

Tailored cognitive-behavioral E-health care in patients with rheumatoid arthritis

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

Summary

ID

NL-OMON32692

Source

ToetsingOnline

Brief title

E-health cognitive-behavioral therapy

Condition

- Joint disorders

Synonym

rheumatic disease, rheumatoid arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: ZON-MW

Intervention

Keyword: cognitive behavioral therapy, E-Health, rheumatoid arthritis

Outcome measures

Primary outcome

The primary outcome is the impact of the rheumatic disease on daily life, including its impact on physical and psychological functioning and daily activities.

Secondary outcome

Secondary outcomes of cost-effectiveness, disease severity and compliance with regular rheumatological care are assessed.

Study description

Background summary

Research has shown that a part of the patients with rheumatoid arthritis are at risk for long-term adjustment problems (Evers et al., 2001, 2002, 2003a/b, 2005). Previous research also demonstrated that these risk groups of patients can be identified by screening with standardized questionnaire assessments at an early stage of the disease. Research of the project group has also shown that these problems of this group of high-risk RA patients can be successfully treated by tailored cognitive-behavior therapy. An innovative solution for the regional and national application is to offer this care through E-health, by systematic screening and tailored cognitive behavior therapy via internet for patients at risk. Based on the previous research findings, it can be expected that about 30% of all patients have a psychological risk profile and can benefit from this type of E-health care of tailored cognitive-behavioral therapy.

There is increasing evidence that interventions with cognitive-behavioral therapy for protocolized treatments are about as effective through E-health as interventions with face-to-face contact for a broad range of psychological problems, such as anxiety disorders, depression or grief processing (e.g. see Berstrom et al., 2003; Christensen et al., 2004, Langeet al., 2003). The need for E-health care and the applicability of psychological E-health programs have

also been examined for patients with chronic physical conditions, such as chronic pain and functional impairments (Buhrman et al, 2004; Devineni et al., 2005; Hoppe et al., 2003; van Lankveld et al., 2006). Since the most important working mechanisms in cognitive-behavior therapy are the same for chronic physical conditions of RA as for psychological problems, it can be expected that tailored cognitive-behavior therapy through E-health is also effective for this patient group. The feasibility of this program has been demonstrated in a pilot study with patients with rheumatoid arthritis, with CMO registration number NL21785.091.08.

Study objective

The aim of the present research project is to evaluate the (cost-)effectiveness of medical psychological screening and tailored cognitive-behavioral therapy for patients with rheumatoid arthritis with psychological risk profiles through E-health care in comparison to usual care (care without face-to-face or E-health cognitive-behavioral therapy).

Study design

Inform

About 600 patients will receive a letter with information about the study.

Screening

Patients who are willing to participate will receive specific information on the screening with a link to the questionnaires. At home behind their PC they can fill in the questionnaires. The questionnaires are individually screened for a psychological risk profile for long-term physical and emotional adjustments problems. Patients are informed by mail about the results of the questionnaires. Patients at risk (30%) receive further information about the treatment with cognitive behavioral therapy, together with an application form.

The intervention: E-Health treatment

Every patient with a risk profile who is willing to participate will randomly be assigned to either the treatment group (65 participants) or the control group (65 participants). Patients who are assigned to the treatment group will receive E-health care with tailored cognitive-behavior therapy during six months. Six times both the patients from the intervention and the control group will fill in standardized questionnaires on the internet.

Intervention

Tailored cognitive-behavioral therapy will be offered through E-health, consisting of 10 sessions. Two out of five possible treatment modules will be offered during the treatment, depending on the risk profile of the patients.

The treatment modules are: coping with pain and disability, fatigue, itch, social relationships and negative mood.

At least once a week chat patients will receive feedback from the therapist about the assignments, by means of a mail box. Treatment will be conducted by therapists who are specifically trained in the tailored cognitive-behavioral protocol.

Study burden and risks

For the participating patients, there are no risks connected to the study. We only ask the patients to invest some of their time.

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 older than 18 years diagnosed with rheumatoid arthritis

Exclusion criteria

Severe physical comorbidity
Psychiatric disorders that interfere with the protocol
Pregnancy
Being without the capability of the dutch language
Ongoing psychological treatment elsewhere

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO	
Date:	08-12-2008
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	NL24343.091.08