Improving beliefs about medication in patients with Rheumatoid Arthritis: randomised controlled study into the effect of a motivational patient-centered intervention for non-adherent patients compared to usual care controls

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To determine if a short motivational patient-centered intervention for non-adherent patients is more successful in improving beliefs about medication (and adherence) compared to a usual care control group of non-adherent patients. Barriers of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33599

Source
ToetsingOnline

Brief title
Improving beliefs about medication in patients with Rheumatoid Arthritis

Condition

- Other condition

Synonym
rheumatic ailment, Rheumatoid arthritis

Health condition

reumatische ziekten

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Keyword: Adherence, Beliefs about medication, Rheumatoid arthritis

Outcome measures

Primary outcome

Beliefs about medication:

-Beliefs about Medicines Questionnaire (BMQ)

Secondary outcome

-Adherence: Refill rates, Medication Adherence Report Scale (MARS) and

Compliance Questionnaire Rheumatology (CQR)

-Statisfaction with information about medication: Satisfaction with Information

about Medicines Scale (SIMS)

-Physical functioning: Health Assessment Questionnaire (HAQ)

-Disease activity: Disease Activity Score (DAS28)

-Pain: Visual Analoge Scale (VAS) Pain

-Self-efficacy: UitvoerbaarheidsVerwachting bij het omgaan met de gevolgen van

Reuma

-Self-efficacy: Self-Efficacy Scale Medication Adherence DMARDs

-Mood: Hospital Anxiety and Depression Scale (HADS)

-Illness cognitions: Illness Perception Questionnaire (ICQ)

-Acceptance of and anxiety for medicatie: Acceptance of Medication and Anxiety

about Medication Scale DMARDs

-Concordance: Besluitvorming Patiënt

-Patient provider shared concerns: Patient Provider Shared Concerns

-Experienced adverse effects and health care utilisation: patient registration

card (every month)

Study description

Background summary

Average adherence in patients with a chronic disease is low. People who take less that 80% of their prescribed medication are defined as non-adherent. To improve adherence, interventions that target adherence should be aimed at patients for which adherence is a problem, and the content of the intervention must be focused to the personal barriers of adherence.

This study focuses on patients with Reumatoid Arthritis (RA). Adherence to medication in RA is low. Previously research showed that 33% of the patients with RA do not take their Disease Modifying Anti Rheumatic Drugs (DMARDs) as prescribed. DMARDs reduce disease activity and radiological progression and improve long term functional outcome in patients with RA. Non-adherence to DMARDs can reduce efficacy of treatment. Previous research showed that beliefs about medication in RA is associated with adherence.

Study objective

To determine if a short motivational patient-centered intervention for non-adherent patients is more successful in improving beliefs about medication (and adherence) compared to a usual care control group of non-adherent patients. Barriers of adherence can vary between patients. Beliefs about medication seem to play an important role in adherence. Efforts to improve adherence should only be aimed at non-adherent patients. For the non-adherent patients the primary cause of non-adherence should be identified, and the intervention to improve adherence should target the personal barriers(s) of the patient. If adherence in non-adherent RA-patients improves the efficacy of DMARD-treatment can be optimized.

Study design

Non-adherent patients will be randomly assigned to the experimental and control condition. The researcher will be blinded for condition allocation. With a validated questionnaire (Compliance Questionnaire Rheumatology) non-adherent RA-patients using DMARDs will be selected. Beliefs about medication, adherence and several psychological and physical outcomes will be assessed using questionnaires. Also, adherence will be measured using refill rates. The patient completes four measurements: prior to the intervention and 1 week, 6 months and 12 months after the intervention. In addition, the patient reports experienced adverse effects and care utilization every month.

Intervention

The experimental group will receive a motivational patient-centered intervention aimed at the participant's personal barrier(s). The intervention includes two group sessions of 90 minutes each and a short follow-up conversation with the intervention supervisor, the pharmacist, by phone. Besides giving participant focused education about DMARDs, personal beliefs about medication will be discussed during the group sessions (6 persons). The intervention method is based on Motivational Interviewing.
The control group will receive usual care in the Sint Maartenskliniek (brochures with information about the prescribed DMARDs and rheumatic related medication). We do not inform the participants explicitely in which condition they are allocated, because this possibly influence the effect of the intervention. The participants will be informed about two education programs: education in writing and group education.

Study burden and risks

Nature
Patients in the experimental group will be invited to participate in a short intervention. Patients will attend two group sessions during 90 minutes each. Two months after the last session the intervention counselor will call the participants for approximately 10 munites (follow-up call). In the group session patients will receive written and verbal information about DMARDs prescription, the working mechanism of DMARDS, and the necessity of DMARDs in general. Two topics of barriers for adherence will be discussed:
1. Aides and routine habits are discussed and implemented.
2. Personal beliefs about medication will be identified and discussed.

The patients in the control group will receive written information about their prescribed DMARDs (usual care in the Sint Maartenskliniek).

All patients receive questionnaires prior the intervention, 1 week, 6 months and 12 months after the intervention.
Also, during the study the patient will report experienced adverse effects and care utilization every month.

Extent
Time investment for participants in the experimental group: maximal 10 hours
Time investment for participants in the control group: maximal 7 hours

Both the measurements as the intervention program do not constitute a risk for the participants.

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

-RA according to the 1986 ARA criteria for at least 1 year
-Prescription of anti-rheumatic medication (DMARDs)
-Non-adherent (less than 80% adherence) assessed with the Compliance Questionnaire Rheumatology

Exclusion criteria

-Co-morbidity (physical or psychological) that unables the patient to participate in the intervention
-Illiteracy
-Inability to communicate in Dutch
-Younger than 18 years
-Participation in focusgroups June 2008
-Participation in other studies with significant patient burden

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2009
Enrollment:	120
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	29-05-2009

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	NL25019.091.09