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Psychological flexibility mediates the effect of an online-based acceptance and commitment therapy for chronic pain: an investigation of change processes

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Authors' contributions

JL and LK drafted the manuscript and JL and HB facilitated the conception of the study, designed the study and were responsible for the execution of the study. All authors participated in the review and revision of the manuscript and have approved the final version for publication.

Abstract

One way to improve treatment effects of chronic pain is to identify and improve control over mechanisms of therapeutic change. One treatment approach that includes a specific proposed mechanism is Acceptance and Commitment Therapy (ACT) with its focus on increasing psychological flexibility (PF). The aim of the present study was to examine the role of PF as a mechanism of change in ACT. This is based on mediation analyses of data from a previously reported randomized controlled trial evaluating the effectiveness of an ACT-based online intervention for chronic pain (ACTonPain).

We performed secondary analyses on pre-, post-treatment, and follow-up data from 302 adults, receiving a guided (n=100) or unguided (n=101) version of ACTonPain, or allocated to the waitlist control group (n=101). Structural equation modelling (SEM) and a bias-corrected bootstrap approach were applied to examine the indirect effects of the treatment through pre- and post-treatment changes in the latent construct reflecting PF. The latent construct consisted of data from the Chronic Pain Acceptance Questionnaire and the Acceptance and Action Questionnaire. The outcomes were pre-treatment to follow-up changes in pain interference, anxiety, depression, pain, and mental and physical health.

SEM analyses revealed that changes in PF significantly mediated pre-treatment to follow-up changes in all outcomes in the intervention groups compared to waitlist (standardized estimates ranged from I0.16I to I0.69I). Global model fit yielded modest but acceptable results.

Findings are consistent with the theoretical framework behind ACT and contribute to growing evidence supporting a focus on PF in order to optimize treatment effects.

Keywords: Acceptance and Commitment Therapy; chronic pain, online-based; intervention; change processes; structural equation modelling; psychological flexibility

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1. **Introduction**

Acceptance and Commitment Therapy (ACT) is a current form of Cognitive Behavior Therapy (CBT) that has been shown to be effective in the treatment of chronic pain based on several recent reviews [34,44,87]. The effect sizes of ACT and more traditional forms of CBT are comparable, suggesting ACT as a potential alternative to other forms of CBT [64,93]. Recent meta-analyses and reviews of ACT and CBT in the treatment of pain however indicate that the effect sizes vary considerably across outcomes and trials, including weak effects of unknown clinical significance [44,66,97]. One way to overcome weak treatment effects is to design and evaluate interventions on a theoretically coherent basis [66] and investigate treatment processes in order increase treatment outcomes. ACT includes an explicit theoretical framework and model of treatment process [62,64]. The overarching treatment process is referred to as "psychological flexibility" (PF), defined as 'the capacity to persist with and change behavior in a manner that incorporates conscious and open contact with thoughts and feelings, and that is consistent with one's values and goals" [62,79]. PF includes six underlying components: acceptance, cognitive defusion, present moment awareness, self-as-context, values, and committed action [39,80].

A growing number of observational studies, uncontrolled and controlled trials, and reviews support the potential of PF specifically in relation to chronic pain [59,61–64,86,88,90], and in health and wellbeing more generally [28,46]. Evidence for the role of components of PF in relation to physical, emotional and social functioning in chronic pain is generally consistent and supportive [65,79,84,89,92,94,95]. However, while current data suggest that improved outcomes observed in ACT result from improvements in PF, this conclusion comes primarily from correlational studies and not from studies that can directly test mediation as such. Currently, studies examining the impact of ACT-related mechanisms on intervention outcomes using robust statistical approaches to mediation analysis, such as structural equation modelling (SEM), are missing [91]. Better analyses of mediation in randomized controlled studies of ACT represent a means to better understand treatment processes and perhaps a means to improve treatment outcomes [99].

Along with a focus on treatment process, another important challenge is to improve accessibility of effective, evidence-based treatments [37,77], especially for chronic pain. It is repeatedly demonstrated that individuals with chronic pain do not or cannot access adequate treatments [11,81]. In light of the high prevalence of chronic pain, affecting approximately one in five adults worldwide [11,32], Internet- and Mobile-based interventions (IMIs) might be a feasible means to improve chronic pain health care [6,23,58,76,98].

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Whereas numerous clinical trials demonstrate the efficacy of IMIs for chronic pain [14,26,42,58], little is known about the effective ingredients in IMIs in general [2,12,67]. While recent research has focused on a mediating role of therapist support (comparing guided versus unguided self-help) [5,75], less work has been done investigating the impact of the key, underlying, theoretically-based, treatment processes [67], as outlined here, particularly in relation to chronic pain.

The aim of the present study was to examine treatment process in a recently conducted randomized controlled trial (RCT) examining the effectiveness of guided and unguided versions of online ACT for chronic pain (ACTonPain) compared to a waitlist control group (WLC) [54,55]. A significant role for PF in relation to all outcomes was predicted.

2 Methods
2.1 Participants and setting
The sample has been described in detail in previous reports [54,55]. Briefly, we recruited individuals with chronic pain between October 2014 and August 2015 through a comprehensive online and offline advertisement strategy including collaboration with a large German health insurance company. Inclusion criteria were as follows: (a) age $\geq$ 18 years, (b) chronic pain duration of at least six months (c) Chronic Pain Grade $\geq$ II (CPG, [50]), (d) sufficient knowledge of the German language, (e) sufficient computer and Internet literacy, (f) Internet access (g) and medical suitability for participation in an online intervention for chronic pain. Participants were excluded in case of (a) cancer-related pain, (b) ongoing or planned psychological pain treatment within the following three months, (c) and elevated risk of suicide.

All outcomes were assessed via online assessments at pre-treatment (T0), post-treatment (T1, nine weeks after randomization) and at follow-up (T2, six months after randomization). In total, 302 participants were included and randomly allocated to ACTonPain either with or without therapist support (n=100 and 101, respectively) or WLC (n=101). At baseline, the mean age of the sample was 51.7 years (SD=13.1), they ranged in age from 20 to 86. 84% of the participants were women, the majority was well educated with at least 10 years of school (87.7%), (self-)employed (58%) or retired (34%) and reported other physical (57%) and psychiatric problems (39%) (see discussion on sample characteristics published in [55]). The three groups did not differ significantly on any of the demographic variables or symptoms and all outcome and process measures were comparable at T0 (all variables p> .05).

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On average, 92% of the participants reported prior pain treatments and all participants had unrestricted access to routine care. Treatment uptake was assessed as part of the health-economic analysis of the study that is currently being carried out and will be published in a separate article [70] due to the complexity of the subject.

2.2 Measures of outcome variables and mediators

For this secondary analysis, we chose all outcomes as in the main analysis [54,55] except for the Patient Global Impression of Change Scale (PGIC;[33]) that is not considered in this study because it was only collected following treatment. These outcomes were chosen in accordance to the recommendations of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT [24,25]). Unlike in the main analysis, the assessed ACT-related process variables were summarized as the latent construct psychological flexibility (PF) that was used as the mediating variable in the present analysis.

2.2.1 Primary outcome

Pain interference. The interference subscale of the Multidimensional Pain Inventory (MPI [48], German version: MPI-D, [29]) was used to measure the degree to which pain interferes with everyday activities. The subscale comprises 10 items rated on a 7-point scale ranging from 0 = "no interference/change" to 6 = "extreme interference/change". The summary score results from the arithmetic mean of all items.

2.2.2 Secondary outcomes

Physical functioning. The IMMPACT recommends the use of both MPI and Brief Pain Inventory (BPI [47]; German version: [74]) to assess physical functioning as when doing so it would not impose an undue burden on participants [24]. Participants rated the degree of pain interference within the last 24 hours on seven interference items with regard to sleep, mood, social relations, and enjoyment of life. Higher mean scores of the seven interference items indicate higher interference of pain with physical functioning [19].

Emotional functioning. Emotional functioning was measured using the Patient Health Questionnaire (PHQ-9 [51]) and the Generalized Anxiety Disorder Screener (GAD-7 [56]). The PHQ-9 assesses nine symptoms of depression over the past two weeks based on DSM-IV. The GAD-7 assesses the core symptoms in Generalized Anxiety Disorder according to DSM-IV criteria for the past two weeks. In both questionnaires, higher sum scores indicate greater symptom severity.

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Pain intensity. Pain intensity is assessed using an 11-point Numeric Rating Scale (NRS; 0 = "no pain", 10 = "pain as bad as you can imagine"). Required ratings refer to participants' worst, least, and average pain with in the past week as well as their currently experienced pain. The mean of all four scales was calculated.

Health related quality of life. The Short Form 12 (SF-12 [57]) consists of 12 items assessing different aspects of physical and mental health. Altogether, the SF-12 covers the following health domains: physical functioning, role limitations, pain, general health perception, vitality, mental health, emotional role, and social functioning. The items are scored using the Quality Metric's Scoring Software. The raw scores from each subscale are used to generate a composite score for mental (MCS) and physical (PCS) health (range: 0 to 100) with higher scores indicating higher levels of health.

2.2.3 ACT-related process variables

Two questionnaires were used to assess the latent construct for PF, the core process of ACT.

Acceptance and action. The German version (Fragebogen zu Akzeptanz und Handeln II [FAH-II]; [43]) of the Acceptance and Action Questionnaire-II (AAQ-II [8]) was used as a general measure of psychological inflexibility. As outlined in the literature, the FAH-II assesses a person's willingness to experience unwanted thoughts and feeling (e.g. "I worry about getting my worries and feelings under control") and a person's ability to act despite the presence of undesirable thoughts and feelings (e.g. "My painful memories keep me from having a fulfilling life"). However, the assessed construct is inconsistently referred to as (general psychological) acceptance, experiential avoidance, or psychological (in)flexibility [9,60]. Note that items were reverse coded in this study so that higher sum scores indicate higher PF (range: 0 to 42). The AAQ has been frequently employed in investigations of treatment process yielding evidence of PF as a mediator of ACT interventions in a variety of populations [7,27,31,53].

Pain-related acceptance. The Chronic Pain Acceptance Questionnaire (CPAQ [96], German version;[68]) was used as a more pain specific measure of psychological flexibility. The CPAQ assesses two constructs of pain-related acceptance, namely activity engagement (CPAQ AE, 11 items, range: 0 to 66) and pain willingness (CPAQ PW, 9 items, range: 0 to 54). Activity engagement refers to engagement in daily activities in the presence of pain [65]. Pain willingness reflects a pattern of refraining from attempts to control or avoid pain [65]. Higher CPAQ AE, PW, and total scores (range: 0 to 114) indicate higher activity engagement, pain willingness and pain acceptance, respectively.

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Numerous studies show that the CPAQ is a well validated measure with high internal consistency, reliability over time, and significant relations with measures of emotional, physical, and social functioning [65,68].

2.3 Intervention: ACTonPain

Detailed information on the online intervention ACTonPain can be found in Lin et al.[54]. Briefly, ACTonPain comprises one introduction module and seven treatment modules. All treatment modules target core change processes proposed by Hayes, Strosahl and Wilson [38–40] and consist of psychoeducative elements, videos and audio files, metaphors, mindfulness exercises, and interactive features such as quizzes. In addition, three testimonials with "typical examples" of persons with chronic pain are introduced and these stories accompany the participants throughout the different modules to model behavior patterns that reflect all core processes in PF. Within homework assignments module content is applied and skills are practiced and developed. Participants were encouraged to work on one module each week. Each module requires approximately 60 minutes to be completed. Table 1 provides a summary of the modules' content and the corresponding PF processes, mainly addressed in treatment modules 1 to 7. Further, participants could choose to receive supportive text messages throughout the course of the intervention and access to administrative and technical support via email.

\-   Table 1 about here -

Participants were randomly allocated to receive either a guided or unguided version of the intervention (ACTonPain guided/unguided). Guidance was provided by trained eCoaches (psychologists) and included standardized feedback messages, positive reinforcement for behavior reflecting PF, as well as reminder messages in case of delayed module completion. Participants in WLC were allowed to receive any treatment as usual (TAU) and were provided access to the intervention after having completed the last online-assessment.

2.4 Summary of previously reported RCT results

As previously reported [55], a repeated measure MANOVA was performed. In this model, significant Group*Time effects of the three groups and three time levels (pre- (T0), post-treatment (T1) and follow-up (T2)) were found for the primary and secondary outcome measures. Subsequent univariate, repeated measures, follow-up tests were conducted examining the interaction effects with regard to each outcome variable as well as each time-comparison (T0 to T1 and T0 to T2, respectively).

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Post-hoc analyses on group comparisons with Bonferroni correction concerning the primary outcome were conducted for outcomes with significant Group*Time effects. These analyses revealed that at T1 and T2, guided – but not unguided – ACTonPain showed significantly (p<.05) lower pain interference (T1: d=0.58; T2: d=0.58) and higher pain acceptance (T1: d=0.59; T2: d=0.76) compared to WLC. Unguided ACTonPain showed a significant benefit compared to WLC in depression at T2 (d=0.50). No differences were found between the two ACTonPain-groups (p>.05).

However, participants in the ACTonPain guided group completed more modules than those in the ACTonPain unguided group (M=5.94; SD=2.80 vs. M=4.74; SD=2.89, F(1,199)=8.92; p<.01, the number of completed modules ranging between 0 to 8, see Lin and colleagues [55] for analysis details). 40% and 61% in the guided and unguided group, respectively did not complete intervention. Both groups showed a high level of treatment satisfaction, assessed with the adapted, eight-item version of the German Client Satisfaction Questionnaire (CSQ-8 [3,10]). In both ACTonPain conditions, the majority of subjects (82%) would recommend the training to a friend in need of psychological help (item 4, answers of "rather yes" or "yes, completely") in T1.

2.5 Mediation Model, Indirect and direct effects

The purpose of mediation analyses is to explore the impact of a mediating variable (M) on the relationship between an independent (X) and a dependent (Y) variable [35,101]. In general, the indirect effect (denoted as ab) can be defined by the cross-product of the regression coefficient for the relationship between X (treatment allocation) and M (a-path) and the coefficient for the relationship between M and Y (b-path,[101]). In turn, the direct effect (c-path connecting the X and Y) reflects the extent to which differences in X relate to differences in Y independent of the mediator's influence [35]. In this study, we investigate if the reported effect in the ACTonPain RCT [55] results from changes in PF.

To assess the indirect effect of the treatment on the outcomes through changes in PF, the model as depicted in Figure 1 was proposed. It is important to note that all outcomes in the model were represented by their change scores with regard to the change between T0 to T2. The latent variable PF however, was represented by the change scores between T0 to T1 in this model since the PF theory suggest that changes in the outcomes appear as a consequence of changes in PF. We refrained from using PF data that was assessed during the treatment since attrition from treatment in the unguided group was high with rates of 46%, 58% and 61% after the modules two, four and six, respectively.

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In contrast, the attrition rates in the guided group were at 29%, 35%, and 40% after the modules two, four, and six, respectively. Therefore, we were not able to investigate the influence of change in PF during the course of the treatment on the change of outcomes from T0 to T1.

Due to the multidimensional nature of the treatment variable, the indicator coding approach proposed by Hayes and Preacher [36] was applied. Treatment groups were represented by two dummy coded variables, denoted as D1 and D2. D1 coded the unguided treatment group with all codes set to 1 for cases receiving ACTonPain unguided and 0 otherwise. Similarly, D2 coded the guided treatment group with all codes set to 1 for cases receiving ACTonPain guided and 0 otherwise. The WLC functioned as the reference category in the analysis receiving a code of 0 on both D1 and D2. Consequentially, parameters in the model related to group differences quantify differences relative to this reference group. Further, variables were modelled with measurement error, denoted with the capital letter E. Process variables were modelled with covarying error terms, assuming shared variability other than that due to the underlying factor [49]. In order to attain model identification, the path leading from the latent construct to CPAQ AE is constrained to equal one.

- Figure 1 about here -

2.6 Statistical Analysis

According to the intention-to-treat principle (ITT), analysis was conducted including all available data regardless of completion of the online intervention. Analysis of missing data patterns did not indicate a strictly monotone pattern or any other systematic pattern of missing values. Little's MCAR test indicated data as missing completely at random, $\chi 2(1779) = 604.73$, $p=.99$. Missing data were imputed using the expectation maximization algorithm (EM) in Statistical Package for the Social Sciences (SPSS, version 20).

2.6.1 Structural Equation Modeling

Structural Equation Modeling (SEM) was used to investigate if changes in PF mediated changes in the assessed outcomes. SEM analysis was conducted with specialized SEM software, IBM SPSS AMOS 22, using maximum likelihood (ML) estimation. SEM is considered superior to standard regression methods since it allows for a simultaneous test of the proposed relationships and provides model fit measures that can substantially add to the information

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gained from a mere significance test [22,73]. Further, SEM is a much more flexible approach than standard regression analysis for multiple mediators or dependent variables can easily be included simultaneously [22].

To assess the significance of the indirect and direct effects, bias-corrected 95% confidence intervals (CI) were calculated using nonparametric bootstrapping procedures as recommended by Preacher and Hayes [72]. All analyses were based on a total of 5000 bootstrap samples. Estimates were considered statistically significant if the CI does not include zero. Standardized estimates, their corresponding standard error and p-values (two-tailed) are reported. Since AMOS does not calculate regular standard errors for indirect effects, bootstrap standard errors are reported. We refrained from calculating formal measures of effect size since each method for doing this in mediation analyses is limited and the magnitude of the indirect effect in its standardized form is already interpretable [101]. The standardized indirect effect provides a scale-free measure that allows a direct comparison of effects across differently scaled outcomes and can be used for synthesis across studies (73).

In accordance with Woody [101], we regard mediation as demonstrated if paths a and b, and ab (the indirect effect), are statistically significant on the basis of acceptable or adequate model fit. Model fit was assessed using the $\chi2$ goodness-of-fit statistic and approximate fit indices, i.e. root mean square error of approximation (RSMEA), the Goodness-of-Fit index (GFI) the Standardized Root Mean Square Residual (SRMR) and the χ^2/df. According to Schermelleh-Engel et al. [78], it is necessary to consider multiple criteria and to evaluate model fit on the basis of various measures simultaneously.

4 Results

We considered participants who did not complete all questionnaires at T1 or T2 as dropouts from the study. The overall study dropout rate was 24% and 39% at T1 and T2, respectively. In the ACTonPain guided, unguided, and WLC groups, 29%, 33% and 11% of the participants dropped out at T1 and 46%, 45% and 26% at T2, respectively. Reasons for these study dropouts were not assessed. We checked data for (univariate) normality and found it suitable for parametric analysis. However, the assumption of multivariate normality, which is required for SEM analysis, was not met. Nevertheless, the maximum likelihood technique has proven to be relatively robust to violations of the multivariate normality assumption and is recommended by several authors for this case [45,69].

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4.1 Model fit

The mediation model fit the data at $X^2(35)=164.65$, $p<.00$, RMSEA=0.11, GFI=0.90, SRMR=0.06, $\chi^2/df=4.70$. While the RMSEA and χ^2/df values were indicative of unacceptable fit [13], the SRMR and the GFI values were indicative as of acceptable fit [78]. The low model fit shown by the RMSEA and χ^2/df values might reflect that the data did not meet the assumption of multivariate normality [4]. Given that the indices of model fit were inconclusive and modifying the model solely on the basis of modification indices should never be conducted [78], we did not apply any model modifications. The model under investigation reflects the assumptions of the PF theory and therefore, no further theory-based modifications were applied in this model.

4.2 Mediation Analysis

Standardized parameter estimates of the direct and indirect paths, standard errors, their corresponding significance effects and confidence intervals are provided in Table 2.

-        Table 2 about here -

Group membership was positively associated with increases in PF (a-paths). Specifically, increases in PF in the treatment groups were larger than changes in WLC with growth differing by 0.62 standardized units (95% CI [0.36; 0.88], p<.01) in the unguided treatment group and by 0.72 units (95% CI [0.44; 0.97], p<.01) in the guided treatment group. Furthermore, holding group membership constant, PF was, in turn, significantly associated with improvements in all outcomes (b-paths), CIs did not include zero, all p<.05.

In both treatment groups, treatment showed an indirect effect on all outcomes through changes in PF as all indirect effects (ab-paths) were significantly different from zero without 95% CIs covering zero (all p<.0). The estimates for the indirect effects can be interpreted as the difference in T0 to T2 change between the treatment groups compared to WLC. For example, the unguided group, compared to WLC (grouping variable D1), showed less pain inference by 0.54 standardized units mediated through PF. A comparison of indirect effects across both group variables further revealed that indirect effects through the change in PF were larger for the grouping variable D2 (ACTonPain guided vs. WLC) on all outcomes.

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When the influence of PF was held constant, direct effects of group membership could be found (c-paths) with regard to the outcomes MPI, BPI, PHQ, GAD and SF-12 MCS but not regarding pain intensity and SF-12 PCS. A closer examination of direct and indirect effects showed that they have opposite signs which can indicate a suppression effect [17,45,49,69,101] of PF on the relationship between treatment and outcomes.

5 Discussion

The central purpose of the present analysis was to examine the underlying change mechanisms in the course of an internet-based ACT for chronic pain (ACTonPain). Results support the role of PF as a mechanism of change in ACTonPain.

5.1 Treatment effects on psychological flexibility

PF significantly increased in both ACTonPain groups compared to WLC. This finding is in line with numerous studies demonstrating that ACT is associated with increases in facets of PF in individuals with chronic pain [15,30,55,60,79]. Overall, the increase in aspects of PF fits with previous expectations since elements of ACTonPain explicitly aim at promoting PF. Like in other trials of online ACT for chronic pain [15,85], this study shows that PF can increase when the treatment is delivered online. Consistent with findings that guided IMIs may yield greater effects than unguided ones [4,70,84], greater changes in PF according to the coefficients were found in the guided treatment group.

5.2 Psychological flexibility as a mediator

Our mediation analysis revealed that treatment effects on T0 to T2 changes were mediated by T0 to T1 changes in PF in all outcomes. We note some inconsistency here relative to earlier reported results. In the main RCT [55] significant differences between the treatment groups and WLC were only found with regard to a few outcomes. This inconsistency may be partly due to different methodological approaches that were applied, such as from calculating change scores and comparing the groups using dummy variables in order to conduct the SEM. Our findings are in line with previous investigations of change processes in the course of ACT for chronic pain [16,60,84,91,92]. Thus, these findings highlight the functional importance of PF as an underlying mechanism of therapeutic improvement.

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5.3 Limitations

This study has some limitations. First, study dropouts were high and reasons for dropping out were not assessed. Future research on IMIs should use a standard method (that still needs to be developed) for assessing these to improve the acceptance of IMIs for a broad group of patients. Second, treatment attrition in this study was high, but comparable with IMI trials in general (treatment dropout rates ranging from 1 to 50% [18]). One equivalent trial on a CBT IMI for chronic pain found attrition rates to be at 24%, 29% and 36% in the groups with regular, optional, or no guidance, respectively [23]. In the two existing ACT-based IMIs for chronic pain, attrition rates of 28% [85] and 8% [15] were reported. There was a high treatment attrition in the unguided ACTonPain group with regard to the assessment of change in PF during the course of the treatment, thus change in PF during ACTonPain and its effect on the outcomes at T1 could not be analyzed. Further, not all core facets of PF were reflected in the latent construct of PF in our model. Although most processes within the PF model have been examined in chronic pain using separate questionnaires [62,79,84,91,95,102], few of these measures are available in German. Furthermore, questions have been raised concerning the content validity of measures of acceptance [52], including the AAQ [99], and some of these find weak content validity [31,52,100] which may have resulted in lower model fit indices in this study. However, recent research highlights that measures of individual components of PF are highly interrelated and should be used in a more integrative manner (73). A factor analysis by Scott and colleagues (73) revealed a bifactor model including an overarching, general openness-related factor, largely dominated by items on acceptance and defusion. The findings are consistent with the reconceptualized three-part model of PF, i.e. 'open, aware, and active' [41]. Therefore, the measures that were used in this study, mainly reflecting acceptance, are likely to register the main quality of PF. Moreover, the authors point out that a unidimensional focus on single facets might not reliably reflect the portions of variance related to the theoretically distinct sub-processes of PF (73), thus, supporting our approach of using a latent construct as a measure of PF. Finally, it should be noted that other potential mechanisms not necessarily theoretically related (e.g., catastrophizing), were not assessed and competing models were not tested. Future studies should compare different treatment processes in order to compare their fit and select the most adequate model for further study.

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5.4 Strengths

This study is one of relatively few to explicitly focus on mediation in an RCT design. Although the evidence-base for IMIs (not only for chronic pain) is growing and promising [1,14,26], consistent findings that identify mediators are still lacking in the literature [1,2]. This is partly due to the high heterogeneity of studies on the efficacy and effectiveness of IMIs, in terms of therapeutic models (e.g. CBT or psychodynamic therapy), clinical setting (e.g. stand-alone or blended) and target population (e.g. anxiety, depression, chronic pain). Another important barrier is the lack of a fully coherent theory to guide the conceptualization and testing of potentially relevant mediators in a way that is specific to the treatments under investigation. The theoretical framework and SEM approach chosen to examine mediation effects represents an explicit strength of this study. In particular SEM has been shown to outperform standard regression approaches [43,99] used in prior research applied to ACT and PF, and can, beyond that, substantially add to the mere assessment of indirect effects using SPSS or SAS procedures by providing model fit statistics [22].

In our mediation model, PF was reflected as T0 to T1 change and outcomes were reflected as T0 to T2 changes. This temporal ordering contributes to the implicit causal assumption that the effects of ACTonPain on PF occur prior to the treatment effects on the outcomes. The findings of this study based on this methodological approach support the theoretical assumption that changes in aspects of PF precede corresponding changes in the outcomes.

In addition, this is the first investigation of internet-based ACT comparing both a guided and unguided version of the intervention. Albeit not necessarily surprising, the present analysis showed that previous findings of PF functioning as a mediator in the context of guided internet-based ACT [85] also appear applicable in the context of unguided interventions.

5.5 Conclusion and future directions

In conclusion, the present study contributes to evidence in favor of the theoretical framework incorporated in ACT by showing that PF may function as a mechanism of change in an IMI for chronic pain. The limitations and strengths discussed above reflect the challenges and opportunities for developing an adequate design for the investigation of change processes, not only in the treatment of chronic pain, but more generally in the application of ACT.

For the future, the assessment of both process and outcome variables at multiple time points, such as daily or weekly ratings, are needed to allow for more sophisticated methodological approaches and designs, such as latent growth curve models [82], and autoregressive models [20].

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A central requirement for this kind of analysis however, is approximately complete data sets [21] and therefore higher treatment completion and study retention rates among the participants. Therefore, more effective engagement and retention strategies are needed in future on- and offline interventions.

Future research ought to focus more widely on all key facets of PF [80] and their interaction and explicitly combine outcome analyses with theoretically-based treatment processes in ACT. Current measures are limited, can be imprecise or heterogeneous in their content, and can overlap in their data, such as the CPAQ and FAH (German AAQ-II) that were used in this study. Both questionnaires are explicitly developed to assess acceptance and PF and they are neither the same nor completely different. A recent review on different measures for acceptance revealed that acceptance has been defined in different ways within different measures [51]. To a certain extent, this is based on differing assumptions and theoretical frameworks being applied. It will be important to more clearly acknowledge and state these background assumptions.

The research on change processes in ACT remains in development. With further detailed research into aspects of PF, it may be possible to enhance treatment effects. For example, a recent study of treatment-resistant panic disorder with/without agoraphobia showed that increased (re-)engagement in valued behaviors occurs prior to reductions in suffering [32]. This study supports more frequent assessments of effect-relevant aspects of PF in the course of ACT. This is so that that those who design and deliver treatments can continuously adjust the content of the treatment and ultimately maximize treatment effects. In the population of chronic pain, if change in components of PF underlie improvements in outcome and data show that these components are not changing to an adequate degree, some adjustment in treatment methods would appear necessary.

Further study of treatment processes in IMIs is recommended. First, ACT-based IMIs can be implemented widely and thus provide effective evidence-based interventions for many individuals that would otherwise remain untreated. Second, ACT-based IMIs can be tailored; thereby explicitly and automatically targeting individual needs with the result that treatment effects may be greater. Considering the findings of Gloster and colleagues [31], an IMI can be strategically designed to focus on specific priority processes in an order that optimizes outcome. Finally, as ACT is regarded as a generally applicable therapeutic model [39] that focusses on the promotion of PF rather than specific clinical symptoms, developed ACT IMIs may be easily transferable to other health problems.

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In general, a case is made here for greater focus on unifying theory, and on process-focused or mechanism-based treatment development, in conjunction with innovative implementation and delivery methods [37,77].

Acknowledgments

References

[1]   Andersson G. Internet-Delivered Psychological Treatments. Annu. Rev. Clin. Psychol. 2015;12:157–179. doi:10.1146/annurev-clinpsy-021815-093006.

[2]   Andersson G, Carlbring P, Berger T, Almlöv J, Cuijpers P. What makes internet therapy work? Cogn. Behav. Ther. 2009;38:55–60. doi:10.1080/16506070902916400.

[3]   Attkisson CC, Zwick R. The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval. Program Plann. 1982;5:233–237. doi:10.1016/0149-7189(82)90074-X.

[4]   Barrett P. Structural equation modelling: Adjudging model fit. Pers. Individ. Dif. 2007;42:815–824. doi:10.1016/j.paid.2006.09.018.

[5]   Baumeister H, Reichler L, Munzinger M, Lin J. The impact of guidance on Internet-based mental health interventions - A systematic review. Internet Interv. 2014;1:205–215. doi:10.1016/j.invent.2014.08.003.

[6]   Bender JL, Radhakrishnan A, Diorio C, Englesakis M, Jadad AR. Can pain be managed through the Internet? A systematic review of randomized controlled trials. Pain 2011;152:1740–1750. doi:10.1016/j.pain.2011.02.012.

[7]   Bond FW, Bunce D. Mediators of change in emotion-focused and problem-focused worksite stress management interventions. J. Occup. Health Psychol. 2000;5:156–163.

16

doi:10.1037/1076-8998.5.1.156.

[8] Bond FW, Hayes SC, Baer RA, Carpenter KM, Guenole N, Orcutt HK, Waltz T, Zettle RD. Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: a revised measure of psychological inflexibility and experiential avoidance. Behav. Ther. 2011;42:676–688. doi:10.1016/j.beth.2011.03.007.

[9] Bond GE, Burr RL, Wolf FM, Feldt K. The effects of a web-based intervention on psychosocial well-being among adults aged 60 and older with diabetes: a randomized trial. Diabetes Educ. n.d.;36; Jg. 20:446.

[10] Boss L, Lehr D, Reis D, Vis C, Riper H, Berking M, Ebert DD. Reliability and Validity of Assessing User Satisfaction With Web-Based Health Interventions. J. Med. Internet Res. 2016;18:e234. doi:10.2196/jmir.5952.

[11] Breivik H, Collett B, Ventafridda V, Cohen R, Gallacher D. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur. J. Pain 2006;10:287–333. doi:10.1016/j.ejpain.2005.06.009.

[12] Brouwer W, Kroeze W, Crutzen R, Nooijer J de, Vries NK, Brug J, Oenema A. Which intervention characteristics are related to more exposure to internet-delivered healthy lifestyle promotion interventions? J. Med. Internet Res. 2011;13:25–43. doi:10.2196/jmir.1639.

[13] Browne MW, Cudeck R. Alternative ways of assessing model fit. Sage Focus Ed. n.d.;154:136.

[14] Buhrman M, Gordh T, Andersson G. Internet interventions for chronic pain including headache: A systematic review. Internet Interv. 2016;4:17–34. doi:10.1016/j.invent.2015.12.001.

[15] Buhrman M, Skoglund A, Husell J, Bergström K, Gordh T, Hursti T, Bendelin N, Furmark T, Andersson G, Bergstrom K, Gordh T, Hursti T, Bendelin N, Furmark T, Andersson G, Bergstr??m K, Gordh T, Hursti T, Bendelin N, Furmark T, Andersson G.

Guided internet-delivered acceptance and commitment therapy for chronic pain patients: A randomized controlled trial. Behav. Res. Ther. 2013;51:307–315. doi:10.1016/j.brat.2013.02.010.

[16] Cederberg JT, Cernvall M, Dahl JA, Essen L, Ljungman G, von Essen L, Ljungman G. Acceptance as a Mediator for Change in Acceptance and Commitment Therapy for Persons with Chronic Pain? Int. J. Behav. Med. 2015;23:21–29. doi:10.1007/s12529-015-9494-y.

[17] Cheung GW, Lau RS. Testing mediation and suppression effects of latent variables: Bootstrapping with structural equation models. Organ. Res. Methods n.d.;11:296–325.

[18] Christensen H, Griffiths KM, Farrer L. Adherence in internet interventions for anxiety and depression: systematic review. J. Med. Internet Res. 2009;11:e13. doi:10.2196/jmir.1194.

[19] Cleeland CS, Ryan KM. The brief pain inventory. 1991. Available: http://www.anesthesiologie.nl/uploads/kwaliteit/4_-_Toelichting_BPI.pdf.

[20] Cole DA, Maxwell SE. Testing mediational models with longitudinal data: questions and tips in the use of structural equation modeling. J. Abnorm. Psychol. 2003;112:558–577. doi:10.1037/0021-843X.112.4.558.

[21] Curran PJ, Obeidat K, Losardo D. Twelve Frequently Asked Questions About Growth Curve Modeling. J. Cogn. Dev. 2010;11:121–136. doi:10.1080/15248371003699969.

[22] Danner D, Hagemann D, Fiedler K. Mediation analysis with structural equation models: Combining theory, design, and statistics. Eur. J. Soc. Psychol. 2015;45:460–481. doi:10.1002/ejsp.2106.

[23] Dear BF, Gandy M, Karin E, Staples LG, Johnston L, Fogliati VJ, Wootton BM, Terides MD, Kayrouz R, Perry KN, Sharpe L, Nicholas MK, Titov N. The Pain Course: a randomised controlled trial examining an internet-delivered pain management program when provided with different levels of clinician support. Pain

18

2015;156:1920–1935. doi:10.1097/j.pain.0000000000000251.

[24]   Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, Kerns RD, Stucki G, Allen RR, Bellamy N, Carr DB, Chandler J, Cowan P, Dionne R, Galer BS, Hertz S, Jadad AR, Kramer LD, Manning DC, Martin S, McCormick CG, McDermott MP, McGrath P, Quessy S, Rappaport BA, Robbins W, Robinson JP, Rothman M, Royal MA, Simon L, Stauffer JW, Stein W, Tollett J, Wernicke J, Witter J. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain 2005;113:9–19. doi:10.1016/j.pain.2004.09.012.

[25]   Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J. Pain 2008;9:105–121.

[26]   Eccleston C, Fisher E, Craig L, Duggan GB, Rosser BA, Keogh E. Psychological therapies (Internet-delivered) for the management of chronic pain in adults. Cochrane database Syst. Rev. 2014:CD010152. doi:10.1002/14651858.CD010152.pub2.

[27]   Flaxman PE, Bond FW. A randomised worksite comparison of acceptance and commitment therapy and stress inoculation training. Behav. Res. Ther. 2010;48:816–820. doi:10.1016/j.brat.2010.05.004.

[28]   Fletcher L, Hayes SC. Relational frame theory, acceptance and commitment therapy, and a functional analytic definition of mindfulness. J. Ration. Cogn. Ther. 2005;23:315–336. doi:10.1007/s10942-005-0017-7.

[29]   Flor H, Rudy TE, Birbaumer N, Streit B, Schugens MM. Zur Anwendbarkeit des West Haven-Yale multidimensional pain inventory im Deutschen Sprachraum. Der Schmerz 1990;4:82–87.

[30]   Gauntlett-Gilbert J, Connell H, Clinch J, McCracken LM. Acceptance and values-based treatment of adolescents with chronic pain: outcomes and their relationship to

19

acceptance. J. Pediatr. Psychol. 2013;38:72–81. doi:10.1093/jpepsy/jss098.

[31] Gloster AT, Klotsche J, Chaker S, Hummel K V, Hoyer J. Assessing psychological flexibility: what does it add above and beyond existing constructs? Psychol. Assess. 2011;23:970–982. doi:10.1037/a0024135.

[32] Goldberg DS, McGee SJ. Pain as a global public health priority. BMC Public Health 2011;11:770. doi:10.1186/1471-2458-11-770.

[33] Guy W. Clinical global impression scale. ECDEU Assess. Man. Psychopharmacol. Vol. DHEW Publ No ADM 76 n.d.;338:218–222.

[34] Hann KEJJ, McCracken LM. A systematic review of randomized controlled trials of Acceptance and Commitment Therapy for adults with chronic pain: Outcome domains, design quality, and efficacy. J. Context. Behav. Sci. 2014;3:217–227. doi:10.1016/j.jcbs.2014.10.001.

[35] Hayes AF. Beyond Baron and Kenny: Statistical mediation analysis in the new millennium. Commun. Monogr. n.d.;76:408–420.

[36] Hayes AF, Preacher KJ. Statistical mediation analysis with a multicategorical independent variable. Br. J. Math. Stat. Psychol. n.d.;67:451–470.

[37] Hayes SC. The Situation Has Clearly Changed: So What Are We Going to Do About It? Cogn. Behav. Pract. 2016;23:446–450. doi:10.1016/j.cbpra.2015.09.001.

[38] Hayes SC, Strosahl K. A practical guide to acceptance and commitment therapy. New York, NY: Springer, 2004 p. Available: http://www.worldcat.org/oclc/55534832.

[39] Hayes SC, Strosahl K, Wilson KG. Acceptance and commitment therapy: The process and practice of mindful change. 2nd ed. New York: Guilford Press, 2012 p. Available: http://www.worldcat.org/oclc/713181786.

[40] Hayes SC, Strosahl KD, Wilson KG. Acceptance and commitment therapy: An experiential approach to behavior change. New York: Guilford Press, 1999 p. Available: http://www.worldcat.org/oclc/487262239.

20

[41] Hayes SC, Villatte M, Levin M, Hildebrandt M. Open, Aware, and Active: Contextual Approaches as an Emerging Trend in the Behavioral and Cognitive Therapies. Annu. Rev. Clin. Psychol 2011;7:141–68. doi:10.1146/annurev-clinpsy-032210-104449.

[42] Heapy AA, Higgins DM, Cervone D, Wandner L, Fenton BT, Kerns RD. A Systematic Review of Technology-assisted Self-Management Interventions for Chronic Pain: Looking Across Treatment Modalities. Clin. J. Pain 2015;31:470–492. doi:10.1097/AJP.0000000000000185.

[43] Hoyer J, Gloster AT. Psychologische Flexibilität messen: Der Fragebogen zu Akzeptanz und Handeln II. Verhaltenstherapie 2013;23:42–44. doi:10.1159/000347040.

[44] Hughes LS, Clark J, Colclough JA, Dale E, McMillan D. Acceptance and Commitment Therapy (ACT) for Chronic Pain: A Systematic Review and Meta-Analyses. Clin. J. Pain 2017;33:552–568. doi:10.1097/AJP.0000000000000425.

[45] Iacubucci D, Saldanha N, Deng X. A Meditation on Mediation: Evidence That Structural Equations Models Perform Better Than Regressions. J. Consum. Psychol. 2007;17:139–153. doi:10.1016/S1057-7408(07)70020-7.

[46] Kashdan TB, Rottenberg J. Psychological flexibility as a fundamental aspect of health. Clin. Psychol. Rev. 2010;30:865–878. doi:10.1016/j.cpr.2010.03.001.

[47] Keller S, Bann CM, Dodd SL, Schein J, Mendoza TR, Cleeland CS. Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain. Clin. J. Pain 2004;20:309–318.

[48] Kerns RD, Turk DC, Rudy TE. The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Pain 1985;23:345–356. doi:10.1016/0304-3959(85)90004-1.

[49] Kline RB. Principles and practice of structural equation modeling. Guilford publications TS - EndNote Tagged Import Format, 2015 p.

[50] Korff M, Ormel J, Keefe FJ, Dworkin SF. Grading the severity of chronic pain. Pain

1992;50:133–149. doi:10.1016/0304-3959(92)90154-4.

[51]   Kroenke K, Spitzer RL. The PHQ-9: A New Depression Diagnostic and Severity

        Measure. Psychiatr. Ann. 2002;32:509–515. doi:10.3928/0048-5713-20020901-06.

[52]   Lauwerier E, Caes L, van Damme S, Goubert L, Rosseel Y, Crombez G. Acceptance:

        what's in a name? A content analysis of acceptance instruments in individuals with

        chronic pain. J. Pain 2015;16:306–317. doi:10.1016/j.jpain.2015.01.001.

[53]   Lillis J, Hayes SC. Measuring avoidance and inflexibility in weight related problems.

        Int. J. Behav. Consult. Ther. 2008;4:348–354. doi:10.1037/h0100865.

[54]   Lin J, Lüking M, Ebert DD, Buhrman M, Andersson G, Baumeister H. Effectiveness

        and cost-effectiveness of a guided and unguided internet-based acceptance and

        commitment therapy for chronic pain: Study protocol for a three-armed randomised

        controlled trial. Internet Interv. 2015;2:7–16. doi:10.1016/j.invent.2014.11.005.

[55]   Lin J, Paganini S, Sander L, Lüking M, Ebert DD, Buhrman M, Andersson G,

        Baumeister H. An Internet-based intervention for chronic pain—a three-arm

        randomized controlled study of the efficacy of guided and unguided commitment and

        acceptance therapy. Dtsch. Arztebl. Int. 2017. doi: 10.3238/arztebl.2017.0681.

[56]   Löwe B, Decker O, Müller S, Brähler E, Schellberg D, Herzog W, Herzberg PY.

        Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7)

        in the general population. Med. Care 2008;46:266–274.

        doi:10.1097/MLR.0b013e318160d093.

[57]   Luo X, Lynn George M, Kakouras I, Edwards CL, Pietrobon R, Richardson W, Hey L,

        George ML, Kakouras I, Edwards CL, Pietrobon R, Richardson W, Hey L. Reliability,

        validity, and responsiveness of the short form 12-item survey (SF-12) in patients with

        back pain. Spine J. 2003;28:1739–1745. doi:10.1097/01.BRS.0000083169.58671.96.

[58]   Macea DD, Gajos K, Daglia Calil YA, Fregni F. The efficacy of Web-based cognitive

        behavioral interventions for chronic pain: a systematic review and meta-analysis. J.

22

Pain 2010;11:917–929. doi:10.1016/j.jpain.2010.06.005.

[59]   McCracken LM. Contextual cognitive-behavioral therapy for chronic pain. Seattle:

IASP Press, 2005 p. Available: http://www.worldcat.org/oclc/57564664.

[60]   McCracken LM, Gutierrez-Martinez O. Processes of change in psychological

flexibility in an interdisciplinary group-based treatment for chronic pain based on

Acceptance and Commitment Therapy. Behav. Res. Ther. 2011;49:267–274. Available:

http://www.sciencedirect.com/science/article/pii/S0005796711000404.

[61]   McCracken LM, MacKichan F, Eccleston C. Contextual cognitive-behavioral therapy

for severely disabled chronic pain sufferers: Effectiveness and clinically significant

change. Eur. J. Pain 2007;11:314–322. doi:10.1016/j.ejpain.2006.05.004.

[62]   McCracken LM, Morley S. The psychological flexibility model: a basis for integration

and progress in psychological approaches to chronic pain management. J. Pain

2014;15:221–234. doi:10.1016/j.jpain.2013.10.014.

[63]   McCracken LM, Sato A, Taylor GJ. A Trial of a Brief Group-Based Form of

Acceptance and Commitment Therapy (ACT) for Chronic Pain in General Practice:

Pilot Outcome and Process Results. J. Pain 2013;14:1398–1406.

doi:10.1016/j.jpain.2013.06.011.

[64]   Mccracken LM, Vowles KE. Acceptance and commitment therapy and mindfulness for

chronic pain: Model, process, and progress. Am. Psychol. 2014;69:178–187.

doi:10.1037/a0035623.

[65]   McCracken LM, Vowles KE, Eccleston C. Acceptance-based treatment for persons

with complex, long standing chronic pain: a preliminary analysis of treatment outcome

in comparison to a waiting phase. Behav. Res. Ther. 2005;43:1335–1346. Available:

http://www.sciencedirect.com/science/article/pii/S0005796704002475.

[66]   Morley S, Williams A, Eccleston C. Examining the evidence about psychological

treatments for chronic pain: time for a paradigm shift? Pain 2013;154:1929–1931.

doi:10.1016/j.pain.2013.05.049.

[67]   Murray E. Web-Based Interventions for Behavior Change and Self-Management:

Potential, Pitfalls, and Progress. Med. 2.0 n.d.;1:e3.

[68]   Nilges P, Köster B, Schmidt CO. Schmerzakzeptanz – Konzept und Überprüfung einer

deutschen Fassung des Chronic Pain Acceptance Questionnaire. Der Schmerz

2008;22:90. doi:10.1007/s00482-007-0614-8.

[69]   Olsson UH, Foss T, Troye S V, Howell RD. The performance of ML, GLS, and WLS

estimation in structural equation modeling under conditions of misspecification and

nonnormality. Struct. Equ. Model. n.d.;7:557–595.

[70]   Paganini, S., Lin, J., Kählke, F., Buntrock, C., Leiding, D., Ebert, D.D., Baumeister H.

A guided and unguided internet- and mobile-based intervention for chronic pain: health

economic evaluation alongside a randomized controlled trial. n.d.

[71]   Palmqvist B, Carlbring P, Andersson G. Internet-delivered treatments with or without

therapist input: does the therapist factor have implications for efficacy and cost? Expert

Rev Pharmacoeconomics Outcomes Res (Expert Rev. Pharmacoeconomics Outcomes)

2007;7:291–297. doi:10.1586/14737167.7.3.291.

[72]   Preacher KJ, Hayes AF. SPSS and SAS procedures for estimating indirect effects in

simple mediation models. Behav. Res. Methods n.d.;36:717–731.

[73]   Preacher KJ, Zyphur MJ, Zhang Z. A general multilevel SEM framework for assessing

multilevel mediation. Psychol. Methods 2010;15:209–233. doi:10.1037/a0020141.

[74]   Radbruch L, Loick G, Kiencke P, Lindena G, Sabatowski R, Grond S, Lehmann KA,

Cleeland CS. Validation of the German Version of the Brief Pain Inventory. J. Pain

Symptom Manage. 1999;18:180–187. doi:10.1016/S0885-3924(99)00064-0.

[75]   Richards D, Richardson T. Computer-based psychological treatments for depression: A

systematic review and meta-analysis. Clin. Psychol. Rev. 2012;32:329–342.

doi:10.1016/j.cpr.2012.02.004.

24

[76]   Rini C, Williams DA, Broderick JE, Keefe FJ. Meeting them where they are: Using the Internet to deliver behavioral medicine interventions for pain. Transl. Behav. Med. 2012;2:82–92. doi:10.1007/s13142-011-0107-2.

[77]   Safren SA, Kircanski K, Craske MG. Introduction to ABCT's 50th Anniversary Special Series of Commentaries by Selected Past Presidents of the Association. Cogn. Behav. Pract. 2016;23:413–414. doi:10.1016/j.cbpra.2016.07.001.

[78]   Schermelleh-Engel K, Moosbrugger H, Müller H. Evaluating the fit of structural equation models: Tests of significance and descriptive goodness-of-fit measures. Methods Psychol. Res. online n.d.;8:23–74.

[79]   Scott W, Hann KEJ, McCracken LM. A Comprehensive Examination of Changes in Psychological Flexibility Following Acceptance and Commitment Therapy for Chronic Pain. J. Contemp. Psychother. 2016;46:139–148. doi:10.1007/s10879-016-9328-5.

[80]   Scott W, McCracken LM. Psychological flexibility, acceptance and commitment therapy, and chronic pain. Curr. Opin. Psychol. 2015;2:91–96. doi:10.1016/j.copsyc.2014.12.013.

[81]   Shapiro DA, Cavanagh K, Lomas H. Geographic Inequity in the Availability of Cognitive Behavioural Therapy in England and Wales. Behav. Cogn. Psychother. 2003;31:185–192. doi:10.1017/S1352465803002066.

[82]   Soest T, Hagtvet KA. Mediation Analysis in a Latent Growth Curve Modeling Framework. Struct. Equ. Model. A Multidiscip. J. 2011;18:289–314. doi:10.1080/10705511.2011.557344.

[83]   Spek V, Cuijpers P, Nyklícek I, Riper H, Keyzer J, Pop V. Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: a meta-analysis. Psychol. Med. 2007;37:319. doi:10.1017/S0033291706008944.

[84]   Trompetter HR, Bohlmeijer ET, Fox J-PP, Schreurs KMG. Psychological flexibility and catastrophizing as associated change mechanisms during online Acceptance &

25

Commitment Therapy for chronic pain. Behav. Res. Ther. 2015;74:50–59.

doi:10.1016/j.brat.2015.09.001.

[85] Trompetter HR, Bohlmeijer ET, Veehof MM, Schreurs KMG, Karlein @bullet,

Schreurs MG. Internet-based guided self-help intervention for chronic pain based on

Acceptance and Commitment Therapy: a randomized controlled trial. J. Behav. Med.

2015;38:66–80. doi:10.1007/s10865-014-9579-0.

[86] Veehof MM, Oskam M-J, Schreurs KMGG, Bohlmeijer ET. Acceptance-based

interventions for the treatment of chronic pain: A systematic review and meta-analysis.

Pain 2011;152:533–542. doi:10.1016/j.pain.2010.11.002.

[87] Veehof MM, Trompetter HR, Bohlmeijer ET, Schreurs KMG. Acceptance- and

mindfulness-based interventions for the treatment of chronic pain: a meta-analytic

review. Cogn. Behav. Ther. 2016;45:5–31. doi:10.1080/16506073.2015.1098724.

[88] Vowles KE, McCracken LM. Acceptance and values-based action in chronic pain: A

study of treatment effectiveness and process. J. Consult. Clin. Psychol. 2008;76:397.

doi:10.1037/0022-006X.76.3.397.

[89] Vowles KE, McCracken LM. Comparing the role of psychological flexibility and

traditional pain management coping strategies in chronic pain treatment outcomes.

Behav. Res. Ther. 2010;48:141–146. doi:10.1016/j.brat.2009.09.011.

[90] Vowles KE, McCracken LM, O'Brien JZ. Acceptance and values-based action in

chronic pain: A three-year follow-up analysis of treatment effectiveness and process.

Behav. Res. Ther. 2011;49:748–755. doi:10.1016/j.brat.2011.08.002.

[91] Vowles KE, Sowden G, Ashworth J. A comprehensive examination of the model

underlying acceptance and commitment therapy for chronic pain. Behav. Ther.

2014;45:390–401. doi:10.1016/j.beth.2013.12.009.

[92] Vowles KE, Witkiewitz K, Sowden G, Ashworth J. Acceptance and Commitment

Therapy for Chronic Pain: Evidence of Mediation and Clinically Significant Change

26

Following an Abbreviated Interdisciplinary Program of Rehabilitation. J. Pain
2014;15:101–113. doi:10.1016/j.jpain.2013.10.002.

[93] Wetherell JL, Afari N, Rutledge T, Sorrell JT, Stoddard JA, Petkus AJ, Solomon BC,
Lehman DH, Liu L, Lang AJ, Atkinson JH, Atkinson HJ, Hampton Atkinson J,
Atkinson JH. A randomized, controlled trial of acceptance and commitment therapy
and cognitive-behavioral therapy for chronic pain. Pain 2011;152:2098–2107.
doi:10.1016/j.pain.2011.05.016.

[94] Wicksell RK, Olsson GL, Hayes SC. Mediators of change in Acceptance and
Commitment Therapy for pediatric chronic pain. Pain 2011;152:2792–2801.
doi:10.1016/j.pain.2011.09.003.

[95] Wicksell RK, Olsson GL, Hayes SC. Psychological flexibility as a mediator of
improvement in Acceptance and Commitment Therapy for patients with chronic pain
following whiplash. Eur. J. Pain 2010;14:1059.e1-1059.e11.
doi:10.1016/j.ejpain.2010.05.001.

[96] Wicksell RK, Olsson GL, Melin L. The Chronic Pain Acceptance Questionnaire
(CPAQ)-further validation including a confirmatory factor analysis and a comparison
with the Tampa Scale of Kinesiophobia. Eur. J. Pain 2009;13:760–768.
doi:10.1016/j.ejpain.2008.09.003.

[97] Williams AC de C, Eccleston C, Morley S, Williams AC de C, Morley S.
Psychological therapies for the management of chronic pain (excluding headache) in
adults. Cochrane Database Syst Rev 2012;2:CD007407.
doi:10.1002/14651858.CD007407.pub3.

[98] Williams DA. Web-based behavioral interventions for the management of chronic pain.
Curr. Rheumatol. Rep. 2011;13:543–549.

[99] Windgassen S, Goldsmith K, Moss-Morris R, Chalder T. Establishing how
psychological therapies work: the importance of mediation analysis. J. Ment. Health

2016;25:93–99. doi:10.3109/09638237.2015.1124400.

[100] Wolgast M. What does the acceptance and action questionnaire (AAQ-II) really measure? Behav. Ther. 2014;45:831–839. doi:10.1016/j.beth.2014.07.002.

[101] Woody E. An SEM Perspective on Evaluating Mediation: What Every Clinical Researcher Needs to Know. J. Exp. Psychopathol. 2011;2:210–251. doi:10.5127/jep.010410.

[102] Yu L, Norton S, McCracken LM. Change in "Self-as-Context" ("Perspective-Taking") Occurs in Acceptance and Commitment Therapy for People With Chronic Pain and Is Associated With Improved Functioning. J. Pain 2017;18:664–672. doi:10.1016/j.jpain.2017.01.005.

Figure legends

Figure 1. Hypothesized mediation model. Note: D1 = dummy coded grouping variable representing the contrast between WLC and ACTonPain unguided, D2 = dummy coded grouping variable representing the contrast between WLC and ACTonPain guided, PF = Psychological flexibility, represented by the pre- to post-treatment (T0-T1) change scores. All outcomes are represented by their pre-treatment to follow-up (T0-T2) change scores. The red arrows indicate covariances that was added to the model due to the theoretically assumed high correlation between the variables. Dotted arrows represent indirect effects with dark blue arrows indicating a-paths (relationship between group and PF) and light blue arrows indicating b-paths (relationship between PF and outcomes). Direct effects are represented by continuous green arrows (c-paths represent the relationship between groups and outcomes).

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Table 1. Overview of the intervention's content. Modified from Lin et al. (2015).

Module	ACT processes	Content
Introduction: What to expect from the training?	-	Overview and summary of the intervention's content, introduction of case examples of chronic pain patients
Module 1: Welcome	present moment awareness	Mindfulness exercise, psychoeducation: acute and chronic pain, creative hopelessness, metaphor: "the man in the hole"
Module 2: Control and acceptance	present moment awareness, acceptance	Primary and secondary pain, short-term and long-term consequences, mindfulness exercise, metaphors: "the shark trap" and "the radio"
Module 3: Thoughts and emotions	present moment awareness, defusion, values	Mindfulness exercise, defusion exercise on coping with thoughts and emotions, formulation of goals, metaphor: "the bus"
Module 4: You and your self	present moment awareness, self-as-context, values	Mindfulness exercise, metaphor: „the chessboard", values assessment
Module 5: What I value in life	present moment awareness, values	Mindfulness exercise, values compass, metaphor: "the farewell party"
Module 6: Commitment	present moment awareness, acceptance, committed action	Mindfulness exercise, to live according to one's values, willingness exercise, metaphor: "my party"
Module 7: Looking ahead	present moment awareness, values	Summary, maintenance plan, evaluation of previously set goals, mindfulness in daily life, metaphor: "the skier"

Table 2. Parameter estimates (standard errors), significance tests and confidence intervals for the model

		Direct Effects (a-, b- and c-paths), *p*-values		Indirect Effects (ab-paths)	
		Standardized estimates (SD)	95% CI	Standardized estimates (SD)	95% CI
	D1				
c-paths	MPI-D	0.42 (0.28), *p*=.00	0.13;1.03	-0.54 (0.27), *p*=.00	-1.16; -0.26
	BPI-D	0.47 (0.30), *p*=.00	0.15; 1.12	-0.57 (0.30), *p*=.00	-1.23; -0.28
	NRS	0.24 (0.26), *p*=.14	-0.05; 0.80	-0.41 (0.24), *p*=.00	-0.98; -0.18
	PHQ-9	0.41 (0.29), *p*=.01	0.09; 1.11	-0.60 (0.29), *p*=.00	-1.33; -0.30
	GAD-7	0.49 (0.27), *p*=.00	0.21; 1.18	-0.54 (0.26), *p*=.00	-1.19; -0.27
	SF12 MCS	-0.38 (0.22), *p*=.01	-0.90; -0.11	0.44 (0.20), *p*=.00	0.04; 0.95
	SF12 PCS	-0.07 (0.14), *p*=.57	-0.37; 0.12	0.16 (0.13), *p*=.00	0.21; 0.49
	PF (a-path)	0.62 (0.13), *p*=.00	0.36; 0.88		
	D2				
c-paths	MPI-D	0.36 (0.32), *p*=.02	0.04; 1.06	-0.62 (0.31), *p*=.00	-1.31; -0.31
	BPI-D	0.46 (0.35), *p*=.01	0.11; 1.21	-0.66 (0.35), *p*=.00	-1.39; -0.34
	NRS	0.22 (0.28), *p*=.17	-0.07; 0.88	-0.48 (0.28), *p*=.00	-1.14; -0.22
	PHQ-9	0.49 (0.34), *p*=.01	0.13; 1.26	-0.69 (0.33), *p*=.00	-1.47; -0.36
	GAD-7	0.54 (0.31), *p*=.00	0.21; 1.28	-0.63 (0.30), *p*=.00	-1.34; -0.32
	SF12 MCS	-0.39 (0.24), *p*=.01	-0.98; -0.10	0.51 (0.23), *p*=.00	0.25; 1.07
	SF12 PCS	-0.09 (0.17), *p*=.45	-0.44; 0.12	0.19 (0.15), *p*=.00	0.05; 0.56
	PF (a-path)	0.72 (0.14), *p*=.00	0.44; 0.97		
PF (b-paths)					
	MPI-D	-0.87 (0.25), *p*=.00	-1.35; -0.63		
	BPI-D	-0.93 (0.28), *p*=.00	-1.43; -0.68		
	NRS	-0.67 (0.24), *p*=.00	-1.14; -0.39		
	PHQ-9	-0.97 (0.26), *p*=.00	-1.53; -0.73		
	GAD-7	-0.88 (0.25), *p*=.00	-1.37; -0.58		
	SF12 MCS	0.71 (0.20), *p*=.00	0.39; .1.05		
	SF12 PCS	0.27 (0.15), *p*=.00	0.07; 0.57		

Note: CI = Confidence Interval, PF = Psychological flexibility, SE = standard error. D1 = dummy coded grouping variable representing the contrast between WLC and ACTonPain unguided, D2 = dummy coded grouping variable representing the contrast between WLC and ACTonPain guided. Direct effects of D1 and D2 on PF represent a-paths; direct effects of PF on outcome measures represent the corresponding b-paths, direct effects of D1 and D2 on outcome measures represent the corresponding c-paths. The product of a- and b-paths results in the respective indirect effect (ab).