Effectiveness of a group-based intervention to change medication beliefs and improve medication adherence in patients with rheumatoid arthritis: A randomized controlled trial

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ABSTRACT

Objective: To assess the effect of a group-based intervention on the balance between necessity beliefs and concern beliefs about medication and on medication non-adherence in patients with rheumatoid arthritis (RA).

Methods: Non-adherent RA patients using disease-modifying anti-rheumatic drugs (DMARDs) were randomized to an intervention or control arm. The intervention consisted, amongst others, of two motivational interviewing-guided group sessions led by the same pharmacist. Control patients received brochures about their DMARDs. Questionnaires were completed up to 12 months follow-up.

Results: 123 patients (mean age: 60 years, female: 69%) were randomized. No differences in necessity beliefs and concern beliefs about medication and in medication non-adherence were detected between the intervention and control arm, except at 12 months' follow-up: participants in the intervention arm had less strong necessity beliefs about medication than participants in the control arm (b: −1.0 (95% CI: −2.0, −0.1)).

Conclusion: This trial did not demonstrate superiority of our intervention over the control arm in changing beliefs about medication or in improving medication adherence over time.

Practice implications: Absent intervention effects might have been due to, amongst others, selection bias and a suboptimal treatment integrity level. Hence, targeting beliefs about medication in clinical practice should not yet be ruled out.

1. INTRODUCTION

Adherence to disease-modifying anti-rheumatic drugs (DMARDs) in patients with rheumatoid arthritis (RA) is not optimal and ranges from 22% to 107% [1], [2], [3], [4] and [5]. As non-adherence can reduce treatment efficacy and can intensify disease activity, pain, joint damage and a lower quality of life [6], [7] and [8], interventions to improve adherence are warranted.

Existing interventions to improve medication adherence in chronic diseases are mostly complex and of limited effect [9]. To date, three studies have assessed the effectiveness of a medication adherence intervention in RA [10], [11] and [12]. Only one of these studies demonstrated a slight improvement in adherence to D-penicillamine following a patient education program [11], but this program was intensive (51 individuals × six sessions × 30 min).

Time-efficient and effective adherence interventions are, thus, needed. Therefore, we developed a short, group-based intervention to improve medication adherence in non-adherent patients with RA using DMARDs [13]. Of the five WHO domains comprising possible targets for adherence improving interventions (i.e., the socio-economic, healthcare system, condition-related, therapy-related and the patient-related domain) [14], our intervention focusses on the patient-related domain. It aims to improve adherence by resolving patients' practical barriers to taking medication, and by improving patients' individual balance between necessity beliefs and concern beliefs about medication. Despite the apparent association between these beliefs and medication adherence [15], [16], [17], [18], [19], [20], [21] and [22], they have seldom been the main focus of adherence-improving interventions [13].

This randomized clinical trial evaluated the effectiveness of our group-based intervention on medication beliefs (primary outcome of interest) and adherence in non-adherent patients with RA.

2. METHODS

2.1. Design

This is a single-center, researcher-blinded randomized clinical trial. Participants were randomly allocated to two arms at a ratio of 1:1, and were asked to complete questionnaires at baseline (T0), and at one week (T1), six months (T2), and one year (T3) after the second group session (Section 2.3). In addition to questionnaires, refill data were used to assess medication adherence. This trial was approved by the local medical ethical board (CMO 2009/090; NCT00968266), and has been reported according to the CONSORT guidelines [23].

2.2. Participants and recruitment

Patient inclusion took place between September 2009 and February 2011 at the Sint Maartenskliniek (SMK Nijmegen, the Netherlands), a clinic specialized in rheumatology, rehabilitation and orthopedics.

Consecutive, adult patients having RA for at least one year according to the 2010 ACR-criteria [24] and using at least one DMARD were screened for eligibility by their rheumatologist during regular outpatient visits. Patients with severe mental or physical constraints or illiterate in the Dutch language were excluded. Eligible patients filled in an informed consent form and questionnaires (including the

Compliance Questionnaire Rheumatology for adherence assessment (CQR)) [25] at home. Subsequently, as we only wanted to include non-adherent patients, patients taking ≤80% of prescribed medication according to the CQR were telephonically invited for trial participation. Interested patients were scheduled for an intake meeting with one of the two involved researchers [BvdM/HZ]: trial information was discussed and written informed consent was obtained.

2.3. Interventions

2.3.1. Intervention arm (arm 1: sessions)

The systematic development of the intervention (based on the Intervention Mapping framework)[26] and its content is published by Zwikker et al. in this journal [13].
The intervention consisted of two motivational interviewing (MI) guided [27] group sessions (one week apart, with 5–7 RA patients), designed to improve patients' balance between necessity beliefs and concern beliefs about medication and to resolve patients' practical barriers to medication taking. During the Intervention Mapping process, beliefs about medication and practical barriers were selected as intervention targets by an interdisciplinary expert group, based on a (1) literature study, (2) cross-sectional study, and (3) focus groups. MI was chosen as central communication style, amongst others, for its suitability to explore patients' individual ambivalence regarding necessity – and concern beliefs about medication.
Two pharmacists alternately led the pair of sessions. During these sessions, the participants made an inventory of their own medication beliefs and practical barriers to take medication. These were non-judgmentally discussed in the group, with co-participation of a rheumatologist during the second session. Participants were encouraged to provide constructive feedback and solutions. The session closed with handing out brochures about the DMARDs that the patients were using.
Four of nine pairs of sessions were randomly audio-recorded and analyzed: an independent assessor checked treatment integrity in terms of potential omission errors in the intervention content [28] and the degree of patient-centeredness (or MI ' ambiance' as measured with the validated BECCI-instrument [29], see Appendix I).

2.3.2. Control arm (arm 2: brochures)

Participants allocated to the control arm received brochures at home about the DMARDs they were using at the time, with a request to thoroughly read the brochures.

2.4. Trial randomization and implementation

Appendix Figure I presents the randomization and implementation process. (See online Supplementary Material).
A blinded, computer-generated randomization list was obtained [BvdB] for subjects in permuted blocks of 10 [30]. Based on order of inclusion and availability, patients were allocated to one of nine clusters between 2009 and 2011 (one cluster consisted of 12–14 patients, half of whom were allocated to arm 1 and the other half to arm 2).

The researcher was responsible for data collection and – analyses, and remained blind to treatment allocation.

2.5. Measures

2.5.1. Baseline characteristics (T0)

Socio-demographic factors measured were age, sex, living with others, educational level, and employment status. *Clinical factors* measured were disease duration and physical functioning (such as physical abilities and pain severity, see Appendix Table I).
Electronic hospital/pharmacy data were used to assess the types of DMARDs used at baseline, and to assess the presence of anti-CCP and rheumatoid factor values in the participants (descriptive use only).

2.5.2. Primary measures (T0, T1, T2, T3)

Beliefs about medication were measured using the validated Beliefs about Medicines Questionnaire [19], which consists of two parts. Part one, the BMQ 'specific', has two subscales of five items each, measuring patients' beliefs about the necessity of prescribed medication (e.g., "Without my medicines I would be very ill"), and their concerns about potential adverse consequences of taking the medication. Within the subscales, items are scored from 5 (strongly agree) to 1 (strongly disagree) and are summed to obtain a total score ranging from 5 to 25. Higher scores indicate stronger beliefs. By subtracting the concerns score from the necessity score, a necessity-concerns differential score can be calculated (ranging from −20 to +20, where positive scores mean that patients perceive that benefits of medication outweigh costs, and vice versa).
Part two, the BMQ 'general', assesses general beliefs about pharmaceuticals as a class of treatment [20], and also has two subscales of four items each. The 'overuse' subscale includes beliefs about the way in which medicines are endorsed by doctors (e.g., "Doctors place too much trust on medicines"). The 'harm' subscale includes beliefs about the potential of medication to harm (e.g., "Medicines do more harm than good"). The scoring method is identical to the BMQ 'specific': total subscale scores range from 4 to 20.

2.5.3. Secondary measures (T0, T1, T2, T3)

Medication non-adherence was assessed with the Compliance Questionnaire Rheumatology [25]. The CQR is able to detect whether a patient takes ≤80% of prescribed medication (binary score) with a sensitivity of 62% and a specificity of 95%.
Non-adherence was also measured using a dichotomized score of the five-item Medication Adherence Report Scale (MARS [31], non-adherent when total score ≤23

[22] and [41]) and using pharmacy refill data [42]. Using these data, Medication Possession Ratios (MPR: days of DMARD supply divided by the number of days within an observation period) were calculated [32]. (Calculation) details about the non-adherence measures and *other secondary measures* that might be affected by our intervention [17] are provided in Appendix Table I [33], [34], [35], [36], [37], [38], [39] and [40].
All questionnaires used were validated and had a sufficient level of internal consistency in this RA sample (alpha: 0.68–0.95). Reminders were sent to stimulate patients to fill in the questionnaires.

2.6. Sample size and data analyses

To detect a difference in the BMQ differential score of two points at 12 months' follow-up between the two arms [15], we aimed to include 60 participants in each arm (based on an alpha of 0.05, beta of 0.2, a pilot-derived SD of 3.9, and taking 28% drop-outs into account).
Data analyses were based on the intention-to-treat principle [23], and on complete cases. For all outcomes except refill rates (MPRs), intervention effects were analyzed using generalized estimating equations (GEE [43]) with robust standard errors [44], two-sided p set at 0.05, and an assumed unstructured correlation working matrix. Beforehand, severely skewed outcomes were dichotomized (MARS and SIMS, cut-off at 95% of their scales [22] and [41]). Furthermore, one fixed set of confounders was selected from the baseline measures (selected when visually unbalanced between the arms [45], univariately associated with ≥one outcome measure, and when not strongly correlated to other potential confounders). Time was handled as a dummy variable [46].
Intervention effects as assessed by refill data, and differences between the non-adherent trial participants and the non-adherent patients who refused to participate were tested by means of *t*-tests (unequal variances assumed) or Chi-square tests.
Baseline scores of the initial sample and the remained sample at 12 months' follow-up were compared using standardized mean differences to assess the influence of attrition on the study results [47]. All data analyses were verified by a statistician.

3. RESULTS

3.1. Participants and attrition

1819 RA patients were assessed for eligibility; the participant flow trough the trial is depicted in Fig. 1. The 123 non-adherent, randomized patients did not differ in terms of baseline characteristics and outcome measures from the 118 non-randomized, non-adherent patients.

[FIGURE 1]
Overall attrition in the baseline sample up to 12 months after baseline was 8.9%, and had no influence on the main outcomes of this study.

3.2. Baseline sample characteristics

Most participants were female and lived together with others. A quarter of the total sample was highly educated. Also, participants had a mean disease duration of >14 years (Table 1).

[TABLE 1]

Descriptive data on all outcome measures at baseline and follow-up are presented in appendix Table II.

3.3. Effects of the intervention

Table 2 presents outcomes regarding beliefs about medication and non-adherence at baseline and 12 months' follow-up, and the corresponding adjusted effect sizes.

[TABLE 2]

Generally, no differences in BMQ scores were detected between both arms over time. Only at 12 months' follow-up, participants in the intervention arm did have less strong necessity beliefs about medication than participants in the control arm.
No differences between the two arms could be detected for other secondary outcome measures, except pain and accepting illness cognitions: at one week follow-up, participants in the intervention arm reported less pain (adjusted *b*: −7.8, 95% CI −13.7, −1.8), and stronger accepting illness cognitions (unadjusted *b*: 0.9, 95% CI 0.1, 1.8, adjusted b not significant) than those in the control arm.

3.4. Additional analyses

Three additional analyses were performed.
First, we studied changes in outcomes between the intake meeting and baseline, since we noted that non-adherence had changed between these moments (decreased from 100% of patients being non-adherent, to 65%). It appeared that the balance between necessity – and concern beliefs about medication had improved (paired *t*-test, difference 0.9, 95% CI −0.0, 1.8). Also, the amount of change in CQR adherence in the participants depended on the researchers involved in the inclusion procedure (44% of patients included by researcher 'A' became adherent at baseline, versus 25% of patients included by researcher 'B'; $p = 0.03$). This association was also reflected in the refill rates: the mean refill rate was 98% at baseline, and 104% at 12 months' follow-up in those patients included by researcher 'A', versus 100% and 93% by researcher 'B', respectively ($p < 0.05$, paired two sample *t*-test).
Second, in a sensitivity analysis, we found that the direction of our results did not change when excluding patients who were medication-adherent at baseline.
Third, treatment integrity analyses were performed (Appendix I). 49% of the intervention content, as described in the intervention protocol [13] was conducted. In practice, participants had a greater need for education about medication than for discussions about medication use; the intervention leaders felt it was important to

serve this need. The degree of patient-centeredness during the intervention was 3.1 on a scale of 0 ('not at all') to 4 ('a great extent').

4. DISCUSSION AND CONCLUSION

4.1. Discussion

This study evaluated the effects of a short, group-based intervention, which primarily aimed to change the balance in beliefs about medication, and subsequently, to improve medication adherence to DMARDs in non-adherent patients with RA. However, the intervention was not superior to the control arm in changing beliefs or improving adherence.

Our results are in line with the systematic review by Haynes and colleagues [9], which states that most existing interventions to improve medication adherence are not particularly effective. However, our results do not correspond with the studies by Clifford and Bender [15] and [48], who found that their telephone interventions elicited more positive beliefs about medication and better adherence than the control condition. Since baseline measures were missing [15] or no long term effects had been examined [48] in these studies, however, our results seem to be more solid. To place our results in context, more studies about the effectiveness of targeting beliefs about are needed, though.

There are several explanations for the absence of intervention effects.

First, there may not have been sufficient room for improvement in beliefs and adherence: beliefs and adherence had already favorably changed before the actual intervention took place. This might have been due to the phenomenon of 'regression to the mean' [49], Hawthorne effects [50], but also to our intake meeting [51], a notion supported by the correlation between the change in adherence and the two researchers involved during intake.

Second, although we established a good level of patient-centeredness, the total treatment integrity level of our intervention was suboptimal. This might have affected our study results. In contrast, it is still unknown to what extent a suboptimal treatment integrity level affects treatment outcomes [28], so more research into the topic of treatment integrity is needed.

Third, this trial suffered from selection bias by including patients with a long disease duration (mean: >14 years). *Modifying existing* beliefs and adherence behaviors in patients with such a long disease duration might be harder to establish than *forming new* beliefs and behavior in recently diagnosed RA patients who are, essentially, busy with adopting a new lifestyle [52].

Last, ineffectiveness of our intervention might be due to focusing on patient-related factors only, while non-adherence is also caused by other types of factors according to the WHO [14]. Targeting beliefs about medication in RA patients, however, still remains an understandable choice according to a recent systematic review of Pasma et al. [53], indicating beliefs about medication to be one of the most relevant and *modifiable* determinants of non-adherence in RA patients.

This study has both limitations and strengths regarding internal validity. Non-adherence rates differ according to the questionnaires and the refill rates, for example (60% versus 1.5% non-adherence). The refill rate, however, is a medication

possession measure, rather than a medication adherence measure [54]. Moreover, a strong feature of this trial is the combination of three different adherence measures [55]. Neither the self-report questionnaires nor the refill rate data showed superiority of the intervention arm over the control arm in changing beliefs or adherence, indicating robustness of findings.
This study has also strengths and limitations regarding external validity. A limitation is that we do not know if our non-adherent trial participants represent non-adherent RA patients in general, since no comparison material is available. A strength was the low attrition rate in our trial [56].

4.2. Conclusion

This trial did not demonstrate superiority of our intervention over the control arm in changing beliefs about medication, in improving medication adherence or in improving any other secondary outcome measures over time.

4.3. Practice implications

Beliefs about medication are relevant and modifiable determinants of non-adherence in RA patients. Hence, the potential value of targeting beliefs about medication and practical barriers to take medication in improving medication adherence should not yet be ruled out in clinical practice. Ineffectiveness of our intervention, namely, might have been due to selection bias, Hawthorne effects, and a suboptimal level of treatment integrity. Further research on other types of interventions which are embedded in clinical practice (non-trial setting) and with early RA-patients is warranted.
I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

CONFLICT OF INTEREST
None.

FUNDING
None.

ACKNOWLEDGEMENTS
We would like to thank all patients for participating in this trial. We would also like to thank Victor Huiskes for leading some of the group sessions.

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TABLES AND FIGURES

Fig. 1. Participant flowchart.

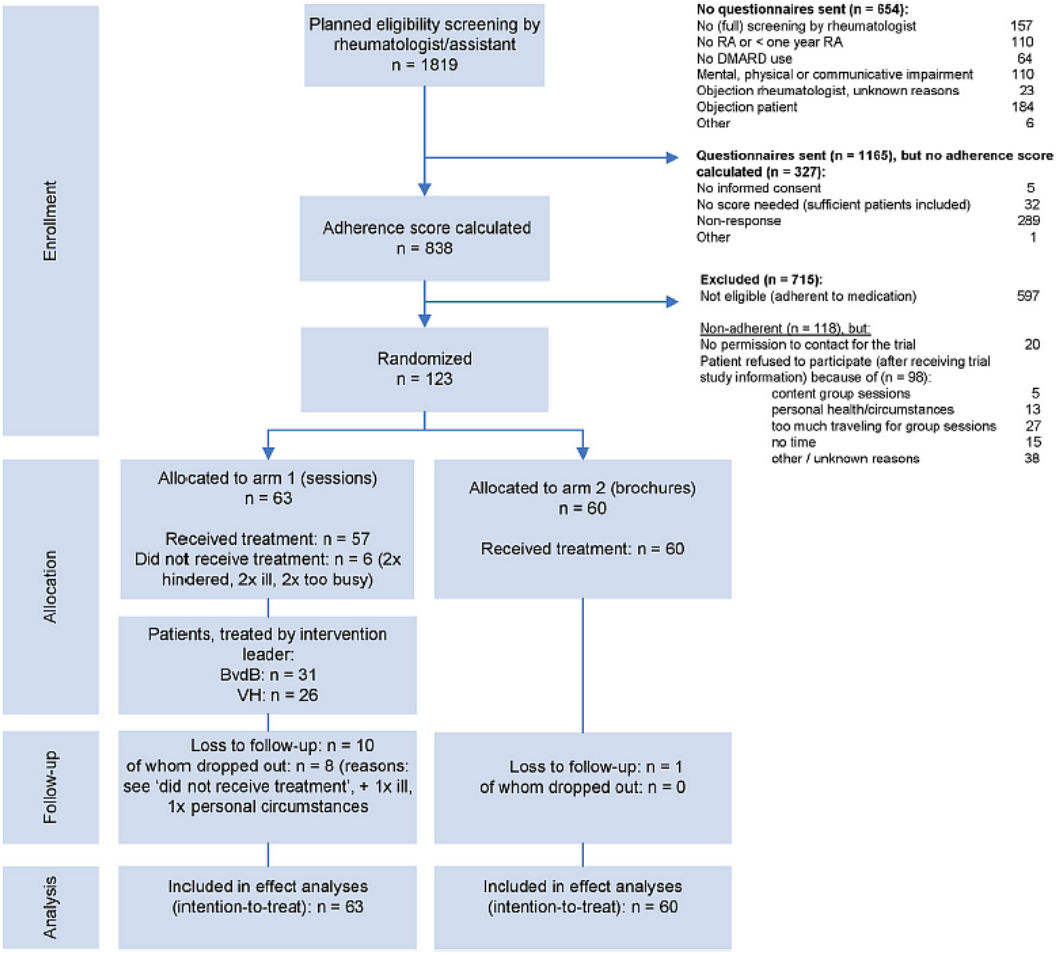

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Table 1
Baseline study sample characteristics.[a]

Characteristics	Arm 1 (sessions), $n=63$	Arm 2 (brochures), $n=60$
Socio-demographic characteristics		
Age (years)	60.4 (12.1)	59.3 (11.3)
Female	42 (66.7%)	43 (71.7%)
Living with others	44 (72.1%)	50 (84.8%)
Higher education[b]	15 (24.6%)	15 (25.4%)
Currently employed/studying	28 (48.2%)	31 (51.7%)
Clinical characteristics		
Disease duration (years)	15.3 (10.5)	14.2 (9.1)
n DMARDs used[c,d]		
1 DMARD	25 (41.7%)	36 (61.0%)
2 DMARDs	29 (48.3%)	17 (28.8%)
≥ 3 DMARDs	6 (10.0%)	6 (10.2%)
Route of DMARD administration		
Oral[c]	43 (71.7%)	34 (57.6%)
Parenteral[d]	41 (68.3%)	38 (64.4%)
Rheumatoid factor (positive)	29 (78.4%)[e]	30 (79.0%)[e]
Anti-CCP (positive)	24 (72.7%)[e]	24 (68.6%)[e]
RADAI disease activity (0–10)[f]	2.5 (1.7)[e]	2.5 (1.9)[e]
VAS pain score (0–100 mm)[f]	27.2 (19.2)	26.8 (21.0)
HAQ Disability Index (0–3)[f]	1.0 (0.7)	0.9 (0.7)

[a] Data are means (SD) or numbers (%).
[b] Higher education means having at least a bachelor's or master's degree.
[c] Azathioprine, hydroxychloroquine, leflunomide, methotrexate, prednisone/prednisolone or sulfasalazine.
[d] Adalimumab, depomedrol, etanercept, methotrexate, abatacept, infliximab, or mabthera. Four patients received infusion mono-therapy.
[e] >10% missing data. Number of non-missing cases in intervention and control arm is 37/38 for the rheumatoid factor, 33/35 for anti-CCP, and 51/52 for the RADAI score, respectively.
[f] Higher scores = greater disability/disease activity/pain.

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Table 2
Adjusted effect sizes for beliefs about medication and medication non-adherence, 12 months after the intervention.[a]

Measures	T0: baseline, $n=119$		T3: 12-month follow-up, $n=115$		Adjusted effect size
	Arm 1 (sessions)	Arm 2 (brochures)	Arm 1 (sessions)	Arm 2 (brochures)	b (95% CI)[b]
Beliefs about medication					
BMQ specific necessity (5–25)[c]	18.8 (3.6)	18.8 (3.3)	18.2 (3.8)	19.1 (3.3)	−1.0 (−2.0, −0.1)[e]
BMQ specific concerns (5–25)[c]	13.3 (3.4)	14.3 (3.3)	12.8 (3.5)	13.6 (3.5)	0.0 (−1.0, 1.1)
BMQ differential (−20 to +20)[d]	5.6 (4.7)	4.6 (4.8)	5.5 (5.1)	5.5 (4.2)	−1.1 (−2.4, 0.3)
BMQ general overuse (4–20)[c]	11.0 (2.5)	11.1 (2.7)	10.6 (2.8)	10.9 (2.5)	−0.2 (−1.1, 0.7)
BMQ general harm (4–20)[c]	9.9 (2.5)	10.0 (2.6)	9.8 (2.5)	10.1 (2.3)	−0.2 (−0.9, 0.5)
Measures	T0: baseline, $n=119$		T3: 12-month follow-up, $n=115$		Adjusted effect size
	Arm 1 (sessions)	Arm 2 (brochures)	Arm 1 (sessions)	Arm 2 (brochures)	OR (95% CI)[b]
Medication non-adherence					
CQR, non-adherent	36 (62.1%)	40 (67.8%)	28 (50.9%)	29 (49.2%)	1.3 (0.5, 3.3)
MARS, non-adherent	32 (54.2%)	33 (56.9%)	30 (54.6%)	28 (46.7%)	1.7 (0.8, 3.8)
Measures	T0: baseline, $n=119$		T3: 12-month follow-up, $n=115$		Adjusted effect size
	Arm 1 (sessions)	Arm 2 (brochures)	Arm 1 (sessions)	Arm 2 (brochures)	Difference in means (95% CI)[f]
% Refill adherence	94.4%	103.1%	96.6%	102.0%	2.2% (−11.1%, 15.6%)

[a] Descriptive data are means (SD) or numbers (%). Effect sizes (except for refill rate adherence) adjusted for age, sex, living with others yes/no, disease duration, parenteral medication yes/no, and baseline depression score (HADS).

[b] Regression coefficient or odds ratio (OR) with 95% confidence interval for the difference in outcome values between the intervention arm and control arm at 12 months' follow-up, corrected for baseline. Control arm = reference category. OR: odds of being non-adherent at 12 months' follow-up is smaller (OR < 1) or bigger (OR > 1) for participants in the intervention arm in comparison with participants in the control arm.

[c] Higher scores indicate stronger beliefs.

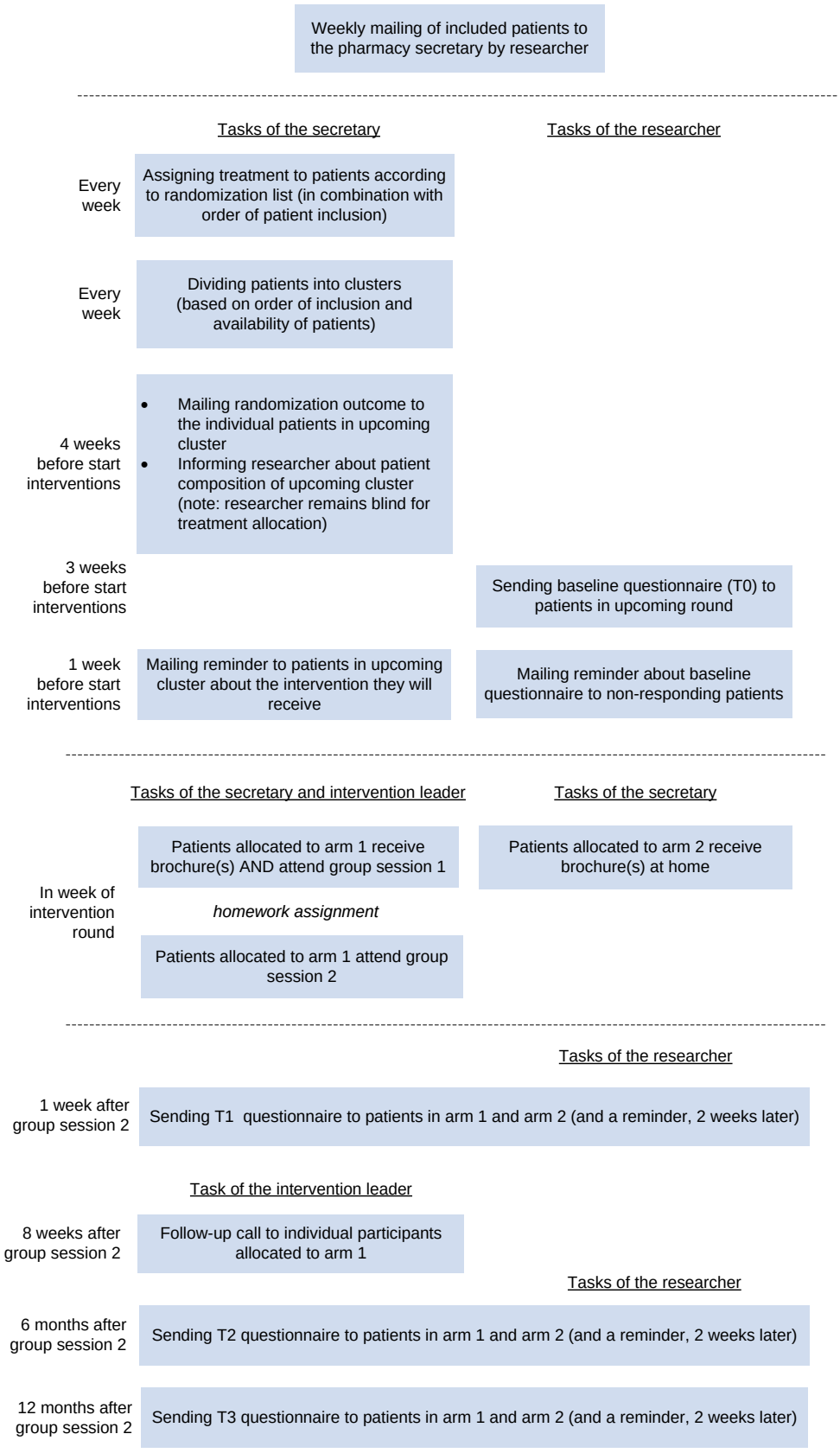
[d] Positive scores mean that necessity beliefs about medication are stronger than concern beliefs about medication, and vice versa.

[e] p value ≤ 0.05.

[f] The mean change in refill adherence in participants in the intervention arm minus the mean change in refill adherence in participants in the control arm.

APPENDIX

Appendix figure I – Trial randomization and implementation process



Appendix table SI – Treatment integrity: checklist and scores

	Audio sessions of intervention leader A or B							
	***A** 11-1-2011*	***A** 18-1-2011*	***B** 15-3-2011*	***B** 22-3-2011*	***A** 4-2-2011*	***A** 11-2-2011*	***B** 25-3-2011*	***B** 1-4-2011*
FIRST GROUP SESSION (omission)	1 = addressed/yes 0 = not addressed/no n.r. = not recorded n.a. = not applicable/not brought up by patients							
Welcome								
Explaining background of the group sessions								
Exchanging experiences, thoughts, feelings, advantages, and disadvantages relating to the medication & medication use	1		1		1		0	
Provision of information about medicines by the intervention leader, whenever participants feel the need for this information	1		1		1		1	
Intervenion leader emphasizes that he does not wish to dictate how medication should be used by the participants	0		1		0		0	
Intervenion etiquette: intervention leader explains that:								
experiences should be exchanged in an open, honest, and respectful way	0		1		1		0	
participants should not try to convince each other	0		0		0		0	
participants should actively contribute	1		1		1		0	
Getting to know each other								
Participants interview each other for about 15 minutes	1		1		1		1	
Aim of the group sessions								
To talk about the use of medication (including the fact that many patients skip medication doses, and the consequences of skipping doses)	1		1		1		1	
Discussing the necessity of using medication, concerns about medication, and practical barriers to taking medication	0		0		0		0	
Introduction of the simple behavioral model								
Explaining the meaning and role of a behavioral model in general	1		1		1		1	

Appendix table SI – Treatment integrity: checklist and scores (continued)

	Audio sessions of intervention leader A or B							
	***A** 11-1-2011*	***A** 18-1-2011*	***B** 15-3-2011*	***B** 22-3-2011*	***A** 4-2-2011*	***A** 11-2-2011*	***B** 25-3-2011*	***B** 1-4-2011*
FIRST GROUP SESSION (omission)	1 = addressed/yes 0 = not addressed/no n.r. = not recorded n.a. = not applicable/not brought up by patients							
Specification and personalization of the simple behavioral model								
Explanation of the behavioral model, applied to the use of medication	1		1		1		1	
Short, plenairy brainstorm session: participants state advantages, disadvantages and practical barriers regarding medication & medication use. The intevenion leader clusters these elements (advantages, disadvantages, practical barriers) into the simple model	1		1		1		1	
Developing an inventory of beliefs about medication in pairs								
Intervention leader emphasizes that no-one should interrupt other participants	0		0		0		0	
Intervention leader emphasizes that no-one should try to convince other participants	0		0		0		0	
All beliefs/barrieres are written down (in pairs), and, together with all participants, clustered into advantages, disadvantages, and practical barriers	1		1		0		1	
The intervention leader asks each participant to indicate their two most important beliefs and barrierrs	1		1		1		1	
Participants and intervention leader offer solutions for overcoming practical barriers to taking medication	1		1		1		1	
Explaining the homework assignment								
Aim of the homework assignment (rethinking one's own beliefs and barriers regarding medication/medication use & being well prepared for the second group session)	1		0		1		1	
Evaluation and closure of first session								
Group looks back at this first session and their experiences during this session	1		0		1		1	
The intervention leader asks if participants feel that tey were able to ask and say whatever they wanted during this session	0		0		0		0	
TREATMENT INTEGRITY SCORE FIRST GROUP SESSION: 63% (20 items; maximum score = 80 points, true score = 50 points)								

Appendix table SI – Treatment integrity: checklist and scores (continued)

	Audio sessions of intervention leader A or B							
	A *11-1-2011*	***A*** *18-1-2011*	***B*** *15-3-2011*	***B*** *22-3-2011*	***A*** *4-2-2011*	***A*** *11-2-2011*	***B*** *25-3-2011*	***B*** *1-4-2011*
SECOND GROUP SESSION (omission)	1 = addressed/yes	0 = not addressed/no	n.r. = not recorded	n.a. = not applicable/not brought up by patients				
Welcome								
Reflections on the first group session (including reference to any group-specific events)		0		0		0		1
Intervention etiquette: emphasizing the desire for open, respectful and non-threatening interactions, and the need for participants to avoid interrupting and trying to convince others		1		0		0		0
Repeating the themes of the first group session		0		1		0		1
Briefly repeating the simple, behavioral model								
Briefly repeating the model		1		0		1		0
Presentation by rheumatologist, discussion of beliefs and barriers raised within the group, answers to questions								
Presentation by the rheumatologist about rheumatoid arthritis (RA), medication, and the necessity of using RA medication		1		n.r.		1		n.r.
Participants are able to ask questions about RA and the necessity of taking RA medication		1		1		1		1
Beliefs and barriers as mentioned in the first group session are repeated by the intervention leader		1		1		0		1
Intervention leader asks the participants if their medication beliefs have changed in response to the rheumatologist's presentation		0		0		0		0
The information provided by the rheumatologist is compared with the medication beliefs mentioned in the first group session		1		0		0		0
Group specific medication concerns and barriers are discussed		1		1		1		1
At the end of this part of the session, participants are given the opportunity to raise questions, doubts, and ambiguities		1		1		1		1
Individual input from participants regarding their own beliefs and barriers								
Each participant describes his/her most important necessity and concern beliefs, and practical barriers regarding medication taking		1		1		1		1
The intevention leader states that participants are allowed to respond to each other in an open, respectful and non-threatning manner (i.e., without trying to convince, etc.)		0		0		0		0

Appendix table SI – Treatment integrity: checklist and scores (continued)

	Audio sessions of intervention leader A or B							
	A *11-1-2011*	***A*** *18-1-2011*	***B*** *15-3-2011*	***B*** *22-3-2011*	***A*** *4-2-2011*	***A*** *11-2-2011*	***B*** *25-3-2011*	***B*** *1-4-2011*
SECOND GROUP SESSION (omission)	1 = addressed/yes 0 = not addressed/no n.r. = not recorded n.a. = not applicable/not brought up by patients							
The intervention leader:								
places the listed beliefs and barriere in the simple behavioral model, together with the participant		0		0		0		0
asks the participants what their beliefs are based on		0		0		0		0
asks the participant if the rheumatologist or intervention leader may provide information about the participant's beliefs, if these are unrealistic		0		0		0		0
asks the participant which of his/her beliefs are most important to him/her, and why this is the case		0		0		0		0
describes contradictions in the information provided by the participant, in a non-threatning, empathic way		0		0		0		0
Evaluation and closure of second session								
Intervention leader describes 'actions to take if medication use seems difficult in the future'		0		0		0		n.r.
The intervention leader asks each participant concrete questions to evaluate the group sessions		0		1		1		n.r.
o In what way did you benefit from the group sessions?		0		1		1		n.r.
o Which of your beliefs about medication have been changed?		0		0		0		n.r.
o What did you feel was missing from the group sessions? Were you able to say anything that you wanted to say?		0		0		0		n.r.
If a participant states that he/she intends to improve medication use: intervention leader stimulates participant to make a concrete action plan ('where and how will you conduct behavior changes?')		n.a.		n.a.		n.a.		n.r.
Intervention leader explains procedure for the follow-up call by the pharmacist		1		1		1		n.r.
Intervention leader briefly repeats the medication concerns raised within the group, and provides some reassuring information		0		0		0		n.r.
Intervention leader tells participants where they can find additional information about medication		0		1		1		n.r.
GENERAL: in one of the two group sessions, the intevention leader mentions the personal DMARD brochures that the participants received	0		1		0		0	
TREATMENT INTEGRITY SCORE SECOND GROUP SESSION: 39% (28 items; maximum score = 98 points (14 x not recorded or not applicable), true score = 38 points)								
MEAN TREATMENT INTEGRITY SCORE: 49 % (48 items; maximum score = 178 points, true score = 88 points)								

Appendix table SI – Treatment integrity: checklist and scores (continued)

	Audio sessions of intervention leader A or B							
	A *11-1-2011*	***A*** *18-1-2011*	***B*** *15-3-2011*	***B*** *22-3-2011*	***A*** *4-2-2011*	***A*** *11-2-2011*	***B*** *25-3-2011*	***B*** *1-4-2011*
Degree of patient-centeredness (BECCI)	*0 = not at all 1 = minimally 2 = to some extent 3 = a good deal 4 = a great extent n.a. = not applicable*							
Domain 1: agenda-setting and permission-seeking								
1. The practitioner invites the patient to talk about behavior change	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2. The practitioner demonstrates sensitivity to talking about other issues	4	4	4	4	4	4	3	3
Domain 2: the why and how of change in behavior								
3. Practitioner encourages patient to talk about current behavior or status quo	3	2	1	1	2	3	2	4
4. Practitioner encourages patient to talk about behavior change	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
5. Practitioner asks questions to elicit how patient thinks and feels about the topic	4	4	4	4	4	4	3	4
6. Practitioner uses empathic listening statements when patient talks about the topic	4	4	4	4	4	4	4	4
7. Practitioner uses summaries to bring together what the patient says about the topic	1	1	1	1	1	1	1	2
Domain 3: the whole consultation								
8. Practitioner acknowledges challenges about behavior change that the patient faces	3	2	3	2	3	3	3	3
9.When practitioner provides information, it is sensitive to patient concerns and understanding	4	4	4	4	3	4	4	4
Domain 4: talk about targets								
10. Practitioner actively conveys respect for patient choice about behaviour change	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
11. Practitioner and patient exchange ideas about how the patient could change current behavior	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
**The intervention does not focus on changing behavior, but on changing beliefs about medication . Therefore, BECCI-items 1, 4, 10 and 11 are not scored.*								