Exploring change processes within a smartphone-delivered intervention using electronic diaries and written situational feedback to support self-management in persons with a chronic illness

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UNDERTAKING A DOCTORAL DEGREE IS BOTH A DREAM AND AN INTELLECTUAL JOURNEY FOR THOSE WHO SEEK AN ACADEMIC CAREER. IT IS EXPECTED THAT THE DOCTORAL DEGREE STUDY PERIOD WILL BE HARD, BUT AT THE SAME TIME INSPIRING AND MEANINGFUL. CHALLENGES OCCUR THROUGHOUT THIS PROCESS; SOME ARE EXPECTED, AND OTHERS COME AS A SURPRISE. IN MY CASE, THE MOST UNEXPECTED WERE THE NEED TO TOTALLY CHANGE MY PhD THEME, AND ALMOST DYING OF SEPSIS IN A HOSPITAL BED. CHANGING MY THESIS THEME BECAME A POSITIVE EXPERIENCE IN WHICH I WAS ABLE TO ACQUIRE MORE KNOWLEDGE AND EXPERIENCE. SURVIVING A SERIOUS INFECTION GAVE ME A NEW PERSPECTIVE ON MY LIFE AND MADE IT POSSIBLE TO FINISH THIS WORK.

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**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACT</td>
<td>Acceptance and Commitment Therapy</td>
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<tr>
<td>ADDQoL-19</td>
<td>Audit of Diabetes-Dependent Quality of Life 19</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>CD</td>
<td>Cognitive Defusion</td>
</tr>
<tr>
<td>CPAQ</td>
<td>Chronic Pain Acceptance Questionnaire</td>
</tr>
<tr>
<td>CWP</td>
<td>Chronic Widespread Pain</td>
</tr>
<tr>
<td>DMT2</td>
<td>Diabetes Mellitus Type 2</td>
</tr>
<tr>
<td>EA</td>
<td>Experiential Avoidance</td>
</tr>
<tr>
<td>EAM</td>
<td>Experiential Avoidance Model</td>
</tr>
<tr>
<td>E-diary</td>
<td>Electronic diary</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioners</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Glycated Haemoglobin</td>
</tr>
<tr>
<td>HCP</td>
<td>Health Care Provider</td>
</tr>
<tr>
<td>IACT</td>
<td>Internet-delivered Acceptance and Commitment therapy</td>
</tr>
<tr>
<td>IBS</td>
<td>Irritable Bowel Syndrome</td>
</tr>
<tr>
<td>LMC</td>
<td>Learning and Mastering Centers</td>
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<tr>
<td>MLM</td>
<td>Multi-Level Model</td>
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<tr>
<td>NCD</td>
<td>Non-Communicable Disease</td>
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<tr>
<td>NPT</td>
<td>Normalization Process Theory</td>
</tr>
<tr>
<td>PA</td>
<td>Pain Acceptance</td>
</tr>
<tr>
<td>PAID</td>
<td>Problem Areas In Diabetes</td>
</tr>
<tr>
<td>PC</td>
<td>Pain Catastrophizing</td>
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<tr>
<td>PCS</td>
<td>Pain Catastrophizing Scale</td>
</tr>
<tr>
<td>PDA</td>
<td>Personal Digital Assistant</td>
</tr>
<tr>
<td>PF</td>
<td>Positive Feelings</td>
</tr>
<tr>
<td>PFA</td>
<td>Pain Fear and Avoidance</td>
</tr>
<tr>
<td>PSM</td>
<td>Pain Self-Management</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized Controlled Trial</td>
</tr>
<tr>
<td>REP</td>
<td>Replicating Effective Programs</td>
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<tr>
<td>RFT</td>
<td>Relational Frame Theory</td>
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<tr>
<td>SMI</td>
<td>Smartphone-delivered Maintenance Intervention</td>
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<td>TAM</td>
<td>Technology Acceptance Model</td>
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<tr>
<td>TA</td>
<td>Template Analysis</td>
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</table>
LIST OF PAPERS

Paper I

Paper II

Paper III

Paper IV
1. INTRODUCTION

Living with a chronic illness is challenging. Complex interventions (CIs) are widely used to support behavioural change, stimulating recovery and coping processes in several chronic diseases. Usually, when developing a CI, researchers take a pragmatic approach based on the research question and the use of the best available evidence and appropriate theory. In 2006, researchers from the Netherlands developed a CI with an innovative concept using mobile technology to receive information from, and deliver support to, participants during their daily life. Participants completed daily electronic diaries (e-diaries) and received tailored situational written feedback from a therapist. A randomized controlled trial (RCT) was conducted to test the feasibility and effectiveness of this CI concept in supporting people with irritable bowel syndrome (IBS). A personal digital assistant (PDA) was used to deliver the intervention based on cognitive behavioural therapy (CBT) (Oerlemans, van Cranenburgh, Herremans, Spreeuwenberg, & van Dulmen, 2011). In 2008, in Norway, this CI concept was refined and tested in an RCT maintenance intervention for women with chronic widespread pain (CWP) after they had participated in in-house rehabilitation. The intervention was delivered via first-generation smartphones and was based on acceptance and commitment therapy (ACT) (Kristjánsdóttir et al., 2013a, 2013b). These two trials showed promising results; the developed CI concept was feasible and resulted in positive effects.

Designing a CI involves several phases: development, feasibility, evaluation and implementation (Craig et al., 2013). The current thesis builds on the two mentioned RCTs, and the main aim was to explore the intervention phase of a CI by investigating factors influencing the change processes. The purpose of analysing the change mechanisms was to understand why this intervention was effective and how these types of interventions can be optimized and implemented in daily health-care. The CWP study produced extensive material collected from 48 participants in the intervention group, and this study was selected for further investigation. The feedback messages were broken down into text segments and analysed. The analyses resulted in a coding scheme representing the different feedback elements. The inter-rater reliability of the coding scheme and the fidelity of the intervention, specifically the therapists’ adherence to the protocol based on ACT theory were tested (Paper I). In a second study, the developed coding scheme was used to investigate whether and how specific elements of ACT theory, applied in the e-diaries and feedback, influenced participants’ behaviour (change processes). The methodology used, statistical analysis and results of this study are described in Paper II.
The development and testing of this CI concept in a new patient group with chronic illness is also part of this thesis. Persons with diabetes mellitus type II (DMT2) were invited to participate in a pilot study to test the feasibility and acceptability of the intervention. By designing and performing the pilot study it was possible to acquire theoretical knowledge especially, but not exclusively, on ACT. The practical experience in developing and performing a CI gave unique insight into all steps and details of a CI and generated valuable knowledge. The pilot study and its results are described in Paper III.

To complete this thesis, a study comparing the use of the new CI concept for three patient groups with chronic illness (IBS, CWP and DMT2) was carried out (Paper IV). In this study, similarities, differences and implementation challenges were investigated.

In Summary, the current thesis (a) explores the change processes in the CWP study (Papers I and II), (b) tests the intervention’s feasibility for persons with DMT2 (Paper III), and (c) compares the three interventions to look at similarities, differences and implementation challenges (Paper IV). Table 1 gives an overview of the timeline of the different studies.

Table 1

<table>
<thead>
<tr>
<th>Background information*</th>
<th>Studies included in the current dissertation</th>
</tr>
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<tbody>
<tr>
<td>Chronic illness</td>
<td>IBS</td>
</tr>
<tr>
<td>Design</td>
<td>RCT study</td>
</tr>
<tr>
<td>Aim</td>
<td>Effect evaluation</td>
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</table>

* The RCT of the IBS and CWP are not a part of this dissertation, but these trials are reviewed in the comparison study (Paper IV).

** The data from the participants who were randomly assigned to the intervention group, and completed the RCT of the CWP, was used in the evaluation of the fidelity and the change processes (Papers I and II).
2. BACKGROUND AND LITERATURE REVIEW

2.1 THE CHALLENGE OF LIVING WITH A CHRONIC ILLNESS

The three chronic illnesses focused on in this thesis, CWP, DMT2 and IBS, are defined as non-communicable diseases (NCDs) which are chronic conditions that are not transmissible, last more than 3 months and are usually of slow progression and incurable. NCDs are the leading cause of disability and mortality worldwide, currently representing 60% of all deaths, and are predicted to increase in the coming decade (World Health Organization, 2012). The prevalence of NCDs in adults is 80% in developed countries and 70% in middle-income countries. NCDs negatively affect people’s general functioning, mental health, work status, relationships and family life, impacting severely on their quality of life (Boutayeb & Boutayeb, 2005; Chodosh et al., 2005; World Health Organization, 2012). Additionally, there is an increase in costs related to increased severity and years lived with the disease, due to the inability to work and increased consumption of medical care (Muka et al., 2015). The cumulative costs of NCDs in low- and middle-income countries are predicted to reach US$ 47 trillion by 2030. The numbers indicate that NCDs have the potential to not only bankrupt health systems but also slow down the global economy (Bloom et al., 2011).

2.1.1 Chronic widespread pain (CWP)

Pain is a subjective experience encompassing multiple dimensions, and is defined by the International Association of the Study of Pain as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994, p. 210). It is important to emphasize that this definition considers the two most important aspects of pain. The first relates to tissue damage and the second relates to cognition, behaviour and emotions (Jensen & Turk, 2014). When the pain experience (a) lasts for more than 3 months, (b) persists beyond the expected period of healing and (c) affects both sides of the body, the axial skeleton and both above and below the waist, the pain is defined as CWP (Wolfe et al., 1990). This is often accompanied by other symptoms, including fatigue, sleep disturbance, emotional distress and functional disability (Lee, Kim, Shin, & Sung, 2011; Salaffi, Sarzi-Puttini, Ciapetti, & Atzeni, 2011). In the general population, the prevalence of CWP ranges from 11.4% to 24% (Cimmino, Ferrone, & Cutolo, 2011), appears to be constant across age groups and affects more females than males (Mundal, Grawe, Bjorngaard, Linaker, & Fors, 2014). In Norway, CWP prevalence is reported to be between 10.6% and 13.5% (Henschke, Kamper, & Maher, 2015), and it is the most common cause of sick leave and disability pension (Ihlebaek,
Brage, Natvig, & Bruusgaard, 2010; Nielsen, Steingrímsdóttir, Berg, & Hånes, 2016). Research indicates that ACT can be an effective approach for teaching individuals with chronic pain ways of managing their pain more effectively (McCracken, 2005).

2.1.2 Diabetes mellitus type 2 (DMT2)

DMT2 results from pancreatic beta cells being unable to secrete sufficient insulin to maintain normal levels of blood glucose, or when peripheral insulin resistance is present. Insulin resistance is a consequence of environmental factors acting across the life-course (reduced physical activity, obesity, low birth weight, and advancing age) and genetic factors. DMT2 accounts for around 90% of all diabetes in developed countries, and accounts for an even higher percentage in developing countries. It occurs most frequently in adults, but is being noted increasingly in adolescents as well (Alberti & Zimmet, 1998).

In the general world adult population, the prevalence of diabetes in 2015 was estimated to be 415 million people (8.8%) and is expected to increase to reach 642 million (10.4%) by 2040. In Norway, there were 289, 600 (7.8%) adults diagnosed with diabetes in 2015 (International Diabetes Federation, 2015).

Diabetes self-management education is a multifaceted process involving much more than helping people with diabetes to monitor their blood glucose or take their medication as prescribed. Diabetes education must be an ongoing process rather than a one-off event because a person’s health status and need for support change over time. Self-management support is established as an evidence-based intervention for diabetes (Norris et al., 2002) and it has been concluded that self-management support is effective, at least in the short to medium term (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Glasgow, Boles, McKay, Feil, & Barrera, 2003; Norris et al., 2002).

2.1.3 Irritable bowel syndrome (IBS)

IBS is a functional bowel disorder and is characterized by a number of symptoms, including bouts of abdominal pain. The pain or discomfort is associated with abdominal bloating and the presence of disordered defecation (constipation or diarrhoea or both). The diagnosis is based on symptomatic criteria such as the Rome III criteria. In the general population, the prevalence of IBS ranges from 5% to 20% and more women than men are affected (Dekel, Drossman, & Sperber, 2015). In Norway, the prevalence has been estimated to be 8% (9.8% for women and 6.3% for men) (Hungin et al., 2014; Vandvik, Lydersen, & Farup, 2006). Psychiatric and somatic
comorbidities are common features in IBS, resulting in working disability and consultations with physicians for the majority of those in the long run (Vandvik et al., 2006).

Treatment options include a wide range of dietary modifications, pharmacological agents and behavioural interventions (Dekel et al., 2015).

2.2 CHRONIC ILLNESS AND SELF-MANAGEMENT

The number of persons with chronic illness is growing due to globalization, the concentration of people in big cities, lifestyle changes and the rapid aging of the population. People with chronic illness often face obstacles in coping with their condition, and self-management is essential to overcoming these obstacles. Self-management can be defined as “the individual’s ability to manage symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition” (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002, p. 178). Constructive self-management “encompasses the ability to monitor one’s condition and to effect the cognitive, behavioral and emotional responses necessary to maintain a satisfactory quality of life” (Barlow et al., 2002, p. 178). Examples of self-management strategies are goal setting, stress management, adhering to medications, attending appointments with health professionals or adjusting one’s activities and diet (Barlow et al., 2002; Flor & Turk, 2011; Gregg, Callaghan, & Hayes, 2007a; Heitkemper et al., 2004).

One of the keys to successful self-management by patients with chronic illness is patient-centred care, where patients start to have an active rather than a passive role in their own treatment. The patients are the ones who best know their limits, challenges and life situation. Therefore, they need support from a health-care provider (HCP) to assist them in making decisions related to the self-management of their chronic condition, rather than having HCPs make decisions for them. When people make conscious decisions based on their own reflection, experience and knowledge, they become committed to their decisions, and the probability that the planned actions based on these decisions will be executed is much higher (World Health Organization, 2005a). Patients with chronic health problems need care that is coordinated across time and centred on their needs, values and preferences. They need self-management skills to ensure the prevention of predictable complications, and they need HCPs who understand that chronic conditions require management over many years and who are able to help them to cope with their health condition (World Health
Furthermore, the involvement of patients in self-managing their disease can improve their health outcomes (Free et al., 2013).

Behavioural change is an integral part of the improved self-management of many chronic health disorders, including CWP, DMT2 and IBS. Interventions designed to support self-management of chronic illness are essential (Lorig, Ritter, Laurent, & Plant, 2006) and often categorized as complex (Craig et al., 2013).

### 2.3 Complex Interventions and Self-management of Chronic Illness

Complex interventions involve many interacting components and involve several phases (development, feasibility, evaluation and implementation). These phases do not necessarily follow a linear, sequential or cyclical order and can take a wide range of different forms (Craig et al., 2013).

According to the Medical Research Council guidelines, a key element of the rationale for the expected patient changes from CI is the use of existing evidence and theory. A good understanding of the theory chosen in the development phase of the CI will be necessary to explain its eventual achieved effects (Craig et al., 2013). When choosing the appropriate theory in interventions aimed at supporting self-management, it is important to understand the process of dysfunctional behaviour, explained by the *experiential avoidance model* (EAM).

![Figure 1. Phases of a CI model with their respective key elements (adapted from Craig et al., 2013).](image)
Receiving a diagnosis of a chronic illness is difficult to deal with, and the responsibility for keeping the illness under control—when a cure is not possible—evokes a range of negative emotions. Anger, fear, guilt, sadness, shame and anxiety frequently affect patients with a chronic illness (Crews, Schneider, Yalla, Reeves, & Vileikyte, 2016; Gregg et al., 2007a; Håkanson, Sahlberg-Blom, Nyhlin, & Ternestedt, 2009; Muscatello et al., 2010; Okifuji, Turk, & Sherman, 2000; Toner & Akman, 2000). There is a mutual relationship between how a person feels and cognitive their interpretation processes. Thoughts affect mood, which in turn affects behaviour. Illness-related thoughts can hinder motivation and the acceptance of treatment, including rehabilitation and self-management (Turk & Monarch, 2006).

The EAM explains this cognitive process. Experiential avoidance (EA) includes any behaviour that functions to let a person avoid, or escape from, unwanted internal experiences or those external conditions that elicit them (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). The avoidance of negative experiences is a protective and survival-instinct mechanism of all animals, including humans. Thus, a rat that receives an electric shock in a chamber will be reluctant to return to that chamber (Blanchard & Blanchard, 1968), and a child will no longer put his/her finger in a power socket after having received a shock. However, although it is a protection mechanism physically, avoidance may be harmful when related to emotions. According to the EAM, avoiding experiences, which may include thoughts, feelings, somatic sensations or other internal experiences, that are uncomfortable or distressing gives short-term relief from discomfort. However, in the long run, this avoidance makes the discomfort even more powerful and intense (Clark, Ball, & Pape, 1991), resulting in maintenance and/or exacerbation of dysfunctional behaviours (Hayes, Strosahl, & Wilson, 1999; Zettle, Hocker, Mick, & Scofield, 2005). In the context of CWP, individuals may curtail their range of activities to avoid coming into contact with painful sensations, leading to passivity and disability and consequently to increased pain (Linton, Flink, Schrooten, & Wicksell, 2016; Turk & Monarch, 2006). For instance, a person with diabetes may avoid feelings of guilt and shame and avoid thoughts of having failed in self-management by not testing their blood glucose regularly. This behaviour contributes to poor control of the level of sugar in the blood, and so a vicious cycle commences. For IBS patients, the experience of bodily sensations associated with illness is often aversive and anxiety provoking. Anxiety can cause altered gastrointestinal mobility, increasing IBS symptoms. In an attempt to diminish the anxiety, a person with IBS may, for example avoid social or work-related situations when experiencing symptoms. This attitude can consequently cause social isolation and depression, worsening the
symptoms through increased anxiety (Ljótsson et al., 2010). These three examples of dysfunctional behaviour differ in form but are functionally equivalent, with the process mechanism represented by EAM being the major driving force for the maintenance of avoidance and disability.

Figure 2. The experiential avoidance model of dysfunctional behaviour (adapted from Chapman, Gratz, & Brown, 2006).

As previously mentioned, behavioral change is needed to achieve self-management. Therefore, overcoming the dysfunctional behaviour driven by the EAM is essential. Evidence-based psychotherapeutic treatments such as CBT and ACT are effective in improving self-management and health outcomes for patients with a chronic illness (Matthews & Doorley, 2016), and ACT has the advantage of being particularly effective in breaking down the EA cycle.

2.5 ACCEPTANCE AND COMMITMENT THERAPY (ACT) TO SUPPORT THE SELF-MANAGEMENT OF CHRONIC ILLNESS

Acceptance and commitment therapy or “ACT” (pronounced as the word “act”) is often called the third generation of CBT. It is based on an extensive research programme studying human
language and cognition called *relational frame theory* (RFT). It is beyond the scope of this thesis to go into RFT in detail. Both ACT and RFT stem from a pragmatic philosophical tradition called functional contextualism. The effectiveness of ACT has been proven for a diverse range of clinical conditions including IBS, CWP and diabetes (Graham, Gouick, Krahé, & Gillanders, 2016; Ljótsson et al., 2011; Trompetter, Bohlmeijer, Veehof, & Schreurs, 2015).

Acceptance and commitment therapy differs from Western psychotherapy (which is founded on the assumption of healthy normality) in the assumption that the psychological processes of a normal human mind are often destructive. The ACT model explains the psychopathology in conjunction with psychological processes, especially those involving human language. Human language is a highly complex system of symbols, which includes words, images, sounds, facial expressions and physical gestures. Language is used in two domains: public (e.g., speaking, gesturing, writing, painting, dancing, etc.) and private (e.g., thinking, imagining, planning, etc.). A psychological term for the private use of language is *cognition*. The mind is a complex set of cognitive processes, such as analysing, planning, remembering and visualizing, and these processes are dependent on human language. An assumption of ACT is that human language naturally creates psychological suffering for us all. The uniqueness of ACT is that, in contrast to most Western variants of psychotherapy, ACT does not have symptom reduction as a goal. When personal experiences are tagged as "symptoms", one will most likely immediately oppose them, because a symptom is by definition something pathological; something one tries to get rid of. Within ACT, one has a contrasting perception that ongoing attempts escape such experiences will actually lead to clinical ailments. This process is, as mentioned previously, called EA. By avoiding unwanted sensations, a person can experience a short-lived sense of relief, but in the long run, these sensations may become even stronger.

The goal in ACT is to change the relationship one has to difficult thoughts and feelings, so that one perceives them not as symptoms, but rather as normal, transient processes. It is through this process that ACT has been proven to lead to symptom reduction—but as a consequence rather than as a goal (Harris, 2006; McCracken, 2005). The ACT approach offers people alternative means of breaking the negative cycle of EA through a variety of therapeutic interventions applying mindfulness and acceptance. It is not a disease-specific treatment, but rather a general approach that can form the basis for the development of several treatment protocols tailored to specific conditions, patient populations or contexts. Examples of suitable conditions might include anxiety, depression, several chronic diseases and addiction. Examples of suitable contexts might include the family, primary care and/or hospital. Although language is seen as the originator of
many psychological problems, it is also responsible for numerous human advantages over other species. People use language to shape the world, structure it and give it meaning. Unlike other forms of therapy, which seek to change the mind’s content, ACT seeks to help the client put her or his language and thoughts under appropriate contextual control (Hayes, Strosahl, & Wilson, 2003; McCracken, 2005).

The goal with ACT is to achieve psychological flexibility, which is the ability to be in contact with the moment as a fully conscious human being, and either change or persist with behaviour depending on whether it serves one’s goals (Hayes, Strosahl, & Wilson, 2012). All ACT interventions aim to increase flexibility in one’s actions and to increase sensitivity to those actions’ functionality. Because all ACT elements have the same goals, they can be introduced in different orders. Therapists working with ACT often rely on paradoxes, metaphors, stories, exercises, behavioural tasks and experience-based processes. Direct instruction and logical analysis have a relatively limited role, although they do occur (Hayes, 2004; Hayes et al., 1999). The six core elements of ACT (values, committed action, self as context, cognitive defusion, acceptance and mindfulness) are overlapping and interrelated, supporting each other in the development of psychological flexibility (Hayes, Luoma, Bond, Masuda, & Lillis, 2006).

Values are the deep, meaningful things in a person’s life, or their choice of life direction. Values concern how we want to live; the ideals we have; and what kind of friend, partner, parent, child or employee we want to be. Values differ from goals in that they can never be fully realized, but they can give a continuous sense of motivation, direction and purpose. Values give life meaning, and according to ACT theory, having a clear understanding of ones’s values is an effective component of a dynamic and meaningful life. For people with chronic disease, one of the life values connected to health might be to have the illness under control. To achieve such control, physical exercises are recommended, at least for the three chronic illnesses mentioned in this thesis. Beginning and/or maintaining regular physical exercise is stimulated by committed action, a specific and concrete action plan guided by one’s values, anticipating and taking into account barriers along the way. This is a continuous process that one must always work on. Committed action means living according to one’s own values and simultaneously taking responsibility for restarting the process when one does not succeed. Unlike values, which are defined but never “achieved”, one works in the committed action process actively with short- and long-term, value-oriented goals. Goals are most effective if they are consistent with values and if they comprise many small steps to achieve a main objective (Hayes et al., 2003; McCracken, 2005). In a
physical exercise context, a person who has a final goal of running at least one hour a day can start by walking 15 minutes daily and then increase this gradually.

As previously mentioned, people with chronic diseases have different degrees of psychological burden, and in an attempt to relieve this burden, unconsciously, the cycle of EA is triggered. Acceptance, as opposed to EA, means openness to experience, emotions and thoughts and allowing them to come and go without a struggle. It is natural to try to control painful experiences, and many patients invest a lot of time and energy in avoiding these experiences. In reality, suffering is a natural part of life. When we grow and develop, we learn to deal with and accept negative emotions instead of letting them be a barrier (Hayes, Levin, Plumb-Vilardaga, Villatte, & Pistorello, 2013). Acceptance based-approaches are increasingly used to reduce suffering in persons with various chronic illnesses (Graham et al., 2016).

Mindfulness is to be fully aware of the present moment with openness, interest and receptiveness. According to ACT, by being in the moment and aware, and observing and describing experiences without judgment, people will be better able to act on what they really want in life. Mindfulness involves the self-regulation of one’s attention and the quality of one’s acceptance. Mindfulness exercises include meditation and daily life exercises to teach the ability to become aware and accept present experiences and sensations rather than struggling with thoughts about the past and future (McCracken, 2005). Mindfulness exercises can also increase awareness of self-as-context, which allows people to be aware of psychological content without linking it to their personal identity. By learning to consciously take the position of the so-called “observing self”—creating a sense of distance between one’s self and one’s thoughts—and then making decisions, in this state, one can live according to one’s life values and base one’s actions on value-oriented directions. Thus, it may become easier to view thoughts as cognitive events and their content as something that the mind produces that may or may not reflect the reality. Stepping back from the process of thinking is called the cognitive defusion process, and this is where people learn how to distance themselves from their own thoughts, and avoid being affected by them, as an “outside observer” (Hayes et al., 2013; Hayes et al., 2006; McCracken & Keogh, 2009).

In summary, the application of ACT in the treatment of a chronic illness can be tailored to patients’ needs and has the objectives helping people to clarify their life values and stimulating them to act according to these values with commitment. It teaches people to be in contact with the present moment, to accept unpleasant thoughts and feelings and to be aware that these do not necessarily need to have an impressive influence on their lives. By doing this, it is possible to
break the EA cycle and move from maladaptive cognition to psychological flexibility, and consequently, to achieve self-management.

![Diagram of psychological flexibility](image)

**Figure 3.** From maladaptive cognition to psychological flexibility (adapted from Hayes et al., 2006).

The use of therapy based on theory, such as ACT, increases the chance that interventions aiming to support self-management in chronic illness will be effective. Clinical psychologists and healthcare professionals in related disciplines also play a key role in the treatment of people with long-term conditions (Chawla & Ostafin, 2007; Hayes et al., 1996; Webb, Joseph, Yardley, & Michie, 2010).

Conventional treatments to stimulate self-management, based on CBT with ACT, are delivered face-to-face weekly or less frequently, but the internet and devices such as smartphones have opened up new possibilities for delivering CBT.

### 2.6 Smartphone-Delivered Self-Management Interventions

Research on chronic illnesses is extensive and expanding. Enhanced self-management, as mentioned previously, significantly reduces the burden of disease and improves health outcomes (Matthews & Doorley, 2016). However effective management of a chronic illness is time
Consuming. Expertise in chronic conditions is often linked to a specialist and not available where the patient lives. In addition, health-care institutions and providers are constantly pressured to make care more effective and affordable, especially for patients with a chronic illness (Coye, Haselkorn, & DeMello, 2009).

Communicating via the internet has become an integral and accepted part of Norwegian society, as it has elsewhere in the world. Since 2009, global internet penetration has increased from 25% (June 2009) to 49.2% (June 2016), with estimates in Europe and North America being considerably higher (73.9% and 89%, respectively). Iceland has the highest penetration in the world (98.2%), followed by Bermuda (96.8%) and Norway (96.3%) (Internet World Stats, 2016). These data show that internet penetration is in a constant and rapid increase, with the potential to reach almost all people worldwide within a few years. The internet has opened up a new way of delivering health: e-health services. E-health, according to the World Health Organization, "is the cost-effective and secure use of information and communication technology in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research" (World Health Organization, 2005b, p. 3). The internet has made health-care more accessible to people, especially for those who suffer from a chronic illness and live far from hospitals and qualified therapists. The internet can enhance health literacy and health-related knowledge and support people to become responsible for their own health (Jacobs, Lou, Ownby, & Caballero, 2016). Examples of e-health can vary from digitally collecting health-related information and monitoring disease symptoms (Johansen, Henriksen, Horsch, Schuster, & Berntsen, 2012) to a digitally enable CI with several interactive elements. Normally, these interventions have a similar effect at a lower cost than face-to-face interventions (Buhrman, Gordh, & Andersson, 2016; Eccleston et al., 2014). The internet also provides the health promoter with opportunities for the continuous maintenance and updating of interventions (Kohl, Crutzen, & de Vries, 2013). Researchers in the field of health promotion have followed the exponential growth of the internet, and an increasing number of interventions designed to promote changes in health behaviour have been delivered using the internet (Webb et al., 2010). In addition, studies show that people with different chronic conditions (including CWP, DMT2 and IBS) are positive about the use of e-health interventions with the goal of improving self-management (Kerr, Murray, Stevenson, Gore, & Nazareth, 2006; Proudfoot et al., 2010; Rosser et al., 2011).

The use of a recognized theory in internet interventions associated with positive results and large effect sizes (Webb et al., 2010). Most internet interventions that stimulate behavioural change are
based on CBT, because CBT suits the self-help format well (Andersson et al., 2008; Andersson, Carlbring, & Lindefors, 2016; Proudfoot et al., 2011).

Although traditional CBT is widely used to stimulate self-management, several researchers have argued that ACT has elements better suited than other psychotherapeutic models to treat chronic illnesses, and HCPs are increasingly adopting ACT techniques when working with long-term conditions (Graham et al., 2016). This trend is also being followed by researchers, and an increasingly large number of studies that use the internet-delivered ACT (IACT) interventions have been reported. The IACT interventions reported since 2012 have included patients with chronic pain, tinnitus and mental health problems such as anxiety, stress and depression. Most of the IACT interventions reported from 2012 to 2016 comprised several modules corresponding to the different ACT processes, weekly homework and therapist feedback based on the homework responses (Böing, 2014; Brown, Glendenning, Hoon, & John, 2016; Buhrman et al., 2016; Buhrman et al., 2013; Hesser et al., 2012; Hesser, Westin, & Andersson, 2014; Lappalainen et al., 2014; Levin, Haeger, Pierce, & Twohig, 2016; Lin et al., 2015; Pots et al., 2016; Trompetter et al., 2015). Some of these reported interventions used additional interactive features, such as visual presentations (videos and films) (Levin et al., 2016; Lin et al., 2015), audio files with instructions for mindfulness exercises (Buhrman et al., 2013; Hesser et al., 2014; Lappalainen et al., 2014; Levin et al., 2016; Lin et al., 2015; Pots et al., 2016), phone calls and SMS (i.e., short message service) reminders (Lappalainen et al., 2014; Levin et al., 2016).

Today, we can access the internet using different devices, such as computers, tablets and smartphones. Smartphones are made to be pocket sized and are carried everywhere by their owners. They can be connected to the internet all the time, using mobile networks such as via 3G, 4G or 5G. Most smartphones are cheaper than computers and tablets, with relatively low maintenance costs, making them more accessible for people in developing countries. For many of these people, a smartphone is their first computer and their only internet-connected device (Bonnington, 2015). Smartphones can be programmed, run applications, record and play media (audio, photographs and video) and interact with the user to allow the input of data using a touchscreen. Therefore, smartphones are currently the best way of delivering e-health (Boschen & Casey, 2008; Tufano & Karras, 2005). Several studies have already shown that smartphone delivered-interventions are effective in supporting people with different chronic conditions (Free et al., 2013; Whitehead & Seaton, 2016), including interventions based on ACT (Kristjánsdóttir et al., 2013a, 2013b; Ly, Asplund, & Andersson, 2014; Wayne & Ritvo, 2014). The advantages of smartphone-delivered interventions for self-management support may include reduced time
constraints and travel costs, a self-determined work pace and increased access for stigmatized groups and home-bound persons. Interventions with no therapist contact or limited contact may be cost effective and increase the general availability of support (Barak & Grohol, 2011; Keogh, 2013).

Additional advantages of smartphones delivered-interventions are the use of real-time self-monitoring and interactivity. The interactivity can involve situational feedback, either automatically generated by a computer and tailored to input, or personalized by a HCP (Bäck & Mäkelä, 2012; Heron & Smyth, 2010; Keogh, 2013). For the past decade, there has been considerable research on smartphone interventions to support behavioural change and self-management in persons with chronic conditions. Most studies have reported positive changes in health outcomes (Fjeldsoe, Marshall, & Miller, 2009; Wei, Hollin, & Kachnowski, 2011). However, the field is still immature, with relatively few high-quality RCTs on each condition, with the exception of diabetes. Smartphone-delivered interventions to the support self-management of diabetes have been established as being effective in recent review and meta-analysis studies (De Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car, & Atun, 2012; Jeon & Park, 2015; Whitehead & Seaton, 2016). For other conditions, there is some evidence of positive effects but research on long-term effects is generally limited (De Jongh et al., 2012; Fjeldsoe et al., 2009). More research in this field is therefore needed.

Even though positive effects of smartphone interventions have been found in some studies, the mechanisms leading to these effects have not been explored (Jeon & Park, 2015). The main objective of this thesis is to contribute to this research field by exploring the change mechanisms of a complex “smartphone-delivered maintenance intervention” (SMI) with e-diaries and written feedback based on ACT. The SMI was tested in an RCT with the aim of supporting women with CWP after a rehabilitation period, and showed positive results immediately after and 5 months after the intervention (Kristjánsdóttir et al., 2013a, 2013b). Understanding the change processes is a key element in the evaluation phase of a CI. It is important to emphasize that although the focus of the current thesis is on analysing change mechanisms, it also covers all phases of the CI model, including feasibility testing for people with DMT2 and a discussion of implementation challenges in daily health-care.
3. AIMS

3.1 OVERALL AIMS

1. To investigate the processes leading to the effect of the SMI for women with CWP by examining:
   - the therapists’ adherence to the protocol when writing feedback messages; and
   - the association between participants’ e-diaries outcomes and feedback content.

2. To develop and test the feasibility of a pilot study using a smartphone-delivered intervention, with e-diaries and individualized feedback, for stimulating self-management in people with DMT2.

3. To compare three web-based interventions based on the same intervention concept delivered by mobile technology for different chronic illnesses (CWP, DMT2 and IBS)

3.2 SPECIFIC AIMS OF EACH PAPER

The aims of the studies reported in this thesis were:

1. To evaluate the therapists’ adherence to the treatment protocol based on ACT theory in the written individualized feedback for women with CWP (Paper I) by:
   - creating a feedback coding scheme;
   - calculating the inter-rater reliability; and
   - comparing the coded feedback content with the intervention protocol content

2. To investigate change processes resulting from an RCT of an SMI with e-diaries and individualized written feedback based on ACT to support self-management in women with CWP (Paper II) by:
   - analyzing e-diary content during the intervention period (38 days); and
   - analyzing the associations between the coded feedback and participant outcomes, as conveyed by their e-diary content.

3. To systematically develop a smartphone-delivered intervention with e-diaries and individualized written feedback based on ACT to stimulate and support self-management in people with DMT2, and to test and evaluate the usability and acceptability of this
intervention (Paper III).

4. To compare three similar web-based CBT-grounded interventions including e-diaries and individualized written feedback messages delivered through mobile technology (PDA or smartphone) (Paper IV) by:
   - summarizing the content and features of these interventions; and
   - discussing implementation challenges.
4. MATERIAL AND METHODS

The methodology applied to a study influences how well the research question is answered. Therefore, the four studies presented in this thesis had different designs and approaches. Different statistical methods were also required to analyse the results. In this chapter, information about the samples, intervention concept, data collection, assessments, statistical analyses and ethical considerations for each of the four studies is presented.

4.1 DESIGN

4.1.1 Fidelity study of a smartphone intervention for women with CWP (Paper I)

This was a study with a qualitative, descriptive design that investigated the treatment fidelity of an SMI based on ACT for women with CWP by developing a coding scheme based on elements from written therapist feedback messages. Further, the inter-rater reliability and therapist adherence to the treatment protocol based on ACT were analysed.

![Figure 4. CWP fidelity study design](image_url)
4.1.2 Change processes during the intervention period of the CWP study (Paper II)

Paper II describes a quantitative study combining longitudinal and correlation designs to investigate the change processes resulting from the RCT of the SMI for women with CWP. Associations between coded situational feedback messages written by a therapist and participant outcomes, as conveyed by their e-diary daily responses, were analysed over time, making it possible to evaluate how different variables behaved over that period.

![Change processes study design](image)

Figure 5. Change processes study design

4.1.3 Pilot study of a smartphone intervention for persons with DMT2 (Paper III)

This was a single-group feasibility study with a 3-month smartphone delivered-intervention. The assessment scales were completed before the intervention (T1) and after the intervention (T2) the intervention. Two semi-structured interviews were carried out to explore participants’ experiences with the intervention; the first after phase 1 of the intervention (I1) and the second after phase 2 of the intervention (I2).
4.1.4. The comparison study of the CWP, DMT2 and IBS interventions (Paper IV)

Paper IV presents a comparison study with a descriptive design presenting and discussing the content and the efficacy of three comparable CBT-grounded, web-based interventions delivered by PDA/smartphone for people with IBS, CWP and DMT2, respectively. In this study, the similarities, differences and implementation challenges of the interventions were also investigated.

Figure 6. Feasibility study design

Figure 7. Descriptive study design
4.2 Samples

4.2.1 The CWP fidelity study (Paper I) and change process study (Paper II)

The participants were women with CWP who were randomly assigned to the intervention group of the RCT of the SMI (Kristjánsdóttir et al., 2013a).

For the fidelity study, 42 women (out of 51 in total) were included. The inclusion criterion for choosing these participants was that they had received ≥75% of scheduled feedback messages.

For the change process study, all participants who completed the intervention (48 women) were included.

4.2.2 The DMT2 pilot study (Paper III)

Fifteen participants (five women and ten men) aged 46–71 years (mean 59.6) met the inclusion criteria and 11 completed the intervention. The inclusion criteria were: age 18–71 years; glycated haemoglobin (HbA1c) 7.5–10%; DMT2 diagnosed >3 months prior to the study; capable of completing Norwegian questionnaires; able and willing to give signed informed consent; willing to attend the full treatment schedule, including the ability to use smartphones; and not being diagnosed with a profound psychiatric disorder. Participants were recruited through general practitioners (GPs) and research networks in Oslo, Norway, between April and September, 2010.

4.2.3 The comparison study (Paper IV)

Three studies including PDA/ smartphone delivered-interventions incorporating e-diaries and feedback written by a therapist for patients with IBS (Oerlemans et al., 2011), CWP (Kristjánsdóttir et al., 2013a) and DMT2 (Nes et al., 2012).

4.3 The Intervention concept

The intervention concept, as mentioned in the introduction, was developed in 2006 by a research group in the Netherlands for stimulating self-management by people with IBS (Oerlemans et al., 2011). In Norway, this concept was refined and tested in an RCT as a maintenance intervention for women with CWP (Kristjánsdóttir et al., 2013a, 2013b) and in a pilot study for persons with DMT2, conducted as part of this dissertation (Paper III, described in Appendix 1). The CWP fidelity study (Paper I) and change process study (Paper II) for this dissertation were possible
because of the data generated from the 2013 CWP study. These data consisted of the e-diaries and feedback messages that were the principal elements of the intervention concept in this study.

Paper IV compares and summarizes three similar studies with web-based CBT/ACT-grounded interventions delivered through PDAs/smartphones for patients with IBS, CWP and DMT2, respectively. The common core of the intervention concept applied in these three studies is described in detail in that comparison paper. Such knowledge about the intervention concept is important as background for understanding the main studies in this thesis. The principal elements of the intervention concept shared across all the three studies were: (a) mobile technology with internet access, (b) the theoretical background, (c) daily e-diaries and (d) daily individualized situational feedback, as described below. (For detailed information about finer nuances of the intervention concepts for these studies, we refer to the respective studies’ original articles).

a) Mobile technology with internet access: The mobile technology chosen for each intervention was the newest-generation PDA/smartphone available on the market. The IBS study used a PDA while the CWP and DMT2 studies used a smartphone. These technologies made it possible to access a system for completing in the e-diaries and reading the feedback messages. The system transferred, encrypted and stored the data on a secure server. No data were saved on the participants’ devices.

b) Theoretical background: This element is in line with the Medical Research Council guidelines, which state that evidence and theory are the principal reasons for the expected changes in a CI (Craig et al., 2013). In the IBS study, CBT, a recognized theory often applied in self-management interventions, was chosen. For the CWP and DMT2 studies, the third generation of CBT, ACT, was chosen.

c) Daily e-diaries: The number of questions in the e-diaries ranged from 9 to 15 (IBS study), 16 to 24 (CWP study) and 16 to 21 (DMT2). Shorter diaries increase participants’ adherence to interventions (Morren, Dulmen, Ouwerkerk, & Bensing, 2009). The questions were formulated with the aim of supporting self-management. Most of the questions could be answered by choosing predefined alternatives or by scoring on a Likert scale. A few questions contained a text field giving participants the opportunity to provide the therapist additional information. The participants filled in three e-diaries daily. The times scheduled for receiving and sending the morning and the evening diaries were decided between the participants and their therapist. The timing of the midday diary was chosen by the server at random and varied from 1p.m to 3 p.m. (IBS study) and 11 a.m. to
2 p.m. (CWP and DMT2 studies). The purpose of the three diary entries, including one at a randomly chosen time, was to encourage self-monitoring and reflection at different times and in different situations, and to identify the associated emotions, thoughts and coping practices, which usually fluctuate during the day. The participants completed the first diary at the initial meeting with the researcher, and continued for 1 week before receiving the first feedback. This was considered a run-in period; that is, a training period in which the participants became accustomed to completing the e-diaries without receiving feedback. According to the literature, a start-up training session in the use of e-diaries is necessary and a run-in period is recommended (Piasecki, Hufford, Solhan, & Trull, 2007). After the run-in period the participants continued to complete the e-diaries until the end of the intervention period (3 weeks for the IBS study, 4 weeks for the CWP study and 12 weeks for the DMT2 study). During the intervention period the researcher was available to answer any question regarding the intervention, including technology issues.

d) Daily individualized situational feedback: After the run-in period, the participants started to receive daily individualized situational feedback (excluding on weekends) written by a therapist. The feedback messages were based on the diary responses and the chosen theory (CBT/ACT) with the aim of promoting self-management. They were written in an empathetic style and included repetition of the content reported in the diaries, positive reinforcement and reminders of self-management strategies. There was no limit on the length of the feedback, and this ranged from a few sentences to a few paragraphs. The feedback focused on different CBT or ACT elements, according to the protocol, over the course of the intervention period. The e-diaries and feedback messages were adapted to the target patient group in accordance with the diagnosis. The participants of the CWP study received the intervention following an intensive treatment period in a rehabilitation centre. The IBS and DMT2 participants received the treatment in addition to their current treatment.

4.4 PROCEDURE FOR DATA COLLECTION

4.4.1 The CWP fidelity study (Paper I) and change process study (Paper II)
In the fidelity study, the qualitative data consisted of 790 de-identified feedback messages written by a therapist. These were collected daily during the 4 weeks, excluding weekends.
In the change process study, both quantitative and qualitative data were collected. The analysed material consisted of de-identified e-diaries (3,372 entries) collected three times a day over 5 weeks and 799 de-identified written feedback messages.

4.4.2 The DMT2 pilot study (Paper III)
Quantitative and qualitative data were collected. The quantitative data were collected with self-reported questionnaires and blood tests before and after the intervention. The qualitative data were gathered during two semi-structured interviews, after the first phase and at the end of the intervention. One of the two researchers involved in writing feedback participated in each interview, which generally lasted one hour. Although the interviews were recorded and transcribed, the interviewer(s) also took notes during and after each interview. The self-report questionnaires were completed in the first meeting with the researcher and after the second interview with the participants. The blood test was taken in the GP’s office. An overview of the time points of the assessments is given in Figure 6. Copies of the assessment questionnaires and the interview guide (in Norwegian) is provided in Appendices 4–9.

4.5 ASSESSMENTS

4.5.1 The CWP fidelity study (Paper I)

Assessment of feedback messages
The de-identified written feedback messages from the RCT of the SMI for women with CWP (Kristjánsdóttir et al., 2013a) were qualitatively analysed based on ACT and communication framework and a coding scheme/system was created.

Assessment of fidelity
The developed coding scheme was used to access the protocol’s adherence to the theoretical background of ACT (adherence is one of the measures of fidelity). The coding team consisted of four members (AAGN, EAB, RW & HE) who participated actively in the coding process, discussions and revisions. The final phase of coding process were done by two researchers (AAGN & EAB) that independently coded 280 text segments from 91 feedback messages, and the inter-rater reliability was calculated. All feedback messages were then coded to identify how ACT principles were used in the daily feedback.
4.5.2 The CWP change process study (Paper II)

Assessment of daily diaries

Physical activities (represented by PLA, PMA, PHA, ELA, EMA and EHA): The daily diaries had a list of activities to choose from for planned activities (morning and midday) and executed activities (midday and evening). Both planned and executed activities included low-level activities (horizontal exercises, relaxing, and stretching), medium-level activities (slow-tempo exercise), and high-level activities (aerobic exercise). The variables constructed were planned activity (Low = PLA, Medium = PMA and High = PHA) and executed activity (Low = ELA, Medium = EMA and High = EHA). It was possible for the participants to select one or more options. All responses were coded as 1 (for selected options) or 0 (for options that were not selected). The activities were analysed as dependent variables to measure change over time. All types of activities were analysed separately, as were the times (morning, afternoon, and evening). All activities of all types on each day were added to measure the daily total.

Evaluation of performed physical activities: The daily diaries (midday and evening) were guided by the question “How satisfied am I with my level of activity since the last entry?” Participants answered by choosing one answer on a five-point Likert scale (very satisfied, satisfied, neutral, dissatisfied, very dissatisfied). By analysing their responses as a dependent variable, it was possible to ascertain how the participants’ satisfaction with their physical activities varied over time. The scale responses were coded from 0 (very satisfied) to 4 (very dissatisfied).

Commitment to physical activities: By using the executed activity as a dependent variable and the planned activity as an independent variable in predicting the activity, it was possible to measure the participants’ commitment.

Pain catastrophizing (PC): Three statements from the Pain Catastrophizing Scale (PCS) (Sullivan, Bishop, & Pivik, 1995) were included in the random diary.

1. “Right now, I worry about whether the pain will end”
2. “Right now, I feel that there’s nothing I can do to reduce the intensity of the pain”
3. “Right now, it feels like I can’t stand the pain anymore”

A five-point Likert scale measured the responses (agree completely, agree, not sure, disagree and disagree completely), coded from 0 (agree completely) to 4 (disagree completely). The higher the score, the more the participants disagreed with the statements, indicating less catastrophizing. The independent variable representing pain catastrophizing was a sum score from these three
questions. By analysing this sum score as a dependent variable, it was possible to evaluate how the participants’ pain catastrophizing varied over time.

Pain acceptance (PA): The statement “Right now, I feel my life is going well, even though I have chronic pain” represented pain acceptance. This is an item taken from the Chronic Pain Acceptance Questionnaire (CPAQ) (McCracken, Vowles, & Eccleston, 2004). Responses were measured on the same five-point Likert scale and coded from 0 (agree completely) to 4 (disagree completely) as above, with lower scores indicating more acceptance. By analysing the score for this statement as a dependent variable, it was possible to evaluate how the participants’ pain acceptance varied over time.

Pain fear and avoidance (PFA): Four statements represented pain fear and avoidance.

1. “Right now, I don’t dare to move a lot because of the pain.”
2. “Right now, I try to avoid activities that cause pain.”
3. “Right now, I am afraid of the pain.”
4. “Right now, I believe it is dangerous for me to move my body”

Responses were measured on the same five-point Likert scale and coded from 0 (agree completely) to 4 (disagree completely) as above, with higher scores indicating less fear and avoidance. By analysing the sum for the scores of these statements as a dependent variable, it was possible to evaluate how the participants’ pain fear and avoidance varied over time.

Pain self-management (PSM): Five statements represented pain self-management.

1. “Right now, I use what I’ve learned to help keep my pain under control.”
2. “Right now, I cope well with the pain.”
3. “Right now, I do what I want, even though it causes increased pain or makes the pain reappear.”
4. “Right now, I’m using some strategies to help me better deal with my pain problems.”
5. “Today, I was able to do what I wanted and needed despite the pain.”

Responses were measured on the same five-point Likert scale and coded from 0 (agree completely) to 4 (disagree completely) as above, with lower scores indicating better self-management. By analysing the sum of the scores of these statements as a dependent variable, it was possible to evaluate how the participants’ pain self-management varied over time.

Positive feelings (PF): Five statements represented positive feelings.

1. “Right now, I am in a good mood.”
2. “Right now, I am grateful.”
3. “Right now, I am relaxed.”
4. “Right now, I am satisfied.”
5. “Right now, I am enthusiastic.”

Responses were measured on the same five-point Likert scale and coded from 0 (agree completely) to 4 (disagree completely) as above, with lower scores indicating more positivity. By analysing the sum score of these statements as a dependent variable, it was possible to evaluate how the participants’ positive feelings varied over time.

**Evaluation of feedback:** Participants’ evaluation of feedback was also investigated. Each evening the participant could choose from a list of seven statements.

1. “The feedback has helped me to stay suitably active.”
2. “The feedback has helped me to be aware of my feelings.”
3. “The feedback has helped me to stay positive.”
4. “The feedback has helped me to be aware of my coping strategies.”
5. “The feedback was not helpful today.”
6. “Received no feedback today.”
7. “Something else.”

It was possible to choose all or to submit the diaries without answering these questions. In the first 6 days, participants were at the rehabilitation centre and did not receive feedback messages. Therefore, the first week and the weekends were not included in the analysis of participants’ evaluation of feedback.

**Assessment of feedback messages**

In a previous study (Paper I), the feedback messages were qualitatively analysed based on ACT and a communication framework. A coding scheme/system was created (Nes et al., 2015). Based on this coding scheme, the feedback messages the therapists wrote for all participants who completed the SMI were divided into text segments and coded, making it possible to investigate correlations between the participants’ outcomes, as conveyed by their diary responses, and the specific content of feedback messages.
4.5.3 The DMT2 pilot study (Paper III)

Participants’ evaluation of the intervention
At the end of the intervention, the participants received a questionnaire to assess their experience with the study. The questionnaire had five main areas: (a) participation in the project, (b) use of the smartphone, (c) daily diaries, (d) the received feedback messages, and (e) self-management. Answers were scored on a five-point Likert scale from totally disagree to totally agree. The participants also answered seven questions about the project structure. The development of this questionnaire was based on a similar questionnaire from a previous study (Kristjánsdóttir et al., 2011). The entire questionnaire developed for the evaluation of the intervention is available in Appendix 4.

The aim of this study was to develop an intervention in line with participants’ needs. They were invited to attend two semi-structured interviews conducted by AAGN. The interviews were performed in a place convenient for the participant (at the GP’s office, at a researcher’s workplace or at a researcher’s home). The interviews lasted about one hour and were recorded, and the interviewer also took notes during and after each interview. In these interviews, the patients shared their experiences of the intervention and provided suggestions for improvement. An interview guide was used (see Appendix 5) to maintain the desired focus on the topics to be addressed. These interviews were performed after phase 1 of the intervention and after the completion of the study. The interviews were transcribed and qualitatively analysed together with the interviewer’s notes. From these analyses, themes were identified, e.g., technical problems and usability issues. The therapists’ experiences were also considered in the feasibility evaluation process.

Socio-demographic data
A socio-demographic questionnaire was applied before starting the intervention to obtain information on sex, age, marital status, friends and acquaintances, education, employment and changes in life situation (Appendix 6).

Disease characteristic data
Questions about how the diabetes was diagnosed, diabetes-related and other regular medication, diabetes control, blood sugar level control, eye problems, foot problems, any other addiction
disease and smoking behaviour were answered on a self-report questionnaire before the intervention (Appendix 7).

**Primary outcome**

**Glycated haemoglobin (HbA1c)** is a measure of the average plasma glucose concentration over the previous 3 months. These objective data were collected as part of usual care by taking a blood test before and after the intervention. The results were registered in each patient’s journal in the GP’s office and were available for the researcher.

**Secondary outcomes**

**Audit of Diabetes-Dependence Quality of Life19 (ADDQoL-19)** (Bradley et al., 1999) is a diabetes-related quality of life self-report questionnaire designed to assess the extent to which diabetes may affect different aspects of life. The ADDQoL-19 includes two overview items that are scored individually and 19 specific life-domain items, with the purpose of assessing, according to the participant’s perspective, how much better/worse his or her life quality would be if he/she did not have diabetes, and how important each one of these 19 aspects of life quality is for the individual (Bradley et al., 1999) (Appendix 8). The ADDQoL-19 was applied before and after the intervention.

**Problem Areas in Diabetes (PAID)** (Snoek, Pouwer, Welch, & Polonsky, 2000) is a brief self-report measure of diabetes-related distress that has been found to be useful in patients with diabetes (types 1 and 2). PAID scores have been found to show positive associations with HbA1c and are major predictors of poor adherence to treatment, independently of general emotional distress (Appendix 9). PAID was applied before and after the intervention.

### 4.6 DATA ANALYSIS AND STATISTICAL METHODS

#### 4.6.1 The CWP fidelity study (Paper I)

To develop a coding scheme, the feedback messages were analysed qualitatively using *template analysis* (TA), which combines deductive and inductive approaches (Crabtree & Miller, 1999; King, 2004; Thagaard, 2003).

The kappa statistic was calculated to measure the inter-rater reliability after the development of the coding scheme (McHugh, 2012).
4.6.2 The CWP change process study (Paper II)
Multilevel models (MLMs) were used to analyse the correlation between variables resulting from
diary responses and variables resulting from the feedback messages. To analyse the internal
consistency of the PC, PFA, and PSM results, the ordinal reliability test was applied. For this
study, the variables were analysed using MLMs with the intercept and time slope as covariates,
both as fixed and random effects. All calculations were done using an R statistical program. For
the mixed models, the lme multilevel package was used. For internal consistency analyses, the
Rcmdr, psych and GPArotation packages were used (R Development Core Team, 2011). The
correction for multiple testing was done using the Bonferroni test (Gordi & Khamis, 2004).

4.6.3 The DMT2 pilot study (Paper III)
Descriptive statistics, such as means and frequencies were, calculated using the Statistical
Package for Social Science (SPSS) version 18. A descriptive summary of the information
extracted from the interviews was made, the content was analysed and themes were identified.

4.7 Ethical considerations

4.7.1 The CWP fidelity study (Paper I) and change process study (Paper II)
The studies conformed to all relevant ethical guidelines, including adherence to the legal
requirements of the study country. The RCT of the CWP was approved by the Regional Ethics
Committee in South East Norway and by the Norwegian Social Science Data Services. All
participants signed an informed consent form. The study is registered at ClinicalTrial.gov
(NCT01236209).

4.7.2 The DMT2 pilot study (Paper III)
The DMT2 pilot study was approved by the Regional Ethics Committee in South East Norway.
All participants signed an informed consent form. The study is registered at ClinicalTrial.gov
(NCT01297049).
5. **SUMMARY OF RESULTS**

5.1 **THE CWP fidelity study (PAPER I)**

The fidelity study examined the therapists’ adherence to the protocol when writing individualized feedback in the RCT of the SMI for women with CWP. The main results of this study were as follows.

1. A coding scheme with 12 items (five representing ACT elements and seven representing communication and motivation strategies) was developed, based on the analyses of the feedback messages using TA, as shown in Table 2.

<table>
<thead>
<tr>
<th>ACT codes*</th>
<th>Motivation and communication codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Values (V)</td>
<td>• Behavioural support (BS)</td>
</tr>
<tr>
<td>• Committed action (CA)</td>
<td>• Advice (AD)</td>
</tr>
<tr>
<td>• Contact with the present moment (PM)</td>
<td>• Empathetic statements (ES)</td>
</tr>
<tr>
<td>• Cognitive defusion (CD)</td>
<td>• Stimulate participation (SP)</td>
</tr>
<tr>
<td>• Acceptance (AC)</td>
<td>• Creative communication (CC)</td>
</tr>
<tr>
<td></td>
<td>• General information (GI)</td>
</tr>
<tr>
<td></td>
<td>• Educational information (EI)</td>
</tr>
</tbody>
</table>

*Note that the sixth ACT element, self-as-context, was not identified in the material.*

2. The inter-rater reliability between the two coders (researchers) was tested in the last development phase of the coding scheme. The inter-rater reliability was calculated based on 280 text segments. The number of observed agreements was 230 (82.14% of the observations). The number of agreements expected by chance was 41.9 (14.95% of the observations), resulting in a kappa = 0.790 with a 95% confidence interval of [0.737, 0.843] and standard error of kappa = 0.027. According to Cicchetti, this degree of agreement is considered to be excellent (Cicchetti’s scale: poor < 0.40; fair = 0.40–0.59; good = 0.60–0.74; excellent = 0.75–1.00) (Cicchetti, 1994).

3. Fidelity to the intervention protocol was analysed by comparing the content of feedback given to the participants with the intervention protocol. For this analysis, therapist feedback to
42 participants (790 messages) was divided into text segments and coded. Out of the total of 2,231 text segments coded, 806 were ACT and 1,436 were motivation/communication codes. All 42 participants received text segments that represented the AV and CA codes; 41, the PM code; 39, the CD code; and 36, the CC code. Thirty-two received text segments representing all ACT codes. In general, all codes were well represented in the feedback messages, showing the therapists’ fidelity to the treatment protocol and a high level of treatment integrity.

5.2 THE CWP CHANGE PROCESS STUDY (PAPER II)

This study investigated change processes during the RCT of the SMI with daily e-diaries and personalized written feedback based on ACT for women with CWP. The investigation of the change processes started with the analysis of the content of diary responses over time, and finished with a correlation analysis of the specific content of therapist feedback messages and participant outcomes as conveyed by their e-diary responses.

The investigation of participant outcomes as indicated by their e-diary responses included participants’ daily ratings of their physical activities, commitment to physical activities, satisfaction with performed physical activities, PC, PF, PFA, PA, PSM (as defined in Section 4.5.2) and evaluation of feedback during the intervention period.

The results showed that participants’ performance of physical activities decreased slightly over time, and in five out of six models, the time effect was statistically significant, as shown in Table 3.

Table 3

Results of the analysis of planned and executed physical activities

<table>
<thead>
<tr>
<th>Diary content</th>
<th>Variable</th>
<th>Time slope (S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Planned Physical Activity</td>
<td>PLA (Planned Low-level Activity)</td>
<td>–0.029, &lt;.01</td>
</tr>
<tr>
<td></td>
<td>PMA (Planned Medium-level Activity)</td>
<td>–0.004, 0.16</td>
</tr>
<tr>
<td></td>
<td>PHA (Planned High-level Activity)</td>
<td>–0.009, &lt;.01</td>
</tr>
<tr>
<td>2. Executed Physical Activity</td>
<td>ELA (Executed Low-level Activity)</td>
<td>–0.029, &lt;.01</td>
</tr>
<tr>
<td></td>
<td>EMA (Executed Medium-level Activity)</td>
<td>–0.004, &lt;.01</td>
</tr>
<tr>
<td></td>
<td>EHA (Executed High-level Activity)</td>
<td>–0.007, &lt;.01</td>
</tr>
</tbody>
</table>
Results regarding participants’ commitment to planned activities showed positive parameter estimates and p-values < .01, confirming that participants were committed to their planned activities. The analysis of participants’ satisfaction with their physical activities showed a negative value (–0.012) and was statistically significant (p < .01). Lower values of this dependent variable represent greater satisfaction with activities. Participants became more satisfied with their physical activities over time.

Most of the participants who responded to the evening diaries chose one item for the evaluation of feedback messages every day. The feedback evaluation that was most often marked was “The feedback has helped me to stay sufficiently active” (mean = 26%), and the feedback message least often marked was “The feedback has helped me to be aware of my coping strategies” (mean = 6%), as shown in Table 4.

Table 4

<table>
<thead>
<tr>
<th>Feedback evaluation</th>
<th>Mean (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed evening diaries</td>
<td>57</td>
</tr>
<tr>
<td>Completed feedback evaluation</td>
<td>62</td>
</tr>
<tr>
<td>The feedback has helped me to stay suitably active</td>
<td>26</td>
</tr>
<tr>
<td>The feedback has helped me to be aware of my feelings</td>
<td>23</td>
</tr>
<tr>
<td>The feedback has helped me to stay positive</td>
<td>17</td>
</tr>
<tr>
<td>The feedback has helped me to be aware of my coping strategies</td>
<td>6</td>
</tr>
<tr>
<td>The feedback was not helpful today</td>
<td>20</td>
</tr>
</tbody>
</table>

The internal consistency of the three PC items was acceptable (ordinal alpha coefficient 0.79) (Bacon, 2004; Davis, 1964; Murphy & Davidshofer, 1988). By using the sum score of the PCS as the dependent variable, its dynamics could be evaluated. No statistically significant changes in PC occurred over time (time slope 0.004; p < .46).

Participants’ PA and PF increased significantly over time. The parameter estimates for time were negative (means of –0.011 and –0.015, respectively; p < .01). For these variables, the lower the parameter values, the more the patient agreed with the PA and PF statements.
In the analysis of participants’ PFA, the internal consistency of the items was acceptable (ordinal alpha coefficient 0.78) (Bacon, 2004; Davis, 1964; Murphy & Davidshofer, 1988). Lower values indicate lower PFA. The time parameter estimate was negative and significant (–0.019, \( p < .05 \)), showing that PFA diminished over time.

The analysis of participants’ PSM items showed acceptable internal consistency (ordinal alpha coefficient 0.68) (Bacon, 2004; Davis, 1964; Murphy & Davidshofer, 1988). PSM was also analysed over time. The parameter estimate for time was negative and significant (–0.030, \( p < .001 \)), and the significant decrease in values indicated improvement in self-management over time.

No correlation was found between patient outcomes, as indicated by their e-dairy responses, and the specific content of feedback messages.

5.3 THE DMT2 PILOT STUDY (PAPER III)

The pilot study aimed to develop and test the feasibility of a 3-month smartphone-delivered intervention with diaries and feedback based on ACT to support self-management in persons with DMT2. The smartphone enabled access to daily e-diaries and individualized situational feedback written by a therapist. The participants registered their eating behaviour, medication taking, physical activities and emotions three times daily. They also registered their fasting blood glucose level in the morning diary. A therapist had immediate access to the submitted diaries and used the situational information, in addition to ACT theory, to formulate personalized feedback messages.

Fifteen participants were included in the study. Eleven completed the intervention, which was evaluated as supportive and meaningful. The mean average HbA1c level was 7.39\% (SD = 1.11\%) the week before inclusion and 6.9\% (SD = 0.8\%) at the end of intervention. Most of the participants reported positive lifestyle changes. The response rate for the daily registrations was good, with an average of 68\%. Most of the participants reported the diaries to be a positive experience and considered the content and questions easy, inspiring and useful. The patients also rated their satisfaction with the content of the feedback as high. They reported that the feedback helped them to manage their diabetes by reinforcing favourable coping strategies.

The main conclusion was that the mobile intervention pilot tested on persons with DMT2 was feasible.
5.4 THE COMPARISON STUDY (PAPER IV)

This comparison study summarized the content, feasibility and efficacy of three web-based CBT-grounded interventions including e-diaries and feedback delivered through PDAs/smartphones for supporting self-management in people with IBS and CWP (in RCTs) and DMT2 (in a pilot study). This study also discussed relevant issues for implementing web-based therapeutic interventions delivered by mobile technology in clinical practice.

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. (Kristjánsdóttir et al., 2013a; Oerlemans et al., 2011). The effects persisted for three months in the IBS study and for five months in the CWP study. In the diabetes study, most participants reported positive life style changes (Nes et al., 2012).

The compared web-based interventions appeared to be feasible, acceptable and supportive. In short- and medium-term timeframes, the interventions promoted self-management. 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 type of counselling. To achieve successfully implementation in daily practice of developed intervention, the use of implementation science is strongly recommended.
6. DISCUSSION

This dissertation embraces the study that analysed the fidelity (Paper I) and the change processes (Paper II) of an RCT of an SMI for women with CWP (Kristjánsdóttir, 2014). In addition, it includes the development and feasibility testing of a smartphone-delivered intervention based on ACT with e-diaries and situational feedback written by a therapist to enhance self-management by patients with DMT2 (Paper III). It also includes Paper IV, which discusses and summarizes the findings of three similar interventions delivered by mobile technology (PDA/smartphone) for persons with different chronic illnesses (IBS, CWP and DMT2). In this section, the main results are discussed in relation to methodological issues, the research literature and future research areas.

6.1 DISCUSSION OF METHODOLOGICAL ASPECTS

Different designs, approaches, samples and methods for data collection were applied in the studies presented in this thesis. An important question to be answered when evaluating CIs is whether the intervention has an effect. With a positive answer, the next question to be explored is how the intervention works (Craig et al., 2008). The practical effectiveness of the SMI for women with CWP was examined in a previous RCT study (Kristjánsdóttir et al., 2013a, 2013b), while the change processes were investigated in the present thesis (Papers I and II). For this purpose, quantitative, qualitative and descriptive methods were applied. By blending qualitative and quantitative methods, it was possible to enhance our theoretical insight into the treatment perspectives and increase our understanding of the results. However, the mixed-method design is challenging and time consuming (Polit & Beck, 2004). The methodological issues will be discussed in relation to Papers I, II and III.

6.1.1 Design

CWP fidelity study (Paper I)

A qualitative method, TA, was chosen to investigate the treatment fidelity of the RCT of the SMI for women with CWP. The feedback messages collected resulted in a large volume of textual material. To evaluate the therapists’ fidelity to the ACT-based treatment protocol, the feedback messages needed to be analysed and interpreted. Template analysis is a set of procedures combining deductive and inductive approaches that enables thematic organization and data analysis (Crabtree & Miller, 1999). This method was also applied in a study that examined the role of feedback in relation to performance features in nursing practice (Fereday & Muir-
Cochrane, 2006). The researchers employed a combined approach where they integrated inductive codes with deductive codes derived from the basic principles of social phenomenology, and showed how this approach met the search requirements for qualitative methods. This method is also often used in other health-care research (Fereday & Muir-Cochrane, 2006). This qualitative study resulted in the development of a coding scheme based on written therapist feedback messages for patients with CWP. The coding scheme made it possible to investigate therapist adherence to the treatment protocol.

**CWP change process study (Paper II)**

This study combined longitudinal and correlation designs. The longitudinal design was used to investigate, during a 5-week period, patient outcomes as indicated by their e-diary responses rating their physical activity levels, satisfaction with their physical activities, PF, PFA, PC, PA, PSM and evaluation of the feedback. Longitudinal designs are appropriate for studying the dynamics of a phenomenon over time. In such designs, it is important to evaluate the attrition. The risk of attrition is directly related to the time between data collection points (Polit & Beck, 2004). In this study, the data were collected daily. Despite this, the attrition markedly increased in the last week of the intervention. The decrease in the response rate for the diaries might indicate that the length of the intervention increases the attrition. The reason for the decrease in the response rate should be investigated in future studies.

Diaries were collected up to three times a day. The mean diary response rate was 70%. Although there is no absolute standard for acceptable missing data, biases are usually of concern if the response rate is lower than 80% (Polit & Beck, 2004). This may be valid when instruments are applied at specific time points; then, the results can be highly biased by a number of factors, such as mood, health and social conditions (Morren et al., 2009; Podsakoff, MacKenzie, Lee, & Podsakoff, 2003). By using repeated daily measures, as in the present study, it is possible to evaluate the development of measures over time. This reduces the risk of bias caused by random effects (Morren et al., 2009). Even if the results might have been influenced by bias, it is possible to identify trends that should support the main findings and/or provide knowledge for the future development of the intervention. The design is therefore appropriate for the study aims, and the repeated measurements are a strength of the study.

Correlational designs are used to determine whether and to what degree a relationship exists between two or more quantifiable variables (Cunningham, Weathington, & Pittenger, 2013). This
design was therefore chosen to explore the association between patient outcomes, as conveyed by their e-diary responses, and the specific content of daily situational feedback written by a therapist. This analysis was possible because of the feedback coding scheme developed in the previous study (Paper I).

**DMT2 pilot study (Paper III)**

The DMT2 pilot was a preliminary study conducted to evaluate the feasibility, time and cost of the study design as well as adverse events, effect sizes and necessary design improvements prior to the performance of a large-scale RCT research project. Two similar interventions have been found feasible and effective for persons with IBS (Oerlemans et al., 2011) and women with CWP (Kristjánsdóttir, 2014; Kristjánsdóttir et al., 2013a, 2013b; Kristjánsdóttir et al., 2011). User representatives and a multidisciplinary team (a diabetes researcher, a diabetes nurse, researchers who were also practising nurses, a psychologist/researcher, a nutritionist and a physician) were involved in the development phase of the study. The representatives informed the researchers about their experiences, preferences and needs. Adjustments were made in accordance with this feedback before the pilot study was performed. This procedure is in line with recommendations for the development of smartphone interventions. Including user representatives in the research group from the start is also necessary to enhance patient-centredness (Whittaker, 2012). Craig et al. (2008) have recommended focus groups with users as another alternative for receiving feedback about the intervention. If this interactive method had been used, qualitative data could have brought new information to the study. Although focus groups were not a data collection method used in the pilot study, the users were engaged and participated actively together with the multidisciplinary research group in all stages of the development of the intervention. According to Craig et al. (2008), including representatives of the target group in the development phase of an intervention is likely to result in better and more relevant science and a higher chance of producing implementable data (Craig et al., 2008). The active involvement of the users and multidisciplinary researcher group in the intervention’s development is a major strength of this study.
6.1.2 Samples

The CWP fidelity study (Paper I), change process study (Paper II) and comparison study (Paper IV)

The summary of the three similar studies including smartphone interventions with e-diaries and feedback (Paper IV) presented an opportunity to acquire an overview of the treatment concept and effects for three different chronic diseases. Nevertheless, the relationship between the specific content of feedback messages and patient outcomes, as indicated by their e-diary responses, is still unknown. To investigate this, the data from participants who were randomly assigned to the intervention group and completed the treatment from the RCT of the SMI for women with CWP (Kristjánsdóttir et al., 2013a) were analysed.

First, a qualitative study was performed to develop a coding scheme based on the therapist feedback messages. To ensure that included patients had received sufficient feedback, the following inclusion criterion was determined: to enter the study, the participant had to have received a minimum of 75% of the scheduled feedback messages. Problems with receiving feedback could be caused by technical errors or by the participant dropping out. A review of the feedback content for participants who did not meet the criterion showed that the feedback was dominated by non-therapeutic communication (e.g., repetitions of the same feedback, several explanations about why technical errors occurred, etc.). This suggests that the excluded feedback messages, if included in the analysis, would not have meaningfully influenced the results.

The second step was to code the 2,231 text segments based on the 799 feedback messages. This was necessary to make it possible to investigate correlations between the content of feedback messages and patient outcomes, as indicated by their e-diaries (3,372 entries) (Paper II). For such studies, 30 or more participants are recommended; this is important to increase the validity of the research (Waters, 2010). The change process study had 48 participants. It is important to emphasize that the results can be generalized only to women because men did not participate in the RCT of the SMI for patients with CWP.

The DMT2 pilot study (Paper III)

The aim was to recruit participants via their GPs, but this method posed challenges. First, most of the GPs we approached were not interested in participating in the project. Second, the number of patients that were invited and agreed to participate in the pilot was low. Therefore, the research group network was also invited to participate, to achieve the necessary number of participants in the pilot study. In total, 36 persons were invited to participate, 15 were included and 11 completed
the intervention (see Figure 8). The power calculation to test this smartphone-delivered intervention for persons with DMT2 in an RCT indicated that 100 participants were required. This result confirms that the recruited number of participants for the pilot study was in line with Connelly (2008) recommendation that a pilot study sample should be 10% of the sample projected for the larger study. Other authors suggest 10–30 participants for pilots in survey research (Hill, 1998; Isaac & Michael, 1995).

![Figure 8. Recruitment process in the DMT2 pilot study](image)

The sample represented the target group well, with 10 men and five women aged 46–71 years. The sample included persons who were single, divorced, married, active workers and retired. According to Doody and Doody (2015), a pilot study is a trial run of a project with a small group of participants that may represent the target group to be recruited in the larger-scale study. The level of participants’ knowledge of their own disease was poor. This fact made it more time consuming to create feedback messages. In many cases, it was necessary to first give participants basic information on diabetes and introduce the ACT elements later. For future studies, other recruitment methods must be evaluated. An alternative may be to recruit participants from Learning and Mastering Centres (LMSs). The LMSs in Norway offer basic courses covering several chronic diseases, including DMT2 (Lerdal et al., 2011). The feasibility study of the SMI for women with CWP describes similar challenges in recruiting participants (Kristjánsdóttir et al., 2011). In the RCT of the SMI, the women with CWP were successfully recruited from a rehabilitation centre (Kristjánsdóttir et al., 2013a). By recruiting participants from LMSs, it would
be possible to ensure the necessary number of participants for an RCT and a more homogenous study population.

6.1.3 Procedure for data collection

_CWP fidelity study (Paper I) and change process study (Paper II)_

The diaries were collected over 5 weeks, and the feedback messages over 4 weeks excluding weekends. As previously mentioned, the feedback was intended to support and stimulate self-management. All three therapists who wrote the feedback messages had a background in healthcare sciences (nursing and/or psychology) and had received training in ACT. This may be one of the reasons for the therapists’ adherence to the intervention protocol. The protocol was based on ACT with a focus on different elements each day (values, committed action, contact with the present moment, cognitive defusion and acceptance). The information from the submitted e-diaries and the overall aims expressed in an individual start-up meeting with the participants provided input to the feedback. In addition to the ACT processes (e.g., ACT exercises and questions aimed at encouraging mindfulness, willingness and engagement in meaningful activities), the feedback messages also included positive reinforcement, information and metaphors.

The e-diaries were completed three times daily and included 16–24 self-report questions. In many cases the use of self-report measures is the only established method for assessing variables (e.g., some cognitive and emotional variables), but it is important to be aware of the limitations of using this method of data collection. The results may be biased by different factors, such as social desirability and internal bias (Piasecki et al., 2007). One of the largest sources of bias is caused by the complex cognitive processes involved in retrieving information from memory, and the responses should therefore be considered estimations rather than accurate information (Piasecki et al., 2007). The e-diaries contained self-reported actions, and the fact that these data were collected three times a day might have reduced the bias and increased the validity of the assumption that the reports accurately reflected what had occurred in participants’ daily life.

Self-report questionnaires have been criticized for not considering variations in symptom levels, which is one reason for the increasing use of pain diaries for a few weeks to assess pain levels (Buhrman, Nilsson-Ihrfelt, Jannert, Ström, & Andersson, 2011). The strength of the present study is the fact that the analysed data were daily repeated measures, collected up to three times a day, giving the opportunity to evaluate the development of measurements over time. Despite the
importance of limiting self-report questionnaires to minimize the burden on participants, most of the participants evaluated the diary concept as suitable.

DMT2 pilot study (Paper III)
Two guided, semi-structured interviews were conducted with the aim of capturing the participants’ experiences and identifying any need for change in the interventions. These interviews were performed after the intervention’s first phase and after the completion of the study. The interviewers took notes, and the interviews were also recorded and transcribed. In addition, at the end of the intervention, after the second and final interview, the participants received a questionnaire to assess their experience with the study. The evaluation questionnaires were developed based on previous experience with the feasibility study and the RCT of the SMI for women with CWP (Kristjánsdóttir et al., 2013a; Kristjánsdóttir et al., 2011)

An intention of the pilot study was also to test whether the outcomes were suitable for measuring the expected effect of the intervention (e.g., improved control of one’s blood sugar level, self-management and quality of life). Another purpose of conducting a pilot study is to allow the researcher to consider the usefulness of the proposed data collection and analysis techniques (Doody & Doody, 2015). The outcome questionnaires were completed in the introductory meeting with the participants and at the end of the intervention (after the second interview). The instruments chosen for testing in the pilot study were shown to be feasible, and self-management was measured using the patient’s HbA1c level. For future studies, instruments to measure diabetes self-care activities and other ACT-related outcomes would be an advantage, making it possible to compare results with similar studies among diabetes populations. After all, it is important to bear in mind that the number of included questionnaires needs to be limited to reduce the burden on participants. This issue was well discussed in the development phase of the pilot study, and the number of questionnaires applied in the study was reduced to only those necessary.

The primary outcome was HbA1c. This measure reveals the mean blood sugar level over the past 3 months, which makes it a good indicator of self-management and has the advantage of being objective. Another strength of the study was the use of self-report questionnaires that were easy to apply and cost effective. The costs could have been even lower if self-report measures were collected electronically, saving the researchers time. However, having the researcher available when participants completed the questionnaires was an advantage, because participants could be prompted to answer a question if they were in doubt.
6.1.4 Data analysis and statistical methods

CWP fidelity study (Paper I)

The analysis of the fidelity of therapists’ adherence to the treatment protocol started with an investigation of how ACT and other possible processes were used in the written situational feedback. For this purpose, TA was applied, with the first step in the analysis using a deductive approach by creating a preliminary coding scheme built upon predefined categories from ACT theory (values, committed action, contact with the present moment, acceptance, cognitive defusion and self-as-context) (Hayes et al., 2006). Template coding is a method of organizing similar or related text segments. In this process, it is important to consider how extensive the template should be. Too many predefined codes can prevent the exploration of possible new aspects of the data. On the other hand, too few codes may lead to large text segments with an overwhelming mass of rich and complex data (King, 2004). Finding the right balance is very important. The developed coding scheme, based on ACT, had few categories that resulted in large text segments in the analysed feedback messages. These text segments were evaluated by the researchers as not complex.

When choosing this deductive approach, the risk of limiting the interpretation of the text content can be high. Therefore, TA is a good alternative, combining deductive and inductive approaches. After the thematic organization of the data, an inductive analysis to identify other therapeutic processes (i.e., those not explicitly related to ACT theory) was applied. For the inductive analysis of the feedback messages, an editing organizing approach was chosen. This approach consists of systematic reading of all data material with relevant observations registered for further interpretation (Crabtree & Miller, 1999). An advantage of using the editing organizing style after first analysing the data deductively is that it offers new insight into the data, enabling the emergence of important new elements and the identification of possible patterns. The ATLAS.ti software (version 7, student licence) was used primarily to organize the data and as a tool for the analyses (Muhr, 1991).

When the final coding scheme was developed, the inter-rater reliability was calculated. Inter-rater reliability is a measure used to examine the agreement between two or more persons assigning categories to a categorical variable. It is an important measure in determining how well the implementation of a coding or measurement system works. The kappa statistic was chosen in this study, as it is frequently applied to test inter-rater reliability and corrects for agreement by chance (McHugh, 2012).
CWP change process study (Paper II)
The data from this study were collected up to three times daily over 4 weeks as repeated measurements. For this type of data, MLMs are the recommended statistical method; their advantages over other statistical methods are well documented (Kwok et al., 2008). The ordinal reliability test was applied for internal consistency analysis. The ordinal alpha more accurately estimates reliability for ordinal item response data (i.e., PC, PFA and PSM) than alternative methods (Gadermann, Guhn, & Zumbo, 2012). For this study, the variables were analysed using MLMs with the intercept and time slope as covariates, both as fixed and random effects. See Section 4.6.2 for further methodological details. This study included only data from participants who completed the intervention; drop-out cases were not included. Because the code was run as a standalone analysis, differing in the number of covariates, the results did not interact with each other.

DMT2 pilot study (Paper III)
In the diabetes pilot study, only descriptive statistics (means and frequencies) were calculated, using SPSS version 18. The sample was too small for further statistical analyses to provide meaningful results, but the objective of this study, to verify feasibility and usability, was achieved. A rigorous qualitative design was used for the interviews. Notes were taken and the interviews were recorded and transcribed. A descriptive summary of the information extracted from the interviews was made, the content was analysed and themes were identified. Self-report questionnaires were developed to evaluate feasibility, and participants’ satisfaction with the intervention. The development of these questionnaires was based on experience from previous studies (Kristjánsdóttir et al., 2013a; Kristjánsdóttir et al., 2011).

6.2 Discussion of the results
This discussion is structured according to the three main topics investigated: (a) the change processes, with the development of the code scheme and fidelity analysis, (b) the intervention concept tested in a new context (persons with DMT2) and (c) the comparison of the three studies that shared the same intervention concept for different target groups, with a focus on implementation challenges.
6.2.1 The processes leading to the effect of the SMI for women with CWP

The first aim of this thesis was to investigate the processes leading to the effect of the SMI for women with CWP by means of the therapists’ fidelity to the protocol when writing feedback messages (Paper I), and the association between participant outcomes from the e-diary intervention and the specific content of feedback (Paper II).

The SMI resulted in positive effects (Kristjánsdóttir et al., 2013a, 2013b), and ACT was the chosen theory that grounded the intervention. Results of several other studies also indicate that ACT can be effective as a framework for self-management interventions for people with chronic illness (Graham et al., 2016), including in internet-based studies (Buhrman et al., 2013; Buhrman et al., 2015; Trompetter et al., 2015).

Despite the increasing number of studies confirming the positive effect of interventions based on ACT to support self-management (Brown et al., 2016; Graham et al., 2016), few studies are dedicated to exploring the change mechanisms of such interventions (McCracken & Gutiérrez-Martínez, 2011; Vowles & McCracken, 2008; Vowles, McCracken, & Eccleston, 2007; Wicksell, Olsson, & Hayes, 2010, 2011), and to the best of my knowledge this thesis includes the first study to analyse the change processes in an internet-based intervention delivered by smartphone (Paper II). To identify the change processes leading to the positive results of the treatment, it is fundamental to optimize the treatment impact (McCracken & Vowles, 2014). This thesis has contributed to this development.

Until recently, ACT theory was applied only to treating patients face to face, but Riley et al. (2011) have emphasized the need to adapt existing theories to new forms of intervention delivery (web/smartphone-based). Another difference between ACT interventions delivered in face-to-face and web-based modes is the intensity. In a face-to-face format, the treatment takes place in a clinical setting on a weekly basis or even less frequently. Patients usually receive feedback on dysfunctional cognition and behaviours retrospectively and may find it difficult to adequately incorporate the feedback into their daily life. Achieving individual improvements in self-management and support for the maintenance of new habits may be more effective when ACT is delivered in an intensive format of daily diaries and feedback using smartphones, which can be given at any place and any time. The SMI for women with CWP applied the ACT elements in a written format. Our experience shows that applying ACT theory in a written format suited internet-based interventions well, and enabled and facilitated the analysis of the intervention’s change processes.
The developed feedback messages in the RCT of the SMI resulted in more than 400 pages of coherent text. Analysis of texts has become an important research tool in numerous areas, and coding is a key part of these analyses. As far as we know, this is the first study to analyse, in detail, the content of personalized situational feedback written by a therapist. This analysis used TA and resulted in a final coding scheme containing 12 items. The deductive approach allowed the identification of five of the six possible ACT elements in the feedback messages, and the inductive approach made it possible to identify elements other than ACT elements in the data. These were seven elements related to communication and motivation strategies (Table 2).

Messages reflecting the ACT processes were given in the form of direct instructions, reflection exercises, awareness training and references to available audio files. The use of communication strategies was needed to deliver written feedback messages with ACT content, and the motivation elements were required to support and stimulate the participants to complete the intervention. Self-as-context was the only ACT element that was not identified in the feedback messages. Although not present in the feedback messages, the process of coaching a self-as-context perspective among patients was well represented in the questions in the daily e-diaries. As an example, by answering questions about thoughts and feelings, participants were stimulated to be aware of psychological topics. This was the first step for them to learn how to consciously take the position of the observing self, allowing for distance from thoughts and feelings.

The next step after the development of the coding scheme was to test the inter-rater reliability. The results of the analysis showed an excellent level of inter-rater reliability between the researchers, confirming the necessary level of precision and consistency between the text segments and the coding for further analysis. Quality control of this consistency is essential for attributing the results to the treatment (Hruschka et al., 2004). To achieve this high level of inter-rater reliability, an interactive process involving several coding rounds and refinement of the coding scheme was needed. The first time the coding scheme and codebook were used, there was a lower level of alignment between the individual codes. Experience from the coding process supported the need for an interactive process, and a similar experience was described by Hruschka and collaborators (Hruschka et al., 2004). As mentioned previously, the coding team consisted of four members who participated actively in the coding process, discussions and revisions. Further studies should examine how the number of coders could affect the coding process and results.
The final coding scheme was used to code all feedback messages from the SMI. All codes were well represented in the feedback messages (Paper I). All participants received text segments coded V and CA, and these were equally distributed among the participants. These two ACT elements are important for building participants’ understanding of the therapeutic process. In these V and CA text segments, participants were first motivated to freely choose values important to them in living a personally valuable and meaningful life. Exercises were applied to help participants to identify their values in different life domains. Further, they were stimulated to formulate concrete and achievable goals based on identified values. Values and committed action processes were paired together in the engaged response style (Hayes et al., 2012), encouraging women with CWP to be intrinsically motivated to take concrete actions guided by life values even in the presence of pain. As shown in the results, not all participants received text segments representing all ACT codes. It is important to emphasize that although the development of feedback messages was based on ACT theory, this does not imply that all ACT elements are required for the treatment of each participant.

Representation of the different ACT codes in the feedback messages confirms that these were developed according to the framework and principles established for the RCT of the SMI for women with CWP, and that the therapists adhered to the treatment protocol. This reflected a high level of treatment integrity. Treatment fidelity is defined as the therapist’s adherence to the treatment protocol (investigated in this study) and the therapist’s competence. Competence refers to the degree to which the therapist delivered the intervention skillfully. To ensure the competence of the therapist, only professionals with a health-care background and who are trained in ACT should write the feedback messages. Methods for analysing therapists’ competence have only been developed for face-to-face treatment sessions (Breitenstein et al., 2010). A method to investigate the therapist’s competence in web-based interventions, with e-diaries and written feedback messages, needs to be developed.

The investigation of the change processes continued with the analysis of e-diary responses over time showing substantially positive results, even though the level of participants’ physical activities had decreased significantly over time. To interpret these results, it is fundamental to understand that at the rehabilitation centre, the patients engaged in intensive physical activity because of the heavy physical programme there (Kristjánsdóttir et al., 2013a; Wigers & Finset, 2007), and that the challenge was to continue to stay active in their daily life after the rehabilitation period. The level of activities performed at the rehabilitation centre was high, and it was expected that this level would decrease at home.
One of the main components of chronic pain treatment is to stimulate physical activity, and many studies show effective results from doing so (Hauser, Bernardy, Arnold, Offenbacher, & Schiltewolk, 2009; Häuser, Thieme, & Turk, 2010). The objectives of the SMI were to stimulate self-management by women with CWP. This included staying sufficiently active at home. The presented results suggest that the objectives of the intervention related to daily activities were achieved. In addition to maintaining a suitable level of physical activity at home, the results also showed that the participants were committed to and satisfied with their activities. To our knowledge, no other studies have focused on how to stimulate women with CWP to stay suitably physically active after a rehabilitation period. The intervention presented here may thus represent a proposal. Future studies with an RCT design are necessary to confirm the obtained results.

Participants’ evaluations of the feedback support this finding related to physical activities, as the feedback evaluation that was most often marked was “The feedback has helped me to stay sufficiently active.” Although participants’ evaluations of the feedback messages were useful for the therapist, for research purposes, the use of a fixed format with a quantitative rating scale would be more appropriate for strengthening the results and would enable more precise evaluation of several feedback elements.

The only variable measured in the e-diaries that did not exhibit positive and significant improvements was PC. However, a significant reduction in PC was seen in the RCT of the SMI for women with CWP when the effect of the intervention was investigated using time point assessments (Kristjánsdóttir et al., 2013a). This may be due to differences in the methodology used to assess PC in these two studies: in the SMI RCT (Kristjánsdóttir et al., 2013a), PC was measured by the full PCS, comprising 13 items (Sullivan et al., 1995); in the change process study, PC was assessed using only three items from the PCS. However, the lack of a significant reduction in catastrophizing corresponds with a previous mediation analysis (Wicksell et al., 2011); together, these results suggest that catastrophizing may not be a central change process in ACT-based treatment.

In contrast to PC, the PA results support the findings from the SMI RCT (Kristjánsdóttir et al., 2013a), in which PA increased after the intervention period, as well as findings from earlier research illustrating that ACT-oriented interventions alter the level of PA (McCracken et al., 2004; Wicksell et al., 2012). As mentioned in the introduction, PA is the opposite of EA: the increase in acceptance corresponds to a decrease in avoidance (Hayes et al., 2012). In the SMI RCT, women with CWP were encouraged to take an open and aware stance towards their pain,
applying their energy and effort towards engagement in values-based living instead of struggling against their pain. It is important to emphasize that a different methodology was used to evaluate the change in PA in the SMI RCT than in the change process study. In the SMI RCT, the 20-item CPAQ was used (McCracken et al., 2004). In the change process study, only one statement from the CPAQ was included (“Right now, I feel my life is going well, even though I have chronic pain”). However, even though the results are not comparable, they point in the same direction.

In addition to physical activity, CBT is another major element of the treatment of CWP (Hauser et al., 2009; Häuser et al., 2010). The theoretical framework of EAM (Hayes et al., 1996) and ACT (the third generation of CBT) (Hayes, 2004) for chronic pain (McCracken, 2005) guided the development of the SMI. The elements of ACT were applied to stimulate psychological flexibility and promote self-management. Therefore, questions to stimulate awareness about pain-related thoughts (measured as PFA), feelings (measured as PF) and behavioural support (measured as PSM) were included in the diaries. The results measured by these three variables are encouraging, indicating that the psychological condition of the participants, as well as their self-management, improved. Further studies are necessary to replicate these findings.

The studies presented in this thesis confirm the importance of the use of theory in health-related interventions for achieving positive results. To choose a suitable theory, it is important to understand the psychological and pathophysiological process of the illness in focus. For people with a chronic condition, such as CWP, DMT2 and IBS, the presence of negative emotions is a daily experience due to the demands of the illness regarding self-management and the difficulty of controlling the impact of the illness (Crews et al., 2016; Gregg et al., 2007a; Håkanson et al., 2009; Muscatello et al., 2010; Okifuji et al., 2000; Toner & Akman, 2000). There is a mutual relationship between mood and cognitive interpretation processes. Negative thoughts about chronic illness can affect mood, which in turn can lower a person’s self-management capability, as discussed in Section 2.4. According to the EAM, avoiding experiences that may include negative thoughts and feelings will give short-term relief of discomfort, but the discomfort may reappear more strongly or intensely later (Clark et al., 1991). This results in the maintenance or exacerbation of dysfunctional behaviours (Zettle et al., 2005) in the long run (Hayes et al., 1999). The intervention based on ACT offers an effective treatment, applying mindfulness and acceptance to break the negative cycle of EA (Harris, 2006). This was confirmed by the results of the change process study shown in the present thesis.
The results of the multiple tests analysis showed no correlation between patient outcomes, as indicated by their diary responses, and the specific elements of the feedback messages. This result suggests that the daily self-monitoring of planned and performed physical activities, feelings and thoughts related to avoidance, catastrophizing and acceptance is helpful in increasing self-management, irrespective of the content of feedback received. Collinge, Yarnold, and Soltysik (2013) also suggested that the effects achieved in their study were not dependent on the feedback given. They concluded that by reporting their symptoms electronically, the participants increased their awareness, thereby influencing their behaviour positively, leading to symptom reduction (Collinge et al., 2013). These results are also in line with the explanation of how ACT manages to break the cycle of EAM. Answering the questions about thoughts, feelings and acceptance in the e-diaries possibly increases the person’s understanding that they do not necessarily need to struggle with their unwanted feelings and thoughts. Consequently, they may experience a decrease in the degree of their psychological burden, resulting in a change from dysfunctional to functional behaviour.

By contrast, Baumeister, Reichler, Munzinger, and Lin (2014) concluded in their review that guided interventions (with feedback) produced better results than unguided interventions (self-monitoring), albeit with only a slight improvement. Although there was no significant correlation between the specific feedback elements given and the results indicated by the e-diary responses, participants experienced the feedback as supportive. This might be due to the individualization and tailoring of the feedback messages to the participants’ answers, goals and values. Unfortunately, the instrument that measured the participants’ evaluation of feedback was not designed to measure participants’ satisfaction with specific ACT elements.

A possible explanation for the missing correlation between participant outcomes, as conveyed by the diary responses, and the specific content of feedback messages is the fact that the different ACT elements included in the feedback messages were analysed separately for their associations with participant outcomes. ACT processes interact with each other, and therefore it may be difficult to identify a single ACT process that generates an effect. We cannot, therefore, discard the possibility that the entire feedback message influenced the positive results shown in the analysis of diary content. A three-arm RCT would be needed to investigate this hypothesis further, with one control group and two intervention groups (the first with e-diaries only and the second with e-diaries and feedback).
6.2.2 Development and feasibility testing of the SMI for persons with DMT2

The second aim of the thesis was to test whether the SMI, based on ACT principles, was feasible in another context, namely for persons with DMT2. The results of the pilot study indicate that the intervention is feasible with regard to its practical usability and acceptability to the participants, thus suggesting that the intervention concept would be feasible in other contexts. The intervention was rated as supportive, meaningful, motivating and user-friendly by the majority of the participants. They also evaluated their satisfaction with the content of the feedback at a high level. They reported that the feedback helped them to manage their diabetes by reinforcing favourable coping strategies. The response rates for the daily registrations were generally high, and the diary response rate ranged from 21% to 97%. This suggests that the acceptability of the diaries varied considerably between participants. However, the mean and median were close to 70%, which indicates general acceptability. This is in accordance with response rates from other studies using e-diaries (Kristjánsdóttir et al., 2013a; Morren et al., 2009; Stone et al., 2003). In the diabetes pilot study, most participants found three diary entries and one feedback message per day to be suitable. They were also satisfied with the number of questions in each diary entry. However, despite the participants’ satisfaction with the intervention design, it is important to bear in mind the need to reduce the burden on the respondents as much as possible, as it has a negative effect on the respondents’ motivation and thus their response quality (Morren et al., 2009). In the IBS and CWP studies, all participants completed all three daily diary entries for the 4-week duration of the interventions (Kristjánsdóttir et al., 2013a; Oerlemans et al., 2011). In the diabetes pilot study, all participants completed the diaries over 12 weeks. Although the diabetes study included fewer questions per diary, no difference in the response rates was identified when compared with the CWP study. On the other hand, the IBS study also included fewer questions per diary and had a higher response rate (Oerlemans et al., 2011). The fact that the diabetes pilot study lasted longer than the IBS and CWP studies may have influenced the results. In another pilot study on e-diaries and feedback for supporting self-management of migraines, the mean response rate was 85% (Kleiboer, Sorbi, Mérelle, Passchier, & Doornen, 2009). The reason for the good response rate in the migraine study is not clear, so a comparison with the response rate of the present study was not possible.

The diabetes pilot study was also evaluated by means of two interviews with the participants; one in the middle and the other at the end of the study. No changes were made in the intervention after the first interview with the participants. The information collected through the interviews midway and at the end of the project gave additional insight into the patients’ perceptions and evaluations of the intervention. The patients experienced the intervention as useful. They reported the content
and questions in the diaries to be relevant and understandable, and that completing the diaries gave them better insight into their diabetes and improved their coping and self-management strategies. The stimuli to perform physical activities helped them be more active. However, the participants would have liked to receive more information about diet, as they reported that this was difficult to deal with. They also desired more variation in the questions and wanted a break from diary-filling over the weekend. Participants mentioned that a long period of filling in the diaries led to decreasing awareness, but that this period contributed positively to increasing their honesty in answering the diary questions. One possible explanation for this phenomenon is directly linked to ACT theory. As participants became more aware of their values, they also became more committed to their goals, understanding that they themselves were responsible for their self-management. This process also contributed to their comprehension that the therapist’s role was to advise and not to control or judge. The feedback messages were experienced as personal and relevant to the patients’ current situation. The patients reported that the feedback helped them to define their own goals based on health values, identify barriers related to goal achievement and develop strategies to overcome the barriers. They reported that they became committed to their values and goals, and most of them were willing to change their lifestyle to achieve a good health status. Those who did not work towards their goals for achieving better diabetes self-management also reported a sense of guilt. Several studies show that guilt, among other feelings, is commonly felt by people with diabetes and other chronic diseases (Crews et al., 2016; Gregg et al., 2007a; Håkanson et al., 2009; Khumalo & Mathunjwa-Dlamini, 2016; Muscatello et al., 2010; Okifuji et al., 2000; Toner & Akman, 2000).

Other difficulties with the intervention were reported. As the smartphone with the intervention application was borrowed, the participants found it uncomfortable and sometimes inconvenient to take the smartphone along with their own mobile phone. In future studies, giving the smartphone to the participants instead of loaning it could be a solution. Some experienced problems submitting the diaries (e.g., the registered information disappeared and they had to fill in the diary again). This study was conducted six years ago, and the technology has developed hugely since. Recent smartphones are much more powerful, and with substantially improved user interfaces, which may lead to fewer errors and higher response rates. Pre-tests using current technological platforms must be done before initiating a large-scale study.

Generally, the diary questions relating to participants’ feelings were evaluated as difficult to answer. The participants had doubts, especially about how to interpret these questions. This is important feedback, because feelings are directly related to EA. The purpose of monitoring
thoughts and feelings is to apply ACT to break the negative cycle of EA and achieve psychological flexibility. Therefore, it is very important to ensure that participants’ and researchers’ interpretations of questions are aligned.

As mentioned previously, involving the users in the development of the pilot project is important. Most of the participants said they would have liked to have had a record of all feedback messages, where they could have found and read them again when they wanted. This feature can easily be adopted for future studies. A similar experience was reported by Jelin, Granum, and Eide (2012) in a qualitative study, based on interviews with women who had participated in an RCT of a smartphone-delivered intervention for CWP. In summary, the intervention was perceived as supportive in breaking habits and establishing new, healthy behaviours for most participants.

The therapist’s (ISS) and researcher’s (AAGN) clinical impressions were also investigated. They reported that an interactive relationship was established with most of the patients. Both believed that the first meeting and the telephone conversation prior to the intervention were important to ensure the formation of a therapeutic alliance. However, it was challenging to achieve the goal of always being empathetic once the intervention had started and communication through nonverbal signals and dialogue was missing.

The therapist analysed the participant’s answers in the three previous diary entries before writing the feedback. It was time consuming for the therapist to build this overview of the diaries. The system did not show this information as a summary, and it was necessary to navigate through several pages to get the needed information. In addition, the therapist had to look at the feedback history to avoid repeating information. A feedback “bank” was developed by the therapists (ISS and AT, nurses) and the researcher (AAGN, also a nurse) with help from other professionals: a researcher in therapeutic communication (HE), a researcher in diabetes care, a nutritionist and another nurse/researcher with clinical experience. After the first month, the feedback bank started to be useful, and the time used to formulate the feedback messages was reduced to 15–20 minutes. Although this might seem acceptable, multiplying this by the 5 days of the week gives approximately 1.5 hours weekly per patient. If this time is compared with the time used for a weekly conventional (face-to-face) therapy session (45–50 minutes), it becomes clear that a smartphone-delivered intervention for people with DMT2 requires almost twice the professional time input of conventional therapies. Several studies have shown effects from web-based interventions similar to those of face-to-face interventions (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Cuijpers, Van Straten, & Andersson, 2008; Spek et al., 2007). But these studies did
not analyse the use of therapist time compared with face-to-face interventions. Regarding the intervention concept present in this thesis, to use twice as much time on web-based therapy as is required for traditional therapist treatment is not justified in terms of cost. Therefore, decreasing the time to develop feedback is necessary to make the smartphone-delivered alternative competitive. However, in this calculation, cost/benefit elements other than the hourly cost of a therapist must be included (travelling cost, lost worktime for the patient, flexibility for the patient and therapist, etc.). With the data available at present, it is not possible to draw a conclusion about the cost/benefit balance of a large-scale implementation of web-based therapy for the patient groups discussed in this paper.

6.2.3 Comparison of the three web-based interventions and their implementation
The third aim of the thesis was to compare the three different web-based interventions to identify similarities and differences and also to elaborate on implementation challenges.

The PDA/smartphone-delivered interventions for people with a chronic illness (IBS, CWP and DMT2) can be classified as CIs. The key questions in the evaluation of CIs are related to practical effectiveness (feasibility and usability) and change processes (how the intervention works) (Craig et al., 2008). The three similar studies presented in Paper IV confirm that the concept of PDA/smartphone-delivered intervention with e-diaries and situational feedback written by therapists is effective, feasible and suitable for treatment and/or follow-up purposes. As the effect of web-based interventions is directly connected to the extensive use of theory (Webb et al., 2010), these studies followed a protocol in which the chosen theory was an important part of the intervention’s development process. For the IBS study, CBT was chosen, and for the CWP and DMT2 studies, EAM (Hayes et al., 1996) and ACT (Hayes, 2004; McCracken, 2005) were used. The choice of the theory that grounded the intervention concept was based on literature that demonstrated the positive effect of interventions based on CBT (Sperry, 2009). Following the development of CBT, ACT (the third generation of CBT) was chosen in the refined intervention concept tested with persons with CWP and DMT2. The advantage of using ACT is that in addition to behaviour activation (a common feature of both CBT and ACT), ACT offers acceptance and cognitive defusion strategies, which have the capacity to break cycles of EA by changing dysfunctional thoughts, at least in short- and medium-term timeframes.

It is common in self-management interventions for the achieved effects to diminish over time (Foster, Taylor, Eldridge, Ramsay, & Griffiths, 2007; Franks, Chapman, Duberstein, & Jerant,
To maintain the positive effects, we suggest offering intensive counselling over a short period followed by booster sessions on a more ongoing basis. A web-based intervention may also substitute for or be used in addition to standard treatments. Our experience indicates that the web-based intervention concept developed in the IBS, CWP and DMT2 studies would be feasible for follow-up purposes. A study conducted by Solomon and colleagues 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 the effect duration and the potential to reach a broader population (Solomon, Wagner, & Goes, 2012).

Web-based intervention offers an alternative to HCPs for the delivery of tailored counselling to persons suffering from chronic diseases. A person who lives far from a health-care institution could greatly benefit from web-based interventions. Those who are unable to meet the HCP for other reasons would experience similar advantages (Kahn, Yang, & Kahn, 2010). Nevertheless, it remains important to explore each individual patient’s needs regarding the format of the web-based intervention. The main elements of the intervention concept presented in this thesis are the use of individualized situational feedback and e-diaries, but web-based interventions aimed at stimulating self-management can take a wide variety of forms, including interactive elements such as games (“serious gaming”) (de Boer, Versteegen, Vermeulen, Sanderman, & Struys, 2014; Riva, Camerini, Allam, & Schulz, 2014) and visual presentations, such as video clips (Hayes et al., 2014; Lin et al., 2015) and video-delivered experiential exercises (Levin et al., 2016), as well as social networking with peer support (Lorig et al., 2013) and social media (Rod, 2016). Different intervention methods are effective for different people. A participant from the DMT2 study who did not experience a positive effect from the intervention concept presented in this thesis expressed his preference for an intervention enabling him to contact other people with the same diagnosis to share experiences. When implementing web-based interventions in daily health-care practice, the possibility of offering alternative intervention formats to suit different participants’ needs would be an advantage.

Although there was some variation over the three studies (IBS, CWP and DMT2), the participants’ adherence to the intervention was good. One of the reasons may be the situational feedback received daily (Ambeba et al., 2012; Morton et al., 2016) and another may be the therapists’ commitment. Demotivated professionals are recognized as an adherence barrier (Robben et al., 2012). De Veer and colleagues also analysed factors that 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...
malfuctioning, ease of use, relevance for patients and risks to patients. Furthermore, the nursing staff in that study stressed the importance of an adequate innovation strategy (De Veer, Bekkema, Francke, & Fleuren, 2011). In our projects, we encountered some problems connected to technology failures (Kristjánsdóttir et al., 2011; Nes et al., 2012; Oerlemans et al., 2011), and these did bother the participants. Thorough testing in the health-care institutions where the new technology and therapeutic procedures will be embedded is needed to anticipate potential failures. Involvement of HCPs at the beginning of an intervention study is therefore considered essential. It is important to bear in mind that the DMT2 study, our most recently updated intervention, was performed six years ago, and technology has developed considerably since then. It is probable that the failure experienced then would not have happened today.

Implementation science can also be helpful throughout the process of translating research into practice, as it provides a better understanding and explanation of how and why implementation succeeds or fails (Nielsen et al., 2016). The technology acceptance model (TAM) (Venkatesh & Davis, 2000) and normalization process theory (NPT) (May & Finch, 2009) are good frameworks for the implementation of internet-based interventions in daily health-care practice. The TAM specifies the relationships between system design features, perceived usefulness, perceived ease of use, attitudes towards use and user behaviour. It provides a model for understanding the connection between design and user acceptance, and it is recommended that this be applied to the smartphone-delivered intervention in the current study before it is rolled out to the health-care system on a greater scale (Venkatesh & Davis, 2000). The NPT provides a framework that can help researchers ensure that the interventions they develop and evaluate can be widely implemented; consideration of implementation is done even before the trial begins, which may be an advantage. The NPT describes four main components of embedding CIs in practice: coherence, engagement, collective action and reflexive monitoring. These components interact with each other and with the wider context of the intervention, such as the organizational context, structures, social norms and group processes and conventions (Murray et al., 2010).

In all three interventions, 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 and DMT2 studies, feedback was given by a nurse with clinical experience or by a counsellor with a degree in psychology. Although it is known that there are self-management-based interventions that do not use a HCP as a provider (Fisher et al., 2012; Lorig et al., 2010), our experience shows that the method we developed requires a HCP with knowledge in the specific chronic disease of the participants. Knowledge of CBT/ACT is also needed to assess the
information received from the diaries and, subsequently, to write the feedback messages. Apart from knowledge and training in CBT-based treatment, for any treatment to be effective it is also important that the patient trusts the professional who delivers the intervention (Lauffenburger, Vu, Burkhart, Weinberger, & Roth, 2012). Our experience showed that an initial face-to-face meeting was important to establish a therapeutic alliance with the participants. In addition, it is important to examine each patient individually to identify severe psychological problems or chronic somatic health problems as early as possible and, if needed, to inform the patient’s GP. To make this possible, co-operation with multidisciplinary teams was established in all three studies. To have a similar structure when implementing web-based personalized feedback interventions in the daily health-care system would be a significant advantage.

Studies show that web-based interventions are cost effective, in addition to their positive impact on health outcomes (Levin et al., 2013; Zhang & Ho, 2016). Sustaining positive changes achieved in research studies when implementing these interventions in health-care institutions may require deliberate strategies, and the use of a conceptual framework and implementation protocol is strongly recommended. Kilbourne and collaborators (Kilbourne, Neumann, Pincus, Bauer, & Stall, 2007) described a framework called Replicating Effective Programs (REP) and concluded that it is well suited for implementing health-care interventions. The main components of REP are intervention packaging, training, technical assistance and fidelity assessment. As we mentioned before, training in CBT-based treatment is important in the delivery of our proposed intervention. Training is one of the main components of REP and covers a large part of the implementation process (Kilbourne et al., 2007). In our studies, participants also received technical assistance, and the fidelity of the CWP study was assessed. In the USA, the USA Government, represented by the Centers for Disease Control and Prevention and health departments, funds the implementation of REP-packaged interventions by over 500 prevention organizations nationwide (Pincus, Hough, Houtsinger, Rollman, & Frank, 2003). In Norway, the Norwegian Government, represented by the Norwegian Research Council and other minor actors, funds such implementation projects (Helsedirektoratet, 2012).

Another challenge when implementing web-based interventions in daily health-care practice is the lack of coverage and reimbursement policies regarding electronic coaching (e-coaching). It is hoped that the rapid development of e-health and studies showing its economic advantages may influence a positive change in the near future, so that e-coaching becomes an integral part of health-care, to be reimbursed in the same way as face-to-face consultations (Coye et al., 2009).
6.2.4 Future research

Technologies used for communication, including smartphones, are rapidly developing. The interventions that apply this kind of technology are at great risk of being outdated before they are even implemented. Therefore, the replication of such interventions is challenging. The dissemination of results can take time, and older results must be interpreted with caution, taking into account the context of rapid technological development.

The internet has great potential for providing understandable and useful health information to increase health literacy (Jacobs et al., 2016). However, there is a risk of overlooking vulnerable groups such as immigrants, older citizens, retired people and people living in rural areas when implementing internet interventions (DeMonte, DeMonte, & Thorn, 2015). These groups may face language barriers or have no interest in or no access to the internet. Strategies to identify and overcome the barriers preventing e-health access by these specific groups in internet-based interventions are essential.

The smartphone-delivered interventions presented in this thesis used self-reported e-diaries and feedback in written format. Such data open new possibilities for analysis. The feedback data in the SMI RCT study were collected daily over 4 weeks (excluding weekends). The diary data were collected daily for 5 weeks, with several variables collected more than once a day. The analysis of daily repeated data made it possible to evaluate the development of measures over time, identify trends that supported the main findings achieved in the RCT of the SMI for women with CWP and provide knowledge for the further development of this kind of intervention.

The development of a coding scheme in one of the studies presented in this thesis (Paper I) was necessary for the analysis. A reliable and valid coding system is essential for exploring therapeutic change processes in this type of smartphone-delivered intervention. The coding scheme for ACT-oriented web-based personal feedback was developed with high inter-rater reliability. Results of the analyses based on the developed coding scheme showed that the feedback provided was consistent with ACT theory. The coding scheme also has the potential to be a foundation for the automation of feedback messages, together with a bank or database of these messages.

Automatic feedback could be generated from a database and combined with individualized feedback if the diaries indicate this is required. The intervention could then be developed as an application for smartphones, reducing therapist time and costs. Making such an application
available as support for clinical practices and/or in maintenance treatments would help treat people who do not have easy access to health-care institutions. The use of new technology to make this kind of intervention more effective, while still taking care of the patients’ individual needs, suggests a very interesting future area of research. The first step would be to develop and test the concept of automation in an RCT intervention. In a further development of the intervention, it would be interesting to explore the effects of using more technologically advanced capabilities to gather rich and complex data. This could include sensors to measure activity levels and context-triggered diary questions (Miller, 2012; Riley et al., 2011). In addition, the automated feedback on registered data could be provided in progress charts, graphs and summaries. Educational information could be given by interactive animations or videos (Ritterband & Thorndike, 2006).

Despite the positive effects achieved in ACT-based interventions, it is common for the achieved effects to diminish over time, with the return of old cognition patterns (Franks et al., 2009; Linton et al., 2016). Other studies also show that the long-term effect of cognitive therapies is generally limited (De Jongh et al., 2012; Fjeldsoe et al., 2009). This may indicate a need for more continuity and a longer duration of intervention to support self-management in people with chronic illness. With the automation of the feedback messages, it would become more viable to offer an intensive smartphone-delivered intervention over a short period followed by booster sessions on an ongoing basis to maintain the effect.

As previously mentioned, the smartphone-delivered interventions required professionals with a background in health-care and knowledge of and training in CBT-based treatment. The first face-to-face meeting was important to establish a therapeutic alliance with the participants. Automation of the feedback process would enable an evaluation of the impact of the absence of a HCP in the development of feedback messages. The best solution might prove to be a combination of automated and personal feedback.

Patients with long-term conditions, who participated in a qualitative study conducted in the United Kingdom with the aim of investigating patients’ and caregivers’ criteria for internet interventions, suggested that the potential of technological alternatives should be explored (Kerr et al., 2006). Although the results of the studies presented in this thesis showed that the intervention concept developed was suitable for people with IBS, CWP and DMT2, and that this kind of intervention seems to meet the needs of caring for patients with chronic conditions, further developments integrating more technological alternatives (e.g., interactive elements such as games, video, etc.)
should be included to meet the diverse expectations of people with a chronic illness (Kerr et al., 2006). Testing the intervention concepts presented in this thesis with some refined technological elements and with other types of chronic illness would be an interesting area of research.

Social media platforms and mobile apps are changing the health-care system. Social media creates a relationship between patients and contributes to the change from unhealthy lifestyles (Coiera, 2013). Mobile apps can help to empower patients and put them at the centre of their own care (i.e., they can facilitate patient-centred care), and they give HCPs new possibilities for working more effectively. Patients will be able to take greater responsibility for managing their own health. This will reduce the health-care costs to society by moving treatment away from centralized and expensive hospitals and treatment centres and letting patients receive treatment directly, wherever they may be (Lopez, Seville, & Javit, 2016).

Today’s mobile apps can communicate with data stored in the cloud, making them independent of local server availability and giving access to a wide range of data and analytic tools (Lopez et al., 2016). If, for example, the intervention concept applied in this thesis had been tested with some thousand users, and all feedback messages and diaries were stored in a huge cloud-based database, there would be great opportunities for analysis. The effects of different kinds of feedback on patient behaviour could be analysed continuously. Feedback messages to patients, if automated, could then be adjusted immediately according to new knowledge. Other examples could include sensor data from glucose meters and heart monitors that, when stored and analysed, can trigger an immediate response to the patient, supporting the patient to change his/her behaviour and thereby self-manage the disease.

With health-care portals becoming more powerful and better integrated with mobile apps, patients will be able to see their own health picture with recommendations and guidance, and statistics from similar patient groups, and have the opportunity to communicate with peers. Better-informed patients can more easily take responsibility for their own health (Santoro, Castelnuovo, Zoppis, Mauri, & Sicurello, 2015).

It was identified in the diabetes pilot study (Paper III) that patients had much poorer knowledge of their diabetes than expected, but that they were interested to learn more. An app could be the right format to deliver tailored information for many of these patients. Lack of proximity to physicians or convenient access to suitable written material often hinders patients’ absorption of information. Many people enjoy playing games on their mobile phones, and educational game apps are
common for children. It will be interesting to follow the development of game apps for different types of chronic diseases.

When developing health-care apps is it important that HCPs, users and information technology developers work closely together. Good apps should make use of new technical features as well as being based on health-care theory and best treatment practice. The major concerns around such solutions are safety and privacy. Information about a person’s health is private and sensitive, and must be stored safely and well protected. Hackers are always trying access this type of data, because it attracts a high price on the market. Security concerns thus might slow the adoption of mobile apps for health-care
7. CONCLUSION

The main objective of this thesis was to analyse the change processes of the SMI that has been tested successfully in an RCT for women with CWP. The intervention concept consisted of mobile technology with internet access to deliver daily e-diaries and individualized situational feedback based on the theoretical background of CBT/ACT. To my knowledge, this is the first study to have explored this field.

Despite no support being found for an association between participant outcomes, as conveyed by their e-diary content, and the specific content of feedback messages, when analysed in terms of the individual ACT elements comprising these feedback messages, the analysis of the diary responses over time showed promising results. The fact that the diary questions were consistent with the ACT model may have influenced the change processes positively. In particular, the process of committed action towards realizing one’s own life values may have helped participants to stay sufficiently active at home. The diary content may also have contributed to increased levels of PA, PSM and PF, and to decreased PFA. Although tentative, the results from the present study provide relevant information that will contribute to the further development of smartphone-delivered interventions to enhance the treatment of CWP. This analysis was possible after developing a feedback coding scheme, which was also applied to evaluate the fidelity of the intervention. The treatment integrity was judged as high and the feedback provided was consistent with ACT theory.

The other studies presented in this thesis showed that the intervention concept was feasible for persons with DMT2 (Paper III) and effective for persons with IBS (Paper IV). In summary, the intervention concept was accepted by all three target groups presented in this thesis. The positive effects achieved suggest that this form of intervention is promising. It is important to bear in mind the fast development of technology when interpreting and applying the results. This represents challenges as well as opportunities.

According to the WHO, there is a consensus that in order to provide effective health-care for people with chronic conditions, HCPs need to adopt a patient-centred approach, identifying patients’ concerns, emotions, social situations, behaviours, values and preferences for care. Ideally, patients should be monitored over time, and HCPs should be able to collaborate and share information through available technology (World Health Organization, 2005a). The presented smartphone-delivered intervention based on ACT appears to offer an alternative to HCPs for
delivering tailored counselling to people suffering from chronic illness, and meets the WHO recommendation for patient-centredness.

Patients with long-term conditions are highly positive about internet interventions and appreciate their potential (Kerr et al., 2006). A recent review showed a high rate of adherence to interventions that were based on ACT theory delivered via the internet, indicating that this therapeutic approach is highly acceptable to patients and the general public (Brown et al., 2016). Web interventions based on CBT, and more specifically ACT, are a promising complement to established treatments and may be a valuable alternative for future treatments for people with a chronic illness (Brown et al., 2016; Kristjánsdóttir et al., 2013a; Nes et al., 2012; Oerlemans et al., 2011). The advantages of web-based interventions may include reductions in therapist time and waiting lists, avoidance of the stigma associated with therapist visits and allowing patients to work at their own pace and save travel time (Cuijpers et al., 2008). Thus, they appear to be valuable person-centred therapeutic approaches to support self-management in daily health-care.
8. REFERENCES


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Appendix 1: The DMT2 pilot study - Description of the smartphone-delivered intervention
The smartphone intervention was developed by building on the experiences of two previously projects that used the similar technology to support people coping with IBS (Oerlemans et al., 2011) and CWP (Kristjánsdóttir et al., 2013a; Kristjánsdóttir et al., 2011). A multidisciplinary group of health professionals choose the theoretical background, i.e., ACT (Eide, Kristjánsdóttir, & Nes, 2011) and supported the development of the content of the intervention.

The intervention started with an individual meeting between the participants and the researcher (AAGN) for the project at the GP’s office. The meeting lasted for 1 hour were the participants received detailed information about the intervention. As recommended by ACT, life values and health related values were discussed. The participants received written value-based exercises and they were encouraged to read and complete those at home. Each participant was given a smartphone (Samsung Omnia i 900) and they were taught how to use the smartphone during the intervention period. All verbal information received could be consulted by the participants in an instruction manual delivered together with the smartphone. The participants took blood test and completed the study assessment instruments during this first meeting. They also received the name of their therapist for the intervention and they were informed that the therapist would make a telephone call to present herself and ask about their goals for health-related behavior and support needs.

The four main elements of the DMT2 smartphone intervention were: (1) An internet program that made possible to connect to a secure server to access the (2) e-diaries based on ACT, (3) individualized written situational feedback based on ACT and (4) five installed audio files with mindfulness and relaxation exercises.

1. Internet Program. The technological platform, Open Source Content Management System (Drupal) was used. The data security was maintained through a combination of system design, hypertext transfer protocol secure (HTTPS) and proprietary mobile phone authentication system (Eide, Eide, Kristjánsdóttir, & van Dulmen, 2010).

2. Electronic Diaries (E-diaries). The participants were asked to complete three diary entries daily. See Figure 9 for a view of the screen display.
A pre-pilot with two participants was performed to test all the steps and the content of the diaries. Based on the Pre-pilot, a few adjustments were done for the feasibility study. Adjustments included e.g., the reduction of number of questions of the diaries, modification of wording of some question in the diaries, and increasing the number of predefined answers alternatives from five to six-point Likert scale.

The e-diaries included 16 to 21 questions chosen for supporting self-monitoring of health behavior and applied self-management strategies. The questions were also intended to stimulate awareness and reflection of thought content, feelings and its relationship to their health behavior. The awareness of thoughts and feelings is an essential element in ACT (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007b). Most of the questions were answered by choosing predefined alternatives or by scoring on a six-point Likert scale. A few questions contained a text field giving the participants of the project the opportunity to provide the therapist additional information. The e-diaries included questions about current level of blood glucose, diet, medicine, planned and performed physical activities, feelings and a brief evaluation of the received feedback. The questions related to thoughts and feelings were formulated in accordance with the experience sampling methods (ESM) principles designed to capture experience in real time without retrospective bias (e.g., "right now I am feeling.....") (Napa Scollon, Prieto, & Diener, 2009).

The diaries also included a comment field where the participants could write a short personal message to the therapist (a complete version of the e-diaries is shown in the Appendix 2). The participants completed three diaries daily by receiving short message service (SMS) alerts on the smartphone. Each SMS message had a link to a secure web site where the diaries could be opened, completed and submitted. If the diary entry was not returned within 45 minutes, the server automatically sent an SMS reminder message. Two reminders within 1 h per diary were allowed. The submission of the diary was only possible when it was fully completed within 90
minutes, then the diary was closed. The participants could decide the most convenient time to receive the morning and evening diary. This agreement was concluded at the first meeting with the participants and was intended to adapt the intervention to the participants’ daily routines. The web server chose the midday diary entry at random. The participants completed the first diary at the initial meeting with the researcher, and continued for one week before receiving the first feedback. This was a run-in-period, where the participants were getting use to complete the e-diaries without receiving feedback. A start-up training session in the use of e-diaries is needed and a run-in-period is recommended (Piasecki et al., 2007). During the intervention period the researcher was available to answer any question regarding the intervention included technological issues. After the run-in-period the participants continued to complete the e-diaries for more three months. The content of completed diaries was the basis for the formulation of participants received situational feedback writing by a therapist.

3. Individualized written situational feedback messages. For one month (after the run-in-period) participants received daily feedback (excluding weekends) followed by two months’ weekly feedback. The feedback messages were developed by one of the three nurses that received training in ACT (AAGN, ISS and AT) supported by a multi-disciplinary group that included a clinical communication researcher, a diabetic researcher, a nurse with clinical experience with diabetes and a nutritionist. The feedback messages were based on the ACT theory with a focus on values, value-based behavior, mindfulness and acceptance and tailored to each participant’s situation reported in the e-diaries. The aim was to promote self-management by stimulating participants living according to their life values improving their daily functioning. It was written in an empathetic style and included repetition of content reported in the diaries, positive reinforcement, reminders of self-management strategies, ACT exercises and reflective questions. The instructions for the exercises were written directly in the feedback message or the participant was referred to exercises available as audio files in the smartphone. The feedback was usually available for the participant within 90 minutes of completing the second diary of the day. If this diary was not submitted, a feedback based on information from latest submitted diary was sent. When the feedback was available, the participant received an SMS with a link to the website where the feedback could be read. There was no limitation on the length of the feedback, that ranged from a few sentences to a few paragraphs. The feedback had different focus during each of the twelve weeks of the project, started with a welcome message and identification of the life values and continued with all the ACT processes that could be applied for diabetes disease (see Table 5). Although a guideline for the enforcement of the ACT theory was used when writing the feedback messages, it is important to emphasize that the feedback messages were tailored and formulated
based on several input at the first meeting with the participants, daily e-diaries and the ACT theory. The therapists had the freedom to evaluate and choose the ACT component that suited the participant in that specific moment.

Table 5  
*Focus of daily feedback (four weeks) and weekly (eight weeks) based on ACT*

<table>
<thead>
<tr>
<th>Week</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>Welcome to the project</td>
<td>Identification of life values</td>
<td>Identification of values related to health</td>
<td>Identification of the connection between values and valued behavior</td>
<td>Reinforcement of values and valued behavior</td>
</tr>
<tr>
<td>Week 2</td>
<td>Reminder of values</td>
<td>Identification of goals related to health values</td>
<td>Understanding of goals balance to achieve the goals related to health values</td>
<td>Stimulation of goal achievement</td>
<td>Reinforcement of goal balance to achieve the desirable goals</td>
</tr>
<tr>
<td>Week 3</td>
<td>Reminder of goals</td>
<td>Identification of the barrier related to goal achievement</td>
<td>Identification of strategies to defeat the barriers</td>
<td>Working with strategies to defeat the barriers</td>
<td>Reinforcement of strategies to defeat the barriers</td>
</tr>
<tr>
<td>Week 4</td>
<td>Reminder of strategies to defeat the barriers</td>
<td>Understanding how thoughts and feelings influences behavior</td>
<td>Working with awareness and acceptance strategies connected to thoughts and feelings to defeat negative behaviors</td>
<td>Working with willingness to act in accordance with health-related values</td>
<td>Reinforcement of willingness to act in accordance with health-related values</td>
</tr>
<tr>
<td>Week 5 and 9</td>
<td>Reminder of values and goals. See week 1 and 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 6 and 10</td>
<td>Reminder of strategies to defeat the barriers. See week 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 7 and 11</td>
<td>Reminder of awareness and acceptance strategies connected to thoughts and feelings to defeat negative behaviors. See week 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 8 and 12</td>
<td>Reminder of willingness to act in accordance with health-related values. See week 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The feedback messages developed in the project became a part of a feedback “‘bank’”. The content of the growing “bank” of feedback was used to develop new feedback messages for other participants when it was relevant. In the beginning to write a feedback could take more than one hour. After the first month, when the feedback bank was completed, the average time used to formulate a feedback message was 15–20 minutes. See examples of feedback messages in Appendix 3.

4. Audio files with mindfulness exercises installed on the smartphone. Four audio files with mindfulness exercises (e.g., focused breathing, awareness of thought content) were available on the smartphones. The themes of the exercises were: (1) presence, (2) thoughts, feelings and breath, (3) attention, and (4) relaxation.
Appendix 2: The DMT2 pilot study - Question in the diaries (in Norwegian).
1. Blodsukkeret mitt fastende er...*  

2. Nattens søvn var...*  

3. Jeg våknet i løpet av natten...  
   - Fordi jeg var sulten  
   - Fordi jeg var tørr  
   - Fordi jeg var svett  
   - Av andre grunner  
   - Ikke aktuelt  
   Viere vil og mulig

4. I dag har jeg tenkt å...*  
   - Måte blodsukkeret mitt som anbefalt  
   - Ta mine medicin eller som anbefalt  
   - Spise som anbefalt  
   - Drøyt som anbefalt  
   - Være i fysisk aktivitet for eksempel tur i riktig tempo, huserbleid  
   - Være i fysisk aktivitet i minimum 30 minutter (for eksempel tur med rask gange)  
   - Være i fysisk aktivitet i minimum 20 minutter (for eksempel jogging med høy intensitet)  
   - Være i moderat eller høy fysisk aktivitet i ca 60 minutter  
   - Gjøre spørsmålstegn/avslapp  
   - Gjøre andre lyttbesluttende aktiviteter  
   - Annet  
   Viere vil og mulig

5. Hvis du svarte "annet" på forrige spørsmål vennligst skriv hvilke aktiviteter her  

6. Akkurat nå er jeg glad*  

7. Akkurat nå er jeg stresset*  

8. Akkurat nå er jeg lett  

9. Akkurat nå er jeg trist  

10. Akkurat nå er jeg opplagt  

11. Akkurat nå er jeg irritert  

12. Akkurat nå er jeg tekknemlig  

13. Akkurat nå er jeg bekymret  

14. Akkurat nå er jeg skuffet  

15. Akkurat nå er pusten min dyp og avslappet  

16. Hvis du har noen kommentarer, vennligst skriv dem her  

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1. Siden forrige dagboknotat har jeg spist/drukket som anbefalt *

2. Siden forrige dagboknotat har jeg tatt diabetesmedisinen min som anbefalt*

3. Jeg har holdt på med...
   - Lett fysisk aktivitet (for eksempel tur i rolig tempo)
   - Moderat fysisk aktivitet i minimum 30 minutter (for eksempel tur med rask gange)
   - Høy fysisk aktivitet i minimum 20 minutter (for eksempel jogging med høy intensitet)
   - Moderat eller høy fysisk aktivitet i ca 60 minutter
   - Avspenningsøvelser
   - Andre lysbetonte aktiviteter
   - Annet

4. Hvis du svarte "annet" på forrige spørsmål vennligst skriv hvilke aktiviteter her

5. Akkurat nå er jeg fornøyd*

6. Akkurat nå er jeg trygg på at jeg mestrer det jeg må passe på i forbindelse med diabetes*

7. Akkurat nå er jeg stresset*

8. Jeg er tilfreds med mitt aktivitetsnivå*

9. Jeg er tilfreds med det jeg har spist/ drukket*

10. Jeg er tilfreds med min egen kontroll av blodsglukornivået mitt*

11. Resten av dagen har jeg tenkt å ...
   - Ta mine medikamenter som anbefalt
   - Spise/ drikke som anbefalt
   - Være lett fysisk aktiv (for eksempel tur i rolig tempo)
   - Være moderat fysisk aktiv i minimum 30 minutter (for eksempel tur og rask gange)
   - Være i høy fysisk aktivitet i minimum 20 minutter (for eksempel jogging med høy intensitet)
   - Være i moderat eller høy fysisk aktivitet i ca 60 minutter
   - Gjøre avspenningsøvelser
   - Gjøre andre lysbetonte aktiviteter
   - Annet

12. Hvis du har noen kommentarer, vennligst skriv dem her
1. Jeg har siden forrige dagboknotat spist drukket som anbefalt* □ □

2. Jeg har siden forrige dagboknotat tatt diabetesmedicin som anbefalt* □ □

3. Siden forrige dagboknotat har jeg holdt på med ...* □ Lett fysisk aktivitet (for eksempel tur i en liten tur) □ Moderat fysisk aktivitet i minimum 30 minutter (for eksempel gåtur med raske grep) □ Høy fysisk aktivitet i minimum 60 minutter (for eksempel jogging med høy intensitet) □ Når det er vanskelig for meg å-likevært med fysisk aktivitet i ca. 60 minutter □ Andre lystbrosse aktiviteter □ Ansatt

4. Hvis du svarer "nej" på forrige spor er mulig å skrive hvilke aktiviteter her □ □

5. Akkurat nå er jeg glad* □ □

6. Akkurat nå er jeg stresset* □ □

7. Akkurat nå er jeg lettet* □ □

8. Akkurat nå er jeg triet* □ □

9. Akkurat nå er jeg oppsagt* □ □

10. Akkurat nå er jeg irritert* □ □

11. Akkurat nå er jeg takknemlig* □ □

12. Akkurat nå er jeg bekymret* □ □

13. Akkurat nå er jeg skuffet* □ □

14. Akkurat nå er poenget min dyp og overlappet* □ □

15. I dag har jeg hatt fioling* □ □

16. I dag er jeg fordømt med mitt aktivitetsnivå* □ □

17. I dag er jeg fordømt med det jeg har spist/ drikket* □ □

18. Jeg er fordømt med innstak av medisiner i dag* □ □

19. I dag har jeg regulært blodsockeret mitt fint* □ □

20. Tilbakekommende har hjelpet meg til å ...* □ Være så fysisk aktiv som jeg ønsket □ Spise/ erkeie mat som jeg vet er bra for meg □ Ha en god kontroll over blodsockeret mitt □ Være bevrurt det som er viktig for meg □ Et lite hjelpet noe □ Ikke aktuelt

21. Hvis du har noen kommentarer, venligst skriv dem her
Appendix 3: The DMT2 pilot study - Examples of feedback messages (in Norwegian)


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Hvis du ikke klarer å tenke på noen utfordringer er det greit. Målet med dette er å få kunnskap om de områdene du kan mer jobbe med. Ved å reflektere over dette kan det hjelpe deg å finne nye strategier til å håndtere din diabetes. Nå er det igjen en langhelg, og du vil ikke få tilbakemelding før på tirsdag. Jeg vil se på skjemaene du fyller ut i løpet av disse dagene, for å gi deg tilbakemelding på tirsdag. I denne perioden vil jeg igjen foreslå at du forsøker å reflektere over det jeg har skrevet til deg i tilbakemeldingene så langt. Ønsker deg en riktig fin pinsehelg! Hilsen X


Hei, denne er den siste uken der du får daglige tilbakemeldinger. Det er spennende å se hvordan du nå vil jobbe videre med telefonen på egen hånd. Jeg har lyst til at du skal tenke litt over et begrep som "villighet". La oss si at det i denne sammenhengen handler om det daglige liv. I ditt daglige liv kan det være en del ting du er nødt til å gjøre. Det betyr at du gjør disse tingene enten du ønsker det eller ikke. For eksempel er det ikke alltid en er opplagt til å dra på jobben selv om en ikke er syk. En drar likevel fordi de finnes en god grunn til det ofte knyttet til moral og forpliktelser både for seg selv og andre. Å la være er da kanskje ikke i overensstemmelse med hvordan du ønsker å se på deg selv eller fordi andre ikke vil synes at det du gjør er ok. Derfor kan villighet i denne sammenheng være knyttet til det som "må gjøres". En kan være villig til å gjøre noe selv om en ikke ønsker det. Har du tenkt på det før? Dette er det samme prinsippet som vi bruker når vi snakker
om dine verdier og behandling av din diabetes. Det er ikke alltid du ønsker å gjøre det som
er nødvendig for å kontrollere ditt blodsukker. Slik er det også med de fleste personer.
Selv om du ikke ønsker det gjør du det likevel fordi det egentlig er bra for deg å gjøre det,
oegentlig kanskje i tråd med dine verdier. Framover vil du kun få tilbakemeldinger på
fredager. Disse ukentlige tilbakemeldingene vil baseres på spørreskjemaene du svarer på i
løpet av uken. Ta kontakt hvis du lurer på noe. God helg! Hilsen X

Hei. Dette er siste uken i prosjektet, og også den siste tilbakemeldingen. Hvordan synes du
disse 12 ukene har gått? Utfordringen din framover blir å vedlikeholde alt det du har
oppnådd i disse ukene, og gjøre det til en naturlig del av hverdagen og din livsstil. Jeg er
imponert over deg og hvor langt du har kommet på kort tid! Det er viktig å huske at det er
de små skrittene man tar som ofte fører fram til en varig endring. Derfor kan det være
nyttig å sette seg små mål når man jobber med livsstilsendring. Avslutningsvis vil jeg
opfordre deg til å oppsøke legen din dersom blodsukkeret blir vanskelig å håndtere, eller
hvis det er andre ting vedrørende din helse som du behøver assistanse i forhold til. Takk
for samarbeidet, det har vært en glede å følge utviklingen din og å skrive tilbakemeldinger
til deg! Lykke til videre med et fortsatt godt og meningsfylt liv! Hilsen X
Appendix 4: The DMT2 pilot study - Questionnaire for the evaluation of the intervention (in Norwegian)
EVALUERING AV PILOTSTUDIE

- Spørsmålene handler om bruk av mobiltelefonen, utfylling av dagboken og tilbakemeldinger, vi ber deg å svare så godt du kan på disse.

- Opplysningen vil bli brukt i det videre utvikle teknologien for å bedre diabetesomsorgen.

- Venligst sett inn et kryss i boksen som indikerer hvor sterkt enig eller uenig du er i følgende påstander:

<table>
<thead>
<tr>
<th>1. Jeg synes det har vært ........ å delta i dette prosjektet</th>
<th>Helt enig</th>
<th>1</th>
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<th>Helt uenig</th>
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<thead>
<tr>
<th>2. Jeg synes det var positivt å fylle inn dagbøker på mobiltelefonen</th>
<th>Helt enig</th>
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<th>Helt uenig</th>
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<tr>
<th>3. Jeg kan godt tenke meg å begynne å bruke mobiltelefonens for å fylle inn daglige registreringer som fast dagbok.</th>
<th>Helt enig</th>
<th>1</th>
<th>2</th>
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<th>Helt uenig</th>
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113
<table>
<thead>
<tr>
<th>4. Når det gjelder telefonen synes jeg den var ...</th>
<th>Helt enig</th>
<th>Helt uenig</th>
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<tr>
<td>Brukervennlig</td>
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<td>Passe stor</td>
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<td>Passe tung</td>
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<td>Skjermen var god</td>
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<td>Bokstaver var passe store</td>
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<tr>
<td>Alarmlyden var grei</td>
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Kommentar: .................................................................................................................................
......................................................................................................................................................

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<tr>
<th>5. Jeg synes det har vært .......... å bruke telefonen</th>
<th>Helt enig</th>
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6. Jeg synes det har vært ....... å fylle ut dagbokskjemaer

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7. Jeg synes att...

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<thead>
<tr>
<th>Antall spørsmål i dagboken var</th>
<th>For mange</th>
<th>Passe</th>
<th>For få</th>
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<tbody>
<tr>
<td>Antall utfyllinger per dag (3) var</td>
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<tr>
<td>Antall uker (4) du fylte ut dagboken daglig var</td>
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<tr>
<td>Antall uker (3) du fylte ut dagboken ukentlig var</td>
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8. Temaet det spørrtes om var relevante

9. Spørsmålene var forståelige

10. Spørsmålene var relevante

11. Jeg synes jeg har fått mer innsikt i min diabetes ved å fylle ut dagboken

12. Jeg synes det har vært en god støtte å fylle ut dagboken?
13. Savnet du noen tema?
   ☐ Nei
   ☐ Ja: Hvilke______________________________________________________________.

14. Savnet du noen spørsmål?
   ☐ Nei
   ☐ Ja: Hvilke______________________________________________________________.

15. Er det noen andre tema du hadde ønsket deg?
   ☐ Nei
   ☐ Ja: Hvilke______________________________________________________________.

16. Er det noen spørsmål du hadde ønsket deg?
   ☐ Nei
   ☐ Ja: Hvilke______________________________________________________________.

17. Hvor ofte fikk du fylt ut dagboken innen en time fra du mottok første sms?
   ☐ Sjeldnere enn halvparten av gangene
   ☐ Halvparten av gangene
   ☐ Som oftest
   ☐ (Nesten) alltid

18. Hvis jeg ikke fikk fylt ut skjemaet så var grunnen til det oftest? (Sett et kryss foran ett eller flere svar)
   ☐ Opptatt med noe annet
   ☐ Hadde ikke med mobilen i nærheten
   ☐ Hadde ikke lyst til å fylle ut
   ☐ Annet: ________________________________________________________________.
### 19. Jeg synes det har vært ....... å motta tilbakemeldinger

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### 20. Jeg synes at....

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<tr>
<td>Antall tilbakemeldinger (1) daglig</td>
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<tr>
<td>Antall tilbakemeldinger (1) ukentlig</td>
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<tr>
<td>Antall uker (4) du fikk tilbakemelding daglig</td>
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<td>Antall uker (8) du fikk tilbakemelding ukentlig</td>
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<tr>
<td>21. Jeg har fått noen metoder jeg kan bruke for å håndtere min diabetes</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>22. Jeg føler at jeg har blitt mer bevisst på mestrengs-strategiene mine ved å delta i dette prosjektet</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>23. Jeg klarte å gjennomføre oppgavene og rådene jeg fikk</td>
<td>☐</td>
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<tr>
<td>24. Jeg har blitt motiveret til å trene</td>
<td>☐</td>
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<tr>
<td>25. Jeg har blitt motiveret til å gjøre avspenningsøvelser</td>
<td>☐</td>
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<tr>
<td>26. Jeg har blitt motiveret til å følge diettplanen min</td>
<td>☐</td>
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<tr>
<td>27. Jeg har blitt motiveret til å kontrollere blodsukkeraktiviteten mitt</td>
<td>☐</td>
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<tr>
<td>28. Jeg har blitt motiveret til å ta diabetesmedikamenter i riktig tid og doser</td>
<td>☐</td>
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29. Hvis du har noen kommentarer angående innholdet i tilbakemeldingen fra sykepleieren vennlig skriv her.

_____________________________________________________________________________________
_____________________________________________________________________________________

☐ De fikk meg til å tenke igjen verdiene mine
☐ Jeg synes det var vanskelig å forstå spørsamålene
☐ De fikk meg til å skrive ned verdiene mine
☐ Jeg kunne tenkt meg mer informasjon om dette
☐ Jeg synes det har vært motiverende å bli bevisst på verdiene mine
Appendix 5: The DMT2 pilot study - Interview guide (in Norwegian)
INTERVJU GUIDE FOR EVALUERING AV PILOTEN

Deltakere:
Dato:

1. Hvordan har dette vært så langt?
2. Din opplevelse av dagboken
3. Din opplevelse av tilbakemeldingene fra diabetessykepleier
4. Telefon og funksjon
5. Hvordan har/har deltakelse i prosjektet bidratt til…
   • … egen oppfatning av hva som er viktig for deg?
   • … identifisering av dine verdier?
   • … målsetting for helse i tråd med dine verdier?
   • … identifisering av barrierer som hindrer gjennomføring av målene?
   • … identifisering av løsninger til hindringene?
   • … at dine aktiviteter er o tråd med dine verdier?
   • … aksepterer tanker og følelser som du har?
   • … at du mestrer det som du selv forventer?
6. Hvordan ønsker du å støttes i fortsettelsen?
Appendix 6: The DMT2 pilot study - Sociodemographic questionnaire (in Norwegian)
BAKGRUNNS OPPLYSNINGER

PERSONLIGE OPPLYSNINGER

1. Kjønn
   □ Mann
   □ Kvinner

Alder (Bruk tall)

2. Hvilket år ble du født?

3. Sivilstand (Sett bare et kryss)
   □ Ugift
   □ Gift/registrert partner
   □ Skilt
   □ Separert
   □ Enke/enkemann

   □ Bor alene
   □ Ektefelle eller samboer
   □ Søster/bror
   □ Annen familie/slekt
   □ Barn/svigerbarn
   □ Bor på institusjon

5. Hvilken utdanning har du fullført? (Sett et kryss)
   □ Grunnskole 7-10 år, framhalsskole, folkehøgskole
   □ Real - eller middelskole, yrkesskole
   □ Ett- eller toårig videregående skole
   □ Artrium, økonomisk gymnas eller allmennfaglig
   □ Retning videregående skole
   □ Høgskole eller universitet mindre enn fire år
   □ Høgskole eller universitet mer enn fire år
6. Hva slags arbeidssituasjon har du nå? *(Sett et kryss)*
- □ Lønnet arbeid
- □ Selvstendig næringsdrivende
- □ Heltids husarbeid
- □ Utdanning, militærtjeneste
- □ Arbeidsledig, permittert
- □ Pensjon, trygdet

7. Sett et kryss hvis du den senere tiden (de siste fire uker) har opplevd noen av følgende hendelser:
- □ Giftet deg/flyttet sammen med samboer
- □ Fått barn
- □ Dødsfall familie/nære venner
- □ Alvorlige bomessige eller økonomiske problemer
- □ Andre betydelige livshendelser
Appendix 7: The DMT2 pilot study - Disease characteristics questionnaire (in Norwegian)
**SYKDOMSSPESIFIKKE DATA**

Spørsomlene videre handler om diabetes, vi ber deg å svare så godt du kan på disse.

Vær vennlig og sett et kryss i den boksen som passer best.

**DIAGNOSE**

1. Hvordan ble din diabetes oppdaget?
   - Jeg søkte lege pga. symptomer
   - Ble oppdaget uten at jeg hadde symptomer (ved legeattest, bedriftselskontroll, undersøkelse for annen sykdom eller lignende)

2. Hvilket årstall ble din diabetes oppdaget?

**BEHANDLING**

**INSULIN**

3. Bruker du insulin (sprøyter, penn, pumpe) mot din diabetes nå?
   - Ja
   - Nei (Hvis nei, gå til spørsmål 8)

4. Hvilket årstall begynt du med insulin?

5. Hvordan tar du insulin?
   - Insulinpenn
   - Insulinpumpe
   - Jet - (trykk-) injektor

6. Hvor mange ganger tar du insulin hver dag?

7. Hvor mange enheter (IE) insulin tar du vanligvis til sammen hver dag?
TABLETTER
8. Bruker du tabletter mot din diabetes?
   ☐ Ja
   ☐ Nei
9. Hvilket årstall begynte du med tabletter mot din diabetes?

ANDRE MEDIKAMENTER
10. Noter nedenfor alle de medikament du bruker for tiden (både diabetesmedisiner og andre medisiner som for eksempel smertestillende, muskelavslappende, beroligende, sovedemisin, antidepressiva og andre)

<table>
<thead>
<tr>
<th>Navn</th>
<th>Styrke</th>
<th>Dosering</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

DIABETESKONTROLL

LEGEKONTROLL

11. Går du til regelmessig kontroll hos lege for din diabetes?
   ☐ Ja
   ☐ Nei

12. Går du til kontroll hos sykepleier eller annet helsepersonell?
   ☐ Ja
   ☐ Nei

13. Hva slags lege går du til kontroll hos for din diabetes?
   ☐ Fastlege, allmennpraktiserende lege, bedriftslege, osv.
   ☐ Sykehuslege (poliklinikk på sykehus)
14. Måler du noen ganger hjemme hvor mye sukker (glukose) du har i blodet (blodsukker)? (Svar "Ja" også om noen hjelper deg eller gjør det for deg)
   □ Ja
   □ Nei

15. Omtrent hvor mange ganger måler du blodsukker i løpet av en vannlig dag/uke?
   _____________ ganger per dager
   _____________ ganger per uker

16. Hvordan opplever du stort sett at det er å kontrollere blodsukkeret ditt?
   □ Svært vanskelig
   □ Vanskelig
   □ Både/og
   □ Lett
   □ Svært lett

17. Har du noen ganger hatt for lavt blodsukker?
   □ Ja
   □ Nei

18. Hvis ja, hvor mange ganger har du hatt det i den siste uka?

19. Har du noen ganger hatt så lavt blodsukker ("sjokk") at du måtte ha hjelp av andre for å komme over det?
   □ Ja
   □ Nei

20. Hvor mange ganger har du ligget på sykehus etter at du fikk diabetes?

21. Hvis du har ligget på sykehus etter at du fikk diabetes, hva har du ligget for?
   (kryss for en eller flere)
   □ Lavt blodsukker/insulinsjokk eller skade pga. dette
   □ Høyt blodsukker/ ”sukkerslag”
   □ Hjerte/karsykdom (hjerteinfarkt, hjertesvikt, slag osv.)
   □ Nyresykdom
   □ Annen sykdom
SYN

22. Har du hatt problemer med synet som lege har sagt skyldes din diabetes?
   □ Ja
   □ Nei

23. Går du til regelmessig øyeundersøkelse (av netthinna/ øyebunnen) på grunn av din diabetes?
   □ Ja
   □ Nei

24. Har du fått laserbehandling av øynene pga. øyebunns - forandringer som skyldes din diabetes?
   □ Ja
   □ Nei

FOTPROBLEMMER

25. Er du operert for trange blodårer til beinet?
   □ Ja
   □ Nei

26. Har du fått amputert (skjært bort) en del av ett eller begge bein svarende til:
   (Skriv årstall til høyre)
   □ Tær/fot? ___________________________ Årstall
   □ Legg/kne? ___________________________ Årstall
   □ Lår? ___________________________ Årstall

27. Har du hatt sår på føttene som har brukt over tre uker på å gro?
   □ Ja
   □ Nei

28. Hvis ja, omtrent hvor mange uker tok det før såret grodde?

TOBAKK

   □ Nei, jeg har aldri røykt (Hvis du aldri har røykt, hopp til spørsmål 44)
   □ Nei, jeg har sluttet å røyke
   □ Ja, sigaretter av og til (fest/ferie, ikke daglig)
   □ Ja, sigarer/sigarillos/pipe av og til
   □ Ja, sigaretter daglig
   □ Ja, sigarer/sigarillos/pipe daglig
30. Bruker du, eller har du brukt, snus?

☐ Nei, aldri
☐ Ja, men jeg har sluttet
☐ Ja, av og til
☐ Ja, daglig

31. Har du, eller har du noen gang hatt, noen av disse sykdommene/plagene?

☐ Hjerteinfarkt
☐ Angina pectoris (hjertekrampe)
☐ Hjertesvikt
☐ Annen hjertesykdom
☐ Hjerneslag/hjerneblødning
☐ Nyresykdom
☐ Kronisk bronkitt, emfysem, KOLS
☐ Psoriasis
☐ Eksem på hendene
☐ Kreftsykdom
☐ Mage- og tarmsykdommer
☐ Epilepsi
☐ Leddgikt (reumatoid artritt)
☐ Bechterews sykdom
☐ Sarkoidose
☐ Beinskjørhet (osteoporose)
☐ Fibromyalgi
☐ Slitasjegikt (artrose)
☐ Psykiske plager som du har søkt hjelp for
Dette spørreskjemaet handler om din livskvalitet – med andre ord hvor godt eller dårlig du føler at livet ditt er.

Vennligst sett en ”X” i den boksen som best angir ditt svar på hvert spørsmål.

Det vi ønsker å få vite er hvordan du opplever livet ditt nå.

<table>
<thead>
<tr>
<th>I det store og hele er min nåværende livskvalitet:</th>
</tr>
</thead>
<tbody>
<tr>
<td>fremragende</td>
</tr>
</tbody>
</table>

Nå vil vi gjerne vite hvordan din livskvalitet påvirkes av din diabetes, behandlingen og eventuelle komplikasjoner som du måtte ha.

<table>
<thead>
<tr>
<th>Hvis jeg ikke hadde diabetes, ville min livskvalitet vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td>svært mye bedre</td>
</tr>
</tbody>
</table>
Vennligst besvar de mer spesifikke utsagnene på de neste sidene. For hvert aspekt ved livet som beskrives vil du finne to utsagn:

| For utsagn (a): | sett en "X" i en av bokserne for å vise hvordan diabetes påvirker dette aspektet ved livet ditt; |
| For utsagn (b): | sett en "X" i en av bokserne for å vise hvor viktig dette aspektet ved livet ditt er for din livskvalitet. |

<table>
<thead>
<tr>
<th>1 (a)</th>
<th>Hvis jeg <strong>ikke</strong> hadde diabetes, ville gleden ved mine fritidsaktiviteter vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td>svært mye større</td>
<td>mye større</td>
</tr>
</tbody>
</table>

(b) Mine fritidsaktiviteter er:

<table>
<thead>
<tr>
<th>svært viktige</th>
<th>viktige</th>
<th>litt viktige</th>
<th>ikke viktig i det hele tatt</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>2</th>
<th>Er du for tiden i arbeid, arbeidssøkende, eller ville du ønske å arbeide?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ja</td>
<td>Hvis <strong>ja</strong>, besvar (a) og (b).</td>
</tr>
<tr>
<td>Nei</td>
<td>Hvis <strong>nei</strong>, gå videre til 3a.</td>
</tr>
</tbody>
</table>

(a) Hvis jeg **ikke** hadde diabetes, ville mitt arbeidsliv vært:

<table>
<thead>
<tr>
<th>svært mye bedre</th>
<th>mye bedre</th>
<th>litt bedre</th>
<th>det samme</th>
<th>dårligere</th>
</tr>
</thead>
</table>

(b) For meg er det å ha et arbeidsliv:

<table>
<thead>
<tr>
<th>svært viktig</th>
<th>viktig</th>
<th>litt viktig</th>
<th>ikke viktig i det hele tatt</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>3 (a)</th>
<th>Hvis jeg <strong>ikke</strong> hadde diabetes, ville korte (handling, legebesøk etc.) eller lengre turer vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td>svært mye enklere</td>
<td>mye enklere</td>
</tr>
</tbody>
</table>

(b) For meg er korte eller lengre turer:

<table>
<thead>
<tr>
<th>svært viktig</th>
<th>viktig</th>
<th>litt viktig</th>
<th>ikke viktig i det hele tatt</th>
</tr>
</thead>
</table>
### 4

**Drar du noen gang på ferie eller ønsker du å dra på ferie?**

<table>
<thead>
<tr>
<th>Ja</th>
<th>Hvis ja, besvar (a) og (b).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nei</td>
<td>Hvis nei, gå videre til 5a.</td>
</tr>
</tbody>
</table>

**Hvis jeg **ikke** hadde diabetes, ville feriene mine vært:**

| svært mye bedre | mye bedre | litt bedre | de samme | dårligere |

**For meg er ferier:**

| svært viktige | viktige | litt viktige | ikke viktig i det hele tatt |

### 5

(a) **Hvis jeg **ikke** hadde diabetes, kunne jeg fysisk gjort:**

| svært mye mer | mye mer | litt mer | det samme | mindre |

(b) **For meg er det jeg kan gjøre fysisk:**

| svært viktig | viktig | litt viktig | ikke viktig i det hele tatt |

### 6

**Har du familie/slektnings?**

<table>
<thead>
<tr>
<th>Ja</th>
<th>Hvis ja, besvar (a) og (b).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nei</td>
<td>Hvis nei, gå videre til 7a.</td>
</tr>
</tbody>
</table>

(a) **Hvis jeg **ikke** hadde diabetes ville familieleivet mitt vært:**

| svært mye bedre | mye bedre | litt bedre | det samme | dårligere |

(b) **Familieleivet mitt er:**

| svært viktig | viktig | litt viktig | ikke viktig i det hele tatt |

### 7

(a) **Hvis jeg **ikke** hadde diabetes ville vennskap og sosialt liv vært:**

| svært mye bedre | mye bedre | litt bedre | det samme | dårligere |

(b) **Vennskap og sosialt liv er:**

| svært viktig | viktig | litt viktig | ikke viktig i det hele tatt |
### 8
**Har du eller ville du gjerne ha et nært personlig forhold (t. eks. ektefelle, partner)?**

- **Ja** □ Hvis ja, besvar (a) og (b).
- **Nei** □ Hvis nei, gå videre til 9.

**(a)** Hvis **ikke** hadde diabetes ville mitt nærmest personlig forhold vært:

- □ svært mye bedre
- □ mye bedre
- □ litt bedre
- □ det samme
- □ dårligere

**(b)** For meg er det å ha et nært personlig forhold:

- □ svært viktig
- □ viktig
- □ litt viktig
- □ ikke viktig
  i det hele tatt

### 9
**Har du eller ville du gjerne ha et seksualliv?**

- **Ja** □ Hvis ja, besvar (a) og (b).
- **Nei** □ Hvis nei, gå videre til 10a.

**(a)** Hvis **ikke** hadde diabetes ville mitt seksualliv vært:

- □ svært mye bedre
- □ mye bedre
- □ litt bedre
- □ det samme
- □ dårligere

**(b)** For meg er det å ha et seksualliv:

- □ svært viktig
- □ viktig
- □ litt viktig
- □ ikke viktig
  i det hele tatt

### 10(a)
**Hvis jeg **ikke** hadde diabetes ville mitt utseende vært:**

- □ svært mye bedre
- □ mye bedre
- □ litt bedre
- □ det samme
- □ dårligere

**(b)** Mitt utseende er:

- □ svært viktig
- □ viktig
- □ litt viktig
- □ ikke viktig
  i det hele tatt

### 11(a)
**Hvis jeg **ikke** hadde diabetes ville selvtilitten min vært:**

- □ svært mye bedre
- □ mye bedre
- □ litt bedre
- □ den samme
- □ dårligere

**(b)** Min selvtilitten er:

- □ svært viktig
- □ viktig
- □ litt viktig
- □ ikke viktig
  i det hele tatt
<table>
<thead>
<tr>
<th>12(a)</th>
<th>Hvis jeg ikke hadde diabetes ville min tiltakslyst vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>svært mye bedre</td>
</tr>
<tr>
<td>(b)</td>
<td>Tiltakslysten min er:</td>
</tr>
<tr>
<td></td>
<td>svært viktig</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>13(a)</th>
<th>Hvis jeg ikke hadde diabetes ville måten folk reagerer på meg vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>svært mye bedre</td>
</tr>
<tr>
<td>(b)</td>
<td>Måten folk reagerer på meg er:</td>
</tr>
<tr>
<td></td>
<td>svært viktig</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14(a)</th>
<th>Hvis jeg ikke hadde diabetes ville mine tanker om fremtiden (f.eks. bekymringer, håp) vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>svært mye bedre</td>
</tr>
<tr>
<td>(b)</td>
<td>Mine tanker om fremtiden er:</td>
</tr>
<tr>
<td></td>
<td>svært viktige</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>15(a)</th>
<th>Hvis jeg ikke hadde diabetes ville mine økonomiske situasjon vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>svært mye bedre</td>
</tr>
<tr>
<td>(b)</td>
<td>in økonomiske situasjon er:</td>
</tr>
<tr>
<td></td>
<td>svært viktig</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>16(a)</th>
<th>Hvis jeg ikke hadde diabetes ville min bosituation vært:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>svært mye bedre</td>
</tr>
<tr>
<td>(b)</td>
<td>Min bosituation er:</td>
</tr>
<tr>
<td></td>
<td>svært viktig</td>
</tr>
</tbody>
</table>
### 17(a)

Hvis jeg *ikke* hadde diabetes ville jeg vært avhengig av andre selv om jeg ikke ønsker det:

- [ ] svært mye mindre
- [ ] mye mindre
- [ ] litt
- [ ] det samme
- [ ] mer

### 17(b)

For meg er det å ikke måtte være avhengig av andre:

- [ ] svært viktig
- [ ] viktig
- [ ] litt viktig
- [ ] ikke viktig
  - [ ] i det hele tatt

### 18(a)

Hvis jeg *ikke* hadde diabetes ville friheten min til å spise det jeg ønsker være:

- [ ] svært mye større
- [ ] mye større
- [ ] litt større
- [ ] den samme
- [ ] mindre

### 18(b)

Frihet til å spise det jeg ønsker er:

- [ ] svært viktig
- [ ] viktig
- [ ] litt viktig
  - [ ] ikke viktig
  - [ ] i det hele tatt

### 19(a)

Hvis jeg *ikke* hadde diabetes ville friheten min til å drikke det jeg ønsker (f.eks. fruktsaft, alkohol, søte varme og kalde drikker) være:

- [ ] svært mye større
- [ ] mye større
- [ ] litt større
- [ ] den samme
- [ ] mindre

### 19(b)

Frihet til å drikke det jeg ønsker er:

- [ ] svært viktig
- [ ] viktig
- [ ] litt viktig
  - [ ] ikke viktig
  - [ ] i det hele tatt

Hvis det at du har diabetes, håndtering av sykdommen og eventuelle komplikasjoner påvirker din livskvalitet på andre måter, vennligst beskriv dette nedenfor:

---

Takk for at du har fylt ut dette spørreskjemaet.
Appendix 9 The DMT2 pilot study - PAID (in Norwegian)
PAID: SPØRRESKJEMA OM PROBLEMOMRÅDER VED DIABETES


<table>
<thead>
<tr>
<th></th>
<th>Ikke et problem</th>
<th>Mindre problem</th>
<th>Middels problem</th>
<th>Nokstå alvorlig problem</th>
<th>Alvorlig problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Har ikke klare og konkrete mål for diabetessorgens mål</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Behandlingsplanen for min diabetes gjør meg motløs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Føler meg engstelig når jeg tenker på at jeg må leve med diabetes.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Opplever ubehagelige sosiale situasjoner knyttet til min diabetessorg (f.eks. folk som forteller meg hva jeg bør spise)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Følelse av forsøkelse og tap i forhold til mat og måltider</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Føler meg deprimert når jeg tenker på at jeg må leve med diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Vet ikke om humøret eller følelsene mine er knyttet til diabetes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Får jeg overveldet av diabetessykkdommen</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Bekymrer meg for å få føling</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>---</td>
</tr>
<tr>
<td>10. Føler sinne når jeg tenker på at jeg må leve med diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Føler meg konstant opptatt av mat og spising</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Bekymrer meg for fremtiden og sjansen for alvorlige komplikasjoner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Føler skyld og/eller engstelse når jeg kommer ut av rytme i håndteringen av min diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. “Aksepterer” ikke at jeg har diabetes i mine anstrengelser for å håndtere min diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Føler meg misfornøyd med diabetes legen min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Føler at diabetes tar for mye av min fysiske og psykiske energi i det daglige</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Føler meg alene med min diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Føler at familie og venner ikke støtter meg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Kunne takle komplikasjoner ved diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Føler meg “utbrent” av den konstante anstrengelsen diabeteshåndteringen krever</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. PAPERS I-IV