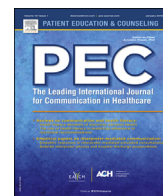




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# Creating a synergy effect: A cluster randomized controlled trial testing the effect of a tailored multimedia intervention on patient outcomes

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### ABSTRACT

**Objective:** Improving adherence is a challenge and multiple barriers are likely to explain non-adherence. These barriers differ per patient and over course of the regimen. Hence, personalized interventions tailored to the specific barriers are needed. In a theoretical and evidence-based Tailored Multimedia Intervention, technology (online preparatory assessment, text messaging) was used as an add-on to a tailored counseling session (learned during a communication skills training), with the expectation of synergistic effects.

**Methods:** A cluster randomized controlled trial was conducted in six hospitals, eight nurses and 160 chronic patients. Patient satisfaction with communication, beliefs about medication, self-efficacy and medication adherence were assessed at initiation of the treatment and after six months.

**Results:** Intervention effects were found for patient satisfaction with nurses' affective communication and self-efficacy at the initiation of treatment. The effect on self-efficacy remained after six months.

**Conclusion:** By combining tailored counseling with technology, this intervention resulted in positive changes in important prerequisites of medication adherence.

**Practical implications:** Technology can contribute significantly to health care providers' ability to tailor information to the patients' needs.

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## 1. Introduction

Non-adherence rates over 40% have been reported within chronic patients [1–4] which may lead to an increase in health care costs, the probability of relapse of disease activity and reduced quality of life [5–8]. As a consequence, many adherence interventions have been developed. However, effective interventions are scarce. This may be due to interventions being applied to patients for whom these are not suited: interventions are often aimed at one particular adherence barrier, regardless of the barriers patients perceive. One of the proposed solutions for improving medication adherence is tailoring [9]. Tailoring is a communication strategy that is based on personal data related to determinants that are unique to that person (i.e., adherence

barriers), associated with the outcome of interest (i.e., medication adherence) [10]. Based on these data, a tailored message that meets the needs of the patient can be developed. This message is expected to be personal and therefore more relevant. The Elaboration Likelihood Model (ELM) could be helpful to explain the processes underlying the effect of tailored messages. People tend to pay more attention to information that they perceive as relevant which stimulates deeper processing, and more persistent persuasion [11,12]. Tailored interventions have been moderately successful in changing health behavior [13–15]. A potential explanation for the small effects sizes in previous tailoring research might be that existing interventions often use either technology or counseling [16]. Combining technology with counseling could significantly improve the ability to tailor messages to patients' needs. We expect that combining technology and counseling in a tailored intervention will work synergistically to enhance medication adherence in comparison to either one strategy applied in isolation [17,18].

Technology for example, can particularly be used to collect data from patients regarding their adherence barriers [19]. By

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identifying these specific adherence barriers, cognitive acceptance, perceived relevance, and message impact can be enhanced [10]. Moreover, data can be used as a tool for providers to optimize the extent to which they tailor their communication to patients' needs [20]. In addition, while counseling is limited by factors such as time and space, technology such as mobile phones can be used to send tailored text messages to successfully support patients over time with limited effort [21]. On the other hand, while technology is more suitable for fulfilling instrumental needs (need to know and understand information), counseling has the opportunity to tailor to both patients' instrumental and in particular affective needs (need to feel known and understood [22]). Thus, both technology and counseling have their own value in tailoring the message.

We developed a theoretical and evidence-based Tailored Multimedia Intervention (TMI) to improve medication adherence. In this intervention, technology and counseling are combined. More specifically we hypothesize that the TMI improves patient satisfaction with the communication of the nurse at initiation of the treatment (H1a) and after six months (H1b), reduces patients' barriers at initiation of the treatment (H2a) and after six months (H2b) and improves patients' medication adherence at initiation of the treatment (H3a) and after six months (H3b).

## 2. Methods

### 2.1. Design

Six hospitals in the Netherlands, in which eight nurses specialized in Inflammatory Bowel Disease (IBD) were working, participated in the study. IBD is a group of chronic diseases with a relapse-remitting disease course necessitating lifelong medication in most cases.

The first part of the study was the same for all six hospitals. IBD patients who were referred to the nurse for a counseling session about newly prescribed medication (i.e. immunosuppressive or biological therapy) were approached to participate. Before patients started their medication, nurses provided intake instructions and informed them about possible side effects and risks during counseling sessions of approximately 30 min. Patient characteristics and outcomes were measured before this consultation (T0), at the initiation of the treatment (i.e., at three weeks; T1), and at six months (T2). Based on the results of part I of this study, the TMI was developed, consisting of an Online Preparatory Assessment (OPA) for nurses and patients, a communication skills training for nurses, and tailored text messages for patients (see 2.3 and 2.3 for a description of the intervention).

After the first part of this study, the hospitals were randomized to either the experimental group (three hospitals) or the control group (three hospitals). We randomized at hospital level to prevent contamination. The experimental group received the TMI, the control group continued to provide usual care (i.e. standard education). Hence, a cluster randomized controlled trial was used. In a cluster randomized trial, groups of subjects (in our case hospitals and associated nurses) are randomized to either the experimental or the control group. As we were interested in first consultations in which nurses were informing patients about their newly prescribed medication, we had to include different patients in both parts of the study. This means that we needed to include new patients in part II of the study (see Fig. 1). This design is in line with previous research [24,25] and allowed us to compare 1) the overall effectiveness of the intervention by comparing the scores of the experimental group in part I of the study, i.e., before the implementation of the intervention (experimental group 1), with the scores of the experimental group in part II of the study, i.e., after the implementation of the intervention (experimental group 2); and 2) compare these change in scores with the change in scores in

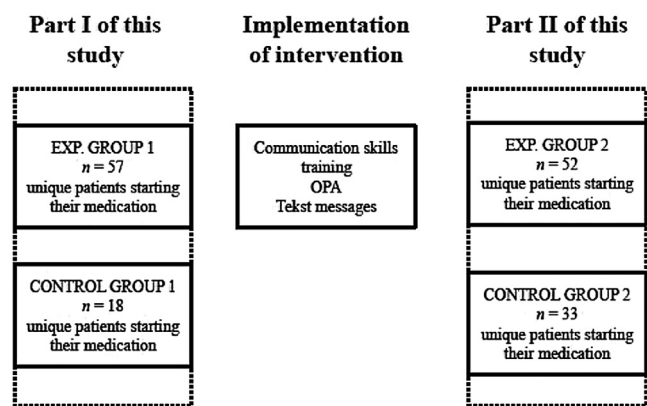


Fig. 1. Study flow.

the control group (control group 1 in part I of the study and control group 2 in part II of the study).

The data-collection lasted from December 2008 to March 2014 and participating hospitals were consecutively included. The Medical Ethical Committee of the VU Medical Center, Amsterdam, The Netherlands, granted permission for this study, which was supplemented with local feasibility statements (Trial No NTR2892). Table 1 provides a summary of the design of the study.

### 2.2. Participants

Nurses were invited to participate in the study voluntarily and had to meet the following criteria 1) having a certificate to provide IBD care and, 2) providing patient education about immunosuppressive or biological therapy as part of their regular employment duties. Their patients had to meet the following inclusion criteria: (1) diagnosed with Crohn's disease or Ulcerative Colitis according to classical clinical, endoscopic, radiographic and/or path histological criteria as determined by an experienced gastroenterologist, (2) initiate immunosuppressive or biological therapy for the first time and, (3) being able to read and write in Dutch.

In line with the meta-analyses on tailoring [13–15] and a meta-analysis on adherence interventions indicating small to large effect sizes for interventions involving multiple elements and interventions which were delivered over time [26], we conducted a power analysis with adherence as primary outcome and expecting a medium effect size. This analysis revealed that, with alpha set at 0.05 and power at 0.40, a minimum of 176 patients was required. Counting for 20% drop-outs at follow-up we aimed to enroll 211 unique patients. We included 57 patients in experimental group 1, 52 patients in experimental group 2, 18 patients in control group 1 and 33 patients in control group 2. In total, 201 patients were enlisted for participation by their nurses, 29 patients refused to participate, twelve patients were excluded before allocation because they did not fulfill the inclusion criteria or for other reasons; see Fig. 2 for more information about allocation and follow-up.

### 2.3. Intervention

The Medical Research Council's (MRC) Framework was used to guide the development of this intervention. A detailed description of the intervention has been published before [23].

#### 2.3.1. Online preparatory assessment (OPA)

The OPA was a tool that had to be completed by the patient preceding the consultation. It existed of a structured list with example questions and discussion topics designed to aid question asking behavior and concern expression during the consultation.

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