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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. ☆

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ABSTRACT

Background: Acceptance and Commitment Therapy (ACT) is an effective intervention for the treatment of chronic pain. Internet-based pain interventions might be an effective and cost-effective way to overcome treatment barriers of traditional face-to-face pain interventions such as the lack of availability and accessibility. However, little is known about the general (cost-)effectiveness of internet-based pain interventions and the specific (cost-) effectiveness of guided and unguided pain interventions. Therefore, the aim of this study is to investigate the effectiveness and cost-effectiveness of a guided and unguided ACT-based online intervention for persons with chronic pain (ACTonPain).

Methods: ACTonPain is a pragmatic three-armed randomised controlled trial comparing ACTonPain with or without therapist guidance against a waitlist control group. Both active conditions differ only with regard to guidance provided by an eCoach, who sends feedback after each module. This study aims to include 300 participants. Randomisation and allocation will be performed using permuted block randomisation with variable block sizes. The intervention contains seven ACT-based modules with interactive exercises, and audio and video clips. Furthermore, the participants have the opportunity to receive daily text messages. Online self-assessments will take place at pre- and post-treatment, as well as at 6 month follow-up. The primary outcome is pain interference. Secondary outcomes include physical and emotional functioning, pain intensity, ACT-related variables as well as health-related quality of life. Moreover, a cost-effectiveness analysis will be conducted from a societal perspective. Demographic and medical variables will be assessed on the basis of self-reports in order to detect potential moderators or mediators of the effects. The data will be analysed on an intention-to-treat basis and also using per-protocol analyses.

Discussion: This study will contribute to the evidence base of internet-based pain interventions and provide valuable information about the treatment success and cost-effectiveness regarding the intervention's level of guidance (self-help only vs. guided self-help). If ACTonPain is shown to be effective, investigations in different healthcare settings should follow, to examine possible ways of implementing ACTonPain into existing healthcare systems. The implementation of ACTonPain could help to shorten waiting times, expand access to pain treatment and, potentially, also reduce treatment costs.

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1. Introduction

Chronic pain seriously affects quality of life, including physical, psychological and social functioning of the affected persons (Breivik et al., 2006; Gatchel et al., 2007). In addition, chronic pain is highly prevalent and a recent study indicated the prevalence of chronic pain in Germany to be 17% (Wolff et al., 2011); comparable to prevalence found in large scale international studies (Breivik et al., 2006; Gureje et al., 1998; IASP, 2005). Taking direct and indirect costs into account, chronic pain carries a high economic burden for societies around the world (Baumeister et al., 2012; Breivik et al., 2006; IASP, 2005; Phillips & Schopflocher, 2008; Turk, 2002).

A multidimensional and interdisciplinary treatment approach is an effective and cost-effective setting for the treatment of chronic pain (Sanders et al., 2005). Psychological interventions such as Cognitive-Behavioural Therapy (CBT) and Acceptance and Commitment Therapy (ACT) are core elements within such treatment plans (Kerns et al., 2011; Turk et al., 2011). In contrast to CBT, ACT focuses on the process and functions of emotions, thoughts or behaviour rather than on their form, frequency or appearance alone (McCracken & Vowles, 2014). According to the model of ACT, the therapeutic target is psychological flexibility, defined as "the ability to contact the present moment more fully as a conscious human being, and to change or persist in behavior when doing so serves valued ends" (Hayes et al., 2006). In order to develop psychological flexibility, the six interrelated core processes – cognitive defusion, acceptance, contact with the present moment, self-as-context, values and committed action – need to be facilitated (Hayes & Strosahl, 2004; Hayes et al., 2012; Vowles et al., 2014a). A considerable number of clinical trials highlight the potential of ACT for effectively treating chronic pain in different patient samples and clinical settings (McCracken et al., 2007; Thorsell et al., 2011; Veehof et al., 2011; Vowles et al., 2009, 2011, 2014b; Vowles & Thompson, 2011; Wetherell et al., 2011; Wicksell et al., 2009a, 2013). A meta-analysis of 22 acceptance-based interventions for chronic pain with controlled (waitlist or treatment as usual (TAU)) and non-controlled study-designs showed a small but significant effect size on pain intensity with a standardised mean difference (*SMD*) of 0.37 at post-treatment (Veehof et al., 2011). Accordingly, the effect size is comparable to those reported for CBT approaches (Eccleston et al., 2009; Hoffman et al., 2007; Morley et al., 1999), demonstrating ACT to be an alternative to CBT in the treatment of chronic pain (McCracken & Vowles, 2014; Wetherell et al., 2011).

Despite the potential of various treatments for chronic pain, many affected persons remain untreated or inadequately treated (Breivik et al., 2006; Shapiro et al., 2003). Internet-based interventions might be a feasible means through which to increase uptake rates of chronic pain-specific interventions and, thus, help to improve health care for persons with chronic pain (Bender et al., 2011; Bennett & Glasgow, 2009; Eccleston, 2011; Keogh, 2013; Long & Palermo, 2009; McGeary et al., 2012; Rosser et al., 2011; Williams, 2011). To date, there is a growing evidence base for the effectiveness of internet-based CBT interventions for the treatment of chronic pain, with a considerable number of different interventions trialled (Berman et al., 2009; Eccleston et al., 2014; Keogh et al., 2010; Macea et al., 2010; Velleman et al., 2010). Two recent meta-analyses on internet-based interventions for chronic pain reported overall combined effect sizes on pain at post-treatment compared to active control, waitlist or treatment as usual of $d = .29$ (Macea et al., 2010) and $SMD = .37$ (Eccleston et al., 2014), respectively.

Despite several promising efficacy and effectiveness studies, the evidence base of internet interventions for chronic pain remains limited, with an almost exclusive focus on CBT-based pain interventions (Eccleston et al., 2014; Macea et al., 2010). To the best of our knowledge, there are only two internet intervention trials based on ACT for chronic pain, and these studies show promising effects of ACT-based interventions on pain outcomes (e.g. pain interference: $d = .33$ when compared to an online expressive writing intervention (Trompetter et al., 2014)

and $d = .56$ when compared to a discussion forum for chronic pain (Buhrman et al., 2013)). Yet, none of the trials of internet interventions for chronic pain went beyond the evaluation of efficacy to focus on potential effect-modifying or mediating covariates and their cost-effectiveness (Macea et al., 2010; Rini et al., 2012). The costs of internet interventions are, once developed, substantially linked with guidance time whereby participants are provided with some form of professional support, mostly in the form of personal feedback (Ebert et al., 2014). To date, internet interventions without guidance are often found to be less effective than internet interventions including at least some guidance (Baumeister et al., 2014b; Johansson & Andersson, 2012; Richards & Richardson, 2012). One recent meta-analysis examining unguided and guided versions of an internet intervention for varying mental disorders reported an average *SMD* of 0.27 (Baumeister et al., 2014b). This finding suggests that guidance has an adherence-facilitating effect, keeping users engaged in the internet intervention (Baumeister et al., 2014b). A growing body of evidence highlights further possibilities for enhancing users' adherence to interventions, such as automated prompts, videos, audios, interactive web-design and mobile features (Ritterband et al., 2009; Wangberg et al., 2008). So far, however, little is known about the general cost-effectiveness of internet interventions and, in particular, the cost-effectiveness of guided versus unguided interventions. Based on the extant research regarding internet interventions, an unguided intervention may produce clinically significant effects at a population level (Ebert et al., 2014), due to the possible higher accessibility of unguided interventions at potentially lower costs. On the other hand, unguided interventions show higher dropout rates than their guided counterparts and thus may still be less cost-effective due to the potentially increased costs associated with dropout, such as continuous absence from work and uptake of more treatments.

1.1. Aims

To examine the effectiveness and cost-effectiveness of both guided and unguided ACT-based internet interventions, we developed both guided and unguided versions of an online interactive ACT-based intervention for chronic pain (ACTonPain). Potential effect-modifying and -mediating covariates will also be investigated in order to gain a deeper understanding of the mechanisms underlying any effects found of ACTonPain. The specific aims of the study are:

1. To examine the effectiveness of guided and unguided ACTonPain compared to a waitlist control group (WLC).
2. To examine the comparative effectiveness of guided and unguided ACTonPain.
3. To examine the cost-effectiveness of guided and unguided ACTonPain compared to WLC.
4. To examine the comparative cost-effectiveness of guided and unguided ACTonPain.
5. To investigate which factors moderate and mediate the effects of guided and unguided ACTonPain.

We hypothesise that both guided and unguided ACTonPain will be more effective and cost-effective than a waitlist control group (WLC).

2. Methods

2.1. Study design

This study is a three-armed pragmatic RCT of parallel design with guided and unguided ACTonPain intervention groups, and a WLC (see CONSORT flow diagram, Fig. 1). Participants in all intervention arms will have full access to treatment as usual, with the exception of ongoing or planned psychological pain interventions within the upcoming three months. Thus, participants can receive treatment that will be monitored in order to control for potential confounding effects. The trial will be conducted and reported in accordance with the CONSORT 2010