



# ACT WITH PAIN

Measurement, efficacy and mechanisms  
of Acceptance & Commitment Therapy

Hester Trompetter



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MEASUREMENT, EFFICACY AND MECHANISMS OF  
ACCEPTANCE & COMMITMENT THERAPY

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# ACT WITH PAIN

## MEASUREMENT, EFFICACY AND MECHANISMS OF ACCEPTANCE & COMMITMENT THERAPY

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# CHAPTER 1

General Introduction

*Anja is 46 years old and lives together with her husband and 14-year old daughter. Anja suffered from pain complaints for a long time. It started in her left hand, the hand coloured, was warm and sweaty at one moment and then very cold the next. Later the complaints started in her right leg. The diagnosis for her symptoms is Complex Regional Pain Syndrome (CPRS). In popular language this syndrome is often called 'post traumatic dystrophy'. It took a long time before a diagnosis could be given and this negatively impacted on her. Over the years she received multiple forms of treatment: physiotherapy, occupational therapy, TENS, nerve blocks, medication. The pain lasted. She regularly suffers from intense and unbearable pain flares. Anja can hardly walk and since two years uses a wheelchair.*

*Anja felt extremely distraught and doubted herself. Especially when her daughter was young, she tried to ignore the pain and pretended nothing was wrong. She grew more tired and was able to do less and less. She tried to find paid work, but was turned away at job applications. She doesn't look for paid work anymore. Anja also felt less inclined to leave home and see other people. She kept trying to control the pain and ignored her complaints for as long as possible. Whenever the pain flared, she withdrew herself. She didn't want her family to feel burdened by her pain. Slowly she became exhausted and depressed. Anja decided she couldn't continue like this and sought professional help in a rehabilitation centre.*

Case 'Anja' (modified version). Veehof, M. M., Schreurs, K. M. G., Hulsbergen, M., & Bohlmeijer, E. T. (2010). *Leven met pijn. De kunst van het aanvaarden [Living with Pain. The art of acceptance]* Boom: Amsterdam.

My interview with Anja took place at a very early stage of my PhD. At the time, I had little actual knowledge about chronic pain and its debilitating consequences for the quality of life of people suffering from it. Her story made a deep impression. Unfortunately, Anja's case is not unique. Approximately 1 in 5 adults worldwide report some degree of chronic pain - loosely defined as prolonged pain of more than three months in duration that persists the time of healing - which in the Netherlands alone equals more than 2.2 million individuals (Bekkering et al., 2011; Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Gureje, Von Korff, Simon, & Gater, 1998). This is more than the combined number of Dutch residents suffering from highly prevalent chronic diseases such as diabetes, chronic heart diseases and cancer (Gommer & Poos, 2013).

Those suffering from chronic pain often report impaired functioning in physical, emotional and social life domains. For example, the prevalence of mental disorders such as anxiety and depression among pain sufferers is as high as 25% and 40%, respectively (Haggman, Maher, & Kathryn, 2004; Miller & Cano, 2009). Additionally, a large proportion

of pain patients experiences impairments in performing household chores, sleeping, attending social activities, maintaining healthy relationships with family and friends, exercising, and maintaining an independent lifestyle (Breivik et al., 2006; Smith, Perlis, Smith, Giles, & Carmody, 2000). Not only pain sufferers and their significant others are affected. Also society experiences a burden through large direct costs generated by doctors' visits and other forms of health care use, and mainly, through much larger indirect costs generated by factors such as lost productivity and work absenteeism (Gaskin & Richard, 2012; Lambeek et al., 2011). More than 60% of chronic pain patients reports to be less able or unable to work outside home, and 19% lost their job due to chronic pain disabilities (Breivik et al., 2006). In the Netherlands alone the total costs of chronic low back pain in 2007 were estimated at 3.5 billion Euro's, which equals 0.6% of the gross national product (Lambeek et al., 2011).

It is clear that chronic pain conditions negatively impact individuals and society. Scientists have therefore increased their efforts to better understand the etiology and assessment of chronic pain, and increase the availability of treatment options (Turk, Wilson, & Cahana, 2011). The focus of this dissertation is on a specific subset of available interventions for chronic pain, namely psychological and multidisciplinary rehabilitative interventions. More specifically, this dissertation focuses on one of the most recently developed psychological frameworks that underlie these interventions in treating chronic pain, namely Acceptance & Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 1999, 2012). This introductory chapter will shortly outline the neurophysiology of pain and the importance of psychological factors in the understanding and treatment of chronic pain. Hereafter, the theoretical and clinical underpinnings of the framework underlying ACT will be discussed in the context of chronic pain. Finally, following an overview of challenges and venues for future progress, an outline of the studies bundled in this thesis will be given. These span the range from improving assessment procedures of therapeutic processes within ACT, to testing the efficacy of ACT and the implementation of ACT in Dutch multidisciplinary chronic pain rehabilitation.

## **NEUROPHYSIOLOGY OF PAIN**

During the 19<sup>th</sup> and 20<sup>th</sup> century, theoretical approaches towards pain followed a unidimensional perspective that viewed pain as a purely biomedical process (Flor & Turk, 2011). Pain severity and pain symptoms were thought to be one-on-one related to the underlying pathology in the body. Based on a dualistic perspective, it was hypothesized that pain functioned independently and separately from processes of the mind. On the one hand, it was assumed that localizing and curing underlying organic pathology would directly lead to recovery. On the other hand, when such localizable and curable tissue

damage was absent, it was simply inferred that pain was a physical expression of underlying psychopathology.

From the 1960's, neuroscientific study has revealed a much more complex picture of the neurophysiology of pain (e.g. Melzack & Wall, 1965; Melzack, 2001). The gate control theory (Melzack & Wall, 1965) was the first neurophysiological model to shift focus from peripheral to central bodily processes and integrate psychological aspects of pain. The model suggested that bottom-up sensory input forms only a fraction of an individuals' pain response output. While sensory pain input travels from peripheral nerve endings through the spinal cord towards the thalamus and (sub)cortical areas of the brain, top-down information dynamically modulates pain input prior to conscious awareness. This information includes, for example, information originating from brain areas responsible for the integration of affective, emotional and motivational information. Although not all premises of the gate control theory have withstood scientific development, also contemporary neurophysiological models acknowledge that the human brain is not just a passive receiver of peripheral information (Jensen & Turk, 2014). As an example, the neuromatrix theory of pain (Melzack, 2001; Melzack, 2005) proposes that pain is the product of a 'neurosignature' that stems from repeated cyclical processes and synthesis of nerve impulses from a widely distributed brain neural network. The neurosignature is a pattern of output that evolves from the integration of sensory-discriminative, cognitive-evaluative and motivational-affective information. As pointed out by Gatchel and colleagues (2007), central to the neuromatrix theory is the acknowledgement that pain evolves from the output of a multidimensional, widely distributed brain neural network rather than being a direct response towards peripheral sensory information.

Several pathophysiological mechanisms have been identified that are involved in chronic pain states (Flor & Turk, 2011). A basic mechanism to play a role in chronic pain is sensitization, an increase in the physical response to pain after repeatedly presenting a pain stimulus. In the case of prolonged pain, sensitization can evolve to such an extent that pain becomes present even in the absence of an actual pain stimulus or the original cause of acute pain. An increased sensitivity towards pain is one example of the cascade of events at both peripheral and central levels of the body characteristic for chronic pain. Other events include muscular and autonomic system responses, and plastic alterations to brain structures that influence pain perception (Apkarian, Hashmi, & Baliki, 2011; Flor & Turk, 2011). The bodily deregulations and neural, autonomic and central responses involved in prolonged pain have been proposed to resemble the homeostatic imbalance and complex system activations involved in chronic stress (McBeth et al., 2005; Melzack, 2005).

## THE ROLE OF PSYCHOLOGY IN UNDERSTANDING AND TREATING CHRONIC PAIN

### Psychological factors in chronic pain

To fully understand the complexities of chronic pain it is important to differentiate between nociception and pain (Loeser, 1982). While nociception refers to the physiological activation of sensory transmission of stimulus information through the nerves, pain perception refers to the modulated outcome of neurophysiological processes and requires conscious awareness of an individual. As discussed earlier, neurophysiological models of pain incorporate both these dimensions and reveal that psychological factors interact with pain nociception prior to pain perception at both lower- and higher-order levels of the body. In his classical model of pain (Figure 1), Loeser (1982) recognized two additional dimensions in which cognitions and emotions play an even larger role.

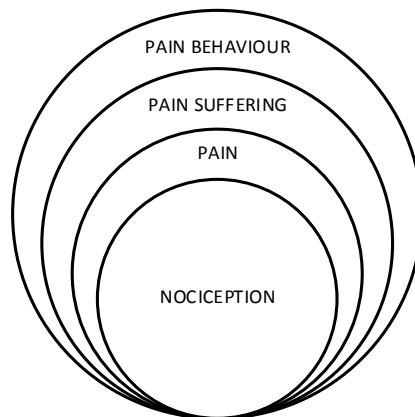


Figure 1. Loeser's model of pain. Loeser, J. D. (1982). Concepts of pain. In J. Stanton-Hicks & R. Boaz (Eds.), *Chronic low back pain* (pp. 109–142). New York: Raven Press.

Pain suffering involves the emotional reactions to nociception and pain perception, such as feelings of anxiety, depression or helplessness, and any other feelings that pertain to the meaning that is attached to the pain by the individual. The fourth dimension, pain behavior, involves all behavior associated with pain that is visible to people around the person suffering from pain. Examples of pain behavior are communication patterns about pain, or the avoidance of fear-related activities. Note that this often-used figure is misleading to some extent, as in reality consecutive dimensions not necessarily need to fully close in previous dimensions. As is acknowledged in the now widely accepted 'biopsychosocial view' of chronic pain, all four dimensions of pain have to be taken into

account to be able to fully grasp and successfully treat an individual suffering from chronic pain (Gatchel et al., 2007; Turk, Meichenbaum, & Genest, 1983).

The centrality of psychological factors in understanding chronic pain has fueled a large body of research. Over the last decades, a variety of motivational, psychosocial and contextual traits and mechanisms were identified that function as either vulnerability or resilience factors in chronic pain (for reviews, see Gatchel et al., 2007; Keefe, Rumble, Scipio, Giordano, & Perri, 2004; Sturgeon & Zautra, 2010; Turk & Okifuji, 2002). Among others, these traits and mechanisms include emotions such as anxiety, depression and positive affect, cognitive factors such as pain catastrophizing, perceived pain control, self-efficacy and pain acceptance, social factors such as experienced social support, social expectations and previous treatment experiences, an individuals' learning history, and resilience factors such as optimism and hope. The International Association of the Study of Pain (IASP) recognizes the emotionality and subjectivity of pain in defining pain as 'an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage' (IASP, 1986). Another relevant aspect of this definition is the acknowledgement that organic pathology does not necessarily underlie pain, as is the case with individuals suffering from medically unexplained physical symptoms (Burton, 2003).

### **Psychological frameworks for understanding chronic pain**

Several cognitive behavioural frameworks have been developed that underlie existing cognitive behavioural interventions for chronic pain. These models incorporate classical and operant learning principles to explain the process of pain chronification. Two primary frameworks are the Fear Avoidance model of chronic pain (Crombez, Eccleston, Damme, Vlaeyen, & Karoly, 2012; Leeuw et al., 2007; Vlaeyen & Linton, 2000), and the Avoidance Endurance model of chronic pain (Hasenbring & Verbunt, 2010; Hasenbring et al., 2012; Hasenbring, 1993). The Fear Avoidance model of chronic pain focuses on the beliefs and cognitions of pain patients, and the role of these beliefs in promoting fear and subsequent behavioural avoidance. According to the model, pain sufferers respond towards pain on a cognitive level with ruminative and exaggerated, negative thoughts. These cognitions lead to fear of movement and reinjury, which in turn, fuel the avoidance of pain-related activities. The model adequately explains the behaviour of a subgroup pain patients who enter an impairing and vicious circle of catastrophizing, fear, behavioural avoidance and inactivity (Crombez et al., 2012). A wide range of evidence for the model has been reported, and successful treatment strategies, such as graded exposure, have been developed based on the model (Boersma et al., 2004; Keefe et al., 2004; Leeuw et al., 2007, 2008; Pincus, Smeets, Simmonds, & Sullivan, 2010).

The Avoidance Endurance model of chronic pain extends the number of response patterns towards pain beyond the fear avoidance response pattern accounted for by the

Fear Avoidance model. For example, pain sufferers engaging in a distress endurance response pattern react to pain with thought suppression, anxiety/depression and task persistence in spite of pain, while the eustress endurance response pattern accounts for those pain sufferers who react by ignoring either the pain itself or by minimizing the meaning they pertain to the pain, accompanied by task persistent behaviour and possible feelings of elevated positive mood despite pain (Hasenbring & Verbunt, 2010). An adaptive response pattern would be characterized by a high flexibility in the use of different response patterns over time in different situations. As in the Fear Avoidance model, it is assumed that people responding towards pain with rigid response patterns enter a vicious, negative learning cycle that in the long-term leads to more impairment and interference of pain in daily life. Although investigated to a much lesser extent than the Fear Avoidance model, the Avoidance Endurance model fits well with clinicians' experiences, and evidence for the model has been found in subacute low back pain patients (Hasenbring et al., 2012). Both models are combined in Figure 2.

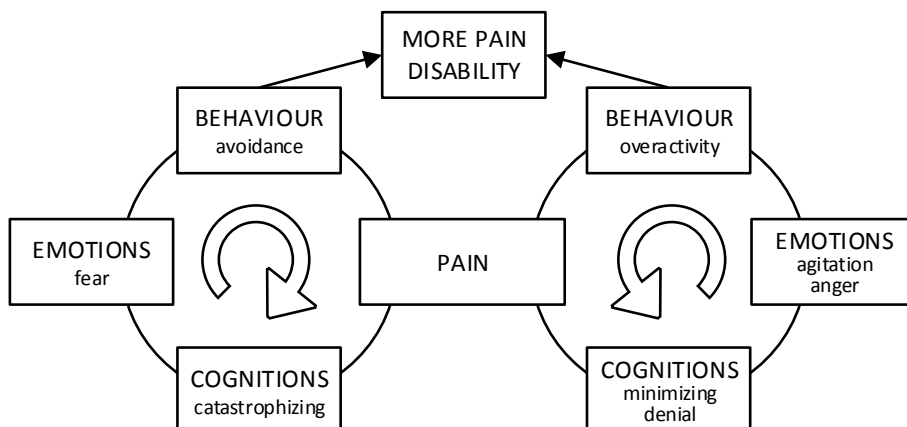


Figure 2. Fear Avoidance model and Avoidance Endurance model combined. Schreurs, K. M. G. (2013). *Chronische pijn en toch vitaal. Een uitdaging voor de patient en de gezondheidszorg [Vital despite chronic pain. A challenge to the patient and health care]*. Enschede: University of Twente. Based on Hasenbring & Verbunt, 2010; Vlaeyen & Linton, 2000.

## CHRONIC PAIN TREATMENT

Scientists have worked hard not only to increase our understanding of chronic pain, but also to increase the availability of effective and efficient treatment options. Momentary available treatment modalities include pharmacological approaches, invasive interventional treatments such as surgery or the use of implantable devices, and physical approaches such as exercise therapy (Turk et al., 2011). Although our understanding of chronic pain continues to improve, it appears that available biomedical treatments for



chronic pain are not improving at the same rate. Unfortunately, momentary existing biomedical modalities such as pharmacology or surgery are unable to completely resolve, remove or relieve pain symptoms. Concretely, this means that the prospect for many pain sufferers is that they will have to continue to live with at least some level of chronic pain (Turk et al., 2011).

As chronic pain is a very complex problem that is not easily managed with medical treatments alone, psychological and multidisciplinary rehabilitation programs are central treatment modalities for chronic pain. Instead of a focus on pain removal, the therapeutic focus of such treatment is on improvement of functioning and reducing pain interference in physical, psychological, occupational and social life domains. In multidisciplinary treatment, different health-care providers (e.g. physicians, physiotherapists, psychologists, social workers and occupational therapists) bundle their services within a comprehensive rehabilitation program (Gatchel, McGeary, McGeary, & Lippe, 2014). All team members share continuous communication about their patients, actively involve patients in the rehabilitation program, and, most importantly, share a common philosophy and theoretical framework of rehabilitation. Cognitive behavioural therapy (CBT) is the prevailing framework underlying both psychological and multidisciplinary treatment programs (Ehde, Dillworth, & Turner, 2014; Vlaeyen & Morley, 2005). The aims of CBT are to increase patient functioning, and reduce psychological distress and pain intensity by identifying and challenging maladaptive pain-related cognitions, beliefs and behaviour and replace them with more adaptive ones. By doing so, care providers hope to increase patient coping with pain and related experiences. Techniques that are used during CBT-based programs include relaxation training, cognitive restructuring, problem-solving training, and the systematic increase of exercise, activities and adaptive behaviour using to step by step goal setting (Turner & Romano, 2001; Winter, 2000). Psychological and multidisciplinary rehabilitative treatment programs are in general moderately effective in increasing physical and psychosocial patient functioning. These effect sizes are similar to effects of more biomedical-oriented interventions (Hoffman, Papas, Chatkoff, & Kerns, 2007; Scascighini, Toma, Dober-Spielmann, & Sprott, 2008; Turk et al., 2011; Williams, Eccleston, & Morley, 2013).

### **ACCEPTANCE & COMMITMENT THERAPY (ACT)**

A reasonably new form of CBT that fits very well to the complex challenges imposed to psychological and multidisciplinary chronic pain treatment is Acceptance & Commitment Therapy (ACT) (Hayes et al., 1999, 2012). The clinical application of ACT is based on Relational Frame Theory (RFT) (Hayes, Barnes-Holmes, & Roche, 2001). Below, I will elaborate on the theoretical and clinical underpinnings of ACT and sketch the relevance of

ACT in the context of chronic pain, after which I will discuss the current evidence-base for ACT.

### **Relational Frame Theory**

RFT is a theory of human language and cognition that offers an explanation of how we humans influence each other and ourselves through language. By doing so, RFT also inherently explains the negative side effects of the power of thinking that are evident in many forms of psychopathology. Philosophically, RFT is based on functional contextualism, a philosophy of science that contains two essential elements. The first is that human behaviour should always be understood within the context, or setting, in which it occurs. Furthermore, behaviour should be understood pragmatically by evaluating the endpoint towards which the behaviour is aimed. An impressive body of evidence derived from bottom-up experimental studies underlies RFT. This body of evidence, as is a highly accessible reading of RFT and its clinical application that has been used to shortly outline the essence of RFT below, is summarized by Törneke (2010).

For long time, among other paradigms, psychologists have used the paradigm of operant conditioning to understand human behaviour. In operant conditioning, it is acknowledged that an antecedent (A) functions as a stimulus that precedes behaviour (B), which in turn is followed by a consequence (C). Here, the specific content of the latter serves as a reinforcer for (B) whenever (A) occurs again. Giving a simple example, eight-year old John will know not to play with his food during dinner as he has received punishment from his father for doing so before. Despite the fact that the ABC-paradigm is highly essential in understanding human behaviour and learning, researchers have been troubled to use this paradigm successfully in understanding the complexities of human language, especially our ability to arbitrarily relate stimuli to each other that do not co-occur directly in time and space. RFT explains this ability that has been named relational framing, or more technically, arbitrarily applicable relational responding. The essence of relational framing can be understood through an explanation of three relevant phenomena, being (combinatorial) mutual entailment, transformation of stimulus functions and rule-governed behaviour.

The first phenomenon, (combinatorial) mutual entailment, entails that, when we directly learn that (#) = (&) and (&) = (@), we automatically and implicitly derive that (&) = (#) and (@) = (&), which is called mutual entailment. Furthermore and most crucially, we derive that (#) = (@) and (@) = (#). This is called combinatorial entailment. The implicit derivation of stimulus relations can involve much more than three stimuli, and it can also involve multiple types of relation. Examples of these relations are opposition (is not), comparison (larger than), and causal (if-then), temporal (then-now), or perspective (I-you) relations. The phenomenon of combinatorial mutual entailment shows that we are able to indirectly relate large groups of stimuli to each other in many different ways. This is

especially so as the relations between stimuli are not controlled by direct or formal relationships, but by contextual cues that are independent of these stimulus relations. Hence, we are able to indirectly, randomly and implicitly relate all sorts of stimuli to each other, which can include random gestures, pictures, words, feelings, etc. A related and equally important phenomenon that is involved in this relation framing and further expands our ability to arbitrarily relate is transformation of stimulus functions through derived relations. This phenomenon entails that the function a stimulus has attained can be transferred indirectly to other stimuli in the same framework. Taking the example above, let us assume that (#) gained a respondent function by eliciting pain each time when presenting (#). Through the derivation of stimulus relations described above, the respondent function of pain becomes implicitly transferred to (&) and (@). As a consequence, even without direct learning individuals will anticipate pain prior to presenting the previously neutral stimuli (&) and (@). Despite the fact that the above is just a rudimentary explanation of these two phenomena, it is easy to recapitulate that we are able to create complex, and especially, uncontrollable, mental networks of relations (relational frames) between all sorts of stimuli. In other words, RFT simply shows that humans are able to relate anything to about everything else verbally.

Derived relational responding has two important effects, being the ability to take perspective and verbally discriminate yourself from other people, and the formation of rule-governed behaviour. In rule-governed behaviour, we create rules for others and ourselves that function as antecedents of behaviour (A). These rules, which take place in our relational frames, already contain arbitrarily specified behaviour (B) and consequences (C), and take the form of 'I mustn't show my pain to my partner (B), for he/she will leave me (C).' Although the consequences might never be experienced when actually performing the behaviour, we act to the verbal rules specified as if they were true. Rule-governed behaviour - as all verbal behaviour - can make us highly flexible and exponentially increases our ability to learn and create. Nevertheless, rule-governed behaviour can have highly negative consequences for the individual. This is especially so when rule-governed behaviour is used to unsuccessfully control, avoid or change unwanted experiences such as pain and pain-related thoughts and feelings. The latter phenomenon is what is called experiential avoidance in ACT. Although the avoidance of pain experiences can be rewarding in the short term, in the long term previously helpful attempts to control or eliminate the pain experience can instigate a vicious cycle of unfruitful and narrowing behaviour patterns. As rules are not learned by the principles of operant conditioning, but via the phenomena explained above, an important consequence for therapeutic intervention is the recognition that these rules are very difficult to change or unlearn through direct learning. The therapeutic model of ACT incorporates all knowledge derived from RFT, and targets six therapeutic processes to overcome

experiential avoidance.

### **Psychological flexibility model**

Based on RFT, Steven Hayes and co-founders developed the therapeutic model of ACT (Hayes, 2004; Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Hayes et al., 1999, 2012). As other forms of CBT, ACT focuses primarily on cognitive processes and emotional experiences (McCracken & Vowles, 2014). Due to its roots in functional contextualism ACT adopts a pragmatic approach, which means that experiences are always analysed in the context of successfully reaching goals. Whether or not these experiences actually correspond with reality, as is a central premise in more traditional CBT, is not the primary matter of analysis.

The overarching goal of ACT in chronic pain is to attain psychological flexibility, the capacity to act effectively in accordance with intrinsically motivating values and goals in the presence of pain and associated cognitions and emotions. In doing so, ACT applies mindfulness and acceptance processes, combined with values identification and behaviour change processes. Experiential exercises and the use of metaphors are important modalities in therapy, which is done to sidetrack the governing and sometimes overpowering role of verbal behavior. The six interrelated therapeutic processes that underlie psychological flexibility are represented in the hexaflex model (Figure 3). Each of the processes will be outlined below (Hayes et al., 2012).

- 1) Acceptance is offered as an alternative to experiential avoidance. In the context of pain, pain sufferers are encouraged to let go of unfruitful struggles with pain, and instead, are encouraged to take an open and aware stance towards the pain. Acceptance is not a goal in itself. Rather, it is promoted to refrain from putting energy and effort in unsuccessful attempts at controlling the pain, and redirect this energy and effort towards the engagement in values-based living.
- 2) Of all six processes, cognitive defusion is most directly derived from RFT. Technically, this process encourages pain sufferers to alter the function of undesirable pain-related thoughts, feelings and other experiences rather than trying exhaustively to change their content or their frequency. Concretely, this means that individuals are encouraged through multiple exercises to take perspective towards cognitive processes that do not stem from direct contextual experience, and de-literalize the meaning of pain-related thoughts without necessarily changing their content. This is done in order to reduce personal attachment to, or believability of, these experiences.

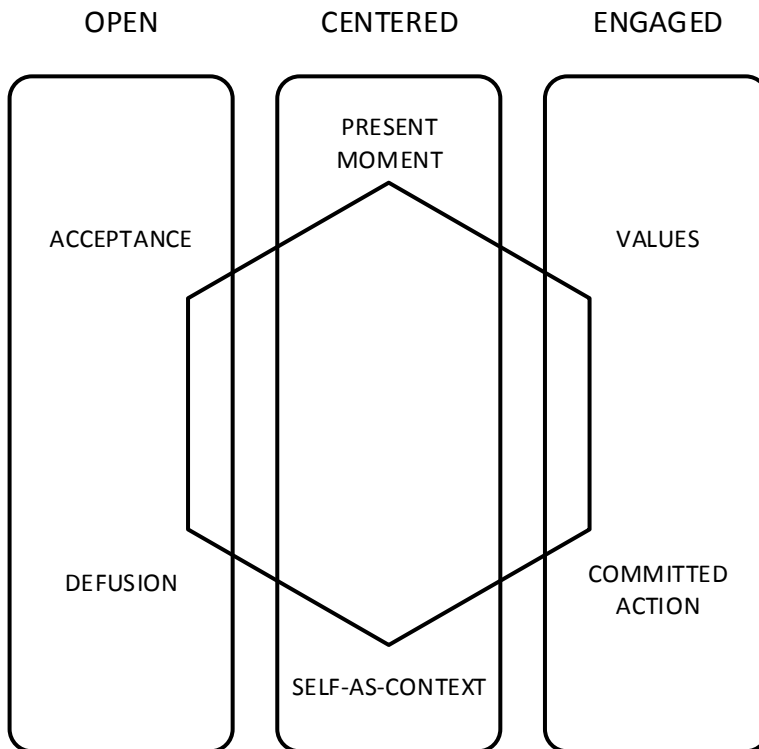


Figure 3. Response styles and six therapeutic processes that make up the ACT hexaflex. In Hayes, S. C., Strosahl, K., & Wilson, K. G. (2012). *Acceptance & Commitment Therapy: The process and practice of mindful change* (2nd. ed.). New York: Guilford Press.

In the most recent explanation of ACT, the processes acceptance and cognitive defusion are paired together in an open response style (Hayes et al., 2012). This response style promotes disengagement from unhelpful and undesirable cognitions and emotions by taking a de-literalized and distanced perspective towards these experiences ('open up'). More analytically explained, pain sufferers are encouraged to map the unsuccessful consequences (C) of previous pain-related behavior (B), and furthermore, are encouraged to gain insight in and take a different perspective towards unhelpful implicit rules (A).

3) Being present is the therapeutic process most directly related to mindfulness. It entails a non-judgemental presence in the here-and-now, without being consummated by the past or the future. Through the use of mindfulness exercises pain sufferers are encouraged to contact their pain experience and other psychological and environmental events without trying to change or alter these events.

4) As is the process being present, the process self-as-context is applied to promote pure awareness. Pain sufferers are encouraged to differentiate between a 'self-as-content' - a sense of self composed of all the labels, ideas, thoughts, and judgements we have about our 'Me' which we are fused with - and the 'self- as-context' - a sense of self from which we can take perspective and merely observe the on-going stream of physical and psychological events that occur in our lives.

The processes being present and self-as-context are paired together in the centered response style (Hayes et al., 2012). This response style helps to take perspective and experience the flow of contextual, bodily and psychological events and processes in a non-judgemental and dis-attached way ('be present'). In doing so, this response style offers a necessary and energy-efficient working ground from where to foster both the open response style and the pursuit of valued living. Analytically, in this response style pain sufferers are encouraged to take an open and observing stance towards behaviour (B) and related antecedents (A) and consequences (C).

5) Values are freely chosen, intrinsically motivated qualities of meaningful and purposeful action, or rather, 'paths to be taken' to lead a personally valuable and vital life. During therapy, multiple exercises are applied to help pain sufferers identify their values in different life domains (e.g. career, family life, social activities, spirituality). All energy that serves as output of engagement in the previously discussed therapeutic processes is fuelled to leading a values consistent life.

6) Committed action is a pure behavioral process and entails the formulation of short-term, concrete and reachable goals based on identified values. Behavioral activation exercises and goal setting are used to help pain sufferers to perform these actions. Furthermore, barriers that can interfere with values-based living in the future are recognized and action plans in dealing with these barriers are formulated.

The processes values and committed action are paired together in the engaged response style (Hayes et al., 2012). This response style encourages pain sufferers to identify what intrinsically motivates them in multiple life domains and take subsequent, concrete actions to lead a vital and valuable life in the presence of pain ('do what works'). More analytically said, pain sufferers are encouraged to react to antecedents (A) in a way that builds desired and helpful consequences (C).

*Being home a few weeks now from intensive inpatient multidisciplinary treatment Anja feels better. It was a tough journey, but she came out stronger. While she used to be hard on herself, a real fighter, she is now able to let her sorrow and pain exist. Of course she feels frequently distressed or angry when pain increases, but she also*

*feels she can live with it. Accepting the pain enabled her to ask for help from others. Anja stopped the on-going fight with herself and her pain, and is now less judgemental and more aware of her thoughts and feelings. She judged less hard on her husband than she would have done before when he was in pain after recent surgery, and is able to tell her daughter that she is in pain on bad days.*

*Every day she scans her body using breathing exercises and mindfulness. Can she perform the activities she scheduled today? Can she stand up from her wheelchair? A few weeks ago she had to concentrate hard when doing a body-scan. It now feels more automatically and unconsciously. Anja decided she valued to be there for her significant others. To really listen to their stories. Opening up to others has made her more emotional and less harsh. She fully enjoys her hobby as a radio DJ at the local radio station. A few weeks ago, for the first time in years she visited her best friend with her husband. Last week she spontaneously took the car and dropped by her friend's house for a cup of coffee. She enjoys life more and is better able to savour happy moments.*

## EVIDENCE FOR ACT

ACT is designed to be applicable to a broad range of psychological problems. Several systematic reviews offer evidence for the effectiveness of ACT in a mix of disorders including, for example, depression, anxiety and OCD (Ost, 2008; Powers, Zum Vorde Sive Vording, & Emmelkamp, 2009; Ruiz, 2010). Furthermore, experiential avoidance has been recognized an important trans diagnostic risk factor (Biglan, Hayes, & Pistorello, 2008; Kashdan, Barrios, Forsyth, & Steger, 2006). In the context of chronic pain, the effectiveness of ACT has been examined intensively due to its fit to the challenges imposed to chronic pain rehabilitation. A highly recent review of the ACT model and its evidence and progress is given by McCracken & Vowles (2014).

A rapidly growing body of research shows that ACT effectively improves pain-related emotional and physical disability in pain patients in comparison the control conditions (Jensen et al. 2012; Johnston, Foster, Shennan, Starkey, & Johnson 2010; McCracken, Sato, & Taylor 2013; Thorsell et al. 2011; Veehof, Oskam, Schreurs, & Bohlmeijer 2011; Vowles, McCracken, & O'Brien 2011; Wetherell et al. 2011; Wicksell et al. 2013). In general, effect sizes seem to be similar to those found for more traditional CBT-based interventions for chronic pain (Veehof et al., 2011; Wetherell et al., 2011). Additional research into treatment process has revealed that all aspects of psychological flexibility serve significant purposes in explaining adjustment to chronic pain disability (e.g. McCracken, Gauntlett-Gilbert, & Vowles, 2007; McCracken, Vowles, & Eccleston, 2005; McCracken & Gutiérrez-Martínez, 2011; Vowles & McCracken, 2008). Following this

evidence, the American Psychological Association has recognized ACT as a clinical intervention for chronic pain with strong research support (APA Div 12 SCP, 2012).

## **THIS THESIS**

At present, the overarching challenge for the field of pain research is to find solutions to the magnitude of the growing societal problem of pain, in light of the modest treatment gains for both biomedical and psychological interventions (Turk et al., 2011). As ACT evidently has a philosophical, theoretical and practical fit to the goals and challenges of psychological and multidisciplinary chronic pain rehabilitation, the framework deserves further examination. Although outcomes of existing trials are positive, more adequately designed and large controlled trials are necessary to further examine the effectiveness of ACT for chronic pain (Williams et al., 2013). Also in other areas than mere effectiveness, knowledge on ACT is lacking. The specific research questions in the context of ACT for chronic pain posed in this thesis were inspired by several proposed venues for progress in research on psychosocial interventions for chronic pain.

### **Venues for progress in psychosocial approaches to chronic pain**

Among others, a central and often proposed venue to enhance the effectiveness of future psychosocial intervention is to more closely monitor and examine the working mechanisms of change of specific treatments (Eccleston, Morley, & Williams, 2013; Jensen & Turk, 2014; Kazdin, 2007; Kraemer, Wilson, Fairburn, & Agras, 2002). As formulated more precisely by Jensen and Turk (2014, pp. 112), 'With the focus in the last several decades on if psychological treatments are effective, the field has to a large extent ignored asking which ones, provided how, when, and with whom, on what outcomes, with what level of maintenance, compared to what alternative, and at what costs psychological pain treatments 'work'. ACT is especially suitable for such type of research questions given the unified underlying theoretical model of psychological flexibility that is clearly defined and process-oriented (McCracken & Vowles, 2014). In relation to this focus on processes of change, researchers have proposed to use other designs than RCT's, such as single case methodologies, when trying to better understand change (Morley, 2011; Williams et al., 2013). Potential advantages of single case methodologies, or n-of-1 studies, are a focus on the individual pain sufferer instead of the aggregate, detailed monitoring procedures that directly expose therapeutic processes and behaviour over time, and a fit to the natural environment of daily clinical practice outside the laboratory (Barlow, Nock, & Hersen, 2009).

Another venue for future progress is the technology-assisted delivery of psychosocial interventions (Jensen & Turk, 2014; Pincus & McCracken, 2013). Potentially, web-based programs can be a cost- and time-effective mode of treatment that can foster



self-management for large groups of chronic pain patients in learning to live with pain. Fostering self-management has been proposed a central issue in future pain treatment given that complete pain removal or pain control is not an option for every pain sufferer at present (Turk et al., 2011). Early studies on web-based CBT are positive, although more large-scale and well-designed trials are necessary, especially in the context of ACT (Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Eccleston et al., 2014).

Additionally, in the specific context of ACT, to be able to adequately assess efficacy and specific mechanisms of change, more process-oriented assessment instruments are needed. At present, questionnaires with good psychometric properties are available within the framework of ACT, such as the Chronic Pain Acceptance Questionnaire (CPAQ) (McCracken, Vowles, & Eccleston, 2004) and the Psychological Inflexibility in Pain Scale (PIPS) (Wicksell, Lekander, Sorjonen, & Olsson, 2010). Nevertheless, existing questionnaire require further examination, and furthermore, not each of the six ACT therapeutic processes can be adequately assessed at present.

Finally, an important topic is the dissemination of scientific knowledge to practice. In 2001, the Institute of Medicine reported on a ‘gap’ – or even ‘chasm’ – between science and health care practice. Providing proper quality of treatment delivery – for example by ensuring adherence and competence of therapists to specific chronic pain treatment frameworks – is a necessary premise to efficient and effective treatment following scientific effort (Morley, 2011; Pincus & McCracken, 2013; Waltz, Addis, Koerner, & Jacobson, 1993).

### **General outline**

Following from existing challenges and subsequent venues for future study, the overarching aim of this dissertation is to contribute to the scientific progress of knowledge on the (a) measurement, (b) efficacy and (c) mechanisms of ACT for chronic pain.

In the first three studies presented in chapter 2, 3 and 4, we contribute to the availability of psychometrically sound measurement instruments to be able to adequately assess ACT treatment processes. In *chapter 2*, we present evidence for problems with factorial validity of the Dutch version of the Chronic Pain Acceptance Questionnaire (CPAQ) (McCracken et al., 2004), the most widely used and validated questionnaire to assess pain acceptance in English speaking samples. To provide an alternative, in *chapter 3* we show that the Dutch version of the Psychological Inflexibility in Pain Scale (PIPS) (Wicksell, Lekander, Sorjonen, & Olsson, 2010) is a psychometrically sound questionnaire to assess psychological inflexibility in chronic pain patients. *Chapter 4* reports on the development and evidence for the psychometric properties of the Engaged Living Scale as a new, process-oriented questionnaire to measure the engaged response style in a range of samples, among which chronic pain.

Following these basic psychometrical studies, we developed and evaluated the efficacy of a web-based self-help intervention based on ACT ('Living with Pain') in improving pain interference in daily life. This evaluation was performed in a large, three-armed randomized controlled trial with 238 participants. The outcomes of this efficacy study can be found in *chapter 5*. Following these outcomes, in *chapter 6* we present the results of exploratory analyses to examine possible predictors and moderators of change during web-based ACT, and provide evidence that web-based ACT is potentially useful for a specific subgroup of pain sufferers. Hereafter, we report on two studies that were performed to further deepen our understanding of the working mechanisms of change during ACT, both during the RCT presented in chapter 5 and 6, and in a clinical multidisciplinary rehabilitation setting. First, *chapter 7* presents evidence for psychological flexibility as the central working mechanism of change during the web-based self-help intervention compared to both control conditions. Additionally, we provide a first step in disentangling the interrelationship over time between psychological flexibility and catastrophizing as theorized mediators of change central to ACT and CBT, respectively. Following this chapter, we further focus on working mechanisms in *chapter 8* using a within-person approach. We present outcomes of an exploratory n-of-1 study in which we followed three chronic pain patients over a prolonged period of time before, during and after receiving ACT treatment. In *chapter 9*, we describe the systematic implementation of ACT in Dutch multidisciplinary chronic pain rehabilitation that was performed between September 2010 and September 2012, and subsequently report on changes in therapists' competence in working with ACT and other factors related to implementation success during the course of the implementation. Finally, *chapter 10* contains a general discussion of the results of studies presented, and discusses venues for future research on the topics of measurement, efficacy and working mechanisms of ACT for chronic pain.

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# CHAPTER 2

Acceptatie van pijn: Problemen met de factoriële  
validiteit van de Nederlandse vertaling van de Chronic  
Pain Acceptance Questionnaire (CPAQ)

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2011, *Psychologie en Gezondheid*,  
39(5), 292-300



**ABSTRACT**

Acceptance of pain appears as an important factor in pain research and in practice. Different measurement instruments were developed, among which the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken, Vowles & Eccleston, 2004). In this study possible psychometric problems with the Dutch version of the CPAQ are investigated. Different models of the CPAQ, among which the general two-factor model (subscales Activity Engagement and Pain Willingness), were tested in confirmatory factor analysis (N = 584). None of the models met the established fit criteria for adequate fit. It is concluded that the factor structure of the Dutch version of the CPAQ can not be confirmed; the scale as such should be rejected as a useful measurement instrument. Alternative questionnaires to measure acceptance of pain (ICQ, PaSol, PIPS) are suggested.

## INTRODUCTIE

Het afgelopen decennium is er in onderzoek en de praktijk van chronische pijn en pijnrevalidatie meer aandacht gekomen voor het concept acceptatie. Het is een centraal construct in de zogenoemde derde generatie gedragstherapieën, waaronder Acceptance & Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999). In ACT en aanverwante acceptatiegerichte therapieën is het uiteindelijke doel de ontwikkeling van psychische flexibiliteit. Psychische flexibiliteit is te omschrijven als 'de mogelijkheid om op bewuste wijze in het huidige moment te kiezen voor acties die leiden tot een waardevol leven'. Acceptatie maakt onderdeel uit van psychische flexibiliteit (Hayes, Luoma, Bond, Masuda, & Lillis, 2006) en impliceert in de context van pijn het toelaten van de ervaring van pijn, zonder deze ervaring te willen veranderen of vermijden (McCracken, 1999). Verschillende studies hebben laten zien dat acceptatie in de context van chronische pijn gerelateerd is aan beter fysiek, emotioneel en sociaal functioneren, kwaliteit van leven, verminderd medicatiegebruik en betere werkstatus (Evers et al., 2001; Mason, Mathias & Skevington, 2008; McCracken, 1998; McCracken & Eccleston, 2003; McCracken & Eccleston, 2005; Viane et al., 2003; Vowles & McCracken, 2008).

Verschillende meetinstrumenten zijn ontwikkeld om psychische flexibiliteit en acceptatie te meten. Vanuit de hierboven beschreven visie op acceptatie, psychische flexibiliteit en chronische pijn zijn de Acceptance and Action Questionnaire (AAQ: Hayes et al., 2004), de Chronic Pain Acceptance Questionnaire (CPAQ: McCracken, Vowles & Eccleston, 2004) en de Psychological Inflexibility in Pain Scale (PIPS: Wicksell, Renofalt, Olsson, Bond & Melin, 2008b) ontwikkeld. Onlangs is de AAQ vervangen door een nieuwe, psychometrisch verbeterde versie van de schaal, de AAQ-II. Deze versie is recentelijk in het Nederlands vertaald en gevalideerd (Jacobs, Kleen, De Groot & A-Tjak, 2008).

De itempool van de originele AAQ is begin jaren '90 is gebruikt ter ontwikkeling van de CPAQ om acceptatie van pijn in pijnpopulaties te kunnen meten (Geiser, 1992, ongepubliceerde dissertatie). Deze vroegste versie van de CPAQ bestond uit 34 items, waarvan er 24 gebruikt werden om tot een totaalscore te komen. Hierna zijn verschillende onderzoeken uitgevoerd naar de psychometrische kwaliteiten van de schaal (McCracken, 1999; McCracken et al., 2004; Vowles, McCracken, McLeod & Eccleston, 2008; Wicksell, Olsson & Melin, 2008a). Aanvankelijk leek een factoroplossing met vier componenten het meest passend, hoewel één van de vier factoren afweek van het algemene construct (McCracken, 1999). Latere studies resulteerden in een definitieve versie van de schaal bestaande uit twintig items met twee componenten, te weten 'Activity Engagement' en 'Pain Willingness' (McCracken et al., 2004). Hoewel verschillende onderzoeken hebben geconcludeerd dat de CPAQ bruikbaar is (bijvoorbeeld Reneman, Dijkstra, Geertzen, & Dijkstra, 2010), is er discussie geweest over de invulling van het concept acceptatie en de best passende factorstructuur voor de schaal (Nicholas & Asghari, 2006; Nicholas &

Asghari, 2007; McCracken, Vowles, & Thompson, 2006). Zo stelden Nicholas en Asghari (2006) aan de hand van exploratieve factoranalyse dat een factoroplossing met vier factoren beter passend zou zijn voor de schaal. Enkel de eerste subschaal, 'Activity Engagement', zou volgens deze onderzoekers bewaard moeten blijven. Inmiddels lijken verschillende recente studies, waarin gebruikt gemaakt is van confirmatieve factoranalyses, toch de twee-factorstructuur van de schaal te bevestigen (Vowles et al., 2008; Wicksell et al., 2008a).

De CPAQ is bij aanvang van het onderzoek naar de psychometrische kwaliteiten van de schaal vertaald naar het Nederlands (Crombez, Vlaeyen, Van Houdenhove & Wauters, 1999). Er zijn drie verschillende versies beschikbaar, bestaande uit 34 items, 28 items en 20 items. De laatste versie is gebaseerd op de algemeen gebruikte versie van de CPAQ, zoals hierboven beschreven. Hoewel deze Nederlandse 20-item versie wordt gebruikt in praktijk en onderzoek, is de factoriële validiteit van de schaal tot nog toe niet onderzocht. Omdat deze vorm van validiteit de basis is voor de verdere psychometrische kwaliteiten van een schaal, is het relevant deze te onderzoeken. De ontwikkelingen en discussies rondom de originele Engelstalige versie van de CPAQ geven des te meer reden om de factorstructuur van deze Nederlandse vertaling nader te willen bestuderen. In deze huidige studie wordt dan ook de factoriële validiteit van de CPAQ nagegaan.

## METHODE

### Deelnemers

De steekproef bestond uit chronisch pijnpatiënten die een indicatie hadden voor deelname aan een revalidatieprogramma in twee Nederlandse revalidatiecentra ( $N = 591$ ). De belangrijkste kenmerken van de steekproef en gemiddelde scores op de CPAQ en andere gebruikte meetinstrumenten zijn vermeld in Tabel 1. Voor alle twintig items van de CPAQ bleek minder dan 5% van de gegevens uit missende waarden te bestaan. Deelnemers die voor meer dan 50% van de items van de CPAQ missende waarden hadden zijn verwijderd alvorens de factoranalyses werden uitgevoerd ( $N = 7$ ).

### Metingen

*Achtergrondvariabelen:* Geslacht, leeftijd, burgerlijke staat en opleidingsniveau, diagnose (ICD-9 code) en werkstatus zijn vastgesteld bij alle deelnemers. Verder werden scores op verschillende meetinstrumenten in kaart gebracht; score voor pijnintensiteit op de Nederlandse versie van de Multidimensional Pain Inventory (MPI-DLV; Lousberg, van Breukelen, Groenman, Schmidt, Arntz & Winter, 1999), de totaalscore op de Nederlandse versie van de Tampa Scale of Kinesiophobia (TSK-DV; Vlaeyen, Kole-Snijders, Boeren & van Eek, 1995) en de totaalscore op de Nederlandse versie van de Pain Catastrophizing Scale

(PCS-DV; Crombez & Vlaeyen, 1996). De metingen vonden plaats voor aanvang van het revalidatieprogramma.

Tabel 1. Kenmerken van de respondenten

	Gemiddelde	SD	Range
Geslacht ( <i>N</i> = 590)			
Man	30.4%		
Vrouw	69.6%		
Leeftijd in jaren ( <i>N</i> = 566)	44.1	11.7	18-79
Huwelijkse status ( <i>N</i> = 575)			
Getrouwd/relatie	74.9%		
Geen relatie	25.1%		
Opleidingsniveau ( <i>N</i> = 569)			
Laag (basisschool, vmbo)	44.8%		
Middelbaar (mbo, havo, vwo)	40.3%		
Hoog (hbo, universiteit)	14.9%		
Diagnose ( <i>N</i> = 591)			
Fybromyalgie	20.5%		
Whiplash	10.6%		
Gegeneraliseerde pijn	32.1%		
CVS	0.6%		
Rugaandoeningen	24.4%		
Gewrichtsaandoeningen	10.5%		
Overige aandoeningen	1.3%		
Werkstatus ( <i>N</i> = 400) <sup>1</sup>			
Werkend	30.0%		
Niet-werkend	70.0%		
CPAQ ( <i>N</i> = 584)			
Activity Engagement	34.5	9.6	
Pain Willingness	23.9	7.9	
Totaal	58.1	13.3	
Pijnintensiteit MPI ( <i>N</i> = 581)	4.2	1.1	1-6
PCS – totaalscore ( <i>N</i> = 582)	23.3	11.2	0-52
TSK - totaalscore ( <i>N</i> = 582)	36.9	8.4	18-62

<sup>1</sup>Werkstatus enkel bekend voor één van beide revalidatie

*Chronic Pain Acceptance Questionnaire (CPAQ)*: De CPAQ bestaat uit twintig items, welke op een schaal van 0 ('nooit van toepassing') tot 6 ('altijd van toepassing') gescoord worden. De eerste subschaal, Activity Engagement, bestaat uit elf items (item 1, 2, 3, 5, 6, 8, 9, 10, 12, 15 en 19) en meet de mate van het uitvoeren van gewone dagelijkse activiteiten ondanks ervaren pijn. De tweede subschaal, Pain Willingness, bestaat uit de overige negen items (4, 7, 11, 13, 14, 16, 17 en 18) en meet de wil tot het ervaren van pijn

zonder deze ervaring te willen vermijden of verminderen. Alle items van de Pain-Willingness schaal zijn negatief geformuleerd en moeten worden gespiegeld, alvorens een totaalscore te kunnen berekenen waarbij hogere scores een hogere mate van acceptatie betekenen (McCracken et al., 2004). Ook deze metingen vonden plaats voor aanvang van het revalidatieprogramma. De Nederlandstalige versie van de CPAQ is toegevoegd in Appendix A.

### **Statistische analyses**

Alvorens factoranalyses uitgevoerd werden, zijn de eigenschappen van de twintig items in kaart gebracht aan de hand van het programma SPSS 18 (SPSS Inc., Chicago, IL). Bij deze itemanalyse werden frequentieverdelingen, missende waarden en inter-correlaties tussen de items onderling en tussen de items en de subschalen en totale schaal geanalyseerd.

De factoriële validiteit van de CPAQ werd getoetst door het uitvoeren van verschillende confirmatieve factoranalyses (CFA) met behulp van het programma Lisrel 8.70 (Scientific Software International, Lincolnwood, IL). Vanwege het ordinale karakter van de CPAQ-items werd gebruikt gemaakt van robuuste schattingsmethoden (Robust Maximum Likelihood). Deze schattingsmethode past door gebruikmaking van de asymptotische covariantiematrix een correctie toe op data die niet normaal verdeeld zijn, waardoor meer accurate fit-maten gevonden worden. Aangezien gebruik gemaakt werd van deze robuuste schattingsmethoden werd de Satorra-Bentler chi-kwadraat als fit-maat gebruikt naast de conventionele chi-kwadraat (Joreskog, Sorbom, Du Toit & Du Toit, 2001).

Omdat de chikwadraat, de conventionele teststatistiek in confirmatieve factoranalyses, onder andere door gevoeligheid voor steekproefgrootte vaak een onderschatting geeft van de fit van een model, werden ook andere fit-maten meegenomen (Hu & Bentler, 1998). Dit zijn de root mean square error of approximation (RMSEA), de standardized root mean square residual (SRMR), de non-normed fit index (NNFI) en de comparative fit index (CFI). Waarden  $\leq .08$  voor de RMSEA en SRMR indiceren een acceptabele fit, terwijl waarden  $\leq .05$  voor de RMSEA en de SRMR een goede fit indiceren. Voor zowel de NNFI en de CFI worden waarden  $\geq .90$  als acceptabel en waarden  $\geq .95$  als goed beschouwd. Bij het uitvoeren van de analyses werden enkele restricties opgelegd: De variantie van de latente factoren werd vastgezet op een waarde van 1 en deze factoren mochten vrij met elkaar correleren. Daarnaast werd aan alle items de restrictie opgelegd dat zij maar op één enkele latente factor konden laden.

## **RESULTATEN**

Frequentieverdelingen toonden geen enkel item met zeer scheve of gepiekte waarden: er was sprake van lage tot matige non-normaliteit van de data. Vanwege lage inter-

correlaties met andere items en een niet-significante item-totaal correlatie van  $-.040$ , leek item 16 ('Mijn leven wordt aangenamer als ik niet negatief over mijn pijn denk') een problematisch item. Omdat dit item onderdeel is van de bestaande modellen die getoetst worden in dit onderzoek, is besloten item 16 te behouden in de aanvankelijke analyses. Voordat factoranalyses werden uitgevoerd, werd de betrouwbaarheid (Cronbach's  $\alpha$ ) van de subschalen en de totale schaal berekend. Waarden voor Cronbach's  $\alpha$  waren  $.81$  (Activity Engagement),  $.71$  (Pain Willingness) en  $.75$  (totale schaal).

Verschillende confirmatieve factoranalyses werden uitgevoerd om de factorstructuur van de CPAQ te onderzoeken. De resultaten van deze analyses staan beschreven in tabel 2. Alvorens de analyses uit te voeren werden missende waarden in het programma Lisrel vervangen door gemiddelden op de desbetreffende variabelen. Allereerst werd het algemene model van de CPAQ getoetst (McCracken et al., 2004), waarbij twee factoren worden onderkend ('Activity Engagement' en 'Pain Willingness')<sup>1</sup>.

Tabel 2. Fit-maten voor de verschillende confirmatieve factoranalyses.

Model	2 factor	4 factor	Activity Engagement	2 factor, zonder 16
$\chi^2$	1335.896	1797.509	417.137	1026.395
<i>df</i>	169	146	44	151
RMSEA	.086	.113	.092	.086
NNFI	.862	.763	.918	.868
CFI	.877	.797	.934	.884
SRMR	.098	.144	.075	.087

*N* = 584.  $\chi^2$  = Normal theory weighted least squares chi-square; *df* = degrees of freedom; RMSEA = root mean square error of approximation; NNFI = non-normed fit index; CFI = comparative fit index; SRMR = standardized root mean square residual.

De uitkomsten van de analyses lieten zien dat een model met twee factoren geen goede fit had: Geen van de fit-maten voldeed aan de eerder vermelde fit criteria. Aangezien verschillende studies hebben gesuggereerd dat een model met vier factoren beter passend zou zijn, werd ook dit model getoetst. Het model is gebaseerd op de uitkomsten van het exploratieve onderzoek van Nicholas en Asghari (2006). Hierbij blijft de subschaal Activity Engagement nagenoeg intact en worden de items behorende bij de subschaal Pain Willingness opgedeeld over drie verschillende subschalen. Item 8 werd hierbij verwijderd uit de itempool. De uitkomsten van de analyses lieten zien dat de fit van dit model met vier factoren zeer slecht is. Geen van de gebruikte fit-maten voldeed aan de gestelde criteria. Daarnaast hadden de gevonden fit-maten beduidend lagere waarden dan de fit-maten in het model met twee factoren. Hoewel de fit van het model met twee

<sup>1</sup> Ook een model met één factor is getoetst. Dit leverde een zeer slechte fit op ( $\chi^2 = 1791.65$ , *df* = 170, RMSEA =  $.122$ , NNFI:  $.717$ , CFI =  $.747$ , SRMR =  $.125$ ).

factoren beter is dan de fit van een vier-factormodel, suggereren de uitkomsten van beide analyses dat de factorstructuur van deze Nederlandse versie van de CPAQ niet overeenkomt met de veronderstelde factorstructuur van de schaal.

Omdat voorgesteld is uitsluitend de subschaal Activity Engagement te bewaren omdat deze stabiel zou zijn dan de subschaal Pain Willingness (Nicholas & Asghari, 2006), is bekeken of deze subschaal op zichzelf een goede fit bereikte. De fit van dit model was beter dan de fit van de voorgaande twee modellen: Zowel de CFI, NNFI en SRMR voldeden aan de gestelde criteria voor adequate fit. Ook in dit model voldeed de gevonden waarde voor de RMSEA echter niet aan de gestelde criteria. Hoewel de fit van dit model beter is dan van voorgaande modellen, suggereren ook deze uitkomsten dat de subschaal Activity Engagement onvoldoende unidimensioneel lijkt te zijn om gebruikt te worden.

Bij het uitvoeren van bovenstaande analyses is het slecht functionerende item 16 niet verwijderd. Omdat de inclusie van dit mogelijk problematische item een reden kon zijn voor de gevonden uitkomsten, is getoetst of de factorstructuur van het model met twee factoren wel bevestigd kon worden wanneer dit item verwijderd werd uit de analyses. Dit bleek niet het geval: ook zonder item 16 voldeden de gevonden fit-maten niet aan de gestelde criteria voor een adequate fit. De uitkomsten van de analyses voor het model met twee factoren zonder item 16 zijn vermeld in Tabel 2. Voor het model met vier factoren zonder item 16 was het niet mogelijk de factorstructuur te toetsen. De reden hiervoor was dat de vierde factor van dit model na verwijdering van item 16 uit slechts één item bestond. Hierdoor was het onmogelijk een model te convergeren.

## DISCUSSIE

In deze studie werd de factoriële validiteit van de Nederlandse vertaling van de Chronic Pain Acceptance Questionnaire (CPAQ; Crombez et al., 2009) onderzocht. De resultaten van deze studie laten zien dat de factorstructuur van het algemene model met twee factoren (McCracken et al., 2004), evenals de factorstructuur van een alternatief model met vier factoren (Nicholas & Asghari, 2006), niet bevestigd kan worden. Hoewel getracht is de subschaal Activity Engagement te bewaren, blijkt ook hier onvoldoende bewijs voor de veronderstelde één-factorstructuur van dit construct. Op basis van psychometrische problemen die in deze studie gevonden zijn met betrekking tot de factorstructuur van de schaal, concluderen we dat het niet raadzaam is deze versie van de CPAQ te gebruiken voor diagnostische- dan wel onderzoeksdoeleinden.

Er is in deze studie afgezien van het uitvoeren van verdere analyses zoals correlaties met andere meetinstrumenten en uitkomstmaten. Hier is voor gekozen omdat de factoriële validiteit van een schaal de basis is voor het aantonen van verdere psychometrische kwaliteiten. Hoewel de interne consistentie van de CPAQ in deze studie

voldoende is, is de factoriële validiteit van de CPAQ onvoldoende gebleken. Hierdoor zal het uitvoeren van verdere analyses waarschijnlijk enkel meer psychometrische problemen aantonen.

Het slechte functioneren van item 16, vanwege lage inter-correlaties met andere items en een niet-significante item-totaal correlatie, had een mogelijke verklaring voor de gevonden resultaten kunnen zijn. Het uitvoeren van dezelfde analyses zonder item 16 leverde echter geen andere conclusies op over de factoriële validiteit van de schaal. In een recente studie naar de validiteit van de Zweedse vertaling van de CPAQ (Wicksell et al., 2008) bleek item 16 om dezelfde redenen (zeer lage, niet-significante item-totaal correlatie) problematisch te zijn. Het item is verwijderd uit de analyses en niet opgenomen is in de uiteindelijke Zweedse versie van de CPAQ.

Een mogelijke verklaring voor de problemen met de factorstructuur van de schaal is de mogelijk problematische vertaling van enkele items. Zo is het Engelse item 13 'Keeping my pain level under control takes first priority whenever I'm doing something.', vrij vertaald naar het Nederlandse item 13: 'Als ik ergens aan begin, dan zorg ik ervoor dat de pijn niet zal toenemen.'. Ook het methodologisch slecht functionerende item 16 lijkt op inhoudelijke gronden problematisch. In een mogelijke nieuwe vertaling van de CPAQ moet men hier dan ook rekening mee houden en wordt aangeraden de methode van 'vertaling en hervertaling' toe te passen.

Er zijn enkele alternatieve zelfrapportage instrumenten om acceptatie en aanverwante constructen te meten in de context van chronische ziekte en pijn. Zowel de Ziekte Cognitie Lijst (ZCL; Evers, Kraaimaat, van Lankveld & Bijlsma, 1998; Evers et al., 2001) als de Pain Solutions Questionnaire (PaSol; De Vlieger, Van Den Bussche, Eccleston, & Crombez, 2006) bevatten een subschaal die acceptatie meet. Beide instrumenten komen voort uit een ander theoretisch kader dan de CPAQ. Dit uit zich in verschillende definiëring, operationalisering en gebruikte terminologie met betrekking tot het concept acceptatie. Dat de instrumenten niet precies hetzelfde concept meten, blijkt ook uit de matige tot redelijke correlaties tussen deze instrumenten en de CPAQ (bijvoorbeeld De Vlieger et al., 2006).

De ZCL is een generiek instrument dat verschillende cognities ten opzichte van chronische ziekte meet. Een van deze cognities is acceptatie. Het instrument is afkomstig uit een meer cognitief-gedragsmatig kader dan de CPAQ. Waar de CPAQ zich meer richt op gedragsaspecten ligt de focus van de ZCL meer bij cognities van de patiënt (Reneman et al., 2010). De ZCL is geschikt bevonden voor mensen die lijden aan chronische pijn en chronische vermoeidheid (Lauwerier, Crombez, Van Damme, Goubert, Vogelaers & Evers, 2010; Logie, Crombez & Evers, 2007). Onderzoek naar psychometrische kwaliteiten van de ZCL duidt op goede interne consistentie (Chronbachs  $\alpha > .80$ ), goede predictieve en constructvaliditeit, en een invariante factorstructuur voor verschillende chronische aandoeningen (Evers et al., 2003; Lauwerier et al., 2010; Viane et al., 2003).



De PaSol is gebaseerd op de ZCL, de CPAQ en de Tenacious Goal Pursuit and Flexible Goal Adjustment Scale (Brandstatter en Renner, 1990). Gebaseerd op de 'dual process theory of goal- motivated behaviour' (Brandstatter & Renner, 1990), meet dit instrument de manier waarop patiënten omgaan met de pijn in termen van accommodatie (acceptatie van de pijn en aanpassen van levensdoelen) en assimilatie (trachten de pijn te veranderen). De PaSol benadert het concept acceptatie op een meer integrerende manier dan de andere twee instrumenten. Hoewel de PaSol in een aanvankelijke studie goede interne consistentie en validiteit leek te bezitten (De Vlieger et al., 2006) lijken er statistische problemen te zijn. Zo werden bijvoorbeeld in een recente studie enkel totaalscores van de PaSol gebruikt voor analyses. Dit vanwege zeer scheve verdeling van de items in de subschalen (Crombez, Eccleston, van Hamme & De Vlieger, 2008). Daarnaast is de PaSol nog weinig gebruikt in onderzoek en praktijk.

Een derde alternatief wordt gevormd door Psychological Inflexibility in Pain Scale (PIPS: Wicksell et al., 2008b). De schaal meet psychologische inflexibiliteit aan de hand van twee subschalen ('vermijding' en 'cognitieve fusie'). Hoewel de PIPS niet het concept acceptatie meet, komt het instrument voort uit hetzelfde theoretisch kader als de CPAQ (Hayes et al., 2006). Binnen dit theoretisch kader maakt acceptatie onderdeel uit van psychologische inflexibiliteit. Eerdere studies naar de PIPS toonden goede psychometrische kwaliteiten (Wicksell et al., 2008; Wicksell et al., 2010), waaronder redelijke tot goede interne consistentie (.65 - .90) en goede constructvaliditeit (correlaties met verschillende gerelateerde constructen, waaronder levenstevredenheid en pijninterferentie). Op dit moment wordt de Nederlandse versie van deze schaal gevalideerd door de auteurs van dit artikel.

Er zijn verschillende beperkingen aan dit onderzoek. Een eerste beperking is dat de onderzoeksgroep in deze studie een specifieke groep chronisch pijnpatiënten is, namelijk patiënten aangemeld voor een pijnprogramma in een revalidatiecentrum. Enerzijds bestaat deze patiëntengroep uit een zeer heterogene mix van pijngerelateerde diagnoses, wat de generaliseerbaarheid van deze studie ten goede komt. Anderzijds hebben patiënten die in aanmerking komen voor een pijnprogramma in een revalidatiecentrum doorgaans meer psychosociale problemen dan patiënten in ziekenhuizen. Mogelijk zijn hierdoor de gevonden resultaten ten aanzien van de factorstructuur van de CPAQ niet generaliseerbaar naar alle chronisch pijnpatiënten. Bij patiënten in een revalidatiecentrum zou men kunnen verwachten dat acceptatie lager is dan bij chronische pijnpatiënten in het algemeen. De scores in deze studie voor de subschalen en totale schaal van de CPAQ blijken gelijk of iets hoger zijn dan de gerapporteerde gemiddelden in andere studies (McCracken et al., 2004; Viane et al., 2003; Vowles et al., 2008; Wicksell et al., 2008a). Deze uitkomsten wijzen erop dat de onderzoeksgroep in deze studie niet of nauwelijks afwijkt van andere onderzoeksgroepen. Nadere bestudering van de gebruikte studies laat zien dat een groot deel van de andere studies ook pijnpatiënten verwezen

naar een revalidatieprogramma onderzoekt. Om tot goed generaliseerbare conclusies te kunnen komen is het aan te raden de gevonden resultaten te repliceren in een meer algemene groep van pijnpatiënten. Daarnaast is het ook voor studies naar chronische pijn in het algemeen raadzaam gebruik te maken van een meer heterogene groep van pijnpatiënten dan nu vaak het geval is.

Een tweede mogelijke beperking van dit onderzoek is de variatie in diagnoses in de gebruikte steekproef. Men kan zich afvragen of de gevonden problemen met de factoriële validiteit meer of minder van toepassing zijn op bepaalde subgroepen. Het is echter niet aannemelijk dat psychologische variabelen als acceptatie van pijn, gerelateerd zouden zijn aan de pijnlocatie zoals gereflecteerd wordt in verschillende diagnostische categorieën van de ICD.

Hoewel de resultaten van deze studie laten zien dat een nieuwe vertaling van de CPAQ nodig lijkt om bruikbaar te zijn in onderzoek en praktijk, lijken er voldoende alternatieven te zijn om op onderbouwde wijze acceptatie van pijn en aanverwante concepten in de context van chronische ziekte en pijn te kunnen meten. Gezien de groei van het aantal onderzoeken naar de derde generatie gedragstherapieën en daaraan gerelateerde concepten zal de toekomst meer mogelijkheden brengen voor het meten van acceptatie in de context van chronische pijn.

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## APPENDIX A

### Chronic Pain Acceptance Questionnaire – Nederlandse Versie

1. Ik ga gewoon verder met mijn leven, hoe erg mijn pijn ook is.
2. Mijn leven verloopt uitstekend, zelfs al heb ik pijn.
3. Het is oké om pijn te ervaren.
4. Ik zou het niet erg vinden om belangrijke zaken in mijn leven op te geven als ik daardoor minder pijn zou hebben.
5. Ik hoef niet noodzakelijk minder pijn te hebben om mijn leven aan te kunnen.
6. Hoewel sommige zaken veranderd zijn, heb ik ondanks de pijn een normal leven.
7. Het is belangrijk voor mij om te weten hoe ik van de pijn af kom.
8. Ik onderneem veel activiteiten als ik pijn voel.
9. Ik leid een volwaardig leven ook al heb ik chronische pijn.
10. Er zijn andere dingen die belangrijker zijn in mijn leven dan de pijn proberen te verminderen.
11. Mijn gedachten en gevoelens over de pijn moeten veranderen voor ik belangrijke stappen in mijn leven zet.
12. Ondankse de pijn blijf ik vasthouden aan mijn manier van leven.
13. Als ik ergens aan begin, dan zorg ik ervoor dat de pijn niet al toenemen.
14. Voor ik grote plannen maak, moet de pijn eerst iets minder worden.
15. Ook al wordt de pijn erger als ik iets onderneem, ik blijf de dingen doen die ik mij heb voorgenomen.
16. Mijn leven wordt aangenamer als ik niet negatief over mijn pijn denk.
17. Ik vermijd situaties die mijn pijn verergeren.
18. Ik maak mij echt zorgen over wat de pijn zal aanrichten in mijn leven.
19. Het is een opluchting om te beseffen dat ik mijn pijn niet moet veranderen om door te gaan met leven.
20. Als ik pijn heb, heb ik veel moeite met het uitvoeren van activiteiten.

Activity Engagement: 1, 2, 3, 5, 6, 8, 9, 10, 12, 15, 19

Pain Willingness: 4, 7, 11, 13, 14, 16, 17, 18, 20

Alle 20 items worden gescoord op een 7-punts Likertschaal, die oploopt van 0: 'nooit van toepassing' tot 6: 'altijd van toepassing'. De items behorende bij de subschaal 'Pain Willingness' moeten worden gespiegeld.





# CHAPTER 3

## The Psychological Inflexibility in Pain Scale (PIPS): Exploration of psychometric properties in a heterogeneous chronic pain sample

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**ABSTRACT**

Psychological flexibility receives increasing attention as the overarching process in Acceptance & Commitment Therapy (ACT). This study investigates the psychometric properties of the Psychological Inflexibility in Pain Scale (PIPS), measuring 'avoidance' and 'cognitive fusion' with pain, in a heterogeneous clinical sample of 428 chronic pain patients from four rehabilitation centres. Furthermore, the relationship between the PIPS and mindfulness (Five Facet Mindfulness Questionnaire, FFMQ) as a theoretically related measure within ACT is explored. Confirmatory factor analyses replicated acceptable/good model fit and internal consistencies. In a subsample from two rehabilitation centres (n = 237), the PIPS showed moderate to high relationships with aspects of mindfulness, pain interference in daily life, pain disability and mental health, and small relationships with pain intensity and physical functioning. The avoidance subscale explained additional variance in outcome variables beyond the FFMQ, ranging from 4.5 to 15.8%. Outcomes support the psychometric properties of the PIPS in a heterogeneous chronic pain sample. The PIPS and FFMQ measure slightly overlapping, but distinct constructs, and can be used complementary to assess a broad range of processes within ACT. Potential problems with the cognitive fusion subscale are acknowledged for future research.

## INTRODUCTION

As the overarching treatment process in Acceptance & Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 2012), psychological flexibility has received increasing attention in the treatment of multiple disorders, among which chronic pain (e.g. Kashdan & Rottenberg, 2010; McCracken & Gutiérrez-Martínez, 2011; McCracken & Velleman, 2010). It is defined as the ability to act effectively in accordance with personal values and goals in the presence of unwanted experiences (Hayes et al., 2006). In the most recent notion of the ACT model, the six treatment processes that underlie psychological flexibility have been taken together in three different ‘response styles’ (Hayes et al., 2012). First of all, *acceptance* and the process of *cognitive defusion* are defined as aspects of an ‘open response style’. In addition to a readiness to experience pain, this response style entails the ability to let go of the entanglement with unwanted thoughts and experiences. As acceptance is never targeted as a goal in itself, but always enhanced in order to be able to pursue meaningful activities, the act of values-based living is represented by the processes *values* and *committed action*. Both are aspects of the ‘engaged response style’. Finally, the ‘grounded response style’ - encompassing *present moment awareness* and the process *self-as-context* – focuses on a conscious grounding in the here and now as a basic stance towards life (Hayes et al., 2012).

Acceptance and mindfulness techniques are applied within ACT-based interventions to modify the impact of chronic pain and improve individual functioning. Although a growing body of research shows that ACT can be applied to effectively treat pain-related disability (e.g. McCracken & Gutiérrez-Martínez, 2011; McCracken & Velleman, 2010; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011), a more specific focus on processes of change within ACT-based interventions is necessary to refine the application of treatment to individuals. Therefore, the development of process-specific, psychometrically sound measurement instruments is necessary. Until recently, the only available measures of ACT processes in chronic pain were the Chronic Pain Acceptance Questionnaire (CPAQ) (McCracken, Vowles, & Eccleston, 2004) and the Chronic Pain Values Inventory (CPVI) (McCracken & Yang, 2006). The Psychological Inflexibility in Pain Scale (PIPS) is now available as a measure of psychological inflexibility (Wicksell, Lekander, Sorjonen, & Olsson, 2010; Wicksell, Renöfält, Olsson, Bond, & Melin, 2008). The PIPS assesses *avoidance* and *cognitive fusion with pain*. Within the framework of ACT, pain *avoidance* is seen as an opposite strategy to acceptance. Cognitive fusion is operationalised within the PIPS as ‘being caught up’ with the idea that pain has to be controlled in order to be able to lead a valuable life (Wicksell et al., 2010). A first validation study of the final 12-item version of the PIPS showed acceptable/good model fit, strong internal consistencies, and provided evidence for construct and incremental

validity beyond a measure of kinesiophobia in a sample of individuals experiencing Whiplash Associated Disorder (WAD) (Wicksell et al., 2010).

A first aim of this study is to investigate further the psychometric properties of the PIPS in a heterogeneous clinical sample of chronic pain patients. We will assess model fit of the proposed factor structure in a confirmatory factor analysis and investigate internal consistency of the PIPS. Another specific focus is on the relationship of the PIPS with an existing, established measure of mindfulness, the Five Facet Mindfulness Questionnaire (FFMQ) (Baer et al., 2006). This relationship is investigated as both ACT and mindfulness-based approaches recognises the relationship between mindfulness and the processes acceptance, cognitive defusion, contact with the present moment and self-as-context (Baer et al., 2006; McCracken & Gutiérrez-Martínez, 2011; McCracken & Thompson, 2008). The FFMQ is chosen as a multifaceted measure of mindfulness that has been validated in healthy samples and a clinical sample of fibromyalgia patients (e.g. Baer et al., 2006; Veehof, Ten Klooster, Taal, Westerhof, & Bohlmeijer, 2011). We will explore construct validity of the PIPS by assessing the relationship with theoretically related concepts and chronic pain outcomes. In addition, we will examine the incremental validity of the PIPS in explaining variance in outcome variables beyond the FFMQ.

With regard to construct validity, we expected negative, moderate correlations of the PIPS with the FFMQ facets - especially awareness, nonjudging and nonreactivity - as related but distinct aspects of the ACT framework (Hayes et al., 2012; Veehof, Ten Klooster, et al., 2011; Wicksell et al., 2010). Additionally, we expected moderate to high correlations with mental health (Wicksell et al., 2010). For the specific pain-related outcomes, small to moderate correlations were expected with pain intensity (positive), physical health (negative) and pain disability (positive), and moderate to high (positive) correlations were anticipated with pain interference in daily life (Wicksell et al., 2010, 2008). We expected the highest correlations between the PIPS and pain interference as the latter is the most psychologically defined from all pain-related outcomes. Overall, somewhat higher correlations with outcomes were expected for the avoidance subscale compared to the cognitive fusion subscale (Wicksell et al., 2010, 2008).

## METHOD

### **Participants and procedure**

Participants in the sample (n = 428) were adults experiencing chronic pain who were referred for an admission interview at one of four Dutch rehabilitation centres to receive outpatient or inpatient multidisciplinary treatment. Part of the data was retrieved from databases containing questionnaire data from regular, standardised data collection methods. Additionally, patients who were willing to fill out a questionnaire package containing the PIPS could either do this at the rehabilitation centre or take the

questionnaire home. If the latter was the case, a pre-paid return envelope was included with the questionnaire. Together with the questionnaire, participants received a letter explaining the goal of the study. Written informed consent was provided by all participants for the use of data for scientific research purposes. Mean age of the participants was 43.7 years (SD: 12.5; range 17-75 years) and the majority was female (72.2%). Other background characteristics and mean scores on the PIPS are described in Table 1.

Table 1. Background characteristics and scores for PIPS

	Mean	sd	Range
Age, years (n = 368)	43.7	12.5	17-75
Gender (% female; n = 367)	72.2		
Educational level (n = 290)			
Low (%)	31.4		
Intermediate (%)	52.4		
High (%)	16.2		
Marital status (% married/living together; n = 309)	69.3		
Work status (% working part- or full-time; n = 309)	52.4		
Diagnosis (%; n = 388)			
CLBP	23.2		
Other back- and neck pain disorders	15.2		
Fibromyalgia	14.3		
Generalised pain disorders	12.1		
Chronic fatigue syndrome	4.4		
Whiplash associated disorders	14.3		
Joint pain disorders	4.9		
Carpal tunnel syndrome	4.7		
Other	6.8		
Psychological Inflexibility (PIPS; n = 428)			
Avoidance	31.3	10.7	8-56
Cognitive Fusion	21.7	4.4	4-28
Total	53.0	13.3	12-84

Note: CLBP = Chronic Low Back Pain

## Measures

*Psychological Inflexibility in Pain Scale (PIPS)*: The Dutch version of the PIPS is an indirect translation of the original Swedish version of the PIPS (Wicksell et al., 2010). Initial translation was based on an English version of the PIPS. More thorough translation took place by translation, back-translation and subsequent comparison of the indirectly translated Dutch version with the Swedish version by three independent Swedish/Dutch native speakers. Item content and wording chosen were assessed thoroughly, and

translation was evaluated positively for all items. The PIPS is a 12-item instrument measuring *psychological inflexibility*. The scale consists of two subscales measuring *avoidance* (PIPS-av; 8 items) and *cognitive fusion* (PIPS-cf; 4 items). The answering scale ranges from 'never true' (1) to 'always true' (7). Higher scores indicate more psychological inflexibility.

*Five Facet Mindfulness Questionnaires (FFMQ)*: The FFMQ is a 39-item questionnaire measuring five facets of *mindfulness*: observing (8 items), describing (8 items), acting with awareness (8 items), nonjudging (8 items) and nonreactivity (7 items) (Baer et al., 2006). The answering scale ranges from 'never true' (1) to 'always true' (5). Cronbach's  $\alpha$ s in the current study were .76 (observing), .90 (describing), .90 (acting with awareness), .87 (nonjudgmental) and .74 (nonreactive).

*Multidimensional Pain Inventory (MPI); subscale pain interference*: The Multidimensional Pain Inventory was developed to assess various aspects of chronic pain and disability (9 items) (Kerns, Turk, & Rudy, 1985). The subscale pain interference measures the degree to which pain interferes in daily life activities such as work and social activities. Answering categories range from 'no change' (0) to 'much change' (6). Due to data storage procedures in the rehabilitation centres no internal consistency could be calculated.

*Rand-36 Health Survey – scales physical functioning and mental health (Rand-36)*: The RAND-36 Health Survey is a measure of health related quality of life (Hays, Sherbourne, & Mazel, 1993). In this research the subscales 'physical functioning' (PF) and 'mental health' (MH) were used. The scale PF considers limitations performing daily activities. The scale MH considers general feelings of mental health over the past four weeks. Both raw scale scores were linearly converted to a 0 to 100 scale. Cronbach's  $\alpha$  in this study was .87 (PF) and .87 (MH).

*Pain disability Index (PDI)*: The Pain Disability Index (PDI) (7 items) assesses the degree to which chronic pain disables a person to perform daily activities (Pollard, 1984). Answering categories range from 'no impairment' (0) to 'totally impaired' (10). In the present study, the PDI showed good internal consistency ( $\alpha = .81$ ).

*Pain intensity – Numeric Rating Scale (NRS)*: Momentary pain intensity was measured with an 11-point numeric rating scale, ranging from 'no pain' (0) to 'pain as bad as you can imagine' (10) (Dworkin et al., 2005).

## Data analysis

### *Item analysis, factor structure and internal consistency of the PIPS*

Descriptive analyses were performed using the program SPSS Statistics 20 (SPSS Inc., Chicago, IL). Frequency distributions, intercorrelations between items and item-total statistics were computed and analysed. Before assessing factor structure and internal

consistency, participants missing more than half of the scores on the PIPS were excluded. Remaining missing values were imputed using the Expectation Maximization (EM) algorithm. Based on the original validation study (Wicksell et al., 2010), a 12-item CFA model of the PIPS was tested in LISREL 8.70 (Scientific Software International, Lincolnwood, IL). Because of the ordinal character of the items in the PIPS, robust estimation methods were used (Robust Maximum Likelihood). By using the asymptotic covariance matrix, this estimation method corrects data with non-normal distributions. Model fit was assessed by the overall model chi-square statistic ( $\chi^2$ ). As this index often underestimates the data due to sensitivity to sample size, additional indices were used (Hu & Bentler, 1998). First, as robust estimation methods were applied, the Sattora-Bentler Chi-square is added as a fit measure (Joreskog, Sorbom, Du Toit, & Du Toit, 2001). Furthermore, the root mean square error of approximation (RMSEA), the standardized root mean residual (SRMR), the non-normed fit index (NNFI) and the comparative fit index (CFI) were used. For the SRMR and RMSEA, values  $\leq .10$  and  $.08$ , and  $\leq .08$  and  $.06$ , respectively, were considered indicative of acceptable and good model fit. For both the NNFI and CFI values  $\geq .90$  were considered acceptable, whereas values  $\geq .95$  were considered good (Browne & Cudeck, 1993; Hu & Bentler, 1999). Before performing the CFA analyses several model restrictions were applied: Variance of the latent factors was fixed to a value of 1 and latent factors were free to correlate with each other. Furthermore, all items were restricted to load on only one latent factor.

Internal consistencies of the PIPS subscales and total scale were assessed using Cronbach's  $\alpha$  coefficients. Values above  $.70$  were considered acceptable and values above  $.80$  high (Kline, 2000).

#### *Construct and incremental validity*

Construct and incremental validity of the PIPS were assessed in a sample of two rehabilitation centres for which standardised data collection methods were similar ( $n = 237$ ). Participants with completely missing data were excluded from further analysis. For the remaining participants, missing data was imputed using the EM-algorithm. Pearson correlation coefficients were calculated between the PIPS-av, PIPS-cf and PIPS total scale, and the FFMQ, MPI interference, Rand-36 PF and MH, PDI and pain intensity. Means and standard deviations for these scales can be found in table 3. Correlations between  $.50$  and  $1.00$  were considered strong, correlations between  $.30$  and  $.50$  considered moderate, correlations between  $.10$  and  $.30$  as small and correlations  $< .10$  as weak (Cohen, 1988). For examining the incremental validity of the PIPS beyond the FFMQ facets, Pearson correlation coefficients were first calculated between the PIPS-av and PIPS-cf, the FFMQ facets and MPI Interference, PDI and Rand-36 PF and MH scales. Hierarchical regression analyses were conducted with each of the different outcome variables as dependent variables. For each dependent variable, facets of the FFMQ that correlated significantly

with the dependent variable were entered in the first step, after which both the PIPS-av and PIPS-cf were entered in step two. The change in variance from the second step accounted as a test for incremental validity of the PIPS subscales ( $p < .05$ ).

## RESULTS

### Item analysis, factor structure and internal consistency of the PIPS

Frequency distributions showed no items with extremely skewed responses or low variability. Item-total statistics revealed no items with item-total correlations  $< .30$ . No more than 5% of data was missing for every item of the PIPS. Little's MCAR test showed values were missing completely at random ( $\chi^2 = 197.453$ ,  $df = 203$ ,  $p = .597$ ). Before replacement of missing values, 17 participants missing more than half of the scores on the PIPS subscales or total scale were excluded, leaving 411 participants to test factor structure and internal consistency.

Table 2. Descriptive data and completely standardized factor loadings (LISREL) for the 12 item two factor solution of the PIPS

Item	Mean (sd)	Standardized factor loadings	
		Avoidance	Cognitive fusion
1. I cancel planned activities when I am in pain.	3.77 (1.7)	.74	
2. I say things like "I don't have any energy", "I am not well enough", "I don't have time", "I don't dare", "I have too much pain", "I feel too bad", or "I don't feel like it"	4.18 (1.6)	.67	
3. I need to understand what is wrong in order to move on.	4.55 (1.9)		.72
4. Because of my pain, I no longer plan for the future.	3.26 (1.9)	.71	
5. I avoid doing things when there is a risk it will hurt or make things worse	4.19 (1.6)	.74	
6. It is important to understand what causes my pain.	5.79 (1.4)		.83
7. I don't do things that are important to me to avoid pain.	3.80 (1.6)	.67	
8. I postpone things because of my pain.	4.15 (1.7)	.82	
9. I would do almost anything to get rid of my pain.	5.83 (1.2)		.53
10. It's not me that controls my life, it's my pain.	3.85 (1.7)	.71	
11. I avoid planning activities because of my pain.	3.90 (1.6)	.81	
12. It is important that I learn to control my pain.	5.55 (1.4)		.72

All model fit indices revealed adequate to good model fit ( $\chi^2 (53) = 264.06$ ,  $SB-\chi^2 (53) = 158.93$ ,  $RMSEA = .070$ ,  $SRMR = .058$ ,  $NNFI = .97$ ,  $CFI = .98$ ). Furthermore, the model found high factor loadings for all items, ranging from .53 to .83 (Table 2).

Results of the internal consistency analyses show adequate to good internal consistency. Cronbach's  $\alpha$  was .88 for the total scale, and .89 and .73 for the subscales avoidance and cognitive fusion respectively. Correlations between the two subscales showed the scales to measure are related, but not overlapping constructs ( $r = .44$ ). Both subscales correlate highly with the total scale,  $r = .95$  and  $r = .70$  for the PIPS-av and PIPS-cf respectively.

### **Construct and incremental validity**

In the dataset available to assess construct and incremental validity, 17 participants were removed prior to analyses due to completely missing data. For the remaining 220 participants, the total percentage of missing data was 5.4%. Little's MCAR test showed values were missing completely at random ( $\chi^2 = 116.084$ ,  $df = 119$ ,  $p = .559$ ). Pearson correlation coefficients between the PIPS-av, PIPS-cf, PIPS total scale and constructs used to assess construct validity can be found in Table 3. Most correlations were in line with expectations. The PIPS-av correlated moderately with the FFMQ acting with awareness and nonjudging facets, MPI Interference, RAND-36 MH and PDI. The PIPS-cf showed significant, but small correlations with these variables. Also, both subscales had small correlations with the RAND-36 PF and pain intensity. Correlations that deviated from expectation were a zero correlation between both PIPS subscales and the FFMQ nonreacting facet, and a positive correlation between the PIPS-av and the FFMQ observing facet.



Table 3. Means, standard deviations and correlations for outcome variables with PIPS sub- and total scales and five FFMQ facets

	Mean (sd)	PIPS-av	PIPS-ct	PIPS	ffmq-obs	ffmq-desc	ffmq-aw	ffmq-nonj	ffmq-nour
FFMQ									
Observing	24.75 (5.77)	.217**	.014	.177**					
Describing	25.91 (6.43)	-.203**	-.098	-.195**					
Act aware	26.40 (6.58)	-.346**	-.137*	-.323**					
Nonjudging	27.42 (6.45)	-.392**	-.181**	-.374**					
Nonreacting	24.09 (5.55)	-.013	-.035	-.023					
MPI Interference	34.14 (10.25)	.477**	.220**	.457**	.066	-.170*	-.243**	-.228**	-.037
Rand-36									
Mental Health	63.34 (23.06)	-.544**	-.305**	-.539**	-.087	.314**	.456**	.517**	.195**
Physical Functioning	44.72 (20.35)	-.243**	-.180**	-.257**	-.095	.136*	-.014	.137*	-.017
PDI	39.90 (11.73)	.421**	.169*	.394**	.183*	-.123	-.159*	-.162*	-.054
Pain intensity (NRS)	6.41 (1.78)	.211**	.244**	.254**	-.067	-.134*	-.075	-.094	-.112

Notes: \* = p < .05; \*\* = p < .01; PIPS-av = PIPS avoidance subscale; PIPS-ct = PIPS cognitive fusion subscale; PIPS = PIPS total scale; fmq-obs = FFMQ observing facet; fmq-desc = FFMQ describing facet; fmq-aw = FFMQ acting with awareness facet; fmq-nonj = FFMQ nonjudging facet; fmq-nour = FFMQ nonreacting facet.

With regard to incremental validity, Pearson correlation coefficients between the five FFMQ facets and outcome variables used to assess incremental validity were added in Table 3. The total amount of variance that could be explained by the model including both the FFMQ facets and the PIPS subscales ranged from 5.7% (RAND-36 PF) to 45.5% (RAND-36 MH) (see Table 4). The PIPS subscales, mainly PIPS-av, were able to explain additional variance beyond relevant FFMQ facets in all outcome variables, ranging from 4.5% (RAND-36 PF) to 15.8% (MPI Interference).

Table 4. Hierarchical multiple regression analyses for the contribution of the PIPS beyond the FFMQ in explaining relevant outcome variables

		Beta (step 2)	$\Delta R^2$	Adjusted R <sup>2</sup>
<u>MPI Interference</u>				
<i>Step 1</i>	Describing	-.053		
	Awareness	-.067		
	Nonjudging	-.006	.079**	
<i>Step 2</i>	Avoidance	.433**		
	Cognitive Fusion	.017	.158**	.219**
<u>PDI</u>				
<i>Step 1</i>	Awareness	-.019		
	Nonjudging	.012	.034*	
<i>Step 2</i>	Avoidance	.425**		
	Cognitive Fusion	-.015	.143**	.162**
<u>Rand-36 MH</u>				
<i>Step 1</i>	Describing	.057		
	Awareness	.159*		
	Nonjudging	.276**		
	Nonreacting	.162**	.355**	
<i>Step 2</i>	Avoidance	-.333**		
	Cognitive Fusion	-.079	.115**	.455**
<u>Rand-36 PF</u>				
<i>Step 1</i>	Describing	.083		
	Nonjudging	.028	.029*	
<i>Step 2</i>	Avoidance	-.176*		
	Cognitive Fusion	-.090	.045**	.057**

Note: \* =  $p < .05$ ; \*\*  $p < .01$ ; MPI Interference = Multidimensional Pain Inventory, subscale Pain Interference; PDI = Pain Disability Index; Rand-36 MH = Rand-36 Mental Health component; RAND-36; PF = Rand-36 Physical Functioning component

## DISCUSSION

The first aim of this study was to evaluate the psychometric properties of the Psychological Inflexibility in Pain Scale (PIPS) in a heterogeneous clinical sample of 428 chronic pain patients. The proposed two-factor solution (Wicksell et al., 2010), measuring *avoidance of pain* (8 items) and *cognitive fusion with pain* (4 items), is supported by acceptable to good model fit indices in confirmatory factor analyses, good internal consistencies, and factor structure reveals two discernible but related subscales. Further outcomes mostly provide evidence for the relationships we hypothesised a priori with theoretically related constructs. In general, the results of this study are in line with outcomes of a previous validation study in a specific sample of individuals experiencing Whiplash Associated Disorder (WAD) (Wicksell et al., 2010), and provide further support for the psychometric properties of the PIPS in a heterogeneous clinical sample of individuals experiencing chronic pain.

The second aim of our study was to investigate the relationship between the PIPS subscales and mindfulness as measured with the FFMQ. Higher scores on the PIPS as a measure of psychological inflexibility are related to lower scores on the describing, awareness and nonjudgmental aspects of mindfulness. More specifically, our results support findings from earlier studies revealing that the nonjudgmental aspect of mindfulness in particular - defined in terms of taking a nonevaluative stance towards thoughts and feelings - is related to acceptance (e.g. Baer et al., 2006; McCracken, Gauntlett-Gilbert, & Vowles, 2007; McCracken & Zhao-O'Brien, 2010; Veehof, Ten Klooster, et al., 2011). Also, the cognitive fusion subscale was related most highly to the nonjudging facet of mindfulness, which fits the theoretical notion of both concepts (Baer et al., 2006; Hayes et al., 2012).

Furthermore, the pain avoidance subscale explains additional information in outcomes beyond FFMQ facets, and additionally, together both scales are able to explain a substantive amount of variance in psychological and physical outcome variables. Overall, these outcomes fit the theoretical notion of ACT, suggesting that mindfulness, acceptance and cognitive defusion are related processes contributing independently to the promotion of psychological (in)flexibility (Hayes et al., 2006, 2012; McCracken et al., 2007; McCracken & Zhao-O'Brien, 2010).

There are a few findings that deserve further exploration. We found no relationship between avoidance of pain and the observing facet of mindfulness. These findings corroborate previous research indicating that this subscale only relates adequately to theoretically related variables in people having meditation experience (Baer et al., 2006; Veehof, Ten Klooster, et al., 2011). Furthermore, there was no significant relationship between avoidance of pain and the nonreacting facet, the latter defined as allowing thoughts and feelings to come and go without getting caught up in or carried

away by them (Baer, 2003). This contradicts the suggestion that both nonjudging and nonreactivity may be seen as ways of operationalising acceptance (Baer, 2003; Baer et al., 2006). As from a theoretical point of view, we find no reason to discard this hypothesis; future research should assess this issue further.

As in previous studies, we found differences between the PIPS avoidance and cognitive fusion subscales in the magnitude of correlations and power to explain additional variance in outcome variables (Wicksell et al., 2010, 2008). We presume that the item content of the cognitive fusion subscale may play a role. First of all, cognitive fusion is defined as a *process* in which interpretative thoughts are regarded as true and literal representations of an actual event or situation (Hayes et al., 2006). However, in the PIPS cognitive fusion is restricted to thoughts about not being able to stand the pain and that it has to be avoided (Wicksell et al., 2010). The items of the scale therefore focus on the *content* of thoughts about pain and not on the actual *process* of cognitive fusion. Moreover, the cognitive fusion subscale has become a quite narrow operationalisation of possible thoughts one can become fused with when experiencing chronic pain. Finally, a closer look at the cognitive fusion items reveals that the items seem to measure avoidance to some degree. For example, an item like 'I would do anything to get rid of my pain', could be seen as a dominant pattern of experiential avoidance. Focusing more on the process of cognitive fusion and broadening or revising item content of the cognitive fusion subscale will promote the utility of the subscale. Overall, further research is warranted to assess if the PIPS is a representative measure of psychological inflexibility - or perhaps rather the 'open response style' - or is only useful to assess pain avoidance as a more narrow construct (Hayes et al., 2012). In the meantime, we would recommend including the cognitive fusion items in the total PIPS score and interpret the scale as a whole.

As the PIPS has been developed primarily as a process measure of central therapeutic processes within ACT, we recommend to use the questionnaire in clinical settings where exposure and acceptance-based treatments are applied. Specifically, the PIPS can be assessed at baseline and set time-intervals during treatment to monitor changes in psychological inflexibility and increase the understanding of pain-related disability in individual patients. The information provided can subsequently guide tailoring of individual treatment content and intensity to the patients' needs.

There are a few limitations to this study. First, this study concerns a cross-sectional design. Future research should examine the relationship between aspects of psychological flexibility over time. In addition, research should focus on the stability of the PIPS over time and its predictive ability in longitudinal designs. Another limitation is that this study only included the PIPS and the FFMQ as representative measures of processes within the ACT framework. Future studies should also include other measures of acceptance, such as the AAQ-II (Acceptance & Action Questionnaire-II; (Bond et al., 2011) or CPAQ (McCracken

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et al., 2004), and measures of the engaged response style (e.g. CPVQ; McCracken & Yang, 2006, or the Engaged Living Scale, ELS (Trompetter et al., in press). By pushing the rapidly growing range of studies in this area another step further, more knowledge will develop on the possibilities for interchangeable or complementary use of questionnaires to assess a broad range of processes of change within ACT. We believe this study has contributed to this endeavour.

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# CHAPTER 4

Measuring values and committed action with the  
Engaged Living Scale (ELS): Psychometric evaluation in a  
nonclinical and chronic pain sample

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## ABSTRACT

This article describes the development and evaluation of the Engaged Living Scale (ELS) as a new self-report, process-specific measure to assess an engaged response style as conceptualized in Acceptance and Commitment Therapy (ACT). The psychometric properties of the ELS test scores were evaluated in both a nonclinical sample (N = 439) and a clinical sample consisting of chronic pain patients who participated in a study on the effects of an online ACT intervention (N = 238). Item analysis and exploratory factor analysis in the nonclinical sample suggested a 16-item version of the ELS with two subscales, Valued Living (ten items) and Life Fulfillment (six items). A bifactor model, with two specific factors and one general underlying factor showed the best fit in confirmatory factor analyses in the chronic pain sample. In both samples, the scores on the ELS and its subscales showed good internal consistency and construct validity by consistent patterns of relationships with theoretically related process- and outcome variables, such as psychological well-being, anxiety/depression, acceptance, mindfulness and pain interference in daily life. Furthermore, in the chronic pain sample the ELS showed incremental validity in explaining anxiety and depression, positive mental health and pain interference beyond both acceptance and mindfulness. This study suggests the ELS shows promise as a useful tool for the measurement of an engaged response style, enabling more comprehensive evaluation of working mechanisms of ACT.

## INTRODUCTION

New developments within Cognitive Behavioral Therapies emphasize accepting rather than controlling and changing negative private experiences, such as depressive thoughts and chronic pain. An example of newly developed treatments from this perspective on psychopathology is Acceptance & Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999, 2011), as ACT aims to enhance acceptance in order to be able to evaluate and engage in valued life activities. A growing body of research shows ACT to be effective for a range of psychopathology and other problems, such as depression and anxiety (e.g. Bohlmeijer, Fledderus, Rokx, & Pieterse, 2011; Fledderus, Bohlmeijer, Pieterse, & Schreurs, 2012; Forman, Herbert, Moitra, Yeomans, & Geller, 2007; Roemer, 2009; Twhig, Hayes, & Masuda, 2006), stress (Brinkborg, Michanek, Hesser, & Berglund, 2011), psychotic disorders (Gaudio & Herbert, 2006) and chronic pain (McCracken, Vowles, & Eccleston, 2005; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011; Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008; for a general review of the effectiveness of ACT, see Ost, 2008; Powers, Zum Vorde Sive Vording, & Emmelkamp, 2009).

In ACT, *experiential avoidance* (EA) is seen as the opposite of acceptance. EA can be defined as the attempt to escape or avoid private events such as emotions, memories or thoughts, even when doing so causes psychological harm (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). Multiple studies have shown that EA is a primary mechanism in explaining emotional, psychological and social problems (Biglan, Hayes, & Pistorello, 2008; Hayes, Luoma, Bond, Masuda, & Lillis, 2006). Although the use of EA can regulate behavior effectively in certain situations in the short term, in the long term avoidance strategies generate an inflexible and narrow range of possible behaviors. This psychological and behavioral inflexibility prevents a person from performing valued life activities, thereby disabling one from leading a meaningful life (Hayes et al., 2006). The ACT model of human functioning describes six processes that together compose *psychological flexibility*, the ability to act effectively in accordance with personal values in the presence of negative private experiences. In the latest update of the ACT model (Hayes, Strosahl, & Wilson, 2011), the six core processes are paired together in three different response styles, the first being an 'open response style'. *Acceptance* and *cognitive defusion* (letting go of entanglement with negative and unwanted thoughts and experiences by viewing them from a distance in a non-judgemental way) are both key processes in creating an openness to direct personal experience. Being open and accepting towards direct personal experience promotes flexibility, thereby enabling a person to (re-)evaluate and focus on where one wants to go in life. The processes in ACT related to this evaluation and the performance of valued and meaningful life activities are *values* and *committed action*. These two processes are together defined as an 'engaged response style'. Finally, a 'centered response style' consists of the processes *present moment* and *self-as-context*,

helping a person in consciously centering in the here-and-now. This grounded awareness in the present moment is a necessary premise to be open and flexible to experience and undertake valued daily life activities (Hayes et al., 2011).

The ACT model enables investigation of the mediating or working mechanisms of the individual treatment processes or response styles. This can help to specify what therapies or specific treatment processes work best for whom. The development of process-specific questionnaires is therefore necessary. Various measures are already available to assess processes from the framework of ACT. For example, the most frequently used measure of psychological inflexibility is the Acceptance and Action Questionnaire (AAQ; Bond et al., 2011; Bond & Bunce, 2003; Hayes et al., 2004). Both the AAQ-I (16 items; Hayes et al., 2004) and the AAQ-II (Bond et al., 2011; Fledderus, Oude Voshaar, ten Klooster, & Bohlmeijer, 2012) are available to measure different aspects of psychological inflexibility, such as avoidance of negative private events and the need for emotional or cognitive control (Hayes et al., 2004). Another example of available process measures is the Five Facet Mindfulness Questionnaire to assess the centered response style, in particular the process of mindfulness (FFMQ; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). In the FFMQ, mindfulness is defined as ‘a state of being attentive to and aware of experiences occurring in the present moment in a nonjudgmental and accepting way’ (Baer, 2003; Baer et al., 2006). Five different facets of mindfulness are assessed with the FFMQ, such as the ability to describe inner experiences and the ability to relate to these inner experiences in a nonjudgmental way. Unfortunately, with regard to the measurement of the engaged response style there is a lack of process-specific questionnaires that are easy to administer and suitable for scientific research in both clinical and nonclinical populations. This study therefore aims to develop and evaluate the psychometric properties of a new measure of an engaged response style or the process of ‘engaged living’, the Engaged Living Scale (ELS).

From the perspective of ACT, values can be seen as an intrinsic motivating framework for leading a meaningful life. Values are not goals or ends in themselves but rather freely chosen, ongoing and dynamic patterns of activity or ‘paths to be taken’. These verbally constructed ‘paths to be taken’ cannot be found, completed or achieved, but are individually defined, re-evaluated and elaborated in the course of life (Hayes et al., 2011). The process of committed action helps people to translate values into smaller goals and steps to take in the short term. As the daily practice of values can induce a renewed struggle with emotions and experiences that prompted avoidance strategies in the past, commitment is necessary to keep on the valued path despite barriers one will encounter (Hayes et al., 2006). With regard to the measurement of engaged living a few measures have been created. For example, the Bull’s Eye Values Survey (BEVS; Lundgren, Luoma, Dahl, Strosahl, & Melin, 2012) is an idiographic measure that stems from clinical practice. The BEVS measures 1) values attainment and 2) the extent to which obstacles or barriers

prevent one from values attainment by use of dartboards with seven rings. For four life domains (e.g. work/education) a person describes personal values in terms of the qualities or expectations in that specific domain. Hereafter one marks how close one is living to these values on the dartboard. In the second part of the questionnaire, obstacles are defined and written down that stand between the current and valued life. Thereafter it is estimated to what extent the obstacles(s) prevent one from living one's life in a way that is in keeping with personal values. A first validation study of the BEVS in a small sample of South African adults suffering from epilepsy and a sample of Swedish university students indicated that the questionnaire is reliable and correlates moderately with theoretically related variables (Lundgren et al., 2012). However, due to its idiographic and clinical nature the questionnaire focuses on the description and evaluation of the specific content of individual values. This focus on content makes the questionnaire very time-consuming to fill in, disabling fast (online) data collection in larger groups for use in scientific research.

In addition to the BEVS, the Valued Living Questionnaire (VLQ; Wilson, Sandoz, Kitchens, & Roberts, 2010) and the Chronic Pain Values Inventory (CPVI; McCracken & Yang, 2006) are available. Both questionnaires consist of two parts in which one rates 1) the 'importance' of predefined life domains (such as work, education, family and leisure time) and 2) the 'consistency' (VLQ) or 'success' (CPVI) with which one has lived in accordance with values in these life domains. The CPVI has been developed and validated specifically for chronic patients and has therefore limited generalizability. The VLQ on the other hand was developed as a general measure, validated in two undergraduate student populations (Wilson et al., 2010). Originally used as a qualitative measurement tool for clinical practice, the measure is quantified by creating a composite 'valued living score'. This overall score is taken as the average of the ten domain-specific products of 'importance' x 'consistency'. Although these product scores can be compared between people, the use of the product scores in the VLQ is problematic as it is not possible to determine or compare the underlying scales. In other words, a similar composite score for two individuals can reflect very different profiles on the individual domains and scales of the VLQ. This also seems to be a problem for the CPVI, as an overall 'discrepancy' score is calculated by subtracting individual scores on 'importance' from 'success'. A second problem is the fact that the authors of the VLQ propose that individuals are not expected to relate similarly to different life domains, which is also reflected in the low inter-total correlations found for the different domains. Therefore, one could argue about the possible lack of an underlying latent construct in the VLQ. In sum, all three available questionnaires focus on the content of domain-specific values within individuals. Although very useful in clinical practice, this focus makes filling in the questionnaires time-consuming or troubles the comparison of scores between different individuals. As questionnaires that focus on the *process* of engaged living are lacking in this area, it is

presently not possible to test the extent to which improvement in this response style serves to mediate improvements in mental health and behavioral effectiveness.

We therefore developed the Engaged Living Scale (ELS) as a process measure of engaged living. In the present article, we reflect on the development of the ELS and assess the psychometric properties of the ELS test scores. After reporting the steps taken to generate an initial item pool, two studies are described. In the first study, we assess the psychometric properties of the ELS in a nonclinical adult sample ( $N = 439$ ). Specifically, we performed item analysis and exploratory factor analysis on the initial 26-item pool of the ELS and investigated internal consistency and construct validity of the remaining 16 items by assessing relationships with other theoretically related constructs. In the second study we cross-validated the 16-item ELS in a sample of chronic pain patients ( $N = 238$ ). In this sample we further examined its underlying structure by performing three different confirmatory factor analyses among which a bifactor model (Reise, Moore, & Haviland, 2010; Reise, Morizot, & Hays, 2007). Furthermore, internal consistency, construct validity and incremental validity beyond acceptance and mindfulness as relevant and related aspects from the framework of ACT were evaluated.

To assess construct validity, in both studies the relationship of the ELS with theoretically related variables was assessed. These variables are processes variables from the framework of ACT that measure constructs theoretically related to engaged living, as well as important outcomes variables in mental health (study 1) and chronic pain (study 2). In general, we expected that the ELS shows positive moderate correlations with acceptance and mindfulness as related constructs from the framework of ACT (Hayes et al., 2011). Furthermore, based on ACT theory and outcomes of previous studies on acceptance (AAQ-II) and mindfulness (FFMQ) (e.g. Baer et al., 2008, 2006; Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011; Fledderus et al., 2012; Hayes et al., 2006), we expected moderate to high, positive correlations between test scores on the ELS and positive outcomes of mental health (i.e. psychological well-being and positive mental health) and moderate to high, negative correlations with anxiety and depression. With regard to the relationship between the ELS and personality we based our hypotheses on previous studies in the area of personality and ACT (Bond et al., 2011; Costa & McCrae, 1992). First, we hypothesized that people high in neuroticism would be less likely to engage in life, perhaps because they are more vulnerable to psychological distress. We also expected that extraversion would be related to engaged living, as higher levels of extraversion are associated with assertiveness, enthusiasm, and engagement with the external world. For both personality constructs we expected moderate to high correlations with the ELS. Finally, following Bond et al. (2011), we expected no relationship of the ELS with the personality facet of openness to experience, as people interested in intellectual and cultural pursuits need not be high in engagement in life. Furthermore, based on previous studies on ACT in the area of chronic pain (e.g.

McCracken & Eccleston, 2005; Trompetter et al., 2013; Vowles & McCracken, 2008; Wicksell, Lekander, Sorjonen, & Olsson, 2010), non-significant to small negative correlations were anticipated with pain intensity and small to moderate correlations were expected with physical health (positive), pain disability (negative) and pain interference in daily life (negative). As pain interference in daily life is a more psychologically defined variable than the other measures related to pain disability, we expected the highest correlations between the ELS and pain interference.

## ITEM GENERATION

In this section we will describe the steps taken to form an initial item pool for assessing an engaged response style from the framework of ACT. Prior to item generation different facets of engaged living were identified based on key literature regarding the framework of Acceptance & Commitment Therapy (Hayes et al., 2011) and valued living from the perspective of ACT (Wilson et al., 2010; Wilson & Murrell, 2004). The preliminary facets that were formulated were 'values' (awareness and knowledge of personal values as an intrinsic, dynamic and on-going motivating framework for choosing direction in life), 'committed action' (undertaking actions and performing behaviors that are congruent with chosen values, even when barriers or obstacles are encountered) and 'evaluation' (the evaluation of the outcome or fulfillment of living in accordance with values and performing committed actions). Both the facets 'values' and 'committed action' are central processes from the ACT-framework that belong to the engaged response style (Hayes et al, 2011). The 'evaluation' facet was developed to be able to operationalize the dynamic, on-going act of valued living that is central to the definition of an engaged response style.

Based on these facets, a preliminary item pool of 31 items was created by a team of three scientists with ample experience in ACT. The item pool existed of theoretically derived items (n = 15) and items derived from or based on items from theoretically related questionnaires on meaning in life and authenticity. These questionnaires were the Life Regard Index (Battista & Almond, 1973; n = 7), the Meaningful Life Measure (Morgan & Farsides, 2007; n = 5) and the Authenticity Inventory-3 (Kernis & Goldman, 2006; n = 4). Items from the Life Regard Index and the Meaningful Life Measure were used primarily to formulate items for the facets 'values' and 'evaluation', and items from the Authenticity Inventory-3 for the facet 'committed action'. 5-point Likert scale answering categories, ranging from 'completely disagree' to 'completely agree', were used.

The item pool was tested in a pilot-study in which 108 undergraduate students were asked to fill in the questionnaire. Participants in the pilot study were mostly female (75.9%) and were on average 22.48 years old (SD = 4.56, range = 18 – 52 years). In



addition, two researchers/clinical psychologists with ample experience in working with ACT, who did not select items for the preliminary item pool, reflected on all items.

Based on both the descriptive statistics and the content of each item, the item pool was evaluated again by all five members of the research team with a specific focus on item overlap and transparency of item wordings. In total, seven items were omitted from the initial item pool. Two of these items were omitted because item wordings were too difficult and replaced by newly developed items. The other five items showed extremely skewed responses (kurtosis > 2, 88% of scores 'agree or totally agree';  $n = 1$ ), low item-total correlations ( $r < .35$ ) and overlap with other questions ( $r > .70$ ;  $n = 1$ ). Based on the final evaluation the item wordings were made more transparent and comprehensible for 4 of the 26 remaining items. Finally, it was decided to reframe five items to assure all items were framed in the same (positive) direction.

The final item pool existed of thirteen rationally derived items, six items based on items from the Life Regard Index, four items based on items from the Meaningful Life Measure and three items based on items from the Authenticity Inventory-3. The final item pool of 26 items was used in study 1.

## STUDY 1

### METHOD

#### Participants and procedure

The participant sample ( $N = 439$ ) consisted of 386 parents and grandparents of undergraduate students, and 53 undergraduate students. Mean age of the participants was 57.43 years ( $SD = 16.80$ ), 58.3% was female and 65.1% was married. Educational level varied from 18.7% lower educated (< 12 years of education), 45.7% intermediate educated (< 16 years of education) and 35.6% highly educated participants (> 16 years of education). Individuals were invited through (grand)sons, (grand)daughters or undergraduate professors to complete an online battery of questionnaires. Ordering of the questionnaires in the online measurement battery was the same for all participants.

#### Measures

The battery of questionnaires included the 26-item ELS and the following questionnaires.

The Acceptance and Action Questionnaire-II (AAQ-II) (Bond et al., 2011) is a 10-item questionnaire measuring psychological inflexibility. Participants rated a 7-point Likert scale (1 = 'never true', 7 = 'always true'). A total score, ranging from 10 to 70, was computed by summing the scores on the individual items. Higher scores indicated higher levels of psychological flexibility. The Dutch AAQ-II (Fledderus et al., 2012; Jacobs, Kleen, Groot, & A-tjak, 2008) showed good internal consistency in the present study ( $\alpha = .88$ ).

The Short-Form 12 Health Survey (SF-12) (Ware, Kosinski, & Keller, 2009) is a shortened version of the Short-Form 36 Health Survey measuring health related quality of life. The SF-12 measures physical and mental health. The Physical Component Score (PCS) considers limitations and problems due to physical impairment and general feelings of physical health. The Mental Component Score (MCS) considers limitations and problems due to mental impairment and general feelings of mental health. Higher scores indicate higher levels of physical and mental health. The Dutch SF-12 as based on the Dutch SF-36 (Aaronson et al., 1998) showed good internal consistency in the present study ( $\alpha = .88$ ).

The NEO Five Factor Inventory (NEO-FFI) (Costa & McCrae, 1992) measures five different dimensions of personality. In this study we used the dimensions 'neuroticism', 'extraversion' and 'openness to experience'. All three dimensions were measured each with 12 items on a 5-point Likert Scale (1 = 'strongly disagree', 5 = 'strongly agree'). A total score for each dimension, ranging from 12 to 60, was computed by summing the scores on each of the 12 individual items. Higher scores indicated more neuroticism, extraversion and openness to experience. All three subscales of the NEO-FFI (Hoekstra, Ormel, & de Fruyt, 1996) showed good internal consistency in the present study (neuroticism,  $\alpha = .86$ ; extraversion,  $\alpha = .78$ ; openness to experience,  $\alpha = .76$ ).

The Psychological Well-Being Scales (PWB Scales) (Ryff & Keyes, 1995; Ryff, 1989) were developed to measure psychological well-being. The questionnaire is comprised of six different dimensions of psychological well-being, including 1) a positive attitude towards the self (self-acceptance), 2) having quality relationships with others (positive relationships with other), 3) a sense of continued growth and development as a person (personal growth), 4) a sense of self-determination (autonomy), 5) a sense of mastery and control in managing one's life and the world (environmental mastery) and 6) the feeling or belief that one's life has meaning and purpose (purpose in life). The original version of the questionnaire (Ryff, 1989) consists of 120 items; in this study the medium form of 54 item was used. All six dimensions consist of nine items that are score on a 6-point Likert scale (1 = 'completely disagree', 6 = 'completely agree'). Higher scores on a scale represent higher psychological well-being on that specific domain. The different subscales of the PWBS showed good internal consistency in the present study (self-acceptance,  $\alpha = .80$ ; positive relations,  $\alpha = .79$ ; personal growth,  $\alpha = .83$ ; autonomy,  $\alpha = .79$ ; environmental mastery,  $\alpha = .80$ ; purpose in life,  $\alpha = .75$ ).

## RESULTS

### Item analysis, factor structure and internal consistencies

Item analysis and exploratory factor analysis were performed using the program IBM SPSS Statistics 20 (IBM Corp., Armonk, NY). Frequency distributions, inter-correlations between items and item-total statistics were computed and analyzed. Distribution of the item

scores was assessed by visual inspection and by assessing skewness and kurtosis statistics. Skewness did not exceed 1 for any of the items. As kurtosis was higher than 1 for some items, five items were omitted from the item pool due to extreme responses in both study samples. The exclusion of these items was based on both study samples as the descriptive statistics of all items varied considerably between both study groups. Overall, the variance in scores was higher for the chronic pain sample. Therefore, it was decided to excluded items with > 60% 'agree' in the nonclinical sample *and* > 45% 'agree' in the chronic pain sample used in study 2. The 21 remaining items were subjected to an exploratory maximum likelihood factor analysis with direct oblimin rotation (Fabrigar, Wegener, MacCallum, & Strahan, 1999). On the basis of this exploratory factor analysis (EFA), two factors were identified. Although the pattern matrix produced three factors with eigenvalues >1, the scree plot indicated two factors. This indication was supported by a low eigenvalue (1.038) and small additional explained variance of the third factor (2.7%). Further evaluation of item content revealed that two of three items in the third factor originated from the Meaningful Life Measure. The factor seemed to reflect a general evaluation of life and was very similar in item content to the second factor. Based on these statistical and theoretical considerations it was concluded that the third factor did not contribute sufficiently beyond the first two factors. The three items forming the third factor were therefore removed from further analysis. Finally, for each of the two remaining factors one item was removed due to low factor loadings (< .35).

The resulting two-factor solution consisted of 16 items that explained 43.64% of the variance in scores (the explained variances reported for both the total scale and subscales were obtained prior to rotation). Table 1 presents the descriptive statistics (means and standard deviations), pattern coefficients and structure coefficients for the remaining items. The first factor consisted of ten items and was labeled 'Valued Living' (eigenvalue 5.91; 36.95% explained variance). The factor is composed of items measuring the recognition and knowledge of personal values and undertaking behavioral actions congruent with these values. The second factor consisted of six items and was labeled 'Life Fulfillment' (eigenvalue 1.07; 6.69% explained variance). The factor is composed of items regarding the evaluation and sense of fulfillment in life as a consequence of recognizing and living in accordance with personal values. The intercorrelation between both factors was moderately high ( $r = -.64$ ). Calculation of Cronbach's  $\alpha$  for the test scores of both subscales and the total scale of the ELS revealed good to excellent internal consistencies, ranging from .86 (both Valued Living and Life Fulfillment) to .90 (total scale).

Table 1 Descriptive data, pattern coefficients, structure coefficients and Cronbach's  $\alpha$  for the two-factor solution from exploratory factor analysis in a nonclinical sample

Item	Mean (SD)	Pattern coefficients		Structure coefficients	
		VL	LF	VL	LF
		$\alpha = .86$	$\alpha = .86$		
1. I have values that give my life more meaning	4.01 (.70)	<b>.72</b>	.11	<b>.69</b>	-.49
2. I know what motivates me in life	3.94 (.65)	<b>.72</b>	.12	<b>.65</b>	-.36
3. I believe that I've found important values to live according to	4.15 (.69)	<b>.64</b>	.04	<b>.65</b>	-.35
4. I know exactly what I want to do with my life	3.82 (.74)	<b>.63</b>	-.08	<b>.63</b>	-.47
5. I make choices based on my values, even if it is stressful	3.80 (.72)	<b>.59</b>	-.02	<b>.63</b>	-.47
6. I know how I want to live my life	4.02 (.68)	<b>.57</b>	-.10	<b>.62</b>	-.38
7. I know what I want to do with my life	3.94 (.79)	<b>.56</b>	-.11	<b>.60</b>	-.40
8. I believe that my values are really reflected in my behaviour	3.78 (.72)	<b>.54</b>	-.07	<b>.58</b>	-.41
9. I believe that how I behave fits in with my personal wants and desires	3.91 (.60)	<b>.44</b>	-.18	<b>.55</b>	-.46
10. My emotions don't hold me back from doing what's important to me	3.79 (.75)	<b>.39</b>	-.21	<b>.53</b>	-.46
11. I live the way I always intended to live	3.39 (.92)	-.01	<b>-.80</b>	.50	<b>-.79</b>
12. I am satisfied with how I live my life	3.90 (.75)	-.04	<b>-.79</b>	.57	<b>-.79</b>
13. Nothing can stop me from doing something that's important to me	3.36 (.97)	.10	<b>-.72</b>	.47	<b>-.77</b>
14. I believe that I am living life to the full right now	3.47 (.94)	-.05	<b>-.69</b>	.55	<b>-.69</b>
15. I make time for the things that I consider important	3.75 (.76)	.06	<b>-.58</b>	.40	<b>-.66</b>
16. I feel that I am living a full life	3.77 (.88)	.19	<b>-.58</b>	.43	<b>-.61</b>

Note: SD = standard deviation; VL = Valued Living, LF = Life Fulfillment; Pattern coefficients (representing the unique relationship between a factor and the item, controlling for the other factor) and structure coefficients (simple correlations between the factor and the item, not adjusted for the correlation between the factors) in bold are included in the factors Valued Living and Life Fulfillment.

Finally, the root mean square error of approximation (RMSEA), the standardized root mean square residual (SRMR) and the comparative fit index (CFI) were calculated for the resulting 16-item two-factor solution (Gignac, 2009). For the RMSEA and SRMR, values  $\leq .08$  and  $\leq .05$ , respectively, were considered indicative of acceptable and good model fit. For the CFI values  $\geq .90$  were considered acceptable, whereas values  $\geq .95$  were

considered good (Bandalos & Finney, 2010; Browne & Cudeck, 1993; Hu & Bentler, 1999). All model fit indices indicated acceptable to good model fit in the present sample (RMSEA = .066, SRMR = .039, CFI = .936), justifying further exploration of model fit and dimensionality of the ELS by use of confirmatory factor analysis in study 2.

### Descriptive statistics and construct validity

To assess construct validity, Pearson's correlations coefficients were calculated between the summed ELS total and subscale scores and test scores for acceptance (AAQ-II), physical and mental health (SF-12), the personality domains neuroticism, extraversion and openness (NEO-FFI) and the six facets of psychological well-being (PWB). Correlations between .50 and 1.00 were considered strong, correlations between .30 and .50 were considered moderate, correlations between .10 and .30 as small and correlations < .10 as weak (Cohen, 1988).

Table 2. Descriptive statistics and Pearson's correlations coefficients for the ELS and measures considered related theoretically in a nonclinical sample

	Mean (SD)	Valued Living	Life Fulfillment	Total Scale
<u>ELS</u>				
Total scale	60.80 (7.83)	.92*	.89*	--
Valued Living	39.14 (4.66)	--	.62*	.92*
Life fulfillment	21.62 (4.03)	.62*	--	.89
AAQ-II	40.27 (6.47)	.43*	.49*	.51*
<u>SF-12</u>				
Physical health	16.25 (3.09)	.15*	.25*	.22*
Mental health	17.34 (2.60)	.39*	.50*	.49*
<u>NEO-FFI</u>				
Neuroticism	27.30 (7.30)	-.47*	-.51*	-.55*
Extraversion	21.22 (5.99)	.45*	.47*	.51*
Openness	37.90 (6.79)	.14*	.01	.09
<u>PWBS</u>				
Self-acceptance	40.03 (5.84)	.51*	.60*	.61*
Positive relations	41.82 (5.76)	.45*	.47*	.51*
Personal growth	38.33 (6.87)	.38*	.25*	.35*
Autonomy	39.51 (5.92)	.40*	.31*	.40*
Environmental mastery	41.47 (5.48)	.55*	.61*	.64*
Purpose in life	39.68 (5.82)	.54*	.47*	.56*

Note: N = 439; \* = all correlations are significant at  $p < .01$ . SD = standard deviation; ELS = Engaged living Scale; AAQ-II = Acceptance and Action Questionnaire-II; SF-12 = 12-item Short Form Health Survey; NEO-FFI = NEO – Five Facet Inventory; PWBS = Psychological Well-Being Scales

Means and standard deviations for all measures and correlations with the ELS test scores can be found in Table 2. In line with expectation, moderate (to high) correlations were found for both subscale and the total scale scores with the AAQ-II test scores. Positive moderate to high correlations were found with the SF-12 Mental Component Score and all six subscales of the PWB scales. Furthermore, a moderate (Valued Living) to high (Life Fulfillment) correlation was found with the Neuroticism dimension of personality. In addition, similar positive correlations were found for the Extraversion dimension of personality, while (contrary to our hypothesis) no correlations were observed with the personality dimension Openness to experience. Finally, as expected, small negative correlations were found between the ELS subscales and the SF-12 Physical Component Score.

## CONCLUSION

The aim of this first study was to examine the psychometric properties of the ELS test scores in a nonclinical sample. An exploratory maximum likelihood factor analysis with direct oblimin rotation revealed a two-factor solution with 16 items, measuring 'Valued Living' and 'Life Fulfillment'. Furthermore, Pearson's correlation coefficients were in line with expectations, in general showing moderate to high correlations in the hypothesized direction for both the total ELS and the subscales Valued Living and Life Fulfillment with measures of mental health, psychological well-being, neuroticism, extraversion and acceptance. Small correlations existed for both subscales with physical health. Overall, these results provided preliminary evidence for the factor structure, internal consistency and construct validity of the ELS test scores in a nonclinical sample.

## STUDY 2

In the second study, we further investigated the factor structure of the ELS. Three different confirmatory factor analyses to assess the dimensionality of the ELS were performed in a sample of chronic pain patients. In addition to internal consistency, both construct validity and incremental validity of the ELS above and beyond measures of acceptance in chronic pain and mindfulness were assessed.

## METHOD

### Participants

Baseline data from a randomized controlled trial (N = 238) on the effectiveness of an online ACT- and mindfulness based self-help program on pain interference in daily life were used. In February 2012, participants were recruited through advertisements in

Dutch newspapers and through online patient platforms. The target group of the intervention was described as people experiencing chronic pain that interfered with their daily living and with performing important and valued life activities. Inclusion criteria were an age of 18 years or older, experiencing chronic pain on a daily basis (at least three days per week) for at least six months. People with severe psychological distress were excluded from the study and advised to seek help from their general practitioner (total score > 1 standard deviation (total score > 24) above the mean score on the Hospital Anxiety Depression Scale (HADS; Zigmond & Snaith, 1983) compared to chronic pain patients admitted to receive intramural multidisciplinary pain treatment in a local rehabilitation centre), as severe psychological distress would require more intensive treatment. Another exclusion criterion was a low score on psychological inflexibility (> 2 standard deviations above the average score on the Psychological Inflexibility in Pain Scale (PIPS; Wicksell, Lekander, Sorjonen, & Olsson, 2010) compared to chronic pain patients admitted to receive intramural multidisciplinary pain treatment in a local rehabilitation centre), as this was the expected mediating mechanisms of treatment. Finally, prior to randomization people were excluded based on self-ratings of a) having no internet and/or e-mail address, b) having reading problems due to insufficient Dutch language skills or illiteracy and c) anticipating a lack of time to participate (approximately 30 minutes per day).

### **Procedure**

A total of 334 people responded to the advertisements and received an information letter explaining the study and an informed consent form. The consent form was signed and returned by 281 people who received an invitation to fill in an online screening questionnaire. Twelve people did not fill in the screening questionnaire. Furthermore, 25 people were excluded from further participation based on the exclusion criteria. Six participants did not fill in the remaining baseline questionnaire and were therefore excluded from random assignment to one of the intervention groups. Ordering of the questionnaires included in both the screening and the remaining baseline questionnaire battery was the same for all participants. In total, 238 participants were included in the study and randomly assigned to the ACT intervention (N = 82), a minimal intervention control condition based on Expressive Writing (Pennebaker, 1997) (N = 79), or to a waiting list condition (N = 77). More detailed information about the study can be found in Trompetter et al. (2013).

### **Measures**

The battery of questionnaires included the 16-item ELS and the following questionnaires.

The Multidimensional Pain Inventory (MPI) was developed to assess various aspects of chronic pain and disability (Kerns, Turk, & Rudy, 1985). The subscale pain interference (MPI Interference) measures the degree to which pain interferes in daily life

activities such as work, household work and social activities. The scale consists of nine items. All items can be answered on a 7-point Likert scale, ranging from zero ('no change/interference') to six ('much change/interference'). Total scores range from 0 to 54, with higher scores indicating more pain interference. Test Dutch version of the MPI (Lousberg et al., 1999) showed good internal consistency in the present study ( $\alpha = .86$ ).

The Psychological Inflexibility in Pain Scale (PIPS) (Wicksell et al., 2010; Wicksell, Renöfält, Olsson, Bond, & Melin, 2008) is a 12-item instrument measuring *psychological inflexibility*. The scale consists of two subscales measuring *avoidance* (eight items) and *cognitive fusion* (four items). Higher scores indicate more psychological inflexibility. All items have to be scored on a 7-point Likert-type scale ranging from 'never true' (1) to 'always true' (7). Total scores range from 8 to 56 (avoidance) and 4 to 28 (cognitive fusion). In the present study, the Dutch version of the PIPS (Trompetter et al., 2013) showed good internal consistency (avoidance,  $\alpha = .90$  ; cognitive fusion,  $\alpha = .63$  ; total scale  $\alpha = .87$ ).

The Five Facet Mindfulness Questionnaire - Short Form (FFMQ-SF) is a 24-item questionnaire measuring five facets of mindfulness, based on the original 39-item version of the FFMQ: observing (four items), describing (five items), acting with awareness (five items), nonjudging (five items) and nonreactivity (five items) (Baer et al., 2006; Bohlmeijer et al., 2011). All items are scored on a 5-point Likert-type scale ranging from (1) 'never or rarely true' to (5) 'very often or always true'. Facet scores range from 5 to 25 (except for the observe facet which ranges from 5 to 20). Higher scores indicate more mindfulness. The Dutch FFMQ (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011; Veehof, Ten Klooster, Taal, Westerhof, & Bohlmeijer, 2011) showed adequate to good internal consistency in the current study for four facets:  $\alpha = .71$  (observing),  $\alpha = .83$  (describing),  $\alpha = .81$  (acting with awareness),  $\alpha = .64$  (nonjudgemental), and marginal internal consistency for the facet score 'nonreactive' ( $\alpha = .58$ ).

The Mental Health Continuum-Short Form (MHC-SF) is a 14-item questionnaire that measures three dimensions of positive mental health (Keyes, 2002): emotional well-being (three items), defined in terms of positive feelings and satisfaction with life; psychological well-being (six items), defined in terms of positive functioning in individual life (self-realization); social well-being (six items), defined in terms of positive functioning in community life (being of social value). Participants are asked to rate the frequency of feelings they had experienced in the past month. Items are scored on a 6-point scale ranging from (1) 'never' to (6) 'every day'. Higher scores indicate better positive mental health. Test Dutch MHC-SF (Lamers, Westerhof, Bohlmeijer, ten Klooster, & Keyes, 2011; Lamers, Glas, Westerhof, & Bohlmeijer, 2011) had good internal consistency in this study:  $\alpha = .85$  (emotional well-being),  $\alpha = .73$  (psychological well-being) and  $\alpha = .82$  (social well-being).



Pain intensity was measured with an 11-point numeric rating scale (NRS), ranging from 'no pain' (0) to 'pain as bad as you can imagine' (10). The format of this rating is recommended in the last IMMPACT recommendations on core outcome measures in chronic pain research (Dworkin et al., 2005).

The Hospital Anxiety Depression Scale (HADS) measures presence and severity of anxiety and depressive symptoms (Zigmond & Snaith, 1983). Both the subscales *depression* and *anxiety* consist of seven items. For each item, answering categories a scored on a 4-point Likert scale ranging from zero ('not at all') to three ('very often'). A summed score can be achieved ranging from 0 – 21 for both subscales separately. In the present study the Dutch version of the HADS (Spinhoven et al., 1997) showed good internal consistency (depression,  $\alpha = .80$  ; anxiety,  $\alpha = .73$  ; total scale  $\alpha = .83$ ).

The Pain Disability Index (PDI) is an instrument developed to assess the degree to which chronic pain disables a person to perform daily activities (Pollard, 1984). Seven items regarding various activities are rated by the participants on a 0-10 point scale ranging from (1) 'no disability' to (10) 'total disability'. In the present study, the PDI showed good internal consistency ( $\alpha = .81$ ).

## RESULTS

### Confirmatory factor analysis (CFA)

To further examine the dimensionality of the ELS, three CFA models were tested and compared in the chronic pain sample using LISREL 8.70 (Scientific Software International, Lincolnwood, IL). First, a strict unidimensional model in which all 16 items loaded on a single factor was fitted to the data. Next, based on the exploratory factor analysis results in study 1, a correlated two-factor model was fitted in which six items loaded on the Life Fulfillment factor and ten items on the Valued Living factor. Finally, to evaluate the plausibility of scoring the ELS as a total scale as well as two subscales, a bifactor model was fitted in which each item loaded on a single general factor and on one specific (Valued Living or Life Fulfillment) group factor (Chen, Hayes, Carver, Laurenceau, & Zhang, 2012; Chen, West, & Sousa, 2010; Reise et al., 2010, 2007). Superior fit of the bifactor model would suggest that using total ELS scores may be a tenable addition to the use of subscale scores only.

Robust maximum likelihood estimation with Satorra-Bentler (SB) scaled statistics (Joreskog, Sorbom, Du Toit, & Du Toit, 2001) was used to account for the ordinal, non-normal nature of the item scores of the ELS. Several restrictions were applied to the models. In all three models, the variance of the factors was fixed to one and error terms were not allowed to correlate. In the two-factor model, items were constrained to load on one factor only and the two factors were free to correlate with each other. In the bifactor model, each item was constrained to load only on the general factor and its specific group

factor and the group factors were not allowed to correlate with each other or with the general factor. Model fit was assessed by the overall model SB chi-square statistic ( $SB\chi^2$ ), where smaller values indicate better fit, the root mean square error of approximation (RMSEA), the standardized root mean square residual (SRMR), the non-normed fit index (NNFI) and the comparative fit index (CFI). For the RMSEA and SRMR, values  $\leq .08$  and  $\leq .05$ , respectively, were considered indicative of acceptable and good model fit. For both the NNFI and CFI values  $\geq .90$  were considered acceptable, whereas values  $\geq .95$  were considered good (Bandalos & Finney, 2010; Browne & Cudeck, 1993; Hu & Bentler, 1999).

Table 3 displays the fit indices for the different factor models. The single-factor model yielded a poor fit to the data, suggesting that the ELS is not strictly unidimensional. Although the NNFI and CFI slightly exceeded the criteria for acceptable model fit, the RMSEA and SRMR did not approach acceptable thresholds. The correlated two-factor model showed a better fit to the data, with the RMSEA and SRMR approaching acceptable fit and the NNFI and CFI meeting the criteria for good fit. The intercorrelation between the two factors was moderate ( $r = .56$ ), suggesting that both measure related but somewhat distinct aspects of engaged living. The bifactor model, however, demonstrated the best fit. The SRMR, NNFI, and CFI met the criteria for good fit, whereas RMSEA was acceptable and approached the threshold for good fit. Inspection of the factor loadings for the general factor in the bifactor model revealed high factor loadings for all items (.49 to .92) which were generally only slightly lower than those for the single-factor model. This suggests that the loadings for the single-factor model were not substantially distorted by multidimensionality. Also, the item loadings for the general factor in the bifactor model were generally higher than those for either of the group factors and group factor loadings were substantially lower than those in the two-factor model, indicating that the variance in item responses is mostly accounted for by a singly underlying factor. However, after partialling out the general factor, five out of six items from the Life fulfillment factor and seven out of ten items from the Valued Living factor remained substantially high ( $> .40$ ). Based on these findings together, we concluded that the ELS can best be scored using both total scale scores as well as two subscale scores.

Table 3. Model fit indices for three models tested in confirmatory factor analysis in a chronic pain sample

Model	SB- $\chi^2$	df	RMSEA	SRMR	NNFI	CFI
Single factor	551.43	104	.186	.128	.905	.921
Correlated two-factor	270.83	103	.082	.096	.953	.971
Bifactor	181.23	88	.067	.057	.969	.984

Note: N = 238. SB-  $\chi^2$ ; Sattora-Bentler scaled chi-square; df = degrees of freedom; RMSEA = root mean square error of approximation; SRMR = standardized root mean square residual. NNFI = non-normed fit index; CFI = comparative fit index.

**Descriptive statistics and internal consistencies**

Mean age of the participant sample ( $N = 238$ ) was 52.78 years ( $SD = 12.37$ ), 76.1% was female and 74.4% was married. Educational level varied from 20.2% lower educated and 35.7% intermediate educated, to 43.1% highly educated participants. 82.7% of the participants self-reported that a diagnosis was given for their pain complaints. Furthermore, 39.9% was working part-time or full-time. Scores on the ELS and all other measures can be found in Table 4. The chronic pain sample showed significantly lower scores on the total scale of the ELS ( $M = 50.90$ ,  $SD = 9.81$ ) compared to the nonclinical sample ( $M = 60.77$ ,  $7.83$ ),  $t(676) = 8.670$ ,  $p < .001$ , Cohen's  $d = 1.11$ ), as expected. Internal consistency for both subscale and total scale ELS test scores were comparable to the internal consistencies reported in study 1 (Valued Living,  $\alpha = .89$ , Life Fulfillment,  $\alpha = .87$ , total score ELS,  $\alpha = .91$ ).

**Construct validity**

To assess construct validity, Pearson's correlations coefficients were calculated between both the ELS total scale and subscales, and avoidance and cognitive fusion (PIPS), facets of mindfulness (FFMQ), anxiety and depression (HADS), emotional, psychological and social well-being (MHC-SF), pain disability (PDI) and pain intensity (NRS). Correlations of these variables' test scores with the ELS scores can be found in Table 4. In line with expectation, the ELS correlated moderately with scores on the PIPS-avoidance subscale as a measure of acceptance. With regard to mindfulness, overall small to moderate correlations were found (except for the nonjudging facet, for which no correlations existed with the ELS scores). Overall moderate to high correlations were found for the ELS with (positive) mental health as measured with the HADS and MHC-SF. As expected with regard to the pain-related outcomes, no correlations were found with pain intensity, while small to moderate correlations were found with the PDI and MPI-interference.

**Incremental validity**

To assess incremental validity of the ELS above and beyond the PIPS and FFMQ as measures of related ACT processes, hierarchical regression analyses were performed with the MPI interference, MHC-SF (total score) and HADS (total score) as dependent variables. In the first step, the PIPS and FFMQ total scores were entered when correlating significantly to the dependent variable. The total score for the ELS was entered in step two. The change in variance from the second step accounted as a test for incremental validity ( $p < .05$ ). With regard to MPI interference, the ELS explained 1.6% additional variance beyond the PIPS scores ( $F_{\text{change}}(1, 235) = 5.98$ ,  $p = .015$ , adjusted  $R^2$  step 2 = .351), while 15.3% additional variance could be explained beyond the PIPS and FFMQ test scores in the MHC-SF ( $F_{\text{change}}(1, 234) = 55.61$ ,  $p < .001$ , adjusted  $R^2$  step 2 = .355).

Finally, an additional 3.7% of variance in the HADS could be explained by the ELS beyond both the PIPS and FFMQ ( $F_{\text{change}}(1, 234) = 14.26, p < .001, \text{adjusted } R^2 \text{ step } 2 = .393$ ).

Table 4. Descriptive statistics and Pearson’s correlations coefficients for the ELS and measures considered related theoretically in a chronic pain sample.

	Mean (SD)	Valued Living	Life Fulfillment	Total Scale
<u>ELS</u>				
Total scale	50.90 (9.81)	.92**	.84**	--
Valued Living	35.42 (6.40)	--	.55**	--
Life fulfillment	15.49 (6.69)	--	--	--
<u>PIPS</u>				
Total scale	54.86 (11.54)	-.25**	-.36**	-.33**
Avoidance	33.06 (9.62)	-.33**	-.43**	-.42**
Cognitive Fusion	21.80 (3.96)	.00	.08	.06
<u>FFMQ</u>				
Observing	15.28 (2.91)	.31**	.11	.26**
Describing	17.62 (3.95)	.34**	.11	.28**
Acting with awareness	17.00 (3.75)	.34**	.20*	.32**
Nonjudging	16.11 (3.37)	.11	.10	.12
Nonreacting	15.66 (2.88)	.31**	.17*	.28**
MPI interference	32.57 (9.81)	-.17*	-.43**	-.32**
<u>MHC-SF</u>				
Emotional well-being	11.95 (3.11)	.52**	.54**	.60**
Psychological well-being	23.55 (5.96)	.50**	.44**	.53**
Social well-being	16.11 (4.86)	.37**	.31**	.39**
<u>HADS</u>				
Anxiety	7.20 (3.25)	-.25**	-.28**	-.30**
Depression	6.25 (3.42)	-.40**	-.42**	-.46**
PDI	36.17 (12.64)	-.11	-.36**	-.26**
Pain Intensity	6.20 (1.65)	.12	.03	.09

Note: N = 238; \* = correlations significant at  $p < .05$ ; \*\* = correlations significant at  $p < .01$ . ELS = Engaged living Scale; PIPS = Psychological Inflexibility in Pain Scale; MPI interference = Multidimensional Pain Inventory – interference subscale; MHC-SF = Mental Health Continuum – Short Form; HADS = Hospital Anxiety Depression Scale; PDI = Pain Disability Index.

## CONCLUSION

The aim of this second study was to further investigate the psychometric properties of the ELS test scores in a sample of chronic pain patients. Confirmatory factor analyses confirmed the suggested two-factor model from study 1, although a bifactor model showed the best fit to the data. Internal consistency of the ELS total scale and subscales was good. Pearson correlation coefficients were in line with expectations, in general showing moderate to high correlations in the hypothesized direction of the ELS with measures of acceptance, mindfulness and (positive) mental health. Furthermore, as hypothesized, no correlations were found with pain intensity and small to moderate correlations were found between the ELS and pain disability and pain interference respectively. Finally, assessment of incremental validity showed that the ELS was able to explain additional information in important outcome variables beyond related measures of acceptance (PIPS) and mindfulness (FFMQ).

## GENERAL DISCUSSION

In the present set of studies, we reflected on the development and psychometric properties of the Engaged Living Scale (ELS), a new measure of an engaged response style from the framework of Acceptance & Commitment Therapy (ACT). Psychometric properties of the ELS test scores were examined in both a nonclinical and clinical sample consisting of chronic pain patients. The ELS was developed as no process-specific measures of the engaged response style were available. Availability of easy-to-administer, process-specific questionnaires is necessary to further examine mediating mechanisms of treatment and the contribution of specific treatment processes to outcome. Overall, the outcomes of both studies suggest that the ELS factor structure is best represented by a bifactor model, comprising of two subscales (Valued Living and Life Fulfillment) and a general underlying factor. In both samples the ELS showed good internal consistency and construct validity by consistent patterns of relationships with theoretically related constructs, such as psychological well-being, anxiety and depression, pain interference in daily life, personality, acceptance and mindfulness. The ELS scores also have incremental validity in explaining pain interference in daily life, positive mental health and psychological distress beyond acceptance and mindfulness. Overall, these outcomes suggest that the ELS is a valid and reliable measure of an engaged response style from the framework of ACT. Based on the superior fit of the bifactor model to the correlated two-factor and unidimensional model, we suggest that the ELS can be best used in clinical practice and research by scoring both the total scale and the individual subscales (Chen et al., 2010).

Some important theoretical, clinical and research implications result from our findings. First, the resulting factor solution fits very well with theoretical foundations of ACT. Although separated during the steps of item generation, in the resulting exploratory and confirmatory factor solution both ACT-processes values and committed action are assembled into one factor. This corroborates the recent theoretical notion that both knowing and living in accordance with values are highly interlinked aspects of an overall, generic engaged response style (Hayes et al., 2011). Our findings also suggest that valued living and life fulfillment are related, but distinct aspects of a generic engaged response style. Compared to the subscale Valued Living, the items in the subscale Life Fulfillment reflect more of an outcome or evaluation of knowing and living in accordance with values. Although life fulfillment is not as directly related to a specific process from the framework of ACT as valued living is, the definition and operationalization of the subscale is consistent with ACT theory. Namely, the pragmatic and on-going evaluation of personal values and subsequently formulated goals is inherent to the dynamic act of valued living that elaborates of the course of life (Hayes et al., 2011; Wilson & Murrell, 2004).

With regard to measurement of ACT-processes, questionnaires are now available to measure each of the three key response styles and psychological (in)flexibility in general. The psychometric properties of test scores on the AAQ-II and PIPS (Bond et al., 2011; Fledderus et al., 2012; Trompetter et al., 2013; Wicksell et al., 2010), FFMQ (Baer et al., 2006; Bohlmeijer et al., 2011) and ELS are examined in different nonclinical and clinical samples. The findings from our studies and previous studies on the incremental validity of the different process measures suggest that these measures are able to contribute individually to the explanation of variance of important outcomes (Fledderus et al., 2012; McCracken & Zhao-O'Brien, 2010; Trompetter et al., 2013). This also corroborates the theoretical notion that all three response styles are related, but distinct aspects from the overall framework of ACT (Hayes et al., 2006, 2011).

A few interrelationships between engaged living and related processes and outcomes deserve further exploration. No correlations were found between engaged living and the nonjudging facet of mindfulness, defined in terms of taking a nonevaluative stance towards thoughts and feelings (Baer et al., 2006). This finding could reflect that, in general, a person may still move towards their values even if they judge their inner experiences as unwelcome. From an ACT-perspective, it can be hypothesized that a relationship between the constructs only exists when a person judges their inner experiences as highly unwelcome, or is very high in non-judging. Nevertheless, although the findings with regard to the nonreact facet should be treated with caution due to the low internal consistency of its test scores, all other mindfulness facets correlated with engaged living as expected. This confirms the assumption that mindfulness and engaged living are related in a sense that conscious, present-moment awareness is necessary to be able to contact and reflect on personal values and subsequent goals (Hayes et al., 2011;

Wilson & Sandoz, 2008). Looking at the individual relationship of the different subscales of engaged living with mindfulness, correlations with mindfulness facets were similar for the subscale Valued Living and for the total scale. However, the subscale Life Fulfillment only showed small correlations with the facets acting with awareness and nonreacting. Future studies are necessary to further investigate the differential relationships between facets of mindfulness and engaged living.

With regard to the different aspects of psychological well-being as measured with the Psychological Well-Being Scales (PWB Scales; Ryff & Keyes, 1995), varying moderate to high correlations were found with engaged living. The highest correlations were found with the aspect environmental mastery (a sense of mastery and control in managing one's life and the world). This suggests that awareness and realization of personal values and feelings of life fulfillment increase feelings of control in managing one's life and surroundings, and/or vice versa. In addition, especially the subscale Life Fulfillment showed the lowest (small to moderate) correlations with the aspects personal growth (a sense of continued growth and development as a person) and autonomy (a sense of self-determination). This confirms findings from previous studies on the relationship between these aspects of psychological well-being and outcomes theoretically related closely to life fulfillment, such as happiness and satisfaction with life (Ryff & Keyes, 1995; Ryff, 1989). In general, the moderate to high correlations that were found between engaged living and psychological well-being suggest a substantial relationship between these concepts. This is possibly due to the fact that both psychological well-being and engaged living (as also ACT in general) reflect a positive approach to mental health (Hayes et al., 2006; Ryff & Singer, 2006). This approach is based on the assumption that mental health is more than the absence of psychological distress. Knowledge on the additional value of positive mental health is growing rapidly (e.g. Westerhof & Keyes, 2010), supporting the idea that a focus on concepts as resilience, flourishing and psychological flexibility is a useful complement to existing treatment models.

Several limitations and opportunities for future research can be acknowledged. A first limitation of this study is the relatively high age of participants in both samples. As it is possible that engaged living is interpreted and evaluated differently by different age groups, future research should study generalizability of the validity of the ELS to younger age groups. Another limitation is the fixed administration order of the scale (see scale in appendix A). This makes it not possible to rule out the possibility of administration order effects when using the ELS in future studies. Furthermore, we suggest Item Response Theory (IRT) (Chang & Reeve, 2005; Embretson & Reise, 2000) to be applied in future studies to further investigate the item characteristics of the ELS. The superior fit of the bifactor model and the comparable factor loadings found for both the general factor in the bifactor model and the unidimensional model suggest that unidimensional IRT analyses can be applied to the total ELS. By use of IRT, future research can assess

differential item functioning for different age groups and explore opportunities for shortening the scale by assessment of item difficulties. Shortening the scale will enable faster administration of the ELS in test batteries.

Despite the limitations of the present study, our findings suggest that the ELS is a valid and reliable instrument to measure an engaged response style from the framework of ACT. The ELS can be a useful measure in both clinical and nonclinical populations to further investigate interrelationships between different ACT-processes and –outcomes and the possible working mechanisms of the engaged response style. As research and evidence for the effectiveness of ACT for a range of psychopathology is growing rapidly, further development of psychometrically sound instruments for adequate and precise measurement of treatment processes is necessary. The availability of the ELS hopefully takes the research on ACT and disentanglement of specific treatment processes a step further in the right direction.



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### APPENDIX A- ENGAGED LIVING SCALE\*

The following questions concern 'value based living'. Values are the choices that we make about how we want to live our lives. This means that you determine what you believe to be important in your life, what makes it all worthwhile and what motivates you. The question that you ask yourself here is what do I want from life? What do I consider important and what sort of person do I want to be? This questionnaire is about learning to identify these values and to live according to them.

1. I have values that give my life more meaning. *(VL)*
  2. I know what motivates me in life. *(VL)*
  3. I believe that I've found important values to live according to. *(VL)*
  4. I know exactly what I want to do with my life. *(VL)*
  5. I make choices based on my values, even if it is stressful. *(VL)*
  6. I know how I want to live my life. *(VL)*
  7. I know what I want to do with my life. *(VL)*
  8. I believe that my values are really reflected in my behaviour. *(VL)*
  9. I believe that how I behave fits in with my personal wants and desires. *(VL)*
  10. My emotions don't hold me back from doing what's important to me *(VL)*
  11. I live the way I always intended to live. *(LF)*
  12. I am satisfied with how I live my life. *(LF)*
  13. Nothing can stop me from doing something that's important to me. *(LF)*
  14. I believe that I am living life to the full right now. *(LF)*
  15. I make time for the things that I consider important. *(LF)*
  16. I feel that I am living a full life. *(LF)*
- 

\*This questionnaire was translated from Dutch to English and translated back to Dutch by independent native speakers to ensure reliable translation. All items are scored on a 5-point Likert Scale, ranging from 'completely disagree' to 'completely agree'. No reversed scoring of items is necessary. Sum scores can be calculated for each subscale and for the total scale.





# CHAPTER 5

Internet-based guided self-help intervention for  
chronic pain based on Acceptance & Commitment Therapy:  
A randomized controlled trial

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**ABSTRACT**

Acceptance-based psychological interventions can potentially minimize the burden of chronic pain. This randomized controlled trial evaluated an internet-delivered, guided self-help intervention based on Acceptance & Commitment Therapy (ACT). A total of 238 chronic pain sufferers from the general population were randomly allocated to either ACT (n=82), an internet-based control condition Expressive Writing (n=79) or a Waiting List condition (n=77). Participants completed measures at baseline, post-treatment (three months) and at a three-month follow-up. At follow-up, ACT-participants had improved in pain interference in daily life (primary outcome) compared to participants in Expressive Writing (Cohen's  $d = .47$ ), but not compared to waiting list participants ( $p$ -value =  $.11$ ). Those who adhered to the ACT-intervention (48%) did improve significantly compared to waiting list participants ( $d = .49$ ). ACT-participants also showed superior improvement on depression, pain intensity, psychological inflexibility and pain catastrophizing ( $d: .28 - .60$ ). Significant clinical improvement was present. Especially, 28% of ACT-participants showed general clinically relevant improvement in pain interference, as well as in pain intensity and depression (versus Expressive Writing and waiting list: 5%). Given these findings, internet-based ACT programs may be a promising treatment modality for chronic pain.

## INTRODUCTION

Chronic non-malignant pain is highly prevalent and impacts physical, emotional and social life domains of the affected individual (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). Multiple studies indicate a strong relationship between chronic pain and other health problems such as impaired sleep and psychological distress (e.g. Miller & Cano, 2009; Smith, Perlis, Smith, Giles, & Carmody, 2000). Chronic pain conditions not only place a high burden on the individual, but also generate substantial costs to society through the individual's use of the healthcare system. In addition, chronic pain conditions generate even greater indirect costs to society, for example, through work absenteeism (Breivik et al., 2006; Gaskin & Richard, 2012). While our understanding of chronic pain continues to improve, treatments for chronic pain do not appear to be developing at the same rate. Treatment options that are currently in use show only modest effects with regard to pain control or pain removal (Turk et al. 2011). Because chronic pain is often a complex problem that is not easily managed with medical treatments alone, psychological treatments play an important role in reducing pain interference. One type of psychological treatment for chronic pain is Acceptance & Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 2012).

ACT is a form of cognitive behavioural therapy (CBT) that targets *acceptance* of the unavoidable aspects of chronic pain in order to create space for pursuing valued life activities. Acceptance is seen as an alternative strategy to persistent and generally fruitless attempts to avoid or gain control over the pain experience. By fostering acceptance and related processes such as present-moment awareness and values-based living, the ultimate goal of ACT is to increase *psychological flexibility*. Psychological flexibility reflects the ability to act effectively in accordance with personal values in the presence of chronic pain (Hayes et al., 2012). Due to its inherent focus on acceptance as an alternative to pain avoidance, ACT can play an integral role in chronic pain treatment when healthcare providers dialogue with patients to help them form more realistic expectations regarding future pain relief (Turk et al. 2011). Recently, multiple studies have revealed that ACT interventions are able to improve disability-related functioning of chronic pain sufferers (Jensen et al. 2012; Johnston, Foster, Shennan, Starkey, & Johnson 2010; McCracken, Sato, & Taylor 2013; Thorsell et al. 2011; Veehof, Oskam, Schreurs, & Bohlmeijer 2011; Vowles, McCracken, & O'Brien 2011; Wetherell et al. 2011; Wicksell et al. 2013). In addition, current research has shown the importance of aspects of psychological flexibility in the adjustment to pain disability (e.g. Cho, McCracken, Heiby, Moon, & Lee 2013; McCracken, Gauntlett-Gilbert, & Vowles 2007; McCracken & Gutiérrez-Martínez 2011a; McCracken & Velleman 2010; McCracken & Yang 2006; Vowles & McCracken 2010; Vowles et al. 2011; Vowles, Witkiewitz, Sowden, & Ashworth 2014; Wicksell, Olsson, & Hayes 2010).

In an attempt to increase time- and cost-effectiveness of psychological interventions, treatment modalities that augment face-to-face treatment have been developed during the past years. Numerous studies have demonstrated that web-based CBT self-help interventions are a promising mode of treatment for chronic pain and related disorders (Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Cuijpers, van Straten, & Andersson, 2008; Macea, Gajos, Daglia Calil, & Fregni, 2010). Current research in this area is developing rapidly and has led to better understanding of, for example, adherence to web-based treatments (Kelders, Kok, Ossebaard, & Gemert-Pijnen, 2012). Internet-based psychological interventions have demonstrated their possible usability and effectiveness as alternative or complimentary treatment modalities to existing treatment options for chronic pain. However, only one two-armed randomized controlled trial studied the effectiveness of an internet-based ACT-intervention for chronic pain (Buhrman et al., 2013). Further research is, therefore, warranted.

In this three-armed randomized controlled trial, we evaluated the efficacy of an internet-based, guided self-help intervention based on ACT, called 'Living with Pain.' The intervention is based on a successful ACT-based program for mild to moderate depression (Fledderus et al. 2012). We supplemented the ACT-condition with a waiting list control condition, and an internet-based control condition based on Expressive Writing (Pennebaker 1997) to control for non-specific effects such as receiving counseling and paying active attention to the pain experience. A large meta-analysis showed that Expressive Writing can have small effects on mental and physical health outcomes (Frattaroli, 2006). Therefore, we expected small improvement for the Expressive Writing condition in all outcomes. ACT was, however, hypothesized to be superior to both control conditions in reducing pain interference in daily life, and subsequently, depression, anxiety, pain intensity and pain disability as secondary outcomes. These outcomes were chosen as recommended outcomes in chronic pain research (Dworkin et al., 2005). Specifically, although psychosocial treatment does not directly focus on reducing pain intensity, we included a measure of pain intensity as previous ACT-interventions were able to indirectly improve pain reports (e.g. McCracken & Gutiérrez-Martínez 2011; Vowles & McCracken 2008). Pain intensity is also related to several psychosocial constructs such as pain acceptance (e.g. Cho et al. 2013; Wicksell, Lekander, Sorjonen, & Olsson 2010). Therefore, it can be expected that pain intensity may reduce as a consequence of targeting pain acceptance and related psychosocial constructs during ACT. Additionally, possible changes in positive mental health were explored, as ACT's focus is theoretically supportive of increasing a positive and engaged life (Fledderus et al., 2012). We also expected greater positive effects in the ACT condition compared to both control conditions with regard to ACT-related measures of psychological inflexibility, mindfulness and values-based living. Finally, possible changes in pain catastrophizing as a central construct in CBT-interventions and the well-established fear-avoidance model of chronic

pain (Crombez, Eccleston, Damme, Vlaeyen, & Karoly, 2012) were explored to further examine outcomes of previous studies indicating that acceptance-based treatments can improve pain catastrophizing (Buhrman et al., 2013; Vowles, McCracken, & Eccleston, 2007).

## METHOD

### Participants

Participants were recruited in February and March 2012 through advertisements in Dutch newspapers and online patient platforms. Inclusion criteria were age  $\geq 18$  years, a momentary pain intensity score  $\geq 4$  (11-point Numeric Rating Scale), and having pain for  $\geq 3$  days per week for  $\geq 6$  months. The criterion ' $\geq 3$  days per week' was chosen as the protocol was explicitly written for individuals suffering from highly regular or daily pain complaints. Exclusion criteria were a very low level of psychological inflexibility, a score  $< 24$  on the Psychological Inflexibility in Pain Scale (Wicksell et al. 2010), and a low level of severe psychological distress, that is, a total score  $> 24$  on the Hospital Anxiety Depression Scale (Zigmond & Snaith, 1983). Cut-off scores were based on one standard deviation above (HADS) or below (PIPS) the mean scores of a sample of chronic pain patients who were receiving in-patient multidisciplinary treatment in a local rehabilitation centre. We excluded candidates based on low psychological inflexibility scores as they already scored highly beneficial at baseline on the expected working mechanism of treatment. Candidates who were excluded due to severe psychological distress were advised to seek help from their general practitioner, as this would require more intensive diagnostics and treatment. Remaining participants completed two questions from a web screener for depressive disorder (Donker, van Straten, Marks, & Cuijpers, 2009). As this Web Screening Questionnaire yields a high number of false positives, those who were screened positively (score on Q1  $> 6$  and Q2 = 1) underwent a telephone interview using the depressive episode module of the Mini International Neuropsychiatric Interview (Sheehan et al., 1998). Candidates diagnosed as having a major depressive disorder were excluded and also advised to seek help from their general practitioner. Excluded were also candidates who (a) currently participated in another CBT-based program, (b) had no internet and/or e-mail address, (c) experienced reading problems due to insufficient Dutch language skills or illiteracy (d) or were unwilling to invest approximately 30 minutes per day in the programme.

### Procedure

Candidates who provided their personal information on the intervention website received an information letter by post explaining the study and an informed consent form (N = 334). Consenting participants (N = 281) completed a computerized screening

questionnaire in the online intervention environment (N = 269). Based on the inclusion and exclusion criteria, 31 people were excluded. No candidates had to be excluded based on Psychological Inflexibility in Pain Scale scores or telephonic interviews using the Mini International Neuropsychiatric Interview. Of the remaining participants that met the inclusion and exclusion criteria, 238 participants completed the online baseline questionnaire and were randomly assigned to one of three conditions (Figure 1).

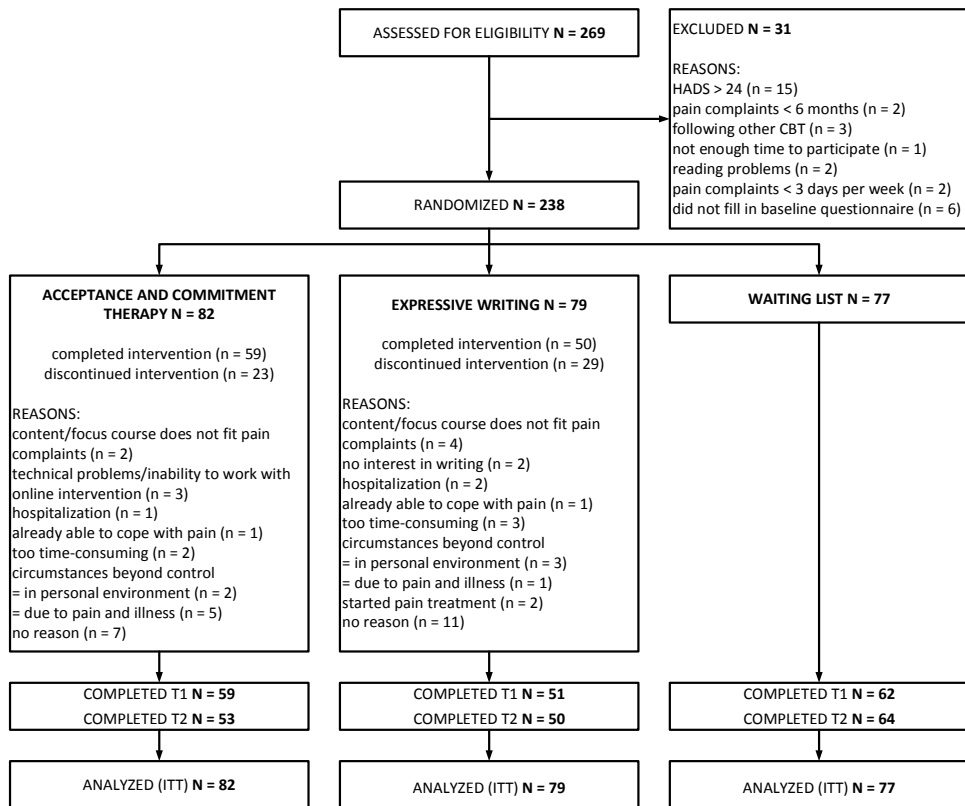


Figure 1. Participant flow

Allocation to conditions was performed by sequential block wise randomization (block size three) using an electronically written key, with stratification on gender, age ( $\leq 40$  and  $> 40$ ) and educational level (low,  $\leq 10$  years of education; moderate, 10 – 15 years; high,  $\geq 15$  years). Participant characteristics and scores on all measures appear in Tables 1 and 2.

### Power analysis

A minimum sample size of 53 participants per group at post-intervention and three-month follow-up was estimated assuming a significance level of 5%, a power of 80%, an estimated effect size of  $d = .66$  on the primary outcome and a drop-out rate of 30%.

Table 1. Baseline characteristics of study participants

	ACT (%)	EW (%)	WL (%)
Age (years, mean (sd))	52.9 (13.3)	52.3 (11.8)	53.2 (12.0)
Gender (% female)	76.8	75.9	75.3
Education			
Low	19.5	19.0	22.1
Intermediate	35.4	36.7	35.0
High	45.1	44.3	42.9
Marital status (% married/living together)	80.0	68.4	74.0
Race (% Dutch)	97.6	94.9	97.4
Work			
Paid work (< 24 hours)	23.1	31.6	16.9
Paid work (> 24 hours)	19.6	16.5	11.7
Unpaid work (e.g household)	25.0	19.6	32.5
Retirement	18.3	17.7	22.1
Other	14.0	14.6	16.8
Duration of complaints > 5 years	58.5	69.6	61.0
Diagnosis			
None	14.6	17.7	19.5
Back complaints	9.8	13.9	14.3
Fibromyalgia	15.9	29.1	15.6
Joint complaints	8.5	7.6	9.1
Rheumatic disease	9.8	7.6	11.7
Neuropathic complaints	11.0	6.3	9.1
Other*	30.5	20.8	20.7
N days per week pain (median)	7.0	7.0	7.0
Medication use			
No medication use	30.5	31.6	26.0
≤ once per day	23.2	24.1	
> once per day	46.3	44.3	42.9
N GP/specialist visits last 12 months			
0 visits	8.5	5.1	11.7
1 – 5 visits	43.9	38.0	46.7
6 – 10 visits	26.9	32.9	22.1
> 10 visits	20.7	24.1	19.5

Note: \*Other, includes different conditions ( $n < 5$  per treatment group) including (a.o.) Whiplash Associated Disorder (WAD), Chronic Fatigue Syndrome (CFS), Chronic Regional Pain Syndrome (CPRS) and Complaints of Arms Neck and Shoulders (CANS); ACT = Acceptance & Commitment Therapy; EW = Expressive Writing; WL = Waiting List

Table 2. Means and standard deviations on all primary and secondary outcomes

		Baseline	Post (3 months)	FU (6 months)
		Mean (sd)	Mean (sd)	Mean (sd)
<b>Primary outcomes</b>				
MPI	ACT	32.3 (9.8)	28.7 (12.0)	27.2 (12.0)
	EW	32.2 (9.8)	32.7 (12.3)	32.9 (12.2)
	WL	33.3 (9.8)	32.1 (11.5)	30.6 (11.3)
<b>Secondary outcomes</b>				
HADS depr	ACT	6.1 (3.4)	5.1 (3.7)	4.3 (3.8)
	EW	6.5 (3.4)	5.7 (3.8)	6.2 (3.9)
	WL	6.1 (3.4)	5.8 (3.5)	5.7 (3.6)
HADS anx	ACT	7.2 (3.3)	6.0 (3.8)	5.2 (3.8)
	EW	7.5 (3.3)	5.9 (3.9)	6.2 (3.8)
	WL	6.9 (3.3)	6.1 (3.6)	5.8 (3.5)
Pain NRS	ACT	6.3 (1.6)	5.4 (2.2)	4.9 (2.3)
	EW	6.1 (1.6)	5.9 (2.3)	5.8 (2.4)
	WL	6.2 (1.6)	5.6 (2.1)	5.6 (2.1)
PDI	ACT	36.0 (12.7)	30.6 (14.5)	28.5 (14.8)
	EW	36.4 (12.7)	34.6 (14.3)	34.5 (15.0)
	WL	36.1 (12.7)	33.0 (14.0)	32.0 (13.6)
MHC-SF	ACT	52.6 (11.8)	54.7 (12.2)	56.7 (15.5)
	EW	53.1 (11.8)	55.9 (15.2)	55.3 (15.6)
	WL	49.9 (12.8)	52.6 (14.3)	54.1 (14.5)
PIPS	ACT	55.0 (11.6)	40.7 (13.8)	39.0 (15.3)
	EW	55.1 (11.6)	46.3 (14.1)	46.4 (15.5)
	WL	54.5 (11.6)	48.8 (13.1)	47.0 (14.1)
FFMQ	ACT	81.4 (10.7)	86.7 (12.2)	87.6 (13.1)
	EW	83.2 (10.7)	88.8 (12.5)	88.9 (13.2)
	WL	80.4 (10.7)	83.3 (11.7)	83.0 (12.3)
ELS	ACT	51.5 (10.4)	55.1 (12.4)	57.0 (13.2)
	EW	51.5 (9.9)	56.1 (12.8)	55.4 (13.3)
	WL	49.8 (9.1)	52.8 (11.8)	52.8 (12.2)
PCS	ACT	18.6 (9.5)	13.5 (11.3)	11.9 (11.9)
	EW	17.6 (10.2)	15.6 (11.7)	15.5 (12.0)
	WL	19.1 (9.6)	17.8 (11.0)	16.3 (11.1)

Note: ACT = Acceptance & Commitment Therapy; EW = Expressive Writing; WL = Waiting List

## Intervention

### *Living with Pain*

Participants in the experimental condition received the internet-based intervention 'Living with Pain.' This program was based on the self-help program 'Living to the Full' (Fledderus

et al., 2012) and the protocol ‘Living with Pain’ (Veehof et al. 2010; Schreurs & Hulsbergen 2012). The intervention consisted of nine modules, which could be worked through in nine to twelve weeks. Each module used text, experiential exercises and metaphors for illustrating the six processes of ACT (Hayes et al., 2012). Additionally, participants downloaded mindfulness exercises that lasted 10-15 minutes (e.g. ‘body scan’), and were encouraged to practice mindfulness daily. An overview of the content of the intervention and therapeutic processes addressed can be found in Table 3. Other functionalities were the opportunity to read experiences of previous ACT-participants and the opportunity to keep a personal diary. Approximate time-investment asked was  $\geq$  three hours per week.

Table 3. Schematic overview of ACT intervention protocol

Module	Therapeutic processes(es)	Mindfulness exercise
‘Pain and pain treatment’	Psycho-education	Body scan
‘Avoiding the pain’	Experiential avoidance of pain	Paying attention to breath
‘Happy despite pain?’	Values	Body scan/paying attention to breath
‘Blossoming of the rose’	Values & committed action	Breathing towards the pain
‘To give up the fight’	Pain acceptance	Create space & allow what is present
‘Yes....but I have pain’	Cognitive (de)fusion	Observe your thinking
‘I am.....who am I actually?’	Self-as-context	Three minutes breathing space
‘You don’t suffer alone’	Pain, social context & communication	--
‘Living with pain, a new story’	Committed action	Combination of above: ‘All in one’

#### *Expressive Writing control condition*

Participants in the first control condition received an internet-based intervention based on Expressive Writing in which they were invited to write, or rather emotionally disclose, about a highly stressful experience, usually in multiple sessions. Pennebaker’s Expressive Writing method was adapted into an intervention format with nine modules on expressive writing, which could be worked through in nine to twelve weeks. Each module started with psycho-education about emotions and emotion regulation related to the pain experience, followed by a specific writing assignment, e.g. focusing on specific negative or positive experiences. The general assignment was to write on a regular basis about experiences and emotions either related to chronic pain or to other situations. Participants were advised to write at least three times a week, for approximately 15 minutes. An online, personal diary was included in the intervention. Approximate time-investment asked was  $\geq$  two hours per week.



### *Waiting list control condition*

In the waiting list control condition, no interventions were offered and no further requirements were made. Participants were free to access other forms of treatment, including regular appointments with practitioners and new treatment or medication. Six months from baseline these participants could follow the ACT-intervention without counselling.

### **Counselling**

Counselling was provided once per week for guidance, encouragement and support of the process (Andersson 2009). Counsellors were five recently graduated psychology students who were trained and supervised by a registered cognitive behavioural therapist with ample experience in working with ACT and Expressive Writing (K.M.G.S.). During their training, the student counsellors received information on chronic pain, studied both internet-based intervention programs, performed the exercises included in both manuals and practiced writing e-mails from the perspective of the participant and counsellor. Each counsellor provided approximately 30 participants with e-mail support. Allocation of the counsellors to participants was randomized. After completing a weekly module, each participant sent a message to his/her counsellor reflecting on the progress made during the previous week. Participants were allowed to ask questions on texts and exercises. The counsellor provided a structured response at a fixed day of the week. The general structure for each of the replies was to: a) compliment/reinforce the participant, b) answer questions/explain unclear aspects of intervention, c) present next weeks' assignment, and d) provide positive reinforcement to motivate the participant to continue the intervention. All communication between counsellor and participant was handled within the enclosed and encrypted web-based system.

### **Assessment**

Multidimensional assessments were made at baseline, at post-intervention (3 months), and at follow-up (6 months). All questionnaires were administered online.

### *Primary outcome*

The Multidimensional Pain Inventory, subscale *pain interference* (MPI-interference) (nine items) measures the degree to which pain interferes with work, household work and social activities (Kerns et al. 1985). This scale was chosen as a primary outcome based on core outcome recommendations by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (Dworkin et al., 2005). Higher scores indicate more pain interference (range 0 – 54). Internal consistency in the present study was at baseline  $\alpha = .86$ .

### *Secondary outcomes*

The Hospital Anxiety Depression Scale (HADS) measures psychological distress by assessing the presence and severity of *anxiety* (seven items) and *depressive* symptoms (seven items) (Zigmond & Snaith, 1983). In this study the both subscales of the Hospital Anxiety Depression Scale were used separately, with higher scores indicating higher anxiety or depression (range for each of the subscales 0 – 21). Internal consistency in the present study was at baseline  $\alpha = .73$  (anxiety) and  $\alpha = .79$  (depression).

Pain intensity was measured with an 11-point numeric rating scale (NRS), ranging from (0) 'no pain' to (10) 'pain as bad as you can imagine' (Dworkin et al., 2005).

The Pain Disability Index (PDI) (seven items) assesses the *degree to which chronic pain disables a person to perform daily activities* (Pollard, 1984). Scores range from 7 to 70, with higher scores indicating more disability. Internal consistent in the present study was at baseline  $\alpha = .81$ .

The Mental Health Continuum-Short Form (MHC-SF) measures three dimensions of *positive mental health* (Keyes, 2002): (1) emotional well-being (three items), defined in terms of positive feelings and satisfaction with life; (2) psychological well-being (six items), defined in terms of positive functioning in individual life; and (3) social well-being (five items), defined in terms of positive functioning in community life. Participants rate the frequency of feelings in the past month. In this study the total scale was used, with higher scores indicating better positive mental health (range 14 – 84). Internal consistency in the present study was at baseline  $\alpha = .89$ .

The Psychological Inflexibility in Pain Scale (PIPS) (Wicksell et al. 2010) is a 12-item instrument measuring *psychological inflexibility*. The scale consists of two subscales measuring *avoidance* (eight items) and *cognitive fusion* (four items). In this study the total scale was used, with higher scores indicating more psychological inflexibility (range 12 - 84). Internal consistency in the present study was at baseline  $\alpha = .87$ .

The Five Facet Mindfulness Questionnaire - Short Form (FFMQ-SF) is a 24-item questionnaire that measures five facets of *mindfulness*: observing, describing, acting with awareness, nonjudging and nonreactivity (Baer et al. 2006; Bohlmeijer et al. 2011). In this study the total scale was used, with higher scores indicating more mindfulness (range 24 - 120). Internal consistency in the present study was at baseline  $\alpha = .82$ .

The Engaged Living Scale (ELS) measures *engaged living* (Trompetter et al., 2013). The scale consists of two subscales: (1) valued living (ten items), defined as knowing personal values and acting upon these values; and (2) life fulfillment (six items), defined as a sense of fulfillment in life as a consequence of living in accordance with personal values. In this study the total scale was used, with higher scores indicating more engaged living (range 16 – 80). Internal consistency in the present study was at baseline  $\alpha = .91$ .

The Pain Catastrophizing Scale (PCS) is a 13-item questionnaire developed to measure pain catastrophizing (Sullivan, Bishop, & Pivik, 1995). The scale consists of three

subscales measuring ‘rumination’, ‘magnification’, and ‘helplessness.’ In this study the total scale was used, with higher scores indicating more catastrophizing (range 0 – 52). Internal consistency in the present study was at baseline  $\alpha = .91$ .

### **Completion, adherence and treatment satisfaction**

By completing at least the first six modules of the intervention, participants were introduced minimally to each of the six core ACT-processes, and hence were labelled ‘completers’. Adherence was defined as completing the intervention and working with the ACT-intervention  $\geq 3$  hours ( $\geq 2$  hours for Expressive Writing) per week. The average number of hours spent on the intervention over the last weeks was self-assessed by the participants at four and eight weeks from baseline.

The Client Satisfaction Questionnaire (CSQ-8) was used to evaluate the overall satisfaction with services at post-treatment (Attkisson & Zwick, 1982). Higher scores indicate more satisfaction (range 8 – 32), and internal consistency was good in this study ( $\alpha = .93$ ). Finally, a question was included on how the participants graded the intervention program on a scale from 1 (extremely poor) to 10 (excellent). Following the Dutch school system, rating  $> 5.5$  can be interpreted as satisfactory (6 = adequate, 7 = more than adequate, 8 = good, 9 = extremely good, 10 = excellent), while grades  $\leq 5$  can be interpreted as insufficient.

### **Statistical analyses**

All statistical analyses were performed using SPSS 20.0 (IBM SPSS Statistics). First, one-way analysis of variance (ANOVA) and  $\chi^2$  tests showed there were no significant differences at baseline between the conditions for any of the demographic variables or outcome measures, indicating successful randomization. In addition, there were no significant differences between the three conditions at the start of new treatment or medication at post-treatment (3 months) and follow-up (6 months). At 3 months, data were available for 172 participants, and at six months for 167 participants (Figure 1). Little’s MCAR test indicated data were completely missing at random ( $\chi$ -square (65) = 62.38,  $p = .569$ ).

Intention-to-treat (ITT) analyses were performed using the general linear mixed model (GLMM) procedure (IBM SPSS Statistics 20.0) to assess effects on all variables. Differences at 3 months (post-treatment) and 6 months (three-month follow-up) from baseline were used as repeated measures, with treatment (3 levels), time (3 levels) and their first-order interactions as fixed factors. Estimation methods used were restricted to maximum likelihood (REML). The covariance structure was specified as unstructured. For all outcomes, 95% confidence intervals were calculated based on estimates and their standard errors. Results of the analyses based on the ITT sample using GLMM procedures were similar to results of analyses on both the observed data and the ITT sample with

data imputed according to the Expectation-Maximization (EM) algorithm (Dempster, Laird, & Rubin, 1977). Because of this, only results from the ITT GLMM analyses are reported. Furthermore, ITT outcomes are based on the analyses of the total scales of the measures assessed. Post hoc testing revealed that conclusions for each of the separate subscales were similar to conclusions based on the scores from the total scales. As drop-out and non-adherence are common in web-based interventions, secondary analyses as described above were also performed to assess effects on all outcome variables for only those who adhered to either ACT or Expressive Writing compared to waiting list participants (Eysenbach, 2011). Additionally, for all outcomes, effect sizes in terms of Cohen's *d* were calculated using means and standard deviations at 3 and 6 months from baseline for the different conditions. Effect sizes of 0.80 were considered large, effect sizes of 0.50 were evaluated as moderate, and effect sizes of .20 were considered small (Cohen 1988).

To evaluate the proportion of participants showing clinically significant change, IMMPACT recommendations were followed (Dworkin et al., 2008). Clinical improvement was assessed in the dataset with missing values imputed by the EM-algorithm. Proportions of clinically improved participants and  $\chi^2$ -difference tests to assess statistically significant differences in proportions for the three conditions were calculated for the recommended outcome domains pain interference in daily life (Multidimensional Pain Inventory, subscale pain interference), pain intensity (11-point Numeric Rating Scale) and depression (Hospital Anxiety Depression Scale, subscale depression). For the Multidimensional Pain Inventory, subscale pain interference, a decrease of  $\geq 0.6$  standard deviation was assessed as evidence of clinically significant change. In addition,  $\geq 20\%$  and  $30\%$  decreases in pain intensity scores were assessed as minimum and moderate changes respectively. For depression, the well-established and recommended cut-off point of 8 on the Hospital Anxiety and Depression Scale, subscale depression, was used (Lowe, 2004; Zigmond & Snaith, 1983). We calculated the ratio of participants that scored below this cut-off at follow-up in each condition. Finally, to assess more general clinical improvement over time, we also examined the number of participants who scored beneficially in more than one outcome.

## RESULTS

### **Completion, adherence and treatment satisfaction**

Chi-square tests revealed non-significant differences in the number of completers, defined as participants who completed six to nine modules of either ACT (72%) or Expressive Writing (63%) ( $\chi^2 (1) = 1.380, p = .240$ ). Of these 'completers,' 92% finished all nine modules in both interventions. There were no differences between completers and non-completers with regard to demographic variables and outcome measures at baseline (all

p-values >  $p = .130$ ). After 6 months, 77% of ACT-participants reported to have incorporated mindfulness exercises into their daily life ( $n = 41/53$ ). Mindfulness exercises were most often performed for three days per week (by 21% of participants) for 15-20 minutes (by 36% of participants). In total, 48% ( $n = 39$ ) and 47% ( $n = 37$ ) of participants adhered to ACT and Expressive Writing respectively, with adherence defined as completing the intervention and working with either the ACT-intervention for  $\geq 3$  hours (or Expressive Writing for  $\geq 2$  hours) per week. There were no differences between adherers and non-adherers with regard to demographic variables and outcome measures at baseline. However, chi-square tests approached significance for gender ( $\chi^2(1) = 3.370$ ,  $p = .066$ ), revealing a tendency that women more often than men adhered to the intervention as intended.

On the CSQ-8, ACT-participants evaluated the intervention significantly higher than participants in Expressive Writing (scale range 8 – 32, ACT: mean = 24.69,  $sd = 4.01$ ,  $n = 59$  versus Expressive Writing: mean = 21.39,  $sd = 4.79$ ,  $n = 51$ ;  $F(109) = 15.448$ ,  $p < .001$ ). Also on a scale from 1 – 10 the ACT-intervention was rated significantly higher than Expressive Writing (ACT: mean = 7.4,  $sd = 1.17$  vs. EW: mean = 6.5,  $sd = 1.41$ ;  $F(109) = 12.326$ ,  $p = .001$ ).

### Outcomes

With regard to the primary outcome, significant improvement was present in the Multidimensional Pain Inventory pain interference subscale in favour of ACT compared to Expressive Writing at both 3 months (treatment effect (95%CI) = 4.1 (1.1 – 7.1),  $p = .008$ , Cohen's  $d = .33$ ) and 6 months (treatment effect (95%CI) = 5.6 (2.7 – 8.7),  $p < .001$ , Cohen's  $d = .47$ ) (Table 4). No significant improvement was present for ACT compared to waiting list (although nearly significant; at 3 months,  $p = .109$ , and at 6 months,  $p = .110$ ). Means and standard deviations (Table 2) show that both groups improved over the 6 month period. When differences between adherers were assessed, the results showed significant improvement for participants adhering to ACT compared to waiting list at both 3 months (treatment effect (95%CI) = 3.3 (0.3 – 6.3),  $p = .029$ , Cohen's  $d = .35$ ) and 6 months (treatment effect (95%CI) = 4.1 (1.1 – 7.0),  $p = .008$ , Cohen's  $d = .40$ ). Adherers included in this assessment participated in: (1) either one or both intervention conditions and (2) all waiting list participants (Table 5).

With regard to the secondary outcome variables, when compared to Expressive Writing at 3 months, participants in the ACT condition significantly improved on pain intensity (treatment effect (95%CI) = .73 (0.0 – 1.4),  $p = .040$ , Cohen's  $d = .23$ ), and at 6 months on the Pain Disability Index (treatment effect (95%CI) = 5.6 (1.4 – 9.9),  $p = .011$ , Cohen's  $d = .40$ ). At 6 months, participants in ACT had significantly improved compared to both other conditions in scores on the Hospital Anxiety Depression Scale, subscale depression, and pain intensity (Cohen's  $d$  ranging from .28 on pain intensity compared to

waiting list to .49 on Hospital Anxiety Depression Scale, subscale depression, compared to Expressive Writing), but no on the Mental Health Continuum. Finally, at 3 months, participants in the ACT condition had significantly improved on the Psychological Inflexibility in Pain Scale (versus waiting list: treatment effect (95%CI) = 8.6 (4.6 – 12.6),  $p$ -value < .001, Cohen's  $d$  = .60; versus Expressive Writing: treatment effect (95%CI) = 5.4 (1.3 – 9.6),  $p$  = .011, Cohen's  $d$  = .40) and Pain Catastrophizing Scale compared to waiting list (treatment effect (95%CI) = 3.7 (0.8 – 6.6),  $p$  = .013, Cohen's  $d$  = .39) (Table 4). At 6 months, participants in ACT had significantly improved compared to both other conditions in scores on the Psychological Inflexibility in Pain Scale, Pain Catastrophizing Scale and Five Facet Mindfulness Questionnaire (compared to waiting list), but not in engaged living (Cohen's  $d$  ranging from .30 compared to Expressive Writing on the Pain Catastrophizing Scale to .54 on Psychological Inflexibility in Pain Scale compared to waiting list).

In general, when comparing those who adhered to ACT with those who adhered to Expressive Writing and waiting list participants (Table 5), the secondary analyses revealed that ACT-adherers showed superior improvement at both 3 and 6 months compared to waiting list (Cohen's  $d$  ranging from .17 on pain intensity to .62 on the Psychological Inflexibility in Pain Scale) and also to Expressive Writing (Cohen's  $d$  ranging from .17 on pain intensity to .42 on the Hospital Anxiety Depression Scale, subscale depression) on all outcomes, except for the Engaged Living Scale and Mental Health Continuum. Compared to the outcomes of ITT-analyses on the total dataset, additional significant improvement occurred compared to waiting list in both the Pain Disability Index (at 6 months,  $p$  = .010, Cohen's  $d$  = .32) and marginal significant improvement occurred in the Mental Health Continuum (at 6 months,  $p$  = .066, Cohen's  $d$  = .30).







### Clinically relevant improvement

Table 6 shows the proportion of participants with clinically significant improvements on between baseline and 6 months. Clinical improvement ranged from 38% (> 30% improvement in pain intensity) to 84% (score > 8 on the Hospital Anxiety Depression Scale, subscale depression) in the ACT-condition. Compared to Expressive Writing, Fisher's exact test outcomes showed that a significantly higher proportion of ACT-participants improved in the Multidimensional Pain Inventory pain interference subscale (ACT: 52%, Expressive Writing: 16%,  $p = .001$ ), pain intensity (ACT: 38%, Expressive Writing: 22%,  $p = .026$ ) and the Hospital Anxiety Depression Scale, subscale depression (ACT: 84%, Expressive Writing: 67%,  $p = .016$ ).

Table 6. Clinically relevant improvement at six months in ACT and both control conditions on pain interference in daily life (Multidimensional Pain Inventory, subscale pain interference), pain intensity (NRS) and depression (HADS, subscale depression)

	N participants improved / total						p-value*	
	ACT		EW		WL		vs EW	vs WL
<b>MPI</b>								
≥ 0.6 SD improvement	43/82	52%	13/79	16%	25/77	32%	.001	.072
<b>Pain intensity (NRS)</b>								
≥ 20% improvement	44/82	52%	24/79	30%	18/77	23%	.004	.000
≥ 30% improvement	31/82	38%	17/79	22%	15/77	19%	.026	.014
<b>HADS depression</b>								
Score < 8 at follow-up	69/82	84%	53/79	67%	54/77	70%	.016	.032
<b>More than 1 outcome</b>								
≥ 2 outcomes	52/82	63%	24/79	30%	29/77	38%	.000	.001
All 3 outcomes	23/82	28%	4/79	5%	5/77	5%	.000	.000

Compared to waiting list, a significantly higher proportion of ACT-participants improved in pain intensity (ACT: 38%, waiting list: 19%,  $p = .014$ ) and the Hospital Anxiety Depression Scale, subscale depression (ACT: 84%, waiting list: 70%,  $p = .032$ ). Additionally, a marginally significant higher proportion of ACT-participants improved when compared to waiting list participants in the Multidimensional Pain Inventory pain interference subscale (ACT: 52%, waiting list: 32%,  $p = .072$ ). Further outcomes revealed that, compared to both control conditions, approximately twice as many ACT-participants improved on two or more outcomes (ACT: 63%, Expressive Writing: 30%, waiting list: 38%,  $p < .001$  and  $p = .001$  respectively), and approximately five times the number of ACT-participants improved on all three outcomes (ACT: 28%, Expressive Writing: 5%, waiting list: 5%,  $p < .001$ ).

## DISCUSSION

This study showed that an internet-based, guided self-help intervention based on ACT may be effective in improving functioning in a heterogeneous group of chronic pain sufferers. Three months after the intervention, ACT-participants had improved significantly in pain interference, depression, pain intensity, psychological inflexibility and pain catastrophizing as compared to participants in Expressive Writing. Compared to the waiting list control condition, improvement by the ACT-participants over the same time period was present in depression and pain intensity, and additional improvement occurred in psychological inflexibility, mindfulness, and pain catastrophizing. Some, but not significant, improvement was present in pain interference for the ACT-participants compared to waiting list. Finally when compared to the two other interventions, ACT was not more effective in changing engaged living and positive mental health for its participants.

One of the findings in this study showed that no improvement, with regard to the primary outcome, occurred for ACT-participants compared to those on the waiting list. In general, this finding relates to the general results that not only individuals receiving ACT or Expressive Writing, but also the waiting list participants improved significantly over time. In fact, such improvement over time is inconsistent with findings from related RCTs (Buhrman et al. 2013; Wicksell, Ahlqvist, Bring, Melin, & Olsson 2008). Since most participants experienced chronic pain for a long duration and there were no differences in the start of new treatment or medication between all three groups, this particular finding in our study was not anticipated. We, therefore, hypothesize that the waiting list group hoped for a solution to their impairments and highly anticipated starting the ACT-intervention directly after filling in the questionnaire at follow-up. Other explanations for this unanticipated improvement are symptom monitoring effects over time, and the existence of seasonal variation as the intervention started in winter and ended in summer. Unfortunately, we were unable to test these hypotheses.

Despite the fact that waiting list participants improved over time, still, clinical improvement occurred in at least two out of three core outcome domains compared to both control groups. In addition, two to five times as many participants in the ACT-intervention showed general clinical improvement - indicated by clinical change in more than one chronic pain core outcome domain. Additionally, participants who adhered to the ACT-intervention as intended showed improvement at the three-month follow-up compared to the waiting list participants in all primary and secondary outcomes, except for engaged living. Despite the fact that the selection of adherers created a self-selected, not unbiased sample, these outcomes clearly supported the efficacy of the ACT-intervention. The much stronger effects found for adherers compared to waiting list

participants corroborate earlier findings on the relationship between adherence and effect in psychological interventions (Donkin et al., 2011).

In general, the small to moderate effects sizes that we found are similar to, or somewhat larger than the outcomes reported by a large, recent review on the effectiveness of face-to-face cognitive behavioural therapies for chronic pain (Williams, Eccleston, & Morley, 2013). Additionally, these findings corroborate outcomes of previous studies suggesting that ACT is an effective intervention for chronic pain, being delivered face-to-face or offered as a stand-alone (internet-based) self-help intervention (Buhrman et al. 2013; Jensen et al. 2012; Johnston et al. 2010; McCracken et al. 2013; Thorsell et al. 2011; Veehof et al. 2011; Vowles et al. 2011; Wetherell et al. 2011; Wicksell et al. 2013). These results also add to a growing body of literature that emphasizes the potential of internet-based CBT-interventions for a range of chronic pain populations and the comparability of internet-based CBT-interventions to face-to-face interventions (Bender et al., 2011; Buhrman et al., 2013; Cuijpers et al., 2008). This is one of the first studies in the area of internet-based psychological interventions for chronic pain to include an active control condition (Bender et al., 2011). Additionally, the ACT-intervention was more effective than the intervention based on Expressive Writing in changing individual functioning. Overall, these findings corroborate results from a recent meta-analysis, revealing there is only mixed evidence for small effects of emotional disclosure for chronic pain (Lumley, Sklar, & Carty, 2013). These results emphasize that the efficacy of the guided ACT self-help intervention is due to its intervention-specific factors beyond any non-specific, generic treatment factors. We anticipated that Expressive Writing would be able to affect all secondary measures operationalizing ACT processes – which was confirmed by significant within-group improvement on all ACT-processes – albeit to a much lesser extent than ACT as ACT-processes are not specifically targeted in Expressive Writing. Although ACT was more capable of improving psychological inflexibility and pain catastrophizing, participants in ACT and Expressive Writing improved similarly in mindfulness and engaged living. With regard to changes in mindfulness, our findings imply that one observes, describes and attends to one's emotions and personal experiences in the here-and-now during the act of emotional disclosure (Pennebaker, 1997), and all these actions are central components of mindfulness practice (Baer et al., 2006).

Not only compared to participants in Expressive Writing, but also compared to waiting list participants there were no significant changes for ACT in engaged living, and, changes in positive mental health were minimal. We included a measure of positive mental health as ACT-intervention is related to the positive approach to mental health (WHO). With regard to engaged living, observational studies in the area of chronic pain that used other measurement instruments have shown ACT interventions are certainly capable of improving engaged living (McCracken & Gutiérrez-Martínez, 2011; McCracken & Vowles, 2008; Vowles et al., 2011). Moreover, studies in the area of depression

revealed ACT-based programs are capable of improving participants' positive mental health (Fledderus et al., 2012). A possible explanation for these findings could lie in problems with the measurement instruments used. The Mental Health Continuum (Keyes, 2002) has not been validated specifically for chronic pain patients, and furthermore, the Engaged Living Scale, used in this study for the first time, is a newly designed measure. Another explanation could be that the current version of our ACT-intervention focused too much on the avoidance-acceptance conflict, and not enough on establishing long-term positive outcomes such as engaged living and positive mental health. As this study is one of the first RCTs on ACT that evaluated all of ACT's most central components, more research on this topic is needed.

This study has several limitations. First of all, the participants in this study were chronic pain sufferers recruited from the general Dutch pain population. This makes it possible that our study participants differ from individuals entering clinical settings with regard to, for example, severity of baseline complaints or motivation to participate. Especially the formulation of several of our in- and exclusion criteria – mainly the exclusion of participants experiencing pain less than three days per week, and also the exclusion of those reporting very severe psychological distress and/or high psychological flexibility – could have led to a sample that does not necessarily generalize to the type of daily, severe chronic pain patients seen in chronic pain management centers. A comparison with 220 participants entering clinical multidisciplinary chronic pain treatment reveals that, although clearly much higher educated, our study sample does not seem to differ systematically from the clinical sample on comparable variables (MPI, PIPS, pain intensity and PDI) (Trompetter et al., 2014). Also, most participants experienced pain complaints for a long duration, took pain medication on a daily basis and visited their GP or specialists regularly. Nevertheless, we cannot be sure that our findings are generalizable to a clinical population of chronic pain patients. One should be cautious to interpret the outcomes of this efficacy trial as such.

Additionally, almost all effect sizes in this study were small. Despite the fact that these findings are in line with meta-analyses on the effectiveness of ACT- and CBT-based interventions for chronic pain (Veehof et al., 2011; Williams et al., 2013), future research in this area faces some challenges. Examples of recommendations are to further focus on individual trajectories, or examine in more detail what works for whom (Williams et al., 2013). Furthermore, all data gathered in this study was self-assessed, which could have influenced our findings. In a related fashion, the questionnaires that were administered were not specifically developed or validated for online administration (except for one screening instrument). Core distributions for similar samples can vary between different modes of questionnaire administration. Therefore, our interpretation could have been problematic (see Buchanan 2003) with regard to the online questionnaire data for which

we used paper-and-pencil derived normative data to produce cut-off scores, such as, the Hospital Anxiety Depression Scale.

Finally, although comparable to other internet-based CBT interventions, numbers of non-completion, non-adherence and questionnaire attrition rates were relatively high. As displayed in Figure 1, the reasons for non-completion varied between participants, and in some occasions, we were not able to derive why participants dropped out. Future research could examine in more detail why pain sufferers drop out of web-based interventions, and additionally, assess further if and which patient groups are most able to self-manage an intensive online psychological intervention. Half of the participants did not adhere to the intervention as intended. This finding was measured by two self-reported questions at four and eight weeks from baseline. This use of two self-reported items to operationalize adherence is a limitation to this study, and future studies should, therefore, implement more objective measures of adherence. A related limitation is the fact that no a priori upper limit of working with the intervention was formulated. In hindsight, seven hours per week (equivalent to one hour per day) seems to be a reasonable upper limit of time-investment. Post-hoc analyses showed that 11 participants worked with ACT for eight or more hours per week, of which three participants worked for more than 14 hours per week with the intervention (rough equivalent of spending two hours per day). As especially the latter limit seems very high and possible detrimental, providing an upper limit of time investment is recommended for future self-management interventions. Adherence is an essential topic in the rapidly evolving area of web-based interventions, especially since it is related to positive treatment outcomes (Donkin et al., 2011). We, therefore, recommend that future research in the area of web-based CBT highly focuses on possibilities for heightening adherence to web-based interventions. A promising endeavour would be to focus on employing persuasive technology to heighten adherence (Kelders et al., 2012). Overall, by performing intention-to-treat analysis and applying statistical tests that are capable of handling missing data, we believe we made the best possible adjustment for the questionnaire attrition rates.

This study was a promising starting point to further unravel the added value of both ACT and internet-based self-help interventions in future treatment of a growing and heterogeneous group of individuals with chronic pain. Given the explicitly positive findings for those who adhered to ACT-intervention as intended, we believe one of the main challenges in the future is to enhance participants' adherence towards web-based interventions.

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# CHAPTER 6

Is positive psychological functioning a must to self-manage chronic pain? Moderators and predictors of change during a randomized controlled trial on web-based Acceptance & Commitment Therapy

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**ABSTRACT**

Both Acceptance & Commitment Therapy (ACT) and web-based delivery of interventions are promising innovations in psychosocial treatment for chronic pain. Although necessary to enhance future efficacy and efficiency of therapeutic intervention for pain, evidence is missing on moderators and predictors of change during ACT, and specifically web-based ACT. We therefore explored for whom exactly web-based ACT was (in)effective during a recently performed three-armed randomized controlled trial. Data from 238 heterogeneously diagnosed pain sufferers following either web-based ACT (n=82), or one of two control conditions (web-based Expressive Writing (EW; n=79) and waiting list (WL; n=77)) were analysed. Exploratory linear regression analyses were performed using the PROCESS macro in SPSS. Pain interference at three-month follow-up was predicted from baseline demographic, physical and emotional domain moderator/predictor variables for ACT compared to both control conditions. None of the demographic and most physical characteristics moderated ACT treatment changes. The only significant moderator of change compared to both control conditions was baseline psychological well-being, an aspect of positive mental health that represents optimal psychological functioning. Pain intensity was a moderator of change compared to EW. Furthermore, higher pain interference, depression and anxiety, and also lower levels of emotional well-being at baseline, were generically associated with higher pain interference in daily life six months later. Web-based self-help ACT may not be allocated to pain sufferers experiencing low levels of mental resilience resources. Other subgroups are identified that potentially need specific tailoring of (web-based) ACT. Evidence from subsequent trials is necessary.

## INTRODUCTION

Chronic pain is a prevalent condition that affects both individual pain sufferers and society (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Gaskin & Richard, 2012; Lambeek et al., 2011). Long-term pain complaints can highly disable those experiencing chronic pain and interfere with effective physical and emotional functioning in a multitude of life domains. A large array of treatment modalities is available to alleviate pain and treat disability related to chronic pain (Turk, Wilson, & Cahana, 2011). Where biomedical oriented treatment modalities focus on pain removal, psychological and multidisciplinary treatments based on a cognitive behavioural framework try to effectively restore functioning and enhance pain management (Scascighini, Toma, Dober-Spielmann, & Sprott, 2008; Williams, Eccleston, & Morley, 2013).

Despite the fact that large advances have been made in the knowledge on chronification and treatment of pain, momentary available biomedical and psychological interventions for chronic pain are unable to effectively treat every patient. Specifically, average treatment effects of psychological interventions are small to modest (Eccleston, Morley, & Williams, 2013; Pincus & McCracken, 2013; Williams et al., 2013). A promising pathway is to explore what, how, why and for whom treatment does or does not work (Eccleston, Morley, & Williams, 2013; Kraemer, Wilson, Fairburn, & Agras, 2002; Morley & Keefe, 2007). Specifically, knowledge on moderators of change ('for whom') can inform future allocation of patients to treatment and guide tailoring of interventions to patient characteristics, thereby potentially enhancing both treatment effectiveness and efficiency. Unfortunately there is a paucity of knowledge in this area. Reasonably, this paucity especially exists with regard to the most recent innovations in the availability of psychological treatments for chronic pain. One such therapeutic innovation is web-based Acceptance & Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 2012). The focus of this study is to examine for whom web-based ACT is especially effective or ineffective.

ACT is a recently new form of Cognitive Behavioural Therapy (CBT) that teaches pain patients to recognize and abandon unfruitful and narrowing attempts to avoid the pain experience itself and related thoughts and feelings (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). By introducing pain acceptance as an alternative to pain avoidance, patients are enabled to actively explore and engage in intrinsically motivated actions. Related therapeutic processes involve the deliteralization of pain-related thoughts and the application of mindfulness to promote non-judgemental present-moment awareness. Overall, therapeutic processes that are targeted in ACT promote psychological flexibility, the ability to behave in accordance with personal, meaningful values from an open, accepting and present-moment stance towards the pain experience (Hayes et al., 2012). Due to its focus on pain acceptance and the (re-)engagement in valued life activities as the opposite of pain control, ACT fits well to the challenges imposed to chronic pain

rehabilitation in treating highly disabled patients for whom pain removal is not a negotiable treatment option. Given this fit, it is not surprising that ACT can effectively restore pain-related disability in physical, emotional and social domains (e.g. Thorsell et al., 2011; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011; Wetherell et al., 2011; Wicksell et al., 2013).

Parallel to ACT, the last decade has seen an expansion in studies exploring web-based delivery of psychological interventions as a possible cost- and time-effective treatment modality. Besides its possible time- and cost-effectiveness, advantages of web-based delivery of interventions in health care include the possibility to reach physically disabled, stigmatized, or isolated patient groups. Also, web-based treatment enables individuals to follow an intervention at their own pace (Andersson & Cuijpers, 2008; Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006). Even minimal improvements during self-help interventions that can be easily disseminated through the Internet to many individuals may contribute to alleviate the general disease burden of chronic pain (Andersson & Cuijpers, 2008). First review studies indicate that web-based CBT in general seems to be a promising endeavour for a range of disorders, among which chronic pain (Andersson, 2009; Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Cuijpers, van Straten, & Andersson, 2008). However, at present we do not know for whom especially web-based CBT can be profitable (Bender et al., 2011; Macea, Gajos, Daglia Calil, & Fregni, 2010). And, until recently, not much was known about the possible effectiveness of web-based ACT for chronic pain (but see Buhrman et al., 2013), let alone that knowledge existed on possible moderators of change during web-based ACT.

Recently, we performed a large-scale, three-armed randomized controlled trial to examine the possible efficacy of a web-based self-help program based on ACT. Outcomes of the randomized controlled trial showed small to moderate effects for the ACT-program 'Living with Pain' compared to two control conditions in improving several disability-related processes and outcomes (Trompetter, Bohlmeijer, Veehof, & Schreurs, in press). The largest effects were present for those participants that adhered to the intervention as intended, an issue that has been recognized previously and is central to momentary e-health research (Donkin et al., 2011; Kelders, Kok, Ossebaard, & Gemert-Pijnen, 2012). Furthermore, psychological flexibility revealed to be the main working mechanism of change during the intervention (Trompetter, Bohlmeijer, Fox, & Schreurs, 2014), a finding that is in concordance with ACT theory and previous studies examining processes of change during ACT (Hayes et al., 2012; McCracken & Gutiérrez-Martínez, 2011; McCracken & Velleman, 2010; Wicksell, Olsson, & Hayes, 2010). Following these studies, the aim of the current study was to explore for whom web-based ACT as a promising treatment modality was especially (in)effective by investigating moderators and non-specific predictors of treatment change during the RCT described. Outcomes can give insight into future allocation of the web-based ACT interventions – and perhaps web-

based CBT in general - towards patients, and might highlight specific patient subgroups for which tailored guidance and monitoring during web-based ACT could be helpful.

Examples of factors that have been identified in face-to-face CBT for chronic pain to be negatively associated with treatment response include baseline levels of high psychological distress, low perceptions of pain control, high levels of negative thinking (e.g. catastrophizing) towards the pain, and stress (e.g. McCracken & Turk, 2002; Turner, Holtzman, & Mancl, 2007). Most previous CBT-studies have found no relationship between patient outcomes and demographic variables, such as age, gender, education and duration of pain (McCracken & Turk, 2002). Unfortunately, no such studies have been performed for either face-to-face or web-based ACT for chronic pain. We therefore performed exploratory analyses using a range of demographic characteristics, and furthermore, included all physical and emotional domain outcome measures assessed in the study. In addition to these often used demographic, physical and emotional illness-oriented factors, we were specifically interested in positive mental health (Keyes, 2002). Positive mental health can be described as a state of optimal mental functioning that consists of the aspects emotional, psychological and social well-being (Keyes, 2002; Lamers, Westerhof, Bohlmeijer, ten Klooster, & Keyes, 2011). While emotional well-being relates to hedonic aspects of happiness, positive affect and satisfaction with life, psychological well-being relates to eudemonic aspects of optimal psychological human functioning (Ryff, 1989; Ryff, 2014). These aspects include, for example, feelings of personal growth, positive social relations, environmental mastery and self-acceptance. As positive functioning also includes optimal functioning in social challenges and tasks, social well-being pertains to feelings of social coherence, integration and social contribution (Keyes, 2002). Positive mental health - especially psychological well-being - is related to resilience, the ability to maintain or recover high well-being despite life challenges such as enduring pain (Fava & Tomba, 2009; Ryff, Friedman, Morozink, & Tsenkova, 2012). As is resilience, positive mental health is much more than just the absence of mental illness or psychopathology (Fava et al., 2001; Keyes, 2005; Suldo & Shaffer, 2008; Westerhof & Keyes, 2010). We included a measure of positive mental health since the focus of ACT is theoretically supportive of increasing a positive and engaged life. This has been corroborated by outcomes of an ACT-based program for mild to moderate depressive disorder during which positive mental health increased significantly (Fledderus, Bohlmeijer, Smit, & Westerhof, 2010). We hypothesized that self-managing a comprehensive intervention that requires a transformation of pain-related thoughts and actions might be least achievable or effective for those individuals experiencing low positive mental health at baseline.



## METHOD

### Participants and procedure

The sample for the current study stems from the original sample in the RCT on the effectiveness of web-based ACT (Trompetter et al., in press). In brief, participants were a heterogeneously diagnosed group of pain sufferers recruited from the general Dutch population through advertisements in national newspapers and patient Internet platforms. Study inclusion criteria were a) 18 years or older, b) momentary pain intensity Numeric Rating Scale (11-point NRS) score > 4, (c) having pain for at least three days per week, (d) for at least six months. Exclusion criteria were partly based on the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) and Psychological Inflexibility in Pain scale (PIPS) (Wicksell, Lekander, Sorjonen, & Olsson, 2010), and were (a) severe psychological distress (HADS > 24), (b) extremely low levels of psychological inflexibility (PIPS < 24), (c) current participation in another CBT-based treatment, (d) having no internet or e-mail address, (e) reading problems due to insufficient Dutch language skills or illiteracy, and (f) an unwillingness or inability to invest approximately 30 minutes per day. The primary reason for exclusion prior to randomization was severe psychological distress.

Participants in this study followed either the ACT-condition (n = 82) or were allocated to one of both control conditions, being either Expressive Writing (EW) (n = 79) or Waiting List (WL) (n = 77). Those allocated to ACT or EW followed a nine-week web-based self-help program. The programs consisted of nine modules that could be worked through in nine to twelve weeks. Each participant received weekly e-mail counseling on a fixed day of the week, which was mainly offered for guidance and support of the process. In the ACT-condition, modules consisted of text, metaphors and exercises based on the six ACT-therapeutic processes (Hayes et al., 2012). These were supplemented with an introductory lesson on psycho-education regarding chronic pain, downloadable weekly audio mindfulness exercises, a diary and the opportunity to read weekly experiences from patients that previously participated in an ACT-intervention. In EW, the general assignment was to write (emotionally disclose) on a regular basis about experiences and emotions either related to chronic pain or to other situations. Modules started with psycho-education about emotion regulation related to the pain experience, followed by a specific writing assignment (e.g. focusing on specific negative or positive experiences). WL-participants were not offered any intervention, but were free to access any other form of treatment. These participants could follow the ACT-intervention six months from baseline.

## Measures

Both moderators and predictors of change were assessed. Moderators are baseline characteristics that interact with treatment to affect outcome, meaning that patient improvement depends on the value on the moderator variable. When a variable is not a moderator, it is possibly a non-specific predictor of change. Nonspecific predictors do not interact with treatment but predict later scores on outcomes for all participants. Both moderators and predictors of change should be measured prior to treatment randomization (Pincus et al., 2011; Turner et al., 2007). The primary outcome was measured at three-month follow-up, six months after baseline assessment (T1). All other measures functioned as possible moderators/predictors of change and were assessed at baseline, prior to randomization (T0).

### *Outcome*

*Pain interference in daily life* - The Multidimensional Pain Inventory (MPI), subscale *pain interference* consists of nine items and measures the degree to which pain interferes with different life domains, such as work, household work and social activities (Kerns, Turk, & Rudy, 1985; Lousberg et al., 1999). Higher scores indicate more pain interference (range 0 – 54). Internal consistency in the present study was at baseline  $\alpha = .87$ , at T1  $\alpha = .89$ .

### *Moderator/predictors*

*Demographic variables* – Demographic variables that were assessed as possible moderators/predictors were age, gender, educational level, employment status, and duration of pain complaints.

*Pain intensity* - Pain intensity was measured with a 11-point Numeric Rating Scale (NRS), ranging from ‘no pain’ (0) to ‘pain as bad as you can imagine’ (10). Item formulation and response categories were consistent with IMMPACT recommendations on core outcome measures in chronic pain research (Dworkin et al., 2005).

*Pain disability* – The Pain Disability Index (PDI) (Pollard, 1984) consists of seven items and assesses the degree to which chronic pain disables a person from performing daily activities, such as work, household responsibilities and recreational activities. Total scores range from 7 to 70, with higher scores indicating more pain disability. Internal consistency in the current study at baseline was  $\alpha = .82$ .

*Psychological distress* – The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) consists of 14 items. The scale measures the presence and severity of symptoms regarding anxiety (7 items) and depression (7 items). In this study the both subscales were used, with sum scores for each scale ranging from 0 – 21. Higher

scores indicate more anxiety or depression. Internal consistency in the present study at baseline was at  $\alpha = .73$  (anxiety) and  $\alpha = .79$  (depression).

*Positive mental health* – The Mental Health Continuum-Short Form (MHC-SF) (Keyes, 2002) consists of 14 items that measure three dimensions of positive mental health. Participants rate their frequency of feelings over the past month. Dimensions are *emotional well-being*, pertaining to positive feelings, happiness and satisfaction with life (three items) (score range 3 - 18); *psychological well-being*, pertaining to aspects of positive psychological functioning, such as autonomy, environmental mastery and personal growth (six items) (score range 6 – 36); and *social well-being*, pertaining to feelings of positive functioning in community life (five items) (score range 5 – 30). The MHC items did not show differential item functioning in a sample of individuals suffering from physical diseases compared to a healthy subsample (Lamers, Glas, Westerhof, & Bohlmeijer, 2012). The total scale and all subscales are analysed separately in this study. In general, higher scores indicate more well-being. Internal consistency in the current study at baseline was  $\alpha = .91$  (total MHC),  $\alpha = .85$  (emotional well-being),  $\alpha = .82$  (psychological well-being) and  $\alpha = .73$  (social well-being).

### Statistical analyses

Prior to main analyses, independent sample t-tests and  $\chi^2$ -tests were applied to determine if there were significant differences in all potential moderator/predictor variables at T0 between ACT and both control conditions.

In performing exploratory analyses, we followed steps taken by Turner and colleagues in a well-regarded study on moderators and predictors of change during CBT for chronic pain (Morley & Keefe, 2007; Turner et al., 2007). Pain interference in daily life at three-month follow-up, as measured with the MPI interference subscale, was used as indicator of treatment effect. To determine if selected moderator/predictor variables functioned as moderators or predictors of change in MPI interference, linear regression models were applied using the PROCESS macro for SPSS (Hayes, 2013). With regard to the demographic moderator/predictors, dummy variables were created for gender (male = 1, female = 0), employment status (working full/parttime = 1, other = 0), and duration of pain complaints (> 5 years = 1, < 5 years = 0). Educational level was divided into three groups (low, medium and high). During the analyses, each potential moderator/predictor was grand mean centered to reduce possible scaling problems and multicollinearity (Aiken & West, 1991). In the regression models, the MPI-interference score at T1 was entered as the dependent variable. The dummy variable representing Treatment (web-based ACT = 1, WL = 0 or EW = 0), the centered potential moderator/predictor, and the Treatment by centered moderator/predictor interaction variable were entered as independent variables. To control for baseline variation in outcome scores, the MPI interference score at T0 was added as independent variable to the model in the same step as all other

independent variables. Analyses were performed separately for ACT compared to EW, and ACT compared to WL.

In general, in the presence of a significant interaction effect the variable in concern was interpreted as being a moderator of change. In case the interaction effect was not significant but the main effect for the variable was, a variable was interpreted as being a predictor of change. Overall, significance of the moderators and predictors was interpreted at  $p < .05$ . Although the number of tests performed could call for a restriction on the borderline p-value, the p-value was not adjusted as such given the exploratory nature of this study. In case of significant interactions, simple slopes for mean, -1 and + 1 standard deviation moderator values as calculated in PROCESS were interpreted, as were outcomes of the Johnson-Neyman technique (Hayes, 2013; Johnson & Fay, 1950). This latter method derives a zone of significance, thereby identifying exact cut-off values of the moderator for which web-based ACT was (not) more effective compared to control conditions.

## RESULTS

There were no missing data at T0. Missing data at T1 (29.8%) were imputed using the Expectation Maximization (EM) Algorithm (Dempster, Laird, & Rubin, 1977). Outcomes of independent sample t-tests and  $\chi^2$ -tests revealed there were no significant differences at T0 between ACT and both control conditions on all included potential moderator/predictor variables, although the difference between ACT and WL in the percentage of people working full/part-time reached marginal significance ( $\chi^2(1) = 3.439$ ,  $p = .064$ ).

In general, a large proportion of participants in the study were highly educated (44.1%), female (76.0%) pain sufferers with an average age of 52.80 years ( $sd = 12.37$ ). More than half of the participants suffered from pain complaints for more than 5 years (63.0%), and almost all participants (93%) reported pain on a daily basis. 17.3% of participants reported a diagnosis had not been given for their complaints. Most prevalent diagnoses were fibromyalgia (20.0%), back complaints (12.7%), rheumatic diseases (9.7%), neuropathic complaints (8.8%), and other joint complaints (8.4%). An overview of demographic characteristics and baseline scores on all physical and emotional domain measures for participants can be found in Table 1.

### **Moderators of changes in MPI interference**

Outcomes of interaction tests for all 14 potential moderators can be found in Table 2. No significant interaction effects on MPI interference at three-month follow-up were present for any of the demographic variables. Of the remaining measures, the only interaction

Table 1. Baseline characteristics of participants in ACT and both control conditions

	ACT (n = 82)	EW (n = 79)	WL (n = 77)
<u>Demographic characteristics</u>			
Mean age, years (sd)	52.9 (13.3)	52.3 (11.8)	53.2 (12.0)
Female gender (%)	76.8	75.9	75.3
Education (%)			
Low	19.5	19.0	22.1
Intermediate	35.4	36.7	35.0
High	45.1	44.3	42.9
Working full-/part-time (%)	42.7	48.1	28.6
Pain duration > 5 years (%)	58.5	69.6	61.0
<u>Physical domain measures</u>			
Mean MPI Interference (sd)	32.3 (9.8)	32.2 (9.8)	33.3 (9.8)
Mean Pain intensity (sd)	6.3 (1.8)	6.1 (1.6)	6.2 (1.6)
Mean Pain Disability (sd)	36.0 (12.7)	36.4 (12.0)	36.1 (12.7)
<u>Emotional domain measures</u>			
Mean HADS depression (sd)	6.1 (3.5)	6.5 (3.5)	6.1 (3.2)
Mean HADS anxiety (sd)	7.2 (3.1)	7.5 (3.2)	6.9 (3.4)
Mean MHC emotional (sd)	12.4 (3.1)	12.1 (2.9)	11.1 (3.2)
Mean MHC psychological (sd)	23.9 (5.7)	23.9 (5.8)	22.8 (6.4)
Mean MHC social (sd)	16.2 (4.9)	16.2 (5.1)	16.0 (4.6)

Note: ACT = Acceptance & Commitment Therapy; EW = Expressive Writing; WL = Waiting List; MPI = Multidimensional Pain Inventory; HADS = Hospital Anxiety and Depression Scale; PDI = Pain Disability Index; MHC = Mental Health Continuum

effect that reached significance compared to both control conditions was MHC Psychological well-being (vs. EW:  $b = -.424$ ,  $p = .035$ ; vs WL:  $b = -.419$ ,  $p = .022$ ). A visual representation of the outcomes of simple slope analyses for mean scores, and scores one standard deviation below and above the mean value, are displayed in Figure 1. Web-based ACT was no more effective than WL in changing MPI interference for those scoring one standard deviation below mean (effect MPI interference T1 ACT versus WL =  $.323$ ,  $p = .837$ ). More specifically, an interpretation of the output of the Johnson-Neyman technique showed that the MHC Psychological well-being cut-off score for reaching significant effects of ACT compared to WL was 23.57. ACT was more effective in changing the primary outcome MPI interference than WL for those in the highest 51% of MHC scores. Compared to control condition EW, the MHC Psychological Well-being cut-off score for reaching significant effects of ACT was 16.97. ACT was more effective in changing MPI interference than EW for those in the highest 88.2% of MHC scores.

Table 2. Interaction effect outcomes of linear regression models to assess possible moderators of change in MPI interference

	ACT vs EW			ACT vs WL		
	<i>b</i>	95% CI	<i>p</i>	<i>b</i>	95% CI	<i>p</i>
<u>Demographic characteristics</u>						
Age	-.152	-.37 ; .07	.172	.804	-4.56 ; 6.18	.768
Gender	-2.422	-9.10 ; 4.25	.475	-.003	-.18 ; .18	.978
Educational level	2.190	-1.39 ; 5.77	.228	-.110	-3.07 ; 2.85	.941
Employment status	3.018	-2.00 ; 8.04	.237	-2.788	-7.59 ; 2.02	.253
Pain duration	.878	-3.85 ; 6.61	.763	2.289	-2.35 ; 6.93	.332
<u>Physical domain measures</u>						
Pain intensity*	-2.018	-3.36 ; -.68	.003	-.371	-1.74 ; 1.00	.594
Pain disability (PDI)	-.179	-.37 ; .02	.073	-.161	-.34 ; .01	.071
Pain interference (MPI)	-.077	-.37 ; .22	.606	-.135	-.37 ; .10	.251
<u>Emotional domain measures</u>						
Depression (HADS)	.263	-.40 ; .92	.431	.169	-.46 ; .80	.599
Anxiety (HADS)	.254	-.51 ; 1.01	.510	.732	-.04 ; 1.50	.063
Emotional well-being (MHC)	-.712	-1.50 ; .07	.074	-.525	-1.22 ; .17	.138
Psychological well-being (MHC)*	-.424	-.82 ; -.03	.035	-.419	-.78 ; -.06	.022
Social well-being (MHC)	-.460	-.99 ; .07	.128	-.451	-.95 ; .05	.078

Note: 95% CI = 95% Confidence interval

None of the measures representing the physical domain, being pain intensity, PDI and MPI interference, showed significant interaction effects compared to WL. However, a significant moderation effect existed for ACT compared to EW alone on pain intensity (NRS) ( $b = -2.018$ ,  $p = .003$ ). An inspection of the output of the Johnson-Neyman technique indicated that ACT was more effective than EW for those individuals having the highest 85.1% scores on pain intensity (NRS) at baseline. The corresponding cut-off score was 4.61.

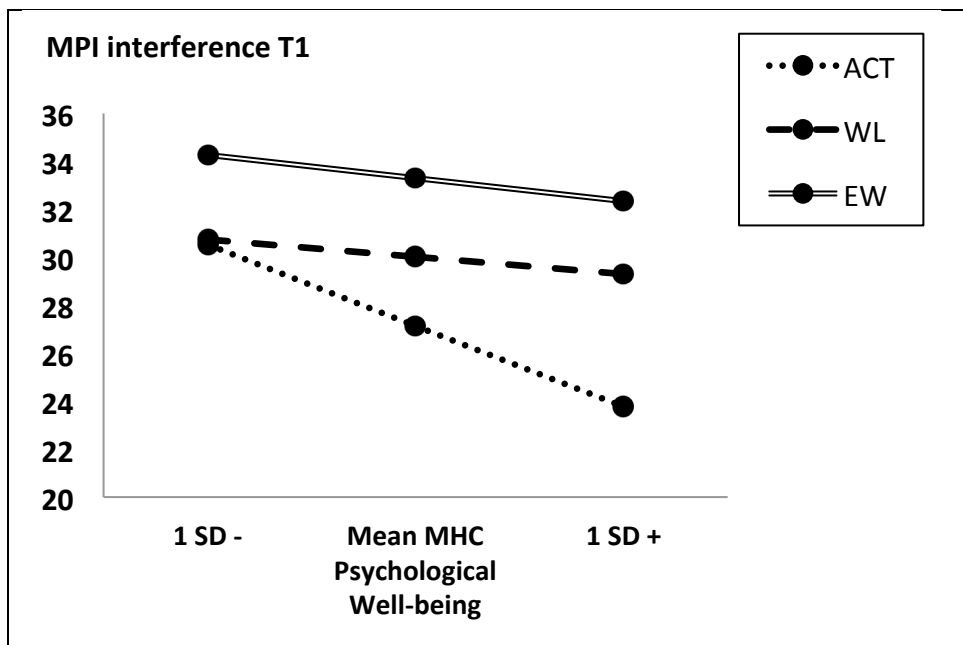


Figure 1. Pain interference outcome scores at different baseline values of moderator MHC Psychological Well-being for ACT compared to both control conditions.

### ***Predictors of change in MPI interference***

Outcomes regarding non-specific predictor analyses can be found in Table 3. As was the case for moderator analyses, none of the demographic characteristics were significantly associated with MPI interference at three-month follow-up, and neither were baseline PDI and pain intensity. T0 measures that were significantly associated with MPI interference six months later were similar for both sets of analyses (ACT compared to EW and ACT compared to WL). Significant predictors were MPI interference (vs EW:  $b = .732$ ,  $p < .001$ , vs WL:  $b = .760$ ,  $p < .001$ ), HADS depression (vs EW:  $b = .632$ ,  $p < .001$ , vs WL:  $b = .628$ ,  $p < .001$ ), HADS anxiety (vs EW:  $b = .806$ ,  $p < .001$ , vs WL:  $b = .529$ ,  $p = .013$ ) and MHC Emotional well-being (vs EW:  $b = -.554$ ,  $p = .007$ , vs WL:  $b = -.627$ ,  $p = .001$ ).

Table 3. Main effect outcomes of linear regression models to assess possible predictors of change in MPI interference

	ACT vs EW			ACT vs WL		
	<i>b</i>	95% CI	<i>p</i>	<i>b</i>	95% CI	<i>p</i>
<u>Demographic characteristics</u>						
Age	.012	-.10 ; .12	.830	-.061	-.15 ; .03	.183
Gender	2.997	-.34 ; 6.33	.078	1.412	-1.27 ; 4.11	.299
Educational level	-1.054	-2.85 ; .74	.247	.084	-1.40 ; 1.56	.911
Employment status	-.928	-3.53 ; 1.67	.482	2.006	-.383 ; 4.39	.099
Pain duration	.369	-2.45 ; 3.19	.796	-.332	-2.65 ; 1.99	.778
<u>Physical domain measures</u>						
Pain intensity	.344	-.44 ; 1.13	.388	-.570	-1.30 ; .15	.118
Pain disability (PDI)	.009	-.20 ; .22	.931	-.054	-.18 ; .08	.420
Pain interference (MPI)*	.732	.59 ; .88	<.001	.760	.64 ; .88	<.001
<u>Emotional domain measures</u>						
Depression (HADS)*	.632	.22 ; 1.04	.003	.628	.27 ; .99	.001
Anxiety (HADS)*	.806	.37 ; 1.25	<.001	.529	.11 ; .95	.013
Emotional well-being (MHC)*	-.554	-.96 ; .15	.007	-.627	-.99 ; -.26	.001
Psychological well-being (MHC)*	-.384	-.59 ; -.18	<.001	-.377	-.57 ; -.19	<.001
Social well-being (MHC)	-.205	-.47 ; .06	.128	-.197	-.44 ; .05	.117

Note: 95% CI = 95% Confidence interval

## DISCUSSION

The aim of the present study was to examine for whom web-based ACT may be especially effective or ineffective. This was done by assessing possible moderators and non-specific predictors of changes in pain interference in daily life during a previously evaluated web-based Acceptance & Commitment Therapy (ACT) intervention (Trompetter, Bohlmeijer, Veehof, et al., in press). Our exploratory, post-hoc analyses revealed that, compared to both control conditions, neither demographic nor physical domain factors functioned as moderators or non-specific predictors of pain interference in daily life scores six months later. Despite variable findings in individual studies, this is in line with the outcomes of a main review on predictors of CBT treatment effects (McCracken & Turk, 2002). The only existing moderator compared to both control conditions was psychological well-being as a central aspect of positive mental health and optimal human functioning (Keyes, 2002). Interpretation of findings showed that approximately 50% (compared to waiting list) and 88% (compared to Expressive Writing) of the highest scoring participants in web-based ACT benefited from following Living with Pain. On a practical level, these results indicate that web-based ACT should perhaps not be allocated to those having low positive



psychological functioning at baseline. Theoretically, these findings require more detailed clarification.

It is important to remind oneself that positive mental health, and hence psychological well-being, has been unequivocally shown to be more than just the absence of mental illness or psychopathology (Fava et al., 2001; Keyes, 2005; Lamers et al., 2011; Suldo & Shaffer, 2008; Westerhof & Keyes, 2010). As hypothesized, the present findings suggest that self-managing a challenging intervention that requires the transformation of cognitive-behavioral patterns that narrowed effective living for a prolonged period of time, could simply be too much for individuals lacking psychological resources. This process could evolve, for example, through a lack of feelings of environmental mastery, personal growth and positive social relations. Among other things, these processes relate to the feeling that oneself is able to develop new attitudes and behaviors, a sense of control over the external world, and the feeling that one is supported by significant others (Fava & Tomba, 2009; Ryff & Keyes, 1995; Ryff, 1989; Ryff, 2014). Overall, the fact that those lacking positive psychological functioning did not benefit highly from their participation is all the more important, as participation in the self-help intervention could have then become another 'failure', increasing feelings of hopelessness.

The only physical factor that functioned as a moderator of change in web-based ACT was pain intensity. ACT was more effective than Expressive Writing for the highest 88% of pain intensity scorers. In our main efficacy study, ACT approached moderate effects compared to Expressive Writing, while Writing was no more effective than placement on a waiting list (Trompetter, Bohlmeijer, Veehof et al., in press). From one perspective, our findings indicate that Expressive Writing might not work so well when high in pain intensity. This could explain outcomes from a range of studies indicating that Expressive Writing has mixed and at best, modest, benefits for people suffering from chronic pain (for a review, see Lumley, Sklar, & Carty, 2013), while it seems more effective for those suffering from mild and major depression (e.g. Baikie, Geerligs, & Wilhelm, 2012; Gortner, Rude, & Pennebaker, 2006; Krpan et al., 2013). As discussed by Lumley and colleagues (2013), in some instances emotional disclosure can be an unsettling experience that can instigate more pain and negative mood in those suffering from chronic pain. We hypothesize that Expressive Writing does offer insight in pain-related emotions, but at the same time does not help to develop any alternatives to highly impairing pain-related behavioral patterns and actions. Although not the primary target of our study, these findings are illuminating and can possibly fuel further study on the possible benefit of Expressive Writing in chronic pain populations.

In addition to these moderators of change in web-based ACT compared to WL, several nonspecific predictor of change were identified. These factors were depression, anxiety, emotional well-being and pain interference in daily life. Higher baseline levels of depression, anxiety and pain interference in daily life, and lower levels of emotional well-

being, were prospectively and generically related to higher levels of pain interference in daily life six months later. As for moderator analyses, most of these factors are emotional domain factors, which is in line with findings regarding predictors of change in CBT (McCracken & Turk, 2002; Turner et al., 2007). Practically, this knowledge could be used to further assess if specific tailoring of web-based ACT towards these characteristics, for example by applying more intensive therapist guidance and monitoring, could be a worthwhile endeavor in enhancing treatment effectiveness. Also, within the area of web-based psychological interventions the application of persuasive technology offers interesting future venues for tailoring of interventions (Kelders et al., 2012). However, it might also be worthwhile not to allocate these individuals to web-based self-management courses, but directly allocate them to more intensive face-to-face treatment.

A limitation to this study is that the RCT protocol was not powered a-priori for the application of moderator analyses. Therefore, analyses were post-hoc and exploratory, and should be interpreted accordingly. Due to possible under powering of the RCT, it might be that the number of participants available to perform moderator analyses was not sufficient to indicate other potential relevant moderators of change in addition the moderators we identified. As this is the first study to take into account a measure of positive mental health, a primary task for future trials would also be to examine if aspects of resilience and psychological well-being recurrently function as moderators or predictor of treatment change. Nevertheless, our study pertains to methodological requirements of exploratory moderators studies (Pincus et al., 2011; Turner et al., 2007), and highlighted several interesting outcomes. Another limitation is that we produced specific cut-off scores to exemplify for whom self-help ACT seems specifically (in)effective. This is the first efficacy trial to produce cut-off scores, which are therefore not readily transferable to clinical practice. However, we believe that the production of our cut-off scores is one step forward to translating scientific output into useful applications for practice.

Overall, this study was the first to assess moderators and predictors of change during web-based ACT for chronic pain. This resulted in relevant insights with regard to the future allocation of the 'Living with Pain' intervention towards pain sufferers, and highlighted specific patient subgroups for which tailored guidance and monitoring during the ACT-intervention could be helpful. In addition to these practical outcomes, illuminating theoretical insights were gathered regarding ACT theory (Hayes et al., 2012) and findings revealed that, broadly, moderators of change for ACT-based treatment follow similar patterns as in CBT. Finally, we indicated the potential importance of resilience in chronic pain research and self-help interventions. In doing so, we added to a growing range of studies indicating that a broadened focus in chronic pain research and interventions on factors pertaining to positive mental health and resilience could be worthwhile. Positive emotional well-being and positive affect are highly relevant factors in predicting mental and physical illness (Boehm & Kubzansky, 2012; Keyes, Dhingra, &

Simoes, 2010; Lamers, Bolier, Westerhof, Smit, & Bohlmeijer, 2012; Steptoe, Dockray, & Wardle, 2009). It is therefore possible that interventions aiming to enhance resilience resources in chronic pain patients could help to manage physical and emotional disability in the long-term. First efforts to introduce resilience as a new, worthwhile paradigm in individual chronic pain adaptation have been made, and can be used as a springboard to further dive into this interesting research field (Sturgeon & Zautra, 2010, 2013).

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# CHAPTER 7

Psychological flexibility and catastrophizing as associated  
change mechanisms during an online acceptance-based  
intervention for chronic pain

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**ABSTRACT**

The underlying mechanisms that contribute to the effectiveness of cognitive behavioural interventions for chronic pain require further clarification. The role of, and associations between, psychological flexibility (PF) and pain catastrophizing (PC) were examined during a randomized controlled trial on internet-based Acceptance & Commitment Therapy (ACT) for chronic pain. We assessed (1) the unique and combined indirect effects of PF and PC on outcomes, and (2) the existence and nature of possible temporal associations between PF and PC during the ACT-intervention. 238 individuals were allocated to web-based ACT, a control condition on web-based Expressive Writing, or a waiting list control condition. Non-parametric cross-product of coefficients mediational analyses and a cross-lagged panel design were applied. Compared to both control conditions, baseline to post-intervention changes in PF and PC uniquely mediated baseline to three-month follow-up changes in pain interference and psychological distress. Only PF mediated changes in pain intensity. Indirect effects were approximately twice as large for PF ( $\kappa^2 = .09-.19$ ) than for PC ( $\kappa^2 PCS = .05-.10$ ). During ACT, early and late changes in both PF and PC predicted later changes in the other variable. Although overall effects for PF were stronger, both PF and PC may function as unique mechanisms of change during ACT that reciprocally influence and strengthen each other over time. Further implications are discussed.

## INTRODUCTION

Acceptance & Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 2012) is an effective cognitive behavioural therapy in reducing psychosocial and physical disability related to chronic pain (Buhrman et al., 2013; Thorsell et al., 2011; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011; Wetherell et al., 2011). As with other cognitive behavioural therapies (CBT), the primary aim of many studies on ACT has been to examine treatment efficacy. A complementary focus on proposed treatment mechanisms (i.e. 'process variables') is necessary to clarify how and why changes in individual functioning occur during treatment. This knowledge can help to further enhance clinical procedures and guide more successful allocation of patients to treatment (Kazdin, 2009; Kraemer, Wilson, Fairburn, & Agras, 2002). This is especially relevant in the realm of chronic pain where treatment effects are known to be modest, and momentary available treatment modalities are not effective for everyone (Turk, Wilson, & Cahana, 2011; Williams, Eccleston, & Morley, 2013).

The central, overarching therapeutic mechanism in the framework of ACT is *psychological flexibility* (Hayes et al., 2006, 2012). In targeting psychological flexibility, ACT firstly fosters the adoption of an 'open' response style which includes both acceptance, the uptake of an open stance towards the pain experience that is offered as an alternative towards fruitless attempts to control or avoid the pain, and the process of *cognitive defusion*. Cognitive defusion reflects the ability to distance oneself from thoughts and learn to recognize these thoughts as separate from the experiences they refer to, thereby facilitating the choice not to react on their content. Acquiring an open response style enables one to actively choose and engage in valued life activities, even in the presence of pain. This second response style includes the processes *values* and *committed action* and is termed the 'engaged' response style. The interrelated processes *self-as-context* and *present-moment awareness* are represented in the 'grounded' response style, which are associated with mindfulness and enable the uptake of an unbiased stance in the here-and-now from where one can open up and actively engage in life (Hayes et al., 2012). Observational studies have shown that aspects of psychological flexibility are associated with disability in chronic pain patients (McCracken & Eccleston, 2005; McCracken, Gauntlett-Gilbert, & Vowles, 2007; McCracken & Yang, 2006; Viane et al., 2003). Furthermore, several studies show that psychological flexibility specifically contributes in predicting patient improvement during ACT-based treatment (McCracken & Gutiérrez-Martínez, 2011; McCracken & Vowles, 2008; Vowles & McCracken, 2008), and one randomized controlled trial on ACT showed that psychological flexibility is an actual mediator of improvement in individuals experiencing whiplash associated disorder. In this study, psychological flexibility mediated outcomes beyond other process variables such as kinesophobia and self-efficacy (Wicksell, Olsson, & Hayes, 2010).

Unfortunately, knowledge from other randomized controlled trials on mediating mechanisms of change during ACT is lacking. Therefore the overall aim of this study was to further clarify the treatment mechanisms of change during a recently performed randomized controlled trial on web-based ACT for chronic pain (Trompetter, Bohlmeijer, Veehof, & Schreurs, in press). In addition to specific ACT-related processes, we focused on pain catastrophizing as an established, key process in the fear avoidance model of pain (Crombez, Viane, Eccleston, Devulder, & Goubert, 2013; Vlaeyen & Linton, 2000) and CBT-based psychosocial interventions (Turner & Romano, 2001). Pain catastrophizing refers to the degree to which a patient employs overly negative, exaggerated cognitive appraisals of the pain experience (Sullivan et al., 2001). It is theoretically and clinically associated with avoidance behaviour (Vlaeyen & Linton, 2000), and additionally, shares a focus with cognitive defusion on pain-related thoughts. Contrastingly, ACT explicitly targets the function of these thoughts without trying to change their specific content or frequency as is the case in CBT (Hayes et al., 2012). Studies have shown that catastrophizing is associated with disability in pain patients (Peters, Vlaeyen, & Weber, 2005; Sturgeon & Zautra, 2013; Swinkels-Meewisse, Roelofs, Oostendorp, Verbeek, & Vlaeyen, 2006), and outcomes of a large array of randomized controlled trials show that reduction of catastrophizing is an important process variable of patient improvement during CBT-based treatment (Smeets, Vlaeyen, Kester, & Knottnerus, 2006; Spinhoven et al., 2004; Turner et al., 2007).

Interestingly, a handful of studies have shown that both CBT- and ACT-based treatments are able to simultaneously affect catastrophizing and acceptance as a central aspect of psychological flexibility. Although not targeted directly, acceptance improved during CBT-based treatment (Vowles, Wetherell, & Sorrell, 2009; Wetherell et al., 2011), and similarly, catastrophizing decreased significantly during ACT-based treatment (Buhrman et al., 2013; Vowles, McCracken, & Eccleston, 2007). Given the conceptual and clinical associations between aspects of psychological flexibility and catastrophizing, one may question the specific contributions of both processes in explaining changes in patient outcomes during cognitive behavioural interventions for chronic pain. At present only two studies, one in CBT and one in ACT, suggested that changes in both acceptance and catastrophizing are uniquely related to changes in outcomes beyond the other process (Baranoff, Hanrahan, Kapur, & Connor, 2013; Vowles et al., 2007). Even less is known about the level and course of change in both process variables in relation to each other during and after either CBT- and ACT-treatment. One cross-sectional study indicated that pain acceptance mediates changes in catastrophizing (Vowles, McCracken, & Eccleston, 2008). However, such research questions have not been investigated in controlled trials, and especially, have not been investigated *during* the course of treatment. A further detailed examination of the exact interrelationship between aspects of psychological flexibility and pain catastrophizing during ACT, can help to intergrate existing knowledge,

and contributes to overcoming the suggested non-uniformity, within existing psychosocial models and frameworks of chronic pain (e.g. Pincus & McCracken, 2013).

We used data from a recently performed, three-armed randomized controlled trial on the efficacy of an internet-based guided self-help ACT-intervention (Trompetter, Bohlmeijer, Veehof, et al., in press). During the trial, not only several patients outcomes improved significantly in ACT compared to both control conditions, but also both psychological flexibility and catastrophizing improved. To follow-up on these findings and extend outcomes of previous studies, we first examine the unique indirect effects of both process variables in changing pain interference, psychological distress and pain intensity in ACT compared to the control conditions. Additionally, we investigate the combined indirect effects of both processes when modelled simultaneously. Finally, we pursue a much more detailed investigation of the levels and courses of change in psychological flexibility and catastrophizing during the ACT-intervention in relation to each other. Using additional data that was available at two time-points during ACT, the existence and nature of possible temporal associations between psychological flexibility and catastrophizing during and after treatment will be assessed.

## METHOD

### Participants and procedure

Participants were a heterogeneous group of individuals experiencing chronic pain, who were recruited through advertisements in Dutch national newspapers and web-based patient platforms. People were included who (a) were older than 18 years, (b) had a momentary pain intensity score  $\geq 4$  on an 11-point Numeric Rating Scale, (c) who experienced pain for at least 3 days per week, (d) for at least 6 months. In short, patients were excluded if they (a) experienced very low levels of psychological inflexibility (score  $< 24$  on the Psychological Inflexibility in Pain Scale, Wicksell, Lekander, Sorjonen, & Olsson, 2010), (b) experienced very high levels of psychological distress (score  $> 24$  on the Hospital Anxiety and Depression Scale, Zigmond & Snaith, 1983) (c) currently participated in another CBT-based program, (d) had no access to internet/e-mail address, (e) had reading problems with Dutch language, or (f) were unwilling to invest approximately 30 minutes per day.

Of the 269 individuals that were assessed for eligibility, 238 participated and were randomly allocated to either ACT, an active control condition based on Expressive Writing (Pennebaker, 1997) or a waiting list control condition (see Appendix for flow chart). Baseline characteristics can be found in Table 1.

Table 1. Baseline characteristics for study participants

	ACT (n = 82)	EW (n = 79)	WL (n = 77)
Mean age, years (sd)	52.9 (13.3)	52.3 (11.8)	53.2 (12.0)
Female gender (%)	76.8	75.9	75.3
Education (%)			
Low	19.5	19.0	22.1
Intermediate	35.4	36.7	35.0
High	45.1	44.3	42.9
Married/Living together (%)	80.0	68.4	74.0
Duration of complaints > 5 years (%)	58.5	69.6	61.0
Diagnosis (%)			
none	14.6	17.7	19.5
back complaints	9.8	13.9	14.3
fibromyalgia	15.9	29.1	15.6
joint complaints	8.5	7.6	9.1
rheumatic disease	9.8	7.6	11.7
neuropathic complaints	11.0	6.3	9.1
other*	30.5	20.8	20.7
Mean MPI Interference (sd)	32.3 (9.8)	32.2 (9.8)	33.3 (9.8)
Mean Pain intensity NRS (sd)	6.3 (1.8)	6.1 (1.6)	6.2 (1.6)
Mean HADS (sd)	13.3 (5.8)	14.0 (6.0)	13.0 (5.5)
Mean PIPS (sd)	55.0 (11.6)	53.1 (11.8)	54.5 (11.6)
Mean PCS (sd)	18.6 (9.5)	17.6 (10.2)	19.1 (9.6)

Note: \*Other, includes different conditions (n < 5 per treatment group) including (a.o.) Whiplash Associated Disorder (WAD), Chronic Fatigue Syndrome (CFS), Chronic Regional Pain Syndrome (CPRS) and Complaints of Arms Neck and Shoulders (CANS); ACT = Acceptance & Commitment Therapy; EW = Expressive Writing; WL = Waiting List.

There were no significant baseline differences between the conditions for any of the demographic variables. Additionally, the groups were comparable on all outcomes and process measures at baseline (all variables  $p > .245$  in ANOVA group comparisons).

### Intervention

The internet-based ACT-intervention 'Living with Pain' consisted of 9 sessions that could be worked through in 9 to 12 weeks. The protocol was based on the successful self-help intervention 'Living to the Full' (Fledderus, Bohlmeijer, Pieterse, & Schreurs, 2012) and the protocol 'Living with Pain' (Schreurs & Hulsbergen, 2012; Veehof, Schreurs, Hulsbergen, & Bohlmeijer, 2010). In seven sessions, text, metaphors and experiential exercises were used to exemplify the six therapeutic processes of ACT (Hayes et al., 2012). Two additional sessions focused on psycho-education regarding chronic pain and social aspects of the pain experience. Downloadable mindfulness exercises were part of each session. Weekly e-mail counselling by trained graduate psychology students was offered for guidance, encouragement and support of the process.

Expressive Writing (EW) was an internet-based program based on the work of Pennebaker (1997), consisting of 9 sessions which could be worked through in 9 to 12 weeks. Each session started with psycho-education about emotions and emotion regulation related to the pain experience, followed by a specific writing assignment. In general, participants were instructed to disclose about stressful experiences that could be related to the chronic pain experience. Participants were asked to write at least three times a week for approximately 15 minutes. E-mail counselling was offered similar to the ACT-condition.

Participants in the waiting list control condition (WL) were offered no intervention and were free to access any other form of treatment. Six months from baseline participants received the opportunity to follow the ACT-intervention without e-mail counselling.

### Measures

Assessments were performed at baseline (T0), post-intervention at 12 weeks (T3) and three-month follow-up (T4). Additional data for the ACT-intervention was used that was collected at four weeks (T1), and eight weeks from baseline (T2). For this study we used primary and secondary outcome measures from the RCT that are recommended core outcome domains in chronic pain research by Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (Dworkin et al., 2005). Process variables used were psychological flexibility and pain catastrophizing. Internal consistency at baseline was good for all measures in this study (Cronbach's  $\alpha > .83$ ).

*Pain interference in daily life* - The Multidimensional Pain Inventory, subscale Pain interference in daily life (MPI-interference, nine items) (Kerns, Turk, & Rudy, 1985) measures the self-reported degree to which pain interferes with daily activities in different life domains (e.g. family, work, social activities). Higher scores indicating more pain interference (range 0 – 54).

*Psychological distress* – The Hospital Anxiety and Depression Scale (HADS, 14 items) (Zigmond & Snaith, 1983) measures both symptoms and severity of depression (seven items) and anxiety (seven items). Higher total scores indicate higher psychological distress (range total scale 0 – 42).

*Pain intensity* – Pain intensity was rated by an 11-point Numeric Rating Scale (NRS), ranging from (0) 'no pain' to (10) 'pain as bad as you can imagine' (Dworkin et al., 2005)

*Psychological inflexibility in pain* – The Psychological Inflexibility in Pain Scale (PIPS, 12 items) assesses psychological inflexibility in relation to chronic pain, by measuring both 'avoidance of pain' (8 items) and 'cognitive fusion related to pain' (Trompetter et al., 2014; Wicksell, Lekander, et al., 2010). The PIPS measures a tendency to engage in behaviour that functions to avoid pain and distress, and assesses the frequency of specific



pain-related thoughts that are likely to lead to avoidance behaviour when acted upon. Higher scores indicate higher psychological inflexibility (range 12 – 84).

*Pain catastrophizing* - The Pain Catastrophizing Scale (PCS, 13 items) was developed to measure pain catastrophizing (Sullivan *et al.* 1995). The scale consists of three subscales measuring ‘rumination’, ‘magnification’, and ‘helplessness’. The three subscales represent tendencies to increase attention towards pain-related thoughts, exaggerate the threat value of pain stimuli, and adopt a helpless orientation towards coping with the pain. Higher total scores indicate more catastrophizing (range 0 – 52).

### **Summary of previously reported RCT outcomes**

As reported in Trompetter *et al.* (in press), analyses using General Linear Mixed Model procedures in SPSS Statistics 20.0 showed superior improvement for ACT compared to EW in all three outcomes and both process variables. Compared to WL, ACT showed superior improvement in both process variables, HADS and pain NRS. Most effects occurred between T0 to T4. Overall, effect sizes were small to moderate and ranged from .23 to .60. No significant improvement occurred compared to WL in MPI interference ( $p = .109$  at T3 and  $p = .11$  at T4). Superior outcomes existed for those who adhered to the ACT intervention as intended (48% of participants), among which significant improvement compared to WL in MPI interference ( $p = .029$  at T3 and  $p = .008$  at T4).

### **Analyses**

Statistical analyses were in agreement with the Intention-To-Treat (ITT) principle. Available data at each time-point was 100% (T0), 85.7% (T1), 79.8% (T2), 72.3% (T3) and 70.2% (T4). Missing data were imputed using the Expectation-Maximization (EM) algorithm (Schafer, 1997).

### **Mediational analyses**

We applied a cross-product of coefficients approach using nonparametric bootstrapping procedures following Preacher and Hayes (2004, 2008). In this approach, the cross-product of the coefficient for the relationship between treatment (X) and mediator (M) (the  $a$ -path) and the coefficient for the relationship between the mediator (M) and outcome measure (Y) while controlling for X (the  $b$ -path) is calculated, after which the overall significance of the  $a*b$  effect is tested. We examined if improvements in PIPS and PCS from T0 to T3 indirectly affected changes in MPI-interference, HADS and pain NRS from T0 to T4 in ACT compared to both control conditions. We used PROCESS (version 2.10) in SPSS to test both simple and multiple mediation models and estimate the indirect effects and bias-corrected 95% confidence intervals (CI). All analyses were based on 5000 bootstrapped samples. An indirect effect was considered significant when the confidence interval did not include zero. For simple mediation models,  $\kappa^2$  was reported as a

recommended standardized measure of effect size, where .01 can be interpreted as small, .09 as medium and .25 as large (Preacher & Kelley, 2011).

**Cross-lagged panel design**

To assess the existence and nature of temporal associations between changes in PIPS and PCS during ACT a cross-lagged panel design was applied (e.g. Burns, Glenn, Bruehl, Harden, & Lofland, 2003; Fledderus et al., 2012). Data from all five available measurement points during the ACT-intervention were used. Measurement points were baseline (T0), four weeks after baseline (T1), eight weeks after baseline (T2), post-intervention at 12 weeks (T3), and follow-up three months after post-intervention (T4). First, within-subject t-tests were applied to examine at what time-intervals during and after the intervention (T0-T1, early intervention; T1-T2, mid-intervention; T2-T3, late intervention; T3-T4, follow-up) significant changes occurred in PIPS and PCS, and between-subject t-tests were applied to check whether there were significant differences in improvement between both processes at each time-interval.

To perform cross-lagged panel analyses, first, by regression, residualized change scores were computed for each consecutive time-interval for both variables (i.e. PIPS and PCS). As modelled in Figure 1, hierarchical regression analyses were applied to test whether changes in either PIPS or PCS at each time-interval significantly predicted later changes in the other factor (c in Figure 1) after controlling for autocorrelation within each process variable (a in Figure 1) and synchronous correlations between both process variables (b in Figure 1).

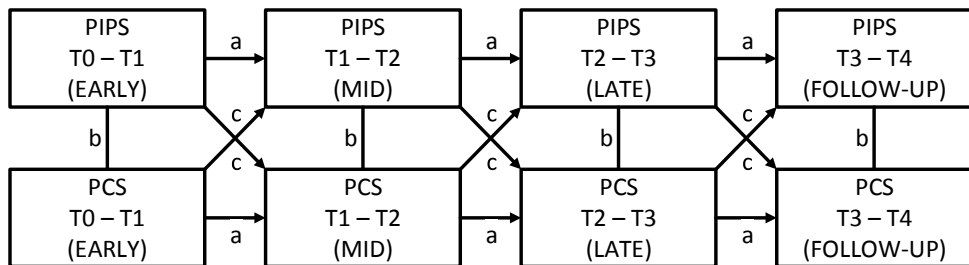


Figure 1. Model of cross-lagged panel design showing autocorrelations (a), synchronous correlations (b), and cross-lagged correlations (c).

**RESULTS**

**Unique and combined indirect effects of PIPS and PCS**

Outcomes of simple mediation analyses are shown in Table 2. For informative purposes the coefficients of the c-paths (total effect X on Y), a-paths and b-paths are reported additional to the indirect effects (ab). All coefficients for the c-paths and a-paths were

significant, except for the total effect (*c*-path) of ACT versus WL on change in MPI interference, which was marginally significant ( $p = .062$ ). Coefficients of the *b*-paths revealed that PIPS and PCS showed relatively similar associations with outcomes, except for pain NRS that showed significant, small associations with PIPS but not with PCS.

The 95% bootstrap confidence intervals indicated that significant indirect effects were present in ACT compared to both control conditions for PIPS in changes in MPI interference, HADS and pain NRS. Effect sizes ( $\kappa^2$ ) ranged from .09 to .18, suggesting moderate mediating effects of PIPS on outcomes. Also changes in PCS mediated changes in MPI interference and HADS in ACT compared to both EW and WL. No significant mediation was present for PCS on pain NRS (*ab* ACT versus EW:  $-.009$  [ $-.18, .19$ ]; *ab* ACT versus WL:  $.038$  [ $-.12, .29$ ]). For significant indirect effects,  $\kappa^2$  ranged from .05 to .10, generally indicating small to moderate indirect effects of PCS on outcomes. Indirect effects of both process variables were strongest for MPI interference.

Table 2. Outcomes of simple mediation analyses assessing indirect effects of both PIPS and PCS on changes in MPI interference, HADS and pain NRS for ACT compared to both control conditions

		c-path	a-path	b-path	Indirect effects		Effect sizes
					ab	95%CI	$\kappa^2$ (95%CI)
<u>MPI interference</u>							
PIPS	vs EW	-6.200**	-7.768**	.386**	-3.002	-4.84 ; -1.55*	.184 (.10 - .27)
	vs WL	-2.261	-9.599**	.260**	-2.499	-4.00 ; -1.47*	.159 (.09 - .24)
PCS	vs EW	-6.200**	-3.906**	.375**	-1.465	-2.97 ; -.50*	.087 (.03 - .16)
	vs WL	-2.261	-3.815**	.384**	-1.466	-2.66 ; -.59*	.098 (.04 - .17)
<u>HADS</u>							
PIPS	vs EW	-2.126**	-7.768**	.142**	-1.101	-1.90 ; -.51*	.120 (.06 - .19)
	vs WL	-1.900**	-9.599**	.137**	-1.320	-2.13 ; -.71*	.130 (.07 - .20)
PCS	vs EW	-2.126**	-3.906**	.130**	-.506	-1.11 ; -.12*	.055 (.01 - .12)
	vs WL	-1.900**	-3.815**	.126**	-.483	-1.11 ; -.12*	.050 (.02 - .11)
<u>Pain NRS</u>							
PIPS	vs EW	-1.142**	-7.768**	.044**	-.338	-.66 ; -.13*	.085 (.03 - .16)
	vs WL	-.881**	-9.599**	.048**	-.464	-.83 ; -.17*	.112 (.04 - .20)
PCS	vs EW	-1.142**	-3.906**	.002	-.009	-.18 ; .19	.002 (.00 - .01)
	vs WL	-.881**	-3.815**	-.010	.038	-.12 ; .29	.010 (.00 - .04)

Note: ACT = Acceptance & Commitment Therapy; EW = Expressive Writing; WL = Waiting List; \* Significant at  $p < .05$ . \*\* Significant at  $p < .01$ ; a Marginally significant at  $p < .10$

Additional multivariate mediational analyses were performed to assess the indirect effects of PIPS and PCS when modelled simultaneously (Table 3). *C*-paths and *a*-paths were similar to those reported in outcomes of simple mediation models. As in the simple models, only PIPS significantly mediated changes in pain NRS. With regard to MPI

interference and HADS, especially for PCS *b*-path coefficients and indirect effects generally became smaller with PIPS in the model when compared to outcomes of simple models. The mediating effects of changes in PCS on HADS became somewhat less consistent and were only significant for ACT compared to WL (*ab* ACT versus EW: -.203 [-.73, .17]; *ab* ACT versus WL: -.337 [-.96, -.01]. Overall, both process variables still significantly and uniquely affected changes in MPI interference.

Table 3. Outcomes of multiple mediation analyses assessing indirect effects of both PIPS and PCS on changes in MPI interference, HADS and pain NRS for ACT compared to both control conditions.

		b-path	Indirect effects	
			ab	95%CI
<u>MPI interference</u>				
ACT vs EW	PIPS	.347**	-2.694	-4.37 ; -1.38*
	PCS	.167*	-.653	-1.68 ; -.07*
ACT vs WL	PIPS	.213**	-2.044	-3.31 ; -1.07*
	PCS	.319**	-1.217	-2.25 ; -.49*
<u>HADS</u>				
ACT vs EW	PIPS	.129**	-1.005	-1.85 ; -.41*
	PCS	.052	-.203	-.73 ; .17
ACT vs WL	PIPS	.124**	-1.193	-2.04 ; -.55*
	PCS	.088	-.337	-.96 ; -.01*
<u>Pain NRS</u>				
ACT vs EW	PIPS	.050**	-.389	-.73 ; -.16*
	PCS	-.028	.108	-.04 ; .38
ACT vs WL	PIPS	.052**	-.501	-.88 ; -.22*
	PCS	-.026	.099	-.04 ; .38

Note: c-paths and a-paths are similar to outcomes of simple mediation models; ACT = Acceptance & Commitment Therapy; EW = Expressive Writing; WL = Waiting List; \* Significant at  $p < .05$ . \*\* Significant at  $p < .01$ ;

### Changes in PIPS and PCS during the ACT-intervention

Changes in both PIPS and PCS over time are displayed in Figure 2. Outcomes of simple within-group t-tests revealed that significant improvement occurred for PIPS during all time-intervals (all  $p < .001$ ) except during follow-up (T3-T4) ( $p = .924$ ). Improvement was largest during the first four weeks of treatment. Also with regard to PCS, significant improvement occurred on all time-intervals (all  $p < .019$ ), except for the time-interval T0–T1 ( $p = .732$ ). Improvement in PCS was largest during mid-intervention (T2-T3). When comparing changes in both variables, changes in PIPS were significantly larger than changes in PCS both early (T0-T1) (mean difference = -7.445,  $t(81) = -5.133$ ,  $p < .001$ ) and late in the intervention (T2-T3) (mean difference = -1.798,  $t(81) = -1.960$ ,  $p = .05$ ).

Inspection of Pearson correlations revealed that especially synchronous correlations between PIPS and PCS were significant ( $r = .37 - .50, p < .001$ , except for T0-T1). As Table 4 shows, results of hierarchical regression analyses showed that changes in PIPS both early (T0-T1) and late (T2-T3) during the intervention significantly predicted later changes in PCS after controlling for synchronous correlations and autocorrelation (T0-T1:  $\Delta R^2 = .042, p(\Delta R^2) = .022$ ; T2-T3:  $\Delta R^2 = .315, p(\Delta R^2) < .001$ ). Vice versa, changes in PCS at the same time-intervals significantly predicted later changes in PIPS (T0-T1:  $\Delta R^2 = .164, p(\Delta R^2) < .001$ ; T2-T3:  $\Delta R^2 = .134, p(\Delta R^2) < .001$ ), indicating the existence of reciprocal relationships between both process variables.

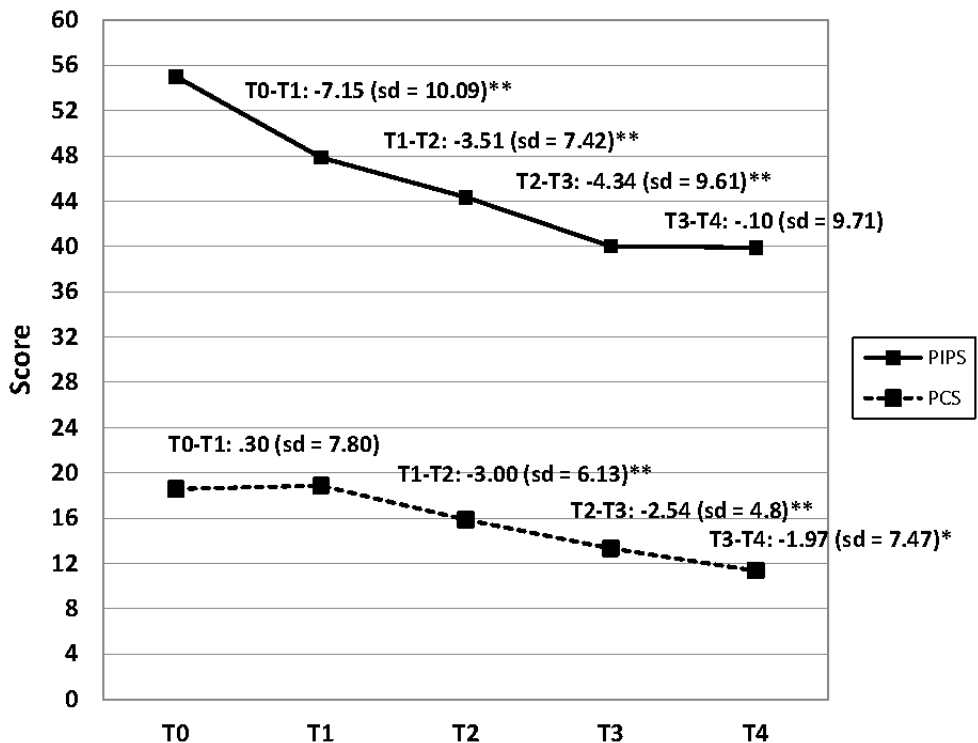


Figure 2. Changes in PIPS and PCS during and after the course of treatment.

Table 4. Outcomes of hierarchical multiple regression analyses: cross-lagged panel design assessing the directionality of changes in PIPS and PCS during and after the ACT-intervention

Outcome variable	PCS				PIPS			
	B	SE(B)	ΔR <sup>2</sup>	p (ΔR <sup>2</sup> )	B	SE(B)	ΔR <sup>2</sup>	p (ΔR <sup>2</sup> )
<u>Mid-intervention</u>								
Step 1	-.282	.075			-.121	.080		
	Early PCS				Early PIPS			
	Mid PIPS	.480	.350	<.001	Mid PCS	.122	.267	<.001
Step 2	.134	.057	.042	.022	.404	.085	.164	<.001
	Early PIPS				Early PCS			
<u>Late-intervention</u>								
Step 1	-.175	.083			-.306	.126		
	Mid PCS				Mid PIPS			
	Late PIPS	.176	.052	.235	.819	.201	.248	<.001
Step 2	.056	.072	.006	.440	-.235	.190	.014	.219
	Mid PIPS				Mid PCS			
<u>Follow-up</u>								
Step 1	-.018	.165			-.562	.096		
	Late PCS				Late PIPS			
	Follow-up PIPS	.271	.077	.135	.003			
Step 2	.549	.081	.315	<.001	.721	.125	.379	<.001
	Late PIPS				Late PCS			
	Follow-up PCS				Follow-up PIPS			

Note: Early intervention = T0-T1; Mid-intervention = T1-T2; Late intervention = T2-T3; Follow-up = T3-T4

## DISCUSSION

The overall purpose of this study was to help clarify the treatment mechanisms of change during an internet-based guided self-help ACT-intervention for chronic pain. In a previous manuscript (Trompetter, Bohlmeijer, Veehof, et al., in press), we described that participants in the ACT-intervention significantly improved on several domains of chronic pain disability compared to participants in an active and a waiting list control condition and, additionally, showed that both psychological flexibility and pain catastrophizing improved during the course of the intervention. These outcomes initiated a detailed exploration of the changes in the theoretically and clinically related treatment processes of psychological flexibility in pain and pain catastrophizing.

In both unique and combined models, improvements in psychological flexibility independently mediated changes in pain interference, psychological distress and pain intensity. These findings confirm the relevance of psychological flexibility as the central process variable in the theoretical framework of ACT, and extend previous outcomes of mainly uncontrolled trials on the importance of aspects of psychological flexibility in explaining psychosocial, emotional and physical domains of pain disability (e.g. Hayes et al., 2012; McCracken & Gutiérrez-Martínez, 2011; Vowles & McCracken, 2008; Wicksell, Olsson, et al., 2010). In addition to psychological flexibility, also catastrophizing improved significantly over the course of the intervention and uniquely and indirectly affected long-term improvements in pain disability. Indirect effects were most notably present in pain interference in daily life. Although this is the first randomized controlled trial to show that catastrophizing is an actual treatment mechanism of change during ACT beyond psychological flexibility, findings from earlier ACT-trials reporting similar improvements in catastrophizing suggest that these conclusions are not coincidental (Buhrman et al., 2013; Vowles et al., 2007).

Given the content and goals of the ACT-intervention, improvements in psychological flexibility were anticipated. Exercises, texts and metaphors were applied explicitly to reduce fruitless attempts to control or avoid the pain and impede the restricting influence of negative thoughts on behaviour, while at the same time increasing present-moment-awareness and actions that are in accordance with personal, meaningful values and goals. These are all aspects of psychological flexibility (Hayes et al., 2006, 2012; Veehof et al., 2010), and therefore, the focus of the intervention is in line with the larger effect sizes reported for psychological flexibility. As additionally, changes in psychological flexibility occurred earlier and were significantly larger at several time-intervals compared to catastrophizing, psychological flexibility was the most prominent and influential change mechanism of both processes. As mentioned earlier, this is in line with, and further strengthens the theoretical framework of ACT (Hayes et al., 2012). What requires more clarification is that catastrophizing functioned as an independent change mechanism

while not actively targeted during ACT. Although these conclusions seem unexpected at first, at a theoretical and clinical level associations seem to exist between the *function* of pain-related thoughts and behaviour as targeted in ACT, and the *content or frequency* of pain-related thoughts as targeted in CBT. As already put forward by Vowles and colleagues (2007), one can imagine situations in which the function of pain-related thoughts and experiences changes due to acceptance and cognitive defusion techniques. Changing the function of pain-related thoughts directly leads to a shift in attention from the content of pain-related thoughts to other life aspects, which, in turn, can easily and indirectly lead to changes in the frequency or content of these thoughts. The fact that catastrophizing, in contrast to psychological flexibility, did not increase until halfway the intervention fits with these considerations.

Reflecting the presence of theoretical and clinical associations between both processes it is perhaps not surprising that reciprocal relationships between both processes were reported at several time-intervals during the intervention. These outcomes extend findings from a previous cross-sectional study showing that changes in pain acceptance mediated changes in catastrophizing (Vowles et al., 2008), and reveal a much more complex interplay between the levels and courses of change in aspects of psychological flexibility and catastrophizing during treatment. At a clinical level, these findings imply that changes in catastrophizing strengthen the influence of psychological flexibility as an independent, but related treatment mechanism of change during ACT, and vice versa. Nevertheless, in every instance where catastrophizing significantly affected later changes in flexibility a non-significant main effect was included in the equation for either one of both processes. One can therefore debate if the actual influence of changes in catastrophizing on psychological flexibility in this specific intervention has been very large in nature. Future research is necessary to explore the interplay between both processes further and in more detail during the course of treatment. In the meantime, we propose that both psychological flexibility and catastrophizing should be monitored at set time-intervals during ACT-treatment of chronic pain in the future. Frequent monitoring of both processes can enhance the understanding of changes in individual functioning and help tailoring of the content of the intervention to specific patient's needs.

This study has several limitations. First of all, the original study sample consisted of a heterogeneous group of chronic pain patients recruited from the general Dutch population through newspapers and online patient platforms. It is therefore possible that this sample does not represent the typical chronic pain patient treated in psychological and multidisciplinary clinical care. However, as previously reported (Trompetter, Bohlmeijer, Veehof, et al., in press), the study sample did not differ consistently on clinical baseline measures from a sample of pain patients entering a multidisciplinary chronic pain setting (Trompetter et al., 2014). Furthermore, the number of dropouts and subsequent questionnaire attrition rates were relatively high. Although not uncommon in online



interventions (Eysenbach, 2005), the EM imputation used may not have been entirely successful in eliminating bias. Nevertheless, the EM algorithm was the best possible imputation method, whereby covariance structure in our data was retained and most plausible values have been imputed for missing data. Finally, we only performed additional data collection at two set time-intervals during the intervention. Given the small number of assessments, and the fact that participants were free to work on the treatment program over the course of a variable time-period, it is difficult to relate outcomes at specific time-intervals to the specific content of the intervention. Nevertheless, this was the first study ever to assess process measures during the course of the intervention in this specific area of research.

Our findings invoke research questions that can serve as inspiration for future research. For example, future studies could examine if reciprocal relationships between both processes – or other relevant treatment processes – exist and function in a similar, mirrored fashion during CBT. Also, the number of measurements taken during treatment should be extended to give an even much more detailed exploration of the exact time-intervals during which relevant changes occur (see for example Arch, Wolitzky-Taylor, Eifert, & Craske, 2012). Earlier studies have already taken first steps towards this endeavour by studying changes in aspects of psychological flexibility during CBT (e.g. Baranoff et al., 2013; Wetherell et al., 2011), and could serve as a starting point for further study.

In conclusion, this study shed more light on the treatment mechanisms of change during ACT for chronic pain, showing that both psychological flexibility in chronic pain and pain catastrophizing can function as reciprocally related, but independent mechanisms of change in individual functioning that can strengthen each other during the course of treatment. We believe that our current examination of the existence, uniqueness, course and strength of, and associations between, changes in two highly relevant change mechanisms of patient functioning in ACT was illuminating, and will guide further refinement of the theoretical and clinical frameworks underlying current psychological treatment for chronic pain.

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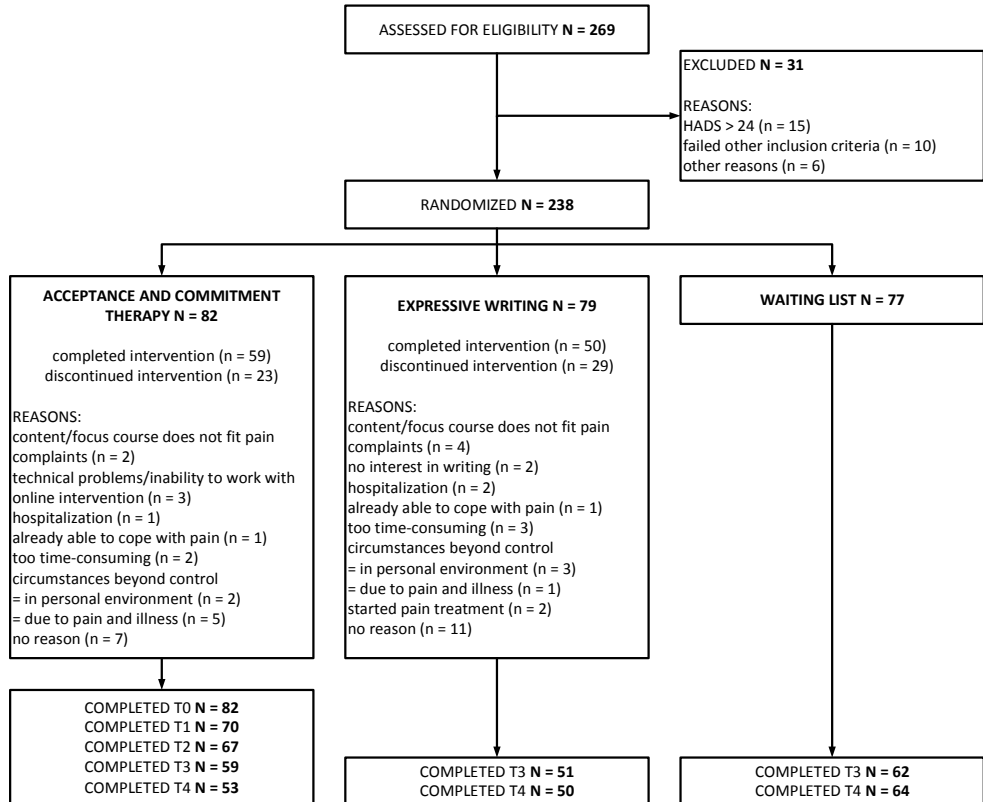
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APPENDIX. FLOW CHART







# CHAPTER 8

Are processes from Acceptance & Commitment Therapy (ACT) related to chronic pain outcomes within individuals over time? An exploratory study using n-of-1 designs

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**ABSTRACT**

Acceptance & Commitment Therapy (ACT) explicitly postulates experiential avoidance (EA) and values-based living (VBL) as essential treatment processes. We explored the temporal characteristics of, and associations between, EA and VBL and outcomes beyond that explained by pain intensity *within* individuals experiencing chronic pain. Using n-of-1 designs, three participants following a multidisciplinary treatment program filled in 12 items over 87 – 110 days. Both EA and VBL were related to at least one of five outcome variables (four domains of pain interference and emotional well-being) beyond pain intensity in two participants, but not in the third participant. In all three participants, pain intensity was inconsistently related to outcomes. Outcomes show that the predicted processes operate in some, but not all people and can be examined even in the absence of significant clinical improvement. Future research should further focus on unfolding of clinical treatment processes within individuals.

## INTRODUCTION

Efforts are made in different disciplines of psychology to improve the evidence-based nature of theory and interventions (e.g. Chambless & Hollon, 1998; Davidson et al., 2003; Michie & Prestwich, 2010). In addition to generating knowledge on general effectiveness of interventions, it is important to derive *how*, *why*, for *whom* and to *what extent* changes in behaviour occur (Elliott, 2010; Kazdin, 2009; Kraemer, Wilson, Fairburn, & Agras, 2002). Such research questions can focus on the identification of relevant treatment processes by assessing the relationship of these processes with individual functioning, and subsequently the ability of these processes to serve as causal working mechanisms of change. Especially in the area of chronic pain it is important to adopt research questions beyond mere average effectiveness on the group level, as treatment effects of psychological interventions are generally modest and treatment is not effective for everyone (McCracken & Turk, 2002; Turk, Wilson, & Cahana, 2011; Williams, Eccleston, & Morley, 2013).

A form of cognitive behaviour therapy that is very suitable to the treatment of chronic pain is Acceptance & Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 2012). Contrary to many other forms of cognitive behaviour therapy (Williams et al., 2013), ACT is built on a clearly outlined theoretical framework that explicitly postulates hypothesized treatment processes. ACT focuses on *acceptance* of pain and pain-related cognitions and emotions in order to create room for (re-)evaluation and commitment towards *valued life activities*. Pain acceptance is offered as an alternative strategy to *experiential avoidance*, a generic process that is characterized by on-going, fruitless attempts of an individual to avoid, control or change the pain experience (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). In ACT, the ultimate goal is to promote *psychological flexibility*, a process that can be understood as an umbrella process including the processes of acceptance, values-based living and related treatment processes (cognitive defusion, present-moment awareness, self-as-context and committed action). Psychological flexibility can be defined as the ability to perform values based behaviour in the presence of unwanted private experiences (Hayes et al., 2004, 2006, 2012). Many studies have shown that ACT is effective in the treatment of multiple conditions, including chronic pain (e.g. Fledderus, Bohlmeijer, Pieterse, & Schreurs, 2012; Ost, 2008; Powers, Zum Vorde Sive Vording, & Emmelkamp, 2009; Thorsell et al., 2011; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011; Wetherell et al., 2011).

Considerable efforts have been made in the area of chronic pain to study the relationship of ACT-processes to patient functioning, and the ability of these processes to function as working mechanisms of treatment change (McCracken & Eccleston, 2005; McCracken & Gutiérrez-Martínez, 2011; McCracken, Vowles, & Eccleston, 2005; Vowles & McCracken, 2008; Vowles, McCracken, & Eccleston, 2008; Wicksell, Olsson, & Hayes,

2010). Unfortunately, these studies all employed between-subject designs, thereby assessing between-subject variance. In other words, these studies – even when performing sequential measurements in a group of individuals over time – assessed if *differences between people* in treatment processes are able to predict outcomes (Johnston & Johnston, 2013). However, like many other psychological theories, ACT proposes that an individual's behaviour varies depending on one's personal variance in, e.g. experiential avoidance. As outcomes from between-subject studies in psychology are almost never stationary (stable over time) and homogeneous (apply to the same extent across all people) (Molenaar, 2004; Molenaar & Campbell, 2009), conclusions based on group level aggregates cannot be transferred to the individual level, something that is often implicitly assumed (Borsboom, Mellenbergh, & van Heerden, 2003; Curran & Bauer, 2012).

Reflecting the above, both clinical and statistical considerations lead one to consider the necessity to step down from the level of aggregate group studies and additionally focus on the individual. Nevertheless, very few studies in the area of ACT have applied research designs and/or statistical techniques suitable for the analysis of within-subject variance, such as multilevel (hierarchical) modelling or n-of-1 designs (Arch, Wolitzky-Taylor, Eifert, & Craske, 2012; Forman et al., 2012; Twohig, Hayes, & Masuda, 2006a, 2006b). In addition, the within-subject studies that have been performed in the area of ACT focus on questions regarding effectiveness of interventions. To the best of our knowledge, not many studies in both health and clinical psychology addressed basic research questions regarding the exploration of functioning of processes and the relationship with outcomes within individuals over time (e.g. Crombez, Viane, Eccleston, Devulder, & Goubert, 2013; Hobbs, Dixon, Johnston, & Howie, 2013; Peters et al., 2000; Quinn, Johnston, & Johnston, 2013).

We applied a series of n-of-1 studies in three people suffering from chronic pain in the weeks before, during and after enrolment in an eight-week, ACT-based multidisciplinary chronic pain rehabilitation program. The n-of-1 design is applied by taking multiple measurements within an individual for a prolonged period of time, with equal time intervals between the successive measures (e.g. daily) (Barlow, Nock, & Hersen, 2009; Borckardt et al., 2008; Hadert & Quinn, 2008; Morgan & Morgan, 2001). Power is in the number of measurements taken within individuals, not in the number of study participants. The n-of-1 design been recognized as a useful tool for the evaluation of complex interventions in the area of health care (Craig et al., 2008), and has been advocated as a possible alternative to the performance of new, expensive RCT's in the area of chronic pain to refine knowledge on what aspects of treatment works for whom to what extent (Williams et al., 2013). Although often used to study the effectiveness of interventions, the design can be used to study the natural history of relationships

between processes and outcomes and thereby establish how well these relationships are described by theory (Hobbs et al., 2013).

As this is the first study to be performed in this area, we employed a basic and exploratory research question: Are experiential avoidance and values-based living – hypothesized to be important treatment processes that are representative of the two main processes (i.e. avoidance as the counterpart of acceptance on the one hand, and commitment to life values on the other hand) from the theoretical framework of Acceptance & Commitment Therapy (ACT) – significantly related beyond pain intensity to chronic pain outcomes over time *within* individuals? We will assess our research question by undertaking the following steps sequentially for each of the participants separately.

(1) Describe the temporal characteristics of experiential avoidance and values-based living, and of pain interference in daily life in multiple life domains and emotional well-being. Pain interference in daily life is a recommended core outcome in chronic pain research (Dworkin et al., 2005). Emotional well-being is assessed to reflect a more positively formulated and psychological outcome variable. In addition to these process- and outcome variables, pain intensity will be assessed as an important context-variable.

(2) Assess the temporal associations of pain intensity, experiential avoidance and values-based living, and the association of both treatment variables beyond the effects of pain intensity with pain interference in daily life and emotional well-being over time. Hereby, we will assess both concurrent relationships at the same day, as well as prospective relationships on consecutive days.

We hypothesized that both experiential avoidance and values-based living would be related to at least one of five outcome variables (one of four pain interference domains or emotional well-being) within each individual beyond pain intensity. Confirmation of this hypothesis would imply that an ACT-based intervention can be applied to change an individuals' functioning by targeting experiential avoidance and values-based living as key treatment components of psychological flexibility.

## METHOD

### Participants

Study participants followed an eight-week, inpatient, multidisciplinary group rehabilitation program in a local pain rehabilitation centre in the Netherlands. Assignment to the inpatient treatment program occurred between approximately two to eight weeks before the start of the program. Once assigned, participants from two parallel, six-member treatment groups who were interested in the study received an information letter and consent form. The aim was to invite participants until four study participants

would be obtained. Six people were contacted by telephone in one to two weeks after receiving the information letter to meet the required number of four study participants. After five weeks of measurement, one of four participants dropped out of the study as the burden of simultaneous participation in both the study and treatment program was too high. Data from this participant are not analysed. All three of the remaining participants were female and between 22 and 32 years old. A description of participant characteristics can be found in the results section.

### **Procedure**

At the start and end of the study, the participants were visited at their homes by a member of the research-team. Both home-visits took approximately one hour. During the first visit, participants received instructions on using the PDA (smartphone) that was used to gather daily questionnaire data and discussed with the researcher the best time and place to fill in the daily questionnaire. Furthermore, they had the opportunity to ask for clarification of the diary items. Participants were instructed to fill in 17 questions on a PDA at the end of each day, in the weeks before (one to four weeks,), during and after (three to four weeks) the treatment program. Baseline measurement were made as long as possible depending on the moment of assignment to the in-patient treatment program. During the final visit, a short exit-interview was performed with each of the participants. During the interview, participants were asked to reflect on the measurement period and the multidisciplinary treatment received.

The PDA was programmed specifically for this study. A time window for filling in the questionnaire was installed on the PDA, ranging from 6 PM – 10 AM the following morning. Although the ordering of the variables within the questionnaire was kept constant, the ordering of the separate questions within each variable was randomised. One - two weeks after the start of the study and in the first week of treatment, the researcher contacted the participants to discuss and solve any problems. SMS text-message reminders were sent if the daily questionnaire was not filled in for two or more consecutive days.

### **Measures**

The daily questionnaire consisted of 17 items, 12 of which were used for this report. All items were taken from validated questionnaires. As suggested by IMMPACT recommendations with regard to core outcome measures in chronic pain research (Dworkin et al., 2005), all items were measured on a 10-point Numeric Rating Scale (NRS). Slight adjustments to the items or answering categories were made to make these suitable for daily assessment. Overall, item correlations and reliability over time were sufficient or good for each of the variables for each participant (items correlated  $> .30$  in the expected direction and Cronbach's  $\alpha > .65$  over time), except for pain interference in

daily life. As some of these items showed very low intercorrelations and Cronbach's  $\alpha < .65$  in two participants, the different life domains were analysed separately. A description of each of the concepts and items is given below.

### *Process variables*

Items to assess both process variables were selected during a pilot study with ten chronic pain patients following the multidisciplinary rehabilitation program. During this pilot study, different items formulated by the researchers (values-based living) or taken from existing, validated questionnaires (experiential avoidance) were filled in by the participants and evaluated with a member of the research-team. Final item selection was based on a clear and comprehensible format for participants, applicability in the daily diary, and, additionally, the evaluation of items by the research team as being both inherently formulated and comprehended by participants consistent with ACT theory.

*Values-based living* – No process-oriented questionnaires were available to assess the process values from the framework of ACT. Therefore, items were formulated by the research team and selected during a short pilot study as described above. These items were *'Today I feel I... (1) ..was able to do things that make life worthwhile, (2) ..did things that are important to me.'* Answering categories ranged from (0) 'not agree' to (10) 'totally agree'. An average score was calculated from both items, with higher scores indicating more values-based living.

*Experiential avoidance* – The Psychological Inflexibility in Pain Scale (PIPS) assesses psychological inflexibility (Trompetter et al., 2014; Wicksell, Lekander, Sorjonen, & Olsson, 2010). Two items of the subscale experiential avoidance (eight items) were used in this study, formulated as *'Today I... (1) ..avoided doing things when there was a risk it would hurt or make things worse, (2) ..postponed things because of my pain complaints.'* Answering categories ranged from (0) 'not true' to (10) 'very much true'. An average score was calculated from both items, with higher scores indicating more experiential avoidance.

### *Outcome variables*

*Pain interference in daily life* - The Multidimensional Pain Inventory - Interference subscale assesses interference in daily life due to pain (Kerns, Turk, & Rudy, 1985; Lousberg et al., 1999). Items assessing interference or changes in the life domains household chores, recreational activities, social activities, and enjoyment from family-related activities were relevant for the participants and used in the study. The items were *'Today my pain complaints interfered with/influenced... (1) ..my ability to do household chores, (2) ..undertaking recreational activities, (3) ..undertaking social activities, (4) ..the enjoyment I get from family-related activities.'* Answering categories were adjusted to fit the daily item format and ranged from (0) 'not true/not influenced' to (10) 'very much true/very much

influenced', with higher scores indicating more interference in daily life. The different interference domains were analysed separately.

*Emotional well-being* – The Mental Health Continuum (MHC) (Lamers, Westerhof, Bohlmeijer, ten Klooster, & Keyes, 2011) measures positive mental health. This study used the subscale emotional well-being (three items) that assesses feelings of happiness and satisfaction with life. Items were formulated as '*Today I felt... (1) ..happy, (2) ..interested in life, (3) ..satisfied.*' As the original item format of the MHC is on the frequency of feelings experienced over the last month, the answering scale were adjusted. Answering categories ranged from (0) 'not true' to (10) 'very much true', with higher scores indicating more emotional well-being.

*Pain intensity* - Pain intensity was assessed in this study as a crucial context-variable in chronic pain rehabilitation. Pain intensity was assessed with one question, '*How much pain did you experience over the last 24 hours?*' Answering categories ranged from (0) 'no pain' to (10) 'pain as bad as I can imagine'.

## **Analysis**

The n-of-1 daily measures data represent a time series for which specific analysis are applicable. All data was analysed separately for each of the participants.

### *Missing data*

Missing data was 14% for participant 1 (PP1; 15 of 110 observations), 25% for participant 2 (PP2; 23 of 89 observations) and 29% for participant 3 (PP3; 25 of 87 observations). As both PP1 and PP2 felt they were unable to adequately rate their pain interference in the domains 'family' and 'household' during the days staying overnight at the rehabilitation centre (two consecutive nights during eight weeks of total measurement period), data for these two questions on these specific days were also treated as missing values. All missing data was imputed with the AMELIA II software package using bootstrapping procedures within R (Honaker & King, 2010; Honaker, King, & Blackwell, 2009). The AMELIA-II software programme applies multiple imputation of missing values taking into account the time-series nature of the data. As quite a large proportion of missing data had to be imputed for each participant, boundaries (0 – 10; range of answering categories) were included in AMELIA-II to ensure more stable imputation. Multiple imputation produced five different datasets for each of the participants. Each of these datasets was used separately to perform all analyses. After performing the analyses, the results for each of the five datasets were combined based on the point estimates' averages and standard errors (Rubin, 1987).

*Descriptives and autocorrelation*

SPSS 20.0 statistics was used to calculate descriptive statistics for the data. This resulted in 40 data series per participant (four separate MPI-interference variables, emotional well-being, experiential avoidance, values-based living and pain intensity x five imputed datasets for each variable). For each participant, average means and standard deviations (over the five imputed datasets) for all variables can be found in Table 2. After graphically displaying the data series for visual inspection of variability over time, the SPSS Forecasting analysis tool was applied to assess serial dependency/autocorrelation in each of the data series. Intra-individual variability was present in all constructs in each of the participants. Outcomes of forecasting procedures were assessed to detect any significant time lags exceeding 95% confidence intervals. A maximum time lag of seven days was assessed.

*Relationships between processes and outcomes*

Further analysis was performed using the open source McKnight time series software package (McKnight, Mckean, & Huitema, 2000). This software package applies double bootstrapping procedures and is especially useful in analysing small sample time-series interventions in the behavioural sciences. The package is also very useful when assessing small numbers of data points in the total measurement period or one of the phases (baseline, intervention or follow-up) in the design and can account for deviations from normality often encountered in small samples. The general model used to test the process-outcome relationships was  $Y = X * b + error$ , with the error following an autoregressive time series of order  $p$ . Full models were tested in which pain intensity, experiential avoidance and values were included simultaneously. This was done to assess the relationship of both ACT treatment processes beyond pain intensity. Also, three variables representing the value of these predictor variables *the day before (-1)* were included in the full model together with the first three predictors. This was done to assess if there were any carry-over effects of pain intensity, experiential avoidance or values during consecutive days beyond the same day in predicting outcome variables. This resulted in 25 data series for each participant (one model for each of the five dependent variables x five imputed datasets).

A first-order autoregressive model was applied, taking into account lag 1 autocorrelation for each of the models assessed. Nevertheless, outcomes of SPSS Forecasting procedures indicated that a lag 2 relationship fitted the data better for two variables in two participants and a second-order autoregressive model was applied in these instances. Taking into account a lag 1 or lag 2 autocorrelation correctly applied adjustments for autocorrelation in 80% - 90% of the data series for each participant.



### Check on intervention effects

Before assessing the process-outcome relationship, we tested if there were intervention effects present on both processes and outcomes for each individual. Again, we used McKnight Time Series analyses procedures. The model applied was  $Y = X1 * b1 + X2 * b2 + X3 * b3 + X4 * b4 + error$ . As recommended by McKnight, predictors included in the model were a constant (X1), a time-variable (X2: measurement number, starting at 1, 2, 3 etc), a phase-variable (X3: 0 during baseline phase, 1 from start of intervention) and a slope-variable (X4: 0 during baseline, measurement number 1, 2, 3 etc during the intervention phase). Outcomes of this check revealed there were no significant changes in any of the processes or outcomes over time or during the intervention for each of the individuals, indicating ineffective treatment.<sup>2</sup>

In addition to a check on intervention effects on the individual level, we checked if there were any aggregate interventions effects for the twelve attendees of the two six-member groups which our participants attended. Data from standard test batteries at start and end of treatment during the intervention program was available for the MPI and PIPS. Paired sample t-tests (IBM SPSS Statistics 20) for the total group showed significant aggregate reductions in both pain interference in daily life as measured with the MPI, subscale pain interference in daily life,  $t(11) = 2.73$ ,  $p = .02$ , and psychological inflexibility as measured with the PIPS ( $t(11) = 4.26$ ,  $p < .001$ ).

## RESULTS

### PP1

PP1 is a 22-year old female. She lives together with a partner, has one child and was pregnant with her second child during the study. Her educational level is medium (received 12-16 years of education). PP1 does not work outside the house but is responsible for all household and family caretaking activities. She is diagnosed with fibromyalgia. Her current complaints started one to two years ago during pregnancy. PP1 filled in the daily diary during 23 days of baseline prior to start of treatment.

Variability over time in experiential avoidance and values-based living are displayed in Figure 1 in the Appendix. Descriptive statistics (Table 1) showed that the average scores for both experiential avoidance (mean = 4.49, sd = 1.65) and values-based living (mean = 4.90, sd = 1.51) on approached the median score of the answering categories.

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<sup>2</sup> Outcomes regarding the check on intervention effects for individuals are not included in the article. Tables consisting this information for each of the participants can be requested from the corresponding author.

Table 1. Means and standard deviations within individuals over time for all three participants

	PP1	PP2	PP3
N measurements	110	89	87
<b>Outcome variables</b>			
Pain interference domains (MPI)			
Household	6.19 (1.33)	3.81 (3.39)	3.98 (2.12)
Social activities	2.02 (2.13)	3.49 (2.96)	4.59 (2.13)
Family	3.55 (1.81)	2.75 (2.62)	4.94 (2.21)
Recreation	6.10 (1.44)	4.54 (3.77)	4.69 (1.89)
Emotional Well-being (MHC)	6.29 (1.01)	6.88 (1.17)	6.97 (0.99)
<b>Process/context variables</b>			
Pain avoidance	4.49 (1.65)	3.82 (3.25)	3.83 (2.05)
Values-based living	4.90 (1.51)	6.35 (1.80)	6.09 (1.51)
Pain intensity	6.81 (1.16)	6.34 (1.97)	7.20 (0.90)

Note: All variables were measured on an NRS-scale ranging from 0 to 10.

The highest interference in daily life due to the pain was experienced in the domains of 'recreation' and 'household activities' (mean = 6.19, sd = 1.33; mean = 6.10, sd = 1.44 respectively). Almost no interference was experienced in 'social activities' (mean 2.02, sd = 2.13). In addition to pain intensity, emotional well-being scores were relatively high compared to other variables and the most stable over time (mean 6.29, sd = 1.01).

Table 2 shows there were significant relationships over time of the processes experiential avoidance and values-based living beyond pain intensity with various pain interference domains and emotional well-being.

Table 2. Results PP1 on relationship between pain avoidance, values and outcome variables beyond pain intensity on concurrent and consecutive days

	Pain Interference in daily life				Emotional WB
	Household	Social Act	Family	Recreation	
Constant	3.730*	-2.794	-3.568	4.833*	6.466*
Pain intensity	.330*	.148	.501*	.384*	-.190*
Pain intensity (-1)	-.168	-.110	-.131	-.178	-.051
Avoidance	.306*	.402*	.550*	.215*	-.026
Avoidance (-1)	.030	.201	.120	-.013	-.024
Values	-.127	.223	.075	-.197*	.344*
Values (-1)	.095	.146	.249*	-.015	-.008

Note: \* Outcomes shown are combined results from five multiple imputed datasets; Significant effects based on 95% CIs; Social Act = social activities; Emotional WB = emotional well-being; (-1) = value for specific construct one day earlier (lag 1) Values shown are unstandardized Beta estimates

Pain avoidance was related to all four pain interference outcomes, ranging from beta = .215 (domain 'recreation') to beta = .550 (domain 'family'), but not to emotional well-being. Values-based living was related to emotional well-being and the domain 'recreation' (beta = -.197), but not to the other interference domains. Both process variables were simultaneously related to one outcome variable, being the pain interference domain 'recreation'. In general, there were no relationships between ACT-processes measured one day earlier and any of the outcome variables, indicating cross-correlations between process- and outcome variables at the present day for this participant. These outcomes confirmed our hypothesis for this participant.

## PP2

PP2 is a 23-year old, married female, with one child. Her educational level is medium (received 12-16 years of education). PP2 in general works outside the house on a part-time basis, but not during the weeks before, during and after following the multidisciplinary treatment program. She was recently retrained by her employer because of her pain complaints. PP2 is primarily responsible for household and family caretaking activities. She is diagnosed with low back complaints after hernia and subsequent failed surgery. Her current complaints started a few years ago with the onset of the hernia. PP2 filled in the daily diary during 28 days of baseline prior to start of treatment. Variability over time in experiential avoidance and values-based living is displayed in Figure 2 in the Appendix.

Descriptive statistics (Table 1) showed that the average experiential avoidance scores were below the median score of the answering scale and quite unstable over time (mean = 3.82, sd = 3.25). Scores for values-based living were more stable than scores on experiential avoidance (mean = 6.35, sd = 1.80). As for experiential avoidance, mean scores for the interference in daily life domains were below the median score of the answering categories, with the least interference in the domain 'family' (mean = 2.75, sd = 2.62). Again, variability in the pain interference domains seemed relatively high. In addition to pain intensity, emotional well-being scores were relatively high compared to other variables and the most stable over time (mean 6.88, sd = 1.17).

Table 3 shows there were a few significant relationships over time of the processes experiential avoidance and values-based living beyond pain intensity with various pain interference domains and emotional well-being. Experiential avoidance was related to the pain interference domain 'recreation' (beta = .237). Values-based living was also related to one out five pain interference domains, being the domain 'household' (beta = -.794). In addition, both process variables were not related simultaneously to any of the outcome variables. There were no further relationship between any of the predictor variables or pain intensity and each of the five outcome variables. As there was no simultaneous

relationship of experiential avoidance and values-based living with any of the outcome variables, our hypothesis was disconfirmed for this participant.

Table 3. Results PP2 on relationship between pain avoidance, values and outcome variables beyond pain intensity on concurrent and consecutive days

	Pain Interference in daily life				Emotional WB
	Household	Social Act	Family	Recreation	
Constant	8.54*	5.549*	.687	1.230	7.184*
Pain intensity	-.005	.214	.214	.369*	-.033
Pain intensity (-1)	-.037	.010	.180	.076	-.078
Avoidance	.158	.115	-.136	.237*	-.054
Avoidance (-1)	-.049	.000	-.134	-.037	-.026
Values	-.794*	-.364	.203	-.048	.133
Values (-1)	.025	-.116	-.131	.003	-.023

Note: \* Outcomes shown are combined results from five multiple imputed datasets; Significant effects based on 95% CIs; Social Act = social activities; Emotional WB = emotional well-being; (-1) = value for specific construct one day earlier (lag 1) Values shown are unstandardized Beta estimates

### PP3

PP3 is a 32-year old, married female, with two children. Her educational level is high (receiving > 18 years of education). Prior to start of the study she lost her full-time job in which she was very ambitious. She is now responsible for household and family caretaking activities and explores how to realize her work ambitions more realistically in the future. She is diagnosed with low back complaints that started approximately one to two years ago during pregnancy with her second child. PP3 filled in the daily diary during six days of baseline prior to start of treatment.

Variability over time in experiential avoidance and values-based living are displayed in Figure 3 in the Appendix. Descriptive statistics (Table 1) showed that the average experiential avoidance scores were below median (mean = 3.83, sd = 2.05), and that average values-based living scores over time were above median (mean = 6.09, sd = 1.51). The mean scores for the four pain interference domains were relatively similar and all approached the median score of the answering categories. The highest pain interference was experienced in the domain 'family' (mean = 4.94, sd = 2.21). Both pain intensity and emotional well-being scores were relatively high compared to other variables and the most stable over time (pain intensity, mean = 7.20, sd = 0.90, emotional well-being mean, 6.97, sd = 0.99).

Table 4 shows there were significant relationships over time of the processes experiential avoidance and values-based living beyond pain intensity with various pain interference domains and emotional well-being. Experiential avoidance was significantly related to both the interference domains 'household' (beta = .429) and 'recreation' (beta = .338), but not to emotional well-being. Furthermore, values-based living was related to

each of the dependent variables, ranging from beta = .379 (emotional well-being) to beta = -.722 (the pain interference domain 'family'). Both process variables were simultaneously related to two pain interference domains ('household' and 'recreation'). Significant relationships were also present between the interference domains 'household' and 'recreation' and values-based living scores one day earlier beyond the values-based living scores on the current day. Overall, these outcomes confirmed our hypothesis for this participant.

Table 4. Results PP3 on relationship between pain avoidance, values and outcome variables beyond pain intensity on concurrent and consecutive days

	Pain Interference in daily life				Emotional WB
	Household	Social Act	Family	Recreation	
Constant	12.004*	7.249*	4.554*	6.297*	5.423*
Pain intensity	-.226	-.056	1.173*	.148	-.040
Pain intensity (1)	-.262	.207	-.291	.029	-.108
Avoidance	.249*	.032	-.013	.338*	-.025
Avoidance (-1)	-.098	.134	-.075	.011	-.007
Values	-.388*	-.619*	-.722*	-.456*	.379*
Values (-1)	-.462*	-.088	-.202	-.272*	.068

Note: \* Outcomes shown are combined results from five multiple imputed datasets; Significant effects based on 95% CIs; Social Act = social activities; Emotional WB = emotional well-being; (-1) = value for specific construct one day earlier (lag 1) Values shown are unstandardized Beta estimates

## DISCUSSION

This study described the temporal characteristics of, and temporal associations between psychological treatment processes from the framework of Acceptance & Commitment Therapy (ACT) (Hayes et al., 2012) and outcomes over time within individuals experiencing chronic pain. Intra-individual variability was present in all constructs in each of the participants. This enabled us to explore whether individuals high (or low) in experiential avoidance and values-based living on a certain day were also high (or low) in pain interference in daily life and emotional well-being on these days. We also explored if these relationships applied to earlier days when allowing for the effects of the current day, whereby chronic pain outcomes would be related temporally to experiential avoidance and values-based living on the day before. As both experiential avoidance and values-based living are explicitly postulated as treatment processes that within the theoretical framework of ACT, we were able to test clearly outlined hypotheses. Our results showed that both experiential avoidance and values-based living as key components of psychological flexibility were related to at least one out of four pain interference domains or emotional well-being in two out of three participants. In the third participant, our hypothesis is not confirmed. In theory, these results suggest that ACT-

based interventions can be applied to change an individuals' functioning – but not every individuals' functioning - by targeting experiential avoidance and values-based living as key treatment processes. Our findings thereby corroborate and elaborate on outcomes from previous between-subject, group studies that show ACT processes are related to chronic pain outcomes and that these processes are able to function as working mechanisms of treatment change (e.g. McCracken & Eccleston, 2005; McCracken & Gutiérrez-Martínez, 2011; Wicksell, Olsson, et al., 2010).

A few findings deserve further discussion. We assessed if both ACT treatment processes were simultaneously related to chronic pain outcomes *beyond* pain intensity. Pain intensity was thereby assumed to be a crucial context variable when assessing cognitions and behaviour in chronic pain patients. Remarkably, pain intensity was only consequently related to chronic pain outcomes in one of three participants (PP1), replicating the finding of Quinn et al. (2013) that pain intensity did not predict activity limitations in any of six n-of-1 studies of chronic pain. Even for PP1, pain intensity was not more highly related to outcomes variables than both ACT treatment variables. In all three participants, experiential avoidance and values-based living seem at least equally or even more important. These findings corroborate ACT theory and other theories acknowledging that the chronic pain experience is not only related to and influenced by pain intensity, but is a complex interplay between physical, emotional and social factors (Gatchel, Peng, Peters, Fuchs, & Turk, 2007; Hayes et al., 2006). Our findings also revealed that significant temporal associations between values-based living one day earlier and outcome variables were present in only one of three participants (PP3). These findings imply that, overall, the relationship between ACT and behaviour was not a stable relationship for each of our participants in which ACT was able to predict behaviour. Rather, the relationships found were concurrent and quite variable over time. We hypothesize that temporal and more stable relationships can be formed during effective ACT treatment and subsequently represent internalization of ACT principles. Future research should further assess the variation between individuals in temporal relationships and implications thereof.

In general, this study builds on previous findings in two ways. First of all, we showed that ACT theory does not only apply between individuals but also within individuals. Although the transfer from group level conclusions to the individual level is very often implicitly assumed in psychology, the statistical and methodological conditions necessary to justify this assumption are often not met (Molenaar, 2004; Molenaar & Campbell, 2009). As the level of the individual is the level where change is theoretically described and assumed in ACT and many other psychological theories (Hayes et al., 2012), research within individuals is necessary to properly address research questions regarding treatment effectiveness and working mechanisms of treatment. Our study showed that the n-of-1 design is an appropriate, useful and feasible method to test clinical theory and

assess the natural history of relationships between treatment processes and outcomes within individuals, as also shown by Hobbs et al (2013).

Second, the applicability of ACT theory at the level of the individual was disconfirmed for one of the participants. This implies that ACT is not a suitable treatment modality for everyone. Furthermore, it implies that conclusions on the group level as often made in group studies, such as randomized controlled trials or tests of theory (Quinn et al., 2013), do not apply uniformly to each individual within that group. Researchers have recognized that average effects mask large changes for some patients and little or none for others (Williams et al., 2013). This is especially the case in the area of chronic pain, where aggregate treatment effects are often modest and inconsistent, and treatment is not effective for everyone (McCracken & Turk, 2002; Turk et al., 2011; Williams et al., 2013). Our results also indicate that the picture regarding the effectiveness and working mechanisms of chronic pain treatment is even more blurred and perhaps more difficult to entangle on the individual level than acknowledged previously (Turk et al., 2011; Williams et al., 2013). The multidisciplinary ACT-based treatment program that our participants followed did not bring about any significant changes within each individuals' functioning over time. This implies that, although theoretically ACT could have brought about changes in two participants by targeting change in experiential avoidance and values-based living, the intervention still failed to improve and stabilize both processes and outcomes. For these participants, factors such as non-compliance with therapeutic recommendations during treatment and deliverance of treatment by inexperienced staff could have interfered with possible treatment effects (Turk & Rudy, 1991; Williams et al., 2013). In this study, deliverance of treatment by ineffective staff does not seem to be a significant intervening factor as shown by the presence of aggregate improvement for the total group of participants with whom our study participants attended treatment. On the other hand, in the exit-interviews held all participants spontaneously revealed that they had not followed the recommendations made by at least one of the professional disciplines involved in the treatment program, which suggests possible non-compliance with therapeutic recommendations during treatment.

There are some limitations to this study and implications for future research. Although the n-of-1 design has proven to be a useful design to explore the within-subject level of behaviour change in detail, generalization from outcomes of n-of-1 studies to the larger chronic pain population is not possible (Barlow et al., 2009). Furthermore, as applied here the n-of-1 design was an observational design. Although the use of the design heightened the ecological validity of our study, each of our participants experienced a significant life-event during the measurement period (pregnancy and moving house) that probably influenced our measurements. In general, other designs and methodologies should be used together with, or follow up on, the n-of-1 design. We

propose the use of multilevel models that can account for both variance within and between individuals. A final limitation was the amount of missing data in our study for two out of three participants. To overcome this limitation we explicitly chose to use a program for multiple imputation of missing data. As all statistical analyses were performed in five datasets and combined thereafter, we feel we properly accounted for the uncertainty related to imputation of many missing data points. We suggest that future research focuses on both the aggregate and individual level in larger-N studies when testing the applicability and effectiveness of ACT (Johnston & Johnston, 2013). Such studies could replicate our exploratory findings and further unravel subsequent, related research questions focusing on working mechanisms of treatment change within individuals for whom ACT was effective, but also on further unraveling differences in within-subject and between-subject variance in chronic pain patients for whom ACT was ineffective.

Overall, this study was the first to show that ACT theory is confirmed within individuals experiencing chronic pain. We also showed the feasibility and utility of the n-of-1 design - and probably other within-subject designs - to assess the unfolding, natural history and relationship of important treatment processes and outcomes over time. Assessing research questions related to our study aim on the individual level can help to generate more knowledge on the effectiveness and specific working mechanisms of ACT and other cognitive behavioural therapies. Hopefully, effectiveness, efficiency and fit of chronic pain treatment to the individual can thereby be enhanced in the future.



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**APPENDIX. VARIABILITY OVER TIME IN PAIN AVOIDANCE, VALUES-BASED LIVING, AND THE HIGHEST CORRELATING OUTCOME VARIABLE FOR PP1, PP2 AND PP3 SEPARATELY.**

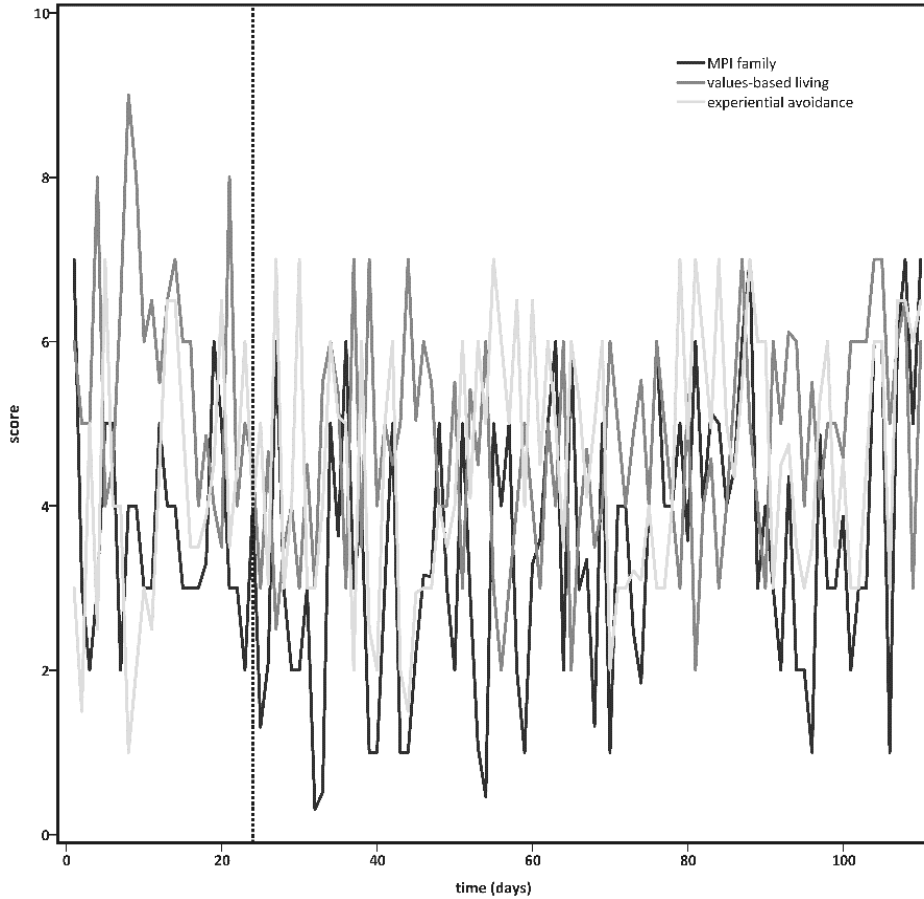


Figure 1. Variability over time for PP1 in pain avoidance, values-based living, and MPI family as highest correlating outcome variable. The vertical dotted line marks start treatment phase at day 24.

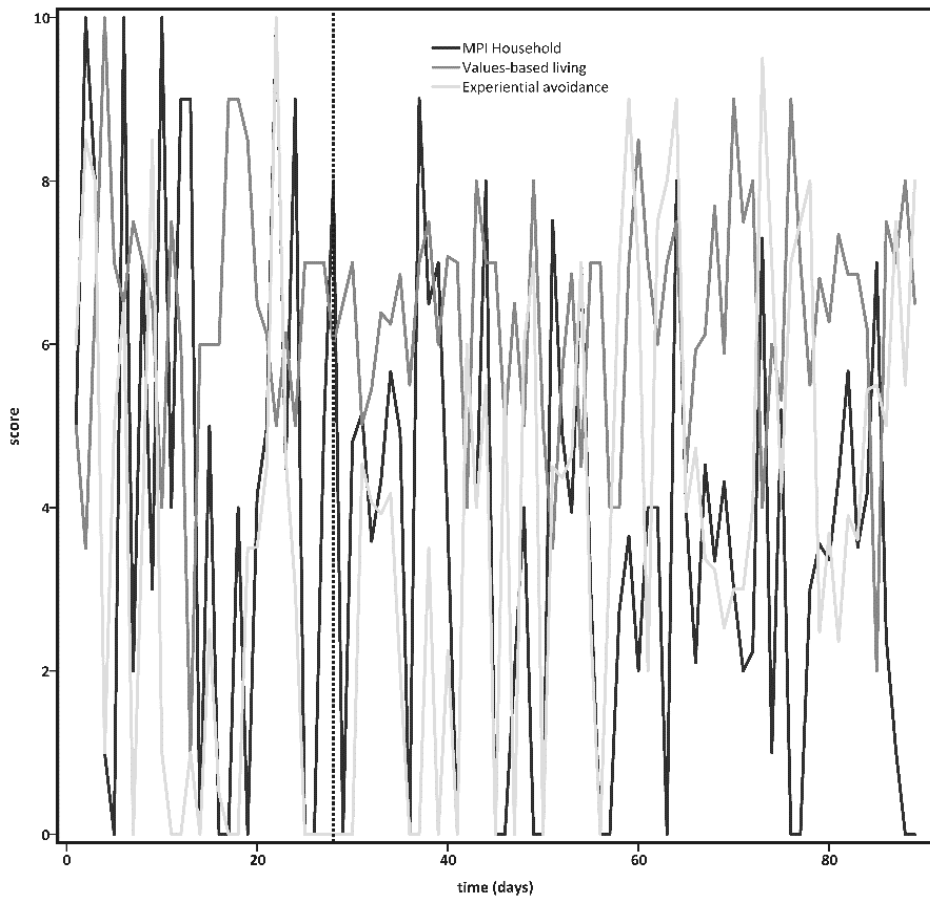


Figure 2. Variability over time for PP2 in pain avoidance, values-based living, and MPI Household as highest correlating outcome variable. The vertical dotted line marks start treatment phase at day 29.

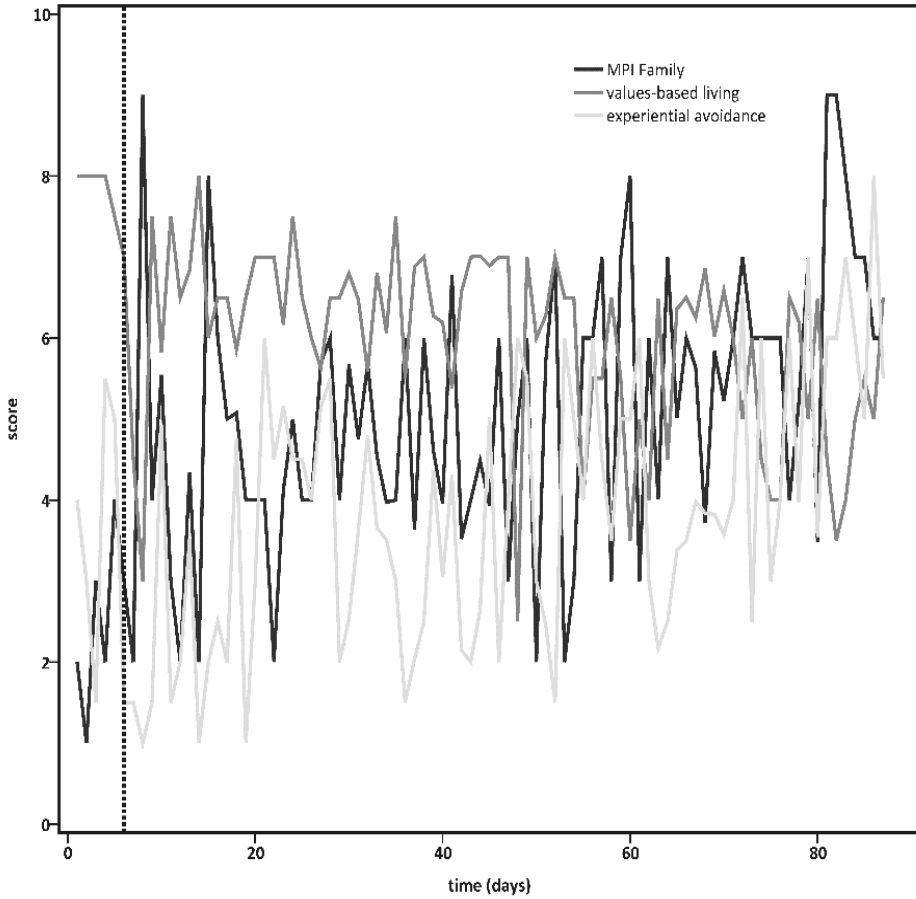


Figure 3. Variability over time for PP3 in pain avoidance, values-based living, and MPI family, as highest correlating outcome variable. The vertical dotted line marks start treatment phase at day 6.



# CHAPTER 9

## The systematic implementation of Acceptance & Commitment Therapy (ACT) in Dutch multidisciplinary chronic pain rehabilitation

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**ABSTRACT**

This study evaluates the implementation of Acceptance & Commitment Therapy (ACT) in Dutch chronic pain rehabilitation centres. Changes in multidisciplinary professionals' self-perceived competencies in working with ACT were evaluated and corroborated with patients' ratings of treatment adherence. To inform subsequent implementation efforts, relevant determinants of implementation success were monitored and the relationship with self-perceived competencies over time was explored. Data was gathered from 111 professionals, 9 managers and 79 patients using questionnaires at the start (T0), halfway (T1) and end (T2) of implementation, and at the end of treatment. All professionals adhered to ACT, improved significantly in self-perceived competencies over time and rated competence in working with ACT  $\geq$  adequate at T2. Determinants of success were evaluated extremely positive by professionals and management. Professionals' self-perceived competencies at T2 were most strongly related to ratings of more workload ( $b = -.43$ ), and experienced difficulties in working with ACT ( $b = -.38$ ) at T0 and T1. Multidisciplinary chronic pain rehabilitation professionals rated their improvement in working with ACT positively during the implementation period. Impeding and facilitating factors were explored successfully. A multi-faceted, long-term, educational, train-the-trainer approach may help to guide systematic changes in multidisciplinary treatment.

## INTRODUCTION

### **Multidisciplinary chronic pain treatment**

Chronic pain, defined as pain that lasts over three months that surpasses the normal healing time of tissue damage, is a highly prevalent and debilitating condition (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006). Physical, but also cognitive, emotional and social factors play a role in the understanding and treatment of chronic pain (Fordyce, 1976; Gatchel, Peng, Peters, Fuchs, & Turk, 2007; Turk & Okifuji, 2002). Since biomedical treatment modalities that focus on pain removal are not effective for everyone, psychological and multidisciplinary rehabilitation focuses on improvement of functioning in physical, psychological and social domains (Turk, Wilson, & Cahana, 2011). In multidisciplinary rehabilitation, different health-care providers work closely together to restore individual functioning of chronic pain patients. Most rehabilitation programs combine aspects as physical rehabilitation, exercise therapy, cognitive restructuring and behavioural treatment (Brown & Folen, 2005; Turk et al., 2011). Often, methods stemming from cognitive behaviour therapy (CBT) are used to provide an underlying treatment framework (Vlaeyen & Morley, 2005). Intensive multidisciplinary treatment is effective in improving functioning and quality of life (Flor, Fydrich, & Turk, 1992; Guzmán et al., 2006; Scascighini, Toma, Dober-Spielmann, & Sprott, 2008), with effect sizes in both mono- and multidisciplinary treatment settings ranging from small to moderate (Turk et al., 2011; Williams, Eccleston, & Morley, 2013).

### **Acceptance & Commitment Therapy**

Recent developments in cognitive behavioural treatments introduced Acceptance & Commitment Therapy (ACT) (S. C. Hayes, 2004; Steven C. Hayes, Strosahl, & Wilson, 2012). ACT is a form of CBT that targets *acceptance* of unavoidable aspects of chronic pain. Acceptance is an alternative to persistent, fruitless attempts to avoid or control the pain experience. By promoting acceptance and related processes such as present-moment awareness and values-based living, the goal of ACT is to increase *psychological flexibility* and take effective action in accordance with long-term meaningful values despite chronic pain (Steven C Hayes, Luoma, Bond, Masuda, & Lillis, 2006). By this focus, ACT offers an alternative to the paradoxical message of many rehabilitation programs that often implicitly focus on pain control. The inherent fit of the underpinnings of ACT to chronic pain treatment is reflected in outcomes of multiple studies showing that ACT is effective, both as a stand-alone psychological intervention and when interwoven in multidisciplinary rehabilitation (Buhrman et al., 2013; Dahl, Wilson, & Nilsson, 2004; McCracken & Gutiérrez-Martínez, 2011; McCracken, Vowles, & Eccleston, 2005; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011; Vowles & McCracken, 2008; Wetherell et al., 2011; Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008). In general, effect sizes are small to

moderate, which is similar to effect sizes of other CBT-interventions for chronic pain (Veehof et al., 2011). The American Psychological Association has recognized ACT as a clinical intervention for chronic pain with strong research support (APA Div 12 SCP, 2012). The above considerations resulted in consensus by collaborating professionals within a leading national consortium of chronic pain rehabilitation centers that ACT is the best practice for Dutch chronic pain rehabilitation (Heuts, Schreurs, & Koke, 2005). The merit of ACT was reflected in a large, but diffuse, interest from health-care professionals as observed by the authors to receive training in ACT. To overcome the gap - or even 'chasm' - reported by the Institute of Medicine (2001) between research findings and health-care practice and to prevent subsequent poor dissemination of ACT, we guided systematic implementation of ACT in Dutch chronic pain rehabilitation. In this paper, we describe the implementation and investigate factors related to successful implementation from start to post-implementation.

### **Developing an implementation blueprint**

Multidisciplinary teams from nine Dutch rehabilitation centers offering individual and/or group-based treatment participated. All centers were self-referred to the authors and expressed a wish and readiness to adopt ACT (Powell et al., 2012). Research indicates implementation requires considerable time and effort consisting of several recursive processes or stages of change (Fixsen, Blase, Naoom, & Wallace, 2009), especially when teams are involved in the process (Medves et al., 2010). Therefore implementation was designed to be rolled out over a relatively long period of time using multiple implementation and training strategies. In total, the implementation was designed to take 18 months. This trajectory consisted of a six-month pre-implementation phase followed by 12 months of implementation.

We adopted an effective implementation model developed by Grol and colleagues (Richard Grol & Wensing, 2005), taking into account the situation, setting, and our target of behavior change. In the planning phase, we developed academic partnerships, and visited all rehabilitation centers to communicate possible barriers and obtained formal commitments from each organization involved (Powell et al., 2012). Materials to aid the implementation process were developed, among which a secured website containing a blueprint of the implementation, worksheets and contact information of participating professionals. An ACT therapist manual for interdisciplinary teams (Schreurs & Hulsbergen, 2012) was written to be used parallel to a patient self-help book 'Living with Pain' (Veehof, Schreurs, Hulsbergen, & Bohlmeijer, 2010). All planning and developmental strategies resulted in a formal implementation blueprint - containing information on ACT, the goals of implementation, all materials developed and an optimal timeline for training activities - that served as a guide for systematic implementation (Richard Grol & Wensing, 2005; Powell et al., 2012).

**Education & training**

ACT adheres to several factors that can help successful implementation, such as clear advantages of use, compatibility with existing procedures and values, and proven efficacy (Chorpita & Regan, 2009; R. Grol & Wensing, 2005; Rogers, 2003). Nevertheless, ACT is a complex intervention asking for the use of new intervention techniques and long-term behavioral change of professionals. We therefore focused on educational strategies to heighten competencies in working with ACT (Wensing, Fluit, & Grol, 2005). Previous studies showed that didactics training alone do not create substantial change in therapy adherence and skills of professionals (Jensen-Doss, Cusack, & de Arellano, 2008; Oxman, Thomson, Pt, Davis, & Haynes, 1995). Therefore, we applied a multifaceted, interactive training program using coaching sessions and feedback (Chorpita & Regan, 2009; Fixsen et al., 2009; Miller, Yahne, Moyers, Martinez, & Pirritano, 2004; Sholomskas et al., 2008), using a train-the-trainer approach. This approach included the assignment of individuals as 'early adopters' and 'late adopters' in each organization. Both groups received outreach visits from a trained supervisor and attended peer review meetings, while in the meantime applying ACT in their daily work. Early adopters received more educational opportunities for a longer period of time, most importantly a full six-day course 'ACT for interdisciplinary teams'. Additionally, early adopters played a role in educational activities for late adopters in the second half of implementation. ACT was applied by both groups of adopters with selected patients, while other patients still received standard care. A schematic representation of the implementation process can be found in Figure 1.



impeded or facilitated implementation success, for example professionals' attitude towards ACT or experienced capability of teams to implement ACT, can be helpful for future implementation efforts in selecting appropriate implementation strategies. We therefore asked professionals and management to rate possible determinants of implementation success. First, we described the ratings of these determinants and explored if any significant changes in ratings occurred over time for professionals. Furthermore, we explored which determinants as measured in early phases of the implementation were related to self-perceived competencies in working with ACT at the end of implementation.

## METHOD

### Participants and procedure

Participating professionals worked in multidisciplinary teams in nine Dutch rehabilitation centres. Professionals were invited to fill in online questionnaires via the secured implementation website. Assessments were performed at the start of implementation (T0, baseline), halfway through the implementation when late adopters received a workshop in working with ACT and actively started participating in the program (T1, 6 months after T0), and at the end of the implementation (T2, 12 months after T0) (Figure 1). Each professional received a username and password to access the secured website. Reminders were sent by researchers and management. The response rate was 86% (T0), 77% (T1) and 70% (T2). Of the 111 professionals that participated, 94 professionals followed the whole trajectory and filled in  $\geq$  two out of three assessments. Data from these professionals are used in further analyses. Drop-outs were randomly divided over rehabilitation centres and professions. The number of participating professionals ranged from 7 to 15 in each of the rehabilitation centres. Baseline characteristics can be found in Table 1.

During the entire implementation period, patients specifically treated with ACT were asked to fill in a questionnaire at post-treatment regarding adherence by professionals. Questionnaires were distributed by secretaries in rehabilitation centres. Patients filled in the questionnaire directly or could take the questionnaire home and send it back in an accompanying pre-stamped envelope. In total, over 177 patients were treated with ACT during the implementation (data available from 7 of 9 centres). The response rate was 44.6% (n = 79).

Managers from all nine rehabilitation centres filled in a questionnaire at T2. The questionnaire was sent and returned by email. The response rate was 100%.

Table 1. Baseline characteristics of participating professionals from nine rehabilitation centres and exposure to ACT at T2

	T0	T1
Age (years, mean (sd))	43.2 (10.3)	
Gender		
Female	70 (74.5%)	
Male	24 (25.5%)	
Group		
Early adopters	38 (40.4%)	
Late adopters	56 (59.6%)	
Profession		
Psychologist	15 (16.0%)	
Rehabilitation Physician	8 (8.5%)	
Physical Therapist	21 (22.3%)	
Occupational Therapist	26 (27.7%)	
Social Worker	12 (12.8%)	
Other (e.g. nurse)	11 (11.7%)	
Years working in present job (years, mean (sd))	11.5 (10.0)	
Treatment time spent on ACT*		
0 – 20%	62 (66.0%)	31 (40.3%)
20 – 40%	18 (19.1%)	29 (37.7%)
40 – 60%	10 (10.6%)	10 (13.0%)
60 – 80%	4 (4.3%)	5 (6.5%)
80 – 100%	0 (0.0%)	2 (2.6%)
Additional experience with ACT at T0 and T0-T2*		
Read ≥ 1 book	70 (74.4%)	62 (66.0%)
Read academic literature	71 (75.5%)	57 (60.6%)
Followed other training or education	40 (44.4%)	15 (16.0%)
Hours exposure to ACT training ** (mean, sd)		11.2 (6.6)

Note: \* n = 77 at T2. \*\*n = 67, missing for 2 centers. Variable = Total hours of outreach visits (max 6, approximately 2 hours) + peer review meetings (max 8 – 20, varying per center, approximately 1 hour) attended between T0 and T2.

## Measures

### Professionals

A written survey for professionals was constructed. The questionnaire assessing *self-perceived competencies in working with ACT* was based on a not-validated questionnaire published in an ACT therapist learning manual (Luoma, Hayes, & Walser, 2007). The questionnaire consisted of 51 detailed statements about competencies an ACT-therapist should acquire, categorized for each of the six therapeutic ACT-processes. Below the detailed statements regarding each process we added general items that were used for data analyses: ‘How would you grade your competence in working with the process ‘undermining cognitive fusion?’’ Items were rated on a scale from 1 to 10. Following the

Dutch school system, grades > 5.5 are interpreted as satisfactory (6 = adequate, 7 = more than adequate, 8 = good, 9 = extremely good, 10 = excellent), while grades ≤ 5 can be interpreted as insufficient. In addition, the six general items were summed to form a total, average competency score. Cronbach's  $\alpha$  of the total scale was .92 at T0.

The questionnaire used to measure *determinants of success* was based on an overview of the most important determinants of innovations within health care organizations resulting from an extensive Delphi study (Fleuren et al., 2004). Three experts with knowledge of ACT and Dutch pain rehabilitation rated which determinants related to the adopting health professionals would be most relevant to the implementation. This resulted in 17 statements pertaining to factors such as attitude and work-related stress in applying ACT. All determinants were scored on a 5-point Likert-scale ranging from 1 (totally disagree) to 5 (totally agree). To accommodate for late adopters not yet knowledgeable in ACT early in the implementation, the option 0 (do not know) was added. Determinants were analysed separately.

A few self-compiled items were added at T0 and T2. We measured *additional experience with ACT* with items on attending additional workshops or other training activities, reading books and literature on ACT. We also assessed at both T0 and T2 *what percentage of treatment time ACT was applied*. Finally, at T2 we derived the hours of exposure to ACT-training from the number of outreach visits from a supervisor and peer review meetings attended.

### *Patients*

To measure *adherence to ACT by professionals*, patients filled in a short, self-compiled six-item questionnaire at the end of treatment. Each item started with a short introduction of each therapeutic ACT-process, which were introduced as therapist 'skills'. These introductions were similar to the information in a leaflet that patients received at the start of ACT-treatment. Each introduction was followed by a question: 'Was this component dealt with during your treatment?' Answers were given on a 7-point Likert scale, ranging from 1 (not at all) to 7 (very extensively). The six items were summed to a total score. Cronbach's alpha was .88.

### *Management*

A written survey for managers was constructed containing primarily closed questions on determinants of success (Fleuren et al., 2004). In selecting determinants, the same procedure as for the professionals' questionnaire was followed. Determinants of success questioned at the organizational level were possible cut backs, changes in key figures, planned reorganizations, attitude of teams working with ACT, possible problems with logistic procedures (e.g. allocating patients to staff), and satisfaction with assistance received by the project team (e.g. provision of materials). Statements were scored on a 5-



point Likert-scale ranging from 1 (totally not agree) to 5 (totally agree). Furthermore, managers rated the overall success of the implementation (0 – 10). Finally, they were asked if their organization planned on working further with ACT.

### **Statistical analysis**

Data were analysed using IBM SPSS Statistics 20. First, descriptive statistics in the professionals' database were applied. Missing data (13.01%) were analysed with SPSS Missing Values Analysis. As Little MCAR's test (Little, 1988) showed data was completely missing at random ( $\chi^2 (2838) = 2857.221, p = .396$ ), missing data in self-perceived competencies and determinants of success were imputed using the Expectation-Maximization algorithm. Self-perceived competencies and determinants of success were assessed at T0, T1 and T2 with descriptive statistics. One strong outlier was removed from analyses on self-perceived competencies. Furthermore, as five items on determinants of success showed a very heavy, negative skew ( $> -2$ ) at all three assessments, log transformed items were used in further analyses. Repeated Measures ANOVA's were used to assess changes from baseline to post-implementation. Two factors representing 'group' and 'time x group-interaction' were added to assess if the changes in self-perceived competencies or determinants of success evolved differently for both early and late adopters. Post-hoc one-way ANOVA's were performed to explore at what time-point differences existed. Furthermore, Pearson correlation coefficients were calculated to explore the relationship between determinants of success at T0 and T1 with the total score for self-perceived competencies at T2.

No missing data existed in the patients' and managers' databases. Means and standard deviations were calculated for each item and total scale of adherence to ACT. Finally, answers given by all nine managers were summarized by analysing frequencies on statements pertaining to each determinant.

## **RESULTS**

### **Professionals' exposure to ACT**

Most participants worked 0-20% of their treatment time with ACT at T0 (Table 1). At T2, most participants applied ACT approximately 0 – 40% of treatment time, with just a few professionals applying ACT the majority of time working with patients. Most professionals acquired additional information or training to what was offered as part of the implementation program. On average, professionals received 11 hours of training in ACT. The number of peer review meetings scheduled in participating centres varied and ranged from 8 to 20.

**Self-perceived competencies and adherence to ACT**

Self-perceived competencies significantly improved from T0 to T2 for both early and late adopters (Table 2). Averaged over time, early adopters rated themselves significantly more competent than late adopters

Table 2. Descriptive statistics and changes in self-perceived competencies in working with ACT

		Baseline (T0)	6 months (T1)	12 months (T2)	Repeated Measures ANOVA (F)		
		Mean (SD)			time	group	time*group
Acceptance	EA	5.87 (1.12)	6.33 (1.05)	6.53 (0.99)	19.301**	14.961**	5.087*
	LA	4.81 (1.84)	5.10 (1.68)	6.04 (1.42)			
Cogn Fusion	EA	5.13 (1.34)	5.90 (1.33)	6.22 (1.15)	30.204**	13.981**	2.751
	LA	3.95 (1.83)	4.71 (1.75)	5.66 (1.61)			
Pres Moment	EA	6.16 (1.39)	6.59 (1.33)	6.99 (1.09)	22.629**	3.022	.500
	LA	5.60 (1.75)	6.12 (1.56)	6.69 (1.47)			
S-a-context	EA	4.53 (1.54)	5.32 (1.34)	5.93 (1.05)	37.309**	24.157**	.739
	LA	3.37 (1.94)	4.19 (2.02)	5.10 (1.56)			
Values	EA	6.42 (1.39)	6.94 (1.27)	7.00 (1.22)	16.576**	15.199**	3.615*
	LA	5.34 (1.56)	5.75 (1.60)	6.53 (1.24)			
Com Action	EA	5.92 (1.50)	6.66 (1.32)	6.95 (1.10)	17.641**	17.687**	.869
	LA	4.77 (1.86)	5.44 (1.75)	6.15 (1.48)			
Total score	EA	5.66 (1.14)	6.29 (1.06)	6.60 (0.89)	36.352**	17.068**	3.026
	LA	4.64 (1.49)	5.22 (1.52)	6.26 (1.16)			

Note: EA = Early adopters, LA = late adopters; Cogn Fusion = Cognitive Fusion; Pres Moment = Present Moment; S-a-context = Self-as-context; Com Action = Committed Action; \* significant at  $p < .05$ , \*\* significant at  $p < .01$ .

Post-hoc one-way ANOVA tests revealed that early adopters perceived themselves as more competent at the start of the implementation than late adopters on all processes

and the total competency scale (total competency scale:  $t(91) = 3.602$ ,  $p = .001$ ), except in working with 'present-moment' ( $t(91) = 1.624$ ,  $p = .104$ ). At T2, again late adopters did not rate themselves differently on 'present moment' ( $t(91) = 1.069$ ,  $p = .288$ ), but still rated themselves significantly lower than early adopters on working with all other processes.

Table 3. Average descriptive statistics for early and late adopters and changes in determinants over time

	T0	T1	T2	Repeated Measures ANOVA (F)		
	Mean (SD)			time	group	time*group
Enthusiastic about ACT	4.84 (0.41)	4.85 (0.42)	4.88 (0.35)	.148	.170	1.272
More workload due to ACT	3.20 (1.40)	3.19 (1.32)	3.07 (1.36)	.390	.072	1.305
ACT is a significant supplement to existing treatment options	4.90 (0.36)	4.86 (0.41)	4.91 (0.27)	.901	3.291	1.973
Working with ACT is imposed	2.27 (1.38)	2.53 (1.34)	2.58 (1.43)	2.538	5.732*	.948
Involved in implementing ACT in our organization	4.43 (1.02)	4.49 (0.97)	4.51 (0.87)	.284	22.907**	2.205
ACT is difficult to apply	3.63 (1.14)	3.61 (1.16)	3.40 (1.28)	1.390	.436	4.168*
ACT fits my professional ideas	4.77 (0.48)	4.76 (0.63)	4.80 (0.49)	.041	.256	.636
ACT fits my task orientation	4.39 (.805)	4.57 (0.67)	4.54 (0.70)	2.139	2.585	.021
Supported by direct colleagues	4.38 (0.91)	4.62 (0.62)	4.51 (0.74)	2.457	.984	2.205
Supported by team members	4.31 (1.03)	4.72 (0.54)	4.61 (0.63)	4.742*	5.023*	4.163*
Supported by management	4.19 (1.09)	4.20 (1.17)	4.35 (0.96)	.481	1.524	2.235
Direct colleagues find implementing is important	4.40 (0.81)	4.52 (0.57)	4.57 (0.66)	2.271	3.073	2.434
Team members find implementing is important	4.61 (.671)	4.68 (0.58)	4.67 (0.61)	1.352	.462	1.947
Team is capable of applying ACT appropriately	4.27 (1.10)	4.55 (0.61)	4.40 (0.87)	3.102*	3.288	.061
Expect that patients are satisfied	4.55 (0.65)	4.56 (0.62)	4.63 (0.59)	.699	.231	2.337
Expect that patients will benefit	4.78 (0.46)	4.79 (0.44)	4.82 (0.35)	.191	.278	.127

Note: \* significant at  $p < .05$ , \*\* significant at  $p < .01$ .

Nevertheless, these ratings were only marginally significantly lower for the processes 'acceptance' ( $t(91) = 1.972, p = .052$ ), 'cognitive fusion' ( $t(91) = 1.850, p = .068$ ) and 'values' ( $t(91) = 1.794, p = .056$ ). Significant interaction effects for the processes 'acceptance' and 'values' revealed that early adopters mainly improved during the first half of the implementation phase, while late adopters improved most during the second half.

All patients rated the adherence to ACT by professionals very positively. Adherence scores for the six individuals ACT-skills ranged from 5.87 ( $sd = 1.017$ ) on 'committed action' to 6.19 ( $sd = 1.052$ ) on 'cognitive defusion'. The adherence score for the total scale was 6.11 ( $sd = .769$ ).

### **Determinants of success**

Over time, late adopters felt more inclined to work with ACT, felt less involved in the implementation and felt less supported by team members in working with ACT (Table 3). Although on average it was perceived relatively difficult to work with ACT and somewhat more workload was experienced, most determinants were rated extremely positive at T0 by both groups. Repeated measures ANOVA's showed these determinants were rated equally positive at T2. All patients rated the adherence to ACT by professionals very positively. Adherence scores for the six individuals ACT-skills ranged from 5.87 ( $sd = 1.017$ ) on 'committed action' to 6.19 ( $sd = 1.052$ ) on 'cognitive defusion'. The adherence score for the total scale was 6.11 ( $sd = .769$ ).

Furthermore, significant improvement over time was seen in the experienced support by direct colleagues and team members and feelings of team capability at applying ACT appropriately. Significant interaction effects showed that early adopters found working with ACT easier than late adopters at T0, but more difficult at T1. At T2, both groups found working with ACT equally difficult. Additionally, early adopters felt less supported by team members at T0, but this difference was very small at T2.

More than half of the total of nine managers indicated determinants that impeded implementation success. Some indicated changes in key figures ( $n = 3$ ) as being problematic, others indicated cut backs ( $n = 1$ ) and planned reorganisations ( $n = 1$ ). Most managers indicated problematic logistical procedures. Impeding factors ranged from planning difficulties in allocating patients to ACT-professionals ( $n = 3$ ) to problems in planning supervision sessions and peer review meetings ( $n = 5$ ). Each manager rated the attitude of the teams in working with ACT extremely positive. 7 out of 9 managers were (extremely) satisfied with assistance received by the project team, and all managers were (extremely) satisfied with their allocated supervisors. These positive outcomes were corroborated by the average rating of overall success of the implementation, being a 7.3 ( $sd = 1.5$ ). All managers indicated to continue working with ACT.

### Relationship between determinants of success and self-perceived competencies

Pearson correlation coefficients (Table 4) showed that different significant correlations ( $p < .05$ ) existed for early and late adopters between self-perceived competencies in working with ACT (T2) and determinants of success. Early adopters experiencing more workload due to implementing ACT at both T0 and T1 felt less competent at T2. Additionally, for late adopters positive significant correlations existed between self-perceived competencies and experienced support by team members and management (T0), enthusiasm about ACT, seeing ACT as an meaningful supplement to existing treatment options, fit of ACT to perceived task orientation, and the degree to which ACT is seen as satisfactory and beneficial to patients (T1). Additionally, a negative significant correlation existed with the feeling that ACT is difficult to apply (T1).

Table 4. Correlations between determinants of success at T0 and T1 and self-perceived competencies at T2 for early adopters (EA) and late adopters (LA) separately

	r self-perceived competencies			
	EA(T0)	LA (T0)	EA(T1)	LA (T1)
Enthusiastic about ACT	-.055	.250	-.219	.335*
More workload due to ACT	-.429**	-.055	-.437**	.214
ACT is a significant supplement to existing treatment options	.000	.154	-.078	.310*
Working with ACT is imposed	-.101	-.023	-.278	-.213
Involved in implementing ACT in our organization	.241	.025	-.142	.143
ACT is difficult to apply	-.041	-.151	-.384*	-.358**
ACT fits my professional ideas	.018	.033	.109	.217
ACT fits my task orientation	.270	.168	.145	.340**
Supported by direct colleagues	-.155	.156	-.094	-.084
Supported by team members	-.316	.358**	-.118	.166
Supported by management	.042	.363**	-.059	.012
Direct colleagues find implementing is important	.189	-.052	.070	.167
Team members find implementing is important	-.271	.241	.241	.254
Management finds implementing is important	.037	.078	.013	.188
Team is capable of applying ACT appropriately	-.249	-.023	-.030	.037
Expect that patients are satisfied	.015	.238	.001	.331*
Expect that patients will benefit	.203	-.147	-.011	.327*

Note: \* significant at  $p < .05$ , \*\* significant at  $p < .01$ .

## DISCUSSION AND CONCLUSION

### Discussion

The overall goal of the implementation was to train rehabilitation professionals working in multidisciplinary teams to apply ACT competently. Overall, both early and late adopters improved in self-perceived competencies for each of the six therapeutic ACT-processes, and both groups rate their skills in working with ACT at the end of the implementation trajectory at least adequate on almost all therapeutic processes. Additionally, patients treated with ACT confirm their treatment providers adhered to ACT during treatment. Managers also rate implementation success positively.

A few findings deserve further exploration. Contrary to our hypotheses, outcomes revealed that not only early adopters learned in the first half of the implementation. Also late adopters reported improvement in self-perceived competencies on some therapeutic processes during this time-span. As late adopters generally did not participate in educational meetings at this stage, it is possible that the application of simple dissemination strategies such as gaining information through team-members already working with ACT and/or by self-learning through searching for additional information were effective first steps prior to implementation (Richard Grol & Wensing, 2005). There is also considerable variation in the ratings of self-perceived competencies, especially in late adopters, revealing that not every professional feels able to apply ACT competently at the end of implementation. More specifically, late adopters rated themselves insufficient at the end of implementation in working with 'self as context', and also ratings of working with the process 'cognitive defusion' were relatively low. Both these processes are highly ACT-specific showing little overlap with other cognitive behavioural therapies, are theoretically challenging to grasp and not easily related to direct behavioural consequences (S. C. Hayes, 2004; Steven C. Hayes et al., 2012). The fact that learning to work adequately with these processes needs more time and learning effort can inform future educational activities (Waltz et al., 1993). Overall, these findings confirm that implementation trajectories may take up to two to four years involving different stages of changes between and within individuals, especially when team efforts are required (Fixsen et al., 2009; Medves et al., 2010). As all managers indicated peer review meetings are followed up and working with ACT will be extended, we anticipate further improvement in self-perceived competencies. In a related fashion, it is debatable how the division of roles within each of the multidisciplinary teams should evolve beyond the basic expertise achieved. As each discipline specializes in different aspects of the pain experience, perhaps not every professional must become highly competent in applying all aspects of ACT. Thorough communication within each team about effective division of tasks in working with ACT therefore is and remains highly important (Brown & Folen, 2005).

A second aim of this study involved the assessment of relevant determinants of innovation success (Fleuren et al., 2004). Overall, the determinants of success were rated positively by all professionals and management, which did not change over time. Probably this very positive innovation climate contributed to the positive outcomes of the implementation. A few recommendations can be made to inform future implementation efforts, especially those efforts applying a train-the-trainer approach. First of all, as project team we feel that especially the obtainment of formal commitments from management helped to follow up on the implementation blueprint and timely planning of outreach visits and peer review meetings (Powell et al., 2012), something which was perceived as problematic by most managers. Furthermore, although findings were correlational and should be interpreted cautiously, for early adopters the experience of higher workload due to ACT was related to lower self-perceived competencies at the end of implementation. As early adopters supplemented their work with many hours of education and training and served as key figures and educators during the implementation, we recommend future implementation efforts monitor the possible burden of implementation. With regard to late adopters, several determinants at multiple levels of implementation, being the level of the patient, team, organization and aspects of ACT itself, were related to self-perceived competencies at the end of implementation (Fleuren et al., 2004). We recommend to involve late adopters on all developments, not only aspects most relevant to the professionals him- or herself, but also developments regarding the content of implementation or those residing at the team- and organizational level directly from the start of all (pre-)implementation efforts.

There are several methodological limitations. We used a questionnaire on self-perceived competencies to operationalize competence. Although the outcomes were very informative in light of our research questions, self-perceived competencies do not equal evidence of objective competence in working with ACT. Future studies should investigate competencies in working with ACT using video-material and systematic coding schemes (Plumb & Vilardaga, 2010). Furthermore, the response rate for the patients' assessment of adherence to the ACT protocol was relatively low. Another limitation was that we performed multiple tests in relation to the number of observations available. Unfortunately it appeared impossible to discern any reliable subscales or factors within the 17 determinants assessed. The correlational analyses we provided should therefore be interpreted with caution.

### **Conclusion**

This study was one of the first to describe a systematic implementation effort in the delivery of therapy in chronic pain multidisciplinary rehabilitation. Trained professionals improved in self-perceived competencies in working with ACT and rated their skills at the end of the implementation at least adequate. Patients confirmed the application of ACT

during their treatment. Determinants related to implementation success - all evaluated positively - related differently to self-perceived competencies later in time for both early and late adopters and were present at multiple levels of implementation, being the level of the adopting professional him/herself, the team, the organization and factors relating to ACT.

**Practice implications**

Establishing long-term changes in the delivery of treatment in complicated multidisciplinary team settings should be encouraged to be performed systematically, using a prolonged period of time and by applying a multi-faceted educational approach. The application of a train-the-trainer approach can help to guide systematic implementation over time, preventing too much of a burden on resources within organizations. Finally, all professionals and other stakeholders should be informed and involved in the implementation process from an early stage.



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# CHAPTER 10

General Discussion

## INTRODUCTION

The overall aim of this thesis was to contribute to the scientific progress of knowledge on the measurement, efficacy and mechanisms of ACT for chronic pain. This aim was based on the philosophical, theoretical and pragmatic fit of ACT to the challenges imposed on psychological and multidisciplinary chronic pain rehabilitation. Specific research questions were inspired by proposed venues for research in psychosocial approaches to chronic pain. In chapters 2 to 9, the design and outcomes of several studies performed in light of this general aim were presented.

In this discussion section, first, some general conclusions will be shortly drawn to summarize the outcomes of this thesis. Hereafter, several relevant topics that relate to measurement, efficacy and mechanisms of ACT and the broader range of psychosocial chronic pain interventions will be discussed. Opportunities for future research based on our and other findings in the area of ACT and general CBT for chronic pain are evaluated. Finally, we give a summarized outline of implications for future research, and discuss the general limitations of this thesis.

## GENERAL CONCLUSIONS

First of all, questionnaires with adequate to good psychometric properties are now available to assess the different response styles and therapeutic processes of ACT in more detail. These questionnaires include the Psychological Inflexibility in Pain Scale and the newly developed Engaged Living Scale. Due to a problematic factor structure the Chronic Pain Acceptance Questionnaire should at present not be used in Dutch language settings.

When offered via a web-based platform as a self-help intervention, ACT may be effective for a heterogeneous group of chronic pain sufferers in reducing pain interference in daily life and other physical and emotional outcomes. Web-based ACT was only effective compared to waiting list for those participants having the highest 50% of scores on the subscale psychological well-being of the Mental Health Continuum, measuring positive mental health. This suggests that working through ACT individually in an online environment is especially helpful for pain sufferers that already experience positive psychological functioning at the start of the intervention. Furthermore, web-based ACT is most effective for participants who adhere to the web-based protocol. Due to its general effectiveness and its fit to the challenges imposed to chronic pain rehabilitation, ACT is successfully implemented into Dutch rehabilitation practice. During implementation, a large time-span should be allowed for multidisciplinary teams to acquire treatment skills and competency in working with ACT, and all healthcare professionals should be actively involved in the implementation process from a very early stage.

With regard to processes, aspects of psychological flexibility are - as assumed within the theoretical framework of ACT - important processes during ACT both between and within individuals. In addition to psychological (in)flexibility, pain catastrophizing as a central therapeutic process within more traditional CBT also seems to be a possible process of change during ACT. Changes in pain catastrophizing are reciprocally related to, but also independent from, larger and earlier changes in psychological flexibility during the web-based intervention.

## MEASUREMENT

Valid and reliable measurement of emotional states, thoughts and behavior is a highly relevant topic within both group-based and individual-based psychological research. Especially the availability of process-specific measurement instruments with good psychometric properties is important for both practice and research. Such measures can be used not only to explore mere efficacy, but also in choosing a focus of treatment for specific individuals or tracking changes in processes during ACT-based treatment over time. Over the last years, a relatively broad array of questionnaires has become available to properly assess different aspects of psychological flexibility in the context of chronic pain in group-based studies. Furthermore, challenges exist in proper measurement *within* individuals over time in methodologies such as the n-of-1 design reported in chapter 8 of this thesis. Both topics will be discussed below.

### **Currently available measurement instruments on ACT response styles**

At present, several scales are available that measure experiential avoidance and psychological inflexibility in the context of chronic pain. The most recently developed questionnaire is the Dutch-language Acceptance and Action Questionnaire-II-Pain Version (AAQ-II-P) (Reneman et al., 2014). This scale is as a pain-adapted version of the most often used measure of experiential avoidance and psychological inflexibility in general populations (AAQ-II) (Bond et al., 2011). The scale showed proper internal consistency, structural and construct validity in a heterogeneous chronic pain sample. Also the Psychological Inflexibility in Pain Scale (PIPS) (Trompetter et al., 2014; Wicksell, Lekander, Sorjonen, & Olsson, 2010; Wicksell, Renöfält, Olsson, Bond, & Melin, 2008) shows good factor structure, internal consistency, criterion, construct and incremental validity in homo- and heterogeneous pain samples. Despite its well-examined and promising psychometric properties, it is confusing to define at this point what construct(s) the PIPS exactly measures. Although the scale's name refers to psychological inflexibility and its item-pool was developed as such, inspection of the conceptualization and item formulation of both subscales – experiential avoidance and cognitive fusion – rather suggests the questionnaire addresses the negatively counterpart of the open response



style. Also, in the Dutch version of the PIPS the subscale cognitive fusion did not function optimally when assessed independently. Possible inconveniences with the content formulation of specific items in this subscale exist, and have been discussed in this thesis. Given these considerations, we applied the total questionnaire instead of the separate subscales as such in our studies, and suggest that other researchers do so in the future.

With regard to the measurement of pain acceptance, at present a vast number of questionnaires are available that are based on related but different theoretical frameworks. For pragmatic purposes, the present discussion will not provide an in-depth description of the approximately 13 pain and illness acceptance questionnaires that are available (Lauwerier et al., 2014). However, when selecting a pain acceptance questionnaire it is important to carefully reflect on the differences in theoretical background, psychometric properties, and content of each of these questionnaires (Lauwerier et al., 2014; Reneman, Dijkstra, Geertzen, & Dijkstra, 2010) In the specific context of ACT, we presently advise against the use of the currently available Dutch-language version of the Chronic Pain Acceptance Questionnaire (CPAQ) (McCracken, Vowles, & Eccleston, 2004) due to insufficient item translation (Trompetter, ten Klooster, Koke, & Schreurs, 2011). However, the CPAQ is a popular questionnaire that has been designated a promising measurement instrument compared to other measures of pain acceptance based on good content validity and other psychometric properties (Lauwerier et al., 2014; Reneman et al., 2010). Therefore, we advise for future research to focus on a new translation and evaluation of a Dutch-version CPAQ. With regard to cognitive fusion, no questionnaires are specifically available in the context of chronic pain. The Cognitive Fusion Questionnaire (CFQ) (Gillanders et al., 2014) is a generic measure of fusion with unwanted thoughts that showed good psychometric properties in six heterogeneous samples. The psychometric properties of the CFQ could be further assessed in chronic pain samples.

At present, the Engaged Living Scale (ELS) (Trompetter et al., 2013) is the only available short and easy to use, generic process-specific measure of the engaged response style. The ELS revealed good factor structure, internal consistency, construct and incremental validity over the PIPS and a generic measure of mindfulness in two samples, among which a heterogeneous chronic pain sample. Nevertheless, further research into its psychometric properties is necessary. For example, at the moment the items of the ELS are reformulated to measure aspects of engaged living more state-like - and less trait-like - as we expect that the sensitivity for change of the ELS can be optimized. This adapted 'ELS-state' needs further validation and a comparison with the original ELS in the future. In measuring values in the specific context of chronic pain, an alternative measure is the Chronic Pain Values Inventory (CPVI) (McCracken & Yang, 2006). The CPVI has a different approach towards the assessment of values than the ELS and focuses on the content of, and success in, reaching domain-specific values. Alternatively, the newly developed

Committed Action Questionnaire (CAQ) (McCracken, 2013) can be applied to address the single process committed action. Although the CPVI and CAQ are not validated for use in Dutch language settings, at this moment the CAQ has been translated into Dutch by careful translation and retranslation. Its psychometric properties are evaluated at the moment.

Finally, to measure aspects of the centered response style, most explicitly the process 'contact with the present moment', we applied the Five Facet Mindfulness Questionnaire (FFMQ) as a general and broad measure of several facets of mindfulness (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). A shortened, 24-item version of the FFMQ has been validated in a sample of fibromyalgia sufferers (Veehof, Ten Klooster, Taal, Westerhof, & Bohlmeijer, 2011). Although the FFMQ is not designed to measure ACT-specific processes, the conceptual framework of the questionnaire fits very well to the framework of ACT. Mindfulness exercises are a central aspect of ACT-based interventions as mindfulness is conceptually related to the ACT therapeutic processes contact with the present-moment, self-as-context, acceptance and cognitive defusion (Baer et al., 2006; McCracken & Thompson, 2008). In measuring the process contact with the present moment, an alternative for the FFMQ is the dispositional Mindful Attention Awareness Scale (MAAS) (Brown & Ryan, 2003; Schroevers, Nyklíček, & Topman, 2008). Future research could focus on the development of specific measures of the process self-as-context. As is the case with existing mindfulness measures, in doing so it will probably prove difficult to develop adequate self-report measures of abstract concepts such as a consciousness of subjective self. This will be especially so when assessing people unfamiliar with aspects of mindfulness and ACT.

Reflecting the above, it is clear that the last years have seen a fast growth of available questionnaires with at least adequate psychometric properties to measure aspects of psychological flexibility in chronic pain. Now, in avoiding wild growth and inefficient, overlapping use of questionnaires, future research may focus on which combinations of questionnaires can be best used to properly assess all aspects of psychological flexibility at once. Following ACT theory (Hayes, Strosahl, & Wilson, 2012), the concepts measured within questionnaires used alongside each other must be related, but not overlapping. To avoid such conceptual overlap, the examination of the incremental validity of each of the different questionnaires beyond and over each other in explaining variance in important chronic pain outcome variables would be a useful endeavor. In this thesis, for example, we tested incremental validity of the PIPS, FFMQ and ELS to generally cover the three response styles from the psychological flexibility framework (Trompetter et al., 2013), before applying them in further study (Trompetter, Bohlmeijer, Veehof, & Schreurs, in press).

**Measurement issues in n-of-1 designs**

Basic measurement issues not only play a role in group-studies. They are also important in less often performed within-person studies where measurements are repeatedly sampled within individuals for a prolonged period of time, such as experience sampling studies (Hektner, Schmidt, & Csikszentmihalyi, 2007) and n-of-1 studies (Barlow, Nock, & Hersen, 2009; Morgan & Morgan, 2001). Several practical issues appeared during the design, data collection and analysis of our n-of-1 study. These issues need timely consideration in future within-person research.

Rating scales on the methodological quality of single-subject studies recommend to 'operationally define and specify the target behavior with use of relevant, precise and repeatable measures' (Tate et al., 2008, pp. 389). In chronic pain research, not often an observable and countable target behavior is the primary outcome of study. This makes it important to timely consider what specific items should be used to measure psychological target constructs, such as pain acceptance and values. In our study, especially the content of items measuring experiential avoidance caused problems. For example, experiential avoidance items that were developed to operationalize the same construct, correlated highly negatively with each other within one participant, and showed different, unexpected correlational patterns in other participants (Trompetter, Johnston, Johnston, Vollenbroek-Hutten, & Schreurs, 2013). Furthermore, some reviewers requested the use of multiple items or even total questionnaires to measure specific constructs, as this is the common practice in group-based studies. However, one may question if group-based evaluations of psychometric properties, such as a scale's construct validity and reliability, are readily transferable to the application within individuals. Also, using a large number of items is highly impractical in repeated within person studies, and can easily create a burden on participants. Research suggests that typical studies in the area of chronic pain hold no more than the recommended maximum of 20 items (Burton, Weller, & Sharpe, 2007; Morren, van Dulmen, Ouwerkerk, & Bensing, 2009). With regard to these challenges, we advise to use pilot studies to test items, focus strongly on the content validity and interpretability of items, consider well if using one specific or multiple item to operationalize a targeted construct, and, whenever possible, operationalize observable and countable behavior.

**EFFICACY**

At the turn of the first decade of this century, there was preliminary evidence for the effectiveness of ACT in improving physical and emotional functioning related to chronic pain (for a review, see Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). The then existing list of mainly uncontrolled or small trials has been supplemented since with several (randomized) controlled trials (e.g. Buhrman et al., 2013; Jensen et al., 2012; Johnston,

Foster, Shennan, Starkey, & Johnson, 2010; McCracken, Sato, & Taylor, 2013; Thorsell et al., 2011; Wetherell et al., 2011; Wicksell et al., 2013). The results of these studies indicate that ACT has moderate, small to medium effects in improving pain interference and physical disability, and emotional factors such as depression, anxiety and quality of life. Effects with regard to pain intensity are mixed, but note that reducing pain intensity in itself is not a target of psychological and multidisciplinary chronic pain treatment. The RCT on the effectiveness of the program 'Living with Pain' presented in this thesis can now be added to this list. Outcomes of our trial are generally similar to the outcomes presented above (Trompetter, Bohlmeijer, Veehof, & Schreurs, in press). Overall, more large controlled trials are necessary that are designed and powered a priori to examine not only effectiveness of ACT, but to also assess mediating and moderating mechanisms of treatment (Williams, Eccleston, & Morley, 2013).

The current evidence indicates that ACT's effect sizes are equal to those of more traditional CBT-interventions (e.g. Hoffman, Papas, Chatkoff, & Kerns, 2007; McCracken & Vowles, 2014; Veehof et al., 2011; Wetherell et al., 2011; Williams et al., 2013). These summarized findings have several implications for ACT and other psychological interventions in chronic pain. First of all, it is clear that vast efforts have been made by scientists and clinicians to improve the understanding and treatment of pain as a highly complex and difficult-to-treat problem. Psychological knowledge is now indispensable in clinical care for longstanding chronic pain (Jensen & Turk, 2014). Nevertheless, the moderate group average results reveal that psychological interventions are presently ineffective to help every individual pain sufferer effectively and efficiently. This latter conclusion seems to be in place for all momentary available pharmacological, biomedical and psychosocial treatment modalities (Turk, Wilson, & Cahana, 2011). The question now is: how to move on further from here? Several opportunities for scientific psychological study that are relevant in light of this thesis exist. These are discussed in the remainder of this chapter.

### **Put the stakes on the psychological flexibility model**

At present, different theoretical psychological models are in use to guide the understanding and treatment of chronic pain (Jensen & Turk, 2014). In the first chapter of this thesis a few were discussed shortly, among which the Fear Avoidance model (Crombez, Eccleston, Damme, Vlaeyen, & Karoly, 2012), the Avoidance Endurance model (Hasenbring & Verbunt, 2010), and general CBT (Turner & Romano, 2001). The psychological flexibility model underlying ACT now adds to this list of related models. The availability of different models has resulted in the development of an equally vast amount of psychological treatment modalities. The question is if this non-uniformity helps to generate further advances in the understanding and clinical care of chronic pain (Pincus & McCracken, 2013). Several leading researchers in the field of chronic pain have recently

reviewed the existing psychological models. Some proposed a necessity to develop or choose an organizational framework for future psychosocial chronic pain treatment (Jensen, 2011; McCracken & Morley, 2014; Pincus & McCracken, 2013; Thorn & Burns, 2011).

McCracken and Morley (2014), specifically, make a clear and convincing case for the applicability of the psychological flexibility model as a future organizational framework. One reason for this, is that the theoretical model underlying ACT is able to integrate many of the abundant (in)dependent variables that have been successfully identified in CBT. This integration leads to a much more parsimonious and thereby, better testable theoretical model than CBT. CBT could perhaps be better seen as a general framework of cognitive and emotional factors that play a role in the pain experience. On the other hand, psychological flexibility as a model is not too scarce to explain a broader range of pain behaviors than either the Fear Avoidance model or the Avoidance Endurance model. Despite its enormous utility, the Fear Avoidance model was never developed to encompass all possible chronic pain profiles. Overall, the psychological flexibility model is a broad, but unified theoretical model build around explicitly formulated, organized, coherent, and philosophy- and theory-driven core principles (McCracken & Morley, 2014; McCracken & Vowles, 2014). This creates a workable and testable model that can instigate empirical progress in the long run. Outcomes of this thesis indicate, for example, that pain catastrophizing as a central aspect in CBT and the fear avoidance model is conceptually and clinically related to psychological flexibility. Pain catastrophizing can be placed in the psychological flexibility framework at the level of the open response style, and be interpreted as a narrowing form of cognitive fusion with pain-related thoughts. Despite the outcomes of this study and the advantages of the psychological flexibility model on paper, it is clear that much more empirical examination is necessary in the future to determine if the premises of the model remain as solid in practice.

### **Refine web-based pain interventions**

Including the RCT presented in this thesis, at present two studies have investigated the effects of ACT as a web-based intervention for chronic pain (Buhrman et al., 2013; Trompetter et al., submitted). Both studies showed mostly small (to medium) effects compared to control conditions on factors such as pain interference in daily life, pain acceptance, disability, and anxiety and depression. These results are comparable to conclusions of several recent reviews on the effectiveness of web-based CBT for chronic pain and other chronic somatic conditions (Bender, Radhakrishnan, Diorio, Englesakis, & Jadad, 2011; Eccleston et al., 2014; Macea, Gajos, Daglia Calil, & Fregni, 2010; van Beugen et al., 2014). These outcomes are promising, especially in light of the advantages that are associated with web-based interventions. Potentially, 'I-CBT' is time-effective, reaches

isolated and stigmatized patient groups, provides more user control and the ability to follow interventions at one's own pace, reduces healthcare costs and waiting lists, provides easy opportunity for data storage, personalized intervention and feedback, and finally, provides the opportunity to disseminate automated programs to very large groups of receivers (Andersson & Cuijpers, 2008; Cuijpers, van Straten, & Andersson, 2008; Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006).

Albeit positively tempered, all reviews cited above point out that the present conclusions are reasonably uncertain. More rigorous and methodological sophisticated studies on eHealth interventions in the area of chronic pain are needed (Eccleston et al., 2014; Rini, Williams, Broderick, & Keefe, 2012). As eHealth is a young research field with specific challenges, we firstly propose researchers use the specified 'CONSORT E-HEALTH' guidelines when designing and reporting future web-based efficacy studies (Eysenbach, 2011). Furthermore, present research in the area of I-CBT for chronic pain only focuses on mere efficacy of online interventions. Therefore, more can be done to fully benefit from the potential of web-based ACT for individual pain sufferers. For example, future study should unravel if there are specific subgroups of pain patients for whom web-based ACT is either highly effective or ineffective. Outcomes of this thesis indicate that demographics such as age, gender and education did not moderate the efficacy of the 'Living with Pain' program. However, mainly highly educated females were motivated to participate in the intervention, as is the case in most existing web-based ACT- and CBT-interventions for chronic pain (e.g. Bender et al., 2011; Buhrman et al., 2013). Given the underrepresentation of certain subpopulations, at present we cannot convincingly conclude that web-based ACT is as effective for higher educated females as for other subgroups. More research is therefore warranted.

Another aspect of I-CBT that has been reported, but should receive more attention is non-adherence to web-based interventions for chronic pain (Bender et al., 2011; Macea et al., 2010). Unfortunately, web-based health interventions in general show large attrition rates (Eysenbach, 2005). The adherence rate in our trial in terms of time-investment and module completion (48%) is similar to average adherence numbers reported for a range of health promotion web-interventions (50%) (Kelders, Kok, Ossebaard, & Gemert-Pijnen, 2012). Improving adherence is highly relevant in the context of I-CBT for several reasons. First of all, not only our study, but also studies in areas other than chronic pain indicate a positive relationship between adherence and outcome (e.g. Donkin et al., 2011). A further investigation of adherence can also give us more insight in how and under what conditions web-based interventions work. Such study could provide information not only with regard to content of CBT-based programs, but also with regard to aspects of the technological systems and services applied (Kelders, 2012). In future development of web-based interventions for chronic pain, it is necessary to enhance the fit between the characteristics and aims of participants, and the characteristics and aims

of the delivered intervention. This can be done, for example, through the use of persuasive design elements, such as rewards, personalized reminders, and tailoring to individual characteristics. Another recommendation is - as has been done in developing the Living with Pain program and its predecessor Living to the Full - to involve participants as early as possible in the design of the intervention (Kelders, 2012).

### **Explore the potential of positive psychology**

‘Positive psychology’ entails the science of positive emotion, positive character and positive institutions, and the investigation of how these aspects help people to flourish in life (Seligman & Csikszentmihalyi, 2000). Over the last decade, this scientific field has grown fast and triggered new research on constructs such as positive emotions, flow, and optimal emotional, psychological and social well-being (e.g. Bolier et al., 2013; Csikszentmihalyi, 2013; Fredrickson, 2001; Keyes, 2002; Seligman, Steen, Park, & Peterson, 2005).

Positive psychology - in the form of positive mental health - played a role in several studies in this thesis. More than other psychological frameworks in the context of chronic pain, ACT’s psychological flexibility framework describes processes of normal human functioning and pathways for recovery rather than pathopsychological processes (Pincus & McCracken, 2013). Concepts such as pain acceptance, mindfulness, values and psychological flexibility take place in a positive psychology framework. Furthermore, they are supportive of increasing an open, aware, motivated and engaged life (Hayes et al., 2012; Kashdan & Ciarrochi, 2013). This compatibility with positive psychology was our primary argument for including a measure of positive mental health – which is undoubtedly more than the mere absence of mental illness – in our RCT (e.g. Fava et al., 2001; Lamers, Westerhof, Bohlmeijer, ten Klooster, & Keyes, 2011; Westerhof & Keyes, 2010). We hypothesized that ACT could function as a positive intervention and increase optimal mental functioning instead of merely decreasing pain-related illness. However, no significant changes occurred when set off against both control groups. This contrasted with previous findings on the ability of a similar self-help ACT-protocol to increase positive mental health of individuals suffering from mild depression (Fledderus, Bohlmeijer, Pieterse, & Schreurs, 2012). Given the contradictory findings, it could be that chronic pain leads to such prolonged and moment-to-moment impairments, that more explicit positive intervention is necessary to increase optimal mental health and resilience.

Interestingly, positive mental health pointed out to be the only moderator of the efficacy of web-based ACT (Trompetter, Bohlmeijer, Lamers, & Schreurs, submitted). Post hoc analysis using the 51% of participants who showed most optimal mental health, revealed that the corresponding between group effect size at follow-up compared to waiting list on our primary outcome was .63 (Cohen’s d). This effect is moderate, but considerable larger when compared against reported effect sizes in ACT- and CBT-based

pain trials (Hoffman et al., 2007; McCracken & Vowles, 2014; Williams et al., 2013). It is especially considerable when set of against the non-significant findings on our primary outcome for the total intention-to-treat sample. As discussed earlier, it is sensible that self-managing a full-blown cognitive behavioral intervention may be too overwhelming to benefit from for pain sufferers lacking personal resources. The question is if these moderating effects will hold in replication studies. In performing these studies, we need to examine if resilience is a necessary premise to successfully self-manage chronic pain interventions in general. Given the small to medium general effect sizes, it even might be possible that these moderation effects pertain to the content of interventions, and therefore apply to intensive ACT- and CBT-based treatment in general. If this is the case, increasing positive well-being and resilience should perhaps take place in early or pre-chronic stadiums of pain to be able to benefit fully from their possible buffering effects (Fledderus, Bohlmeijer, Smit, & Westerhof, 2010).

Following this line of reasoning, it would be worthwhile to extend the research presented and further consider positive psychology constructs in chronic pain research. Knowing what makes certain pain sufferers psychologically flexible and able to adapt, can help to intervene effectively in the lives of those struggling to live a happy, meaningful and engaged life in the daily presence of chronic pain (Sturgeon & Zautra, 2010). At present, only few research groups have worked on positive constructs such as positive emotions and optimism in chronic pain (Boselie, Vancleef, Smeets, & Peters, 2014; Smith & Zautra, 2008; Sturgeon & Zautra, 2013; Zautra et al., 2008). We therefore suggest that future studies further examine positive aspects of adaptation to chronic pain.

## MECHANISMS

It has been recurrently discussed in this chapter that this thesis not only focused on mere efficacy of ACT, but also reported on studies that relate to processes in ACT. Building knowledge on processes of change is an important venue to possibly improve the effectiveness of therapeutic intervention for individuals (Elliott, 2010; Kazdin, 2007; Kraemer, Wilson, Fairburn, & Agras, 2002). More knowledge on processes of change during treatment can give insight in how exactly ACT and other treatments have their effects. It may also give information on why interventions possibly do not work for other pain sufferers. Furthermore, it enables a clear test of the theoretical assumptions that underlie our interventions. As discussed by several leading researchers in the research field of psychosocial interventions for chronic pain, such knowledge could help to progress beyond the average small to medium effects we repeatedly find at present in our efficacy trials (Eccleston, Morley, & Williams, 2013; Pincus & McCracken, 2013). Below, several venues to progress in this area of research based on the findings in this thesis are discussed.



**Further explore processes of change using theory-based interventions**

Given the unified underlying theoretical framework of ACT, we were able to formulate and test specific hypotheses of the mediating effects of psychological flexibility over the course of the web-based Living with Pain program (Trompetter, Bohlmeijer, Fox, & Schreurs, submitted). Furthermore, the psychological flexibility model enabled the formulation of exact hypotheses on experiential avoidance and values in our test of ACT theory within individuals following multidisciplinary rehabilitation (Trompetter, Johnston, Johnston, Vollenbroek-Hutten, & Schreurs, 2014). The outcomes of both process studies generally supported the premises of the ACT model. The importance of aspects of psychological flexibility in explaining psychosocial, emotional and physical domains of pain disability were confirmed. Our outcomes support a vast and growing array of studies on the importance of different aspects psychological flexibility in pain adjustment (e.g. Cho, McCracken, Heiby, Moon, & Lee, 2013; McCracken, Gauntlett-Gilbert, & Vowles, 2007; McCracken & Gutiérrez-Martínez, 2011; Vowles, McCracken, & Eccleston, 2007; Vowles, Witkiewitz, Sowden, & Ashworth, 2014; Wicksell, Olsson, & Hayes, 2010).

A focus on the unfolding of processes of change over time can not only help us to test and refine individual theories. They can also illuminate how different psychosocial theories and interventions on chronic pain relate to each other. We showed in a longitudinal design, that not only psychological flexibility, but also pain catastrophizing as a core principle in the fear avoidance model and CBT-based interventions functioned as a mechanism of change in pain interference in daily life during the course of our web-based intervention (Trompetter, Bohlmeijer, Fox, et al., submitted). Changes in both concepts were related to each other, but also functioned independently from each other. These outcomes are supported by preliminary findings from several studies that found that either pain acceptance changed during CBT, or pain catastrophizing changed during ACT (Buhrman et al., 2013; Vowles et al., 2007; Vowles, Wetherell, & Sorrell, 2009; Wetherell et al., 2011). Given these highly interesting findings, we strive for a further examination of processes of ACT and other psychosocial pain frameworks, both separately and in combination with each other.

**Assess processes within individuals**

One specific issue in further studying processes of change is the use of between-group versus within-group designs. In this thesis we advocate idiographic research – the intensive study of the individual organism - in the specific form of n-of-1 designs (Barlow & Nock, 2009). Notwithstanding the value of group-based studies and RCT's, we believe that group studies should be supplemented with a detailed focus on the individual, to contribute more knowledge, and also to contribute *different* knowledge. As discussed in detail in chapter 8, hypotheses in n-of-1 studies function at the level where our theories specify that actual cognitive and behavioral changes should occur, namely, within the

individual (Johnston & Johnston, 2013). For example, ACT proposes that changes in an individual pain sufferers' behavior depend on variations in this individuals' cognitions and emotions (i.e. aspects of psychological flexibility). Until now, however, group studies have only been able to reveal that changes in this *average* individuals' behavior resulted from variations in this *average* individuals' pain acceptance and its related processes. It is highly probable that this average person might not exist at all. Molenaar (2004) explains clearly that, to function similarly within and between individuals, factors should apply equally across individuals (be homogeneous), and also should be unchanging over time (be stationary). Homogeneity and stationarity are highly rare in psychology (Johnston & Johnston, 2013; Molenaar, 2004). An important goal for psychosocial research in chronic pain should be to bridge the gap from average scientific outcomes to more adequate treatment of individual pain sufferers who ask for help in clinical practice. Therefore it is necessary to start assessing changes within individual pain sufferers, rather than using an aggregate number that does not in any way relate to each of the individuals assessed (Borsboom, Mellenbergh, & van Heerden, 2003; Curran & Bauer, 2012; Molenaar, 2004; Molenaar & Campbell, 2009).

There are a few interesting examples of well-performed n-of-1 studies in psychosocial studies on chronic pain (e.g. Boersma et al., 2004). Nevertheless, the n-of-1 design is not often used in health and clinical psychological research. One reason for this is that many researchers are unaware that the n-of-1 design is acknowledged by several institutions – such as the American Psychological Association and the UK Medical Research Council – as a reliable and illuminating methodology to gain evidence on the efficacy and mechanisms of interventions (Craig et al., 2008). In recent years, the n-of-1 design has also been recognized as an alternative to the application of more randomized controlled trials in the area of chronic pain. Probably, these RCT's will only continue to reveal similar group average effects in improving pain and pain management (Morley, 2011; Williams et al., 2013). Reflecting upon the above, we propose to apply n-of-1 designs more dynamically in congruence with observational and randomized trials, and also other illuminating 'mixed' designs such as experience sampling procedures in larger groups of individuals. When using the n-of-1, randomized n-of-1 trials can be used to test interventions within individuals. Furthermore, correlational studies such as the one reported in this thesis can be applied to test theory (Johnston & Johnston, 2013; Quinn, Johnston, & Johnston, 2013). The latter relates to the outcomes of chapter 8 in this thesis, where outcomes of our correlational study showed that the premises of ACT were confirmed within two individual pain sufferers, but not in a third.

## IMPLICATIONS FOR FUTURE RESEARCH

In discussing the outcomes of studies presented in this thesis, we have proposed a number of important venues for future research. To summarize, with regard to measurement we would strive to advance the availability and understanding of the assessment of each of the six ACT-processes. We also propose to further study basic methodological research questions on the application of n-of-1 designs. Additionally, several venues for research exist that can help to enhance the effectiveness of ACT and other psychosocial interventions in the future. We propose to 1) consider a further examination of the psychological flexibility framework as a promising overarching organizational framework, 2) further refine web-based interventions for chronic pain, for example through moderator analysis and further studying adherence to I-CBT pain interventions, 3) explore the potential of aspects of positive psychology beyond the study of pain acceptance in relation to chronic pain theory and intervention, 4) focus on the examination of theory-based hypotheses regarding mechanisms of change during ACT and other psychosocial pain interventions, and 5) apply the n-of-1 designs and other within-person methodologies more often, to be able to assess change at the level where it is theorized to occur in clinical practice.

Most of the above suggestions for future research can be brought together in a proposal for future personalized monitoring and treatment of individual pain sufferers.

### **Bringing it all together? Personalized monitoring and treatment using mHealth**

The n-of-1 design reported on in this thesis is a small and preliminary example of studies designed to intensively monitor psychological functioning within pain sufferers over time. A technology-based avenue for future research in psychosocial research for chronic pain that is related to this study is the application of 'mHealth'. The term mHealth refers to mobile health using mobile or smartphones, patient monitoring devices, personal digital assistants and other wireless devices (Luxton, Mccann, Bush, Mishkind, & Reger, 2011; Richardson & Reid, 2013). Possible applications of mHealth that fit psychological chronic pain intervention are the opportunity to deliver psychoeducation and information, and to monitor pain and disability-related emotional and physical functioning in daily life. Furthermore, mHealth can be applied to intensively track changes in psychological and physical processes during treatment. It also has the opportunity to give distal feedback and/or psychological treatment (Ebner-Priemer & Trull, 2009; Luxton et al., 2011).

Potentially, ambulatory assessment of pain patients overcomes problems associated with retrospection by enabling data collection in real time, and has a better fit to the individual due to large numbers of repeated measures within the same individual over time. Finally, ambulatory assessment has the possibility to better integrate multiple forms of information, such as psychological self-reports, physiological ambulatory

measures, and real-time behavior and activities (Ebner-Priemer & Trull, 2009). Other studies in the area of chronic pain and mental health care using mHealth-based interventions show the feasibility and possible efficacy of well-designed mHealth applications (Donker et al., 2013; Kristjánsdóttir et al., 2013; Rosser et al., 2011). Given the above considerations, we highly recommend researchers to further examine the possibilities for the use of mHealth in ACT and CBT for chronic pain.

### **STRENGTHS AND LIMITATIONS**

This thesis has several strengths and limitations. It is both a strength and limitation that the samples in each of our studies were heterogeneous in nature. All samples included pain sufferers whom received highly heterogeneous diagnoses for their pain complaints. Also, samples ranged from self-selected and motivated individuals reporting pain from the general Dutch population, to pain patients undergoing tertiary clinical multidisciplinary care in pain clinics. A further strength is the range of study topics and methodologies applied in this thesis. Studies focused on multiple important aspects of the scientific cycle that include basic design procedures, efficacy tests and implementation of ACT into practice. We also applied highly variable methodologies and matching analyses procedures, including questionnaire construction, randomized controlled trials and different group-based and individual-based longitudinal designs. However, a limitation of this thesis is that we advocate the use of the n-of-1 design as a promising and illuminating design, while the actual n-of-1 study we performed had several drawbacks. These drawbacks made it difficult to answer some of our research questions. Among others, disadvantages included the selection of three participants for whom the multidisciplinary intervention turned out not to be effective. Also, in hindsight, some choices made during the design of the repeated assessments and the data collection period could be improved. The excessive ecological validity we gained with this design proved to be somewhat of a limitation in our study. However, when channelled correctly in future studies it can be a major advantage. As this was a first study on a complicated topic that requires a thorough change in thinking as well as in its methods applied, it was a learning experience that will provide for new opportunities in the future.

### **TO CONCLUDE**

This thesis described eight studies on measurement, efficacy and mechanisms of ACT for chronic pain. Questionnaires with good psychometric properties are now available to assess the processes of ACT, among which the open and engaged response style. We extended existing evidence on the importance of processes such as psychological flexibility, pain acceptance and values in our understanding of the adjustment to chronic

pain, and showed that ACT may be an effective self-help web-based treatment for specific subgroups of heterogeneous chronic pain patients. Finally, we bridged the gap between research and practice, and thoroughly trained multidisciplinary health care professionals to apply ACT competently in their daily work with pain patients. The outcomes of this thesis are illuminating and promising. We therefore hope they will contribute to a further refinement of the theoretical and clinical frameworks underlying current psychosocial interventions for chronic pain as a highly disabling condition for both individuals and society.

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## SUMMARY

In *chapter 1*, I first gave a short overview of basic knowledge on neurophysiology of pain, and sketched several existing psychological frameworks for understanding and treating chronic pain. This outline showed that vast efforts have been made by scientists and clinicians to improve the understanding and treatment of pain as a highly complex and difficult-to-treat problem. Knowledge on psychosocial factors and mechanisms is indispensable in the understanding and treatment in clinical care for longstanding chronic pain. At present, the overarching challenge for the field of pain research is to find solutions to the magnitude of the growing societal problem of pain, in light of the modest treatment gains for both biomedical and psychological interventions.

Acceptance & Commitment Therapy (ACT) is a relatively new form of Cognitive Behavioral Therapy (CBT). The overarching goal of ACT is to attain psychological flexibility, the capacity to act effectively in accordance with intrinsically motivating values and goals in the presence of pain and associated cognitions and emotions. In doing so, ACT applies mindfulness and acceptance processes, combined with values identification and behaviour change processes. Due to its focus on pain acceptance in the context of motivating values and goals, ACT fits very well to the goals and challenges of psychological and multidisciplinary chronic pain rehabilitation in helping pain sufferers to learn to live with their daily pain. Although a growing range of studies underscores the efficacy of ACT for chronic pain, the framework deserves and needs further examination. After describing the basic theoretical and clinical premises of ACT, I outlined several research questions that were inspired by proposed venues for future psychosocial research in the area of chronic pain.

One proposed venue for future research was to develop and test more process-oriented assessment instruments, to be able to adequately assess efficacy and mechanisms of change in ACT. Therefore, in chapters 2 to 4 I outlined the outcomes of several studies that assessed psychometric properties of either existing or newly developed questionnaires in the area of ACT. In *chapter 2*, I showed that the Dutch language version of the often-used Chronic Pain Acceptance Questionnaire (CPAQ) does not possess adequate factor structure, which is probably due to problematic item translation. We proposed that the CPAQ must not be used as an assessment instrument of pain acceptance in its present Dutch form. New translation and retranslation of the original CPAQ and renewed validation procedures are necessary. Hereafter, in *chapter 3* we investigated the properties of the Psychological Inflexibility in Pain Scale (PIPS) as an alternative measure of psychological inflexibility (or, more specifically, experiential avoidance of pain as the counterpart of pain acceptance, and cognitive fusion with pain-related thoughts). The Dutch version of the PIPS showed good factor structure and

internal consistency in a large and heterogeneous sample of chronic pain patients from different Dutch rehabilitation centres. Furthermore, the PIPS showed moderate to high relationships with aspects of mindfulness, pain interference in daily life, pain disability and mental health, and small relationships with pain intensity and physical functioning. Especially the avoidance subscale was able to explain additional variance in outcome variables beyond the FFMQ as a measure of mindfulness. Outcomes supported the psychometric properties of the PIPS, and showed that the PIPS and FFMQ measure slightly overlapping, but distinct constructs. Overall, chapter 2 and 3 showed that adequate measures were available to assess the open and centred response styles of ACT. To be able to adequately measure the last - engaged - response style, we developed a new, generic measure of engaged living, the Engaged Living Scale (ELS). The development of the ELS and its psychometric properties were described in *chapter 4*. The ELS showed adequate psychometric properties in a healthy sample and a sample of chronic pain sufferers. Among these psychometric properties were good factor structure, internal consistency, construct validity, and incremental validity beyond the PIPS and FFMQ in explaining outcome measures. Overall, with the addition of the scales discussed here, a range of psychometrically adequate assessment instruments is now available to assess each of the six therapeutic processes of ACT. Future research should further discern which combinations of psychometrically sound questionnaires are best able to cover the range of ACT therapeutic processes in a time-effective manner.

A second proposed venue for future progress was to further study the effects of technology-assisted delivery of psychosocial interventions. As outlined in chapter 1, web-based interventions can potentially be a cost- and time-effective mode of treatment that can foster self-management for large groups of chronic pain patients in learning to live with pain. Therefore, we developed a self-help web-based intervention based on ACT for chronic pain patients, called 'Living with Pain'. In *chapter 5*, I described the outcomes of a large, three-armed randomized controlled trial to study the potential efficacy of Living with Pain. Despite the fact that the effects for the primary outcome – pain interference in daily life – were not significant compared to a waiting list control condition, the overall picture was positive. Improvement over a six-month period during web-based ACT was superior compared to both a minimal self-help web-based control condition based on Expressive Writing and a waiting list control condition for depression, pain intensity, psychological inflexibility and pain catastrophizing. Effect sizes were small to moderate. Furthermore, significant improvement was present in pain interference in daily life against both control conditions - and other effects were larger - for those who adhered to the intervention as intended (48% of ACT participants). These outcomes call for a further focus in future study on understanding and heightening adherence to web-based interventions. Clinically relevant improvement in pain interference, depression and pain

intensity after six months was present for 28% of ACT participants, compared to 5% in both other conditions.

Given these positive outcomes, I proposed to further investigate web-based interventions for chronic pain in the future, and more specifically, to assess for whom exactly self-managing web-based interventions works. In *chapter 6* we examined if Living with Pain worked equally effective for everyone by assessing moderators and predictors of change during the RCT. The outcomes revealed that neither demographic nor physical variables moderated outcomes of the RCT. The only existing, significant moderator of changes in pain interference in daily life for ACT compared to both control conditions was positive mental health, or more specifically, positive psychological functioning. Positive psychological functioning relates to eudemonic aspects of optimal psychological human functioning. These aspects include, for example, feelings of personal growth, positive social relations, environmental mastery and self-acceptance. The outcomes of chapter 6 seem to indicate that self-managing a web-based intervention that requires the transformation of cognitive-behavioral patterns that narrowed effective living for a prolonged period of time, could simply be too much for individuals lacking psychological resources. These findings warrant further investigation of positive psychological functioning, and perhaps other aspects of positive and successful adaptation to chronic pain, in future research. Furthermore, with regard to technology-assisted delivery of interventions I proposed to also examine other form of technology, such as the use of smartphones to monitor and coach chronic pain sufferers from a distance.

The outcomes of chapter 7 and 8 relate to a third proposed venue for progress, namely a call for a more detailed study of the working mechanisms of change of specific treatments. In addition to mere efficacy, we need to examine how exactly treatments work. ACT is especially suitable for such type of research questions given the unified underlying theoretical model of psychological flexibility that is clearly defined and process-oriented. In addition to moderator assessment in chapter 6, we assessed mediators or mechanisms of change during Living with Pain in *chapter 7*. Outcomes first revealed that psychological inflexibility - as proposed by the psychological flexibility model - was a central mechanism of change during the web-based program. Furthermore, not only psychological inflexibility, but also pain catastrophizing as a central concept to CBT, functioned as a mechanism of change during ACT. Changes in both concepts reciprocally influenced each other over time. However, changes in pain catastrophizing were smaller and occurred later than changes in psychological inflexibility with pain. These findings indicated that changing the function of pain-related thoughts (as is the focus of ACT) could potentially lead to a direct shift in attention from the content of pain-related thoughts to other life aspects, which, in turn, can easily and indirectly lead to changes in the frequency or content of these thoughts (as is the focus of CBT). Further examination of the

interrelationship between these and other concepts from relating psychosocial frameworks for understanding chronic pain has been proposed.

In relation to this group-based focus on processes of change, researchers have proposed to use other designs than RCT's, such as single case methodologies, when trying to better understand change. Potential advantages of single case methodologies, or n-of-1 studies, are a focus on the individual pain sufferer instead of the aggregate, detailed monitoring procedures that directly expose therapeutic processes and behaviour over time, and a fit to the natural environment of daily clinical practice outside the laboratory. *Chapter 8* presented the outcomes of an exploratory within-person study. In this study, we assessed whether individuals high (or low) in experiential avoidance and values-based living on a certain day were also high (or low) in pain interference in daily life and emotional well-being on these and consecutive days. As this was the case for two out of three participants, these results suggested that ACT-based interventions can be applied to change an individuals' functioning - but not every individuals' functioning - by targeting experiential avoidance and values-based living as key treatment processes. As in previous studies, we additionally showed that daily levels of pain intensity did not significantly predict daily levels of each of the chronic pain outcomes, again revealing the importance of emotional and cognitive factors beyond pain intensity in the experience of chronic pain. Despite the fact that chapter 8 presented an illuminating study showing the potential of single case methodologies, the study also had several methodological drawbacks that call for further study in the future.

A final important venue for progress was the adequate dissemination of scientific knowledge to practice. Providing proper quality of treatment delivery by ensuring adherence (application of treatment according to protocol) and competence (level or skill of treatment application) of therapists to specific chronic pain treatment frameworks is a necessary premise to efficient and effective treatment. In *chapter 9*, we reported on the systematic implementation of ACT in nine Dutch chronic pain rehabilitation centres that we performed between 2010 and 2012. A prolonged multifaceted, interactive training program using coaching sessions and feedback was applied to systematically train professionals in working with ACT. In addition to giving a blueprint of the implementation process, the main goals of the presented study were to assess changes in professionals' self-perceived competencies in working with ACT over the course of the implementation trajectory, and to examine determinants of implementation success in the context of the implementation. Overall, trained professionals improved in self-perceived competencies in working with ACT and rated their skills at the end of the implementation at least adequate. Patients confirmed the application of ACT during their treatment, and also management evaluated the implementation positively. Determinants related to implementation success - which included a.o. enthusiasm in working with ACT, perceived



support from team members and management, expected benefit for patients from ACT, experienced workload - were evaluated positively from start until end of implementation by professionals. Several determinants of success at multiple levels of implementation were significantly related to changes in self-perceived competencies. Outcomes indicated that all professionals and other stakeholders should be informed and involved in the implementation process from an early stage in future, similar, implementations.

Finally, *chapter 10* discussed the main findings and implications thereof. Furthermore, I proposed a number of important venues for future research. The most important findings, implications and proposed venues have been summarized above.

## SAMENVATTING

In *hoofdstuk 1* gaf ik een kort overzicht van de bestaande kennis over de neurofysiologie van pijn, en schetste ik verschillende bestaande psychologische modellen en frameworks voor het verklaren en behandelen van chronische pijn. Wetenschappers en klinici hebben grote inspanning geleverd om ons begrip van pijn als een complex en moeilijk te behandelen probleem te verbeteren. Hierbij zijn psychosociale factoren en mechanismen onmisbaar gebleken. De huidige uitdaging voor het onderzoeksveld is het vinden van oplossingen voor pijn als een omvangrijk en groeiend maatschappelijk probleem. Dit is vooral het geval wanneer chronische pijn wordt gezien in het licht van de matige behandelresultaten van bestaande biomedische als psychologische interventies.

Acceptance & Commitment Therapy (ACT) is een relatief nieuwe vorm van Cognitieve Gedragstherapie (CGT). Het doel van ACT is het bereiken van psychologische flexibiliteit, het kunnen leven en handelen vanuit intrinsiek motiverende waarden en doelen, in de aanwezigheid van pijn en bijbehorende pijngerelateerde cognities en emoties. Om dit te bereiken maakt ACT gebruik van mindfulness- en acceptatieprocessen, gecombineerd met de identificatie van levenswaarden, en gedragsverandingsprocessen. Door een focus op acceptatie van pijn en waardengericht leven ondanks pijn, past ACT erg goed bij de doelen en uitdagingen van psychologische en multidisciplinaire pijnrevalidatie. Hoewel een groeiend aantal studies laat zien dat ACT effectief is, is verder onderzoek naar het framework nodig. Na het beschrijven van de theoretische en klinische aannames van ACT, heb ik in hoofdstuk 1 verschillende onderzoeksvragen uiteengezet. Deze vragen waren gebaseerd op eerder voorgestelde mogelijkheden tot vooruitgang voor het psychosociale onderzoeksveld.

Een voorgestelde mogelijkheid voor verder onderzoek was het ontwikkelen en toetsen van meer proces-georiënteerde vragenlijsten, om op deze manier het effect en de mechanismen van ACT op adequate wijze te kunnen onderzoeken. Daarom zijn in hoofdstuk 2 tot en met 4 de uitkomsten van verschillende onderzoeken besproken die tot doel hadden de psychometrische kwaliteiten van bestaande, dan wel nieuw ontwikkelde, ACT-vragenlijsten te toetsen. In *hoofdstuk 2* liet ik zien dat de Nederlandstalige versie van de veel gebruikte Chronic Pain Acceptance Questionnaire (CPAQ; Chronische Pijn Acceptatie Vragenlijst) geen adequate factorstructuur heeft. Dit probleem is waarschijnlijk veroorzaakt door problematische vertaling van Engelstalige items naar het Nederlands. Voorgesteld is de CPAQ in zijn huidige Nederlandse vorm niet te gebruiken. Nieuwe vertaling en hervertaling van de originele CPAQ en hernieuwde validatieprocedures zijn nodig. In *hoofdstuk 3* onderzochten we de psychometrische eigenschappen van de Psychological Inflexibility in Pain Scale (PIPS; Psychologische Inflexibiliteit in Pijn Schaal) als een alternatieve maat voor psychologische inflexibiliteit (of specifiek, experientiele

vermijding van pijn als tegenovergesteld aan pijnacceptatie, en cognitieve fusie met pijngerelateerde gedachten). De Nederlandse versie van de PIPS liet goede factorstructuur en interne consistentie zien in een grote en heterogene sample chronische pijnpatienten afkomstig uit verschillende Nederlandse revalidatiecentra. Verder liet de PIPS gemiddelde tot hoge correlaties zien met aspecten van mindfulness, pijninterferentie in het dagelijks leven en geestelijke gezondheid, en kleine correlaties met pijnintensiteit en fysiek functioneren. Vooral de subschaal experientiele vermijding van pijn was in staat om aanvullende variantie in uitkomstvariabelen te verklaren voorbij de FFMQ als een maat voor mindfulness. Deze resultaten ondersteunen de psychometrische kwaliteiten van de PIPS, en lieten zien dat de PIPS en FFMQ licht overlappende, maar verschillende constructen meten. In het algemeen toonden hoofdstuk 2 en 3 zien dat adequate meetinstrumenten beschikbaar zijn om de zogenaamde open en gecentreerde respons stijl van ACT te meten. Om de laatste – geengageerde of betrokken – respons stijl van ACT goed te kunnen meten, ontwikkelden we een nieuwe algemene maat van betrokken leven, de Engaged Living Scale (ELS; Betrokken Leven Schaal). De ontwikkeling en psychometrische kwaliteiten van de ELS zijn beschreven in *hoofdstuk 4*. De ELS bezit adequate psychometrische eigenschappen in zowel een gezonde sample als in een sample van chronische pijnpatienten. Deze adequate psychometrische eigenschappen hielden onder andere een goede factor structuur, goede interne consistentie, goede constructvaliditeit en incrementele validiteit voorbij de PIPS en FFMQ bij het verklaren van uitkomstmaten in. Op dit moment is een flink aantal meetinstrumenten beschikbaar om ieder van de zes therapeutische ACT-processen in kaart te brengen. Toekomstig onderzoek moet uitwijzen welke combinaties van bestaande vragenlijsten het best gebruikt kunnen worden om alle ACT-processen op een efficiënte manier te meten.

Een tweede voorgestelde mogelijkheid voor verder onderzoek was het toetsen van de effecten van technologie-ondersteunde behandelingen. Zoals uiteengezet in hoofdstuk 1, kunnen internetbehandelingen in potentie kosten- en tijdeffectief zijn, en het zelfmanagement in het leren omgaan met dagelijkse pijn voor grote groepen pijnpatienten bevorderen. Daarom ontwikkelden we een zelfhulp internetbehandeling voor chronische pijnpatienten gebaseerd op ACT, genaamd ‘Leven met Pijn’. In *hoofdstuk 5* beschreef ik de uitkomsten van een grote, drie-armige gerandomiseerde controlestudie (RCT) om de effectiviteit van Leven met Pijn te toetsen. Ondanks het feit dat het effect op de primaire uitkomst – pijninterferentie in het dagelijks leven – niet significant was in vergelijking met een wachtlijst controleconditie, was de algemene indruk positief. Vooruitgang over een periode van zes maanden wat betreft depressie, pijnintensiteit, psychologische inflexibiliteit en catastroferen over pijn was significant groter voor de mensen die Leven met Pijn hadden gevolgd, dan voor mensen die een minimale zelfhulp internetbehandeling gebaseerd op Expressief Schrijven volgden of waren ingeschreven in

een wachtlijst controleconditie. De gevonden effecten waren klein tot matig, wat vaak het geval is bij zowel face-to-face als online psychosociale pijnbehandelingen. Klinisch relevante vooruitgang in *zowel* pijninterferentie, depressie als pijnintensiteit was na zes maanden aanwezig voor 28% van de deelnemers aan ACT, in vergelijking tot maar 5% van de deelnemers in beide andere condities. Verder was significante vooruitgang in pijninterferentie in het dagelijks leven aanwezig in vergelijking met beide controlegroepen – en andere bestaande effecten waren groter – voor de mensen die adherent (therapietrouw) waren aan de interventie (48% van deelnemers aan Leven met Pijn). Deze laatste uitkomsten vragen om een verdere focus in toekomstig onderzoek op het begrijpen en vergroten van adherentie aan internetbehandelingen.

Gegeven deze positieve uitkomsten heb ik voorgesteld verder onderzoek te doen naar de effecten van internetbehandelingen voor chronische pijn, en meer specifiek, verder te onderzoeken voor welke mensen precies het zelfmanagen van een online interventie effect heeft. In *hoofdstuk 6* onderzochten we daarom of Leven met Pijn even effectief was voor alle deelnemers, door moderatoren en predictoren van verandering gedurende de RCT te toetsen. De uitkomsten lieten zien dat noch demografische, noch fysieke factoren de uitkomsten van de RCT beïnvloedden. De enige significante moderator van veranderingen in pijninterferentie in het dagelijkse leven in vergelijking met beide controlecondities was positieve geestelijke gezondheid, en meer specifiek, positief psychologisch functioneren. Het volgen van Leven met Pijn was alleen effectiever in vergelijking met het staan op een wachtlijst voor de 50% hoogst scorenden op een maat voor positief psychologisch functioneren. Positief psychologisch functioneren is gerelateerd aan eudaimonische aspecten van optimaal psychologisch menselijk functioneren. Deze aspecten houden onder andere gevoelens van persoonlijke groei, positieve sociale relaties, grip op de omgeving en zelf-acceptatie in. De uitkomsten van hoofdstuk 6 indiceren dat het zelfmanagen van een internetbehandeling die vraagt om transformatie van cognitief-gedragmatige patronen die een individu voor een zeer lange tijd hebben belemmerd, gewoonweg te veel kan zijn voor mensen die niet beschikken over de juiste mentale bronnen. Deze uitkomsten vragen om verder onderzoek naar positief psychologisch functioneren in de context van chronische pijn, en eventueel ook andere aspecten van positieve en succesvolle pijnadaptatie. Verder heb ik voorgesteld om meer onderzoek te doen naar de inzet van andere vormen van technologie dan internet, zoals het gebruik van smartphones om chronische pijnpatienten op afstand continue te monitoren en coachen.

De uitkomsten van hoofdstuk 7 en 8 relateerden aan een derde voorgestelde mogelijkheid tot verder onderzoek, namelijk een vraag naar meer gedetailleerde studie van de werkingsmechanismen van verandering gedurende behandelingen. Het is belangrijk dat we niet alleen uitzoeken *of* behandelingen effect hebben, maar ook *hoe* ze effect hebben.

ACT is zeer geschikt voor dit type onderzoeksvragen, omdat het een eenduidig, helder gedefinieerd en proces-georiënteerd onderliggend theoretisch framework heeft. Daarom toetsten we in *hoofdstuk 7* mediators, of mechanismen van verandering, gedurende Leven met Pijn. De uitkomsten lieten allereerst zien dat psychologische inflexibiliteit – zoals verondersteld door het ACT model – een centraal mechanisme van verandering was gedurende de internetbehandeling. Verder bleek niet alleen psychologische inflexibiliteit, maar ook catastroferen over pijn (als centraal concept in CGT) een significant mechanisme van verandering. Vroegtijdige veranderingen in beide concepten beïnvloedden wederkerig latere veranderingen in het andere concept. Veranderingen in pijncatastroferen waren echter kleiner, en vonden later plaats, dan veranderingen in psychologische inflexibiliteit in de context van pijn. Deze bevindingen passen bij de uitgangspunten van ACT, en indiceren dat het veranderen van de *functie* van pijn-gerelateerde gedachten (de focus van ACT) kan leiden tot een directe verplaatsing van aandacht van de inhoud van pijn-gerelateerde gedachten naar andere levensaspecten, welke, op hun beurt, gemakkelijk op een indirecte manier kunnen leiden tot veranderingen in de *frequentie of inhoud* van deze gedachten (de focus van CGT). Verder onderzoek naar de onderlinge relatie tussen deze en andere concepten uit gerelateerde psychosociale modellen van het begrijpen en verklaren van pijn is nodig.

Verschillende wetenschappers hebben voorgesteld andere designs dan op groepsgemiddelden gebaseerde RCT's, zoals 'single case' methoden, te gebruiken wanneer het doel van een studie is om veranderingen binnen personen beter te begrijpen. Mogelijke voordelen van single case methoden, of n-of-1 studies, zijn een focus op de individuele persoon in tegenstelling tot de (niet bestaande) gemiddelde persoon, het gebruik van gedetailleerde monitoring procedures die direct processen en gedrag kunnen blootleggen, en een focus op de natuurlijke omgeving van een persoon buiten een laboratorium. *Hoofdstuk 8* behandelde de uitkomsten van een exploratieve binnenpersoons studie. In deze studie onderzochten we of personen die op bepaalde dagen hoog (of laag) scoorden op experientele vermijding van pijn en waardengericht leven, ook hoog (of laag) scoorden op pijn interferentie in het dagelijks leven en emotioneel welbevinden op dezelfde en opvolgende dagen. Dit was het geval voor twee van de drie deelnemers, wat suggereert dat interventies gebaseerd op ACT gebruikt kunnen worden om het functioneren van een persoon te veranderen - maar niet iedere persoon - door het beïnvloeden van experientiele vermijding en waardengericht leven als centrale behandelprocessen van ACT. Deze studie liet ook zien dat dagelijkse scores op pijnintensiteit niet dagelijkse scores in pijnuitkomsten konden voorspellen, wat opnieuw het belang van cognitieve en emotionele factoren voorbij pijnintensiteit in de ervaring van chronische pijn laat zien. Hoewel hoofdstuk 8 een verhelderende en interessante studie samenvatte die het potentieel van single case methoden heeft bevestigd, had de studie ook enkele methodologische nadelen die vragen om verdere studie in de toekomst.

Een laatste belangrijke voorgestelde mogelijkheid voor verder onderzoek was de adequate disseminatie van wetenschappelijke kennis naar de praktijk. Het waarborgen van goede behandelkwaliteit via een streven naar adherente (toepassing van behandeling volgens protocol) en competente (niveau waarmee de behandeling wordt toegepast) toepassing van specifieke behandelmodellen voor chronische pijn door therapeuten is een noodzakelijke voorwaarde voor efficiënte en effectieve behandeling. In *hoofdstuk 9* rapporteerden we over de systematische implementatie van ACT in negen Nederlandse revalidatiecentra voor chronische pijn die werd uitgevoerd tussen 2010 en 2012. Een langdurig, multilateraal, interactief trainingsprogramma werd toegepast dat gebruik maakte van coaching- en feedbacksessies om therapeuten systematisch te trainen in het werken met ACT over een periode van 12 maanden. Naast het geven van een zogenaamde blauwdruk van de implementatie, waren doelen van het onderzoek het volgen en toetsen van veranderingen in zelfgerapporteerde competenties van de professionals in het werken van ACT, en het in kaart brengen van theoretisch vastgestelde determinanten van mogelijk succes gedurende de implementatie. Samengevat lieten de uitkomsten van de studie zien, dat de getrainde therapeuten significante vooruitgang lieten zien in hun competenties in het werken met ACT, en hun niveau van werken met alle zes de ACT-processen minstens ‘ voldoende ’ beoordeelde aan het einde van de implementatie. Patiënten bevestigden de toepassing van ACT gedurende hun behandeling, en ook management evalueerde de implementatie positief. Determinanten gerelateerd aan het succes van de implementatie – bv. enthousiasme in het werken met ACT, het ervaren van steun van teamgenoten en management, verwachte profijt dat patiënten hebben van ACT, en de ervaren werkdruk – werden allemaal positief geëvalueerd door deelnemende therapeuten van start tot einde van de implementatie. Resultaten impliceerden dat alle professionals en andere belanghebbenden bij vergelijkbare, toekomstige implementaties vanaf het begin van het proces geïnformeerd en betrokken moeten worden.

Tot slot behandelde *hoofdstuk 10* de belangrijkste bevindingen van deze thesis, en voornamelijk, de belangrijkste implicaties van deze bevindingen. Ook stelde ik verschillende mogelijkheden voor vervolgonderzoek vast. De belangrijkste van deze resultaten, implicaties en mogelijkheden voor vervolgonderzoek zijn hierboven samengevat.

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**CURRICULUM VITAE**

Hester Rianne Trompetter was born in Gorinchem (province of South-Holland, The Netherlands), on June 15<sup>th</sup> 1987. In 2004 she received her high school diploma from the Gymnasium Camphusianum in Gorinchem, and commenced a study in Psychology at the Radboud University in Nijmegen. After receiving her Bachelors degree (cum laude) in 2007 in Psychogerontology, Hester received her Masters degree (cum laude) after finishing a two-year Research Master in Behavioural Science. During her whole studies Hester has been involved in several Psychology courses as an assistant lecturer and course coordinator. In January 2010, Hester was appointed to work on the present PhD project by prof. dr. Karlein Schreurs and prof. dr. Miriam Vollenbroek-Hutten in a collaboration between the department of Psychology, Health & Technology from the University of Twente, and Roessingh Research & Development (Enschede, The Netherlands). Hester has lived in Enschede since. After holding a post-doc position with Roessingh Research and Development, Hester continues her work at the Department of Psychology, Health and Technology at the University of Twente as an Assistant Professor.

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