Goal management training for patients with arthritis.

No registrations found.

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

Summary

ID

NL-OMON21736

Source
NTR

Health condition

arthritis, polyarthritis, depression, rheumatic disease, rheumatoid arthritis, cognitive behavioural techniques, psychosocial,
reumatoïde artritis, psychosociaal, depressie

Sponsors and support

Primary sponsor: University of Twente, Dept. of Psychology, Health & Technology (PHT), P.O. Box 217, 7500 AE Enschede, Streekziekenhuis Koningin Beatrix (Winterswijk) and St. Elisabeth Ziekenhuis (Tilburg)
Source(s) of monetary or material Support: Stichting Reumaonderzoek Twente

Intervention

Outcome measures

Primary outcome

Effect of the intervention on depressive symptoms.

Secondary outcome

1. Adaptation outcomes: Anxiety symptoms, positive affect, purpose in life, participation;

2. Goal management: Broadening, use and flexibility of goal management strategies;

3. Disease related outomes: Self-efficacy, pain and fatigue;

4. Cost-effectiveness: Medical and non-medical costs.
Cost-utility.

Study description

Background summary

Existing self-management programs try to improve coping with rheumatic disease but revealed very limited effects and low participation rates. These programs narrowly focus on illness-related aspects. However, adaptation problems are more complex and include various domains of life. The new program starts from personal goals of the patients which are threatened by arthritis. It aims to broaden and improve patients competencies to manage these threatened personal goals in order to improve adaptation to arthritis.

The main objective of the study is to evaluate the goal management training in terms of the effect on depressive symptoms. Secondary objectives of the intervention are to study the effect of the intervention on the secondary outcome measures: anxiety symptoms, positive affect, purpose in life and social participation; use of and preference for goal management strategies; and disease related outcomes. Furthermore the cost-effectiveness and cost utility of the goal management intervention will be evaluated from a societal perspective.

16-07-2013: Changes to the design. A number of changes have been made, since the recruitment of participants went slow. Randomization is not performed and the waiting list control condition lapses. The intervention group will be compared to an existing cohort that ran from 2010 to 2011. The cohort exists of 330 patients with polyarthritis that participated in an observational study. Patients in the cohort will be selected based on the baseline criteria from the intervention study. These patients did not participate in an intervention at the time of the study, making it possible to compare the natural course of adaptation to the intervention group.

Study objective

The main objective is to evaluate the goal management training in terms of the effect on depressive symptoms. It is expected that people with arthritis will experience lower levels of depressive symptoms after participation in the group training, compared to the control group.

Study design

T0: Baseline (all measures);

T1: Post-intervention (all measures);

T2: Only cost-effectiveness measures;

T3: Only cost-effectiveness measures;

T4: Follow-up (all measures).

Methods:

Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The depression subscale of the HADS is used to measure our primary outcome depressive symptoms.

Intervention

The new training aims to teach patients to recognize personal goals which are threatened by arthritis and learn to apply beneficial goal management strategies to improve adaptation to arthritis. The training is to be delivered by specialized nurses in hospital settings to groups with 8-10 participants. The training consists of 6 group meetings, based on informing, learning, and practicing goal management strategies. In addition to the group sessions, participants work individually on a personal goal. This individual trajectory is discussed within the group.

Control condition: Participant in the control condition recieve care-as-usual and fill in the same questionnaires as the intervention condition.

Contacts

Public
Universiteit Twente
Postbus 217
R.Y. Arends
Enschede 7500 AE
The Netherlands
NA
Scientific

Universiteit Twente
Postbus 217
R.Y. Arends
Enschede 7500 AE
The Netherlands
NA

Eligibility criteria

Inclusion criteria

1. Age: 18 years and older;

2. Diagnosed with polyarthritis;

3. Score on depression subscale of Hospital Anxiety and Depression Scale.

Exclusion criteria

1. Severe distress (screening with HADS);

2. Insufficient Dutch language skills;

3. Enrolment in psychotherapeutic treatment at moment of study entry.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-09-2012
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	NL3455
NTR-old	NTR3606
CCMO	NL40257.044.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A