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

Gepubliceerd: 09-11-2009 Laatst bijgewerkt: 18-08-2022

The aim of the study is to show the effectiveness of tailored cognitive-behavioral E-health care for risk groups of patients with rheumatoid arthritis in comparison to usual care.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28299

Bron
Nationaal Trial Register

Verkorte titel
E-health

Aandoening

Rheumatoid arthritis

Reumatoïde artritis

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: ZonMw: The Netherlands Organisation for Health Research and Development.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the impact of the rheumatic disease on daily life, including its impact on physical and psychological functioning and daily activities at post-treatment and follow-up measurements after 9, 12, 15 and 18 months.

The primary outcome measures are measured as follows:

1. Impact on physical functioning: composite z-scores of
A. Pain (IRGL, Huiskes, 1990);
B. Fatigue (CIS, Vercoulen, 1996).
2. Impact on psychological functioning: composite z-scores of:
A. Negative mood (IRGL, Huiskes, 1990);
B. Anxiety (IRGL, Huiskes, 1990);
C. Depression (BDI, Beck, 1988).
3. Impact on daily activities: composite z-scores of
A. Mobility and self-care (IRGL, Huiskes, 1990);
B. Role limitations due to emotional and physical health problems (SF-36. Ware, 1993).

Toelichting onderzoek

Achtergrond van het onderzoek

In the present project, the effects of tailored E-health cognitive-behavior care are studied for patients with rheumatoid arthritis. In a randomized, controlled trial, rheumatoid arthritis patients are screened for psychological risk profiles. Patients at risk will be randomized to E-health cognitive-behavioral treatment care or a control condition with care as usual (without E-health or face-to-face cognitive-behavioral E-health care). It is expected that the E-health cognitive-behavioral care will be effective for the impact of the disease on physical and psychological functioning and daily activities at post-treatment and follow-up assessments. Secondary outcomes include cost-effectiveness as well as effects on disease severity and treatment compliance.

Doel van het onderzoek

The aim of the study is to show the effectiveness of tailored cognitive-behavioral E-health care for risk groups of patients with rheumatoid arthritis in comparison to usual care.

Onderzoeksopzet

For the treatment group, assessments take place before and after treatment and at the follow-up measurements 3, 6, 9 and 12 months post treatment. For the control group, assessments take place at 0, 6, 9, 12, 15 and 18 months.

Onderzoeksproduct en/of interventie

The intervention of E-health tailored cognitive-behavioral therapy consists of tailored individual treatments with E-health treatment modules that target the most frequently experienced problems which rheumatoid arthritis patients have to cope with: pain and functional disability, fatigue, negative mood and social relationships. Choice of E-health treatment modules are determined on the basis of patient priorities and therapist judgments. All E-health treatments modules consist of cognitive and behavioral interventions with homework assignments of about half hour per day. In all treatments modules, the final booster session deal with relapse prevention and further improvement of the attained goals. For the E-health application, patients have at least once a week mail contact with the therapist.

Patients in the control group will receive standard rheumatology care without E-health or face-to-face applications of tailord cognitive-behavioral care.

Contactpersonen

Publiek

LUMC
PO Box 9555
A.W.M. Evers
Leiden 2300 RB
The Netherlands
+31 (0)71 527 3627

Wetenschappelijk

LUMC
PO Box 9555
A.W.M. Evers
Leiden 2300 RB
The Netherlands
+31 (0)71 527 3627

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. ACR diagnosis rheumatoid arthritis;

2. Age above 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Severe physical and/or psychiatric comorbidity that interfere with the study procotol;

3. Illiteracy;

4. Current psychological treatments.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	130
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-11-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1983
NTR-old	NTR2100
Ander register	ZonMw : 170992803
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A