The influence of Type D and Mindfulness on psychological well-being, quality of life and disease activity in rheumatoid arthritis patients.

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In this research the effects of Type D and mindfulness on psychological well-being and physical functioning is reported in two different treatment groups. Rheumatoid arthritis is a chronic disease. Personality could be an important factor in...

| Ethical review | Approved WMO |
|-----------------------|------------------------|
| Status | Recruitment stopped |
| Health condition type | Autoimmune disorders |
| Study type | Observational invasive |

Summary

ID

NL-OMON31186

Source ToetsingOnline

Brief title

The role of Type D and Mindfulness in rheumatoid arthritis patients.

Condition

- Autoimmune disorders
- Joint disorders

Synonym Rheumatoid arthritis

Research involving Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Mindfulness, Rheumatoid arthritis, Type D, well-being.

Outcome measures

Primary outcome

The primarary study parameters are the quality of life, psychological

well-being

Secondary outcome

The disease activity

Study description

Background summary

Rheumatoid arthritis is a chronic disease. This disease leads to functional disability. Patients confronted with the diagnosis of RA have to change their way of living and they experience psychological distress. Individuals can vary greatly in their psychological adaptation to the disease. Patients with a comparable clinical picture and time since their diagnosis can evaluate their quality of life quite differently. This means that other factors than only the medical parameters may be responsible for these differences. There is little research about the relation between personality and the individual differences in quality of life and physical functioning in rheumatoid arthritis patients. The influences of psychological factors in other diseases has been investigated. Patients with cardiovascular diseases who score high on Type D personality report a lower phycological well-being and physical functioning. The influence of mindfulness has also been investigated. High scores on mindfulness leads to a better psychological well-being, a better physical functioning and decreases in inflammatory cytokines.

This personality factors could also be important in rheumatoid patients. We hypothesize that:

1 a) Patients who score high on Type D personality report a lower psychological well-

Being and quality of life.

1 b) Patients who score high on Type D personality show more severe disease activity.

2 a) Patients who score high on mindfulness report a higher psychological well-being and

quality of life.

2 b) Patients who score high on mindfulness show less severe disease activity.

Study objective

In this research the effects of Type D and mindfulness on psychological well-being and physical functioning is reported in two different treatment groups. Rheumatoid arthritis is a chronic disease. Personality could be an important factor in physical functioning and psychological well-being in an individual patient. It is very important to know these effects to treat the patients as good as possible.

Study design

The research design is a prospective follow-up study. The study time is 3 years. The first two years patients can be included in the study. After this, 1 year of follow up is included. All patients fill out the questionnaires at home on three moments. Additional medical information is gathered from the medical files. Follow-up moments are six (T1) and twelve (T2) months after baseline.

Study burden and risks

The burden of this research is minimal. Rheumatoid arthritis patients have always their usual control appointments with the rheumatologist. The only extra burden are the questionnaires. The answering takes half an hour at most. With 2 follow-ups this adds up to 1,5 hours at most.

The benefits of this study are potentially very important. When we know the influences of personality on psychological well-being and physical functioning, we can adjust our treatments to psychological profiels of patients associated with enhanced or decreased risk, ameliorating our care.

Contacts

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Scientific Máxima Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Diagnosis of rheumatoid arthritis; Use of methotrexate or TNF-* antagonist; sufficient understanding of written and spoken Dutch language.

Exclusion criteria

Age * 80; chronic severe psychiatric conditions (e.g. psychosis)

Study design

Design

Study type: Observational invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Prevention

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Recruitment

| NL | |
|---------------------------|---------------------|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2008 |
| Enrollment: | 200 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|---|
| Date: | 30-11-2007 |
| 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

No registrations found.

In other registers

Register CCMO **ID** NL19565.015.07