



Treatment processes during exposure and cognitive-behavioral therapy for chronic back pain: A single-case experimental design with multiple baselines

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ARTICLE INFO

Keywords:

Treatment processes
Chronic low back pain
Exposure therapy
Cognitive-behavioral therapy
Single-case experimental design
Biological stress response
Cortisol
Alpha-amylase

ABSTRACT

Our aim was to evaluate isolated elements of psychological pain treatments and explore treatment effects on biological stress markers. We employed a single-case experimental design with multiple baselines. Matching pairs of twelve participants (chronic low back pain > 6 months; elevated pain-related fear) were randomly assigned to graded in vivo exposure (EXP) or cognitive-behavioral therapy (CBT) in a yoked design. Primary assessments were taken during baseline (7–26 days), treatment (23–44 days) and at 6-months follow-up (11–30 days) including changes in pain symptoms, disability, pain-related fear, acceptance, body confidence, self-efficacy, and positive thoughts. Psycho-educational, behavioral, cognitive, and exposure interventions were compared to baseline. EXP exhibited immediate middle-to-large effects; CBT's small-to-middle effects were delayed. Within the EXP approach, change mainly occurred during exposure but not during psycho-educational sessions. Overall cortisol was lower in EXP than CBT at post-treatment. We recommend integrating exposure elements in the management of CLBP to increase its efficacy. Psycho-educational sessions might not be necessary or should be adapted, e.g. with stronger focus on motivational aspects. Since CBT seemed to produce delayed effects, core CBT interventions such as cognitive restructuring might be added after exposure treatment to sustain therapeutic effects.

1. Introduction

Several psychological approaches for treating individuals with chronic low back pain (CLBP) exist. Graded in vivo exposure (EXP) is directly based on the fear-avoidance model (Vlaeyen, Morley, Linton, Boersma, & de Jong, 2012). Patients are motivated to move through an individualized fear hierarchy and reduce their avoidance behavior via exposure. Cognitive-behavioral therapy (CBT) combines techniques such as cognitive and behavioral interventions (not including exposures but rather elements of activity pacing), which aim to teach coping strategies (McCracken & Turk, 2002).

Randomized control trials (RCTs) seek to evaluate overall treatment effects. However, they have their limits to disentangle the influence of individual treatment elements (Morley, Williams, & Eccleston, 2013).

Single-case experimental designs are considered an efficient means of evaluating both the feasibility of new treatments (stage I according to the stage model; see Oken, Blaine, & Battjes, 1997) and the effectiveness of isolated elements (stage II).

The effectiveness of CBT (e.g. Eccleston, Morley, & Williams, 2013), and other CBT-based approaches for chronic pain was initially investigated in single-case studies (e.g. Vlaeyen, de Jong, Geilen, Heuts, & van Breukelen, 2001) focusing on treatment feasibility, and later in several RCTs (e.g. Leeuw et al., 2008). Their results revealed no large differences between these treatments (Macedo, Smeets, Maher, Latimer, & McAuley, 2010). Most study effects were small to moderate.

We seem to be witnessing the “Dodo-Bird-Verdict” phenomenon in psychological pain treatment research (Budd & Hughes, 2009) accompanied by overall effect sizes that are rather disappointing. To improve

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<https://doi.org/10.1016/j.brat.2018.07.002>

Received 24 March 2018; Received in revised form 21 June 2018; Accepted 9 July 2018

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treatment efficacy, we therefore need to step back and take a closer look at the efficacy of single treatment components. Long-term aim of this line of research could be combining successful interventions from different approaches to make psychological pain treatments more effective and tailor therapies to each patient's needs.

To our knowledge, there are no published studies on the efficacy of single different treatment components of CBT-based approaches in pain. Previous Stage 1 single-case for exposure studies focused on the feasibility of general EXP to CLBP. Only one trial differentiated between the effects of psycho-educational and exposure elements (de Jong et al., 2005). Few dismantling studies have identified effective CBT components in other disorders. A recent review addressing panic disorders concluded that interoceptive exposure and the face-to-face setting were associated with better treatment efficacy, while muscle relaxation and virtual-reality exposure were associated with significantly less efficacy (Pompoli et al., 2018). It is generally assumed that active treatment components such as exposures are more effective than other components (Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014). On the other hand, cognitive interventions and psycho-education are regarded as core CBT interventions (Hofmann, Asmundson, & Beck, 2013).

To contribute to this line of research, we are the first to have employed a single-case design to evaluate the effect of isolated psychological pain treatment elements such as psycho-educational, behavioral, cognitive, and exposure interventions. These elements were embedded in therapy rationales of either a specific (EXP) or general (CBT) pain management approach. In contrast to previous single-case studies (e.g. Vlaeyen et al., 2001) that covered the Stage I research, we conducted a Stage 2 study. We theoretically expected that interventions specifically addressing avoidance behavior such as exposures would reveal significant treatment effects on functional disability. Following the EXP rationale, we focused on individuals with enhanced pain-related fear.

We also hoped to supplement the literature by exploring, for the first time, effects of CBT and EXP on biological stress markers.

2. Method

2.1. Study design

A single-case experimental design with multiple baselines was employed. Matching pairs of individuals suffering from CLBP and enhanced pain-related fear were randomly assigned to either CBT or EXP in a yoked design. Participants were matched regarding gender, age, and disability. We did not combine the two treatment approaches for two reasons: first, both approaches convey different therapeutic messages; while the CBT approach encourages a pain-coping approach, EXP aims to promote action despite pain and negative emotions, thus assimilating these competing therapeutic goals appears inconsistent. Second, there is evidence that shorter treatment duration is superior to longer treatment duration in the CLBP context (Glombiewski et al., 2018). In the EXP condition, psycho-educational and exposure elements were compared to baseline. In the CBT condition, psycho-educational, behavioral, cognitive and combined CBT-specific elements were contrasted to baseline. Primary assessments were made during baseline (7–26 days), treatment (23–44 days), and the 6-month follow-up (11–30 days). Participants ran through intensive secondary assessments including psychobiological measures at pre-treatment, post-treatment, and the 6-month follow-up. The trial protocol was registered (ClinicalTrials.gov NCT03157622) and approved by the institutional ethics committee of the psychology department at the Philipps-University of Marburg, Germany.

2.2. Participants

Our sample comprised six individuals in each treatment condition (see Table 1). Patients were included if they met all of the following criteria:

- Basic criteria:
 - CLBP > 6 months
- Additional criteria:
 - Substantial disability as defined by QBPDS > 30 (Quebec Back Pain Disability Scale; Kopec et al., 1995) and PDI > 20 (Pain Disability Index; Tait, Chibnall, & Krause, 1990).
 - Substantial pain-related fear defined by PASS > 20 (Pain Anxiety Symptom Scale; McCracken & Dhingra, 2002), PCS > 35 (Pain Catastrophizing Scale; Sullivan, Bishop, & Pivik, 1995) and a specific PHODA profile with harm ratings of 13 activities > 50, including 8 > 80 (range 0–100, with 0 = “not harmful at all” and 100 = “extremely harmful for my back”) to entail enough movements for exposure treatment (Photograph Series of Daily Activities; Leeuw, Goossens, van Breukelen, Boersma, & Vlaeyen, 2007).

Exclusion criteria were back surgeries during the previous six months or planned surgeries, inability to read or write German, pregnancy, and ongoing psychological therapy. Individuals were also excluded if they suffered from alcohol addiction or psychotic disorders as determined in a screening interview for psychological disorders (Margraf, 2013). For further details see Supplementary Material: Recruitment Procedure, Flow of Participants.

3. Intervention and therapists

Patients participated in ten individual 50-min sessions of either CBT or EXP (see Fig. 1). Sessions were held twice a week over a 5-week period in a university-based clinic in Marburg (Psychotherapieambulanz der Philipps-Universität Marburg, PAM), Germany. Treatments were based on detailed manuals and patients were offered personalized workbooks. Two advanced clinical psychology doctoral students delivered the treatment. Matching pairs were assigned whenever possible to the same therapist. An experienced psychologist supervised the treatment process. The supervision was mainly concerned with the therapist-patient-interaction by analyzing video-recorded sessions. For further details see Supplementary Material: Treatment Manuals, Workbooks.

3.1. Graded *In vivo* exposure

The EXP protocol consisted of two phases. (1) Psycho-education (sessions 1–4): patients were introduced to biopsychosocial understanding of their chronic pain using video material, which included information about the physiology of pain, influences of top-down processes, differences between acute and chronic pain, and a short interview sequences with other pain patients. Patients watched the videos together with their therapist. The therapist would stop the videos occasionally to explain some information in greater detail and ask patients about their own experiences. Patients were then encouraged to adopt the fear-avoidance model to their own situation focusing on the negative consequences of avoidance behavior. Patients developed an individual fear hierarchy using the PHODA to prepare for the exposure sessions. (2) Exposures (sessions 5–9): subsequent *in vivo* exposure sessions targeted at changing the emotional response towards feared movements until distress declined significantly. Additional behavioral experiments aimed to modify fear-avoidance beliefs. One 50-min exposure session usually focused on one specific movement in the patient's fear hierarchy, but related movements could also be confronted in the same session to facilitate generalization effects. Patients were encouraged to engage in these activities as often as possible between sessions until anxiety levels decreased.

3.2. Cognitive-behavioral therapy

The CBT protocol included three elements. (1) Psycho-education

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