

# The use of an interactive self-management care booklet by patients with rheumatoid arthritis: a comparison of two distribution strategies

<b>Submission date</b> 21/03/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/03/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Rheumatoid arthritis (RA) is a long-term condition that causes pain, swelling and stiffness in the joints. Patients with RA experience pain, fatigue, and limitations in daily activities and participation. Apart from the consequences of the disease, patients with RA deal with different treatments and a variety of healthcare providers during the course of their illness. Therefore, supporting RA patients in self-managing their disease is important. One strategy to enhance self-management is the use of an interactive care booklet. A care booklet can provide patients with information on their disease, treatment options and what they can do for themselves. Additionally, it includes tools for monitoring symptoms, preparing for consultations, and recording treatment targets and medication. Although the use of a care booklet can be beneficial, not a lot of patients use a care booklet. However, little is known about the best strategies to introduce a care booklet to patients. Therefore the aim of this study is to compare two different distribution strategies: unsolicited supply (unsolicited mailing of the care booklet free of charge to the home-address of patients) and supply on demand (mailing a letter about the care booklet to the home address of patients with the option to order the booklet free of charge by sending back a reply card).

### Who can participate?

Patients aged 18 and over with rheumatoid arthritis who have a future scheduled visit with a rheumatologist in one of the participating hospitals

### What does the study involve?

Participants are randomly allocated to be sent the care booklet (unsolicited supply) or to be sent an information letter with the option to order the care booklet (supply on demand). Participants can choose for themselves if they want to order and/or use the care booklet. Four months later, some of the participants are sent a questionnaire asking whether they have used the care booklet in the past 4 months.

What are the possible benefits and risks of participating?

There are no direct benefits or risks to those taking part. Receiving the care booklet for free can be seen as a benefit.

Where is the study run from?

1. Sint Maartenskliniek Hospital (Netherlands)
2. Leids University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?

September 2013 to June 2014

Who is funding the study?

The Dutch Arthritis Foundation (Reumafonds) (Netherlands)

Who is the main contact?

1. Miss Aniek Claassen
2. Dr Cornelia van den Ende

## Contact information

### Type(s)

Scientific

### Contact name

Miss Aniek Claassen

### Contact details

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## Additional identifiers

### Protocol serial number

676-RA-ZORGWIJZER

## Study information

## **Scientific Title**

The use of an interactive self-management care booklet by patients with rheumatoid arthritis: a multicenter, randomised comparison of two distribution strategies

## **Acronym**

ZORGWIJZER RA

## **Study objectives**

It is hypothesized that the method of distribution of a care-booklet, unsolicited supply (i.e. sending a care-booklet without being requested) versus supply on demand (i.e. offering the option to order a care booklet), affects the use of the care-booklet. Patients who are offered the option to order a care booklet are expected to be better motivated to use this care booklet than patients who receive the care booklet unsolicited.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

The Institutional Review Board of the University Medical Centre, Nijmegen (11/07/2013, ref: 2013/292) and the Medical Ethics Review Committee of the University Medical Centre, Leiden (07/11/2013, ref: P13.202), The Netherlands, both reviewed the study protocol. An exemption was obtained, as ethical approval for this type of study is not required under Dutch law.

## **Study design**

Multicenter randomised trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rheumatoid arthritis

## **Interventions**

A care booklet for patients with RA was developed. The RA care booklet is a patient-held booklet with information about RA, living with RA and self-management of RA. It covers the following topics: symptoms and complaints, general health, medication, healthcare providers, daily activities, work, leisure time and environment. With respect to self-management the following questions are included: "what do I want to achieve?", "what can I do?", "how can I stay physically active?", "how can I take it easy on myself?" and, "what do I would like to discuss with healthcare providers?". The care booklet also incorporates a separate booklet, the RA care pass ('zorgpas RA'), where patients can describe personal information about their medical history, medication use, healthcare providers, results of laboratory and physical examinations (i.e. Disease Activity Score (DAS28-Score)), complaints and symptoms, treatment goals and preparing for an appointment with the healthcare provider.

Participants are randomised to one of two distribution strategies:

1. Unsolicited mailing of the care booklet free of charge to the home-address of patients

accompanied by an introductory letter on behalf of the medical head of the Department of Rheumatology

2. Distribution on demand: mailing an introductory letter about the care booklet on behalf of the medical head of the Department of Rheumatology to the home-address of patients with the option to order the booklet and pass free of charge. Patients can order the RA care booklet and care pass by sending back a reply card.

Participants are assessed at a single time endpoint 4 month after baseline. Patients are asked whether they used the care booklet in the past 4 months. Answer-options include: "no", "yes, I read (parts of) the care booklet", "yes, I made notes in the care pass", "yes, I discussed (parts of) the care booklet/pass with my healthcare provider", "yes, I used the care booklet in a different way, namely....". Multiple answers are possible. Patients who answer "no", or state that they did not receive or order the care booklet are classified as "non-users". Patients answering 1 or more of the "yes" answers are classified as "users".

### **Intervention Type**

Other

### **Primary outcome(s)**

Self-reported use of the RA care booklet, assessed using a questionnaire at 4 months follow-up

### **Key secondary outcome(s)**

Assessed using a questionnaire at 4-months follow-up:

1. Clinical characteristics including disease duration (years since diagnosis) and medication use (NSAIDs, corticosteroids, DMARDs, biologicals, other)
2. Disease activity, measured using the Rheumatoid Arthritis Disease Activity Index (RADAI)
3. Limitations in activities, measured using the Health Assessment Questionnaire Disability Index
4. Self-efficacy, measured using the Dutch General Self-efficacy Scale
5. Illness perceptions, measured using the Revised Illness Perception Questionnaire
6. Educational needs, measured using the Dutch version of the Educational Needs Assessment Tool

### **Completion date**

01/06/2014

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosed with RA
2. Aged  $\geq 18$  years old
3. Having a future scheduled visit with a rheumatologist

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients from the LUMC hospital who are participating in another ongoing study

**Date of first enrolment**

01/09/2013

**Date of final enrolment**

01/02/2014

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

**Sint Maartenskliniek Hospital**

Hengstdal 3

Ubbergen (Nijmegen)

Netherlands

6574 NA

**Sponsor information****Organisation**

Sint Maartenskliniek

**ROR**

<https://ror.org/0454gfp30>

**Funder(s)****Funder type**

Charity

**Funder Name**

Reumafonds

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

Netherlands

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Cornelia van den Ende

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	27/03/2018		Yes	No
<a href="#">Participant information sheet</a>		23/03/2017	27/03/2017	No	Yes