Norway.

When is the study starting and how long is it expected to run for?

The study starts in March 2013, and is expected to run till March 2017.

Who is funding the study?

The Norwegian Directorate for Children, Youth and Family Affairs (Norway); Ministry of Children, Equality and Social Inclusion (Norway); the Norwegian Directorate of Health (Norway); the Norwegian Directorate for Primary and Secondary Education (Norway).

Who is the main contact?

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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Early Initiatives for Children at Risk (TIBIR) an evaluation of the intervention modules: Teacher Consultation. A randomised controlled trial

Acronym

TIBIR

Study objectives

The aim of the present study is to compare the effects of Teacher Consultation (TC) to regular services given to prevent and treat children identified as having behavior problems at school or kindergarten.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Committees for Medical and Health Research Ethics, South- East, 7th March 2013, ref: 2012/468

Study design

Randomised controlled trial (RCT)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Prevention and reduction of behavioral problems

Interventions

The intervention studied in this trial is part of an early intervention program for use in municipalities, based on the principles of PMTO.

The program consists of six modules: a multiple gate assessment tool for early identification and five interventions. Three modules, PMTO, PMTO Parent Group (PMTO PG), and Brief Parent Training (BPT), target parents; one module, TC, focuses on other significant adults in important arenas, such as schools and kindergartens; and one module, Child Social Skill Training (CSST), is designed to improve the child's social skills. The modules of TIBIR are intended to both supplement and compensate for one another.

In this RCT, the intervention studied is the TC. Children identified as having behavioral problems

at school or kindergarten will be offered a TC intervention. This intervention consists of six to eight consultations offered to classroom or preschool teachers that focus on the design and implementation of classroom and individual strategies and techniques aimed at stopping or reducing conduct problems and at promoting prosocial behavior.

A training period of 4- days is required to become a Teacher Consultant. The training presupposes that they are Brief Parent Trainers or PMTO therapists. The training in TC adressess behavior problems in school and kindergarten, the role of consultants, the assessment of behavior problems in school and preschool settings, compliance, skill encouragement, various skills and techniques that promote prosocial behavior, and the management of behavior problems.

The TC intervention will be compared to regular services (with pre-, post- and follow-up assessment). Examples of regular services are: teacher/assistant guidance, full- or part-time assistant, and evidence based programs like The Incredible Years. The services given will vary from one municipality to another.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The assessment in both the intervention and comparison group will be conducted before treatment and approximately 12 weeks after the initiation of the intervention, and again 6 months following the second assessment.

Outcome name: Behavior Problems

Metric/method of measurement:

Parent Questionnaires:

1. Eyberg Behavior Child Inventory (ECBI)
2. Child Behavior Checklist (CBCL) for Externalizing Problems
3. Home and Community Social Behavior Scale (HCSBS) Social competence scale (32 items)

Teacher Questionnaires:

1. Class environment and Problem behavior in the Classroom
2. Teacher Report Form (TRF) for Externalizing Problems
3. School Social Behavior Scales (32 items SSBS)

Secondary outcome measures

Parent Questionnaires:

1. Child Behavior Checklist (CBCL) for Internalizing Problems
2. Parenting Practices Interview- Positive Parenting (15 items) and Harsh discipline (14 items)
3. Stressfull Life Events (12 items)

Teacher Questionnaires:

1. Teacher Report Form (TRF) for Internalizing Problems
2. Teacher- Consultant Alliance Form (Measure of alliance between classroom or preeschool teachers and consultant)
3. Teacher Consultation Adherence Form
4. Mapping of Regular Services (Kartlegging av kontrolltiltak)

Consultant Questionnaires:

1. Consultant Teacher Alliance Form (Measure of alliance between classroom or preeschool teachers and consultant)
2. Teacher Consultation Adherence Form

Overall study start date

15/03/2013

Completion date

15/03/2017

Eligibility

Key inclusion criteria

1. Child exhibiting conduct problems in school or kindergarten
2. Child is 3 - 12 years old, either sex

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

Children who:

1. were diagnosed with autism
2. has been exposed to documented sexual assaults
3. are mentally retarded
4. has parents with serious mental health problems or severely retarded

Date of first enrolment

15/03/2013

Date of final enrolment

15/03/2017

Locations

Countries of recruitment

Norway

Study participating centre
Postboks 7053 Majorstuen
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Sponsor information

Organisation

The Ministry of Children, Equality and Social Inclusion (BLD) (Norway)

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Sponsor type

Government

Funder(s)

Funder type

Research organisation

Funder Name

The Norwegian Center for Child Behavior Development (Norway)

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