

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	<input type="checkbox"/> Prospectively registered
Registration date 08/08/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/08/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration