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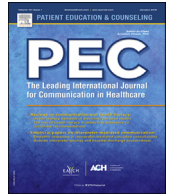
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## Creating a synergy effect: A cluster randomized controlled trial testing the effect of a tailored multimedia intervention on patient outcomes

Annemiek J. Linn<sup>a,\*</sup>, Liset van Dijk<sup>b</sup>, Julia C.M. van Weert<sup>a</sup>, Beniam G. Gebeyehu<sup>a</sup>, Ad. A. van Bodegraven<sup>c,d</sup>, Edith G. Smit<sup>a</sup>

<sup>a</sup> Amsterdam School of Communication Research/ASCoR, University of Amsterdam, Amsterdam, The Netherlands

<sup>b</sup> Department Pharmaceutical Care, Netherlands Institute for Health Services Research (NIVEL), Utrecht, The Netherlands

<sup>c</sup> Department of Gastroenterology, Celiac Centre Amsterdam, VU University Medical Centre, Amsterdam, The Netherlands

<sup>d</sup> Department of Internal Medicine, Gastroenterology and Geriatrics, Zuyderland Medical Centre, Heerlen-Sittard-Geleen, The Netherlands

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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

\* Corresponding author at: Amsterdam School of Communication Research/ASCoR, University of Amsterdam, Nieuwe Achtergracht 166, P.O. Box 15793, 1001 NG Amsterdam, The Netherlands.

E-mail address: [a.j.linn@uva.nl](mailto:a.j.linn@uva.nl) (A.J. Linn).

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

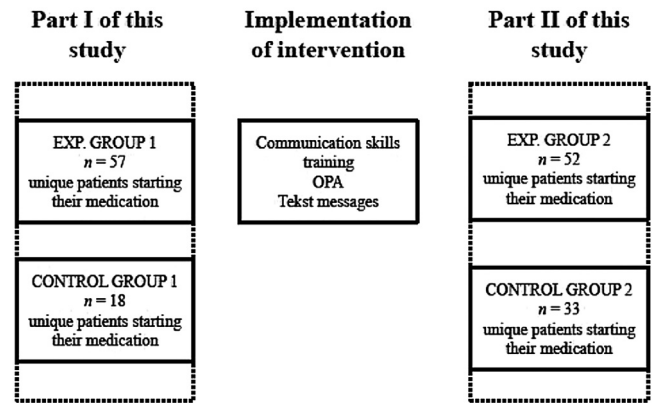


Fig. 1. Study flow.

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

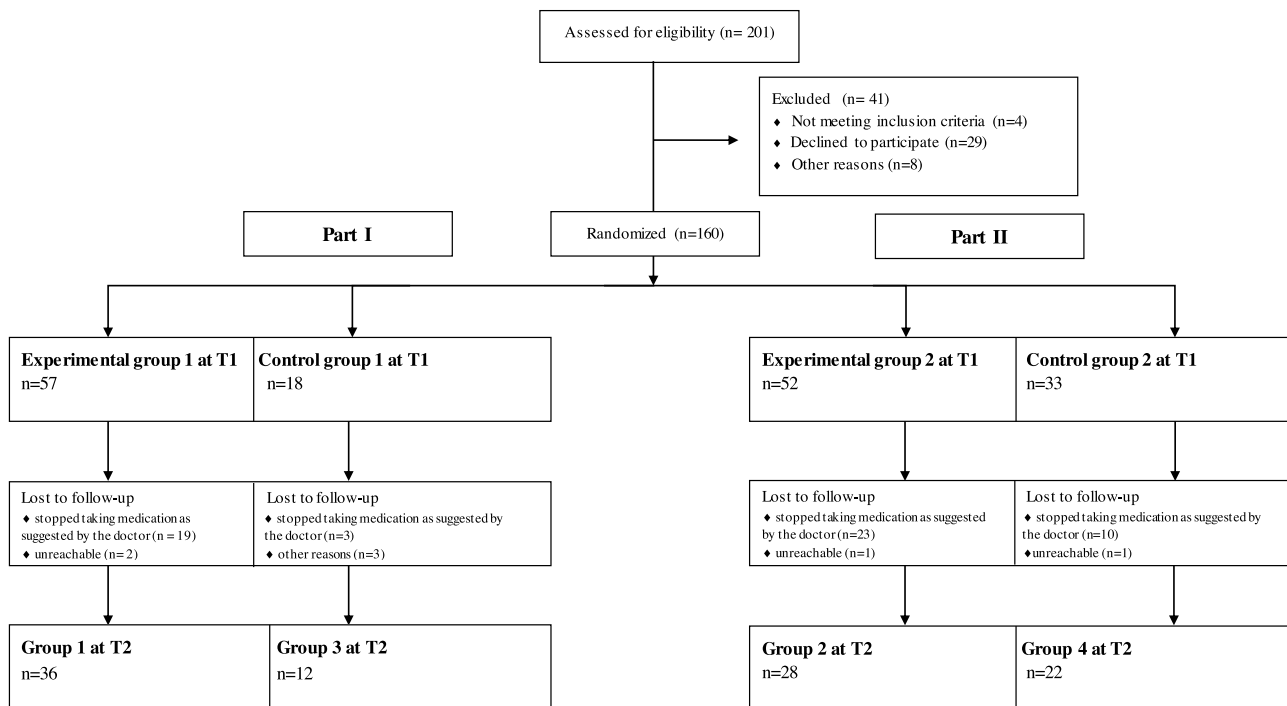
The Medical Research Council's (MRC) Framework was used to guide the development of this intervention. A detailed description of the intervention has been published before [23].

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

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

**Table 1**  
Design of the study.

Part I	
<b>MRC: Development/Feasibility and piloting (December 2008–October 2011)</b>	
Systematic literature reviews: the effects of Internet interventions and reminders on adherence	
Development of the PPAB-typology	
Experimental group 1	Control group 1
3 hospitals, 4 nurses	3 hospitals, 4 nurses
57 new IBD patients	18 new IBD patients
<b>MRC: Development</b>	
Development intervention	
Pre-test text messages	
<b>MRC: Implementation (November 2011–January 2012)</b>	
Intervention for nurses	
Week 1: Communication skills training	Education as usual
Week 2–11: Practice, reflection tasks	
Week 12: follow-up	
Intervention for patients	
OPA	
Text messages	
Part II	
<b>MRC: Evaluation (February 2012–March 2014)</b>	
Experimental group 2	Control group 2
3 hospitals, 4 nurses	3 hospitals, 4 nurses
52 new IBD patients	33 new IBD patients
<i>Measurements:</i>	
Concerns and Necessity	Concerns and Necessity
Self-efficacy concerning taking and learning	Self-efficacy concerning taking and learning
Satisfaction	Satisfaction
Background characteristics	Background characteristics



**Fig. 2.** Flow chart inclusion patients.

Patients were asked to bring it with them to consultation. In addition, the OPA assessed patient's adherence barriers. If scores before the consultation (T0) indicated that a patient might perceive barriers, the nurse was informed by e-mail. This e-mail contained 1) the list with questions; 2) the possible barriers and; 3) tailored communication strategies to be used by the nurse to address these barriers.

### 2.3.2. Communication skills training

A communication skills training day was developed based on the first part of this study. Prior to the training, nurses were provided with a reader containing results from part I of this study and information about basis and tailored communication skills. Twelve weeks after the training, a half-day follow-up meeting was conducted, providing the nurses the opportunity to refresh and

enhance communication skills acquired during the initial training day. Additionally, nurses were trained to use the OPA.

### 2.3.3. Text messages

Patients received one text message per week for six months if scores at T0 or T1 indicated that they perceived adherence barriers. Patients were sent text messages chosen at random from that category that was designed to change the barrier in a direction more consistent with higher adherence. Each week patients received a different message that was related to that particular barrier. If a patient scored high on multiple barriers, they received one text message per week chosen at random from the pool of messages for these multiple barriers [23].

## 2.4. Procedure

Patients were phoned to be invited for participation by one of the researchers. Before consultation, patients were asked to fill out a questionnaire including personal and disease characteristics. Patients were contacted for a telephone interview to assess patient satisfaction, adherence barriers (i.e., patients' beliefs about the medication and patients' perceived self-efficacy) and adherence at T1 and T2.

Patients were blind to the purpose of the intervention and were debriefed afterwards. Due to the design of this study, nurses were not blind for the intervention. Data were collected by several research assistants who were blind for the intervention. To ensure intervention compliance, one of the researchers (AL) and a student assistant checked whether patients used the OPA, and whether they received the text messages. Every patient included in the analysis filled out the OPA and reported to have received the required text messages.

## 2.5. Measurements

### 2.5.1. Patient satisfaction

To measure patients' satisfaction, a 29-item questionnaire comprising three scales concerning satisfaction with *information provided* ( $\alpha_{T1} = 0.87$  and  $\alpha_{T2} = 0.92$ ), *support with treatment progress* ( $\alpha_{T1} = 0.71$  and  $\alpha_{T2} = 0.85$ ) and *affective communication* ( $\alpha_{T1} = 0.90$  and  $\alpha_{T2} = 0.93$ ) was used. An example of patient satisfaction about the information provided is: "The nurse gives me information about my disease". An example used for the treatment progress component is: "The nurse discusses my medication experiences". An example of affective communication is: "The nurse treats me with respect". Responses ranged from "poor" to "very good" [27].

### 2.5.2. Patients' beliefs about medication

The Beliefs about Medicines Questionnaire (BMQ-Specific) was used to assess the patients' beliefs toward medication. This 10-item scale assesses specific patients' concerns about taking their current medication (e.g., "Having to take medicines worries me"  $\alpha_{T1} = 0.72$  and  $\alpha_{T2} = 0.72$ ) and patients' beliefs about the necessity of taking their current medication (e.g., "My medicines protect me from getting worse"  $\alpha_{3T1} = 0.79$  and  $\alpha_{T2} = 0.86$ ). Responses ranged from 'strongly disagree' (1) to 'strongly agree' (5). The scores on each scale were summed ranging from 5 to 25. A necessity-concerns differential (NCD) was calculated by subtracting the patients' concerns score from his/her necessity score, resulting in a range from -20 to 20. Positive scores indicated that necessity was valued higher than concerns [28–31].

### 2.5.3. Patients' self-efficacy

The Medication Understanding and Use Self-Efficacy Scale (MUSE) assessed patients' self-efficacy of *understanding* (e.g., "it is easy for me to understand instructions on medication leaflets") ( $\alpha_{T1} = 0.82$  and  $\alpha_{T2} = 0.85$ ) and *taking* (e.g., "it is easy to set a schedule to take my medication") ( $\alpha_{T1} = 0.93$  and  $\alpha_{T2} = 0.93$ ) medication.

The MUSE is an 8-item validated questionnaire. Patients were able to indicate their level of agreement ranging from 'strongly disagree' (1) to 'strongly agree' (4). The scores on each scale were summed and a higher score indicated a higher perceived self-efficacy [32].

### 2.5.4. Medication adherence

Medication adherence was measured with the 5-item Medication Adherence Report Scale (MARS) [33,34]. The MARS asks patients to rate the frequency with which they engage in each of the five types of non-adherent behavior (e.g., deciding to miss a dose, forgetting to take a dose). This scale was found to have acceptable reliability at both time intervals ( $\alpha_{T1} = 0.72$  and  $\alpha_{T2} = 0.61$ ).

### 2.5.5. Demographic and medical characteristics

Nurses were asked to specify their age, gender, years of work experience, and how many consultations about immunosuppressive/biological therapy they had on average each month. Patients were asked to specify their age, gender, education, diagnosis and duration of disease. Level of education was classified into low, middle and high.

## 2.6. Statistical analysis

For the non-response analysis, Chi-square ( $\chi^2$ ) tests and independent sample *t*-tests were used. Mean scores and standard deviation (*SD*) for patient satisfaction, the NCD, the MUSE and MARS were calculated. ANOVAs were carried out to compare mean scores between groups. The following variables were selected as potential relevant covariates; duration of disease, gender, age, and education. As all of these potential covariates were equally distributed across groups and did not statistically significantly co-vary with the outcome variables, they were not included. We expected that patient outcomes would be improved after the implementation of the intervention in the experimental group, while remaining the same in the control group. For this reason, a comparison of the rate of change across the experimental and control groups was conducted. This was done by comparing the difference between the mean scores in experimental group 1 and experimental group 2 to difference in mean scores in control group 1 and control group 2.

## 3. Results

### 3.1. Participants

Eight nurses participated. The mean age of the nurses was 46.3 years ( $SD = 12.2$ ) and on average, the nurses worked for 4.7 years as an IBD nurse. A total of 160 patients was included in the analysis: 75 unique patients were included in part I of this study (experimental group 1  $n = 57$  and control group 1  $n = 18$ ) and 85 unique patients were included in part II of this study (experimental group 2  $n = 52$ , control group 2  $n = 33$ ). The mean age of the sample was 43.4 years and almost half was male. Patients had been diagnosed with IBD for 11.6 years on average and most patients had been diagnosed with Crohn's disease. The majority was highly or moderately levelled educated (see Table 2). The non-response analysis revealed that there was neither a difference in gender between participants and nonparticipants ( $\chi = 1.19$ ,  $p = .275$ ) nor in age ( $F(1, 182) = 0.05$ ,  $p = .820$ ).

### 3.2. The effectiveness of the TMI on patient satisfaction

The intervention did not improve patient satisfaction with the communication about the disease and treatment ( $F(1, 96) = 1.03$ ,

**Table 2**  
Patient characteristics.

Patient characteristics N = 160	Experimental group				Control group			
	Part I (n = 57)		Part II (n = 52)		Part I (n = 18)		Part II (n = 33)	
	% or mean	SD	% or mean	SD	% or mean	SD	% or mean	SD
Gender (male)	42.1%		40.4%		33.3%		51.5%	
Age	44.55	15.47	40.84	14.51	44.11	13.86	45.21	17.15
Type of disease (Crohn's disease)	84.2%		50.0%		55.6%		51.5%	
Diagnosed in years	13.21	10.96	10.16	10.11	10.81	7.26	11.56	12.04
Educational level								
Low	26.3%		19.2%		17.6%		18.2%	
Medium	36.8%		30.8%		41.2%		51.5%	
High	36.8%		48.1%		41.2%		30.3%	

$p = .312$ ) and support with treatment progress ( $F(1, 85) = 0.53$ ,  $p = .468$ ) at T1. However, experimental group 2 had a higher satisfaction rating of nurse regarding their affective communication, when compared with the scores of experimental group 1 ( $F(1, 95) = 5.66$ ,  $p = .019$ ) at T1. Therefore, H1a can partly be supported. The intervention did not improve patient satisfaction with the communication about the disease and treatment ( $F(1, 65) = 1.91$ ,  $p = .172$ ), patient satisfaction with support with treatment progress ( $F(1, 62) = 0.41$ ,  $p = .523$ ) and affective communication ( $F(1, 64) = 0.04$ ,  $p = .842$ ) at T2. Thus, H1b was not supported (see Tables 3 and 4).

### 3.3. The effectiveness of the TMI on patients' barriers

There was no difference in beliefs between experimental group 1 and 2 ( $F(1, 94) = 0.87$ ,  $p = .044$ ) at T1. Self-efficacy increased in experimental group 2 as compared to experimental group 1 ( $F(1, 89) = 4.18$ ,  $p = .044$ ) at T1. Patients who received the intervention reported that they were better able to overcome obstacles that might hinder them from taking the medication as prescribed. There was no difference in beliefs at T2 between experimental group 1 and 2 ( $F(1, 62) = 0.16$ ,  $p = .691$ ). Patients' self-efficacy was higher in the experimental group 2 than in group 1 ( $F(1, 62) = 3.76$ ,  $p = .057$ ) at T2. Thus, patients who received the intervention still reported after six months that they were better able to overcome obstacles that might hinder them from taking the medication as prescribed. Thus, H2a and H2b are partly supported (see Table 4).

### 3.4. The effectiveness of the TMI on adherence

There was no significant difference between experimental group 1 and 2 at T1 on adherence ( $F(1, 94) = 0.32$ ,  $p = .570$ ), nor at T2 ( $F(1, 63) = 0.35$ ,  $p = .554$ ). As such, the intervention did not

significantly increase patient adherence at three weeks or at six months. Therefore, H3a and H3b were not supported (see Tables 3 and 4).

### 3.5. Change in scores

A relevant change in score was defined as that change in experimental group 1 and 2 was statistically significantly different from the change in control group 1 and 2. Positive scores indicate a change in favor of the experimental group 2, negative scores indicate a change in favor of the control group 2. Only patient satisfaction about the nurses' affective communication changed in favor of the experimental group as compared to the control group after three weeks. None of the differences changed in favor of the experimental group after six months (see Tables 3 and 4).

## 4. Discussion and conclusion

We tested the effect of a TMI on patient satisfaction, adherence barriers and medication adherence. A positive intervention effect for patient satisfaction with nurses' affective communication after three weeks and self-efficacy after three weeks and six months was observed. This indicates that the TMI resulted in positive changes in the application of one of the most essential communication skills and reduced barriers to medication intake.

By combining technology with counseling we aimed to optimally use the advantages of each of these separate components. We used the internet to gain more insight into patients' barriers. This way, we were able to assist both nurses and patients in tailoring their communication and set an agenda for the consultation. This may have contributed to the improved satisfaction [35]. We used text messages to support patients over time. This support is especially relevant to chronic patients, which

**Table 3**  
Scores after three weeks.

Outcome measures	Experimental group				Control group				Change score
	Part I (n = 57)		Part II (n = 52)		Part I (n = 18)		Part II (n = 33)		
	M	Se	M	Se	M	Se	M	se	
Patient satisfaction <sup>1</sup>									
Affective	24.69	.99	25.94 <sup>a,*</sup>	0.54	25.79	0.53	23.03	0.68	4.00 <sup>b,*</sup>
Information	31.77	0.72	32.68	0.75	31.35	1.25	32.68	0.75	2.23
Treatment	17.16	0.45	17.62	0.53	16.77	0.89	18.32	0.64	-1.09
Adherence <sup>1</sup>	24.86	0.48	26.27	0.53	25.25	0.854	25.58	0.67	0.05
Beliefs <sup>1</sup>	5.75	0.65	4.93	0.71	2.69	1.14	5.15	0.91	-3.38
Self-efficacy <sup>1</sup>	24.86	0.48	26.27 <sup>c,*</sup>	0.53	25.25	0.85	25.58	0.67	1.08

\*  $p < .05$ .

<sup>1</sup> A higher score indicates higher adherence, resp. more positive beliefs resp. higher believe in self-efficacy and patient satisfaction.

<sup>a</sup> The experimental group 2 had a higher satisfaction rating of their consulting nurse regarding their affective communication, when compared to the experimental group 1.

<sup>b</sup> A significant change score means that the change in the experimental group 1 and 2 was significantly different from the change in the control group 1 and 2.

<sup>c</sup> The MUSE showed to be better in the experimental group 2 as compared with the experimental group 1.

**Table 4**  
Scores after six months.

Outcome measures	Experimental group				Control group				Change score
	Part I		Part II		Part I		Part II		
	M	Se	M	Se	M	Se	M	se	
Patient satisfaction									
Affective	24.33	0.76	24.56	0.91	24.47	1.22	23.05	1.09	1.636
Information	31.95	1.01	30.11	1.19	30.73	1.63	29.55	1.35	−0.654
Treatment	16.90	0.70	16.24	0.87	17.67	1.12	16.37	1.00	0.641
BMQ <sup>1</sup>	5.29	0.94	4.71	1.06	5.07	1.45	4.78	1.17	−0.279
MUSE <sup>1</sup>	24.81	0.56	26.37 <sup>a,†</sup>	0.65	25.50	0.91	26.59	0.72	0.472
MARS <sup>1</sup>	19.34	0.25	19.18	0.29	19.71	0.39	18.83	0.32	0.720

<sup>\*</sup>  $p < .05$ .

<sup>1</sup> A higher score indicates higher adherence, resp. more positive beliefs resp. higher believe in self-efficacy and patient satisfaction.

<sup>a</sup> The MUSE showed to be better in the experimental group 2 as compared to the experimental group 1  $p < .05$ .

requires patients to engage in long-term self-management behavior. Moreover, sending text messages has the advantage of being inexpensive, easy to access, and accessible to large populations [36]. Lastly, we combined technology with a communication skills training. Counseling has been shown to be a powerful tool to improve medication adherence: patients of providers who communicate well have a 19% higher medication adherence than patients whose providers do not communicate effectively [37].

The results of this study showed that the intervention improved important prerequisites of medication adherence [35], but not adherence itself. Also, the TMI did not result in statistically significant changes in patients' beliefs about medication. As such, our results do not correspond with previous research [36] that demonstrated that tailored text messages resulted in an increased perceived necessity of medication use and improved adherence. There are several explanations for this. First, adherence was found to be high in all groups, which might indicate a ceiling effect with insufficient room for improvement in adherence. Second, we tailored our intervention to specific non-adherence determinants, but did not target non-adherence behavior. As we included patients who newly started their medication, it was not possible to screen them on their non-adherence rates. The inclusion of non-adherent patients only is likely to increase the difference in adherence between control and experimental groups [38]. Researchers are encouraged to replicate this study among a non-adherent population.

We tailored the content of the intervention to the self-reported scores on patients' barriers. Research has explored new and innovative ways of tailoring. In particular when patients are confronted with a substantial amount of detailed and emotional information [35], message frame tailoring and mode tailoring seem promising strategies. Message frame tailoring is a strategy in which a message is tailored to a patients' information processing style such as someone's need for cognition (i.e., need to seek or avoid information), need for affect (i.e., need to approach or avoid emotions) and need for autonomy (i.e., high or low). Mode tailoring is a strategy in which the mode of delivery is tailored to a patients' learning style and mode preference [39]. Another relatively new way of tailoring is to provide patients with the possibility to adapt the intervention to their own needs. According to this more user-initiated approach, patients can choose themselves if and how they prefer adherence support. This approach is expected to exert persuasive effects [11,40]. Future research should further explore these new approaches.

We hypothesized that because a tailored intervention is perceived as more relevant, processed more deeply and commands more attention, thus resulting in better communication outcomes. As rightfully pointed out by a recent study [12], very little work has

been conducted on the underlying mechanisms of tailoring. The few studies exploring these underlying mechanism indeed found that the effects of tailored interventions are mediated by perceived relevance, attention and elaboration [12,40]. Future research is needed to examine the pathways of these processing variables to unravel how tailoring works. This will contribute to the development of more efficacious tailoring.

Conclusive statements regarding the effectiveness of the TMI cannot be made without information about the fidelity of the intervention [41]. Although we monitored the use of the OPA and the delivery of the text messages, we did not analyze the extent to which the nurses used the trained communication skills. Thus, the communication of the nurses might not have been delivered as intended, especially considering the duration of the data-collection. Our results should therefore be interpreted with caution since control group 2 slightly improved as well. Only the change in satisfaction with affective communication remained statistically significant in favor of the experimental group. Perhaps participation in this study has resulted in changes of the nurses' communication behavior. Another explanation might be contamination: although we randomized at hospital level, participating nurses were all members of a well-organized professional group with regularly joint conferences, workshops and (in)formal meetings. Discussion of the intervention between nurses can therefore not be excluded [42].

A potential limitation is the design of this study. We chose to assign nurses and patients to the experimental group which was provided with the TMI. Although we assumed that integration of these different components might increase their effectiveness, it would be recommended to test their effect in isolation to get insight in the separate effects. This was a practical consideration because of the number of participating nurses. More research is needed to test possible synergy effects in health communication. A second limitation is that we used self-reported outcomes to measure adherence. Although the MARS has been shown to be a reliable and valid tool for estimating medication adherence [43], it had a relatively low alpha score at six months. A MARS validation study also found a moderate internal consistency. The authors of this study argue that this may not represent a weakness of the scale but they argue that because of the binary response choice, small number of items, and scale multidimensionality, this level of consistency can be expected [44]. However, the use of objective adherence measurements would support the validity of our findings.

#### 4.1. Practical implications

Technology is expected to contribute significantly to health care providers' ability to tailor information to the patients' needs. We

tested the effectiveness of TMI in a sample of IBD patients, but our intervention may be useful for all patients coping with chronic illness. The developed intervention is quite general and the content of the instruments could easily be applied to other diseases.

#### 4.2. Conclusion

The strength of this study is that we assessed patients' modifiable adherence barriers on different time-points (i.e., at treatment initiation and after three weeks) and tailored the content of different intervention components accordingly. In addition, we developed and tested a theoretical and evidence-based TMI that combines technology and counseling. Each component of the intervention had its own specific ability to tailor the message to the patients' needs. By combining technology and counseling, this intervention resulted in positive changes in the application of one of the most essential communication skills, being affective communication, and additionally reduced adherence barriers. The results are encouraging for further development of TMIs in the context of medication adherence.

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#### Conflict of interest

The authors declare no conflicts of interest.

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