Het ontwikkelen en testen van een online ondersteuningsprogramma voor Reumatoide Artritis patiënten

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26097

Source
Nationaal Trial Register

Brief title
Reuma zelf te lijf

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Radboud University Medical Center Nijmegen
Source(s) of monetary or material Support: -ZoNMw, The Netherlands Organization for Health Research and Development.

-Roche

Intervention

Outcome measures

Primary outcome

We will use the following questionnaires:

The Patients Activation Measure (PAM-13) to measure self-management

The RAND-36 to measure health related quality of life

The Modified Pain Coping Inventory for Fatigue (MPCI-F) to measure coping with fatigue

The Rheumatoid Arthritis Self-Efficacy Scale (RASE) to measure task specific Self-efficacy

The Patient Efficacy in Patient-Physician Interactions (PEPPI-5) to measure patients'efficacy in obtaining medical information and attention to their medical concerns from physicians.

The Self-Management Ability Scale Short Form (SMAS-S) to measure self-management skills in relation to welfare.

NRS pain and NRS fatigue to measure the level of pain and fatigue of patients

Secondary outcome

The process evaluation of the e-health self-management program will be on actual use, added value of the e-health intervention, and dropping out of the e-health intervention. Both patients and their healthcare professionals will take part in the evaluation. Qualitative data on
the feasibility of the e-health self-management program will be obtained via semi-structured interviews. The patients will be interviewed about their experience using the intervention asking questions on worthiness, time consumption and relevance. The actual use of the ehealth
self-management program will be monitored quantitatively during the intervention period counting data on frequency of the patients’ visits to the e-health self-management program.

Study description

Background summary

Rationale: Rheumatoid Arthritis (RA) is a chronic inflammatory and systemic disease, which predominantly affects the joints. RA occurs in 0.5-1.0% of the adult population worldwide and two to four times more in women than in men. In the Netherlands approximately 150.000 people suffer from RA, making it the most common inflammatory joint disease. Because of the large impact of RA on health status and healthcare expenditures, there is a growing interest in self-management for RA patients. However, while traditional delivery of selfmanagement support is effective overall, several problems in the development of e-delivered programs have led to variations in their effectiveness.

Objective: 1) To evaluate the potential effectiveness and effect size of the e-health selfmanagement support program for patients with RA. 2) To identify outcome measures most likely to capture potential patient benefit. 3) To evaluate continued participation or dropping out of the e-health intervention.

Study design: The intervention will be tested in an early randomized controlled trial with a six and twelve month follow-up from baseline.

Study population: Patients with RA and their healthcare professionals at the outpatient clinic of two hospitals in the Netherlands.

Intervention: On top of usual care the treatment group will receive a e-health selfmanagement program. The intervention consists of nine modules and strategies to support the behavioural change and behavioural maintenance of self-management behaviour.

Outcome: We will measure self-management behaviour (PAM-13), quality of life (RAND-36), self-management skills (SMAS-S), coping with fatigue (using MPCIF),
Self-Efficacy (PEPPI-5 and RASE), pain and fatigue (NRS)

Study objective

The aim of the pilot trial is to:

1. evaluate the potential effectiveness and effect size of the online self-management program for Rheumatoid Arthritis patients

2. to identify outcome measures most likely to capture potential patient benefit;

3. to evaluate continued participation or dropping out of the online self-management program.

Study design

Baseline data collection will start in December 2014. Repeated measures will be executed at six months and 12 months when the intervention is finished, again by filling out the questionnaire. The estimated time to fill out the questionnaire is 30 to 45 minutes.

Intervention

All participants in the study receive usual care containing regular visits to a rheumatologist and a specialized nurse from whom they receive medical treatment, advice and information about their disease and socio-psychological aspects. RA patients receive this care in a structural way.

In addition to the care as usual, participants in the treatment group will receive the e-health intervention. The intervention consists of nine modules:1) Finding balance between rest and activity, 2) Setting boundaries, 3) Communication with professionals, 4) Coping with assistive devices and home and household products, 5) Medication intake, 6) Coping with worries, 7) Coping with RA, and 8) Coping with social support, 9) Performing physical activities.
Strategies to support the behavioural change and behavioural maintenance of selfmanagement
behaviour are: 1) providing information to increase patients' knowledge, 2) creating awareness by making assignments, 3) persuasive communication to change the attitude of patients, 4) modelling through video's and texts to increase patients' self-efficacy, 5) social comparison through video's and texts to increase patients' self-efficacy, 6) reinterpreting emotional and somatic state by texts to increase self-efficacy, 7) feedback and planning coping response by text messages to maintain changed behaviour and 8) selfevaluation
through past temporal comparisons to maintain changed behaviour.

Contacts

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Eligibility criteria

Inclusion criteria

- RA Patients;

- an age of 18 years or older;

- the ability to speak and read the Dutch language;

- the availability of a computer.

Exclusion criteria

-Patients receiving psychiatric and psychological treatment will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-11-2014
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	29-10-2014
Application type:	First submission

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
NTR-new	NL4726
NTR-old	NTR4871
Other	CMO : 2014-1208

Study results