Efficacy of an online self-management enhancing programme for patients with rheumatoid arthritis: an explorative RCT

Rixt Zuidema, Sandra van Dulmen, Maria Nijhuis-van der Sanden, Inger Meek, Cornelia van den Ende, Jaap Fransen, Betsie van Gaal

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Abstract

Background: Online self-management enhancing programmes has the potential to support patients with Rheumatoid Arthritis in their self-management, for example improve their health status and self-efficacy or decrease overuse of medication. We developed an online self-management enhancing program in collaboration with RA patients and professionals as co-designers, based on the Intervention Mapping Framework. While self-management programs are complex interventions, it is informative to perform an explorative Randomized Controlled Trial before embarking on a larger trial.

Objective: This study aimed to evaluate the efficacy of an online self-management enhancing programme for patients with rheumatoid arthritis and to identify outcome measures most likely to capture potential benefits.

Methods: A multicentre exploratory randomised controlled trial was performed with an intervention and a control group. Both groups received care as usual. In addition, the intervention group received 12 months of access to an online self-management programme. Assessment occurred at baseline, 6 and 12 months. Outcome measures included self-management behaviour (PAM-13, SMAS-S), self-efficacy (RASE, PEPPI-5), general health status (RAND-36), focus on fatigue (MPCI-F), perceived pain and fatigue (NRS scales). A linear mixed model for repeated measures, using the intention-to-treat principle, was applied to study differences between the patients in the intervention (n=78) and control (n=79) groups. A sensitivity analysis was performed in the intervention group to study the influence of patients with high (N=30) and low (N=40) use of the intervention.

Results: The intervention group scored statistically significantly better on the subscale RAND-36 vitality. The group with high use scored statistically significantly better on the subscale RAND-36 perception, although the effect sizes were small. No other statistically significant or clinically relevant effects were found.

Conclusions: Based on these results, it is not possible to conclude on the positive effects of the intervention or to select outcome measures to be regarded as the primary/main or secondary outcomes for a future trial. A process evaluation should be performed to provide more insight into the low compliance with and effectiveness of the intervention. Clinical Trial: The trial is registered in the Dutch Trial Register (ID: NTR4871). URL: http://www.trialregister.nl/trialreg/admin/rctsearch.asp?Term=4871

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Efficacy of an online self-management enhancing programme for patients with rheumatoid arthritis: an explorative RCT

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**Background:** Online self-management enhancing programmes has the potential to support patients...
with Rheumatoid Arthritis in their self-management, for example improve their health status, by increasing their self-efficacy or taking their prescribed medication. We developed an online self-management enhancing program in collaboration with RA patients and professionals as co-designers, based on the Intervention Mapping Framework. While self-management programmes are complex interventions, it is informative to perform an explorative Randomized Controlled Trial before embarking on a larger trial.

Objective: This study aimed to evaluate the efficacy of an online self-management enhancing programme for patients with rheumatoid arthritis and to identify outcome measures most likely to capture potential benefits.

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Results: No positive effects were found regarding the outcome measurements. Effect sizes were low.

Conclusion: Based on these results, it is not possible to conclude on the positive effects of the intervention or to select outcome measures to be regarded as the primary/main or secondary outcomes for a future trial. A process evaluation should be performed to provide more insight into the low compliance with and effectiveness of the intervention. This can determine for whom this sort of programme will work and to fine tune the inclusion criteria.
**Trial registration:** The trial is registered in the Dutch Trial Register (ID: NTR4871). URL: http://www.trialregister.nl/trialreg/admin/rctsearch.asp?Term=4871

**Keywords:** online self-management program, rheumatoid arthritis patients, exploratory RCT

**Introduction**

Rheumatoid arthritis (RA) is one of the most prevalent chronic conditions, with a pervasive impact on daily life[1]. Despite the introduction of biological therapies and conventional disease-modifying anti-rheumatic drugs (DMARDs), RA patients experience a high level of pain [2] and fatigue [3, 4], which leads to disabilities like restrictions in work participation [5, 6] and leisure activities [7-9]. Also, many RA patients experience disease-related psychological problems, like depressive mood and helplessness [10, 11].

To optimally manage the consequences of RA and reduce the impact of the disease on patients in daily life, effective self-management programmes are needed. Online self-management programmes can easily reach a large group of RA patients in their own place and time and provide more anonymity than face-to-face programmes. Studies have shown that patients feel more comfortable sharing sensitive information like reports on daily activity or feelings online [12]. Other advantages are the possibility of tailoring information, avoiding waiting lists and 24-hour availability [13].

Studies about online self-management programmes have shown to be effective in RA patients on several health outcomes, including increased self-efficacy, knowledge and physical activity [14], less pain, disability and depression, and a reduction in the overuse of medication and the number of visits to physicians [15-17]. However, many of these programmes are developed without end user involvement. As a consequence, these programmes may not suit patient support needs for self-management as patient preferences for programme use are not well-known [18, 19].

To guarantee optimal patient involvement, we developed an online self-management programme based on intervention mapping (IM), called "Reuma zelf te lijf" [“Coping with RA”]
According to the Medical Research Council (MRC), complex interventions such as this programme can be evaluated in a randomised controlled trial (RCT); however, it is advised to first perform an explorative study investigating potential outcome measurements to be used in a larger trial [23].

Therefore, the present explorative RCT study in patients with RA aimed to: 1) explore the potential efficacy of an online self-management enhancing programme versus ‘usual care’ on self-management behaviour, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue and to determine the effect sizes at 6 and 12 months after baseline and 2) to identify outcome measures most likely to capture the potential benefits covered by the performance objectives, by exploring their floor and ceiling effects at baseline.

Methods

Design

A multicentre exploratory randomized controlled trial was conducted in two Dutch hospitals, The Radboudumc (a University hospital) and the Sint Maartenskliniek (a specialized hospital in rheumatology, rehabilitation and orthopedic surgery), both located in Nijmegen, the Netherlands. An intervention and a control group were compared at 6 and 12 months after baseline on six outcome measurements to explore the efficacy of the online programme and to identify outcome measures [20]. The medical ethics committee of Arnhem-Nijmegen approved this study (number 2014-1208). The trial is registered at the Dutch Trial Register (ID: NTR4871).

Participants

Between December 2014 and June 2015, patients with a diagnosis of RA aged 18 years or older were invited by letter to participate in this study, in collaboration with rheumatologists, until the required number of 190 patients were reached. Patients received: 1) information about the study, 2) a questionnaire for screening eligibility and 3) an informed consent form. Eligibility criteria were the
ability to speak and read Dutch and having access to a computer with an internet connection. Patients receiving psychiatric or psychological treatment were excluded. Patients willing to participate were asked to return the informed consent with the completed questionnaire. When patients agreed to participate and were eligible, the researcher sent the patient an email with the baseline questionnaire.

**Randomisation**

Eligible patients were stratified by the hospital and randomly assigned to the intervention or control group, by an independent statistician using an automated randomisation programme. The researcher informed the patients by post if they were allocated to the control or intervention group. Patients in the control group continued with their care as usual, which existed of medical treatment at the outpatient clinic. The patients in the intervention group received, in addition to their care as usual, 12 months of access to the intervention directly after randomisation.

**Intervention**

**Online self-management enhancing programme**

The intervention was developed between January 2013 and July 2014 in collaboration with RA patients and professionals as co-designers [20, 24]. The theory of planned behaviour was used as the underlying theory and essential behavioural change techniques (BCTs) were applied to induce behavioural change formulated as performance objectives, selected according to the Intervention Mapping(IM) steps [21, 25, 26]. The online self-management enhancing programme consists of nine modules with 13 performance objectives (Table 1) and a diary to track patients’ fatigue and pain over time [20]. Each module consists of 2 to 5 sessions, with informational and persuasive texts, videos with instructions and role models, exercises and assignments. The programme is unguided, patients need to choose a module by their own and could work through it at their own pace, whenever they want.
Table 1. Overview of the nine modules and their performance objectives

| Module name                          | Performance objective:                                                                 |
|--------------------------------------|----------------------------------------------------------------------------------------|
| 1. Balancing activity and rest       | - find balance between rest and activity  
- make choices when participating in daily life activities to keep balance |
| 2. Setting boundaries                | - set boundaries for their partner, relatives, colleagues and social environment         |
| 3. Asking for help and social support| - ask for social support or practical help from their partner, relatives, colleagues and social environment in daily life  
- ask for social support and practical help from colleagues  
- accept receiving social support or practical help from their partner, relatives, colleagues and social environment in daily life |
| 4. Use of medicines                  | - take prescribed medication                                                              |
| 5. Communication with health professionals | - prepare for a visit to a health professional  
- ask questions and/or express concerns during an appointment with a health professional |
| 6. Use of assistive devices          | - use, if necessary, assistive devices                                                    |
| 7. Performing physical exercises     | - perform daily physical exercises                                                        |
| 8. Coping with worries               | - cope with worries about RA                                                              |
| 9. Coping with RA                    | - cope with RA                                                                             |

**Implementation of the online self-management enhancing programme**

To implement the online programme and to increase use of the programme by patients, three implementation strategies were deployed during the study: 1) patients received a written instruction manual for the programme, 2) reminders to (re)-visit the programme were sent via e-mail two weekly, 3) nurses brought the programme to the attention of the intervention group participants during their consultation.

**Measurements and outcomes**
All included patients who filled in the baseline questionnaire between January 2015 and June 2015, received a questionnaire after six months (T1) and 12 months (T2). At baseline, demographic and disease characteristics were assessed. Patient-reported outcome measurements were assessed at baseline and during follow-up (T1 and T2). When patients preferred a paper questionnaire, a version was sent by post. When patients did not return the questionnaire at T1, but filled in the questionnaire at T2, this was indicated as a missing value at T1. Patients who did not return the T2 questionnaire are indicated as drop-outs.

**Baseline characteristics**

The following demographic and disease characteristics were assessed: age, gender, education level, employment status, disease duration, NRS pain/fatigue, physical disability and satisfaction with health status (M-HAQ-questionnaire). The M-HAQ consists of eight questions on difficulties in daily activities in the following domains: dressing, rising, eating, walking, hygiene, reach, grip and usual activities. Patients responded on a four-point scale, with a higher score indicating more difficulty in performing daily activities. Health satisfaction was assessed using one question about patient (dis)satisfaction about the course of their disease last week, with four response options, with a higher score meaning less satisfied than before and an "I don't know" option [27].

**Outcome measurements**

Based on the theory of planned behaviour, six outcome measures were relevant: self-management behaviour, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue.

**Self-management behaviour**

The Patient Activation Measurement (PAM-13) includes statements about an individual's knowledge, confidence and skills for self-management of their chronic illness behaviour, and the level of activation. It includes 13 items on a five-point scale with a higher score indicating a higher level of
patient activation. The scores of the 13 items are summarised as a total score. Total PAM scores were computed if at least 10 items were completed [28]. The short Self-Management Ability Scale (SMAS-S) consists of 18 items scored on a six-point scale with a higher score indicating better self-management behaviour [29].

Self-efficacy

The Rheumatoid Arthritis task specific Self-Efficacy (RASE) questionnaire consists of 28 items scored on a five-point Likert scale. Higher scores reflect higher self-efficacy [30]. This questionnaire was translated into Dutch via forward-backward translation and decisions were based on consensus with a group of five researchers, four RA patients and one RA patient who was a native English speaker. The Perceived Efficacy in Patient-Physician Interaction (PEPPI-5) consists of a five-point Likert scale. A higher score reflects more confidence in patient interactions with their physician [31].

General health status

The RAND-36 consists of 36 questions measuring eight dimensions: physical functioning, social functioning, physical role limitations, emotional role limitations, mental health, vitality and pain, with various response options based on three- to six-point Likert scales, with a higher score indicating better perceived health related quality of life. Scores were transformed to a 0-100 point scale for each subscale [32].

Level of pain and fatigue

Pain and fatigue were measured with Numeric Rating Scales (NRS), ranging from 0-10 with 0 meaning no pain/fatigue and 10 meaning severe pain/very tired. For both outcomes, two questions were asked: the level of pain/fatigue today and the mean level of pain/fatigue during the last two weeks.

Coping with fatigue
The Modified Pain Coping Inventory for Fatigue (MPCI-F) was used. This questionnaire is based on a subscale of the Pain Coping Inventory (PCI) questionnaire, and modified to assess coping with fatigue instead of coping with pain [33]. The questionnaire consists of eight items to assess the focus on fatigue. A higher score reflects more focus on fatigue.

**Statistical analysis**

Descriptive statistics were used to describe the control and intervention groups at baseline. T-tests and chi-square tests were used to analyse baseline differences. It was analysed whether the patients who dropped out differed from the group that returned the questionnaire at T2 [34]. Between-group differences in outcomes were analysed using a linear mixed model to account for repeated measurements and to handle missing data under the missing-at-random assumption. Differences between the intervention and control group were analysed at baseline, after six months (T1) and twelve months (T2). The fixed variables in the model were: group (intervention/control), hospital (hospital 1 or hospital 2), age, gender, disease duration, education level, employment status, physical functioning (M-HAQ) and the interaction terms between measurement time points and groups. The first analysis was done using the intention-to-treat principle. Subsequently, a sensitivity analysis was performed to explore the influence of programme use within the intervention group. The intervention group was divided into three groups: 1) a group with low usage (0-1 visits), 2) a group with moderate usage (2-5 visits) and 3) a group with high usage (6 or more visits). In the analysis, the group with a moderate usage was left out to increase the contrast between the groups with low and high usage. T-tests and chi-square tests were performed to analyse between-group differences in demographics, disease-related characteristics and outcomes at baseline, T1 and T2. Statistical significance was defined as p<0.05.

For all outcome measurements, Cohen’s D was used to quantify effect sizes by calculating the difference in means, divided by the pooled within-group standard deviation [38]. Following Cohen’s
definition of effect sizes, less than 0.4 was defined as a small effect, between 0.5 to 0.7 as moderate and \( \geq 0.8 \) was considered as a large effect [35]. Floor and ceiling effects were explored for all outcome measures by examining the percentage of minimum and maximum scores, which reflects the extent that patients scored the lowest or the highest score. For a three- or five-point Likert scale, floor and ceiling effects were defined as more than 80% of the patients scoring lowest/highest.

Statistical analyses were performed using SPSS V22 for Windows. For exploratory RCT such as these, sample sizes are not calculated based on formal power analyses. For this trial, a sample size of 200 patients was chosen, which was considered a sufficient size for a representation of the relevant variation in the target group.

**Results**

Figure 1. *Patient flow chart*
Figure 1. Patient flow chart

Recruited patients who met the eligibility criteria judged by rheumatologists and the researchers: 693 in total
N = 354 hospital 1
N = 315 hospital 2

Expressed interest and met eligibility criteria judged by themselves: 189 in total
N = 90 hospital 1
N = 99 hospital 2

Returned baseline questionnaire: 157 in total
N = 74 hospital 1
N = 83 hospital 2

Randomized to usual care: N = 79 in total
N = 38 hospital 1
N = 41 hospital 2

Randomized to intervention: N = 76 in total
N = 35 hospital 1
N = 42 hospital 2

Follow-up T1

Usual care: N = 66
N = 36 hospital 1
N = 30 hospital 2

Intervention group: N = 69
N = 30 hospital 1
N = 39 hospital 2

Follow-up T2

Usual care: N = 74
N = 36 hospital 1
N = 38 hospital 2

Intervention group: N = 74
N = 38 hospital 1
N = 36 hospital 2

Included intention to treat analysis

Usual care: N = 78
N = 38 hospital 1
N = 40 hospital 2

Intervention group: N = 78
N = 38 hospital 1
N = 40 hospital 2
In total, 669 patients were eligible and invited. Of these, 191 patients expressed interest and 189 met the inclusion criteria (see Figure 1). In total, 157 patients completed the baseline questionnaire between January 2015 and June 2015. These patients were randomly assigned to the intervention group (n=78) and control group (n=79), stratified by hospital. At T1, 59 in the intervention group and 65 in the control group filled in the questionnaire. At T2, 54 patients in the intervention group and 74 patients in the control group completed the questionnaire. Overall, in the intervention group less patients (69% (54 of 78)) participated at T2 than in the control group (94% (74 of 79)). Most of these patients gave the burden of their illness as the reason for drop-out. Some patients refused to fill in the questionnaire at T1, but completed the questionnaire at T2, which explains the higher number of patients who filled in the questionnaire at T2 compared to T1. Differences in demographics and disease-related characteristics between the group of patients who refused to fill in the questionnaire at T2 and the group who returned the questionnaire at T2 were small (<10%), which indicated that drop-out did not influence the outcomes.

**Baseline characteristics of patients**

Demographics and disease-related characteristics at baseline were compared for the control group and intervention group, shown in Table 2. The only significant between-group difference in the patient characteristics was education level (p=0.003). Fewer patients in the intervention group had a lower education level (12.8% versus 35.4%) and more patients had a moderate (55.1% versus 35.4%) or higher education level (32.1% versus 29.1%). Some patients who filled in a paper questionnaire did not complete all items, which explains the missing data in Tables 3 and 4.
Table 2. Demographics and disease-related characteristics at baseline

| Demographics and disease-related characteristics at baseline | Control group | Intervention group |
|-------------------------------------------------------------|---------------|--------------------|
| **Age in years (mean (SD))**                                | 62.9 (10.2)   | 61.0 (11.3)        |
| **Gender**                                                  |               |                    |
| Men                                                         | 2             | 2                  |
| 7                                                           | 7             |                    |
| 65.8 %                                                      | 34.2 %        | 34.6 %             |
| 2                                                           | 7             |                    |
| 65.8 %                                                      | 65.4 %        |                    |
| **Disease duration (median (25th,75th percentiles))**       | 7             | 7                  |
| 9                                                           | 9             |                    |
| 17 (6.0, 26)                                                | 9 (5.0, 19.5) |                    |
| **Education level**                                         |               |                    |
| Low                                                         | 2             | 1                  |
| 8                                                           | 8             |                    |
| 35.4 %                                                      | 12.8 %        |                    |
| Medium                                                      | 2             | 4                  |
| 8                                                           | 8             |                    |
| 35.4 %                                                      | 55.1 %        |                    |
| High                                                        | 2             | 2                  |
| 3                                                           | 3             |                    |
| 29.1 %                                                      | 32.1 %        |                    |
| **Employment status**                                       |               |                    |
| Not working                                                 | 5             | 4                  |
| 0                                                           | 0             |                    |
| 63.3 %                                                      | 52.6 %        |                    |
| Part-time working                                           | 7             | 7                  |
| 8                                                           | 8             |                    |
| 8.90 %                                                      | 9.0 %         |                    |
| Working                                                     | 2             | 3                  |
| 2                                                           | 2             |                    |
| 27.80 %                                                     | 38.5 %        |                    |
| **Physical disability (M-HAQ) (median (25th,75th percentiles))** | 7             | 7                  |
| 9                                                           | 9             |                    |
| 0.5 (0.1, 1.4)                                              | 0.6 (0.1, 1.1)|                    |
| **NRS pain today (mean (SD))**                              | 7             | 7                  |
| 9                                                           | 9             |                    |
| 3.3 (2.3)                                                   | 3.2 (2.2)     |                    |
| **NRS mean pain last two weeks (mean (SD))**                | 7             | 7                  |
| 9                                                           | 9             |                    |
| 3.9 (2.3)                                                   | 3.6 (2.3)     |                    |
| **NRS fatigue today (NRS) (mean (SD))**                     | 7             | 7                  |
| 9                                                           | 9             |                    |
| 4.1 (2.5)                                                   | 3.8 (2.4)     |                    |
| **NRS mean fatigue last two weeks (mean (SD))**             | 7             | 7                  |
| 9                                                           | 9             |                    |
| 4.3 (2.4)                                                   | 4.3 (2.3)     |                    |

* Values are %, unless otherwise indicated;

NRS= numerical rating scale (higher score means more pain and fatigue);
HAQ: Health Assessment Questionnaire (0-3 = best possible functioning-worst functioning)

The outcome measurements at baseline and follow-up

Table 3 gives an overview of the mean scores of outcome measurements of the patients in the intervention and control group at baseline and after 6 and 12 months. The baseline scores of the two groups did not differ significantly.
Table 3. Mean scores of outcome measurements on baseline, T1 and T2 of Control (C) and Intervention (I) groups

| Scales                              | Group | N   | T0 mean (SD) | N   | T1 mean (SD) | N   | T2 mean (SD) |
|-------------------------------------|-------|-----|--------------|-----|--------------|-----|--------------|
| PAM (10-65)                         | C     | 57  | 46.9 (4.9)   | 49  | 47.7 (4.8)   | 45  | 47.8 (3.8)   |
|                                     | I     | 47  | 47.2 (3.7)   | 35  | 46.7 (6.9)   | 31  | 47.8 (2.9)   |
| SMAS-S (0-60)                       | C     | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |
| RASE (28-140)                       | C     | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| PEPPi-5 (5-25)                      | C     | 79  | 21.6 (3.0)   | 75  | 21.0 (3.2)   | 73  | 20.6 (3.4)   |
|                                     | I     | 78  | 21.2 (3.3)   | 57  | 21.3 (3.1)   | 54  | 20.8 (3.1)   |
| RAND physical functioning (0-100)   | C     | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |
| RAND social functioning (0-100)     | C     | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| RAND physical role limitations (0-100)| C   | 79  | 21.6 (3.0)   | 75  | 21.0 (3.2)   | 73  | 20.6 (3.4)   |
|                                     | I     | 78  | 21.2 (3.3)   | 57  | 21.3 (3.1)   | 54  | 20.8 (3.1)   |
| RAND emotional role limitations (0-100)| C   | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |
| RAND mental health (0-100)          | C     | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| RAND vitality (0-100)               | C     | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| RAND pain (0-100)                   | C     | 79  | 21.6 (3.0)   | 75  | 21.0 (3.2)   | 73  | 20.6 (3.4)   |
|                                     | I     | 78  | 21.2 (3.3)   | 57  | 21.3 (3.1)   | 54  | 20.8 (3.1)   |
| RAND general health perception (0-100)| C   | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |
| RAND health change (0-100)          | C     | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| NRS pain today (0-10)               | C     | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |
| NRS mean pain last two weeks (0-10) | C     | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |
| NRS fatigue today (0-10)            | C     | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| NRS mean fatigue last two weeks (0-10)| C   | 79  | 99.4 (12.7)  | 75  | 101.5 (10.6) | 74  | 99.9 (11.6)  |
|                                     | I     | 78  | 102.9 (10.2) | 57  | 101.9 (10.3) | 54  | 102.0 (7.4)  |
| MPCI-F (4-32)                       | C     | 79  | 36.0 (6.3)   | 75  | 37.9 (6.8)   | 74  | 37.6 (6.8)   |
|                                     | I     | 78  | 36.7 (7.1)   | 57  | 39.4 (6.4)   | 54  | 38.8 (7.0)   |

T1= six months after baseline, T2= twelve months after baseline.
PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPi-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.
In Table 4, the estimated differences between the intervention and control groups of the intention-to-treat analysis at 6 and 12 months are presented. Overall, the scores show no significant differences and small effect sizes. Only the outcome measurement of the subscale RAND-36 vitality at T2 (5.41 95% CI: 0.16-10.65, p=0.04) showed a significant difference, with a small effect size (Cohen’s D) of 0.01 in favour of the intervention group. Floor and ceiling effects were explored for all specified outcomes at baseline, but were not found.

| Scales                                      | T0-T1 Δ | 95% CI  | P value | Cohens d | T0-T2 Δ | 95% CI  | P value | Cohens d |
|---------------------------------------------|---------|---------|---------|----------|---------|---------|---------|----------|
| AM (10-65)                                  | -0.7    | -3.4 to 1.5 | 0.44 | 0.0 | -0.1 | -1.6 to 1.5 | 0.93 | 0.00 |
| MAS-S (0-60)                                | 0.3     | -1.4 to 2.0 | 0.72 | 0.0 | 0.7 | -1.1 to 2.5 | 0.43 | 0.03 |
| RASE (28-140)                               | -2.1    | -4.9 to 0.8 | 0.16 | 0.0 | 0.3 | -2.2 to 2.9 | 0.81 | 0.00 |
| EPPI-5 (5-25)                               | 0.4     | -0.5 to 1.2 | 0.40 | 0.0 | 0.3 | -0.7 to 1.3 | 0.51 | 0.03 |
| RAND physical functioning (0-100)           | 2.5     | -3.3 to 8.1 | 0.40 | 0.0 | -0.2 | -5.4 to 5.1 | 0.96 | 0.00 |
| RAND social functioning (0-100)             | 4.1     | -1.5 to 9.6 | 0.15 | 0.0 | -2.7 | -9.2 to 3.8 | 0.42 | -0.01 |
| RAND physical role limitations (0-100)       | 5.6     | -7.0 to 18.2 | 0.38 | 0.0 | -2.8 | -14.9 to 0.65 | 0.00 | 0.00 |
| RAND emotional role limitations (0-100)      | -3.2    | -14.1 to 7.6 | 0.56 | 0.0 | -3.9 | -16.0 to 8.3 | 0.53 | 0.00 |
| RAND mental health (0-100)                  | 2.8     | -1.1 to 6.8 | 0.16 | 0.0 | 0.9 | -3.0 to 4.7 | 0.66 | 0.00 |
| RAND vitality (0-100)                       | 3.4     | -1.5 to 8.3 | 0.17 | 0.0 | 5.4 | 0.2 to 10.7 | 0.04 | 0.01 |
| RAND pain (0-100)                           | 2.6     | -3.7 to 8.9 | 0.42 | 0.0 | -6.1 | -12.5 to 0.4 | 0.06 | -0.01 |
| RAND general health perception (0-90)        | 2.2     | -2.2 to 6.7 | 0.33 | 0.0 | -0.1 | -4.5 to 4.4 | 0.98 | 0.00 |
| RAND health change (0-100)                  | 0.1     | -6.8 to 7.1 | 0.97 | 0.00 | -1.4 | -9.0 to 6.2 | 0.72 | 0.00 |
| RS pain today (0-10)                        | 0.0     | -0.6 to 0.7 | 0.97 | 0.00 | 0.5 | -0.1 to 1.2 | 0.13 | 0.10 |
| RS mean pain last two weeks (0-10)           | 0.0     | -0.7 to 0.6 | 0.97 | 0.00 | 0.7 | 0.0 to 1.4 | 0.60 | 1.13 |
| RS fatigue today (0-10)                     | 0.2     | -0.5 to 0.8 | 0.66 | 0.0 | 0.3 | -0.4 to 0.9 | 0.46 | 0.01 |
| RS mean fatigue last two weeks (0-10)        | -0.9    | -0.9 to 0.4 | 0.45 | 0.04 | -0.1 | -0.6 to 0.7 | 0.81 | 0.00 |
| PCI-F (4-32)                                 | 0.1     | -0.8 to 0.9 | 0.90 | 0.00 | -0.3 | -0.7 to 1.2 | 0.58 | 0.01 |

Significant differences (P<0.05) between control and intervention group values represent outcomes of the ITT analysis without confounders. After adding confounders, no changes in values appear.

AM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.
Sensitivity analysis

Baseline characteristics of patients

High users of the intervention scored statistically significantly better than low users of the intervention on the following baseline characteristics: physical disability (M-HAQ) (p=0.031), RAND-36 subscale social functioning (p=0.016), RAND-36 subscale physical role limitations (p=0.029), RAND-36 pain (p=0.025), and all the NRS scales, i.e. pain today (p=0.002), mean pain last two weeks (p=0.020), fatigue today (p=0.001) and mean fatigue last two weeks (p=0.001) (Table 5).
Table 5. Scores at baseline for the groups with a low and high usage of the intervention

| Demographic characteristics, disease related characteristics and outcome measures at baseline | N | Low usage | N | High usage |
|---|---|---|---|---|
| **Age in years** | 29 | 63.8 (10.5) | 40 | 58.9 (10.8) |
| **Gender men/women (%)** | | | | |
| Men | 10 | 33.3% | 14 | 35.0% |
| Women | 20 | 66.7% | 26 | 65.0% |
| **Disease duration (median (25th, 75th percentiles))** | 29 | 8.0 (4.5, 22.5) | 40 | 8.5 (5.0, 18.7) |
| **Education level (%)** | | | | |
| Low | 3 | 10.0% | 5 | 12.5% |
| Middle | 19 | 63.3% | 22 | 55.0% |
| High | 8 | 26.7% | 13 | 32.5% |
| **Employment status (%)** | | | | |
| Not working | 22 | 73.3% | 23 | 57.5% |
| Working | 8 | 26.7% | 17 | 42.5% |
| **Physical disability (M-HAQ) (median (25th, 75th percentiles))** | 30 | 1.1 (0.2, 1.6)* | 40 | 0.5 (0.1, 1.0) |
| **PAM (10-65)** | 29 | 48.0 (3.3) | 20 | 46.2 (3.8) |
| **SMAS-S (0-60)** | 30 | 36.5 (7.3) | 40 | 37.7 (7.0) |
| **RASE (28-140)** | 30 | 102.1 (10.9) | 40 | 103.4 (9.1) |
| **PEPPI-5 (5-25)** | 30 | 21.5 (3.9) | 40 | 21.2 (2.8) |
| **RAND physical functioning (0-100)** | 29 | 54.3 (28.3) | 40 | 66.3 (24.6) |
| **RAND social functioning (0-100)** | 30 | 64.6 (24.8) | 40 | 77.8 (17.1)* |
| **RAND physical role limitations (0-100)** | 30 | 36.7 (43.9) | 40 | 60.0 (42.7) |
| **RAND emotional role limitations (0-100)** | 29 | 74.7 (41.5) | 40 | 85.8 (33.7)* |
| **RAND mental health (0-100)** | 30 | 72.1 (16.1) | 40 | 78.7 (11.6) |
| **RAND vitality (0-100)** | 30 | 53.1 (22.9) | 40 | 61.7 (15.4) |
| **RAND pain (0-100)** | 30 | 56.9 (25.5) | 40 | 69.8 (19.2)* |
| **RAND general health perception (0-100)** | 29 | 46.0 (19.4) | 40 | 54.0 (17.6) |
| **RAND health change (0-100)** | 30 | 43.3 (20.7) | 40 | 52.5 (24.6) |
| **NRS pain today (0-10)** | 29 | 4.3 (2.5) | 40 | 2.5 (1.8)* |
| **NRS mean pain last two weeks (0-10)** | 30 | 4.4 (2.5) | 40 | 3.1 (2.1)* |
| **NRS fatigue today (0-10)** | 30 | 4.8 (2.4) | 40 | 3.0 (2.2)* |
| **NRS mean fatigue last two weeks (0-10)** | 30 | 4.8 (2.4) | 40 | 3.0 (2.2)* |
| **MPCI-F (4-32)** | 30 | 15.0 (4.8) | 40 | 13.2 (3.0) |

*Significant differences (P<0.05) between the group low and high users

Values are means and SD, unless otherwise indicated;
NRS= numerical rating scale (higher score means more pain/fatigue);
HAQ= Health Assessment Questionnaire (0-3 = best possible functioning- worst functioning).
PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.

After performing the sensitivity analysis, a statistically significant effect was found for the group with high usage on the subscale RAND-36 general health perception after 12 months (9.65, 95% CI: 0.83 -18.48, p=0.03), with a small effect size of 0.02 (Table 6). No floor and ceiling effects were
found for any of the specified outcomes at baseline in the groups with low or high usage.

Table 6. The estimated difference between the group with low and high usage of the intervention after sensitivity analysis at 6 months and 12 months after baseline

| Scales                        | T0-T1 | 95% CI       | P     | Cohen's d | T0-T2 | 95% CI       | P     | Cohen's d |
|-------------------------------|-------|--------------|-------|-----------|-------|--------------|-------|-----------|
| PAM (10-65)                   | 2.4   | -1.7 to 6.4  | 0.2   | 0.12      | 0.0   | -2.9 to 2.9  | 0.99  | 0.00      |
| SMAS-S (0-60)                 | -0.4  | -3.4 to 2.7  | 0.8   | 0.00      | 1.3   | -2.0 to 4.5  | 0.44  | 0.02      |
| RASE (28-140)                 | -1.7  | -6.8 to 3.4  | 0.5   | -0.00     | -0.6  | -5.3 to 4.1  | 0.81  | 0.00      |
| PEPPI-5 (5-25)                | 1.0   | -2.5 to 0.5  | 0.2   | -0.11     | -0.1  | -1.9 to 1.7  | 0.93  | 0.00      |
| RAND physical functioning (0-100) | 9.2  | -0.7 to 19.2 | 0.0   | 0.01      | 2.2   | -7.4 to 11.8 | 0.65  | 0.00      |
| RAND social functioning (0-100) | 1.5  | -8.4 to 11.4 | 0.7   | 0.00      | 5.3   | -6.7 to 17.4 | 0.38  | 0.01      |
| RAND physical role limitations (0-100) | 7.4  | -14.7 to 29.5 | 0.5  | 0.00      | 3.7   | -18.6 to 25.9 | 0.74  | 0.00      |
| RAND emotional role limitations (0-100) | 16.1 | -3.6 to 35.7 | 0.1  | 0.01      | -1.7  | -24.5 to 21.0 | 0.88  | 0.00      |
| RAND mental health (0-100)    | 0.8   | -6.3 to 7.9  | 0.8   | 0.00      | 4.2   | -11.2 to 2.8 | 0.24  | 0.02      |
| RAND vitality (0-100)         | 2.9   | -5.6 to 11.5 | 0.5   | 0.01      | -1.2  | -10.8 to 8.4 | 0.81  | 0.00      |
| RAND pain (0-100)             | 1.7   | -4.5 to 12.9 | 0.7   | 0.00      | 8.8   | -3.0 to 20.6 | 0.14  | 0.02      |
| RAND general health perception (0-100) | 2.9  | -5.1 to 10.8 | 0.4   | 0.01      | 9.7   | 0.8 to 18.5  | 0.03  | 0.02      |
| RAND health change (0-100)    | 8.3   | -4.0 to 20.5 | 0.1   | 0.02      | 6.4   | -7.9 to 20.6 | 0.38  | 0.01      |
| NRS pain today (0-10)         | 0.0   | -1.2 to 1.2  | 0.9   | 0.00      | -0.6  | -1.9 to 0.8  | 0.41  | -0.11     |
| NRS mean pain last two weeks (0-10) | -1.8 | -1.8 to 0.5  | 0.2   | -0.12     | 0.9   | -2.3 to 0.6  | 0.24  | -0.16     |
| NRS fatigue today (0-10)      | 0.2   | -1.0 to 1.3  | 0.7   | 0.03      | -0.9  | -2.2 to 0.5  | 0.22  | -0.14     |
| NRS mean fatigue last two weeks (0-10) | 0.2  | -1.0 to 1.3  | 0.7   | 0.03      | -0.5  | -1.7 to 0.8  | 0.51  | -0.08     |
| MPCI-F (4-32)                 | -0.2  | -1.7 to 1.3  | 0.7   | -0.01     | -0.4  | -2.1 to 1.3  | 0.67  | -0.01     |

*Significant differences (P<0.05) between control and intervention group
Values represent outcomes of the ITT analysis without confounders. After adding confounders, no changes in values appear.
PAM= Patient Activation Measurement; SMAS-S= short Self-Management Ability Scale; RASE= Rheumatoid Arthritis Self-Efficacy; PEPPI-5= Perceived Efficacy in Patient-Physician Interaction; RAND-36= General Health Status, NRS pain/fatigue= Numeric Rating scales pain/fatigue; Coping with fatigue= Modified Pain Coping Inventory for fatigue.

Discussion

https://preprints.jmir.org/preprint/12463

[unpublished, peer-reviewed preprint]
This study aimed to evaluate the efficacy of an online self-management enhancing programme in patients with RA in an explorative trial on six outcomes: self-management behaviour, self-efficacy, general health status, coping with fatigue and the level of pain and fatigue.

Results show no remarkable statistically significant difference between the intervention and control group. Also, effect sizes were low.

Consequently, the results of this exploratory show no convincing trend regarding the efficacy of the programme. This was unexpected, as the theory based intervention was carefully designed, according the IM steps, based on patients support needs [36, 37]. Also, the range of outcome measures were selected carefully and the study was well-performed. Randomisation was successful and the number of missing was limited. It is thought that the size was adequate for a pilot study (N=157).

Notably, the lack of a trend for a positive result is not in line with other studies showing that self-management programmes seem promising for patients with a chronic illness, including arthritis [15, 38]. However, these studies cannot be compared with each other in a straightforward manner, because of the various self-management approaches (e.g. offering weekly vs. non-weekly online courses, with face-to-face help or without), various contents of the self-management programmes and the different outcome measures used in these studies [15, 39]. For example, it is unexpected that our online programme yielded no results for RA patients, while the online programme evaluated by Lorig and colleagues (2008) concluded that RA patients showed increased self-efficacy and improved health status for four of the six health status measures that were included [14]. These different results may be explained by the different questionnaires used for the same outcomes, i.e. self-efficacy and health status.

Also, differences in the content and delivery of the programmes could be a reason for the different results. Other programmes focused on different topics (e.g. pain/stress management, problem solving and nutrition, which were not covered by our programme). Moreover, in our
programme patients received no help with logging in to the programme or using the programme in contrast of the programme described by Lorig et al. (2008) were patients received help and were encouraged to use the programme. Patients could choose which modules to work through and follow it at their own speed. In the programme described by Lorig et al. (2008), peer moderators helped patients to log in, encouraged them to use the weekly programme and moderate posts patients could leave on the programme website [14].

There are potentially five reasons for the lack of efficacy of our online programme: 1) the use of inappropriate outcome measures, 2) individual patients had no need for self-management support, 3) low usage of the programme/high drop-out of the intervention group and 4) inadequate embedding of the programme in healthcare, 5) selecting not the appropriate patients.

First, in the case of inappropriate outcome measures, it could be that the carefully selected validated questionnaires still did not exactly measure the pursued behaviour changes formulated in the performance objectives. That is, the intervention aimed to result in specific self-management behaviours. The validated questionnaires consisted of more generic questions and therefore did not exactly measure these specifically formulated behavioural changes in performance objectives (Table 1). However, it was expected that a positive significant result would be found on the RASE questionnaire, because this measures task-specific self-efficacy for patients with RA with items closely related to the specific formulated performance objectives. Finding no positive results suggests that it is possible that our intervention did not support patients in increasing their level of self-efficacy. This could mean that the absence of positive results is less driven by the choice of outcomes than by the other points discussed below.

Second, it could be that recruited patients did not have a perceived need for enhancing self-efficacy when they agreed to participate in the programme. Although the programme was developed based on the support needs for self-management of RA patients, individual participating patients in this study were not asked whether, and if yes, what kind of support needs they had themselves for
self-management. It could be that patients differ in their needs and more tailoring toward individuals is needed, for example pre-selection of the offered modules.

Third, the low usage of the programme by patients in the intervention group could have resulted in finding only a significant effect on RAND-36 vitality, with a small effect size. The low usage of the programme can have several reasons. As stated above, patients could have not felt a need for support. Another reason could be that patients were not motivated to change their behaviour or had a negative attitude toward the online programme. The programme consisted of several elements to stimulate patients’ usage of the programme, such as persuasive texts or modeling videos. It could be that these elements did not work or that elements were lacking in the programme. Also, the characteristics of the online programme, for example attractiveness or the ease of logging in, are factors that could have influenced patient usage of the programme. It was also notable that patients in the intervention group dropped out more than patients in the control group. A high drop-out rate is a common finding in online programmes [40, 41]. Crutzen et al. (2015) gave as possible explanation for these higher drop-out rates that patients in an intervention group have several expectations of the intervention. In cases where these expectations are not met, or if patients feel the intervention is not supporting them, patients will refuse to fill in the measurements and will not re-visit the programme [42]. In our study, patients in the intervention group were significantly higher educated than in the control group. It could be that higher educated patients use more resources that could support them (e.g. support of health professionals), which could lead to lower usage of the programme.

Fourth, this programme was not adequately embedded in patient care. Although nurses brought the programme to the attention of intervention group patients during their consultation, they did not discuss the self-management topics of the programme with patients to continue the support for self-management during consultations. It has been shown that self-management programmes with the possibility of interacting with health professionals (blended care) can lead to positive results [14, 43].
Fifth, it could be that there was a selection bias in this study. Rheumatologists selected patients with diagnosis Rheumatoid Arthritis, aged 18 years or were invited by letter to participate in this study, in collaboration with rheumatologists, until the required number of 190 patients were reached. Probably, rheumatologists selected mainly the patients who had a low functional disability (HAQ) because in their opinion these patients would benefit of a self-management programme most.

Given the results of this study, relevant recommendations for future studies and practice can be given. Firstly, using a questionnaire with questions referring to the programme objectives is recommended to measure the effects in patient behavioural change [37]. For example, one the performance objectives of this online programme, ‘set boundaries in their work situation’, could be evaluated with an item like ‘I’m able to set boundaries with my colleagues in my work situation’ (measuring skills). Patients can set their own objectives in the programme, using goal setting as strategy. Goal setting requires that patients set a clear, specific and achievable goal to change their behaviour. This concrete formulation of the goal ensures that the behavioural change is measurable [44].

Secondly, before inclusion, it is recommended to investigate whether patients have a need for self-management support and if so, what kind of support they need. A next step is to decide if patient support needs are handled in the programme and to tailor the programme to their support needs. This can avoid patients feeling that the programme did not support them, which often results in no re-visits. Investigation of support needs could take place over the telephone. This also offers the possibility of helping patients formulate their support needs, which is in general difficult to do.

Thirdly, to increase the usage of the programme and limit drop-out, during the development phase, it is important to pay attention to factors that could enhance usage of the programme (first visit, staying on the website, re-visits).

Patients input, in combination with attention to dissemination, reach, adoption and implementation (emphasised in diffusion theory or RE-AIM theory), could be used to identify factors
Fourthly, to embed the programme in regular healthcare, it is important that patient needs are also recognised by their rheumatologists or specialised rheumatology nurse and be used as a starting point during consultation. Nurses could also assist patients in performing exercises mentioned in the programme, reminding patients to log on to the website and encourage patients to maintain their self-management behaviour.

Fifthly, to increase the usage and efficacy of the programme, a specific patient selection is needed. Further research is needed to assess which patient characteristics influence the use of an online programme and the outcomes, for example by performing subgroup analysis between groups with a low or high functional disability or by assessing their level of motivation to use the programme. This can determine which inclusion criteria should be used to select patients likely to benefit most.

In conclusion, although there is external evidence in favour of the efficacy of online self-management interventions [14, 15], it is not recommended to conduct a larger trial yet. As advised the MRC framework, a detailed process evaluation of the programme should be conducted to gain thorough insight into the implementation of the programme, the working elements of the programme and the usage of the programme by patients, which could be both important conditions for the success of a self-management programme. This could also satisfy the need for attention to the usage and the perceived impact of the programme to find out for whom this sort of programme will work [47].

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