



# Sudden gains in routine care cognitive behavioral therapy for depression: A replication with extensions



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## ABSTRACT

**Background:** Over the last decade, a substantial amount of findings have been reported on the association between sudden gains (large symptom improvements in a between-session interval) and treatment outcome. Accurate replications of previous findings are needed to tackle inconsistencies and to shed light on the clinical implications of sudden gains. This study investigates whether similar effects of sudden gains can be expected under routine care conditions, when the patients are comparable to those examined in the original study by Tang and DeRubeis (1999).

**Method:** Using propensity score matching (PSM), 462 patients treated with cognitive behavioral therapy (CBT) under routine conditions were matched stepwise to patients of the original study on sudden gains, a randomized controlled CBT trial (RCT).

**Results:** After the application of PSM, the effects of sudden gains on treatment outcome were similar to those found by Tang and DeRubeis (1999). The closer the match between the RCT and the naturalistic sample, the more similar the association between sudden gains and treatment outcome.

**Conclusion:** Sudden gains seem to have a significant impact on recovery rates, even in treatments under routine care. Results suggest that one important aspect of replication success is to control for confounding baseline covariates.

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## 1. Introduction

Recently, the Open Science Collaboration (2015) conducted replications of 100 studies published in psychological journals and revealed a mean effect size of only half the magnitude of the original effects.

This substantial decline emphasizes the need to acknowledge a degree of uncertainty to what we believe we already know. Accordingly, concerns have been raised that publishing and analytic strategy are likely to be biased toward false positive findings (Ioannidis, 2005; Simmons, Nelson, & Simonsohn, 2011). Collaborative research and accurate replications are needed to verify previous findings and to overcome such bias. Reproducibility is, however, not well promoted in the scientific community and novelty is often prioritized over replication (Ioannidis, 2014; Schmidt, 2009).

Following these considerations, we want to address the

reproducibility of a framework known as *sudden gains*. This framework was developed by Tang and DeRubeis (1999) and can be utilized for a fine-grained analysis of individual change patterns. *Sudden gains* are defined as large between-session symptom improvements. Three criteria must be fulfilled to consider a rapid symptom shift a *sudden gain*: The improvement from one session to the next must be meaningful (a) in absolute terms, (b) in relation to symptom severity before the gain, and (c) relative to symptom fluctuations observed for that patient.

In recent years, a substantial amount of findings have been reported on sudden gains in a variety of treatments and psychopathologies. Initially, sudden gains were investigated in cognitive behavioral therapy for depression (Hardy et al., 2005; Lutz et al., 2012; Tang & DeRubeis, 1999; Tang, DeRubeis, Beberman, & Pham, 2005), subsequently in other treatments for depression such as interpersonal psychotherapy (Kelly, Cyranowski, & Frank, 2007; Lemmens, DeRubeis, Arntz, Peeters, & Huibers, 2016), family therapy (Gaynor et al., 2003), group therapy (Kelly, Roberts, & Ciesla, 2005) and even pharmacotherapy (Vittengl, Clark, & Jarrett, 2005). Sudden gains have also been found in various

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treatments for anxiety disorders (Hofmann, Schulz, Meuret, Moscovitch, & Suvak, 2006; Norton, Klenck, & Barrera, 2010), obsessive-compulsive disorders (Aderka, Anholt et al., 2012), posttraumatic stress disorders (Keller, Feeny, & Zoellner, 2014; Kelly, Rizvi, Monson, & Resick, 2009), bulimia nervosa and alcohol abuse (Wilson, 1999). Moreover, the reverse phenomenon of sudden gains, known as sudden losses, has been discussed (Lutz et al., 2012).

Although sudden gains seem to be a widespread phenomenon prevalent in several different interventions, there are inconsistencies regarding the association between sudden gains and ultimate treatment outcome. Tang and DeRubeis (1999) found that patients who experienced sudden gains (39.34% of the sample) revealed treatment outcomes superior to patients without sudden gains (Hedges'  $g_{\text{gain vs. no gain}} = 0.98$ ). Previous replications point in different directions. Hardy et al. (2005) were able to confirm Tang and DeRubeis (1999)' findings, whereas Stiles et al. (2003) revealed no considerable association between sudden gains and outcome. In their meta-analysis, Aderka, Nickerson, Bøe, and Hofmann (2012) found a mean effect size of sudden gains on outcome of Hedges'  $g_{\text{gain vs. no gain}} = 0.62$  (range: 0.03–1.19). The mean effect is composed of 19 studies ranging from large effects (Doane, Feeny, & Zoellner, 2010; Hardy et al., 2005; Tang & DeRubeis, 1999) to small or no effects (Kelly et al., 2007; Present et al., 2008; Stiles et al., 1996; Stiles et al., 2003). Further, Aderka, Nickerson et al. (2012) showed that smaller effects of sudden gains can be expected for so-called secondary outcomes, that is, when treatment outcome and sudden gains are assessed with different measures. The mean effect size of sudden gains on secondary outcomes was Hedges'  $g_{\text{gain vs. no gain}} = 0.34$  (range: 0.01–1.01).

There may be different explanations of these inconsistent findings concerning the association between sudden gains and treatment outcome. Apparently, it is important to apply a procedure for the identification of sudden gains comparable to that of Tang and DeRubeis (1999) in order to investigate the very same construct (Stiles et al., 2003). Moreover, divergent findings may be due to variation in the time points when sudden gains occur. Sudden gains experienced early in treatment tend to yield stronger effects than sudden gains experienced in later treatment sessions (Busch, Kanter, Landes, & Kohlenberg, 2006; Kelly et al., 2005; Stiles et al., 2003).

Results of process outcome research have shown that a significant proportion of variance in outcome is explained by the variance attributable to patient characteristics (e.g. Barber, 2007; DeRubeis, Gelfand, German, Fournier, & Forand, 2014; Delgadillo, Moreea, & Lutz, 2016). Similarly, there is a substantial variance across patients with regard to how they sustain a sudden gain. Some patients experience long lasting improvements, others only temporary improvements with a marginal effect on treatment outcome (Hardy et al., 2005; Stiles et al., 2003; Tang, Luborsky, & Andrusyna, 2002). Accordingly, we expect that even within the same treatment, the experience of a sudden gain may be more beneficial to some patients than to others. In a recent review, Kessler et al. (2016) showed that baseline variables such as intake symptom severity, number of comorbid disorders, age, employment status and marital status have been repeatedly found to predict treatment response for depressed patients. Consequently, these baseline variables may be associated with patients' differential ability to sustain a sudden gain and eventually to recover.

The analysis by Tang and DeRubeis (1999) is based on data drawn from two randomized controlled trials (RCT). Their sample is selective, as many patients encountered in clinical practice were excluded (see Fig. 1).

Different study designs (RCT and naturalistic studies) may vary in

their degree of clinical representativeness (Shadish, Navarro, Matt, & Phillips, 2000). Treatments in RCTs are usually carried out by intensively trained therapists using highly structured treatment manuals. Patients have to meet a series of specific inclusion criteria and treatment duration is restricted by standardization. However, in clinical practice, treatments are not subjected to comparable standardizations and patients are less homogeneous with respect to their diagnosis and socio-demographic variables. Findings observed in RCTs are not necessarily representative for treatments under routine care conditions (Castonguay, Barkham, Lutz, & McAleavey, 2013; Shadish et al., 2000). Currently, there is only little knowledge about the association of sudden gains and treatment outcome in clinical practice. The vast majority of findings are based on RCTs. For instance, Hardy et al. (2005) found effects, but their treatment context was subjected to standardizations comparable to RCTs. On the contrary, the treatment context of the study by Stiles et al. (2003) was less standardized, however, they were unable to show a meaningful association between sudden gains and outcome.

This points to the necessity of a further investigation of the generalizability of the original findings under routine care conditions. Ioannidis (2005; 2014) suggests improving practice by means of a culture of replication, which is based on appropriate statistical methods and on utilizing data and protocols from original studies. Following this recommendation, we based our replication on data adjusted by a statistical method known as propensity score matching (PSM). PSM offers a solution to reduce bias by balancing two samples based on a range of pretreatment differences (Rosensbaum & Rubin, 1983).

In a previous study, Lutz and colleagues demonstrated the merits of PSM adjustment for the comparison of treatments under routine care with those in RCTs. Their results suggest that cognitive behavioral therapy (CBT) for depression in clinical practice is equally effective as in RCTs when applied to comparable patients (Lutz, Schiefele, Wucherpfennig, Rubel, & Stulz, 2016). To our knowledge, Tang and DeRubeis (1999)' findings have yet to be replicated based on PSM adjustment.

This study aims at assessing the reproducibility of the original findings under routine care conditions with a high level of clinical representativeness according to the criteria by Shadish et al. (2000). In a first step, we applied the inclusion/exclusion criteria of the original sample to a routine care sample. Subsequently, we implemented PSM to enhance the comparability between samples and to adjust for confounding baseline variables. By doing so, we wanted to see if we could find a similar association between sudden gains and treatment outcome, when our patients are comparable to those examined by Tang and DeRubeis (1999).

## 2. Methods

### 2.1. Setting and patients

The routine care sample comprised a total of 462 patients treated at the University Outpatient Clinic Trier between 2010 and 2014. Applying the same inclusion and exclusion criteria used by Tang and DeRubeis (1999), 227 patients were eligible for this study (see section 2.3 sample selection).

All 227 patients included in our analysis had a primary diagnosis of major depression and received at least 8 sessions of individual treatment, with a mean treatment length of 36.67 sessions ( $SD = 17.32$ , interquartile range = 24–45). Treatment was provided by 89 therapists who took part in a three (full-time) or five year (part-time) postgraduate training program with a cognitive behavioral therapy (CBT) focus. All therapists had received at least one year of training before entering the study and were supervised by licensed CBT clinicians. According to German healthcare

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