

# Observational study Psychiatric Medical Unit.

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(Short) stay and, if possible, treatment at the PMU, will give an improvement in regular psychometrics or at least in some of them.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON26587

### Bron

NTR

### Aandoening

somatoform disorder (somatoforme stoornis, SOLK)  
anxiety disorder (angststoornis)  
depressive disorder (depressieve stoornis)

### Ondersteuning

**Primaire sponsor:** Atrium Medical Centre Heerlen

**Overige ondersteuning:** Atrium Medical Centre Heerlen

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Change in somatic as well as psychiatric symptomatology.

# Toelichting onderzoek

## Achtergrond van het onderzoek

The psychiatric Medical unit of the Atrium MC in Heerlen is one of three in Limburg and Noord Brabant (others are located in Eindhoven en Maastricht). Suitable patients for stay at the PMU are patients with a psychiatric disorder as well as a somatic disorder. Very common is the somatoform disorder, fibromyalgia and IBS etc. Frequently seen psychiatric comorbidity are anxiety disorder and depressive disorder. Patients are referred by medical specialist, GP, clinical psychologist or mental health institution. At the PMU further analysis will be performed, next to observation and (if possible) start of treatment.

The study is an observational study, no specific intervention will be studied, all of the interventions that are used on the PMU will be included, as needed in the individual treatment. There will be no placebo/non-interventiongroup.

In this study we want to observe systematically if there's any change on regular standard psychometrics before and after stay at the PMU. And if there's a change; describe the trend that can be seen. Patient will be recruited only in the Netherlands.

## Doel van het onderzoek

(Short) stay and, if possible, treatment at the PMU, will give an improvement in regular psychometrics or at least in some of them.

## Onderzoeksopzet

t0 (day 1 at PMU):

1. MINI (Mini-International Neuropsychiatric Interview);
2. JTV-SV (Jeugd Trauma Vragenlijst 1997);
3. HADS (Hospital Anxiety and Depression Scales);
4. HAM-D (Hamilton Rating Scale for Depression);
5. SCL-90 (Symptom Checklist);
6. ORS (Outcome Rating Scale);
7. WHO Quality of life questionnaire.

T=1 week: ORS;

T=2 weeks: HADS, HAM-D, ORS;

T=8 weeks: WHO Quality of life questionnaire, SCL-90, HADS, HAM-D, ORS.

### **Onderzoeksproduct en/of interventie**

The study is an observational study, no specific intervention will be studied, all of the interventions that are used on the PMU will be included, as needed in the individual treatment.

Most common interventions are:

1. (Re)activation (therapy);
2. Medication: Most common are; antidepressants, anxiolytic med., antipsychotic med., benzodiazepines;
3. Psychoeducation;
4. Combination.

The study is an observational study, so there will be no placebo/non-interventiongroup.

In this study we only want to observe systematically if there's any change on regular standard psychometrics before and after stay at the PMU. And if there's a change; describe the trend that can be seen.

## **Contactpersonen**

### **Publiek**

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H.J.H. Bremer

Heerlen 6419 PC  
The Netherlands  
045-5766490

## **Wetenschappelijk**

Psychiater  
Atrium Medisch Centrum Parkstad  
Henri Dunantstraat 5  
H.J.H. Bremer  
Heerlen 6419 PC  
The Netherlands  
045-5766490

## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

1. > 18 yr;
2. Referred by GP, medical specialist or psychologist to the "Soma en Psyche" centre of the Atrium MC;
3. Axis I disorder according to DSM IV;
4. "SOLK" / Somatoform disorder according to DSM IV;
5. Informed consent.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. < 18 yr;
2. Cognitive disorder / dementia according to DSM IV.

## **Onderzoekopzet**

## Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
<b>Controle:</b>	N.v.t. / onbekend

## Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-12-2010
Aantal proefpersonen:	20
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	10-12-2010
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL2530
NTR-old	NTR2648

**Register**

Ander register  
ISRCTN

**ID**

METC Atrium Orbis Zuyd : 10-N-98  
ISRCTN wordt niet meer aangevraagd.

## Resultaten

**Samenvatting resultaten**

N/A