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

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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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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 (ClinicalTrial.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:
  - o CLBP > 6 months
- Additional criteria:
  - o 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).
  - o 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

Table 1
Baseline characteristics of matching partners (n = 12).

No.	Cond.	Baseline (days)	Gender	Age	Work status	Pain description
1	EXP	14	female	58	disability pension	*"Back problems for 15 years. Operation on the lower back did not alleviate symptoms. Is unable to work anymore."*
	CBT	14	female	56	employed	*"Low back pain for 20 years. Is afraid of losing control over her life due to back pain."*
2	EXP	9	male	57	employed	*"Low back pain for 20 years after herniated disc. Feels guilty being unable to play with his son."*
	CBT	7	male	51	sick leave	*"Pain problems from early adulthood. Interprets pain as warning signals for severe body damage."*
3	EXP	11	female	58	employed	*"Low back pain for 15 years after bicycle accident. Pain attacks at her work as school counselor."*
	CBT	9	female	67	pension	*"Lower back pain for 10 years after falling down stairs. Pain causes problems with sitting and pursuing household activities."*
4	EXP	20	male	58	disability pension	*"Low back pain for 26 years. Cannot work anymore. Reports severe sleep deprivation."*
	CBT	21	male	62	disability pension	*"Pain in lower back for 3 years. Two hip replacement surgeries led to pain in his lower back. Unable to drive long distances."*
5	EXP	14	female	41	sick leave	*"Unexplained back pain for 2 years. Suffers from being incapable of engaging in former leisure activities* (e.g. *basketball)."*
	CBT	21	female	55	employed	*"Back pain for 5 years. Several herniated discs in upper and lower pain. Was on sick leave for more than a year. Afraid of long sitting periods during work."*
6	EXP	26	male	58	unemployed	*"Back pain for 19 years. Fears ending up in a wheelchair. Several operations did not reduce pain severity."*
	CBT	18	male	58	employed	*"Back pain for 5 years after herniated disc in lower back. Struggles especially with depressive side effects."*

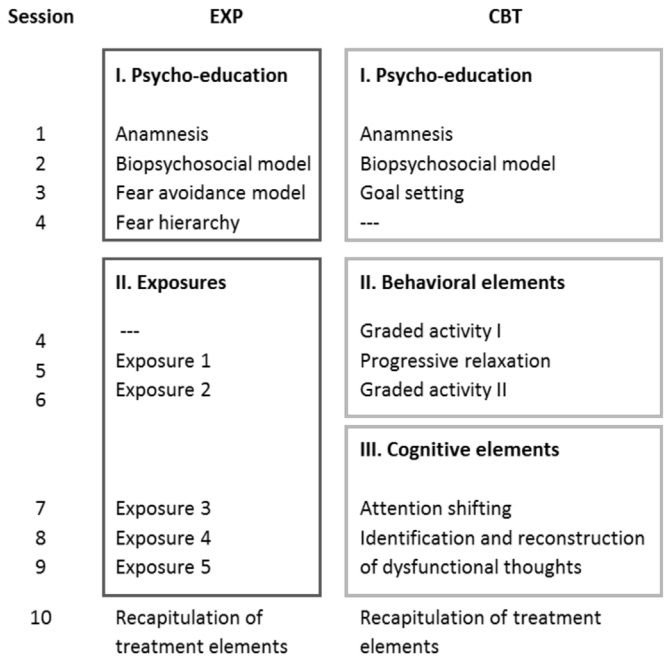

Fig. 1. Overview on treatment sessions.

(sessions 1–3): patients were introduced to a biopsychosocial understanding of their chronic pain using the same video material as in the EXP condition and then encouraged to formulate feasible treatment goals discussing negative and positive consequences of their chronic pain. (2) Behavioral elements (sessions 4–6): patients were introduced to graded activity as a strategy to re-engage in former activities by dividing activities into smaller steps. Predetermined resting periods were offered to prevent phases of excessive demands followed by long terms of recovery. The goal of graded activity is to shape healthy behaviors by modifying contingencies between pain behaviors and their direct consequences. In contrast, exposure-based approaches intend to alleviate the fear towards specific movements. Progressive muscle relaxation was introduced as a further behavioral technique to decrease muscle tension. (3) Cognitive elements (sessions 7–9): attention shifting aimed at developing external and internal diversion strategies. Maladaptive pain-related cognitions were identified and challenged by restructuring techniques. Patients were encouraged to practice the presented pain coping strategies as often as possible between sessions; we also gave them homework assignments.

3.3. Treatment Fidelity

Treatment fidelity was evaluated by relying on video recordings using the method of assessing treatment delivery (MATD) (Leeuw, Goossens, de Vet, & Vlaeyen, 2009). Since we were interested in evaluating isolated treatment components, we assessed the adherence to the specified chronological order of treatment elements. For further details see Supplementary Material: Treatment Fidelity.

4. Primary Assessments

Primary assessments were taken via iPod touch® on a daily basis. Each patient was provided with coherent item definitions to enhance comparable item interpretations. An alarm clock reminded patients to complete their assessments every evening. Our selection of daily measures was based on theories and treatment rationales underlying EXP and CBT.

4.1. Pain symptoms

We assessed daily changes in pain symptoms and disability according to international guidelines (Dworkin et al., 2005). Patients had to quantify their current and average pain intensity during the day (0 = no pain, 10 = worst pain), and their pain perception (0 = bearable, 10 = unbearable) on an 11-point scale. To assess disability, we had patients nominate one personally-relevant activity for each day and rate their difficulty in performing this activity (0 = no problem, 10 = impossible), and its expected harmfulness *before* and *after* engaging in the activity (0 = not harmful, 10 = very harmful).

4.2. Treatment processes

Treatment processes included changes in different aspects of pain-related fear, namely cognitive anxiety, catastrophizing, and self-reported exposure. We also examined effects on acceptance and body confidence, since these constructs are additional EXP targets. Finally, we included self-efficacy and positive thoughts, as teaching pain-coping strategies and changing dysfunctional thoughts are core features of CBT. We selected three items possessing high internal consistency from five different standardized measures for each treatment process (see Table 2). Item formulations were adapted to statements about the present day and CLBP, which patients had to rate on an 11-point scale (0 = total disagreement, 10 = total agreement). Related statements were summarized by calculating mean values. The item order was presented randomly to maintain the patients' attention. One item in each item group was inverted to avoid answering patterns.

Table 2
Primary assessments of treatment processes.

	Example item	Reference
Self-efficacy:		
Fragebogen zur Erfassung von Schmerzverarbeitung, FESV – Experience of Competence	When I experienced back pain today, I still had the feeling of being in control.	Geissner, E. (1999). Verarbeitung chronischer Schmerzen - Skalen zur Erfassung der Schmerzbewältigung und der schmerzbedingten psychischen Beeinträchtigung. Zeitschrift für Klinische Psychologie und Psychotherapie, 28, 280–90.
Positive thoughts:		
Fragebogen zur Erfassung von Schmerzverarbeitung, FESV – Cognitive Restructuring	When I experienced back pain today, I told myself that I could handle it better than before.	Geissner, E. (1999). Verarbeitung chronischer Schmerzen - Skalen zur Erfassung der Schmerzbewältigung und der schmerzbedingten psychischen Beeinträchtigung. Zeitschrift für Klinische Psychologie und Psychotherapie, 28, 280–90.
Acceptance:		
Chronic Pain Acceptance Questionnaire, CPAQ	My life is going well even though I have chronic back pain.	McCracken, L. M., Vowles, K. E., & Eccleston, C. (2004). Acceptance of chronic pain: component analysis and a revised assessment method. Pain, 107(1–2), 159–66.
Exposition:		
Pain Anxiety Symptom Scale, PASS-D20 - Escape/ Avoidance	Today, I continued activities even though I felt my back pain returning.	McCracken, L. M., & Dhingra, L. (2002). A short version of the Pain Anxiety Symptom Scale (PASS-20): preliminary development and validity. Pain Research and Management, 7(1), 45–50.
Cognitive anxiety:		
Pain Anxiety Symptom Scale, PASS-D20 – Cognitive Anxiety	When I was in pain today, I did not constantly think about my back pain.	McCracken, L. M., & Dhingra, L. (2002). A short version of the Pain Anxiety Symptom Scale (PASS-20): preliminary development and validity. Pain Research and Management, 7(1), 45–50.
Catastrophizing:		
Pain Catastrophizing Scale, PCS - Rumination	Today, there was a moment when I stopped thinking about my back pain.	Sullivan, M. J. L., Bishop, S. R., & Pivik, J. (1995). The Pain Catastrophizing Scale: development and validation. Psychological Assessment, 7(4), 524–32.
Body confidence:		
Frankfurter Körperkonzeptskalen, FKKS Fragebogen zur Beurteilung des eigenen Körpers, FbeK	I had confidence in my body today.	Deusinger, I. (1998). Die Frankfurter Körperkonzeptskalen (FKKS): Handlungsanweisungen. Göttingen: Hogrefe. Strauß, B., & Richter-Appelt, H. (1996). Fragebogen zur Beurteilung des eigenen Körpers (FBeK). Göttingen: Hogrefe.

Note. Fragebogen zur Erfassung von Schmerzverarbeitung, FESV: Questionnaire for assessing pain processing; Frankfurter Körperkonzeptskalen, FKKS: Frankfurt body concept scales; Fragebogen zur Beurteilung des eigenen Körpers, FbeK: Questionnaire for the assessment of body perception.

5. Secondary assessments

Secondary outcomes were considered following IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) recommendations (Dworkin et al., 2005) and included pain symptoms, physical functioning, emotional functioning, treatment motivation and satisfaction. Having only included individuals with elevated pain-related fear, we were also interested in treatment effects on this outcome (see Table 3).

5.1. Physiological Assessments

Saliva samples from each participant were collected to extract salivary cortisol (marker for HPA axis activity) and salivary alpha-amylase (marker for ANS activity) during the Behavioral Avoidance Test (BAT-back) (Holzapfel, Riecke, Rief, Schneider, & Glombiewski, 2016). In this test participants first observed the investigator; they then had to repeatedly lift a water crate themselves (see Fig. 2). Hair cortisol samples were taken as a marker for long-term stress. As some male hair samples were too short, they could not be included in our later analysis (see Tables 5 and 6). For further details see Supplementary Material: Physiological Assessments.

6. Statistical Analyses

6.1. Primary Assessments

Our statistical analyses of primary assessments were conducted with the R package. The data were initially analyzed on an individual level via the single-case randomization test (SCRT) (Bulté, & Onghena, 2013). The null hypothesis (= no mean difference between baseline vs. respective treatment phase) was tested against the one-tailed alternative hypothesis (= significant decrease in pain symptoms/increase in treatment processes during the respective intervention phase). Second, we used the single-case meta-analysis (SCMA) to pool p-values based on Edgington's additive approach. We also calculated pooled standardized mean differences (SMD) across participants in each group.

6.2. Secondary assessments

Statistical analyses of the main assessments were conducted with the SPSS package. We calculated the reliable change index (RCI) and clinically significant change (CSC) to evaluate the practical importance of treatment effects. For further details see Supplementary Material: Statistical Analysis of Secondary Assessments.

6.3. Physiological Assessments

Physiological measures were analyzed using visual inspection and descriptive values. We calculated the difference between baseline (pre-BAT-back) and +25 min value for cortisol (Δcort) and baseline (pre-BAT-back) to post-BAT-back value in alpha-amylase (Δaa) to analyze the expected peak in the respective parameters. We also calculated the slope of both salvia parameters throughout the entire assessments.

7. Results

7.1. Treatment Fidelity

Both groups fulfilled our preset criterion of good protocol adherence (EXP: 83%, SD = 9.49; CBT: 86%, SD = 6.99). No prohibited elements occurred in either treatment group. For session differentiation, 100% of the sessions were correctly allocated. Sufficient treatment fidelity was therefore assured.

Table 3
Secondary assessments.

	Description	Reference
Fear Avoidance:		
Pain Anxiety Symptom Scale, PASS-D20	20-item self-rating instrument to assess pain-related fear	McCracken, L. M., & Dhingra, L. (2002). A short version of the Pain Anxiety Symptom Scale (PASS-20): preliminary development and validity. Pain Research and Management, 7(1), 45–50.
Pain Catastrophizing Scale, PCS	13-item self-rating instrument to assess pain-catastrophizing thoughts	Sullivan, M. J. L., Bishop, S. R., & Pivik, J. (1995). The Pain Catastrophizing Scale: development and validation. Psychological Assessment, 7(4), 524–32.
Photograph Series of Daily Activities, PHODA	40 photographs to assess perceived harmfulness pursuing daily activities	Leeuw, M., Goossens, M. E. J. B., van Breukelen, G. J. P., Boersma, K., & Vlaeyen, J. W. S. (2007). Measuring perceived harmfulness of physical activities in patients with chronic low back pain: the Photograph Series of Daily Activities - short electronic version. The Journal of Pain, 8(11), 840–49.
Behavioral Avoidance Test, BAT-back	Behavioral test to assess safety and avoidance behaviors 1) Observation phase: Investigator performs three isolated sequences of movements (bending forward, lifting a water crate, and rotating). 2) Execution phase: Participants repeatedly lift the water crate (no more than ten times)	Holzapfel, S., Riecke, J., Rief, W., Schneider, J., & Glombiewski, J. A. (2016). Development and validation of the behavioral avoidance test -back pain (BAT-Back). Clinical Journal of Pain, 32(11), 940–947.
Pain Symptoms:		
Brief Pain Inventory, BPI	Items 13–15 to assess highest, lowest, average, and current pain intensity during the past week	Cleeland, C. S., & Ryan, K. (1994). Pain assessment: global use of the Brief Pain Inventory. Annals of the Academy of Medicine Singapore, 23(2), 129–38.
Physical Functioning:		
Pain Disability Index, PDI	7-item self-rating instrument to assess subjective disability to participate in essential life activities (e.g. leisure activity)	Dillmann, U., Nilges, P., Saile, H., & Gerbershagen, H. U. (1994). Behinderungseinschätzung bei chronischen Schmerzpatienten [Disability assessment in chronic pain patients]. Schmerz [Pain], 8(2), 100–110.
Quebec Back Pain Disability Scale, QBPDS	20-item self-rating instrument to assess behavior-specific disability pursing daily activities (e.g. climbing stairs)	Kopec, J. A., Esdaile, J. M., Abrahamowicz, M., Abenhaim, L., Wood-Dauphinee, S., Lamping, D. L., & Williams, J. I. (1995). The Quebec Back Pain Disability Scale. Measurement properties. Spine, 20(3), 341–52.
Emotional Functioning:		
Hospital Anxiety and Depression Scale, HADS-D	14-item self-rating instrument to assess depression and anxiety symptoms during the past week	Zigmond, A. S., & Snaith, R. P. (1983). The Hospital Anxiety and Depression Scale. Acta Psychiatrica Scandinavica, 67(6), 361–70.
Treatment Motivation and Satisfaction:		
Motivation	4-item self-rating instrument to assess treatment motivation	Self-developed questionnaire
Satisfaction	10-item self-rating instrument to assess treatment motivation	Self-developed questionnaire

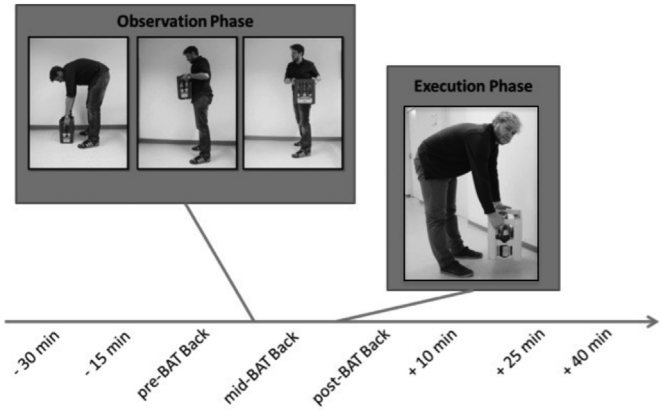

Fig. 2. Collection of salvia samples during the Behavioral Avoidance Test (BAT Back) at pre-treatment, post-treatment, and 6-months follow-up. The BAT Back consisted of observation phase: study participants observed the investigator performing three isolated sequences of movements (bending forward, lifting a water crate, and rotating), and execution phase: participants were instructed to repeatedly lift the water crate themselves (no more than ten times). Salvia samples were taken 8 times: (1) −30 min, (2) −15 min and (3) immediately prior to the observation phase, (4) between the observation and execution phase, (5) immediately after the execution phase, as well as (6) +10 min, (7) +25 min, (8) +40 min delayed.

7.2. Primary Assessments

For EXP, we noted significant changes ($p \leq .05$) in pain perception (SMD = −.50), perceived harmfulness of personally-relevant activities (SMD = −.40), self-efficacy (SMD = 1.07), pain acceptance (SMD = 1.16), and body confidence (SMD = 1.18) during exposure, but not during psycho-educational elements. Only changes in self-reported exposure reached the level of significance during follow-up (SMD = .93; $p \leq .05$). For CBT, we observed no significant changes across patients in either comparison. We did, however, identify significant changes ($p \leq .05$) in the difficulty of performing personally-relevant activities (SMD = −.62) and their expected harmfulness *before* engaging in these activities (SMD = −.13) during follow-up. Meta-analytic results are presented in Table 4.

8. Results of secondary assessments

8.1. Fear-avoidance

Our secondary assessment results are presented in Tables 5 and 6 For EXP, the highest number of participants reported clinically-relevant symptom reductions in pain-related anxiety (PASS-D20: Post = 3(66.7%); FU = 3(66.7%)), followed by pain catastrophizing (PCS: Post = 2(33.3%); FU = 1(16.7%)), perception of the harmfulness of daily activities (PHODA: Post = 1(16.7%); FU = 1(16.7%)), and avoidance behavior (BAT-back: Post = 2(33.3%); FU = 1(16.7%)). For CBT, fewer participants reported clinically-relevant symptom reductions in pain-related anxiety (PASS-D20: Post = 1(16.7%); FU = 1(16.7%)), pain catastrophizing (PCS: Post = 1(16.7%); FU = 1(16.7%)), and avoidance behavior (BAT-back: Post = 1 (16.7%)).

8.2. Pain intensity

For EXP, about one in three patients reported clinically-relevant symptom reductions in highest pain intensity (Post = 2(33.3%); FU = 1(16.7%)) and average pain intensity (Post = 2(33.3%)). For CBT, we noted clinically-relevant symptom reductions in average pain

Table 4
Meta-analytical results of patients in the exposure (EXP) and cognitive behavioral therapy (CBT) condition.

	EXP condition			CBT condition				
	Psycho-edu. (1–4)	Exposure (5–10)	FU	Psycho-edu. (1–3)	Behav. elements (4–6)	Cog. Elements (7–10)	Combination (4–10)	FU
Symptoms:								
Pain intensity (now)	.24	.24	.70	.35	.49	.34	.55	.06
Pain intensity (av)	.33	.06	.44	.07	.09	.34	.41	.05
Pain perception	.13	≤ **.05**	.22	.14	.43	.09	.47	.05
Disability	.06	.07	.24	.62	.23	.23	.31	≤ **.05**
Expectation	.19	.06	.07	.32	.47	.74	.60	≤ **.05**
Harmfulness	.06	≤ **.05**	.15	.73	.50	.18	.43	.17
Treatment processes:								
Self-efficacy	.75	≤ **.05**	.26	.63	.23	.35	.12	.34
Positive thoughts	.90	.43	.17	.40	.57	.14	.22	.50
Acceptance	.86	≤ **.05**	.15	.59	.66	.15	.88	.55
Exposition	.70	.24	≤ **.05**	.75	.73	.71	.23	.99
Cognitive anxiety	.86	.08	.26	.74	.48	.15	.76	.16
Catastrophizing	.86	.09	.51	.53	.56	.42	.33	.07
Body confidence	.84	≤ **.05**	.15	.80	.74	.31	.47	.46

Note. Individual p-values were combined by Single-Case-Meta-Analysis (SCMA) using the Edgington's additive approach.

intensity (Post = 2(33.3%); FU = 1(16.7%)) and current pain intensity (Post = 1(16.7%); FU = 3(50%)).

8.3. Physical functioning

Patients reported clinically-relevant reductions in their subjective disability (Post = 2(33.3%); FU = 1(16.7%)) and behavior-specific disability (Post = 2(33.3%); FU = 3(50%)) only in conjunction with EXP.

8.4. Emotional functioning

For EXP, about one in three patients reported clinically-relevant reductions in their depressive (Post = 2(33.3%)) and anxiety symptoms (Post = 2(33.3%); FU = 1 (16.7%)). For CBT, some patients reported reliable reductions in their depressive (FU = 1(16.7%)) and anxiety symptoms (FU = 1(16.7%)).

8.5. Motivation and satisfaction with treatment

The average treatment motivation for EXP (Pre: M = 33.5, SD = 2.4) and CBT (Pre: M = 34.5, SD = 3.6) was equally high before treatment. Patients in EXP (Post: M = 86.2, SD = 9.4) and CBT (Post: M = 90.7, SD = 6.2) reported similarly high treatment satisfaction at post-treatment.

8.6. Physiological Assessments

We detected no pattern of increase in cortisol or alpha-amylase during the BAT Back at the expected peaks (see Tables 5 and 6). The delta and slope values rather suggest a decrease or no difference in both parameters regardless of group and assessment. Visual inspection

Table 5
Results of secondary assessments of participants in the exposure (EXP) condition.

	Pre M (SD)	Post M (SD)	RCI (%)	CSC (%)	FU M (SD)	RCI (%)	CSC (%)
Fear-avoidance							
PASS-D20	53.2 (6.2)	32.7 (14.1)	1 (16.7)	3 (66.7)	30.3 (17)	1 (16.7)	3 (66.7)
PCS	22.8 (7.1)	16.3 (7.3)	–	2 (33.3)	19.5 (8.4)	–	1 (16.7)
PHODA	50.7 (8.1)	41.6 (23.4)	1 (16.7)	1 (16.7)	45.5 (23.4)	1 (16.7)	1 (16.7)
BAT Back	26.7 (9.2)	24.5 (8.6)	–	2 (33.3)	32.7 (11.5)	1 (16.7)	1 (16.7)
Pain (BPI)							
highest	7.3 (2)	7.3 (2.3)	–	2 (33.3)	5 (2.2)	2 (16.7)	1 (16.7)
lowest	3 (1.7)	2.5 (1.5)	–	–	7.2 (1.6)	–	–
average	5.2 (1.2)	4.8 (1.9)	1 (16.7)	2 (33.3)	3.3 (2.4)	–	–
current	4.3 (1.9)	4.8 (2)	–	–	5.3 (1.6)	–	–
Physical functioning							
PDI	30 (7.3)	27.5 (13.3)	–	2 (33.3)	32 (12.2)	–	1 (16.7)
QBPDS	47.5 (8.6)	37.3 (11.9)	–	2 (33.3)	36.5 (10.4)	–	3 (50)
Emotional functioning							
HADS-D	11.5 (3.9)	7.2 (3.1)	–	2 (33.3)	9 (2.5)	1 (16.7)	–
HADS-A	10.3 (3.4)	6.5 (4)	–	2 (33.3)	8.5 (3.7)	–	1 (16.7)
Cortisol							
Δcort	−1.0 (0.5)	−0.4 (0.5)	–	–	−0.3 (1.3)	–	–
slope	−0.03(0.01)	−0.02(0.02)	–	–	−0.01(0.02)	–	–
Alpha-amylase							
Δaa	−24.6(58.4)	−17.6(64.9)	–	–	−5.8(42.7)	–	–
slope	−0.5 (0.7)	0.3 (0.5)	–	–	−0.2 (0.6)	–	–
Hair cortisol	12.3 (14.0)	13.5 (5.2)	–	–	15.4 (15.7)	–	–
	n = 5	n = 4			n = 3		

Note. Secondary assessments including psychobiological measures were made at pre-treatment, post-treatment, and 6-month follow-up. Values represent means (standard deviations) and number (percentage) of participants with reliable and/or clinically significant change. PASS-D20, Pain Anxiety Symptom Scale; PCS, Pain Catastrophizing Scale; PHODA, Photograph Series of Daily Activities; BAT Back, Behavioral Avoidance Test Back; BPI, Brief Pain Inventory; PDI, Pain Disability Index; QBPDS, Quebec Back Pain Disability Scale; HADS, Hospital Anxiety and Depression Scale.

Table 6
Results of secondary assessments of in the cognitive behavioral therapy (CBT) condition.

	Pre M (SD)	Post M (SD)	RCI (%)	CSC (%)	FU M (SD)	RCI (%)	CSC (%)
Fear-avoidance							
PASS-D20	47.5 (17.7)	41.8 (17.3)	–	1 (16.7)	41 (22.6)	–	1 (16.7)
PCS	30.5 (8.1)	24.5 (8.6)	–	1 (16.7)	26 (12.9)	–	1 (16.7)
PHODA	51.6 (4)	52 (7.7)	–	–	48.2 (9.5)	1 (16.7)	–
BAT Back	23 (4)	29.3 (14.5)	–	1 (16.7)	27.7 (6.9)	–	–
Pain (BPI)							
highest	7.7 (1.5)	8 (1.4)	1 (16.7)	–	3.8 (2.3)	2 (33.3)	–
lowest	2.3 (2.1)	2.5 (2.3)	–	–	8.2 (1.2)	–	–
average	5.5 (1.4)	4.8 (1.6)	–	2 (33.3)	1.8 (1.9)	–	1 (16.7)
current	4.7 (2.1)	3.5 (1.9)	1 (16.7)	1 (16.7)	4.7 (1.4)	–	3 (50)
Physical functioning							
PDI	32.7 (13.3)	30.3 (9.2)	1 (16.7)	–	31.5 (12.9)	1 (16.7)	–
QBPDS	49.3 (12.6)	47.3 (10.7)	2 (33.3)	–	51 (8.7)	1 (16.7)	–
Emotional functioning							
HADS-D	11.5 (2.6)	9.3 (3.3)	2 (33.3)	–	8.8 (3.6)	2 (33.3)	1 (16.7)
HADS-A	10.3 (4.8)	10.2 (4.8)	–	–	8.5 (5.8)	–	1 (16.7)
Cortisol							
Δcort	−0.1 (0.3)	−1.8 (1.4)	–	–	−0.4 (0.8)	–	–
Slope	−0.01(0.02)	−0.03(0.02)	–	–	−0.02(0.01)	–	–
Alpha-amylase							
Δaa	−21.5(35.9)	−7.7 (17.8)	–	–	−15.1(27.1)	–	–
slope	0.7 (1.2)	−0.2 (0.6)	–	–	−0.7 (2.1)	–	–
Hair cortisol	4.2 (1.4)	4.6 (4.1)	–	–	10.2 (8.7)	–	–
	n = 5	n = 4			n = 3		

Note. Secondary assessments including psychobiological measures were made at pre-treatment, post-treatment, and 6-months follow-up. Values represent means (standard deviations) and number (percentage) of participants with reliable and/or clinically significant change. PASS-D20, Pain Anxiety Symptom Scale; PCS, Pain Catastrophizing Scale; PHODA, Photograph Series of Daily Activities; BAT Back, Behavioral Avoidance Test Back; BPI, Brief Pain Inventory; PDI, Pain Disability Index; QBPDS, Quebec Back Pain Disability Scale; HADS, Hospital Anxiety and Depression Scale.

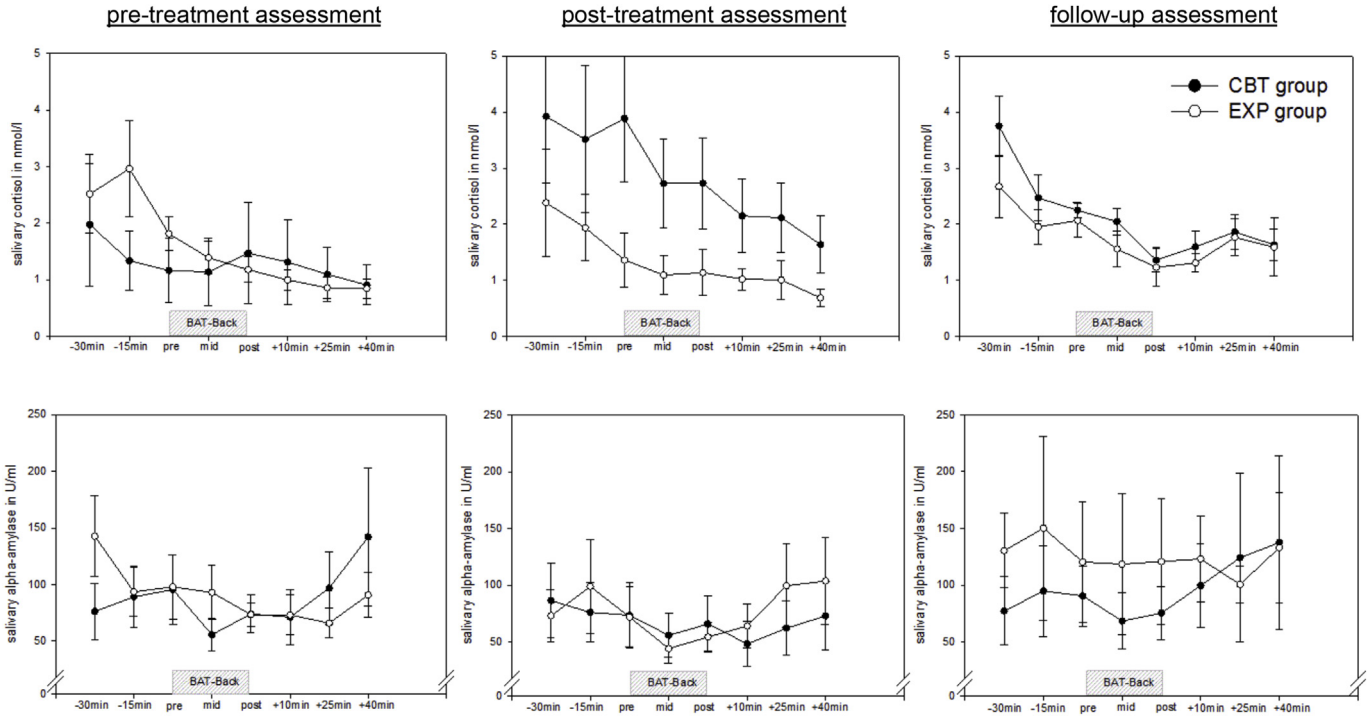

Fig. 3. Mean values and standard errors of salivary cortisol (reflecting HPA axis activity; top 3 graphs) and salivary alpha-amylase (reflecting ANS activity; bottom 3 graphs) of the participants in the cognitive behavioral therapy (CBT) condition and in the exposure (EXP) condition during the Behavioral Avoidance Test (BAT) at pre-treatment, post-treatment and 6-months follow-up.

suggested a decrease in cortisol and a slightly u-shaped curve for alpha-amylase during assessments (see Fig. 3). Notably, overall cortisol was apparently lower for EXP than CBT at post-assessment. This effect is not attributable to inter-individual differences (when compared with pre-assessment and follow-up) or time of day (which did not differ between groups).

Increases and decreases in hair cortisol were apparent in both groups between pre-treatment and post-treatment. Visual inspection suggested that hair-cortisol levels approached the pre-treatment value at follow-up in every participant who provided hair samples at all three assessments (see Fig. 4).

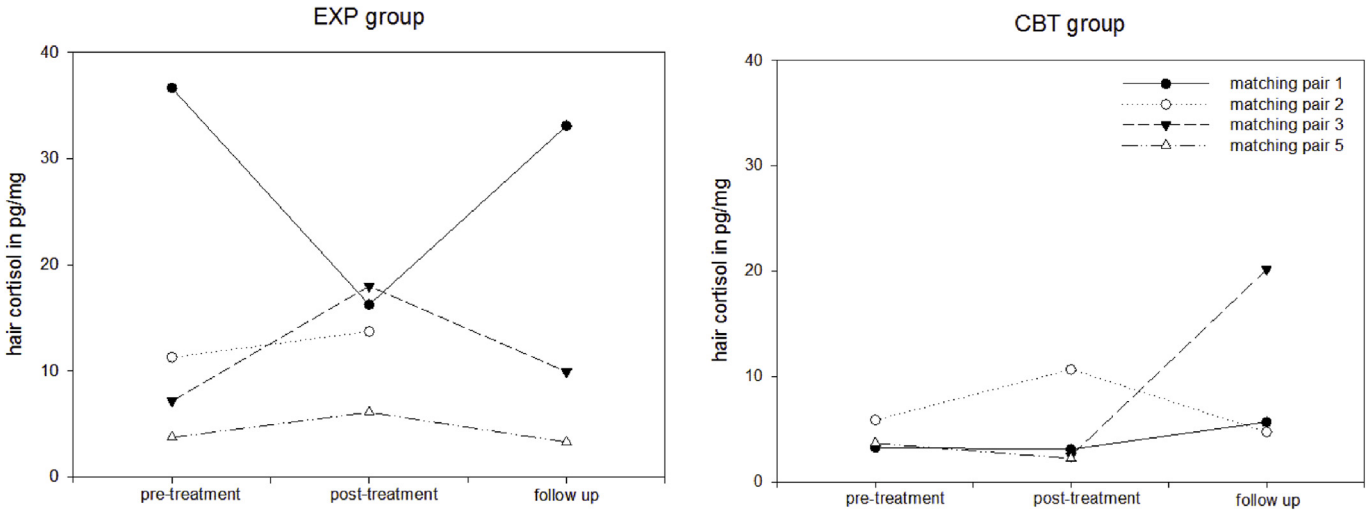

Fig. 4. Hair cortisol levels of matching pairs 1, 2, 3, and 5 in the cognitive behavioral therapy (CBT) condition and in the exposure (EXP) condition at pre-treatment, post-treatment and 6-months follow-up.

9. Discussion

9.1. Summary of our main findings

We were able to disentangle more and less effective treatment components during a specific (EXP) and general (CBT) treatment of CLBP using a single-case experimental design with multiple baselines. According to pooled effect sizes, EXP revealed immediate middle-to-large effects, while CBT showed delayed small-to-middle effects. Change occurred primarily during exposure but not during educational sessions when taking the EXP approach. Exposure sessions led to modifications in pain perception, in the perceived harmfulness of personally-relevant activities, self-efficacy, pain acceptance, and body confidence. We identified no isolated or especially strong elements taking the CBT approach.

The key message of our study is that, as far as measurements taken immediately after treatment suggest, exposure was the most effective intervention offered for CLBP and elevated pain-related fear. Psychoeducational sessions alone were ineffective. CBT and EXP revealed "sleeper effects", namely changes in other variables at follow-up than during treatment.

9.2. Treatment processes during EXP therapy

In line with results from previous Stage I single-case studies (e.g. Vlaeyen et al., 2001), we found that change mainly occurred during exposure sessions. EXP exhibited a strong impact on pain-related fear. We are the first to demonstrate that EXP immediately initiates other improvements such as increases in self-efficacy, pain acceptance, and body confidence. Our findings reveal no effect from the first educational sessions. The educational sessions were held with a physician in another study (de Jong et al., 2005). It is therefore possible that our educational intervention (relying mainly on video material) was not robust enough. One could also argue that, being less effective, psychoeducational sessions could be omitted or shortened to achieve maximum "expectation violation" in exposure sessions (Craske et al., 2014).

9.3. Treatment processes during CBT therapy

We observed no indication of particularly powerful therapy elements during CBT. Dose effects could explain our results. While patients in the EXP condition experienced five sessions of the same technique, those in the CBT condition were introduced to more techniques within less time. Another potential explanation our data supports is that CBT reveals its effects through delayed cognitive changes that cannot be identified during the week after a therapy session.

9.4. Delay and maintenance of treatment processes

Interestingly, both CBT and EXP appeared to initiate changes that only evolved during follow-up. While EXP elicited later changes in self-reported exposure, CBT facilitated changes in the difficulty of performing personally-relevant activities and their expected harmfulness. Patients were perhaps only able to practice and transfer new coping strategies to their everyday life after treatment. This might be an important limitation in our earlier assumption of time-contingent changes. Other previously-relevant changes during the exposure phase, however, disappeared during follow-up. This raises the question of how to sustain therapeutic change.

9.5. Alignment of our main assessments

The percentages of patients experiencing clinically significant changes ranged from 16.7% to 66.7% for EXP and from 16.7% to 50% for CBT depending on the outcome and time of measurement. Some measures revealed that no patient experienced any clinically significant improvement (e.g. in pain intensity). Our results resemble other study findings. In a more representative study on the clinical effectiveness of a multi-disciplinary treatment (Morley, Williams, & Hussain, 2008), the percentage of clinically significant improvements was 13% for average pain intensity (compared to 0%–33.3% in the present study) and 14–19% for depressive and anxiety symptoms (compared to our study's 0%–33.3%). For EXP, Leeuw et al. (2008) found clinically significant improvements in functional disability ranging from 34% to 58% (compared to 16.7%–50% in their EXP group). Note that we detected no clinically-relevant effect of CBT on disability in our study.

We are the first to investigate the cortisol and alpha-amylase response to pain-related movements in a group of CLBP patients scoring high on pain-related fear. The fact that participants in our EXP group presented lower cortisol levels at post-treatment than the CBT group could be associated with their stronger improvement in anxiety symptoms. However, this effect must be interpreted with caution in light of

our small sample size. Of note: changes in hair cortisol occurred and seemed to return to pre-treatment levels at follow-up. More research is needed on treatment effects on hair cortisol and potential moderating factors that contribute to changes in the cortisol concentration.

9.6. Strengths and limitations

Strengths of this study include the use of multiple baselines, matching of individuals, detailed treatment manuals, verification of treatment fidelity, inclusion of psychobiological measures, and daily assessments during the follow-up phase.

There are also some limitations. In contrast to traditional group-based research, single-case designs examine individual treatment effects before accumulating results from similar patients. In this study, we only included pain patients with elevated pain-related fear. Subsequent studies are needed to verify our results' general validity, perhaps by investigating other subgroups of chronic pain patients. Second, we only relied on self-report measures in our primary assessments. Making daily assessments in an outpatient setting introduced various other sources of error (e.g. large amounts of missing data, technical difficulties). Third, 33% of our randomized sample dropped out or were excluded from the later analyses. For example, we were forced to exclude three participants with > 50% missing values, raising concerns of possible motivational bias. A fourth limitation is that usually, matching pairs should be allocated to the same therapist to control for cofounding effects. Due to organizational difficulties this was impossible for two of the six pairs.

10. Conclusion

Our results indicate that while exposure experience initiated several immediate treatment processes, cognitive-behavioral interventions build their effect only later in time. Exposure treatment was especially effective in the short-term, initiating several different processes and leading to lower stress responses to a behavioral test after treatment. We thus strongly recommend integrating exposure elements in the management of CLBP to raise its efficacy. Psycho-educational sessions might be unnecessary or at least 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.

To conclude: single-case experimental designs enable us to investigate specific change processes triggered by isolated treatment elements. They are nevertheless limited in describing delayed change processes. Studies matching patient characteristics to treatments are the future of psychotherapy research, especially in pain due to its very heterogeneous patient population. We regard our study as an initial step towards that future because we tested which and how treatment elements work in a subgroup of patients.

Conflicts of interest

This study was supported by a doctoral thesis scholarship from the Philipps-University Marburg. The authors have no conflicts of interests to declare.

Acknowledgments

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.brat.2018.07.002.

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