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Providing therapists with client progress and feedback during psychological treatments

Submission date
02/04/2019

Recruitment status
No longer recruiting

Registration date
02/04/2019

Overall study status
Completed

Last Edited
14/07/2020

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
Providing therapists and clients feedback on client progress during psychological treatments, also known as feedback-informed treatment, potentially can improve the outcome of therapy.

Feedback informed treatment (FIT) is a method to monitor treatment outcome and to evaluate with the client whether therapy is helping them, and if not, to discuss what is necessary to make it work Studies on the effects of FIT show that that treatment results, such as symptom reduction or social functioning, can be enhanced and that using feedback can prevent treatment failure. Feedback also potentially has a positive effect on other relevant treatment outcomes such as dropout rates and treatment efficiency. However, differences between studies on FIT makes it difficult to determine whether the effect is due to feedback or due to differences in treatment methods or settings. Therefore there is a necessity for investigating the effect of feedback in a setting with a uniform treatment method and therapist who all receive the same basic training in this method.

The objective of this study is to investigate whether a structured cognitive behavioural therapy (CBT) when combined with an intensive form of client feedback improvises treatment efficiency, symptom reduction and drop out.

Who can participate?
All adult clients who after intake were to receive treatment at the outpatient mental health care institution where the study took place were asked to participate in the study.

What does the study involve?
Two treatment conditions were compared: a control condition, where CBT is provided combined with a standard, low intensive form of feedback/monitoring of progress, and a feedback condition were CBT is combined with an intensive form of feedback. In the feedback condition a feedback system called the Partners for Change Outcome Management System PCOMS) is used. Clients were asked to fill in the feedback measures every session in the feedback condition and therapists were instructed to discuss the results with their clients.

What are the possible benefits and risks of participating?
Clients might need fewer treatment sessions to recover. No risks or adverse effects are expected.

Where is the study run from?
Six different locations of the HSK Groep, a Dutch nationwide outpatient mental health organisation.

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

Who is funding the study?
The study was funded by the principal investigator and the HSK Groep.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
The effect of adding a client feedback system to cognitive behavioural therapy: a randomised controlled trial.

Acronym
CFCBTRCT

Study objectives
1. Overall treatment efficiency will improve using the Partners for Change Outcome Management; Miller & Duncan, 2004 (PCOMS)
2. Overall feedback will not have an effect on symptom reduction, or on classification of outcome based on symptom reduction
3. Drop out in the feedback condition will be less when PCOMS is used. Post hoc analyses will be performed to explore whether the clients' diagnoses moderates the effect of feedback on outcome and whether the frequency of feedback predicts the effect of feedback.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2017, the ethical review board of Radboud University (Faculteit Sociale Wetenschappen, Montessorilaan 3, Postbus 9104, 5500 HE Nijmegen; +31 24 36 16236; ecsw@ru.nl), ref: ECSW2017-1303-49.

Study design
This study was a randomized controlled trial in which the effect of the use of feedback on treatment outcome was investigated.

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Mental health care

Interventions
Control condition. The control condition consisted of cognitive behavioural therapy (CBT) combined with a standard, low intensive form of client feedback. Specific treatment protocols, based on CBT techniques, were used by therapists during treatment. Clients were asked to complete the SCL-90 at intake, after five sessions and at the end of treatment and therapists were provided the results.

Manipulation. As an add-on to the control condition, an intensive form of feedback, namely PCOMS, was used in the feedback condition. Therapists were trained by an independent trainer together with the main researcher in the use of PCOMS and the web-based program FIT-Outcomes. Therapists were instructed to use FIT-Outcomes on a session to session basis with every new client in the Feedback condition and to evaluate with their clients whether enough progress was made during treatment. A client was considered “not on track” (NOT) if they did not have an improvement of 5 points on the ORS within the first five sessions or did not meet the expected recovery curve within the first five sessions. Therapists were instructed to discuss with their client why they were NOT and what needed to change. The cut-off score on the SRS that was used was 34 points based on the study of Janse et al. (2014). Therapists were instructed to discuss with their clients how to improve the therapeutic alliance if the score dropped below the cut-off point.

Procedure. Clients were referred to the mental health care organisation for treatment by their general physician or company physician. After intake clients who thereafter were to receive treatment were asked to participate in the study. They received written information on the study and were asked to give consent for the use of their data for research purposes. After giving consent, clients were randomly assigned to either the TAU or the Feedback treatment condition using Excel 2010 (Microsoft, Redmond, WA, USA). The method of randomisation was a simple randomisation procedure. Therapists were then informed to which treatment condition their client was assigned.

Intervention Type
Behavioural

Primary outcome measure
The number of sessions clients received is determined using the total amount of face to face sessions clients received, which were registered in the clients Electronic Health Record.

Secondary outcome measures
1. The reduction of symptoms is measured using Symptom Checklist Revised (SCL-90-R; Derogatis, 1994) at intake, the fifth session and at the end of treatment.
2. The percentage of drop-out from treatment is measured using the registration in the Electronic Health Record of how the client ended treatment (by mutual agreement or drop out from treatment).

Overall study start date
01/04/2013

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. After intake was to receive treatment at the outpatient mental health care institution where the study took place

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 395 clients were approached to participate.

Total final enrolment
368

Key exclusion criteria
Only needed basic care (with a restriction in the amount of sessions)

Date of first enrolment
01/09/2013

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
HSK Utrecht Hoograven
Giessenplein 59E
Utrecht
Netherlands
3522 KE

Study participating centre

HSK Amersfoort Centrum
Stadsring 175
Amersfoort
Netherlands
3817 BA

Study participating centre
HSK Zwolle
Dokter Stolteweg 54
Zwolle
Netherlands
8025 AX

Study participating centre
HSK Groningen
Laan Corpus Den Hoorn 102-1
Groningen
Netherlands
9728 JR

Study participating centre
HSK Hoogeveen
Griendtsveenweg 27 B-2
Hoogeveen
Netherlands
7901 EB

Study participating centre
HSK Assen
Transportweg 10
Assen
Netherlands
9405 PR

Sponsor information

Organisation
HSK Groep

Sponsor details
Oude Oeverstraat 120
Arnhem
Netherlands
6811 JZ
088 115 5815
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Sponsor type
Hospital/treatment centre

Website
https://www.hsk.nl/

ROR
https://ror.org/02hcvyf40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
HSK Groep

Results and Publications

Publication and dissemination plan
Results of this study will be published in a peer-reviewed scientific journal.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	14/07/2020	Yes	No