Feedback Informed Treatment in child- and adolescent psychiatry. A randomized cluster controlled Intervention study

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Objective: To test the hypotheses that Feedback Informed Treatment together with treatment as usual will show significant more improvement than treatment as usual alone.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON41121

Source
ToetsingOnline

Brief title
A cRCT on Feedback Informed Treatment in child- and adolescent psychiatry

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
Autism and ADHD

Research involving
Human

Sponsors and support

Primary sponsor: Karakter, Kinder en Jeugdpsychiatirie
Source(s) of monetary or material Support: Eigen instelling;Karakter

Intervention

Keyword: Child Psychiatry, Feedback, Psychological, Randomized Controlled Trials, Treatment Outcome

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary outcome measure will be quality of

life measured with the KIDSCREEN-27.

Secondary outcome

Secondary outcome measure will be parental distress measured with the OBVL.

Study description

Background summary

The efficacy of evidence-based treatment drastically decreases in everyday clinical practice (Weisz, Ugueto, Cheron &Herren, 2013). The use of immediate feedback is one important recommendation in improving the outcome of treatment (Weisz et al. 2013). Feedback Informed Treatment (FIT) is a promising feedback approach developed by Scott Miller and Barry Duncan (2004). Research showed promising results when this method is used with adult patients in general mental health care (Miller, Duncan, Brown, Sorrel &Chalk, 2006, Anker, Duncan &Sparks 2009).

The basic assumption of FIT is to be better understand changes in the patient by systematically monitor the results of the therapeutic allience and changes in the patient wellbeing. By using the results in each session and provide direct feedback, it can be assessed whether the treatment is appropriate and useful. Insufficient progress may lead to other actions. This study will evaluate the efficacy of FIT in children and adolescents diagnosed with (comorbid) and autism spectrum disorders (comorbid) ADHD and their parents on their quality of life.

Study objective

Objective: To test the hypotheses that Feedback Informed Treatment together with treatment as usual will show significant more improvement than treatment as usual alone.

Study design

Study design: Cluster Randomized controlled intervention study. Departments will be randomized assigned to the experimental group (FIT department) or the *treatment as usual* (control) group. The unit of randomization will be the departments. Individual patients will be the unit of analysis.

Intervention

Intervention: Two groups of patients will be compared; an intervention group and a control group. Both treatment groups will receive care as usual. Care as usual is a multi-disciplined treatment program that consists of the following treatments; medication, cognitive behavioral therapy, behavioral therapy, psycho-education group for parents and children, EMDR, psycho-motorial therapy and creative therapy. Treatment for ADHD and ASS is protocolled, but may vary depending on the severity of the illness, preferences of parents and/or therapists. The experimental group will add the FIT method to the care as usual. FIT consists of two brief, patient rated, four-item visual analogue scales called the Outcome Rating Scale (ORS) and Session Rating Scale (SRS). The ORS measures the patients perception of well-being and the SRS the patients perception of the therapeutic alliance. A web-based program called "FIT-Outcomes" will be used to support the use of the ORS and the SRS. With FIT-Outcomes it's possible to administer the scales online with the use of an IPad and get instant feedback. Each session, the graphical results are discussed with the patient.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden and the risks for children and parents are minimal, since both groups receive treatment as usual. The ORS and SRS are two brief lists and will just take one minute to score in the session. The departments who are invited to participate in the study will be given information about the objectives of the study and the practical impact it may have on their practice. They will be told that they will be randomized to an experimental or control group. A written consent from all practices will be asked.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children, adolescents and young adults aged from 6-18 year (IQ *85) referred to the specialized outpatient ASS and ADHD teams

Exclusion criteria

IQ <85

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2016
Enrollment:	580
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48681.091.14