Effect of mindfulness on patients with rheumatoid arthritis: a controlled effect study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON34919

Source
ToetsingOnline

Brief title
MBSR for RA

Condition

- Autoimmune disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: medische psychologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive behavioral therapy, mindfulness, random control trial, rheumatoid arthritis

Outcome measures

Primary outcome

The five primary endpoints of the current study are quality of life,

psychological well-being, pain acceptance, stress, and physical functioning.

Standard questionaires will be used to measure these endpoints.

Secondary outcome

Medical variables include time since diagnosis (from medical file), disease

activity at baseline, co-morbidity (from medical file), and use of medication,

in particular anti-depressant medication. Socio-demographic variables (obtained

by self report at the baseline) include age, gender, education level, and

marital status. Psychological variables (obtained by self report) include type

D personality, mindfulness, and social desirability.

Study description

Background summary

Rheumatoid arthritis (RA) is a chronic, unpredictable and one of the most common autoimmune diseases (Symmons, 2002; van Riel, 1996; Krol, 1996). It is estimated that the prevalence of RA is about 1%, making it a common condition. RA is typically a progressive illness that has the potential to cause joint destruction and functional disability. Disability has a significant effect on quality of life as experienced by people, as well as on depression and anxiety (Symmons, 2002).

Until now, the most common types of intervention in psychological treatment for

RA-patients were self-management programmes and cognitive-behavioral therapy. Both approaches emphasize learning new skills helpful in managing one's disease.

Mindfulness meditation was initially introduced as a clinical intervention for conditions such as chronic pain and anxiety in 1979. It is currently taught and studied in many clinical trials as the Mindfulness-Based Stress Reduction Program (MBSR)

Study objective

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. Furthermore, the current study hypothesizes that MBSR will be at least as effective in changing the complaints of type D personality RA patients in comparison with non-type D personality RA patients. Thus, the moderating effect of Type D personality will be examined.

Study design

The research design is a randomized controlled trial (RCT). The study time is 2 years, during which patients can be included in the study. Both CBT and MBSR are administered in patient groups en will consist of 8 weekly gatherings. A third group, consisting of patients on the waiting list, acts as the control group. Patients are blindly assigned to one of the therapy groups.

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 researcher. Follow-up moments are planned, at two months after the intervention (T1), and at 6 months after the intervention (T2).

Intervention

See ''study design''.

Study burden and risks

Patients are asked, in addition to filling in a number of questionaires, to participate in an 8 weeks therapy which will teach them to cope with their complaints. Scientific studies have shown that both forms of therapy have a

postive effect on patients' complaints, both for this and other patient populations. There are no risks attached and from own experience and other studies it is known that the additional demands are not problematic, since patients will notice the beneficial effects right from the start of the therapy.

Contacts

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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 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.

Exclusion criteria

Exclusion criteria are: age over 80; chronic severe psychiatric conditions (e.g. psychosis or a personality disorder); previously participated in a MBSR program.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2010
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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: 28153
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL31677.015.10
OMON	NL-OMON28153