Effect- and processevaluation of an internet- based intervention of Acceptance & Commitment Therapy for chronic pain patients: a randomized controlled trial

“Living with Pain online”

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Abstract

Background. Chronic pain is remarkably common. In Europe almost 20% of adults suffer from chronic pain. The impact of chronic pain is multifaceted, extensive and reduces the quality of life more than any other chronical condition. Common pharmacological treatments do not help in handling with the consequences. Therefore, it is important to treat pain interference in daily life correctly. In order to improve functioning in daily life an online-delivered self- help intervention named 'Living with pain online' is developed, which is based on Acceptance and Commitment Therapy [ACT] and mindfulness. The focus of ACT is not on controlling, reducing or fighting the pain as it is the case with other forms of treatment, but rather on improving functioning by increasing the ability to act effectively in the presence of pain.

Aims. The present study aimed to examine the effects of the ACT on pain interference. Moreover, the underlying processes of the intervention are analyzed in order to understand how the ACT works and to develop effective and viable interventions for people with chronic pain.

Method. After eligibility for the participation in this study, based on different in- and exclusion criteria, randomization took place. The individuals were randomized either to the online ACT group or to a minimal intervention condition, the expressive writing group [EW] or to the waiting list control group [WL]. The participants completed measures of pain interference as the main outcome measure and process measures (MPI- pain interference scale, PIPS, ELS, FFMQ-SF) at pre-, post- and 3- months follow up assessment. Additionally, the ACT and the EW group completed measures at a 9- months follow- up measurement.

Results. The online ACT was effective in the improvement of pain interference in comparison to the EW group, but not in comparison to the WL group. Thereby the open response style mediated the relation between the treatment and pain interference.

Conclusion. The present study of the online- based ACT intervention 'Living with pain online' suggests to be an effective method for the treatment of chronic pain conditions and worked by improving the open response style. More research is needed to confirm these results.

Samenvatting

Achtergrond. Chronische pijn komt opvallend vaak voor. In Europa lijden bijna 20% van de volwassenen aan chronische pijn. De invloed van chronische pijn is veelzijdig, uitgebreid en vermindert de kwaliteit van leven meer dan elk andere chronische aandoening. Daarom is het belangrijk om de pijn interferentie in het dagelijks leven goed te behandelen. Algemene farmacologische behandelingen helpen niet in de omgang met de gevolgen. Ter verbetering van het functioneren in het dagelijks leven werd een online- gebaseerde zelfhulp interventie genaamd 'Leven met pijn online' ontwikkeld, die is gebaseerd op Acceptatie en Commitment Therapie [ACT]. De focus van ACT is niet op beheersen, terugdringen of het bestrijden van de pijn, zoals het het geval is met andere vormen van behandeling, maar op aanvaarding van de pijn. Het doel van de interventie was daarenboven het leren van een waardegericht leven, ondanks de blijvende pijn. ACT doet dit door middel van de ontwikkeling van een open antwoordstijl.

Doel. De studie had als doel om de effecten van de ACT op pijn interferentie te onderzoeken. Daarenboven werden de onderliggende processen van de interventie geanalyseerd om te begrijpen hoe de ACT werkt en om effectieve en haalbare interventies voor mensen met chronische pijn te ontwikkelen.

Methode. Na in aanmerking te komen voor deelname aan dit onderzoek, op basis van verschillende in- en uitsluitingscriteria, vond randomisatie van de drie groepen plaats. De personen werden gerandomiseerd ofwel naar de online ACT groep of naar de minimale interventie conditie, de expressieve schrijfgroep [EW] of naar de wachtlijst controle groep [WL]. De deelnemers vulden vragenlijsten bij voor-, na- en na 3- maanden follow-up meting in. Daarnaast vulde de ACT en de EW groep de vragenlijsten bij een 9 - maanden follow-up meting in.

Resultaten. De online ACT was effectief bij de verbetering van pijn interferentie ten opzichte van de EW-groep, maar niet in vergelijking met de WL groep. Daarbij medieerde de open antwoordstijl de relatie tussen de behandeling en pijn interferentie.

Conclusie. De online-based ACT interventie 'Leven met pijn online' blijkt een effectieve methode voor de behandeling van chronische pijn omstandigheden te zijn en werkt via het verbeteren van de open antwoord stijl. Meer onderzoek is nodig om deze resultaten te bevestigen.

Preface

This studie was done within the framework of the Master ’Geestelijke Gezondheids-bevordering’ at the University of Twente.

I would like to thank the following people for their support and help.
First and foremost I would like to thank my loving parents for their unconditional love and support. Without you I would never have come this far! Mom and Dad, thank you so much. I love you for all that you are.
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With my master thesis I finish my time as a student and approach my dream job one step further.

Structure

Introduction

Chronic Pain: Definition, Prevalence, Impact and Treatment

In literature one speaks of chronic pain as the pain persists longer than three to six months (Breivik, Collet, Ventafridda, Cohen & Gallacher, 2006). In contrast to acute pain, which is useful and serves a protective purpose, chronic pain has little protective significance. Chronic pain persists despite normalization after injury or disease and ultimately interferes with daily functioning (Cole, 2002). People report the experience of pain also in the absence of any pathophysiological causes, this occurs most often for psychological reasons (International Association for the Study of Pain [IASP], 2011; Sullivan et al., 2001). Research has shown that these psychological factors may be responsible for long- term restrictions for many forms of chronic pain and emotional stress (Turk & Okifuji, 2002). There is a growing recognition that chronic pain is a complex perceptual experience of the whole person who is influenced by a wide range of psychosocial factors, including emotions, social and environmental context, the degree of attention to the pain, beliefs, attitudes, expectations etc. (Tsang et al., 2008; Turk & Gatchel, 2002; Turk & Monarch, 2006; Von Korff et al., 2005).

There are millions of people throughout the world who suffer from chronic pain (Turk & Burwinkle, 2005). Several studies have explored the prevelence of chronic pain among adults, whereby chronic pain occurs in about 20% of all European adults (Breivik et al., 2006; Reid et al., 2011). Comparable statistics were documented internationally (Turk & Melzack, 2011). In regard to these high numbers it is beyond all questions how important it is to handle chronic pain in the public health- care sector. The importance is magnified if you look at the expansive implications of chronic pain.

The impact of chronic pain is multifaceted, broad and reduces the quality of life more than any other chronical condition (Donaldson, 2008). The consequences of chronic pain affects every aspect of a person`s life. Chronic pain impairs the quality of social and working life on persons who suffer from it. A large study of Breivik et al. (2006) has shown that many people with chronic pain were less or not at all able to take part in various actions, whereby about 60% of the respondents answered that they were less or not anymore able to work outside their houses. One- fifth had lost their job because of the pain. Chronic pain makes it hardly possible to maintain an independent lifestyle. This is also demonstrated by the fact that nearly every other aspect of social functioning is impaired. The self- perceived burden from

the impact on others of one`s cure needs again can result in distress, guilt, feelings of responsibility and in a diminished sense of self (Kowal, Wilson, McWilliams, Péloquin & Duong, 2012). Because of the overarching and enormous impact of chronic pain on individuals, it is not suprising that partners, friends and family functioning is affected by the experience of living with someone with chronic pain (Romano, Cano, & Schmaling, 2011). Moreover, chronic pain patients show a high comorbidity with other psychological problems and psychiatric disorders (Demyttenaere, 2007; Dominick, 2012). That applies especially depression and anxiety disorders. Research by Miller and Cano (2009) found out that 35% of people with chronic pain show also a comorbidity with depression. They have also an increased chance of getting addicted to alcohol or other drugs (Von Korff et al., 2005). Besides several inner- en interpersonal impacts, there are the accompanied costs to the society. Research does not give consistent data, but almost certainly these costs are enormous. A Dutch study of Lambeek et al. (2011) investigated that the costs of back pain alone amounted to 3.5 billion euro in 2007, mainly because of production losses and increased morbidity and mortality rates. These large amounts are not unique to the Netherlands. Because of the previously explained vicious circles and bidirectional asssociations on the self and others you can only imagine how expansive the impact of chronic pain actually is. Based on the high prevalence and the devastating impact of chronic pain it is of prime importance to develop (cost-) effective treatment methods for people with chronic pain.

There are two broad areas of treatment for the handling of chronic pain. On the one hand there are pharmacological treatments and on the other hand there are non-pharmacological treatment methods. The most traditional medical treatments try to reduce the pain. These treatment methods usually use painkillers, antidepressant drugs and muscle relaxants, which have a lot of side- effects (Dahl & Lundgren, 2006). Research has shown that these methods are not effective in reducing chronic pain (Turk, Hilary, Wilson & Cahana, 2011). Because of the mentioned limitations for the handling of chronic pain and the knowledge that chronic pain affects the whole functioning of the individual, there has been growing interest in developing new psychological treatment methods over the last decades. These psychological oriented interventions focus more on the consequences that pain has on the patients' lives, rather than on pain reduction or pain intensity as a possibility of addressing adaptive behavior change (Kerns, Sellinger & Goodin, 2011). Since then cognitive behavioral therapy [CBT] became the most prominent treatment for chronic pain. This form of therapy aims at teaching skills in pain control, problem solving, adaptation and self- management.

Although research shows evidence for the effectiveness of CBT for patients with chronic pain, the effect sizes are only moderate and not all patients can benefit from it (Hoffman, Papas, Chatkoff, & Kerns, 2007; Van Tulder, Ostelo, Vlaeyen, Linton, Morley & Assendelft, 2005). In addition, the effects can be found mainly in the improvement of patients' mood, rather than a reduction of interference through the pain (Ecclestone, Williams & Morley, 2009). Therefore, researchers express the need for efficient and cost- effective alternative treatment forms, which focus not only on controlling, fighting or reducing the pain, but more on bringing the focus to improvement of functioning and an increase in the quality of life (Turk et al., 2011). Within CBT methods are developed which seem to meet these challenges. In this regard one of the most promising forms of treatment for chronic pain are the Acceptance and Commitment Therapy [ACT] based interventions (Hayes, Strosahl & Wilson, 1999).

Roots, Principles and Aims of Acceptance & Commitment Therapy

ACT belongs to the third generation of behavior therapy. Behavior therapy can be divided into three waves. The traditional behavior therapy, the CBT and the current third generation, the more context- related treatments (Hayes, 2004). In the third generation of CBT the function is emphasized in contrast to the form, meaning to understanding behavior in relation to the history and current circumstances that coordinate it. With ACT it can be explored how thoughts, beliefs, and other psychological experiences have an impact on behavior and how a particular behavior is maintained (Hayes et al., 1999). Thereby insights from the behavioral-, cognitive behavioral therapy and mindfulness- based therapies are integrated (Hayes, Pistorello & Levin, 2012). But in contrast to the CBT, the focus of ACT lies not on the control of the symptoms, but rather on acceptance of pain and on the learning of a value- oriented life despite the persistent pain (Hayes, Luoma, Bond, Masuda & Lillis, 2006). One central principle in ACT is that much of the suffering one experiences is caused by attempts to avoid the painful experiences. Several studies have shown that people suffering from chronic pain generally try to avoid experiences that may create pain in the future or did so in the past (Hayes & Duckworth, 2006; Wicksell, Melin, Lekander & Olsson, 2008). From this point of view, chronic pain can be considered as an experiental avoidance disorder (Buhrman et al., 2013). Experiental avoidance has been defined as the effort to avoid thoughts, feelings, memories, physical sensations and other internal experiences which are associated with

suffering such as pain (Vowles & McCracken, 2010). ACT is an approach which targets the behavioral rigidity that roots in the unwillingness to experience these factors. Chronic pain patients undertake high energy and time efforts to supress the associated experience with pain. Thereby, the pain is put more and more into focus in the sufferer' s life and values- based aims in life could become lost (Vowles & McCracken, 2010). As a result of such a problem solving strategy, people become continuously psychological inflexible in changing this strategy, related to their thoughts. Therefore, the focus of ACT lies not on reducing the pain, but on acceptance of pain or the willingness to experience pain without attempts to control it (Hayes, et al., 2006). Thereby, ACT tries to improve effective functioning and the quality of life of chronic pain patients by teaching them acceptance and mindfulness techniques to experience such negative events in a more flexible and open way in accordance with their personal values (Wicksell, Olsson & Hayes, 2011). Therefore, the main goal of ACT is to create a meaningful life while the pain goes inevitable with it. ACT attempts to achieve this main goal by developing psychological flexibility (Hayes, et al., 2006). Thus, an increase in psychological flexibility fosters a decrease in the perceived interference of chronic pain, although the pain is present. Wicksell, Olsson & Hayes (2010b) define psychological flexibility as "...the ability to act effectively in accordance with personal values in the presence of interfering thoughts, emotions, and bodily sensations."
In ACT this increase of psychological flexibility can be achieved through six core processes or three response styles.

The underlying Processes of Acceptance & Commitment Therapy

Psychological flexibility is seen as the overarching treatment process in ACT and consists of six psychological interrelated processes that revolve around psychological flexibility (Hayes, et al., 2006). These processes are acceptance, cognitive defusion, values, commited action, self- as- context and present moment awareness. The six core processes are not only interrelated, they are also overlapping. These elements support each other and together they all target psychological flexibility (Hayes et al., 2006). In the latest research results by Hayes, Strosahl & Wilson (2012) the six core processes are taken together to three different units or 'response styles'. These three processes are the open response style, the engaged respone style and the centered response style. They are depicted in the so- called 'Triflex Model' (Figure 1).

Cognitive defusion and acceptance are aspects of an ‘open response style’. Through this style one gets the abilty to let go of all struggles and entanglements with the unwanted emotions, thoughts and experiences of pain. Cognitive defusion is seen as the ability to watch and observe thoughts without being dominated or ruled by them (Thompson & McCracken, 2011). Chronic pain patients often take their painful thoughts and associations literally too serious. Cognitive defusion techniques try to change these undesirable functions of thoughts and associated experiences (Hayes, et al., 2011). Acceptance as the opposite of experiental avoidance is a further determinant to the psychological model of ACT (Reneman, Dijkstra, Geertzen & Dijkstra, 2008). In ACT acceptance involves the willingness to experience difficult and painful experiences without defense (Thompson & McCracken, 2011). Through this, psychological flexibilty is promoted and people get the abilty to (re-) evaluate and focus on meaningful personal activities and goals in life.

This is also fostered in the second response style, the so- called ‘engaged respone style’. Values and committed action are aspects of this values- based response style (Hayes et al., 2012). Values give the directions in life. This is an essential step in creating a meaningful life. In ACT the core processes are not ends in themselves, they are interrelated and clear the way to a value- consistent life (Hayes et al., 2006). The committed action process fosters sustained, sustainable and flexible behavior in the direction of their values (Thompson & McCracken, 2011).

The third style, the ‘centered response style’, consists of the processes of self- as-context and present- moment awareness. These processes focus on a conscious centering in the present as a basic position towards life (Hayes et al., 2012). Self as context means a perspective on the self that is unchanged by time or experience. It is a process by which the individual learns to discriminate between the thinking self, and the self as observer (Harris, 2006). From this point of view one can be aware of one`s own experiences without attachment to them. The process of present- moment awareness is seen as an ability to be aware of how and when thoughts have a past or future quality, and to be able to be more frequently connected with the present (Kabat- Zinn, 1982). ACT fosters a non- judgemental contact with the psychological and environmental events. It implies to be conscious of one`s physical and psychological reality (Thompson & McCracken, 2011). The aim is to perceive the world and experiences more directly, so that people can behave more flexible and thereby make their actions more consistent with their personal values and not be influenced by the cognitive load of one`s experiences with the pain (Twohig, 2012).

Figure 1
ACT ‘Triflex Model’

Note. ACT= Acceptance and Commitment Therapy

Effectiveness of Acceptance & Commitment Therapy and Chronic Pain

The American Psychological Association [APA] (2011) recognized ACT as face- to face therapy as an evidence- based method for the treatment of chronic pain. A systematic review of Veehof, Oskam, Schreurs & Bohlmeijer (2011) demonstrated that acceptance- based therapies could be good alternatives to CBTs, although the researchers stated the need for more high controlled quality studies. Because the number of randomized controlled trials [RCT] was small with nine studies out of 22. Analyses of the acceptance- based treatments, which were only RCTs showed small but significant effects on pain and depression. Only two of these RCTs used ACT as the main treatment method with a small effect on pain (0.29) and a large effect on depression (1.09). The other studies were mainly directed to mindfulness-based methods. That indicates that there were much larger effects for the ACT- based treatments for the interference of pain complaints. Nevertheless, pain intensity was the most frequently used outcome measure in many of the 22 studies. Reduction of pain is not a primary focus of acceptance- based therapies. Therefore, the researchers emphasized the interference of pain in daily life as more suitable as the outcome measure for future studies of chronic pain. Since then, only a small but growing number of RCTs have been conducted

which meet the criterion of pain interference as the main outcome measure (Buhrman et al., 2013; Smout, Hayes, Atkins, Klausen & Duguid, 2012; Wetherell et al., 2011; Wicksell, Melin, Lekander & Olsson, 2009). These studies explored that ACT is an effective intervention for patients with chronic pain at post- test and at six- months follow-up assessment. Thereby ACT participants improved on pain interference with small to medium effect- sizes. The above mentioned investigations provide increasing evidence for the efficacy of ACT- based treatments regarding the improvement of functioning of chronic pain patients, but there are still relatively few ACT- based RCTs which focus on pain interference.

In sum, ACT is effective in the improvement of pain interference in daily life, but there are still not enough controlled studies to infer that ACT is more effective than other treatment approaches for chronic pain complaints (Hayes et al., 2006).

Internet- delivered Treatments and Acceptance & Commitment Therapy

Today, ACT interventions are carried out mainly face- to face, which causes high costs. Based on the tremendous benefits of internet- delivered interventions, over other more traditional forms of offering, increasingly research in this area has been carried out in the last years. Advantages are inter alia that it could reduce therapists' time and waiting lists, allow patients to work in their own pace, there would be no need for time- scheduling with a therapist, availability to a greater number of patients, it could overcome access barriers, and, of course, it would provide cost- effectiveness (Bender, Radhakrishnan, Diorio, Englesakis & Jadad, 2011; Cuijpers, Van Straten & Andersson, 2008). In the exploration of effective interventions for chronic pain online- based treatments have been developed, which mostly concerned CBT (Bender et al., 2011; Buhrman, Nilsson- Ihrfelt, Jannert, Ström & Andersson, 2011). In a systematic review, Cuijpers et al. (2008) found out that the effects of internet-delivered CBT targeting pain are comparable to the effects which were found for traditional face- to- face interventions. In a latter systematic review Bender et al. (2011) confirmed these findings. Until now, there is only one study known which used a guided internet- delivered self- help ACT approach for chronic pain patients. This intervention was shown to be effective in the treatment of chronic pain, in increasing activity engagement and pain-willingness. Reductions were found of pain-related distress, anxiety and depressive symptoms. A six months follow-up measurement has shown maintenance of the improvements (Buhrman

et al., 2013). Due to the advantages of an online- delivered ACT, this study wants to investigate if an internet- based ACT is effective in reducing pain interference in daily life. Moreover, it is not only important to know if the intervention works, but also how the intervention works, to develop effective and viable interventions for people with chronic pain. Therefore, it is important to investigate more about the underlying processes of this approach.

Mediation of Acceptance & Commitment Therapy

Although there is a growing body of evidence that ACT effectively can be used to treat pain-related interference in daily life, RCTs evaluating possible mechanisms of change are very rare and more tentative (Wicksell et al., 2011). These few studies have in common that changes in measures of psychological flexibility as the overarching process significantly mediate the effects of changes in the improved functioning. Vowles, Witkiewitz, Sowden and Ashworth (2013) showed that changes in measures of psychological flexibility significantly mediated changes in disability. In another mediation analysis Wicksell et al. (2011) demonstrated significant effects for psychological flexibility in relation to changes in pain-related disability and life satisfaction. Although tentative, these results support the mediating role of psychological flexibility in ACT- based interventions aimed at improving functioning and life satisfaction in people with chronic pain.

Further, improvements appear to be mediated by changes in the processes specified within the theoretical model underlying psychological flexibility as the overarching process (Vowles et al., 2013). Thereby different research studies provide support for the role of three underlying processes of psychological flexibility in relation to chronic pain conditions. These include the open-, the engaged- and the centered response style, which correspond to the three mentioned response styles underlying ACT. Process analyses investigated by Vowles and McCracken (2008) suggested that improvements in processes of the open- and the engaged response style were related to improvements in domains of functioning and accounted for about 17% of variance in these outcome measures. McCracken & Gutiérrez-Martínez (2011) showed that components of all three response styles combined accounted for about 18% of variance in measures of disability. Until now most studies, which explored the mechanisms underlying ACT are not RCTs and were more tentativelly with no reference group. Moreover, these studies mainly analyzed isolated components of one of the response styles or only the

combined influence, whereby the unique variance for some of these process variables were not taken into account.

In sum, more focus on the processes of change is necessary to understand and refine the application of treatment. With the present RCT all of the three hypothetized main processes of ACT should be investigated to explore more fully how an ACT intervention works.

The Current Study

To date there is no other research study known which has investigated the effectiveness of an internet- delivered ACT and mindfulness based intervention concerning pain interference as the main outcome measure and the mediating effects of the three response styles of ACT. Therefore, the following questions and hypotheses are deduced:

Questions and Hypotheses

Is there a significant decrease in pain- interference at the end of the intervention and after a 3- and a 9- months follow- up measurement in the ACT group in comparison to the control groups?

Hypothesis 1
There is a significant decrease in pain- interference in the ACT group after the intervention and at the follow- up measurements in comparison to the control groups.

Is there a significant increase in the processmeasures of the open-, engaged- and centered response style at the end of the intervention and after a 3- and a 9- months follow- up measurement in the ACT group in comparison to the control groups?

Hypothesis 2
There is a significant increase in the open-, engaged- and centered response style in the ACT group after the intervention and at the follow- up measurements in comparison to the control groups.

Is there a significant decrease in pain- interference in the ACT group mediated by the processmeasures of the open-, engaged- and centered response style at the end of the intervention and at the follow- up measurements in comparison to the control groups?

Hypothesis 3
There is a significant decrease in pain- interference in the ACT group mediated by a significant increase in the open-, engaged- and centered response style after the intervention and at the follow- up measurements in comparison to the control groups.

Method

Study design

In the current study data of a randomized controlled trial with three parallel groups was used. The first group received the internet- delivered ACT 'Living with pain online', referred as the experimental condition or ACT group [ACT]. The second group is the first control group, they received a minimal online intervention based on Expressive Writing [EW], constituted as the minimal intervention control condition (Pennebaker,1997). The third group is the second control group and received no treatment, referred to the waiting list [WL]. There were four points of measurement: the baseline measurement (T0) before the intervention started, one post- assessment (T1) after the end of the intervention and two follow- up measurement points at 3- (T3) and 9- months (T4) after the intervention. The WL was not assessed at the second follow- up measurement. The intervention and the questionnaires could be worked through online in the patients' own living environment.

Participants

The sample consisted of 269 adult chronic pain patients of the general Dutch population. Inclusion criteria for participation were an age of 18 years or older, their chronic pain lasting longer than six months and a pain intensity score of 4 or higher for four days or more within a 7- day period, assessed during the baseline period at screening with the Numeric Rating Scale [NRS] for pain- intensity (Dworkin et al., 2010). Exclusion criteria were having a severe psychiatric problem and/or having severe anxiety and/or depressive symptomatology, assessed with the Hospital Anxiety and Depression Scale [HADS], in which more than one standard deviation above the mean of the population of chronic pain patients in a pain rehabilitation center means exclusion from the intervention. Moreover, if someone was screened as having a psychological disorder, measured with the Web Screening Questionnaire [WSQ], they were called to fill in the Mini-International Neuropsychiatric Interview Plus [M.I.N.I.-plus] to ensure proper diagnostics, because the WSQ yields a high number of false positives (Donker, Van Straten, Marks, & Cuijpers, 2009; Sheehan et al., 1998). Moreover, if

among the remaining participants severe psychological disorders were diagnosed with the M.I.N.I., these participants were excluded from the intervention and were advised to see their general practitioner. Also participants with an extremely low score on Psychological Inflexibility in Pain Scale [PIPS], in which the cut- off score was 26.4 points, represented by two or more standard deviations below the mean of a chronic pain population in a rehabilitation center were excluded (Wicksell, Lekander, Sorjonen & Olsson, 2010). Other exclusion criteria were reading problems due to insufficient Dutch language skills or education, no acces to the internet at home and/or no email address, not enough time to follow the intervention or already receiving psychological treatment. After this screening, there were finally 238 people eligible to participate in this study. In Table 1 an overview of the characteristics of the remaining participants is given. Thereby the main findings were the following. First, ¾ of the participants per group were women. Second, the average age was about 53 years and the level of education per group was medium. Moreover, it was striking that about 60-70% of the participants had suffered more than 5 years under their pain complaints.

Table 1
Characteristics of participants

Characteristic (%)	ACT (n= 82)	EW (n= 79)	WL (n= 77)
Gender (rounded)			
Female	77.0	76.0	75.0
Male	24.0	24.0	25.0
Age			
M (SD)	52.9 (13.3)	52.3 (11.8)	53.2 (12.1)
Education			
High	12.2	10.1	11.7
Middle	68.3	70.9	66.2
Low	19.5	19.0	22.1
Duration of complaints			
3– 6 month	0.0	0.0	1.3
6 month–1 year	8.5	6.3	3.9
1–2 years	14.6	6.3	10.4
2–5 years	18.3	17.7	23.4
<5 years	58.5	69.6	61.0
Diagnosis			
No diagnosis	14.6	17.7	19.5
Back pain	9.8	13.9	14.3
Fibro	15.9	29.1	15.6
Joint pain	8.5	7.6	9.1
Rheumatic complaints	9.1	7.6	11.7
Neuropathic pain	11.0	6.3	9.1
Other diagnosis	30.5	17.7	20.8

Note. N= 238. ACT= Acceptance and Commitment group, EW= Expressive Writing group, WL= Waiting list.

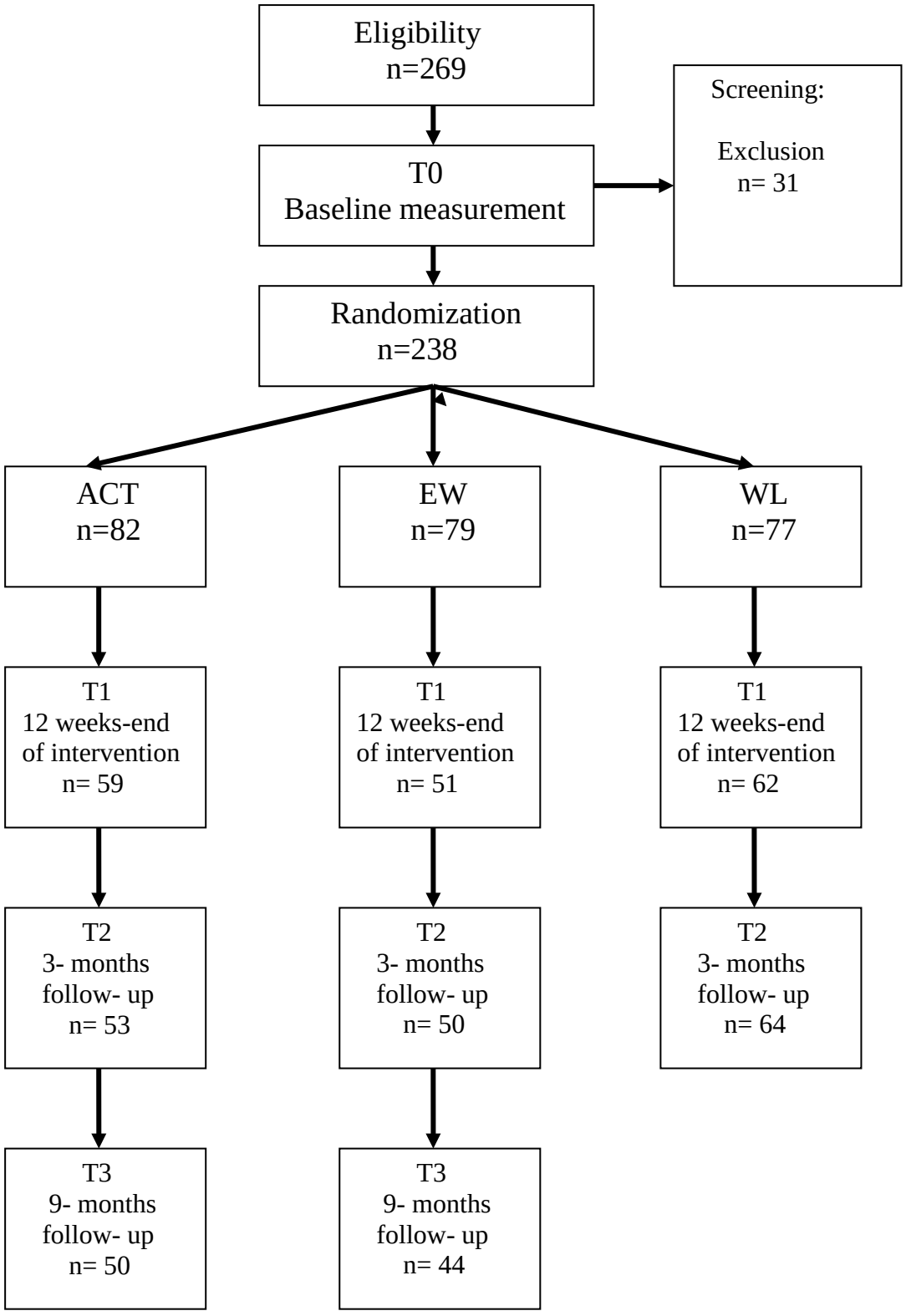
Procedure

In Figure 2 a general overview of the procedure and the number of participants at each point of measurement is represented.

Recruitment took place through advertisements in national newspapers and magazines and through frequently attended chronic pain websites. In the advertisements the website www.psychologievandelevenskunst.nl was mentioned. Respondents could read through and download the patient information letter. 269 people were enrolled in the study. They were able to do a self- assessment of eligibility on basis of the in- and exclusion criteria. Thereafter, the respondents provided written informed consent. After allocation of written informed consent the participants filled in the online screening questionnaires, the PIPS and the WSQ. When people were diagnosed as having a severe psychological disorder, they were excluded from the study and advised to see their general practitioner. When they were still eligible, participants filled in a 7-day baseline period to assess pain intensity as further screening for eligibility. Based on the in- and exclusion criteria mentioned above, 31 people were excluded. The remaining 238 participants assessed as eligible for enrolment in the study received an email to inform them about continuing enrolment procedures. Thereby, they got the link to fill in the baseline questionnaires (T0). These participants were randomized individually and divided over the three conditions. 82 people were assigned to the online- based ACT 'Living with pain online', 79 people were assigned to the first control group, the minimal web- based intervention group based on Expressive Writing [EW], and 77 people were assigned to the second control group, the waiting list group [WL] (Figure 2). In order to guarantee that the three groups could be optimally compared, stratification was conducted for sex, age and education. Thereafter, the participants were informed via email about group enrolment and received a further link to start the intervention. During the intervention period the experimental and the minimal intervention group worked through their mentioned intervention in nine to twelve weeks (T1). Three months after the end of the intervention all three groups filled in the first follow- up questionnaires (T2). Thereafter, the waiting list control group could start the intervention if they had decided for that. Nine months after the end of the intervention a last follow- up assessment was conducted by the treatment and the expressive writing group (T3).

Figure 2

Number of participants completed measurements at each point of measurement



Note. ACT= Acceptance and Commitment, EW= Expressive Writing, WL= Waiting list

Intervention

The participants in the experimental group received the free, guided, web- based intervention 'Living with pain online'. The intervention is based on the self- help book 'Living with pain' (Veehof, Hulsbergen, Bohlmeijer & Schreurs, 2010) and the intervention 'Living to the full' (Bohlmeijer & Hulsbergen, 2008). The 'Living with pain online' intervention is based on ACT and mindfulness and consisted of nine modules, which could be worked through in nine to twelve weeks. The nine modules are based on the three response styles of ACT.

In module 1 the participants got psychoeducation on pain. For example, they received information about acute versus chronic pain and treatment options for chronic pain. During this first module they were also informed about the goals of the intervention and became acquainted with mindfulness exercises. In the second module the participants learned about the aversive effects of 'experiental avoidance'. In module 3 and 4 values were introduced. The respondents did exercises to recognize their personal values and to think about how they can apply these values in their daily life. In module 5 they focused on the possibility of acceptance of their pain complaints. In module 6 and 7 processes of cognitive defusion and self- as- context were introduced to the participants. They practiced to recognize their unhelpful thoughts about their pain. Furthermore, they could learn the difference between the subjective, the judging, and the objective self. In the eighth module the social environment of the respondent with chronic pain was taken into account. In the final module nine the participants focused on applying their formulated goals and values on their daily life and also on prevention of relapse. After the participants completed a module, they wrote a reflection over their experiences with that module. Once a week the participant got feedback via email for this reflection from a counsellor, then the participant could enter the next module. The feedback was about the participants' progress during the intervention and could be used to discuss problems, questions or other topics. The email contact is important for guidance and support of the process (Cuijpers & Schuurmans, 2007). Through this adherence to the intervention was promoted. Moreover, the email contact could also serve to discover if respondents developed serious problems during the intervention. They were then advised to find help. Counselling was carried out by graduated master students Psychology of the University of Twente, under the supervision of a GZ- psychologist. There are a lot of other functionalities used in this web- based intervention, such as experience stories of people who have followed an ACT and mindfulness intervention. These were added to each module. They could also keep a web- based diary.

People in the active control condition received the web- based intervention 'Expressive Writing' [EW]. The general assignment was to write on a regular basis on negative emotions which they experienced during the day. They could choose if they wanted to email parts of the diary or a conclusion of this. The respondents then got weekly feedback by a counsellor via email during the nine to twelve weeks of the intervention. The diaries were only accessible to the respondents, not to the counsellors. The theoretical setting of the intervention was based on expressive writing by Pennebaker (1997). The central mechanism was that expressive writing can help to give meaning to stressful events and can help to gain acceptance of the stressful event (Boals & Klein, 2005; Pennebaker, 1993; Pennebaker, 1997). In regard to psychological problems and quality of life, research of expressive writing found moderate positive effects (Pennebaker & Chung, 2007). The background of this intervention is that respondents received a sensible, but minimal intervention. The expectation for this condition is a decrease in pain interference in daily life, but to a smaller range compared to the experimental condition. Equally, we expect smaller or minimal long- term effects, compared to the experimental group.

Participants in the second control condition (WL) received no intervention at all. This was done to compare if the hypothesized effects of the ACT are specific for this treatment group. The participation ends after the 3- months follow- up measurement, then they got the possibility to follow the ACT intervention without email counselling (Figure 2). The expectation for this condition is no or a barely visible decrease in daily interference of the pain complaints and possible psychological problems. Equally, we expect no long- term effects of this waiting list group.

Measures

Multidimensional Pain Inventory – Subscale Interference

This study used pain interference as outcome measure to prove the effectiveness of the ACT based intervention. Therefore, we made use of the Multidimensional Pain Inventory [MPI-Interference] to measure several aspects of chronic pain and disabilty (Kerns, Turk & Rudy, 1985). The subscale pain interference of the MPI focuses on psychological impairment aspects of chronic pain patients. The total scale score was used to measure the interference in daily life. This subscale consists of eleven items, which measure the pain interference in daily life with social activities, work household chores and relationships. One of these items was

for example: " How much has your pain interfered with your daily activities?". All items can be answered on a 7- point Likert scale, whereby higher scores mean more interference in daily life (Kerns et al., 1985). The MPI has been translated into Dutch and validated thoroughly (Lousberg, Van Breukelen, Groenmanc, Schmidt, Arntz & Winter (1999). In the current sample the subscale interference showed a high internal consistency (Cronbach`s α= 0.858 (T0), α= 0.907 (T1), α= 0.895 (T2) and α= 0.914 (T3)).

Psychological Inflexibility in Pain Scale

The Psychological Inflexibility in Pain Scale [PIPS] measures the open response style, which is one of the three processes underlying ACT (Hayes et al., 2006). The open response style was operationalized by measuring psychological *in*flexibility (Wicksell, Lekander, Sorjonen & Olsson, (2010a)). Here psychological *in*flexibility was viewed as opposite of the open response style, in terms of avoidance and cognitive fusion related to pain. The PIPS was found to mediate the relation between pain and disability. That shows the usefuleness of the PIPS as a process measure in the treatment of people with chronic pain. Thus, the PIPS used to analyze processes of change in people with chronic pain in ACT- based interventions (Wicksell, et al., (2010a)). The PIPS is a 12- item version and consists of two subscales, which measure two aspects of this response style. In the present study the total scale score was used to measure the open response style. The items had to be scored on a 7- point Likert-type scale ranging from "Never true" (1) to "Always true" (7). Higher scores mean greater psycholgical inflexibility. Examples of items are, " I avoid planning activities, because of my pain" and " I would do almost anything to get rid of my pain". Research showed acceptable model fit, adequate internal consistencies, and correlations with different criteria variables, like disability and life satisfaction (Wicksell et al., 2010b). The Dutch version of the PIPS showed acceptable to good model fit, good internal consistencies, as well as good construct validity (Trompetter, submitted). In the current sample the total scale showed a high internal consistency (Cronbach`s α= 0.862 (T0), α= 0.874 (T1), α= 0.906 (T2) and α= 0.868 (T3)).

Engaged Living Scale

The Engaged Living Scale [ELS] was developed and assessed to measure the second process variable, the engaged response style (Trompetter, ten Klooster, Schreurs, Fledderus, Westerhof & Bohlmeijer, 2013). The scale consists of 16 items with two subscales. The first subscale focused on valued living. The subscale valued living refers to the knowledge and recognition of personal values and the behavior congruent with these personal values. One example statement is, " I know exactly what I want to do with my life". The second subscale

focuses on 'life fulfillment'. This subscale refers to the evaluation and sense of fulfillment as a consequence of recognizing and living in accordance with personal values (Trompetter et al., 2013). An example of a statement is, "I am satisfied with how I live my life". All items can be answered on a 5- point Likert scale, ranging from " not true at all" (1) to " very much" (5). In the current study the total score of the ELS was used, ranging from 16 to 80. Higher scores indicate a higher degree of the engaged response style. Preliminary analysis of the ELS and its subscales showed good internal consistency and construct validity by consistent patterns of associations with the theoretically related process and outcome variables like acceptance and pain interference (Trompetter, et al., 2013). In the current sample the scale showed a high internal consistency (Cronbach`s α= 0.941 (T0), α= 0.961 (T1), α= 0.966 (T2) and α= 0.961 (T3)).

Five Facet Mindfulness Questionnaire- Short Form (FFMQ-SF)

The third process of measurement is the Five Facet Mindfulness Questionnaire- Short Form [FFMQ- SF], which is a twenty- four item questionnaire and thus a reduced form of the FFMQ (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011; Baer et al., 2008). The FFMQ- SF was used to measure the centered response style. Aspects of this style are observing, describing, acting with awareness, non- judging and non reactivity. Respondents were asked to rate the degree to which each statement is true for them. The items were scored on a 5- point Likert- type scale, ranging from "never or rarely true" (1) to "very often or always true" (5). The total scale score used in the present study ranges from 24- 120. Thereby, higher scores mean a more centered response style. Examples of these mindfulness items are, "I do jobs or tasks automatically without being aware of what I am doing" (acting with awareness facet) and "I pay attention to physical experiences, such as the wind in my hair or sun in my face" (observe). The FFMQ- SF showed good psychometric properties (Bohlmeijer et al., 2011). In the current sample the scale showed a high internal consistency (Cronbach`s α= 0.823 (T0), α= 0.840 (T1), α= 0.858 (T2) and α= 0.862 (T3)).

Statistical Analysis

The analyses were performed using SPSS version 21.

The missing data was replaced by values estimated by the expectation- maximization- likelihood method, in order to increase the power (Dempster, Laird & Robin, 1977).

For further analysis the total scores of the process and outcome measures were calculated (MPI, PIPS, ELS, FFMQ- SF). Analyses of socio- demographic data, process- and outcome

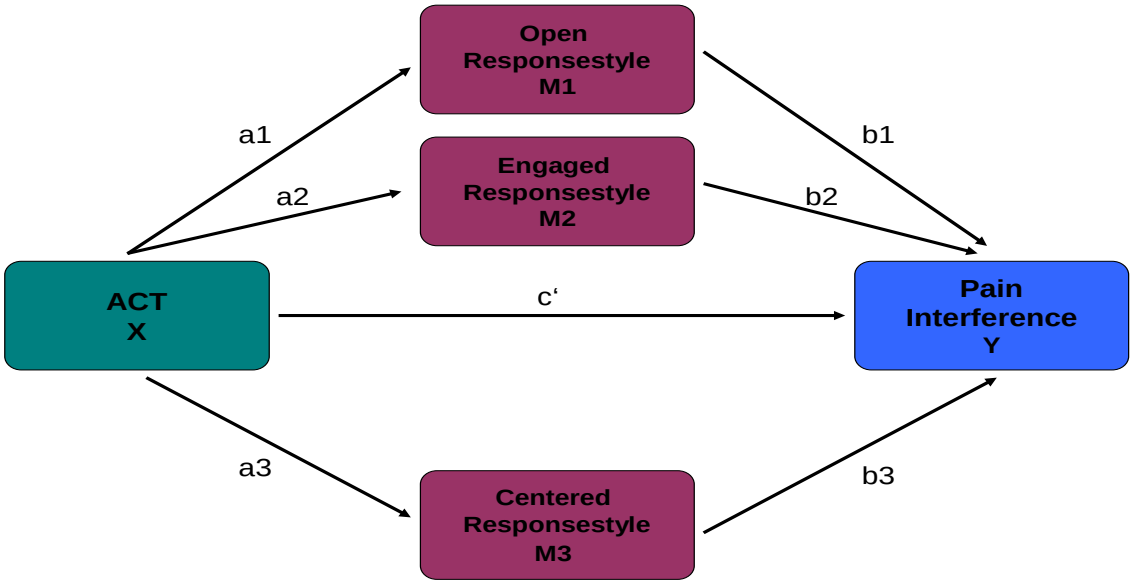
measures were performed to ascertain comparability of the three groups. X^2 test and one way ANOVA showed no significant differences at baseline measurement between the groups in gender, education, age, diagnosis, duration of complaints, use of medicine, pain interference, the open-, engaged- and centered response style, indicating that randomization was successful.

To answer the first and second question and the associated hypotheses, repeated measures ANOVAs with simple contrasts were executed with the within subject factor measurement (pre- to post- assessment and pre- to 3- months and 9-months follow- up assessment) and the between subject factor group (ACT, EW, WL) for the three process measures (open-, engaged- and centered response style) and the outcome measure (pain interference). Additionally, if an interaction effect between the factor measurement and group was found, for every measured variable there were further repeated measures ANOVAs with repeated contrasts executed, for the measurements of post treatment to 3- months follow- up measurement and 9- months follow- up measurement and from the 3- to the 9- months follow- up measurement. This was carried out to determine if the interaction effects remain stable, or even to see if the effects improve again or decrease after the intervention. If a significant interaction effect was found between the factor measurement and group, it was further investigated between which groups these differences were significant. This was carried out with change scores (pre- to post change scores, pre- to 3- months follow- up change scores and pre- to 9- months follow- up change scores) and the Post Hoc Tukey HSD test (Lowry, 2008). Moreover, effect sizes were calculated between the ACT and the EW and between the ACT and the WL group for effects at post-, 3- months follow- up- and 9- months follow- up measurement, compared to the baseline measurement. Therefore, the change scores were used to calculate cohen`s d. An effect size of 0.2 means a small effect, an effect size of 0.5 means a medium effect, and an effect size of 0.8 means a large effect (Cohen, 1988).

To answer the third question and thus how the effects between the treatment and pain interference can be explained, mediation analyses were carried out for measurement at post treatment and also for follow- up measurements. Therefore, the associated change scores were used. This was carried out with the simple mediation model by Hayes (2013). Model 4 was tested in PROCESS for the groups (ACT/EW, ACT/WL and EW/WL) for the post assessment and also for the 3- months follow- up assessment. At the 9- months follow- up assessment one simple mediation analysis was carried out for the ACT group with the only reference of the EW group. Bias corrected bootstrap confidence intervals of 10.000 bootstrap samples were

drawn to estimate the direct and indirect effects. In order to meet the requirements for a mediation the three following requirements are necessary (Baron & Kenny, 1986). First, X (independent variable: treatment approach) needs to significantly predict M (meditaor), thus being unequal to 0. Second, M (mediator) needs to significantly predict Y (dependent variable: pain interference), thus being unequal to 0. Third, X needs to significantly predict Y, thus being unequal to 0. A distinction is made between full and partial mediation. In a full mediation, the relationship between X and Y is fully explained by M. This means that the direct path between X and Y: c' is not significant when M is also included as a predictor of Y. The Y, therefore, only predicted by M and not by X. If in this situation a connection between X and M exists, then the relationship between X and Y is an indirect link (via M) and therefore a full mediation. The indirect effect of X to Y through M can be calculated as the product of the two regression coefficients a and b: ab (Figure 3). In a partial mediation, the relationship between X and Y is partly explained by M, but there still remains a significant direct link between X and Y.

Figure 3
Proposed model of the current study



Note. ACT condition= independent variable (X), response styles = proces measures/mediators (M1, M2, M3), Pain Interference= dependent variable/outcome measure (Y)

Results

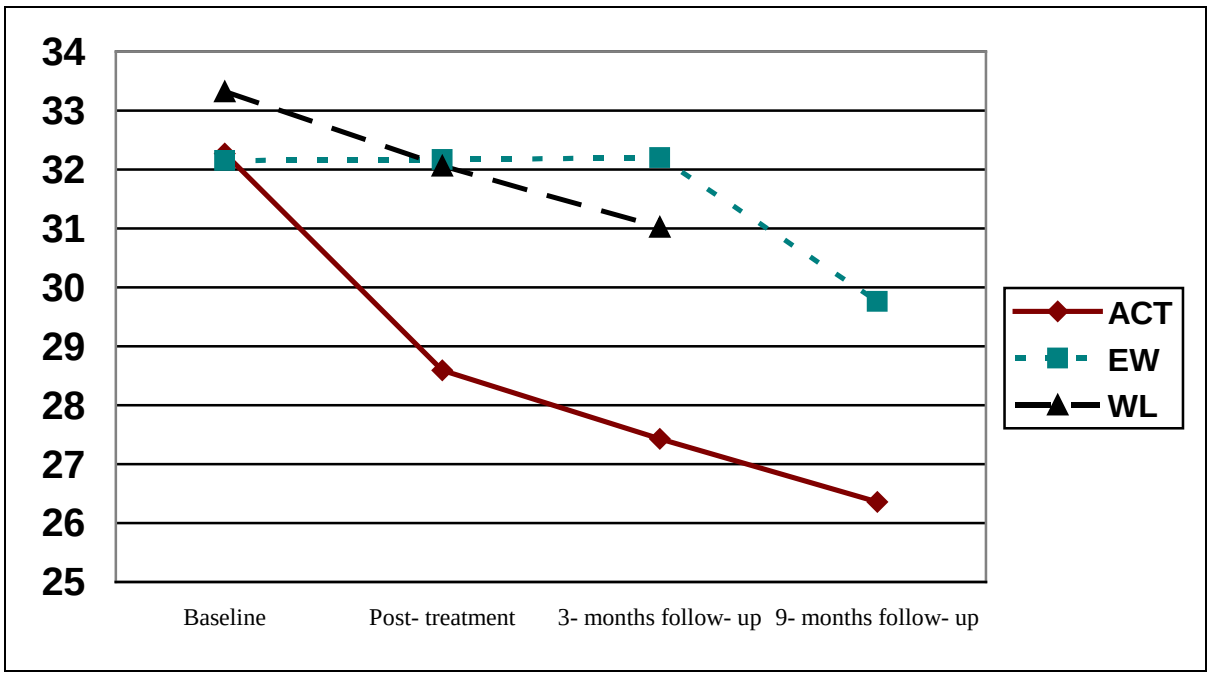
Pain interference

The ACT group showed a relative strong decrease in means of pain interference from baseline- to post- and from baseline to the follow- up assessments, in comparison to the control groups (Figure 4, Table 2).

A significant interaction effect on the MPI interference subscale for the pre- to post-assessment was detected ($F(2, 235)= 4.54$; $p= 0.012$) (Table 3). The post- hoc test showed that the changes in scores were significant between the ACT and the EW group, in favour of the ACT group (95% CI: -6.72; -0.76). The corresponding effect size was small (Table 3). The 3-months follow- up results showed a significant interaction effect of measurement (T0- T2) and group ($F(2, 235)= 6.33$; $p= 0.002$). This treatment effect was significant between the ACT and the EW group, also in favour of the ACT group (95% CI: -8.12; -1.64) with a medium effect size (Table 3). Moreover, the treatment effect was significant for the pre- to the 9-months follow- up assessment between the ACT and the EW group ($F(1, 159) = 4.79$; $p= 0.030$). The corresponding effect size was small (Table 3). No significant interaction effects from post- to 3-months follow-up assessment and from the 3- to the 9-months follow-up measurement were detectd. This means that changes in scores were not significant between the groups at these measurements.

In sum, there is only a significant treatment effect between the ACT and the EW group from baseline- to post- and to the follow-up assessments, but not between the ACT and the WL group regarding pain interference.

Figure 4
Effect on Pain Interference (MPI)



Note. ACT= Acceptance and Commitment group, EW= Expressive writing group, WL= Waiting list; MPI= Multidimensional Pain Inventory – Subscale Interference

Open Response Style

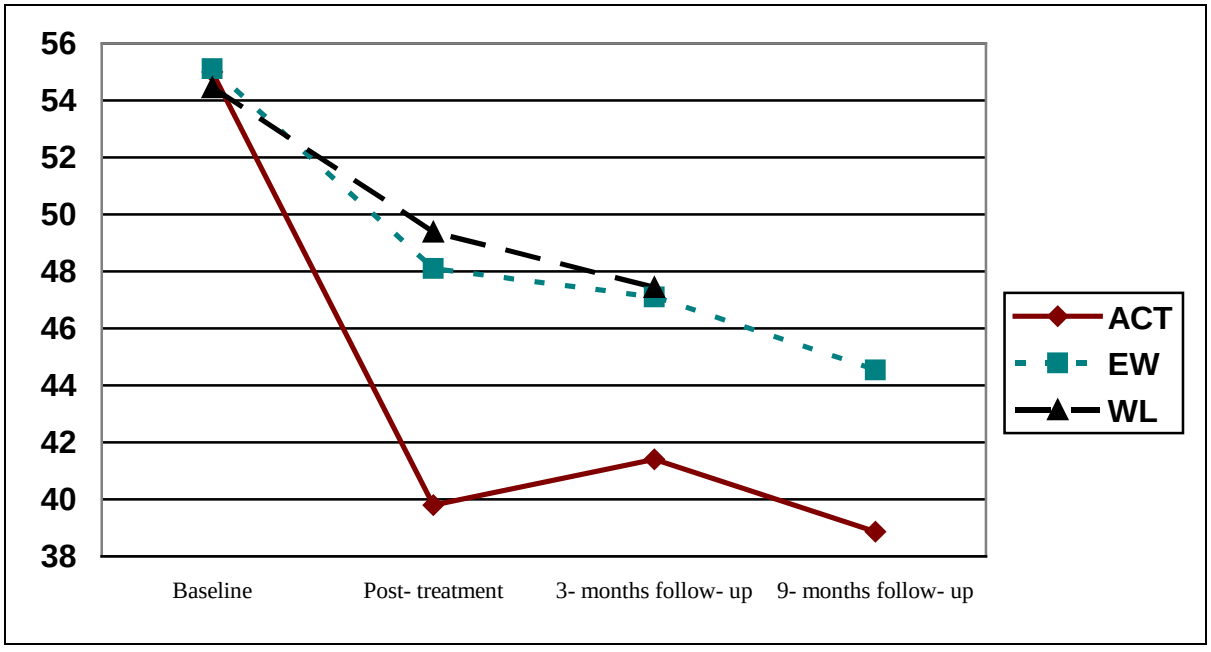
All three groups showed an improvement in mean scores for the open response style from baseline- to post- measurement. The ACT group showed a relative strong decrease in mean scores from baseline- to post- and from baseline to the follow- up assessments in comparison to the control groups (Figure 5, Table 2).

The repeated measures ANOVA for the open response style showed a significant interaction effect between the groups and measurements from baseline- to post- assessment (F (2, 235)= 16.15; p= 0.000) (Table 3). The post- hoc test showed that the changes in scores were significant between the ACT and the EW and between the ACT and the WL group (ACT/EW: 95% CI: -12.65; -3.73, ACT/WL: 95% CI: -14.62; -5.64). Medium and large effects were obtained for comparisons between the groups (ACT/EW: d= 0.64; ACT/WL: d= 0.89) (Table 3). The results from pre- to the 3- months follow- up assessment showed a significant treatment effect between measurement and group (F(2, 235)= 5.92; p= 0.003) (Table 3). The changes in scores were significant between the ACT and the EW and between the ACT and

the WL group (ACT/EW: 95% CI: -10.42; -0.72, ACT/WL: 95% CI: -11.46; -1.69). The corresponding effect sizes were small (Table 3). Moreover, the treatment effect was significant from baseline- to the 9- months follow- up assessment between the ACT and the EW group (F(1, 159)= 6.06; p= 0.015) with a small effect size (Table 3). There were no significant treatment effects detected from post- to the 3- months follow- up assessment and from the 3- to the 9- months follow- up measurement, meaning that the changes in scores were not significant between the groups at these measurements.

In sum, there is a significant treatment effect between the ACT and the EW and between the ACT and the WL group from baseline- to post- and to the follow- up assessments, regarding the open response style.

Figure 5
Effect on the open response style (PIPS)



Note. ACT= Acceptance and Commitment group, EW= Expressive writing group, WL= Waiting list; PIPS= Psychological Inflexibility in Pain Scale

Engaged Response Style

All three groups showed an increase in mean scores for the engaged response style from baseline- to post- measurement. Thereby, the EW group showed the strongest and the WL

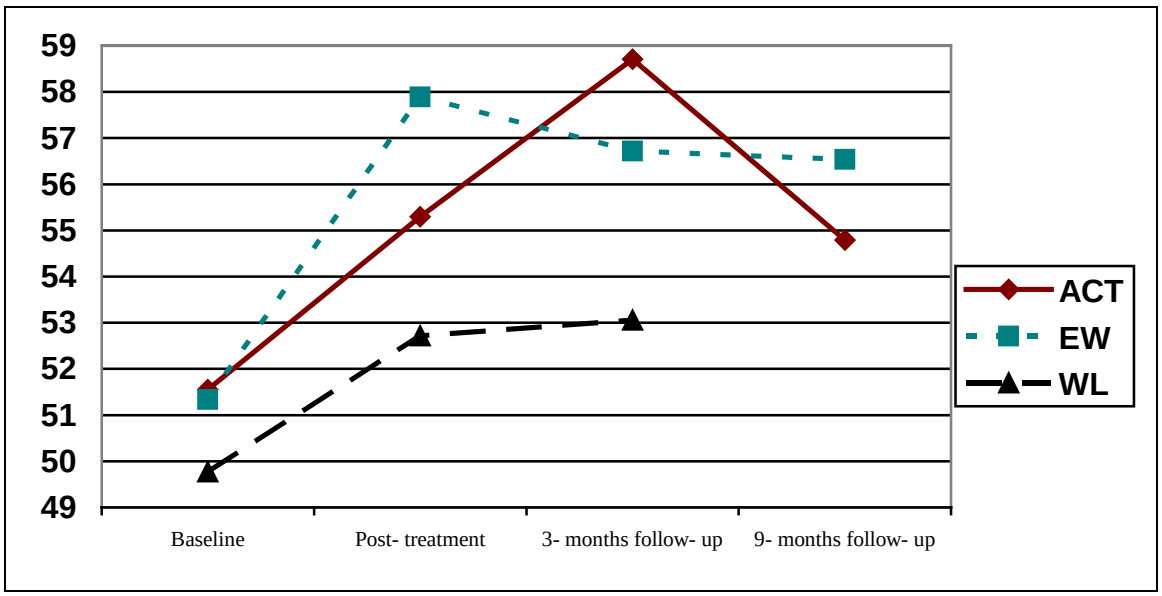
group the smallest increase at post- treatment (Figure 6, Table 2). At the 3- months follow- up assessment the mean scores of the treatment group showed a further increase in mean scores (Table 2). On the other hand the scores of the ACT group decreased at the last follow- up measurement (Table 2).

The repeated measures ANOVA showed no significant interaction effects between the factors of measurement and group, meaning no significant differences of effects between the groups from pre- to post- test and from pre- to the follow- up measurements. Moreover, no treatment effects were found from post- test to the follow- up measurements and from 3- to the 9- months follow- up measurement.

In sum, there is no observable significant treatment effect, regarding the engaged response style.

Figure 6

Effect on the engaged response style (ELS)



Note. ACT= Acceptance and Commitment group, EW= Expressive writing group, WL= Waiting list; ELS= Engaged Living Scale

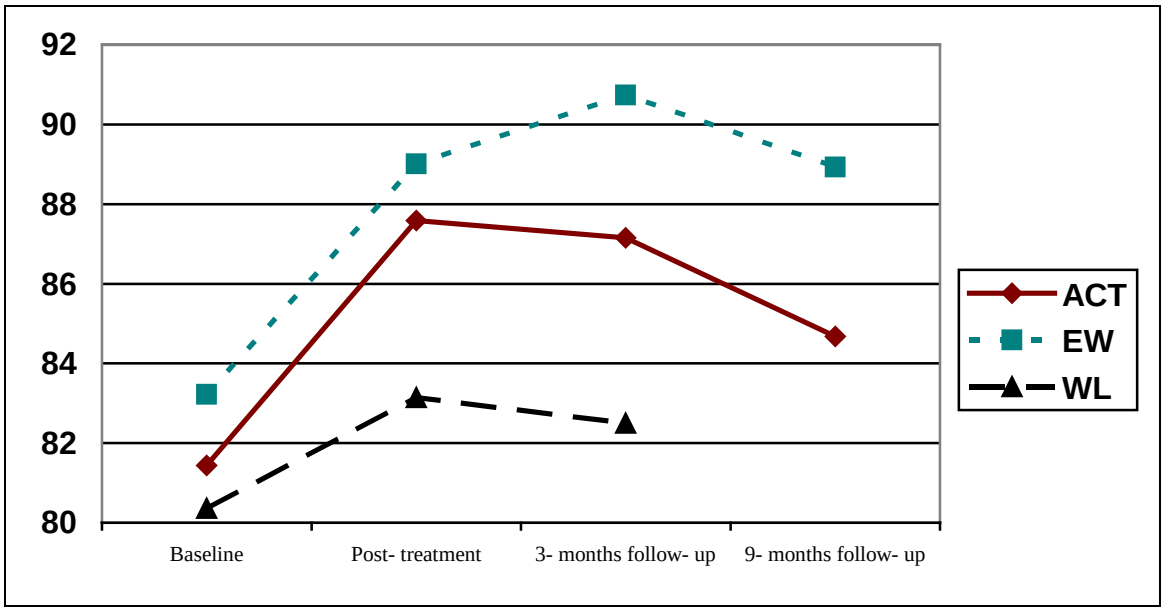
Centered Response Style

All three groups showed an increase in mean scores for the centered response style from baseline- to post and to the follow- up measurements (Table 2). Thereby, the EW group

showed the strongest and the WL group the smallest increase at post and at the 3- months-follow- up assessment (Figure 7). The repeated measures ANOVA showed no significant treatment- effect between the factor measurement and group, meaning no significant difference of effects between the groups from pre- to post- test. A significant interaction effect was found from pre- to 3- months follow- up assessment (F(2, 235)= 6.26; p=0.002) (Table 3). The post- hoc test showed that the changes in scores were significant only between the EW and the WL group (EW/WL: 95% CI: -1.73; 0.94) and not between the ACT and the control groups. No significant interaction effect was found at the 9- months follow- up measurement, meaning that the groups did not differ in effects from baseline to 9- months after the intervention. Moreover, no other treatment effects were found.

In sum, there were no significant treatment effects regarding the ACT intervention.

Figure 7
Effect on the centered response style



Note. ACT= Acceptance and Commitment group, EW= Expressive writing group, WL= Waiting list; FFMQ- SF= Five Facet Mindfulness Questionnaire- Short Form

Table 2
Means, standard deviations of pain interference (MPI), the open response style (PIPS), the engaged response style (ELS), the centered response style (FFMQ- SF) for pre- and post- assessement and follow- up assessments after 3- and 9- months

Outcome variables	Condition	T0		T1		T2		T3	
		M	SD	M	SD	M	SD	M	SD
MPI	ACT	32.27	9.57	28.59	10,08	27.43	11.25	26.36	14.03
	EW	32.15	9.75	32.17	10,91	32.20	11.83	29.76	11.31
	WL	33.32	10.21	32.06	11,07	31.02	10.85		
PIPS	ACT	55.00	11.94	39.80	11,20	41.41	16.26	38.87	13.47
	EW	55.11	11.23	48.10	13,60	47.10	14.27	44.54	13.44
	WL	54.45	11.57	49.38	13,14	47.44	13.33		
ELS	ACT	51.55	10.42	55.30	11,00	58.71	10.75	54.79	10.88
	EW	51.34	9.86	57.89	10,06	56.72	11.33	56.54	14.27
	WL	49.77	9.08	52.72	12,73	53.06	12.76		
FFMQ-SF	ACT	81.44	10.80	87.59	10,47	87.15	11.73	84.68	13.25
	EW	83.22	10.40	89.01	10,35	90.74	11.60	88.93	12.41
	WL	80.36	10.93	83.14	11,96	82.50	13.23		

Note. ACT= Acceptance and Commitment therapy group; EW= Expressive writing group; WL= Waiting list group, MPI= Multidimensional Pain Inventory – Subscale Interference, PIPS= Psychological Inflexibility in Pain Scale, ELS= Engaged Living Scale, FFMQ- SF= Five Facet Mindfulness Questionnaire- Short Form, T0= Baseline-, T1= Post-, T2= 3- months follow-up-, T3= 9- months follow- up measurement

Table 3
Change Scores, effect sizes (ACT/EW and ACT/WL) between post- and pre- assessement and between follow- up assessments after 3- and 9 months and pre- assessment for pain interference (MPI), open response style (PIPS), engaged response style (ELS) and the centered response style (FFMQ- SF) and results of the repeated measures ANOVAs (F) with simple contrasts (T0- T1; T0- T2; T0- T3) of the interaction effect between the factors measurement and group

Outcome variables	Condition	T1-T0				T2-T0				T3-T0			
		M	SD	d	F	M	SD	d	F	M	SD	d	F
MPI	ACT	-3.71	7.65		4.54*	-4.84	9.00		6.33**	-5.90	10.69		4.79*
	EW	0.03	9.00	0.37		0.04	8.74	0.50		-2.39	9.65	0.32	
	WL	-1.26	7.25	0.29		-2.30	8.34	0.25					
PIPS	ACT	-15.20	13.10		16.15***	-13.59	16.38		5.92**	-16.13	14.17		6.06*
	EW	-7.02	12.90	0.64		-8.02	11.80	0.36		-10.57	14.50	0.43	
	WL	-5.70	9.55	0.89		-7.02	9.90	0.46					
ELS	ACT	3.75	9.78		2.59	7.16	10.10		2.29	3.24	10.49		1.09
	EW	6.55	11.58	0.30		5.38	12.29	0.18		5.20	13.31	0.17	
	WL	2.96	9.72	0.11		3.29	11.78	0.38					
FFMQ-SF	ACT	6.15	9.13		2.87	5.72	8.31		6.26**	3.24	11.04		1.93
	EW	5.80	11.14	0.10		7.53	10.73	0.22		5.71	11.50	0.18	
	WL	2.78	8.59	0.47		2.14	9.89	0.35					

Note. ACT= Acceptance and Commitment therapy group; EW= Expressive writing group; WL= Waiting list group, MPI= Multidimensional Pain Inventory – Subscale Interference, PIPS= Psychological Inflexibility in Pain Scale, ELS= Engaged Living Scale, FFMQ- SF= Five Facet Mindfulness Questionnaire- Short Form, T0= Baseline-, T1= Post-, T2= 3- months follow-up-, T3= 9- months follow- up measurement; Cohen`s d: 0.2= small effect, 0.5= medium effect, 0.8= large effect; F: *= $p < 0.05$, **= $p < 0.01$, ***= $p < 0.001$

Mediation- analysis

Mediation- analysis of the open response style at post-, 3- and 9- months follow- up measurement

The above mentioned results exposed no significant effect of the intervention on the two proposed mediators of the engaged and the centered response style, which is a requirement for a mediation. Because the requirements for a mediaton are not met by these variables, further analysis involves the open response style as the only mediator between the treatment and pain interference (Baron & Kenny, 1986). The proposed mediator is analyzed in relation to the dependent variable pain interference, with pre- to post and pre- to follow- up change scores. Figures 8a- 10 present the direct and indirect effects of the simple mediation model, comparing the ACT to the EW and the ACT to the WL group. Thereby 95% confidence intervals of the multiple mediator model are shown under the figures, without zero, meaning that the mediations are significant. Additionally, the confidence intervals of the mediation effects of the open response style of the comparison of the EW versus WL group did include zero. Due to this, it is concluded that the mediation effects are specific for the ACT group.

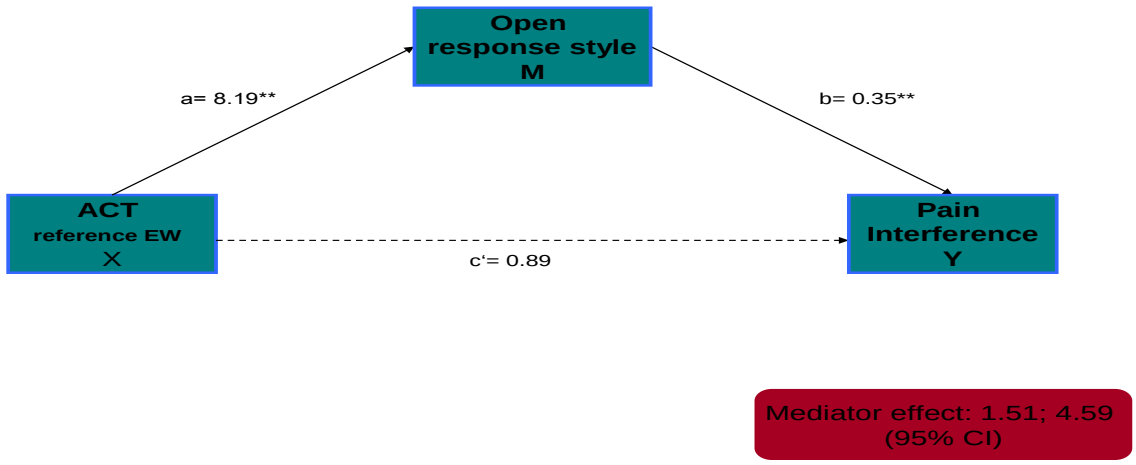
Mediation of the open response style at post- measurement

The estimation of the simple mediation model for the open response style comparing the ACT to the EW and the ACT to the WL group showed no significant direct effect (Figure 8a and 8b: path coefficient *c'*), indicating that there was no influence of the experimental condition on pain interference independent of the mediator of the open response style (Verboon, 2010). Consistent with our prediction, the experimental condition (ACT/EW, ACT/ WL) was related to the mediator (Figure 8a and 8b: path coefficient *a*). Additionally, the open response style positively predicted pain interference while controlling for the experimental condition (Figure 8a and 8b: path coefficient *b*), meaning that those participants who showed a higher open response style (here measured as the negative construct: psychological *in*flexibility) also showed higher pain interference. Thus, the relation between the experimental condition on pain interference is the product of the indirect effect of path a and b (Figure 8a and 8b: path coefficient $a \times b$). In other words, the indirect effect (ACT/EW: $a \times b = 2.87$, 95% CI: 1.51; 4.59, ACT/WL: $a \times b = 1.59$, 95% CI: 0.99; 2.38) of the open response style mediates the effect of treatment on pain interference.

In conclusion, we accept the hypothesis that the effect between the treatment of ACT and pain interference at post- treatment is fully mediated through the open response style.

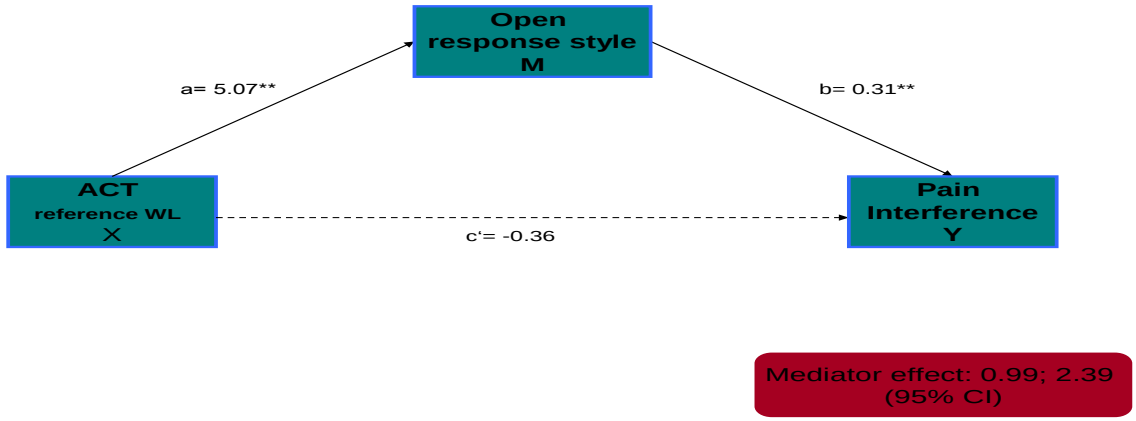
Figure 8a

Mediation Model: ACT/EW (pre- to post- assessment)



Note. Open response style= mediator (M), ACT= Acceptance and commitment group with reference EW= Expressiv writing group = independent variable (X), pain interference= dependent variable (Y).

Figure 8b
Simple Mediation Model: ACT/WL (pre- to post- assessment)



Note. Open response style= mediator (M), ACT= Acceptance and commitment group with reference WL= Waiting list group= independent variable (X), pain interference= dependent variable (Y)

Mediation of the open response style at 3- months follow- up measurement

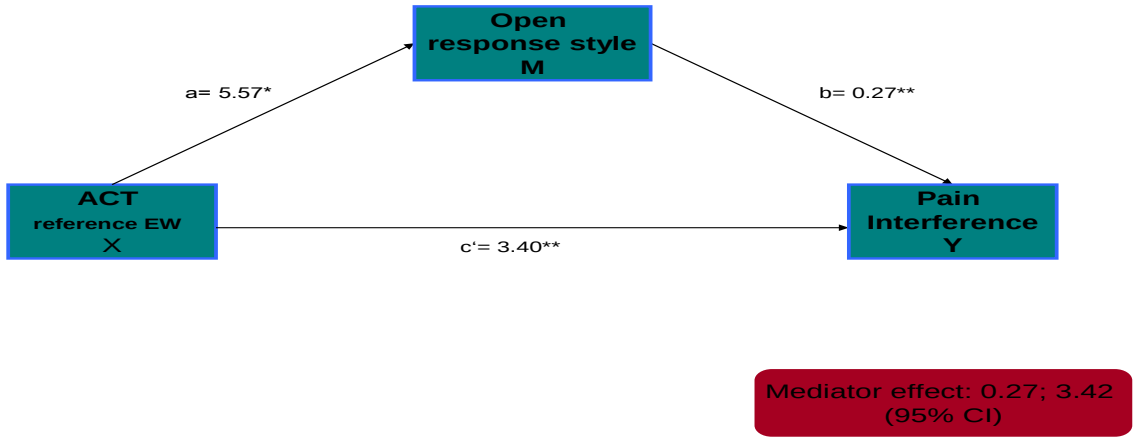
The estimation of the simple mediation model for the open response style comparing the ACT to the EW group showed a significant direct effect (Figure 9a: path coefficient *c'*), indicating that there was an additionally influence of the experimental condition on pain interference independent of the mediator of the open response style. The association between X and Y is explained partially through the mediator M, but there is also a direct relation between X and Y (Verboon, 2010). Consistent with our prediction, the experimental condition (ACT/EW) was related to the mediator (Figure 9a: path coefficient *a*). Additionally, the open response style positively predicted pain interference while controlling for the experimental condition (Figure 9a: path coefficient *b*), meaning that those participants who showed a higher open response style (here measured as the negative construct: psychological *in*flexibility) also showed higher pain interference. Thus, the relation between the experimental condition on pain interference is partially the product of the indirect effect of path a and b (Figure 9a: path coefficient $a \times b$). In other words, the indirect effect (ACT/EW: $a \times b$ = 1,50, 95% CI: 0,26; 3,37) of the open response style mediates partially the effect of treatment on pain interference.

The estimation of the simple mediation model for the open response style comparing the ACT to the WL group showed no significant direct effect (Figure 9b: path coefficient *c'*), indicating that there was no influence of the experimental condition on pain interference independent of the mediator of the open response style (Verboon, 2010). Consistent with our prediction, the experimental condition (ACT/ WL) was related to the mediator (Figure 9b: path coefficient *a*). Additionally, the open response style positively predicted pain interference while controlling for the experimental condition (Figure 9b: path coefficient *b*), meaning that those participants who showed a higher open response style (here measured as the negative construct: psychological *in*flexibility) also showed higher pain interference. Thus, the relation between the experimental condition on pain interference is the product of the indirect effect of path a and b (Figure 9b: path coefficient $a \times b$). In other words, the indirect effect (ACT/WL: $a \times b$ = 0.70, 95% CI: 0.18; 1.54) of the open response style mediates the effect of treatment on pain interference.

In conclusion, we accept the hypothesis that the effect between the treatment of ACT and pain interference in reference to the EW group at 3- months follow- up measurement is partially mediated through the open response style. Moreover, we accept the hypothesis that the effect between the treatment of ACT and pain interference in reference to the WL group at post- treatment is fully mediated through the open response style

Figure 9a

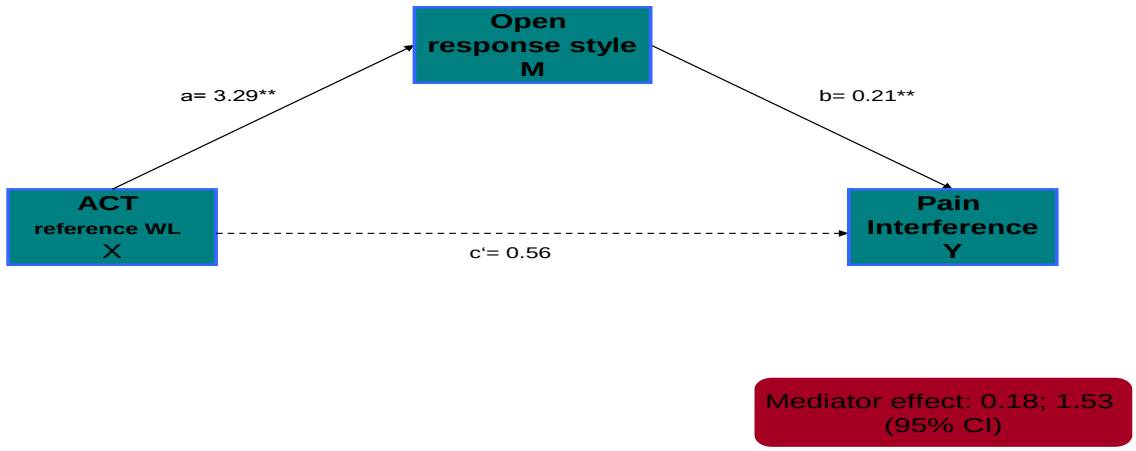
Simple Mediation Model: ACT/EW (pre- to 3- months follow- up assessment)



Note. Open response style= mediator (M), ACT= Acceptance and commitment group with reference EW= Expressiv writing group = independent variable (X), pain interference= dependent variable (Y).

Figure 9b

Simple Mediation Model: ACT/WL (pre- to 3- months follow- up assessment)



Note. Open response style= mediator (M), ACT= Acceptance and commitment group with reference WL= Waiting list group= independent variable (X), pain interference= dependent variable (Y).

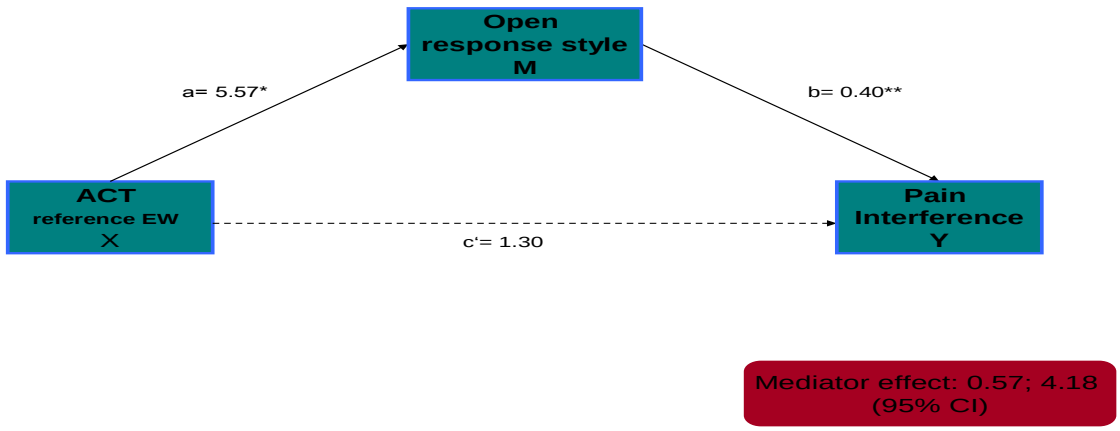
Mediation of the open response style at 9- months follow- up measurement

The estimation of the simple mediation model for the open response style comparing the ACT to the EW and the ACT to the WL group showed no significant direct effect (Figure 10: path coefficient *c'*), indicating that there was no influence of the experimental condition on pain interference independent of the mediator of the open response style (Verboon, 2010). Consistent with our prediction, the experimental condition (ACT/EW, ACT/ WL) was related to the mediator (Figure 10: path coefficient *a*). Additionally, the open response style positively predicted pain interference while controlling for the experimental condition (Figure 10: path coefficient *b*), meaning that those participants who showed a higher open response style (here measured as the negative construct: psychological *in*flexibility) also showed higher pain interference. Thus, the relation between the experimental condition on pain interference is the product of the indirect effect of path a and b (Figure 10: path coefficient $a \times b$). In other words, the indirect effect (ACT/EW: $a \times b$ = 2.22, 95% CI: 0.53; 4.20) of the open response style mediates the effect of treatment on pain interference.

In conclusion, we accept the hypothesis that the effect between the treatment of ACT and pain interference at 9- months follow- up measurement is fully mediated through the open response style.

Figure 10

Simple Mediation Model (pre- to 9- months follow- up assessment)



Note. Open response style= mediator (M), ACT= Acceptance and commitment group with reference EW= Expressiv writing group = independent variable (X), pain interference= dependent variable (Y).

Discussion

The present study investigated if the internet- based intervention 'Living with Pain online', based on ACT and mindfulness, is effective for chronic pain patients in reducing pain interference in daily life, as well as in short- and long- term effects. In order to determine if and how long these effects are maintained, we aimed at investigating the effects of the intervention at a 3- and 9- months follow-up measurement.

Moreover, one part of this study examined how the intervention works in terms of the hypothesized mechanisms of change processes of the three response styles (open-, engaged- and centered response style), also for short- and long- term effects.

The results of the present study show that pain interference levels were decreased after the 'Living with pain online' intervention and also at the follow- up measurements.

Small to medium treatment effects on pain interference in daily life were found with the strongest effect at the 3- months follow- up assessement. The treatment effect was found to be significant only between the ACT and the EW group but not between the ACT and the WL group. Therefore, the conclusion that the treatment effect of the online ACT intervention is generally effective in decreasing pain interference can only be drawn with caution. Nevertheless, the scores for the open response style showed a greater improvement for the ACT group compared to the WL group at all points of measurement.

The effectiveness of the treatment of ACT in reference to the EW group is in accordance with findings of other research studies. Wetherell et al. (2011) investigated in a randomized controlled trial that ACT participants improved on pain interference after the intervention and at 6- months follow- up. In an internet- delivered ACT for chronic pain patients Buhrman et al. (2013) discovered that the treatment group improved significantly on the MPI- interfering scale, in relation to the active control group, and follow- up data showed that the experimental group still improved six months after the intervention. The findings of the current study suggest that the internet- delivered ACT intervention is successful in the decrease of pain interference in daily life and is more effective than another online treatment approach based on expressiv writing (Pennebaker, 1997). Therefore, the results support the consideration that ACT could be more effective in the treatment of chronic pain conditions than other treatment approaches (Hayes et al., 2006; Buhrman et al., 2013).

Suprisingly, the treatment effect was not significant between the ACT and the WL group, which is not consistent with the proposed first hypothesis and other research studies (Lynch et

al., 2008; Wicksell, Ahlquist, Bring, Melin & Olsson, 2008). The reasons for the decrease in the WL group could be multifaceted, because we could not control and hold steady the acts of this group. Not otherwise specified factors could be responsible for the unexpected decrease in pain interference in this group. Nonspecific factors are not directed by a theory underlying a treatment and could lead to nonspecific effects and therefore influence study outcomes (Greenberg, Constantino, & Bruce, 2006). Responsible factors could be patients' positive expectations, due to the knowledge of participating in a therapy in the near future. By that, their awareness of themselves could have changed. By that, in turn, their attitudes and behaviour could have changed. This has eventually led to the change of perception of interference through the pain itself (Constantino, Arnkoff, Glass, Ametrano & Smith, 2010).

Results of the online ACT intervention regarding the open response style indicate that there is a significant treatment effect between the ACT and the two control groups, demonstrated among other things through the medium to large effect sizes. Although all three groups improved, the ACT group showed much more improvement than the two control groups. It can be concluded that the improvements in the open response style were due to the ACT treatment. The above mentioned results of the treatment effect for the open response style are in accordance with the second hypothesis and other research findings. Studies by McCracken & Gutiérrez-Martínez (2011) and Wicksell et al. (2008) found out that the improvements in the open response style were due to the participation in the acceptance and commitment- based treatment. Although the effect sizes decline a little bit after the intervention, improvements in scores were visible from baseline- to the follow- up measurements. With regard to the small decrease of the effect sizes, future studies should measure more points of measurement to detect when the effects decline and/or when the effects maybe disappear completely at long term. Another recommendation for future studies would be to develop interventions whereby the open response style is triggered over the whole time and perhaps the interventions should be longer per se to give the participants the possibility to adopt and maintain the effects mor stable.

Although significant effects were achieved, it is suprising and not in accordance with other studies that the control groups improved over the whole time (Wicksell et al., 2008). With regard to the WL group the improvement of the open response style could here as well be due to non specific factors as positive expectations (Greenberg et al., 2006). The mere willingness and motivation to tackle their problems and the mere confrontation that in the near future the intervention is going to start could lead to a modified thinking, perception and view on themselves, their daily acting and functioning in a more flexible way. Another reason could

be that the mere filling in of the questionnaires has set in gear a realization of their own thinking and acting and this has in turn lead to a more flexible way of thinking and acting. This could also be true for the EW group. A second reason for the decrease in the EW group could be due to the expressive writing treatment per se. Research has shown that disclosing of one`s stressful or painful experiences could lead to good health, but the underlying mechanism is still not completely clear (Pennebaker, 1985; Baikie & Wilhelm, 2005). One consistent finding is that individuals who have written about emotional topics report that the experiment made them think differently about their experiences (Pennebaker, 1989; Klein & Boals, 2001). Maybe the open response style is one aspect of this modified cognition. The mere participation and/or examination and realization of one`s own thoughts and actions through the expressive writing and reflection could result in a more flexible way of thinking and acting. Another reason for the improvment could be that one process by which EW works may be acceptance, through the repeated realization of one`s thinking (Vowles, Wetherell & Sorrell, 2009). Further research is necessary to investigate the processes in EW. Future research should explore the underlying mechanisms of EW to make more accurate distinctions between treatment approaches and to design more suitable interventions.

Results of the online intervention for the engaged response style indicate that there is no significant interaction effect between the factors of measurement and group, meaning no significant differences of effects between the groups from pre- to post- test and from pre- to the follow- up measurements. All three groups improved from baseline- to post- and from baseline- to the follow- up measurements. The increases were not specific for the ACT group as previously hypothesized. This result is not consistent with other study results (McCracken & Gutierrez- Martinez, 2011; Vowles & McCracken, 2008). Possible reasons thereof may be the following. First, the EW group may possibly be able to see things in another way, as a result of the expressive writing treatment per se (Pennebaker & Chung, 2007), maybe in a more values- consistent way. Thereby, sharing one`s experiences allows individuals to relieve the negative emotions arising from stressful life events (Smyth, Pennebaker & Arigo, 2012). As a result of realizing and being more aware of oneself and the associated thinking, one could maybe rethink their way of thinking and associated actions and focus more on other important things in life, like values and goals. Another reason could be that the mere filling in of the questionnaires could maybe set in gear a realization of their own thinking and acting and this has in turn lead to a values- based thinking and living. That could also be true for the WL group. A third reason for the increase in the engaged response style by the EW and WL group could here as well be positive expectations, so that the mere decision to participate in

the intervention and the associated willingness to change something in their life that could made them think differently about their experiences (Klein & Boals, 2001). Fourth, because the results of the ELS are only preliminary, it may be that the good internal consistency is not conclusive enough, so that it could be that the measurement does not adequately measure the process of the engaged response style (Trompetter et al., 2013). Another reason may be that mainly the last modules treat this topic and therefore it could be that the consolidation of this process takes much more time to be adopted. This is also emphasized by the fact that this response style increased after the intervention and therefore after the treated modules. The participants maybe need more practice and exercise. Another possibility is that values- related methods are more vulnerable to a loss of effect and are more likely to need some type of reinforcement during the follow-up intervals, this is emphasized by the decrease at the 9-months follow- up measurement. Future studies should design interventions wherein this aspect will be involved more frequently and right at the beginning of the intervention, to make sure that the participants have enough time and the possibility to exercise and to adopt and implement this values- based style.

Results of the online intervention indicate that the centered response style showed no significant treatment effects between the groups from baseline- to post- measurement. Nevertheless, all three groups improved from baseline- to post- treatment and from baseline- to the follow- up measurements. The increases for the ACT group were not specific, as previously hypothesized. The result is suprising and not consistent with other study results (Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012; McCracken & Gutierrez- Martinez, 2011). It is unclear why the effectiveness of the centered response style was not specific for the ACT group, although mindfulness was a core component in the ACT treatment. Possible reasons for the missing treatment effect may be the following. Rosenzweig, Greeson, Reibel, Green, Samar & Beasley (2010) demonstrated that greater home meditation practice was associated with improvement on several outcome measures. With regard to this theoretical background, one reason for the missing treatment- effect of the centered response style and the not discovered long- term effects of the ACT group may be that the participants did not do their mindfulness exercises as stated through the intervention and through that only a small increase in mean scores was achieved. A recommendation for future studies would be to investigate the home practice of the participants, to analyze if this has influenced the effects on mindfulness. One possibility to clear this is with log- data analysis. Log- data analysis could also be helpful to find out more about when and how frequent someone uses an online tool and if this in turn has influence the effects. Second, it could be that the general increase in

the degree of mindfulness was initiated by the measurements. It could be that participants in the EW and WL group showed improvements in the centered response style purely through the mere reading and filling in of the questionnaire, so that they could have adopted a more mindful way of thinking. Third, the WL group could increase mindfulness through non-specific factors like positive expectations, which set in gear a possibly modified way of thinking about and therefore they may be indeed more present in the here and now. Research has demonstrated that expectations could have a huge impact on different outcomes of participants who were enrolled in a study (Constantino et al., 2010). Fourth, it could also be that participants read about the upcoming form of intervention as a way of explicit preperation for the treatment and through this they adopted relating thoughts and suggestions of being mindful. This last reason could also be true for the EW group. Another possible reason of the increased centered response style with regard to the EW group could be due to the expressive writing treatment per se. Research has investigated a possible overlap between expressive writing and mindfulness- based interventions (Brody & Park, 2004; Poon & Danoff- Burg, 2011). They demonstrated that writing repeated narratives may "involve the process of mindfulness in that the self- directed attention required in the writing process can heighten awareness of internal states" (Moore, Brody & Dierberger, 2009, p. 973). Further research is necessary to draw clear conclusions about the process of the centered response style in EW and its share in the health outcome measures. Another recommendation is that future reasearch studies should analyze the effects of only reading and filling in the used questionnaires with several measurement points as a seperate intervention, to investigate the proportion of influence on the effects of other treatment approaches like EW. This applies to all three response style measurements.

To contribute to the understanding of how an ACT works and to enhance the effectiveness of this treatment method, mediation analyses for short- and long- term effects were examined. The engaged- and centered response style did not function as mediators for changes in pain interference. This in an unexpected finding because these response styles are important processes in psychological flexibility. Possible explanations therefore were mentioned above. The proposed process variable of the open response style, as the only process variable with a significant treatment effect, was included. We hypothesized that the variable functioned as a mediator of change between the treatment and pain interference, immediately after the intervention, at 3- months- and at 9- months after the intervention. The open response style, assessed by the PIPS total change scores, functioned in all mediator analyses as a significant indirect mediator between the ACT and mindfulness- based treatment

and pain interference (pre- to post, pre- to 3- months follow- up and pre- to 9- months follow-up change scores). The mediating effects indicated that the effectiveness of this intervention lies in changes of the open response style. This is partially in accordance with the third hypothesis and with other more tentative research studies. Wicksell et al. (2010b) showed that the open response style functioned as a significant mediator between the treatment group and outcome measures on pain- related disability and life satisfaction. Thus, it is concluded that the improvements in pain interference in daily life in this randomized controlled trial were obtained through changes in the open response style. Moreover, we can conclude that this mechanism of change was maintained at three and nine months after the intervention. Therefore, future ACT studies for chronic pain patients should involve and strenthen the important role of the open response style in improving pain interference. Moreover, future studies should investigate the mediating effects even more accurately. That means first, to analyze not only the total scores of the response styles, but also the specific subprocesses of the measurements. That means second, to explore more points of measurement and at which points of measurement which process will be adopted and at which point the processes decrease or disappear exactly. That could also help to understand the underlying mechanism of change and to develop more effective ACT interventions and therefore enhancing the effectiveness of these treatment forms.

Quality of the Present Study

A strong point of this study is the research design with a randomized controlled trial [RCT]. RCT studies have demonstrated a “gold standard”, a high standard for the evaluation of interventions in the health care sector (Moher, Schulz & Altman, 2001). Another stregnth is the use of the control groups whereby the advantage is given that the effects of the intervention may be better explained. The groups help to control the effects of non- specific treatment- effects, like positive expecations. Moreover, a further advantage of the minimal intervention group is that they served as a good comparative instrument for the effects, meaning that we can conclude that the ACT is more effective than another treatment approach. Another strength is the large number of people who participated in the study, which were screened prior to the study on the basis of selection criteria. This resulted in a population that was relatively homogeneous and large enough to find significant effects. A further strength of this study is that there were four points of measurement to investigate the short- and also the

long- term effects of the treatment approach. Moreover, this is one of the first studies which investigated the effects of an internet- delivered ACT. The delivery format has tremendous advantages over the traditional forms of presentation (achieve more individuals, cost- efficient, could reduce the waiting lists etc.) (Hedman et al., 2011; Bender et al., 2011).

In spite of the strong points there are also limitations to the present study. First, one possible disadvantage may also regard the internet- delivered format. In the fact that the participants must have access to the internet and they must have sufficient internet skills there is a selection bias. Especially the elderly and those with low SES may therefore not be reached (Eysenbach, 2000). In this study these factors have not been confirmed. Another weak point regarding the format is that individuals may show less involvement in an online treatment than in a face- to- face treatment (Schalken & Wolters, 2010). This often has a higher attrition rate and/or drop- out rate as a result, which is also seen in the attrition rate of this study, with about 20% attrition rate in the ACT and the EW group at the end of the intervention. Moreover, another limitation of the current study is that the participants were mainly women. This means that the results should be generalized with prudence. With regard to the theoretical background that mainly women are affected by chronic pain and that another analysis of this intervention has investigated the moderator effects of gender with no significant influencing effects, this point has not so much emphasis (Tsang et al., 2008). Another weak point of the present study is that only the total scores of the measurements are used to analyze the treatment- and mediating effects. We can not exactly say which aspects of the open response style has which weighting between the treatment and pain interference.

Clinical and Practical Recommendations and Scientific Insights

The effects of the present study are only partially proved as effective, therefore it is still too early to say that the online tool ‘Living with pain online’ for people suffering from chronic pain provides a practical instrument for clinical implications. More high standardized research is necessary to draw conclusions over the short- and long- term effects of online- delivered ACT- and mindfulness- based interventions on pain interference in daily life of chronic pain patients. Thereby, they should involve the open response style which mediates this relation.

In Conclusion

Although the results of the present study are only partially proved as effective, it is suggested that the online- delivered ACT treatment is an effective method in the treatment of chronic pain interference for short- and long- term effects over a 3- and 9- months follow- up period. Therefore the study contributes to the growing body of evidence of acceptance and commitment- based treatments in the improvement of pain interference in chronic pain patients, for short- and long- term effects (Buhrman et al., 2013; Smout et al., 2012; Wicksell et al., 2011). Moreover, the current study provides a contribution to the underlying mechanism of ACT. Thereby, the developement of an open response style is of main importance to effective functioning in daily life. Thus, this study showed that effective functioning is possible through the improvement of the process of the open response style. Although other research studies showed that ACT is effective in the treatment of chronic pain complaints, the current research study is the first which shows that an online- delivered intervention based on ACT and mindfulness can be effective in reducing pain interference in daily life through the open response style.

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