Psychophysiological stress mechanisms in chronic inflammatory diseases; an experimental study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30321

Source
ToetsingOnline

Brief title
Psychophysiological stress mechanisms in RA and PS

Condition

- Joint disorders
- Cornification and dystrophic skin disorders

Synonym
psoriasis, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: chronic inflammatory diseases, psychophysiology, risk groups, stress mechanisms

Outcome measures

Primary outcome

Psychological distress (anxiety and depression)

Secondary outcome

Fysiologic assessments: concentrations cortisol, ACTH, IL-1, IL-6, IL-18, MIF

en TNF-alfa

Other measurements:

- Clinical assessment of disease activity (DAS or PASI)

- Autonomous stress response (heart rate variability and skin conductance)

- Self-reported variables (using standardized questionnaires) such as

self-reported disease activity, physical symptoms (f.e. pain, itching,

fatigue), psychological risk factors and stressors

Study description

Background summary

There is increasing evidence for the idea that psychological stress factors can influence chronic inflammatory diseases, such as rheumatoid arthritis (RA) and psoriasis (PS). These relationships are assumed to be (at least partly) mediated by immune and neuroendocrine function. Despite preliminary evidence, the limited research revealed inconsistent findings, particularly regarding immune and neuroendocrine mediation. In addition, our and other previous work suggests that stress mechanisms affecting disease activity and immunological parameters are primarily evident in patients with a psychological risk profile for stress.
Referring to the previous CMO approved research proposal (2004/222), the

present experimental project is aimed at elucidating the effects of short-term stress and a short-term stress management intervention in a group of 64 RA patients and 64 PS patients (high risk and low risk). It is expected that, only in patients at risk, short-term stress and the stress management intervention affect self-reported, immune and neuroendocrine indicators of stress-reactivity, which in turn affect disease activity and physical symptoms of pain and itching.

Study objective

Referring to the previous CMO approved research proposal (2004/222), in this study the effects of a short-term stressor and a stress-reducing intervention on neuroendocrine, immune and self-reported indicators of stress reactivity in patients with RA and PS will be investigated. Special attention will be paid to patients psychologically at risk for stress.

Study design

This study is composed of two parts: a stress experiment and a stress management intervention.

Stress experiment:
During 4 months, 128 patients (64 RA and 64 PS patients) will visit the Radboud hospital 3 times for an experimental stress experiment (Trier Social Stress Task). During these visits, different clinical, physiological and self-reported variables will be assessed. Additionally, for matching control data 32 healthy participants will participate in the stress experiment once.

Stress management intervention:
In a randomized controlled trial half of all RA and PS patients with respectively a high and low risk profile for stress (2 times 32 patients) will receive a stress management intervention. This intervention takes place in between the first and second visit for the stress experiment. Patients in the intervention group will visit the hospital twice every week during one month. Additionally, they have some homework assignments (15 minutes daily).

Intervention

The intervention study is a randomized controlled trial. Half of all participants with respectively a high and low risk profile for stress will be asked to participate in a stress management intervention. Participants will visit the Radboud hospital 8 times (2 sessions a week during 4 weeks; ca. 1 hour each session). During these visits participants are offered relaxation therapy. Additionally, they will get homework assignments (15 minutes each day). The control groups (half of all RA and PS patients and all healthy

controls) will not be offered the stress management intervention.

Study burden and risks

There are no risks involved for the participants of this study, only investment in time. The design of this study is necessary to elucidate the role of psychophysiological stress mechanisms in the chronic inflammatory diseases RA and PS. In the long run, this study might contribute to the improvement of diagnostics and treatment of chronic inflammatory diseases.

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 diagnosed with rheumatoid arthritis (Arnett et al., 1988) or psoriasis (van de Kerkhof, 2003). This criterion is not applicable to healthy controls
18 years or older
Informed consent

Exclusion criteria

Severe physical comorbid conditions (e.g. psoriatic arthritis, malignancy, renal insufficiency)
Psychiatric disturbances that interfere with the study protocol
pregnancy
non-Dutch speakers

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	ID
CCMO	NL15023.091.06