“Living with pain” – the effectiveness of a web-based intervention for people with chronic pain

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**Abstract**

Established interventions based on Acceptance and Commitment-Therapy (ACT) show positive effects for chronic pain patients on several domains. Amongst others mental health problems like depression and anxiety can be positively influenced. In modern times of e-health, interventions that can be provided via internet are more and more required. Furthermore, controlled studies about processes that mediate possible effects of ACT interventions are still scarce, though needed. In this randomized controlled trial, the effects of a web-based self-guided intervention on depression and anxiety in chronic pain patients are evaluated. Furthermore, underlying processes of change are examined. Therefore, 238 chronic pain sufferers were randomly assigned to one of three conditions: web-based ACT intervention (ACT, N=82), web-based Expressive Writing intervention (EW, N=79) or Waiting List condition (WL, N=77). Measures, such as the Hospital Anxiety and Depression Scale (HADS) were taken at baseline, post-treatment and three-month follow-up. Results show decreased depression and anxiety levels at post-treatment (after 3 months of intervention) in all three groups. At follow-up ACT-participants had improved significantly compared to the EW group but not compared to the WL group concerning their depressive symptoms. No differences between groups could be detected concerning anxiety. Regarding processes that possibly influence the discovered effects, pain catastrophizing as well as psychological flexibility were found to mediate anxiety and depression when ACT was independently compared to both control groups. Furthermore, changes in depression in the ACT condition were also mediated by mindfulness when compared to the Waiting List. These findings mainly suggest the long-term effectiveness of web-based ACT-interventions for chronic pain patients, positively influencing depression and anxiety. They also stress the relevance of psychological flexibility as a key process of ACT and insinuate its relation to catastrophizing. This study is a promising starting point for future research in this area and indicates that the internet may function as a suitable medium for ACT interventions.

Interventies die gebaseerd zijn op Acceptance and Commitment-Therapy (ACT) laten positieve effecten zien op verschillende gebieden voor patiënten met chronische pijn. Onder andere kunnen depressieve en angstige symptomen bij chronische pijn patiënten positief beïnvloed worden. Tegenwoordig wordt e-health steeds meer bekend, dus zijn interventies die via internet kunnen aangeboden worden meer en meer gevraagd. Bovendien is onderzoek naar onderliggende processen die mogelijke effecten medieren, nog beperkt. In deze
gerandomiseerde studie werden de effecten van een web-gebaseerde self-hulp interventie op depressie en angst bij chronische pijn patienten onderzocht. Verder werden onderliggende processen van veranderingen geanalyseerd. Daartoe werden 238 chronische pijn patienten op een random manier drie groepen toegewezen: web-gebaseerde ACT interventie (ACT, n=82), web-gebaseerde Expressief Schrijven interventie (ES, n=79) of Wacht Lijst controle conditie (WL, n=77). Metingen zoals de Hospital Anxiety and Depression Scale (HADS) werden voor, meteen na afloop en drie maanden na afloop van de interventie afgenomen. De resultaten laten gereduceerde depressie en angst op post-metingen (na drie maanden) voor alle drie groepen zien. Op follow-up, drie maanden na afloop van de interventie, verbeterden ACT-deelnemers significant ten opzicht van de deelnemers in de ES groep wat betreft depressiviteit, maar niet ten opzicht van de WL groep. Met betrekking tot processen die de gevonden effecten wellicht beïnvloeden, werd gevonden dat psychologische flexibiliteit en catastroferen deze effecten medieeren als ACT werd onafhankelijk vergeleken met beide controle condities. Verder werden verschillen op depressiviteit in ACT-deelnemers medieert bij mindfulness indien ACT wordt vergeleken mit WL deelnemers. Deze uitkomsten tonen vooral de langdurige effecten van web-gebaseerde ACT interventies voor chronische pijn patienten aan, die depressiviteit en angst positief beïnvloeden. Zij verder benadrukken de relevantie van psychologische flexibiliteit als hoofdprocess van ACT en laten een relatie met catastroferen zien. Dit onderzoek is verder een goed begin voor toekomstige onderzoeken op dit gebied en laat zien dat het internet een geschikt medium is om ACT interventies aan te bieden.
Introduction

Chronic pain is a major health problem, affecting people all over the world and causing a range of problems for patients as well as for the health care system. Therefore, effective and accessible treatment is requested that can help patients to deal with their pain.

Worldwide about one of five people of the general population suffers from chronic pain (Andrew et al., 2013; Breivik et al., 2006), with prevalence varying from 16.9% in New Zealand (Dominick et al., 2011) up to 30.7% in the USA (Johannes et al. 2010). The International Association for the Study of Pain (IASP) defines pain as “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”, that subsists longer than the foreseen, normal time of healing which in most cases will be after a period of three month (IASP, 1986).

Besides the high degree of pain, which is mostly moderate (66%) to severe, the suffering in patients causes a multitude of other negative implications: Most of the patients (79%) reduce their general activity level what leads to restraints of the patients daily living such as less housekeeping, being less active or even a decreased amount of hygiene activities (Frießem, et al. 2009; Andrew et al. 2013; Breivik et al., 2006). Furthermore, chronic pain patients show a significant lower quality and satisfaction of life and report negative work-related outcomes such as more sick days, a loss of productivity or unemployment (Andrew et al. 2013). Thus not only has chronic pain a major impact on the private lives of patients but it also affects the economic sector in an adverse and costly way. Also the ramifications on the health care system are huge: 60 percent of the chronic pain patients visit their doctor 2 to 9 times a week and 54% have 2 to 6 different doctors who they pay regularly visits to, causing immense costs (Breivik et al., 2006; Andrew et al., 2013).

One severe negative implication of chronic pain is the relatively high risk of developing comorbid disorders and mental health problems like anxiety and depression that are known to have a high interaction with pain and increase suffering further (Cho et al., 2013; Demyttenaere et al., 2007; Orenius et al., 2013). The general prevalence for depression in chronic pain patients lies around 21% and, for example, a general anxiety disorder (GAD) can be found in about 7% of the patients (Breivik et al., 2006). Due to these comorbid mental health problems, health care costs as well as suffering and negative implications on the patients’ health status increase compared to chronic pain without comorbid disorders. Patients are found to exhibit a higher level of pain intensity, a greater fear of movement, greater pain interference and a poorer quality of life (Antunes et al., 2013, Olfson et al., 2007). Furthermore anxiety in chronic pain patients leads to anxious mood, tension and general somatic symptoms (Krishnan et al., 1985).
One key component of developing depressive and anxiety symptoms, seems to be catastrophizing: Thoughts about events or situations that are perceived as negative as possible and where the worst outcomes are expected. According to the fear avoidance model (Lethem et al., 1983), catastrophizing can result from past experiences that are perceived as negative and therefore cause fear and anxiety. Consequently, patients avoid any possible painful movement or stressing event to manage these negative emotions or events and deal with anxious feelings. Although reducing anxiety in the short term, this strategy is maladaptive, because over time anxiety maintains and cultivates fear, leading to reduced physical fitness, increased functional disability as well as generating depressive symptoms (Vlaeyen & Linton, 2000; Vlaeyen et al., 2002). Due to its proposed influence on anxiety and depression in chronic pain patients, catastrophizing (or catastrophic thoughts) is targeted in some forms of treatment, like Cognitive Behavioral Therapy (CBT) (Wicksell et al., 2011; Smeets et al., 2006).

Overall, about 70% of the chronic pain patients seek help and get treated, in which the most commonly known and used form of treatment is medication (70%) which about 35% of the patients find to be effective. (Breivik et al. 2006, Turk, 2011). However, although medication seems to be preferred, many patients (67%) also fear the negative side effects and seek other options, indicating that alternative treatment should be considered (Frießem et al., 2010).

Currently, there are several other treatment options available and new ones are steadily emerging to manage pain and its other related impairments. In the field of psychotherapy, Cognitive Behavioral Therapy (CBT) is a prominent form of treatment that has been shown to be effective for chronic pain patients (Morley et al., 1999; Butler et al., 2006). Instead of trying to control pain CBT interventions focus on modifying negative, unhelpful thoughts (like catastrophic thoughts) and maladaptive behaviors to ultimately reduce distress and pain. (Eccleston, 2001).

Acceptance and Commitment Therapy (ACT)

One form of CBT that has become more prominent throughout the last years is Acceptance and Commitment Therapy (ACT). The core assumption of ACT is that patients often engage in experiential avoidance when confronted with discomfort, meaning they try to avoid feared private events such as negative thoughts or feelings to stay in control (Hayes, 2004). This kind of behavior might be temporarily reinforcing, but on the long term causes psychological inflexibility, which means that patients act according to the feared private events and are not able to be in contact with present the moment. They are unable to persist or change behavior in the service of long-term valued ends what leads to a loss of quality of life and a range of other negative implications, like depression or anxiety.
Therefore, ACT interventions aim at increasing psychological flexibility, the ability to contact the present moment fully as a conscious human being and persist or change behavior in line of chosen values, to help patients to cope with distressing events and to live a fuller life in accordance with their personal values. They do not attempt to directly reduce pain or related symptoms like depression or anxiety, but through mindfulness and acceptance strategies change the way one interacts with or relates to (negative) thoughts, which are per se not viewed as right or wrong, but as useful or useless in obtaining a valued life (Ruiz, 2010; Hayes et al. 2006, Hayes, 2004).

In order to achieve the goal of ultimately reaching psychological flexibility, ACT builds around six core processes which are acceptance, cognitive defusion, being present, self as context, values and committed action (Hayes et al., 2006). As one of the most important core processes, “acceptance” implies that inner, negatively perceived experiences such as pain, negative feelings or thoughts are actively embraced instead of being controlled (Thorsell et al., 2011). For example, pain patients are given methods, like exposure exercises, that encourage them to let go of a struggle with pain and instead open themselves up to personal important values. Targeting “Cognitive defusion” in this model, means that patients should try to change their relation to negative thoughts, therefore alter its unhelpful function and personal meaning. The goal of practice in “being present” is being in relatively neutral contact with ones’ environment and perceive occurring events as they are, without any judgmental thoughts. It is claimed that one should flexibly shift ones attention to the present and current events instead of ruminating or worrying about the past. (Twohig, 2012). By promoting the “self as context” the clear awareness of one’s own flow of experiences is the essential process. In this context it is of importance to become mindful, which means recognizing one’s self instead of having a special attachment to the own experiences. Mindfulness exercises, where patients are asked to be aware of their mind-body relationship, notifying everything that is going on inside are a common used method in this context (Hassed, 2013). Another important process is for the patient to choose life directions in different domains, called “values”, which shall help to state personal important aspects in life. In the end all the other processes are strongly connected to “values”, because they are all aiming at living a values based life. The last of the six processes in ACT, “committed action”, is finally thought to seek out actions that are connected to the chosen values and aimed to actively achieve concrete goals that are values consistent.
Effectiveness of ACT interventions

Up to the present day various studies on interventions based on ACT have been published pointing to its overall effectiveness. Reviews on this topic show that compared to other therapeutic models like applied relaxation (AR) or traditional CBT, ACT is able to compete by showing equitable effects on for instance pain interference, pain-related anxiety or depression and concerning variables such life satisfaction or immediate improvement of quality of life may even outperform them (Wetherell et al., 2011; Ruiz, 2012). In their systematic review and meta-analysis on acceptance-based interventions for chronic pain patients, Veehof et al. (2011) found medium effect sizes for improvements on pain intensity, depression, anxiety, physical wellbeing and quality of life. These authors concluded that patients responded well to acceptance based therapies and stated the importance of acceptance and mindfulness in treatment, although further controlled studies are needed.

Many other (mostly uncontrolled) studies on ACT based treatment for chronic pain indicate the effectiveness of its proposed targeted core processes by showing increased psychological flexibility rates, due to higher acceptance and values-based action (e.g. McCracken & Jones, 2012; Thorsell et al., 2011; Wicksell et al., 2010; Vowles et al., 2011). Although not directly targeted, significant improvements on depression, anxiety, pain levels, activity levels, emotional functioning as well as quality of life were found (e.g. Thorsell et al., 2011; Wicksell et al., 2009; McCracken & Jones, 2012; Vowles & McCracken, 2008). Not only do the results of various studies show profitable outcomes for patients as well as for health care systems, but Vowles et al. (2011) showed that effects of ACT treatment on emotional and physical functioning are durable and long lasting. On top of that, amongst others Wetherell et al. (2011) found that patients reported to find acceptance based interventions more satisfying and enjoyable compared to CBT, which may increase its usability and the ease of implementation in primary care settings.

Processes of change

Besides the research on effectiveness of ACT based interventions and its improvements for chronic pain patients, the identification of the working mechanisms, that lead to the above mentioned changes, has lately become of greater scientific interest. Knowing what works to produce changes and what does not, helps improving interventions and optimizing treatment for chronic pain patients (Murray, 2011).

Most research in this field has been done on psychological flexibility and the six core processes of ACT and their influence on outcome variables such as pain interference, quality of life, anxiety or depression. Ruiz (2010) concluded in a review that overall experiential
avoidance of negative private events and cognitive fusion are highly related to a wide range of psychological disorders and that they are influential to change. When experiential avoidance can be decreased and changed into acceptance and ultimately psychological flexibility their mediating role becomes evident by showing positive effects on outcome variables such as (comorbid) depression and anxiety.

Studies on ACT interventions for chronic pain patients confirm these general finding and stress the key role of psychological flexibility with acceptance or mindfulness to mediate positive outcomes like depression and anxiety (Vowles & McCracken, 2008; Vowles et al., 2011; Hayes et al., 2006; McCracken & Jones, 2012; Johnston et al., 2010).

Beside the mediating role of the core processes of ACT, also (pain) catastrophizing was examined in some studies. As previously mentioned, anxiety as well as depression are known to highly relate to pain catastrophizing (Sullivan, 1990; Linton et al., 2011). It has been found to be an effective key process in CBT interventions where altering the content of catastrophic thoughts ultimately changes associated avoidance behavior (Wicksell et al., 2011; Smeets et al., 2006). However, although catastrophizing is rather a targeted CBT process, recent research showed that effects of catastrophic thinking on anxiety and depression were also mediated by acceptance. (Vowles et al., 2008). Thus, catastrophizing seems to be also related to processes targeted in ACT and may indirectly effect outcome variables in ACT interventions for chronic pain patients. However, more research on this topic is needed to further clarify the possible role of catastrophizing in ACT. Generally, randomized controlled studies of ACT interventions on processes of change for comorbid mental disorders like depression and anxiety in chronic pain patients are still scarce. Especially treatment mechanisms of change in web-based ACT interventions are missing.

Web-based self-help interventions

ACT based treatment can be administered in several ways and embedded in different contexts: one can find face to face - group or single sessions, web-based interventions or self-help books that are either embedded in an interdisciplinary treatment context or presented as one time course. (McCracken & Gutiérrez-Martínez, 2011; Johnston et al., 2010; Buhrman et al., 2013).

As can be imagined, interdisciplinary treatment involving psychologists, physiotherapists and doctors is quite costly. Therefore, the need for more cost-effective treatment such as self-help interventions is high. Meta-analyses and reviews on self-help intervention show positive effects for anxiety disorders (Lewis et al., 2012), depression (Newman et al., 2011) and also chronic pain (Murray, 2011) making them a suitable form of offering treatment.
In modern times, where technology is omnipresent, the advantages of the internet can be used to administer treatment, possibly making it even more cost-effective and accessible. In their review on the medium internet as a treatment delivery platform Griffith and others (2006) found several reasons to make use of web-based interventions. They state that the internet can overcome the isolation of time, mobility, and geography and is thus suitable for chronic pain patients. It furthermore reduces health service costs and increases the control of the intervention for the users as well as for the suppliers. Thus, many patients can be reached at once and over a long distance without much effort and energy.

Up to the present day several different web-based interventions have been offered to treat chronic pain, whereas some were more successful than others, but overall support the thesis that the internet is a suitable medium for providing treatment for chronic pain patients (Pozo-Cruz et al., 2012; Chiauzzi et al., 2010). Generally, interventions with well-considered models and theoretical foundations like ACT seem to have very good chances of being effective (Murray, 2011). However, there is only one study available that administered an ACT based self-help intervention for chronic pain via internet (Buhrman et al., 2013). Results of this study indicate the effectiveness of a web-based intervention and show significant increases regarding activity engagement and pain willingness. Furthermore pain-related distress, anxiety and depressive symptoms decreased. On top of that these effects were found to be long-lasting and were still present at six month follow-up.

Aims
Likewise, the present RCT study aims at examining the effectiveness of a self-help web-based ACT intervention with mindfulness exercises for chronic pain patients called “Living with pain”, concerning comorbid depression and anxiety. Through an RCT set-up, the study seeks to find out whether the constructed web-based intervention is of influence on positive changes in depression and anxiety compared to an active control group and a waiting list condition. This study tries to find out how high these possible effects are compared to both control groups. Furthermore, underlying processes or treatment mechanisms that are indirectly influencing possible changes are examined to increase the knowledge of working mechanisms in ACT interventions which helps to improve such interventions further. For reasons mentioned above catastrophizing and psychological flexibility were chosen to be examined regarding their indirect influence on depression and anxiety. Furthermore, the indirect effects of mindfulness are of interest as it is overall implied that the role of being mindful is a core principle of ACT to produce changes (Hayes, 2004). Research questions are: 1. what are the effects of the web-
based self-help intervention “Living with pain” on depression and anxiety in chronic pain patients compared to an expressive writing and a waiting list control group? 2. In how far do “catastrophizing”, “mindfulness” and “psychological inflexibility” mediate effects of depression and anxiety?

It is hypothesized that the web-based ACT intervention will generate significant changes in depression as well as in anxiety levels. Moreover, these changes are predicted to be significantly higher, compared to the changes of the two included control groups. Furthermore it is supposed to be shown that the theoretical ACT processes psychological inflexibility and mindfulness will mediate changes in anxiety and depression. It is also hypothesized that catastrophizing is related to outcome variables and mediate its effects.

**Method**

**Participants**

Participants of this study were adults, suffering from chronic pain for more than six months. They were recruited from the general Dutch population through advertisements in national newspapers and magazines and via frequently attended chronic pain websites. Exclusion criteria were severe psychiatric problems, an extremely low score on psychological inflexibility, a lack of possible access to Internet at home and no e-mail address, having not enough time to follow the intervention, another ongoing CBT treatment and having reading problems (due to insufficient Dutch language skills or illiteracy).

In total, 269 people were enrolled and screened online. Of these people, 238 eventually made up the sample of the present study (31 were excluded due to exclusion criteria) of whom 76% were women and 24% were men. The average age was 54 years (SD 12; range 20-84 years) and 74% of the participants that took part in this study were married or living together with their partner. Regarding education, 20% had followed a low education, 36% a medium education and 44% were highly educated. For the medical status it can be noted that 63% of the included participants suffered from pain more than 5 years and for 83% the diagnosis is known (mostly rheumatic illnesses).

**Procedure**

Participants were involved in this RCT study for the duration of 14 months from entry until the last follow-up measurement. Detailed information of the participants’ flow through the study is given in figure 1. Before participants were definitely enrolled they were informed, signed consent and undertook an online screening as well as a brief 7-day baseline assessment
concerning their pain level. After excluding those participants that were not suitable for the study, due to fulfilled exclusion criteria, all others followed the baseline assessment (T0). Next, they were randomly assigned to one of the three conditions: receiving the web-based ACT intervention “Leven met pijn” (experimental group; n=82), receiving the web-based intervention “Expressive writing” (control group 1; n=79) or being on the waiting list (control group 2; n=77). During the intervention period, the experimental group and the minimal intervention condition (control group 1) worked through their respective interventions where they read information, completed exercises and received weekly feedback.

In the present study there were three points of measurement, at which participants were asked to fill in a set of questionnaires which they could do online within their own desirable schedule and environment. Besides the baseline assessment (T0) all groups (including the waiting list control group) filled in a questionnaire at the end of the intervention after 12 weeks (T1) and a follow-up assessments that was taken three months after completion of the interventions (T2).

*Figure 1. Patient flow in a randomized, controlled trial of acceptance and commitment therapy (ACT)*
Interventions

Experimental condition

Participants in the experimental condition received the free ACT self-help web-based intervention ‘Leven met Pijn’, which is based on the self-help book ‘Leven met Pijn’ (Veehof et al., 2010) and the web-based intervention ‘Voluit Leven’. This intervention consisted of 9 lessons that focused on the six core processes of ACT. Every lesson contained information and exercises which participants should individually work through during a period of 9 to 12 weeks. Furthermore each lesson contained mindfulness exercises that every participant was asked to practice every day. During the first lesson participants were given some general information on pain and the intervention including its goals, mindfulness exercises and psycho-education on pain. Lesson 2 was built around the process of experiential avoidance whereas in lesson 3 and 4, the focus lay on defining values as well as on thinking of possible ways of applying these values. Acceptance of pain complaints and how that can possibly be achieved was the topic of lesson 5 whereas lesson 6 and 7 dealt with cognitive fusion and self-as-context. In lesson 8, the social environment of the person experiencing pain was taken into account and the final lesson, lesson 9, focused on applying earlier formulated values. Every week, after completing the respective lesson, participants received a short e-mail feedback from a counsellor containing personal progress and possible problems.

In addition to the 9 lessons and the received feedback, participants were provided with several other functions like a web-based diary as well as access to experience reports of other participants. They also had the possibility to read back each completed lesson and completed exercises.
Control condition 1: minimal intervention

Participants in the minimal intervention condition received the web-based intervention ‘Expressive writing’ which was based on the method ‘Expressive Writing’ (EW) of Pennebaker (1997). The idea of Expressive Writing is that while writing down negative emotions and experiences people start to better understand them and thus give some meaning to perceived stressful, negative events. This can ultimately help to manage those events and reach acceptance.

Therefore, in this intervention group participants were asked to write down negative emotions they experienced during the day on a daily or regular basis in approximately 15-30 minutes. Just like participants in the experimental condition, participants in this minimal intervention condition also received weekly e-mail feedback from a counsellor.

For this kind of intervention moderate positive effects have been shown in the area of psychological problems (Pennebaker & Chung, 2007) and it was chosen to give participants a sensible, but minimal treatment.

Control condition 2: waiting list

Participants of the waiting list group did not receive a web-based intervention immediately, but had the opportunity to access treatment as usual (TAU). Six months after entry, which was directly after the first follow-up measurement at three months, participants on the waiting list were given the opportunity to follow the web-based intervention ‘Leven met pijn’ or the ‘Expressive Writing’ intervention.

Measures

Outcome Measure

Hospital Anxiety Depression Scale (HADS) (Zigmond & Snaith, 1983): The HADS is a commonly used scale to detect as well as define the severity of anxiety and depression in people with physical health problems. The scale consists of 14 items in total of which 7 relate to depression (HADS-d) and 7 to anxiety (HADS-a). Answering categories range from 0 (‘not at all’) to 3 (‘very often’), therefore a summed score ranging from 0 – 21 can be achieved for both subscales separately. It has been shown that the HADS performs well in measuring the presence as well as symptom severity of anxiety and depression (Bjelland et al., 2002).
**Possible Mediators**

Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF) (Baer, Smith, Hopkins, Krietemeyer & Toney, 2006; Bohlmeijer, ten Klooster, Fledderus, Veehof & Baer, 2011): The FFMQ-SF is the short form of the FFMQ and measures five facets of mindfulness: observing, describing, acting with awareness, nonjudging and nonreactivity. It contains 24 items that can be scored on a 5-point Likert-scale ranging from ‘never or rarely true´ (1) to ‘very often or always true´ (5). In this questionnaire higher scores indicate more mindfulness. This developed short form shows good model fit and reliability (Bohlmeijer et al., 2011).

Pain Catastrophizing Scale (PCS) (Sullivan, Bishop & Pivik, 1995): The PCS is a 13-item questionnaire that measure pain catastrophizing in three subscales: ‘rumination’ (4 items), ‘magnification’ (3 items) and ‘helplessness’ (6 items). It is scored on a 5-point Likert Scale, ranging from ‘never’ (0) to ‘always’ (4) that can be summed to a total score or can be calculated for the subscales separately. Lower scores indicate less catastrophizing. Internal consistency, test-retest reliability and construct validity are all good.

Psychological inflexibility in Pain Scale (PIPS) (Wicksell et al, 2010): The PIPS consists of 12 items that measure psychological inflexibility. Two subscales can be calculated that measure avoidance (8 items) and cognitive fusion (4 items). All items are scored on a 7-point Likert-type scale ranging from ‘never true´ (1) to ‘always true´ (7). Higher scores on these scales indicate greater psychological inflexibility.

**Statistical Analyses**

All data analyses and calculations were performed by means of SPSS, version 21.0. The significance level chosen was p<0.05 for all analyses. For calculations a data-set was used in which missing data from post-assessment and follow-up were replaced with the expectation–maximization-likelihood method (EM) (Trompetter et al., 2014).

In a first set of analyses, possible significant improvements in outcome variables, namely depression (measured with HADS-d) and anxiety (measured with HADS-a), over time and within each condition were examined. For this purpose Repeated Measures ANOVAs were conducted that first displayed changes on HADS-d and HADS-a between the three important assessments (T0, T1, T2), thus possible main effects of time but also main effects of condition as well as possible interaction effects between time*condition were supposed to be shown. Discovered differences in time between pretreatment (T0), posttreatment (T1), and 3-month follow-up (T2) data were further analyzed separately for each group using the split file function. A series of One-Way ANOVAs were executed, comparing baseline data to posttreatment and...
follow-up data as well as comparing the differences between the three conditions (MF, EW and WL) with Post-Hoc tests to detect significant effects and changes. In order to determine effect sizes Cohen’s d were calculated for all outcomes. Therefore, means and standard deviations at 3 and 6 months were used for all conditions. Effect sizes of .80 were considered large, effect sizes of .50 were stated as moderate, and effect sizes of .20 indicated small effects (Cohen 1988).

Secondly, mediation analyses were executed to examine all hypothesized mediators in relation to the two dependent variables: HADS-d and HADS-a. In general, mediation analyses explore the impact of a mediating variable (M) on the significant relationship between an independent (X) and a dependent (Y) variable. This reflects the treatment effect on the outcome measure through a third variable (mediator) and mediation effects are therefore referred to as indirect effects. They illustrate the functional importance of the treatments impact on a process (referred to as the a path), and that process’ effect on outcome while controlling for treatment (i.e. the b path). Mediation is the combination of these two relations, which elevate it above for example mere correlation by requiring that a variable that is altered by treatment must continue to be functionally relevant over and above that effect.

![Figure 2. Model of mediation showing a-path, b-path and c (c’)-path](image_url)
For calculations change scores from pretreatment to follow-up change scores (T0-T4) of HADS-d and HADS-a were used. Regarding the hypothesized mediators, change scores from pre- to post-assessment (T0-T3) of PCS (catastrophizing), FFMQ (mindfulness) and PIPS (psychological inflexibility) were applied. Dummy variables with ACT=1 and EW or WL =0 were created and entered as independent variable whereby calculations were done separately for ACT vs. EW and ACT vs. WL. The cross-product of coefficients approach was chosen to directly examine the indirect effects. PROCESS macro (Preacher and Hayes, 2008) was used for these calculations and a nonparametric bootstrap approach was applied to oppose the common issue of violation of the assumption of normality that is required in parametric approaches. In the present study a bootstrap sample of 5000 was chosen for all analyses. A bias-corrected 95% confidence interval was further provided for the tested mediators (Preacher and Hayes, 2004, 2008).

Results

Outcome
Detailed results on pre-assessment, post-assessment and follow-up means and standard deviations are presented in Table 1. Notably there were no significant pretreatment differences between conditions found concerning outcome variables used in the present study.

Repeated measures ANOVAs indicated a significant main effect for time (of measurement) regarding HADS-d, (p<.001) as well as HADS-a (p< .001). The ACT group as well as the EW group produced significant reductions in HADS-d from T0 to T1 as well as from T0 to T2. No significant improvements were found in the WL condition.

No main effect for condition (ACT,EW, WL) was found. An interaction effect between time (T0,T1,T2) and condition could only be detected regarding HADS-d (p<.05), which indicates that scores in one or two groups improved significantly more across time than in the other group(s).
Results of calculations on comparisons between the three conditions on the three points of measurement (T0, T1 and T2), using One-Way ANOVA with Post-Hoc tests are shown in Table 2. Outcomes revealed significant differences in HADS-d at T2 ($p < .05$) between ACT and EW with an effect size of Cohen’s from .4. No significant differences between the groups were found regarding HADS-a (all $ps > .05$) nor were any significant differences between ACT and WL detected.

Table 3 displays all detailed information about indirect effects and corresponding confidence intervals. Coefficients of a-paths, b-paths, c-paths and c’-paths are shown.

**Mediational analyses**

Concerning HADS-d, changes in PCS as well as changes in PIPS were found to be indirectly effecting changes between pre and follow-up assessment in ACT compared to EW and compared to WL. Thus lower rates of catastrophizing and higher rates of psychological flexibility influence reduced depression rates. Regarding changes in FFMQ, significant mediating effects were only detected for ACT vs WL.
**HADS-a**

Examining indirect effects on HADS-a, significant mediating effects were found for changes in PIPS and PCS on ACT compared to both control groups. No mediation was present for FFMQ on HADS-a.

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<tr>
<td>PIPS  ACT vs EW</td>
<td>-4.805</td>
<td>.076</td>
<td>-.852</td>
<td>-.487</td>
<td>-.743; -.101*</td>
</tr>
<tr>
<td>ACT vs WL</td>
<td>-7.927</td>
<td>.060</td>
<td>-.987</td>
<td>-.511</td>
<td>-.905; -.184*</td>
</tr>
<tr>
<td>FFMQ  ACT vs EW</td>
<td>.273</td>
<td>-.058</td>
<td>-.852</td>
<td>-.836</td>
<td>-.221; .114</td>
</tr>
<tr>
<td>ACT vs WL</td>
<td>2.373</td>
<td>-.060</td>
<td>-.987</td>
<td>-.845</td>
<td>-.438; .004*</td>
</tr>
</tbody>
</table>

|                  |        |        |        |         |               |
| **HADS-a**       |        |        |        |         |               |
| PCS   ACT vs EW  | -2.628 | .100   | -.425  | -.162   | -.607; -.040* |
|        ACT vs WL | -3.194 | .065   | -.792  | -.586   | -.543; -.029* |
| PIPS  ACT vs EW  | -4.805 | .087   | -.425  | .008    | -.869; -.103* |
|        ACT vs WL | -7.927 | .075   | -.792  | -.197   | -1.051; -.287*|
| FFMQ  ACT vs EW  | .273   | -.025  | -.425  | -.418   | -.186; .066   |
|        ACT vs WL | 2.373  | -.057  | -.792  | -.657   | -.481; .005   |

Number of bootstrap resamples: 5000. The indirect effect is significant at 95% level when the confidence interval does not include zero.
* The point estimate is significant at p<0.05.

**Discussion**

The present study has been designed to examine the effects of the web-based self-help ACT-intervention “Living with pain” on comorbid mental health problems namely depression and anxiety in patients suffering from chronic pain. Furthermore, its purpose was to identify underlying processes of change that indirectly influence detected effects in ACT versus an expressive writing control group (EW) and a waiting list control group (WL).

Results of this RCT show only little effects concerning depression and anxiety for participants of the ACT intervention in comparison to the two control conditions. Overall no significant differences between the three groups were sought out on reduced anxiety levels. Also depression levels did not significantly differ between the ACT group and the waiting list. However, compared to the expressive writing group improvements were significant at follow-up regarding depression.

Although in comparison to EW and WL there were little significant differences, participants of the ACT intervention showed significant reduced levels of depression as well as reductions
in anxiety scores at post assessment as well as at three month follow up. Comparable effects were also found for the EW group, but not the WL group, which indicates that the active interventions (ACT and EW) are of some positive influence on depression and anxiety and outperform the inactive waiting list.

Regarding the results of the mediational analysis on possible underlying processes of change, psychological flexibility and pain catastrophizing were both found to be indirectly affecting differences in depression as well as in anxiety levels when ACT was compared to EW or WL. Moreover, mindfulness mediated effects on depression when ACT was compared to the waiting list.

The fact that no significant differences between the ACT group and the inactive waiting list control group were found is against our predictions assuming improvements to be higher in the active intervention groups. It is also widely inconsistent with results of related studies that showed the ACT group being superior to the control condition in reducing depression and anxiety (e.g. Wicksell et al. 2008; Buhrman et al., 2013). This probably relates to the finding that in the present study also participants of the waiting list improved slightly over time. Knowing that a new possible treatment option becomes available that might offer help to cope with the long-lasting suffering, already may reduce symptoms of depression and anxiety. Although the participants of the ACT intervention improved significantly, the effects on outcome were relatively small, which possibly made them not sensitive enough to produce differences between the three conditions. One possible reason for these small effects could be that the intervention, though guided, was not offered as part of an interdisciplinary pain program as performed in many other studies (e.g. McCracken & Jones, 2012). Participants were self-responsible for completing their online lesson once a week and had to deal with their given feedback by themselves rather than having a continuous supervision and constant review. Therefore, this kind of program might be less intensive as well as less productive than other interventions. However, Buhrman et al. (2013) found in their RCT study on a web-based self-help ACT intervention positive results on the anxiety and depression scales (measured with the HADS), which persisted in comparison to the waiting list control group. As one component of their intervention which differed from the present study they provided participants with two professional, motivational phone calls. Regarding these outcomes guided self-help interventions without intensive and constant supervision are sufficient enough to achieve some effects. Another explanation why the ACT intervention might not have been as effective as hypothesized could lie in its design and focus. Although all theoretical ACT-relevant process variables were included, especially those concerning the acceptance-avoiding conflict were
targeted here, possibly neglecting other important factors linked to positive mental health (Hayes, 2004). Thus, several intervention-specific factors that focus on various processes with different contents should be included in future research. Furthermore, it should be noted that Trompetter et al. (2014), who used the same dataset as in the present study, did find significant differences between ACT participants and participants of both control groups three months after the intervention. Hence, their findings overall indicate the effectiveness of the web-based ACT intervention on depression and anxiety in chronic pain patients. This inconsistency with findings of the present study possibly occurred due to the particular choice of calculation methods. In comparison to the applied post hoc tests in present study those authors used the General Linear Mixed Model (GLMM) for calculations, which mainly handles missing values differently what ultimately explains the slight differences in outcome.

The present study is one of the first to investigate effects of a web-based ACT-intervention and the first to include an active control group. Improvements at three month follow up were significantly higher for the treatment group compared to the active control group (EW group) emphasizing that effects of the ACT intervention are long-lasting compared to effects of EW. In the EW group, levels of depression increased during three month after completion, indicating its effectiveness only during the active intervention phase. In this phase participants actively cope with distressing events and feelings, which seems to be effective but might not establish long-term strategies for coping when the writing stops. On the contrary, ACT interventions attempt to change the way one interacts with or relates to thoughts by creating contexts in which their unhelpful functions are diminished because thoughts per se are not viewed as right or wrong, but as useful or useless in obtaining a valued life (Ruiz, 2010; Hayes et al. 2006, Hayes, 2004). Due to these changes in the general interaction with thoughts patients might internalize coping strategies for future distressing events or thoughts. Referring to this, we were able to corroborate findings that effects of ACT interventions are long lasting and persist over some period of time after completing the intervention (McCracken & Jones, 2012; Vowles et al., 2011; McCracken et al., 2004). These findings also constitute a promising starting point for future research on web-based interventions for chronic pain patients and insinuate potential advantages of ACT interventions over other cognitive coping strategies such as expressive writing.

Although the differences in outcome between the treatment group and the two control groups were hardly significant, participants in the ACT group generally showed the greatest reduction in depression and anxiety scores indicating higher clinical improvements. These findings support the advantage of the ACT intervention at least in some way and reveal a positive trend
which should be followed up in future research. Concerning the improvements in the ACT intervention on depression and anxiety, results of the present study are in line with recent related (mostly uncontrolled) studies showing that ACT interventions are effective in helping chronic pain patients to cope with their suffering and influence depression and anxiety in a positive way, although effects were relatively small (Veehof et al., 2011; McCracken et al., 2012; Wetherell et al. 2011). It adds to the growing number of meta-analyses and reviews on self-help interventions that show positive effects for anxiety disorders (Lewis et al., 2012), depression (Newman et al., 2011) and also chronic pain (Murray, 2011), making them a suitable form of offering treatment.

Regarding potential mediators we hypothesized mindfulness, pain catastrophizing and psychological flexibility to mediate effects on depression and anxiety symptoms. In support with these assumptions, as well as in accordance with existing literature on ACT, psychological flexibility was found to mediate effects on depression and anxiety when ACT was compared to expressive writing as well as when compared to the waiting list. These findings support the relevance of psychological flexibility as being a core process in ACT (Hayes, 2004; Hayes et al. 2006). It indicates that when the ability to contact the present moment more fully as a conscious human being, and change or persist in behavior in accordance to ones values, anxiety and depression in chronic pain patients are influenced in a positive way (Ruiz, 2010; McCracken & Jones, 2012).

Furthermore, also mediating effects for catastrophizing on depression and anxiety were found being significant for the ACT intervention compared to both control groups. The present study is the first randomized controlled trial that detected mediating effects of catastrophizing in ACT on outcome variables, but results can be interpreted in the light of earlier studies that pointed out the relation of acceptance and catastrophizing thoughts (Hayes et al., 1999; Vowles et al., 2008). Also Buhrmann and others (2013) found decreases in catastrophizing after patients participated in their web-based ACT intervention. Although catastrophizing is primarily targeted in CBT interventions that seek to change the content of thoughts instead of ones relation to it (as in ACT), these findings suggest that processes targeted in ACT are likewise influential to catastrophizing. Patients seem to successfully gain awareness of thoughts and feelings, change their relations to them and start to engage in activity (Hayes et al., 1999). Possibly, although not directly targeted the content of negative, pain-related thoughts simultaneously changes when patients in the ACT intervention start to change their relation to them, as targeted by cognitive defusion techniques. Thus, when patients try to alter the
unhelpful function and personal meaning of pain-related thoughts they may draw their attention to other, helpful aspects which may also indirectly change the content of these thoughts.

In comparison to the waiting list also mindfulness was found to indirectly effect changes in depression which suggests that patients following the ACT intervention became mindful of ongoing events in a way that positively influences depression. It is overall implied that the role of being mindful is a core principle of ACT to produce changes, because recognizing one’s self and trying not to have a special attachment to the own experiences should ultimately help to increase psychological flexibility (Hayes, 2004). The finding that mindfulness was not found to indirectly effect changes in depression when ACT was compared to the expressive writing patients indicates that also those patients achieved some higher levels of mindfulness. This can be interpreted in the light of the theory behind Expressive Writing that states that writing down negative emotions and experiences helps to understand as well as giving meaning to perceived stressful, negative events (Pennebaker, 1993). Through the writing process patients willingly experience unwanted thoughts, sensations, and emotions making it possible to become aware of ongoing events and thus becoming mindful. Surprisingly, no mediating effects for mindfulness were found on anxiety when ACT was compared to both control groups which indicates that mindfulness does not indirectly influence anxiety.

Although the effects of the ACT intervention group on depression and anxiety were hardly significant compared to the two control groups, results of mediational analyses still confirm the proposed working mechanisms of ACT. These are mostly in line with related research and stress the effectiveness of processes targeted in ACT interventions, especially psychological flexibility, that influence depression as well as anxiety. It adds to the existing literature in a way that the internet can indeed be regarded as a suitable medium for providing treatment for chronic pain patients (Williams, 2011), likewise face-to-face interventions.

There are some limitations to this study that should be discussed. First, participants were mainly recruited through advertisement and forums possibly missing out certain kind of pain patients. Those taking part in this study may not represent the typical pain patients and may have had different pain, depression and anxiety levels than patients from pain clinics or others. Therefore, in future studies it could be better to extend the recruitment procedure to doctors, clinics and pain hospitals. Second, as this study was provided via internet, this intervention might miss certain groups of patients due to their unfamiliarity with internet or lack of its access, although participants with different educational levels as well as participants with a wide range of age were included. Third, although many participants were included in this study, the drop-out rate was relatively high. To address this non-completion rate, statistical tests to handle
missing data were adjusted, but those missing values can still undermine our data and provide different outcome depending on the choice of statistical analyses. Fourth, all data gathered during this study is based on self-assessment, undermining objectivity.

Despite those limitations, results are somewhat promising, revealing positive effects of an internet-based self-help intervention based on Acceptance and Commitment Therapy (ACT) on comorbid psychological distress in chronic pain patients. Although improvements in depression and anxiety levels were not directly targeted, small effects became evident. Furthermore, these effects were found to be mediated through hypothesized processes targeted in ACT (as well as CBT), which indicates that the present web-based intervention seems indeed to work through its hypothesized processes. It especially stresses the function of psychological flexibility as a core process of ACT, but also indicates a relation between ACT processes and the CBT process “catastrophizing” which influence anxiety and depression in a positive way. On top of that, effects seem to be long-lasting, potentially offering long-term relief for chronic pain sufferers and even possibly favoring an ACT intervention over other coping interventions, such as Expressive Writing interventions.
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