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Sigal Zilcha-Mano
University of Haifa

Paula Errázuriz
Pontificia Universidad Católica de Chile

Lirit Yaffe-Herbst
University of Haifa

Ramaris E. German
National Institute of Mental Health, Bethesda, Maryland

Robert J. DeRubeis
University of Pennsylvania

Objective: It has been widely demonstrated that the process of change many patients undergo in therapy is not linear. Some patients benefit greatly from large sudden improvements, commonly referred to as "sudden gains." It is less clear whether certain baseline characteristics make patients more prone to displaying sudden gains, as well as what mechanisms are responsible for the lasting effects of sudden gains. ***Method:*** In a sample of 547 patients receiving treatment in an outpatient mental health clinic, a machine learning approach was used to search for potential predictors of sudden gains. A within-patient mediation model was used to investigate whether alliance serves as a mechanism underlying the sustained effect of sudden gains. ***Results:*** Twelve percent of patients showed sudden gains. Consistent with previous studies, no robust predictors of sudden gains were found, even when using an approach capable of evaluating the contributions of multiple predictors and their interactions. A significant within-patient mediation model was found, according to which sudden gains predict subsequent strengthening in alliance, which in turn predict subsequent improvement in life satisfaction and psychological dysfunction. These findings support the proposed theoretical framework whereby alliance is an important ingredient of an upward spiral that may results in sustained sudden gains. ***Conclusions:*** The findings provide first evidence of the presence of an ingredient responsible for the sustained effect of sudden gains, using a within-patient mediation model. The findings support the important role alliance may play in the consolidation and subsequent expansion of the effect of sudden gains.

What is the public health significance of this article?
Findings suggest that the alliance may act as an important ingredient in sustaining large sudden improvements (commonly referred to as "sudden gains") over time. The analyses support the conceptual model according to which sudden gains drive subsequent strengthening in alliance, which in turn serves to improve life satisfaction and psychological dysfunction.

Keywords: sudden gain, alliance, upward spiral, psychotherapy process, within-patient process of change

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In the last two decades, advances in the methods used to study the process of change in treatment for mental disorders have made it possible to better capture the nuances of the changes in individual patients. An important step forward was marked in the last decades by the understanding that not only do different patients show different processes of change, but that the rate of change within the treatment of a given patient is not fixed in time (Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007; Tang & DeRubeis, 1999). Tang and DeRubeis (1999) revealed that the group mean change in the course of treatment often blurs the unique pattern of change of individual patients. A close look at the nuances in the progress of therapeutic change of many patients showed that more than half the total improvement was concentrated in a single between-session interval. These changes, referred to as "sudden gains," capture an important process in patients' therapeutic change, and they were found to be extensive and long-lasting. Numerous studies have followed and implemented the sudden gain framework to examine the process of change in

Sigal Zilcha-Mano, Department of Psychology, University of Haifa; Paula Errázuriz, Department of Psychology, Pontificia Universidad Católica de Chile; Lirit Yaffe-Herbst, Department of Psychology, University of Haifa; Ramaris E. German, Neuroscience and Novel Therapeutics Unit, National Institute of Mental Health, Bethesda, Maryland; Robert J. DeRubeis, Department of Psychology, University of Pennsylvania.

Correspondence concerning this article should be addressed to Sigal Zilcha-Mano, Department of Psychology, University of Haifa, 199 Aba Khoushy Avenue, Mount Carmel, Haifa 3498838, Israel. E-mail: sigalzil@gmail.com

symptoms over the course of treatment (Aderka, Nickerson, Bøe, & Hofmann, 2012). Many of these studies have attempted to identify (a) patient characteristics that can be used to predict who will display a sudden gain and (b) mechanisms that underlie sudden gain phenomena. The present study offers a new perspective for addressing these questions.

Tang and DeRubeis (1999) operationalized sudden gains as a symptom change within a single between-sessions interval that must be large in absolute and relative terms, and that must represent a stable change, such that symptom severity at the three sessions following the gain is substantially lower than in the three sessions preceding it. The finding that patients displaying sudden gains evidence superior outcome at the end of treatment and at the 12- and 18-month follow-ups has been replicated numerous times (e.g., Abel, Hayes, Henley, & Kuyken, 2016; Tang, DeRubeis, Beberman, & Pham, 2005; Tang & DeRubeis, 1999; for a meta analysis see Aderka, Nickerson, et al., 2012). Sudden gains have also been shown to predict lower depression at follow-up, even beyond the slope of linear change in symptoms across the course of active treatment (Abel et al., 2016).

Sudden gains are prevalent and may be regarded as a pantheoretical and trans-diagnostic phenomenon (Aderka, Nickerson, et al., 2012), given that overall (albeit with some inconsistencies) (a) sudden gains were found to be prevalent and to predict outcome across treatment orientations, such as cognitive–behavioral therapy (Abel et al., 2016; Wucherpfennig, Rubel, Hollon, & Lutz, 2017), behavioral activation (Masterson et al., 2014), interpersonal therapy (Bohn, Aderka, Schreiber, Stangier, & Hofmann, 2013; Lemmens, DeRubeis, Arntz, Peeters, & Huibers, 2016), and supportive-expressive therapy (Tang, Luborsky, & Andrusyna, 2002); and (b) sudden gains were found to be prevalent and predict outcome across mental health disorders, such as depression (Wucherpfennig, Rubel, Hollon, et al., 2017), social anxiety disorder (Bohn et al., 2013), PTSD (Keller, Feeny, & Zoellner, 2014), obsessive-compulsive disorder (Aderka, Anholt, et al., 2012), and anorexia nervosa (Cartwright, Cheng, Schmidt, & Landau, 2017).

The percentage of patients experiencing sudden gains has varied greatly between studies, from 16.2% (Present et al., 2008; or even as low as 2.3% in children, Mychailyszyn, Carper, & Gibby, 2017) to 61.8% (Cartwright et al., 2017). Although this still requires a detailed systematic review of the literature, it appears that there is a relatively narrower range of sudden gain occurrence in depression (32.7%, Wucherpfennig, Rubel, Hofmann, & Lutz, 2017 vs. 54%, Abel et al., 2016) than in anxiety disorders (2.3% in a youth sample, Mychailyszyn et al., 2017, and 16.2% in an adult sample, Present et al., 2008, vs. 52%, Collins & Coles, 2017). Nevertheless, among the abundant studies that directly tested potential predictors of sudden gains, no variables have been identified that predict, across investigations, which patients are more likely to show evidence of a sudden gain. For example, although many studies focused on age as a potential predictor, we could find only one that reported significant findings (e.g., Jun, Zoellner, & Feeny, 2013, vs. Collins & Coles, 2017). The same seems to be true for education, where out of the many studies that tested it as a potential predictor, we could find only two that revealed significant findings (e.g., Cartwright et al., 2017, vs. Jun et al., 2013). And the same is true also for depressive symptoms, where we found only two studies that showed significant findings out of the many that tested it (e.g., Drymalski & Washburn, 2011, vs. Masterson et al., 2014).

The inconsistencies in the literature suggest that although the search for a single factor to explain variability in sudden gains may help identify important potential predictors, it also produced little consistency and many mixed results. One reason for these divergent results may be that the search for a single predictor treats all other variables as merely noise, although it is more intuitive to hypothesize that no single factor is as important as a set of interrelated ones in predicting who may show sudden gains. Furthermore, traditional approaches, which test each predictor factor as a separate hypothesis, can lead to erroneous conclusions because of multiple comparisons (inflated Type I errors), model misspecification, and multicollinearity. Findings may also be affected by publication bias, because the statistically significant predictors have a better chance of being reported in the literature. This suggests the need to search for a different method to address this question. One option is to use machine learning approaches, which have been found to be instrumental in identifying predictors and moderators where few consistent findings could be reached using traditional methods (e.g., Cohen & DeRubeis, 2018; Zilcha-Mano, Roose, Brown, & Rutherford, 2018). Our first goal in the present study is to implement a machine learning method capable of evaluating the contributions of multiple predictor variables and their interactions, in the search for baseline predictors of sudden gains.

A second question of theoretical and clinical importance, which has attracted empirical attention, concerns the mechanisms underlying the effect of sudden gains on treatment outcome. Tang and DeRubeis (1999) proposed a three-phase process meant to capture the causes of sudden gains as well as how they become stable enough to affect treatment outcome. First, there is a preparation stage, taking place at the pregain sessions, in which the therapists use techniques that establish the foundation for the critical change to occur. The second stage is when the therapeutic breakthrough occurs, resulting in the sudden gain. In the third stage, an upward spiral is established, which not only preserves the change that has already occurred (avoiding reversal), but also drives further change.

Most of the studies that have tested features of this three-phase process have focused on the discovery of the drivers of sudden gains in the session or sessions that precede them. Although not without exceptions (e.g., Bohn et al., 2013; Hofmann, Schulz, Meuret, Moscovitch, & Suvak, 2006), findings have supported the proposal that sudden gains are the result of theory-specific mechanisms of change (Tang & DeRubeis, 1999). In cognitive–behavioral therapy, an adequate case conceptualization (Abel et al., 2016) and changes in depression-related core beliefs and schemas evident in the pregain session (Tang et al., 2005; Tang & DeRubeis, 1999) have been shown to predict sudden gains. Similarly, in supportive-expressive treatment, insights gained into maladaptive interpersonal patterns predicted sudden gains in a study by Andrusyna, Luborsky, Pham, and Tang (2006).

Tang and DeRubeis (1999) hypothesized that in the third stage the sudden gain may trigger an “upward spiral,” helping improve not only theory-specific factors, such as cognitive changes, but also strengthening the working alliance at subsequent therapy sessions. In turn, these improvements are expected to alter the course of therapy, resulting in sustained therapeutic change. Although this proposed mediation model is an important ingredient in the process following the sudden gain, conceptualized as critical for sustained recovery, little is known empirically about it. Detecting this gap in the literature, a recent paper by Wucherpfennig, Rubel, et al. (2017) sought to shed light on the role of alliance in the upward spiral. The authors found significant improvement in the alliance following the gain, and reported that the extent of improvement in alliance moderated the effect of sudden gains on outcome. The important role alliance may be playing received support also from other studies, which demonstrated higher overall working alliance in patients experiencing sudden gains than in those experiencing sudden losses (Hansen, Lambert, & Vlass, 2015). Studies also reported improved alliance following symptomatic improvement in general (Strunk, Brotman, & DeRubeis, 2010), and following sudden gain sessions in particular (Lutz et al., 2013; Tang & DeRubeis, 1999). These studies highlight the potentially crucial role alliance may play in achieving sustained change following a sudden gain. Yet, to the best of our knowledge, no study to date has examined directly the hypothesized role of alliance as mediating the effect of sudden gains on further symptom change. Thus, the second goal of the present study is to examine a potential mediating role of alliance in the association between sudden gains and subsequent treatment outcome.

The present study investigates two important questions in the literature on sudden gains: (a) Is it possible to identify at pretreatment the patients who are more likely to show sudden gains? and (b) Can shifts in the alliance mediate the effect of sudden gains on treatment outcome? Because of the potentially circular nature of exploring mechanisms in which sudden gains have their effect on outcome when using the same measure to calculate both the predictor and the outcome, in addition to a more traditional measure of outcome, we also used life satisfaction as our treatment outcome for the mediation model. To broaden the scope of the current literature, we focused on an outpatient mental health clinic in Chile, a population that so far has not received research attention within the framework of sudden gains, seeking to understand how generalizable the sudden gains framework may be.

Method

Study Design

The trial from which the present data were obtained was a randomized study of five feedback conditions, conducted in an outpatient mental health clinic in Santiago, Chile (Errázuriz & Zilcha-Mano, 2018). The five feedback conditions were no feedback, feedback on symptomatology, feedback on the alliance, feedback on both symptomatology and alliance, and Lambert's Outcome Questionnaire (OQ) progress feedback report. All patients answered the same questionnaires, independent of feedback condition. Diagnoses were made based on a clinical interview conducted by a psychiatrist. At the beginning of treatment, each patient completed demographic surveys, and they also completed the OQ, the Working Alliance Inventory (WAI; Tracey & Kokotovic, 1989), and life satisfaction measures at every session. As reported previously (Errázuriz & Zilcha-Mano, 2018), there was no effect of feedback on outcome, session attendance, or the alliance.

Participants

All 953 adult patients who began therapy at the clinic at the time of the study were asked to participate; 547 (57.4%) responded affirmatively and participated in the study. Data were collected from a total of 3,174 sessions. Patients' demographic and clinical characteristics appear in Table 1. The mean level of psychological functioning (as measured by the OQ-30.2, Lambert et al., 2004) at baseline was 58.59 (SD = 16.67), considered dysfunctional with respect to the healthy population in Chile, which was found to have a mean OQ-30.2 score of 29.8, SD = 14 (Errázuriz, Opazo, Behn, Silva, & Gloger, 2017). As shown in Table 1, the majority of patients with an Axis I diagnosis were diagnosed with depressive

Table 1
Patient Demographic and Clinical Characteristics

Patient characteristics	Total sample (N = 547)
Demographic variables	
Age, years, M (SD)	41.3 (12.8)
Female	74.4
Income in USD, median (range)	$1,130 ($452–3,612)
Education, years, M (SD)	14.1 (2.9)
Occupational status	
Employed	66.7
Student	11.3
Homemaker	18.5
Retired	3.5
Marital status	
Single	27.8
Married	52.9
Divorced	17.3
Widowed	2
Ethnic identity	
Indigenous	5
Nonindigenous	95
Religion	
Catholic	64.1
Evangelical or Protestant	8.3
Jehovah's witness	18.5
"Other" religious affiliation	3.7
No religious affiliation	5.4
Clinical variables	
OQ-32 at baseline	58.6 (16.7)
On psychiatric medication	89.8
Previous psychiatric hospitalization	10.7
Psychiatric diagnosis	
Depressive disorders	68.7
Bipolar disorder	5.5
Adjustment disorder	2.2
Dysthymic disorder	1.8
Diagnosis of at least one comorbid	23
Substance-related disorders	4
Panic disorder without agoraphobia	3.7
Generalized anxiety disorder	2.6
Axis II diagnosis	
Borderline personality disorders	2.6
Dependent personality disorders	1.5
Histrionic personality disorder	.6

Note. OQ = Outcome Questionnaire. Values shown as % unless otherwise noted. In 2013, when most of data were collected, the average monthly household income in Chile was $1,749.20 (Instituto Nacional de Estadísticas de Chile, 2013).

disorders. This is not surprising given the fact that the clinical center in which the study was conducted is a preferred provider of treatment for patients with MDD of several insurance companies. All participating patients signed informed-consent forms, and the study was approved by the relevant ethical review boards.

Therapists

Twenty-eight therapists took part in the study. All had a professional degree in psychology, which means that they had all graduated from a 5-year, full-time professional program in psychology that commonly includes 1 or 2 years of clinical psychology training. In the current sample, all but two of the therapists completed formal studies in psychotherapy after receiving their professional degrees as psychologists. Mean clinical experience was 8.38 years ($SD = 5.33$), mean age was 37.79 ($SD = 7.79$), and 68% were women. All therapists were Chilean, and none identified themselves as indigenous. Regarding the therapists' religion, 56% were Catholic, 4% Evangelical or Protestant, 4% Jewish, 4% Bahá'í Faith, and 32% reported no religious affiliation. The mean number of patients treated by each therapist was 20 ($SD = 14.6$; range = 1–51).

Treatments

Except for the feedback received, treatments were delivered as usual. All patients were treated in individual therapy. The usual treatment at the clinic, and perhaps generally in Chile, follows an integrative approach. The typical length of time between sessions was 1 week. The duration of each session was approximately 50 min. Treatment length was determined jointly by patients and therapists, as well as by practical concerns (patients' financial considerations, health insurance, etc.). The mean length of treatment was 7.82 sessions ($SD = 6.62$, $Mdn = 6$), with a range of 1–55. This is similar to what has been reported in primary care routine practice in the United States (Hansen, Lambert, & Forman, 2002), United Kingdom (Stiles, Barkham, Mellor-Clark, & Connell, 2008), and Sweden (Falkenström, Granström, & Holmqvist, 2013). On average, patients attended 74.15% ($SD = 18.94$) of their scheduled sessions.

Measures

Therapeutic alliance. The patient's perception of the quality of the therapeutic alliance was assessed using the 12-item patient-rated version of the WAI (Tracey & Kokotovic, 1989). Items were rated on a 7-point Likert scale, ranging from 1 (*never*) to 7 (*always*). In the present study, the mean internal reliability level across time points was .85. Previous analyses conducted on this dataset demonstrated the ability of within- and between-patients alliance to predict treatment outcome (Zilcha-Mano & Errázuriz, 2015).

Symptom measure. Psychological dysfunction was assessed with the 30-item patient-rated version of the OQ (Lambert et al., 2004), designed to measure patient progress over the course of therapy along three primary dimensions: (a) subjective discomfort (e.g., anxiety and depression: "I feel blue"), (b) interpersonal relationships (e.g., "I feel lonely"), and (c) social role performance (e.g., "I have too many disagreements at work/school"). Possible scores ranged from 0 to 120, higher scores reflecting higher severity of distress. In the present study we used the total score, a global assessment of patient functioning. The mean internal reliability level across time points was .93.

Life satisfaction. Life satisfaction was assessed with a one-item patient-rated measure, taken from the World Values Survey (WVS, 2009), to measure patient life satisfaction over the course of therapy. The item was rated by patients on a 10-point Likert scale, with higher scores reflecting greater life satisfaction. The instructions were as follows: "All things considered, how satisfied are you with your life as a whole these days? Using a scale on which 1 means that you are 'completely dissatisfied' and 10 means you are 'completely satisfied,' where would you put your satisfaction with life as a whole?" The validity of this one-item measure has been repeatedly demonstrated in previous studies (Bjørnskov, 2010; Bjørnskov, Dreher, & Fischer, 2010; Diener, Kahneman, & Helliwell, 2010; Fleche, Smith, & Sorsa, 2012).

Data Analyses

Definition of sudden gains. Consistent with previous literature (Tang & DeRubeis, 1999), we used the following definition of sudden gains:

1. The gain between two consecutive sessions must be at least 10 points on the OQ-30. The threshold of 10 points was chosen because it is the reliable change index for OQ-30 (Ellsworth, Lambert, & Johnson, 2006), following previous studies that used the reliable change index to determine the threshold (e.g., Greenfield, Gunthert, & Haaga, 2011).

2. The gain must be large relative to pregain severity, that is, at least 25% of the OQ-30 score of the pregain session.

3. The gain must be large relative to symptom fluctuation before and after the gain; the difference between the mean OQ-30 score of the three sessions before the gain (n-2, n-1, and n) and the three sessions after the gain ($n + 1$, $n + 2$, and $n + 3$) must be at least 2.78 times greater than the pooled standard deviations of the OQ-30 scores of these two groups of sessions. When gains occur after the second session or on the second-to-last session, n-2 and $n + 3$ are not used. Following previous studies (e.g., Busch, Kanter, Landes, & Kohlenberg, 2006; Clerkin, Teachman, & Smith-Janik, 2008; Grilo, Masheb, & Wilson, 2006; Kelly, Cyranowski, & Frank, 2007), we also considered gains occurring after the first session (see also, Kelly, Roberts, & Ciesla, 2005). When gains occur after the first session, 50% of the gain must be maintained for two sessions. When patients missed a session, the observation before or after that session (whichever relevant) was used.

Identifying predictors of sudden gains. To identify the most robust predictors of sudden gains, we conducted decision tree analyses with the "rpart" function of the R "rpart" package. The analysis is based on a classification tree algorithm minimizing the Gini Index. We used the following baseline characteristics as potential predictors of sudden gain: patients' age, gender, education, baseline symptomatology (symptom severity at baseline, as assessed by the OQ), previous psychiatric hospitalization, baseline tendency to self-conceal, initial alliance level as assessed after the first session of treatment, and feedback condition. Given the missing values in some of the baseline variables, missing observations in those variables were imputed using Multivariate Imputation by Chained Equations (van Buuren & Oudshoorn, 2011), which is implemented by the R package "mice."

Exploring the role of alliance as a potential mechanism underlying the effect of sudden gains on outcome. The data were hierarchically nested on three levels: assessments nested within patients nested within therapists. Therapist effect was null in all analyses ($S^2 = 0.00$, $p = .99$, intraclass coefficient = .00), and therefore two-level models with patient as a random effect were used. To examine life satisfaction, OQ and alliance behavior over time, we evaluated the following trend models for each: linear, quadratic, linear in log of time, and stability over time either as fixed or random effects. We started with a model with only a fixed intercept and no random effects, and added sequentially a random intercept, fixed effect of week, random effect of week, and a quadratic effect of week in therapy. Next, we examined the models with fixed and random linear effect of log of week. We used the log likelihood test and the Akaike information criterion (AIC) to determine whether the inclusion of each term improved the model fit. The model found to have the best fit based on the AIC for life satisfaction, OQ, and alliance was the one with a fixed effect of log of time, random intercept, and random slope in log of time. This model was used in all the analyses. To assess potential differences in the trajectories of alliance and OQ between patients who showed sudden gains and those who did not, we examined the interactions between time and sudden gains in predicting alliance and OQ, controlling for all main effects.

To focus on the within-patient effect, we disentangled it from the between-patients effect. We followed the recommendations of Wang and Maxwell (2015) and centered the patient-reported alliance within the individual patient's mean. This procedure yielded an independent coefficient for the within-patient effect (Bolger & Laurenceau, 2013). Given the low prevalence of sudden gains and the fact that they rarely happened more than once per patient, we used the uncentered sudden gain variable in the analyses. We used lagged design to establish a correct temporal relationship between predictor and outcome. The proposed mediation model tested whether sudden gain at Session T predicted WAI at Session T + 1, which in turn predicted life satisfaction at Session T + 2, even when controlling for sudden gain at Session T (see Figure 1). In all models, we controlled for the number of sessions available to the patient and for time (in log of time). The mediation model was tested using the Quasi-Bayesian Monte Carlo method (King, Tomz, & Wittenberg, 2000) with 5,000 simulations, and White's heteroskedasticity-consistent estimator for the covariance matrix (Zeileis, 2005). We repeated the mediation analyses for OQ as the outcome variable, testing whether sudden gain at Session T predicted WAI at Session T + 1, which in turn predicted OQ at Session T + 2, even when controlling for sudden gain at Session T.

Missing data. Multilevel models are based on the assumption that observations are missing at random (MAR), therefore the missing values are allowed to be related to covariates and to the

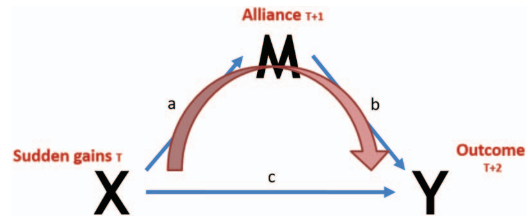

Figure 1. The mediating effect of the working alliance (at Time T + 1) on the association between sudden gains (Time T) and outcome (Time T + 2). The mediation model was significant for both life-satisfaction and psychological functioning as the outcome variables. See the online article for the color version of this figure.

dependent variable on other occasions, but not to the dependent variable on the dropout occasion (e.g., Gallop & Tasca, 2009). This assumption is not likely to be confirmed in a naturalistic dataset (Baldwin, Berkeljon, Atkins, Olsen, & Nielsen, 2009; Falkenström et al., 2013). Statistical models treat all observations after termination of treatment for patients with shorter treatments than the longest one (e.g., successful ending of treatment, dropout, etc.) as missing data. Therefore, following Falkenström et al. (2013), we used a pattern-mixture approach to test whether the parameter estimates depend on missing data, by estimating the associations separately in subgroups with different length of treatment. Based on visual inspection of the outcome means over time, four distinct patterns were identified. Because few patients attended more than 35 sessions ($n = 5$), and because these patients showed a distinct pattern of change in outcome over time, analyses were repeated without these patients. In subsequent analyses, all models were tested for an interaction of each covariate with the missing pattern group. If no significant interaction was found, we concluded that missing data did not influence or bias the proposed mediation model. If any interactions were significant, we kept them in the model. To estimate the marginal mediation of the covariate, we used a weighted average of the effect of the covariate, using the proportion of each missing pattern group as weights. We also repeated the pattern-mixture approach analyses, comparing the two patterns of completers and dropouts.

Results

Identifying Sudden Gains and Preliminary Analyses

Sixty-eight (12.4%) patients showed sudden gains. Most of them (59) had only one sudden gain. Of the 68 patients showing sudden gains, more than a half had a sudden gain in the first four sessions of treatment: 13 had sudden a gain at Session 2, 13 at Session 3, and 9 at Session 4. The median was Session 4 and the mean was 5.4.

At baseline, there were no significant differences in alliance between sudden gainers and those not showing sudden gains ($t = -.47$, $p = .63$), but there were significant differences in baseline OQ levels ($t = -2.04$, $p = .04$). The general mean of changes between sequential sessions in OQ was -2.14 ($SD = 9.59$), whereas the mean of change in sudden gains was -21.02 ($SD = 9.65$). The effect sizes of the estimated OQ slopes for those showing sudden gains versus those not showing sudden gains were −1.2 and −0.46, respectively. There were significant differences between patients showing and those not showing sudden gains in both alliance and OQ. For OQ, there were significant differences between those showing and those not showing sudden gains, $F_{(1,3170)} = 110.90$, $p < .0001$, with those showing sudden gains displaying faster reduction in symptoms over the course of treatment. There were also significant differences in the trajectories of alliance between those showing and those not showing sudden gains, $F_{(1,3170)} = 7.51$, $p = .006$, with those showing sudden gains also showing greater strengthening of the alliance over the course of treatment. Furthermore, the change in alliance following a gain among those who showed a sudden gain was significantly higher (2.6 points higher) than the general change in alliance among those who did not show sudden gains, $t_{(469)} = 2.88$, $p = .004$.

Identifying Predictors of Sudden Gains

The decision tree analysis revealed a first split in the patients' pretreatment symptom severity, a second split in the patients' initial alliance levels (as measured after the first session), and a third split in the patients' years of education (see Figure 2 in the online supplement materials). We regulated tree complexity (the number of splits) for out-of-sample prediction by cross-validation, using the "rpart" procedure in R. We estimated the cross-validation prediction error for several tree complexities and found that the empty tree had the best out-of-sample prediction. Thus, no robust predictors of sudden gains could be identified. Repeating the decision tree analyses to include patient clinical diagnosis, comorbidity, and therapists' treatment orientation as potential predictors yielded similar results.

Exploring the Role of Alliance as a Potential Mechanism Underlying the effect of Sudden Gains on Outcome

Life satisfaction as the outcome variable. The effect of sudden gains at Time T on life-satisfaction at T + 2 was significant, $B = 0.47$, $SE = 0.20$, $t_{(1878)} = 2.3$, $p = .02$. The effect of sudden gains at Time T on WAI at T + 1 was also significant, $B = 0.15$, $SE = 0.06$, $t_{(2623)} = 2.64$, $p = .008$. The effect of within-patient WAI at T + 1 on life-satisfaction at T + 2, when controlling for sudden gains at T, was significant as well ($B = .11$, $SE = 0.06$, $t_{(2620)} = 2.82$, $p = .031$). The mediation model was significant (0.02, 95% confidence interval [CI]: 0.01 to 0.05, $p = .042$), with the indirect path explaining 6% of the total effect. All analyses controlled for the number of sessions the patient attended. Repeating the analyses using an alternative method to disentangle the between-patients from the within-patient effect of alliance yielded similar results (Curran & Bauer, 2011).

OQ as the outcome variable. We repeated the mediation model analyses with OQ as the outcome variable. The effect of sudden gains at Time T on OQ at T + 2 was significant, $B = -6.71$, $SE = 1.09$, $t_{(1629)} = -6.17$, $p < .0001$. The effect of sudden gains at Time T on WAI at T + 1 was also significant, $B = 0.15$, $SE = 0.06$, $t_{(2623)} = 2.64$, $p = .008$. The effect of within-patient WAI at T + 1 on OQ at T + 2, when controlling for sudden gains at T, was significant as well, $B = -1.14$, $SE = 0.32$, $t_{(2037)} = -3.49$, $p = .0005$. The mediation model was significant (−0.21, 95% CI: −0.42 to −0.05, $p = .008$), with the indirect path explaining 4% of the total effect. All analyses controlled for the number of sessions the patient attended.

Reverse causation. We tested a reverse causation hypothesis according to which alliance levels at Time T predicted the occurrence of sudden gain at Time T + 1, which in turn, predicted outcome at T + 2. Findings do not support the alternative mediation model. The mediation model was not significant either for life satisfaction (0.001, 95% CI: −0.59 to 0.71, $p = .95$) or for OQ (−0.01, 95% CI: −0.17 to 0.08, $p = .68$).

Missing Data

The dropout percentage was 26.6%, which is similar to what has been reported in the literature for this type of setting (Swift & Greenberg, 2012). To search for a potential bias effect of missing data, at the first step all analyses included interactions of each covariate with the missing pattern groups. At the second step, all analyses included interactions of each covariate with the completers versus the dropout group. All the interactions with the missing pattern groups and with the completers versus dropout groups were found not significant (all $ps \geq .23$) and were therefore removed from the model. Repeating the analyses without the five patients who had more than 35 sessions did not affect the findings.

Discussion

In the present naturalistic study, similar to Tang and DeRubeis's original study (1999) and to those that followed, many individual patients' symptomatology improved suddenly, in a single between-sessions interval. The percentage of patients showing at least one sudden gain was, however, lower than in other studies (12.4%). This is most likely because of the short length of the treatment, especially compared with the RCTs on which much of the literature on sudden gains is based. Because the mean length of treatment was 7.82 sessions ($SD = 6.62$, $Mdn = 6$), many patients did not remain in treatment long enough to meet the sudden gain criteria, especially the third one, requiring that the symptom severity at the sessions following the gain remain lower than in the sessions preceding it. Given our intention to provide information that can be generalized to clinical practice, and the fact that our treatment length was similar to that reported in routine primary care practice around the world (United States, Hansen et al., 2002; United Kingdom, Stiles et al., 2008; and Sweden, Falkenström et al., 2013), we conducted the analyses on the sample as a whole. Based on previous studies, however, it may be suggested that after matching the characteristics of patients from naturalistic settings to those of patients in RCTs, the prevalence and characteristics of sudden gains do not differ significantly (Wucherpfennig, Rubel, Hollon, et al., 2017).

In the present study, we focused on two critical questions in the literature on sudden gains, having to do with predicting sudden gains and understanding their underlying mechanisms: (a) whether it is possible to identify patients who are more prone to showing sudden gains based on pretreatment and early treatment characteristics, and (b) what is the source of the "upward spiral" mechanism that may produce the continuing effect of sudden gains. The present findings suggest that even with the use of machine learning methods, we were not able to identify any characteristics of patients more likely to show sudden gains. Although our findings suggest that a certain subgroup of patients, characterized by interactions between predictors that have been identified previously in the literature, was more likely to show sudden gains than were others, these findings were not strong enough to replicate even within our sample. Of note, the machine learning approach used in the present study goes beyond previous research, taking into account interactions between predictors to identify who is more likely to show sudden gains. But even when using this method, which enables us to better capture the richness of human complexity when seeking to identify individuals most likely to show sudden gains, we were not able to consistently identify such patients.

When interpreting the findings of this study on its own, the inability to detect predictors of sudden gains may be explained by the limitations of the study (such as the low percentage of patients showing sudden gains and a limited number of potential baseline predictors). But when the present findings are integrated with the accumulating literature on sudden gains, a broader picture emerges. Using a wide range of study populations and treatment orientations, previous studies also failed to detect consistent predictors of sudden gains. Although when focusing on each study, it is possible to argue that it happened for reasons inherent in their various designs and in their own limitations, it seems also possible that together, these studies may have stronger implications than any single study. Two main directions can be suggested for future research based on the available findings. First, we may consider changing the way we research this question. As suggested in other fields of research (e.g., in predicting suicide attempts and deaths as the result of suicide; Simon et al., 2018), prospective trials with large samples and many baseline variables that may be expected, based on theory, to predict sudden gains are needed to predict who may show sudden gains during treatment. Such trials provide rich data sets for the implementation of machine learning approaches.

Second, we may want to revise our research questions. The question of interest in the present study was "Who is more likely than average to be a sudden gainer?" in other words, whether there are individuals who are more prone to showing sudden gains. An alternative question, which yielded promising results so far, was: "What should the therapists do to facilitate sudden gains?" Integrating the two questions, a third one can be suggested: "Are some individuals more prone to showing sudden gains if certain effective techniques are used to help them realize this potential?" In other words, within-treatment processes may interact with between-patients trait-like characteristics to predict who may show sudden gains. For example, patients scoring higher on a pretreatment measure that assesses a certain capability may be more likely to benefit from techniques focusing on enhancing that capability (Cheavens, Strunk, Lazarus, & Goldstein, 2012). To the best of our knowledge, no study on sudden gains has examined this question to date.

When interpreting the present findings, it is important to take into account potential limitations of machine learning approaches in general, and their potential implementation on the present data. Although machine learning may have many advantages over traditional approaches, it is still an exploratory technique that requires independent prospective replications, using traditional hypothesis testing methods in independent samples (Cohen & DeRubeis, 2018). Given the flexibility of methods like decision tree analysis, there is a risk of overfitting, which reduces validity of out-of-sample inferences, so that the model will fit specifically the sample on which it was built, and make its generalizability in an independent application unlikely (Cohen & DeRubeis, 2018; Open Science Collaboration, 2015; Ioannidis, 2005). Thus, there is a risk of identifying predictors that may not be found to be important in a new sample. It is important, therefore, to test out-of-sample predictions, either on a different sample or a subsample of the original one (e.g., cross-validation). In this way, it is possible that findings that may have been significant using traditional methods will not reach significance while implementing machine learning approaches with cross-validation (as it appeared in the present study). Other limitations relevant to our study are the low occurrence of sudden gains, and the restriction to only the variables that were collected, omitting other potentially important constructs that were not measured.

The second focus in the present study was on the mechanism underlying the lasting and continuing effect of sudden gains on treatment outcome, conceptualized as the third stage in Tang and DeRubeis' model, or as the upward spiral (Tang & DeRubeis, 1999). We found a significant theory-driven mediation effect at the within-patient level: sudden gains predict subsequent strengthening in the alliance, which in turn predicts subsequent treatment outcome improvement, as manifested in better psychological functioning and greater life satisfaction. These findings are consistent with previous studies stressing the important role of alliance in the processes occurring following the sudden gain, as part of the upward spiral (Wucherpfennig, Rubel, Hofmann, et al., 2017). The findings provide important support to the theorized mechanisms of change underlying sudden gains (Tang & DeRubeis, 1999), complementing the findings reported so far in support of the first and second stages. The current findings support the theorized upward spiral according to which a positive feedback loop is triggered after the gain, which is expected to lead to additional changes in the aftergain sessions (Tang & DeRubeis, 1999). The findings stress the role of the therapeutic alliance in the process of consolidating of the sudden symptom improvements. Discovering how the alliance may bring about such changes is a task for future research, but it can be speculated that such processes may involve collaboration between patient and therapist in ascribing meaning to the rapid improvement (Wucherpfennig, Rubel, Hofmann, et al., 2017). For example, therapists may use the supportive collaborative relationship with the patients to discuss the meaning of such gains, in a way that may strengthen the patients' self-efficacy and sense of competence in overcoming problems and difficulties (Flückiger, Grosse Holtforth, Del Re, & Lutz, 2013).

The focus on within-patient effects when testing the theorized mediation model is an important contribution of the present study. A between-patients mediation effect may suggest that patients who experience sudden gains generally form stronger alliance and show better outcome than those who do not experience sudden gains. By contrast, a within-patient mediation model may suggest a within-patient process in which sudden gains may increase the chance of improvements in the alliance, which in turn may increase the chance of improvement in subsequent treatment outcome. The theoretical model describing the change following a sudden gain is a within-patient model, like all similar models of therapeutic change during treatment (Curran & Bauer, 2011). As shown repeatedly in the methodological literature, the within-patient and between-patients levels of influence can operate simultaneously and even in opposite directions, and the relation at one level is neither necessary nor sufficient to imply the same relation at another level (Curran & Bauer, 2011; Wang & Maxwell, 2015). Therefore, demonstrating a within-patient mediation model is crucial for supporting the mechanisms underlying the continuing effect of sudden gains, and it may make an important contribution to the literature on sudden gains.

An important limitation of the present study is the flip side of one of its main merits: its unique population. Using the sudden gains framework with this population expands its applicability to outpatient clinical settings, especially given that the study lends support to the mechanism theorized on the basis of RCTs, among patients with different sociocultural characteristics from those of the populations typically used to study sudden gains. At the same time, a caveat is in order because of the relatively low percentage of patients showing sudden gains. The low percentage of patients showing sudden gains may limit generalization to settings showing higher percentages of sudden gains and may further amplify the need to replicate the findings, especially those produced using machine learning and multilevel analysis methods. In addition, as in several other studies, the trial from which the data were derived did not find a significant direct effect of feedback (see review by Davidson, Perry, & Bell, 2015), although in other aspects the data showed similar patterns to those documented by RCTs conducted worldwide (e.g., the expected alliance-outcome association and moderators of this association; Zilcha-Mano & Errázuriz, 2015, 2017). Another limitation is the result of the fact that to avoid using the same variable to calculate the predictor (sudden gains) and outcome, we used the life satisfaction measure, which is widely accepted (Bjørnskov, 2010; Bjørnskov et al., 2010; Diener et al., 2010; Fleche et al., 2012), but it is based on only a single item. Some support for the validity of the findings may be suggested by the fact that the results of the within-patient mediation model were replicated when we used the OQ as the outcome variable. However, the results need to be replicated in future studies, using full-scale measures of life satisfaction, with strong psychometric properties. The percentage of variance explained by the mediation model is small, but comparable to other studies in the literature. Other limitations include the fact that diagnoses were made based on a clinical interview conducted by a psychiatrist, reliance on patient self-reports, and the fact that sessions were not videotaped, precluding our ability to code for adherence and competent use of techniques, which could have supported explorations of mechanisms other than those described in this report.

In sum, the present study is the first to use a machine learning approach to systematically examine who is more likely to show sudden gains. It suggests that even when broadening our search to include interactive effects between variables for better capturing the richness and nuances of human complexity, our findings were consistent with previous literature failing to find any deterministic characteristics of "sudden gainers." The present study also helps elucidate a mechanism by which the change following sudden gains may become lasting and continuing, creating an upward spiral. It is the first study to test the hypothesized mediation model according to which sudden gains affect further improvements in outcome by strengthening the alliance. The support the study provides to the theorized within-patient mediation model, even among a population with different sociocultural characteristics from those of the populations on which the sudden gain theory was built, serves as an important validation of the sudden gains framework.

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