

# Effect of mindfulness on patients with rheumatoid arthritis: A controlled effect study.

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON28153

### Bron

Nationaal Trial Register

### Aandoening

rheumatoid arthritis,  
mindfulness-based stress reduction, MBSR, cognitive behavioral therapy, CBT

### Ondersteuning

**Primaire sponsor:** Since this is a self-financed research, the primary sponsor is the faculty Medical Psychology at the Maxima Medisch Centrum (MMC) where I work as a clinical psychologist trainee. Also the regional arthritis center (RRC) plays an important part. In addition, the METC (Medical Ethical Examination Committee) of the MMC is involved in checking the progress and reporting of the research. At a higher level, Maxima Medisch Centrum is the sponsor/executive.

**Overige ondersteuning:** Since this is a self-financed research, the fund is also the faculty Medical Psychology at the Maxima Medisch Centrum (MMC) in cooperation with the RRC, and at a higher level the MMC itself.

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

The five primary endpoints of the current study are quality of life, psychological well-being, pain acceptance, stress, and physical functioning.<br>

The primary outcome will be determined by letting participants fill in questionnaires at pre-determined times. In particular, on several occasions the DAS28 score will be measured in order to measure disease activity. The DAS28 is measured in any event several times per year for RA (Rheumatoid Arthritis) patients.

## Toelichting onderzoek

#### Achtergrond van het onderzoek

This study is concerned with the effects of Mindfulness interventions for Rheumatoid arthritis (RA) patients, in comparison with Cognitive Behavioral Therapy. An important covariant variable may be the presence or absence of a type D personality in a patient.

Aspects of RA and common medical treatments are discussed, as well as a number of non-pharmacological treatments including Cognitive-behavioral Therapy (CBT) and Mindfulness-based Stress Reduction (MBSR).

The research proposal concerning Mindfulness and RA is discussed, with details regarding the design and procedure, the patients, and expected outcome.

#### Doel van het onderzoek

The present study will test the effect of MBSR on RA in comparison to cognitive behavioral therapy (CBT) and a no-treatment control group. It is hypothesized that Mindfulness will be at least as effective in changing quality of life, psychological and social functioning, pain intensity and pain acceptance, functional ability and disease activity and stress as CBT and more effective than no therapy (the waiting-list control condition), evaluated at post-treatment and in follow up. In addition, it is expected that on some aspects the MBSR intervention may be even more effective than CBT, specifically regarding higher pain acceptance, lower impact of pain on one's life and higher positive affect.

#### Onderzoeksopzet

The baseline measurement is defined by the moment of the start of the therapy or wait list. At this time, they will be asked to fill in a number of questionnaires at the hospital to assess

the baseline measurements. Additional medical information will be collected in the medical file by the rheumatologist. Follow-up moments are planned, at two months after the intervention (T1), and at 6 months after the intervention (T2).

## **Onderzoeksproduct en/of interventie**

The research is set up as a randomized controlled trial (RCT). The research period is two years, during which time patients can be admitted to the program. Both CBT (Cognitive Behavioural Therapy) and Mindfulness Based Stress Reduction (MBSR) therapies are provided for patient groups, and will comprise 8 weekly sessions. A third group, consisting of waiting list patients, will function as the control group. Patients will be blindly assigned to one of the groups.

As part of the mindfulness therapy, patients will be taught to experience events in a non-judgemental way. Patients will learn to be more aware of their emotions and to better regulate these emotions, by living in the here and now. They will be better able to effectively deal with their disease.

In the cognitive behavioural therapy, patients will be asked to be more aware of their thoughts concerning the disease and their coping with the disease. They will learn to change these thoughts so as to deal more effectively with disease-related complaints such as pain.

In the control (waiting list) group, patients will only receive the standard care.

## **Contactpersonen**

### **Publiek**

Afd Medische Psychologie<br>  
De Run 4600  
M.W.A.C. Jong, de  
Veldhoven 5504 DB  
The Netherlands

## Wetenschappelijk

Afd Medische Psychologie<br>  
De Run 4600  
M.W.A.C. Jong, de  
Veldhoven 5504 DB  
The Netherlands

## Deelname eisen

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

Patients with RA diagnosis received at least one year ago and no more than five years ago will be included. Sufficient understanding of written and spoken Dutch is required.

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

1. Age over 80;
2. Chronic severe psychiatric conditions (e.g. psychosis or a personality disorder);
3. Previously participated in a MBSR program.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

## Deelname

Nederland  
Status: Werving gestopt  
(Verwachte) startdatum: 29-04-2010  
Aantal proefpersonen: 120  
Type: Werkelijke startdatum

## Ethische beoordeling

Positief advies  
Datum: 23-04-2012  
Soort: Eerste indiening

## Registraties

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

ID: 34919  
Bron: ToetsingOnline  
Titel:

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

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL3311
NTR-old	NTR3458
CCMO	NL31677.015.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34919

## Resultaten

## **Samenvatting resultaten**

No publications yet.