An Internet-delivered version of the Unified Protocol as a secondary intervention for individuals with persistent pain and co-morbid emotional problems: A pilot study

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Abstract

Many individuals with persistent pain suffer from co-morbid emotional disorders. Since co-morbid emotional disorders have been linked to suboptimal pain rehabilitation gains, new approaches are needed in the treatment of these individuals. Using a single-case experimental design, the current study evaluated the feasibility, effectiveness and acceptability of a guided Internet-delivered version of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP), as a secondary intervention for former pain rehabilitation patients (n=9) with residual pain problems and co-morbid depressive symptoms and/or anxiety. The feasibility of the treatment was found to be low and with one exception, no positive effects of the treatment were established. Acceptability was found to be reasonable, however, acceptability data were scarce. Implications for future research and practice are discussed.

Keywords: Persistent pain, emotional disorders, treatment, Internet, Unified Protocol, single-case

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En Internet-administrerad version av Unified Protocol som en sekundär intervention för personer med långvarig smärta och komorbid emotionell problematik: En pilotstudie

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Sammanfattning


Nyckelord: Långvarig smärta, emotionell problematik, behandling, Internet, Unified Protocol, single-case

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An Internet-delivered version of the Unified Protocol as a secondary intervention for individuals with persistent pain and co-morbid emotional problems: A pilot study

Persistent pain affects a large proportion of the population (see eg. Leadley, Armstrong, Lee, Allen & Kleijnen, 2012), and is associated with extensive individual suffering (see eg. Banks & Kerns, 1996) as well as negative consequences for the society at large (see eg. Statens beredning för medicinsk utvärdering [SBU], 2006). Among the numerous individuals living with persistent pain, many also struggle with co-morbid emotional disorders (see eg. Demyttenaere et al., 2007). Since co-morbid emotional disorders have been linked to various negative pain-related outcomes, including suboptimal treatment gains (see eg. Nicholas, 2007), it is urgent that efforts are made in order to improve the treatment of individuals with such co-morbidity. The current study constitutes such an effort. Specifically, the study aims to explore the benefits of complementing standard pain rehabilitation with a guided Internet-delivered version of the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders (UP; Barlow, 2013), in a sample consisting of former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems.

To introduce the reader to the area of interest, we begin by clarifying the nature of pain as well as the nature and consequences of persistent pain, and briefly describe common methods for treating persistent pain. Thereafter, the co-occurrence of persistent pain and emotional disorders will be discussed and the rationale and empirical support for the utilization of an Internet-delivered version of the UP in the treatment of individuals with persistent pain and co-morbid emotional disorders will be reviewed. Finally, the purpose and the research questions of the current study will be presented.

Pain

Perspectives on the meaning of pain have changed over time. Early views on pain were consistent with specificity theory, which maintained that pain is indicative of tissue
damage and suggested a straightforward, fixed relationship between tissue damage and pain (Campbell, Clauw & Keefe, 2003). However, empirical studies have shown that pain may be substantially less than what would be expected on basis of observed tissue damage, and may be present although no tissue damage is to be found (Keefe & France, 1999). Possibly as a consequence of such evidence, contemporary perspectives on pain often incorporate factors beyond tissue damage as determinants of the pain experience. Today, a frequently used definition of pain maintains that pain constitutes “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (International Association for the Study of Pain [IASP], 1994, p. 209). This is in line with the biopsychosocial model of pain (Keefe & France), which has emerged over the past three decades and rests on several newer pain theories (Campbell et al.). According to the biopsychosocial model, pain is a highly complex and dynamic phenomenon, influenced by as well as influencing biological, psychological and social factors.

**Persistent pain**

In the current study, the term *persistent pain* refers to non-malignant (i.e. non-cancer-related) pain of constant or frequent nature that has been present for at least three months. Non-malignant pain of shorter duration than three months is referred to as *acute pain*. This is in line with common pain taxonomies (see eg. Kennedy, Roll, Schraudner, Murphey, McPherson, 2014; SBU; 2006; Socialstyrelsen, 2011), although in some cases the term *subacute pain* (i.e. pain with a longer duration than acute pain but a shorter duration than persistent pain) is used in addition to acute and persistent pain (see eg. Linton, 2013). Despite the fact that this way of distinguishing between acute pain and persistent pain is a question of time, persistent pain should not be viewed as acute pain with an extended duration but rather as a distinct phenomenon (IASP, 1994). Unlike acute pain, which generally demonstrates a clear connection with a certain somatic diagnosis (eg. a certain type of injury or disease),
persistent pain is less readily explained by identifiable tissue pathology or medical illness. Accordingly, persistent pain is usually considered a condition in its own right rather than a complication, and can often be treated in the same way regardless of somatic origin (SBU, 2006).

**Prevalence and consequences of persistent pain.** As stated initially, persistent pain is a common problem. In a systematic review including 29 prevalence studies conducted in different European countries, the average point prevalence of persistent pain in the general population was found to be 27% (Leadley et al., 2012). Moreover, although consequences of persistent pain vary across individuals (Linton, 2013), there is abundant evidence to suggest that persistent pain is associated with detrimental effects on the afflicted individual’s physical and psychological well-being (see eg. Becker et al., 1997; Breivik, Collette, Ventafridda, Cohen & Gallacher, 2006; Cvijetic et al., 2014; Dureja et al., 2014; Gullacksen & Lidbeck, 2004; Jameie, Shams-Hosseini, Jahnzadeh, Sharifi & Kerdari, 2012; Jonsdottir, Aspelund, Jonsdottir & Gunnarsdottir, 2013; Ojala et al., 2015 and Smith et al., 2001). This is understandable considering the “unique set of challenges” carried by persistent pain (Banks & Kerns, 1996, p. 19). To begin with, as seen above, pain constitutes an aversive physical sensation. In addition, pain is associated with aversive emotional experiences, eg. anxiety and fear resulting from the instinct to interpret pain as a sign of danger. Furthermore, persistent pain implicates that the individual is exposed to pain constantly or frequently and for long periods of time, thus continuously having to confront physical and emotional aversiveness.

Persistent pain also poses challenges to the individual’s well-being through its consequences on the individual’s ability to maintain their usual way of life (Banks & Kerns, 1996). Common sequels of persistent pain include impairment/disability in various important areas of life, sleep deprivation, financial strain (resulting from medical expenses, job loss etc.) and experiences of loss in the domains of identity and role functioning. Moreover, many
individuals with persistent pain feel invalidated by the medical system, since the messages they receive from health providers (eg. that there is no medical basis for their pain complaints) frequently conflict with their own perspective.

With regard to the consequences of persistent pain on a societal level, these include large direct and indirect economic costs. The direct socioeconomic costs relate to medication and contacts with the health care system, while the indirect costs relate to production loss due to sick leave and early retirement (SBU, 2006). In total, the yearly socioeconomic burden of persistent pain in Sweden has been estimated to 87.5 billion SEK.

**Treatment of persistent pain.** The methods for treating persistent pain are abundant and varied (SBU, 2006). Examples include medication, electrical stimulation, neurosurgery, physical activity, relaxation, biofeedback, massage, manipulation, acupuncture and yoga. Psychological methods include among others visualization, hypnosis, pedagogical interventions, behavioral therapy and cognitive behavioral therapy (CBT). Within the conventional health care system, the treatment of persistent pain is usually referred to as rehabilitation (see eg. Socialstyrelsen, 2011). According to Gerdle and Elert (1999, as cited in SBU), rehabilitation can be schematically divided into three different levels: unimodal, intermediate and multimodal. At the unimodal level, rehabilitation consists of a single intervention, eg. physiotherapy or psychotherapy, and does not involve different professional disciplines. This is in contrast to rehabilitation at the intermediate level, which includes various interventions and involves health care professionals from several disciplines (eg. physicians, physiotherapists and psychologists). The involved professionals communicate on a regular basis but are not organized in teams. Pain rehabilitation at the unimodal and intermediate level is directed at individuals with relatively limited and uncomplicated needs (SBU, 2011). In cases where individuals demonstrate more comprehensive and complex needs, and where severe illness has been ruled out as an explanation for the pain condition,
multimodal rehabilitation (MMR) is warranted (Socialstyrelsen). This form of rehabilitation includes a number of well-planned and synchronized interventions carried out by personnel from various disciplines (SBU, 2006). The personnel is organized in teams characterized by a biopsychosocial perspective on pain as well as a strive to coordinate interventions across disciplines in order to reach common goals. MMR is primarily carried out in pain clinics or in other specialized care contexts (Socialstyrelsen, 2010), although some MMR teams operate within the primary care. In terms of content, the components of MMR vary considerably across individuals and treatment sites. However, most MMR programs include physical exercise and psychological interventions (SBU, 2010). The latter usually include CBT techniques (Linton, 2013; SBU, 2006; SBU, 2010; Socialstyrelsen, 2011), which have a large body of evidence to support their positive effects on the physical, psychological and social functioning of individuals with persistent pain (Morley, Eccleston & Williams, 1999). As with CBT in general, the overarching goals of CBT in a pain context is to help individuals decrease cognitions and behaviors contributing to the severity and/or maintenance of their problems and increase cognitions and behaviors related to recovery (Ehde, Dillworth & Turner, 2014). There is no standard CBT protocol for pain, however, techniques commonly include relaxation training, behavioral activation, activity pacing, problem-solving training and cognitive restructuring (Thorn, 2004 and Turner & Romano, 2001, as cited in Ehde et al.) as well as exposure in vivo for feared movements (Linton; Socialstyrelsen). In some cases, CBT for pain also includes interventions directed at co-morbid emotional disorders and sleep disorders (Ehde et al., Linton; Socialstyrelsen).

**Persistent pain and co-morbid emotional disorders**

**Emotional disorders.** In the current study, the term *emotional disorders* refers to depressive disorders and anxiety disorders. According to the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM; American Psychiatric Association [APA],
2013), the common feature of depressive disorders is “the presence of sad, empty, or irritable mood, accompanied by somatic and cognitive changes that significantly affect the individual’s capacity to function” (p. 155). Distinctions between depressive disorders are made primarily on basis of variations in severity and duration. In terms of anxiety disorders, common features include excessive fear and anxiety (i.e. fear or anxiety that is out of proportion to the actual danger) and avoidance of fear- or anxiety-inducing objects/situations, which lead to clinically significant distress or impairment in important areas of functioning. The anxiety disorders differ from each other with regard to the specific objects or situations that induce fear, anxiety and avoidance.

**Co-occurrence of persistent pain and emotional disorders.** Various empirical studies have demonstrated that emotional disorders frequently co-occur with persistent pain and are more common among individuals with persistent pain than in the general population. For example, in a study using a nationally representative sample (McWilliams, Cox & Enns, 2003), 21.7% of the individuals with persistent pain were found to meet criteria for a depressive disorder and 35.1% were found to meet criteria for an anxiety disorder. The corresponding rates for individuals without persistent pain was 18.1% and 10.0%, respectively. Other studies have demonstrated concordant results, both in non-clinical and clinical contexts (Demyttenaere et al., 2007; McWilliams, Goodwin & Cox, 2004; Klemenc-Ketis, Kersnik & Tratnik, 2009). With regard to the prevalence of co-morbidity in pain rehabilitation contexts, Becker and colleagues (1997) found that among 150 patients referred to a multidisciplinary pain clinic, 40% were likely to have a depressive disorder and 50% were likely to have an anxiety disorder. Similar results were obtained by Castro and colleagues (2009) in a sample of 400 individuals receiving care at a pain clinic.

**Theoretical models concerning persistent pain and co-morbid emotional disorders.** The high co-occurrence of persistent pain and emotional disorders suggests a
relationship between the conditions. Various theoretical models have been put forward in order to illuminate how such a relationship may be understood. Below, two of these models are briefly outlined.

**The fear-avoidance model.** The fear-avoidance model (the FA model; Vlaeyen, 1995, as cited in Vlaeyen & Linton, 2000) describes the development and maintenance of persistent pain and co-morbid depression. Specifically, the FA model explains the path towards persistent pain and depression as follows: When pain befalls an individual, the individual reacts with catastrophizing (i.e. an exaggerated negative pattern of thinking; Landström Flink, 2011) about the meaning and consequences of the pain experience (Vlaeyen & Linton, 2000). The catastrophizing elicits fear of pain, which results in a behavioral pattern characterized by escape from and avoidance of pain-inducing and/or potentially pain-inducing activities. As a consequence of the escape and avoidance behaviors, the individual does not accomplish daily activities to the same extent as before. Over time, this has detrimental effects on the individual’s musculoskeletal and cardiovascular systems, and gives rise to depression due to withdrawal from essential reinforcers. Via these physiological and emotional consequences, the escape and avoidance behaviors results in decreased pain tolerance, thus promoting the experience of pain. Furthermore, the escape and avoidance behaviors maintain the individual’s fear of pain, since they prevent correction of catastrophizing appraisals.

**The shared vulnerability model.** The shared vulnerability model (SVM; Asmundson & Katz, 2009) describes the development and maintenance of persistent pain and co-morbid anxiety disorders. According to the SVM, the path to persistent pain and a co-morbid anxiety disorder starts with a stressor of some kind – physical and/or psychological. Partly due to anxiety sensitivity (i.e. fear of anxiety based on the belief that it may have harmful consequences) and selective attention to threat, the stressor elicits strong negative emotions (i.e. anxiety, fear and agitation) and problematic reaction patterns in response to the negative
emotions. The problematic reaction patterns include heightened autonomic nervous system and muscular responsivity (physical reaction pattern), avoidance of situations or activities perceived as threatening (behavioral reaction pattern) as well as hypervigilance and cognitive biases (cognitive reaction pattern). Over time, depending on whether the stressor implicates pain or not, the reaction patterns result in the development and maintenance of either a) persistent pain, b) an anxiety disorder, or c) persistent pain and a co-morbid anxiety disorder. To clarify, in the subgroup of pain patients with co-morbid anxiety disorders, the SVM suggest that the pain condition and the anxiety disorder may have developed either along separate paths or in parallel. In either case, however, the pain condition and the anxiety disorder are assumed to have a shared etiology. Moreover, once co-occurrence is a fact, the pain condition and the anxiety disorder are assumed to maintain each other.

**Summary of the theoretical models.** Taken together, the FA model and the SVM suggest that individuals with persistent pain and co-morbid emotional disorders are characterized by 1) anxiety sensitivity, 2) overly threat-focused cognitive tendencies (e.g. catastrophizing and selective attention to threat) and 3) problematic ways of managing negative emotions. Among the problematic ways of managing negative emotions, avoidance appears to be central. The mentioned characteristics are assumed to underlie the development and maintenance of persistent pain and co-morbid emotional disorders. In other words, the characteristics are assumed to operate in a *transdiagnostic* fashion, i.e. causally influence both the pain condition and the co-morbid emotional disorder.

**The impact of co-morbid emotional disorders on pain-related outcomes.** The occurrence of co-morbid emotional disorders in the context of persistent pain has been linked to various poor pain-related outcomes. Cross-sectionally, co-morbid emotional disorders have been associated with less self-efficacy with regard to communication of pain-related needs in the workplace (Blennqvist & Buchholz, 2014; Johnson & Ejnefjäll, 2014; Thomtén, Boersma,
Flink & Tillfors, in press), higher levels of pain-related fear (Wurm, Larsson, Boersma & Tillfors, 2013) as well as higher levels of pain-catastrophizing (Thomtén et al.). Moreover, individuals with persistent pain and emotional disorders have been found to report higher pain severity and higher pain interference in comparison with their counterparts without emotional disorders (Morasco et al., 2013), and there is evidence that emotional disorders contribute significantly to pain-related disability (von Korff et al., 2005). Furthermore, in longitudinal studies, co-morbid emotional disorders have been found to contribute to a worsened prognosis of persistent pain in terms of pain intensity (Bair, Robinson, Katon & Kroenke, 2013; Castillo et al., 2013; Edwards et al., 2007; Lerman, Rudich, Brill, Chalev & Shahar, 2015) and functional ability in various domains (Castillo et al.; Edwards et al.; Lerman et al.; Lillefjell, Krokstad & Espnes, 2007).

Negative consequences of co-morbidity also include suboptimal pain rehabilitation gains. Specifically, co-morbid emotional disorders have been associated with less pain reduction following MMR (Michaelson, Sjölander & Johansson, 2004), lower levels of return to work self-efficacy following MMR (Johnson & Ejnefjäll, 2014; Wurm, Edlund, Tillfors & Boersma, submitted), less likelihood of having returned to work following interdisciplinary pain rehabilitation (Vowles, Gross & Sorrell, 2004), less likelihood of having returned to work following CBT (Sullivan, Adams, Thibault, Corbière & Stanish, 2006) and higher levels of pain-related disability following physical therapy (Bergbom, Boersma, Overmeer & Linton, 2011) as well as exposure in vivo (Flink, Boersma & Linton, 2010). Moreover, co-morbid emotional disorders have been found to remain at clinical levels following MMR (Johnson and Ejnefjäll; Wurm et al.).

To summarize, empirical evidence suggest that in the subgroup of pain patients characterized by co-morbid emotional disorders, pain-related rehabilitation gains are compromised and emotional problems tend to remain despite rehabilitation. In the current
study, this state of affairs is understood as a consequence of a general failure of pain rehabilitation programs to replace avoidant reaction patterns in response to negative emotions with more helpful ways of managing emotions, as well as a failure to reduce overly threat-focused cognitive tendencies and anxiety sensitivity. This interpretation is in line with the argumentation of distinguished researchers within the pain field (see eg. Linton & Fruzetti, 2014) as well as the findings in the previously mentioned study by Wurm and colleagues (submitted), where MMR patients with co-morbid emotional problems reported clinical levels of anxiety sensitivity both preceding and following rehabilitation. It is also in line with the previously mentioned study by Flink and colleagues (2010), which investigated the benefits of exposure in vivo for individuals with persistent pain. In this study, individuals with high levels of catastrophizing did not benefit from the treatment.

**The Unified Protocol**

In order to improve pain rehabilitation gains, individuals with persistent pain and co-morbid emotional disorders may benefit from interventions targeting overly threat-focused cognitive tendencies, anxiety sensitivity and avoidant behavioral reaction patterns in response to negative emotions. An example of such an intervention is the UP, which is an emotion-focused, manual-based intervention developed for the treatment of all anxiety disorders and unipolar mood disorders as well as other disorders where emotions are assumed to play a crucial role (Farchione et al., 2012). Central aims of the UP include increasing cognitive flexibility, emotion recognition, emotion experiencing and emotion awareness/acceptance (Barlow, 2013; Barlow, Allen & Choate, 2004) and reducing excessive emotional responding to both internal and external cues (Wilamowska et al., 2010). To achieve these aims, the UP utilizes empirically supported and widely used CBT techniques, including psychoeducation, mindfulness, cognitive restructuring, behavioral experiments and gradual exposure (Barlow). In order to allow application of the techniques to a range of emotional problems, the
techniques are taught in a generic way. Thus, the UP requires a substantial effort from the therapist and the patient in terms of figuring out how to apply the techniques in order for the patient’s needs to be satisfied.

**Empirical evidence regarding the effectiveness of the UP.** The UP has been evaluated in several single-case experimental designs (SCEDs) and one randomized controlled trial (RCT). In the SCEDs, the UP has been found effective in the treatment of individuals with a principal diagnosis of bipolar disorder and co-morbid emotional disorders or co-morbid attention-deficit hyperactivity disorder (Ellard, Deckersbach, Sylvia, Nierenberg & Barlow, 2012), individuals with a principal diagnosis of borderline personality disorder and co-morbid emotional disorders (Lopez et al., 2014) as well as individuals with a principal diagnosis of social anxiety disorder (SAD), obsessive-compulsive disorder (OCD), generalized anxiety disorder (GAD), panic disorder with agoraphobia (PDA), dysthyemia, specific phobia, anxiety disorder not otherwise specified or agoraphobia (Bullis et al., 2015). In the RCT (Farchione et al., 2012), the UP was found effective in reducing anxiety, depressive symptoms and functional impairment among individuals with a principal diagnosis of GAD, SAD, OCD, PDA, anxiety disorder not otherwise specified or post-traumatic stress disorder (PTSD). Moreover, in a long-term follow-up study of the RCT, treatment gains were found to remain 18 months post-treatment (Bullis, Fortune, Farchione & Barlow, 2014).

To our knowledge, there is yet no empirical evidence regarding the effectiveness of the UP in the treatment of adult populations with persistent pain. However, one case study evaluated the UP in the treatment of two adolescents experiencing problems with pain and emotional difficulties (Allen, Tsao, Seidman, Ehrenreich-May & Zeltzer, 2012). Positive effects were found on depressive symptoms and anxiety as well as on emotion regulation skills.
Empirical evidence regarding the construct validity of the UP. The assumption that
the UP may undermine emotional disorders by reducing excessive emotional responses to
internal cues and by increasing emotional awareness/acceptance is to some extent supported
by empirical evidence. Specifically, using data from the RCT by Farchione and colleagues
(2012), Sauer-Zavala and colleagues (2012) found that the UP was effective in reducing fear
of emotions (defined as negative reactions to emotions that occurs based on the belief that the
emotions will be long-lasting and spiral out of control) as well as anxiety sensitivity, and led
to increases in emotional awareness/acceptance. Moreover, these positive effects were found
to be associated with reductions in anxiety and depressive symptoms. Importantly, decreases
in fear of emotions remained significantly associated with decreases in depressive symptoms
and anxiety when controlling for negative affect, and decreases in anxiety sensitivity
remained significantly associated with decreases in depressive symptoms.

The UP as an Internet-delivered intervention

The UP was developed as a face-to-face intervention (Barlow, 2013), and has not yet
been evaluated in other forms. However, several arguments can be proposed in favor of
offering the treatment as an Internet-delivered intervention. These include the potential of
Internet-delivered interventions to a) reduce health service costs, b) reduce costs and increase
convenience for patients, c) allow treatment of individuals who are in need of help but would
not seek face-to-face treatment due to geographical isolation, mobility issues or fear of
stigmatization/embarrassment, d) allow frequent communication between therapists and
patients and e) increase supplier control of the intervention (Griffiths, Lindenmeyer, Powell,
Lowe & Thorogood, 2006). Drawbacks of Internet-delivery include a) requirements on
patients in terms of computer and Internet access as well as computer skills, b) difficulties in
identifying and managing psychological crisis in patients and c) lack of non-verbal
communication that may facilitate understanding (Carlbring & Andersson, 2004). Moreover,
the drop-out rate in Internet-delivered interventions tend to be higher than in face-to-face interventions (van Ballegooijen et al., 2014).

**Empirical evidence regarding Internet-delivered CBT.** To our knowledge, there is no empirical evidence regarding the UP delivered through the Internet. However, there is a large body of research with regard to Internet-delivered CBT in general. Meta-analyses suggest that Internet-delivered CBT is effective in the treatment of depression (Andersson & Cuijpers, 2009), anxiety disorders (Andrews, Cuijpers, Craske, McEvoy & Titov, 2010) as well as persistent pain (Macea, Gajos, Calil & Fregni, 2010). Moreover, in several RCTs, Internet-delivered CBT has been found effective in the treatment of individuals with persistent pain and co-morbid emotional disorders (Alehagen & Nilsson, 2014; Lekström, 2014; Buhrman et al., 2015; Dear et al., 2013). Established positive effects include reductions in depressive symptoms, anxiety, catastrophizing, pain catastrophizing, pain and pain-related disability as well as increases in activity engagement and pain acceptance.

One earlier study, an RCT conducted by Buhrman and colleagues (2013), has investigated the effectiveness of Internet-delivered CBT for individuals with residual pain problems and emotional problems following MMR. The treatment was found effective in reducing pain, catastrophizing, anxiety and depressive symptoms.

In terms of transdiagnostic Internet-delivered CBT interventions, the evidence base is yet small but growing. In a review of the evidence base regarding such interventions, Titov, Dear, Johnston and Terides (2012) concluded that the results of the studies conducted so far were encouraging and that transdiagnostic Internet-delivered CBT interventions may reduce symptoms of both principal and co-morbid disorders.

**Purpose and research questions of the current study**

The purpose of the current study is to evaluate a guided Internet-delivered version of the Unified Protocol as a secondary intervention (i.e. as a complement to a prior intervention)
for former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems. As seen above, previous research points to the benefits of utilizing guided Internet-delivered CBT in the treatment of individuals with persistent pain and co-morbid emotional disorders, either as a stand-alone intervention or as a secondary intervention. However, the current study is the first to evaluate an Internet-delivered version of the UP as a secondary intervention for individuals with residual pain problems following rehabilitation and co-morbid emotional disorders/problems. It is also the first study to evaluate the UP in a web-based format and the first study to evaluate the UP in the treatment of adults with persistent pain and co-morbid emotional disorders/problems. Thus, the study has the potential to make an important contribution to the evidence base regarding the treatment of individuals with persistent pain and co-morbid emotional disorders/problems as well as to the evidence base regarding the UP.

In order to fulfill its purpose, the study will seek answers to the following questions: 1) Is a guided Internet-delivered version of the UP a feasible intervention among former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems (i.e. depressive symptoms and/or anxiety)?, 2) Is a guided Internet-delivered version of the UP effective in reducing pain (i.e. pain intensity and pain dysfunction) in former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems?, 3) Is a guided Internet-delivered version of the UP effective in reducing emotional problems in former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems?, 4) Is a guided Internet-delivered version of the UP effective in reducing anxiety-related avoidance in former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems?, 5) Is a guided Internet-delivered version of the UP effective in reducing anxiety sensitivity in former pain rehabilitation patients with residual pain problems and co-morbid emotional
disorders/problems? and 6) Is a guided Internet-delivered version of the UP acceptable to
former pain rehabilitation patients with residual pain problems and co-morbid emotional
disorders/problems? Given the absence of previous research addressing these questions, no
hypotheses were formulated.

Method

The current study constitutes a cooperation between Örebro University, Uppsala
University and Uppsala county council, as well as three pain rehabilitation clinics and five
primary care centers located in central Sweden. The study forms part of the Social Anxiety
and Pain project (SAP; see eg. Thomtén et al., in press; Wurm et al., submitted; Wurm et al.,
2013), which includes of a number of studies aiming to explore the relationship between
persistent pain and emotional disorders/problems and contribute to the development of
effective interventions for individuals with persistent pain and co-morbid emotional
disorders/problems.

Design

The study was intended to be an RCT with a wait list control group. However, due to
an insufficient number of participants, the research questions were instead addressed utilizing
a SCED. Although not comparable with RCTs in terms of internal and external validity,
SCEDs nevertheless allow for conclusions about treatment effect (Barlow, Nock & Hersen,
2009; Kazdin, 2011) and may be especially appropriate at early stages of research.
Furthermore, when the design includes systematic replication, external validity is enhanced.

There are several ways of performing a SCED. The current study utilized an AB
design with systematic replication across individuals and therapists. The AB design consists
of two phases: the baseline phase (the A phase) and the treatment phase (the B phase). During
the baseline phase, the dependent variables are continuously measured without manipulation
of the independent variable, i.e. without the introduction of an intervention. The purpose of
the baseline is twofold. To begin with, the baseline serves a descriptive function, i.e. provides a description of the natural variation of the dependent variables. Moreover, the baseline serves a predictive function, i.e. makes it possible to predict how the dependent variables would develop if no intervention would be introduced (Barlow, Nock & Hearson, 2009). During the treatment phase, the dependent variables are continuously measured while the treatment is carried out. By comparing the variation in the dependent variables observed during the treatment phase with the variation observed during the baseline phase, the effect of the treatment may be evaluated.

In order to explore the effect of the treatment on emotional problems, the continuous measurements were complemented with pre- and post-treatment assessments of diagnostic status, as well as pre-, mid- and post-treatment measurements of social anxiety. In terms of anxiety sensitivity, treatment effectiveness was explored using pre- and mid- or post-treatment measurements alone.

Participants

**Description of the sample.** The sample consisted of six females (67%) and three males (33%). The participants’ age ranged from 40 to 66 (M=56.3) and the duration of persistent pain ranged from 3 to 25 years (M = 8.8). The number of psychiatric diagnoses pre-treatment ranged from none to 3 (mode = 1). All participants had completed MMR within the past two years.

**Selection criteria.** In order to be eligible for inclusion in the study, individuals were required to: a) be at least 18 years old, b) be fluent in Swedish, c) have continuous access to the Internet and a computer, d) have completed MMR within the past two years, e) experience subclinical depressive symptoms or MDD (i.e. receive a total score of at least 15 points on the Montgomery Åsberg Depression Rating Scale Self-rating version; MADRS-S, Svanborg & Åsberg, 1994) and/or subclinical anxiety or an anxiety disorder (i.e. receive a total score of at
least 7 points on the Overall Anxiety Symptoms and Impairment Scale; OASIS, Norman, Cissell, Means-Christensen & Stein, 2006) and e) experience persistent pain and pain-related functional impairment (i.e. receive a total score of at least 30 points on six items selected from a 10-item version of the Örebro Musculoskeletal Pain Screening Questionnaire; ÖMPSQ, Linton, Nicholas & McDonald, 2011). Apart from not meeting the inclusion criteria, grounds for exclusion were: a) an ongoing or planned psychological treatment delivered by a psychologist or a psychotherapist, b) a planned surgery with expected impact on the participant’s mood or ability to follow through with the treatment, c) suicidality (i.e a score of 4 points or higher on the ninth item in the MADRS-S, or as assessed with the Mini International Neuropsychiatric Interview; MINI, Sheehan et al., 1997), d) severe depression (i.e. a total score of 35 points or higher on MADRS-S), e) ongoing alcohol or substance abuse (as assessed with the MINI), and f) ongoing psychosis (as assessed with the MINI).

**Recruitment.** See Figure 1 for an overview of the flow of participants in the study. Participants were recruited from three pain clinics and five primary care centers in different municipalities in central Sweden. A total of 600 letters with information (see Appendix 1) regarding the study were sent out to individuals who had completed MMR at the clinics/primary care centers within the past two years. Participants were also recruited via the Internet through an advertisement (see Appendix 2) at the official website of Örebro University. The advertisement was connected to Google Ads during two months. No reward was offered for taking part in the study.

After obtaining social security numbers by telephone, individuals interested in study participation were installed at a secure web treatment platform. Via self-rating questionnaires administered on the platform, the potential participants were screened for pain, depressive symptoms and anxiety. In connection with this, the potential participants also provided personal and demographic information as well as other information related to the selection
Figure 1

The flow of participants in the study

Information letters (n=600)/online advertisement

Declared interest (n=53) (Responded to letter [n=51], responded to advertisement [n=2])

Online screening (n=47)

Excluded (n=16) (Suicidality [n=3], Other treatment/surgery [n=4], No clinically relevant emotional problems [n=4], Technical reasons [n=2], No clinically relevant pain [n=1], No pain rehabilitation [n=2])

Screening with MINI (n=25)

Excluded (n=1) due to insufficient emotional problems

Block randomization (24)

Wait list group (n=12)

Treatment group (n=10) with repeated ratings

Treatment group without repeated ratings (n=2)

Began the treatment (n=10)

Dropped out after section 1 and did not provide informed consent (n=1)

Included in analyses of feasibility (n=9)

Dropped out before the fifth treatment section (n=4) (After section one =1, after section four =3)

Included in analyses of effectiveness (n=5)

Dropped out after section five (n=1) Did not complete the treatment in time (n=2)

Completed the treatment (n=2)

Included in analyses of acceptability
criteria. Individuals who did not meet selection criteria according to the online screening were excluded from the study. Excluded individuals received information about the reason for exclusion via telephone and were offered the treatment material. When the reasons for exclusion included severe depression and/or suicidality, excluded individuals were given recommendations via telephone regarding alternative treatment options. Participants who met selection criteria according to the online screening were interviewed by the authors using selected parts of the MINI (i.e. the parts regarding emotional disorders, bipolar disorders and psychotic disorders, as well as the parts regarding alcohol/substance abuse and suicidality if indicated), which is a semi-structured clinical interview designed to facilitate diagnosis of a range of common psychiatric disorders. Before the clinical interview began, the interviewees were informed about the practical demands implicit in study participation and inquired about their ability to meet those demands. Moreover, the interviewees were given the opportunity to receive information about the study. Individuals who met selection criteria based on the clinical interview were included in the study and randomized in blocks of four into either a treatment group or a wait list control group. The reason for the randomization procedure was the intended RCT design. Following the block randomization, participants were randomly assigned to one of four therapists, i.e. either one of the authors (undergoing the last year of training at the professional psychology program), a clinical psychologist or a psychologist/postgraduate student. Of the twelve participants randomly assigned to the treatment group, the first ten provided repeated baseline ratings of the dependent variables before beginning the treatment. The purpose of this was to enable a SCED if the number of participants would not amount to the number needed for an RCT. A couple of weeks into the recruitment process, the number of participants was indeed found to be insufficient for an RCT and the intended RCT design was dropped in favor of a SCED. This implies that the study is concerned solely with the participants who provided baseline data. Since one of the
ten participants who provided baseline data did not provide informed consent, only nine participants were included in analyses.

**Procedure**

The baseline consisted of two or three measurements of the dependent variables, i.e. pain, depressive symptoms, anxiety and anxiety-related avoidance. Since there was a substantial overlap between the measures used for screening and the outcome measures, the first of the baseline measurements was to a large extent carried out in connection with the screening procedure. However, since one of the outcome measures (Overall Depression Severity and Impairment Scale, ODSIS; Bentley, Gallagher, Carl & Barlow, 2014) was not used in the screening procedure, participants filled out this questionnaire separately. Consequently, due to logistic reasons, the first baseline measurement was divided into two occasions. In connection with the last baseline measurement, participants filled out self-rating questionnaires regarding anxiety sensitivity and social anxiety. Subsequently, the participants began the treatment. During the treatment, the dependent variables were measured each time a new treatment section was introduced, equaling nine times in total. All continuous measurements were separated by at least five days.

In connection with the fifth and the ninth treatment phase measurements, i.e. mid- and post-treatment, participants once again filled out self-rating questionnaires regarding anxiety sensitivity and social anxiety. Subsequently, participants filled out an evaluation form inquiring about their experience of the intervention. Moreover, they were once again interviewed with the MINI.

The treatment consisted of psychoeducational texts and instructions for exercises and was divided into ten sections with differing themes. The participants were instructed to work with each section over the course of one week. Exercises were carried out or registered on the web platform. The therapists visited the web platform daily in order to monitor the
participants’ activity. Following the completion of an exercise, participants received feedback from their therapist via the web platform. The main purpose of the feedback was to reinforce correct understanding and execution of the exercises. Thus, the feedback was to a large extent characterized by praise. Corrective feedback was given in cases where participants demonstrated pronounced difficulties with comprehension or execution of the exercises or when the participants asked for such feedback. In cases where participants had not been active on the platform for more than three consecutive days, they were e-mailed via the web platform and inquired about the reason for their inactivity. If participants did not respond to these e-mails, they were contacted via telephone. Therapists were able to receive supervision from a clinically active psychologist with extensive experience of Internet-delivered CBT.

**Measures**

All measures were used in Swedish versions.

**Screening and outcome measures.**

**Diagnostic status.** Diagnostic status was explored during the screening procedure and after treatment completion using the MINI (Sheehan et al., 1997). The MINI is a widely used, brief, clinician rated semi-structured interview designed to facilitate psychiatric diagnosis according to the DSM classification system. The MINI has demonstrated satisfactory convergent validity, test-retest reliability and inter-rater reliability, as well as adequate sensitivity and specificity. The version used in the current study was based on the fourth edition of the DSM, however, it was adapted by one of the therapists to match the fifth edition.

**Pain.** In the online screening, pain was measured using six items selected from a 10-item version of the ÖMPSQ (Linton et al., 2011). The ÖMPSQ aims to identify psychosocial risk factors for pain-related work disability and suboptimal recovery (Linton & Boersma, 2003). The 10-item version has demonstrated satisfactory convergent validity as well as
adequate sensitivity and specificity (Linton et al.) The six items that were used for screening purposes in the current study are formulated as questions or statements relating to the amount of pain experienced in the past week, pain-related functioning, emotional functioning and pain-related beliefs. Each item is rated on a scale ranging from 0 to 10. Thus, the total score ranges from 0 to 60. In the current study, a total score of 30 or higher was regarded as an indication of clinically relevant pain problems and was required for inclusion in the study. The cut-off of 30 was chosen in order to mirror the cut-off of 50 that is recommended when using the 10-item version.

In the repeated ratings, pain was measured using two of the six items that were used for screening purposes. One of the two items inquires about pain intensity and is formulated as follows: “How would you rate the pain that you have had during the past week?” Response alternatives range from 0 (No pain) to 10 (Pain as bad as it could be). The other item inquires about pain dysfunction and is formulated as follows: “I can do light work for an hour.” Response alternatives range from 0 (Can’t do it because of pain problem) to 10 (Can do it without pain being a problem). The two items were selected due to their concern with central features of persistent pain.

**Depressive symptoms.** In the online screening, the MADRS-S was used to measure depressive symptoms. The MADRS-S is a self-rating questionnaire intended to measure depressive symptoms in the past three days (Svanborg & Åsberg, 2001). It includes nine items listing different areas of psychological and physiological functioning commonly affected in MDD (e.g. mood, appetite and sleep). Each area is rated on a scale from 0 (e.g. My appetite has been much the same as usual) to 6 (e.g. I need persuading if I am to get anything down), where 0 indicates normal functioning within the area and 6 indicates maximal disturbance. The total score ranges from 0 to 54. With regard to interpretation, a total score of 0-12 points indicates no depression, 13-19 points indicate mild depression, 20-34 points indicate moderate
depression and 34 points or higher indicate severe depression (Carlbring, 2015). The MADRS-S has demonstrated satisfactory internal consistency (Bondolfi et al., 2010), convergent validity (Svanborg & Åsberg, 1994; Svanborg & Åsberg, 2001) and test-retest reliability, as well as adequate sensitivity and specificity (Fantino & Moore, 2009). The psychometric properties of the MADRS-S when administered online have been found to correspond with the psychometric properties of the paper-and-pencil version (Holländare, Askerlund, Nieminen & Engström, 2008).

In the repeated ratings used to evaluate treatment outcome, depressive symptoms were measured using the ODSIS. The ODSIS is a self-rating questionnaire consisting of five items intended to assess depressive symptoms and impairment due to depressive symptoms in the past week (Bentley et al., 2014). It was chosen as an outcome measure of depressive symptoms in favor of the MADRS-S since it is considerably shorter. The five items included in the ODSIS are formulated as questions (e.g. “In the past week, how often have you felt depressed?”), which are answered on a scale from 0 (No depression in the past week.) to 4 (Constant depression. Felt depressed all of the time.). The total score ranges from 0 to 20. Both the paper-and-pencil version and the online version of the ODSIS have demonstrated satisfactory internal consistency, convergent validity and discriminant validity, as well as adequate sensitivity and specificity (Bentley et al.; Ito, Bentley et al., 2015). Moreover, the online version has demonstrated satisfactory test-retest reliability.

**Anxiety:** In the online screening as well as in the repeated ratings, anxiety was measured using the OASIS. The OASIS is a self-rating questionnaire consisting of five items inquiring about the frequency and severity of anxiety in the past week as well as the level of anxiety-related avoidance and functional interference due to anxiety (Norman et al., 2006). The items are formulated as questions, e.g. "During the past week, how often did you experience anxiety?", which are answered on a scale from 0 (No anxiety in the past week.) to
4 (Constant anxiety. Felt anxious all of the time and never really relaxed.). The total score ranges from 0 to 20. A cut-off score of 8 correctly classified 87% of a sample in terms of having or not having an anxiety disorder (Campbell-Sills et al., 2009). On the basis of this finding, a total score of 7 was required for inclusion in the current study. The purpose of using a total score of 7 rather than 8 was to include participants with subclinical anxiety symptoms. The OASIS has demonstrated satisfactory internal consistency, convergent validity, discriminant validity and test-retest reliability (Campbell-Sills et al.; Norman et al.). Moreover, the OASIS has demonstrated adequate psychometric properties when administered online (Ito, Oe et al., 2015).

Social anxiety. In order to complement the primary instrument for measuring anxiety, i.e. the OASIS, social anxiety was measured using the social distress scale included in the Social Phobia Screening Questionnaire (SPSQ; Furmark et al., 1999). The SPSQ is a self-rating questionnaire designed to facilitate diagnosis of social phobia and phobic personality disorder according to the fourth version of the DSM. The social distress scale consists of a list of 14 potentially phobic situations (eg. “Speaking [or performing] in front of a group of people”). Each situation is rated on a scale from 0 to 4 depending on the amount of distress experienced in the situation (0 = no distress, 4 = severe distress). The total score ranges from 0 to 56 and is interpreted according to the following guidelines: 0-16 points = unlikely social phobia, 17-21 points = risk for social phobia, 21 points or higher = likely social phobia, 29 points or higher = likely generalized social phobia (Furmark, Holmström, Sparthan, Carlbring & Andersson, 2013). The SPSQ as a whole has demonstrated adequate convergent validity, sensitivity and specificity, and the social distress scale has demonstrated satisfactory internal consistency (Furmark et al., 1999).

Anxiety-related avoidance. Anxiety-related avoidance was measured using one item from the OASIS, formulated as follows: “In the past week, how often did you avoid
situations, places, objects, or activities because of anxiety or fear?”. Response alternatives range from 0 (Never) to 4 (All the time).

**Anxiety sensitivity.** The Anxiety Sensitivity Index (ASI; Reiss, Peterson, Gursky & McNally, 1986) is a self-report questionnaire intended to assess anxiety sensitivity. The items are formulated as statements (e.g. “It scares me when I feel shaky”), which are rated on a 5-point Likert scale ranging from 0 (Very little) to 4 (Very much). The 16-item version used in the current study has demonstrated satisfactory internal consistency, convergent validity and discriminant validity (Vujanovic, Arrindel, Bernstein, Norton & Zvolensky, 2007) as well as adequate test-retest reliability (Rodriguez, Bruce, Pagano, Spencer & Keller, 2004).

**Feasibility measures.**

**Completion.** Completion was evaluated by exploring the number of participants who a) completed the treatment within the time frame of the study, b) were still involved in the treatment at the end of the study and c) dropped out of the treatment.

**Compliance.** Compliance was evaluated by exploring a) the participants’ conformity to the time schedule of the treatment, b) the number of exercises completed/registered by the participants at least once on the web platform and c) the total number of exercise occasions.

**Acceptability measures.** Acceptability was explored using an evaluation form that was administered via the web platform following treatment completion. In the evaluation form, participants were asked to rate/describe their experiences in terms of a) overall satisfaction with the treatment, b) perceived helpfulness of the treatment, c) perceived adequacy of the treatment tempo, d) perceived negative consequences of the treatment and e) satisfaction with the Internet format. Moreover, participants were asked whether they would recommend the treatment to a friend.
The treatment

The treatment consisted of a guided Internet-delivered version of the UP. The content of the treatment was based on the content of the patient workbook (Barlow & Stalby, 2013) intended for use in face-to-face-treatment with the UP or as a stand-alone self-help manual (Unified Protocol Institute, 2014). Some modifications of the workbook material were made by the therapists in order to adapt the material to Internet delivery and increase the perceived relevance of the material to individuals with persistent pain. Modifications included shortenings of psychoeducational texts, addition of illustrative pain-related examples and addition of an exercise in pain exposure. Due to limitations of the web platform, modifications were also made in terms of layout. As mentioned above, the treatment was divided into ten sections with differing themes. Each chapter included psychoeducational texts amounting to 2-9 A4 pages (M=5) and exercise instructions. In total, the text content of the treatment amounted to 92 A4 pages. Participants were able to download and print most of the material. See Table 1 for an overview of the treatment content.

Table 1

*Overview of treatment content*

<table>
<thead>
<tr>
<th>Treatment section</th>
<th>Theme</th>
<th>Psychoeducation</th>
<th>Exercises</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Motivation and goals</td>
<td>• Motivation</td>
<td>• Problem formulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Goals</td>
<td>• Listing arguments and counter-arguments for change/status quo</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Goal setting</td>
</tr>
<tr>
<td>2</td>
<td>Understanding emotions</td>
<td>• The nature and function of emotions</td>
<td>• Identifying characteristics of different emotions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Components of emotional experiences</td>
<td>• Distinguishing components of emotional experiences</td>
</tr>
<tr>
<td>3</td>
<td>Mapping emotional experiences in</td>
<td>• Antecedents of emotional experiences</td>
<td>• Mapping antecedents, emotional experiences and consequences</td>
</tr>
<tr>
<td></td>
<td>their context</td>
<td>• Operational learning</td>
<td></td>
</tr>
</tbody>
</table>


THE UP FOR PAIN AND EMOTIONAL PROBLEMS

4 Observing emotional experiences non-judgmentally

- Judgmental reactions to emotional experiences
- Non-judgmental awareness of emotional experiences in the present
- Identifying judgmental reactions to emotional experiences
- Practicing non-judgmental awareness of emotional experiences
- Using a cue for non-judgmental awareness of emotional experiences in the present
- Using music to evoke emotional experiences and practicing non-judgmental awareness of the emotional experiences

5 Understanding thoughts

- Appraisals and meaning making
- Common cognitive errors: probability over-estimation and catastrophizing
- The importance of cognitive flexibility
- Identifying core beliefs ("downward arrow technique")
- Counteracting overestimation of probability using socratic questioning
- Counteracting catastrophizing using socratic questioning

6 Emotional avoidance

- The nature and consequences of emotional avoidance
- Identifying emotional avoidance
- Exploring and reflecting on thought suppression ("the white bear experiment")

7 Emotion-driven behaviors

- The nature and consequences of emotion-driven behaviors
- Identifying emotion-driven behaviors
- Identifying the purpose and consequences of emotion-driven behaviors
- Identifying unhelpful emotion-driven behaviors and identifying alternative behaviors
- Testing alternative behaviors and evaluating their consequences

8 Understanding physical sensations

- The relationship between physical sensations and emotions
- Exposure to physical sensations

9 Emotional exposure

- Rationale for emotional exposure
- Creating a hierarchy for emotional exposure
- Emotional exposure

10 Maintaining gains and planning for the future

- Repetition of treatment principles
- Setbacks
- Evaluating progress
- Formulation of new goals
- Planning for continued progress

Ethical considerations

The study was approved by the Regional Ethical Board in Uppsala (registration number 2013:349). In accordance with conventional research ethics, a number of arrangements were made in order to minimize the risk for psychological or physiological damage due to study participation. To begin with, potential participants were informed about a) the purpose of the study, b) the implications of study participation, c) the voluntary nature
of participation and the possibility to terminate participation at any time without having to provide a reason for termination, d) the confidential nature of participant data and the practical implications of confidentiality and e) the utilization of participant data for research purposes. Moreover, all participants included in analyses provided informed consent (see Appendix 3) and were able to terminate their participation at any time. Participants who terminated their participation prematurely were inquired about the reason for termination in a gentle and non-compelling manner. Participant data were handled with confidentiality. In order to strengthen confidentiality, therapists and participants communicated primarily via the web platform or by telephone. Participant data were used only for research purposes.

The fact that the treatment in the current study was delivered through the Internet implied that the therapists’ ability to detect, evaluate and monitor potential suicidality was somewhat limited. Thus, individuals who demonstrated severe depression or suicidality during the screening were excluded from the study. These individuals received recommendations regarding other treatment options and were offered the treatment material.

According to Vetenskapsrådet (2002), the threat to participants’ personal integrity inevitably inherent in research should be balanced by the benefits of the research. The latter is dependent on the ability to draw reliable conclusions on basis of the research. When conducting an RCT, the ability to draw such conclusions is largely influenced by the number of participants. Specifically, if the number of participants is too low, conclusions are characterized by uncertainty. In such situations, conducting an RCT jeopardizes the balance between the risks inherent in the research and the benefits of the research. In order to avoid such an ethical problem in the current study, the study was conducted as a SCED instead of an RCT.
Analyses

**Visual inspection.** The primary method for analyzing treatment outcome was visual inspection, as is standard practice when conducting a SCED (Kazdin, 2011). To begin with, repeated ratings of pain intensity, pain dysfunction, anxiety, depressive symptoms and anxiety-related avoidance were displayed as graphs. Subsequently, the graphs were evaluated in terms of a) slope, i.e. the general direction in which the data is changing, b) change in level, i.e. the difference between the last baseline data point and the first treatment phase data point, c) latency of change, i.e. the time passed between the introduction of the intervention and changes in the dependent variables, d) change in mean, i.e. the difference between the average rating during the baseline phase and the average rating during the treatment phase and e) variability, i.e. the amount of fluctuation in the data.

**Percentage of data points exceeding the median of the baseline phase.** In cases where the visual inspection suggested a treatment effect (either in the expected direction or in the direction opposite of the expected), the percentage of data points exceeding the median of baseline phase (PEM; Ma, 2006) method was used to explore the magnitude of the effect. Thus, to begin with, the central measure (mean, median and mode) of the baseline was calculated and the central measure that provided the most accurate description of the baseline data was selected. Subsequently, the percentage of treatment phase data points below (in cases where the effect was in the expected direction) or above (in cases where the effect was in the direction opposite of the expected) the selected baseline measure was calculated. With regard to interpretation, the criteria formulated by Scruggs, Mastropieri, Cook and Escobar (as cited in Ma, 2006) were used. According to these guidelines, a PEM of 90-100% indicates a strong effect, a PEM of 70-90% indicates a moderate effect and a PEM of 70% or below indicates a questionable or absent effect.
**Change in diagnostic status.** To further explore whether the participants emotional problems changed in a clinically meaningful way due to the treatment, pre-treatment diagnostic status as assessed with the MINI was compared with post-treatment diagnostic status as assessed with the MINI.

**Reliable Change Index.** In order to evaluate the statistical significance of changes in anxiety sensitivity, the Reliable Change Index (RC, Jacobson and Truax, 1991) was calculated. This was done by comparing pre-treatment ASI scores with post-treatment or mid-treatment scores (in cases where post-treatment scores were not available), while controlling for the natural variability in ASI scores as well as the error inherent in the measure. In order to perform the calculation, the standard deviation and test–retest reliability for the ASI were obtained from a previous study (Rodriguez et al., 2004). In order for a change to be reliable, the RC should exceed 1.96 (p<.05; Jacobson & Truax, 1991).

**Percental changes.** In order to explore treatment effects on social anxiety, the difference between pre-treatment and mid- or post-treatment SPSQ scores were calculated for each participant and expressed as a percentage. Mid-treatment scores were used in cases where post-treatment scores were not available.

**Comparisons with cut-offs and clinical/non-clinical sample means.** In order to complement the RC analyses, ASI scores were compared to clinical and non-clinical sample means obtained in previous studies (Reiss et al., 1986; Rodriguez et al., 2004). The clinical sample mean originated from a sample consisting of 145 individuals diagnosed with at least one anxiety disorder. Moreover, in order to complement the analysis of percental changes, SPSQ scores were compared to the cut-offs recommended by Furmark et al. (2013). The purpose of these procedures was to explore the clinical relevance of changes.
Results

Individualized sample description

An individualized description of the sample is presented in Table 2.

Treatment feasibility

Of the nine participants who began the treatment, two completed the treatment within the time frame of the study and two were still involved in the treatment at the end of the study. Of the remaining five participants, four dropped out before completing the mid-treatment measurement and one dropped out immediately following the mid-treatment measurement. Reasons provided for dropping out included a) finding the treatment unhelpful due to the focus on emotions rather than on pain (n=1), b) deterioration due to the treatment (n=1), and c) stressful external circumstances (n=2). One of the participants who dropped out did not provide a reason for doing so.

The five participants who completed the mid-treatment measurement were included in analyses of treatment compliance and effectiveness, whereas the other four participants were excluded from such analyses. The average age and pain duration did not appear to differ in a meaningful way between the group included in analyses and the group excluded from analyses. This was also true for working status, number of pain areas and medication. However, there appeared to be a difference between the groups in terms of education level and diagnostic status at screening. Specifically, the four participants who were excluded from analyses appeared to be less educated than the other five participants and more frequently met criteria for a psychiatric diagnosis at screening.

Feasibility data for participant 1 to 5 are presented in Table 3. As can be seen in the table, three of the participants (participant 1, 2 and 5) demonstrated relatively high conformity
### Table 2

**Individualized description of the sample**

<table>
<thead>
<tr>
<th>Participant</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>60-70</td>
<td>60-70</td>
<td>40-50</td>
<td>40-50</td>
<td>50-60</td>
<td>50-60</td>
<td>60-70</td>
<td>50-60</td>
<td>60-70</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>Female</td>
<td>Female</td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
<td>Female</td>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Pain localisation</td>
<td>Head, neck, shoulders, upper back and arms</td>
<td>Legs and head</td>
<td>Neck, shoulders, upper and lower back, arms, hands, legs</td>
<td>Neck, shoulders, upper and lower back, arms, hands, legs, feet</td>
<td>Neck, shoulders, upper and lower back, arms, hands, legs, feet, head</td>
<td>Neck, shoulders, upper and lower back, arms, hands, legs, feet</td>
<td>Neck, shoulders, upper and lower back, arms, hands, legs, feet</td>
<td>Lower back, legs, feet</td>
<td>Head</td>
</tr>
<tr>
<td>Pain dur.</td>
<td>8 years</td>
<td>9 years</td>
<td>8 years</td>
<td>9 years</td>
<td>8 years</td>
<td>4 years</td>
<td>25 years</td>
<td>3 years</td>
<td>6 years</td>
</tr>
<tr>
<td>Education</td>
<td>Post-secondary</td>
<td>Post-secondary</td>
<td>Secondary</td>
<td>Primary</td>
<td>Post-secondary</td>
<td>Secondary</td>
<td>Secondary</td>
<td>Primary</td>
<td>Primary</td>
</tr>
<tr>
<td>Occupation</td>
<td>Working 50%</td>
<td>Working</td>
<td>On sick leave</td>
<td>Unemployed</td>
<td>Unemployed</td>
<td>Working 50%</td>
<td>Retired</td>
<td>Retired</td>
<td>Retired</td>
</tr>
<tr>
<td>Diagnosis at screening (MINI)</td>
<td>None</td>
<td>None</td>
<td>MDD, SAD (generalized), GAD</td>
<td>None</td>
<td>Agoraphobia</td>
<td>SAD (public speaking situations)</td>
<td>MDD</td>
<td>MDD</td>
<td>SAD</td>
</tr>
</tbody>
</table>

**Note.** Anti-dep. = Anti-depressant; GAD = Generalized anxiety disorder; MADRS = Montgomery Åsberg Depression Rating Scale – Self rating version; MINI: Mini International Neuropsychiatric Interview; MDD = Major depressive disorder; OASIS = Overall Anxiety Severity and Impairment scale; Guidelines for interpretation of MADRS scores: 0-12 = no depression, 13-19 = mild depression, 20-34 = moderate depression, 34 and higher = severe depression. OASIS cut-off: 8.
to the time schedule (completion of one treatment section per week). With regard to exercise completion, all five participants demonstrated high or acceptable compliance. This was also true for the number of exercise occasions.

Table 3

Completion and compliance

<table>
<thead>
<tr>
<th>Participant</th>
<th>Completed treatment sections</th>
<th>Time spent on the treatment</th>
<th>Number of exercises completed at least once</th>
<th>Total number of exercise occasions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-10</td>
<td>10 weeks and 5 days</td>
<td>29 of 35 possible exercises</td>
<td>77</td>
</tr>
<tr>
<td>2</td>
<td>1-10</td>
<td>11 weeks and 4 days</td>
<td>35 of 35 possible exercises</td>
<td>62</td>
</tr>
<tr>
<td>3</td>
<td>1-8</td>
<td>11 weeks and 3 days</td>
<td>22 of 29 possible exercises</td>
<td>35</td>
</tr>
<tr>
<td>4</td>
<td>1-4</td>
<td>9 weeks and 4 days</td>
<td>9 of 12 possible exercises</td>
<td>13</td>
</tr>
<tr>
<td>5</td>
<td>1-6</td>
<td>7 weeks and 2 days</td>
<td>19 of 19 possible exercises</td>
<td>40</td>
</tr>
</tbody>
</table>

Treatment effectiveness

Pain. In Figure 2, the participants’ repeated ratings of pain intensity and pain dysfunction are graphically displayed. The figure also shows changes in mean and the results of PEM analyses (in cases where such analyses where conducted). If not otherwise stated, the PEM represents the percentage of treatment phase data points below the baseline mean. As can be seen in the figure, only two baseline ratings were available for participant 1, 2 and 3. Moreover, treatment phase data were incomplete for participant 3, 4 and 5.

With regard to pain intensity, the repeated ratings for participant 2, 3 and 4 clearly indicated that the treatment was ineffective. For participant 1, treatment phase ratings demonstrated a slight declining slope. However, ratings fluctuated considerably across the treatment phase and the change in mean from the baseline to the treatment phase was negligible. Thus, taken together, the visual inspection did not reveal any treatment effect on pain intensity for this participant. For participant 5, treatment phase ratings initially demonstrated a clear declining slope. However, this slope was reversed in the middle of the treatment phase. Taken together, the data did not suggest any treatment effect. To summarize,
the visual inspection of the participants’ repeated ratings did not reveal any treatment effect on pain intensity for any of the participants.

In terms of pain dysfunction, the repeated ratings for participant 2 and 3 clearly indicated that the treatment was ineffective. In terms of participant 1, the data pattern closely resembled the data pattern for pain intensity. A slight declining trend could be observed during the treatment phase, but the variability in ratings was large and the change in mean was negligible. Taken together, the repeated ratings did not suggest any treatment effect on pain dysfunction. With regard to participant 4, a declining slope could be observed during the treatment phase. However, the change in mean was small and the limited number of treatment phase data points makes it difficult to determine whether the decrease constituted an effect of the treatment or a consequence of natural variation. Moreover, the PEM did not point to any improvement. Taken together, the data did not suggest any treatment effect on pain dysfunction for this participant. In terms of participant 5, the baseline data demonstrated a clear ascending slope. This slope was reversed when the treatment was introduced, where after ratings decreased substantially and remained relatively low. However, the negligible change in mean, the great variability in the data and the PEM value spoke against a treatment effect. Taken together, the data did not suggest any improvement. To summarize, the analyses of the participants’ repeated ratings did not reveal any treatment effect on pain dysfunction for any of the participants.

**Participant 1**

![Graph showing pain intensity and pain dysfunction changes over time](image)

<table>
<thead>
<tr>
<th>Measurement occasion</th>
<th>Pain intensity</th>
<th>Pain dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment phase</td>
<td>+0.28</td>
<td>+0.33</td>
</tr>
</tbody>
</table>

**Change in mean**
- Intensity: +0.28
- Dysfunction: +0.33
### Participant 2

<table>
<thead>
<tr>
<th>Measurement occasion</th>
<th>Pain intensity</th>
<th>Pain dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Treatment phase</td>
<td>7.5</td>
<td>3.5</td>
</tr>
</tbody>
</table>

**Change in mean**
- Intensity: +1.56
- Dysfunction: +0.17

### Participant 3

<table>
<thead>
<tr>
<th>Measurement occasion</th>
<th>Pain intensity</th>
<th>Pain dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>5.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Treatment phase</td>
<td>4.5</td>
<td>2.5</td>
</tr>
</tbody>
</table>

**Change in mean**
- Intensity: -0.21
- Dysfunction: +1.86

### Participant 4

<table>
<thead>
<tr>
<th>Measurement occasion</th>
<th>Pain intensity</th>
<th>Pain dysfunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>8.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Treatment phase</td>
<td>6.5</td>
<td>2.5</td>
</tr>
</tbody>
</table>

**Change in mean**
- Intensity: -0.67
- Dysfunction: -0.35

**PEM**
- Dysfunction: 50%
Participant 5

Figure 2

Repeated ratings of pain intensity and pain dysfunction

Emotional problems.

Results based on repeated ratings. In Figure 3, the participants’ repeated ratings of depressive symptoms and anxiety are graphically displayed. The figure also shows changes in mean and the results of PEM analyses (in cases where such analyses were conducted). If not otherwise stated, the PEM represents the percentage of treatment phase data points below the baseline mean. Treatment phase data were incomplete for participant 3, 4 and 5.

With regard to depressive symptoms, the repeated ratings for participant 2 and 4 clearly indicated that the treatment was ineffective. For participant 5, the repeated ratings clearly pointed to an improvement in depressive symptoms due to the treatment. The PEM suggested that the improvement represented a moderate effect. In terms of participant 1, the repeated ratings clearly indicated an iatrogenic effect of the treatment, i.e. an increase in depressive symptoms. According to the PEM, the increase represented a moderate effect. For participant 3, there was a steep increase in depressive symptoms in connection with the fifth treatment phase rating, where after ratings remained high until the last treatment phase measurement. This pattern of data indicated a deterioration in depressive symptoms. The PEM suggested that the deterioration represented a moderate effect. Importantly, the deterioration coincided with a serious negative health notice, which according to the
participant had detrimental effects on her mood. To summarize, the analyses of the participants’ repeated ratings of depressive symptoms revealed that the treatment was effective for one of the participants. Of the remaining four participants, two neither improved nor deteriorated and two deteriorated.

With regard to anxiety, the repeated ratings for participant 4 clearly indicated an absent treatment effect. For participant 2, there was a decelerating slope in the first half of the treatment phase. However, ratings subsequently increased and neither the change in mean nor the PEM indicated any effect of the treatment. Taken together, the data suggested that the treatment initially had a positive effect, but that this effect was interrupted towards the end of the treatment. According to the participant, the interruption coincided with certain stressful circumstances. Specifically, due to an exercise in interoceptive exposure included in the eighth treatment section, the participant experienced marked and long-lasting increases in pain and nausea as well as sleep difficulties. Moreover, in parallel, the participant experienced an increase in work-related stressors and received a negative health-related notice. In terms of participant 5, the baseline data demonstrated an ascending slope, which was interrupted when the treatment was introduced. This pattern pointed to a potential improvement, however, the change in mean was negligible and the PEM did not indicate any treatment effect. Taken together, the data did not suggest any improvement. For participant 1 and 5, the repeated ratings of anxiety closely mirrored the repeated ratings of depressive symptoms. Thus, in terms of participant 1, the repeated ratings clearly suggested an iatrogenic effect of the treatment, i.e. an increase in anxiety. The PEM indicated that the increase represented a moderate effect. For participant 3, there was a steep increase in anxiety in connection with the fifth treatment phase rating, where after ratings remained high until the last treatment phase measurement. This pattern of data suggested a deterioration in anxiety. According to the PEM, the deterioration represented a moderate effect. To summarize, the analyses of the
participants’ repeated ratings of anxiety revealed that three of the participants neither improved nor deteriorated and the remaining two deteriorated.

**Participant 1**

![Graph showing depression and anxiety levels for Participant 1.](image)

**Note.** = Percentage of treatment phase data points above the baseline mean.

**Participant 2**

![Graph showing depression and anxiety levels for Participant 2.](image)

**Participant 3**

![Graph showing depression and anxiety levels for Participant 3.](image)
Note. $^1$ = Percentage of treatment phase data points above the baseline mean.

**Participant 4**

![Graph showing depression and anxiety levels for Participant 4]

**Participant 5**

![Graph showing depression and anxiety levels for Participant 5]

**Figure 3**

*Repeated ratings of depression and anxiety*

*Results based on pre-, mid- and post-treatment measurements.*

*Diagnostic status.* For the two participants who completed the treatment, i.e. participant 1 and 2, diagnostic status was assessed before and after the treatment using the MINI. According to these assessments, neither of the participants met criteria for any psychiatric disorder preceding or following the treatment.

*Social anxiety.* In Table 4, participants’ pre- and mid- or post-treatment SPSQ scores are displayed, together with the clinical indication for each score and the percental change.
from pre- to mid- or post-treatment scores. Mid-treatment scores are presented instead of post-treatment scores in cases where post-treatment scores were unavailable. For one of the participants, both mid- and post-treatment scores were unavailable. As can be seen in the table, neither of the participants demonstrated any clinically meaningful changes in social anxiety.

Table 4

*SPSQ* scores, clinical interpretations and percental changes

<table>
<thead>
<tr>
<th>Participant</th>
<th>Pre-treatment total score</th>
<th>Clinical interpretation(^1)</th>
<th>Post- or mid-treatment total score</th>
<th>Clinical interpretation(^1)</th>
<th>Percental change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 p</td>
<td>Unlikely SP</td>
<td>16 p (PT)</td>
<td>Unlikely SP</td>
<td>60%</td>
</tr>
<tr>
<td>2</td>
<td>6 p</td>
<td>Unlikely SP</td>
<td>5 p (PT)</td>
<td>Unlikely SP</td>
<td>-17%</td>
</tr>
<tr>
<td>3</td>
<td>38 p</td>
<td>Likely generalized SP</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>10 p</td>
<td>Unlikely SP</td>
<td>5 p (MT)</td>
<td>Unlikely SP</td>
<td>-50%</td>
</tr>
<tr>
<td>5</td>
<td>24 p</td>
<td>Likely SP</td>
<td>25 p (MT)</td>
<td>Likely SP</td>
<td>4%</td>
</tr>
</tbody>
</table>

Note. \(^1\) = According to cut-offs suggested by Furmark et al. (2013). MT = Mid-treatment; PT = Post-treatment; SP = Social phobia; SPSQ = Social Phobia Screening Questionnaire.

**Anxiety-related avoidance.** In Figure 4, the participants’ repeated ratings of anxiety-related avoidance are graphically displayed. The figure also shows changes in mean and the results of PEM analyses (in cases where such analyses were conducted). Treatment phase data were incomplete for participant 3, 4 and 5.

For participant 2, 4 and 5, there was a clear absence of change in anxiety-related avoidance. With regard to participant 1 and participant 3, the repeated ratings suggested increases in anxiety-related avoidance due to the treatment. According to the PEM, the increases represented moderate effects. As with the increases in anxiety and depressive symptoms for participant 3, the increase in anxiety-related avoidance for participant 3 coincided with a negative health notice. To summarize, three of the participants did not
demonstrate any changes in anxiety-related avoidance and the remaining two demonstrated increases in anxiety-related avoidance.

**Participant 1**

![Graph showing anxiety-related avoidance for Participant 1]

**Change in mean** = +0.89

**PEM** = 89%

*Note.* ¹ = Percentage of treatment phase data points above the baseline mean.

**Participant 2**

![Graph showing anxiety-related avoidance for Participant 2]

**Change in mean** = -0.11

**Participant 3**

![Graph showing anxiety-related avoidance for Participant 3]

**Change in mean** = +0.99

**PEM** = 86%

*Note.* ¹ = Percentage of treatment phase data points above the baseline mean.

**Participant 4**

![Graph showing anxiety-related avoidance for Participant 4]

**Change in mean** = 0
Participant 5

Figure 4

Repeated ratings of anxiety-related avoidance

Anxiety sensitivity. In table 5, participants’ pre- and mid- or post-treatment ASI scores are displayed. Mid-treatment scores are presented instead of post-treatment scores in cases where post-treatment scores were unavailable. For each score, the table shows whether it is closest to a non-clinical or a clinical sample mean. The table also displays the results of RC analyses, based on the difference between the pre-treatment and the mid- or post-treatment scores. For four of the participants, the pre-treatment ASI scores were closer to a non-clinical sample mean than a clinical sample mean. In other words, the majority of the participants did not demonstrate clinically relevant anxiety sensitivity preceding the treatment. Post- and mid-treatment scores demonstrated the same pattern. The RC analyses did not suggest any significant changes in anxiety sensitivity due to the treatment.

Table 5

Anxiety sensitivity scores and RC

<table>
<thead>
<tr>
<th>Participant</th>
<th>Pre-treatment score</th>
<th>Closest mean (non-clinical/clinical)</th>
<th>Post- or mid-treatment score</th>
<th>Closest mean (non-clinical/clinical)</th>
<th>RC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>Non-clinical</td>
<td>16 (PT)</td>
<td>Non-clinical</td>
<td>.47 (NS)</td>
</tr>
<tr>
<td>2</td>
<td>23</td>
<td>Non-clinical</td>
<td>27 (PT)</td>
<td>Non-clinical</td>
<td>.47 (NS)</td>
</tr>
<tr>
<td>3</td>
<td>37</td>
<td>Clinical</td>
<td>32 (MT)</td>
<td>Clinical</td>
<td>-.82 (NS)</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>Non-clinical</td>
<td>3 (MT)</td>
<td>Non-clinical</td>
<td>-.71 (NS)</td>
</tr>
<tr>
<td>5</td>
<td>23</td>
<td>Non-clinical</td>
<td>22 (MT)</td>
<td>Non-clinical</td>
<td>-.12 (NS)</td>
</tr>
</tbody>
</table>

Note. 1=20.5, SD = 10.2 (Reiss, et al., 1986); 2=42.45, SD = 11.37 (Rodriguez et al., 2004). MT=Mid-treatment; NS = Non-significant; PT=Post-treatment; RC = Reliable Change Index relating to change between
pre-treatment scores and post- or mid-treatment scores.

**Treatment acceptability**

Acceptability data were provided solely by participant 1 and 2, who completed the treatment within the time frame of the study and filled out the evaluation form. In the evaluation form, both participant 1 and 2 reported being “mainly satisfied” with the treatment overall and stated that the treatment was helpful “to some extent”. Moreover, both participants answered “maybe” to the question if they would recommend the treatment to a friend and stated that they were satisfied with the duration of the treatment as well as the Internet format. Participant 2 did not report any negative consequences of the treatment. However, participant 1 reported that he experienced negative consequences in connection with the interoceptive exposure. Specifically, some of the exercises in interoceptive exposure triggered panic attacks, long-lasting nausea and long-lasting increases in pain. This significantly affected the well-being of the participant.

**Discussion**

The purpose of the current study was to evaluate a guided Internet-delivered version of the UP as a secondary intervention for former pain rehabilitation patients with residual pain problems and co-morbid emotional disorders/problems. Specifically, the study sought to evaluate the intervention in terms of a) feasibility, b) effectiveness in reducing pain intensity, pain dysfunction, depression, anxiety, anxiety-related avoidance and anxiety sensitivity and c) acceptability. For the five participants who completed the fifth treatment phase measurement, feasibility in terms of compliance was found to be adequate. However, only two of the participants in the study completed the intervention within the time frame of the study. Thus, the overall feasibility of the treatment was deemed low. With regard to effectiveness, neither of the participants experienced any improvements in pain intensity, pain dysfunction, anxiety, anxiety-related avoidance or anxiety sensitivity and only one demonstrated improvements in
depressive symptoms. Thus, overall, the treatment was found to be ineffective. Treatment acceptability was found to be reasonable based on data from the two participants who completed the treatment.

Discussion of results

Feasibility. The attrition rate in the current study (60%) was high in comparison to the attrition rate reported in previous studies concerning the UP (15% in the RCT by Farchione et al., 2012 and 11% in the SCED by Lopez et al., 2014). This was partly expected due to the fact that previous studies have evaluated the UP in a face-to-face-format, and the attrition rate in Internet-delivered interventions tend to be higher than the attrition rate in face-to face interventions (van Ballegooijen et al., 2014). Moreover, the treatment evaluated in the current study possessed several characteristics that have been put forward as explanations for non-adherence to Internet-delivered interventions (see Johansson, Michel, Andersson & Paxling, 2015). More specifically, the treatment had an extensive text content, requiring considerable investments from the participants in terms of time and energy and was delivered according to a fixed time schedule, putting pressure on the participants to proceed in a certain tempo. Furthermore, the information about the treatment given to participants before the study was limited. Thus, it is possible that some of the participants dropped out due to the fact that the content and demands of the treatment were poorly matched to their expectations. Finally, the treatment did not involve any face-to-face-contact (thus not allowing for the support, motivation and focus associated with such contact) and was demanding in terms of concentration-, reading- and writing skills. The suggestion that high demands in terms of reading- and writing skills may have contributed to the high attrition rate is in line with the finding that the four participants who terminated the treatment before the fifth treatment section appeared to be less educated than the remaining five participants.
Importantly, the attrition rate in the current study was high also in comparison with similar studies evaluating Internet-delivered interventions, eg. the previously mentioned studies by Buhrman and colleagues (2013; 2015), which evaluated the effectiveness of Internet-delivered CBT in the treatment of individuals with persistent pain and co-morbid emotional disorders either as a primary or secondary intervention. The attrition rates in these studies were 28% and 18%. The higher attrition rate in the current study may be due to a number of factors. To begin with, the sample in the current study was considerably smaller than the treatment groups in the studies by Buhrman and colleagues (which consisted of 28 and 32 individuals, respectively). This implies the sample in the current study was more likely to be unrepresentative of the population in question. Moreover, in contrast to the intervention evaluated in the first study by Buhrman and colleagues (2013), which targeted individuals who had completed MMR, the content of the intervention in the current study rarely touch explicitly upon pain. As a consequence, the face validity of the intervention in the current study in terms of treating pain problems may have been suboptimal. Indeed, for at least one of the participants who dropped out of the intervention, lacking face validity for the treatment of pain was the reason provided for dropping out. In addition, unlike the intervention evaluated by Buhrman and colleagues, the intervention in the current study was not designed to be consistent with MMR. Thus, it is possible that the participants in the current study were required to make a larger effort in order to appreciate the treatment principles compared with the participants in the study by Buhrman and colleagues.

In the latter study by Buhrman and colleagues (2015), a large part of the treatment content was individualized based on information from screening interviews and baseline questionnaires. The absence of such systematic individualization in the current study may be one reason for the discrepancy in attrition rates. Moreover, in the study by Buhrman and colleagues, all participants received technical assistance by telephone at one occasion, and
were at the same time given the opportunity to ask questions about the treatment. In the current study, such support was given only when it was explicitly asked for or obviously needed.

A final explanation for the higher attrition rate in the current study in comparison with the studies by Buhrman and colleagues may be that the UP possesses certain characteristics that make it more intellectually demanding than other CBT interventions. To begin with, due to the transdiagnostic nature of the UP, the treatment material has a generic format and thus requires a substantial effort from the patients in terms of relating the material to their own problems. Moreover, the theoretical principles taught in the UP may be more difficult to grasp than the principles taught in CBT in general. For example, the UP not only emphasizes the importance of emotional reactions and their different components, but also highlights the importance of reactions to emotional reactions (i.e. secondary reactions). The finding that three participants dropped out in connection with the fourth treatment section, in which secondary reactions consisted a central theme, is in line with the suggestion that the intellectually demanding nature of the treatment may have contributed to the high attrition rate. The degree of treatment complexity may be a particularly relevant issue for individuals with persistent pain and co-morbid emotional problems, since persistent pain has been found to be associated with impairments in attention, mental flexibility, information processing speed and memory (Melkumova, Podchufarova, & Yakhno, 2011) and emotional problems frequently include concentration problems (APA, 2013).

**Effectiveness.** The nearly complete absence of positive treatment effects on emotional problems was surprising given the previously reviewed empirical support for the effectiveness of the UP in reducing depressive symptoms and anxiety. However, in previous studies, the UP has been delivered as a face-to-face-treatment and the treatment duration has been considerably longer (see eg. Farchione et al., 2012). Thus, the absence of positive treatment
effects in the current study may have been a consequence of insufficient therapist guidance and insufficient treatment duration. More specifically, due to limited guidance, it is possible that participants did not completely understand the treatment material, did not apply the treatment techniques the way they were intended to and/or did not manage to tailor the techniques to their needs (e.g. failed to identify relevant targets for exposure). In terms of treatment duration, the fact that the participants were required to begin with a new treatment section every week might have impeded the participants’ ability to digest the treatment material and consolidate new skills. The limited treatment duration may be particularly problematic given that the treatment sections concerning exposure, which are considered the most effective parts of the treatment (Barlow, 2013), were among the last treatment sections.

A further potentially relevant difference between the current study and previous studies of the UP has to do with sample characteristics. In previous studies of the UP, samples have generally consisted of individuals diagnosed with multiple psychiatric disorders (see e.g. Farchione et al., 2012). This is in contrast to the current study, in which three of the five participants included in analyses of treatment effectiveness did not meet criteria for any psychiatric disorder according to clinician ratings and only one participant met criteria for multiple disorders. Since individuals with low subjective distress may have difficulties becoming engaged in actively working to change behavior (Groth-Marnat, 2009), the inclusion of individuals without psychiatric disorders in the current study may have contributed to the lack of positive treatment effects on depressive symptoms and anxiety.

The ineffectiveness of the treatment in the current study was also surprising against the backdrop of previous studies demonstrating the effectiveness of Internet-delivered CBT in the treatment of persistent pain and/or emotional problems, eg. the studies by Buhrman and colleagues (2013; 2015). As with the discrepancies between the current study and the studies by Buhrman and colleagues with regard to attrition, the discrepancies in treatment
effectiveness might be attributed to a) the presumably low face validity of the UP for the treatment of persistent pain, b) the potential inconsistency between the UP and the MMR, c) the absence of systematic telephone support in the current study and d) the complex nature of the treatment content in the UP. Moreover, it should be kept in mind that the first study by Buhrman and colleagues did not explore the number of individuals who demonstrated clinically significant changes in pain, depressive symptoms and anxiety. Thus, comparisons between the results obtained in the first study by Buhrman and colleagues and the results obtained in the current study should be made cautiously.

Apart from the lack of positive treatment effects, a further puzzling finding in the current study was that two of the participants (participant 1 and 3) deteriorated during the treatment. Both of these participants reported increases in anxiety, depressive symptoms and anxiety-related avoidance. For participant 3, the deterioration was likely caused by a serious negative health notice, which coincided with the deterioration and (according to the participant) had detrimental effects on her mood. However, in terms of participant 1, the deterioration was likely caused by the treatment. According to Rozental, Boettcher, Andersson, Schmidt and Carlbring (2015) increases in anxiety and depression as a sequel of Internet-delivered treatments are not uncommon and may result from the participants’ increased awareness of their difficulties and the factors underlying them. Moreover, increases in anxiety and depression may occur as a consequence of challenges and complications related to the execution of exercises, due to which the participants may doubt their ability to follow through with the treatment and/or overcome their difficulties.

Another puzzling finding was that one of the participants (participant 4) reported very low levels of emotional problems during the baseline phase, and no emotional problems at all during the treatment phase. This participant was included in the study on basis of her MADRS-S screening score, which suggested that she experienced mild depression. However,
close scrutiny of the participant’s responses revealed that the items generating scores were the ones inquiring about symptoms known to be a common sequel of persistent pain, eg. sleep difficulties and concentration problems. Thus, a possible explanation for the participant’s low ratings of emotional problems during the study may be that the participant did not experience any emotional problems before the study.

Acceptability. The fact that the two participants who filled out the evaluation form (participant 1 and 2) reported that they were mainly satisfied with the treatment and stated that the treatment was helpful to some extent was somewhat surprising given that one of the participants deteriorated during the treatment and the other did not improve. The relatively positive ratings may be taken to indicate that even though their symptoms were not reduced by the treatment, the treatment may have had positive effects in terms of increased awareness/knowledge and/or enhanced skills. The result is in line with previous research demonstrating that the relationship between treatment effectiveness and treatment satisfaction is not clear-cut (see Lebow, 1982, for a review). Specifically, previous research has shown that positive ratings of treatment satisfaction may occur both in the presence and absence of established positive treatment effects.

With regard to negative consequences of the treatment, both participant 1 and participant 2 reported that they experienced aversive somatic symptoms and marked increases in anxiety due to the exercises in interoceptive exposure (although only participant 1 reported this in the evaluation form). While increased anxiety is an expected effect of interoceptive exposure, the somatic symptoms reported by the participants (long-lasting increases in pain, long-lasting nausea and sleep difficulties) are not. However, both of the participants reported that they suffered from medical conditions that could explain the iatrogenic effects.

Correspondence with theoretical assumptions. Based on the fear-avoidance model and the shared vulnerability model, i.e. the theoretical basis for the current study, individuals
with persistent pain and emotional disorders can be predicted to demonstrate high levels of anxiety sensitivity and anxiety-related avoidance. Thus, the finding that only one of the five participants included in analyses of anxiety sensitivity and anxiety-related avoidance demonstrated clinical levels of anxiety sensitivity and reported frequent anxiety-related avoidance pre-treatment was largely unexpected. Possibly, the low levels of anxiety sensitivity and anxiety-related avoidance among the participants may be explained by the fact that the majority of the participants (3 of 5) did not meet criteria for any emotional disorder according to clinician ratings. In other words, the fear-avoidance model and the shared vulnerability model might not be applicable to individuals with persistent pain that do not meet criteria for co-morbid emotional disorders (but rather suffer from subclinical emotional problems). If so, this may undermine the rationale (as put forward in the current study) for the utilization of the UP in the treatment of such individuals.

The theoretical basis for the current study also included the assumptions that anxiety sensitivity and anxiety-related avoidance contribute to the maintenance of persistent pain and co-morbid emotional disorders and that consequently, pain problems and emotional problems may be reduced by reducing anxiety sensitivity and anxiety-related avoidance. Since the treatment in the current study was not found to lead to any improvements neither in pain and emotional problems (with one exception) nor in anxiety sensitivity and anxiety-related avoidance, these assumptions were neither supported nor contradicted. However, the fact that all but one of the participants did not improve on any of the variables and the finding that the two participants who demonstrated deteriorations in anxiety and depression also demonstrated increases in anxiety-related avoidance is consistent with the assumptions.

**Weaknesses and limitations**

The current study possesses a number of weaknesses that limit the reliability of conclusions regarding treatment effectiveness. An obvious such weakness is that only two of
the five participants included in analyses of treatment effectiveness completed the treatment. The fact that the remaining three participants either terminated the treatment prematurely or did not manage to complete the treatment within the time frame of the study might have had a considerable impact on the treatment outcome for these participants, since the latter treatment sections (as mentioned above) are considered the most important. Consequently, conclusions regarding treatment effectiveness for these participants are highly tentative.

Another shortcoming of the study that undermines the reliability of conclusions regarding treatment effectiveness is the limited duration of the baseline phases, which increases the risk for type I- as well as type II-errors. Particularly problematic are the cases where the baseline data were limited to only two ratings, since at least three data points are required to establish dependent measure stability (Kazdin, 2011). Moreover, the sparsity of post-treatment data implies that the study had no possibility of determining the sustainability of treatment effects (positive or negative) or detecting delayed treatment effects. The occurrence of delayed treatment effects would be quite expected given the importance of the latter treatment sections. The last ratings of depressive symptoms and anxiety for participant 1 hinted at a delayed effect, however, the sparsity of post-treatment data implied that this could not be explored further.

Further characteristics of the current study that limit the reliability of conclusions regarding treatment effect include a) the utilization of self-constructed measures (i.e. single items selected from existing questionnaires) whose psychometric properties are unknown, b) the absence of repeated ratings of anxiety sensitivity and social anxiety, c) the general nature of the primary instrument for measuring anxiety (the OASIS), which implies that changes in one particular type of anxiety may have been masked by changes in another type of anxiety and d) the inclusion of participants on basis of self-ratings with the MADRS-S, which may
have resulted in the inclusion of at least one participant without clinically relevant emotional problems.

The current study also possesses a couple of weaknesses that impede generalization of conclusions across individuals. These include the small sample size and the fact that no detailed information was obtained with regard to the content of the MMR undergone by the participants. The latter is problematic since the content of the MMR may have impacted considerably on treatment feasibility, effectiveness and acceptability (eg. through the presence/absence and nature of psychological interventions). In order to facilitate generalization of conclusions, more information about the content of MMR and a discussion of the impact of variations in MMR content would have been beneficial.

Finally, the fact that neither of the therapists in the current study were experienced in the UP and only one was experienced in Internet-delivered CBT constitutes a weakness of the study since it implies a threat to the construct validity of the treatment.

Strengths

Despite the weaknesses mentioned above, the study also possesses a number of strengths. These include the utilization of well-researched self-rating questionnaires (i.e. the OASIS, the ODSIS, the SPSQ and the ASI) as outcome measures and the online administration of all self-rating questionnaires, which may have reduced social desirability. Moreover, the utilization of the MINI as an outcome measure implies that the study did not rely entirely on self-report in the evaluation of treatment effectiveness. Thus, the potential impact of confounding variables related to self-report (eg. suboptimal self-insight) was somewhat reduced. Further strengths of the study include the utilization of the PEM method as a complement to the visual inspections, the utilization of RC analyses in order to evaluate changes in anxiety sensitivity, the utilization of clinical/non-clinical sample means in order to supplement the RC analyses and the utilization of recommended cut-offs in order to
complement the analyses of percental changes. All of these procedures enhance the reliability of conclusions regarding treatment effectiveness and facilitate evaluation of clinical significance. Moreover, the separation of pain problems into pain intensity and pain dysfunction can be considered a strength of the study, since pain intensity and pain dysfunction are not always closely related (Linton, 2013) and looking at them separately may reduce the risk for type II errors. Lastly, a final strength of the study was the formulation of explicit guidelines for therapist feedback and the utilization of continuous treatment conferences where therapist strategies were discussed. These arrangements may have reduced therapist-generated variability in treatment outcomes.

**Future research**

Further research is needed in order to determine the feasibility, effectiveness and acceptability of the UP delivered through the Internet in the treatment of former MMR patients with residual pain problems and co-morbid emotional problems. The current study may constitute a take-off point for such research. Specifically, in order to enhance the feasibility, effectiveness and acceptability of the treatment, the current study points to the need for future studies to consider a) shortening and simplifying the psychoeducational texts, b) prolonging the treatment and/or offering a more flexible time schedule, c) increasing therapist support, eg. by adding weekly phone calls focused on discussion/planning of homework assignments, d) providing participants with a clear rationale for the utilization of an emotion-focused intervention in the treatment of persistent pain and emotional problems, e) complementing the treatment material with further examples related to persistent pain, f) providing extensive information during the recruitment procedure concerning the nature and demands of the treatment and making efforts to ensure that participants’ expectations match reality, g) individualizing the treatment, eg. by framing material as eligible rather than mandatory, h) solely including participants diagnosed with psychiatric disorders based on
clinician ratings, and i) complementing the psychoeducational text about interoceptive exposure with a recommendation to avoid exercises in interoceptive exposure that may be inappropriate due to medical conditions.

Given the early stage of research regarding the UP delivered through the Internet in the population in question, future studies on the subject may well employ a SCED rather than an RCT design. In contrast to the current study, future SCED studies may consider utilizing considerably longer baselines and, if possible, await baseline stability before introducing the treatment. Moreover, also in contrast to the current study, future studies may benefit from a) using a multiple baseline design, i.e. using baselines of different length, b) collecting post-treatment data in the form of continued repeated ratings following treatment, c) using complete, validated questionnaires (rather than selected items) for measuring pain and anxiety-related avoidance, d) using clinician ratings instead of self-report questionnaires in order to evaluate whether inclusion criteria in terms of depressive symptoms are met, e) measuring all dependent variables weekly and f) obtaining detailed information with regard to the content of the MMR undergone by participants. Finally, larger samples are recommended in order to reduce the negative impact of attrition on the internal and external validity of the studies. Given that the recruitment procedure in the current study resulted in an unexpectedly small sample, alternative recruitment strategies should be considered.
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THE UP FOR PAIN AND EMOTIONAL PROBLEMS


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Stark-studien
Smärtpatienter Tränar Alternativa Reaktioner på Känsloupplevelser

Vägledd självhjälpsbehandling via internet för människor med långvarig smärta och samtidiga känslomässiga svårigheter


För att delta i studien krävs att du:
- är över 18
- kan läsa och skriva svenska obehindrat
- är medicinskt utredd
- har genomgått ett rehabiliteringsprogram
- känner dig ångestfyld eller nedstämd
- har tillgång till internet
- ej har en planerad operation som kan hindra medverkande
- ej har en pågående utredning som kan hindra medverkande


Deltagandet är frivilligt och du kan när som helst avbryta ditt deltagande utan närmare motivering. Din relation till den smärtklinik eller vårdcentral du tillhör, kommer inte att påverkas på något sätt.
All information vi erhåller behandlas konfidentiellt och du som enskild deltagare kommer inte att kunna identifieras i resultaten.

Om Du önskar får du en sammanställning av studiens resultat.

**Sekretess och tystnadsplikt**


Data som samlas in t ex svar från frågeformulär kommer att avidentifieras och behandlas konfidentiellt. Deltagarna kommer inte att kunna identifieras.

Personuppgiftsansvarig är Landstinget i Uppsala län. Enligt personuppgiftslagen 26§ (PuL) har Du rätt att gratis en gång per år få ta del av de uppgifter om Dig som hanteras och vid behov få eventuella fel rättade. En skriftlig undertecknad ansökan ställs till kontaktperson Dr Torsten Gordh, Smärtcentrum, Akademiska Sjukhuset, 751 85 Uppsala.

För ytterligare upplysningar kontakta först Matilda Wurm som är kontaktperson för projektet.

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Appendix 2: Online advertisement

HAR DU KVARSTÅENDE PROBLEM EFTER EN SMÄRTBEHANDLING?

Har du känsломässiga svårigheter som exempelvis depression eller ångest?
Är sociala sammanhang eller andra situationer ångestframkallande?

Då kanske detta är något för dig!


Låter det intressant?

Hör av dig snarast till stark-studie@oru.se så får du mer information. Vi ser fram emot ditt mail!

STARK-studie: Smärtpatienter Tränar Alternativa Reaktioner på Känslo upplevelser

Matilda Wurm, psykolog, doktorand
Monica Buhman, fil Dr, leg. psykolog, leg. psykoterapeut
Maria Tillfors, Professor, leg. psykolog
Appendix 3: Form for informed consent

Samtycke för deltagande i STARK-studien

Jag har muntligen och skriftligt informerats om studien ”Smärtpatienter Tränar Alternativa Reaktioner på Känsloupplevelser (STARK)” samt har fått tillfälle att ställa frågor.

Genom att underteckna denna blankett samtycker jag till:

- Att delta i studien frivilligt att jag när som helst kan avbryta deltagande utan att lämna närmare förklaring. Deltagandet påverkar inte ev. fortsatt behandling på någon av klinikerna.

- Att data samlas in för att lagras och bearbetas samt publiceras på ett aidentifierat vis. Sekretess kommer att tillämpas och min identitet kommer inte identifieras.

- Att personuppgifter behandlas i enlighet med beskrivningen i forskningspersoninformationen.

Jag kommer att få en sammanställning av resultatet om jag önskar.

____________________________________  ______________________________________
Deltagares underskrift                     Datum

_____________________________________
Deltagares namnförtydligande

_____________________________________
Forskningsledares underskrift