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Improving feedback: how expected treatment response information helps therapists

Submission date
14/12/2023

Recruitment status
No longer recruiting

Registration date
24/04/2024

Overall study status
Completed

Last Edited
18/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many mental health care organizations measure their patients' progress through routine outcome monitoring. The way that progress is measured and the way therapists are provided with feedback on their patients' progress strongly differs between organizations. The question is whether all methods are equally effective. Research in the United States shows that providing feedback to therapists based on a prediction model can improve patient outcomes, especially for those patients who are not progressing well in treatment. In the Netherlands, a prediction model for Dutch patients was built, based on almost 2000 patients in four mental health care organizations.

Who can participate?
Patients (aged 18-65 years old) who are receiving outpatient treatment at GGZ Noord-Holland-Noord and GGZ Dimence in the four participating locations

What does the study involve?
In this study, two types of feedback and one control condition are compared:
* Control group: the therapist gets no feedback.
* Outcome monitoring feedback: the therapist gets feedback on the patient's progress in a progress chart.
* Complex feedback based on the Dutch prediction model: the therapist gets a progress chart that compares the patient's actual progress with the expected treatment response.

Intervention:
The intervention consists of providing feedback to therapists on their patients' progress. In the outcome monitoring feedback condition, the therapist gets feedback on the patient's progress in progress charts and tables. The progress of the patient can be viewed by the therapist at all times, by logging on to the feedback system (RequestXL), but is also actively provided by e-mail at sessions 1, 3, 5, 10 and 15.

In the complex feedback condition with a prediction model, the actual treatment course (based on the OQ scores) of the patient is compared with the predicted treatment course. The expected treatment course is calculated by a formula. The progress of the patient can be viewed

by the therapist at all times, by logging on to the feedback system (RequestXL), but is also actively provided by e-mail when the patient is not progressing well. The therapist then receives an e-mail with high urgency.

In the complex feedback condition, feedback is also provided on the ASC. The ASC is administered when the patient goes off track (through the 75% negative bound of the confidence interval around the predicted treatment course) and measures the therapeutic alliance, motivation, social support and life events. The ASC is combined with so-called Clinical Support Tools, a set of Microsoft Word documents that provide practical tips on improving therapeutic alliance, motivation and social support. The practical tips are based on a literature review on these topics.

Main study parameters/endpoints:
The primary outcome measure of the study is patients' dysfunctioning on the Outcome Questionnaire. More specifically, the progress that the patient makes during treatment. The results will be analysed using multilevel analysis, which has the advantage of being able to handle missing data well. Therefore, data from all patients, including those that dropped out of treatment or dropped out of the study can be used in the analysis.

What are the possible benefits and risks of participating?
Benefits: Participants in the active conditions may benefit from participating by having their therapists respond to the feedback about treatment progress and being able to identify more quickly when there is a lack of progress. In addition, completing the questionnaires in all conditions may help patients summarize their thoughts before sessions, which has been reported as helpful by previous patients.

Burden: The burden for the patient consists of completing a 5-minute questionnaire before each treatment session, for a maximum of 15 times. After the research period (end of treatment or after 15 sessions) they will get two follow-up measures after 3 and 6 months. The average treatment duration for outpatient individual treatment was around 9 sessions in a previous study at one of the treatment settings. If patients go off track, they are asked to complete an additional questionnaire, which also takes about 5 minutes to complete. In addition to the self-report questionnaires, patients are getting a diagnostic interview that takes approximately 1 hour. The burden for the therapist consists of completing brief questionnaires during the treatment of a participating patient (total commitment around 10 minutes) and completing a longer questionnaire once every 6 months (about 20 minutes per administration, total of 5 administrations).

Risks: The risks for both the patient and the therapist are minimal.

Where is the study run from?
Leiden University (The Netherlands)

When is the study starting and how long is it expected to run for?
April 2009 to September 2014

Who is funding the study?
Investigator initiated and funded (The Netherlands)

Who is the main contact?
Dr Kim de Jong, kjong@fsw.leidenuniv.nl (The Netherlands)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Taking feedback to the next level: Efficacy of expected treatment response feedback to therapists

Study objectives
Main questions:
1. Does providing feedback to therapists improve treatment outcome?
2. Does providing feedback based on the prediction model lead to better outcomes than progress feedback alone?

Secondary questions:
1. How well can therapists predict their patient's progress?
2. Are there differences between therapists in treatment outcomes and is this related to the way they use the feedback?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/11/2010, Medical Ethical Committee of the Leiden University Medical Centre (Postbus 9600, Leiden, 2333 ZC, Netherlands; +31 (0)71 526 91 11; metc_ldd@lumc.nl), ref: NL30987.058.09

Study design
Two-year randomized controlled single-blinded study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychiatric patients

Interventions
The psychiatric patients who applied for outpatient individual psychiatric treatment were randomly assigned, with a simple randomization method using a software program to assign patients to one of the three conditions: The control condition, the outcome monitoring (ROM) condition, or the clinical support tool (CST) condition. The intervention consists of providing feedback to therapists on their patients' progress. In the control condition, therapists receive no feedback about their patient's progress. In the ROM feedback condition, feedback was given in the form that most routine outcome monitoring feedback is being provided. The therapist was presented with a graph of the patient's progress after sessions 1, 3, 5, 10 and 15. In the graph, the patient's progress on the OQ-45 is monitored. The therapist receives feedback on the OQ-45 total score, the subscale scores and the critical items. In the CST feedback condition, the therapists receive feedback on the patient's progress, based on an expected treatment response model. The ETR model is based on data collected from 1540 outpatients in three different mental health care organizations in the Netherlands. Therapists receive an alert when the patient deviates from the expected track. An error bound around the expected treatment response for the patient indicates when the therapist is signalled. If a 75% failure boundary was crossed by the patient, the therapist received an orange warning signal, indicating that the patient had an increased chance of a negative treatment outcome. If the 95% failure boundary was crossed, the therapist received a red warning signal, indicating that the patient was highly likely to have a poor treatment outcome if he or she continued on the current track. When the patient signals orange or red, the clinical support tool, the Assessment for Signal Clients (ASC) questionnaire was administered to the patient, and the therapist received feedback about the scores on the ASC, in addition to the scores on the Outcome Questionnaire (OQ-45).

Intervention Type
Behavioural

Primary outcome(s)
Patient's progress measured using the Outcome Questionnaire-45 item version (OQ-45), Dutch version, measured weekly for up to 15 sessions or a maximum of 1 year

Key secondary outcome(s))
1. Therapist expectations of treatment outcome measured using a self-constructed instrument at sessions 1, 5, 10 and 15
2. Therapists' use of the progress feedback tool measured using the Assessment for Signal Clients (ASC) questionnaire at sessions 5, 10, 15
3. Patients' treatment dropout, defined as the patient ending treatment before the therapist's recommendation, measured using data registered in the electronic patient file as "treatment ended on the initiative of the patient" by the end of the study
4. Patients' study dropout, defined as patients discontinuing participation in the study, measured using data registered in the trial's participants follow system by the research team before ending treatment or reaching 15 sessions of treatment

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Age between 18 to 65 years old
2. Sufficient mastery of the Dutch language in reading and speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
511

Key exclusion criteria
1. Psychotic disorder
2. Current crisis
3. High risk of decompensation
4. Severe manic episode

Date of first enrolment
01/12/2010

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
GGZ Noord-Holland Noord
Postbus 18

Heiloo
Netherlands
1850 BA

Study participating centre
GGZ Dimence
Pikeursbaan 3
Deventer
Netherlands
7411 GT

Sponsor information

Organisation
GGZ Noord-Holland-Noord

ROR
https://ror.org/00b3xjw51

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the participating mental health care organizations owning this data, and we just have permission for its use with the specific research questions that we have. Data collected is highly sensitive data (on patient functioning and symptoms) that cannot be shared as individual data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	29/09/2010	23/04/2024	No	No