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Do Sudden Gains Predict Treatment Outcome in Social Anxiety Disorder? Findings from Two Randomized Controlled Trials

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Abstract

Objective—Sudden gains (SGs) have been found to occur during randomized controlled trials (RCTs) for social anxiety disorder (SAD). Evidence is mixed whether SGs relate to treatment outcome in SAD. We examined SGs in two RCTs for SAD

Method—Study 1 (N = 68) examined SGs in individual cognitive-behavioral therapy (CBT), and Study 2 (N = 100) compared SGs in group CBT and Mindfulness-Based Stress Reduction (MBSR). Weekly ratings of social anxiety were used to calculate SGs. The Liebowitz Social Anxiety Scale-Self-Report and the Social Interaction Anxiety Scale were completed at pretreatment, posttreatment, and follow-up to assess outcome

Results—In Study 1, 17.6% of participants experienced a SG. Participants with SGs started and ended treatment with lower social anxiety. SGs were not associated with greater decreases in social anxiety from pre- to posttreatment or 12-month follow-up. In Study 2, SGs occurred in 27% of participants and at comparable rates in MBSR and group CBT. SGs were not associated with changes in social anxiety during treatment in either condition.

Conclusion—SGs occurred during treatment for SAD. In both RCTs, participants improved regardless of experiencing a SG, suggesting that SGs are not predictive of greater improvement during treatment for SAD.

Keywords

social anxiety; sudden gains; mindfulness-based stress reduction; cognitive behavioral therapy

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Sudden gains (SGs) are defined as rapid improvements in symptoms typically occurring between two subsequent sessions. Tang and DeRubeis (1999) suggested that, in order for a reduction in symptoms to be considered a SG, the gain must be large in absolute magnitude, represent a decrease of 25% in symptom severity from one session to the next, and be stable across time following the session in which the gain is detected. SGs were initially identified and examined by Tang and DeRubeis (1999) in the context of depression and have since become an important focus of treatment outcome research.

Initially, SGs in depression symptoms were thought to be a phenomenon particularly relevant to cognitive-behavioral therapy (CBT), and SGs were associated with cognitive changes in the session prior to the gain (Tang & DeRubeis, 1999; Tang, DeRubeis, Beberman, & Pham, 2005). However, SGs have been found to occur at similar rates in non-CBT approaches, such as supportive-expressive therapy, although these gains were less stable than those occurring in CBT (Tang, Luborsky, & Andrusyna, 2002). SGs have also been reported in pill placebo and pharmacotherapy for depression (Vittengl et al., 2005). SGs appear to predict greater improvement in depression at posttreatment (Gaynor et al., 2003; Stiles et al., 2003; Vittengl, Clark, & Jarrett, 2005) and lower rates of relapse in the two years following treatment (Tang et al., 2007).

Given findings regarding the importance of SGs in the treatment of depression, researchers have endeavored to determine whether SGs occur during the treatment of other mental and emotional disorders and, if so, whether they are related to greater improvements following treatment. SGs have been identified during treatment of disorders such as generalized anxiety disorder, posttraumatic stress disorder, panic disorder, and obsessive-compulsive disorder (Aderka, Anholt, et al., 2012; Clerkin, Teachman, & Smith-Janik, 2008; Doane, Feeny, & Zoellner, 2010; Kelly, Rizvi, Monson, & Resick, 2009; Present et al., 2008). A meta-analysis on SGs in anxiety and depression suggests that SGs are related to better outcome following treatment, and these effects are stronger in CBT than in other treatments (Aderka, Nickerson, Bøe, & Hofmann, 2012). To date, only three studies have investigated the occurrence of SGs during randomized controlled trials (RCTs) for social anxiety disorder (SAD; Bohn, Aderka, Schreiber, Stangier, & Hofmann, 2013; Hofmann, Schulz, Meuret, Moscovitch, & Suvak, 2006; Thorisdottir, Tryggvadottir, Saevarsson, & Bjornsson, 2018). Each of these studies reported that SGs occurred during treatment for SAD; however, these studies yielded different findings regarding whether or not SGs were related to indices of treatment outcome.

Hofmann et al. (2006) were the first to investigate SGs in the treatment of SAD. The authors used a definition of SGs consistent with that put forth by Tang and DeRubeis (1999). First, the gain was required to surpass a cutoff score on the Liebowitz Social Anxiety Scale (LSAS; Liebowitz, 1987) determined by the reliable change index, defined as the mean difference between pretreatment and posttreatment scores divided by the standard error of the difference scores (Jacobson & Truax, 1991). Additionally, the gain had to represent a reduction greater than 25% of the LSAS score at the pre-gain session, and there had to be a significant difference, as determined by an independent samples *t*-test, between the mean of the three pre-gain sessions and the mean of the three post-gain sessions. Hofmann and colleagues (2006) found that 18.7% of participants experienced SGs, and similar rates of

SGs occurred during cognitive-behavioral group therapy (CBGT) and exposure group therapy. Participants who experienced SGs began treatment with higher LSAS scores than those who did not experience SGs. Those with SGs also had greater reductions in social anxiety across treatment compared to those without SGs, but there was no difference between those with and without SGs at 6-month follow-up. There were no differences in improvement of those with SGs in CBGT and exposure group therapy, suggesting that experiencing a SG is not more beneficial in one type of therapy over another. Further, prior cognitive change did not predict SGs, nor did SGs predict whether a participant had a diagnosis of major depressive disorder at baseline. Thus, there was limited initial support for the importance of SGs in treatment outcome for SAD.

Bohn et al. (2013) examined SGs during individual cognitive therapy (CT) and interpersonal therapy (IPT) for SAD. Scores on the 6-item Social Phobia Weekly Summary Scale (Clark et al., 2003) were utilized to calculate SGs based on the original definition proposed by Tang and DeRubeis (1999) and consistent with that implemented by Hofmann et al. (2006). They found that 22.4% of individuals demonstrated SGs during treatment; rates and magnitudes of SG were similar in CT and IPT. When considering the treatments together, SGs were associated with greater decreases in social anxiety from pre- to posttreatment, and SGs were related to lower social anxiety at follow-up on the LSAS but not on the Social Phobia Inventory (SPIN: Connor et al., 2000). Those who experienced a SG in CT had significantly lower scores at posttreatment than those who experienced a SG in IPT on the SPIN but not the LSAS, contributing mixed evidence that treatment modality interacts with SG status. Similar to Hofmann et al. (2006), Bohn and colleagues (2013) found that cognitive changes did not predict subsequent SGs. However, negative cognitions and beliefs appeared to decrease in severity during and after SGs. Additionally, SGs did not predict changes in depression or general symptom distress. Overall, Bohn et al. (2013) contributed some evidence that SGs may improve treatment outcome for SAD.

Thorisdottir et al. (2018) conducted the third study of SGs during treatment of SAD comparing CBGT to non-specific group psychotherapy. However, the researchers modified the definition of SG proposed by Tang and DeRubeis (1999) and implemented by Hofmann et al. (2006) and Bohn et al. (2013). Rather than utilize an independent samples *t*-test comparing scores in the three sessions prior to three sessions following the gain, they utilized a reduction of at least 1.5 standard deviations compared to the participant's mean score as the third criterion. Furthermore, both the Brief Fear of Negative Evaluation-Straightforward items (BFNE-S; Rodebaugh et al., 2004; Weeks et al., 2005) and the Social Interaction Phobia Scale (SIPS; Carleton et al., 2009) were used to identify SGs, and participants could demonstrate SGs on either measure. About one-fifth (22.2%) of participants experienced a SG. SGs were not predictive of treatment response, meaning that those with and without SGs demonstrated similar posttreatment and follow-up improvements. Those who experienced SGs in non-specific group psychotherapy showed greater improvements than those with SGs in CBGT. This study presents further evidence that SGs are not exclusively related to CBT for SAD and can also be related to better outcomes in non-specific therapy.

The previous three studies present several discrepancies in their findings which warrant continued investigation. Whereas Hofmann et al. (2006) found no differences in the effects of SGs between treatment types, Bohn et al. (2013) and Thorisdottir et al. (2018) identified differences in the degree of reduction in social anxiety for those with SGs depending on treatment condition. Furthermore, Hofmann et al. (2006) found that SGs were not predictive of lower social anxiety at follow-up, whereas Bohn et al. (2013) found that SGs were predictive of lower social anxiety at follow-up on some measures. There are a few methodological differences which may explain differences in findings. Thorisdottir et al. (2018) utilized a different definition of SGs and allowed for SGs to occur on either the BFNE-S or the SIPS, which makes comparison of findings regarding the effects of SGs difficult. Therapy was administered individually by Bohn et al. (2013) and in groups in Hofmann et al. (2006) and Thorisdottir et al. (2018), which may also contribute to differences in findings. It remains to be determined whether SGs are associated with significantly greater improvements in symptoms following treatment for SAD and whether these improvements are stable across the follow-up period. Finally, SGs in SAD have been demonstrated in the context of CBT, group exposure therapy, IPT, and non-specific group psychotherapy. Exploration of the SG phenomenon in additional treatment contexts is warranted.

In the current studies, we aimed to clarify the research on SGs in treatment of SAD. We examined the relationship between SGs and treatment outcome in two separate RCTs for SAD. Study 1 was an RCT examining the efficacy of individual CBT compared to a waitlist for SAD. We predicted that SGs would occur in CBT. Based on findings in Bohn et al. (2013) and a meta-analysis on the effects of SGs in treatment for anxiety and depression (Aderka, Nickerson et al., 2012), we expected that those who experienced SGs would demonstrate greater reductions in social anxiety from pre- to posttreatment and that greater reductions would be maintained at follow-up. We also examined whether SGs were associated with changes in depression, life satisfaction, and cognitive reappraisal. Study 2 compared CBGT and Mindfulness-Based Stress Reduction (MBSR) for SAD. We predicted that SGs would occur in both CBGT and MBSR at comparable rates. We expected that, in both CBGT and MBSR, SGs would be related to greater reductions in social anxiety from pre- to posttreatment and that greater reductions would be maintained at follow-up. Additionally, we predicted that the effects of SGs on reductions in social anxiety across treatment would be greater for those in CBGT compared to MBSR given the prior research suggesting that the effect sizes of SGs are greater in CBT interventions (Aderka, Nickerson, et al., 2012). Finally, we explored whether SGs were associated with changes in depression, life satisfaction, cognitive reappraisal, and cognitive distortions.

Study 1

Method

Participants—Participants were drawn from an RCT which included 75 adults who met criteria for generalized SAD based on the Anxiety Disorders Interview Schedule for the *Diagnostic and Statistical Manual of Mental Disorders, 4th edition* (DSM–IV; American Psychiatric Association, 1994)-Lifetime Version (ADIS-IV-L; Di Nardo, Brown, & Barlow,

1994). The full CONSORT figure is available in Goldin et al. (2012). Participants ($N = 68$) were included in the current study if they had weekly ratings for at least 4 of the 16 therapy sessions, as that is the minimum number of sessions required to calculate a sudden gain. Given that participants completed an fMRI appointment as part of the RCT, inclusionary criteria also included passing a magnetic resonance safety screen and right handedness. Participants were excluded for comorbid diagnoses of current major depressive disorder, bipolar or affective disorders, substance abuse, post-traumatic stress, obsessive-compulsive, or thought disorders, or incomplete baseline assessments. Additionally, participants were excluded if they were currently in psychotherapy, using psychotropic medications, had been in CBT in the past, or had any history of cardiovascular or neurological disorders which could impact psychological functioning or cerebral blood flow. All participants provided informed consent, and the study was approved by the Stanford University Institutional Review Board.

Procedure—Participants were recruited through the community and clinician referrals. Clinical psychologists administered the ADIS-IV-L to determine whether participants met criteria for generalized SAD based on DSM–IV criteria. To meet criteria for generalized SAD, patients had to endorse greater than moderate social fear in five or more different social situations. Clinicians rated the severity of the diagnosis on a scale from 0 to 8, with a rating of 4 or greater required for diagnosis. Participants with generalized SAD were randomized to begin individual CBT or be placed on a waitlist (WL). WL participants received treatment following the waiting period, and in the current study we utilized data from all participants as they underwent treatment. Overall, 57 participants from the immediate CBT and WL conditions were considered treatment completers.

Treatment—Individual CBT was administered using *Managing Social Anxiety: A Cognitive-Behavioral Therapy Approach,* a manualized protocol which includes a therapist guide (Hope, Heimberg, & Turk, 2006) and a client workbook (Hope, Heimberg, Juster, & Turk, 2000). The protocol included 15 one-hour weekly sessions and one 90-minute session for the first in-session exposure. Therapists initially administered the protocol to non-study participants as part of their training. Adherence to protocol was assessed during the study, and therapists were highly adherent (see Goldin et al., 2012).

Definition of Sudden Gains—Weekly ratings (described below) were used to calculate SGs, and three criteria were utilized. *Criterion A* required that the magnitude of the gain be large in absolute terms. To calculate this, we used the reliable change index, dividing the mean change score from baseline to posttreatment by the standard error of the difference scores (a change of 8.12 points on the weekly rating). Decreases in weekly rating scores were required to be greater than the reliable change index to be considered a SG. *Criterion B* required that the gain be large relative to the previous week's score, which is represented by a 25% decrease from the previous week's score. *Criterion C* required that the gain be maintained over time, so independent-sample *t*-tests were conducted to compare means of scores from the three sessions prior to a SG and the three sessions following the SG.[1] The mean of scores in the three post-gain sessions must be significantly lower than the mean of scores in the three pre-gain sessions. To be included in this analysis, data had to be present

for at least two of the three sessions prior to the gain and two of the three sessions following the gain. If data were missing from a given session, it was not possible to calculate a SG occurring between that session and the one immediately prior to that session. Baseline and posttreatment weekly ratings were included as "sessions" so that gains which occurred immediately prior to session 2 or session 16 could be included as SGs based on Criterion C. Of the 1,088 sessions, 253 sessions (23%) had missing data.

Measures—Weekly ratings of the severity of social anxiety were gathered using six items designed to assess facets of social anxiety. Three items asked about preoccupation with anxiety in anticipation of, during, and following social events. The remaining three items asked participants to rate the intensity, distress, and interference of social anxiety. Participants were asked to focus on the past week when rating items on a 0 ("not at all") to 100 ("always") scale. Items were averaged to create a composite weekly rating of social anxiety. Cronbach's alpha values for the weekly ratings at each session were excellent and ranged from .985 to .997.

The Liebowitz Social Anxiety Scale-Self Report (LSAS-SR; Fresco et al., 2001; Liebowitz, 1987) comprises 13 performance situations and 11 social interaction situations and asks participants to rate both the severity of fear and anxiety experienced in a given situation from 0 (none) to 3 (severe) and the degree of avoidance of the situation from 0 (never) to 3 (usually; 68–100% of the time). Scores are summed to create a total score of social anxiety severity ranging from 0–144. The LSAS-SR demonstrates excellent convergent validity as it correlates highly with other commonly used measures of social anxiety and avoidance such as the Social Interaction Anxiety Scale and the Social Phobia Scale (Fresco et al., 2001; Mattick & Clarke, 1998). It has demonstrated adequate discriminant validity, as shown by comparisons of correlations between the LSAS-SR and other measures of social anxiety versus measures of depression such as the Beck Depression Inventory (Fresco et al., 2001). The total score has shown adequate test-retest reliability over a 12-week interval ($r = .83$; Baker, Heinrichs, Kim, & Hofmann, 2002) and demonstrated good internal consistency in a sample of patients with SAD ($\alpha = .95$) and among controls ($\alpha = .94$; Fresco et al., 2001). In the current sample, the internal consistency of the LSAS-SR was excellent at baseline ($\alpha = .91$).

The Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998) comprises 20 items which are used to assess anxiety and fear surrounding social interactions in dyads and groups. For example, one item states, "I have difficulty making eye contact with others." Participants respond based on a 5-point Likert-type scale from 0 (not at all characteristic of me) to 4 (extremely characteristic of me). The test-retest reliability and internal consistency of the SIAS are good (Mattick & Clarke, 1998). Rodebaugh et al. (2007, 2011) found that a total score using only the 17 straightforwardly worded items (SIAS-S) afforded greater criterion-related validity in samples of undergraduates and individuals with SAD, so we used the SIAS-S in this study. Internal consistency in the current study was good ($\alpha = .89$).

[1]We conducted independent samples *t*-tests although they do not account for autocorrelation of the data. We chose to do so as a direct replication of the original definition and that used by two of the three prior studies on SGs during treatment of SAD (Bohn et al., 2013; Hofmann at al., 2006; Tang & DeRubeis, 1999). Other researchers have attempted to rectify this by using the critical value of $t(4) = 2.78$, but results are identical.

The Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996) was used to assess the severity of depressive symptoms. It is a 21-item self-report questionnaire, and items are rated on a 4-point scale from 0 to 3. For example, the item assessing worthlessness is rated from 0 ("I do not feel I am worthless") to 3 ("I feel utterly worthless"). In the current study, the internal consistency at baseline was excellent ($\alpha = .93$).

The Emotion Regulation Questionnaire (ERQ; Gross & John, 2003) is a 10-item questionnaire developed to assess an individual's use of cognitive reappraisal and emotion suppression for emotion regulation. We included only the cognitive reappraisal subscale in the current study. Cognitive reappraisal is measured by six items (e.g., "I regulate my emotions by thinking differently about whatever is making me emotional"). Each item is rated on a 7-point Likert-type scale, from "strongly disagree" to "strongly agree." The scale demonstrates strong psychometric properties (Gross & John, 2003). In the current study, the cognitive reappraisal subscale showed excellent internal consistency at baseline ($\alpha = .93$).

The Satisfaction with Life Scale (SWLS; Diener, Emmons, Larsen, & Griffin, 1985) is a self-report questionnaire that assesses overall satisfaction with life or subjective well-being. The questionnaire consists of five items such as "In most ways my life is close to my ideal," and responses range from 1 (strongly disagree) to 7 (strongly agree). The measure shows good convergent validity with other measures of life satisfaction (Pavot, Diener, Colvin, & Sandvik, 1991). A review of the scale suggests that it is internally consistent, demonstrating Cronbach's alphas ranging from .79 to .89 across six studies (Pavot & Diener, 1993). In the current study, the internal consistency at baseline was excellent ($\alpha = .91$).

Results

Characteristics of SGs

We identified 15 SGs occurring in 12 participants (three participants had two SGs). Of the total sample, 17.6% of participants experienced at least one SG. Those with SGs demonstrated a mean change from pre- to posttreatment of 39.17 on the weekly rating, and the mean magnitude of a SG was 22.22, so SGs represented 56.72% of total change from pre- to posttreatment. Those who did not experience a SG demonstrated a mean change of 32.15 from pre- to posttreatment on the weekly ratings. The difference in mean change in weekly ratings from pre- to posttreatment was not significant, $t(49) = -0.64$, $p = .52$, $d = .26$. The median time at which a SG occurred was between sessions 9 and 10. Reversal of SGs, defined by a loss of 50% or more of the gain at any point during treatment, occurred for 5 of the 15 gains (33.3%). Demographic information for participants, differentiated by SG status (i.e., occurrence vs. nonoccurrence of SGs), is presented in Table 1. There were no significant differences in participant demographic characteristics between SG status groups. See Table 2 for a consolidated report of SG characteristics.

Effects of SGs on Treatment Outcome

We examined whether social anxiety changed differentially from pre- to posttreatment as a function of SG status. We used the MIXED procedure in SPSS (Version 24) to apply linear mixed-effects models (LMMs). Random intercepts were included in the model. Maximum

likelihood estimation was used to address missing data at posttreatment and follow-up, so cases with missing data were included. The random effect covariance structure was declared using a scaled identity matrix. Within-group effect sizes were calculated as Cohen's *d* (Cohen, 1988) and used the differences in estimated marginal means divided by the pooled within-group standard deviation (Dunlap, Cortina, Vaslow, & Burke, 1996). Results from LMMs (main effects and interaction effects) are reported in Table 3.

There was a main effect of SG status such that individuals with SGs reported lower LSAS-SR scores compared to those without SGs. There was also a main effect of Time, such that LSAS-SR scores decreased significantly from pre- to posttreatment. There was no Time × SG status interaction, indicating that changes in LSAS-SR scores from pre- to posttreatment were not significantly different for those with versus without SGs. Post-hoc pairwise comparisons revealed that those with SGs had significantly lower LSAS-SR scores than those without SGs at pretreatment, $t(113.38) = 3.00$, $p = .003$, $d = 0.36$, and at posttreatment, $t(113.38) = 2.05$, $p = .04$, $d = 0.25$.

We repeated these analyses using the SIAS-S. There was a significant main effect of SG status such that individuals with SGs reported lower SIAS-S scores. There was also a main effect of Time. There was no Time × SG status interaction, indicating that changes in SIAS-S scores from pre- to posttreatment were not significantly different between SG status groups. Post-hoc pairwise comparisons revealed that those with SGs had significantly lower SIAS-S scores than those without SGs at posttreatment, $t(108.55) = 3.42$, $p = .001$, $d = 0.41$, but not at pretreatment, $t(108.55) = 1.73$, $p = .09$, $d = 0.21$.

Effects of SGs on Follow-up

We tested whether SG status predicted changes social anxiety from pretreatment to 12-month follow-up using LMM as described above. There was a main effect of SG status such that individuals with SGs reported lower LSAS-SR scores. There was also a main effect of Time, such that LSAS-SR scores decreased significantly from pretreatment to 12-month follow-up. There was no Time × SG status interaction, indicating that changes in LSAS-SR scores from pretreatment to 12-month follow-up were not significantly different for those with or without SGs.

There was no main effect of SG status on SIAS-S scores. There was a main effect of Time, such that SIAS-S scores decreased from pretreatment to follow-up. There was no Time × SG status interaction, indicating that changes in SIAS-S scores from pretreatment to follow-up were not significantly different between SG status groups.

Effect of SGs on Treatment-Related Changes in Depression, Cognitive Reappraisal, and Life Satisfaction

BDI-II scores were positively skewed at posttreatment. Thus, we performed a natural log transformation of the data at pretreatment and posttreatment which resulted in a normal distribution. We conducted the following analyses using the natural log transformed variables. There was no significant main effect of SG status on BDI-II scores. There was a main effect of Time on BDI-II scores. There was no interaction between SG status and Time on the BDI-II.

There was no significant main effect of SG status on SWLS scores. There was a marginally significant main effect of Time such that SWLS scores increased from pre- to posttreatment, but no interaction between SG status and Time on SWLS scores.

For cognitive reappraisal, there was no significant main effect of SG status on ERQ cognitive reappraisal scores. There was a main effect of Time, such that cognitive reappraisal increased from pre- to posttreatment, but no interaction between SG status and Time on ERQ cognitive reappraisal.

Discussion

Study 1 examined SGs in the context of individual CBT for SAD. SGs tended to occur later in treatment, with the median session of SGs being session 10. Individuals with SGs reported lower social anxiety at pre- and posttreatment compared to those without SGs. However, SGs did not predict changes in social anxiety from pre- to posttreatment or from pretreatment to 12-month follow-up. SGs did not predict changes in depression, cognitive reappraisal, or life satisfaction across treatment. In Study 2, we explored whether the same pattern of findings emerged in the context of MBSR and CBGT for SAD.

Study 2

Method

Participants—Participants were drawn from a RCT of 108 adults with a primary diagnosis of generalized SAD as evidenced by greater than moderate fear in five or more distinct social situations listed in the social phobia module of the ADIS-IV-L and a score of 60 or higher on the LSAS-SR (Rytwinksi et al., 2009). Clinical psychologists and doctoral students reviewed 20% of the cases; there was 100% agreement with the initial diagnosis and rating. As in Study 1, we included participants for whom we had at least four sessions of weekly data. Thus, the final sample comprised 100 participants. Further exclusion criteria included: having received or participated in pharmacotherapy or psychotherapy in the past year, CBT for anxiety in the past two years, any MBSR course in the past, long-term meditation retreats or regular meditation practice (defined as 10 minutes at least 3 times weekly), a history of neurological, cardiovascular or thought disorders, or bipolar disorder. Participants were additionally required to be in remission from PTSD or alcohol/substance abuse or dependence for at least one year and to not report on the telephone screen significant symptoms of current major depressive disorder (MDD; 14 or more days of depressed mood in the past month) or obsessive compulsive disorder (OCD), given the likelihood that these symptoms would result in a primary diagnosis of MDD or OCD. However, at the in-person interview, clients with secondary MDD or OCD were permitted to enroll in the study. Demographic characteristics of participants, differentiated by SG status, are presented in Table 4.

Procedure—Potential participants were identified through clinician referrals and community listings. Screenings were conducted via telephone followed by an in-person diagnostic interview to determine the participant's history of Axis I disorders as well as symptom severity. As patients were admitted into the study, groups of six consecutive

patients were placed in a group sequence at random, which resulted in six groups each of CBGT, MBSR, and WL. The CONSORT diagram is published in Goldin et al. (2016). Participants who were in the WL condition were re-randomized to CBGT or MBSR conditions following the 12-week waiting period. In the current study, we combined data from the immediate treatment patients and from WL patients after they had been re-randomized and had received treatment, so the numbers of patients in each treatment condition were CBGT (n = 50) and MBSR (n = 50). Patients originally assigned to the CBGT and MBSR conditions completed self-report assessments at baseline, posttreatment, and 12-month follow-up. Patients in the WL condition completed assessments at their original baseline, post-WL (corresponding with posttreatment for the CBGT and MBSR conditions, but treated as baseline for the WL patients here), after they had received one of the two treatments (randomly assigned), and 12-month follow-up. Treatment was provided at no cost, and patients received $150 compensation for completing the 12-month follow-up assessment. Informed consent was obtained from all participants. This study was approved by the Stanford University Institutional Review Board.

Treatment

Cognitive-Behavioral Group Therapy (CBGT): CBGT consisted of 12 weekly sessions which each lasted 2.5 hours. Therapists followed the Heimberg and Becker (2002) CBGT protocol for SAD. This protocol includes psychoeducation, orientation to CBGT, training in cognitive restructuring skills, graduated exposure to feared social situations, and relapse prevention and termination. Portions of the Hope, Heimberg and Turk (2010) client workbook were used to complement the weekly sessions.

Mindfulness-Based Stress Reduction (MBSR): The MBSR group was structured so that there were 12 weekly 2.5-hour sessions, which was equivalent to the CBGT condition in amount of time spent in group meetings and number of sessions. The course curriculum largely followed an outline set forth by Kabat-Zinn and Santorelli in 1993, but the original outline included a full day meditation retreat which was not included in this study in order to maintain the same session structure as in CBGT. A *Mindfulness Based Stress Reduction Workbook* (Stahl & Goldstein, 2010) was also used to supplement the weekly sessions and included exercises and audio files to facilitate patients' home practice.

Treatment adherence and patient attendance did not differ between CBGT and MBSR. Details are reported in Goldin et al. (2016).

Definition of Sudden Gains—SGs were determined using the same criteria as in Study 1. In this sample, the reliable change score was 8.89 based on the weekly ratings. Of the total 1,200 possible sessions, 143 (12%) had missing data.

Measures—As in Study 1, we administered the weekly ratings of social anxiety (α = .88 to .93), the LSAS-SR (α = .92), the SIAS-S (α = .88), the BDI-II (α = .92), the Cognitive Reappraisal subscale of the ERQ (α = .96), and the SWLS (α = .91). Additionally, we administered the Cognitive Distortions Questionnaire (CD-Quest; de Oliveira, 2015), a 15-item self-report questionnaire that assesses both intensity and frequency of common

cognitive distortions experienced over the past week. The CD-Quest has demonstrated good convergent and discriminant validity as well as good internal consistency in undergraduate samples (α = .80, α = .88, respectively; Kostoglou & Pidgeon, 2016; Morrison et al., 2015). Using data from the current sample, Kaplan et al. (2017) found that the CD-Quest showed good convergent and discriminant validity among treatment seeking individuals with SAD. The CD-Quest demonstrated excellent internal consistency in this study (α = .94).

Data Analyses—Data analyses were identical to those conducted in Study 1. Additionally, we conducted LMMs to determine whether there were differential effects of SGs between MBSR and CBGT. Results from LMMs (main effects and interaction effects) are reported in Table 5.

Results

Characteristics of Sudden Gains

We identified 28 SGs occurring in 27 participants (one participant had two SGs). Of the total sample, 27% of participants experienced at least one SG. Those with SGs demonstrated a mean change from pre- to posttreatment of 32.53 on the weekly ratings, and the mean magnitude of an SG was 25.18, so SGs represented 77.39% of total change from pre- to posttreatment. Those who did not experience a SG demonstrated a mean change of 26.95 from pre- to posttreatment. The difference was not significant, $t(83) = 1.24$, $p = .22$, $d = 0.30$. The median time at which SGs occurred was between sessions 1 and 2 in both treatment conditions. Of the participants who experienced a SG, 15 were in CBGT, and 12 were in MBSR, and a chi-square test revealed that there was not a significant difference in rates of participants with SGs and without SGs between treatment conditions ($\chi^2(1) = 0.46$, $p = .50$). Reversal of SG occurred for 10 of the 28 gains (35.7%). Reversals occurred at a similar rate in CBGT (6 reversals) and MBSR (4 reversals). See Table 2 for a consolidated report of SG characteristics. There were no significant differences between those with and without SGs on age, race/ethnicity, or income. Those with a SG reported significantly fewer years of education, $t(95) = 2.48$, $p = .02$, $d = 0.53$.

Effects of SGs on Treatment Outcome

There was no main effect of SG status on LSAS-SR scores. There was a main effect of Time such that LSAS-SR scores decreased over time. Changes in LSAS-SR scores from pre- to posttreatment were not significantly different between SG status groups.

We repeated the set of analyses using the SIAS-S. There was no main effect of SG status on SIAS-S scores. There was no main effect of Time. There was no Time × SG status interaction, indicating that changes in SIAS-S scores from pre- to posttreatment were not significantly different between SG status groups.

Effects of SGs on Follow-up

We tested whether SG status predicted social anxiety at 12-month follow-up, controlling for pretreatment social anxiety using LMMs as described in Study 1. There was no main effect of SG status on LSAS-SR scores. There was a main effect of Time, such that LSAS-SR

scores decreased significantly from pretreatment to 12-month follow-up. There was no Time × SG status interaction, indicating that changes in LSAS-SR scores from pretreatment to 12-month follow-up were not significantly different for those with or without SGs.

There was no main effect of SG status on SIAS-S scores. There was a main effect of Time such that SIAS-S scores were lower at 12-month follow-up. There was no Time × SG status interaction, indicating that changes in SIAS-S scores from pretreatment to follow-up were not significantly different between SG status groups.

Differences Between Treatments

We conducted LMMs using maximum likelihood estimation to compare effects of SG status (two-level between subjects variable: SG vs. no SG) and treatment type (two-level between subjects variable: CBGT vs. MBSR) across time (two-level within subjects variable: pre- vs. posttreatment) on social anxiety. We found no significant interaction between treatment condition, SG status, and Time on LSAS-SR scores, $F(1, 182) = 1.09$, $p = .36$, or SIAS-S scores, $F(1, 178) = .88$, $p = .45$.

Effect of SGs on Treatment-Related Changes in Depression, Cognitive Reappraisal, Life Satisfaction, and Cognitive Distortions

There was no main effect of SG status on BDI-II scores. There was a main effect of Time such that BDI-II scores decreased significantly from pre- to posttreatment. There was no Time × SG status interaction on the BDI-II.

There was no significant main effect of SG status on SWLS scores. There was a main effect of Time such that satisfaction with life increased from pre- to posttreatment, but no Time × SG status interaction on life satisfaction.

There was no main effect of SG status on ERQ cognitive reappraisal. There was a main effect of Time such that cognitive reappraisal increased from pre- to posttreatment. We found no Time × SG status interaction on ERQ cognitive reappraisal.

There was no main effect of SG status on the CD-Quest. There was a main effect of Time such that CD-Quest scores decreased from pre- to posttreatment. We found no Time × SG status interaction on the CD-Quest.

Discussion

Study 2 was the first to examine SGs in the context of MBSR and to compare those to SGs in CBGT. In this study, we found evidence for the occurrence of SGs at comparable rates in CBGT and MBSR. SGs did not predict changes in social anxiety from pre- to posttreatment or from pretreatment to 12-month follow-up. There were no differential effects of SGs on changes in social anxiety from pre- to posttreatment between CBGT and MBSR. SGs did not predict changes in depression, cognitive reappraisal, cognitive distortions, or life satisfaction from pre- to posttreatment.

General Discussion

The findings from the two RCTs for SAD demonstrate several commonalities. First, during treatment for SAD, SGs occurred in individual CBT, CBGT, and MBSR. The rates of SGs occurring in CBT (17.6%), CBGT (28%), and MBSR (22%) are within the range reported in the anxiety and depression literature (Aderka, Nickerson, et al., 2012). This complements prior research which demonstrated that SGs occur during treatment for SAD in CBGT, exposure group therapy, CT, IPT, and non-specific group psychotherapy (Bohn et al., 2013; Hofmann et al., 2006, Thorrisdottir et al., 2018). In fact, when comparing CT to IPT, CBGT to exposure group therapy, and CBGT to group psychotherapy, the studies found that rates of SGs did not differ between treatments for SAD. Thus, there is continued evidence that SGs are not a phenomenon specific to treatment type; rather, SGs seem to occur during a multitude of treatments for SAD.

In both studies, we found that SGs did not predict treatment outcome; those with and without SGs experienced a similar magnitude of change in social anxiety from pre- to posttreatment. This contradicts the findings of Bohn et al. (2013) showing that participants with SGs showed greater improvement across treatment than those without SGs. Hofmann et al. (2006) found that those with SGs improved more across treatment, but SGs did not affect changes from posttreatment to 6-month follow-up, indicating that those who experienced SGs during treatment did not improve to a greater degree once treatment was over. Bohn and colleagues (2013) postulated that the effects of SGs on outcome may be stronger in individual compared to group therapy formats. However, we found no association between SGs and treatment outcome in individual CBT, CBGT, or group MBSR. Thus, therapy format may not be responsible for the relationship between SGs and outcome.

In Study 2, we compared the effects of SGs on treatment outcome in CBGT versus MBSR and found no differences, suggesting that those who experienced SGs had similar degrees of improvement from pre- to posttreatment in both treatment conditions. Hofmann et al. (2006) also demonstrated that SGs had similar effects on treatment outcome in both CBGT and group exposure therapy. However, other studies comparing the effects of SGs in different treatments for SAD found differential effects. In particular, Bohn et al. (2013) found that for those who experienced SGs during treatment, social anxiety, depression, and general psychological distress scores were lower in CT than in IPT. Additionally, Thorisdottir et al. (2018) found that participants with SGs improved to a greater degree in the non-specific group psychotherapy condition than in CBGT. In contrast, a meta-analysis by Aderka, Nickerson, et al. (2012) reported that SGs had greater effects on anxiety and depression treatment outcome in CBT interventions compared to other interventions. This was not replicated in our studies.

In both studies, SGs did not predict changes from pre- to posttreatment in depression, cognitive reappraisal, cognitive distortions, or life satisfaction. Similarly, Hofmann et al. (2006) found that experiencing SGs was not associated with a diagnosis of MDD, and Bohn et al. (2013) found that SGs did not predict changes in depression across treatment. Meta-analysis of the research on SGs in anxiety and depression treatment suggests that SGs are predictive only of reduction in the same symptoms utilized to define the SG (Aderka,

Nickerson, et al., 2012). Although investigation of changes in cognition and depression are commonplace in the SG literature, our examination of the effects of SGs during treatment for SAD on life satisfaction was novel. Further research is needed to determine whether a relationship between SGs during treatment and overall life satisfaction exists.

There were also discrepancies between the two studies. Namely, in Study 1, SGs were associated with lower social anxiety across assessments, but this was not the case in Study 2. This is interesting given that Hofmann et al. (2006) found the opposite at pretreatment; those with SGs had higher social anxiety at pretreatment than those without SGs. However, in Study 2 we found no difference in social anxiety between those with and without SGs at pretreatment, consistent with Thorisdottir et al.'s (2018) findings. The current literature is mixed on whether SGs are associated with baseline levels of social anxiety but, based on the results of Study 1, it is possible that beginning treatment with lower levels of social anxiety would allow for greater chance of experiencing a SG. Those with less severe social anxiety may find it easier to engage in the treatment components (e.g., cognitive reappraisal, exposure) and may experience more rapid changes in social anxiety as a result of greater engagement.

A possible explanation for the lack of association between SGs and treatment outcome in both studies is that SGs may represent normal fluctuations in symptom severity that happen to be large in size. Shalom et al. (2018) found that individuals who had higher session to session variability in reported symptom severity were more likely to experience a SG during CBT for obsessive-compulsive disorder and posttraumatic stress disorder and psychodynamic therapy for a diverse set of disorders. Thus, rather than being important predictors of treatment outcome, SGs may simply be cases of intraindividual variation in symptoms that are large in size. Further, SGs reverse in anywhere from 9.1% to 85.7% of cases (Aderka et al., 2012), suggesting that they are not necessarily associated with stable changes in symptoms. Future research should continue to examine whether SGs are better classified as normal variations in symptoms in individuals who report a higher degree of symptom variability overall.

The research on SGs in depression consistently concludes that SGs are related to better treatment outcome, but the growing body of literature on SGs in SAD, including the current study, is less convincing. One explanation for this difference may be that SGs in depression may represent remission from a depressive episode. This would clearly result in posttreatment levels of depression which are lower for those who experienced a SG (remission) than those who did not. In depressive disorders, SGs may occur during treatment for those who have a less chronic form of depression (e.g., Major Depressive Episode rather than Persistent Depressive Disorder). In that case, those who do not experience SGs during treatment are more likely to comprise a group of individuals who have chronic, unremitting depression and naturally end treatment without as much improvement as those who do experience a SG. Theoretically, this would be in contrast to SAD which is not differentiated by chronic versus episodic types. More research is needed to determine what SGs during treatment for SAD signify.

The current study has several strengths. Primarily, we examined the occurrence of SGs in two separate RCTs, including the first examination of SGs in MBSR for SAD. The methods of the current study (i.e., definition of SGs and data analyses) were intended to replicate those of prior studies on SGs during treatment for SAD to allow for comparison. A limitation of the current study is that, although both studies' samples were approximately half White/Caucasian (57% and 44% respectively), there is an underrepresentation of African-American and multiracial participants in these studies. Without a racially and ethnically diverse sample, our findings are limited in generalizability. We also relied on self-report measures to assess outcomes. Although this is common in the SGs literature, it is considered a limitation of the current studies, and future research should examine whether SGs have proximal effects on behavioral approach and avoidance tasks. Additionally, we replicated the established definition of SGs by using independent samples *t*-tests to compare social anxiety ratings in the three sessions prior to and the three sessions following the gain to assess stability of the gain *(Criterion C)*. However, independent *t*-tests do not properly account for autocorrelations of the data given that they are within-person ratings. We chose to replicate prior definitions of SGs by using the independent *t*-test, but we acknowledge the flaws in this method, and future research should attempt to rectify the definition of SGs by utilizing a more appropriate statistical test.

In these two studies, participants' social anxiety significantly improved across treatment regardless of whether they experienced a SG, suggesting that SGs are not necessary for improvement during treatment for SAD. Additionally, experiencing a SG did not relate to any distinct improvement in cognitions, emotion regulation, depression, or life satisfaction following treatment. SGs may represent a different course of change than gradual improvement, but it appears that the two paths arrive at the same endpoint. At this time, the clinical significance of experiencing SGs during treatment for SAD has limited support; patients are able to experience meaningful reductions in social anxiety during treatment, regardless of experiencing a SG.

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Richard G. Heimberg is an author of the commercially available CBT protocol which was utilized in this study. None of the remaining authors of this manuscript have any financial interests or potential conflicts of interest.

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Highlights

- Sudden gains are sudden, large improvements in symptom severity during treatment.
- We examined sudden gains in RCTs of CBT vs WL and CBGT vs MBSR vs WL for SAD.
- In Study 1, sudden gains were associated with lower SA at pre- and posttreatment.
- In Study 2, sudden gains occurred at similar rates and magnitude in CBGT and MBSR.
- Sudden gains did not predict pre- to posttreatment changes in SA in Study 1 or 2.

Table 1.

Demographic characteristics for Study 1 participants, grouped by sudden gains status

Demographic Characteristic	No Sudden Gains (*n* = 56)		Sudden Gains (*n* = 12)		Statistic	Effect Size	*p*
	Mean or n	***SD* or %**	***Mean or n***	***SD* or %**			
Age (*M, SD*)	34.4	8.7	30.5	7.9	$t(66) = 1.45$	$d = 0.47$	.15
Gender (n, %)					$\chi^2(1) = 0.28$	$\varphi = .06$	.60
Male	28	50	7	58.3			
Female	28	50	5	41.7			
Race/Ethnicity (*n, %*)					$\chi^2(5) = 7.97$	$\varphi = .34$	.16
White/Caucasian	35	52.5	4	33.3			
African-American	1	1.8	--	--			
Multiracial	2	3.6	--	--			
Native Hawaiian/Pacific Islander	1	1.8	--	--			
Asian or Asian American	11	19.6	7	58.3			
Hispanic	6	10.7	1	8.3			
Years of Education (M, SD)	16.9	2.4	16.7	2.4	$t(64) = 0.25$	$d = 0.08$	.80

Table 2.

Characteristics of Sudden Gains in Study 1 and Study 2

Characteristic	Study 1	Study 2	
	CBT	***CBGT***	***MBSR***
Individuals with sudden gains, *N* (%)	12 (17.6)	15 (30.0)	12 (24.0)
Median session of sudden gain	10	2	2
Average magnitude of sudden gain (% total improvement)	56.7	72.6	81.1
Sudden gain reversal (%)	33.3	40.0	33.3

Note. CBT = cognitive-behavioral therapy; CBGT = cognitive-behavioral group therapy; MBSR = mindfulness-based stress reduction

Table 3.

Effects of SG status on Study 1 variables at posttreatment and 12-month follow-up.

	Posttreatment					Follow-up				
	b	***SE***	***df***	***t***	***d***	***b***	***SE***	***df***	***t***	***d***
LSAS-SR										
Time	32.83	7.61	56.37	4.32***	0.52	38.55	7.91	48.21	4.87***	0.59
SG status	14.43	6.91	113.38	2.09*	0.25	20.48	8.30	99.44	2.47*	0.30
Time*SG status	4.07	8.52	57.81	0.48	0.06	−1.97	8.90	49.14	−0.22	0.03
SIAS-S										
Time	21.54	4.02	55.65	5.35***	0.65	22.08	7.75	86.63	2.85**	0.35
SG status	12.73	3.81	108.55	3.34**	0.41	10.02	7.60	92.93	1.32	0.16
Time*SG status	−6.55	4.51	56.82	−1.45	0.18	−3.69	8.03	84.47	−0.46	0.06
BDI-II										
Time	1.10	0.36	51.04	3.09**	0.37	--	--	--	--	--
SG status	0.47	0.35	107.66	1.34	0.16	--	--	--	--	--
Time*SG status	0.37	0.40	53.24	0.93	0.11	--	--	--	--	--
SWLS										
Time	3.56	1.80	40.47	1.98	0.23	--	--	--	--	--
SG status	−2.09	2.51	97.96	−0.83	0.10	--	--	--	--	--
Time*SG status	−0.11	2.05	41.25	−0.06	0.01	--	--	--	--	--
ERQ-CR										
Time	1.32	0.51	46.92*	2.57	0.31	--	--	--	--	--
SG status	0.63	0.48	104.75	1.31	0.16	--	--	--	--	--
Time*SG status	−0.23	0.57	46.77	−0.41	0.05	--	--	--	--	--

Note. LSAS-SR = Leibowitz Social Anxiety Scale - Self-report; SIAS-S = Social Interaction Anxiety Scale - Straightforwardly worded items; BDI-II = Beck Depression Inventory II; SWLS = Satisfaction with Life Scale; ERQ-CR = Emotion Regulation Questionnaire - Cognitive Reappraisal

* $p < .05$

** $p < .01$

*** $p < .001$

Table 4.

Demographic characteristics for Study 2 participants, grouped by sudden gain status.

Demographic Characteristic	No Sudden Gains (*n* = 73)		Sudden Gains (*n* = 27)		Statistic	Effect Size	*p*
	Mean or n	***SD* or %**	***Mean or n***	***SD* or %**			
Age (M, SD)	32.3	8.1	33.9	7.9	$t(98) = .62$	$d = 0.14$	.54
Gender (n, %)					$\chi^2(1) = 2.03$	$\varphi = .14$	.15
Male	36	49.3	9	33.3			
Female	37	50.7	18	66.7			
Race/Ethnicity (n, %)					$\chi^2(5) = 3.85$	$\varphi = .20$	.57
White/Caucasian	32	43.8	12	44..4			
African-American	--	--	1	3.7			
Multiracial	3	4.1	2	7.4			
American Indian/Alaskan Native	1	1.4	--	--			
Asian or Asian American	30	41.1	9	33.3			
Hispanic	7	9.6	3	11.1			
Years of Education (M, SD)	17.0	2.1	15.7	2.8	$t(95) = 2.48$	$d = 0.53$	.02

Table 5.

Effects of SG status on Study 2 variables at posttreatment and 12-month follow-up.

	Posttreatment					Follow-up				
	b	***SE***	***df***	***t***	***d***	***b***	***SE***	***df***	***t***	***d***
LSAS-SR										
Time	35.37	4.34	91.52	−8.14***	0.81	37.30	5.50	96.12	6.81***	0.68
SG status	−1.50	4.29	177.19	−0.35	0.03	3.17	5.19	176.27	0.61	0.06
Time*SG status	4.78	5.14	92.86	0.93	0.09	6.45	6.38	95.49	1.01	0.10
SIAS-S										
Time	−4.65	2.72	92.85	−1.71	0.17	16.13	2.41	89.28	6.70***	0.65
SG status	−0.01	2.82	173.19	−0.005	<0.001	1.26	2.78	167.59	0.45	0.05
Time*SG status	0.37	3.20	93.50	0.12	0.01	−0.90	2.80	88.86	−0.32	0.03
BDI-II										
Time	4.32	1.83	81.44	2.37*	0.24	--	--	--	--	--
SG status	0.12	1.98	157.69	0.63	0.01	--	--	--	--	--
Time*SG status	−0.99	2.16	82.00	−0.46	0.05	--	--	--	--	--
SWLS										
Time	2.75	1.18	81.19	2.34*	0.23	--	--	--	--	--
SG status	1.41	1.85	139.86	0.76	0.08	--	--	--	--	--
Time*SG status	−0.45	1.39	81.46	−0.32	0.03	--	--	--	--	--
ERQ-CR										
Time	1.44	0.28	76.31	5.16***	0.51	--	--	--	--	--
SG status	0.25	0.29	171.16	0.86	0.09	--	--	--	--	--
Time*SG status	0.06	0.33	77.74	0.19	0.02	--	--	--	--	--
CD-Quest										
Time	−8.52	3.22	82.81	−2.65*	0.26	--	--	--	--	--
SG status	3.67	3.49	169.09	1.05	0.11	--	--	--	--	--
Time*SG status	0.53	3.79	83.40	0.14	0.01	--	--	--	--	--

Note. LSAS-SR = Leibowitz Social Anxiety Scale - Self-report; SIAS-S = Social Interaction Anxiety Scale - Straightforwardly worded items; BDI-II = Beck Depression Inventory II; SWLS = Satisfaction with Life Scale; ERQ-CR = Emotion Regulation Questionnaire - Cognitive Reappraisal; CD-Quest = Cognitive Distortions Questionnaire

* $p < .05$

** $p < .01$

*** $p < .001$