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A web-based tool to support shared decision making between clinicians and patients in routine outcome monitoring

Submission date
12/07/2013

Recruitment status
No longer recruiting

Registration date
08/08/2013

Overall study status
Completed

Last Edited
08/08/2013

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Since 2007, Routine Outcome Monitoring (ROM) assessments have been a regular element in care for people with psychotic disorders in the northern provinces of the Netherlands. The ROM protocol which is specifically developed for people with psychotic disorders - this protocol is called Phamous - consists of a physical investigation (e.g., weight, height, waist measurement and glucose levels), multiple interviews and questionnaires concerning psychiatric and psychosocial issues, and service user satisfaction (www.phamous.eu). All service users with schizophrenia who receive care from any mental health care organization involved take part in ROM assessment at least once a year. After completion of the assessment, the parameters of the ROM assessment are uploaded into a central database by clinicians and research nurses via a link in the patients electronic file. Currently, the ROM-results are only reported to clinicians. Clinicians are supposed to discuss the results with their patients so that they can mutually decide whether the course of treatment needs readjustment. However, a large percentage of service users do not receive adequate feedback concerning their ROM-results, as clinicians are not yet accustomed to discussing ROM results with service users.
In an attempt to improve ROM practice and to increase potential for service user empowerment, we developed a prototype of a web-based support system that provides service users diagnosed with accessible information about their ROM results, which may enable them to participate in shared decision making.

Who can participate?
Male and female patients aged >18 years diagnosed with a psychotic disorder, fluent in Dutch and participating in Phamous assessments.

What does the study involve?
In this study, participants will be randomly allocated to an intervention group or a control group. In the intervention group, patients are invited to use the web-based support system. This web system provides patients with information about ROM, access to their ROM results, and access to individualized advice based on these ROM results. Patients in the control group receive care as usual.

What are the possible benefits and risks of participating?
Patients in the intervention group can benefit from participating in the study as they can access their ROM results and get personalized advice based on these results. As a consequence, they have the opportunity to better prepare themselves for the ROM evaluation meeting with their clinician. We do not expect any risks.

Where is the study run from?
The study takes place at the University Center for Psychiatry at the University Medical Center Groningen, the Netherlands.

When is the study starting and how long is it expected to run for?
The study started in March 2013 and will run until November 2013.

Who is funding the study?
1. Netherlands Organisation for Health Research and Development (ZonMw)
2. Foundation for Mental Health (Fonds Psychische Gezondheid), Netherlands)
3. ICT regie, Netherlands
3. Ministry of Health, Welfare and Sport under the name WEGWEIS, Netherlands

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A web-based tool to support shared decision making between clinicians and patients in routine outcome monitoring (ROM): a pilot randomised controlled trial

Study objectives
We hypothesize that a web-based tool can support processes of shared decision making between patients with a psychotic disorder and their clinicians, in the evaluation of routine outcome monitoring results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The medical ethical committee of the University Medical Center Groningen approved our study. Number: METc 2012/367

Study design
Pilot randomized controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Psychotic disorders

Interventions
The intervention is behavioural in nature. It should lead to more patient involvement in medical decision making. In the intervention condition, patients are invited to use the web-based support system that provides patients with information about ROM, access to their ROM results, and access to individualized advice based on these ROM results.
Patients in the control condition receive care as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The degree of shared decision making between patients and clinicians, measured with conversation analysis of audio-taped conversation (using the Mappin' SDM rating instrument, and items of the RIAS).

Secondary outcome measures
Satisfaction with the web-based support tool, knowledge of one's treatment goals, patient's perceived benefit of ROM

Overall study start date
08/03/2013

Completion date
30/11/2013

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Patients with psychotic disorders
3. Participating in Phamous assessments (ROM assessments for people with psychotic disorder)
4. Fluent in Dutch

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
08/03/2013

Date of final enrolment
30/11/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Hanzeplein 1
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.zonmw.nl/en/contact/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Foundation for Mental Health (Fonds Psychische Gezondheid) (Netherlands)

Alternative Name(s)
Foundation for Mental Health

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
ICT regie (Netherlands)

Funder Name
Ministry of Health, Welfare and Sport under the name WEGWEIS (grant number 300020011) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration