Running head: Sudden gains in treatment resistant depression

Sudden Gains in Cognitive Behavior Therapy for Treatment Resistant Depression: Processes

of Change

Anna Abel

Department of Psychology, University of Exeter

Adele M. Hayes

Department of Psychological and Brain Sciences, University of Delaware

William Henley

University of Exeter Medical School

Willem Kuyken

Department of Psychiatry, University of Oxford

Author Note

Anna Abel, Department of Clinical Psychology, Royal Devon & Exeter Hospital, Church Lane, Heavitree, Exeter, EX2 5DY. Tel: +44 1392 676376. Email: anna.abel@nhs.net

Adele Hayes, Department of Psychological and Brain Sciences, University of Delaware; 108 Wolf Hall, Newark, DE 19716 USA, Tel: 302-831-0484. Email: ahayes@psych.udel.edu

William Henley, University of Exeter Medical School; College House, St Luke's Campus, Exeter, Devon, EX1 2LU Tel: +44 1392 726088. Email: W.E.Henley@exeter.ac.uk

Willem Kuyken, University Department of Psychiatry, University of Oxford, Warneford Hospital, Oxford 0X3 7JX. Tel: +44 1865 613139   Email: willem.kuyken@psych.ox.ac.uk

Abstract

Objective: Sudden gains were investigated in cognitive behavioral therapy (CBT) for treatment-resistant depression (TRD). Client and therapist processes in sessions proximal to sudden gains were examined to better understand the antecedents of sudden gains and potential mechanisms linking them to outcome. *Method*: Participants were 156 adults with TRD in a randomized controlled trial of CBT as an adjunct to pharmacotherapy (Wiles et al., 2013). Depression symptoms were assessed by the Beck Depression Inventory-II at each session. In a subsample of 50 clients, audio-recordings of 125 therapy sessions were rated for hope, emotional processing, and therapist competence in case-conceptualization. *Results:* Sudden gains were experienced by 54% of participants. Those with gains reported significantly lower depression severity at 12-month follow-up and more remission of symptoms than those without gains. Sudden gains also predicted lower depression at follow-up, beyond the slope of linear change in symptoms across treatment. Therapists demonstrated greater competence in case conceptualization with clients who reported sudden gains, and those with gains expressed more hope in sessions prior to a gain. In addition, more hope and emotional processing in the pre-gain sessions predicted less depression at follow-up, controlling for depression scores in the prior session. Better therapist conceptualization skills and more client hope in the baseline and pre-gain sessions were also associated with more emotional processing in those same sessions. *Conclusion:* This study extends the phenomenon of sudden gains in CBT for depression to a treatment-resistant population and identified important therapy processes that predicted long-term outcomes: hope and emotional processing.

Public Health Significance Statement. This study suggests that helping patients with treatment resistant depression develop hope and emotionally process and make meaning of their experiences can improve long-term outcomes.

Keywords: sudden gain, treatment-resistant depression, case conceptualization, emotional processing, hope.

Sudden Gains in Cognitive Behavior Therapy for Treatment-Resistant

Depression: Processes of Change

Depression is a prevalent, debilitating illness that carries a major personal and public

health burden (Mathers & Loncar, 2006). It is widely treated with antidepressant medications,

but evidence suggests that treatment-resistant depression is prevalent (Trivedi et al., 2006).

Wiles et al. (2012) provided evidence that cognitive behavior therapy (CBT) can be an

effective adjunctive treatment in patients who have not fully responded to antidepressants.

Yet, a significant proportion of people did not respond[1] to the adjunctive CBT (45% at 12

months, Wiles et al., 2013). Process-oriented research can reveal therapeutic targets that

might enhance treatment outcomes and guide treatment development (Hayes, Yasinski,

Barnes, & Bockting, 2015; Kazdin, 2007; Llewellyn & Hardy, 2001; Lorenzo-Luaces,

German & DeRubeis, 2014). The process of therapeutic change is especially under-

researched in treatment-resistant populations, although such research may be particularly

instructive in guiding therapist behavior in the face of treatment non-response.

One way to isolate and study processes that predict therapeutic outcome is to identify

discontinuities in symptom trajectories, such as periods of rapid symptom change. Such

discontinuities can highlight "critical" transition points in therapy and reveal factors that

mobilize and inhibit change (Hayes, Laurenceau, Feldman, Strauss & Cardaciotto, 2007;

Tang & DeRubeis, 1999). Sudden gains represent one form of discontinuity repeatedly

identified in depression symptom trajectories. Sudden gains refer to large and stable symptom

improvements observed in a single between-session interval (Tang & DeRubeis, 1999).

These gains often occur early in treatment and have been associated with improved

therapeutic outcomes across a range of interventions, including CBT (Greenfield, Gunthert &

Haaga, 2011; Tang & DeRubeis, 1999), behavioral activation (Masterson et al., 2014),

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[1] Treatment response was defined as at least a 50% reduction in symptoms from baseline.

supportive expressive psychotherapy (Tang, Luborsky & Andrusyna, 2002), and routine clinic psychotherapies (Adler, Harmeling & Walder-Biesanz, 2013; Lutz et al., 2013; Stiles et al., 2003). Sudden gains have also been identified in interpersonal therapy (Kelly, Cyranowski & Frank, 2007), family and supportive therapy (Gaynor et al., 2003), and pharmacotherapy (Vittengl, Clark & Jarrett, 2005) for depression. Further, sudden gains have been reported across a range of disorders including depression (Aderka, Nickerson, Bøe & Hofmann, 2012), social anxiety (Bohn, Aderka, Schreiber, Stangier, & Hofmann, 2013), post-traumatic stress disorder (Keller, Feeny & Zoellner, 2014), obsessive compulsive disorder (Aderka et al., 2011), and generalized anxiety disorder (Deschênes & Dugas, 2013). Thomas and Persons (2013) highlight the important caveat that researchers should also examine the unique contribution of sudden gains as a predictor of treatment outcomes beyond the slope of more gradual, linear change.

To date no studies have examined the incidence of sudden gains in treatment-resistant depression. Although there is no consensus definition, treatment-resistant depression typically refers to the persistence of depression despite treatment that might be expected to be effective (Fava, 2003). Cognitive therapy protocols characterize this population in terms of enduring hopelessness, helplessness, and low self-esteem, which are reinforced by persistent depression and successive treatment failures (Moore & Garland, 2003). Patients also engage in cognitive, emotional and behavioral avoidance that further maintains depression and can become more disruptive as depression persists (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996; Trew, 2011). It is a significant challenge for therapists to conceptualize clients' presenting problems and develop tractable treatment plans in this context (Moore & Garland, 2003). It is therefore informative to explore whether sudden gains occur with such entrenched depressive symptoms, and whether these gains are associated with treatment outcomes, as has been demonstrated with other presentations of depression.

Despite the accumulation of literature to support the clinical and prognostic significance of sudden gains (e.g. Aderka et al., 2012), there is little research on why sudden gains are linked to outcome and what therapists and clients can do to bring about such change. Tang and DeRubeis (1999) reported that sudden gains were preceded by cognitive shifts in critical pre-gain sessions, which they contend is consistent with Beck's hypothesis of cognitive mediation as a mechanism of change in CBT. In addition, therapeutic alliance scores improved in post-gain sessions (see also Lutz et al, 2013). Tang and DeRubeis (1999) hypothesized that the cognitive shift and sudden gain might trigger an "upward spiral" (p. 902) that precipitates further therapeutic gains. Tang and colleagues subsequently replicated the finding that cognitive change precedes sudden gains in CBT for depression (Tang, DeRubeis, Beberman & Pham, 2005). In contrast, some studies suggest that cognitive change may not precede sudden gains in non-CBT treatments (e.g. supportive expressive therapy, Andrusyna, Luborsky, Pham & Tang, 2006; non-treatment contexts, Kelly, Roberts & Bottonari, 2007).

Because sudden gains occur across a range of treatments for both depression and anxiety disorders (Aderka et al., 2012), it might be useful to assess transtheoretical variables hypothesized to precede sudden gains. Hope is one type of cognitive change variable that might predict sudden gains across a number of types of treatment. Several researchers have proposed that the development of hope is a key part of a remoralization process that occurs in the first few sessions of most treatments (Howard, Moras, Brill, Martinovich, & Lutz, 1996; Ilardi and Craighead, 1999), and this might be particularly relevant for a depressed population that has not responded to previous treatment. Change in hope typically occurs early in cognitive therapy for depression (DeRubeis et al., 1990; Kuyken, 2004; Rush, Kovacs, Beck, Weissenburger, & Hollon, 1981) and behavioral activation therapy (Jacobson et al., 1996) and is associated with better treatment outcomes. Hayes and colleagues (2007b)

also found that clients who showed an early rapid response to an exposure-based CBT expressed more hope in early sessions than those who did not show a rapid response. Thus, changes in hope might be an important predictor of the sudden gain, a specific type of early symptom improvement.

Evidence is emerging to suggest that emotional processing is another variable that merits exploration as a precursor of sudden gains in depression. Emotional processing (also called cognitive-emotional processing) has been proposed to be a common mechanism of change across a range of treatments and clinical disorders (Carey, 2011; Foa, Huppert, & Cahill, 2006; Foa & Kozak, 1986; Greenberg, 2002; Hayes et al., 2007b, 2015). Indeed, emotional processing is a key target of change in a Barlow's unified protocol for mood and anxiety disorders (Moses & Barlow, 2006). Therapeutic processing involves exposure to corrective information, working through and making meaning of difficult experiences, and a shift in meaning and affective response (Brewin et al., 2010; Foa et al., 2006; Greenberg, 2002). Emotional processing includes cognitive change that is similar to that assessed by Tang and colleagues (Tang & DeRubeis, 1999; Tang et al., 2005). Processing is a broader construct and includes meaning-making and the role of affect in therapeutic change. It has been associated with improved outcomes in exposure-based CBT for depression (Grosse Holtforth et al., 2012; Hayes et al., 2005; Hayes et al., 2007b), dialectical behavior therapy for treatment-resistant depression (Feldman, Harley, Kerrigan, Jacobo & Fava, 2009), and emotion-focused therapy for depression (Pascual-Leone & Greenberg, 2007; Pos, Greenberg, Goldman, & Korman, 2003). In addition, recent research suggests an association between sudden gains and emotional processing in critical pre-gain sessions of clients who received routine clinic psychotherapy (Adler et al., 2013). The current study examined the role of hope and emotional processing in relation to sudden gains in the context of CBT for treatment-resistant depression.

This study builds further on existing literature by examining therapists' competence in case conceptualization, a skill likely to be of particular value with TRD because of the entrenched beliefs and behavioral patterns that maintain this chronic disorder (Moore & Garland, 2003). Case-conceptualization is integral to CBT, but until recently it has received relatively little attention in research (Bieling & Kuyken, 2003). Case conceptualization is an evolving collaborative process between therapist and client that synthesizes theory, evidence, and practice to generate hypotheses about the causes and mechanisms that maintain a person's problems and disorders (Persons, 2012). Its principal function is to guide therapy, especially when the therapist is faced with complexity and treatment non-response, but it is also proposed to provide validation and normalization, foster engagement, and build client hope (Kuyken, Padesky & Dudley, 2009). These authors also propose that when case conceptualization includes a focus on clients' strengths and resilience, it can suggest treatment plans that build on these strengths, thereby potentially enhancing treatment outcomes. CBT for treatment-resistant depression requires a personalized case-conceptualization and treatment plan to first understand and then address the negative triad that can be pervasive and integrally implicated in maintaining depression (Moore & Garland, 2003).

This study examined whether therapists' skillful development of collaborative case conceptualizations can engender hope and facilitate emotional processing. More competent case-conceptualization was hypothesized to be associated with more client hope and to assist clients to process and make meaning of their experiences, both of which might facilitate sudden gains. We also examined case conceptualization, hope, and processing as predictors of 12-month treatment outcomes.

This paper is divided into two parts. The first aims to describe the incidence, magnitude, timing and stability of sudden gains over the course of CBT for treatment-

resistant depression and to evaluate whether sudden gains were associated with improved depression outcomes. The second part characterizes the sessions that preceded sudden gains by exploring client and therapist processes hypothesized to be associated with this therapeutic change, namely case-conceptualization competence, client hope and emotional processing. Sessions that preceded sudden gains were rated for these processes and compared to within- and between-session control sessions. Audio-recordings of therapy sessions were rated by raters blind to session number, sudden gain status, and treatment outcomes.

Method

Data Source: The CoBalT Study

This project is a secondary analysis of data collected as part of the CoBalT trial (Wiles et al., 2013). CoBalT was a multi-center pragmatic randomized controlled trial that examined the clinical and cost-effectiveness of CBT as an adjunct to pharmacotherapy for people with treatment-resistant depression in primary care. Thus, 469 eligible and consenting participants were randomized to continue with usual General Practitioner (GP) care including antidepressants, or to receive a course of CBT plus usual GP care. Thomas et al. (2012) report the protocol in full, Wiles et al. (2013) report the main effectiveness findings, and Hollinghurst et al. (2014) report the cost-effectiveness findings.

The CoBalT trial was approved by a multi-center research ethics committee (NRES/07/H1208/60) and local research governance. The present study utilized the CoBalT dataset in accordance with appropriate consents and ethical approvals. Additional approval for these analyses was granted by the University of Exeter Ethics Committee (2011/540).

Participants

Data from participants who were randomized to receive CBT in addition to usual GP care (n=235) and had consented to the use of their data in future research (n=210, 89%) were available for inclusion in this study. Participants were adults with treatment-resistant

depression, who met criteria for diagnosis of depression according to ICD-10 and had been

taking an adequate dose of antidepressant medication for at least six weeks but were still

reporting significant depressive symptoms. Patients who were currently engaged in

psychotherapy or secondary care or who had received more than 5 sessions of CBT within

the last 3 years were not included in the trial. Given that this study aimed to identify sudden

gains in symptom trajectories, the sample was restricted to participants who had received an

adequate dose of CBT. Sudden gains require a comparison of the means of the three sessions

before and after the gain, so those who attended at least nine sessions of CBT and who

completed the BDI-II in at least six sessions were included. This yielded a sample of 156

individuals (75%).

  Baseline characteristics. Of these 156 individuals, 73.1% were female and 99.4% were

Caucasian. The mean age was 49.6 years (SD=11.6). Just over half (53.2%) were married or

living as married and most (53.8%) were in paid employment. Participants reported severe,

chronic, and treatment-resistant experiences of depression. The mean pre-treatment BDI-II

fell within the severe range (M=31.96, SD=9.93). The majority (92.14%) of the sample

experienced two or more episodes, with 52.5% reporting five or more previous episodes.

Most of the sample (76.92%) reported that the duration of the current depressive episode was

more than a year (1 to 2 years=16.03%; 2 to 5 years= 26.92%; more than 5 years=33.97%).

In addition, most (69.9%) had been taking their current course of antidepressants for more

than a year. Comorbidity was almost universal; all but one individual obtained a secondary

psychiatric diagnosis (according to the Clinical Interview Schedule - Revised, Lewis et al.,

1992), the most frequent of which was generalized anxiety disorder (51.3%). These sample

characteristics were consistent with the full CoBalT intervention group; the only variation is

that this sample contained a slightly higher proportion of people in paid employment (53.8%

compared to 47%).

Therapy and Therapists

Participants were offered 12 to 18 sessions of individual face-to-face CBT. The median number of CBT sessions in this sample was 15 (Range=9-19). CBT sessions lasted approximately 50 minutes and were audio-recorded, subject to written client consent. Therapy was delivered according to seminal treatment manuals (Beck et al., 1979; Beck, 1995), with adaptations to explicitly target cognitive and behavioral avoidance (Moore & Garland, 2003). Consistent with Moore and Garland, emphasis was placed on using individualized case-conceptualizations to guide CBT (Kuyken et al., 2009).

Eleven (10 female), UK trained therapists delivered the CBT across three sites: Exeter, Bristol and Glasgow. Therapists had been practicing therapy for a mean of 9.7 years (*SD*=8.1). Training and regular supervision were delivered by experienced CBT therapists/supervisors. Therapist competence was independently verified using the Cognitive Therapy Scale – Revised (Blackburn et al., 2001) and the level of competence observed in the main trial suggested acceptable levels (Mean= 38.8, *SD*=8.0, Wiles et al., 2013).

Measures

The *Beck Depression Inventory, second edition* (BDI-II, Beck et al., 1996) measured self-reported depression symptoms at the start of each therapy session and also at pre-treatment baseline, six, and 12-month follow-ups. Twenty-one items assess symptom severity over a two-week period; scores range from zero to 63 with higher scores indicating more severe depression. It has strong psychometric properties, having been shown to be reliable, valid, and sensitive to change (Beck et al., 1996).

Coding of therapy sessions. Two different sets of raters were trained by the authors of the two coding systems used in this study. Training included instruction, discussion, and practice of pre-rated training and criterion sessions. Practice continued until inter-rater reliability of ICC $\geq$ .80 was achieved on all items in the criterion coding. Regular supervision

meetings were held between the coders and scale authors to review discrepancies and prevent

rater drift. All coders were blind to session number, sudden gain status, and treatment

outcome.

The *CHANGE Rating Scale* (Hayes, Feldman & Goldfried, 2006) was used to rate the

level of hope and emotional processing from audio-recordings of sampled therapy sessions.

The CHANGE is an observational coding system designed to measure the frequency and

extent of change processes in psychotherapy on a 4-point Likert scale from 0=*not present or*

very low to 3=*high.* Previous research indicates good inter-rater agreement and predictive

validity across a range of settings and disorders (Adler et al., 2013; Cummings, Hayes,

Cardaciotto, & Newman, 2012; Hayes et al., 2005, 2007b; Hayes & Yasinski, 2015; Yasinski,

Hayes, & Laurenceau, in press). *Hope* is the extent to which the person expresses a

commitment to change and an expectation that the future will be better and that progress can

be made on problem areas. Examples of Level 3 hope are: "I am beginning to see a way out

of this black hole. I think I will make it." and "At times I feel as if I am sinking, but another

part of me knows that there *is* a way out of this.") *Emotional processing* refers to the extent

to which a person explores and questions experiences related to their depression, considers

corrective information, and shows some shift in meaning and affective response. This

category is designed to capture cognitive concepts such as meaning-making, benefit finding,

cognitive change, and schema change, but it also includes concepts from emotion-focused

and exposure-based treatments, such as activating, exploring, and discriminating emotional

responses, and better integrating cognitive and emotional responses. Thus, it contains aspects

of both cognitive and affective change. This variable encompasses cognitive variables

assessed by Tang and colleagues (Tang & DeRubeis, 1999; Tang et al., 2005), but it is

broader in scope and intended to be more transtheoretical. Affective arousal without some

insight or perspective shift is not considered processing. Rumination, worry, and other

perseverative thoughts are also not considered processing and are coded by another CHANGE category (Unproductive processing). An example of Level 3 processing is: "I have thought of depression as an "enemy" or some sort of a destructive entity inside my head, but lately I have begun to see it as a sort of persistent delusion. It's like having an abusive manipulator constantly telling me whatever will tear me down and keep me there. My instincts tell me to believe in my own conclusions, but those conclusions always seem to lead me into darkness. Learning to question myself is very difficult, but I realize I must." Another example is: "I am so shut down emotionally. From a young age, I was taught not to feel. I was ridiculed for having emotions and being sensitive, so I became a robot. That worked very well in my family environment, but I've missed out on so much of life. As I realize this, I am letting myself feel again. It's scary, but I feel alive!"

Raters were trained for 10 to 15 hours on criterion codings. Three coders (clinical psychology post-graduates) rated sessions for hope and processing. Each session was rated independently by two coders. Discrepancies of two points or more were discussed in weekly supervision meetings, and consensus scores were used. The ratings for the two raters were averaged, and these scores were used in all analyses. Inter-rater agreement (intraclass correlations, ICC) on the raw scores for all sessions that were coded after training was $r=0.79$ for hope and $r=0.80$ for emotional processing.

Case-conceptualization competence was evaluated using the *Collaborative Case-Conceptualization Rating Scale* (CCCRS - Padesky, Kuyken & Dudley, 2011). The CCCRS provides an operational definition and observational coding system to evaluate therapists' competence in case-conceptualization as outlined by Kuyken et al. (2009). The CCCRS is a 14-item observer-rated scale that assesses the presence and degree of specific case-conceptualization activities on a four point Likert scale from 0=*incompetent* to 3=*expert*. The 14-items can be aggregated into a total score comprising the broad domains of competence

set out in the model (Kuyken et al., 2009): 1) *Evolving levels of conceptualization* refers to therapist and client building a conceptualization from simpler more descriptive conceptualizations early in therapy to more explanatory conceptualizations as therapy progresses (4 items); 2) *Collaboration* refers to therapist and client co-constructing the conceptualization (3 items); 3) *Empiricism* refers to therapist and client using CBT theory and hypothesis testing (3 items); and 4) *Strengths/resilience focus* refers to therapists drawing out clients' strengths and building an understanding of how clients' have responded adaptively to stress and challenges (4 items). Preliminary research has demonstrated high levels of inter-rater reliability, internal consistency and good convergent validity with the Cognitive Therapy Scale–Revised (CTS-R; Blackburn et al., 2001), a validated measure of general CBT competence (Kuyken et al., 2015). In the current study, two coders (clinical psychology post-graduates) independently rated sessions for competence in case-conceptualization using the CCCRS. The coders showed good inter-rater agreement on total competence in a sample of 15 double-rated tapes (ICC=0.83). Total scale competence scores were used in the analyses. The Cronbach's alpha for the CCCRS total score was α=.88.

Procedure

       Defining sudden gains. Individual treatment trajectories were examined to identify sudden gains. Sudden gain criteria should pragmatically distinguish clinically significant gains from transient noise or random symptom variability. Sudden gains were originally identified by Tang and DeRubeis (1999) according to the following criteria: a) at least a 7-point drop in BDI-II from one session to the next, b) the magnitude of the gain must equal at least 25% of the pre-gain BDI-II and c) the mean BDI-II of the three sessions preceding the gain must be significantly greater than that of the three sessions following the gain[2]. These criteria have been repeatedly used to identify sudden gains of clinical and prognostic

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[2] The differences between the two means exceed $t(4) \geq 2.78$ at $p<.05$.

significance (e.g. Keller et al., 2014; Tang & DeRubeis, 1999; Tang, DeRubeis, Hollon, Amsterdam, & Shelton, 2007). However, some have argued the seven- point criterion is arbitrary and have suggested other variations, for example including first-session gains (Gaynor et al., 2003). Aderka et al.'s (2012) meta-analysis of sudden gains reported that adjusting the criteria and including first-session gains did not significantly alter effect sizes. Furthermore, the reliable change index (Jacobson & Truax, 1991) for the current sample was 7.07 BDI-II points[3], and so the seven point cut-off appears justified. Therefore, the original Tang and DeRubeis (1999) criteria were retained.

Sampling procedures. The sample of therapy sessions for analysis was drawn from the 97% of participants who provided written consent to use their therapy audio-recordings for research purposes. The processes associated with sudden gains typically have been studied by comparing the pre-gain session to the pre-pre-gain session (e.g. Adler et al., 2013; Bohn et al., 2013; Hofmann et al., 2006; Tang & DeRubeis, 1999; Tang et al., 2005). While this offers valuable insight into changes that precede sudden gains, it does not shed light on how these changes may differ in those who do not experience sudden gains. In the current study, critical sessions proximal to observed sudden gains were evaluated and compared to both within- and between-person control sessions.

Twenty-five clients with sudden gains were randomly selected for inclusion in the second set of analyses. A yoked control group was constructed by selecting 25 clients without sudden gains and matching them to the sudden gain group by pre-treatment BDI-II score. The second therapy session was sampled from these 50 participants to provide a consistent "baseline" measure early in therapy, prior to the experience of sudden gains. In addition, the sessions immediately preceding and following sudden gains were sampled from

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[3] The reliable change index was calculated according to Jacobson & Truax formula (1991) using a test-retest reliability estimate of 0.93, consistent with the BDI-II manual (Beck, Steer & Brown, 1996).

the 25 clients with sudden gains. The pre-gain sessions for the yoked sample were selected by

sampling the session number that corresponded to the pre-gain session for the sudden gain

participant to whom the person was yoked. Participants who completed at least nine sessions

were included to provide a sufficient number of sessions to identify sudden gains. This

strategy yielded a total of 125 therapy sessions for analysis from 50 clients.

Results

Sudden Gains

To characterize sudden gains in TRD, we examined their frequency, magnitude, and

timing over the course of CBT. In all, 119 sudden gains were observed among 84 individuals,

thus 54% experienced a sudden gain at some point during therapy. Of these, 31 went on to

experience a second gain, and four displayed a third. The median pre-gain session was six,

and the mean magnitude of all sudden gains was 12.29 BDI-II points (*SD*=5.53, Range= 7-

36), which is equal to 62% of the mean symptom change achieved during therapy by sudden

gainers, and exceeded the mean change for those who did not experience a gain. Rates of

reversal were examined to assess the stability of sudden gains. A reversal occurred when at

least 50% of the gain was lost before the end of therapy (Tang & DeRubeis, 1999). Among

those who experienced sudden gains, this represented a stable improvement for 70%.

Sudden Gains and Depression Outcomes

Table 1 shows the mean BDI-II scores at pre-treatment, post-treatment and the 12-

month follow-up and rates of clinical remission at 12 months.

ANCOVA was used to test the hypothesis that individuals who experienced sudden

gains would have better depression outcomes at 12 months than those who did not show

sudden gains, after controlling for pre-treatment depression. There was a significant main

effect of sudden gains: people who experienced sudden gains reported fewer symptoms of

depression at 12 months ($F(1,150) =21.09$, $p<.001$) compared to those without gains[4]. This represents a medium effect size (Cohen's d) of 0.57. In addition, chi square analyses indicated that more clients with sudden gains achieved remission of depressive symptoms[5] at 12 months than those without gains ($\chi^2(1) =5.37$, $p=.02$).

In addition, regression analysis was used to examine whether the sudden gain pattern (0,1) predicted 12-month outcomes beyond the linear slope of change in depression scores across the course of treatment (simple slope estimates of BDI-II scores over time). The individual linear slope parameters (Mean $BDI_{slope} = -1.18$, $SD=.89$) and sudden gain status (0,1) were entered simultaneously in the regression equation, controlling for pretreatment depression scores. Both the slope of total symptom change ($B=5.83$, $SE=1.45$, $\beta =.38$, $t=4.02$, $p<.001$) and the sudden gain pattern ($B=-7.02$, $SE=2.51$, $\beta =-.26$, $t=-2.80$, $p=.008$) were significant predictors of better 12-month depression outcomes, and the model accounted for 67% of the variance. The 12-month BDI scores were on average about 7 points lower for patients experiencing a sudden gain, after accounting for the linear change.

Processes Associated with Sudden Gains

Table 2 shows descriptive statistics for client hope and emotional processing and therapist competence in case-conceptualization. Two-way mixed ANOVAs were conducted to ascertain whether these variables were associated with sudden gains. Specifically, we examined whether those with sudden gains had higher levels of hope, emotional processing, and therapist competence in case-conceptualization than those without sudden gains, and

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[4] Analyses focused on outcome at 12 months, rather than posttreatment, in order to examine the stability of sudden gains in depression. However, posttreatment depression was tested as an alternative outcome measure in the ANCOVA analyses. The results replicated the findings using depression at 12 months as outcome. Those who showed sudden gains reported significantly fewer symptoms of depression at the end of therapy, after controlling for pre-treatment depression.

[5] Remission of depression is indicated by a BDI-II score of 13 or lower (Beck et al., 1996).

whether levels were higher in the pre-gain than baseline sessions. Sudden gain status (present/not) was the between-group factor and time-point (session two baseline /pre-gain) was the repeated measure. There was no significant effect of time on the competence of case-conceptualization ($F(1,45)= 0.06$, $p=.81$), but there was a significant main effect of sudden gain status ($F(1,47)= 5.51$, $p=.02$). As predicted, therapists showed greater competence in case-conceptualization with people who experienced a sudden gain, although competence did not differ significantly between baseline and the pre-gain session. Levels of case-conceptualization competence in the baseline and pre-gain sessions were in the competent range for those who experienced a sudden gain, but in the novice/beginner range for those who did not experience a gain. There was no significant interaction between sudden gain status and time-point ($F(1,45)= 0.01$, $p=.92$), suggesting that the difference in competence levels from baseline to the pre-gain session between those with and without a sudden gain was not significant.

The clients with sudden gains expressed significantly more hope than those without gains ($F(1,47)= 6.14$, $p=.02$). Hope did not differ significantly between the baseline and pre-gain sessions ($F(1,47)=0.54$, $p=.47$), and again the interaction was not significant ($F(1,47)=0.34$, $p=.56$). Emotional processing did increase significantly from baseline to the pre-gain session ($F(1,47)=9.25$, $p=.004$), but did not differ significantly by sudden gain status ($F(1,47)=2.17$, $p=.15$). Again, the interaction between the factors was not significant ($F(1,48)=0.19$, $p=.67$).

Paired two-tailed t-tests examined how the process variables changed in the single between-session interval following a sudden gain (from pre-gain to post-gain) within the sudden gain group. Among clients with sudden gains, therapist competence in case-conceptualization did not differ significantly between pre- and post-gain sessions ($t(24)=-1.28$, $p=0.21$). There was a trend towards an increase in hope following a gain ($t(24)=-2.04$,

p=.052). However, it is noteworthy that the mean increase in hope observed during this single-session interval is more than double that observed in the period from baseline to pre-gain, a period that is equal to a median of four sessions. Emotional processing increased significantly from pre- to post-gain ($t(24)=-3.02$, *p*=.01). These findings imply that hope and processing might precede and also emerge from the sudden gain, whereas as expected, case-conceptualization competence remains relatively stable over time.

Relationships between case-conceptualization, hope, and processing

Intercorrelations between the process variables are shown in Table 3. More competence in case-conceptualization (CCCRS total) and more client hope at the baseline and pre-gain sessions were significantly correlated with more emotional processing in those same sessions. In contrast, more conceptualization competence was not associated with hope at either assessment point. It is interesting to note that more competence in case-conceptualization at baseline was not significantly correlated with subsequent hope or processing in the pre-gain sessions, and neither hope nor processing in the baseline sessions was significantly correlated with later pre-gain CCCRS scores. These findings suggest concurrent rather than lagged associations between therapist and client variables.

Predicting depression outcome. We next examined whether the sudden gain pattern revealed therapist and client variables that might be early prognostic indicators of 12-month treatment outcomes. Hierarchical multiple regression analyses were used to evaluate whether the process variables that differentiated those with and without sudden gains (case-conceptualization, hope) or that changed in the vicinity of sudden gains (emotional processing) predicted treatment outcomes at the 12-month follow-up assessment. Client hope, emotional processing, and total therapist CCCRS scores in the pre-gain sessions were entered simultaneously, after controlling for the depression levels in the session immediately before the pre-gain session. As seen in Table 4, more hope and emotional processing at the pre-gain

session uniquely predicted lower levels of depression at 12 months. Thus, the sudden gain pattern highlighted two client variables early in treatment that predicted long-term functioning. Case-conceptualization was not a significant predictor of treatment outcomes over and above pre-gain depression, hope and emotional processing.

Discussion

This paper contributes to a growing body of literature documenting nonlinear trajectories of therapeutic change (e.g. Forand & DeRubies, 2013; Hayes, et al., 2007a, 2007b, 2015; Lutz et al., 2013; Vittengl, Clark, Thase & Jarrett, 2013). This is the first to demonstrate sudden gains in a treatment-resistant population of individuals with severe and chronic depression symptoms. Sudden gains were of comparable magnitude, timing, and outcome effect sizes, yet they were slightly more prevalent (54%) than has been reported previously (e.g. Aderka et al., 2012, 37.4%; Hardy et al., 2005, 40.8%; Tang et al., 2007, 40%). Extending previous research on sudden gains, those with TRD who experienced sudden gains had significantly better depression outcomes at 12 months than those who did not experience sudden gains. Half of clients with sudden gains achieved remission of depression after 12 months, compared to only one third of people without sudden gains. In addition, the sudden gain pattern predicted 12-month outcomes beyond the slope of linear change in symptoms over the course of treatment.

Sudden gains have been well-documented to occur in treatments for depression (Aderka et al., 2012) and to predict outcome, but it is not yet clear which therapist and client factors might contribute to this change. This study provides promising evidence that sudden gains are associated with case-conceptualization, hope, and emotional processing. In the sessions that preceded sudden gains (baseline and pre-gain), therapists were rated as more competent in case conceptualization for clients with sudden gains than without, and more hope was expressed by clients with sudden gains than without. Emotional processing

increased from baseline to pre-gain sessions in all clients (with and without sudden gains) and might be a key aspect of CBT. A particularly interesting set of findings was that higher therapist conceptualization competence and more client hope were associated with more emotional processing. These two factors might provide facilitative conditions for emotional processing.

CBT with clients with TRD typically presents challenges related to working with pervasive and longstanding cognitive and behavioral patterns of avoidance (Moore & Garland, 2003). Case conceptualization provides a way for therapists to work collaboratively with clients to understand these problems and work to find pathways to change. Our data suggest that when therapists demonstrate greater skill in case conceptualization, clients are more likely to experience significant early improvements in depression that then predict better outcomes at the 12-month assessment. Likewise, hope for change may predispose an individual favorably towards experiencing gains in therapy. The combination of high quality case-conceptualization and client hope may facilitate symptom relief, which can manifest in sudden gains.

Emotional processing increased prior to a gain in clients with and without sudden gains. In those who experienced sudden gains, emotional processing also increased significantly from pre- to post-gain, and hope tended to increase. These findings might suggest an "upward spiral" of change after the gain, as predicted by Tang and DeRubeis (1999). One plausible account is that therapists who can use case-conceptualization effectively to support clients to process and make meaning of their experiences during this critical window of time in therapy contribute to sudden gains, which facilitates longer term change and recovery. These findings also align with and build upon recent literature suggesting that emotional processing is associated with sudden gains in routine clinical practice (Adler et al., 2013) and with greater improvement in cognitive-behavioral treatments

for depression (Feldman et al., 2009; Hayes et al., 2005, 2007b; Grosse Holtforth et al., 2012) and emotion-focused therapy for depression (Pascual-Leone & Greenberg, 2007; Pos et al., 2003). Client hope and emotional processing are specific types of cognitive change that also consider the role of emotion in the change processes. Thus, our findings extend Tang and colleagues findings on cognitive change as a precursor of sudden gains in CBT (Tang & DeRubeis, 1999; Tang et al., 2005).

Client hope and engagement in emotional processing in pre-gain sessions predicted improved depression outcomes at 12 months. Regression analyses revealed that hope and emotional processing uniquely predicted depression at follow-up, after controlling for depression levels in the session immediately before the pre-gain session. Emotional processing seems to contribute to change beyond the generally facilitative condition of having hope and motivation for change. None of the therapy variables held statistically significant predictive value when measured at the second therapy session (baseline) or after the gain had occurred. This supports the notion that sudden gains might signify a "critical" period of transition in the process of therapeutic change that influences therapy outcome and can reveal possible early mechanisms of change (Hayes et al., 2007a, 2015; Lorenzo-Luaces, et al., 2014; Tang & DeRubeis, 1999). This period also highlights where therapists might usefully focus on supporting client hope and emotional processing.

Although many commentators describe case-conceptualization as a cornerstone of CBT, to our knowledge this is the first empirical study to demonstrate associations with a key predictor of long-term outcomes—emotional processing. Better therapist competence in case-conceptualization in the baseline and pre-gain sessions was associated with more client emotional processing in those same sessions. It is interesting that more therapist competence and client hope were not significantly associated with each other, but both were associated with more emotional processing. From a clinical perspective, the combination of therapists'

ability to facilitate clients' conceptualizations of their experiences and clients' hope for change may help clients to process and make meaning of issues and emotions related to their depression. Whilst these findings must be viewed as preliminary, they suggest that future research could investigate more closely the interactive processes between therapist and client that can facilitate change. If we are to better understand patterns of change in therapy and how they occur, it is also important to examine multiple aspects of the therapy process (therapist, client, and their interaction) during periods of transition (Llewellyn & Hardy, 2001). Further research may also unpack the subscales of the CCCRS instrument to more sensitively assess different domains of competence in relation to therapeutic change and processing. With larger samples, other aspects of therapist effects should also be explored.

In examining the impact of the sudden gain, this study suggests that more emotional processing and hope emerge following a gain. Hope and processing were significantly and positively related. One plausible hypothesis is that experiencing a sudden gain validates earlier hope and may foster further hope and commitment for change. This may prime clients' active engagement in the process and tasks of therapy, including efforts to approach, explore and make meaning of their experiences of depression. This aligns with writing on the facilitative role of hope in the process of therapy (e.g. Howard et al., 1996; Kuyken, 2004). Sudden gains may challenge the chronic, defensive, and avoidant cognitive and behavioral processes that inhibit change, thereby unlocking the depressive system to allow clients to approach and make meaning of experiences and emotions related to depression. This hypothesis is consistent with the concept of Tang and DeRubeis' (1999) upward spiral hypothesis and with Hayes et al.'s (2007b; 2015) suggestion that early change might increase flexibility and facilitate later processing. However, without information on "post-gain" sessions of those without sudden gains, more research is needed to understand the impact of sudden gains on therapeutic processes.

Study Strengths and Limitations

This study was embedded within a large well-conducted randomized controlled trial with a treatment-resistant population for whom the process of therapeutic change is especially meaningful, given the entrenched nature of the depressive system. We examined both therapist and client processes during "critical" therapy sessions and compared them to within- and between-person controls to characterize processes of change during transition periods.

This study suggests that hope and processing play a role in understanding how sudden gains are associated with better treatment outcomes. However, a limitation is that it was only possible to rate a subsample of therapy sessions. For example, the "post-gain" session did not have a corresponding between-person control, restricting the conclusions that can be drawn. It was not possible to code the post-gain sessions given the labor-intensive nature of coding, but future research could compare post-gain sessions for those who do and do not experience sudden gains to evaluate the upward spiral hypothesis (Tang & DeRubeis, 1999). In addition, the Tang and DeRubeis (1999) criteria for identifying a sudden gain require that the mean BDI-II of the three sessions preceding the gain is significantly greater than that of the three sessions following the gain, so we included patients who completed at least 9 sessions of CBT. It is possible that findings might be different if all participants were included and if sudden gains in the first three sessions could be identified, but the Tang and DeRubeis criteria preclude this analysis. Another limitation is the potential for type one error due to the number of statistical analyses conducted. However, a more conservative approach could fail to detect potentially important findings given the relatively small sample size. Nonetheless, the study provides effect size estimates for future adequately powered studies. This study explores sudden gains in a new context, where little is known about the mechanisms linking sudden gains to outcome. Therefore, an exploratory approach at this hypothesis-generating stage was warranted. However, we acknowledge that uncertainties remain over how the process

variables change in the period leading up to and following sudden gains, which future research can clarify.

Our definition of "treatment resistance" was a strength in terms of its pragmatism. That is to say, clinicians need to know whether CBT is a viable approach when patients do not respond to antidepressants, and the parent trial answered this question affirmatively (Wiles et al., 2013). However, we acknowledge that different definitions of treatment resistance are used in the field. With respect to the process questions we posed, it may make more sense to characterize this group in terms of "treatment non-response." It is also important to note that although all patients were receiving antidepressant medication for at least six weeks at an adequate dose, mean pre-treatment depression scores fell in the severe range. In addition, almost 90% of the sample had had a previous episode of depression, and more than half reported five or more previous episodes. Thus, this is a sample that for the most part had been struggling with depression without sustained relief.

CBT was delivered in the context of a randomized controlled trial. A strength was that therapists were well-trained, which increases the internal validity of the study. However, future research may increase external validity by extending findings to more naturalistic clinical settings with greater variability in therapist competence (e.g., Adler et al., 2013; Lutz et al., 2013). Similarly it would be instructive to extend to settings with more diverse samples, as this sample was largely Caucasian. The CoBalT usual care group was not included in this study because fewer longitudinal symptom measures were available and of course no therapy audio-recordings were available for these participants. It would be a valuable step to directly compare trajectories of symptom change and the concomitant therapy processes in CBT and usual care groups to better assess the specific effects of CBT. This could also help to establish whether sudden gains are a part of the natural course of depression. It also possible that more hope and emotional processing, precede sudden gains

or early improvement in everyday life outside of therapy and are not specific to CBT. Naturalistic experience sampling methods with the same population could address this question.

The design of this study allowed for a comparison of therapist and client variables in those with and without sudden gains and in sessions at baseline, before the gain, and after the gain. Although attention was paid to temporal sequencing in this design, a larger sample and the inclusion of a control condition would allow for more sophisticated modeling of multiple variables and the timing of change processes. Another step to address causality is to manipulate the variables under question. For example, researchers could compare usual care, with standard CBT and with CBT augmented to enhance therapist case-conceptualization and client hope to facilitate emotional processing and meaning-making.

Conclusions

This study suggests that sudden gains in symptom change are prevalent in people with treatment-resistant depression participating in CBT. It further validates the clinical significance of sudden gains, by suggesting that they represent a meaningful transition point in therapy for depression and contribute to sustained wellness, even in treatment-resistant cases. These findings add to a growing body of literature emphasizing the importance of studying time-course data and the shape of therapeutic change to identify important transitions points and potential mechanisms of change (e.g. Hayes et al., 2007a; Hayes et al., 2015; Lorenzo-Luaces, et al., 2014; Tang & DeRubeis, 1999). Finally, this study suggests that therapist case-conceptualization skills and client hope might be facilitative conditions for clients' emotional processing of the experiences related to their depression, and that these variables together may be instrumental in bringing about sudden gains and contributing to improved depression outcomes. Future research will need to unpack the more precise temporal patterning and causality of these relationships.

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Author Note

Anna Abel, Department of Clinical Psychology, Royal Devon & Exeter Hospital, Church Lane, Heavitree, Exeter, EX2 5DY. Tel: +44 1392 676376. Email: anna.abel@nhs.net

Adele Hayes, Department of Psychological and Brain Sciences, University of Delaware; 108 Wolf Hall, Newark, DE 19716 USA, Tel: 302-831-0484. Email: ahayes@psych.udel.edu

William Henley, University of Exeter Medical School; College House, St Luke's Campus, Exeter, Devon, EX1 2LU Tel: +44 1392 726088. Email: W.E.Henley@exeter.ac.uk

Willem Kuyken, University Department of Psychiatry, University of Oxford, Warneford Hospital, Oxford 0X3 7JX. Tel: +44 1865 613139   Email: willem.kuyken@psych.ox.ac.uk

Correspondence concerning this article should be addressed to Willem Kuyken, Department of Psychiatry, University of Oxford, Warneford Hospital, Oxford 0X3 7JX. Email: willem.kuyken@psych.ox.ac.uk

Table 1

Mean Depression Outcomes by Sudden Gain Status

Participant classification	*n*	Pre-treatment BDI-II	Post-treatment BDI-II	12-month BDI-II	Percent achieving remission at 12 months
Clients with sudden gains	84	32.11 (8.87)	12.07 (10.75)	12.59 (11.43)	49%
Clients without sudden gains	72	31.42 (11.10)	19.82 (14.50)	20.19 (15.22)	31%

Note.

BDI-II = Beck Depression Inventory, 2nd Edition (Beck et al., 1996); Remission of depression is defined by a BDI-II score of 13 or less (Beck et al., 1996); Standard deviations are in parentheses.

Table 2

Means and Standard Deviations for Therapist Case-Conceptualization Competence and Client Hope and Processing at Different Time Points in Therapy Among Clients with and without Sudden Gains

Variable	Clients without sudden gains (*n*=24[†])		Clients with sudden gains (*n*=25)		
	Session 2	Matched pre-gain session	Session 2	Pre-gain session	Post-gain session
Positive hope	1.13	1.15	1.43	1.62	2.04
(*SD)*	(0.47)	(0.83)	(0.70)	(0.89)	(0.75)
Emotional	1.04	1.42	1.24	1.74	2.24
processing (*SD*)	(0.75)	(0.80)	(0.82)	(0.82)	(0.75)
CCCRS Total	18.13	17.71	21.92	21.64	23.40
(*SD*)	(7.47)	(5.68)	(7.14)	(7.02)	(6.95)

Note.

[†] Data from one participant was not usable due to failure of session audio-recordings; Standard deviations are in parentheses; CCCRS = Competence in Case-Conceptualization Rating Scale (Padesky, Kuyken & Dudley, 2011); Pre-gain sessions immediately precede a sudden gain; Post-gain sessions immediately follow sudden gains. Matched pre-gain sessions are selected from the yoked sample of clients without sudden gains to correspond to the pre-gain session number of each person's yoked sudden gain participant.

Table 3

Intercorrelations between Case-conceptualization Competence, Hope and Processing at the Baseline (session two) and Pre-gain sessions, and

Depression Severity at Pre-treatment and 12 months (n=49)

	1	2	3	4	5	6	7
1. Hope at baseline	-						
2. Hope at pre-gain	0.18	-					
3. Emotional processing at baseline	0.40**	-0.08	-				
4. Emotional processing at pre-gain	0.30*	0.59***	0.22	-			
5. CCCRS Total scale at baseline	0.21	0.05	0.38**	-0.05	-		
6. CCCRS Total scale at pre-gain	0.21	0.22	0.11	0.37**	0.40**	-	
7. Pre-treatment depression (BDI-II)	-0.05	-0.10	0.15	-0.10	0.25	-0.07	-
8. Depression at 12 months (BDI-II)	-0.14	-0.50***	0.03	-0.49***	-0.01	-0.33*	0.49***

Note. CCCRS = Competence in Case Conceptualization Rating Scale (Padesky, Kuyken & Dudley, 2011); BDI-II = Beck Depression Inventory – 2nd Edition (Beck et al., 1996); *p<.05, **p<.01, ***p<.001

Table 4

Hierarchical Multiple Regression Table of Case-conceptualization Competence, Hope and Processing in Pre-gain Sessions as Predictors of Depression at the 12-month Assessment, Controlling for Pre Pre-Gain Session Depression

Variables	Step 1				Step 2			
	B	SE of B	β	t	B	SE of B	β	t
Pre-pre-gain depression (BDI-II)	0.75***	0.14	0.62	5.46	0.65***	0.12	0.54	5.50
Hope					-3.98*	1.83	-0.26	-2.18
Emotional processing					-4.20*	2.04	-0.25	-2.05
CCCRS Total scale					-0.06	0.21	-0.03	-0.31
R^2	0.39				0.60			
F for change in R^2	29.82***				7.76***			

Note.
CCCRS = Competence in Case Conceptualization Rating Scale (Padeksy, Kuyken & Dudley, 2011); BDI-II = Beck Depression Inventory – 2nd Edition (Beck et al., 1996). Pre pre-gain session=session immediately before the pre-gain session. *p<.05, **p<.01, ***p<.001,