The Incredible Years in Norway: treatment of oppositional defiant and conduct problems in young Norwegian children

Submission date 22/02/2008	Recruitment status No longer recruiting	Prospectively registered		
		[] Protocol		
Registration date	Overall study status	Statistical analysis plan		
10/03/2008	Completed	[X] Results		
Last Edited	Condition category Mental and Behavioural Disorders	[] Individual participant data		
04/06/2019				

Plain English summary of protocol

Not provided at time of registration

Study website http://www.deutroligearene.no/

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Treatment of oppositional defiant and conduct problems in young Norwegian children: results of a randomised controlled replication trial

Study objectives

The aims of the present study were to compare the effects of the Incredible Years (IY) basic parent training (PT) program, or PT combined with child therapy (PT+CT) to a waiting list control (WLC) condition in a randomised controlled trial including a one-year follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Informed consent was obtained from all parents. The study was approved by The Regional Committee for Ethics in Medical Research, University of Tromsø, and by the Norwegian Data Inspectorate in January 2001.

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Oppositional defiant disorder and/or conduct disorder

Interventions

The treatment program, IY, was developed by Professor Carolyn Webster-Stratton at the parenting clinic at the University of Washington. IY is a manualised and video-based training program for young children with conduct problems.

In child training (CT), groups of six children met with two therapists in the clinic for 18 - 20 weekly two-hour sessions, in all 36 - 40 hours of treatment in the Incredible Years Dinosaur School Program. The parents to children in CT participated in PT parallel to the CT intervention.

The parents assigned to the PT condition were divided into groups of 10 - 12 parents (i.e. the parents of about six children in each group), who met weekly for 12 - 14 weeks for two hours with two accredited therapists. During the sessions, parents watched 250 video vignettes showing parent-child interactions. The therapists led discussions of central aspects of parenting on the basis of the video vignettes. The aims of the parent program are to promote parent competences and strengthen families by increasing parents' positive parenting, self-confidence in parenting, reduce negative parenting, improve parents' problem-solving skills and anger management, and improve school involvement. Parents receive home tasks and each session started with the parents describing their experience of these exercises.

Children/families in the waiting list condition (WLC) were offered treatment after six months of waiting, for ethical reasons and these children were unavailable at the one-year follow-up. The children/families underwent a three-hour assessment before and after the waiting period.

One year after ended treatment, a one-year follow-up assessment (12 months after terminated treatment) was conducted.

Intervention Type

Other

Phase Not Specified

Primary outcome measure

- 1. Eyberg Child Behaviour Inventory (ECBI)
- 2. Kiddie-Schedule for Affective Disorders and Schizophrenia (Kiddie-SADS)

Assessments in the active treatment were conducted before treatment and at the end of the treatment interventions (approximately 21 - 24 weeks after the initiation of the intervention), and 12 months after the post-assessments the one-year follow-up was conducted. The WLC was not available at the one-year follow-up.

Secondary outcome measures

- 1. Child Behaviour Checklist (CBCL)
- 2. Teacher Report Form (TFR)
- 3. Parental Stress Index (PSI)

Assessments in the active treatment were conducted before treatment and at the end of the treatment interventions (approximately 21 - 24 weeks after the initiation of the intervention), and 12 months after the post-assessments the one-year follow-up was conducted. The WLC was not available at the one-year follow-up.

Overall study start date

01/09/2001

Completion date 01/07/2004

Eligibility

Key inclusion criteria

The child characteristics for inclusion in the study were:

1. The child was 4 - 8 years old, either sex

2. The primary referral reason was misconduct (e.g., noncompliance, aggressive or oppositional behaviours)

3. The childs behaviour was within the clinical range and above the 90th percentile (a score above 119 for girls and 126 for boys) on Eyberg Child Behaviour Inventory (ECBI) using Norwegian norms

4. The child met diagnostic criteria for oppositional defiant disorder (ODD) and/or conduct disorder (CD) according to standards set by the Diagnostic and Statistical Manual for Mental Disorders 4th edition (DSM-IV) or sub-clinical diagnostic criteria for ODD or CD

Participant type(s)

Patient

Age group Child

Lower age limit

4 Years

Upper age limit 8 Years

Sex Both

Target number of participants 127

Total final enrolment 127

Key exclusion criteria The child had no debilitating physical impairment.

Date of first enrolment 01/09/2001

Date of final enrolment 01/07/2004

Locations

Countries of recruitment Norway

Study participating centre

University of Tromso Faculty of Medicine Tromsoe Norway N-9037

Sponsor information

Organisation Ministry of Health and Social Affairs (Norway)

Sponsor details P.O. Box 7000 St Olavs Plass Oslo Norway N-0130

Sponsor type

Government

Website http://www.shdir.no/

ROR https://ror.org/01d2cn965

Funder(s)

Funder type Government

Funder Name Ministry of Health and Social Affairs (Norway)

Funder Name Norwegian Research Council (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/05/2018	04/06/2019	Yes	No
Results article	results	01/01/2009	04/06/2019	Yes	No
Results article	results	01/07/2010	04/06/2019	Yes	No