

Postprint Version	1.0
Journal website	http://www.pec-journal.com/article/S0738-3991(13)00050-5/abstract
Pubmed link	http://www.ncbi.nlm.nih.gov/pubmed/23433735
DOI	10.1016/j.pec.2013.01.022

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Web-based, self-management enhancing interventions with e-diaries and personalized feedback for persons with chronic illness: A tale of three studies

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ABSTRACT

Objective: Chronic illness places high demands on patients. Interventions supporting self-management and providing personalized feedback might help patients to gain new perspectives and enhance use of constructive self-management strategies. We developed three comparable web-based CBT-grounded interventions including e-diaries and feedback delivered through PDAs/smartphones. The feasibility and efficacy of these interventions have been investigated for patients with irritable bowel syndrome (in an RCT), chronic widespread pain (RCT) and type 2 diabetes (feasibility study).

Methods: This is a descriptive study that summarizes the content, feasibility and efficacy of the interventions and discusses issues relevant for implementing this type of web-based therapeutic interventions in clinical practice.

Results: The web-based interventions appear feasible, acceptable and supportive. In a short and midterm time frame, the interventions promote self-management.

Conclusion: Booster sessions may be needed for prolonged effects. Given the physical and mental symptoms of the patients under study and the nature of the intervention, providers who deliver the feedback need a health care background and training in this specific way of counseling.

INTRODUCTION

Communicating using wireless devices such as mobile phones and computers has become an integral and accepted part of our daily life. Smartphone services can make health care more accessible to patients, especially for those living in remote areas or those who are housebound ^[1]. Smartphone services can also provide educational information about habits related to health, which help improve preventive care ^[2]. The use and applicability of Internet is still rapidly increasing ^[3]. More and more people receive their health information from the Internet ^[4]. The studies described in this paper contribute to this development by investigating a new type of web-based interventions in three different groups of patients with chronic illness.

Chronic diseases are the leading cause of disability and mortality worldwide, representing 63% of all deaths and 43% of the global burden of disease ^[5]. Easily applicable interventions that have a positive effect on self-management of chronic conditions are needed. After all, the treatment of a chronic illness places high demands on patients; the daily confrontation with restrictions, discomfort, treatment regimens and complex self-management activities can impact heavily on a person's quality of life and psychological wellbeing. This burden of treatment and symptoms seems to be intensified by condition-related thoughts and behaviors. Challenging and correcting dysfunctional thoughts and behaviors in patients with chronic conditions could support them in placing the illness into perspective while stimulating and maintaining constructive self-management.

Such psychological support based on Cognitive Behavioral Therapy (CBT) principles is likely to be especially helpful when tailored to the patients' needs and incorporated in their daily life without entailing extra healthcare visits. Until recently, most CBT interventions take place on a weekly basis or even less. This means that patients usually receive retrospective and non-situational feedback regarding their thoughts and behaviors. Providing immediate, situational feedback close to the moment dysfunctional thoughts and behaviors occur may increase the patients' self-management skills and help alleviate their somatic complaints. Mobile phones and the Internet can assist in this matter by having patients complete electronic diaries and subsequently receiving situational personalized feedback. We recently developed three web-based interventions using CBT and Acceptance and Commitment Therapy (ACT) principles for different types of patients with chronic conditions aimed at increasing their self-management skills and quality of life ^[6], ^[7] and ^[8]. When developing our studies we have used the Medical Research Council framework for developing complex interventions involving four separate stages ^[9]; (a) development, (b) feasibility and piloting, (c) evaluation, and (d) implementation.

In the present paper, the content, feasibility and outcomes of these studies are summarized and subsequently discussed in view of the following questions:

1. Do the results of the studies indicate that it is worthwhile implementing web-based situational feedback interventions in daily healthcare practice for patients with chronic conditions?

2. Who would be the most suitable provider to offer web-based counseling: a family physician, a practice nurse, or a psychologist?

2. METHODS

2.1. Design

This descriptive study presents and discusses the content, the results and the implementation challenges of three web-based therapeutic interventions.

2.2. Content and underlying concepts of the three web-based interventions

Three web-based interventions incorporating electronic diaries and situational feedback were developed for patients with irritable bowel syndrome (IBS) ^[6], chronic widespread pain (CWP) ^[7], and type 2 diabetes (T2DM) ^[8], respectively. The content and set up of these interventions were based on: (1) theoretical frameworks well-known for their relevance in enhancing patients' quality of life and behavior change, i.e. CBT and ACT ^[10], and (2) the results of a systematic review on predictors of adherence to completing electronic diaries ^[11].

CBT teaches patients how events, thoughts, emotions, actions, and physiological responses are interrelated. CBT is oriented toward change and development of new skills and strategies for coping with problems. ACT is regarded as the third-generation CBT based on the assumption that suffering may largely be caused by our thinking about painful experiences rather than the experiences themselves. Suffering can be reduced through an enhanced focus on personal values, mindfulness, acceptance and committed action ^[12].

A systematic review of web-based interventions with electronic diaries (e-diaries) revealed that adherence to the diary protocols was high (83%). Higher compliance rates were reported with shorter diaries and older patients. In addition, several strategies were identified that contributed to compliance, such as providing patients with a manual, a trigger alarm indicating when a diary must be filled out, and financial compensation ^[11]. These theoretical and practical considerations provided input for our three studies, i.e. two randomized controlled trials and one pilot feasibility study ^[6], ^[7] and ^[8] (see ^{Table 1} and ^{Table 2}).

2.3. The studies

In the first trial, participants with IBS were randomized to an intervention and a control group. The 38 participants in the control group received standard care and the 37 intervention group participants received standard care supplemented with a 4-week CBT intervention including e-diaries and situational feedback on a PDA, i.e. a personal digital assistant ^[6]. All participants fulfilled the diagnostic Rome III criteria for IBS ^[4] (see Table 1, Table 2 and Table 3).

In the second trial, 140 women with CWP participated in a 4-week inpatient rehabilitation program and were subsequently randomized into two groups: an intervention group (completers, $n = 48$) with, and a control group (completers, $n = 64$) without a smartphone intervention. Both groups were given access to an informational website after discharge to promote constructive self-management. The smartphone intervention used ACT-principles and consisted of one face-to-face

session and 4 weeks of web-based communication ^[7] (see Table 1, Table 2 and Table 3).

The third study was a pilot feasibility study targeting persons with T2DM. Eleven participants completed the intervention which included individualized written personalized feedback (daily for 4 weeks and weekly for another 8 weeks) based on three daily e-diaries, the provision of audio files with mindfulness and relaxation exercises, and a healthcare tool called the Few Touch Application (FTA), a mobile phone-based system for recording food habits and physical activity ^[13]. The system provides feedback (smile faces), based on users performance viewed in relation to their personal goals ^[8] (see Table 1 and Table 2).

In all studies the intervention group participants completed e-diaries during several weeks on a PDA or smartphone and received personalized, situational feedback based on their input on the same day. In the e-diaries, the participants registered activities, emotions and pain cognitions three times daily using the mobile device by choosing between predefined options and using scales. A therapist had immediate access to this information through a secure website and used the situational information to formulate and send a personalized message to the participant with the aim of stimulating effective self-management in coping with the current situation (see Table 1).

All participants also completed questionnaires at baseline and at 3 or 5-month follow-up, inquiring about distress, symptoms, illness perceptions, quality of life, and experiences with the web-based intervention. To evaluate these tasks the following instruments were used (see Table 2).

1. IBS study: Pain Catastrophizing Scale (PCS) ^[14], Irritable Bowel Syndrome Quality of Life Questionnaire ^[15] and Cognitive Scale for Functional Bowel Disorders ^[16];
2. CWP study: PCS, Chronic Pain Acceptance Questionnaire ^[17], General Health Questionnaire ^[18] and Chronic Pain Values Inventory ^[19].
3. T2DM study: Audit of Diabetes Dependence Quality of Life ^[20] and Problem Areas in Diabetes ^[21].

3. RESULTS

3.1. Feasibility and efficacy of the three intervention studies

The three intervention studies were feasible and evaluated by the participants as supportive and meaningful ^[6], ^[8], ^[22] and ^[23]. The response rate to the daily registration entries was high even though from time to time participants did encounter technical problems in submitting diaries ^[6], ^[8] and ^[22].

In the IBS and CWP studies the results showed that the smartphone delivered intervention with diaries and situational feedback can reduce catastrophizing thoughts and prevent increase in functional impairment and symptom level. The effects persisted for 3 months in the IBS study and for 5 months in the CWP study ^[6] and ^[7]. In the diabetes study, most participants reported positive life style changes ^[8] (see Table 3).

4. DISCUSSION AND CONCLUSION

4.1. Discussion

Self-management support is established as an evidence-based intervention for IBS^[24], CWP^[25], diabetes^[26] and other chronic conditions^[27] and^[28], and shown to be effective, at least in the short to medium-term^[29] and^[30]. The results from our three studies support this evidence by showing that web-based feedback interventions are suitable for treatment and/or follow up purposes.

The interventions targeted persons with chronic conditions known to be bothersome due to their annoying and/or painful symptoms and complicated treatment requiring long-term self-management. In case of patients with IBS or CWP having conditions with not clearly identifiable causes, current guidelines recommend treating patients with persisting symptoms by intervening on their cognitions, behaviors and emotions. These guidelines were followed in the studies described in this paper^[31]. The treatment method was also relevant for T2DM patients, but these needed in addition support to regulate their blood glucose levels and to maintain their healthy lifestyle^[32].

Most participants considered the web-based interventions acceptable and useful. The first results of our studies suggest that the interventions are effective in changing dysfunctional thoughts, at least in the medium and short-term range. This indicates that for patients with less clearly understood physical complaints, as in IBS or CWP, our web-based personalized feedback intervention can be a welcome addition to the more or less effective interventions that are available at present. For patients with T2DM, the presented web-based intervention comes on top of existing evidence-based interventions already embedded in general practice or secondary care. To use and implement web-based interventions for these patients may therefore demand more attitude changes and extra time investment by health care professionals as well as patients, and may, at first, have to be reserved for patients who have specific problems accepting the chronicity and severity of their condition.

In the IBS study the participants were recruited by GPs and announcements, while they received standard care from their GP. This standard care consisted of reassurance, dietary advice and education according to the Dutch guideline in general practice. The CWP study recruited their patients from one rehabilitation center. The rehabilitation program included an educational program in which pain management was offered in a cognitive setting with various forms of aerobic exercises, stretching, myofascial pain treatment, relaxation and medication as was needed. In the diabetes study the patients were recruited from GPs and researchers' networks. A striking observation from the diabetes study was that many patients did not have sufficient knowledge about their disease, and in some cases, the provision of additional information already encouraged life style changes^[8]. Future studies may be needed to distinguish between patients with and without a certain baseline knowledge level of diabetes self-management and to tailor the intervention to this level.

As mentioned above, several self-management studies have shown positive effects on health outcomes, and according to a review by Murray, there is a correlation with studies' having strong theoretical foundations and their positive effects^[33], such as CBT and ACT which grounded the interventions described in this paper. It is also common for such studies that the achieved effects diminish over time^[29] and^[30]. To

maintain the positive effects we suggest offering intensive counseling during a short period followed by booster sessions on a more continuous basis. A web-based intervention may also substitute or be used in addition to standard treatments. Our experience indicates that the web-based interventions developed in our three studies would be feasible for follow-up purposes. A study conducted by Solomon supports this view indicating that web-based interventions can be used to support self-management in the follow-up phase of traditional interventions, thereby increasing effect duration and the potential to reach a broader population ^[34].

A web-based intervention offers an alternative to health care providers to deliver tailored counseling to persons who are suffering from chronic diseases. Nevertheless it remains important to explore each individual patient's needs to elicit the method that best suits him or her. We had a positive experience with this in the diabetes study where one of the participants did not show any improvement. This participant just answered a few electronic diaries and read few feedbacks and his HBA1 was increased at the end of intervention period. During the post-intervention interview it became clear that our proposed intervention did not suit this participant and he would have preferred a group-based intervention where participants could share their experiences. An online diabetes self-management program investigated by Lorig and collaborators in 2010 also stimulated participants' interaction, which lead to positive outcomes ^[35]. Lorig's intervention could be an alternative to the cited participant from the T2DM study. Different intervention methods function for different people. A person who lives far from a health care institution could greatly benefit from a web-based intervention. Those who are unable to meet the health care provider would experience similar advantages ^[1].

Based on the feasibility and effectiveness of the developed interventions, the next step is to implement these methodologies in daily healthcare practice. As described above, the participating patients appreciated the interventions. They found it easy to fill in the diaries and were very positive toward the feedback received. Persisting challenges remain with regard to the time spent to formulate and write the feedbacks and to the implementation of the technology. According to the therapists' evaluation in the CWP and the T2DM studies, the average time to write a tailored feedback was about 10–15 min, with substantially more time used on the initial feedbacks given.

The therapist reported that using information and text segments (for example mindfulness exercises) from earlier feedbacks made the feedback process more time efficient ^[8] and ^[22]. It may be possible to develop a coding system for the different kinds of feedbacks the therapist wants to give and to let the therapist select suitable, more or less standardized feedback messages from pre stored examples. Modifications should then be made to adjust the feedback to each patient's special needs.

To utilize the technology resources even more, it could be possible to use the diary input to automate the feedback from a registered databank. This databank could be automatically extended with new feedbacks given for specific situations, and a “self-learning” data system could be developed taking the results of each feedback into account. The patients reported that personalized feedback was important. It is therefore essential to find a balance between automating the process and making it more effective while taking into account the relevance of giving personalized

feedback to the patients. These new developments result in a new type of intervention, requiring a new round of studies on efficacy and feasibility. Automation of the feedback is one way of making the intervention more time efficient. Another timesaving action could be to give weekly feedbacks instead of daily ones. In the diabetes project the feedbacks were given daily for 4 weeks and weekly for 8 weeks. Although the patients preferred the daily feedbacks they became used to the weekly feedbacks and continued to fill in the daily diaries as before. This indicates that the web-based intervention could be used to maintain adherence to the treatment and thereby achieve the effects with less effort. Further studies are needed to analyze the effects of automation and reducing the feedback intervals.

Although there was some variation over the three studies, adherence to the intervention protocol was not a big problem for the patients, at least not after the startup period. This may be related to the therapist's commitment. Demotivated professionals are recognized as an adherence barrier^[36]. De Veer and colleagues also analyzed factors which impede or enhance the successful implementation of new technologies in nursing care among potential users. The factors most frequently mentioned as impeding actual use were related to the technology itself, such as malfunctioning, ease of use, relevance for patients and risks to patients. Furthermore, the nursing staff stressed the importance of an adequate innovation strategy^[37]. In our projects, we did encounter some problems connected to technology failures^[6],^[8] and^[22], and these indeed bothered the participants. Detailed testing in the health care organization, where the new technology and therapeutic procedures will be embedded, is needed to anticipate potential failures. Involvement of health care providers at the beginning of an intervention study is therefore considered essential. The insights from the Technology Acceptance Model (TAM) can also be helpful throughout the implementation process. The TAM specifies the relationships between system design features, perceived usefulness, perceived ease of use, attitudes toward using on the one hand and actual usage behavior on the other. The TAM provides a model to understand the connection between design and user acceptance and is recommended to be used on this technology before rolled out to the health care system on a greater scale^[38].

In all the three developed interventions the feedback was provided by a professional with a background in health care (nursing/psychology). In the IBS study, a psychologist/researcher performed this task. In the CWP study and in the T2DM study feedback was given by a nurse with clinical experience or by a counselor with a degree in psychology. Although it is known that there are self-management based interventions that do not use a health professional as a provider^[35] and^[39], our experience shows that the method we developed required a health care professional with knowledge in the specific chronic disease and in CBT/ACT to assess the information received from the diaries and, subsequently, write the feedbacks. Apart from the knowledge and training in CBT-based treatment, it is also important – as is for all treatments to be effective – that the patient trusts the professional who delivers the intervention^[40]. Our experience showed that a first face-to-face meeting was important to establish an alliance with the participants. In addition, it is important to examine each patient individually in order to identify severe psychological problems or chronic somatic health problems as early as possible and, if needed, inform the patient's GP. To make this possible, in all three studies cooperation with

multidisciplinary teams was established. To have a similar structure when implementing web-based personalized feedback interventions in the daily health care system would be a significant advantage.

4.2. Conclusion

This paper discusses the possibilities for the implementation of an innovative web-based intervention. This intervention was tested on three patient groups suffering from different chronic diseases. The results show that the methodology was feasible and was evaluated as supportive and meaningful by the participants. Positive effects on health outcomes were identified. Based on our experience and similar studies we may conclude that this type of intervention can be used in addition to more traditional interventions. The patient groups for which our intervention is most suitable should be evaluated separately, considering that patients will receive therapy based on CBT and that the intervention focuses primarily on enhancing self-management. Our experience is restricted to patients suffering from IBS, CWP and T2DM and show that the providers who deliver the intervention should have a health care background and be trained in the intervention methodology, including the theory behind the intervention. Support from a GP or other physician who can be contacted in case of persisting psychological or chronic somatic health problems is important. In addition, the support from a multidisciplinary team is also considered to be advantageous.

4.3. Practice implications

Several advantages of using the Internet to deliver self-care and behavior change interventions are well recognized. Web-based interventions with a strong theoretical foundation can achieve positive results and may be successfully implemented in daily health care practice^[33]. Such interventions have the potential to substitute and/or support treatments in daily practice, making it possible to deliver tailored and personalized interventions with a large scalability that may have low marginal costs per additional user. Several studies suggest that web-based interventions have the potential to be highly cost-effective^[41] and^[42]. To achieve a successful implementation in daily practice of the developed intervention a conceptual framework and implementation protocol is strongly recommended. Kilbourne et al.^[43] described a framework called Replicating Effective Programs (REP) and concluded that REP is a well-suited framework for implementing health care interventions. The main components of REP are intervention, packaging, training, technical assistance and fidelity assessment. As we mentioned before, training of health care providers in CBT-based treatment is important for the implementation of our proposed intervention. Training is also one of the main components of REP and covers a large dimension in the implementation process^[43]. In the USA the government, represented by Centers for Disease Control and Prevention (CDC) and health departments, funds the implementation of REP-packaged interventions by over 500 prevention organizations nationwide^[44] and in Norway the Norwegian Government represented by the Norwegian Research Council and other minor actors also funds such implementation projects^[45]. Positive impact in health outcomes associated with economic gain is highly prioritized. Sustaining changes achieved in the implementation process may require

strategies beyond financial incentives, such as the dissemination of results on improved outcomes^[43]. Further studies are needed to evaluate the effect and economic impact of the developed intervention that includes the return on the investment.

Coverage and reimbursement policies remain a deployment barrier to e-coaching, but the rapid developments in e-health and of studies showing the economic gain, may influence a positive change in the near future where the e-coaching is likely to become an integral part of health care to be reimbursed in the same way as face-to-face consultations are^[46]. Web-based interventions can be very attractive because they are convenient, easily accessible, and can maintain anonymity and privacy^[33].

FUNDING

Grant support for the three described studies: for the IBS study: Dutch Digestive Foundation; for the Diabetes type 2 study: OAUC and The Research Council of Norway (RCN); for the chronic widespread pain study: The Research Council of Norway Grant no: 182014/V50. These funding sources had no involvement in the conduct of the research, preparation of the article, study design, collection, analysis and interpretation of data, writing of the report; and decision to submit the paper for publication.

CONFLICT OF INTEREST

No potential conflicts of interest relevant to this article were reported.

ACKNOWLEDGEMENTS

All authors read and approved the final manuscript. The last author initiated the paper and drafted the first submission, the first author revised the initial draft together with the co-authors. Each author was funded by her own institute. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the article.

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Nes, A.A.G., Eide, H., Kristjánsdóttir, O.B., Dulmen, S. van. Web-based, self-management enhancing interventions with e-diaries and personalized feedback for persons with chronic illness: a tale of three studies. *Patient Education and Counseling*: 2013, 93(3), 451-458



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TABLES

Table 1
Design and content of the 3 interventions.

	Irritable bowel syndrome (IBS)	Chronic widespread pain (CWP)	Diabetes type 2
Aim	The aim of this study was to establish the feasibility and the efficacy of a cognitive-behavioral e-intervention using personal digital assistants (PDAs) on the self-management of IBS patients.	The aim of this study was to investigate the efficacy of a smartphone delivered intervention based on ACT principles following an inpatient chronic pain program.	The aim of the study was to develop and test the feasibility of a 3 months web-based intervention, delivered by a smartphone to support self-management in patients with type 2 diabetes.
Design	This study was a randomized controlled trial (RCT). The intervention followed an AB design: a personal instructional meeting followed by a 1-week electronic diary-monitoring period, without feedback, to get used to the PDA and diaries (A). After this a 3-week diary-monitoring period with feedback (B). Patients completed three diaries daily.	This study was a RCT. The intervention lasted for 4 weeks and started with a personal meeting followed by daily diaries and feedback via a smartphone. The participants registered activities, emotions and pain cognitions three times daily using the smartphone. The therapist had immediate access to this information through a secure website. At a scheduled diary-completion time, the participant received an SMS message with a link to a secure website where the diary could be opened and questions answered and submitted back to the server.	This study was a pilot feasibility study. The intervention lasted for 12 weeks and started with a personal instructional meeting followed by daily diaries and feedback via a smartphone. The participants completed online diaries three times daily using the smartphone. The therapist had immediate access to this information through a secure website. At a scheduled diary-completion time, the participant received an SMS message with a link to a secure website where the diary could be opened and questions answered and submitted back to the server.
Content	The intervention included two principal elements: 1. Electronic diaries 2. Individualized written situational feedbacks.	The intervention included four principal elements: 1. Electronic diaries 2. Individualized written situational feedbacks. 3. Access to a website with information. 4. Audio files with mindfulness exercises installed on the smartphone and available at the website.	The intervention included four principal elements: 1. Electronic diaries 2. Individualized written situational feedbacks. 3. Audio files with mindfulness exercises and 4. Few Touch Application (FTA), a healthcare tool installed on the smartphone.
Device	PDA with an Internet program that made it possible to connect to a secure server.	Smartphone with an Internet program that made it possible to connect to a secure server.	Smartphone with an Internet program that made it possible to connect to a secure server.
Diaries	The morning diary assessed quality of sleep, current severity of complaints, and intended activities for the day. The afternoon diary assessed the current severity of complaints and inquired about the patients' accomplished activities, cognitions, and feelings. The evening diary assessed again the current severity of complaints as well as satisfaction with activity level and achievements of that day. Most items were answered on a Likert-type scale, while other questions required answering by brief open responses to be typed on a small keyboard presented on the screen of the PDA. The number of items in the morning, afternoon and evening diary was 9, 15, and 9, respectively.	The diaries included 16–24 questions. The questions were chosen to support self-monitoring and awareness of feelings, thoughts related to the symptoms and applied self-management strategies. Most of the questions were answered by choosing predefined alternatives or by scoring on a five-point Likert scale. The diaries also included a comment field giving participants the opportunity to write a short personal message to the therapist.	The diaries included 16–19 questions chosen for supporting self-monitoring (level of blood glucose, diet, medicine and achieved activities) and awareness of health behavior, thoughts, feelings and applied self-management strategies. Most of the questions were answered by choosing predefined alternatives or by scoring on a six-point Likert scale. The diaries also included a comment field giving participants the opportunity to write a short personal message to the therapist.
Feedback	During weeks 2–4, participants received daily situational feedback (except weekends) based on the electronic diaries and CBT. The feedback was sent to the participants via SMS and was focused on IBS complaints, catastrophizing thoughts, avoidance behavior and dysfunctional cognitions. A protocol to standardize the feedback was developed based on existing literature. For pragmatic reasons, the protocol was divided into five sets of topics which were structured in a hierarchical way, with the first set of topics (cognitions, emotions, and activities) as the most important to intervene on. If given the input of the patient, the first-order set of topics was not applicable, feedback was provided on the second-order set of topics (eating and drinking) and so on. The purpose of the feedback was to (1) stimulate self-management, (2) provide reassurance and comfort, and (3) give general information about (coping with) IBS.	During 4 weeks participants received daily situational feedback (except weekends). The situational information from the diaries was used to formulate and send a personalized text message grounded in ACT to the participant with the aim of stimulating effective self-management of the current situation. An SMS was sent to signal that feedback was available. The text messages included a link to the website where the feedback was posted. There was no limitation on the length of the feedback, which varied from a few sentences to a few paragraphs.	A therapist had immediate access to submitted diaries and used the situational information to formulate personalized feedback based on ACT. The purpose of the diaries and the situational feedback was to stimulate self-management. Daily written situational feedbacks (except weekends) were given during the first month followed by weekly feedbacks during the next 2 months. The multi-disciplinary group supported development of the feedback during the first period of the study. The therapist used information from the latest submitted diary. An SMS was sent to signal that feedback was available. The text messages included a link to the website where the feedback was posted. There was no limitation on the length of the feedback, which varied from a few sentences to a few paragraphs.
Provider	Psychologist	Nurse and/or psychologist	Nurse

Table 2
Theoretical approach, methods and evaluation.

	Irritable bowel syndrome (IBS)	Chronic widespread pain (CWP)	Diabetes type 2
Theoretical approach	Enhancing appropriate self-management seems to be valuable in terms of improvement of IBS patients' symptoms and quality of life. As the burden of symptoms seems to be associated with symptom-related cognitions and behaviors, an essential part of effective self-management is the restructuring of these dysfunctional cognitions and behaviors, like catastrophizing thoughts and avoidance behavior, through CBT. Patients are oriented toward change and development of new skills and strategies for coping with their problems. Electronic diaries with questions intended to support self-monitoring. The feedback was intended to stimulate self-management. Therefore it was tailored up to a degree according to the registered information, based on CBT and automatically delivered.	Accumulating evidence suggests that web-based interventions using cognitive behavioral approaches are effective in supporting self-management of chronic pain. The feedback was intended to suit the participant's situation as reported in the diary. It was written in an empathic communication style and included positive reinforcement, information, metaphors, CBT exercises and questions aiming to encourage mindfulness and willingness to engage in meaningful activities despite pain or other discouraging intrusions. Electronic diaries with questions intended to support self-monitoring. The feedback was intended to stimulate self-management. Therefore it was tailored up to a degree according to the registered information, based on CBT and automatically delivered.	The theoretical framework was based on ACT regarded as the 3rd generation of CBT. ACT differs from traditional forms of CBT by focusing on articulating and clarifying one's values, on acceptance of one's thoughts, feelings and sensations and on mindfulness together with commitment to behavioral change. Individuals are stimulated to be more flexible and to accept, rather than struggle with, unwanted and dysfunctional disease-related thoughts and emotions. ACT has been successfully applied to support diabetes self-management. Electronic diaries with questions intended to support self-monitoring. The feedback was intended to stimulate self-management. Therefore it was tailored up to a degree according to the registered information, based on ACT and automatically delivered.
Setting and recruitment	GPs were asked to participate by screening their patients based on the IBS ICPC code. The GPs confirmed the diagnoses and checked whether all patients had any comorbidity. They were asked to inform the eligible patients and, if the patient wanted to participate, to notify the researcher. Participants were also recruited via an announcement on the website of the Dutch IBS Association. When patient fulfilled the ROME-III criteria, did not suffer from any comorbidity, and did not receive any other psychological (pharmaceutical) treatment, they were included in the study. After signing an informed consent, patients were allocated at random to either the intervention or the control group. All patients received standard care from their GP. Following the Dutch guideline in general practice, this standard care consisted of reassurance, dietary advice, and education.	Participants were recruited from one rehabilitation center in Norway. Upon admission to the rehabilitation center all patients in the musculoskeletal pain management program received an information letter about the study, where they were invited to attend an information group meeting. At the meeting a researcher presented the study and those interested in participating and who met the inclusion criteria were given an informed consent form to sign. The rehabilitation program for chronic pain included education and pain management in a cognitive setting, various forms of aerobic exercises, stretching, myofascial pain treatment, relaxation and medication as needed. In the fourth week of the rehabilitation program participants were randomized into an experimental group (follow up intervention) or a control group (website only).	The intention was to recruit the participants with diagnosed of type 2 diabetes, through general practitioners (GPs) and to include 10–15 participants to test the feasibility of the intervention in this patient group. Because of the difficulty in recruiting patients through their GPs, the social network of the researchers was also informed about the project and persons asked if they knew potential candidates. The potential candidates with type 2 diabetes who met the inclusion criteria received a letter describing the study. Those interested in participating met with a researcher and received additional information. After receiving complementary information, the patients who agreed to participate in the project, signed an informed consent form. All patients were followed by and received standard care from their GP.
Primary outcome	Pain Catastrophizing Scale (PCS): [14] PCS is a 13 five-point Likert-scaled item questionnaire, with questions on three dimensions: feelings of helplessness when in pain, rumination about pain symptoms, and magnification of pain-related complaints. Patients rate items on a scale from 0 (not at all) to 4 (all the time). The total score range for PCS is 0–52, with higher scores reflecting higher degrees of catastrophizing.	Pain Catastrophizing Scale (PCS)	Glycosylated hemoglobin (HbA1c): This blood test shows the average level of blood sugar over the previous 2–3 months. This indicates how well a person with diabetes is being controlled over time.
Secondary outcome	Irritable Bowel Syndrome Quality of Life Questionnaire (IBS-QoL) [15], Cognitive Scale for Functional Bowel Disorders (CSFBD) [16], Abdominal Pain and Gastrointestinal (GI) symptoms: constipation, diarrhea, bloating, flatulence, and abdominal rumbling.	Pain intensity and fatigue (last couple of days) were assessed on visual analog scales from 0 (no pain/fatigue) to 10 (worst imaginable pain/fatigue), Chronic Pain Acceptance Questionnaire (CPAQ) [17], General Health Questionnaire (GHQ) [18] Chronic Pain Values Inventory (CPVI) [19]	ADDQoL-19 (Audit of Diabetes Dependence Quality of Life) [20] Problem Areas in Diabetes (PAID) [21], BMI A Blood Test to evaluate the HbA1c level, fasting glucose level, HDL cholesterol, LDL cholesterol and triglycerides.
Data collection	The assessment measures were self-administered questionnaires filled out at baseline in the first meeting with the patients (T1), at home immediately after 4-week intervention period (T2) and 3-month follow-up (T3).	The assessment measures were self-administered questionnaires filled out at the rehabilitation center (T1 and T2), at home after the intervention period (T3) and 6 months after discharge from the rehabilitation center (T4). The patients were interviewed in the middle and at the end of intervention.	The data were collected at researcher's and GPs office. The baseline in the first meeting with the patients (T1) at immediately after 12-week intervention period (T2). The participants were interviewed twice. The first time halfway through and the second time at the end of intervention period.

Table 3
Results and conclusion.

	Irritable bowel syndrome (IBS)	Chronic widespread pain (CWP)	Diabetes type 2
Study sample	A total of 116 patients were willing to participate in the study. 40 were excluded, 17 because they did not meet the inclusion criteria and 23 for other reasons. A total 76 were randomized into the two arms. At the end of the study there were 35 patients in the control group and 23 in the intervention group.	A total of 265 patients were invited and 140 were willing to participate in the study. They were randomized into the two study arms. 5 were excluded after randomization because of being included in another research program. 21 withdrew from the intervention group and 2 from the control group. Of those 48 that completed the intervention 47 returned the questionnaires at T3 and 37 at T4. From the control group 37 participants returned the questionnaires at T3 and 40 at T4.	Five GP offices were invited to participate in this pilot study and two agreed. In total, 36 people were invited to participate and 15 agreed to participate in this study. Eleven of the fifteen participants included in the study completed the intervention.
Statistical analysis	Analyses were conducted in MLWIN 2.02 to determine the effects. Analysis with repeated measurements was performed using multilevel analysis, a modern version of the repeated measures ANOVA, which does not require every measurement in every participant at every time point to be available. All estimated means were corrected for autocorrelation between measurements within individuals and standardized for patient's gender, education, age, and diarrhea. All differences between means were tested with the Wald test.	Analyses were conducted in SPSS to determine the effects. The effect sizes were calculated using the difference between the group mean divided by the mean standard deviation of both groups. In the intention to treat analysis last observed value was carried forward. If questionnaires included one or two missing items these were replaced with a mean score (rounded to the closest whole number in case of recoding). If two response alternatives were marked the one indicating more health was chosen. If more than two items were missing a total score was not computed.	Descriptive statistics as means and frequencies were calculated using SPSS version 18. A descriptive summary of the information extracted from the interviews was made, the content was analyzed and themes identified.
Effect	A inter-group comparison of the difference scores between baseline and 4 weeks confirmed that there was significantly more overall quality-of-life improvement ($\chi^2=4.08, P<.05, df=1$), more pain improvement ($\chi^2=5.44, P<.05, df=1$) and more improvement in catastrophizing thoughts in the intervention group ($\chi^2=9.33, P<.01, df=1$). The improvement in the intervention group related to catastrophizing persisted at 3-month follow-up ($\chi^2=7.06, P<.01, df=1$).	After the follow up period the intervention group reported less catastrophizing ($M=9.2, SD=5.8$) compared to the control group ($M=15.7, SD=9.1$), $P\leq 0.001$. Between group effect size (ES) on catastrophizing was large (Cohen's d 0.87, $P< 0.001$) and remained moderate (0.74, $P=0.003$) 6 months after discharge from the inpatient program.	Most of the participants reported positive life style changes. The response rate to daily registration entries was good and few technical problems were encountered. Mean average HBA1c level the week before inclusion was 7.39% (SD=1.11%) and 6.9% (SD=0.8%) at the end of intervention. In summary, the intervention was perceived as meaningful, supportive in breaking habits and establishing new health behavior for most of participants.
Feasibility	As all 37 intervention group patients completed the intervention and completed diaries three times a day for 4 weeks, the e-health intervention seems feasible. However, the higher dropout rate at 3-month follow-up in the intervention group might also indicate a high burden of completing questionnaires as well as diaries for 4 weeks which control group patients did not experience. Future studies should assess this possibility more carefully.	To measure feasibility, we developed a questionnaire to measure patients' experiences and satisfaction with the intervention. Participants were also asked to participate in two semi-structured interviews to explore their experience with the intervention (halfway through and after completion). The results indicated that this intervention is feasible for women with chronic widespread pain.	At the end of the intervention, the participants received a questionnaire to assess their experience with the study. The questionnaire had five main areas with the number of items varying from 8 to 20: (a) participation in the project (12 items), (b) use of smartphone (20 items), (c) daily diaries (12 items), (d) the received feedbacks (12 items), and (e) self-management (8). The scoring range in the answers was on five-point Likert scales from 0 "totally disagree" to 5 "totally agree". Mean average for participation in the project was 4.2 (SD=0.5), for use of mobile phone was 3.3 (SD=0.2), for diaries was 4.4 (SD=0.4), for feedbacks was 4.0 (SD=0.5) and for self-management was 3.4 (SD=0.6). The participants also answered seven questions about the project structure and were invited to participate in two semi-structured interviews (halfway through and after completion).
Conclusion	A cognitive-behavioral intervention on pocket-type computers appears feasible and efficacious for mitigating IBS-related complaints and cognitions in the short-term. The intervention group improved on several aspects, but most on catastrophizing thoughts, and these improvements persisted at 3 months.	Smartphone delivered follow-up intervention based on ACT seems to enhance short- and mid-term effect of inpatient rehabilitation.	The described intervention is feasible and was evaluated as supportive and meaningful. The developed smartphone application seems a promising tool for supporting patients with type 2 diabetes to make important life style changes.