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## Development and content of a group-based intervention to improve medication adherence in non-adherent patients with rheumatoid arthritis

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### ABSTRACT

**Objective:** To describe the systematic development and content of a short intervention to improve medication adherence to disease-modifying anti-rheumatic drugs in non-adherent patients with rheumatoid arthritis (RA).

**Methods:** The intervention mapping (IM) framework was used to develop the intervention. The following IM steps were conducted: (1) a needs assessment; (2) formulation of specific intervention objectives; (3) inventory of methods and techniques needed to design the intervention and (4) production and piloting of the intervention.

**Results:** The intervention (consisting of two group sessions led by a pharmacist, a homework assignment, and a follow-up call) aims to improve the balance between necessity and concern beliefs about medication, and to resolve practical barriers in medication taking. The central communication method used is motivational interviewing.

**Conclusion:** By applying the IM framework, we were able to create a feasible, time-efficient and promising intervention to improve medication adherence in non-adherent RA patients. Intervention effects are currently being assessed in a randomized controlled trial.

**Practice implications:** This paper could serve as a guideline for other health care professionals when developing similar interventions. If the RCT demonstrates sufficient effectiveness of this intervention in reducing medication non-

adherence in RA patients, the intervention could be embedded in clinical practice.

## 1. INTRODUCTION

Adherence to disease-modifying anti-rheumatic drugs (DMARDs) in patients with rheumatoid arthritis (RA) (a chronic polyarthritis often leading to joint damage) is not optimal and ranges from 58% to 82%<sup>[1]</sup>,<sup>[2]</sup> and<sup>[3]</sup>. Taking DMARDs as prescribed can, however, limit or prevent disease activity, pain, joint and radiological damage, and can improve long term functional outcome in RA patients. DMARDs can also cause side effects, such as gastro-intestinal complaints, low white blood counts, and abnormal liver function tests<sup>[4]</sup>. These side effects, amongst other factors, may contribute to non-adherence to DMARDs, which can have serious consequences. Non-adherence reduces treatment efficacy, which in turn can result in unnecessary disease activity, joint/radiological damage, and loss of function<sup>[5]</sup>,<sup>[6]</sup> and<sup>[7]</sup>. Moreover, the annual costs of non-adherence for all conditions in the USA have been estimated to be \$100 billion<sup>[8]</sup>. In view of the negative implications of medication non-adherence, this behavior thus should be addressed.

To date, evidence supporting the effectiveness of health interventions to improve medication adherence in RA and other chronic illnesses remains inconclusive<sup>[9]</sup> and<sup>[10]</sup>. The effectiveness of a medication adherence intervention in RA has been assessed in three studies<sup>[11]</sup>,<sup>[12]</sup> and<sup>[13]</sup>. Only one of these studies demonstrated a slight improvement in adherence to D-penicillamine after a patient education program<sup>[12]</sup>. This program, however, was intensive (51 individuals, 6×30 min) and time-inefficient, as it was not group-based and it was intended for both adherent and non-adherent patients. Moreover, all three studies lacked a description of the development process and grounding of these interventions in empirical evidence, theory, and practice perspectives. Consequently, internal and external validity of these interventions is insufficiently guaranteed.

The aim of the present paper is to transparently describe the systematic development and content of a short, time-efficient intervention to improve medication adherence to DMARDs in non-adherent RA-patients. The intervention consists of two motivational interviewing-guided<sup>[14]</sup> group sessions led by a pharmacist, aimed at improving the individual patient's balance between necessity and concern beliefs about medication and at resolving practical barriers in medication taking. We used the intervention mapping framework<sup>[15]</sup> (a common framework not yet used in RA interventions) to systematically apply theories, empirical evidence, and practice perspectives in the development of the intervention.

## 2. METHODS

Intervention mapping (IM) comprises six steps, each leading to a product that guides the next step. Fig. 1 (derived from Brug and colleagues<sup>[16]</sup>) depicts these steps and their operationalization during our development process.

### [FIGURE 1]

The IM framework was chosen because it (1) enhances the formulation of intervention objectives based on empirical evidence and/or theory; (2) covers all the important objectives; (3) links final materials and activities to theory; and (4) ensures

the intervention is compatible with the target population<sup>[17]</sup>. IM has already been used successfully in, for example, asthma management, HIV prevention, and sun protection<sup>[18]</sup>.

In the present study, the IM steps were conducted by members of a multidisciplinary task group, consisting of pharmacists, researchers, psychologists, rheumatologists, experts on motivational interviewing, and RA patients. Two task group members [WvL, BvdM] were responsible for the daily coordination; final decisions regarding the development process and output of the IM steps were reached through discussion in task group meetings.

This section describes how each IM step was operationalized.

### **2.1. Needs assessment – analysis of determinants**

Possible targets of the intervention were identified by carrying out a literature study, a cross-sectional study, and a focus group study about medication non-adherence and possible determinants among RA patients.

The literature study<sup>[19]</sup> was based on publications about determinants of medication non-adherence in RA that were retrieved from Pubmed, PsychInfo, Embase and Cinahl [BvdB/BvdM]. The search strategy included all possible search terms (MeSH and text word) for rheumatoid arthritis, medication non-adherence, compliance, and persistence.

For the cross-sectional study [BvdB]<sup>[20]</sup>, 228 consecutive RA patients on DMARD therapy treated in the St. Maartenskliniek (a clinic specialized in rheumatology, rehabilitation and orthopedic surgery) completed questionnaires to examine the prevalence and possible determinants of non-adherence, including demographics, coping, beliefs about medication, satisfaction about medicine information, and physical functioning. Non-adherence was measured with the Compliance Questionnaire Rheumatology (CQR<sup>[21]</sup>) and the Medication Adherence Report Scale (MARS<sup>[22]</sup>).

To gain in-depth insight into possible determinants of non-adherence, two patient focus groups led by two psychologists [WvL/BvdM] were organized to discuss necessity and concern beliefs about medication, the need for education, experienced social support, and practical barriers as perceived by RA patients. The focus groups (seven patients per group) consisted of a non-selective sample of fourteen non-adherent RA patients (selected according to CQR data of the cross-sectional study, with non-adherence being defined as taking <80% of prescribed medications).

### **2.2. Intervention objectives**

The results of the needs assessment were discussed during task group meetings. Subsequently, modifiable determinants of non-adherence relevant to our target group (adult, non-adherent RA patients taking DMARDs) were selected as targets for the intervention. To achieve the overall aim of the intervention (improving participants' medication adherence), specific intervention objectives (Section<sup>3.2</sup>) were formulated for each determinant to identify exactly *what* needed to change during the intervention.

### **2.3. Health behavior change methods and techniques**

Literature about established communication – and health behavior (change) models, – methods and – theories was studied [GB], to identify appropriate methods and

techniques in accordance with the specific intervention objectives. Based on this literature study, the task group selected health behavior change methods and techniques to be used during the intervention.

#### **2.4. Intervention content and pilot**

The intervention objectives and selected methods and techniques were combined in a single plan [GB], namely the intervention protocol. Draft versions of this intervention protocol were discussed during task group meetings, resulting in the final version of the intervention protocol. Based on this final intervention protocol, materials were developed, such as a participant workbook with homework assignments (Section <sup>3.4</sup>).

The feasibility of the intervention (consisting of two consecutive group sessions, see Section <sup>3.4</sup>) was examined by piloting the intervention twice. A non-selective sample of twelve adult, non-adherent RA patients (based on CQR data of the cross-sectional study) was recruited for the pilot. The pilot was attended by an expert panel, consisting of two psychologists, and a patient panel (independent advisory board comprising two RA patients familiar with scientific research). A global checklist and a patient satisfaction questionnaire were developed [BvdM] to assess the communication style of the intervention, transparency of information, and satisfaction about general intervention characteristics, such as session duration and group size.

#### **2.5. Implementation and evaluation of the intervention**

Implementation of the intervention was facilitated by (1) the pilot of the intervention (Section <sup>2.4</sup>) and (2) the task group participation of rheumatologists and pharmacists responsible for carrying out the intervention in clinical practice. Furthermore, a practical workbook for use during the intervention was written for these rheumatologists and pharmacists (Section <sup>3.4</sup>). To check treatment integrity, audio-taped intervention sessions will be analyzed.

To objectify intervention effects on treatment outcomes, a research proposal was drafted for a randomized controlled trial (Section <sup>3.5</sup>).

### **3. RESULTS**

#### **3.1. Needs assessment – analysis of determinants**

##### *3.1.1. Literature study*

The literature study into the empirical determinants of medication non-adherence in RA revealed that non-adherence is a multidimensional phenomenon, with determinants not consistently associated with non-adherence across studies <sup>[19]</sup>.

Although regimen complexity, a poor patient–provider relationship, costs of drugs, lack of social support, a low level of self efficacy, and beliefs about medication (including perceived (side) effects of medication) tend to be associated with medication non-adherence, these associations are often weak.

Recently, determinants of medication non-adherence have been conceptualized as ‘unintentional’ or ‘intentional’ factors of non-adherence <sup>[19]</sup>. Unintentional non-adherence reflects a person's lack of ability and skills to take medicines, including forgetting or poor manual dexterity <sup>[23]</sup>, while intentional non-adherence is driven by

a decision not to take medicines as prescribed. It is assumed that adherence decisions are influenced by a cost–benefit assessment in which personal beliefs (assumptions and convictions that are believed to be true by an individual) about the necessity of the medication for maintaining or improving health are balanced against concerns about the potential adverse effects of taking the medication <sup>[24]</sup>. It should be noted, however, that this cost–benefit assessment may be implicit rather than explicit and unconscious rather than conscious <sup>[25]</sup> and <sup>[26]</sup>. Nevertheless, targeting intentional non-adherence (beliefs about medication) as well as unintentional non-adherence (e.g., practical barriers) might improve medication adherence <sup>[27]</sup> and <sup>[28]</sup>.

### 3.1.2. Cross-sectional study

In the cross-sectional study, an association between beliefs about medication and non-adherence was confirmed for *necessity* beliefs about medication <sup>[20]</sup>. Adherent patients had higher mean necessity scores than non-adherent patients (20.3 versus 19.1;  $p = 0.02$ ). Moreover, patients with recent onset RA were more adherent than patients with a longer RA duration (76% and 62%, respectively;  $p = 0.05$ ). Furthermore, adherent patients (according to the CQR) reported fewer adverse medication effects than non-adherent patients.

Although >90% of patients had one or more concerns about their medication, concern beliefs about medication were not associated with non-adherence. This also applied to satisfaction about information, coping, physical functioning, and demographics.

### 3.1.3. Focus groups

The focus groups revealed that all participants had necessity beliefs and concern beliefs about medication. Although the nature of beliefs varied highly between individuals, almost all patients perceived medications as a ‘necessary evil’ and as ‘chemical junk’. Almost half of the participants appeared to experiment with their medication to find a balance between taking it (because of the inevitable necessity) and not taking it (because of (possible) adverse effects).

Participants reported that they preferred receiving oral information about RA and medications from peers and rheumatologists rather than receiving written information. Additionally, participants stressed the importance of practical support from their spouses in overcoming practical barriers such as forgetfulness, difficulties in opening pill strips and bottles, difficulties with cooling medication on holidays, and difficulties with injecting medicines.

## 3.2. Intervention objectives

Based on the needs assessment, the task group selected determinants as targets of the intervention. These determinants are shown in <sup>Table 1</sup>, along with their corresponding intervention objectives.

### [TABLE 1]

The task group chose only to target *modifiable* determinants or resolvable practical barriers in medication taking, and therefore non-adherence determinants like a poor patient–provider relationship or costs of drugs were not selected as intervention

targets. However, the task group found beliefs about medication to be a promising intervention target, since most published interventions failed to systematically target such beliefs and since beliefs about medication played a significant role in all three sub-studies of our needs assessment. Furthermore, since our focus groups revealed that most RA patients experience practical barriers in medication taking, several task group members suggested that effectiveness of adherence interventions could be increased by targeting both intentional non-adherence (i.e., beliefs about medication) and unintentional non-adherence (i.e., practical barriers).

To accomplish the central intervention objectives, three prerequisites (defined as 'enabling determinants') should be met. Two out of three prerequisites were derived from the needs assessment by the task group: (1) 'social influence' had to be incorporated into the intervention, because our focus groups revealed that RA patients prefer receiving oral information about RA and medications from peers and rheumatologists rather than receiving written information; (2) self-efficacy in taking medication should be enhanced. According to the literature study, poor self-efficacy correlates with non-adherence, and the task group therefore assumed that enhancing self-efficacy may help patients to overcome their practical barriers. The last prerequisite, which is unrelated to the outcome of the needs assessment ('RA patients should have adequate knowledge about RA, RA medication, and non-adherence') was suggested by the task group because they felt that adequate medication knowledge in patients is important in changing beliefs about medication <sup>[16]</sup>. The task group decided to focus the intervention on adults (as treatment of children with RA in the St. Maartenskliniek was scarce at the time of intervention development) and on patients with a disease duration of longer than one year (as we assumed medication-taking behavior would be more stable). The intervention was not further tailored to subgroups, as the needs assessment found that demographic factors were no strong predictors of non-adherence.

### **3.3. Health behavior change methods and techniques**

To explain the association between beliefs about medication, practical barriers, and medication non-adherence to patients (knowledge objective, see <sup>Table 1</sup>), easy-to-understand patient education was needed. We therefore developed a simple health behavior model (<sup>Fig. 2</sup>), based on elements of the Health Belief Model <sup>[29]</sup> (used in the field of non-adherence <sup>[24]</sup>), and the Integrated Change Model (the latest version of the widely used ASE model (Attitude–Social Influence–Self-efficacy model) in the Netherlands <sup>[30]</sup>).

#### **[FIGURE 2]**

This simple model was also used as a visual tool and as a stepping stone during the intervention (details of use are described in Section <sup>3.4</sup> and in <sup>Table 2</sup>).

#### **[TABLE 2]**

The central communication style of the intervention had to comply with two requirements, derived from the central intervention objectives of 'beliefs' and 'practical barriers':

1. the communication style should be open and non-judgmental. As it could be uncomfortable for patients to talk about their non-adherence, personal beliefs about medication, and their own practical barriers, patients should feel safe to express their thoughts and feelings;
2. the communication style should be suitable for exploring *individual* necessity and concern beliefs about medication and *individual* ambivalence regarding the pros and cons of medication. According to our needs assessment, beliefs vary highly among individuals, and people are more likely to elaborate on information when messages are personalized<sup>[16]</sup>.

The task group decided that motivational interviewing (MI) could be a useful communication style to explore patients' individual ambivalence and the balance between necessity and concern beliefs about medication. MI is a non-judgmental, patient-centered approach that facilitates behavior change by helping patients to explore and resolve their individual ambivalence about behavior change<sup>[14]</sup>. MI has proven to be successful in different individual and group behavioral settings<sup>[31]</sup>,<sup>[32]</sup> and<sup>[33]</sup>.

Expressing empathy, developing discrepancy (e.g., in the balance of necessity and concern beliefs), avoiding argumentation and confrontation, rolling with resistance, and supporting self-efficacy are underlying MI principles<sup>[14]</sup>. These principles can be translated into the following MI techniques: (1) reflective listening; (2) expressing acceptance and affirmation; (3) monitoring patients' readiness to change beliefs and behavior (ensuring that resistance is not generated by pushing patients to change beliefs or behavior); (4) affirming the patient's freedom of choice and self-determination regarding changing beliefs and behavior; and (5) giving the patient a more active role than the intervention leader<sup>[14]</sup>. To master these techniques, our intervention leaders followed a course in MI at a renowned MI center in the Netherlands.

The task group decided on the following intervention format: two MI-guided group sessions (1.5 h each, 5–7 RA patients (a manageable group size) led by a pharmacist, an individual homework assignment between the two sessions (therefore sessions took place one week apart), and a follow-up call by the pharmacist eight weeks after the last group meeting.

The group format was used to accomplish the intervention objectives of 'social influence/modeling' (whereby modeling is a technique in itself) and 'self-efficacy'. People can enhance self-efficacy, for example, by observing and listening to others according to Bandura's social cognitive theory<sup>[34]</sup>). The number of sessions was set at two to keep the intervention short and time-efficient, to enable discussion about the outcomes of the individual homework assignment, and to repeat shared information from the first session, as repeating messages increases the likelihood of information being recalled<sup>[35]</sup>. The aim of the follow-up call also was recall of information. As trustworthy messengers increase the chance of behavior change and adopting messages<sup>[36]</sup>, the task group decided that a pharmacist should lead the interventions and that a rheumatologist should provide education about RA and RA medications (see knowledge objectives in Section 3.2) during the second session.

All developed intervention materials are described in Section <sup>3.4</sup>.

### **3.4. Program development and production**

All separate intervention mapping steps were combined in the intervention protocol [37]. <sup>Table 2</sup> summarizes the protocol content and shows the link between this content and determinants, intervention objectives, methods, and techniques.

In sum, using MI techniques, a pharmacist invited participants to reflect on their own concern and necessity beliefs and on practical barriers regarding DMARD use, to share those beliefs and barriers with their peers in a non-threatening environment and, eventually, to change unrealistic beliefs and to resolve practical barriers. For example, one participant believed that her medication was poisoning her body. The intervention leader, amongst others, acknowledged that DMARDs do have side effects, but he also emphasized that not taking DMARDs as prescribed would do even more harm to her body. The other participants' opinions about this information were subsequently discussed and, in this way, the participant was invited to change her point of view about DMARDs.

All intervention materials and their function are shown in <sup>Table 3</sup>.

#### **[TABLE 3]**

##### *3.4.1. Pilot of intervention*

During the pilot, the expert panel and the patient panel reported that they found the provided information easy to understand and that they appreciated the motivational interviewing communication style, as they found it to be open and non-judgmental. Although accuracy of the applied MI techniques was not checked with a validated instrument like MITI <sup>[38]</sup>, the panels observed a consistent application of MI skills during the intervention. Moreover, overall patient satisfaction about the intervention was high (see <sup>Table 4</sup>). Patients thought that the provided information was transparent and understandable, and found the atmosphere to be relaxed.

#### **[TABLE 4]**

The patients, however, found the number of sessions to be slightly too low. Nonetheless, the number of sessions was not increased as the task group wished to keep the intervention short. The intervention was, however, adapted in response to three concerns expressed by both the expert panel and the patient panel: (1) the intervention leader had to give participants more opportunity to express themselves. As a result, the active role of the participant was emphasized in the intervention leader workbook; (2) at the start of the intervention, the intervention leader should have told participants that it was not compulsory to answer personal questions.

Apparently, this made participants to feel 'unsafe'. Hence, indicating that answering personal questions is not compulsory was explicitly added as action point for the intervention leader in the workbook; (3) the rheumatologist's white coat was considered undesirable, so the workbook was adapted accordingly.

### **3.5. Evaluation of the intervention**

The effects of the intervention will be determined in a single-blind, randomized, controlled trial (number in trial register: <sup>NCT00968266</sup>). 120 eligible, non-adherent RA



patients (non-adherent defined as taking <80% of medication according to the Compliance Questionnaire Rheumatology<sup>[21]</sup>) were randomized into the intervention group or control group. The control group received care as usual in the form of a brochure about currently used medication.

The primary outcome of interest is medication adherence, measured by the Compliance Questionnaire Rheumatology<sup>[21]</sup>, the Medication Adherence Report Scale<sup>[22]</sup> and pharmacy refill rates<sup>[39]</sup> and<sup>[40]</sup>. The primary parameter of interest is beliefs about medication (measured by the Beliefs about Medicine Questionnaire, BMQ<sup>[41]</sup>). Outcomes and parameters are measured at baseline (questionnaires three weeks before start of the experimental and control intervention) and at one week, six months, and one year follow-up after the intervention. The results are expected to be available in 2013.

## 4. DISCUSSION AND CONCLUSION

### 4.1. Discussion

To the best of our knowledge, this is the first study that transparently describes the systematic development and content of a short, time-efficient intervention to improve medication adherence to DMARDs in non-adherent RA patients. The intervention targets the balance between necessity and concern beliefs about medication and tends to resolve practical barriers in medication taking. As medication non-adherence negatively affects patients' disease activity and quality of life, effective interventions to improve adherence are urgently needed.

The development process of this study had several strengths. Initially, this is the first RA medication adherence intervention in which intervention mapping (IM) has been applied and for which the development process has been thoroughly described. IM structured the development process and enabled systematic use of theory, empirical evidence, and practical perspectives in the development of the intervention. In contrast, most development processes for health interventions are characterized by the ad hoc use of theories and empirical evidence<sup>[18]</sup>, or they are only marginally described.

A second strength of our development process was the multidisciplinary nature of the task group, which enabled use of broad knowledge, experiences and visions. Furthermore, sufficient time, staff, and budget were available to allow the task group to thoroughly carry out every step of the IM framework.

A potential limitation of the development process was that it was not as linear as proposed by the IM framework. Parts of step 1 (mapping determinants), step 2 (formulating intervention objectives), and step 3 (collecting health behavior change methods and techniques) were performed in a more parallel rather than sequential manner. However, we do not believe that this parallel approach has affected the quality of our intervention, since designing processes are iterative and recursive in nature<sup>[42]</sup>. Planning models like IM, moreover, are intended to prompt intervention developers to ask themselves the appropriate questions and to make the appropriate decisions<sup>[16]</sup>.

The intervention itself has strong features compared with other motivational interviewing-based interventions for medication non-adherence in chronic diseases such as HIV<sup>[43]</sup>,<sup>[44]</sup>,<sup>[45]</sup> and<sup>[46]</sup>, glaucoma<sup>[47]</sup>, and asthma<sup>[48]</sup>. In contrast to these interventions, our intervention is short and time-efficient: brief interventions might

be as effective as intensive treatments<sup>[49]</sup>. Furthermore, and in contrast to other studies, we only targeted non-adherent patients. This not only makes our intervention more time-efficient, but also makes MI-based communication during the intervention more meaningful. Finally, most previously reported interventions target individual patients during several one-to-one meetings, which is more expensive and not necessarily more effective than group-based formats<sup>[50]</sup> and<sup>[51]</sup>.

However, one could argue that a group format might compromise MI effectiveness as the format might prevent each individuals' specific needs from being met<sup>[14]</sup>.

Nonetheless, this thought is not in line with the demonstrated successes of group-based MI interventions<sup>[31]</sup>,<sup>[32]</sup> and<sup>[33]</sup>. Moreover, our intervention does address

individuals' specific needs, for example through the individual homework assignment and the discussion of individual beliefs and barriers.

Regarding content of our intervention, there is one significant difference with other MI-based interventions for medication non-adherence<sup>[43]</sup>,<sup>[44]</sup>,<sup>[45]</sup>,<sup>[46]</sup>,<sup>[47]</sup> and<sup>[48]</sup>.

Although the latter do address beliefs, knowledge or barriers regarding medication taking, none systematically focus on changing the balance between necessity and concern beliefs about medication. Instead, significant effort is put into mapping participants' motivation for behavior change and into behavioral goal setting.

However, we believe that a realistic balance between necessity and concern beliefs about medication is necessary and that barriers should be addressed before focusing on behavior change.

The focus on changing the balance between necessity and concern beliefs (in addition to resolving practical barriers) is a fairly unique feature of our intervention compared to other MI-based and non-MI-based interventions for non-adherence in chronic conditions. Despite the apparent link between beliefs about medication and non-adherence<sup>[20]</sup>,<sup>[23]</sup>,<sup>[24]</sup>,<sup>[27]</sup>,<sup>[28]</sup>,<sup>[41]</sup>,<sup>[52]</sup> and<sup>[53]</sup>, other interventions fail to (thoroughly) target those beliefs<sup>[9]</sup>.

A potential limitation of the intervention could be the use of a manual during the intervention, as manual-guided MI might be associated with smaller effect sizes<sup>[31]</sup>. This might occur because, for example, the intervention leaders might end a session by drawing up a concrete behavior change plan (as the manual prescribes), regardless of whether patients seemed ready to do so, thereby violating MI itself<sup>[31]</sup>. However, the manual used in our intervention explicitly states that pressuring participants to decide on adherence intentions or to make behavior change plans is not allowed. In fact, acknowledgment of different needs in individual participants is a key feature of our intervention. A major strength of using manuals, moreover, is that they facilitate standardization of the intervention.

## **4.2. Conclusion**

By applying the IM framework, the task group was able to create a unique, efficient and promising intervention to improve medication adherence in non-adherent RA patients. In line with other authors<sup>[15]</sup> and<sup>[18]</sup>, we believe that the IM framework can improve intervention development. Our RCT will indicate whether the intervention has desirable effects on beliefs about medication and non-adherence.

## **4.3. Practice implications**

Pharmacists and rheumatologists who performed the intervention found the intervention feasible. Moreover, general patient satisfaction about the intervention

was high according to the intervention pilot data. Thus, if the RCT demonstrates sufficient effectiveness of this intervention in reducing medication non-adherence in RA patients, the intervention could be embedded in clinical practice.

The content of this paper could serve as guideline for the development of other interventions and could thereby contribute to a meaningful integration of theory, empirical evidence and practice perspectives in interventions.

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#### **CONFLICT OF INTEREST**

None.

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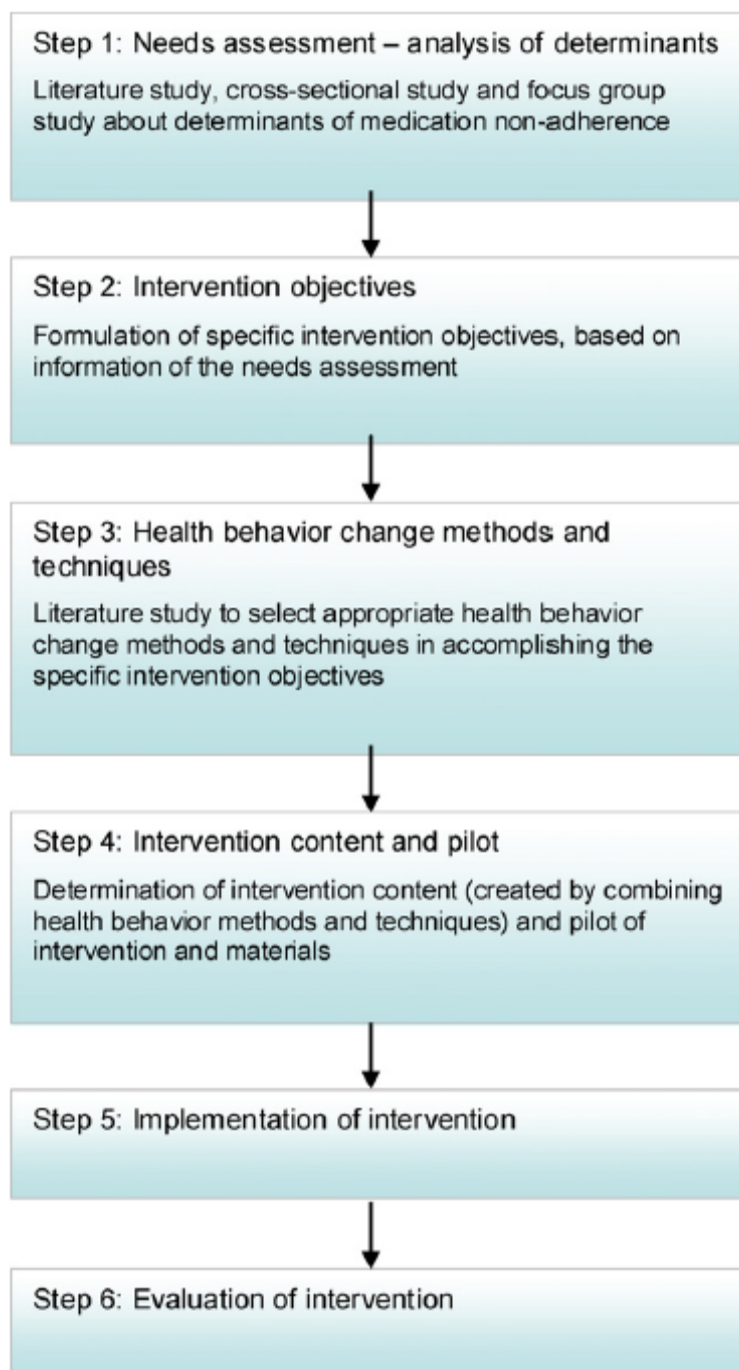
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## TABLES AND FIGURES

Fig. 1. Model of intervention mapping used for intervention development

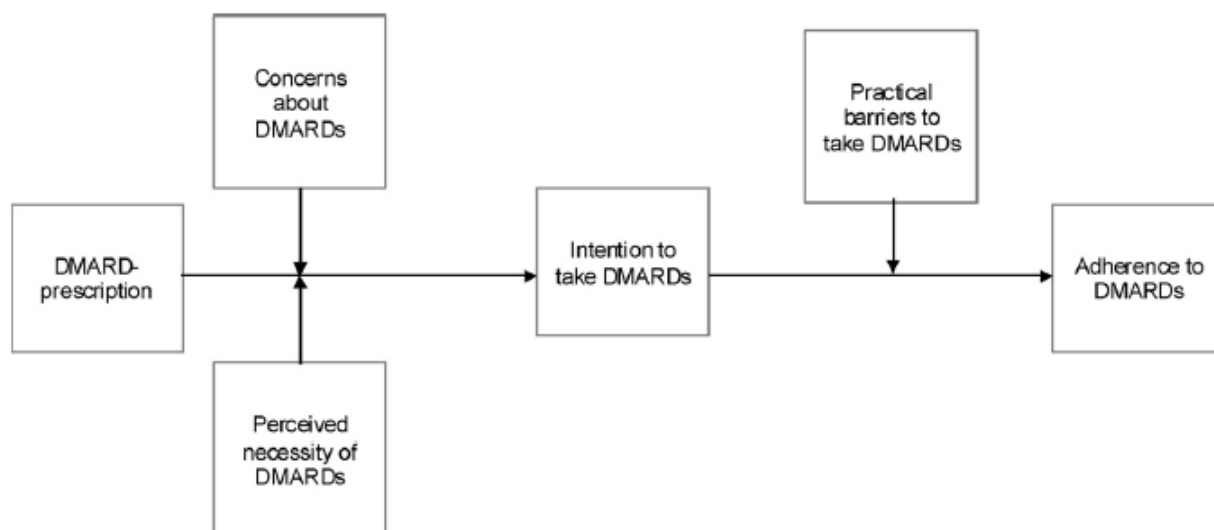


**Table 1**

Determinants and specific intervention objectives.

Overall aim: after the intervention, participants are more adherent in taking their medications as prescribed by their rheumatologist	
After the intervention, participants ...	
<b>Central determinants</b>	
Intentional non-adherence: beliefs about medication	✓ ... have an improved balance between necessity and concern beliefs. That is, participants have stronger necessity beliefs about medication and less unrealistic concern beliefs about medication
Unintentional non-adherence: practical barriers	✓ ... are able to overcome their own practical barriers in using medication
<b>Enabling determinants</b>	
Knowledge	✓ ... have adequate knowledge about RA and RA-medications
Social influence: modeling	✓ ... understand that beliefs about medication and practical barriers contribute to non-adherent behavior
	✓ ... have a clear picture of their own beliefs about medication and practical barriers, by listening and talking to their 'peer participants'
Self-efficacy	✓ ... discussed and obtained skills to overcome their own practical barriers in using medication, so self efficacy is enhanced

Fig. 2. Simple model for guidance during intervention



**Table 2**

Intervention content: function and corresponding determinants, intervention objectives, methods and techniques.

Intervention section	Function	Concerns determinant(s) and intervention objectives (see Table 1)	Used methods and techniques
<b>First group session</b>			
1.1. Welcome	Getting to know each other Understanding intervention etiquettes, content, context and aim intervention. Creating a safe and relaxed atmosphere	–	<ul style="list-style-type: none"> <li>• Trustworthy messenger</li> <li>• Use of PowerPoint</li> </ul>
1.2. Introduction of simple behavior model (Fig. 2)	(See →)	Knowledge: understanding that beliefs about medication and practical barriers contribute to non-adherent medication behavior	<ul style="list-style-type: none"> <li>• Patient education with simple Behavior model (Fig. 2)</li> <li>• Use of PowerPoint</li> </ul>
1.3. Specification and personalization of simple model to participants, regarding beliefs and practical barriers	Making patients think about their own necessity and concern beliefs about medication and barriers in medication taking by means of the simple model (the model was used as visual tool)	All intervention objectives except for self efficacy (see Table 1)	<ul style="list-style-type: none"> <li>• MI-techniques: expressing acceptance and affirmation, giving patients more active role than intervention leader</li> <li>• Simple behavior model as stepping stone</li> <li>• Personalization of information</li> <li>• Modeling</li> <li>• Use of flip-over's (to write down beliefs/barriers inherent in the group)</li> </ul>
1.4. Explaining and conducting homework assignment	Understanding how assignment can be conducted, and how it will be discussed during the second session (in the homework assignment, the participants re-evaluate their own beliefs and barriers to be well prepared for second session)	Beliefs about medication (see Table 1) Practical barriers (see Table 1)	<ul style="list-style-type: none"> <li>• MI-techniques: giving patients more active role than intervention leader, affirming patient's freedom of choice and self-determination (nobody is obliged to decide to change beliefs or non-adherent behavior)</li> <li>• Individual homework assignment, conducted with participant workbook (guides patients in making re evaluating their own beliefs and barriers)</li> <li>• Personalization of information</li> <li>• Repeating information</li> </ul>
1.5. Closure of first session	Sharing of experiences with first session, receiving 'take home' message from intervention leader	–	<ul style="list-style-type: none"> <li>• Repeating information</li> </ul>
<b>Second group session</b>			
2.1. Welcome	Reflecting on previous session, hearing about content second intervention	–	<ul style="list-style-type: none"> <li>• Repeating information</li> </ul>
2.2. Shortly repeating simple behavioral model (see Fig. 2) and beliefs/barriers	'Warming up': memorizing the behavioral model and the beliefs/barriers, inherent in the group in the first session. Rheumatologist can use this information in his presentation (see Section 2.3)	All the intervention objectives in Table 1 except for self efficacy	<ul style="list-style-type: none"> <li>• Repeating information</li> <li>• Simple behavior model (see Fig. 2)</li> <li>• Use of PowerPoint</li> </ul>
2.3. Presentation of rheumatologist and discussing beliefs/barriers, living in the group	Learning about RA and medication (use) from a rheumatologist, comparing beliefs and barriers as mentioned in session 1 with information of the rheumatologist, asking questions to rheumatologist	All the intervention goals in Table 1 except for self efficacy	<ul style="list-style-type: none"> <li>• MI-techniques: reflective listening, expressing acceptance and affirmation</li> <li>• Repeating information</li> <li>• Modeling</li> <li>• Trustworthy messenger</li> <li>• Use of PowerPoint and flip-over's of previous session</li> </ul>
2.4. Individual input of patients regarding their own beliefs and barriers	Individual patient tells his/her most important beliefs about medication and practical barriers and places them in the simple behavioral model. Other participants and intervention leader provide feedback and solutions	All intervention goals in Table 1 except for knowledge	<ul style="list-style-type: none"> <li>• All mentioned MI-techniques in Section 3.3</li> <li>• Simple behavior model</li> <li>• Modeling</li> <li>• Personalization of information</li> <li>• Individual input of participants according to homework assignment</li> </ul>
2.5. Closure of second session	Providing suggestions about 'what to do when medication taking is difficult in future' (regarding barriers), evaluating sessions, explaining follow-up call	Practical barriers, self efficacy (see Table 1)	<ul style="list-style-type: none"> <li>• All mentioned MI-techniques in Section 3.2</li> <li>• Modeling</li> </ul>



**Table 2** (Continued)

Intervention section	Function	Concerns determinant(s) and intervention objectives (see Table 1)	Used methods and techniques
<b>Follow-up call</b> Follow-up call by intervention leader	Repeating personal beliefs and barriers with participant, evaluating effect of intervention on adherence	Beliefs, practical barriers (see Table 1)	<ul style="list-style-type: none"> <li>• MI-techniques: reflective listening, expressing acceptance and affirmation, monitoring readiness for change (ensuring not jumping ahead of patient), affirmation patients freedom of choice regarding changing beliefs and behavior</li> <li>• Repeating information</li> <li>• Personalization of information</li> <li>• Telephone call to the individual patient by intervention leader</li> </ul>

**Table 3**  
Intervention materials and their function.

Material	Function
Intervention protocol	Describes intervention background, content and performing 'rules' in detail
Workbook for intervention leader	Is a shorter and more practical version of the intervention protocol, to guide intervention leader through the sessions
Short guide for rheumatologist	Gives rheumatologist a quick overview of intervention objectives, so he (or she) can place his presentation about RA and medicines in the right context
PowerPoint presentations	To guide the sessions. There is a presentation for session one, session two and for the rheumatologist
Flip-over's	To guide the sessions (giving participants an overview of beliefs and practical barriers, inherent in the group)
Workbook for participants	<p>This workbook contains:</p> <ul style="list-style-type: none"> <li>✓ an overview of the intervention;</li> <li>✓ examples of existing beliefs about medication and practical barriers;</li> <li>✓ the simple, behavioral model;</li> <li>✓ the homework assignment;</li> <li>✓ detailed information about RA and RA-medication (use);</li> <li>✓ space for personal notes and</li> <li>✓ important internet links and contact details of the clinic and clinic pharmacy</li> </ul>

**Table 4**  
Pilot results of patient satisfaction questionnaire (N = 12, two group sessions piloted twice).

Item	Median (range)
<b>Satisfaction about general session characteristics</b>	
N of sessions too less (0)–too much (6)	2.5 (0–4)
Time between sessions (1 week) too short (0)–too long (6)	3 (0–3)
Duration of sessions (1.5 h) too short (0)–too long (6)	3 (0–5)
Group size too small (0)–too big (6)	3 (3–4)
<b>Transparency of provided information</b>	
Participant workbook, hard to understand (0)–easy to understand (6)	5 (2–6)
Information provided by intervention leader (pharmacist) unclear (0)–clear (6)	6 (3–6)
Information provided by rheumatologist unclear (0)–clear (6)	6 (4–6)
<b>Communication style characteristics</b>	
'Enough opportunity to discuss my own experiences and problems with medication', totally disagree (0)–totally agree (6)	5 (1–6)
<b>Intervention leader</b>	
Not stimulating (0)–very stimulating (6)	5 (3–6)
Not listening well to participants (0)–listening well to participants (6)	6 (3–6)
General atmosphere during the sessions very tensed (0)–very relaxed (6)	6 (5–6)