# A pilot study concerning the effectiveness and practice of well-being therapy in the treatment of outpatients with a mild anxiety disorder or a mild depression.

Published: 21-05-2015 Last updated: 19-03-2025

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Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeOther conditionStudy typeInterventional

## Summary

#### ID

**NL-OMON42118** 

#### Source

**ToetsingOnline** 

#### **Brief title**

Well-being therapy in outpatients with mild affective disorders.

#### Condition

- Other condition
- Mood disorders and disturbances NEC

#### **Synonym**

Affective disorders/ anxiety and/or depression

#### **Health condition**

Angststoornissen en symptomen

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#### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Dimence (Deventer)

Source(s) of monetary or material Support: Ult subsidie voor opleiding tot klinisch

psycholoog via de Dimence groep.

#### Intervention

**Keyword:** Anxiety disorders, Depression, Positive psychology, Short-term treatment, Wellbeing therapy

#### **Outcome measures**

#### **Primary outcome**

Well-being, as measured with the Mental Health Continuum-Short Form (MHC-SF).

Psychological complaints as measured with the Hospital Anxiety and Depression

Scale (HADS).

#### **Secondary outcome**

The experience of patients and therapists with well-being therapy.

# **Study description**

#### **Background summary**

People attending mental health care often seek to enhance their mental health because they experience an increase of psychological complaints in their life. The usual response is to offer people psychological treatment that focusses on the reduction of these complaints. The question now arises if this is the only and most preferable route to recovery. There is growing evidence that recovery consists of a combination between reduction of psychological complaints as well as an increase in well-being. Experiencing psychological complaints and experiencing a reduction of well-being are related but seem to be different factors at the same time. However, most treatment in mental health care focuses exclusively on the reduction of psychological complaints, while the treatment in this study is focussed on enhancing well-being. We expect that as a result mental health will increase, because of an increase in well-being as well as a

reduction in psychological complaints.

#### Study objective

Firstly this study tries to answer the question whether applying well-being therapy to outpatients with a mild affective disorder in Dutch mental health care, reveals a trend in which well-being is increased and psychiatric complaints are reduced.

Secondly the intention is to learn more about the experiences of the participants (patients as well as therapists) with this new form of therapy, to be able to carry out further development and adjustments if necessary. The outcome of this study can be used to account for a randomized controlled trail.

#### Study design

A pilot study with a pretest- posttest design. The study is quantitative in its question about the effect of well-being therapy, and qualitative in its question about the experience of the patients and therapists with well-being therapy.

#### Intervention

Participants will be treated with well-being therapy, a short-term protocol (6 sessions) in which they will actively focus on the enhancement of well-being.

#### Study burden and risks

Participants will be treated with well-being therapy. They will be asked to answer two questionnaires at three specific moments. In total participants will spend a maximum of 75 minutes on the questionnaires over a period of 6 months. Also, one in four participants will randomly be invited to participate in a semi-structured interview which is estimated to last approximately half an hour.

There is no expectation of well-being therapy being a risk for participants. In earlier studies well-being therapy has proved to be effective, and patients voluntarily participate in this study.

Participants may benefit from this study with an increase in well-being as well as an expected decrease of psychological complaints.

## **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

- -Classification according to DSM IV-TR of an anxiety or affective disorder as follows from an intake.
- -Participants are indicated for the 'middle' category in mental health care.
- -A below average score (<2.13) on the Mental Health Continuüm-Short Form (MHC- SF) before treatment. (this cut off score was based on the mean minus one SD (Lamers et al., 2011) and the expectation that clients with a higher score will have less possibilities for measurable improvements.
- -Age between 18 and 65 years.

### **Exclusion criteria**

- Poor Dutch language.
- Complex psychiatric problems which requires special mental health care.

# Study design

## **Design**

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

#### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 20-07-2015

Enrollment: 33

Type: Actual

## **Ethics review**

Approved WMO

Date: 21-05-2015

Application type: First submission

Review commission: METC Twente (Enschede)

# **Study registrations**

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

No registrations found.

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

ID: 28550

Source: Nationaal Trial Register

Title:

# In other registers

Register ID

CCMO NL50778.044.15 OMON NL-OMON28550