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Evaluation of Tell Me More, a measurement feedback system in child and adolescent mental health outpatient clinic

Submission date
25/01/2019

Recruitment status
Suspended

Registration date
21/02/2019

Overall study status
Completed

Last Edited
17/04/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Measurement feedback systems (MFS) are solutions that grant patients and relatives the possibility to give information about symptoms, benefit of treatment or other information to their therapist and the institution responsible for the treatment. MFS has the potential to improve treatment by increasing patient and/or parent engagement in treatment, improved therapeutic alliance, better clinical outcome, and more effective services. The aim of this study is to investigate the feasibility of a MFS in a youth psychiatric outpatient clinic, the clinical effects of MFS use, and which components of the MFS are perceived as useful for the therapists.

Who can participate?
Children and youth who receive treatment at a Norwegian outpatient clinic

What does the study involve?
The MFS is gradually introduced by allowing new therapists access to the measurement feedback system every 6.weeks. Participants (patients and parents) are asked to answer a questionnaire before every meeting with their therapist and a 12-month follow-up questionnaire.

What are the possible benefits and risks of participating?
Participation may help to improve services for children and youth with psychological difficulties. Participants are requested to answer sensitive questions. Some might find this uncomfortable.

Where is the study run from?
The study is conducted by the Centre for Child and Adolescent Mental Health Eastern and Southern Norway. Participants are recruited at Nic Waals Institute, a child and youth outpatient clinic in Oslo, Norway.

When is the study starting and how long is it expected to run for?
Recruitment starts 01/05/2019, recruitment is planned to end 31/12/2020, and the study is planned to end 31/12/2021.

Who is funding the study?
Centre for Child and Adolescent Mental Health Eastern and Southern Norway and Lovisenberg Diakonale Hospital (Norway)

Who is the main contact?
Kristian Rognstad
kristian.rognstad@r-bup.no

Contact information

Type(s)
Scientific

Contact name
Mr Kristian Rognstad

Contact details
Gullhaugveien 3-5
Oslo
Norway
0484
+47 (0)41578950
kristian.rognstad@r-bup.no

Additional identifiers

Protocol serial number
REK sør-øst (2018/1892-5)

Study information

Scientific Title
Tell Me More - a randomized controlled trial of a measurement feedback system in a child and adolescent mental health outpatient clinic in Norway

Acronym
Tell Me More

Study objectives
1. The use of measurement feedback system (MFS) will result in greater symptom reduction, compared to treatment-as-usual.
2. The use of MFS will result in better therapeutic alliance, compared to treatment-as-usual.
3. The use of MFS will result in better client satisfaction, compared to treatment-as-usual.
4. Therapist's attitudes toward standardized assessment scales will predict use and perceived benefit of MFS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norwegian national research committees for medical and health research ethics (REK sør-øst), Gullhaugveien 1-3, 0484 Oslo, Tel: 22845511, Email: post@helseforskning.etikkom.no, 27/11 /2018, ref: 2018/1892/REK sør-øst D

Study design
Single-centre stepped wedge cluster randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
All mental disorders

Interventions
Randomization on therapist-level. Once a therapist is introduced to the active condition, all patients in the clinic allocated to this therapist will be in the active condition.

Measurement feedback systems (MFS) are solutions that grant patients and relatives the possibility to give information about symptoms, benefit of treatment or other information to their therapist and the institution responsible for the treatment. MFS has the potential to improve treatment e.g. by increasing patient and/or parent engagement in treatment, improved therapeutic alliance, better clinical outcome, and more effective services. The active condition will be gradually introduced by allowing new therapists access to the measurement feedback system every 6 weeks. The trialists believe this will bolster implementation relative to the alternative of a "standard" parallel randomized controlled study. They plan to introduce the MFS over 10 steps, thus allowing for a full implementation of the MFS in the participating clinic within 1.5 years.

The study will compare effects for patients with therapists that get access to MFS, with effects for patients with therapists that do not get access to MFS. Therapists with access to MFS will have bi-weekly discussion groups and be encouraged to use the feedback when discussing their active cases.

Intervention Type
Device

Primary outcome(s)
1. Externalizing and internalizing problems measured using Behaviour and Feelings Survey (parent report) at baseline, at every meeting at the clinic throughout the patient’s treatment, and at follow up (12 months after baseline)
2. Externalizing and internalizing problems measured using Behaviour and Feelings Survey (self-report) at baseline, at every meeting at the clinic throughout the patient’s treatment, and at follow up (12 months after baseline)
3. Attainment of treatment goals measured using Top Problem Assessment (parent report) at baseline and at every meeting at the clinic throughout the patient’s treatment
4. Attainment of treatment goals measured using Top Problem Assessment (self-report) at baseline and at every meeting at the clinic throughout the patient’s treatment

Key secondary outcome(s))
1. Sleep quality measured using one question about sleep quality over the last week (parent report) at baseline and at every meeting at the clinic throughout the patient's treatment
2. Sleep quality measured using one question about sleep quality over the last week (self-report) at baseline and at every meeting at the clinic throughout the patient's treatment
3. Food intake measured using one question about food intake over the last week (parent report) at baseline and at every meeting at the clinic throughout the patient's treatment
4. Food intake measured using one question about food intake over the last week (self-report) at baseline and at every meeting at the clinic throughout the patient's treatment
5. Externalizing and internalizing problems measured using Brief Problem Monitor (parent report) at baseline and follow up (12 months after baseline)
6. Externalizing and internalizing problems measured using Brief Problem Monitor (self-report) at baseline and follow up (12 months after baseline)

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Youth, 5-18 years old
2. Granted right to treatment in Norwegian specialized mental health care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Norway

Study participating centre
Nic Waals Institutt
Spångbergveien 25
Oslo
Norway
0853

Sponsor information

Organisation
Lovisenberg Diaconal Hospital

ROR
https://ror.org/03ym7ve89

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Centre for Child and Adolescent Mental Health Eastern and Southern Norway

Results and Publications

Individual participant data (IPD) sharing plan
Data will only be shared after a full dataset is obtained and the trialists have deleted the participant identification code key. The purpose of sharing the data is to ensure transparency in the research, use of the data for publication will depend on agreement with the owners of the data (RBUP).

IPD sharing plan summary
Available on request