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The effect of patients' feedback on treatment outcome in child psychiatry

Submission date
03/03/2018

Recruitment status
No longer recruiting

Registration date
13/03/2018

Overall study status
Completed

Last Edited
11/03/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
It is important to know if treatment in child psychiatry is effective because of its impact on a child's life, so there is a growing body of studies about the effectiveness of treatment protocols. It's also known that treatment outcome not only depends on the quality of those protocols but also other factors, known as the common factors. An important factor seems to be the quality of the relation between the therapist and the patient. The effect of feedback in treatment is mainly studied with adults, so this study will use a child psychiatry group. This study aims to find out if using patients' feedback about their experience of this relationship and also about their wellbeing, stimulates a better fit between patient and therapist, and in that way fosters a better treatment outcome (increase quality of life and decrease symptom severity).

Who can participate?
Boys and girls aged 6-18 years referred for diagnostics and treatment to one of the eight outpatient Autism Care Teams of Child Psychiatry Centre 'Karakter'.

What does this study involve?
Eight teams of therapists are randomly allocated to one of two groups. Those in the experimental group add the use of feedback (Feedback-Informed Treatment) in their treatment sessions with the children and/or parents.
Participants attend the necessary treatment (generally psycho-education once a week over a 10 week period).
At the beginning of the session the child and/or the parents fill in the Dutch translation of the Outcome Rating Scale (ORS) about the child on an iPad by putting a mark on a visual ten-centimetre scale ranging from 'very bad' at the left site to 'very well' on the right site. The ORS consists of four items about the wellbeing of the child (at (1) individual level, (2) family level (3) social level, (4) general level). In a similar way at the end of the session the child and/or the parents fill in the Dutch translation of the Session Rating Scale (SRS) for themselves which also contains four items about the way they perceived the session ((1) relationship (2) goals and setting, (3) approach and methods, (4) overall). The Total ORS and SRS-score are shown in the same graph and reflects the curve of the way the patient is experiencing treatment. The progress on the ORS en SRS is set against two reference lines that indicated the average course of successful respectively non-successful treatment-outcomes given the initial patient score.

These reference lines are based on a large database. The therapist and the patient are encouraged to discuss the results shown in the graph. This conversation is the main point of FIT and gives it added value. Therapists in the control condition are not trained in FIT and also they do not add FIT to their treatment as usual.
Parents of the participant complete the Dutch translation of the Kidscreen 27 Questionnaire to measure quality of life. The Kidscreen 27 representing five dimensions: Physical Wellbeing, Psychological Wellbeing, Autonomy and Parents, Peers and Social Support. Parents of the participant also complete the Dutch translation of the Youth Outcome Questionnaire (Y-OQ30) which represents six subscales: Somatic complains, Social Isolation, Aggression, Behaviour problems, Hyperactivity and Depression/ Anxiety. This measures symptom severity. Parents digitally complete all measurements about their child at the start, repeatedly every three months and finally at the end of treatment.

What are the possible benefits and risks of participating?
Using FIT may lead to a better treatment outcome as children experience an increased quality of life and/ or a decreased level of symptom severity. It should provide cues to therapists to improve their qualities of being attuned to the children they work with. There is no additional risk to the normal treatment in this study, as all participants receive care as usual.

Where is this study run from?
1. Karakter Almelo (Netherlands)
2. Karakter Arnhem (Netherlands)
3. Karakter Ede (Netherlands)
4. Karakter Tiel (Netherlands)
5. Karakter Apeldoorn (Netherlands)
6. Karakter Enschede (Netherlands)
7. Karakter Nijmegen (Netherlands)
8. Karakter Zwolle (Netherlands)

When is the study starting and how long is it expected to run for?
September 2013 to January 2017

Who is funding the study?
Karakter Child and Adolescent Psychiatry Centre (Netherlands)

Who is the main contact?
Rint de Jong (Public)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL number 48681.091.14 METC no. 2014/144

Study information

Scientific Title
The effect of patients' feedback on treatment outcome in a child and adolescent psychiatric sample: a randomized controlled trial

Study objectives
The objective is to evaluate whether quality of life increases and symptom severity decreases in children receiving treatment as usual with addition of Feedback Informed Treatment (FIT) compared to children who receive treatment as usual without addition of FIT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethic Committee for Arnhem-Nijmegen, 30/05/2014, refs: NL number 48681.091.14, METC no. 2014/144

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Child mental health

Interventions
Autism Care Teams from the eight trial sites are randomised to one of two conditions (experimental or control). Therapists in the experimental group attend a one day training course in the principles and use of Feedback Informed Treatment (FIT) by a certified trainer, and add the use of feedback in their treatment sessions with the children and/or parents who participate in this study. To standardize the use of feedback, therapists use FIT as described in manual two of the ICCE Manuals on FIT.
Therapists in the control condition are not trained in FIT and do not add FIT to their treatment, so participants in the control condition receive treatment as usual according to the same clinical protocols as treatment as usual in the experimental group.
The vast majority of children receive psycho-education (generally once a week, over a ten-week period). This is followed in some instances by a (social) skills training (weekly, over a period of ten weeks), emotion- and/or behaviour regulation skills training, Psycho-motoric Therapy (generally once a week, over a period of fifteen weeks), (cognitive) Behavioural Therapy during fifteen weeks and/or pharmacotherapy. Parents attend psycho-education and parent mediation therapy ranking from low frequency sessions with a psychologist (for example, once per month) to intensive parental training set up in their home environment (for example twice a week, for 25 weeks) by a family worker.

At the beginning of the session the child and/or the parents fill in the Dutch translation of the Outcome Rating Scale (ORS) about the child on an iPad by putting a mark on a visual ten-centimeter scale ranging from ‘very bad’ at the left site to ‘very well’ on the right site. The ORS consists of four items about the wellbeing of the child (at (1) individual level, (2) family level (3) social level, (4) general level). Filling in the ORS takes two minutes. The Total ORS-score (range 0-40) is immediately shown in a graph, which reflects the progress of the patient over the treatment period. This progress is set against two reference lines that indicate the average course of successful respectively non-successful treatment-outcomes given the initial patient ORS-score based on a large database.

In a similar way at the end of the session the child and or the parents fill in the Dutch translation of the Session Rating Scale (SRS) for themselves which also contains four items about the way they perceived the session ((1) relationship (2) goals and setting, (3) approach and methods, (4) overall). While the ORS is filled in for the child in all cases, the SRS is filled in for the session participant, which can be the child or the parents. The Total SRS-score (range 0-40) is shown in the same graph and reflects the curve of the way the patient is experiencing treatment. The SRS curve is also set against a cut-off line based on the same large dataset. The therapist and the patient in the experimental group are encouraged to discuss the results shown in the graph. This conversation is the main point of FIT and creates added value.

Intervention Type
Behavioural

Primary outcome measure
Quality of Life of the children as assessed by their parents digitally, using the Dutch translation of the Kidscreen 27 Questionnaire at baseline, repeatedly every three months and at the end of treatment.

Secondary outcome measures
Symptom severity level of the children as assessed by their parents digitally, using the Dutch translation of the Youth Outcome Questionnaire (Y-OQ30), at baseline, repeatedly every three months and at the end of treatment.

Overall study start date
25/09/2013

Completion date
04/01/2017

Eligibility

Key inclusion criteria
1. Age between 6 and 18 years
2. Referred to one of the eight participating Autism Care Teams
3. Dutch speaking
4. Ability to complete the outcome questionnaires digitally
5. Informed consent given by the parents and the child if twelve years or older

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
The Required total sample size was 129 for an unclustered RCT (43 patients per arm). To adjust for within-cluster correlation we calculated the design effect or inflation factor (Design effect =1+(m−1)ρ where m is the average cluster size and ρ is the intraclass correlation coefficient or ICC). Based on pilot data, in this study, the average cluster size was set at m=20, the ρ = 0.001. The design effect therefore was set at 1.03. The total sample size for the cluster RCT was 132 patients.

Total final enrolment
166

Key exclusion criteria
1. Patients who do not receive any treatment after diagnostics
2. Treatment was provided in another team or by a therapist who was not trained in FIT
3. FIT was used in less than three treatment sessions
4. The parents' response on the repeated outcome assessment is less than two

Date of first enrolment
07/07/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Karakter Almelo
Vriezenveenseweg 213
Almelo
Netherlands
7602 PT

Study participating centre
Karakter Arnhem
Klingelbeekseweg 19
Arnhem
Netherlands
6812 DE

Study participating centre
Karakter Ede
Horalaan 5
Ede
Netherlands
6717 LX

Study participating centre
Karakter Tiel
Prinses Beatrixlaan 25
Tiel
Netherlands
4001 AG

Study participating centre
Karakter Apeldoorn
Tussen de Eiken 109
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7325 HH

Study participating centre
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Roessinghsbleekweg 39
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Karakter Nijmegen
Reinier Postlaan 12
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6525 GC

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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
www.karakter.com/academie

ROR
https://ror.org/044jw3g30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Karakter Child and Adolescent Psychiatry

Results and Publications

Publication and dissemination plan
Planned publication of the results of the primary and secondary outcomes in 2018 in an international peer reviewed journal.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Rint de Jong, r.dejong@karakter.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	11/03/2019	Yes	No