

# Treatment Preferences and Decision-Making in Mental Health

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39621

### Source

ToetsingOnline

### Brief title

nvt

### Condition

- Other condition
- Mood disorders and disturbances NEC

### Synonym

depression/ anxiety

### Health condition

+ angststoornissen- en symptomen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** GGZ Rivierduinen

## Intervention

**Keyword:** Anxiety Disorders, Decision-Making, Mental Health Care, Mood disorders, Shared Decision Making, Treatment Choices, Treatment Preferences

## Outcome measures

### Primary outcome

In the third stage of this study the following study parameters will be used to evaluate the newly developed decision aid:

- Shared Decision Making, measured by the SDM-Q-9 (Shared Decision Making Questionnaire)
- Decisional Conflict, measured by the DCS (Decisional Conflict Scale)

These parameters will be used to assess the effect of the decision aid on decision-making, by comparing the scores on these scales from patients and clinicians who used the decision aid, to scores of those who did not use it, measured in a earlier stage of the study.

### Secondary outcome

nvt

## Study description

### Background summary

The 'Treatment Preferences and Decision-Making in Mental Health' study focuses on preferences and decision-making in the treatment of mood- and anxiety disorders. These disorders belong to the most prevalent disorders in the Netherlands, they cause a significant burden of disease and high costs. Known

effective treatments are psychopharmacology or psychotherapy, the choice of one of these therapies depends on the illness and treatment guidelines. Yet there are other factors that influence these decisions, for example the personal preferences of patients and clinicians (psychiatrists and psychologists). The last few years the importance of patient centered care and patient involvement in decision-making is emphasized by the medical world. With that there has been a growing interest in treatment preferences of patients. Patients want to be more actively involved in medical decisions. Shared Decision-Making could accomplish this. Despite the fact that the research on SDM in Mental Health Care is clearly behind compared to other areas of medicine, SDM seems to have a role to play in psychiatry too. More knowledge of preferences, their role and the role of other factors in the decision-making process can improve decision-making in mental health care practice and enhance the quality of care.

## **Study objective**

The objective of this study is to gain better insight in decision-making in the treatment of mood and anxiety disorders and treatment preferences of both patients and clinicians. We will explore factors that determine decisions and look for possible differences with regard to these factors between patients with different disorders. In addition personal experiences and needs relating to (shared) decision-making in clinical practice will be investigated. This research project aims to use this information to develop a practical decision aid, which will facilitate and improve decision-making in the treatment of mood and anxiety disorders.

## **Study design**

This observational study consists of three stages and uses both quantitative and qualitative research methods.

Stage I (qualitative), seven focusgroups, made up of patients or psychiatrists, will be used to discuss preferences, different aspects of decision-making and important factors that determine specific choices. The groups shall be composed of: 1. Patients with an anxiety disorder; 2. Patients with a mood disorder. 3; Patients with an obsessive-compulsive disorder; 4./5. Psychiatrists of GGZ Rivierduinen; 6. Psychiatrists of LUMC Psychiatric Department and 7. Psychiatrists of the NedKAD 8. Clinical Psychologists of GGZ-Rivierduinen

Stage II (quantitative), the qualitative data will be used to conduct a cross sectional survey, to measure these factors and other aspects of decision-making. The required sample size for this study is estimated to be N=145 psychiatrists/psychologists and N=200 patients. Relevant information from ROM- measurements (Routine Outcome Monitoring) will be used to supplement the patients data.

Stage III, all collected data is used to develop a practical decision aid, which will be implemented and evaluated on a small scale with semi-structured interviews. For this feasibility study we will ask 20 patients and clinicians to participate.

### **Study burden and risks**

Ethical aspects: The burden and risks associated with participation in this study will be kept to the minimum.

Focusgroup meetings take place at a convenient time and place and will take 1,5 to 2 hours.

Filling in the questionnaires will take no longer than 15 minutes. Since ROM-measurements and therefore completing questionnaires are part of the standard diagnostic and treatment procedure of GGZ Rivierduinen/ LUMC Psychiatric Department, participation will not bring any extra risks and the burden for patients participating in this study is minimal. Obtained data will be rendered anonymous to protect the privacy of participants.

Patients will be well informed about the study and asked to sign an informed consent before participating. They will be given one or two weeks to consider participating in this study. Participants are also informed that they have the right to withdraw from participation at any time and without reason during the study. This will not affect future treatment at Rivierduinen/ LUMC.

## **Contacts**

### **Public**

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NL

### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients:

1. Sufficient proficiency in the Dutch language.
2. Age between 21 and 65 years.
3. Diagnosed with one or more mood and/or anxiety disorders.
4. Newly registered or recently under treatment for one or more mood and/or anxiety disorders;

Clinicians:  
1. Employed as mental health practitioner by GGZ Rivierduinen or LUMC Psychiatric Department.

2. Licensed Psychiatrist (or resident) or clinical psychologist.
3. Experience with decision-making in the treatment of mood and anxiety disorders.

### Exclusion criteria

Patients:

1. Presence of manic and/or psychotic symptoms.
2. Other comorbid problems in the foreground (neurological, personality or addiction problems; suicidal tendency).
3. Severe social dysfunctioning (disabling the patient to come to appointments or a focus group meeting).
4. Participation not desirable in opinion of the clinician, because of the severity of the patients illness and/or the burden of participating.

## Study design

### Design

**Study type:** Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-06-2012
Enrollment:	450
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-04-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	31-03-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

**Other (possibly less up-to-date) registrations in this register**

No registrations found.

**In other registers**

Register	ID
CCMO	NL39043.058.11