Smartphone intervention with diaries and situational feedback for women with fibromyalgia

Randomized controlled trial of a smartphone intervention with therapist feedback to reduce pain-related catastrophizing using elements from Acceptance and Commitment Therapy following inpatient chronic pain rehabilitation

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Ólöf Birna Kristjánsdóttir
Department of Behavioral Sciences in Medicine
Faculty of Medicine, University of Oslo
& Institute of Nursing, Faculty of Health
Oslo and Akershus University College

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Acknowledgements

Since I graduated as a nurse in 2000 I have been fascinated by peoples' capacity to manage the many challenges chronic illnesses may impose. In 2008, I got a position as a PhD fellow at the Institute of Nursing at the Oslo and Akershus University College and was enrolled in the PhD program at the Medical Faculty of the University of Oslo. The project was on the use of innovative communication methods to support self-management of women with fibromyalgia, a chronic pain condition that causes disability and suffering. During this PhD period I have had the opportunity to participate in all phases of a research project, from the theoretical developmental phase through the practicalities involved in conducting a clinical trial and to the analytic stage. The learning opportunities have been abundant and I am grateful to all the kind people that have contributed to the work in this thesis by sharing their clinical and academic expertise.

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Abbreviations

ACR	American College of Rheumatology
ACT	Acceptance and commitment therapy
CBT	Cognitive behavioral therapy
CPAQ	Chronic Pain Acceptance Questionnaire
CPVI	Chronic Pain Values Inventory
CWP	Chronic widespread pain
ESM	Experience sampling method
FA	Fear avoidance
FIQ	Fibromyalgia Impact Questionnaire
GHQ	General Health Questionnaire
GP	General practitioner
HCP	Health care provider
IBS	Irritable bowel syndrome
ICBT	Internet-delivered cognitive behavioral therapy
ITT	Intention-to-treat
LOCF	Last observation carried forward
M	Mean
MI	Multiple imputations
n	Number
PCS	Pain Catastrophizing Scale
PDA	Personal digital assistant
PP	Per protocol
RCT	Randomized controlled trial
SD	Standard deviation
SF	Short-Form
SMS	Short Message Service
SPSS	Statistical Package for Social Science
T1-T5	Timepoint 1-5
VAS	Visual analogue scale

List of papers

Paper I

Kristjánsdóttir, ÓB, Fors EA, Eide E, Finset A, van Dulmen, S, Wigers SH, Eide H. Written online situational feedback via mobile phone to support self-management of chronic widespread pain: a usability study of a Web-based intervention. *BMC Musculoskeletal Disorders* 2011; 12:51.

Paper II

Kristjánsdóttir, ÓB, Fors EA, Eide E, Finset A, Stensrud TL, van Dulmen S, Wigers SH, Eide H. A smartphone-based intervention with diaries and therapist-feedback to reduce catastrophizing and increase functioning in women with chronic widespread pain: Randomized controlled trial. *Journal of Medical Internet Research* 2013; 15(1): e5

Paper III

Kristjánsdóttir, ÓB, Fors EA, Eide E, Finset A, Stensrud TL, van Dulmen S, Wigers SH, Eide H. A smartphone-based intervention with diaries and therapist-feedback to reduce catastrophizing and increase functioning in women with chronic widespread pain. Part 2: 11-month follow-up results of a randomized trial. *Journal of Medical Internet Research* 2013; 15(3): e72

1 Introduction

E-health is increasingly used as a delivery method for cognitive behavioral interventions aiming to support self-management of chronic illnesses. Interventions delivered with smartphones have the advantages of allowing for real time and "on the spot" self-management support. The research field on smartphone interventions is still very new and there is a lack of trials on smartphone-delivered interventions to support persons with chronic pain.

The background section of the present thesis begins with an overview of fibromyalgia and chronic widespread pain (CWP), chronic pain conditions where self-management is considered essential to improve functioning. A description follows of a theoretical framework regarding development and maintenance of the conditions. Therapeutic options are described with multidimensional rehabilitation as the recommended approach to encourage constructive self-management. Rehabilitation programs improve self-management and functioning, but for many persons the positive effects are not maintained at follow-up assessments. Studies on aftercare interventions to support self-management following rehabilitation are few; more have been called for. Internet and mobile phones provide new possibilities for providing aftercare in the everyday environment. The final section of the background is on research on e-health interventions, with particular focus on Internet-based cognitive behavioral interventions, ecological momentary interventions and interventions providing aftercare for persons with chronic pain.

In the present thesis, a four-week smartphone intervention for women with fibromyalgia or CWP who had completed an inpatient chronic pain rehabilitation program is investigated. The aim was to support constructive self-management by the means of daily electronic diaries and written situational therapist-feedback focusing on thoughts, feelings and behavior related to self-management. The therapeutic framework was based on cognitive behavioral therapeutic principles, more specifically elements from Acceptance and Commitment Therapy (ACT). The pilot testing of the intervention is described in Paper I. In Papers II and III, the short- and long-term (5- and 11-month) effects of the intervention were investigated in a randomized controlled trial, with pain-related catastrophizing - maladaptive cognitions - as the primary outcome. The participants' experience of the intervention was assessed with self-report questionnaires (Papers I and II).

2 Background

2.1 Fibromyalgia and chronic widespread musculoskeletal pain

Pain is defined as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey & Bogduk, 1994). *Chronic* pain is pain that has lasted for more than three to six months and has persisted beyond the expected period of healing, and is either not caused by a progressive disease (e.g., cancer) or no physiological pathology is identifiable (Flor & Turk, 2011). In Europe, the average prevalence rate of moderate-to-severe chronic pain is suggested to be 19% in the adult population (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Reid et al., 2011). In Norway, the prevalence has been estimated to be 30% (Breivik et al., 2006). In another sample, from the general population in Norway, the prevalence of substantial musculoskeletal pain was 13% (Ihlebæk, Eriksen, & Ursin, 2002). Pain interrupts attention and is difficult to disengage from (Eccleston & Crombez, 1999). Chronic pain can therefore have severe negative impacts on the quality of life by affecting general functioning, mental health, work status, relationships and family life (Flor & Turk, 2011; Reid et al., 2011). It has been indicated that chronic pain can have as large an impact on health-related quality of life as terminal cancer (Fredheim et al., 2008). Chronic pain leads to significant health care use as patients try to find pain relief (Berger, Dukes, Martin, Edelsberg, & Oster, 2007; Flor & Turk, 2011). Chronic musculoskeletal pain is the most common cause of sick leave and disability pension in Norway (Ihlebæk, Brage, Natvig, & Bruusgaard, 2010).

Previously it was assumed that pain was directly and proportionally related to the level of physical pathology or painful stimuli, i.e., with direct transmission of pain from the periphery to the spine and then the brain (Flor & Turk, 2011). Now it has become clear that pain is a multidimensional experience since cognitive, behavioral and emotional factors may increase or decrease the nociceptive input and impact the perception of the painful stimuli (Flor & Turk, 2011; Melzack, 1999).

Chronic musculoskeletal pain can be local, regional, or widespread (Cöster et al., 2008). Pain in numerous sites is more common than localized pain (Kamaleri, Natvig, Ihlebæk, & Bruusgaard, 2008). Chronic widespread pain (CWP) is defined as pain that affects both sides of the body, the axial skeletal and is both above and below the waist (Wolfe et al., 1990). About 4-11% of the adult population is estimated to experience CWP (Clauw & Crofford, 2003; Croft, Rigby, Boswell, Schollum, & Silman, 1993; Cöster et al., 2008;

Lindell, Bergman, Petersson, Jacobsson, & Herrström, 2000). CWP is often accompanied with other symptoms, including fatigue, sleep disturbance, emotional distress and functional disability (Cöster et al., 2008; Kamaleri et al., 2008). A subgroup of persons with CWP meets the criteria for fibromyalgia. The first classification presented by the American College of Rheumatology (ACR) was published in 1990. Patients with widespread pain for more than three months and pain at palpation in 11 of 18 tender points met the criteria for fibromyalgia if the patient did not have a disorder that would otherwise explain the pain (Wolfe et al., 1990). According to the more recent ACR diagnostic criteria from 2010, fibromyalgia is also diagnosed by means of self-reporting on scales assessing the widespread pain and symptom severity (Wolfe et al., 2010). Fibromyalgia prevalence has commonly been reported on the range between 0.5 and 5% (Clauw & Crofford, 2003; Flor & Turk, 2011; Lindell et al., 2000). In a survey of fibromyalgia prevalence in the general population in five European countries using the same criteria, the prevalence was 2.9% with a range from 1.4% to 3.6% among countries (Branco et al., 2010). In a sample of women, 20 to 49 years old, living in Southern Norway, the prevalence of fibromyalgia was 10.5% (Forseth & Gran, 1992). In another Norwegian sample, the overall prevalence of fibromyalgia was 3.2%; 5.2% for women and .9% for men (Kurtze & Svebak, 2001). The differences between individuals with CWP who meet the fibromyalgia criteria and those who do not may be explained by difference on the continuum of symptom severity rather than other characteristics (Clauw & Crofford, 2003; Wolfe et al., 2010).

Patients with fibromyalgia report feelings of stigmatization, and of not being believed as a patient, and many suffer for years before receiving the diagnosis (Choy et al., 2010; Mengshoel & Heggen, 2004). The severity of the impact of fibromyalgia varies among patients, but most patients report reduction in quality of life and difficulty with activities of daily life (Choy et al., 2010). It is characteristic of fibromyalgia that symptoms fluctuate during the course of a day and from day to day. Fibromyalgia is a chronic condition, commonly with periods of relapse and recurrence of symptoms triggered by stressors and emotional distress (Hassett, Cone, Patella, & Sigal, 2000; Imamura, Cassius, & Fregni, 2009). In a recent longitudinal study including 1555 patients with fibromyalgia receiving standard care, with a mean follow-up period of four years, no clinically meaningful improvement in overall symptom severity was found for the sample. Only about one-fourth of the sample showed meaningful improvement, including 10% with substantial improvement in symptom severity (Walitt et al., 2011). A subgroup seems able to cope and function well despite

symptoms, and may reach a recovery state by effective self-management and lifestyle changes (Mengshoel & Heggen, 2004; Walitt et al., 2011).

The knowledge of the pathogenesis of fibromyalgia is still evolving. Several predisposing factors have been identified. These include being female, genetic predisposition, learning history, pain-related trauma in childhood and occupational factors (Dadabhoy, Crofford, Spaeth, Russell, & Clauw, 2008; Flor & Turk, 2011). However, no clear physiological abnormalities or biomarkers have yet been identified that explain the cause of the illness (Flor & Turk, 2011). Nevertheless, research has shown alteration in numerous physiological variables in patients with fibromyalgia, e.g., dysfunction in the endogenous analgesic system related to diminished diffuse inhibitory control, a flat curve in diurnal plasma cortisol indicating alteration in the hypothalamic-pituitary-adrenal axis, and alterations in the autoimmune system and in neuropeptides levels (Dadabhoy et al., 2008). Central sensitization has been suggested as an important explanation factor for the symptomology of fibromyalgia. The sensitization of pain transmission neurons may lead to altered perceptions of normally non-noxious input, i.e., non-noxious input may be experienced as painful (Nielsen & Henriksson, 2007). It must be noted that most of those findings are not specific for fibromyalgia, but are general for various chronic conditions (Dadabhoy et al., 2008).

To summarize, it is hypothesized that together with genetic and environmental factors, processes involving central sensitization, stress responses and psychological factors contribute to the development and maintenance of chronic pain and fibromyalgia (Flor & Turk, 2011; Nielsen & Henriksson, 2007; Vlaeyen & Linton, 2000).

2.2 Catastrophizing and the Fear Avoidance Model

Cognitive and emotional factors, i.e., thoughts, beliefs, appraisals, expectations and feelings are known to have the ability to modulate the pain experience (Flor & Turk, 2011; Melzack, 1999; Villemure & Bushnell, 2002). Pain-related *catastrophizing* is a central construct in the pain literature. Catastrophizing involves cognitive and emotional processes of magnification of pain-related stimuli, rumination and difficulty with disengaging from thoughts about pain, feelings of helplessness regarding self-management, and a generally pessimistic orientation to the experience of pain and its consequences (Edwards, Bingham, Bathon, & Haythornthwaite, 2006; Sullivan, Bishop, & Pivik, 1995; Sullivan et al., 2001). Catastrophizing is a sign of pain-related distress and may indicate a maladaptive form of coping or self-management (Rosenstiel & Keefe, 1983; Sturgeon & Zautra, 2013). Positive correlations between

catastrophizing and many negative pain-related outcome variables have been established, e.g., more severe and widespread pain, emotional distress, increased attention to pain and greater vigilance to bodily sensations (Edwards et al., 2006). There is also a strong positive correlation between catastrophizing and disability, both on self-reported and more objective measures such as return to work, even when controlled for depression, anxiety, neuroticism, disease severity, and pain level (Edwards et al., 2006; Sullivan et al., 2001; Turk, Robinson, & Burwinkle, 2004). Catastrophizing has been found to account for considerable amount of variation in pain severity and to impact the sensory intensity of the pain (Gracely et al., 2004). There is also evidence from prospective studies that catastrophizing can predict disability and distress (Edwards et al., 2006; Edwards, Cahalan, Mensing, Smith, & Haythornthwaite, 2011).

Research indicates that both physiological and psychological processes are involved in the relation between catastrophizing and functioning. Several possible mechanisms of action have been suggested. On a physiological level the catastrophizing may amplify pain processing in the central nervous system by different mechanisms, e.g., sensitization, endogenous opioids and immunologic dysregulation (Campbell & Edwards, 2009). The pathways are still not entirely clear. It may be that the relation is bi-directional, i.e., catastrophizing may affect central nociception and the pain experience, which in return influences the degree of catastrophizing (Sullivan et al., 2001). Cognitive pathways may involve increased attention on pain and information-processing biases (Edwards et al., 2011). Catastrophizing may also impact behaviors, which in the long run can have reinforcing effect on the pain experience and disability due to avoidance behavior and passivity (Edwards et al., 2011; Vlaeyen & Linton, 2000).

Currently, the most prominent model offering a theoretical explanation of the developmental processes involved in chronic musculoskeletal pain is the fear-avoidance (FA) model; see Figure 1. The model originates in both behavioral and cognitive approaches to chronic pain and is based on a previous FA model (Lethem, Slade, Troup, & Bentley, 1983) that has since been developed further (Vlaeyen & Linton, 2000). The original FA model was presented as a way to explain why a subgroup of individuals develops chronic pain after an episode of acute back pain. A considerably amount of research has since provided support for the validity of the FA model in different chronic pain populations as reported in several reviews, e.g., (Crombez, Eccleston, Van Damme, Vlaeyen, & Karoly, 2012; Leeuw et al., 2007). A recent study supports the validity of the FA model in a sample of persons with

fibromyalgia where catastrophizing was found to mediate the relationship between neuroticism and vigilance to pain (Martínez, Sánchez, Miró, Medina, & Lami, 2011). The studies are mainly cross-sectional but results from prospective studies have also provided some support for the model (Vlaeyen & Linton, 2012).

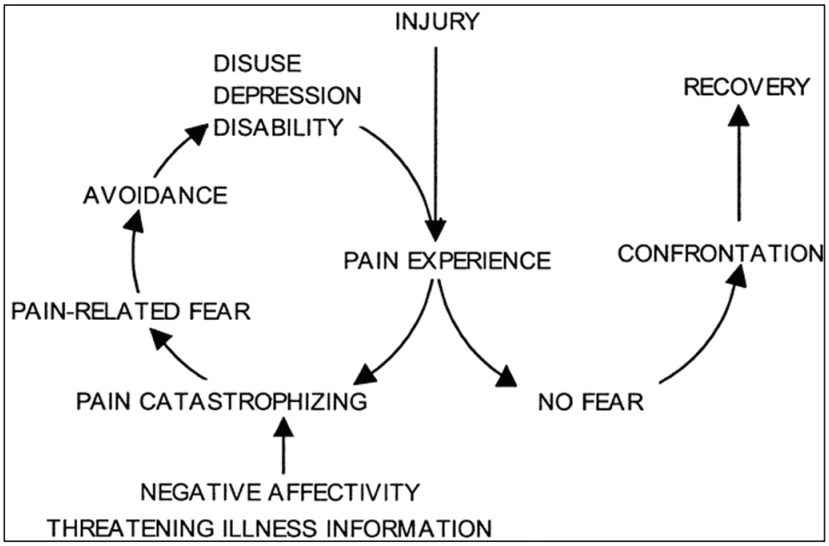

Figure 1. The Fear Avoidance model, a cognitive-behavioral model of chronic pain pathogenesis (Vlaeyen & Linton, 2000).

According to the FA model, several psychological factors play an important role in maintaining and increasing the disability that often accompanies chronic pain. The patient's interpretation of the pain - i.e., level of catastrophizing - is a key feature. Catastrophizing, together with pain-related fear and depression, may result in a vicious cycle of reinforcement with avoidance, passivity, increased pain and disability (Vlaeyen & Linton, 2000). Pain-related fear involves interpreting a stimulus as threatening with accompanied increased sympathetic arousal, hypervigilance and preventative and avoidance behavior (Leeuw et al., 2007). Avoidance behavior refers to a behavior aimed at preventing an aversive situation, i.e., increase in pain levels, from happening. Avoidance behavior can reduce pain-related fear in the short term, but may have maladaptive consequences later on (Leeuw et al., 2007). The fear of pain may easily become conditioned to a number of different situations due to stimulus generalization and thus increase disability (Flor & Turk, 2011).

How is the FA model relevant in explaining development and maintenance of fibromyalgia? Despite large variations in emotional distress and catastrophizing in persons with fibromyalgia, high levels of distress are found to be somewhat prevalent (Edwards et al., 2006). In a study with 233 women with fibromyalgia who were seeking treatment, the total sample reported moderate levels of fear of pain and activity, and 39% reported high levels. High levels of pain-related fear were associated with more disability, depression and pain (Turk et al., 2004). More than half (60%) of this sample met the criteria for depressive disorder, including 43% with major depressive disorder (Turk et al., 2004). Many persons with fibromyalgia originally experienced an acute episode of pain, which may have initiated the maladaptive chain of behavior, as proposed by the FA model. Confrontation and recovery may not involve total reduction in symptoms but rather an increase in functioning, as full recovery from symptoms is rare (Crombez et al., 2012; Walitt et al., 2011).

The FA model does clearly not take into account all variables related to chronic pain and fibromyalgia, e.g., genetic factors and physiological changes. However, the model provides a theoretical framework that links together clinically relevant concepts and explains how a maladaptive reinforcing pattern contributes to the maintenance of disability. There are still some gaps in the knowledge of causality between the constructs in the model. As noted above, the relationship between catastrophizing and disability seems complex, bi-directional and with several possible pathways. Nevertheless, it has been concluded that catastrophizing is an important target for treatment of pain-related disability (Arnow et al., 2011; Edwards et al., 2006; Leeuw et al., 2007; Miles et al., 2011; Turk et al., 2004; Westman, Boersma, Leppert, & Linton, 2011).

2.3 Self-management and Acceptance and Commitment Therapy

As in many other long-term illnesses, self-management is essential in the treatment of fibromyalgia. 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" and constructive self-management "encompasses ability to monitor one's condition and to effect the cognitive, behavioral and emotional responses necessary to maintain a satisfactory quality of life" (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). Examples of self-management strategies are goal setting, stress management, relaxation, activity scheduling and physical exercises (Flor & Turk, 2011).

Most treatment approaches aim to improve functioning and minimize pain and suffering by encouraging constructive self-management and lifestyle changes. Self-management interventions seem to have more effect on physical and psychological status, symptoms, and daily functioning than do pharmacological treatment (Goldenberg, Burckhardt, & Crofford, 2004; Rossy et al., 1999). Most self-management interventions provide information and teach self-management skills aiming to reduce the threat value of the pain and improve functioning. The interventions may include reassurance and education, aerobic and strengthening exercises, and cognitive behavioral therapy (CBT). CBT for chronic pain has been described as an umbrella term covering a somewhat heterogeneous group of approaches with the shared aim of promoting self-management of pain and pain-related consequences (Vowles, McCracken, & Eccleston, 2007). In CBT, persons with chronic pain are generally taught to 1) monitor thoughts, emotions, symptoms and behaviors to identify relations, 2) perform self-management strategies associated with reduction in pain, emotional distress and disability, and 3) respond constructively to relapses/increase in symptom levels, with the goal of improved functioning (Gatchel, 1999). Between sessions homework is assigned so the individual can practice, generalize and maintain skills learned in treatment (Flor & Turk, 2011). Reviews and meta-analyses on the efficacy of different self-management interventions for persons with fibromyalgia, including CBT, are not consistent on either short- or long-term effects (Bernardy, Füber, Köllner, & Häuser, 2010; Glombiewski et al., 2010; Goldenberg et al., 2004; Rossy et al., 1999; Sim & Adams, 2002; van Koulil et al., 2007). Most clinical guidelines recommend a multidimensional approach for individuals with fibromyalgia, aiming to address all levels of the pain experience (Flor & Turk, 2011; Goldenberg et al., 2004; Häuser, Bernardy, Arnold, Offenbächer, & Schiltenwolf, 2009). Multidimensional rehabilitation involves pharmacological treatment, participation in an exercise program and psychoeducation or CBT. The short-term effects have been established, but for many the effects are no longer evident at follow-up assessments (Häuser et al., 2009; Karjalainen et al., 2009). This is a general problem for persons with chronic pain, as well as other populations managing chronic conditions (Turk & Rudy, 1991). It has been indicated that for 30 to 60% of patients participating in pain management programs, the treatment gain is not maintained long-term (at one to five year follow-ups) (Morley, 2008; Turk & Rudy, 1991).

The predictors of positive long-term treatment effects for persons with chronic pain are not clearly established (Miles et al., 2011; Turk & Rudy, 1991). Discontinued practice of constructive self-management behavior established during treatment is generally considered

to correlate with adherence failure, relapse and reduced long-term treatment effects (Flor & Turk, 2011; Turk & Rudy, 1991). For example, the positive effects of aerobic exercise are generally maintained as long as the exercise program is carried out (Wigers, 1996; Wigers, Stiles, & Vogel, 1996). However, results of several studies indicate that use of self-management skills such as pacing, exercise and relaxations is only weakly related to positive long-term treatment effects (Curran, Williams, & Potts, 2009; Vowles & McCracken, 2010; Vowles & Thompson, 2011). Maladaptive cognitions and emotional distress seem to be stronger predictors of reduced long-term effect (Edwards et al., 2011; Finset, Wigers, & Götestam, 2004; Miles et al., 2011; Sullivan et al., 2001). The natural course of fibromyalgia with periods of fewer symptoms and periods of relapse with increased symptoms is likely to continue following rehabilitation. Therefore, strategies to teach individuals to prevent or constructively meet relapses are routinely included in the curriculum of CBT and multidisciplinary programs, and some provide booster sessions (Dysvik, Kvaløy, & Natvig, 2012; Flor & Turk, 2011; Turk & Rudy, 1991). Self-monitoring of cognitions for early detection of warning signals, e.g., reduction in beliefs to manage the symptoms, is assumed to be important to prevent major setbacks (Keefe & Van Horn, 1993). An episode of emotional distress or a pain flare-up may reactivate catastrophizing and negative emotions and lead to relapse with increased symptoms of depression and pain-related disability. This in turns enhances the original experience of pain or distress and the maladaptive pattern of the FA model is again established (Linton & Bergbom, 2011; Vlaeyen & Linton, 2000). Therefore, early detection of signs of relapse (e.g., lowered mood or increase in catastrophizing) and emotion regulation are important to prevent full-blown relapse and activation of the FA pattern (Linton & Bergbom, 2011). Methods to support awareness of early signs of relapse may therefore contribute to improved long-term effects.

It has been suggested that insufficient generalization of the treatment and skills learned in the pain management program into the home environment may contribute to reduction in treatment effects (Turk & Rudy, 1991). There exists a need for strategies to support self-management after participation in in- or outpatient pain management programs. Studies on interventions designed especially for aftercare, i.e., to support maintenance of treatment effects after chronic pain rehabilitation, are few. This has been called one of the most neglected research areas in the pain literature (Morley, 2008). As the treatment of fibromyalgia is unlikely to cure the condition, acceptance-based approaches may be useful for persons living with fibromyalgia (Friedberg, Williams, & Collinge, 2012).

Acceptance and Commitment Therapy (ACT, previously also called contextual CBT) is one of the mindfulness and acceptance-based approaches increasingly used to reduce suffering in persons with various chronic illnesses (Hayes, Strosahl, & Wilson, 2003; Kabat-Zinn, 2003). These adjusted forms of CBT involve less focus on changing or eliminating symptoms, dysfunctional thought content and emotions but more on helping individuals relate to these events differently, i.e., with mindfulness and acceptance. ACT is based on Relational Frame Theory (Hayes et al., 2003; Hayes, Pistorello, & Levin, 2012). According to this theory can relations between cognitions be viewed as a learned behavior, and may or may not reflect an ontological reality, i.e., how it "really" is. Experience from childhood may form lasting cognitions, and since no learned behavior is fully unlearned these cognitions can persist into another context, e.g., in adulthood. This may be problematic since these cognitions may have unconstructive impact on behavior. In some contexts, thoughts may lead automatically to action but importantly, in many contexts, the "impact of thinking is argued to be contextually controlled and not causal in a mechanical way" (Hayes et al., 2012). Therefore, in contrary to the methods traditionally used in CBT and cognitive therapy, the goal in ACT is not to change core beliefs or thoughts, but to change one's relation to them in order to reduce their unconstructive impact on behavior and quality of life (Flor & Turk, 2011; McCracken, 2005; Winterowd, Beck, & Gruener, 2003). This may be specifically useful in situations where change is difficult to achieve (e.g., when symptoms and challenging emotions are persistent) and/or when methods to try to change the situations are themselves causing suffering, e.g., when avoidant behavior leads to reduction in valuable activities (Hayes et al., 2003). ACT may therefore be assumed suitable for persons with fibromyalgia.

The main aim in ACT is to increase functioning by increasing psychological flexibility, i.e., the ability to face challenges in an aware, accepting and active way (Hayes, 2011). This is done by working on the following six dynamic and somewhat overlapping elements: 1) Mindfulness, 2) Observer self, 3) Acceptance, 4) Cognitive defusion, 5) Values, and 6) Values-based action (Hayes et al., 2012). The opposite concept is psychological inflexibility which is assumed to result from dynamic processes within the following maladaptive elements: experiential avoidance, cognitive fusion, dominance of the conceptualized past or future, attachment to a conceptualized self, lack of values clarity, and lack of committed quality in action (McCracken, 2011). Indeed, the elements in ACT seem very suitable to counteract the maladaptive factors of the FA model.

Mindfulness originates from ancient Asian culture. It involves self-regulation of attention and a quality of acceptance to allow for nonelaborative awareness of one's experience in the present moment (Bishop et al., 2004). Mindfulness exercises include meditation and daily life exercises to train the ability to become aware of and accept the present experiences and sensations rather than be "lost" in thoughts about the past or future (McCracken, 2005). The training in self-regulation of attention and the aim of keeping an open and accepting mindset may be beneficial for persons with chronic pain as it may counteract the attention-demanding nature of pain and some of the negative influences of catastrophizing (Schütze, Rees, Preece, & Schütze, 2010). Indeed, greater mindfulness has been shown predictive of lower levels of catastrophizing (Cassidy, Atherton, Robertson, Walsh, & Gillett, 2012; Schütze et al., 2010). Mindfulness exercises can also increase awareness of the distinction between the part of us that observes an experience (*observer self*) and the experience itself. The opposite of the observer self is the conceptualized self, i.e., the story we tell others and ourselves about who and how we are. Rigidly holding on to the conceptualized self (e.g., "I am someone who always tries hard") can limit psychological flexibility when there is a conflict between the conceptualization and what is really experienced, due to the need to preserve the conceptualized self (Hayes et al., 2012). A closer contact with the observer self can allow for a distance from the flow of thoughts and thought content. 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. This swift in function of cognitions, but not their forms, is called *cognitive defusion*. Cognitive defusion of pain-related catastrophizing may reduce its negative impact on behavior (McCracken, 2005).

In ACT, reflection on one's own *values* - i.e., reflection on what is perceived as a personally valuable way of being (e.g., being caring or honest), - is encouraged. Values differ from goals in that they can never be fully obtained, but they can give a continuous sense of motivation, direction and purpose. Also emphasized is, the importance of repeatedly *committing* and choosing to live according to the values, e.g., by setting goals and taking steps toward them (McCracken, 2005). For persons with chronic pain some adjustments of goals may be necessary to improve functioning and quality of life. For those persons where search for pain relief has been unsuccessful it may be constructive to disengage from the goal of pain reduction. Instead of focusing on the goal of pain relief, it may be beneficial to accept the situation and turn attention to positive aspects of everyday life (Crombez et al., 2012). The process of moving toward a goal is associated with increase in positive feelings and increased attention to goal-relevant information; by ways of attentional processes, it may therefore lead

to a reduction in pain experience (Crombez et al., 2012). One of the most severe consequences of avoidance behavior in persons with chronic pain is the withdrawal from valued behavior (Vlaeyen & Linton, 2012). The focus on values may therefore make ACT suitable for persons with chronic pain.

Acceptance is related to mindfulness and involves "the active and aware embrace of private experiences without unnecessary attempts to change their frequency or form" (Hayes et al., 2012). Acceptance in ACT is the opposite of experiential avoidance which refers to efforts to change the frequency or form of unwanted thoughts, emotions, and sensations, even when the avoidance results in personal harm (Hayes et al., 2012; McCracken, 2005). Pain acceptance involves two main components, i.e., the willingness to experience pain sensations and the capability to engage in meaningful activity despite pain (McCracken, Vowles, & Eccleston, 2004). Pain acceptance may be considered a form of adaptive coping. The impact of pain acceptance may in many ways be the opposite of pain catastrophizing; however, pain acceptance cannot be explained only as lack of catastrophizing (Kratz, Davis, & Zautra, 2007). The goal of acceptance is to enhance values-based action (Hayes et al., 2012). Accordingly, several studies show that acceptance does not indicate giving up or resignation as greater acceptance correlates with more engagement in daily activities (Kratz et al., 2007; Rodero et al., 2011; Viane, Crombez, Eccleston, Devulder, & De Corte, 2004). Even when controlled for pain intensity, acceptance is related to less attention to pain (Viane et al., 2004). Acceptance of pain has indeed been shown to correlate with better emotional and physical health (Crombez et al., 2012; Kratz et al., 2007). In the FA model, confrontation has been postulated as the opposite of avoidance on a continuum of behavior responses (Vlaeyen & Linton, 2000), and seems therefore to refer to a concept related to acceptance.

There has been a debate in the literature on whether ACT and other mindfulness-based treatment approaches should be categorized within the CBT umbrella or as a new wave of behavioral therapy (Hayes et al., 2012; Hofmann & Asmundson, 2008). As described above, there are important differences in traditional CBT and ACT in the processes applied to enhance function. In CBT there is more focus on rationally challenging cognitions and reducing symptoms than in ACT with its focus on acceptance, cognitive defusion, and commitment to valued behavior despite symptoms. However, there are many shared elements between ACT and the more standard CBT, and ACT may be considered a specific form of CBT (McCracken, 2011). In common are the focus on cognitive, affective, and behavioral factors associated with the development and maintenance of pain-related suffering and the

aim of improving functioning. In ACT, like other CBT, the assumptions of the FA model are shared, i.e., that the maintenance of symptoms and disability is mediated and moderated at least partly by different cognitive, affective and behavioral factors (Flor & Turk, 2011).

Due to the chronic nature of fibromyalgia and the theoretical match between the FA model and ACT elements, it is assumed that ACT might be suitable as a therapy form. Indeed, since the first randomized controlled trial (RCT) was published on ACT for chronic pain in 2004 (Dahl, Wilson, & Nilsson, 2004) several studies have been published with promising results for persons with chronic pain conditions. A preliminary review of psychological treatments addressing pain-related fear and anxiety in persons with chronic musculoskeletal pain concludes that ACT is promising as an effective treatment to reduce pain-related fear and disability. However, this needs further research support, as only four studies on ACT were included (Bailey, Carleton, Vlaeyen, & Asmundson, 2010). A meta-analysis of 22 trials of acceptance-based interventions for chronic pain found an effect size of .37 on pain and .32 on depression based on the results from controlled studies. Only two of the seven included ACT studies were controlled studies or RCTs. Four of the studies were on mindfulness-based stress reduction for persons with fibromyalgia. Results of long-term effects were not reported (Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). In a study including 252 persons with chronic pain, participation in a three or four weeks interdisciplinary rehabilitation program based on ACT was found to improve depression, pain-related anxiety, disability, catastrophizing, acceptance and pain intensity at post-treatment and at three-months follow-up (Vowles et al.2007). In another study, the long-term effect of this ACT program was examined. At a three-year follow-up there was a large effect on acceptance, medium effect on depression and psychosocial disability and small for values success, pain level and physical disability (Vowles, McCracken, & O'Brien, 2011). The existing follow-up data of the effects of ACT for chronic pain is generally promising (Vowles & Thompson, 2011). ACT has recently been listed as an empirically supported treatment for chronic pain with strong research support (APA, 2013). It has been concluded that acceptance-based interventions may be a good alternative to the more traditional CBT for chronic pain but superiority has not been established for either approach (APA, 2013; Veehof et al., 2011; Wetherell et al., 2011). To my knowledge, only one study has been published on ACT in a sample of persons with fibromyalgia. An RCT including women (n = 40) referred by general practitioners (GPs) compared 12 weekly group sessions of ACT with a waiting-list control. Most of the participants were on full- or part-time sick leave. There was a positive between-group effect on several variables, e.g., psychological flexibility and functioning, despite no improvements

in pain intensity (Wicksell et al., 2013). To conclude, ACT is an effective therapy form for patients with chronic pain but more studies are needed to confirm its effectiveness for persons with fibromyalgia.

2.4 Chronic pain and e-health

E-health involves the use of electronic communication-based technology to provide health care and to support self-management and behavior change to improve health outcomes (Keogh, Rosser, & Eccleston, 2010). It is a rapidly expanding field. The technology is already a natural part of most people's lives in the form of mobile phones, computers and the Internet. The main purposes of e-health interventions for persons with chronic pain involve information provision, assessment, monitoring, and treatment (Keogh, 2013). The advantages of e-health interventions for self-management support may be several. E-health interventions may reduce time constraints due to the possibilities of asynchronous communication, limit resources used for traveling, and allow for self-determined work pace and may increase access for certain stigmatized groups or home-bound persons. Interventions with no therapist contact or limited contact may be cost-effective and increase general availability of support (Barak & Grohol, 2011; Keogh, 2013). In addition, there is the advantage of providing situational care, i.e., ecological momentary interventions providing support in the person's everyday environment (Heron & Smyth, 2010; Keogh, 2013). Importantly, persons with different chronic conditions (including chronic pain) report interest in using e-health interventions with the goal of improving self-management (Proudfoot et al., 2010; Rosser et al., 2011).

Mobile phones have been used to provide self-management support. The advantages of mobile phones include access regardless of time and location, use for real-time self-monitoring and interactivity. The interactivity can involve situational feedback, either automatically generated by computer and tailored to input or personalized by a health care provider (HCP) (Bäck & Mäkelä, 2012). For the last decade, there has been considerable research on mobile phone interventions to support behavior change and self-management in persons with chronic conditions on conditions other than chronic pain. Most studies have reported positive changes in health outcomes (Cole-Lewis & Kershaw, 2010; Fjeldsoe, Marshall, & Miller, 2009; Krishna, Boren, & Balas, 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. Mobile phone interventions to support self-

management of diabetes have been established as effective in a recent review and meta-analysis (de Jongh, Gurol-Urganci, Vodopivec-Jamsek, Car, & Atun, 2012; Liang et al., 2011). For other conditions, there is some evidence on positive effects but more research is needed to confirm the results. Research on long-term effects is generally limited (de Jongh et al., 2012; Fjeldsoe et al., 2009). To the best of my knowledge, there are no trials on mobile phone interventions to support self-management in persons with chronic pain.

The Internet can provide access to computerized self-help material or programs including different modes of communication and interaction. Examples of Internet-based interventions for persons with chronic pain are websites with online registrations and feedback, forums with peer discussions and support, and online chat with HCP. There is also the possibility of e-mail correspondence with a therapist and counseling sessions via web-cameras (Andersson et al., 2008; Elliott, Chapman, & Clark, 2007). Most Internet psychological self-management interventions are based on CBT as it has been shown to suit the self-help format well (Andersson et al., 2008; Proudfoot et al., 2011). The aim is generally to increase self-management skills such as self-monitoring, goal setting, relaxation, physical exercise, attention control, emotion regulation, and belief reappraisal (Ruehlman, Karoly, & Enders, 2012). Internet-based CBT (ICBT) generally involves a website accessed by providing login information to ensure privacy of registered information. The content may be delivered in different formats, e.g., text, audio and video. ICBT can also include online features such as registrations, tests, forums and chats (Andersson et al., 2008). Some ICBT are without any therapist contact, e.g., (Ruehlman et al., 2012; Williams et al., 2010) but most common is the combination of web-based material and limited contact with a therapist (Buhrman et al., 2012; Buhrman et al., 2013; Moessner, Schiltenwolf, & Neubauer, 2012). The therapist can be identifiable (e.g. with name, picture, affiliation) and provide support, encouragement and therapeutic feedback. ICBTs with some level of therapist support are generally more effective and have lower withdrawal rates than unguided programs (Andersson, 2009; Andersson et al., 2008; Palmqvist, Carlbring, & Andersson, 2007). Therapist support is most often provided via non-real-time e-mail contact on a secure Internet-based platform but also via telephone contact, chat or forum functions of websites (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Hedman, Ljótsson, & Lindefors, 2012). Since the year 2000 when the first trial of ICBT was published (Ström, Pettersson, & Andersson, 2000), the efficacy of ICBT has been studied in samples with many different illnesses, e.g., anxiety, depression, tinnitus, insomnia, irritable bowel syndrome (IBS), and chronic pain (Hedman et

al., 2012). The efficacy of ICBT for persons with depression, anxiety, social phobia, and panic disorder has been established by reviews and meta-analyses (Andrews et al., 2010; Hedman et al., 2012). In a meta-analysis including 22 RCTs on ICBT for major depression, panic disorder, social phobia, or generalized anxiety a mean effect size of .88 was found on primary outcomes and effects were maintained at follow-ups (Andrews et al., 2010). Results of studies comparing ICBT to face-to-face CBT indicate that the effects are comparable for persons with depression or anxiety (Andrews et al., 2010). Importantly, ICBT is generally well accepted based on adherence and users' satisfaction reports (Andrews et al., 2010). Research on ICBT for chronic pain is less mature; the results are not entirely consistent and indicate a need for more research. An overview of studies on ICBT for persons with chronic pain is provided in Appendix 1. The samples include heterogeneous types of chronic pain conditions; the most commonly included conditions were back pain and headache/migraine. This is not a homogeneous group of interventions; they vary in duration length, communication format and intensity and therapist involvement. Duration of the interventions ranges from a few days (Sorbi, Mak, Houtveen, Kleiboer, & van Doornen, 2007) to a whole year (Lorig et al., 2002; Schulz, Rubinelli, Zufferey, & Hartung, 2010). The most common durations were between six to ten weeks. The results from the RCTs are somewhat mixed. Many provide support for positive effect on pain-related cognitions, emotional wellbeing and functioning (Buhrman et al., 2012; Buhrman et al., 2013; Carpenter, Stoner, Mundt, & Stoelb, 2012; Chiauzzi et al., 2010; Ruehlman et al., 2012). The evidence for positive effects on pain levels is less convincing even though between-group reduction in pain levels is reported in several studies (Brattberg, 2006; Ruehlman et al., 2012; Williams et al., 2010). In one study there was a positive between-group effect on pain level and several other health outcomes when the whole sample (n = 855) consisting of persons with arthritis or fibromyalgia was analyzed. However, when only those with fibromyalgia were included in the analysis, no effects was found on any outcome measure (Lorig et al., 2008). The mixed results of ICBT for chronic pain have been confirmed by several reviews (Beatty & Lambert, 2013; Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Hedman et al., 2012; McGeary, McGeary, Gatchel, Allison, & Hersh, 2013). In a recent review including 10 RCTs on ICBT for chronic pain, the mean within-group effect size on primary outcomes was moderate (Cohen's d = .60) post-intervention, with ds ranging from .04 to 1.23. However, in three of the studies the within-group effect was small and in two studies no superiority was found for the ICBT compared to control condition. Comparison of between-group effects was not undertaken due to differences in the control group conditions (Hedman et al., 2012). In a recent study, the

efficacy of ICBT using elements from ACT was investigated. More than half of the sample (n = 76) had widespread pain and 60% had a current psychiatric illness. There were small-to-moderate positive between-group effects on several outcomes, including anxiety, depression, acceptance and catastrophizing at post-intervention (Buhrman et al., 2013). In conclusion, ICBT holds some promise for persons with chronic pain, but more RCTs are still needed.

The technology is changing fast. Smartphones allow for interventions combining the advantages of mobile phones and the Internet. Smartphones meet the preference criteria of persons with chronic pain for a self-management support device, i.e., familiar, discreet, multifunctional and mobile for real-time monitoring and feedback (Rosser et al., 2011). It has been suggested that optimal e-health self-management interventions should include an electronic symptom reporting component and be able to provide self-management support (Johansen, Henriksen, Horsch, Schuster, & Berntsen, 2012). Smartphones may be ideal to provide "on the spot" self-management with electronic diaries (e-diaries) to support self-monitoring and provide situational feedback to encourage constructive self-management. Programs made for the smartphones can include scheduling, audible prompts and time/date stamping, which makes them optimal for providing e-diaries (Piasecki, Hufford, Solhan, & Trull, 2007). Self-monitoring of cognitive, emotional, and behavioral variables is an important element of CBT and relapse prevention as it contributes to increased awareness of the relations between mental events and behavior, which may lead to reduction in emotional distress and improved functioning (Flor & Turk, 2011; Gatchel, 1999). E-diaries with ecological momentary assessments or experience sampling method (ESM) are considered to be one of the most reliable methods for investigating inner experiences by having individuals report on their thoughts, feelings, and behavior in the present moment in their everyday setting (Napa Scollon, Prieto, & Diener, 2009; Piasecki et al., 2007; Stone, A. et al., 2003). A great advantage of such diary data is that recall biases are minimized when individuals are asked to report their experiences at or near the time at which they happen (Napa Scollon et al., 2009; Piasecki et al., 2007). The number of diary entries per day depends on the nature of the construct of interest. Time-based schemes are suitable for tracking variables that tend to fluctuate (Piasecki et al., 2007). Daily e-diaries on behavior, mood and pain levels have been found user-friendly in a sample of persons with chronic pain, where most found them easy to use and reported interest in continued use of the diaries (Marceau, Link, Jamison, & Carolan, 2007). The connection to the Internet allows for online submission, which makes real-time, on the spot interactivity available. It has been suggested that use of e-diaries together with

tailored therapeutic messages delivered via the Internet might be a feasible method to extend therapy delivery into the everyday life (Kleiboer, Sorbi, Mérelle, Passchier, & Doornen, 2009; Nes et al., 2012; Oerlemans, van Cranenburgh, Herremans, Spreeuwenberg, & van Dulmen, 2011). This might provide a way to reinforce use and enhance generalization of skills learned in treatment in a real-life setting (Heron & Smyth, 2010; Kleiboer et al., 2009; Piasecki et al., 2007). Results of prior research on ecological momentary interventions, i.e., interventions that provide real-time support in the natural environment, to support behavior change are promising. So far these interventions have mostly been delivered with personal digital assistants (PDAs) or mobile phones. In a review from 2010, 27 interventions were included treating a variety of health behaviors, many based on CBT. No studies on chronic pain were included (Heron & Smyth, 2010). The interventions lasted from two weeks to two years with communication frequency from five times daily to weekly. The PDA interventions were commonly used in combination with individual or group CBT. The mobile phone interventions used voice or text messages. Many of the interventions included access to an interactive website as an additional component. The feedback in the majority of the interventions was automatically delivered using an algorithm-based system. In seven of the interventions there was a personalized feedback by a therapist. It was concluded that such interventions can be successfully delivered, are well accepted by users and can contribute to positive effects on behavior (Heron & Smyth, 2010). The results of a review including trials on various Internet-based interventions, other than ICBT, to promote health behavior change indicated that using additional communications methods could enhance effectiveness. Internet-based interventions including text messages had large effects on behavior and were more effective than interventions using e-mail or telephone contact (Webb, Joseph, Yardley, & Michie, 2010).

Smartphone applications are downloadable programs designed for smartphone use. Since 2009, applications to support different kinds of health-related behavior changes have become increasingly popular. By 2010, more than 100 applications with pain-related content were available through application stores. The applications generally involve education, skills training, self-monitoring, and relaxation training. However, due to lack of trials in this area, the efficacy of such applications is still unknown (Luxton, McCann, Bush, Mishkind, & Reger, 2011; Rosser & Eccleston, 2011; Whittaker, 2012). A few pilot studies, for other conditions than CWP, indicate feasibility of ICBT delivered by mobile devices. Two pilot studies have confirmed the acceptability of an intervention using PDAs with Internet facilities

to support self-management in persons with migraines (Kleiboer et al., 2009; Sorbi et al., 2007). The intervention involved four daily e-diaries on symptoms and behavior and feedback twice a day for a few weeks. The feedback was written by a clinically trained assistant and contained reference to the registered diary information, advice, reinforcement, and encouragement. The intervention was found feasible, as technical problems were few, and acceptability and compliance by the participants high. The efficacy of this intervention has, however, not been confirmed (Kleiboer et al., 2009; Sorbi et al., 2007). A smartphone application including questions and scales to support emotional awareness and a few CBT exercises was well accepted by five persons experiencing stress (Morris et al., 2010). A recent pilot study (n = 35) comporared ICBT delivered with mobile devices (smartphone or tablet computer) to a computer-delivered CBT for persons with depression; both interventions lasted for eight weeks and provided limited support from a therapist. The mobile device group showed clinically significant improvements in outcomes that were remained at a three-month follow-up (Watts et al., 2013). The results of these pilot studies are promising and indicate a need for further investigation of ICBT delivered with smartphones.

The intervention in the present thesis is based on a previously investigated ICBT intervention delivered with PDA in a sample of persons with IBS (Oerlemans et al., 2011). IBS is a condition that is maintained at least partly by behavioral and cognitive processes, and it is a common comorbidity in persons with fibromyalgia (Yunus, 2008). In a study by Oerlemans et al. (2011), the feasibility and efficacy of that intervention using online PDAs for self-monitoring and therapist feedback was tested in a RCT (n =76). The intervention started with a face-to-face meeting with a CBT therapist, followed by one week of monitoring via diaries on the PDA and then three weeks of monitoring and situational feedback from the therapist. Three diaries entries were to be filled out daily on relevant self-management variables such as cognitions, feelings, symptoms levels and behavior. The therapist used the submitted information to formulate feedback that was available to the participant shortly after submission of a diary form. The aim was to reduce catastrophizing and support constructive self-management. There was no between-group effect on a general measure of dysfunctional cognitions at post-intervention or at a three-month follow-up. There was however more reduction in catastrophizing in the intervention group than the control group at both assessments. There was more reduction in pain and increases in quality of life in the intervention group compared to the control group at post-intervention, but no between-group differences on these variables were found at the three-month follow-up. All participants in the

interventions group completed the intervention and submitted all diaries during the four-week intervention period. This indicates acceptability of the intervention by the users (Oerlemans et al., 2011). There is still is lack of research on ICBT for persons with chronic pain delivered by smartphones.

Research on proactive interventions delivered in the home environment of persons with chronic pain to enhance maintenance and generalization of treatment effects has been called for (Turk & Rudy, 1991). E-health aftercare interventions might be an excellent way of providing maintenance support in the everyday environment of persons anticipated to need it. To my knowledge, only three RCTs on e-health aftercare interventions for adults with chronic pain have been published (Buhrman et al., 2012; Moessner et al., 2012; Naylor, Keefe, Brigidi, Naud, & Helzer, 2008).

Naylor et al. (2008) investigated the effect of a telephone-based intervention aiming to support maintenance of treatment outcomes following outpatient CBT. Patients with chronic musculoskeletal pain referred to a mind-body clinic for group therapy were included in this RCT (n = 51). The therapy consisted of 11 weekly 90-minutes sessions of outpatient CBT. The study included patients with various chronic pain conditions. The control group received treatment as usual. The intervention group received a telephone-based intervention for four months. It involved interaction with a therapist and a computer via a telephone. The goals were to change cognitions and decrease maladaptive catastrophizing, enhance patients' ability to use attention diversion, and to change activity patterns to increase control of the pain. Patients were taught to use pain diaries to help them recognize connections between life events and fluctuations in pain levels. The telephone-based intervention had components involving self-monitoring, review of coping skills, guided rehearsal of coping skills, and a monthly therapist feedback. The daily self-monitoring questionnaires were answered by using the home telephone. A recorded voice asked questions about coping, perceived pain control, medications, mood and stress. Review of coping skills, guided exercises, and feedback were available on audio format via the telephone. A record of the therapist's feedback, based on the daily self-monitoring registrations, was provided to encourage and enhance insight into possible relationships between the use of copings skills, mood, and stress. The intervention was found to reduce pain levels and catastrophizing and improve functioning (Naylor et al., 2008). Follow-up results beyond four months are not reported. In a pilot study (n = 10) of this intervention the response rates to questionnaires was high (83%). All participants, including

three with fibromyalgia, viewed the intervention as helpful and most believed that it reinforced what had been learned in the group CBT (Naylor, Helzer, Naud, & Keefe, 2002).

In an RCT (n = 75), Moessner et al. (2012) investigated the efficacy of a pilot version of a website intended for use following multidisciplinary treatment for persons with chronic back pain. The intervention started with a short informational meeting. The website comprised individualized self-monitoring modules to be filled out once per week. It also included weekly scheduled 90-minute chat sessions among participants moderated by the therapist from the multidisciplinary treatment. The duration of the intervention was 12 to 15 weeks. The control group received care as usual. There was a positive between-group effect on disability at post-intervention due to both reduction in the intervention group and increase in the control group. Post-intervention, there was positive effect on a pain subscale but no effect on pain levels rated on a numeric scale. The intervention was well accepted by all participants and most reported finding the previous chat session helpful. However, 38% did not attend any chat session. Follow-up results beyond three months are not reported. The generalizability is reduced by low participation rate among those eligible (27% participated) and low response rates to follow-up assessments (56% at three-month and 67% at six-month follow-up) (Moessner et al., 2012).

Buhrman et al. (2012) explored the efficacy of an aftercare intervention in the form of a website with therapist contact in an RCT (n =72). Persons with residual symptoms one to five years after chronic pain rehabilitation treatment were included. The majority of the participants had widespread pain and most were women. The symptoms were self-reported and later confirmed in an interview. The intervention group received access to an eight-week ICBT with e-mail correspondence with a therapist via a secure platform. Participants were asked to work on one module per week. The modules included information, exercises and assignments and were adapted to serve as a maintenance program, e.g., with mindfulness exercises and activity and maintenance planning. Participants were encouraged to send their homework to the therapist once a week for advice and feedback. The control group received access to a moderated online discussion form with a new discussion theme presented once a week for eight weeks. The between-group effect on catastrophizing was moderate (Cohen's *d* = .70) post-intervention. However, the within-group effect was small (*d* = .16), which may indicate that the difference is partly due to increase in catastrophizing in the control group. There was a small between-group effect on anxiety and depression, and a moderate effect on a pain and impairment relationship scale. There was no effect on pain severity or acceptance post-intervention. The effect on catastrophizing persisted for the intervention group at the

follow-up. There was generally neither deterioration nor improvement within the intervention group in other outcome measures at the follow-up. Between-group effects at six-month follow-up were not reported. Twenty-six of 36 (72%) completed the ICBT intervention. Results at follow-up beyond six-months are not reported (Buhrman et al., 2012).

The results of the studies on e-health aftercare interventions for persons with chronic pain following participation in rehabilitation programs are promising. However, the research is still scarce and the interventions are not homogeneous. In addition, results at follow-ups beyond six-months have not been reported. Therefore, more research is needed to investigate this method of providing support. The research field of e-health aftercare interventions for persons with different psychiatric disorders is also immature. In a recent review, only five studies were identified, of which, only two were RCTs. The interventions were heterogeneous, e.g., involving online peer-chat, telephone support, and mobile phone text message communication, and the results were not entirely conclusive (Clough & Casey, 2011). Clearly more research is needed to explore the efficacy of e-health aftercare.

Based on the theoretical and empirical literature reviewed in this background section, it might be hypothesized that providing an ecological momentary aftercare intervention with smartphone-based diaries and feedback grounded in ACT could counteract elements in the FA model and contribute to improved self-management and reduced risk of relapse into maladaptive behavior patterns in persons with fibromyalgia. Catastrophizing would be a suitable primary outcome as it is a central feature in the FA model and it can be reduced by ACT treatments. Research on ACT-based e-health aftercare delivered via smartphones to support constructive self-management of fibromyalgia is missing.

3 Aims of the study

The aims of this study were to test the usability, acceptability, and efficacy of a smartphone intervention with diaries and feedback based on ACT to support self-management of fibromyalgia/CWP in women following inpatient chronic pain rehabilitation program.

The specific research questions were:

1. Is the smartphone intervention feasible for women with fibromyalgia and CWP? This was assessed by acceptability reports from the participants, compliance, and practical issues encountered (Papers I and II).
2. What are the short-term effects of the smartphone intervention on catastrophizing, the primary outcome? What are the effects on secondary outcomes variables, i.e., acceptance, emotional distress, values-based living and functioning and symptom levels? (Paper II).

3. What are the effects of the smartphone intervention at 5- and 11-month follow-ups on the primary outcome, catastrophizing? What are the effects on secondary outcomes, i.e., acceptance, emotional distress, values-based living and functioning and symptom levels? (Papers II and III).

4 Material and methods

4.1 Design

Paper I was a single group pilot study with assessment scales filled out before and after the smartphone intervention. Semi-structured interviews were used to explore the participants' experience of the intervention. Papers II and III report on a RCT, in which participants were allocated either to 1) the intervention group that received a smartphone-based aftercare and access to an informational website or 2) the control group that only received access to the mentioned website. An overview of the design is provided in Figure 2.

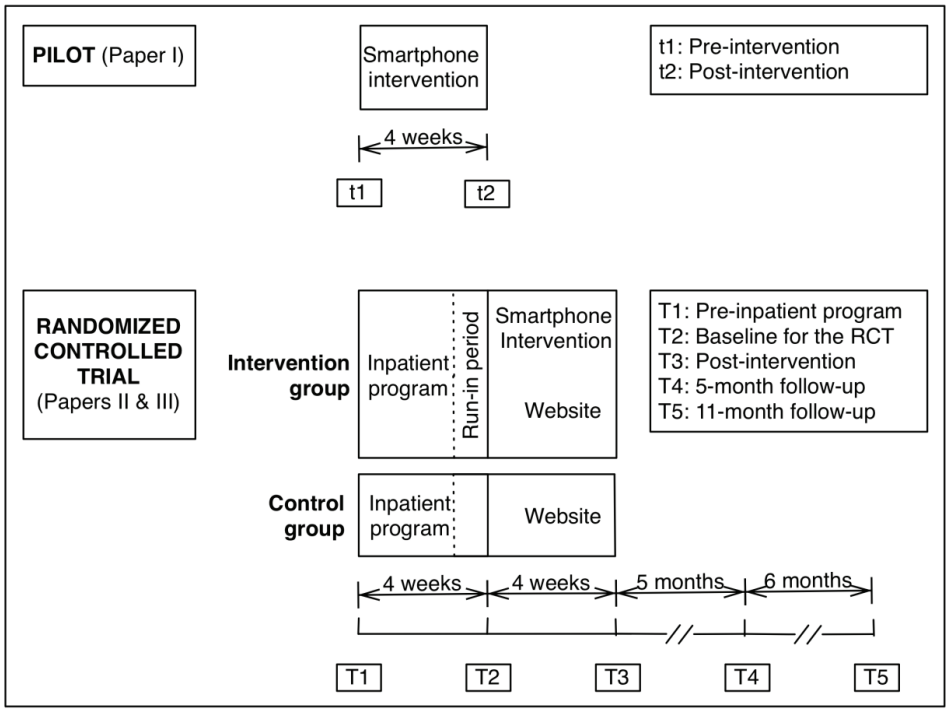

Figure 2. Study design

4.2 Sample

4.2.1 Paper I

The sample in Paper I is a convenience sample. Six women aged 23 to 48 years (mean = 36.3) with CWP participated. All patients had a clinician-confirmed diagnosis of CWP. Four participants were recruited from a rehabilitation center (Jeløy Kurbad, Moss, Norway) where they had just completed a four-week inpatient multidimensional pain management program. Two women were recruited from their general practioner's (GP's) office, i.e., had not been participating in a rehabilitation program.

4.2.2 Papers II and III

In Papers II and III it is reported on the same study and sample. This sample included female patients with fibromyalgia or CWP participating in a four-week inpatient rehabilitation program at Jeløy Kurbad (Moss, Norway). The inpatient program included education in pain mechanisms and CBT-based pain management (approximately 20 hours), group sessions based on motivational interviewing (4 hours), various forms of aerobic exercise, stretching and relaxation. In addition, individual myofascial pain treatment was provided and medication was administered as needed; see (Wigers & Finset, 2007) for details of the inpatient program. Most patients in the inpatient program were of working age and the most common diagnoses were fibromyalgia, generalized pain and myalgia, i.e., chronic widespread musculoskeletal pain. Inclusion criteria to the inpatient program included 1) severe reduction in functionality or a significant worsening in their condition, 2) motivation for and need for changes in coping strategies and lifestyle, 3) not a need of assistance with activities of daily living and the person is able to walk at least 500 m, and 4) referral by primary health care, specialists or hospital. Individuals with severe psychiatric illness were excluded and persons without understanding of Norwegian. Inclusion criteria for the RCT reported on in Papers II and III are given in Table 1.

Table 1. Inclusion criteria for the RCT.

1) Participation in the inpatient chronic pain program at Jeløy Kurbad
2) Not participating in another research project at the rehabilitation center
3) Female, 18 years or older
4) Being able to use a smartphone
5) Not being diagnosed with a profound psychiatric disorder

Two hundred sixty-five women participated in the inpatient program during the study period (February 2009 to July 2010) and were invited to informational meetings about the project. Of these, 124 did not attend a meeting or declined to participate. Only one was excluded because of a severe psychiatric disorder. One hundred and forty were randomized to the two study arms. Five subjects met exclusion criteria after randomization because they did not meet criterion #2, i.e., they were originally submitted for vocational rehabilitation and thus included in another research project. Eight discontinued participation before receiving the allocated intervention. Demographic data and baseline characteristics of the sample by groups are given in Table 2. Information about fibromyalgia diagnosis was available for 132 participants, and 82.6% of these met the ACR's classification criteria for fibromyalgia. Despite randomization, the groups differed in mean pain level ($P = .02$) and physical functioning measured by SF-8 ($P = .03$) at admission to the rehabilitation center. In the per protocol (PP) analysis, no significant group differences were detected at discharge from the rehabilitation center on any of the outcome variables (all Ps > .05; GHQ, and depression (VAS), $P = .08$).

Table 2. Characteristics at admission to the inpatient rehabilitation center.

Characteristic		**Intervention group (n=69)[a]**	**Control group (n=66)[a]**
Age, mean (SD), n		44.59 (11.13), 69	43.80 (11.20), 65
Marital status	Married or cohabiting	60.9% (n=42)	68.2% (n=45)
	Divorced	13.0% (n=9)	9.1% (n=6)
	Single	18.8% (n=13)	15.2% (n=10)
	Widow	5.8% (n=4)	3.0% (n=2)
	Unknown	1.4% (n=1)	4.5% (n=3)
Years of education	< 10 years (elementary)	18.8% (n=13)	12.1% (n=8)
	11-13 years (high school)	27.5% (n=19)	45.5% (n=30)
	>13 years (College/University)	43.5% (n=30)	34.8% (n=23)
	Unknown	10.1% (n=7)	7.6% (n=5)
Employment status	Working/studying	21.7% (n=15)	12.1% (n=8)
	Unemployed	4.3% (n=3)	1.5% (n=1)
	On sick leave	39.1% (n=27)	51.5% (n=34)
	On disability pension	17.4% (n=12)	19.7% (n=13)
	Part time working/studying and part time sick leave	11.6% (n=8)	7.6% (n=5)
	Other combination of the above	5.8% (n=4)	6.1% (n=4)
	Unknown	0%	1.5% (n=1)
Diagnosed with fibromyalgia (valid %)		80.9% (n=55)	84.4% (n=54)
Duration of symptoms (years), mean (SD), n		13.11 (8.78)	15.47 (12.09)
PCS, mean (SD), n		21.24 (10.33), 63	20.80 (9.45), 62
CPAQ, mean (SD), n		56.48 (15.02), 58	53.87 (13.81), 57
FIQ, mean (SD), n		58.75 (16.39), 69	58.58 (16.04), 66
SF-8, physical; mean (SD), n		31.91 (7.57), 65	34.75 (7.35), 62
SF-8, mental, mean (SD), n		39.33 (10.49), 65	39.34 (9.61), 62

GHQ-12, mean (SD), n		3.32 (3.38), 62	3.02 (3.38), 61
CPVI, mean (SD), n		2.07 (0.95), 64	2.01 (0.73), 61
VAS recordings of current level of (last couple of days):	Pain, mean (SD), n	67.08 (17.47), 69	57.85 (21.60), 66
	Fatigue, mean (SD), n	67.40 (23.73), 69	64.72 (21.02), 66
	Sleep disturbance, mean (SD), n	57.24 (26.22), 68	55.16 (23.38), 66
	Depression, mean (SD), n	34.73 (29.15), 68	32.93 (29.26), 65

[a] Patients meeting exclusion criteria after randomization are not included here.
[b] VAS, visual analogue scale (0-100[c]); PCS, Pain Catastrophizing Scale (score range 0-52[c]); CPAQ, Chronic Pain Acceptance Questionnaire (score range 0[c]-120); FIQ, Fibromyalgia Impact Questionnaire (0-100[c]); SF-8 (0[c]-100), Short Form; GHQ-12, questions from the General Health Questionnaire (score range 0-12[c]); CPVI, Chronic Pain Values Inventory (success score, range 0[c]-6).
[c] Values that indicate maximum symptom scores/least health.

4.3 Interventions

4.3.1 The intervention group

4.3.1.1 Development of the smartphone intervention

The smartphone intervention was developed by building on the experiences of a collaborator (SvD) using similar technology to support people coping with IBS (Oerlemans et al., 2011). For the technological platform, the Open Source Content Management System (Drupal) was used. Data security was maintained through a combination of system design, hypertext transfer protocol secure and a proprietary mobile phone authentication system (Eide, Eide, Kristjansdottir, & van Dulmen, 2010). A multidisciplinary group (the authors of the three papers) of health professionals chose the theoretical background and content of the intervention, e.g., the FA-model and ACT (Eide, Kristjansdottir, & Nes, 2011). A few adjustments were made to the pilot version of the intervention before the RCT, i.e., number of questions in the diaries was slightly reduced, the risk for sending feedback to wrong participants was reduced by making adjustment in the website program, and a CD and most of worksheets in paper format was replaced by similar material on an available website.

4.3.1.2 The components in the intervention group

The smartphone intervention had the following 4 components:
(1) *Face-to-face session.* The intervention started with a 1-hour individual session between a nurse working on the project and the participant. The session took place in the last week

before discharge. Each participant was informed about the intervention and asked about functioning, goals for health-related behavior and support needs. Values and values-based activities were discussed and the patient received two written values-based exercises to take home. The participant was lent a smartphone (HTC TyTN II) with a touch screen and a keyboard to use during the study period. The participants received information (name and qualifications) about their therapist for the intervention, which, in some cases was the nurse at the meeting. The nurse attending the face-to-face session summarized the meeting and passed this information to the relevant therapist.

(2) *E-diaries.* The participant was asked to complete 3 diary entries per day using the smartphone. See Figure 3 for a view of the screen display.

Figure 3. Screen display showing a diary (in Norwegian).

The aim of the diaries was to encourage awareness of and reflection of though content, feelings, symptoms and activities and the relationship between these. The awareness of thoughts and feelings is an essential element in CBT and ACT (Flor & Turk, 2011; McCracken, 2005). It was assumed that 4 weeks of registrating agreement or disagreement in statements reflecting thought contents and feelings would provide training in observation and reflection of thoughts and feelings. The diaries included 16 - 24 questions about the current level and interference of pain, feelings and thoughts related to avoidance, catastrophizing and acceptance. They also included questions about planned and previous use of self-management

activities and daily values-based and practical activities. Lists of self-management activities (e.g., mild exercise, stretching, resting, aerobic exercise, pleasurable activity) were provided as a reminder. The questions were formulated in accordance with the ESM principles designed to capture experience in real time without retrospective bias (e.g., "Right now I am feeling…") (Scollon, Kim-Prieto, & Diener, 2003). Participants answered most questions by choosing predefined alternatives or scoring five-point Likert scales. All diaries included a comment field giving participants the opportunity to write a short personal message to the therapist. In the pilot version of the intervention, there were more questions included in the diaries, i.e., 19-32. A few questions contained a text field to give the possibility to provide additional information. Table 3 provides examples from the diaries and description of the involvement of elements of ACT and from the FA model.

The morning and evening diary entries were sent at fixed hours chosen by each participant. The second diary entry of the day was sent at a time randomly chosen by a webserver, between 11 AM and 2 PM. The purpose of including three diary entries, including one at a randomly chosen time, was to encourage self-monitoring and reflection at different hours and in different situations. Appendix 2 includes lists of all the questions in the diaries. At the time scheduled for diary completion, a Short Message Service (SMS) message with a link to a secure website, where the diary could be opened and questions answered and posted, was received by the participant. The participants completed the first diary entry during the face-to-face session, and continued during the last week before discharge with the goal of getting used to the diaries before discharge (a run-in period). A start-up training session in the use of e-diaries is needed and a run-in period is recommended (Piasecki et al., 2007). After discharge the diaries were received for four weeks. The participant could call a member of the research group (OBK, HE) for technical support. Two automated SMS reminders were sent, if needed, within one hour of the first signal. The purpose of the diaries was also to provide possibility of a situational feedback.

(3) Written situational feedback. For four weeks after discharge, excluding weekends, participants received one daily written feedback from a therapist. The feedback was tailored to each participant's situation as reported in the diary. The aim was to support continued use of the self-management strategies learned at the rehabilitation center (e.g., exercise and stretching) and to promote improved daily functioning and values-based living. It was written in an empathic style and included repetition of content reported in the diaries, positive reinforcement, reminders of self-management information given at the rehabilitation center, ACT exercises and reflective questions. In accordance to ACT for chronic pain (Dahl,

Wilson, Luciano, & Hayes, 2005; McCracken, 2005) and the FA model (Vlaeyen & Linton, 2000), the aim of the feedback was to encourage awareness of catastrophizing and to stimulate mindfulness and willingness to engage in meaningful activities despite pain or other discouraging intrusions. The instructions for the exercises were written directly in the feedback or the participant was referred to exercises available on the smartphone and/or the website, see below. The feedback was also personalized to the summary of information given at the face-to-face session (e.g., family situation and health-related goals) and results on self-reported discrepancy between values and values-based living assessed at the end of the rehabilitation program. 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 feedback based on information from the 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 found. There was no limitation on the length of the feedback, which ranged from a few sentences to a few paragraphs. The feedback had slightly different focus during each of the four weeks. For example, in the first week the focus was on supporting the participant to continue doing the exercises/stretches as recommended at the inpatient program, and during the second week, simple mindfulness exercises were introduced (e.g., a few minutes of focused breathing). Once a week, the feedback included an invitation to a values reflection exercise, and every week, questions were included to stimulate reflection on health-related goals. The last feedback comprised a written summary of the registered diary information during the four-week period. Content from the growing "bank" of feedback written by all the therapists was used for other participants when appropriate according to the registered information. It took 10-15 minutes, on average, to write each piece of feedback. The feedback was written by any of three of the authors (OBK, TLS and HE); each participant received signed feedback from the same person throughout the intervention. All therapists had a background in health care sciences (nursing and/or psychology) and had received training in ACT. In the pilot, all feedback was written by one therapist (OBK). Two members of the group supervised the content of the feedback. They had extensive experience in teaching mindfulness meditation (HE) and supervising CBT/ACT (EAF). Representation of ACT concepts and elements from the FA model in the intervention is shown in Table 3. Examples of feedback are provided in Appendix 3.

(4) Audio files with guided mindfulness exercises. Four audio files with mindfulness exercises (e.g., focused breathing, awareness of thought content) guided by the two of the project group members (OBK, HE) were available on the smartphones. In the pilot version of the

intervention, audio files were not available on the phone but were supplied on an audio CD with relaxation and mindfulness exercises developed for an earlier study (Fors, Sexton, & Gotestam, 2002).

Table 3. Examples of elements from ACT and the FA model in diaries and feedback

Elements	**Diaries**	**Feedback**
Cognitive defusion and mindfulness to counteract the impact of catastrophizing	Self-monitoring and awareness supported by making diary entries on thoughts, feelings and behavior three times a day. Examples: "Right now, my breathing is deep and relaxed." "Right now, I believe it is harmful for me to use my body." "Right now, I am coping well with the pain."	Reflection on the relations between symptoms, thoughts, feelings and behavior. Mindfulness exercises described and recommended. Example: I see that you register that your breathing is not relaxed. Can you give yourself a minute or two to just notice your breathing? Maybe you can find a quiet spot and close your eyes. You could try breathing deeply and slowly a couple of times. Try focusing only on your breath. If you want, you can listen to the instructions to a short mindfulness breathing exercise on the smartphone/website.
Values and values-based action to counteract disuse, depression and disability	Self-monitoring, planning and evaluation of values-based behavior and constructive self-management supported by keeping a diary. Examples: "Today, I plan to (multiple choices possible): take a walk/work/rest lying down/do household chores/do relaxation exercises/take care of children or others/eat regularly/exercise at a moderate tempo/do my stretching exercises/spend time with family/rest sitting down/spend time with friends/do some shopping/do aerobic exercises/do something just for the	Reflection on values and values-based behavior (with focus on self-management) based on reports in diaries. Examples: I see you have done your stretching exercises today despite reporting a pain level of 6 (Scale from 0 to 10; 0=no pain, 10=worst imaginable pain). Can you give yourself a moment to reflect on why this is something you value and choose to do? I would like to ask you to reflect again on you values, if you are willing to, over the next few days. Values are qualities we ourselves think are important and can give us a sense of direction in life. We can ask ourselves questions like: What kind of a person would I like to be in my relations with my family? What can I do today that would get me a bit closer to this ideal? Is this something I am willing to do? Our values are something we can continuously work toward (like being a caring friend), not something we will obtain once and for all.

	pleasure of it."	
Acceptance to counteract avoidance	Awareness of spectrum of pain-related thoughts and feelings supported by keeping a diary. Example: "Right now, I am afraid to be active because of my pain." "Right now, I feel my life is good despite my pain." "Right now, I am doing what I want to even if it means increased pain"	Supporting willingness to act in accordance with values despite pain or discouraging thoughts and feelings. Examples: I see that today you are not too pleased with your life. Can you give yourself a moment and reflect on what you would want to do today if you were pain free? Is it possible for you to take a small step toward what you want even with your pain? Could you, instead of saying 'I want this BUT I have pain and therefore I cannot, say 'I experience pain AND I am taking baby steps toward something valuable to me. Are you willing to take small steps? Last night you reported a pain level of 8 and that you felt relaxed, grateful and pleased with the day's activity level. Can you take a moment to reflect on what kind of self-management strategies you used yesterday?

5) Noninteractive website with pain management material

All participants received access to a static website with information on self-management strategies for people with chronic pain, not anticipated to have large effect on the study outcomes on its own. The website was noninteractive, i.e., participants could not register any information or receive feedback. It included two ACT exercises with written descriptions and four audio files with mindfulness exercises (the same audio files that were available on the smartphones). One of the written exercises was a behavior analysis aiming to strengthen the ability to observe thought content, feelings and behavior and the connection between these (adapted from (McCracken, 2005)). The other exercise contained questions to encourage reflection on values. See Appendix 4 for screenshots of the website. In the pilot study, the participants received worksheets in paper format with ACT-based exercises (i.e., emotion and behavior record and exercises for values clarification and supporting values-based activity), but not access to a website.

4.3.2 The control group

Participants in the control group met the project nurse in the last week of the rehabilitation program and received information about their allocated intervention, i.e., the noninteractive website described above. They were given login information to the website and shown how to

access it. They were informed that the use of the website was voluntary. The website was available for approximately one year after inclusion.

4.4 Procedure for data collection

4.4.1 Paper I

Quantitative data was collected with self-report questionnaires. The participants received the questionnaires when they met with the researcher before the intervention and were asked to fill it out before starting the intervention and immediately after the intervention. The participants filled out the questionnaires in their own home and gave them to the researcher when they met for the semi-structured interviews. Qualitative data was gathered in two semi-structured individual interviews, in a place convenient for the participant (at their home, their workplace or at the researcher's workplace). Either one or two interviewers participated in each interview, which lasted generally between 30 minutes to one hour. Both interviewers (OBK, HE) were involved in the study and one was involved with writing the feedback (OBK). The interviewers took notes during and after each interview. Notes from the interviews were compared and themes identified. Technical incidences and usability issues were noted and described.

4.4.2 Papers II and III

Participants completed self-administered questionnaires on arrival at the rehabilitation center and at discharge. Three self-report questionnaires were filled out at home, i.e., immediately after the aftercare intervention period and 5- and 11- months later. Overview of the time points of the assessments is given in Figure 2. Questionnaires filled out at home were returned by mail in a postage-paid return envelope. One reminder letter was sent, followed by a phone call from a researcher if the questionnaire was not returned. Copy of the assessments questionnaires in Norwegian is provided in Appendix 5.

4.5 Self-report assessments

4.5.1 Primary outcome

4.5.1.1 Pain-related Catastrophizing (Papers I, II and III)

The Pain Catastrophizing Scale (PCS) was used to measure the primary outcome variable of the study, catastrophizing. It is a 13-item questionnaire with a three component structure, i.e., helplessness, magnification, and rumination (Sullivan et al., 1995). Participants are asked to rate items on pain-related thoughts and feelings on a scale from 0 (not at all) to 4 (all the time). The total score range for the PCS is 0 to 52, with higher scores reflecting higher degree of catastrophizing. The validity of PCS has been established in a clinical sample (Sullivan et al., 1995). PCS correlates with measures of fear of pain, negative affectivity, trait anxiety, depression, and pain, but has been found to have a distinctive operational and conceptual value (Sullivan et al., 1995). Six-week test-retest correlation has been found high (Sullivan et al., 1995). Internal consistency for the PCS has been shown to be high in samples of persons with chronic pain conditions, including CWP and fibromyalgia (Boer, Struys, & Versteegen, 2012; Martínez et al., 2011; Osman et al., 2000; van Damme, Crombez, Bijttebier, Goubert, & Van Houdenhove, 2002). Scores greater than 24 were considered high as done in prior research (Cassidy et al., 2012; Sullivan et al., 1995). In our sample the internal consistency was high on all assessments (Cronbach's alpha = .89 - .94). The Norwegian version of the PCS had acceptable internal consistency and test-retest reliability in a sample of women with pelvic girdle pain (Grotle, Garratt, Jenssen, & Stuge, 2012).

4.5.2 Secondary outcomes

4.5.2.1 Pain Acceptance (Papers I, II and III)

The Chronic Pain Acceptance Questionnaire (CPAQ) was used to measure acceptance. It is a 20-item instrument developed to capture the extent of participation in daily activities despite pain and willingness to experience pain without trying to control, alter or avoid it (McCracken et al., 2004). A two-factor structure with the components of pain willingness and activity engagement has been conformed in several studies (Fish, McGuire, Hogan, Morrison, & Stewart, 2010; McCracken et al., 2004; Wicksell, Olsson, & Melin, 2009). CPAQ is scored on a seven-point Likert scale from 0 (never true) to 6 (always true) to give the total score (0 to 120). Higher scores reflect higher acceptance of pain. Adequate reliability and validity have been shown in sample of persons with chronic pain (Fish et al., 2010; McCracken et al., 2004;

Vowles & Thompson, 2011; Wicksell et al., 2009). Scores on CPAQ can predicted distress and disability levels (McCracken et al., 2004). In our study, the Cronbach's alpha coefficients were .81 - .92.

4.5.2.2 Values-based living (Papers II and III)

Chronic Pain Values Inventory (CPVI) is a 12-item self-rating measure of importance and success in living according to one's own values in six domains (family, intimate relationships, friendship, work, health and personal growth) (McCracken & Yang, 2006). Each item is rated on a scale from 0 to 5, with higher numbers indicating more importance or success. The mean success rate was used as a measure of values-based action (score range: 0 to 5), as recommended by the authors (McCracken & Yang, 2006) and commonly done in other studies (Vowles & Thompson, 2011). CPVI correlates with measures on acceptance and functioning (McCracken & Yang, 2006). The reliability of the CPVI has been established for persons with chronic pain (Vowles & Thompson, 2011). In the present study the Cronbach's alpha coefficients for the success scale were .75 - .88.

4.5.2.3 Questions from the General Health Questionnaire – 12 items (Papers II and III)

Emotional distress was measured with questions from the 12 items General Health Questionnaire (GHQ) (Goldberg et al., 1997) with modified response alternatives. Responses to all items were given on the same four-point scale ("much less than usual", "same as usual", "more than usual" and "much more than usual"), but not on two scales as in the original. The questions measure changes in emotional distress over the previous couple of weeks. A bimodal scoring method was used (symptom present more than usual = 1, symptom present less than usual or as usual = 0). Total score range is 0 to 12; indicating the number of symptoms present more than usual during the last two weeks. In the current study the Cronbach's alpha coefficients were .72 - .88. The GHQ has been validated in Norwegian (Nerdrum, Rustøen, & Rønnestad, 2006).

4.5.2.4 Fibromyalgia Impact Questionnaire (Papers II and III)

The original version (1991) of Fibromyalgia Impact Questionnaire (FIQ) was used to measure the impact of fibromyalgia on functioning and symptom levels the last week. It consists of 10 questions with different response alternatives. One question includes 10 sub-items related to the ability to perform activities of daily living. The response alternatives are given on a four-point scale. The other questions enquire about general wellbeing, ability to work and level of pain, fatigue, stiffness and symptoms of anxiety and depression. Questions on symptom level

are answered using a scale from 0 to 100 with higher scores indicating greater impairment (Burckhardt, Clark, & Bennett, 1991). The FIQ is a frequently used instrument in studies with persons with fibromyalgia and acceptable validity and reliability has been confirmed (Bennett, 2005). The Norwegian version has been used in a study with persons with chronic musculoskeletal pain participating in an inpatient pain management program (Wigers & Finset, 2007). The Cronbach's alpha coefficients were .78 - .87 (two questions related to work were excluded because of high missing rates).

4.5.2.5 Short-Form Health Survey – 8 items (Papers II and III)

Short-Form Health Survey (SF) was used to measure functioning. SF-8 includes 8 items, scored on five- or six-point Likert scales, regarding level of functioning the last week. Summary measure scales for mental health component and physical component were obtained by using SF-8 Scoring Software 4.5^{TM} (Saris-Baglama et al., 2011). Scoring is standardized using the means and standard deviations (SD) from a survey from the general adult population in USA; the standardized score have a mean of 50 and a SD of 10. Higher scores indicate better functioning; scores above 50 indicate functioning above the average in the US population. In the Norwegian version used in the present study, wording of response options for two items differed slightly from the original. In the original, the response alternatives for the item on Role Physical are "none at all", "a little bit", "some", "quite a lot" and "could not do daily work". In our version, instead of "a little bit" the response was "very little". In the original the response alternatives for the Mental Health item are "not at all", "slightly", "moderately", "quite a lot" and "extremely". In our version "very little" was used instead of "slightly". The Cronbach's alphas for the mental component were .65 - .74 and .79 - .85 for the physical component.

4.5.2.6 Visual analogue scales (Papers II and III)

The current levels, i.e., the past couple of days, of pain, fatigue, sleep disturbance and depression were assessed on visual analog scales from 0 (no pain) to 100 (worst imaginable pain).

4.5.2.7 Feasibility questions (Papers I, II and III)

Participants' experiences and satisfaction with the intervention with the intervention was assessed with self-report 5-point Likert-type questionnaire including both positively and negatively framed items. Response alternatives ranged from "total agreement" to "total disagreement".

4.6 Sample size calculation

Power analysis was based on the level of reported catastrophizing in samples of persons with chronic musculoskeletal pain (Cöster et al., 2008; Severeijns, Vlaeyen, van den Hout, & Picavet, 2004; van Damme et al., 2002), a moderate effect size (Cohen's $d = 0.5$) and allowing for attrition commonly seen in studies on Internet interventions (Andersson, 2009; Macea, Gajos, Daglia Calil, & Fregni, 2010; Wangberg, Bergmo, & Johnsen, 2008). A sample size of 70 participants per group was needed to detect a moderate effect in the primary outcome variable with a two-sided 5% significance level and 80% power.

4.7 Randomization

A sequence list was generated by a program on the website www.randomization.com. The two groups were randomized in blocks of four due to practical reasons to ensure similar numbers in each group at each time point. A research assistant put the allocation information in sequentially numbered envelopes and sealed them. A researcher subsequently gave each participant a number and opened the matched envelope to reveal the group allocation. The information about group allocation was revealed to the participant at the inclusion meeting with a nurse in the last week of the inpatient program.

4.8 Analyses

4.8.1 Paper I

Descriptive statistics were calculated as means and frequencies using The Statistical Package for Social Science (SPSS) version 16. Notes from the interviews were compared and themes identified.

4.8.2 Papers II and III

To investigate differences in demographic variables and baseline characteristics, independent sample *t*-tests, nonparametric tests and chi-square tests were used. Paired t-tests were used to investigate within-group changes. Independent t-tests or non-parametric tests were used to compare outcomes between groups. The Cohen's *d* effect sizes were calculated using the difference between the groups' means divided by the mean of the standard deviation of both groups. Effect sizes were categorized as small (< .5), medium (.5 - .8) and large (> .8) in accordance with Cohen (Cohen, 1988). A significance level of $P = .05$ was chosen and a

tendency toward difference was defined as $P < .10$. SPSS versions 18 to 20 were used.

If one or two items were missing on the GHQ, they were scored as present less than usual or as usual (= 0). If another instrument included one or two missing items, the item(-s) were replaced with the mean of other items from the participant's instrument. If two response alternatives were marked, the healthier option was chosen. Total score was not computed if more than two items were missing, and the case was categorized as missing a total score for the instrument. The number of participants included in each analysis is provided.

The intention-to-treat analysis (ITT) analyses of the primary outcome included all participants (n = 135) except those who met the exclusion criteria after randomization. In Paper II, missing values were replaced with last observation carried forward (LOCF). In Paper III, two methods for replacing missing variables were used; LOCF and multiple imputations (MI). In the MI analysis 50 imputations were made. The following clinically significant variables were included in the MI regression model: age, SF-8 physical component and VAS for pain, sleep, fatigue and depression at admission to the rehabilitation center. Per protocol (PP) analysis was applied on secondary outcomes, i.e., only those who completed the interventions were included (n = 112).

4.9 Ethical considerations

The study was approved by the Regional Ethics Committee in South-East Norway and by the Norwegian Social Science Services. All participants signed an informed consent form. The study is registered at ClinicalTrial.gov (NCT01236209). Profound psychiatric disorder was an exclusion criterion for the study, as well as for the inpatient rehabilitation center most of the participants were recruited from.

5 Results and summaries of papers

5.1 Paper I

Aim: This pretrial study aimed to develop and test the usability of a four-week Internet intervention delivered by a web-enabled mobile phone to support self-management of chronic widespread pain.

Methods: The intervention included daily online entries and individualized written feedback, grounded in a mindfulness-based cognitive behavioral approach. The participants registered activities, emotions and pain cognitions three times daily using the mobile device. The therapist had immediate access to this information through a secure website. The situational information was used to formulate and send a personalized text message to the participant with the aim of stimulating effective self-management of the current situation. Six women participated and evaluated the experience.

Results: The intervention was rated as supportive, meaningful and user-friendly by the majority of the women. The response rate to the daily registration entries was high and technical problems were few.

Conclusion: The results indicate a feasible intervention. Web-applications are fast becoming standard features of mobile phones and interventions of this kind can therefore be more available than before.

5.2 Paper II

Aim**:** The aim of this trial was to study the efficacy of a four-week smartphone-delivered intervention with written diaries and therapist feedback following an inpatient chronic pain rehabilitation program.

Methods**:** A total of 140 women with chronic widespread pain who participated in a four-week inpatient rehabilitation program were randomized into two groups: with or without a smartphone intervention after the rehabilitation. The smartphone intervention consisted of one face-to-face session and four weeks of written communication via a smartphone. Participants received three smartphone diary entries daily to support their awareness of and reflection on pain-related thoughts, feelings, and activities. The registered diaries were immediately

available to a therapist who submitted personalized written feedback daily based on cognitive behavioral principles. Both groups were given access to a noninteractive website after discharge to promote constructive self-management. Outcomes were measured with self-reported questionnaires. The primary outcome measure of catastrophizing was determined using the pain catastrophizing scale (score range 0 to 52). Secondary outcomes included acceptance of pain, emotional distress, functioning, and symptom levels.

Results**:** Of the 140 participants, 112 completed the study: 48 in the intervention group and 64 in the control group. Immediately after the intervention period, the intervention group reported less catastrophizing (mean 9.20, SD 5.85) than the control group (mean 15.71, SD 9.11, $P < .001$), yielding a large effect size (Cohen's $d = 0.87$) for study completers. At 5-month follow-up, the between-group effect sizes remained moderate for catastrophizing (Cohen's d=0.74, $P = .003$), acceptance of pain (Cohen's $d = 0.54$, $P = .02$), and functioning and symptom levels (Cohen's $d = 0.75$, $P = .001$).

Conclusions**:** The results suggest that a smartphone-delivered intervention with diaries and personalized feedback can reduce catastrophizing and prevent increases in functional impairment and symptom levels in women with chronic widespread pain following inpatient rehabilitation.

5.3 Paper III

Aim: The aim was to examine the long-term effects of a four-week smartphone-intervention with diaries and therapist-written feedback following an inpatient chronic pain rehabilitation program, previously found to be effective at short-term and 5-month follow-ups.

Methods: One hundred forty women with chronic widespread pain, participating in a four-week inpatient rehabilitation program, were randomized into two groups: With or without a smartphone intervention after the rehabilitation. The smartphone intervention consisted of one face-to-face individual session and 4 weeks of written communication via a smartphone, consisting of three diaries daily to elicit pain-related thoughts, feelings and activities and a daily personalized written feedback based on cognitive behavioral principles from a therapist. Both groups were given access to an informational website to promote constructive self-management. Outcomes were measured with self-reported paper-and-pencil format questionnaires with catastrophizing as the primary outcome measure. Secondary outcomes included daily functioning, acceptance of pain, emotional distress and symptoms.

Results: By the 11-month follow-up, the favorable between-group differences previously reported post-intervention and at 5-month follow-up on catastrophizing, acceptance, functioning and symptom level were no longer evident ($P > .10$). However, there was more improvement in catastrophizing scores during the follow-up period in the intervention group (M = -2.36, SD = 8.41) compared to the control group (M = .40, SD = 7.20), $P = .045$. Also, per protocol within group analysis showed a small positive effect (Cohen's $d = .33$) on catastrophizing in the intervention group ($P = .04$) and no change in the control group from the smartphone intervention baseline to 11-month follow-up. A positive effect (Cohen's $d = .73$) on acceptance was found within the intervention group ($P < .001$) but not in the control group. Small to large negative effects were found within the control group on functioning and symptom levels, emotional distress and fatigue ($P < .05$) from the intervention baseline to the 11-month follow-up.

Conclusion: The results of this randomized trial are ambiguous. No significant between-group effect was found on the study variables at 11-month follow-up. However, the within-group analyses, comparing the baseline for the smartphone intervention to the 11-month data indicated changes in the desired direction in catastrophizing and acceptance in the intervention group but not within the control group. This study provides modest evidence supporting the long-term effect of the intervention.

6 Discussion

This is the first study on an intervention delivered with smartphones to support self-management in women with fibromyalgia who have completed an inpatient rehabilitation program. The results are promising, especially regarding short and mid-term effects and acceptability by the participants. In this section the main results are discussed in relation to methodological issues, the research literature, and future research areas.

6.1 Methodology

6.1.1 Design

6.1.1.1 Paper I

The study was a pilot with a pre-post design and a qualitative aspect with two semi-structured interviews to assess the feasibility regarding the practical usability and acceptability of the intervention. A similar intervention had been found feasible and effective for persons with IBS in a study led by one of the research group member (SvD) (Oerlemans et al., 2011). The participants in the present study were informed of the study being a pilot study and that they were participating in the developmental phase. It might have strengthened the development phase further to include a representative of user in the research group from the start, e.g., to enhance patient-centeredness. Early collaboration with users has been recommended for improving mobile health interventions (Whittaker, 2012). Focus group on the users preferences and needs might also have been beneficial in the development phase. Pilot studies are important to test acceptability, compliance, and delivery methods of an intervention and also to try out the recruitment procedures (Craig et al., 2008).

6.1.1.2 Papers II and III

An RCT was chosen to investigate the efficacy of the intervention as it is considered the gold standard of intervention's efficacy research (Craig et al., 2008) The randomization to the two groups serves to make the them comparable, i.e., the many variables (confounding factors) that may be assumed to impact the outcome variables are randomly assigned to the groups to limit the effects on the results. This RCT was explanatory rather than pragmatic.

It may be argued that the intervention would have benefited from a longer developmental phase with more active user involvement, and that a research design allowing the intervention to develop and improve in the processes might have been more appropriate. However, based on the literature, experience from the IBS study (Oerlemans et al., 2011) and our pilot, the intervention was considered mature enough for a trial. In retrospect, the positive results support this decision. Also, self-report on how the smartphone intervention was experienced was included with the aim of exploring room for improvements of the intervention.

In RCTs, most ideally the intervention provided to the control group should be comparable to the active intervention regarding use of time, attention, and educational content (Morley & Williams, 2006). This is important to limit placebo effect on the results. The form of the control group in the study was affected by a pragmatic choice and the fact that no comparable intervention was available. The control group intervention was somewhat comparable in educational content, but not in use of time and attention.

6.1.2 Study sample

6.1.2.1 Paper I

The original aim was to recruit only from GPs. However, the recruitment from the GPs was not successful as only a few responded to the invitation to include patients in this study, resulting in recruitment of only two participants. Therefore, other recruitment methods were necessary. This is not an uncommon experience in e-health intervention studies (Danaher & Seeley, 2009) or health research in general (van der Wouden et al., 2007). The knowledge level and need for self-management support may be assumed to be different for the participants completing a four-week inpatient program and those referred by the GPs. As in all studies using convenience samples the results may be impacted by the fact that those agreeing to participate may be those who are most positive toward the intervention. But since the aim was to pilot test the intervention, a convenience sample was found suitable.

6.1.2.2. Papers II and III

Among the strengths of the study is the inclusion of a clinical sample, i.e., a clinician confirmed the diagnoses. Many studies, especially in Internet-based research, rely on self-reported information about diagnoses, which may contribute to less accurate description of the sample and therefore impact the generalizability. The generalizability of the results is, however, affected by several factors. First, just over half of those participating in the inpatient program during the study period (and thus assumed eligible) participated in the study. We

were not able to compare the characteristics of those who participated and those who did not participate in the trial. The introductory meeting for the study was scheduled during the second week of the rehabilitation program. For some it may have been too early to consider involvement in an aftercare intervention, while others may have used the opportunity to prioritize private time in the tight rehabilitation schedule instead of listening to study information. Moreover, in the stress management part of the rehabilitation program, the patients were encouraged to set limits and decline requests they experienced as stressful. Patients with high self-efficacy regarding self-management after discharge may have been more likely to not attend the informational meeting. Also, because all those who were eligible for the study received a short information letter about the study, some may have found the intervention format unsuitable. Therefore, we cannot generalize the results on the population of women seeking treatment at inpatient pain management programs. However, our sample had several comparable characteristics to other samples of treatment seeking persons with chronic musculoskeletal pain (Buhrman et al., 2012; McCracken & Gutiérrez-Martínez, 2011; Naylor et al., 2008; Wigers & Finset, 2007).

A second limitation to the generalizability involves the withdrawal rate. The intervention group had a withdrawal rate of 30%, which might have resulted in differences in the characteristics of completers between groups. This level of withdrawal is common in CBT interventions for persons with fibromyalgia; in nine of 30 trials included in a review the dropout rate was higher than 20% (van Koulil et al., 2007). There was a trend toward the completers being younger and with less depression on VAS. It is unclear how this may have impacted the results. In general, demographic characteristics and physical findings do not predict outcome, whereas high levels of emotional distress and catastrophizing seem to predict reduced treatment effect (McCracken & Turk, 2002). In the PP analysis, no significant group difference ($P > .05$) was found on demographic variables or on any of the outcome measures at the smartphone interventions baseline (T2). We chose therefore to report on the PP analysis for the secondary outcomes.

Third, at admission to the inpatient program (T1), the participants in the smartphone intervention group reported higher pain levels and lower physical functioning compared to the control group. At discharge (T2), this difference was no longer evident. This indicates that participants in the intervention group improved more on those two variables during the inpatient program compared to the control group. It is possible that this implies some not-assessed differences in the groups' characteristics. The baseline assessment (T2) for the

smartphone was made after the initial meeting and start-up phase of the intervention. This was less than optimal, since it may have impacted the results; i.e., participants had already participated in the start-up phase of the intervention, which may have affected anticipations and outcomes. However, it was considered important to include a start-up phase during the last week of the inpatient program, and it would have involved increased burden for the participants to fill out the questionnaire battery both before the start-up phase and then again a few days later for the purposes of the rehabilitation center. Nevertheless, this limitation is acknowledged, since ideally the baseline assessments in RCTs should be made before randomization to prevent impact on results.

Last, but not of least importance, the generalizability is affected by incomplete response rate to follow-up questionnaires and a statistical difference, or a tendency toward a difference, detected on a few variables. There was a trend in the direction of those responding to follow-up questionnaires having reported better functioning on a few variables on prior assessments compared to those not responding. This is not uncommon in treatment studies in samples of persons with chronic pain (Vowles et al., 2011). The response rate was similar between groups at the 5-month follow-up, but at post intervention and at 11-month follow-up the response rate was higher in the intervention group. Response rates below the optimal cutoff criterion of 80% are very common in chronic pain treatment studies (Turk & Rudy, 1991).

The results can be generalized only to women since men were excluded in this study. Men were excluded because they are a minority group in the population of persons with fibromyalgia and their exclusion enhanced the homogeneity of the sample. Even though many studies on fibromyalgia do not exclude men, it is common to see domination (>80%) of women in research samples. Profound psychiatric disorder was an exclusion criterion for both the inpatient program and the RCT. The criteria for profound psychiatric disorder could have been more clearly stated. They included psychosis, severe personality disorder or being actively suicidal. This exclusion criterion is especially important in Internet-based interventions were the therapist has limited opportunity to assess symptoms of crises. Patients with severe symptomology should be referred to a suitable therapy form with face-to-face contact with a specialist. Methods for managing crises in e-health interventions have received little attention in the literature, and the prevention by excluding persons at risk is currently the most common approach (Carlbring & Andersson, 2006; McGeary, McGeary, & Gatchel, 2012). More research is needed to address this important issue.

It should also be mentioned that two nurses wrote separate qualitative M.Sc. theses on two different subgroups (n = 7 and n = 11) of the intervention group sample. The theses were on the experience of participating in the smartphone intervention (Borgaas, 2011; Jelin, Granum, & Eide, 2012). The interviews followed structured guides and were not intended to be therapeutic. It is therefore assumed that this has not influenced the results in any major way.

6.1.3 Method of data collection

6.1.3.1. Paper I

Semi-structured interview guides were followed, with the aim of capturing the experience and need for changes in the intervention. The interviews with the participants on the experience of participating were not taped. It is possible that a different interviewer, i.e., one not involved in the development, would have received different feedback.

6.1.3.2 Papers II and III

The follow-up questionnaires were filled out at home and reminders were provided by a telephone call from one of the researchers. In some cases this was the same person who had served as the therapist in the smartphone intervention. The phone calls were empathic but kept short and not believed to have had any significant therapeutic influence. There was some variation among participants in the length of time it took for them to return questionnaires, which was not accounted for in the analyses. However, this was not assumed to differ between groups and therefore not assumed to influence the results. The long-term follow-up, at 11 months, is a study strength, especially since few e-health interventions studies including persons with chronic pain, have reported on effects beyond six months follow-up. Twelve months has been considered an excellent follow-up length in intervention studies in samples of persons with chronic pain (Morley & Williams, 2006).

6.1.4 Outcome measures

The outcome measures were chosen in accordance with both the FA model (e.g., catastrophizing, emotional distress, pain level, functioning) and ACT (acceptance, values-based living). The outcome variables were in line with guidelines on outcome domains in research on chronic pain interventions (Turk et al., 2003). Other ACT-related outcomes could have been chosen, e.g., mindfulness and, maybe more importantly, psychological flexibility, since it is the core concept of ACT (Hayes et al., 2012). However, since CPAQ measures

processes related to psychological flexibility, and the number of included questionnaires needed to be limited to reduce the burden to participants, more ACT-related outcome were not included. Catastrophizing was chosen as a primary outcome as it is a central feature in the FA model. It may be argued that catastrophizing was not the most logical choice of primary outcome, since the goal in ACT is not explicitly to change or reduce the frequency of catastrophizing thoughts with formal cognitive restructuring techniques, but rather to enhance acceptance of thoughts and feelings and reduce the believability of cognitions. Nevertheless, catastrophizing was chosen because previous studies have shown that interventions based on ACT can reduce catastrophizing in individuals with chronic pain. Catastrophizing may be viewed as a process variable rather than as an "end" outcome. It could therefore be argued that the main goal of treatment, i.e., functioning and values-based living, should have been chosen as primary outcome. However, since catastrophizing has been identified as an important target of interventions for persons with pain, it was chosen as the primary outcome and measures of functioning included as secondary outcomes.

The primary outcome variable was assessed with one of the most commonly used instruments for measuring catastrophizing (Edwards et al., 2006). The questionnaire may be criticized for not varying the direction in the response alternatives, therefore increasing a risk of repetition bias. It is not clear whether catastrophizing should be conceptualized as a stable trait or as a modifiable variable (Edwards et al., 2006). On one hand, high test-retest stability has been reported (Sullivan et al., 1995; Sullivan et al., 2001). Also, it may seem that persons with certain personality styles (e.g., trait anxiety and neuroticism) are more likely to report high levels of pain-related fear and catastrophizing (Leeuw et al., 2007). On the other hand, a number of studies show that catastrophizing can be reduced by CBT. Thus there may be both trait- and state-like aspects of pain-related catastrophizing. In the present study a certain criterion on PCS was used to categorize the scores, as done in at least a couple of studies (Cassidy et al., 2012; Sullivan et al., 1995) This criterion has, however, not been clearly related to clinical significance. Studies on psychological interventions for persons with chronic pain have been criticized for lacking information on clinically significant change. This explanation may partly involve limited availability of relevant criteria for different assessment instruments (Morley & Williams, 2006). As shown in Appendix 1, there is a large number of different assessment instruments applied in the studies of ICBT for chronic pain; more than 40 different instruments were used. PCS was used in 3 of the included ICBT studies.

The Norwegian versions of CPAQ and CPVI were not available prior to the use in this study. The translation to Norwegian was led by the project leader (HE). The questionnaires' author (McCracken) approved the back translations. Unfortunately, the response alternatives to the questions in GHQ, used in this study were not the same as in the original version. The Likert scoring could therefore not be applied, and instead a case score method counting number of symptoms was used. This limits the possibilities of direct comparison with other studies using GHQ. In SF-8, the wording of response options for two items differed slightly from the original; however, this was not assumed to have impacted the results in a significant way. The Cronbach's alpha coefficients were >.70 in all questionnaires; with the exception of the mental component of SF-8 witch was .65 at one assessment point. This can be assumed to reflect acceptable reliability levels (Peterson, 1994).

The strengths of self-report questionnaires include relatively low burden for participants and low cost. Importantly, in many cases there may not exist other established methods for assessing a variable, e.g., some cognitive and emotional variables. There are some limitations to using self-reporting. The results may be biased due to different factors such as social desirability and intentional 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 are therefore often generated from estimation rather than accurate information (Piasecki et al., 2007). In a blinded RCT, these factors would not be expected to differ between groups. In psychological studies, where blinding is often difficult to achieve, the bias may differ between groups, e.g., it could be hypothesized that the group receiving the active intervention would be more prone to desirability bias. In the present study, a few of the questions in the e-diaries were adapted from the PCS and it is not clear if and how this could have affected the outcome assessment with the PCS. 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, Strom, & Andersson, 2011; Hedborg & Muhr, 2011). Pencil and paper format was used in this study, rather than online format. The reason for this was that the collaborating rehabilitation center used traditional pencil and paper form. A measure of self-management could have been included, e.g., exercise frequency and use of mindfulness exercises. There is a lack of validated instruments to measure self-management and adherence in pain treatment studies; importantly, such instruments should consider the context of the strategies as well as their frequency (Curran et al., 2009; Morley & Williams,

2006). To protect the quality of data and minimize response burden it is important to limit the questions included in a battery of self-report questionnaires. The results could have been strengthened by use of more objective behavioral outcomes, e.g., works status or number of visits to HCP.

6.1.5 Data analysis

In the pilot, only descriptive statistics were reported, as the sample was too small for further statistical analysis to provide meaningful results. Notes from the interviews were compared and themes identified. More rigorous qualitative design could have been used, i.e., with recorded and transcribed interviews. This was, however, done in a sample of the participants in the RCT with the aim of investigating the experience of participating in the intervention (Jelin et al., 2012).

In Papers II and III, the argument for using parametric and non-parametric tests to investigate between-group differences was grounded in the RCT design and the similarities of the groups' characteristics at the interventions baseline (T2). Since there was not significant difference on any of the outcome variables at the smartphone intervention baseline we did not control for any variables. However, since there were differences in two variables at the baseline of the inpatient program (T1), it might have been better to control for the effect of these. This might have been done by applying analysis of covariance (ANCOVA), which adjusts for pretest scores (Vickers & Altman, 2001).

Our data analysis was strengthened by the inclusion of ITT analysis on the primary outcome. This is recommended to investigate the effects of treatment intention rather than of the treatment and to reduce bias due to withdrawal (Hollis & Campbell, 1999). The inclusion of ITT analysis is still not the norm in research on CBT for persons with fibromyalgia (Glombiewski et al., 2010). In Paper II, ITT analysis for the primary outcome was included, using LOCF to replace missing values. Since the method of LOCF may not be optimal replacement of missing values (Streiner, 2008), a more advanced method was applied in Paper III. Multiple imputations (MI) have been recommended to improve the validity of results in trials with incomplete datasets (Blankers, Koeter, & Schippers, 2010). In Paper III, missing values were replaced with both LOCF and MI for the primary outcome. In the ITT analysis, the level of catastrophizing in the control group at endpoint (T5) was almost the same for the complete case analysis (mean 14.73, n = 43) and the MI analysis (mean 14.74, n = 66). In the intervention group, the catastrophizing level was somewhat higher with MI (mean 12.80, n =

69) compared to the complete case analysis (mean 11.50, n = 44). This might partly be explained by higher baseline scores on two variables (pain and SF-8 physical component), that were included in the MI regression model. Importantly, in the PP analysis, the difference between the mean levels of catastrophizing with MI or without (complete case analysis) was small. This provides some support for the validity of our results of secondary outcomes, where results of complete case analysis is reported. However, in the within-group analysis, the difference between the intervention baseline (T2) and 11-month follow-up (T5) in the intervention group was significant when applying complete case analysis ($P = .04$) but only borderline significant in the analysis with MI ($P = .09$), thus indicating that the results for complete case analysis should be interpreted with some caution. A mixed-effects model approach could have been a better alternative since it involves methods to reduce bias due to missing data at different assessments time points (Mallinckrodt, Clark, & David, 2001).

As in most other RCTs, our results reflect changes in the groups' means and do not provide information on individual changes. It may therefore be argued that including information on clinically significant changes on individual levels would have strengthened the results. Attempts to identify moderating factors and predictors of treatment effects were not prioritized in the current thesis mostly due to the relatively small size of the intervention sample. This remains an important subject for investigation as knowledge of the moderators and mediators of treatment effects for persons with fibromyalgia is still limited (Glombiewski et al., 2010).

6.2 Main results

6.2.1 Feasibility

The results of both the pilot study and the RCT indicate a feasible intervention with regards to practical usability and acceptability by the participants. The intervention was rated as supportive, meaningful and user-friendly by the majority of the participants in the pilot and found useful by most of the completers in the RCT.

The response rates to the daily registration entries were generally high (mean > 80% for the completers) in the pilot. In the RCT, the response rate to the diary entries varied from 27% to 95%. This suggests that the acceptability of the diaries varied considerably between participants. However, the mean and median were close to 70%, which indicates a general acceptability. This is in accordance with response rates from other studies using electronic

diaries (Morren, Dulmen, Ouwerkerk, & Bensing, 2009; Stone, A.A. et al., 2003). In the pilot, most participants found three diary entries and one feedback per day to be suitable. However, half of the participants found the questions in each diary to be too many. Respondent burden is dependent on the length of assessment period, number of diaries per day and number of questions per diary. The aim should be to limit the respondent burden as much as possible, as it has negative effect on the respondent's motivation and thus data quality (Morren et al., 2009). The number of questions was therefore reduced before the RCT. In the IBS study, all participants completed all three daily entries for the four-week duration (Oerlemans et al., 2011). The IBS included fewer questions per diary, which may contribute to the difference in the response rates. In the pilot study on e-diaries and feedback for supporting self-management of migraine, the mean response rate to diaries was 85% (Kleiboer et al., 2009). It is not clear why the response rate was higher in this study compared to the present one.

Of those in the RCT who reported on the experience of participating, most experienced (86%) the intervention as useful. In a qualitative study, seven women who had participated in the smartphone intervention were invited to share their experience with a researcher not involved in the RCT. They were encouraged to share both positive and negative aspects. In general, the intervention was experienced as motivating and supportive (e.g., "*It forced me further*", "*I felt happy, because the feedback gave me a push to reflect and to do more about my situation*", "*The supportive feedback helped me through the tough days with depression. It was important for me to hear that things take time and that I cannot get well in three weeks*") (Jelin et al., 2012). The participants reported that the intervention had enhanced their reflections on thoughts, feelings, and values, e.g., "*I became more conscious of my mind's structures which led to greater awareness of myself and my life*". The relationship with the therapist was generally experienced as positive (e.g., "*I had full confidence in her*", "*She hit the spot, this was both good and bad*"), even though on some occasion the feedback was experienced as either overly positive, impersonal or as lacking in understanding ("*I felt that I was not understood*"). Some of the participants were extremely positive, e.g., "*I've learned more than ever before in my life*", "*I've missed this kind of therapy follow-up for 12 years*" (Jelin et al., 2012). Nevertheless, in both the pilot and the RCT, some participants experienced some aspects of the intervention as negative. In the pilot, two of the women found some aspects of the intervention disturbing, frustrating, and even difficult, e.g., finding it challenging to report how they were feeling. This was also seen in the RCT where three (7%) participants disagreed somewhat or totally in finding the participation useful.

Approximately one in four participants agreed somewhat that the participation had been experienced as a burden. The method of experience sampling is almost per definition disturbing as it is meant to capture experience in different everyday situations. It is most likely that the diary signal has on occasions been experienced as disturbing. For example on occasions where registration may have been challenging, e.g., in work situations or at times where motivation to register was low. This ambivalence between finding the intervention useful and burdensome is also evident in the results of the qualitative (Jelin et al., 2012). For example: "*It was a bit busy, I felt I had to answer and had a bad conscience if I did not…but it was rewarding in its own way, because I felt I did more*…" (Jelin et al., 2012). The technological aspects could also contribute to frustration and burden, e.g., "*I could not send the diaries; it didn't go through. I only got error. This made me frustrated*". A few temporary problems with the submission of the diaries were reported. It caused frustration to have filled out a diary form and then not be able to send it because of a validation error. It might have been useful with a more systematic assessment of these technical errors, i.e., a log of instances. For some participants, the technological aspects were a source of accomplishment and pride in managing the intervention (Jelin et al., 2012).

In a recent study, a panel of HCPs and people experiencing chronic pain discussed characteristics of a successful Internet self-management program. Use of a small and mobile device for real-time monitoring was preferred. Important features included helping the persons to be more aware of their patterns of behavior and psychological experience, and supporting the pursuit of personal goals and values-based behavior. Feedback should be tailored to the current situation; the key variables to tailor to were amount of movement-based activity, location, participation in goal activity, quality of activity, pain level and affective state (Rosser et al., 2011). The present intervention seems to be in agreement with many of these recommendations.

Two of the pilot participants reported wanting a longer intervention period. For individuals with a long-term condition, such as fibromyalgia, a longer intervention period might be advisable. However, the intervention in the present form may not be optimal due to the relatively high cost/resource of therapist time.

Exact login information for visits to the website was not available. Most participants in the control group (26 of the 38 who reported this information) visited it rarely (two times or less). The impression of the administrator of the website (HE) was that it was seldom

accessed. Based on the content of the website and its limited use, the control group condition is not assumed to have caused any changes seen in the control group. Of the participants who completed the study in the smartphone intervention the website was sparsely visited, 46% reported never visiting the website and only 23% visited it three times or more. This may be explained by the fact that the audio files available on the website were accessible on the smartphone and most instructions for the exercises were written out in the feedback, even though it was sometimes referred to a more detailed description of the exercise available on the website. Unfortunately, we do not have data on the use of the audio files on the smartphone or on practice of the recommended exercises.

The withdrawal rate of 30% in the RCT indicates that all may not find this type of e-health aftercare intervention feasible. It should be noted that several participants withdrew before trying out the intervention. High withdrawal rates have been a challenge in e-health interventions (Fjeldsoe et al., 2009; Macea et al., 2010). The withdrawal rate is similar to those reported in many ICBTs, where an average dropout rate of 27% has been reported in samples of persons with chronic pain (Macea et al., 2010). Based on participation rate of those assessed for eligibility and withdrawal rate, the present intervention seems better accepted than at least one of the others e-health aftercare interventions. In the study by Moessner et al. (2012), 70% of the participants in the e-health aftercare back pain intervention group withdrew before receiving the intervention. The reasons given included lack of time, technical problems and dislike of the concept (i.e., self-monitoring and chat with a HCP) (Moessner et al., 2012). Also, in the Moessner et al. (2012) study, there was a lower participation rate (27.1%) of those assessed for eligibility, compared to the present RCT. In the aftercare intervention in the study by Buhrman et al. (2012), only three of the 36 persons in the intervention group withdrew. However, 112 of the 256 who were sent an inquiry letter declined participation (Buhrman et al., 2012), a similar rate that in the present RCT. In the Naylor et al. (2008) study, 12 (18%) of the 67 eligible persons declined participation (Naylor et al., 2008). Clearly, participation in e-health aftercare interventions does not suit all, and the option to choose a preferred format would be ideal. Therapist contact and tailored or personalized messages have been found to correlate with lower withdrawal rates (Andersson, 2009), but as our results show, other factors clearly also play roles. The patients who withdrew tended to score higher on depression and were older than the completers, which could have influenced their interest and capacity to participate. Information on the reasons for withdrawal for all participants is not available. However, many of those who withdrew before

or during the run-in period reported that the combination of the smartphone intervention and participation in the inpatient program was stressful or expected to be stressful. Our intention with a run-in period during the final week of the inpatient program was to give the participants a chance to get used to the smartphone before returning home, since a start-up phase is recommended in interventions with e-diaries (Piasecki et al., 2007). However, our results may indicate that this might not have been suitable for all participants. It might have been more feasible to give the participants the choice of starting the intervention after discharge from the inpatient program. Participants chose to receive their morning and evening diaries at hours suitable for their schedules at home, which may possibly have been inconvenient while still at the rehabilitation center. Therefore, closer collaboration with the rehabilitation center and flexibility in start-up date for the smartphone intervention might contribute to a reduction in withdrawal rates. Complete elimination of withdrawal is nevertheless unrealistic in clinical trials where persons have the ethical right to withdraw from participation at any time without providing explanations. Also, withdrawal from participation is not uncommon in therapy in general (van Koulil et al., 2007). In a review of 22 studies on acceptance-based interventions delivered face-to-face for persons with chronic pain, a withdrawal rate above 25% was found in six studies (range 25% to 49%) (Veehof et al., 2011). Even so, more knowledge is still needed on characteristics of the population that accepts this kind of intervention and the group that does not find it suitable.

6.2.2 Efficacy at post-intervention and at a five-month follow-up

The immediate between-group effect size on the primary outcome variable, catastrophizing, was large in the PP analysis. Also, all of the seven participants with a high score on the PCS (>24) before starting the smartphone intervention were below this high score limit after completing the intervention. However, when all randomized participants were included in the analysis, the effect size on catastrophizing was small. This may partly be explained by the higher rate of non-response in the control group and the method of carrying the last observed value forward resulting in the possibility of a false positive effect for the control group. At the 5-month follow-up there was a moderate between-group effect on catastrophizing in the PP analysis. Only one of the seven participants was again above the criterion of high score five months later. The opposite trend was seen in the control group; an increased number of participants were classified as “catastrophizers.” The within-group changes are in accordance with the between-group effects with small-to-moderate positive within-group effect in the PP analysis of the intervention group and a tendency toward a small negative effect in the control

group. Two of the three e-health aftercare studies investigated effects on catastrophizing and both had moderate effects that remained at four- or six-month follow-ups (Buhrman et al., 2012; Naylor et al., 2008).

For the secondary outcomes, there were significant between-groups effects on several outcomes post-intervention. There were moderate positive effects on acceptance, mental functioning (SF-8), and values-based living post-intervention. The effects were maintained for acceptance at the 5-month follow-up and were borderline significant for mental functioning and values-based living. At the 5-month follow-up there was also moderate positive effect on functioning and symptom levels (FIQ) and sleep disturbance, and a small borderline significant effect on fatigue. The within-group changes differed on several outcomes variables between the two groups. Improvements in acceptance and values-based living were seen in the intervention group only. In the control group there were negative within-group effects in functioning and symptom levels (FIQ), mental functioning (SF-8), and emotional distress (GHQ-12) between the baseline and post-intervention, and between baseline and the 5-month follow-up. In the control group, between baseline and the 5-month follow-up, there was also negative effect on values-based living, fatigue and a borderline significant effect on sleep disturbance.

Despite the established correlation between catastrophizing and disability in the literature (Arnow et al., 2011; Crombez et al., 2012), there was no improvement post-intervention in functioning and symptom levels measured by either FIQ or SF-8. In accordance with the FA model, catastrophizing can be viewed as one of the mediators of functioning; and one would expect changes in catastrophizing to result in changes in functioning at a following assessment. Indeed, there was a moderate effect on functioning and symptom level at the 5-month follow-up measured with the FIQ. There was an increase in function impairment and symptom levels (FIQ) in the control group at the 5-month follow-up compared to discharge. This worsening contributed to the difference between the groups at the 5-month follow-up. The control group showed an increased level of fatigue and a tendency toward an increase in sleep disturbance at the 5-month follow-up. This may indicate that the smartphone intervention might have provided some preventive effects on functioning and symptom levels. No difference was seen in the physical component of the SF-8. One reason for this may be the general nature of the items in the SF-8 compared to the questions in FIQ, possibly making it less sensitive to changes.

At post-intervention, there was improvement in success in living in according to values, which indicates that some important changes in functioning seem to have taken place early. The 5-month follow-up results showed a tendency toward improvement in values-based living in the intervention group compared to the control group.

No significant difference in pain level was found at any assessments times. The changes in catastrophizing, acceptance, and functioning in those who completed the study can therefore not be attributed to changes in levels of pain, or vice versa. This is in line with the results of two Internet-based aftercare interventions where no effect on pain were found even despite reduction in catastrophizing (Buhrman et al., 2012; Moessner et al., 2012). According to the FA model, reduction in catastrophizing would be expected to lead to reduction in pain experience. However, changes in catastrophizing have not consistently been associated with significant changes in pain level (Crombez et al., 2012). Use of ACT as the therapeutic framework could contribute to explaining the lack of effect on pain level since it is focused more on increased functioning than reduction of pain. However, our results differ from those of some other previous studies since a small effect size on pain intensity was found in a meta-analysis including nine RCTs of acceptance-based interventions (Veehof et al., 2011). Our results are in accordance with other ACT studies that have shown improvement in catastrophizing and/or functioning despite no effect on pain level (Buhrman et al., 2013; Wicksell et al., 2013).

The results are in line with the study on a similar intervention for persons with IBS regarding effects on catastrophizing. In that study a positive effect on catastrophizing was found at post-intervention and the improvement persisted at three-month follow-up. In contrast to the results of the present study, the improvement in outcome variables other than catastrophizing were not maintained at the three-month follow-up (Oerlemans et al., 2011). The reasons for this difference in the results are unclear, but it may be speculated that this kind of smartphone intervention is better suited as a secondary intervention than as a stand-alone intervention.

E-health aftercare studies for persons with chronic pain are few and heterogeneous in mode of communication. However, all have in common with the present intervention a duration of more than a couple of weeks, a self-monitoring component, and some form of feedback from an HCP. The present intervention had the most frequent HCP contact but had the shortest duration. The results of the present study are mostly in accordance with those of

the other e-health aftercare studies for persons with chronic pain. Naylor et al. (2008) found moderate to large between-group effects on several variables, i.e., mental and physical health, pain level and coping at a four-month follow-up (Naylor et al., 2008). The aftercare intervention in the study by Buhrman et al. (2012) yielded in a small positive within-group effect on catastrophizing that persisted at a six-month follow-up. The between-group effect on catastrophizing was moderate, indicating that, as in our study, the intervention may have contributed to preventive effects. The sample had several similarities with ours, e.g., mean age and mainly persons with generalized pain. There were also maintained improvements in distress and anxiety but the between-group changes at the six-month follow-up are not reported. As in our study, there was no effect on pain levels. In contrast to our results, there was no effect on pain-related acceptance. The difference in the results on acceptance might be partly due to differences in theoretical framework, even though this intervention did include mindfulness exercises (Buhrman et al., 2012). The aftercare intervention described in Moessner et al. (2012) was found to have a significant between-group effect on disability and the pain subscale of SF-36. The difference involved both improvement in the intervention group and deterioration in the control group. There was no effect on pain levels, anxiety or depression symptoms in ITT analysis, but PP analysis showed an effect for general psychological impairment (Moessner et al., 2012). The results of the present study are also in line with an Internet intervention based on ACT where improvements were seen in acceptance and catastrophizing but not on pain severity; the effects were maintained at a six-month follow-up (Buhrman et al., 2013).

6.2.3 Efficacy at a 11-month follow-up

From the baseline of the smartphone intervention (T2) to the 11-month follow-up (T5) there was a small significant within-group effect on the primary outcome in the PP analysis and ITT-LOCF analysis. In the ITT-MI analysis there was a tendency toward a small positive effect. In the PP sample, the mean difference score on the PCS were -3.04 in the complete case analysis and -2.45 with the MI method, thus, indicating that the results of the complete case PP analysis may be slightly biased toward a positive effect. There were no within-group changes in catastrophizing in the control group during this period, which indicates that the treatment effects of the inpatient program were maintained. There was no between-group effect on catastrophizing at the 11-month follow-up.

As for the secondary outcomes, there were several differences in within-group changes between the two groups during the period between baseline (T2) and 11-month follow-up

(T5). There was a positive moderate effect on acceptance and a borderline-significant positive effect on values-based living in the intervention group only. Also, there was a significant negative effect on functioning and symptoms levels (FIQ), emotional distress (GHQ) and fatigue in the control group. In addition, there was a borderline significant negative effect on pain, depression levels (VAS) and sleep disturbance. However, there was no significant between-group effect on any of the secondary outcomes at the 11-month follow-up.

The effects on most variables were maintained in the intervention group from the 5-month (T4) follow-up to the 11-month follow-up (T5). Unexpectedly, between the two follow-ups, the control group reported some improvement in several variables (catastrophizing, values-based living, and depression), whereas the intervention group did not. We have no data to support an explanation for this improvement. One could speculate that it takes time for changes in thoughts, behavior, and priorities promoted by the inpatient rehabilitation program to settle and cause positive effects. The control group did not get the smartphone intervention that could promote these changes soon after discharge, and thus the changes may have been achieved at an earlier stage in the intervention group. The spontaneous improvement in the control group, large variations within variables, relatively few participants, and small effect sizes may explain the lack of significant differences between the groups. The results at the 11-month follow-up are in line with the literature indicating that positive post-treatment effects may not be maintained at longer-term follow-up. None of the three e-health aftercare studies provided results of follow-up assessments beyond six months. Long-term results were not reported in the study of the similar intervention for persons with IBS (Oerlemans et al., 2011). In the only ICBT for persons with chronic pain reporting on a follow-up up of 12 months, the positive effects evident at 6-months were maintained. However, when the subgroup of persons with fibromyalgia was analyzed, there were no effects on any outcome measures, either post-intervention or at the follow-up (Lorig et al., 2008). In persons with depression or anxiety, the positive effects of ICBT are generally maintained at follow-ups (Andrews et al., 2010).

It is important to acknowledge that the effects of the inpatient program were sustained at the long-term follow-up in the control group for many of the outcome variables, i.e., catastrophizing, acceptance, mental health, and values-based living. Improvements in those variables indicate that the participants cope better with their situations. However, as less than half of the participants in both the intervention group and the control group reported feeling better at the 11-month follow-up than before the inpatient program, there is clearly room for improvement.

6.2.4 Theoretical implications

Developments of new interventions should be guided by the users' needs and empirically supported treatments, not by the available technology (Keogh et al., 2010). The theoretical frameworks of the FA model (Vlaeyen & Linton, 2000) and ACT for chronic pain (McCracken, 2005) guided the development of the present intervention and are thus expected to provide possible explanations for the effective elements of the interventions. The results of several studies have indicated that ACT can be effective as a framework for self-help interventions and text-based interventions for persons with chronic pain (Buhrman et al., 2013; Johnston, Foster, Shennan, Starkey, & Johnson, 2010; Thorsell et al., 2011), including one Internet-based study (Buhrman et al., 2013). The results of a recent pilot study of a smartphone application based on ACT also indicated a feasible intervention in a sample of healthy volunteers (Ly, Dahl, Carlbring, & Andersson, 2012). ACT and the FA model seem to fit each other, as indicated by a revised version of the FA model suggesting that mindfulness may moderate the relation between catastrophizing and the pain experience, i.e., that purposely paying attention with non-reactivity may counteract catastrophizing (Schütze et al., 2010). However, more research is needed to confirm this. The present intervention applied ACT elements mainly related to the processes of mindfulness, acceptance, and commitment and behavior processes. There was less focus on the elements of observer self. It is acknowledged that metaphors could have been used more frequently and different kinds of de-fusion exercises could have been included. Ad hoc analysis and coding of the feedback to identify behavior change techniques and use of ACT elements indicated that ACT elements were reflected both implicitly and explicitly, e.g., with direct instructions, reflection exercises and referral to exercises (Brembo, 2011). The information from the diaries were found to be used as a reference point and to enhance patient-centered approach (Brembo, 2011). Regarding values, the focus was mainly on health-related goals and values to follow up the work at the rehabilitation center. Health goals have been shown to be difficult to accomplish in persons with fibromyalgia. Pain- and fatigue-related barriers affect behavior toward health-related goals more than social-related goals (Affleck et al., 2001; Gatchel, 1999). Audio files with mindfulness exercises were provided, as done in prior research (Buhrman et al., 2013). The focus was on everyday mindfulness exercises and breathing mediations of short durations. The present intervention is, therefore, not comparable to mindfulness-based interventions including daily meditation often of duration beyond 30 minutes, e.g., the eight-

week programs of mindfulness-based stress reduction (Kabat-Zinn, 2009) and mindfulness-based cognitive therapy (Segal & Williams, 2012).

The smartphone intervention introduced elements from ACT, including mindfulness, which had not been presented in the inpatient program. It is not clear if this influenced the results. Nevertheless, it is acknowledged that the smartphone intervention could have been more strongly integrated in the rehabilitation program, e.g., including the same HCPs. It has been suggested that acceptance-based treatments should not replace the more traditional control-based approaches, but to be integrated or used as an adjunct to make a more complete theoretical model (Friedberg et al., 2012; Kratz et al., 2007).

It is not an easy task to make permanent changes in cognitions and behavior since extinction of emotions and unlearning of behavior is generally difficult to achieve. The return of old cognition patterns and emotions is common (Linton, McCracken, & Vlaeyen, 2008). The rather intensive format of three diaries per day for the first four weeks was therefore chosen to support maintenance of new habits. The present intervention differs, therefore, from the other e-health aftercare interventions, which included less frequent daily interaction and longer intervention duration (Buhrman et al., 2012; Moessner et al., 2012; Naylor et al., 2008).

In interventions using a single therapist it may be difficult to distinguish between effects due to characteristics of the therapist and other treatment elements (Morley & Williams, 2006). In our study there were three therapists with different healthcare background and experience. All of them had basic knowledge of ACT but no prior clinical experience with applying it. There is limited research on the necessary qualifications of ICBT therapists beyond basic knowledge of the CBT principles (Andersson, 2009; Andersson et al., 2008). The written format enabled supervision and collaboration between the therapists and the supervisors, which may have supported adherence to the theoretical framework. As shown in Appendix 1, the qualifications of the persons providing support in ICBT interventions for persons with chronic pain vary from patient expertise (Lorig et al., 2008) to clinical expertise (Brattberg, 2006; Naylor et al., 2008).

The present intervention contained many possibly active components, and the study design did not allow for any distinction between possible mechanisms and explanations. It is possible that the intervention group benefited from having higher expectations of improvement and from the empathic attention and encouragement from an HCP (Proudfoot et

al., 2011). It is not clear how providing situational and personalized feedback may have contributed to the results. In a three-armed RCT (n=210) the additional effect of either self-monitoring with a paper diary, a PDA diary or PDA self-monitoring plus daily tailored feedback, were investigated in persons participating in a six-month program with group sessions for maintaining weight loss for overweight adults. The feedback group obtained larger weight loss than the self-monitoring only groups (Conroy et al., 2011).

As stated in the guidelines for Internet intervention research, it may still be premature to require demonstration of processes of change in Internet interventions because of the newness of the field (Proudfoot et al., 2011). Furthermore, it has been suggested that the current health behavior theories could need a revision to adapt to "the time-intensive, interactive, and adaptive health behavior interventions delivered via mobile technologies" (Riley et al., 2011). Foundation of a generic theory for mobile health interventions has been called for to guide research and implementation of the interventions (Riley et al., 2011; Whittaker, 2012).

6.2.5 Future research

Research on smartphone interventions has been criticized for not taking advantage of the abilities and possibilities associated with current smartphones. However, due to the very fast changes in smartphone technology this may not be easily done (Fiordelli, Diviani, & Schulz, 2013; Miller, 2012). As in most studies on mobile phone interventions published before 2010, the present study used self-report and feedback in written format (Riley et al., 2011). We used first-generation smartphones with simple layout of questionnaires and feedback. In a further development of the intervention, it would be interesting to explore the effects of using more of the technological available methods to gather rich and complex data. It could include sensors to measure activity levels and context-triggered diaries (Miller, 2012; Riley et al., 2011). In addition, in a further development of the intervention, different kinds of feedback could be provided. Automatic feedback on registered data could be provided in progress charts, graphs, and summaries. For example, the tracking of values-based living could be done in a visual way. The questions in the diaries of the present intervention were not tailored to each participant and they remained the same throughout the intervention period. It might increase the feasibility of the intervention to allow for tailoring of the diary questions and/or providing a level of variation. The time burden for the therapist affects the scalability and cost-effectiveness of the intervention, and strategies to reduce therapist-time should be investigated in further development of this intervention. Formulated algorithms could

automatically tailor the feedback, as done in many mobile-phone delivered behavior change interventions (Heron & Smyth, 2010). However, for complex tailoring, the judgment of an HCP may be needed (Riley et al., 2011). For persons with fibromyalgia, the task of behavior change is challenging, and it was therefore assumed that a degree of therapist contact was needed. The results of this study may indicate that nurses can take the role of the therapist. This was, however, not explored in this thesis, and the questions of necessary qualifications of the therapist remain unanswered.

Since the between-group effects of the present intervention were not maintained at the 11-month follow-up, it would be interesting to explore the effects of adding booster periods with therapist feedback and/or a longer period with less frequent therapist contact, e.g., once a week/month. Also, it could be beneficial to provide an intervention with longer duration including a self-monitoring component and automatic feedback, together with low frequency contact with a therapist, e.g., once a month. Continued support for a longer duration of time may be needed for persons with chronic pain, since it is a hard task to maintain new self-management behavior, which often involves extensive lifestyle changes (Turk & Rudy, 1991). It has even been suggested that it may be unrealistic to expect lasting behavior changes from short interventions (Turk & Rudy, 1991). Some of the ICBT interventions mentioned in the background section may be suited for providing self-management support over a long period and might also be able to provide support following participation in a chronic pain management program. However, the aftercare aspect is still to be investigated. In an implementation phase of a smartphone intervention, it would be necessary to consider possibilities to provide smartphones to those who do not own them or provide other alternatives to ensure equitable health care. An optimal e-health intervention might involve use of the individual's own device of personal preference, e.g., smartphone, a tablet computer or a laptop. Tailoring of the intervention's length and interactivity frequency to personal needs and preferences could also be explored. Use of the individuals' own mobile devices raises ethical concerns on security of the communication that would need to be investigated. Since comorbidity of chronic conditions is common, a generic approach including modules for different illnesses is an exciting research field (Johansen et al., 2012). More research on the cost-effectiveness of different e-health interventions, including ICBT for chronic pain, is still needed (Hedman et al., 2012; McGeary et al., 2012).

7 Conclusion

This thesis is the first to report on a smartphone-delivered intervention with e-diaries and feedback designed to support self-management in persons with fibromyalgia following inpatient rehabilitation. The intervention was generally well accepted by the participants and the positive short- and mid-term effects suggest a promising intervention. The lack of between-group effects at the 11-month follow-up is in line with the literature where effects of pain management interventions are commonly not sustained at long term. This may indicate a need for more continuity and longer durations of interventions to support self-management in persons with fibromyalgia. In close collaboration with persons with fibromyalgia, the smartphone intervention could be adapted to suit as a long-term self-management support. Research on practical, technical, and financial feasibility of implementing the intervention in a clinical setting is needed. The field of mobile e-health interventions for chronic conditions is young, and the state of evidence may still be considered immature. However, our results are in agreement with those suggesting that this field is promising and worth pursuing.

8 References

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Appendix 1: Overview of studies on Internet-based CBT for adults with chronic pain.

Design and sample	Interventions	Outcome measures and results	Notes
RCT (n = 76). Persons with chronic pain recruitment from a pain clinic. Screening interview by telephone. Majority was female. Average pain duration 15 years. 72% with generalized pain. 60% with current psychiatric problem. Majority on sick leave. (Buhrman et al., 2013).	Intervention group: Internet-based ACT for 7 weeks. Included 7 sections, homework sent to a therapist once a week. Therapist-feedback was submitted within 24 hours (on weekdays). To gain access to next module the homework from previous module had to be submitted. Text messages were provided as reminders. Two therapist phone calls were included during the program to enhance motivation and allow for questions. Most exercises were available in audio format. Control group: Online moderated discussion forum for chronic pain (7 weeks), similar to (Lorig et al., 2002).	Primary: CPAQ. Secondary: HADS, QOLI, PAIRS, CSQ, MPI. Post-intervention: Positive between-group effects on CPAQ (Cohen's *d* = .41), HADS-anxiety (*d* = .18), HADS-depression (*d* = .44), CSQ-catastrophizing (*d* = .51) and CSQ-praying and hoping (*d* = .28), MPI-interfering (*d* = .56) and MPI-affective distress (*d* = .30). No effect on QOLI, PAIRS or MPI-pain severity. 6-month follow-up: Maintained effects on CPAQ, HADS (anxiety and depression scales), CSQ. Adherence: Mean number of completed modules was 4.2 (SD = 2.7). 39.5% in the treatment group completed all sections.	Active treatment in the control group. Analysis of covariance (ANCOVA) used. Follow-up results based on paired t-tests for within-group changes in the intervention group only. Low withdrawal rate; 35 of 38 received the ICBT intervention.
RCT (n = 75). Persons with back pain recruited from an inpatient pain treatment unit following a minimum of 1-week multidisciplinary treatment. Mean age 45.2/46.6 years. 57.5/54.3%	Intervention group: Aftercare intervention following multidisciplinary treatment for chronic back pain. Website with an individualized self-monitoring module (filled out once/week) and a weekly 90-min chat session moderated by a therapist (from the multidisciplinary treatment) for 12-15 weeks.	NRS pain, SF-36 pain subscale, RMQ, KPD-38. Primary outcome not specified. Post-intervention: Significant positive effect on disability (reduction in intervention group and increase in the control group), SF-36 pain subscale. No effect on pain level (NRS). Effect sizes not reported. Significant between-group effect on psychological	27% of those assessed for eligible participated. Response rate to post-intervention assessments was 56%, and 67% to 3-month follow-up. Both ITT and PP analyses. Hierarchical linear model used for statistical analysis. 70% (28 of 40) in the intervention group withdrew and did not

women. Most common duration of illness: <2 years. Pain level at discharge 2.3/3.0 (0-10, 0 = no pain) (Moessner et al., 2012).	Short informational meeting at start-up. Control group: Care as usual.	impairment in PP analysis but not in ITT analysis. Usability: The intervention was well accepted by all participants. 68% found the previous chat session helpful. Mean chat sessions attended was 3.8 (SD = 4.2). 38% did not attend any session. 30% attended at least 6 sessions.	receive allocated intervention.
RCT (n = 72). Persons with residual symptoms (functional impairment) 1-5 years after rehabilitation treatment. Symptoms were self-reported and later confirmed in an interview. Exclusion criteria included ongoing severe psychiatric disturbance. Majority (72.2%) of the participants were women. Mean age 40.1 years. Mean pain duration 6.2 years. 86.1% with generalized pain (Buhrman et al., 2012).	Intervention group: 8 weeks of ICBT with e-mail correspondence with a therapist. Participants were asked to work on one module (information and assignments) per week and send their homework to the therapist for advice and feedback. Control group: Participation in a moderated online discussion forum with new discussion topics presented weekly for 8 weeks.	Primary: CSQ – catastrophizing. Secondary: CGI-I, HADS, CSQ, MPI, PAIRS, QOLI. CPAQ. Post-intervention: Moderate between-group effect (Cohen's d = .70) on catastrophizing. Within-group effect was however small (d = .16) in the intervention group. Not significant between-group difference on reliable change on the CSQ-catastrophizing. Large significant effect on CSQ-diverting attention (d = 1.13), but small within-group effect (d = .20). Small between-group effect on HADS, both anxiety (d = .45) and depression (d = .32) subscales. There was a moderate effect (d = .76) on PAIRS. No effect on pain severity, acceptance or quality of life. 6-month follow-up: The effect on catastrophizing persisted for the intervention group at the follow-up. There was generally neither deterioration nor improvement in other outcome measures at the follow-up.	At the 6-month follow-up only within-group changes for the intervention group are reported (because the control group received the ICBT later). 26 of 36 (72%) were completers. ITT analysis with missing values at post-intervention (22%) imputed based on maximum likelihood estimates. 256 were sent an inquiry letter, 112 declined participation and 51 could not be reached. 93 assessed for eligibility. In the intervention group 28% (10 of 36) did not receive the intervention or were lost to follow-up. 8% (3 of 36) withdrew.

RCT (n = 330). Persons with chronic pain, including 25.5% with fibromyalgia. Most common diagnosis was migraine. Recruitment from websites (Ruehlman et al., 2012).	Intervention group: Internet-based self-help program without therapist contact. Duration approximately 6 weeks. Included learning modules with 4 categories, i.e., cognitive, behavioral, social and emotional regulation. Multimedia presentation of material. Interactive activities, e.g., to practice evaluating thought content, assisting in developing an exercise program. Descriptions with photos of different exercise programs. Different tools, e.g., self-monitoring tool and pacing tool. Graphic presentation of data. Included a social networking component with profiles, forum and messages. Control group: Treatment as usual.	PCP (subscales of pain interference, severity, emotional burden, perceived disability, pain attitudes and beliefs, catastrophizing, pain knowledge), 10 items on physical functioning. Results: Small but significant positive effects on pain interference (ES = .30), severity (ES = .20), emotional burden (ES = .25), disability (ES = .10), catastrophizing (ES = .18), pain-induced fear (ES = .12), depression (ES = .06), and anxiety (ES = .15).	Modified ITT analysis. 25 of the 330 randomized failed to participate in any aspect of the study and were excluded from the analyses. 29 of the 165 in the intervention group withdrew but were included in the analyses. Linear growth curve models (post-intervention and 7-weeks follow-up). 25$ fee for completing each assessment.
RCT (n = 189). Inclusion criteria included migraine for at least 1 year with migraine at least 2/month. Recruitment via advertisements. Structured interview to confirm diagnosis. Exclusion criteria included presence of fibromyalgia. 60% in full time	Intervention group: ICBT with 5 core components: education, self-management skills, emotional coping, communication skills and medication safety. It included lessons (interactive instructions), tools (visual interactive learning experiences), self-assessments, user-generated content (shared between participants and presented via text, audio and video). Personalized	DHR, MIDAS, CPCI, HSES, HSLOC, DASS-21, PGIC. Primary outcome not specified. Results: Positive significant between-group effect on catastrophizing, depression, stress, self-efficacy, use of relaxation strategies and social support. Clinically significant changes in depression, anxiety, stress. Effect on pain severity and frequency not reported due to loss of data.	Linear mixed modeling. 4 assessment timepoints, i.e., at baseline, 1 month later, 3 months later and 6-months later (post-intervention). 425 persons screened for eligibility. 213 participants enrolled in the 2-week run-in period. During this period 24 persons dropped out. The remaining 189 persons were randomized in to the two groups. 44 of the

employment (Bromberg et al., 2012).	recommendations tailored to users' priorities and needs. Run-in period of 2 weeks with daily pain diaries. Participants received instructions on the use of the website, i.e., to complete a minimum of 8 20-minute sessions during a four-week period and a minimum of one 20-minute follow-up sessions per months during a 5-month follow-up period. E-mail used to provide reminders. Control group: Waiting list.		94 in the intervention group and 74 of the 95 in the control group returned the 6-month questionnaire (post-intervention). 19 withdrew, 14 from the intervention group and 5 from the control group. $25 for completion of each assessment.
RCT (n =141). Persons with chronic low back pain included. Recruitment via the internet. Screening by a telephone interview. Women were in majority (Carpenter et al., 2012).	Intervention group: 3-week ICBT comprising a website with 6 modules (189 pages in total). Information (workbook) on pain, thoughts and pain, stress and relaxation, getting active, relaxation and meditation (included 15-20 minutes of different audio exercises). Material presented in different formats, e.g., text, graphics, animation, patient stories, reflective exercises, interactive exercises, and audio. Control group: Waiting list.	Primary: SOPA. Secondary: FABQ, NMRS, PCS, RMDQ, QPSS, DPAQ. Usability/satisfaction questionnaire. Post-intervention: Significant between-group multivariate effect. Univariate tests indicated significant effect (moderate to large effect sizes) on all variables except medical cure subscale of SOPA, work subscale of FABQ and pain severity rating. Moderate effect on catastrophizing. 3-weeks follow-up: Both groups had by then received the intervention. As hypothesized, no difference between groups. Usability: 59% reported using the site at least 6 hours per week and 28% for at least 10 hours per week. 81% completed all 6 chapters.	Theoretical content was based on CBT and ACT. Fee of $135 for completing assessments. Single MANCOVA including scores on all the subscales and controlling for baseline individual differences (to limit Type I error inflation). No effect on pain severity. Not ITT analysis. Participants that did not complete two thirds of the interventions were considered dropout and were not invited to fill out assessments. 5 of 70 in the intervention group did not complete the intervention.

RCT (n = 54). Persons with chronic back pain included. Recruitment via advertisements. Face-to-face interview prior to inclusion. High level of depression symptoms was an exclusion criterion. Inclusion criteria included being employed or on a short-term sick leave (max 6 months) (Buhrman et al., 2011).	Intervention group: 8 weeks of ICBT (e.g., education, training of cognitive skills, behavioural rehearsal, mindfulness exercises). Daily pain diary for 2 weeks before intervention and 2 weeks after. E-mail contact with therapist (who responded to questions, gave feedback and encouragement). One structured telephone call during the intervention period to provide opportunity to ask questions and get information about the experience of participation. Control group: Waiting list.	Primary: CSQ - catastrophizing. Secondary: HADS, MPI, PAIRS, QOLI. Post-intervention: Significant difference in CSQ-catastrophizing and quality of life (QOLI). Significant difference in numbers of participants who showed reliable improvement in catastrophizing (58% in the intervention group and 18% in the control group). Changes in QOLI were mainly due to reduction in the control group. No significant difference in other subscales of CSQ or MPI, PAIRS or HADS.	80 persons showed interest, 60 fulfilled criteria. ITT analysis. Reported as underpowered. ANOVA and multivariate analysis of variance (MANOVA). Dropout 7.4% (4 of 54).
A 3-armed RCT (n = 83). Persons with migraine included. Online recruitment (Hedborg & Muhr, 2011).	Intervention group I: ICBT with daily diaries and information on self-management (53 text pages). Diaries for 2 months and again 7 months later for 2 months. Intervention period of 11 months. CD with relaxation exercises provided. The possibility to make inquiries via e-mail or phone was provided. Face-to-face meeting at the start. Intervention group II: The same ICBT as in group I but with hand massage by a collaborator as an additional stress management component. Control group: Diary for 2	MADR-S, PQ-23, feasibility questions. Primary outcome not specified. Post-intervention: 42% of the participants in the intervention group I reported 50% or more improvement in headache frequency, compared with 15% in the control group ($P < .05$). No improvement in depression or quality of life. Feasibility: 95% of the responders rated the cognitive elements of the interventions as the most rewarding parts.	8.4% withdrawal rate (7 of 83). Dropouts were excluded from analysis, i.e., PP analysis only.

	months and a CD with relaxation exercises.		
RCT (n = 118). Persons with fibromyalgia included. Referral by physician. Exclusion criteria included severe psychiatric disorder and prior CBT for pain management. The majority was female (95%) (Williams et al., 2010).	Intervention group: ICBT with 13 modules. Duration of intervention was 6 months. Each module included a video with a lecture by a clinician, reading material, homework and self-monitoring forms. No therapist contact. Control group: Care as usual.	Primary: SF-36, physical functioning and BPI. Secondary: MFI, MOS Sleep Scale, CES-D, STPI, PGIC. Post-intervention: Positive between-group effect on pain (Cohen's d = .64) and physical functioning (d = .38). No effect on fatigue, sleep and mood variables. No follow-up results reported. Adherence: At least 1 module was used each month by most of the sample. 91% were generally satisfied with the intervention. 79% reported finding the intervention helpful.	Withdrawal rate was 10.2%. ITT-analysis.
Feasibility study. 40 women with fibromyalgia included. Recruitment via advertisments and diagnosis confirmed in a telephone interview.(Collinge, Soltysik, & Yarnold, 2010).	Website with interactive self-monitoring and feedback system. It involved longitudinal collection and optimal analysis of an individual's self-monitoring data, and delivery of personalized feedback derived from the data. Duration 13 weeks. Start-up meeting. Recommended registration at least 3-4 times per week. Registration of lifestyle behaviors, self-management behavior, stressors and symptoms. Weekly posting of feedback based on data (summarized in a narrative about statistically significant	FIQ, SF-12, SECDS, HLCS. Usability data. Feasibility: High utilization (mean 4.05 times per week), satisfaction and compliance. Higher utilization was predictive of lower anxiety and improved physical functioning and self-efficacy. Within-group changes in outcome measures not clearly reported.	Compensation fee for use of system (up to 5 times/week). 1 dropout.

	associations between registered activities and symptom levels).		
RCT (n = 209). Persons with chronic back pain recruited online and from a pain treatment clinic. Exclusion criteria included fibromyalgia and rheumatologic disorders (Chiauzzi et al., 2010).	Intervention: Four-week ICBT followed by 5 monthly booster visits to the website. The participants were asked to spend at least 20 minutes twice each week during the four-week period. The website included components to support decision making with HCP, improve self-efficacy, emotional management, goal setting, prevent pain relapses, motivational enhancement through tailored feedback, tailored self-management information, interactive tools and articles. No therapist contact. Control: E-mail with a back pain guide in text format. No maintenance component.	BPI, ODQ, DASS, PGIC, CPCI, PCS, PSEQ, FABQ. Primary outcome not specified. Assessments at 4 timepoints (baseline, 1-, 3- and 6- month post-baseline). No follow-up assessment after the booster period. Positive between-group effect on perception of stress, active coping and social support. No between-group effect on pain. Clinically significant within-group changes in pain, depression, anxiety, and global rates of improvement in the intervention group only.	Linear mixed model analysis. 10 participants found ineligible after randomization and excluded from analysis. All others included in analysis, i.e., ITT analysis. Fee of 50$ for each completed assessment. Withdrawal rate not clearly reported. Response rates between 72-99%.
Feasibility study. 371 persons with chronic back pain filled in baseline data. 129 answered post-intervention data. (Schulz et al., 2010).	Intervention: Website with information in written format, audio and videos. Interaction between participants in moderated forums and chat rooms. Once a week possibility for a chat with HCP. Section with answers from specialists and a library with patient histories. The websiste was available for 12 months.	Intensity of use assessed with number of days logged on to the website and total time spent on the website. Qualitative interviews on participants experience with use of the website. Most participants visited the site only a few times. Most popular modules were the library, gym and forums. Reduction in use of painkillers was reported by the subgroup that submitted both pre-and post data.	Based on the health literacy concept. 107 of 371 participants filled in both pre- and post-data. Also reported on in a previous pilot study wich provided modest indications for positive effects on physical activity, reduction in pain-relievers use and increase in knowledge. No information on significance levels

			reported (Schulz, Rubinell, & Hartung, 2007)
Feasibility study. Persons with migraine included. Utility assessment (n = 44). Two groups with intervention group and a matched control group to assess preliminary effects (n =62). Online recruitment. **(**Kleiboer et al., 2009**).**	Intervention: Delivered with PDA with Internet facility. Included a self-monitoring feature with e-diaries to support timely detection of precursors of migraine and a coaching/feedback component. The feedback was tailored to the registrations from the diaries. The goal was to reinforce preventive self-management behavior against migraine attack. The feedback containted remarks regarding the reported state, tips for preventive action and positive reinforcement. 4 daily e-diaries and feedback twice/day. The feedback was written by a clinically trained assistant. Provided as an adjunct aftercare/refresher intervention at the end of/following a 10-week group behavioral training. Two 3-weeks periods with 10-weeks apart. Control group: Matched group (on gender, age, education, migraine attack frequency). Received the same 10-week behavioral training.	Primary: Paper and pencil headache frequency diaries for four weeks. Secondary: HSPLCS, SPQLQ. Feasibility: Minimal technical problems and good compliance. Well accepted by participants regarding usefulness, supportiveness and low burden. Preliminary effects: No between-group difference on outcome measures.	A previous pilot study also concluded that this intervention was feasible and well accepted (Sorbi et al., 2007). Mainly based on behavioral training, but also involved cognitive-behavioral self-regulation skills. 5 of 44 in the intervention group withdrew. Follow-up data was available for 31 in the intervention group. PP analysis of complete cases data. 50 Euros were paid for participation.
Published before the present RCT			

RCT (n = 89). Persons 55 years or older with chronic pain included. Recruitment from community-based settings. Screening in a telephone call and a baseline interview at home. 87% women, mean age 66 years. (Berman, Iris, Bode, & Drengenberg, 2009) (e-pub 2008).	Intervention: 6-week ICBT comprising 6 self-care modules to be visited in any order. Included exercises such as abdominal breathing, relaxation, writing about positive/difficult experiences, creative visual expression and positive thinking. Audio, visual and textual material. E-mail prompts sent by a research assistant/nurse. Online self-assessments of pain levels monitored by the study nurse. Control: Waiting list	HRQOL-14, BPI, PSEQ, CES-D 10, STAI-6, PAQ. Questions on use of self-care techniques. Feasibility questions. Post-intervention: Significant differences in awareness of responses to pain (PAQ) between the groups but not on other outcomes. Both groups improved on several variables but only significant difference on one outcome variable (on this variable there was a decline in the control group). Follow-up results not reported. Feasibility: Found helpful and easy to use by majority. The mean number of visits was 22.5 times during the 6-week period.	ITT analysis not included. 12.4% (n=11) did not respond to post intervention assessment and were not included in the analysis. Fee of 100 USD for completing the follow-up interview. The study was reported as underpowered.
RCT (n = 855). Individuals diagnosed with rheumatoid arthritis, osteoarthritis or fibromyalgia. Recruitment via announcements both online and in paper format. Mean age 52 years. About 90% female. >90% non-hispanic white. About 50% had fibromyalgia. Most subjects had diagnosis confirmed by a	Intervention: Internet-based Arthritis Self-management program for 6-weeks. Designed to replicate the content of small-group peer-leaded self-management program found to be effective for arthritis. The website consisted of information, interactive instructions, peer-leaded online discussion forum, tools such as exercise logs, medication diaries and tailored exercise programs. Control group: Usual care.	Pain, fatigue (NRS). HDS, SRGHS, ALS, HAQ-8, ASES, 4 health-related behaviors. Primary outcome not specified. 6-month follow-up: Significant improvement in health distress, activity limitation, self-reported global health, self-efficacy and pain in the intervention group compared to the control group. There was not significant effect on health behaviors or health care utilization. No significant effect on any of the outcome measure for the subgroup of those with fibromyalgia. Follow-up 1 year after baseline: The effects at 6-month follow-up were maintained.	Based on self-efficacy theory and a cognitive behavioral approach. 50% of those who showed interest in participation submitted informed consent and baseline questionnaire. A gift certificate of 10 USD was given to the control group subject for each questionnaire submitted. ITT analysis with LOCF included.

physician (Lorig et al., 2008).			
RCT (n = 68). Women with fibromyalgia (for < 5 years) on sick leave. Recruitments via advertisements (Brattberg, 2008).	Intervention group: 8-week of self-administered emotional freedom techniques. Distress rating sheet e-mailed to the study leader once a week. When needed instructions were given via email. Control group: Waiting list.	SF-36, HADS, PCS, CPAQ, GSE, SUDS. 8-week follow-up: Statistically significant between-group effects on pain, anxiety, depression, vitality, social function, mental health, pain catastrophizing and activity engagement (CPAQ). Effect sizes not reported.	40% withdrew from the intervention group and 16% from the control group. PP analysis with complete cases. Emotional freedom techniques categorized as within the CBT umbrella in this table due to the emphasis on acceptance and coping.
RCT (n = 60). Persons with chronic pain and/or burnout on sick leave for at least 6 months. Recruitment through advertisements.	Intervention group: 20 weeks rehabilitation program based on 19 films, written material, reflective questions and a discussion forum (with medical expert and a patient expert) delivered via the Internet. Started with a half-day introductory group meeting. Control group: Waiting list.	SF-36, HADS, Stress Barometer. Post-intervention: Significant between-group effects on depression, several items on SF-36 (role-physical, bodily pain, vitality, social functioning) and on several stress symptoms. Follow-up: No difference between group on SF-36, HAD or Stress Barometer. More increase in work capacity was reported in the intervention group (52%). compared to the waiting-list group (13%), *P* = .005.	Withdrawal rate was 10% in the intervention group and 7% in the control group. Unclear if diagnoses were clinically confirmed. Intervention group included 7 with fibromyalgia, the control group included 12. Deterioration in the treatment group and improvement in the control group seen at the 12-month follow-up. 83.3% response rate. ITT analysis not applied.
RCT (n = 156). Persons with chronic tension and/or migraine headache for at least one year. Mostly online referral sources.(Devineni & Blanchard, 2005).	Intervention I: (for those with tension-type headache). Four-week access to a website with information and exercises on progressive muscle relaxation and cognitive stress coping therapy). Intervention II: (for those with migraine- only or mixed headache). Four-week	HSQ, CES-D, STAI, HDI. Headache frequency diaries. Post intervention: Significant between-group effects in HSQ and HDI. No difference in anxiety or depression. 2-month follow-up: Treatment effects maintained at follow-up in completers.	The dropout rate was 38.1% among those who began treatment. Higher if all enrolled were counted. 86 completed post-treatment assessments, 49 the follow-up assessments (response rate 35.2%). PP analysis.

	access to a website with information and exercises on stress management and autogenic training. Control group: Symptom-monitoring, i.e., online diary for 2 weeks. Waiting list. A feedback of the assessment results was offered after the follow-up assessment.		
RCT (n = 56). Persons with chronic back pain. Recruitment via advertisement (diagnosis not clinically confirmed). Mean age 44.6 years. Mean symptom duration 10.1 years. 32% were on sick leave. 69% were females. (Buhrman, Fältenhag, Ström, & Andersson, 2004).	Intervention group: 6-week of ICBT with weekly telephone support from a therapist. 2 x 1 week of self-monitoring with 3 daily diaries (paper-and-pencil/online), 1 week before the ICBT and 1 week after it. The website contained information and exercises (written and audio format). The telephone calls were short and had the purpose of providing encouragement and motivation. E-mail contact with the therapist was available. Control group: Waiting list.	Primary: CSQ. Secondary: MPI, PAIRS, HADS. Pain diary. Post-intervention: Significant positive between-group effects on several subscales of the CSQ, i.e., catastrophizing, control over pain and ability to decrease pain. No between-group effects on MPI, HADS or pain level. Significantly more in the intervention group (39%) showed reliable change in catastrophizing (Jacobson's reliable change index) in the intervention group than in the control group (14%). 3-month follow-up: Positive within-group changes (baseline to 3-month follow-up) in several outcomes, i.e., PAIRS, catastrophizing, control of pain.	56 of 67 eligible participants were interested in participating. Dropout rate was 9%. Response rate to follow-up assessment was 92%. PP analysis. Reported as underpowered.
RCT (n = 44). Persons with chronic headache (at least 6 months). Telephone call with a clinician to semi-confirm diagnosis.	Intervention group: 6-week ICBT with e-mail support from a therapist (very similar to the intervention reported on in (Ström et al., 2000). Included information and	HADS, PSS, HDI, CSQ. Post-intervention: In both groups, there were significant within-group changes found on depression, disability, stress and several several subscales of CSQ, i.e., catastrophizing,	Not a significant difference in dropout rates between the groups; 29% in the intervention group and 35% in the control group. 106 showed interest in

Serious psychological disorder was an exclusion criterion. Various diseases were exclusion criteria, including fibromyalgia. Mean age was 40.3 years. (Andersson, Lundström, & Ström, 2003).	exercises in text and audio format. Weekly telephone contact with a therapist to enhance adherance. The telephone calls were scheduled and lasted between 5-20 minutes. Control group: The same ICBT with e-mail support but without the telephone calls. Both groups: Daily registrations (headache diary 4 times/day including maximum and average pain intensity and pain duration) for 2 weeks before and after the treatment.	reinterpreting pain sensations. There was a significant between-group difference on the CSQ – ignore pain sensations No significant between-group effects on other outcome measures. Follow-up: Not reported.	participating, 44 were included. 29% in the intervention group reached a clinically significant improvement in pain index (based on the diaries) and 23% in the control group (not a significant difference between groups).
RCT (n = 580). Persons with chronic recurrent back pain, with at least 1 outpatient visit due to the pain in the past year. Recruitment via a website. (Lorig et al., 2002).	Intervention: 1 year of closed, moderated, e-mail discussion group, videotape and a book about constructive self-management of back pain. Control group: Subscription to a non-health-related magazine of their choice.	Pain level (VNS), RMS, IIS, HDS. Post-intervention: Significant positive between-group effect on disability, health distress, pain interference, role function, self-care orientation and self-efficacy and in reduction of physician visits. Follow-up: Not reported. Feasibility: 69% sent 1 or more e-mail to the group. 41% reported reading most or all e-mails. 68% watched the entire videotape. 33% read the entire book.	Not a forum, communication via e-mail to all members of the group. 107 of 296 in the intervention group withdrew; 43 of those returned to the intervention later during the study period. ITT analysis with LOCF included. Respose rate to post-intervention assessments was 64%.
RCT (n = 102). Persons with recurrent headache for at least 6 months. Recruitment via	Intervention: 6-week ICBT with written information and exercises. New material sent each week. Content included applied relaxation and problem-solving training.	Headache index (diaries), BDI, HDI, MLPC. Post-intervention: 50% in the intervention group showed clinically significant improvement (reduction of	56% withdrew, 20% withdrew before the ICBT started. 20 participants completed the intervention group. 14 in the intervention

advertisement (diagnosis not confirmed by a clinician). Serious psychological disorder was an exclusion criteria (Ström et al., 2000).	Participants registered their use of the relaxation exercises and send a weekly rapport by email to the therapist. Participants could communicate with the therapist by email (e.g., send questions, comment on information). Control group: Waiting-list. Both groups: Daily (once/day) headache diaries (duration, intensity, medication use) for 4 consecutive weeks before intervention start and after.	symptoms by 50% or more), 4% in the control group (P = .002). No difference in medication use, depression or disability between the groups. Follow-up: Not reported.	group and 11 in the control group filled out BDI and HDI post-treatment. PP analysis presented.

ALS = Activities limitation scale; ASES = Arthritis self-efficacy scale; BDI = Beck depression inventory; BPI = Brief pain inventory; CES-D = Center for epidemiological studies depression scale; CGI-I = Clinical global impression – improvement scale; CPAQ = Chronic pain acceptance questionnaire; CPCI = Chronic pain coping inventory; CSQ = The coping strategies questionnaire; DASS = Depression anxiety stress scale; DHR = Daily headache record; DPAQ = Demographics and pain assessment questionnaire; FABQ = Fear avoidance beliefs questionnaire; GSE = General self-efficacy scale; HADS = Hospital and anxiety depression scale; HAQ = Health assessment questionnaire; HDI = Headache disability inventory; HDS = Health distress scale; HPSLCS = Headache specific locus of control scale; HRQOL = Health-relatad quality of life instrument; HSES = Headache management self-efficacy scale; HSLC = Headache-specific locus of control; KPD = Klinisch psychologishce diagnosesystem (psychological impairment); MDRS = Montgomery-Åsberg depression rating scale; MFI = Multidimensional fatigue inventory; MIDAS = Migraine disability assessment questionnaire; MLPCQ = Multidimensional lovus of pain control questionnaire; MOS sleep scale = Medical outcome studies sleep scale; MPI = Multidimensional pain inventory; MSQOL = Migraine specific quality of life questionnaire; NMRS = Negative mood regulation scale; NRS = Numeric rating scale; PAIRS = Pain and impairment relationship scale; PAQ = Pain awareness questionnaire; ODQ = Oswetry disability questionnaire; PCP = Profile of chronic pain; PCS = Pain catastrophizing scale; PQ23 = Quality of life questionnaire developed at the Uppsala University (Sweden); PSEQ = Pain self-efficacy questionnaire; PSS = Pain self-efficacy scale; QOLI = Quality of life inventory; RMQ = Roland-Morris questionnaire (disability); SF = Short Form; SOPA = Survey of pain attitudes;; STPI = State-trait personality inventory; SRGHS = Self-rated global health scale; STAI = State-trait anxiety inventory; SUDS = Subjective units of distress scale for the experienced pain, the influence of pain and stress.

Appendix 2: Questions in diaries (in Norwegian).

Morgenskjema RCT 030309

View Form Responses

field	type
1. Da jeg våknet i dag hadde jeg ...	select
2. Jeg har sovet ... timer i natt	select
3. Nattens søvn var...	checkboxes
4. I formiddag har jeg tenkt å...	checkboxes
5. Hvis du svarte "annet" på forrige spørsmål vennlig skriv hvilken aktiviteter her	textfield
6. Akkurat nå føler jeg meg i godt humør	select
7: Akkurat nå føler jeg meg tung til sinns	select
8: Akkurat nå føler jeg meg avslappet	select
9: Akkurat nå føler jeg meg irritert	select
10: Akkurat nå føler jeg meg trist	select
11: Akkurat nå føler jeg meg engstelig	select
12: Akkurat nå føler jeg meg tilfreds	select
13: Akkurat nå føler jeg meg trett	select
14: Akkurat nå føler jeg meg entusiastisk	select
15. Akkurat nå føler jeg meg ensom	select
16: Akkurat nå føler jeg meg frustrert	select
17. Akkurat nå er pusten min dyp og avslappet	select
18. Hvis du har noen kommentarer, vennligst skriv de her	textarea

Randomskjema RCT 040309

View Form Responses

field	type
1. Hva gjorde jeg da jeg fikk tekstmelding?	textfield
2. Jeg hadde holdt på med det ... da sms-en kom	select
3. Ble jeg hindret i dette av smertene mine?	select
4. Hvem er jeg sammen men akkurat nå?	checkboxes
5. Siden forrige skjema har jeg ...	checkboxes
6. Hvor tilfreds er jeg med det jeg har gjort siden forrige skjema?	select
7. Resten av dagen har jeg tenkt å gjøre følgende aktiviteter	checkboxes
8. Hvis du svarte annet på forrige spørsmål, vennligst skriv hva du har tenkt å gjøre	textfield
9. I forhold til smertene akkurat nå så har jeg ...	select
10. Er det aktiviteter jeg ville gjort nå hvis jeg ikke hadde hatt smerter?	select
11. Hvis du svarte ja på forrige spørsmål, hva kunne du tenkt deg å gjøre?	textfield
12. Er det aktiviteter som jeg gjør litt roligere på grunn av smertene?	select
13. Hvis du svarte ja på forrige spørsmål, hva gjør du roligere?	textfield
14. Akkurat nå tør jeg ikke bevege så mye på meg på grunn av smertene	select
15. Akkurat nå er jeg bekymret for at smertene ikke vil gi seg	select
16. Akkurat nå føler jeg at jeg bruker det jeg har lært som bidrar til å holde smertene under kontroll	select
17. Akkurat nå tåler jeg smertene godt	select
18. Akkurat nå prøver jeg å unngå aktiviteter som gjør at jeg får vondt	select
19. Akkurat nå gjør jeg det jeg vil, også hvis det fører til forverring av smertene eller fører til at de kommer tilbake	select
20. Akkurat nå bruker jeg noen strategier som hjelper meg bedre å takle smerteproblemene	select
21. Akkurat nå er jeg redd for smerten	select
22. Akkurat nå føler jeg at er ingenting jeg kan gjøre for å redusere smertens intensitet	select
23. Akkurat nå tror jeg det er skadelig for kroppen min å bevege seg	select
24. Akkurat nå føles det som jeg ikke holder ut pga smertene	select
25. Akkurat nå føler jeg at jeg lever et godt liv selv om jeg har langvarige smerter	select
26. Akkurat nå er pusten min dyp og avslappet	select
27. Hvis du ønsker å bemerke noe annet, vennligst skriv her	textarea

Kveldsskjema RCT 030309

View Form Responses

field	type
1. Siden forrige skjema har jeg...	checkboxes
2. I forhold til aktivitetsnivået mitt idag er jeg	select
3. Nå har jeg	select
4. I dag fikk jeg gjort det jeg ville og trengte tiltross for smertene mine	select
5. Nå føler jeg meg i godt humør	select
6. Nå føler jeg meg avslappet	select
7. Nå føler jeg meg tung til sinns	select
8. Nå føler jeg meg irritert	select
9. Nå føler jeg meg trist	select
10. Nå føler jeg meg engstelig	select
11. Nå føler jeg meg tilfreds	select
12. Nå føler jeg meg trett	select
13. Nå føler jeg meg entusiastisk	select
14. Nå føler jeg meg frustrert	select
15. Akkurat nå føler jeg meg ensom	select
16. Akkurat nå føler jeg meg takknemlig	select
17. Akkurat nå er pusten min dyp og avslappet	select
18. I dag har tilbakemeldingen støttet meg til å...	checkboxes
19. Hvis du svarte "annet" på forrige spørsmål, vennligst oppgi hva her	textfield
20. I dag har jeg gjort oppgaven(e) jeg fikk i meldingen	select
21. Jeg har ikke gjort oppgavene fordi...	textfield
22. Før jeg legger meg for natten...	checkboxes
23. Hvis du svarte "annet" på forrige spørsmål, vennligst oppgi hva her	textfield
24. Hvis du har noe å bemerke, vennligst skriv det her	textarea

Appendix 3: Examples of feedback (in Norwegian)

Hei. Gratulerer med å ha klart fire ukers intensivt og krevende opptreningsopphold!
Kan du bruke par minutter til å kjenne etter hvordan det føles å være ferdig med oppholdet? Hva har forandret seg? Hva er det viktigeste som du har lært? Er det noe som du fikk til under oppholdet som du kanskje ikke hadde trodd på forhand at du ville klare? Nå er du på vei mot et liv med mindre smerter og mer aktivitet - du har sikkert allerede forandret på noen helsevaner - utfordringen de neste ukene blir å anvende det du har opplevd nyttig på Jeløy i hverdagslivet hjemme. Særlig nå i starten vil dette kreve innsats men etterhvert vil det bli til en etablert vane og føles mye mindre krevende.Virker som du har hatt en aktiv formiddag og har planer om en aktiv ettermiddag. Flott at du får gått en tur, tøyet ut og gjort avspenningsøvelser tiltross for 6 på smerteskalaen. Ha en fin ettermiddag, hilsen X

Hei. Du klarer å være aktiv tiltross for 6 på smerteskalaen. Veldig bra at du har tatt avspenningsøvelser og gått tur. Du nevnte på møtet vårt at dette med å begrense seg litt i forhold til oppgaver og aktivitet ville være en utfordring. Kan du reflektere litt over balansen du har mellom aktivitet og hvile? Hvordan kan du få til en god balanse for deg? Hvilken forandring må til? Når du holder på med omsorgsarbeidet kan du gi deg et lite pusterom innimellom? – bare for at bevisst senke skuldrene og puste dypt et par ganger.
Før helgen foreslår jeg at du setter av litt tid til å tenke på verdiene dine. Hva er meningsfylt for deg? Hva har du lyst til? De fleste med langvarige smerter ønsker seg naturligvis å bli kvitt smertene – men hvis du ikke hadde smerter hva ville du gjort og hatt lyst til å gjøre? Et av poengene med å tenke over dette er å sette det du synes er meningsfylt litt i fokus – fordi det å ha levd med sterke smerter over lengre tid kan bety at smertelindring har vært førsteprioritet så lenge at mye annet meningsfylt har blitt nedprioritert. Så bruk gjerne litt tid på å tenke over disse spørsmålene. Tenk etter hva du selv ønsker uansett hvor urealistisk du føler at det er akkurat nå. Verdi er noe du selv har valgt og funnet ut at du synes er meningsfylt (f.eks. at være et familiemedlem som gir seg tid til å lytte, gi av seg selv og gjøre noe hyggelig i felleskap). Når man er klar over at en egenskap eller aktivitet er noe man verdsetter kan man bevisst bevege seg mot denne verdien. Smertene kan kanskje føre til at skrittene man tar ikke er så store – men man kan uansett bevege seg i ønsket retning og det kan kanskje være motiverende og meningsfylt i seg selv. Kan du starte med å tenke på spørsmål som: Hvordan ønsker jeg å være som person? Hvordan ønsker jeg å være som partner? Hvordan vil jeg være som venn? Hva engasjerer meg? Hva liker jeg å gjøre som gir meg glede? Dette er store spørsmål, men det å gi seg litt tid til å tenke over dem kan ha verdi i seg selv – man blir mer bevisst på dette og det kan påvirke hva man velger å gjøre. Hvis du har muligheten, kan du notere hva du tenker rundt verdiene dine i en dagbok? I den kan være nyttig å skrive om for eksempel verdier, drømmer, mål, framgang og mestringsstrategier. Lykke til og god helg. Hilsen X

Hei. Du er helt enig i påstanden om at du nå prøver å unngå aktiviteter som gjør at du får vondt og at du er usikker på om du er redd for smerten. Likevel klarer du å gå en tur selv om smertene hindrer deg noe i dette. Det er positivt at du ikke lar være å gå tur pga smertene eller tankeinnholdet ditt i forhold til dem. Skjønner godt at du er tilfreds med egen innsats. Du er helt enig i påstanden om at det føles som du ikke holder ut pga smertene. Ofte dukker negative tanker lettere opp når man har smerter og innholdet i disse tankene trenger ikke å være noe sannhet men de kan lett bidra til følelser som håpløshet, tristhet og sinne. Derfor kan det være viktig og nyttig å prøve å bli bevisst på disse negative tankene slik at de i mindre grad påvirker følelser og handlinger. Det gjør du for eksempel men den øvelsen jeg foreslo i går (og kommer til å foreslå flere ganger). Kan du i kveld (og helst de neste kveldene) identifisere tre ting du er spesielt fornøyd med akkurat nå, glad for eller takknemlig over? Kan du reflektere over hvorfor du er fornøyd med disse tre tingene/handlingene/situasjonene? Skriv dette gjerne ned i en dagbok hvis du har en. Håper det går bra på jobben. Hilsen X

Hei. I går registrerte du at du fikk gjort det du ville og trengte tiltross for smertene. Det kan virker som det er du som styrer hva du gjør og ikke smertene. Hvordan føles det å være tilbake på jobb? Har du i bakhodet dette med å prøve å begrense arbeidsmengden litt av hensyn til kroppen? I morges registrerer du 6 på smerteskalaen OG godt humør, at du er tilfreds og avslappet. Det vil jeg tro krever en aksepterende og positiv holdning. Kan du bruke noen minutter i kveld til å tenke på hvilken verdier du har i forhold til arbeidet ditt? Hvordan vil du være som medarbeider? Hvilken egenskaper ønsker du å vise på jobben? Hva liker du best ved jobben din? Blir nok fint å gå en tur i det fine været i ettermiddag. Hilsen X

Hei. Du registrerer at du er tilfreds, uthvilt og entusiastisk i morges tiltross for at søvnen har vært forstyrret av smertene. Så flott at du har fått bassengtreningen i orden og at du har funnet ut måte å fortsette med triggerpunktbehandling. Det virker som du har fått veldig god rutine på å gå tur og gjøre øvelser for å tøye ut og avspenne musklene. Flott! Kan du sette av ca 5 minutter i dag eller kveld til å gjøre en oppmerksomhetsøvelse? Finn en mest mulig behagelig stilling og pust dypt og rolig (best å være i stillhet, gjerne med øynene lukket). Rett oppmerksomheten mot pusten så godt du kan. Du puster som det er naturlig for deg å puste. Kanskje oppdager du at det ikke er så lett å fokusere på pusten fordi forskjellige tanker og følelser dukker automatisk opp. Det er veldig naturlig. Øvelsen går på at prøve å fokusere på pusten igjen etter å ha registrert hvilken tanker/følelser dukket opp. Prøv å kun observere tankene/følelsene og ikke å dvele ved dem. Hvis det for eksempel oppstår en ubehagelig tanke så prøver man at ikke være dømmende, bare registrere "her var det en ubehagelig tanke" og prøve igjen å fokusere på pusten. Poenget med en slik øvelse er å distansere seg litt fra noe av den negative tankeflommen man ofte har i hodet. Med sånne øvelser kan negative tanker etter hvert misse noe av vekten sin ved at man blir mer bevisst på at tanker ikke nødvendigvis gjenspeiler hverken virkeligheten eller en sannhet. Ha en fin dag, hilsen X

Hei. Du gjør deg klar for årets skitur – så spennende! Siden dette er nest siste tilbakemeldingen har jeg lyst til å skrive en liten oppsummering. Den første uken hjemme registrerte du smerter på 6 og 7 på smerteskalaen, de neste tre ukene har gjennomsnittet vært 5. Om smertene har blitt litt mindre eller at du tåler dem litt bedre er det bare du som vet. Uansett kan det tyde på at det du gjør har bidratt til noe redusering av smertene. I begynnelsen var du enig i påstanden "Akkurat nå er jeg bekymret for at smertene ikke vil gi seg", de siste ukene er du oftere usikker eller uenig i dette. Tror du at en sånn tanke kan påvirke smerteopplevelsen? Nettene dine er som regel forstirret av smertene, men tiltross for det har du ALLTID registrert godt humør og ALDRI frustrasjon om morningen – kan det være at du på et vis har akseptert disse smerteplagene på nettene? Du har oftest registrert at smertene hindrer deg litt i det du gjør og at du føler at du unngår noen aktivitetsformer pga smertene. Men i dag gjør du deg altså klar for en skitur! Og hvis jeg har talt riktig så har du registrert godt over 30 turer! Uttøyning og avspenning virker som du har fått gjort i hvert fall annen hver dag. På oppstartsmøtet vårt på Jeløya nevnte du at hadde som mål å gå mye turer, gjøre uttøyningsøvelser og fortsette med bassengtrening. Dette har du klart! Du nevnte også at du skulle prøve å begrense deg litt i forhold til jobben – hvordan går det føler du? Du har registrert at du har vært tilfreds eller meget tilfreds med dagens aktivitetsnivå. Dette selv om du føler at du må unngå noen aktiviteter. Du tror ikke det er skadelig for kroppen å bevege seg og du er som regel ikke redd for smertene. Om du føler at du holder ut pga smertene varierer dag fra dag men du er ofte usikker på dette – det å ha langvarige smerter kan ikke være lett og det vekker naturligvis mange følelser – prøv å gi deg selv rom til å bli kjent med de følelsene det å ha langvarige smerter vekker hos deg selv – noen snakker om å prøve å bli venn med de følelsene og tankene som smertene vekker og prøve å akseptere disse – samtidig som man gjør det man kan til å redusere smertene på sikt. Ha en fin dag! Hilsen X

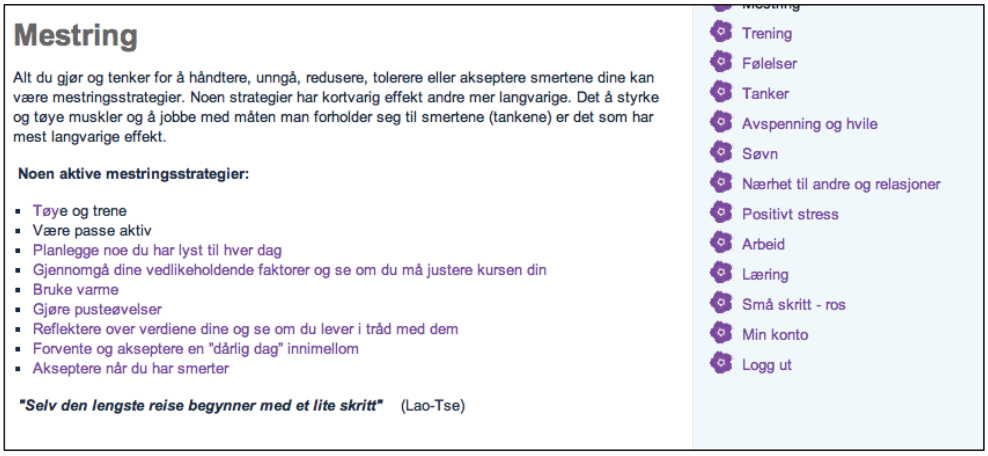
Hei. Hyggelig å få beskjed om å du opplever støtte fra meldingene. Det er motiverende for meg! Virker som du har hatt en helg med sterke smerter og mye aktivitet. Flott at du har få prioritert trening, avspenning og uttøyning! Kan virke som du hadde en kveld med litt tunge tanker og følelser i gårkveld. Der du registrerte tristhet, ensomhet og frustrasjon. I følge registreringen følte du deg noe lettere til sinns i dag tidlig. Hvordan vi har det med oss selv svinger - selvsagt. Ofte finnes det jo åpenbare konkrete grunner til det også - men noen ganger er det ikke så lett å oppfatte årsaken til å at humøret eller følelsene forandre seg. Hva kommer først - tanker eller følelser? Tanker med bestemt innhold (f.eks. minner eller selvkritikk) kan helt klart påvirke følelsene,. Negative følelser kan sikkert også påvirke tankeinnhold, tanker med negativt innhold når lettere fram og vi tror letter på det innholdet heller i et annet moment når vi er glade. Poenget er at det kan være nyttig å være bevisst på både tankeinnhold og følelser og legge merke til hvordan disse påvirker hverandre og hva vi velger å gjøre eller ikke gjøre. På meg virker det som du er bevisst på hvordan du har det - men dette er noe man stadig kan trene på å bli bedre til. I denne sammenhengen kan jeg anbefale øvelse 1 på nettsiden, som handler om å bli

bevisst på tankeinnhold og bli litt skeptisk til noe av det negative tankeinnholdet som har en tendens til å dukke opp hos oss fleste. Ha en fin ettermiddag og kveld, hilsen X

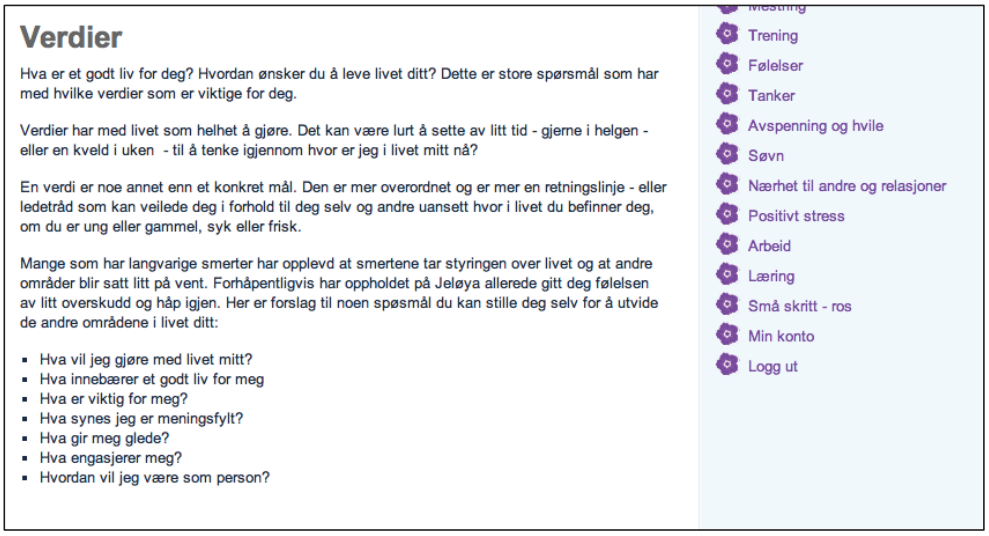
Hei. Dette er siste tilbakemelding som du får fra meg. Jeg er imponert over hvordan du har satt i gang for å endre livet ditt denne måneden etter at du var på Jeløy. Jeg har lyst til å dele noen tanker om tid og forandring med deg. I løpet av de siste ukene har jeg bedt deg tenke igjennom verdiene dine og om du lever i tråd med det som er viktig for deg - ikke bare i forhold til helsen. Det er for å gi deg et kompass å styre etter. Mange skriver ned et slags "verdifundament" for seg selv – hva som er viktig og hvordan man ønsker å leve. Og finner det frem – for å minne seg selv om hva man synes er viktig – eller for å forandre det litt fordi det er behov for det. Den type forandring du ønsker for deg selv tar tid: Du har hatt en kjempestart med meget stor fremgang på kort tid. Innimellom når man et platå der fremgangen kan synes mindre. Dette er ofte perioder der det du har lært og forandret får "sette seg" - For at denne forandringene skal vare og du skal kunne utvikle deg videre slik du ønsker det – er det også viktig at du er realistisk og tålmodig. Det vil også være dager du kan unne deg å krype under dynen, ta en liten pause – kjenne etter hva som er godt for deg akkurat nå. Du ønsker å løpe – kanskje kunne du titte litt på nettet hvordan man anbefaler treningsopplegg for å nå det målet – et halvt til et års perspektiv kan være realistisk her. Kroppen din trenger tid til å endre seg – tåle mer belastning, bli sterkere, slik at du ikke får svingninger som bryter deg ned igjen. Det samme gjelder deg selv – følelsene dine, ditt forhold til deg selv – Du er på vei til å leve et liv mer i tråd med det du ønsker – og du må unne deg tid til å bli kjent med deg selv og oppdage deg selv på nytt, ditt forhold til de rundt deg, hvem du er nå og hvilke muligheter du har. – Det er et spennende prosjekt og jeg vil ønske deg all mulig lykke videre. Takk for følget – for åpenhet, deltakelse og stå-på vilje. Beste hilsen fra X.

Appendix 4: Screenshots from the website.


verdibasert smertemestring
fokus på livskvalitet
Forskergruppen
Nyttige lenker
Smertemestring - hvordan
Velkommen til denne siden. Deltakere i en ny forskningsstudie om smertemestring kan logge seg inn. Andre som ønsker mer opplysning om prosjektet kan kontakte forskergruppen (se under menyen).
Langvarige muskel -skjelett smerter har for mange stor innflytelse på dagliglivet. Forskning viser at det som kan hjelpe de som har disse plagene er tilpasset fysisk trening og tøying, aktvitets regulering og hjelp til å mestre og takle smertene og andre medfølgende plager basert på kognitive behandlingsmetoder.
Det krever en stor innsats å gjøre de endringene som er nødvendige i dagliglivet for å endre fokus fra en hverdag der smerten har kontroll og bestemmer hva man kan gjøre til å ha fokus på hva en selv ønsker, hva som er godt for en selv, og hvordan man kan bevege seg mer i retning av det man ønsker seg for livet sitt.
Et rehabiliteringsopphold på Jeløy Kurbad er meget aktivt; behandlingen innbærer mye fysisk aktivitet, triggerpunkt-behandling, informasjon, coaching og samtaler.
Tilbake til hverdagen etterpå når man skal bruke det man har lært, er en krevende overgang. Denne nettsiden har informasjon om hva det er viktig å tenke på i hverdagen. Det er også forslag til noen oppgaver som kan bidra til å holde fokuset på det som kan være viktig fremover for å leve livet mer slik man ønsker det.
Pålogging
Brukernavn: *
Passord: *
Logg på
Bestill nytt passord


Mestring
Alt du gjør og tenker for å håndtere, unngå, redusere, tolerere eller akseptere smertene dine kan være mestringsstrategier. Noen strategier har kortvarig effekt andre mer langvarige. Det å styrke og tøye muskler og å jobbe med måten man forholder seg til smertene (tankene) er det som har mest langvarige effekt.
Noen aktive mestringsstrategier:
Tøye og trene
Være passe aktiv
Planlegge noe du har lyst til hver dag
Gjennomgå dine vedlikeholdende faktorer og se om du må justere kursen din
Bruke varme
Gjøre pusteøvelser
Reflektere over verdiene dine og se om du lever i tråd med dem
Forvente og akseptere en "dårlig dag" innimellom
Akseptere når du har smerter
"Selv den lengste reise begynner med et lite skritt" (Lao-Tse)
Trening
Følelser
Tanker
Avspenning og hvile
Søvn
Nærhet til andre og relasjoner
Positivt stress
Arbeid
Læring
Små skritt - ros
Min konto
Logg ut


verdibasert smertemestring
fokus på livskvalitet
Et godt liv fremover - nye vaner
Verdier
Oppgaver
Forskergruppen
Nyttige lenker
Oppgave 1. Tanker, følelser og pust
Når du gjør denne øvelsen trener du deg i å både i avspenning og til å la tanker og følelser som dukker opp være det de er - tanker og følelser men ikke nødvendigvis noe som skal bestemme hva du gjør eller hvordan du føler deg.
Sett deg godt til rette i stolen. Kjenn at du sitter godt, har god støtte i ryggen, at du har lagt fra deg armene dine, at bena dine hviler mot setet på stolen. Lukk øynene, og trekk pusten dypt. Fyll lungene din helt og prøv å pust så dypt ned i magen som du kan.
Gjør øvelsen minimum i 5 minutter, men gjerne i 10 eller 15 minutter hvis du har lyst og anledning til det.
Øvelsen kan godt gjøres 2 ganger om dagen og hvis du ikke får sove.
Mestring
Trening
Følelser
Tanker
Avspenning og hvile
Søvn
Nærhet til andre og relasjoner
Positivt stress
Arbeid
Læring
Små skritt - ros
Min konto
Logg ut


Verdier
Hva er et godt liv for deg? Hvordan ønsker du å leve livet ditt? Dette er store spørsmål som har med hvilke verdier som er viktige for deg.
Verdier har med livet som helhet å gjøre. Det kan være lurt å sette av litt tid - gjerne i helgen - eller en kveld i uken - til å tenke igjennom hvor er jeg i livet mitt nå?
En verdi er noe annet enn et konkret mål. Den er mer overordnet og er mer en retningslinje - eller ledetråd som kan veilede deg i forhold til deg selv og andre uansett hvor i livet du befinner deg, om du er ung eller gammel, syk eller frisk.
Mange som har langvarige smerter har opplevd at smertene tar styringen over livet og at andre områder blir satt litt på vent. Forhåpentligvis har oppholdet på Jeløya allerede gitt deg følelsen av litt overskudd og håp igjen. Her er forslag til noen spøsmål du kan stille deg selv for å utvide de andre områdene i livet ditt:
Hva vil jeg gjøre med livet mitt?
Hva innebærer et godt liv for meg
Hva er viktig for meg?
Hva synes jeg er meningsfylt?
Hva gir meg glede?
Hva engasjerer meg?
Hvordan vil jeg være som person?
Trening
Følelser
Tanker
Avspenning og hvile
Søvn
Nærhet til andre og relasjoner
Positivt stress
Arbeid
Læring
Små skritt - ros
Min konto
Logg ut

Oppgave 2. Situasjoner, tanker og følelser

HVORFOR UTSETTE SEG FOR FØLELSESMESSIGE REAKSJONER?

1. For å se at følelser er en naturlig del av livet. Man kan ikke unngå vanskelige følelser helt. I virkeligheten så vil følelsene kunne bli mye sterkere og vedvarende hvis man prøver å løpe vekk fra dem
2. For å se ting i perspektiv. Hvis du lager en øvelses-situasjon så kan det hjelpe deg til ikke å bli så påvirket av følelser i pressede situasjoner
3. For å bli mer bevisst. Hvis man blir mer bevisst og forstår en situasjon bedre så er man bedre i stand til å gjøre det som fungerer godt. Dette kan gjøre at du tar bedre valg for deg selv og kan gå i retning av det som er viktige mål i livet ditt.
4. For å gjøre det du setter pris på. Hvis du ser på emosjonelle situajsoner, så kan du se at tanker og følelser ikke behøver å kontrollere hva du gjør. Du kan oppleve ubehagelige tanker og følelser og oppnå det som er viktig å oppnå i livet ditt.
5. For å leve et helere og fullt liv. De som prøver å unngå altfor mange smertefulle erfaringer, prøver ofte å ta bort deler av livet man ikke ønsker å oppleve

Denne øvelsen kan bidra til at du blir mer bevisst sammenhengen mellom situasjoner du er i som vekker negative følelser hos deg (engstelse, bekymring, tristhet, hjelpeløshet, sinne, frustrasjon).

Sett deg godt til rette i stolen. Kjenn at du sitter godt, har god støtte i ryggen, at du har lagt fra deg armene dine, at bena dine hviler mot setet på stolen. Lukk øynene, og trekk pusten dypt. Fyll lungene din helt og prøv å pust så dypt ned i magen som du kan.

Tenk igjennom dagen din, en situasjon som du synes var vanskelig. Hva skjedde? Hva gjorde du? hvem var du sammen med? Bli så konkret som mulig.

The text continues:

Denne øvelsen kan bidra til at du blir mer bevisst sammenhengen mellom situasjoner du er i som vekker negative følelser hos deg (engstelse, bekymring, tristhet, hjelpeløshet, sinne, frustrasjon).

Sett deg godt til rette i stolen. Kjenn at du sitter godt, har god støtte i ryggen, at du har lagt fra deg armene dine, at bena dine hviler mot setet på stolen. Lukk øynene, og trekk pusten dypt. Fyll lungene din helt og prøv å pust så dypt ned i magen som du kan.

Tenk igjennom dagen din, en situasjon som du synes var vanskelig. Hva skjedde? Hva gjorde du? hvem var du sammen med? Bli så konkret som mulig.

Prøv å husk - Hva tenkte du da? Hvilke tanker gikk gjennom hodet ditt? Bli bevisst hva du tenkte?

Flytt oppmerksomheten til følelsene dine. Hva følte du i situasjonen? Ble du sint? Redd? Ergerlig? Irritert? Forvirret? Lei deg? Ofte føler vi flere følelser på en gang. Hvilke følelser kjente du?

Åpne øynene dine, ta et ark og skriv ned. Bruk de tre overskriftene som står under. Skriv så detaljert som mulig i hver kolonne.

En situasjon som var vanskelig og vekket negative følelser		
Hva skjedde	Hva tenkte du?	Hva følte du?

Appendix 5: Assessment questionnaires.

T3 Deltagernummer: HiO, SU, FoU

Dato _____

Vennligst fyll ut disse skjemaene når du er ferdig med oppfølgingsperioden med mobilen/nettsiden

1) Hvordan føler du deg nå sammenlignet med før du kom til OJK? Sett kryss.
Mye verre ❒ verre ❒ uendret ❒ bedre ❒ mye bedre ❒

Spørsmålene2-5 besvares ved å sette et lite loddrett merke på hver linje. Sett merket på det stedet på linjen som best beskriver din situasjon for tiden (de siste 2-3 dager).

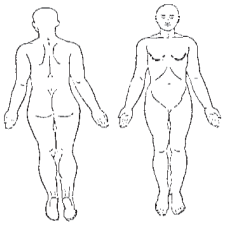
2) Smerte
Ingen ——— Verst tenkelig

3) Dårlig søvn
Ingen ——— Verst tenkelig

4) Tretthet
Ingen ——— Verst tenkelig

5) Depresjon
Ingen ——— Verst tenkelig

6) **Smerteutbredelse:** Skraver inn på figurene de områder som er smertefulle for tiden (de siste 2 - 3 dager). Ingen skravering betyder ingen smerte.



Til legens bruk:									
Sted	occ.	c5	trap	supra	costa 2	lat epi.	glut.	tr. maj.	med.cond.
Dxt									
Sin									

TP antall:_____ ACR kritt: nei ❒ ja ❒

7) Noter alle de **medikamenter** du bruker for tiden (inkl. smertestillende, muskelavslappende, beroligende, sovemedisin, antidepressiva og andre)

Medikament navn	Styrke	Dosering

T3 Deltagernummer: HiO, SU, FoU

Fibromyalgi spørreskjema - FIQ

Fibromyalgia Impact Questionaire

(Besvares selv om du ikke skulle ha fibromyalgi)

1. Klarte du i løpet av den siste uken**, i den grad du ønsket det**, å:
(Sirkle inn tallet som passer, og stryk ellers ut oppgaver du ikke pleier å gjøre eller som du ble forhindret fra å gjøre av andre årsaker enn muskelsmerter / fibromyalgi)

	Alltid	Oftest	Iblant	Aldri
a) Handle?	0	1	2	3
b) Vaske tøy i maskin?	0	1	2	3
c) Lage mat?	0	1	2	3
d) Vaske opp tallerkener og gryter for hånd?	0	1	2	3
e) Støvsuge en rye?	0	1	2	3
f) Re senger?	0	1	2	3
g) Gå lengere enn 1 km?	0	1	2	3
h) Besøke venner eller slektninger?	0	1	2	3
i) Drive med hagearbeid?	0	1	2	3
j) Kjøre bil?	0	1	2	3

2. I hvor mange av de siste 7 dagene hadde du det bra? (Sirkle inn tallet som passer)

0 1 2 3 4 5 6 7

3. I hvor stor grad var du sykemeldt p.g.a. fibromyalgi den siste uken før du kom til OJK? (Besvares ikke hvis du er hjemmeværende, arbeidsledig eller alderspensjonist)

0% 25% 50% 75% 100% (Sirkle inn tallet som passer)

sykemelding /rehabiliteringspenger / attføring / uføretrygd (Sirkle inn)

Snu arket!

T3 Deltagernummer: HiO, SU, FoU

De følgende spørsmålene besvares ved at du setter en liten loddrett strek på det punkt på linjen som best beskriver hvordan du har hatt det ***den siste uken****.*
Hvis du ikke har vært på jobb siste uken går du direkte til spørsmål 5.

4. I hvor stor grad har smerter, eller andre fibromyalgisymptomer, påvirket hvordan du utførte jobben din? *Spørsmål 4 besvares bare hvis du har vært på jobb siste uken.*

Intet problem med å utføre jobben — Store problemer med å utføre jobben

5. Hvor sterk har smerten din vært den siste uken?

Ingen smerte — Meget sterk smerte

6. Har du vært trett den siste uken?

Ingen tretthet — Meget trett

7. Hvordan har du følt deg når du står opp om morgenen den siste uken?

Våknet frisk og uthvilt — Våknet meget trett

8. Hvor kraftig har stivheten din vært den siste uken?

Ingen stivhet — Meget stiv

9. Har du følt deg anspent, nervøs eller engstelig den siste uken?

Ikke anspent — Meget anspent

10. Har du følt deg deprimert eller nedfor i løpet av den siste uken?

Ikke nedstemt — Meget nedstemt

T3 Deltagernummer: HiO, SU, FoU

Nottingham helseprofil

Nottingham Helseprofil er et spørreskjema som er utarbeidet for å kartlegge folks helse.

FØR DU BEGYNNER: VÆR SÅ SNILL Å LESE INSTRUKSENE NØYE.

Nedenfor er det ført opp noen problemer som man kan ha i dagliglivet. Les igjennom listen og sett merke i ***JA****- ruten for de problemene som du har* ***akkurat nå****. Sett merke i* ***NEI-*** *ruten for de problemene du ikke har. Det er viktig at du* ***svarer på alle utsagnene****, selv om det skulle være vanskelig - og verken ja eller nei passer helt. Velg det som best beskriver* ***hvordan du har det nå, i øyeblikket!*** *VENNLIGST SVAR PÅ ALLE SPØRSMÅLENE.*

	JA	NEI
Jeg er trøtt hele tiden	❑	❑
Jeg har smerter om natten	❑	❑
Tingene vokser meg over hodet	❑	❑
Jeg har uutholdelige smerter	❑	❑
Jeg tar tabletter for å få sove	❑	❑
Jeg har glemt hvordan det er å ha det hyggelig	❑	❑
Nervene mine står på høykant	❑	❑
Det er vondt å skifte stilling	❑	❑
Jeg føler meg ensom	❑	❑
Jeg kan bare gå omkring innendørs	❑	❑
Jeg har vanskelig for å bøye meg	❑	❑
Alt er et ork	❑	❑
Jeg våkner svært tidlig om morgenen	❑	❑
Jeg kan ikke gå i det hele tatt	❑	❑
Jeg har vansker med å komme i kontakt med mennesker	❑	❑

Snu arket!

T3 Deltagernummer: HiO, SU, FoU

	JA	NEI
Dagene synes å gå så langsomt	❑	❑
Jeg har vanskelig med å gå opp og ned trapper eller trinn	❑	❑
Jeg finner det vanskelig å strekke meg etter ting	❑	❑
Jeg har smerter når jeg går	❑	❑
Jeg mister lett beherskelsen for tiden	❑	❑
Jeg føler ingen nærhet til noen	❑	❑
Jeg ligger våken mesteparten av natten	❑	❑
Jeg føler det som om jeg er i ferd med å miste kontrollen	❑	❑
Jeg har smerter når jeg står	❑	❑
Jeg har vanskelig for å kle på meg	❑	❑
Snart orker jeg ikke mer	❑	❑
Jeg har vanskelig for å stå lenge (f.eks. ved kjøkkenvasken eller på bussholdeplassen)	❑	❑
Jeg har smerter hele tiden	❑	❑
Jeg ligger lenge før jeg sovner	❑	❑
Jeg føler at jeg er en byrde for andre	❑	❑
Bekymringer holder meg våken om natten	❑	❑
Jeg føler at livet ikke er verd å leve	❑	❑
Jeg sover dårlig om natten	❑	❑
Jeg finner det vanskelig å komme overens med andre	❑	❑
Jeg trenger hjelp for å gå omkring ute (f.eks. hjelpemidler eller en arm å holde meg til)	❑	❑
Jeg har vondt når jeg går opp og ned trapper eller trinn	❑	❑
Jeg er deprimert når jeg våkner	❑	❑
Jeg har vondt når jeg sitter	❑	❑

T3 Deltagernummer: HiO, SU, FoU

Langvarige smerter og verdier

Mange som har kroniske smerter opplever at smertene og andre symptomer er til hinder for å engasjere seg i aktiviteter som er personlig viktige for dem. De har "VERDIER", men lever ikke i overensstemmelse med verdiene sine. For eksempel, du kan ønske å være en kjærlig partner, en varm og støttende forelder, en hjelpsom og pålitelig venn, en person som holder seg i god fysisk form, eller en som alltid lærer nye ferdigheter, - men du kan være i en situasjon hvor du ikke lever på den måten.
Vurder hvordan du helst ønsker å leve livet ditt for hvert av områdene som er beskrevet nedenfor. Vurder så hvor VIKTIG hvert område er for deg. Dette dreier seg IKKE om hvor bra du gjør det på hvert område – men det er hvor viktig det er for deg. Vurder viktigheten av hvert område med et tall fra 0 (helt uviktig) til 5 (særdeles viktig). Hvert område behøver ikke være viktig for deg – vurder området lavt hvis det ikke er viktig for deg personlig.

0 1 2 3 4 5
Helt uviktig | Viktig i ganske liten grad | Viktig til en viss grad | Ganske viktig | Meget viktig | Særdeles viktig

Vurder, ut fra dine verdier, hvor viktig hvert av disse områdene er for deg:	**Dette områdets VIKTIGHET for deg:**
1. Familie: Deltakelse i dine forhold til foreldre, barn eller andre nære slektninger, personer du bor sammen med, eller andre som utgjør din "familie"	____
2. Intime forhold. Å være den partneren du ønsker å være for ektefelle eller din nærmeste livsledsager	____
3. Venner: Å være sammen med venner, gjøre det som trengs for å ivareta vennskap, eller gi hjelp og støtte til andre som en venn	____
4. Arbeid: Å være engasjert i det du driver med, ditt yrke, frivillig arbeid, utdannelse, arbeid i hjemmet	____
5. Helse: Å holde seg i form, i fysisk vigør, og sunn slik du selv helst ønsker det	____
6. Utvikling og læring: Lære nye ting eller tilegne seg kunnskap, eller utvikle seg som person slik du helst ville ønske	____

I den neste delen ønsker vi at du ser på i hvilken grad du har lykkes i å leve i tråd med verdiene dine. Mange ganger, når folk har langvarige helseplager, synes de det er vanskelig å leve livet slik de skulle ønske å leve det.
Vurder på nytt hvordan du ønsker å leve livet ditt for hvert livsområde nevnt nedenfor. Vurder så i hvilken grad du har LYKKES med å leve i tråd med verdiene dine de siste to ukene. Disse spørsmålene gjelder IKKE hvor vellykket du ønsker å være, men i hvilken grad du har lykkes. Vurder hvorvidt du har lykkes ved å bruke tallene på skalaen fra 0 (har ikke lykkes i det hele tatt) til 5 (har lykkes særdeles godt).

0 1 2 3 4 5
Ikke i det hele tatt | I ganske liten grad | Til en viss grad | Ganske godt | Meget godt | Særdeles godt

Vurder i hvilken grad du lykkes å leve i tråd med dine verdier for hvert av disse områdene:	**LYKKES i å leve etter verdiene:**
1. Familie: Deltakelse i dine forhold til foreldre, barn eller andre nære slektninger, personer du bor sammen med, eller andre som utgjør din "familie"	____
2. Intime forhold. Å være den partneren du ønsker å være for ektefelle eller din nærmeste livsledsager	____
3. Venner: Å være sammen med venner, gjøre det som trengs for å ivareta vennskap, eller gi hjelp og støtte til andre som en venn	____
4. Arbeid: Å være engasjert i det du driver med, ditt yrke, frivillig arbeid, utdannelse, arbeid i hjemmet	____
5. Helse: Å holde seg i form, i fysisk vigør, og sunn slik du selv helst ønsker det	____
6. Utvikling og læring: Lære nye ting eller tilegne seg kunnskap, eller utvikle seg som person slik du helst ville ønske	____

T3 Deltagernummer: HiO, SU, FoU

Akseptering av smerter

(Pain Acceptance scale)

Nedenfor finner du en rekke med utsagn. Vær snill å vurdere hvor sant hvert utsagn er for deg. Bruk følgende vurderingsskala når du skal velge. For eksempel, hvis du mener et utsagn er "alltid sant" så skriver du 6 på linjen etter det utsagnet.

0	1	2	3	4	5	6
Aldri sant	Veldig sjelden sant	Sjelden sant	Sant av og til	Ofte sant	Nesten alltid sant	Alltid sant

1. Jeg går videre med livet mitt uansett hvordan smertenivået mitt er _____

2. Livet mitt er bra, selv om jeg har kroniske smerter _____

3. Det er OK å kjenne smerter _____

4. Jeg skulle gjerne ofre viktige ting i livet mitt for å få bedre kontroll over denne smerten_____

5. Det er ikke nødvendig for meg å ha kontroll over smertene for å håndtere livet mitt bra_____

6. Selv om ting har forandret seg, lever jeg et normalt liv til tross for mine kroniske smerter_____

7. Jeg må konsentrere meg om å bli kvitt smerten min_____

8. Jeg gjør mange aktiviteter når jeg føler smerte_____

9. Jeg lever et fullverdig liv selv om jeg har kroniske smerter_____

10. Å kontrollere smerte er mindre viktig enn andre mål i livet mitt_____

11. Mine tanker og følelser om smerte må forandre seg før jeg kan ta viktige skritt i livet mitt_____

12. Til tross for smerten, holder jeg nå fast ved en bestemt kurs i livet mitt_____

13. Å holde smertenivået mitt under kontroll krever første prioritet hver gang jeg foretar meg noe_____

14. Før jeg kan planlegge noe for alvor må jeg ha noe kontroll over smerten min_____

15. Når smerten min øker, så kan jeg fortsatt ivareta mine forpliktelser_____

16. Jeg vil ha bedre kontroll med livet mitt hvis jeg kan kontrollere mine negative tanker om smerte___

17. Jeg unngår å sette meg i situasjoner hvor smerten kan øke_____

18. Mine bekymringer og engstelser for hva smerte kan gjøre med meg er reelle_____

19. Det er en lettelse å innse at jeg ikke trenger å endre smertene mine for å komme videre med livet mitt_____

20. Jeg må kjempe for å gjøre ting når jeg har smerter_____

T3 Deltagernummer: HiO, SU, FoU

Her kommer noen flere spørsmål om hvordan du har hatt det i det siste. Sammenliknet med hvordan du vanligvis har det, har du de siste to ukene (sett kryss)

	mye mindre enn vanlig	**samme som vanlig**	**mer enn vanlig**	**mye mer vanlig**
a) vært i stand til å konsentrere deg fullt ut om det du har drevet med				
b) ligget våken på grunn av bekymringer?				
c) følt at du tar del i ting på en nyttig måte?				
d) følt at du er i stand til å ta beslutninger?				
e) følt deg stadig under press?				
f) følt deg ute av stand til å mestre vanskeligheter?				
g) vært i stand til å glede deg over dine daglige gjøremål?				
h) vært i stand til å møte problemer?				
i) følt deg ulykkelig eller nedtrykt?				
j) mistet troen på deg selv?				
k) tenkt på deg selv som en verdiløs person?				
l) stort sett følt deg tilfreds, alt tatt i betraktning				

Tanker om smertene (PCS)

Alle opplever smerter på et eller annet tidspunkt i livet. Slike smerteopplevelser kan være hodepine, tannverk, ledd- og muskelsmerter. Folk er ofte utsatt for situasjoner som kan forårsake smerter, slik som sykdom, skade, tannbehandling og kirurgi. Vi er interessert i hva slags tanker og følelser du har når du har smerter. Nedenfor står det 13 utsagn som beskriver ulike tanker og følelser som kan være forbundet med smerte. Bruke følgende skala og indiker i hvilken grad du har slike tanker og følelser når du opplever smerte.

Når jeg har smerter…	**Ikke i det hele tatt**	**Litt**	**I moderat grad**	**I stor grad**	**Hele tiden**
a. Jeg er hele tiden bekymret for at smertene ikke vil gi seg	**0**	**1**	**2**	**3**	**4**
b. Jeg føler at jeg ikke klarer å fortsette	**0**	**1**	**2**	**3**	**4**
c. Det er forferdelig og jeg tror at det aldri vil bil bedre	**0**	**1**	**2**	**3**	**4**
d. Det er fryktelig, og jeg føler at det overvelder meg	**0**	**1**	**2**	**3**	**4**
e. Jeg føler at jeg ikke holder det ut lenger	**0**	**1**	**2**	**3**	**4**
f. Jeg blir redd for at smertene skal bli verre	**0**	**1**	**2**	**3**	**4**
g. Jeg tenker stadig på andre smertefulle opplevelser	**0**	**1**	**2**	**3**	**4**
h. Jeg ønsker desperat at smertene skal forsvinne	**0**	**1**	**2**	**3**	**4**
i. Det virker som jeg ikke klarer å få det ut av hodet	**0**	**1**	**2**	**3**	**4**
j. Jeg tenker stadig på hvor vondt det er	**0**	**1**	**2**	**3**	**4**
k. Jeg tenker stadig på hvor inderlig jeg vil at smertene skal gi seg	**0**	**1**	**2**	**3**	**4**
l. Det er ingenting jeg kan gjøre for å redusere smertenes intensitet	**0**	**1**	**2**	**3**	**4**
m. Jeg lurer på om noe alvorlig kan komme til å skje	**0**	**1**	**2**	**3**	**4**

T3 Deltagernummer: HiO, SU, FoU

Din helse og trivsel (SF-8)

1. Hvordan vil du stort sett vurdere din helsetilstand i løpet av den siste uka?

Utmerket Meget god God Nokså god Dårlig Svært dårlig

☐ ☐ ☐ ☐ ☐ ☐

2. I løpet av den siste uka, i hvilken grad begrenset fysiske helseproblemer dine vanlige fysiske aktiviteter (spasere, gå opp trapper)?

Ikke i det hele tatt Svært lite En del Mye Kunne ikke utføre fysisk aktivitet

☐ ☐ ☐ ☐ ☐

3. I løpet av den siste uka, hvor vanskelig var det for deg å utføre ditt vanlige arbeid (både i og utenfor hjemmet) på grunn av din fysiske helse?

Ikke i det hele tatt Svært lite En del Mye Kunne ikke utføre vanlig arbeid

☐ ☐ ☐ ☐ ☐

4. Hvor sterke kroppslige smerter har du hatt i løpet av den siste uka?

Ingen Meget svake Svake Moderate Sterke Meget sterke

☐ ☐ ☐ ☐ ☐ ☐

5. I løpet av den siste uka, hvor mye overskudd hadde du?

Svært mye Ganske mye En del Litt Ikke noe

☐ ☐ ☐ ☐ ☐

6. I løpet av den siste uka, i hvilken grad begrenset din fysiske helse eller følelsesmessige problemer din vanlige sosiale omgang med familie og venner?

Ikke i det hele tatt Svært lite En del Mye Kunne ikke ha sosial omgang

☐ ☐ ☐ ☐ ☐

7. I løpet av den siste uka, i hvilken grad har du vært plaget av følelsesmessige problemer som for eksempel å være engstelig, deprimert eller irritabel?

Ikke i det hele tatt Svært lite En del Mye Svært mye

☐ ☐ ☐ ☐ ☐

8. I løpet av den siste uka, i hvilken grad hindret personlige eller følelsesmessige problemer deg fra å utføre ditt vanlige arbeid, skolegang eller andre gjøremål?

Ikke i det hele tatt Svært lite En del Mye Kunne ikke utføre daglige gjøremål

☐ ☐ ☐ ☐ ☐

Readiness to change / Endringsberedskap

Hvor klar er du til å gjøre viktige endringer i livet ditt i den hensikt å få et bedre liv på sikt?

*Sett et **lite loddrett merke** på det stedet på linjen som best beskriver din situasjon i øyeblikket*

Ikke klar ——— Klar

Usikker / tvilende

10

9 Papers I-III

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RESEARCH ARTICLE Open Access

Written online situational feedback via mobile phone to support self-management of chronic widespread pain: a usability study of a Web-based intervention

Ólöf Birna Kristjánsdóttir[1*], Egil A Fors[2,3], Erlend Eide[1,4], Arnstein Finset[5], Sandra van Dulmen[6], Sigrid Hørven Wigers[7], Hilde Eide[1,8]

Abstract

Background: This pretrial study aimed to develop and test the usability of a four-week Internet intervention delivered by a Web-enabled mobile phone to support self-management of chronic widespread pain.

Methods: The intervention included daily online entries and individualized written feedback, grounded in a mindfulness-based cognitive behavioral approach. The participants registered activities, emotions and pain cognitions three times daily using the mobile device. The therapist had immediate access to this information through a secure Web site. The situational information was used to formulate and send a personalized text message to the participant with the aim of stimulating effective self-management of the current situation. Six women participated and evaluated the experience.

Results: The intervention was rated as supportive, meaningful and user-friendly by the majority of the women. The response rate to the daily registration entries was high and technical problems were few.

Conclusion: The results indicate a feasible intervention. Web-applications are fast becoming standard features of mobile phones and interventions of this kind can therefore be more available than before.

Trial registration number: ClinicalTrials.gov: NCT01236209

Background

Behavior change is an integral part of improved self-management of many chronic health disorders. For people with chronic widespread pain (CWP) or fibromyalgia syndrome (FMS) this is no easy task. The chronic condition of pain without a clear physiological explanation often entails a downward spiral of pain, fear of pain and avoidance behavior, fatigue and depressive symptoms, which makes behavior change extremely challenging [1]. The development of CWP and FMS involves a complex dynamic biopsychosocial process, and multidimensional rehabilitation seems to be the most effective treatment approach [2]. An essential part of the treatment should be an intervention based on cognitive behavioral therapy (CBT) to increase self-management skills [3,4]. CBT with focus on mindfulness and acceptance processes has been found to be effective for people with different chronic health disorders [5], including pain [6]. The goal is for the patient to accept, rather than struggle with unwanted thoughts, emotions and symptoms, and to commit to valued behavior [6,7]. Because of differences in philosophical background and applied techniques between the mindfulness approach and more traditional CBT, some define the mindfulness approach as a new generation of behavioral therapy [8] whereas others view it as consistent with CBT [9].

Internet-administrated cognitive behavioral interventions are increasingly used to support people with health problems [10,11]. Effective operationalization of important elements seems possible because, for some conditions, the effectiveness of Internet-based CBT has been

* Correspondence: olof-birna.kristjansdottir@su.hio.no
[1]Faculty of Nursing, Oslo University College, Oslo, Norway
Full list of author information is available at the end of the article

shown to be similar to that of face-to-face CBT [10-12]. A recent meta-analysis of 11 studies shows that Internet-delivered cognitive behavioral interventions for people with chronic pain have a significantly greater effect on pain level than waiting list conditions [13]. The pooled effect size was small, but all the reviewed interventions also improved significantly other health-related and behavioral outcomes (e.g., distress and work capability) compared with the waiting list group.

Results of a recent review of Internet interventions aiming to support behavior changes indicate that interventions including mobile phone text messages and/or some personal online contact can be more helpful in supporting behavior change than Internet interventions without those features [14]. Today's mobile phones commonly include an integrated Internet facility, (e.g., personal digital assistants (PDAs) and smartphones), which opens new possibilities for Internet-based CBT. By using a Web-enabled mobile phone instead of a desktop or laptop computer, the patient can register and send information to the therapist when in different situations. An important goal of CBT is to improve functioning by detecting how automatic thoughts influence feelings and behavior [6]. For this purpose, patients are encouraged to keep some form of record of their thoughts, emotions and behavior (e.g., "What did I feel in the situation?"). The Experience Sampling Method is a way to obtain information on thoughts, feelings and behavior in real time with minimal retrospective bias (e.g., "Right now I am feeling...") [15]. Questions in this format can be answered using the mobile phone and may support self-monitoring [16,17]. The Internet connection makes it possible to submit this information online and make it immediately available to a therapist. The therapist is thereby provided with situational information with a reduced risk of memory bias. Importantly, this also enables the therapist to give the patient prompt feedback on the registered information via a text message [16,18]. In a randomized controlled trial of 76 patients with irritable bowel syndrome, a cluster of symptoms without clear organic abnormalities, the intervention group kept daily online symptom diaries for four weeks and received daily CBT based feedback on a mobile phone. Compared with the control group, the intervention group showed improvements in key symptoms such as catastrophizing thoughts and in quality of life. The effect on catastrophizing was sustained at a three-month follow-up [16]. Using mobile phones and text messaging to support behavior change seems effective for people with different health conditions [14,19]. To our knowledge, no studies exist on the effect of mobile phone interventions to support people with chronic widespread pain [20].

The purpose of this pretrial study was to describe the development and usability of a cognitive behavioral intervention for people with chronic pain using Web-enabled mobile phones. The mobile phones were used to keep online diaries on thoughts, feelings and behavior and to receive situational feedback from a therapist. Acceptability, response rate and user friendliness of the technological system were investigated.

Methods

Study sample

This pretrial study was performed from October 2008 to January 2009 on a convenience sample. The goal was to include 6 participants diagnosed with CWP or FMS to test the usability of the intervention. Because women are more often affected by these conditions [4], the choice was made to include only women in this study.

The original aim was to recruit all participants from general practitioners (GPs) but letters and phone calls to the GPs' offices resulted in the recruitment of only two participants. It was therefore decided to contact a rehabilitation center for further recruitment. At the rehabilitation center, the researchers gave information about the study to a group of women with CWP participating in a four-week inpatient multidimensional pain management program including education and pain management in a cognitive setting, various forms of aerobic exercises, stretching, myofascial pain treatment, relaxation and medication as needed (see [21] for details of the program). The first four women to contact the researchers were invited to participate in the study after they had completed the pain management program. Participants received a letter describing the study (either at a visit to their GP's office or at the rehabilitation center). The aims of the study were described as being to develop and implement innovative communication methods to support coping in women with chronic pain. The participants were informed of the intervention's intention to increase awareness of the mind and body relationship and support commitment to valued behavior. Those interested in participating met with the first author and received more information, and signed an informed consent form.

The intervention

The intervention was developed by building on the experiences of a collaborator (SvD) using similar technology to support people coping with irritable bowel syndrome [16]. For the technological platform, the Open Source Content Management System (Drupal) was used. Data security was maintained through a combination of system design, Hypertext Transfer Protocol Secure (HTTPS) and a proprietary mobile phone authentication system [22]. The content of the intervention (questions in diaries, feedback content and CBT exercises) was chosen by the authors, a multidisciplinary group of health professionals. The theoretical framework was CBT with a focus on mindfulness and acceptance of

symptoms. In addition, identifying and working with values and valued activities was emphasized, as recommended by McCracken's mindfulness and acceptance-based CBT for people with chronic pain [6].

Face-to-face meeting

The intervention started with a one-hour individual meeting between the therapist (a nurse, OBK) and the participant. Each participant was informed about the intervention, asked about her functioning, her goals for health-related behavior and her need for support. They received written exercises to do at home (see Table 1) and an audio CD with relaxation and mindfulness exercises developed in an earlier study [23]. Each participant was lent a Web-enabled mobile phone (HTC TyTN II) with touch screen and keyboard and made the first diary entry at the meeting.

Online diaries

The participant was asked to complete three diary entries per day using the mobile phone. At a scheduled diary-completion time, she received a Short Message Service (SMS) message with a link to a secure Web site where the diary could be opened and questions answered and submitted back to the server. The morning and evening diary entries were sent at fixed hours chosen by each participant. The second diary entry of the day was sent at a time randomly chosen by the Web server, between 11.30 am and 2 pm. The purpose of including three diary entries, including one at a randomly chosen time, was to encourage self-monitoring of thoughts and feelings at different hours and in different situations. No data were kept on the mobile phone [22]. Two reminder SMS messages were sent within one hour if the diary entry was not returned. If the entry was not submitted within 90 minutes, the form was closed.

The diaries included 19-32 questions. The questions were chosen to support self-monitoring and awareness of feelings, thoughts related to the symptoms and applied self-management strategies. The questions were formulated in line with Experience Sampling Method principles to capture thoughts, feelings and behavior in real time. Most answers were reported by choosing predefined alternatives or scoring on five-point Likert scales. The diaries included questions about current level and interference of pain, planned and achieved activities, feelings, pain-related fear, avoidance, catastrophizing and acceptance (see Table 2). All diaries included a comment field giving participants the opportunity to write a short personal message to the therapist. The participants completed diary entries for a couple of days to get used to the registration, and then they made entries and received daily feedback for four weeks.

Online written situational feedback

For four weeks, excluding weekends, participants received daily written online feedback within 90 minutes of completing the second (midday) diary entry of the day. The feedback was written by a therapist with a M.Sc. in nursing (OBK). The content of the feedback was supervised by two members of the group (HE, nurse and psychologist with 25 years experience in teaching mindfulness meditation, and EAF, a medical doctor, psychiatrist and a CBT therapist and supervisor). Feedback was sent even if the midday diary was not submitted. The therapist used information from the latest submitted diary. An SMS was sent to signal that feedback was available. The text messages included a link to the Web site where the feedback was posted. There was no limitation on the length of the feedback, which varied from a few sentences to a few paragraphs.

The feedback was intended to suit the participant's situation as reported in the diary. It was written in an empathic communication style and included positive reinforcement, information, metaphors, CBT exercises and questions aiming to encourage mindfulness and willingness to engage in meaningful activities despite pain or other discouraging intrusions (Table 1). Either the instructions for the exercises were written directly in the feedback or participants were referred to the written

Table 1 Key concepts and operationalization of the intervention

Concepts	Diaries	Feedback	Worksheet and CD
Awareness of thought content and feelings, their connection and effect on behavior. Mindfulness.	Fill out entries on thoughts, feelings and behavior three times a day.	Feedback aimed to increase awareness of possible connection between thoughts, feelings and behavior in a recent situation. Mindfulness exercises described and recommended.	Emotion and behavior record [6]. Relaxation and mindfulness exercises (CD, [23]).
Values and valued behavior.	Register planned activities and activities done. Rate satisfaction of today's activity.	Questions and metaphors used to promote reflection on values and valued behavior.	Values and value-based activity. Goals and barriers to value-based living [6]
Acceptance vs. avoidance.	Fill out entries on both positive and challenging thoughts and feelings. Register activity.	Registered information used to give feedback on avoidance behavior or willingness to act in accordance with values despite pain or discouraging thoughts and feelings.	Same as above.

Table 2 Content and timing of diary entries (* included in)

Content	Morning diary	Midday diary	Evening diary	Example of questions (Q), statements (S) and answers (A).
Pain	x*	x	x	S: Right now my pain level is... A: Scale from 0 (no pain) to 10 (worst imaginable pain).
Activity planning	x	x	x	S: In the next couple of hours, I plan to... A: List of activities to choose from (including exercise, relaxing and stretching).
Activity evaluation		x	x	Q: How satisfied am I with my level of activity since the last entry? A: Five-point Likert scale from "very satisfied" to "very dissatisfied".
Cognitions		x		S: Right now I worry about my pain getting worse. A: Five-point Likert scale from "agree totally" to "disagree totally".
Emotions	x		x	S: Right now I am grateful... A: Five-point Likert scale from "agree totally" to "disagree totally".
Sleep	x			S: I have slept for... A: Less than 2 hours, 2-4 hours, 4-6 hours, 6-8 hours, 8-10 hours, more than 10 hours.
Evaluation of feedback			x	S: The feedback has helped me to stay active. A: Yes, No, Unsure.
Open space for comments	x	x	x	
Total number of questions	19	32	24	

worksheets or the CD. All participants received feedback texts on values, value-based behavior, mindfulness and acceptance. The texts were tailored to the personal information given at the face-to-face introductory meeting and to the information registered in the diaries. See Table 3 for an example of feedback content.

Evaluation measures

Feasibility of the intervention

To measure feasibility, we developed a questionnaire to measure patients' experiences and satisfaction with the intervention. Participants were also asked to participate in two semi-structured interviews to explore their experience with the intervention (halfway through and after completion). The researchers (OBK and HE) met with the patients individually to evaluate the intervention with questions aiming to capture the experience of participating and suggestions for improvement. Additionally, the experience of the therapist (OBK) was summarized.

Table 3 Example of a feedback message

Focused breathing

Hi! It seems like you are able to stay active and prioritize pleasurable activities despite your pain. You have already taken a walk and stretched out. Well done! You have just registered that you are not afraid of the pain and that you feel you have some strategies to help you cope with it. You register that your breathing is not relaxed. Can you give yourself a moment to focus on your breathing? Take a deep breath and slowly breathe out a couple of times. I recommend again the focused breathing exercise from last week, the one where you find a quiet spot, comfortable posture, focus on your breathing for a few minutes and–as well as you can–give minimum attention to the content of your thoughts that automatically appear.

Regards, Ann

Subjective usefulness of the feedback

In every evening diary entry, participants were asked about the subjective usefulness of the feedback by two questions with predefined answers to choose from.

Assessment questionnaires

To measure possible effects on acceptance and pain-related cognitions, participants were asked to fill out the Chronic Pain Acceptance Questionnaire (CPAQ) [24] and the Pain Catastrophizing Scale (PCS) [25] before and immediately after the intervention period. Catastrophizing and pain acceptance are concepts that seem to mediate effects on treatment outcome in people with chronic pain [26,27]. The CPAQ is a 20-item self-reported instrument containing two subscales: Activity engagement (extent of participation in daily activities despite pain experience) and Pain willingness (willingness to experience pain without trying to control, alter or avoid it). It is scored on a seven-point Likert scale from 0 (never true) to 6 (always true) to give the total score (0-120). Higher scores reflect higher acceptance of pain and higher activities engagement. The PCS is a 13-item questionnaire with three subscales: helplessness, magnification and rumination. Patients rate items on a scale of 0 (not at all) to 4 (all the time). The total score range for PCS is 0-52, with higher scores reflecting higher degrees of catastrophizing. Average pain intensity (previous week) was assessed on a numerical rating scale from 0 (no pain) to 10 (worst possible pain).

Treatment fidelity measures

Data were gathered on how many diary entries were submitted by each participant.

Ethical aspects

The study was approved by the Regional Ethical Committee in Norway and by Norwegian Social Science Services.

Analyses

Descriptive statistics were calculated as means and frequencies using SPSS version 16. Notes from the interviews were compared and themes identified.

Results

Study sample

Six women aged 23-48 years (mean = 36.3) with CWP participated. Four participants were recruited from a rehabilitation center where they had just completed a four-week inpatient multidimensional pain management program. Two were recruited from their GP's office. Three were employed and three were on sick leave. Three were single and the others were cohabiting. Mean average pain level the previous week was 5.33 (SD = 1.51) (0 = no pain, 10 = worst imaginable pain). Table 4 shows pain levels and scores on CPAQ and PCS before and after the intervention period.

Assessment data were gathered for five participants. Four reported reduced catastrophizing and three reported a higher acceptance of pain after the intervention.

Evaluation questionnaires

As shown in Table 5, most of the participants perceived participation as supportive, inspiring and meaningful.

The experience of filling out the diaries was rated as positive and the questions were rated as easily understood. All participants judged the questions in diaries and the content of the feedback to be relevant. Most felt that they were able to do the exercises mentioned in the feedback. All but one participant believed the intervention had increased their insight into their symptoms, and four out of six felt they had learned some new methods to cope with their symptoms. None perceived participation as boring, shameful or invasive of privacy. Most of the participants perceived the mobile phone as user friendly but two found it too heavy and big.

Table 6 shows that most participants agreed that three registrations and one feedback were acceptable per day. Most thought the length of the intervention period to be suitable, but two preferred a longer period. Two women found the number of questions in the diaries to be too many. One participant reported feeling burdened by the intervention, and two agreed that it was somewhat disturbing.

Subjective usefulness of the feedback

In every evening diary entry, participants were asked to rate the subjective usefulness of the feedback using predefined answers. Fifty percent reported the feedback messages as helpful in maintaining activity (to a level perceived as satisfactory by the participant), and 76% as helpful in staying emotionally well.

Interviews

The participants appreciated participation in the intervention. They found it useful to fill out the diaries; it increased awareness of their own reactions to the pain and it supported the use of positive coping strategies. The feedback messages were experienced as personal and relevant to the current situation, with a suitable mix of praise, encouragement and CBT exercises. They considered the exercises helpful but some found a few of the exercises difficult to understand. One participant said that she felt she could be more honest when filling out the diaries than she would have been in a face-to-face setting. One of the participants from the rehabilitation center said she felt the intervention had motivated and helped her to integrate what she had learned at the rehabilitation center. It was perceived as supportive in breaking habits and establishing new health behavior. One mentioned that it had made her prioritize reflection on important things. Two women wanted a print out of the feedback messages to have the content available after the intervention.

However, some frustration and difficulties with the intervention were also mentioned. It was occasionally found inconvenient to take the extra mobile phone

Table 4 Participants' assessment scores before (T1) and after intervention (T2)

Participant number	Mean pain intensity T1 (0-10)	Mean pain intensity T2 (0-10)	PCS T1 (0-52)	PCS T2 (0-52)	CPAQ T1 (0-120)	CPAQ T2 (0-120)
1 (rehab)	4	5	7	1	83	80
2 (rehab)	7	7.5	18	8	51	64
3 (rehab)	3	5.5	20	25	34	53
4 (GP)	6	6.5	29	24	42	36
5 (GP)	6	Missing	Missing	Missing	Missing	Missing
6 (rehab)	6	6	17	5	65	76

Table 5 Participants' reports of the intervention

Statement	Agree (n)	Neutral (n)	Disagree (n)
I found the questions understandable	4	1	1
I think I have gained more insight into my complaints	5	1	0
I found it supportive to fill out the diary	5	1	0
I was able to do the given tasks	4	1	1
I have learned some methods I can use to handle my complaints	4	2	0
I found it fun to use the phone	4	1	1
I found it inspiring to use the phone	4	2	0
I found it meaningful to use the phone	5	1	0
I found it time consuming to use the phone	2	2	2
I found it frustrating to use the phone	0	3	3
I found it difficult to use the phone	0	2	4
I found it scary to use the phone	0	1	5
I found it boring to use the phone	0	1	5
I found it shameful to use the phone	0	0	6
I found it disrupted my privacy to use the phone	0	2	4
I found it burdensome to use the phone	1	1	4
I found it disturbing to use the phone	2	2	2
I found it exciting to use the phone	5	1	0
I found the mobile phone user friendly	4	1	1
I found the size of the mobile phone suitable	3	1	2
I found the mobile phone to be too heavy	2	2	2
I found the display screen on the mobile phone good	4	1	1
The letters on the screen were a suitable size	4	1	1
The sound signaling diaries and feedback were suitable	5	0	1

along, and to fill out the diaries. Some experienced problems with submitting the diaries, e.g. that the registered information disappeared and they had to fill out the diary again. Two mentioned finding it challenging to report on their feelings in the morning diaries. Most wanted a bigger comment field to be able to write more to the therapist. One woman reported sometimes feeling frustrated because she felt misunderstood and was not able to explain herself. The participants' perception of the intervention did not change between the interviews.

The participant who dropped out after three weeks did not experience the intervention as helpful. This woman suffered from flu during the intervention period, something that may have affected her ability and interest in participating.

Response rate and technical issues

Five patients completed the pilot study. They had a mean response rate of 88% (range 78-94%) to the diaries. One woman recruited from general practice dropped out after three weeks (but still gave her evaluation). Her response rate to filling out the diaries was 42%.

Table 6 Evaluation of the intervention structure

	Too many	Suitable	Too few
Number of diary entries per day	1	5	0
Number of questions	3	3	0
Number of feedback messages	0	5	1
Number of weeks receiving feedback	0	4	2

Some experienced a few temporary problems with the Internet connection. It was reported to be frustrating to have filled out a diary form and then not be able to send it because of a validation error. This happened occasionally when the Internet connection was poor, and the validation process from the mobile phone to the server took too long; access was then denied to ensure data security. The researchers were contacted on a few occasions because of problems with submitting a diary form caused by "bad" Internet connections. One feedback message was sent to the wrong participant because the therapist clicked on the wrong feedback button in the system. We had one system breakdown during the pilot period. The system was restored to working order in a few hours and only the submission of the midday entries on one day was disturbed; the evening diary entries that day were completed as usual.

The therapist's clinical impression

The therapist's experience was mainly positive. She felt that an interactive relationship was established with most of the participants. Nevertheless, the goal of always being empathic and accepting without encouraging

avoidant behavior was sometimes found challenging without the ability of providing empathic nonverbal signals and dialog. On occasions, the therapist missed not being able to experience the reaction to questions and statements written in the feedback, especially when metaphors were used to stimulate reflection on values or other exercises anticipated to be emotionally demanding. When a participant reported a high pain score and a low mood it was sometimes tempting to reply with empathy only and not to confront and provide possible challenging questions and/or exercises. The participant's evaluation of how helpful the most recent feedback had been was useful. It might have been beneficial to have the possibility to refer to audio descriptions of more mindfulness exercises (preferably accessible on the mobile phone).

Before writing a feedback message, the therapist would view the three diary entries since the last feedback was sent. It was also necessary to look at the feedback history (all feedback messages were saved on the Web site) to ensure variance in the recommended CBT and mindfulness exercises and to avoid repeating information. No strict feedback template was followed and the amount of time used per feedback varied. Generally, 15-20 minutes were used, with the time decreasing somewhat with experience and the ability to copy and paste content between participants from the growing "bank" of previously written feedback messages.

Discussion

The aim of this pretrial study was to test the feasibility of delivering an online intervention on a mobile phone and to investigate its acceptability to women with chronic widespread pain and to providers. The intervention was mainly considered user-friendly and helpful, indicating a feasible intervention. The format of the diaries was well accepted and the response rate was generally high (> 80%). This is in accordance with response rates from other studies using electronic diaries [28,29]. Most participants rated the intervention as meaningful and some improvements were shown on measures of catastrophizing and pain acceptance. However, because of the small sample size, these results are of limited value. It should be kept in mind that four out of six women had participated in a rehabilitation program prior to the intervention. It needs to be mentioned that the nurse writing the feedback was also involved in the evaluation interviews and this may have affected the evaluation results. The intervention's framework of mindfulness-based CBT was considered acceptable but further studies are needed to investigate effectiveness and possible therapeutic processes.

Two of the women found some aspects of the intervention disturbing, frustrating and even difficult, e.g. found it challenging to report how they were feeling. Restricted emotional processing and a higher prevalence of alexithymia in patients with FMS than others has been indicated [30]. If and how this could affect the perception and outcome of this intervention needs to be explored.

Recruitment from GPs was not successful and only a few GPs responded to the invitation to include patients in this study. This is not an uncommon experience for e-health interventions [31] or health research in general [32]. Recruitment from the rehabilitation center was more successful. In addition, the experience of the participants from the rehabilitation center was more positive than that of the participants recruited from the GPs. Despite originally intending to recruit only from GPs, it was the impression of both the researchers and the therapist that the intervention might be more accessible following completion of a clinic-based program rather than as an independent intervention. Therapist time per participant was estimated to be about 6-8 hours (including initial meeting and 20 feedback messages). Therapist time is expected to decrease with the construction of a feedback "bank". The predicted economical cost of the intervention is greater than for Web-based interventions with no therapist support. However, results comparing Internet interventions with and without therapist support indicate that the role of an identified therapist has important added value for influencing adherence and outcome [33].

The results from this pretrial study indicate that some possible improvements could be made to the intervention. A few temporary problems with submitting diary entries occurred and should be addressed as they may cause frustration and affect dropout rates. Changes need to be made to eliminate the possibility of sending feedback to the wrong participant. A reduction in the number of items per diary entry might increase acceptability even further [28]. The possibility of participants using their own mobile phones instead of borrowed ones would be preferable. The content of the supplementary audio CD and worksheets could be made available on the participant's phone. Furthermore, to be more consistent with the mindfulness-based CBT framework the audio files should include only mindfulness exercises and not relaxation training. A structured theory-based feedback protocol could make replication of results more feasible, but might compromise the tailored situational aspect of the feedback.

Conclusions

The results of this pretrial study indicate that written online situational feedback via mobile phone is a feasible intervention for women with chronic widespread pain. The intervention will be further tested in a randomized

study to investigate therapeutic effectiveness on behavior change. Web applications are fast becoming standard ingredients in mobile phones and CBT interventions of this kind can be more readily available than before.

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Author details
[1]Faculty of Nursing, Oslo University College, Oslo, Norway. [2]Division of Psychiatry, St. Olavs Hospital, Trondheim, Norway. [3]Department of Public Health and General Practice, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway. [4]Stream Networks, Tønsberg, Norway. [5]Department of Behavioral Sciences in Medicine, University of Oslo, Oslo, Norway. [6]NIVEL (Netherlands Institute for Health Services Research), Utrecht, The Netherlands. [7]Jeloy Kurbad Rehabilitation Centre, Moss, Norway. [8]Faculty of Health Science, Buskerud University College, Drammen, Norway.

Authors' contributions
All authors participated in the development of the intervention. OBK recruited participants, helped by SHW who was responsible for Rehabilitation Center patient diagnostics. OBK performed the role of the therapist and participated in evaluation data collection. HE coordinated the study, participated in evaluation interviews and supervised data from participants and feedback. EAF supervised data from participants and feedback. EE was responsible for the design and development of the technological system. OBK and HE analyzed the data and drafted the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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Original Paper

A Smartphone-Based Intervention With Diaries and Therapist-Feedback to Reduce Catastrophizing and Increase Functioning in Women With Chronic Widespread Pain: Randomized Controlled Trial

Ólöf Birna Kristjánsdóttir[1,2], RN, MSc; Egil A Fors[3,4], MD, PhD; Erlend Eide[1,5]; Arnstein Finset[2], MApsych, PhD; Tonje Lauritzen Stensrud[2], MApsych; Sandra van Dulmen[6,7,8], MApsych, PhD; Sigrid Hørven Wigers[9], MD, PhD; Hilde Eide[1,8], RN, MApsych, PhD

[1]Institute of Nursing, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

[2]Department of Behavioral Sciences in Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

[3]Department of Psychiatry; National Competence Centre for Complex Symptom Disorders, St Olav University Hospital, Trondheim, Norway

[4]Department of Public Health and General Practice, Faculty of Medicine, General Practice Research Unit, Norwegian University of Science and Technology, Trondheim, Norway

[5]edesign, Tønsberg, Norway

[6]NIVEL (Netherlands Institute for Health Services Research), Utrecht, Netherlands

[7]Department of Primary and Community Care, Radboud University Nijmegen Medical Centre, Nijmegen, Netherlands

[8]Faculty of Health Sciences, Buskerud University College, Drammen, Norway

[9]Jeløy Kurbad Rehabilitation Centre, Moss, Norway

Corresponding Author:
Ólöf Birna Kristjánsdóttir, RN, MSc
Department of Behavioral Sciences in Medicine
Faculty of Medicine
University of Oslo
Post Box 1111 Blindern
Oslo, 0317
Norway
Phone: 47 22851020
Fax: 47 22851300
Email: kristjansdottir@gmail.com

Abstract

Background: Internet-based interventions using cognitive behavioral approaches can be effective in promoting self-management of chronic pain conditions. Web-based programs delivered via smartphones are increasingly used to support the self-management of various health disorders, but research on smartphone interventions for persons with chronic pain is limited.

Objective: The aim of this trial was to study the efficacy of a 4-week smartphone-delivered intervention with written diaries and therapist feedback following an inpatient chronic pain rehabilitation program.

Methods: A total of 140 women with chronic widespread pain who participated in a 4-week inpatient rehabilitation program were randomized into 2 groups: with or without a smartphone intervention after the rehabilitation. The smartphone intervention consisted of 1 face-to-face session and 4 weeks of written communication via a smartphone. Participants received 3 smartphone diary entries daily to support their awareness of and reflection on pain-related thoughts, feelings, and activities. The registered diaries were immediately available to a therapist who submitted personalized written feedback daily based on cognitive behavioral principles. Both groups were given access to a noninteractive website after discharge to promote constructive self-management. Outcomes were measured with self-reported questionnaires. The primary outcome measure of catastrophizing was determined using the pain catastrophizing scale (score range 0-52). Secondary outcomes included acceptance of pain, emotional distress, functioning, and symptom levels.

Results: Of the 140 participants, 112 completed the study: 48 in the intervention group and 64 in the control group. Immediately after the intervention period, the intervention group reported less catastrophizing (mean 9.20, SD 5.85) than the control group (mean 15.71, SD 9.11, *P*<.001), yielding a large effect size (Cohen's *d*=0.87) for study completers. At 5-month follow-up, the between-group effect sizes remained moderate for catastrophizing (Cohen's *d*=0.74, *P*=.003), acceptance of pain (Cohen's *d*=0.54, *P*=.02), and functioning and symptom levels (Cohen's *d*=0.75, *P*=.001).

Conclusions: The results suggest that a smartphone-delivered intervention with diaries and personalized feedback can reduce catastrophizing and prevent increases in functional impairment and symptom levels in women with chronic widespread pain following inpatient rehabilitation.

Trial Registration: Clinicaltrials.gov NCT01236209; http://www.clinicaltrials.gov/ct2/show/NCT01236209 (Archived by WebCite at http://www.webcitation.org/6DUejLpPY)

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KEYWORDS

Widespread Chronic Pain; Fibromyalgia; Self-management; Mobile phones; Internet; Cognitive Therapy; Catastrophization, Recurrence

Introduction

Chronic widespread pain is a common cause of suffering. An estimated 4% to 10% of the adult population experiences chronic widespread pain, ie, musculoskeletal pain lasting for more than 3 months not caused by an identifiable physical pathology [1-5]. This pain is often accompanied by other symptoms, including fatigue, sleep disturbance, and emotional distress [2]. A subgroup meets the criteria for fibromyalgia syndrome, where in addition to the chronic pain, the pain thresholds are reduced and tenderness in more than 10 of 18 specified trigger points is identified [2,3]. The development and maintenance of chronic widespread pain and fibromyalgia involve a complex dynamic process with biological, cognitive, and psychosocial factors. The cause or underlying mechanisms are still not clearly identified and no single cure is available. Maladaptive thoughts and feelings seem to play an important part in the negative spiral resulting in the maintenance of chronic pain [6]. Multidimensional rehabilitation, including physical exercise and cognitive behavioral therapy (CBT), is recommended as treatment [7-8]. A key element is self-management, eg, balancing activity and rest, stress management, emotion regulation, and doing appropriate physical exercises [6-10]. However, relapse of symptoms is not uncommon [8,11,12] because self-management can be challenging due to the nature of the symptoms. Few studies have examined home-delivered interventions that aim to support self-management of chronic pain following rehabilitation [11-13].

Pain Conditions and Web-Based Interventions

Internet-based interventions using cognitive behavioral approaches can be effective in promoting self-management of chronic pain conditions [14-16]. Web-based programs delivered through smartphones are increasingly used to support the self-management of various health disorders; however, research on smartphone interventions for patients with chronic pain is limited [17]. Among the advantages of using smartphones rather than the traditional personal computer s are their small size and mobility, making self-management support available to the user in most situations [17]. Diaries with questions intended to support awareness and reflection are made available on the phone and the registered information can be submitted to a website and made instantly available to a therapist. Feedback can be automatically delivered and tailored to the registered information to some extent, or it can be even more personalized by a therapist [18-20]. In a recent study, a panel of health care professionals and people experiencing chronic pain discussed characteristics of a successful Internet self-management program. Important features included assisting patients to be more aware of their patterns of behavior and psychological experience, supporting the pursuit of personal goals and values-based behavior, and by using a small and mobile device for real-time monitoring and response [21]. The number of pain self-management applications for smartphones has increased exponentially since 2009 [22]. In 2010, more than 90 applications offering support in the self-management of chronic pain were available in application stores. There is a need for research in this field because many applications seem to have been developed without the involvement of a health care professional and, to our knowledge, none have been tested in randomized trials [22].

Theoretical Model

Cognitive and emotional factors influence the pain experience [23]. Among the psychological constructs that can play an important role in the development and maintenance of chronic pain is catastrophizing [6,23,24]. Pain-related catastrophizing includes the tendency to ruminate about and magnify symptoms, to expect the worst, and to feel helpless regarding self-management [25]. Catastrophizing tends to discourage patients from committing to their valued behavior and it has consistently been found to predict distress and disability [6,26,27]. In rehabilitation, catastrophizing is targeted in a number of ways, such as with CBT and exercise programs [6,28]. However, interventions delivered in the patient's private environment, supporting awareness of maladaptive thoughts and feelings, and providing personalized feedback may further help reduce catastrophizing [13,18]. A mobile phone-delivered intervention with diaries and daily CBT-based feedback has been found to reduce catastrophizing thoughts in patients with irritable bowel syndrome and these effects were maintained at a 3-month follow-up [18].

Acceptance and Commitment Therapy (ACT) is a third-generation CBT based on the notion that suffering may largely be caused by thinking about painful experiences rather than the experiences themselves [29]. Suffering can be reduced through mindfulness, acceptance, and committed action [29]. ACT has been found to be effective for people with various chronic health disorders [30], and has been used successfully to reduce catastrophizing and disability in chronic pain patients [31-33]. The goals are to promote psychological flexibility, such as acceptance of, rather than struggling with, unwanted thoughts, emotions, and symptoms (eg, pain or catastrophizing) and to increase commitment to personal values [28,29,34]. A person's values are described as his or her desired way of being within various life domains (eg, being a caring friend). Values differ from goals in that they can never be fully obtained, but can give a continuous sense of motivation, direction, and purpose [28]. The focus on values is also evident in the self-determination theory (SDT) that states the importance of perceiving behavior as self-determined for intrinsic motivation to be maintained [35]. According to the SDT, context-specific feedback can play a role in enhancing intrinsic motivation to maintain behavior [35]. Guidance was also found in the elaboration likelihood model of persuasion theory [36]. This theory specifies how information can be constructed and presented to enhance either cognitive elaboration or emotional elaboration intending to influence behavior change. Elements focused on in this study are repetition, personal relevance and involvement influencing the cognitive level, and influencing emotional pathways through emotion recognition, mindfulness exercises, and empathic communication.

Aims of the Study

We hypothesized that receiving personalized feedback shortly after having registered pain-related thoughts, feelings, and self-management activities in an everyday setting might reduce catastrophizing and increase functioning. The results of our pretrial study of a similar smartphone intervention indicated feasibility and user-friendliness for patients with chronic widespread pain [20].

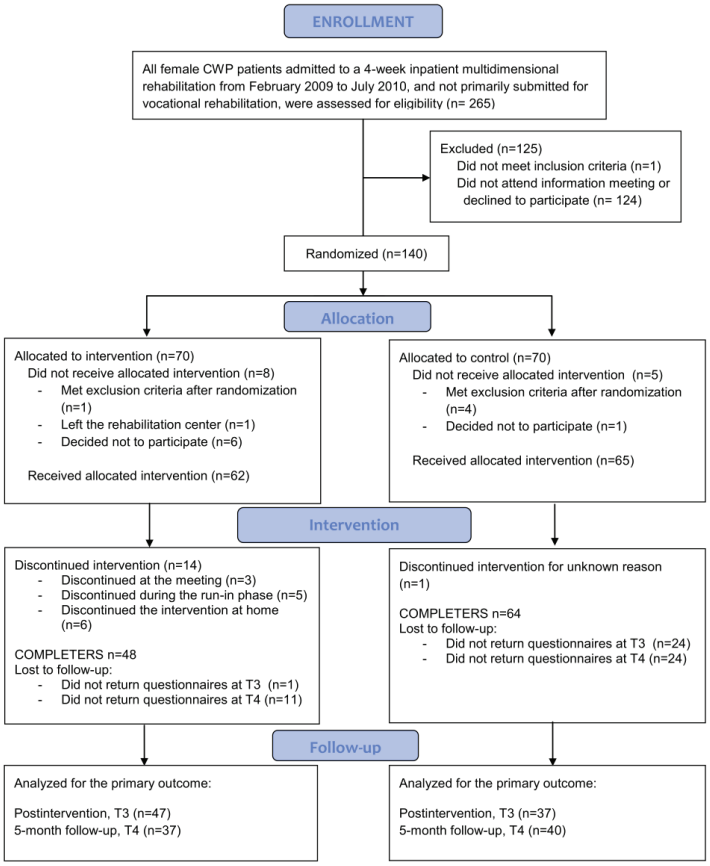
The present randomized controlled trial investigates the efficacy of a smartphone intervention on catastrophizing, acceptance, emotional distress, values-based behavior, and functioning and symptom level in women with chronic widespread pain who had completed a 4-week inpatient rehabilitation program. For the first 4 weeks after discharge, the intervention group received a Web-based intervention comprising registration of symptoms, thoughts, feelings, and self-management behavior through daily smartphone diaries and written personalized CBT-based feedback. It was hypothesized that the intervention group would show less catastrophizing and emotional distress, more acceptance of pain, and success in values-based living, and improved functioning and symptom levels after completing the intervention period and at a 5-month follow-up compared to a control group.

Methods

Study Design

The overall study design is shown in Figure 1. The design is a parallel-group, randomized controlled trial. Block randomization was used for practical reasons to ensure similar numbers in each group at each time point. All participants attended a 4-week inpatient multidimensional rehabilitation program for chronic pain (see Treatment Procedures). In the fourth week of the program, participants were randomly assigned to 1 of the 2 study groups. The intervention group received a smartphone intervention for 4 weeks after completing the inpatient rehabilitation. Both groups were given access to a noninteractive website with self-help pain management material. Self-reported assessments were gathered at 4 time-points: before (T1) and after (T2) the inpatient program, 4 weeks after discharge when the intervention group had completed their smartphone intervention (T3), and 6 months after discharge from the rehabilitation center (T4). The first 2 questionnaires were received and completed at the rehabilitation center and the last 2 were completed at home and returned by mail. One reminder letter was sent followed by a phone call from a researcher if the questionnaire was not returned.

Figure 1. Study design and participant flow.



Participants

Participants were recruited consecutively from Jeløy Kurbad Rehabilitation Center in Moss, Norway. Patients were referred to the center by their general practitioner or a medical specialist. The inclusion criteria were: female, 18 years or older, participating in the inpatient multidimensional rehabilitation program for chronic pain, having chronic widespread pain for more than 6 months (with or without a diagnosis of fibromyalgia), not participating in another research project at

the rehabilitation center, being able to use a smartphone, and not being diagnosed with a profound psychiatric disorder. The study took place between February 2009 and August 2010.

Ethical Aspects

The study was approved by the Regional Ethics Committee in South-East Norway and by the Norwegian Social Science Services. All participants signed an informed consent form. The study is registered at ClinicalTrial.gov (NCT01236209).

Procedures

At admission to the inpatient rehabilitation program, all chronic widespread pain patients received a written invitation to attend an informational group meeting where a researcher or a research assistant presented the study. Those who were interested in participating and met the inclusion criteria were given an informed consent form to sign.

A computer-generated sequence list with the 2 groups randomized in blocks of 4 was used because admission of 4 patients per week was expected. The computer-generated inclusion pattern was either 2 participants in each group or 3 to one group, sometimes 3 in the control group and other times 3 in the intervention group, until the final number of 140 was reached. A research assistant put the allocation information in sequentially numbered envelopes and sealed them. A researcher subsequently gave each participant a number and opened the matched envelope to reveal the group allocation. The information about group allocation was revealed to the participant at the inclusion meeting with a nurse in the final week of the inpatient program.

Assessment Measures

Participants completed self-administered questionnaires in paper format on arrival at the rehabilitation center (T1), at discharge (T2), immediately after the smartphone intervention (T3), and 6 months after discharge from the rehabilitation center (T4), which was 5 months after the smartphone intervention.

The pain catastrophizing scale (PCS) [25] was used to measure the primary outcome variable of the study, catastrophizing. It is a 13-item questionnaire with questions on helplessness, magnification, and rumination. Patients rate items on a scale from 0 (not at all) to 4 (all the time). The total score range for the PCS is 0 to 52, with higher scores reflecting higher degrees of catastrophizing. In our sample, the internal consistency was high on all assessments (Cronbach alpha range .892 to .942). As in prior research, scores greater than 24 were considered high [25,37].

The chronic pain acceptance questionnaire (CPAQ) [38] was used to measure acceptance. It is a 20-item self-report instrument developed to capture the extent of participation in daily activities despite pain and willingness to experience pain without trying to control, alter, or avoid it. It is scored on a 7-point Likert scale (0 = never true; 6 = always true) to give the total score (0-120). Higher scores reflect higher acceptance of pain and higher activities engagement. The reliability of the CPAQ has been established [38]. In our study, the Cronbach alpha coefficients were .814 to .910.

The questions from the 12-item General Health Questionnaire (GHQ) were used [39] with modified response alternatives. Responses to all items were given on the same 4-point scale (much less than usual, same as usual, more than usual, and much more than usual), but not on 2 scales as in the original. The questions measure changes in emotional distress over the previous couple of weeks. A bimodal scoring method was used (1 = symptom present more than usual; 0 = symptom present less than or as usual). Total score range is 0 to 12; indicating the number of symptoms present more than usual during the past 2 weeks. In the current study, the Cronbach alpha coefficients were .703 to .871.

The Chronic Pain Values Inventory (CPVI) is a 12-item measure of importance and success in living according to one's own values in 6 domains (family, intimate relationships, friendship, work, health, and personal growth) [40]. Each item is rated on a scale from 0 to 5, with higher numbers indicating more importance or success. The mean success rating was used as a measure of values-based action (score range 0-5), as suggested by the authors [40]. In the present study, the Cronbach alpha coefficients for the success scale were .754 to .882.

The current levels (past couple of days) of pain, fatigue, and sleep disturbance were assessed on visual analog scales (VAS) from 0 (no pain/fatigue/sleep disturbance) to 100 (worst imaginable pain/fatigue/sleep disturbance) because these are cardinal symptoms of chronic widespread pain and fibromyalgia.

The original version of the Fibromyalgia Impact Questionnaire (FIQ) was used to measure the impact of fibromyalgia on functioning and symptom levels the past week. It consists of 10 questions with different response alternatives. One question includes 10 subitems related to the ability to perform activities of daily living. The response alternatives are given on a 4-point scale. The other questions enquire about general well-being, ability to work, and level of pain, fatigue, stiffness, and symptoms of anxiety and depression. Questions on symptom level are answered using a VAS from 0 to 100 (high symptom level). The score range is 0 to 100; higher scores indicate greater impairment [41]. The Cronbach alpha coefficients were .807 to .860.

The Short-Form Health Survey (SF-8) was also used to measure functioning. The SF-8 includes 8 items, scored on 5- or 6-point Likert scales, regarding level of functioning the past week. Summary measure scales for the mental health component and the physical component were obtained by using SF-8 Scoring Software 4.5 [42]. Scoring is standardized using the means and standard deviations from a survey from the general adult population in the United States (standardized mean 50, SD 10). Higher scores indicate better functioning; scores above 50 indicate functioning above the average in the US population. In the Norwegian version used in the present study, wording of response options for 2 items differed slightly from the original. In the original, the response alternatives for the item on role physical are none at all, a little bit, some, quite a lot, and could not do daily work. In our version, instead of "a little bit" the response was "very little." In the original, the response alternatives for the mental health item are not at all, slightly, moderately, quite a lot, and extremely. In our version, "very

little" was used instead of "slightly." The Cronbach alpha coefficients were .785 to .865 in the present study. Use of the noninteractive website was assessed with a self-report 4 weeks after discharge (T3) on how often the participant had visited the website.

Feasibility of the smartphone intervention was assessed with single questions postintervention (T3). For example, "I feel it has been a burden to participate in this intervention (to fill out diaries and receive feedback)" with a 5-point Likert scale (1 = agree completely; 5 = disagree completely).

Treatment Procedures

Inpatient Multidimensional Rehabilitation

All participants participated in a 4-week inpatient multidimensional rehabilitation program for patients with chronic pain. It included education in pain mechanisms and CBT-based pain management (approximately 20 hours), group sessions based on motivational interviewing (4 hours), various forms of aerobic exercise (outdoors, in the pool, and in the gym), stretching, and relaxation. In addition, individual myofascial pain treatment was given in accordance with the protocol of Travell [43,44] and medication was administered as needed (see [9] for details of the program).

Smartphone Intervention: Diaries and Daily Situational Feedback

The intervention was developed in 2008. One of the authors (EE) was responsible for the software development. The usability of the intervention was tested in a pretrial study with 6 women with chronic pain. Participation was experienced by the majority as supportive and motivating [20]. The key ACT concepts and a summary of their operationalization in the intervention are shown in Table 1 [28,34].

Table 1. Examples of Acceptance and Commitment Therapy (ACT) elements in diaries and feedback.

ACT element	Aim of diaries	Examples of diary questions	Aim of feedback	Examples of feedback
Cognitive defusion/ mindfulness	Awareness supported by making diary entries on thoughts, feelings and behavior three times a day	(1) Right now, my breathing is deep and relaxed. (2) Right now, I believe it is harmful for me to use my body. (3) Right now, I am coping well with the pain.	Reflection on effects of thoughts and feelings on behavior	I see that you register that your breathing is not relaxed. Can you give yourself a minute or two to just notice your breathing? Maybe you can find a quiet spot and close your eyes. You could try breathing deeply and slowly a couple of times. Try focusing only on your breath. If you want, you can listen to the instructions to a short mindfulness breathing exercise on the smartphone/website. All the best, Ann.
Values and values-based action	Awareness, planning and evaluation supported by keeping a diary	Today, I plan to multiple choices possible : take a walk/work/rest lying down/do household chores/do relaxation exercises/take care of children or others/eat regularly/exercise at a moderate tempo/do my stretching exercises/spend time with family/rest sitting down/spend time with friends/do some shopping/do aerobic exercises/do something just for the pleasure of it.	Reflection on values and values-based behavior based on reports in diaries	I see you have done your stretching exercises today despite reporting a pain level of 6 (scale from 0 to 10; 0=no pain, 10=worst imaginable pain). Can you give yourself a moment to reflect on why this is something you value and choose to do? I would like to ask you to reflect again on your values, if you are willing to, over the next few days. Values are qualities we ourselves think are important and can give us a sense of direction in life. We can ask ourselves questions like: What kind of a person would I like to be in my relations with my family? What can I do today that would get me a bit closer to this ideal? Is this something I am willing to do? Our values are something we can continuously work toward (like being a caring friend), not something we will obtain once and for all. Have a nice weekend, Ann.
Acceptance vs avoidance	Awareness of a spectrum of pain-related thoughts, feelings, and behavior supported by keeping a diary	(1) Right now, I am afraid to be active because of my pain." (2) Right now, I feel my life is good despite my pain. (3) Right now, I am doing what I want to even if it means increased pain.	Supporting willingness to act in accordance with values despite pain or discouraging thoughts and feelings	(1) I see that today you are not too pleased with your life. Can you give yourself a moment and reflect on what you would want to do today if you were pain free? Is it possible for you to take a small step toward what you want even with your pain? Could you, instead of saying, "I want this, BUT I have pain and therefore can't" say "I experience pain AND I am taking baby steps toward something valuable to me." Are you willing to take small steps? (2) Last night you reported a pain level of 8 and that you felt relaxed, grateful, and pleased with the day's activity level. Can you take a moment to reflect on what kind of self-management strategies you used yesterday? All the best, Ann

The smartphone intervention had the following 4 components:

1. Face-to-face session. The intervention started with a 1-hour individual session between a nurse working on the project and the participant. The session took place in the final week before discharge. Each participant was informed about the intervention and asked about functioning, goals for health-related behavior, and support needs. Values and values-based activities were discussed and the patient received 2 written values-based exercises to take home. The participant was lent a smartphone (HTC TyTN) with a touchscreen and a keyboard. The participants received information (name and qualifications) about their therapist for the intervention (in some cases this was the nurse at the meeting). The nurse attending the face-to-face session summarized the meeting and sent it to the relevant therapist.

2. Web-based diaries. The participant was asked to complete 3 diary entries per day using the smartphone. See Figure 2 for a view of the screen display. The diaries included 16 to 24 questions about the current level and interference of pain, and feelings and thoughts related to avoidance, catastrophizing, and acceptance. They also included questions about planned and previous use of self-management activities and daily values-based and practical activities. Lists of self-management activities (eg, mild exercise, stretching, resting, aerobic exercise,

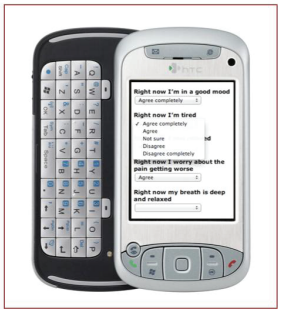
and pleasurable activity) were provided as a reminder. The questions were chosen to support self-monitoring and reflection and were formulated in accordance with the experience sampling method principles designed to capture experience in real time without retrospective bias (eg, "Right now I am feeling...") [45]. See Table 1 for examples of the questions. Participants answered most questions by choosing predefined alternatives or scoring on 5-point Likert scales as shown in Figure 2. All diaries included a comment field giving participants the opportunity to write a short personal message to the therapist. The morning and evening diary entries were sent at fixed hours chosen by each participant. The second diary entry of the day was sent at a time randomly chosen by the Web server, between 11 am and 2 pm. The purpose of including 3 diary entries, including 1 at a randomly chosen time, was to encourage self-monitoring and reflection at different hours and in different situations. At the time scheduled for diary completion, the participant received a Short Message Service (SMS) message with a link to a secure website, where the diary could be opened and questions answered and posted. The participants completed the first diary entry during the face-to-face session, and continued during the final week before discharge with the goal of getting used to the diaries before discharge (a run-in period). After discharge, the diaries were received for 4 weeks. The participant could call a member of the research group (OBK or HE) for technical support. No data were kept on the mobile phone. Up to two automated SMS reminders were sent, if the participant had not responded within 20 to 40 minutes after receiving the SMS signalizing a diary form.

3. Written situational feedback. For 4 weeks after discharge, excluding weekends, participants received daily written feedback from a therapist on the information they had provided in their diaries. The feedback was personalized according to each participant's situation as reported in the diary. It was written in an empathic style and included repetition of content reported in the diaries, positive reinforcement, reminders of self-management information given at the rehabilitation center, ACT exercises, and reflective questions. The aim was to encourage nonjudgmental awareness of catastrophizing and to stimulate mindfulness and willingness to engage in meaningful activities despite pain or other discouraging intrusions (Table 1). The instructions for the exercises were written directly in the feedback or the participant was referred to exercises available on the mobile phone and/or the website. The feedback was also personalized according to the summary of personal information given at the face-to-face session (eg, family situation and health-related goals) and results on self-reported discrepancy between values and values-based living assessed with the CPVI at the end of the rehabilitation program. 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, feedback based on information from the most recent 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 found. There was no limitation on the length of the feedback, which ranged from a few sentences to a few paragraphs.

The feedback was written by any of 3 of the authors (OBK, TLS, and HE); each participant received signed feedback from the same person throughout the intervention. All therapists had a background in health care sciences (nursing and/or psychology) and had received training in ACT. The feedback protocol was based on ACT for chronic pain [28,34] with a different focus during each of the 4 weeks. For example, in the first week, the focus was on supporting the participant to continue doing the exercises/stretches as recommended at the inpatient program, and during the second week, simple mindfulness exercises were introduced (eg, a few minutes of focused breathing). Once a week, the feedback included an invitation to a values reflection exercise, and every week, questions were included to stimulate reflection on health-related goals. The final feedback comprised a written summary of the registered diary information during the 4-week period. Content from the growing bank of feedback written by all the therapists was used for other participants when appropriate according to the registered information. It took 10 to 15 minutes, on average, to write each piece of feedback. Two members of the group supervised the content of the feedback. They had extensive experience in teaching mindfulness meditation (HE) and supervising CBT/ACT (EAF).

4. Audio files with guided mindfulness exercises. Four audio files with mindfulness exercises (eg, focused breathing) guided by the authors were available on the smartphones.

Figure 2. Smartphone screen display of diary.



Informational Website With Self-help Pain Management Material

All participants received access to a website with information on self-management strategies for people with chronic pain; not anticipated to have large effect on the study outcomes on its own. It was noninteractive (ie, participants could not register any information or receive feedback). The website included a few written ACT exercises and audio files with mindfulness exercises (as described previously). An example of the written

exercises is a behavior analysis aiming to strengthen the ability to observe thought content, feelings, and behavior and the connection between these (adapted from [28]).

Statistical Procedures

Power analyses were based on the level of reported catastrophizing in chronic widespread pain samples [5,20,46,47], a moderate effect size (Cohen's *d*=0.5), and allowing for attrition commonly seen in studies on Internet interventions [15,48]. A sample size of 70 participants per group was needed to detect a moderate effect size in the primary outcome variable with a 2-sided 5% significance level and 80% power. To investigate differences in demographic variables and baseline characteristics, independent sample *t* tests, nonparametric tests, and Chi-square tests were used. Data were checked for normal distribution; *t* tests were used when found suitable for parametric analyses, otherwise nonparametric tests (Mann-Whitney) were applied. The Cohen's *d* effect sizes were calculated by using the difference between the groups' means divided by the mean standard deviation of both groups. If 1 or 2 items were missing on the GHQ, they were scored as 0 (symptom present less than or as usual). If another instrument included 1 or 2 missing items, the item(s) were replaced with the mean of other items from the participant's instrument. If 2 response alternatives were marked, the healthier option was chosen. Total score was not computed if more than 2 items were missing, and the case was categorized as missing a total score for the instrument. The number of participants included in each analysis is given. In the intention-to-treat analysis, the last observed value was carried forward when data was missing. Five of the participants who withdrew from the smartphone intervention sent in questionnaires at T3 and at the 5-month follow-up (T4). The intention-to-treat analysis included all participants except those who met the exclusion criteria after randomization (n=135). In the analysis of secondary outcomes, only those who completed the interventions were included (n=112). A significance level of $P<.05$ was used and a tendency toward difference was defined as $P<.1$. Effect sizes were categorized as small (< 0.5), medium (0.5-0.8), and large (> 0.8) in accordance with Cohen [49].

Results

Participants

A total of 265 women eligible for the study were invited to an informational meeting about the project. Of these, 124 did not attend the meeting or declined to participate. Only 1 was excluded because of a severe psychiatric disorder. One hundred and forty were randomized to the 2 study arms (Figure 1). Five participants met the exclusion criteria after randomization (they were originally submitted for vocational rehabilitation and included in another research project) and 8 discontinued participation before receiving the allocated intervention. In the intervention group, 14 participants did not complete the intervention. Many of those who discontinued participation did so either at the meeting were the allocation information was given or during the intervention's run-in period at the rehabilitation center. The most common reason for withdrawal was finding the participation too stressful in combination with the inpatient program. Another 6 participants discontinued the intervention after discharge from the inpatient program. Demographic data and baseline characteristics of the sample by groups are presented in Table 2. Despite randomization, the groups differed in mean pain level ($P=.02$) and physical functioning measured by SF-8 ($P=.03$) at admission to the rehabilitation center. There were no statistically significant differences between the groups at discharge from the rehabilitation center.

Table 2. Participants' characteristics at admission to the inpatient program (T1).

Characteristic		Smartphone intervention (n=69)[a]	Control (n=66)[a]
Age, mean (SD), n		44.59 (11.13), 69	43.80 (11.20), 65
Marital status, n (%)			
	Married or cohabiting	42 (60.9)	45 (68.2)
	Divorced	9 (13.0)	6 (9.1)
	Single	13 (18.8)	10 (15.2)
	Widow	4 (5.8)	2 (3.0)
	Unknown	1 (1.4)	3 (4.5)
Years of education, n (%)			
	10 years (elementary)	13 (18.8)	8 (12.1)
	11-13 years (high school)	19 (27.5)	30 (45.5)
	>13 years (college/university)	30 (43.5)	23 (34.8)
	Unknown	7 (10.1)	5 (7.6)
Employment status, n (%)			
	Working/studying	15 (21.7)	8 (12.1)
	Unemployed	3 (4.3)	1 (1.5)
	On sick leave	27 (39.1)	34 (51.5)
	On disability pension	12 (17.4)	13 (19.7)
	Working/studying part time and part time sick leave	8 (11.6)	5 (7.6)
	Other combination of the above	4 (5.8)	4 (6.1)
	Unknown	0	1 (1.5)
Diagnosed with fibromyalgia, n (%)		55 (80.9)	54 (84.4)
Duration of symptoms (years), mean (SD)		13.11 (8.78)	15.47 (12.09)
Current VAS [b] rating (past couple of days), mean (SD), n			
	Pain	67.08 (17.47), 69	57.85 (21.60), 66
	Fatigue	67.40 (23.73), 69	64.72 (21.02), 66
	Sleep disturbance	57.24 (26.22) 68	55.16 (23.38), 66
Assessments [c] and ranges, mean (SD), n			
	PCS (0-52[d])	21.24 (10.33), 63	20.80 (9.45), 62
	CPAQ (0[d]-120)	56.48 (15.02), 58	53.87 (13.81), 57
	FIQ (0-100[d])	58.75 (16.39), 69	58.58 (16.04), 66
	SF-8, physical (0[d]-100)	31.91 (7.57), 65	34.75 (7.35), 62
	SF-8, mental (0[d]-100)	39.33 (10.49), 65	39.34 (9.61), 62
	GHQ-12 (0-12[d])	3.32 (3.38), 62	3.02 (3.38), 61
	CPVI (0[d]-6)	2.07 (0.95), 64	2.01 (0.73), 61

[a] Patients meeting exclusion criteria after randomization were not included in this analysis.

[b] VAS: visual analog scale, range 0-100.

[c] PCS: pain catastrophizing scale; CPAQ: Chronic Pain Acceptance Questionnaire; FIQ: Fibromyalgia Impact Questionnaire; SF-8: Short-Form Health Survey; GHQ-12: General Health Questionnaire; and CPVI: Chronic Pain Values Inventory.

[d] Values that indicate maximum symptom scores/least health.

Information about fibromyalgia diagnosis was available for 132 participants, and 82.6% of these met the American College of Rheumatology's classification criteria for fibromyalgia. As shown in Tables 3 and 4, no significant group differences were detected at discharge from the rehabilitation center on any of the outcome variables.

Table 3. Means and standard deviations for the primary outcome measure, the pain catastrophizing scale (PCS), at admission to inpatient rehabilitation (T1), at discharge (T2), immediately after intervention (T3), and 5 months after the intervention period (T4).

PCS	T1	T2	T3	T4
ITT and LOCF [a], mean (SD), n				
Intervention	21.24 (10.33), 63	16.06 (10.37), 68	12.32 (9.22), 69	13.59 (9.72), 69
Control	20.80 (9.45), 62	15.33 (9.31), 65	16.07 (9.48), 65	17.43 (11.60), 66
Per protocol, mean (SD), n				
Intervention	20.56 (10.08), 43	14.61 (8.93), 45	9.20 (5.85), 47	10.92 (8.58), 37
Control	20.78 (9.59), 60	15.46 (9.76), 57	15.71 (9.11), 37	18.70 (12.45), 40
PCS score > 24, n (%)				
Intervention	13 (30.2)	7 (15.6)	0 (0)	1 (2.7)
Control	20 (33.3)	10 (17.5)	6 (16.7)	14 (35.0)

[a] ITT: intention-to-treat; LOCF: last observation carried forward.

Table 4. Means and standard deviations for the secondary outcome measures at admission to the inpatient rehabilitation (T1), at discharge (T2), immediately after intervention (T3) and 5 months after the intervention period (T4) for the participants who completed the study.

Secondary outcome measures[a]	T1 mean (SD), n	T2 mean (SD), n	T3 mean (SD), n	T4 mean (SD), n
CPAQ				
Intervention	56.45 (15.22), 40	62.00 (13.62), 44	72.50 (15.67), 44	71.42 (18.38), 36
Control	53.94 (13.92), 56	62.21 (10.15), 57	63.55 (13.33), 38	62.47 (14.87), 38
FIQ				
Intervention	58.46 (17.26), 48	46.38 (16.92), 47	49.12 (19.65), 47	46.45 (19.37), 37
Control	58.35 (16.18), 64	49.10 (17.32), 62	53.07 (18.68), 39	59.92 (16.46), 40
SF-8, physical				
Intervention	32.12 (7.74), 45	36.68 (8.42), 40	35.24 (8.74), 46	37.54 (9.44), 37
Control	34.98 (7.13), 60	35.86 (8.24), 49	36.55 (8.17), 37	34.37 (8.59), 40
SF-8, mental				
Intervention	39.50 (10.67), 45	45.70 (8.06), 40	46.82 (8.85), 47	44.34 (10.42), 37
Control	39.09 (9.61), 60	44.83 (9.69), 49	41.01 (9.70), 37	39.78 (10.70), 40
GHQ-12				
Intervention	3.19 (3.21), 43	1.20 (2.02), 45	1.78 (2.51), 46	1.89 (2.57), 37
Control	2.97 (3.43), 59	0.63 (1.01), 57	1.86 (2.07), 37	2.85 (3.25), 40
CPVI				
Intervention	2.05 (0.95), 44	2.47 (0.91), 46	2.95 (0.99), 46	2.62 (0.93), 37
Control	2.02 (0.74), 59	2.52 (0.68), 54	2.35 (0.91), 38	2.27 (0.83), 40
Pain, VAS				
Intervention	66.59 (17.58), 48	53.07 (22.20), 47	54.14 (24.06), 47	51.96 (23.76), 37
Control	57.32 (21.56), 64	52.99 (21.27), 61	50.56 (23.37), 40	58.45 (22.46), 40
Fatigue, VAS				
Intervention	69.29 (23.98), 48	51.38 (27.75), 47	52.26 (29.18), 47	55.24 (25.73), 37
Control	64.08 (21.01), 64	50.10 (24.28), 61	53.20 (24.04), 40	65.03 (21.64), 40
Sleep disturbance, VAS				
Intervention	54.77 (26.99), 47	43.97 (25.77), 47	43.41 (30.60), 47	43.32 (27.88), 37
Control	54.59 (23.31), 64	48.12 (24.57), 62	48.90 (26.12), 40	57.68 (24.67), 40

[a] CPAQ: Chronic Pain Acceptance Questionnaire; FIQ: Fibromyalgia Impact Questionnaire; SF-8: Short-Form Health Survey; GHQ-12: General Health Questionnaire; CPVI: Chronic Pain Values Inventory; and VAS: visual analog scale.

Within-Group Analysis

Temporal changes within groups and effect sizes within the groups are presented in Tables 5 and 6. Analysis according to the intention-to-treat principles showed a small positive effect on catastrophizing in the intervention group at both assessments and a small negative effect was shown at the 5-month follow-up in the control group. Per-protocol analysis revealed moderate effects on catastrophizing, pain acceptance, and success in living according to values in the intervention group immediately after the follow-up intervention period. The control group did not improve on these variables. The percentage of participants with a total score above 24 on the PCS decreased in the smartphone group, but not in the control group. Increased emotional distress was reported in the control group at 5-month follow-up. Function and symptom impairment, as measured by the FIQ, was increased at both measurements in the control group only. Six months after discharge from the rehabilitation center (5-month follow-up, T4), the improvement in catastrophizing and pain acceptance remained for the intervention group. The changes in success in values-based living were not maintained. However, the control group reported less success in values-based living at the 5-month (T4) follow-up compared to the level at discharge. Pain level was stable in both groups. Fatigue had increased in the control group at the 5-month follow-up and there was a tendency toward more sleep disturbance, which was not seen in the intervention group. Factor analysis of the Norwegian version of the CPAQ revealed some inconsistencies with the 2-factor structure of the scale; 4 items were found to not fit the originally described structure [38]. Because we do

not report on the questionnaire's subscale, we decided to include all questions in our analysis. The results did not differ in a significant way when the 4 items were excluded.

Table 5. Mean differences for the primary outcome measure, the pain catastrophizing scale (PCS) within groups, confidence intervals (CI), and effect sizes (ES).

PCS	Mean difference T2–T3[a] (n)	95% CI T2–T3[a]	Mean difference T2–T4[b] (n)	95% CI T2–T4[b]	ES T2–T3[a]	*P* value[c]	ES T2–T4[b]	*P* value[c]
ITT and LOCF [d]								
Intervention	–3.65 (68)	–5.24 to –2.07	–2.37 (68)	–4.32 to –0.41	0.37	< .001	0.24	.02
Control	0.74 (65)	–0.70 to 2.17	2.30 (65)	0.43-4.16	–0.08	.31	–0.22	.02
Per protocol								
Intervention	–5.09 (44)	–7.00 to –3.18	–2.96 (36)	–5.78 to –0.13	0.69	< .001	0.33	.04
Control	1.67 (34)	–1.06 to 4.40	2.58 (37)	–0.37 to 5.53	–0.18	.22	–0.24	.09

[a] T2: at discharge; T3: immediately after intervention.

[b] T2: at discharge; T4: 5 months after intervention.

[c] *P* values for paired samples *t* tests.

[d] ITT: intention-to-treat; LOCF: last observation carried forward.

Table 6. Mean differences for the secondary outcome measures within groups, confidence intervals (CI), and effect sizes (ES) for the completers.

Secondary outcome measures[a]	Mean difference T2–T3[b] (n)	95% CI T2–T3[b]	Mean difference T2–T4[c] (n)	95% CI T2–T4[c]	ES T2–T3[a]	*P* value[d]	ES T2–T4[c]	*P* value[d]
CPAQ								
Intervention	8.75 (40)	5.96-11.54	7.29 (34)	3.11-11.47	0.58	< .001	0.45	.001
Control	0.69 (36)	–2.90 to 4.29	0.40 (35)	–3.43 to 4.23	0.06	.70	0.03	.83
FIQ								
Intervention	3.10 (46)	–1.01 to 7.20	1.60 (36)	–4.40 to 7.60	–0.17	.14	–0.09	.59
Control	6.61 (38)	2.14-11.09	10.46 (39)	6.43-14.49	–0.36	.005	–0.62	< .001
SF-8, physical								
Intervention	–1.69 (39)	–3.96 to 0.59	0.06 (30)	–3.73 to 3.86	–0.19	.14	0.01	.97
Control	–1.17 (29)	–4.18 to 1.83	–2.41 (32)	–5.17 to 0.36	–0.14	.43	–0.29	.09
SF-8, mental								
Intervention	1.28 (39)	–1.72 to 4.28	–1.51 (30)	–4.93 to 1.92	0.15	.39	–0.17	.38
Control	–3.59 (29)	–7.04 to –0.14	–4.92 (32)	–9.55 to –0.30	–0.37	0.04	–0.50	.04
GHQ-12								
Intervention	0.58 (43)	–0.06 to 1.22	0.80 (35)	–0.42 to 2.02	–0.25	.07	–0.34	.19
Control	1.26 (34)	0.59-1.94	2.38 (37)	1.12-3.63	–0.80	.001	–1.09	< .001
CPVI								
Intervention	0.49 (44)	0.26-0.72	0.15 (36)	–0.11 to 0.42	0.52	< .001	0.16	.25
Control	–0.22 (33)	–0.49 to 0.06	–0.47 (34)	–0.83 to –0.10	–0.28	0.12	–0.63	.01
Pain, VAS								
Intervention	1.11 (46)	–3.94 to 6.16	0.61 (36)	–7.03 to 8.24	–0.05	.66	–0.03	.87
Control	–0.99 (38)	–7.48 to 5.50	5.82 (38)	–1.26 to 12.90	0.04	.76	–0.26	.10
Fatigue, VAS								
Intervention	1.13 (46)	–4.94 to 7.21	7.73 (36)	–2.26 to 17.72	–0.04	.71	–0.29	.13
Control	5.44 (38)	–1.13 to 12.01	12.15 (38)	6.29-18.00	–0.22	.10	–0.51	< .001
Sleep disturbance, VAS								
Intervention	–0.14 (46)	–7.03 to 6.76	2.15 (36)	–7.81-12.12	0.01	.97	–0.08	.66
Control	3.96 (39)	–5.42 to 13.33	7.66 (39)	–0.62 to 15.95	–0.15	.40	–0.30	.07

[a] CPAQ: Chronic Pain Acceptance Questionnaire; FIQ: Fibromyalgia Impact Questionnaire; SF-8: Short-Form Health Survey; GHQ-12: General Health Questionnaire; CPVI: Chronic Pain Values Inventory; and VAS: visual analog scale.

[b] T2: at discharge; T3: immediately after intervention.

[c] T2: at discharge; T4: 5 months after intervention.

[d] *P* values for paired samples *t* tests.

Between-Group Analysis

The between-group effect sizes are shown in Table 7. The intention-to-treat analysis showed a small effect between the groups after the intervention and a tendency (*P*=.05) toward a small effect at 5-month follow-up. The effect size on catastrophizing for completers was large immediately after the intervention period and remained moderate at the 5-month follow-up. Moderate effect sizes were also found for acceptance at both assessments times. There was a moderate effect on values-based living right after the smartphone intervention and a tendency toward moderate effects at 5-month follow-up. A moderate effect on sleep disturbance was found at the 5-month follow-up and a tendency toward moderate effect on fatigue. No effect was found on pain level. A moderate effect was found for functioning and symptom severity measured by the FIQ.

Table 7. Between-group effect sizes (ES) after the smartphone intervention (T3) and at 5-month follow-up (T4).

Outcome measure[a]		ES at T3	*P* value[b]	ES at T4	*P* value[b]
Primary					
	PCS (ITT and LOCF)	0.40	.01	0.36	.05
	PCS (per protocol)	0.87	< .001	0.74	.003
Secondary (per protocol)					
	CPAQ	0.62	.007	0.54	.02
	FIQ	0.21	.35	0.75	.001
	SF-8, physical	–0.15	.64	0.35	.13
	SF-8, mental	0.63	.005	0.43	.06
	GHQ-12	0.03	.56	0.33	.16
	CPVI	0.63	.005	0.40	.08
	Pain, VAS	–0.15	.49	0.28	.22
	Fatigue, VAS	0.04	.87	0.41	.07
	Sleep disturbance, VAS	0.19	.36	0.55	.02

[a] PCS: pain catastrophizing scale; ITT: intention-to-treat; LOCF: last observation carried forward; CPAQ: Chronic Pain Acceptance Questionnaire; FIQ: Fibromyalgia Impact Questionnaire; SF-8: Short-Form Health Survey; GHQ-12: General Health Questionnaire; CPVI: Chronic Pain Values Inventory; and VAS: visual analog scale.

[b] *P* values for independent *t* tests or nonparametric tests.

Withdrawal From Participation

Of the 135 participants, 112 completed the study period (Figure 1). Twenty-one withdrew from the intervention group (30.4%) and 2 withdrew from the control group (3.0%). Because of the small size of the withdrawal group (n=23), group differences with *P*<.2 are described here. The participants who completed the study tended to be younger (mean 43.33, SD 11.18) than the ones who withdrew (mean 48.43, SD 10.06, *P*=.07). There was a tendency toward higher pain level at admission in the group who withdrew (mean 68.79, SD 17.48) than in the group who completed (mean 61.29, SD 20.39, *P*=.15). There was also a tendency toward a higher level of sleep disturbance in the group who withdrew (mean 63.68, SD 23.81) than in the group who completed (mean 54.67, SD 24.81, *P*=.11). A tendency toward a difference was seen in physical functioning as measured by the SF-8; those who withdrew had lower functioning (mean 31.11, SD 7.67) compared to those who completed (mean 33.76, SD 7.50, *P*=.14). At discharge from the rehabilitation center, those who withdrew had more self-reported success in values-based living (mean 2.82, SD 0.91) compared to those who completed (mean 2.50, SD 0.79, *P*=.12).

Response Rates to Assessment Questionnaires

In accordance with the intention-to-treat principle, the response rate for all included participants was 68.1% at T3 (immediately after the smartphone intervention) and 62.2% at T4 (5-month follow-up). There was a higher response rate in the intervention group (75.4%) than in the control group (60.6%) at T3, but the rates were similar at T4 (63.8% and 60.6%, respectively). When only the completers were included in the analysis, more differences in response rates were found. The response rate for the intervention group was 97.9% at T3 and 77.1% at T4. The response rate was 62.5% in the control group at both T3 and T4. The numbers of participants excluded because more than 2 items were missing varied and the number included in each instrument analysis is shown in Table 3.

Comparison of demographic and outcome variables at baseline (T1) between participants who completed the study and returned questionnaires at T3 (n=87) and those who did not return them (n=25) revealed a few differences. Because of the small size of the group who did not return the questionnaires, group differences with *P*<.2 are described here. Those who did return T3 questionnaires had less function impairment and symptom levels at discharge (mean 46.10, SD 17.18) measured by FIQ compared to those who did not return the questionnaire (mean 54.38, SD 15.58, *P*=.04). The same trend was seen in the results of the physical component of the SF-8; those who did return the questionnaires at T3 had better physical functioning (mean 37.20, SD 8.32) at discharge compared to those who did not return them (mean 32.87, SD 7.38, *P*=.04). Those who completed the study, but did not return the questionnaires at T4 (n=35) had lower scores on the CPVI (success scale) (mean 1.78, SD 0.77) at T1 than those returning the questionnaires (mean 2.16, SD 0.84, *P*=.03). At baseline (T1), those who returned T3 questionnaires had higher pain level (mean 62.84, SD 20.02) than those not returning them (mean 55.90, SD 21.17, *P*=.12). There was a tendency toward higher pain level (mean 63.11, SD 20.06) at T1 in those who returned questionnaires at the 5-month follow-up (T4) than those who did not return them (mean 57.29, SD 20.84, *P*=.16). There was also a tendency toward having experienced pain for longer time (mean 17.28 years, SD 13.51) in those who did not return questionnaires at T4 compared with those who did return them (mean 12.77, SD 9.62, *P*=.07). Also, there was a tendency toward worse physical functioning at discharge (mean 34.24, SD 8.54) measured with

SF-8 in those who did not return questionnaires at T4 compared to those who did return them (mean 37.10, SD 8.08, *P*=.14).

Response Rate to the Smartphone Diary Entries and Experience of Participation

The response rate to the diary entries during the 4 weeks after discharge ranged from 27.4% to 95.2%, with a mean of 68.5% and a median of 70.2%. Most (83.3%) participants received 84 entries (4 weeks). A total of 16.7% received additional days of entries to compensate for holidays to ensure 20 days with registration and feedback. Of the 48 participants who completed the study in the smartphone intervention, 43 reported on the experience of participating. Ten (23.3%) participants agreed somewhat that the participation had been experienced as a burden, 9 (20.9%) were neutral in their opinion, 9 (20.9%) disagreed somewhat to the statement, and 15 (34.9%) totally disagreed with the statement that participation was experienced as a burden. Of those who completed the study, 37 (86.0%) agreed somewhat or totally that participation was useful. Three participants (7.0%) were neutral toward this item, and 3 (7.0%) participants disagreed somewhat or totally that participation was useful.

Use of the Informational Website

Of the participants who completed the study in the smartphone intervention, 22 (45.8%) reported never visiting the website. Six (12.5%) visited it once, 8 participants (16.7%) viewed it twice, and 11 (22.9%) viewed it three times or more. One participant did not respond to the question. In the control group, 38 participants who completed the study answered the question. Twelve (18.8%) reported never having visited the website, 5 (7.8%) viewed it once, 9 (14.1%) viewed it twice, and 12 (18.8%) visited 3 or more times.

Discussion

Principal Results

To our knowledge, this is the first study to investigate the efficacy of a smartphone-delivered intervention aiming to reduce catastrophizing and increase functioning in patients with chronic widespread pain. The results from the per-protocol analysis indicate that this intervention with diaries and written personalized feedback reduced catastrophizing and increased acceptance in women with chronic widespread pain and that these effects persisted 5 months after the intervention. At the 5-month follow-up, the control group experienced increased emotional distress compared to the distress at discharge from the inpatient program, whereas the smartphone group did not. The between-group effect size on functioning and symptom level was moderate (0.75) at the 5-month follow-up measured with the FIQ, but no difference was seen in the physical component of the SF-8. One reason for this may be the general nature of the items in the SF-8 compared to the questions in FIQ, possibly making it less sensitive to changes. The results also show a tendency toward increased improvement in values-based living in the intervention group compared to the control group.

When all randomized participants were included in the analysis, the effect size of catastrophizing was small. This may partly be explained by the higher rate of nonresponse in the control group and the method of carrying the last observed value forward resulting in the possibility of a false positive effect for the control group. Scores above 24 on the PCS have been categorized as indicating a high risk for reduced functioning [37]. None of the 7 participants who exceeded this limit before starting the smartphone intervention did so at the end of the intervention. Only one participant was above this criterion again 5 months later. The opposite trend was seen in the control group; an increased number of participants were classified as "catastrophizers."

The intervention was based on CBT, one of the most commonly used models of change in Internet intervention research [50]. We used CBT-related ACT, in which the goal is not to change or reconstruct the content of thoughts, but rather to change how it influences behavior. Behavior change is supported when patients learn to mindfully observe and accept inner experiences and to commit to values-based activity despite challenging thoughts, feelings, or symptoms [28,29,51]. By doing this, the influence of catastrophizing thoughts is expected to be diminished, but by a process other than that described in more traditional CBT, where problematic thoughts are more rationally challenged [28,52]. The reduction in catastrophizing and the increase in acceptance support previous studies that show negative correlations between mindfulness and acceptance, and catastrophizing [37,53,54]. The changes in catastrophizing, acceptance, and functioning in those who completed the study cannot be attributed to changes in levels of pain, or vice versa, because no significant reduction in pain level was found. This is in line with the findings of a recent randomized controlled trial in which fibromyalgia patients who had participated in a 12-week group-based ACT reported more improvement of the condition compared to a waiting-list control group despite no changes in pain level [55]. However, our results differ from that of other previous studies—a small effect size on pain intensity was found in a meta-analysis including 9 randomized trials of acceptance-based interventions [56]. This finding may be explained in part by the fact that the present intervention follows another intervention that had reduced the pain level. The control group showed an increased level of fatigue and a tendency toward an increase in sleep disturbance at the 5-month follow-up. This may indicate that the follow-up intervention might have contributed to the prevention of sleep disturbance. A positive correlation has been found between psychological flexibility and improved sleep quality in people with chronic pain [57].

Strengths and Limitations

To our knowledge, no randomized studies on smartphone interventions based on ACT have been previously published. Our results may support the notion that ACT can be successfully used as a framework for smartphone interventions with mainly written communication. This also supports the results of two recent studies of interventions that provided written ACT-based self-help material and weekly telephone support from a therapist, for 6 and 7 weeks, for patients with chronic pain. Both studies found medium to large effect sizes on pain acceptance [58,59]. However, the present intervention contained many possibly active components and the study design did not allow for any

distinction between possible mechanisms and explanations. It is possible that the intervention group benefited from having higher expectations of improvement and from the empathic attention and encouragement from a health care provider [50]. As stated in the guidelines for Internet intervention research, it may still be premature to require demonstration of processes of change in Internet interventions because of the newness of the field [50]. Our results are consistent with the findings of a study that tested the efficacy of a similar mobile phone-delivered intervention with diaries and daily CBT-based feedback for patients with irritable bowel syndrome. The intervention reduced catastrophizing thoughts and the effects were maintained at a 3-month follow-up [18]. Our results are also in line with the results of a follow-up telephone intervention for chronic pain patients designed to support self-monitoring, to give a review of learned self-management techniques, and to provide monthly feedback from a CBT therapist after 11 weeks of group CBT. The intervention was found to reduce pain catastrophizing [13].

Studies on Internet-based interventions and interventions using SMS to support self-management of chronic illness show promising results [60-62]. A review of 14 studies that used SMS to support health behavior change included 6 randomized controlled trials. The duration of the interventions varied from 6 weeks to 1 year and the frequency of communication ranged from many times daily to less than monthly. All but one were effective in supporting positive behavior change, with effect sizes ranging from small to large. However, follow-up data was limited [60]. Reviews of Internet-based interventions for patients with various chronic pain conditions indicate a positive effect on pain, but results on psychological outcomes have been inconsistent [14,15,62]. An important feature of a successful therapeutic relationship is the therapist's ability to respond to what the patient expresses, and tailored or personalized messages have been found to be more effective in supporting behavior change than standardized ones [60]. Our intention was to support a therapeutic relationship with the therapist responding to the expressions made in the diaries and with the goal of sending the individualized feedback as soon as practically possible.

The present study has some limitations. The generalizability of the results is reduced by several factors. Firstly, the intervention group had a withdrawal rate of 30% and this might have resulted in differences in the characteristics of completers between groups. Indeed, there was a trend toward the completers being younger and having less pain, less sleep disturbances, and better function measured with SF-8 at baseline. At admission to the inpatient program (T1), the participants in the smartphone intervention group reported higher pain levels and lower physical functioning compared to the control group. At discharge (T2), this difference was no longer evident. This indicates that participants in the smartphone intervention group improved more on those two variables during the inpatient program compared to the control group. It is possible that this implies some not-assessed differences in the groups' characteristics. Our intention with a run-in period during the final week of the inpatient program was to give the patients a chance to get used to the smartphone diaries before returning home. However, our results may indicate that this might not have been suitable for all participants because several participants withdrew during the run-in phase; it might have been more feasible to give the participants the choice of starting the intervention after discharge from the inpatient program. During the inpatient program, the participants had a busy schedule with activities and may, therefore, have experienced adding the smartphone diaries as stressful. They chose to receive their morning and evening diaries at hours suitable for their schedule at home, which may possibly have been inconvenient while still at the rehabilitation center. High withdrawal rates have been a challenge in SMS-based and Web-based interventions [60]. In a review of 17 trials of Internet self-management interventions for people with chronic pain, the withdrawal rate ranged from 6% to 59% with a median withdrawal rate of 27% [14]. Therapist contact and tailored or personalized messages have been found to correlate with lower withdrawal rates, but as our results show, other factors clearly also play roles. Despite the high withdrawal rate, most experienced the present intervention as useful. In a qualitative study with 7 of our participants, the intervention was described as motivating and supportive [63].

Secondly, the response rate to assessment questionnaires was below 70% at both follow-ups; this affects the generalizability of the results because data cannot be assumed to be missing at random. The response rate was different between the groups, with a lower response rate in the control group immediately after the intervention period. This is commonly experienced in randomized controlled studies [64]. Those who did not return questionnaires after the intervention period (T3) had lower pain levels at baseline (T1) than those who did. Also, those who did not return questionnaires after the smartphone intervention period (T3) had more function and symptom impairment at discharge from the center compared with those who returned those questionnaires. Since all except 1 participant in the smartphone group returned the questionnaires after the intervention (T3) and those who did not respond belonged to the control group, it may be that the level of functional impairment and symptom severity for the control group was, in fact, higher. The 5-month follow-up results could also be affected because there was a tendency toward those not returning the questionnaires reporting less pain at baseline (T1) and better functioning and less symptom severity at discharge (T2). Finally, the generalizability is also affected by the fact that just over half of those eligible to participate were included in the study. We do not know if those who chose to participate differed in any way from those who declined participation. The introduction meeting for the study was scheduled during the second week of the rehabilitation program. For some it may have been too early to consider involvement in a follow-up intervention and others may have used the opportunity to prioritize private time in the tight rehabilitation schedule instead of listening to study information. Moreover, in the stress management part of the rehabilitation program, the patients were encouraged to set limits and say no to requests they felt added more stress to their everyday burden. Patients with high self-efficacy regarding coping after discharge may have been more likely to not attend the informational meeting. Also, because all those who were eligible for the study received a short information letter about the study, some may have found the intervention format unsuitable. In a future study, this kind of intervention might be made more feasible by adding a virtual social support group

including fellow participants from the inpatient program. The increase in function impairment and symptom levels in the control group after discharge is not in line with the results of a study on 200 patients with chronic widespread pain or fibromyalgia participating in the same kind of 4–week inpatient program at the same rehabilitation center. The results of the study showed significant improvements in functioning and symptom levels, maintained at both 6- and 12-month follow-ups [9]. However, the samples were not identical because we have excluded men in the present study and those submitted primarily for vocational rehabilitation. Selection bias in our sample may also have had an impact (ie, those with positive long-term effects may have elected not to participate in the study). Nevertheless, the results of the long-term effects of multidimensional pain programs are inconclusive and the need for maintenance support has been clearly stated [65,8,11,12].

This smartphone intervention was developed in 2008 and was delivered using first-generation smartphones. Today, the diary part of the intervention can easily be converted to a smartphone application. Future research might investigate whether automatic feedback could be effectively tailored to diaries and integrated in an application to reduce the investment of human resources used in the presented intervention.

Conclusion

Our results give preliminary support to the efficacy of a smartphone intervention for catastrophizing, acceptance, functioning, and symptom level in women with chronic widespread pain. In addition to subgroup analyses of participants and results on long-term effects, research on practice implications, innovation, and added values for the users are needed.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT eHealth V1.6.1 [66].

[PDF File (Adobe PDF File), 595KB - jmir_v15i1e5_app1.pdf]

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Abbreviations

ACT: Acceptance and Commitment Therapy
CBT: cognitive behavioral therapy
CPAQ: Chronic Pain Acceptance Questionnaire
CPVI: Chronic Pain Values Inventory
ES: effect sizes
FIQ: Fibromyalgia Impact Questionnaire
GHQ: General Health Questionnaire
LOCF: last observation carried forward
PCS: Pain Catastrophizing Scale
SD: standard deviations
SDT: self-determination theory
SF-8: Short-Form Health Survey
SMS: Short Message Service
VAS: visual analog scale

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Original Paper

A Smartphone-Based Intervention With Diaries and Therapist Feedback to Reduce Catastrophizing and Increase Functioning in Women With Chronic Widespread Pain. Part 2: 11-month Follow-up Results of a Randomized Trial

Ólöf Birna Kristjánsdóttir[1,2], RN, MSc; Egil A Fors[3,4], MD, PhD; Erlend Eide[2,5]; Arnstein Finset[1], MApsych, PhD; Tonje Lauritzen Stensrud[1], MApsych; Sandra van Dulmen[6,7,8], MApsych, PhD; Sigrid Hørven Wigers[9], MD, PhD; Hilde Eide[2,8], RN, MApsych, PhD

[1]Department of Behavioral Sciences in Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

[2]Institute of Nursing, Faculty of Health, Oslo and Akershus University College of Applied Sciences, Oslo, Norway

[3]Department of Psychiatry; National Competence Centre for Complex Symptom Disorders, St Olav University Hospital, Trondheim, Norway

[4]Department of Public Health and General Practice, Faculty of Medicine, General Practice Research Unit, Norwegian University of Science and Technology, Trondheim, Norway

[5]Driv Digital, Tønsberg, Norway

[6]NIVEL (Netherlands Institute for Health Services Research), Utrecht, Netherlands

[7]Department of Primary and Community Care, Radboud University Nijmegen Medical Centre, Nijmegen, Netherlands

[8]Faculty of Health Sciences, Buskerud University College, Drammen, Norway

[9]Jeløy Kurbad Rehabilitation Centre, Moss, Norway

Corresponding Author:
Ólöf Birna Kristjánsdóttir, RN, MSc
Department of Behavioral Sciences in Medicine
Faculty of Medicine
University of Oslo
Postbox 1111
Oslo, 0317
Norway
Phone: 47 22851020
Fax: 47 22851300
Email: kristjansdottir@gmail.com

Abstract

Background: Internet-based interventions are increasingly used to support self-management of individuals with chronic illnesses. Web-based interventions may also be effective in enhancing self-management for individuals with chronic pain, but little is known about long-term effects. Research on Web-based interventions to support self-management following participation in pain management programs is limited.

Objective: The aim is to examine the long-term effects of a 4-week smartphone-intervention with diaries and therapist-written feedback following an inpatient chronic pain rehabilitation program, previously found to be effective at short-term and 5-month follow-ups.

Methods: 140 women with chronic widespread pain, participating in a 4-week inpatient rehabilitation program, were randomized into two groups: with or without a smartphone intervention after the rehabilitation. The smartphone intervention consisted of one face-to-face individual session and 4 weeks of written communication via a smartphone, consisting of three diaries daily to elicit pain-related thoughts, feelings, and activities, as well as daily personalized written feedback based on cognitive behavioral principles from a therapist. Both groups were given access to an informational website to promote constructive self-management. Outcomes were measured with self-reported paper-and-pencil format questionnaires with catastrophizing as the primary outcome measure. Secondary outcomes included daily functioning and symptom levels, acceptance of pain, and emotional distress.

Results: By the 11-month follow-up, the favorable between-group differences previously reported post-intervention and at 5-month follow-up on catastrophizing, acceptance, functioning, and symptom level were no longer evident (*P*>.10). However, there was more improvement in catastrophizing scores during the follow-up period in the intervention group (M=-2.36, SD 8.41) compared to the control group (M=.40, SD 7.20), *P*=.045. Also, per protocol within-group analysis showed a small positive effect (Cohen's *d*=.33) on catastrophizing in the intervention group (*P*=.04) and no change in the control group from the smartphone intervention baseline to 11-month follow-up. A positive effect (Cohen's *d*=.73) on acceptance was found within the intervention group (*P*<.001) but not in the control group. Small to large negative effects were found within the control group on functioning and symptom levels, emotional distress, and fatigue (*P*=.05) from the intervention baseline to the 11-month follow-up.

Conclusion: The long-term results of this randomized trial are ambiguous. No significant between-group effect was found on the study variables at 11-month follow-up. However, the within-group analyses, comparing the baseline for the smartphone intervention to the 11-month data, indicated changes in the desired direction in catastrophizing and acceptance in the intervention group but not within the control group. This study provides modest evidence supporting the long-term effect of the intervention.

Trial Registration: Clinicaltrials.gov NCT01236209; http://www.clinicaltrials.gov/ct2/show/NCT01236209 (Archived by WebCite at http://www.webcitation.org/6FF7KUXo0)

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KEYWORDS

Internet-based personalized feedback; widespread chronic pain; fibromyalgia; pain management; eHealth; smartphone; Internet; cognitive therapy; catastrophization

Introduction

Chronic widespread pain (CWP) is a common cause of suffering in the adult population, with reported prevalence rates between 4% and 10% [1-5]. In addition to pain, fatigue, sleep disturbance, and emotional distress are common [1,5]. A subgroup has more severe symptoms and meets the diagnosis criteria of fibromyalgia [2,5]. Knowledge of the pathogenesis of CWP and fibromyalgia is still evolving; dynamic processes including biological, social, and psychological factors are known to be involved [6]. Multidimensional rehabilitation is the recommended treatment, including interventions based on cognitive behavioral therapy (CBT) where patients learn how thoughts, beliefs, and feelings can influence the pain experience and functioning [6,7]. The short-term effects are well established, but concerns about the long-term effects have been raised [7-11]. It has been indicated that for 30-60% of patients participating in pain management programs, the treatment gain is not maintained long-term (at 1- to 5-year follow-ups) [8,10]. The need for strategies to maintain treatment effects by supporting self-management following treatment has received little attention in the research field [8].

An increasing number of studies on Internet-based interventions, many based on CBT (iCBT), indicate their efficacy in supporting use of constructive self-management strategies in individuals living with chronic illness [12-15]. The results of research on iCBT for individuals with chronic pain are not entirely consistent, but in a recent systematic review, it was concluded that Internet-based interventions seem promising [16]. At least three recent randomized trials, not included in this review, support this conclusion. A randomized trial of an intervention consisting of a website with self-management information based on CBT and no therapist contact was found to reduce pain and increase physical functioning in individuals with fibromyalgia, compared with a control group receiving standard care alone, at a 6-month follow-up [17]. Another study, testing the effect of a no-therapist contact online intervention found positive effects on pain, catastrophizing, and disability for the intervention group [18]. In the third study, persons with persistent symptoms after multidisciplinary pain management rehabilitation received 8 weeks of guided iCBT. There was a medium between-group effect between the intervention group and the active control group, but a small within-group effect on catastrophizing after the intervention, and the improvements were maintained after 6 months [19].

To date, research on the effects of iCBT for persons with pain beyond 6-month follow-up is limited. Additionally, only a few studies on iCBT have investigated the effect of an intervention aiming to support self-management following participation in a traditional pain management program [19,20].

Most iCBT interventions for chronic pain are based on weekly modules with self-help material and involve weekly written communication with a therapist [16,19]. A few studies have investigated a different approach to iCBT with daily communication with a therapist over a few weeks, using a personal digital assistant (PDA) or smartphone [20-24]. The use of a smartphone instead of a desktop or laptop computer gives the participant the flexibility to register and receive information in different situations of daily life. In these studies, diaries with questions aiming to support awareness of disability-related thoughts (eg, catastrophizing) and feelings have been made available to patients on a Web-enabled mobile phone or a smartphone. Instead of weekly feedback from a therapist, the participants receive a daily written message personalized according to the recently registered information. Two randomized trials provide evidence for positive short-term effects (3-month/5-month follow-up) [20,24].

In our randomized controlled study, 135 women with CWP completing a 4-week inpatient rehabilitation program were included [20]. A large effect on catastrophizing was found between the groups for the completers after receiving personalized feedback via a smartphone for 4-weeks. At 5-month follow-up, the effects remained moderate for catastrophizing,

acceptance of pain, and functioning and symptom level [20]. The objective of the present paper is to report long-term results of the previously published trial on the smartphone intervention, ie, involving the same study with the same sample [20]. It was hypothesized that the intervention group would report less catastrophizing, better functioning, increased acceptance of pain, and success in values-based living than the control group at 11-month follow-up.

Methods

Study Design

The overall study design is shown in Figure 1. The design is a parallel-group randomized controlled trial. Further details of the study can be found in our earlier publication from this trial [20].

All participants attended a 4-week inpatient multidimensional rehabilitation program for chronic pain. The program included education in pain mechanisms and CBT-based pain management (approximately 20 hours), various forms of aerobic exercise, stretching, relaxation, individual myofascial pain treatment, and medication was administered as needed (see [25] for details of the program). In the fourth week of the program, participants were randomly assigned to one of the two study groups. A detailed description of the recruitment procedure is given in the previous report [20].

The intervention group received a smartphone intervention for 4 weeks after completing the inpatient rehabilitation. Both groups were given access to an informational website with self-help pain-management material. Self-reported assessments on paper were gathered at five time-points: before (T1) and after (T2) the inpatient program, 4 weeks after discharge (T3) when the intervention group had completed their smartphone intervention, and 5 (T4) and 11 months (T5) after the smartphone intervention period (ie, 12 months after discharge from the inpatient rehabilitation program). The first two questionnaires were received and completed at the rehabilitation center and the others were completed at home and returned by mail. In this paper, results of the first two assessments (T1 and T2) and the last (11-month follow-up, T5) are reported. The customary self-report administration mode at the rehabilitation center was a paper-and-pencil format and was therefore used in this study.

Participants

Participants were recruited consecutively from Jeløy Kurbad Rehabilitation Centre in Moss, Norway. Patients were referred to the center by their general practitioner, a medical specialist, or from a hospital. The inclusion criteria for the study were: female, 18 years or older, participating in the inpatient program for persons with chronic pain, having suffered from CWP for more than 6 months (with or without a diagnosis of fibromyalgia), not participating in another research project at the rehabilitation centre, being able to use the smartphone, and not being diagnosed with a profound psychiatric disorder.

Ethical Aspects

The study was approved by the Regional Ethics Committee in South-East Norway and by the Norwegian Social Science Services. All participants signed an informed consent form. The study is registered at ClinicalTrial.gov (NCT01236209).

Assessment Measures

The Pain Catastrophizing Scale (PCS [26]) was used as the primary outcome variable of the study. It is a 13-item questionnaire with questions on helplessness, magnification, and rumination. Patients rate items on a scale from 0 (not at all) to 4 (all the time). The total score range for the PCS is 0-52, with higher scores reflecting higher degrees of catastrophizing. In our sample, the internal consistency was high on all assessments (Cronbach alpha = .89-.94). Catastrophizing is among the psychological constructs that can play an important role in the development and maintenance of chronic pain [27,28]. Catastrophizing has consistently been found to be associated with distress and disability [28]. The Chronic Pain Acceptance Questionnaire (CPAQ) was used. It is scored on a 7-point Likert scale from 0 (never true) to 6 (always true) to give the total score (0-120). Higher scores reflect higher acceptance of pain and higher activities engagement. In our study, the Cronbach alpha coefficients were .81-.92. Emotional distress was measured with the questions from the 12-item General Health Questionnaire (GHQ) [29] with modified response alternatives. Bimodal scoring method was used (symptom present more than usual = 1, symptom present less than or as usual = 0). Total score range is 0 to 12; indicating the number of symptoms present more than usual during the last 2 weeks. In the current study, the Cronbach alpha coefficients were .72-.88. The Chronic Pain Values Inventory (CPVI) is a 12-item measure of importance and success in living according to one's own values in six domains (family, intimate relationships, friendship, work, health, and personal growth) [30]. Each item is rated on a scale from 0 to 5, with higher numbers indicating more importance or success. The mean success rating was used as a measure of values-based action (score range: 0-5). In the present study, the Cronbach alpha coefficients for the success scale were .75-.88. The original (1991) version of fibromyalgia impact questionnaire (FIQ) was used to measure the impact of fibromyalgia on functioning and symptom levels the last week. The score range is 0 to 100; a higher score indicates greater impairment [31]. The Cronbach alpha coefficients were .78-.87 (two questions related to work were excluded because of high missing rates). Short-form health survey (SF-8) was also used to measure functioning. Summary measure scales for mental health component and physical component were obtained by using SF-8 Scoring Software 4.5 [32]. The standardized scores have a mean of 50 and a SD of 10. Higher scores indicate better functioning. The Cronbach alpha for the mental component were .65-.74 and .79-.85 for the physical component.

The current levels (last couple of days) of pain, fatigue, sleep disturbance, and depression were assessed on visual analogue scales (VAS) from 0 (no pain/fatigue/sleep disturbance/depression) to 100 (worst imaginable). One question on subjective global improvement was included: "How do you

feel now compared to before you attended the inpatient program?"

Treatment Procedures

Smartphone Intervention: Diaries and Daily Situational Feedback (Intervention Group Only)

The main theoretical framework was based on the cognitive behavioral fear-avoidance model [27] and CBT, and comprised, more specifically, elements from the acceptance and commitment therapy (ACT) [33,34]. ACT has been found to reduce catastrophizing and disability in chronic pain patients [35-37]. The aim was to support continued use of the self-management strategies learned at the rehabilitation center (eg, exercise and stretching) and to promote improved daily functioning and values-based living. In the rehabilitation center, a traditional CBT approach was used, not ACT. Therefore, ACT elements such as mindfulness exercises were added as new components. The smartphone intervention had the following four components.

Face-to-Face Session

The intervention started with an approximately 1-hour individual session between a nurse and the participant. The session took place in the last week before discharge. The participants received information (name and qualifications) about their therapist for the intervention, which, in some cases was the nurse at the meeting. The nurse attending the face-to-face session summarized the meeting and passed this background information to the relevant therapist. For the duration of the study, the participant was lent a smartphone and could call a member of the research group (OBK, HE) for technical support.

Web-Based Diaries

The participant was asked to complete three diary entries per day using the smartphone. Examples of the smartphone's screen display are shown in Figures 2 and 3. The diaries included 16-24 questions about the current level and interference of pain, feelings, and thoughts related to avoidance, catastrophizing, and acceptance. They also included questions about planned and previous use of self-management activities learned at the rehabilitation center and daily values-based and practical activities. Lists of self-management activities (eg, mild exercise, stretching, resting, aerobic exercise, pleasurable activity) were provided as a reminder. The questions were chosen to support awareness and reflection of experience relevant to self-management. Participants answered most questions by choosing predefined alternatives or using scales. The diaries included a comment field giving participants the opportunity to write a short personal message to the therapist.

At the time scheduled for diary completion, a short message service (SMS) message with a link to a secure website, where the diary could be opened and questions answered and posted, was received by the participant. The participants completed the first diary entry during the face-to-face session and continued during the last week before discharge with the goal of getting used to the diaries before discharge (a run-in period). After discharge, the diaries were completed every day for 4 weeks.

Written Personalized Feedback

For 4 weeks after discharge, excluding weekends, participants received daily written feedback from a therapist. The feedback was empathic and personalized according to each participant's situation as reported in the diary. It included repetition of content reported in the diaries, positive reinforcement, reminders of self-management information given at the rehabilitation center, ACT exercises, and reflective questions. The aim was to encourage nonjudgmental awareness of cognitions, feelings, and emotions and to stimulate mindfulness and willingness to engage in meaningful activities despite pain or other discouraging intrusions, eg, to reduce the impact of catastrophizing on self-management behavior. The instructions for the exercises were written directly in the feedback or the participant was referred to exercises available on the smartphone and/or the website (see below). The feedback was also personalized according to the summary of personal information given at the face-to-face session (eg, family situation and health-related goals) and results on self-reported discrepancy between values and values-based living assessed with the CPVI at the end of the rehabilitation program. The feedback was usually available for the participant within 90 minutes after they had completed the second diary of the day. If this diary was not submitted, feedback based on information from the latest submitted diary was sent. There was no limitation on the length of the feedback, which ranged from a few sentences to a few paragraphs.

The feedback was written by any of 3 of the authors (OBK, TLS, and HE); all with a background in health care sciences (nursing and/or psychology).

Audio Files With Guided Mindfulness Exercises

A few audio files with short mindfulness exercises guided by the authors were available on the smartphones.

Informational Website With Self-Help Pain Management Material (All Participants; Control Group Received Only This Intervention)

All participants received access to a static website with information on self-management strategies for people with chronic pain. The website also included a few written ACT exercises and audio files with mindfulness exercises (as described above). See Multimedia Appendix 1 for a screenshot from the website. No specific instruction about frequency of use was given.

Statistics

To investigate differences in demographic variables and baseline characteristics, independent sample *t*-tests, nonparametric tests, and Chi-square tests were used. Paired *t*-tests were used to compare 11-month follow-up (T5) results to the baseline for the inpatient program (T1) and the smartphone intervention (T2). Independent *t*-tests or nonparametric tests (Mann-Whitney) were used to compare outcomes between groups at T5. The Cohen's *d* effect sizes (ES) were calculated using the difference between the groups' means divided by the mean of the standard deviation of both groups. If one or two items were missing on the GHQ, they were scored as present less than usual or as usual (= 0). If another instrument included one or two missing items,

the items were replaced with the mean of other items from the participant's instrument. If two response alternatives were marked, the healthier option was chosen. Total score was not computed if more than two items were missing, and the case was categorized as missing a total score for the instrument. The number of participants included in each analysis is provided. In the intention-to-treat analysis (ITT), the results of complete case analysis for the primary outcome is reported. In addition, two methods for replacing missing variables for the primary outcome at endpoint (T5) were applied: last observation carried forward (LOCF) and multiple imputations (MI). In the MI analysis, 50 imputations were made. The following clinically significant variables were included in the MI regression model: age, SF-8 physical component, and VAS for pain, sleep, fatigue, and depression at admission to the rehabilitation center. Six of the participants who withdrew from the smartphone intervention contributed questionnaires at the 11-month follow-up (T5). The ITT analyses included all participants (n=135) except those who met the exclusion criteria after randomization. In the analyses of secondary outcomes, only those who completed the interventions were included (n=112). IBM SPSS Statistics (versions 19 and 20) was used. A significance level of $P=.05$ was chosen, and a tendency toward difference was defined as $P<.1$. Effect sizes were categorized as small (<.5), medium (.5-.8), and large (>.8) in accordance with Cohen [38].

Figure 1. Study flow chart.

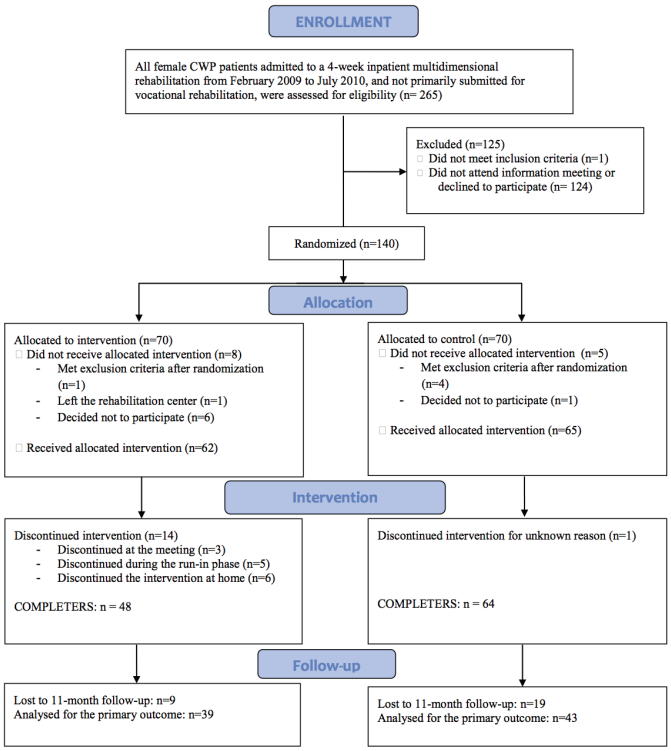

Figure 2. The smartphone's screen showing a diary in Norwegian.

Figure 3. The smartphone's screen showing feedback in Norwegian.

Results

Participants

265 women who were eligible for the study during the study period were invited to informational meetings about the project. Of these, 124 did not attend a meeting or declined to participate, and 1 did not meet the inclusion criteria. 140 were randomized to one of the two study arms (Figure 1). 5 subjects met the exclusion criteria after randomization (they were originally submitted for vocational rehabilitation and thus included in another research project), and 8 discontinued participation before receiving the allocated intervention. In the intervention group, 14 patients did not complete the intervention. Demographic data and baseline characteristics of the sample by groups are given in Table 1. All participants had CWP, and the majority was diagnosed with fibromyalgia. Despite randomization, the groups differed in mean pain level (P=.02) and physical functioning measured by SF-8 (P=.03) at admission to the rehabilitation center.

Primary Outcome: Catastrophizing

Descriptive results for catastrophizing are shown in Table 2 and follow-up differences in Table 3.

Between-Group Effects

At the 11-month follow-up (T5), there was no difference between the groups on the measure of catastrophizing (PCS); neither according to the ITT-analysis (LOCF P=.22 and MI P=.31) nor the per protocol analysis (complete case analysis, P=.18 and analysis with MI .23). When all intended-to-treat were analyzed (LOCF), catastrophizing seemed to improve more during the follow-up period (T2-T5) in the intervention group (M=-2.36, SD 8.41) than the control group (M=.40, SD 7.20), P=.045, using t-test of change scores.

Within-Group Effects

There were small positive within-group effects for the intervention group between T2 and T5 on catastrophizing by ITT (LOCF) and per protocol analyses, P=.02 and P=.04, respectively. In the analysis, where missing variables were imputed, there was a tendency towards a small positive within-group effect during this period (T2-T5). There were improvements regarding to catastrophizing in the T1 to T5 period for both the intervention and control groups, P<.001. Between 5-month follow-up (T4) and 11-month follow-up (T5), paired samples t-tests did not show changes in the intervention group (M=.06, SD 5.05, n=31), P=.94 for catastrophizing. However, in this period (T4-T5), there was a reduction in catastrophizing in the control group (M=-3.25, SD 7.09, n=34), P=.01.

Secondary Outcomes: Functioning and Symptom Levels

Table 4 shows descriptive statistics for the secondary outcomes at admission to the rehabilitation center, at discharge, and at the 11-month follow-up. In the per protocol analysis, no significant group differences were detected at discharge from the rehabilitation center on any of the outcome variables (all Ps>.05; GHQ, and depression (VAS), P=.08, see Table 4).

Between-Group Effects

No between-group differences were found at the 11-month follow-up; P-values ranged from .13 (SF-8, physical) and .17 (CPAQ) to .98 (sleep disturbance).

Within-Group Effects

Table 5 shows within-group changes for the secondary outcomes. When comparing the smartphone intervention's baseline data (T2) to the 11-month follow-up (T5), there was a moderate positive effect on acceptance (CPAQ) in the intervention group, but not in the control group. There was a small negative effect on functioning and symptom levels measured by the FIQ in the control group, but not in the intervention group. For the physical component of SF-8, there was a small negative effect for the intervention group (P=.046), but not the control group. For GHQ, there was a large negative effect for emotional distress but only in the control group. No significant changes were detected for the mental component of SF-8. There was a tendency towards improvement in values-based living in the intervention group but not in the control group. There was a moderate negative effect on fatigue (VAS), and a tendency towards a small negative effect on sleep (VAS) and pain (VAS) in the control group. No changes were detected on these symptoms in the intervention group.

When comparing baseline data for the inpatient program (T1) to the follow-up data (T5), improvement in acceptance, mental health measured by SF8, and values-based living was found in both groups (see Table 5). Reduction in disease impact (measured by FIQ) was found for the intervention group only (Cohen's d=.42, P=.03). There was a significant reduction in pain level in the intervention group between T1 and T5, mostly due to changes during the inpatient program (see Table 4). There was a trend towards improvement on fatigue and depression (VAS scales) in the intervention group only, between T1 and T5. When both groups were analyzed together, with all intended-to-treat included (complete case analysis), there was a reduction in pain level (M=5.68, SD 24.66, n=89) between admission to the inpatient program (T1) and the long-term follow-up (T5), P=.03.

When the 5-month follow-up results (T4) were compared to the 11-month follow-up (T5), no changes were found for acceptance, pain level, functioning, and symptom level (measured by FIQ), sleep disturbance, fatigue, and mental health (all P values > 0.10). During this period (T4-T5), the control group showed improvement in values-based living (M=.25, SD .70, n=33, P=.046), whereas the intervention group did not. The control group also showed improvement in depression (measured by a VAS, M=8.29, SD 20.13, n=35, P=.02), whereas no significant change was found in the intervention group during this (T4-T5) period. Reduction in physical functioning (measured by SF8) was found in the intervention group (M=3.45, SD 7.76, n=31, P=.02) and a trend towards improvement in the control group (M=2.30, SD 7.10, n=34, P=.07).

Of the completers, 47.4% (n=18) in the intervention group and 40.0% (n=18) in the control group reported feeling better now than before the inpatient program. 13.1% (n=5) in the

intervention group and 11.1% (n=5) in the control group reported feeling worse now compared to before the inpatient program. No change was reported by 39.5% (n=15) in the intervention group and by 48.9% (n=22) in the control group.

Withdrawal From Participation

Of the 135 participants (of 140 randomized) that met the inclusion criteria, 112 completed the study period (Figure 1). 21 withdrew from the intervention group (30.4%) and 2 withdrew from the control group (3.0%). There was a trend toward the completers being younger (M=43.33, SD 11.18) than the ones who withdrew (M=48.43, SD 10.06), *P*=.07. Additionally, there was a trend towards a higher level of depression (measured by a single VAS) in the group who withdrew (M=43.62, SD 28.57) compared to the completers (M=31.81, 28.92), at admission to the inpatient program, *P*=.06.

Response Rates to 11-month Questionnaires in Intervention Group and Control Group

The response rate for all included participants (n=135) was 66.7% at 11-month follow-up (T5) (n=45 in the intervention group and n=45 in the control group). When only completers (n=112) were included, the response rate at T5 was 81.3% (n=39) in the intervention group and 70.3% (n=45) in the control group. Among the completers, those who returned the questionnaire at T5 had better physical functioning (M=34.60, SD 7.53), at admission to the inpatient program measured by SF8, compared to those who did not return them (M=31.19, SD 6.93), *P*=.01. Those who returned the questionnaires at T5 reported also less disease impact (M=56.45, SD 16.82) on FIQ at admission to the inpatient program compared to those who did not return them (M=64.22, SD 14.59), *P*=.03. Those who returned the T5 assessments reported more success in living according to values (M=2.13, SD .81) than those who did not return them (M=1.74, SD .85), *P*=.04. There was also a tendency towards more severe depression (measured by a VAS scale) at both admission and discharge among those who did not return questionnaires at T5 compared to those who returned them, *P*=.08-.09.

Table 1. Characteristics at admission to the inpatient rehabilitation center.

Characteristic		Smartphone intervention (n=69)[a]	Control (n=66)[a]
Age, mean (SD), n		44.59 (11.13), 69	43.80 (11.20), 65
Marital status			
	Married or cohabiting	60.9% (n=42)	68.2% (n=45)
	Divorced	13.0% (n=9)	9.1% (n=6)
	Single	18.8% (n=13)	15.2% (n=10)
	Widow	5.8% (n=4)	3.0% (n=2)
	Unknown	1.4% (n=1)	4.5% (n=3)
Years of education			
	≤ 10 years (elementary)	18.8% (n=13)	12.1% (n=8)
	11-13 years (high school)	27.5% (n=19)	45.5% (n=30)
	>13 years (College/University)	43.5% (n=30)	34.8% (n=23)
	Unknown	10.1% (n=7)	7.6% (n=5)
Employment status			
	Working/studying	21.7% (n=15)	12.1% (n=8)
	Unemployed	4.3% (n=3)	1.5% (n=1)
	On sick leave	39.1% (n=27)	51.5% (n=34)
	On disability pension	17.4% (n=12)	19.7% (n=13)
	Part time working/studying and part time sick leave	11.6% (n=8)	7.6% (n=5)
	Other combination of the above	5.8% (n=4)	6.1% (n=4)
	Unknown	0%	1.5% (n=1)
Diagnosed with fibromyalgia (valid %)		80.9% (n=55)	84.4% (n=54)
Duration of symptoms (years), mean (SD), n		13.11 (8.78)	15.47 (12.09)
PCS[b], mean (SD), n		21.24 (10.33), 63	20.80 (9.45), 62
CPAQ[b], mean (SD), n		56.48 (15.02), 58	53.87 (13.81), 57
FIQ[b], mean (SD), n		58.75 (16.39), 69	58.58 (16.04), 66
SF-8, physical[b]; mean (SD), n		31.91 (7.57), 65	34.75 (7.35), 62
SF-8, mental[b], mean (SD), n		39.33 (10.49), 65	39.34 (9.61), 62
GHQ-12[b], mean (SD), n		3.32 (3.38), 62	3.02 (3.38), 61
CPVI[b], mean (SD), n		2.07 (0.95), 64	2.01 (0.73), 61
VAS [b] recordings of current level of (last couple of days):			
	Pain, mean (SD), n	67.08 (17.47), 69	57.85 (21.60), 66
	Fatigue, mean (SD), n	67.40 (23.73), 69	64.72 (21.02), 66
	Sleep disturbance, mean (SD), n	57.24 (26.22), 68	55.16 (23.38), 66
	Depression, mean (SD), n	34.73 (29.15), 68	32.93 (29.26), 65

[a] Patients meeting exclusion criteria after randomization were not included in this analysis.

[b] VAS, visual analogue scale (0-100[c]); PCS, Pain Catastrophizing Scale (score range 0-52[c]); CPAQ, Chronic Pain Acceptance Questionnaire (score range 0[c]-120); FIQ, Fibromyalgia Impact Questionnaire (0-100[c]); SF-8 (0[c]-100), Short Form; GHQ-12, questions from the General Health Questionnaire (score range 0-12[c]); CPVI, Chronic Pain Values Inventory (success score, range 0[c]-6).

[c] Values that indicate maximum symptom scores/least health.

Table 2. Means and standard deviations for the primary outcome at admission to the inpatient rehabilitation (T1), at discharge (T2), and 11 months (T5) after the intervention period.

Primary outcome measure, Pain Catastrophizing Scale	Group	T1[a] Mean (SD), n	T2[a, b] Mean (SD), n	T5[a] Mean (SD), n
ITT (complete case analysis)				
	Intervention	21.24 (10.33), 63	15.12 (9.61), 63	11.50 (8.68), 44
	Control	20.80 (9.45), 62	15.41 (9.62), 59	14.73 (9.95), 43
ITT(LOCF)				
	Intervention	21.24 (10.33), 63	16.06 (10.37), 68	13.72 (10.02), 69
	Control	20.80 (9.45), 62	15.33 (9.31), 65	15.57 (10.40), 66
ITT (MI)				
	Intervention			12.80, 69
	Control			14.74, 66
Per protocol (complete case analysis)				
	Intervention	20.56 (10.08), 43	14.61 (8.93), 45	11.92 (8.97), 39
	Control	20.78 (9.59), 60	15.46 (9.76), 57	14.73 (9.95), 43
Per protocol (MI)				
	Intervention			12.25, 48
	Control			14.66, 64
% (valid) with PCS score >24				
	Intervention	30.2%, 13	15.6%, 7	12.8%, 5
	Control	33.3%, 20	17.5%, 10	18.6%, 8

[a] T1, at admission to the inpatient program; T2, at discharge from the inpatient program; T5, 11-month follow-up

[b] No differences between groups at T2 (all *P* values >.05).

Table 3. Within-group differences and effect sizes (ES) for the primary outcome.

Primary outcome, PCS		Mean difference T2-T5[a] (n)	95% CI T2-T5	ES for T2-T5	*P*-value[b]	Mean difference T1-T5[a] (n)	95% CI T1-T5	ES for T1-T5	*P*-value[b]
ITT (complete case analysis)									
	Intervention	-2.60 (8.72), 42	-5.32, .11	.29	.06	-7.36 (7.87), 39	-9.91, -4.81	.80	< .001
	Control	-.21 (7.32), 40	-2.55, 2.13	.02	.86	-5.30 (7.30), 41	-7.60, -2.99	.56	< .001
ITT (LOCF)									
	Intervention	-2.36 (8.41), 68	-4.39, -.32	.23	.02	-7.57 (8.23), 63	-9.64, -5.50	.76	< .001
	Control	.40 (7.20), 65	-1.39, 2.18	-.04	.66	-4.65 (7.43), 62	-6.54, -2.76	.47	< .001
ITT (MI)									
	Intervention	-2.61, 63	-5.33, .10		.06	-8.22, 63	-10.86, -5.57		< .001
	Control	-.15, 59	-2.75, 2.46		.91	-5.79, 62	-8.12, -3.46		< .001
Per protocol (complete case analysis)									
	Intervention	-3.04 (8.74), 37	-5.95, -.12	0.33	.04	-7.23 (8.01), 34	-10.03, -4.44	.77	< .001
	Control	-.21 (7.32), 40	-2.55, 2.13	0.02	.86	-5.30 (7.30), 41	-7.60, -2.99	.56	< .001
Per protocol (MI)									
	Intervention	-2.45, 45	-5.29, .38		.09	-7.93, 43	-10.72, -5.14		< .001
	Control	-.27, 57	-2.84, 2.30		.84	-5.85,60	-8.15, -3.54		< .001

[a] T1, at admission to the inpatient program; T2, at discharge from the inpatient program; T5, 11-month follow-up.

[b] *P* values for paired samples *t*-tests.

Table 4. Means and standard deviations for the secondary outcomes at admission to the inpatient rehabilitation (T1), at discharge (T2), and 11 months (T5) after the intervention period, for the completers.

Secondary outcome measures	Group	T1[a] Mean (SD), n	T2[a,b] Mean (SD), n	T5[a] Mean (SD), n
CPAQ				
	Intervention	56.45 (15.22), 40	62.00 (13.62), 44	71.62 (14.11), 39
	Control	53.94 (13.92), 56	62.21 (10.15), 57	67.05 (15.18), 42
FIQ				
	Intervention	58.46 (17.26), 48	46.38 (16.92), 47	49.24 (21.34), 38
	Control	58.35 (16.18), 64	49.10 (17.32), 62	53.75 (17.73), 45
SF-8, physical				
	Intervention	32.12 (7.74), 45	36.68 (8.42), 40	34.38 (9.88), 39
	Control	34.98 (7.13), 60	35.86 (8.24), 49	37.35 (7.65), 44
SF-8, mental				
	Intervention	39.50 (10.67), 45	45.70 (8.06), 40	45.50 (10.70), 39
	Control	39.09 (9.61), 60	44.83 (9.69), 49	43.87 (9.09), 43
GHQ-12				
	Intervention	3.19 (3.21), 43	1.20 (2.02), 45	1.95 (2.64), 38
	Control	2.97 (3.43), 59	0.63 (1.01), 57	2.20 (2.82), 44
CPVI				
	Intervention	2.05 (0.95), 44	2.47 (0.91), 46	2.78 (1.00), 39
	Control	2.02 (0.74), 59	2.52 (0.68), 54	2.50 (0.77), 43
Pain, VAS				
	Intervention	66.59 (17.58), 48	53.07 (22.20), 47	56.28 (28.24), 38
	Control	57.32 (21.56), 64	52.99 (21.27), 61	55.85 (22.73), 45
Fatigue, VAS				
	Intervention	69.29 (23.98), 48	51.38 (27.75), 47	60.79 (28.56), 38
	Control	64.08 (21.01), 64	50.10 (24.28), 61	61.63 (23.63), 45
Sleep disturbance, VAS				
	Intervention	54.77 (26.99), 47	43.97 (25.77), 47	51.68 (30.45), 38
	Control	54.59 (23.31), 64	48.12 (24.57), 62	53.08 (25.95), 45
Depression, VAS				
	Intervention	30.68 (28.71), 47	19.84 (24.08), 47	22.82 (25.89), 38
	Control	32.65 (29.29), 63	27.36 (28.51), 61	28.93 (27.71),45

[a] T1, at admission to the inpatient program; T2, at discharge from the inpatient program; T5, 11-month follow-up.

[b] No differences between groups at T2 (all P values >.05; GHQ and depression (VAS), *P*=.08).

Table 5. Mean differences for the secondary outcomes within-groups, confidence intervals (CI) and effect sizes (ES) for the completers.

Secondary outcome measures		Mean difference T2-T5 (n)[a]	95% CI T2-T5[a]	ES for T2-T5[a]	*P*-value[b]	Mean difference T1-T5 (n)[a]	95% CI T1-T5[a]	ES[a] for T1-T5	*P*-value[b]
CPAQ									
	Intervention	10.20 (9.57), 35	6.91, 13.49	.73	<.001	14.12 (12.46), 33	9.70, 18.54	.95	< .001
	Control	2.15 (10.77), 39	-1.34, 5.64	.17	.22	8.45 (14.00), 38	3.85, 13.05	.62	.001
FIQ									
	Intervention	1.40 (21.15), 37	-5.65, 8.45	-.08	.69	-8.15 (21.95), 38	-15.36, -.93	.42	.03
	Control	7.05 (17.24), 44	1.81, 12.29	-.40	.01	-2.27 (16.23), 45	-7.15, 2.60	.13	.35
SF-8, physical									
	Intervention	-3.20 (8.84), 33	-6.33, -.06	-.36	.046	1.11 (8.99), 36	-1.93, 4.15	.12	.46
	Control	.54 (8.18), 34	-2.32, 3.39	.06	.71	1.01 (6.99), 42	-1.17, 3.19	.14	.36
SF-8, mental									
	Intervention	.39 (10.09), 33	-3.19, 3.97	.04	.82	6.45 (11.71), 36	2.49, 10.42	.58	.002
	Control	-1.61 (11.53), 33	-5.70, 2.48	-.17	.43	3.10 (6.99), 42	.93, 5.28	.36	.006
GHQ-12									
	Intervention	.69 (3.06), 35	-.36, 1.74	-.28	.19	-1.12 (4.07), 34	-2.54, .30	.36	.12
	Control	1.68 (2.94), 40	.74, 2.61	-.85	.001	-.61, 3.39, 41	-1.68, .46	.20	.26
CPVI									
	Intervention	.29 (.90), 37	-.01, .59	.30	.06	.56 (.72), 35	.32, .81	.59	< .001
	Control	-.11 (.88), 36	-.41, .19	-.16	.46	.40 (.61), 41	.21, .59	.54	< .001
Pain, VAS									
	Intervention	1.43 (32.58), 37	-9.44, 12.29	-.06	.79	-9.86 (25.54), 38	-18.25, -1.46	.43	.02
	Control	5.53 (20.73), 43	-.85, 11.91	-.25	.09	-1.82 (23.65), 45	-8.92, 5.28	.08	.61
Fatigue, VAS									
	Intervention	8.71 (33.56), 37	-2.48, 19.90	-.32	.12	-8.94 (31.93), 38	-19.43, 1.56	.36	.09
	Control	14.96 (24.50), 43	7.42, 22.49	-.61	<.001	-.93 (22.65), 45	-7.73, 5.87	.04	.78
Sleep disturbance, VAS									
	Intervention	5.55 (33.26), 37	-5.54, 16.64	-.20	.32	-2.29 (33.46), 37	-13.45, 8.86	.08	.68
	Control	7.43 (27.09), 44	-.81, 15.66	-.28	.08	.45 (30.11), 45	-8.59, 9.50	-.02	.92
Depression, VAS									
	Intervention	1.11 (28.71), 37	-8.46, 10.68	-.05	.82	-8.13 (27.78), 37	-17.40,1.13	.29	.08
	Control	7.27 (27.43), 43	-1.18, 15.71	-.26	.09	.99 (23.13), 45	-5.96, 7.94	-.04	.78

[a]T1, at admission to the inpatient program; T2, at discharge from the inpatient program; T5, 11-month follow-up.

[b]*P* values for paired samples *t*-tests.

Discussion

The results of the study are ambiguous. On one hand, there were no significant differences in mean values on any variables between the groups at 11-month follow-up. Thus, the favorable effects previously reported on catastrophizing, acceptance, functioning, and symptom levels at 5-month follow-up were not evident at long-term follow-up. However, there was significantly more improvement in catastrophizing scores during the follow-up period in the intervention group compared to the control group. Moreover, the within-group analyses, comparing the baseline for the smartphone intervention to the 11-month data, revealed changes in the desired direction in catastrophizing and acceptance in the intervention group but not within the control group. Also, increase in disease impact, emotional distress, and fatigue were seen in the control group but not

within the intervention group. Additionally, effects on most variables were maintained in the intervention group from the 5-month follow-up to the 11-month follow-up. Unexpectedly, between the two follow-ups, the control group reported some improvement in several variables (catastrophizing, values-based living, and depression) whereas the intervention group did not. We have no data to support an explanation for this improvement. One could speculate that it takes time for changes in thoughts, behavior, and priorities promoted by the multidimensional inpatient rehabilitation program to settle and cause positive effects. The controls did not get the smartphone intervention that could promote these changes early after discharge, and thus the changes may have been achieved at an earlier stage in the intervention group. We do not have exact login information for visits to the website. As mentioned in our previous paper, most participants in the control group (26 of the 38 who reported this information) visited it rarely (2 times or less). The impression of the administrator of the website (HE) was that it was seldom accessed. Based on the limited use of the website, it is not assumed to have caused any changes seen in the control group. The spontaneous improvement in the control group, large variations within variables, relatively few participants, and small effect sizes may explain the lack of significant differences between the groups. It is important to acknowledge that the effects of the inpatient program were sustained at the long-term follow-up in the control group for many of the outcome variables, ie, catastrophizing, acceptance, mental health, and values-based living. Improvement in those variables indicates that the participants cope better with their situation.

Some of the limitations regarding the generalizability of the study have been discussed in the previous report, eg, the difference in the completers groups versus those withdrawing [20]. Again, at this follow-up we have the limitations of a response rate below 70%. Those not returning the follow-up questionnaires reported generally more symptoms at admission to the inpatient program than those who returned them, thus having the possibility to influence the results. Multiple imputations have been recommended to improve the validity of results in trials with incomplete datasets [39]. In the ITT analysis, the level of catastrophizing in the control group at endpoint (T5) was almost the same for the complete case analysis (mean 14.73, n=43) and the MI analysis (mean 14.74, n=66). In the intervention group, the catastrophizing level was somewhat higher with MI (mean 12.80, n=69) compared to the complete case analysis (mean 11.50, n=44). This might partly be explained by higher baseline scores on two variables (pain and SF-8 physical component), which were included in the MI regression model. Importantly, in the per protocol analysis, the difference between the mean levels of catastrophizing with MI or without (complete case analysis) was small. This provides some support for the validity of our results of secondary outcomes, where results of complete case analysis is reported. However, in the within-group analysis, the difference between the intervention baseline (T2) and 11-month follow-up (T5) in the intervention group was significant applying complete case analysis (P=.04) but only borderline significant in the analysis with MI (P=.09), thus indicating that the results for complete case analysis should be interpreted with some caution.

The withdrawal rate of 30% indicates that this type of secondary intervention may not be found feasible by all. The withdrawal rate is similar to those reported in many iCBT, where an average dropout rate of 27% has been reported [40]. The patients who withdrew tended to score higher on depression and were older than the completers, which could have influenced their interest and capacity to participate. We do not have information on the reasons for withdrawal for all participants. However, many of those who withdrew before or during the run-in period reported that the combination of the smartphone intervention and participation in the inpatient program was stressful or expected to be stressful. Therefore, closer collaboration with the rehabilitation center and flexibility in start-up date of the smartphone intervention might contribute to reduction in withdrawal rates. At the 11-month follow-up, the subjective global improvement measure could have been improved by including a question to assess the participants' evaluation of the smartphone intervention.

Medications, education, CBT, and physical exercises are among the recommended treatment options for individuals with CWP and fibromyalgia [7,9]. The short-term effects are well established, but concerns about the long-term effects have been raised. In a recent longitudinal study including 1555 patients with fibromyalgia receiving standard care, with a mean follow-up period of 4 years, no clinically meaningful improvement in overall symptom severity was found for the sample. Only about one fourth of the sample showed meaningful improvement, including 10% with substantial improvement in symptom severity [41]. The goals of most nonpharmacological treatment are to provide knowledge and teach self-management skills aiming to reduce symptoms or support constructive coping. Adherence to recommended self-management strategies after treatment seems important for long-term effect. The research literature on Internet-delivered interventions to support self-management in individuals with chronic pain is rapidly evolving, with studies on therapist-guided and unguided intervention, as well as on applications for smartphones [16,42,43]. The present smartphone intervention was primarily meant to support use of constructive coping skills and implementation of recommended lifestyle changes the first weeks after discharge from inpatient rehabilitation, in order to prevent the fading of positive effects from the given rehabilitation. The smartphone intervention introduced elements from ACT, including mindfulness, which had not been presented in the inpatient program. We do not know if this influenced the results. Nevertheless, we acknowledge that the smartphone intervention could have been more strongly integrated in the rehabilitation program, eg, including the same health care professionals. The feasibility and long-term efficacy of the intervention might possibly be improved by providing the diaries on the individuals' own smartphones and by providing feedback on a more long-term basis. An 8-week, guided iCBT intervention following multidisciplinary treatment was found to reduce catastrophizing in a randomized trial with 72 persons with residual symptoms post treatment [19]. The intervention lasted twice as long as our intervention but included less therapist contact. The effects on catastrophizing were remained at 6-month follow-up, but more long-term effects are not reported [19]. A smartphone application based on ACT to support

values-based living was found feasible in an exploratory study including 11 healthy volunteers [43]. Ways to tailor the diary content and provide tailored feedback should be investigated. Booster periods with therapist-feedback might be beneficial or a longer period with less frequent therapist contact, eg, once a week/month.

To conclude, the results of this randomized trial are ambiguous. No significant between-group effect was found on the study variables at 11-month follow-up. However, more improvement in catastrophizing scores was seen in the intervention group than the control group in the period between discharge from the inpatient program and the follow-up. Moreover, the within-group analyses, comparing the baseline for the smartphone intervention to the 11-month data indicated changes in the desired direction in catastrophizing and acceptance in the intervention group but not within the control group. Also, increases in disease impact, emotional distress, and fatigue were seen in the control group but not within the intervention group. This kind of smartphone intervention may therefore be suited for providing self-management support following inpatient pain management program. Research on strategies to provide feasible self-management support on a long-term basis for individuals with CWP and ways to enhance cost-effectiveness is needed.

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All authors participated in the development of the intervention. OBK and HE recruited participants and collected data, helped by SHW who was responsible for the patients' diagnostics and data collection at the inpatient center. OBK, TLS, and HE performed the role of the therapist. EE was responsible for the design and development of the technological system. HE was project leader. All authors contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshot from the website.

[PNG File, 179KB - jmir_v15i3e72_app1.png]

Multimedia Appendix 2

CONSORT-EHEALTH Checklist V1.6.2 [44].

[PDF File (Adobe PDF File), 1MB - jmir_v15i3e72_app2.pdf]

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Abbreviations

ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
CPAQ: chronic pain acceptance questionnaire
CPVI: chronic pain values inventory
CWP: chronic widespread pain
ES: effect size
FIQ: fibromyalgia impact questionnaire
GHQ: general health wuestionnaire
iCBT: Internet-based cognitive behavioral therapy
ITT: intention-to-treat
LOCF: last observation carried forward
M: mean
MI: multiple imputations
PCS: pain catastrophizing scale
SF: short-form health survey
SMS: short message service
VAS: visual analog scale

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