

# Caregivers Burden in times of a manic episode of patients with bipolar disorder, a pilot research protocol

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Family issues
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37340

### Source

ToetsingOnline

### Brief title

Manic episodes and caregivers burden

### Condition

- Family issues

### Synonym

Bipolar disorder; Manic-depressive illness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Dimence (Deventer)

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Bipolar disorder, Caregiver burden, manic episodes

## Outcome measures

### Primary outcome

The General Health Questionnaire measures the main parameter \*caregiver distress\*.

### Secondary outcome

Secondary study parameters are the level of caregiver burden, caregiver appraisal, caregivers\* coping styles, level of expressed emotion, social support, need for professional support, and caregivers\* stigma resistance.

## Study description

### Background summary

Bipolar mania causes marked impairment in social or occupational functioning. Acute mania is associated with poor family functioning. Correlations exist between the patients\* changing moods, the caregivers\* lack of understanding patients\* behavior, caregivers\* suspension of social contact and caregivers\* helplessness and hopelessness. Caregiver\*s self-reported lack of professional support is strongly related to their decreased overall health condition. Recruitment of adequate number of caregivers are considered complex because of little time spent in mania and because caregivers are burdened too much to volunteer in research.

Rationale:

Nurses might be in a position to support the caregiver during these difficult times. What is not known is the level of distress during a patients\* manic episode, the relation with other variables, and what kind of professional support the caregivers need.

### Study objective

The overall goal of this research is building a nursing intervention. The primary objective is to identify the level of distress and correlations with the extent of caregiver burden during a patients\* manic episode, and other

stress/coping variables. The secondary objective is assessing feasibility of the study procedure.

## **Study design**

This pilot study is a multicenter observational study with a cross-sectional design.

## **Study burden and risks**

The possible adverse effect of this study is the imaginable inconvenience and intrusiveness of the questionnaires for the participants. The participant has to deal with an extra confrontation to the problems and burdens they face in times of the patients\* bipolar manic episode. It is possible that participants are confronted with problems they were not aware of before answering the questionnaires.

Participants are asked to fill in the before mentioned questionnaires. The participants involved in the study do not have to take any other actions or undergo a treatment on behalf of the study. Because of the likely relationships difficulties during an episode of the patients\* mania, caregivers might hesitate to contribute to this research. Total protection of the privacy of the caregivers needs to be assured.

## **Contacts**

### **Public**

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### **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

Participants are included in the study when the person:

- \* has the most frequent contact with the patient or delivers significant support and care for the patient.
- \* is above 18 years of age.
- \* is able and willing to give informed consent.

### Exclusion criteria

Participants are excluded when they are not able to communicate in the Dutch language

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 15-06-2012

Enrollment: 30

Type:

Actual

## Ethics review

Approved WMO

Date:

11-05-2012

Application type:

First submission

Review commission:

METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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**

CCMO

**ID**

NL39669.041.12