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

Submission date 21/03/2017	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/03/2017	**Overall study status** Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/03/2018	**Condition category** Musculoskeletal Diseases	☐ 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
PO Box 9011
Nijmegen
Netherlands
6500 GM

Type(s)
Scientific

Contact name
Dr Cornelia van den Ende

Contact details
PO Box 9011
Nijmegen
Netherlands
6500 GM

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2013

Completion date

01/06/2014

Eligibility

Key inclusion criteria
1. Diagnosed with RA
2. Aged ≥18 years old
3. Having a future scheduled visit with a rheumatologist

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
372

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

Sponsor details
PO Box 9011
Nijmegen
Netherlands
6500 GM

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2017

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?
Participant information sheet		23/03/2017	27/03/2017	No	Yes
Results article	results	27/03/2018		Yes	No