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Sudden Gains in Internet-based Cognitive Behaviour Therapy for Severe Health Anxiety

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Abstract

Objective—A sudden gain is defined as a large and stable individual improvement occurring between two consecutive treatment sessions. Sudden gains have been shown to predict better long-term improvement in several treatment studies, including cognitive behavioural therapy for depression and anxiety disorders, but have not been studied in the treatment of health anxiety or any form of internet-based cognitive behavioural therapy. The aim of this study was to investigate the role of sudden gains in internet-based cognitive behavioural therapy for severe health anxiety.

Method—We examined the occurrence and significance of sudden gains in measures of health anxiety in 81 participants receiving internet-based cognitive behavioural therapy. We compared patients with sudden gains, patients without sudden gains, and patients with gradual gains.

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Results—Thirteen participants (16%) experienced one sudden gain in health anxiety with individual sudden gains distributed across the treatment. As expected, patients with a sudden gain showed larger improvements than patients without a sudden gain at post-treatment ($d = 1.04$) and at one-year follow-up ($d = 0.91$) on measures of health anxiety.

Conclusions—Consistent with previous studies, sudden gains in internet-based cognitive behavioural therapy are associated with significantly larger and stable treatment effects up to one-year follow-up.

Keywords

Sudden gains; health anxiety; cognitive behaviour therapy; internet

Severe health anxiety or hypochondriasis is characterized by a persistent and debilitating fear of developing serious somatic disease based on misinterpretation of benign bodily sensations (American Psychiatric Association, 2000). The disorder is common in health care contexts, increases the risk of developing major depression, follows a chronic course, and is associated with long-term functional impairment (Barsky, Fama, Bailey, & Ahern, 1998; Barsky, Wyshak, Klerman, & Latham, 1990; Faravelli et al., 1997; Noyes et al., 1993; Noyes et al., 1994). In DSM-5, hypochondriasis has been replaced by somatic symptom disorder and illness anxiety disorder (American Psychiatric Association, 2013) and the findings of the present study are thus mostly relevant for these DSM-5 disorders. Cognitive behaviour therapy (CBT) has been shown to be an effective treatment for severe health anxiety and has the best empirical support among the psychological treatments (Clark et al., 1998; Greeven et al., 2007; Seivewright et al., 2008; Speckens et al., 1995; Warwick, Clark, Cobb, & Salkovskis, 1996). Findings from meta-analyses and systematic reviews indicate that internet-based CBT for anxiety and depressive disorders can be effective (e.g. Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Hedman, Ljótsson, & Lindefors, 2012), even when administered in routine clinical settings (e.g. Hedman et al., 2013c). However, additional efficacy data are needed.

A recent randomized controlled trial of clinician guided internet-based CBT achieved large effects for treating severe health anxiety, similar to effect sizes obtained with conventional CBT (Reference omitted to enable masked review). In short, the treatment comprised online bibliotherapy with therapist support through an online messaging system resembling email (Andersson, 2009). The hypothesized mechanism of change of internet-based CBT is similar to face-to-face CBT as described by Furer and Walker (2005). It also shares similarities to CBT for obsessive compulsive disorder and panic disorder (Barlow, 2002; Franklin & Foa, 2011). The main treatment component includes exposure to health anxiety-related stimuli and response prevention. Specifically, clients engage in exposures to illness-related thoughts while discouraging reassurance seeking behaviours upon detection of perceived threatening bodily sensations.

It has been shown that improvement during CBT for depression typically follows a non-linear course with occasional sudden gains (Aderka, Nickerson, Boe, & Hofmann, 2012b; Hayes, Laurenceau, Feldman, Strauss, & Cardaciotto, 2007). Tang and DeRubeis (1999) defined a sudden gain (SG) as unusually large improvements from one session to another. A SG is defined by criteria. 1) A SG must meet an absolute criterion, reflecting a large improvement in reference to the 'global' over-all improvement from pre to post-treatment; in most publications, a reduction of 1 SD of this overall improvement has been used (i.e. at least seven points on the Beck Depression Inventory in Tang & DeRubeis 1999). 2) A SG must also meet a relative criterion showing more than 25% improvement from one session to another. 3) Finally, a SG has to meet a stability criterion that is the scores of the three sessions preceding the SG have to be significantly higher than three sessions following it.

In their analysis (Tang & DeRubeis, 1999), SGs occurred in 39% of persons treated with CBT for depression in two randomized controlled trials. Interestingly, SGs were strongly associated with larger improvements throughout the overall course of treatment, accounting for more than half of the outcome variance (Tang & DeRubeis, 1999). In an effectiveness study comparing sudden gainers to gradual gainers (i.e., those making the same improvement in absolute and relative terms but not between consecutive sessions), it was found that patients with a SG were significantly more improved than the gradual gainers (Greenfield, Gunthert, & Haaga, 2011). This suggests that the suddenness in itself is a central phenomenon.

Aside from CBT for depression, SGs have also been shown to be a common feature in CBT for social anxiety disorder (Hofmann, Schulz, Meuret, Moscovitch, & Suvak, 2006), panic disorder (Clerkin, Teachman, & Smith-Janik, 2008), generalized anxiety disorder (Present et al., 2008), and obsessive-compulsive disorder (Aderka et al., 2012a). A recent meta-analytic review investigating the effect of SGs for depression and anxiety disorders showed that the between-group effect size of individuals with vs. without SG was moderate to large (Hedges' $g = 0.62$) on primary outcomes (Aderka et al., 2012b). It also showed that SGs occur regularly in CBT and the authors concluded that the phenomenon is non-transient and linked to better outcomes at post-treatment as well as longer-term follow-up (Aderka et al., 2012b).

The seminal paper by Tang and DeRubeis (1999) reported that SGs were preceded by a cognitive change in the pregain session, thus supporting a cognitive meditational hypothesis. However, other studies did not find that cognitive changes precede SGs (Andrusyna et al., 2006; Hofmann et al., 2006). It also seems that SGs can occur as often in exposure-based treatments as in cognitive treatments, suggesting that specific interventions aimed directly at altering thought processes are not necessary for the large and sudden improvement that a SG constitutes (Hofmann et al., 2006). Doane, Feeny, and Zoellner (2010), investigating SGs in a treatment focusing on exposure and response prevention for PTSD, found that 53% of participants experienced SGs, demonstrating that behavioural interventions with little emphasis on directly altering cognitions can produce non-linear sudden improvements on the same scale as treatments based on cognitive interventions. So far, no study has examined SGs in CBT for severe health anxiety or compared internet-based and face-to-face treatment modalities of the same CBT approach.

The aim of the present study was to investigate SGs in internet-based CBT for severe health anxiety with a focus on exposure and response prevention. We hypothesized that the proportion of persons with SG would be in the same range as in CBT for other anxiety disorders and that persons who experienced a SG would make larger short- and long-term improvements than those who did not.

Design

This study employed a within group design with repeated measurements using a sample of participants ($N = 81$) that received treatment within the context of a randomized controlled trial (RCT). Half the sample was crossed over to treatment after 12 weeks being on a waiting list with access to an online discussion forum. There were no significant group differences between participants receiving immediate vs. delayed treatment in terms of sociodemographic variables and psychiatric symptoms.

All randomized participants were included in this study. Assessments were conducted before (pre-treatment), immediately after treatment (post-treatment), six months post-treatment (6MFU), and one year post-treatment (1YFU). During the treatment phase, the primary

outcome measure was administered on a weekly basis. Diagnostic interviews were performed by experienced licensed clinical psychologists at pre- and post-treatment. Participants were classified as sudden gainers or non-sudden gainers, the latter group comprising gradual gainers and non-gainers. A detailed description of classification criteria is provided below. The main outcome study has been reported elsewhere (Hedman et al., 2013a; Hedman et al., 2011)

Sample and Main Inclusion Criteria

The sample comprised 60 women (74%) and 21 men (26%) with a mean age of 39.0 ($SD = 9.7$) years. On average, participants had suffered from severe health anxiety for 21.0 ($SD = 13.2$) years. Of the 81 participants, 70 (86%) were married or in a stable long-term relationship and 54 (67%) had children. A more detailed overview of the characteristics of the sample is presented in Table 1. The study was conducted in a university hospital setting in Stockholm, Sweden and treatments were delivered at a unit specializing in internet-based CBT. That is, the researchers conducting the study and the psychologists delivering the treatments were employed at this unit, but participants accessed the treatment from their home and did not have any appointments at the unit during the treatment. Participants could apply through self-referral or referral from primary or psychiatric care. Informed consent was obtained from all participants and the study was approved by the regional ethics review board in (location omitted to enable masked review).

To be included in the study, participants had to meet the following criteria: (a) have a principal diagnosis of severe health anxiety, i.e. hypochondriasis, according to DSM-IV-TR (American Psychiatric Association, 2000), (b) agree not to undergo any other psychological treatment for the duration of the study, (c) have no history of psychosis or bipolar disorder, and (d) have a constant dosage two months prior to treatment if on prescribed medication for anxiety or depression and agreed to keep dosage constant throughout the study. Implementation of the latter criterion was assessed after treatment. Diagnostic assessments were conducted by clinical psychologists using the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) and the Health Anxiety Interview (Taylor & Asmundson, 2004), further described in the Methods below. Of the 81 participants, 43 (53% of total sample) had a comorbid Axis I disorder and 21 (26% of total sample) had more than one comorbid diagnosis, the most common being panic disorder ($n = 24$; 30% of the total sample) followed by generalized anxiety disorder ($n = 23$; 28% of the total sample).

Outcome Measures

Health Anxiety

As the primary outcome measure, we used the Health Anxiety Inventory (HAI; Salkovskis, Rimes, Warwick, & Clark, 2002) in order to assess levels of severe health anxiety. The HAI consists of 64 items scored from 0 to 3 which are then summed up in an overall score ranging from 0 to 192. The HAI has high internal consistency (Cronbach's $\alpha = .95$), and good test-retest reliability over one week ($r = .76$). The scale has been shown to be sensitive to change, to have good specificity, and has high convergent validity ($r = .90$; Salkovskis et al., 2002).

The weekly health anxiety assessments were completed with the short version of HAI, the SHAI, as a complementary more efficient primary outcome measure. The SHAI has a scale range of 0–54 and consists of a subset of 18 items (again, scored from 0 to 3) from the HAI, which correlated most highly with the full scale (Salkovskis et al., 2002). The SHAI has high internal consistency (Cronbach's $\alpha = .89$) and possesses good specificity (Salkovskis et al., 2002). The SHAI also has good test-retest reliability over three weeks ($r = .87$) and good

convergent and divergent validity (Alberts, Hadjistavropoulos, Jones, & Sharpe, 2013). Analyses of data from the RCT presented in this study (Hedman et al., 2011) showed that the HAI and SHAI were significantly correlated with the clinician-administered Clinical Global Improvement-Severity scale ($r = .51$ and $r = .53$) and that the two measures significantly discriminated participants with and without severe health anxiety ($p < .001$), thus indicating convergent validity with clinician-assessed instruments.

We administered the Illness Attitude Scale (IAS; Speckens, Spinhoven, Sloekers, Bolk, & van Hemert, 1996) as a complementary measure of health anxiety. The IAS consists of 29 items (27 of which are rated on a 5-point scale ranging from 0 (no) to 4 (most of the time), and two of which are open questions used to collect information on the patients' disease and treatment). The items are aggregated to an overall score ranging from 0 to 108. The IAS shows high sensitivity (79%) and specificity (84%) for severe health anxiety. It has demonstrated good test-retest reliability ($r = .89$) over 30 days in clinical populations (Pilowsky, 1967; Sirri, Grandi, & Fava, 2008; Speckens et al., 1996).

We further assessed health anxiety with the Whiteley Index (WI; Pilowsky, 1967) comprising 14 items with binary scoring (yes = 1, no = 0), which are summed up to an overall score ranging from 0 to 14 points. The WI offers high sensitivity (87%) and specificity (72%) for the diagnosis of severe health anxiety.

Clinician-administered measures

To establish whether participants met diagnostic criteria for severe health anxiety and other Axis I disorders, we used the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998). The MINI is a structured diagnostic interview and covers 17 DSM-IV psychiatric disorders, including all of the most common anxiety disorders, mood disorders, and substance abuse. It has good psychometric properties including high concurrent validity, as the kappa values when compared to the Structured Clinical Interview for DSM III-R disorders all are $>.50$ for anxiety disorders (Sheehan et al., 1998).

As a concomitant measure we used the Health Anxiety Interview (Taylor & Asmundson, 2004), which is based on DSM-IV-TR diagnostic criteria (American Psychiatric Association, 2000) and has the advantage of providing extensive health anxiety information compared to other clinician-administered instruments, thereby facilitating accurate diagnostic assessment (Taylor & Asmundson, 2004).

Procedure

The clinician-administered measures were conducted by four clinical psychologists with extensive training in the use of structured clinical interviews and several years of experience in making diagnostic assessments in psychiatric settings. Diagnostic interviews were conducted via telephone, which has been shown to be a reliable and valid method for both diagnostic and self-report assessments (Hedman et al., 2013b; Rohde, Lewinsohn, & Seeley, 1997). Medical comorbidity was assessed via patient self-report, medical records and physician consultation (for details see Hedman et al. 2011). All assessments were blinded with regard to study condition. To ensure consistency of assessments throughout the study and to promote inter-rater reliability, regular group meetings for discussing diagnostic issues were scheduled with all assessors. There was no formal assessment of inter-rater reliability. However, we assessed blinding integrity at post-treatment and found no significant association between the assessors' guess and actual treatment allocation. All self-report measures were administered online on a weekly basis. Participants had to complete pending assessments at logon before getting access to the treatment hence missing assessments only occurred when patients quit participation. The internet has been shown to be a reliable and

valid way of administering self-report measures (Carlbring et al., 2007; Hedman et al., 2010). Assessments were conducted at pre-treatment, post-treatment (12 weeks after treatment start), six-month follow-up, and 12-month follow-up. Only HAI, SHAI, IAS, and WI were administered at 12-month follow-up.

Internet-based CBT

The treatment consisted of a self-help text of 118 pages (Hedman et al., 2011), delivered in 12 weekly modules through an internet-based treatment platform and access to a therapist via a secure online contact system. Participants were granted gradual access to the modules by their therapist. Each module was devoted to a specific theme and included homework exercises. The modules were text-based and did not include any advanced technical features, and the treatment therefore closely resembled therapist-guided bibliotherapy delivered online. No online appointments were made where therapist and patient communicated in real-time. Therefore, the participants could work with the treatment when it best suited them. If participants appeared inactive (e.g. when taking several days between log-ins) or did not complete homework assignments, their therapists sent reminders via email to prompt patients to resume their treatments. However, in such cases, no additional time was allocated for completing single modules or respective homework, and overall treatment time was strictly limited to a 12 weeks maximum. The treatment platform was used as a means of providing the tools and knowledge necessary for conducting *in vivo* behaviour change, viewed as important from a CBT-perspective. All homework reports, work sheets, and communication between therapist and patient were stored online. Figure 1 presents an overview of the treatment content.

The treatment was based on a CBT model for health anxiety, emphasizing the role of avoidance and safety behaviours, internal focus, and interpretations of bodily sensations as signs of serious illness as maintaining factors for hypochondriasis (Furer, Walker, & Stein, 2007; Taylor & Asmundson, 2004). After an introductory phase, exposure (session 4) and response prevention (session 5) was introduced as the main treatment component, continuing up to session 10 (see Figure 1 for an overview of the treatment content), because it has been recommended as an essential component of psychological treatment for severe health anxiety (Furer & Walker, 2005). The treatment also included a form of mindfulness training, which comprised exercises with the aim of enhancing the patients' ability to experience bodily sensations without trying to control them or seek reassurance. This was done to facilitate exposure by lessening attempts to divert attention from aversive bodily sensations, a potential form of safety behaviour that may counteract exposure (Baer, 2003; McCracken, 1997). Benefits of mindfulness training in cognitive therapy for severe health anxiety have been demonstrated in recent studies (Lovas & Barsky, 2010; McManus, Surawy, Muse, Vazquez-Montes, & Williams, 2012). Of note, mindfulness in the present study was not used as a stand-alone intervention but was used specifically to optimize effectiveness of exposure and response prevention exercises.

The treatment protocol was developed by our research group and has been validated in a trial investigating the effects of group CBT for severe health anxiety (reference omitted to enable masked review).

The role of the therapists was mainly to provide feedback regarding homework and to grant gradual access to the treatment modules. Messages were generally short with a focus on reinforcing adaptive behaviours. In general, the therapist role was the same as in previously published studies on internet-based therapy with regards to beneficial procedural aspects, such as bolstering alliance, psycho-education, and task prompting (Paxling et al., 2012). Patient and therapist had no face-to-face contact during the treatment. In general, there was

no telephone contact between patient and therapist, but therapists could call the patient to assist them with any technical difficulties or to remind patients who had not logged in for a week to keep working with the treatment and to encourage them to remain in treatment. On average, therapists spent 9 minutes ($SD = 5.6$; range = 0–27 minutes) weekly per patient. The structure of the treatment made it difficult for therapists to deviate from the protocol (so called therapist drift; Waller, 2009). Because the module content and treatment exercises were fixed and could not be altered by the therapists, no other assessments of therapist adherence were conducted. All therapists were clinical psychologists.

Assessment of Sudden Gains and Gradual Gains

All SGs in the primary analyses were based on the SHAI. No established criteria could be used because no prior research has been conducted on SGs for severe health anxiety. The absolute SG criterion was defined in line with the original criterion suggested by Tang and De Rubeis (1999) (i.e., the baseline standard deviation of the SHAI; $SD = 5.9$). When applying a range of absolute SG criteria (e.g., based on the reliable change index by (Jacobson & Truax, 1991) we obtained a cut-off of 6.3, which changed our outcomes and the number of SGs identified only minimally.

We also used a relative improvement criterion, meaning that the improvement from the pregain session had to be at least 25% to be classified as a SG. For the stability criterion we used the modified criterion introduced by Tang, Luborsky, and Andrusyna (2002). Specifically, the difference in symptom scores between the three sessions before the gain and the three sessions after the gain had to be at least 2.78 times greater than the pooled standard deviations of these two groups. For comparison of sessions with fewer than three data points (e.g. session 2 vs. 3 or sessions with missing data) this cut-off score was adapted based on adjusted degrees of freedom.

To assess whether the suddenness of gains is of specific importance for treatment success we also investigated gradual gains. In line with the procedure by Greenfield and colleagues (2011), we used the same absolute and relative criteria as for a SG, but the change had to occur between any two non-consecutive sessions during the 12-week treatment phase. In addition, a participant making a SG could not be classified as a gradual gainer even if making a gradual gain at some time during treatment.

Statistical Analysis

Statistical analyses were conducted using SPSS version 20.0 (IBM Corp., Armonk, NY). A comprehensive description of the SG analyses is presented in the previous section. Data were analysed on an intent-to-treat basis. As in previous studies investigating SGs, missing data during the treatment phase was not imputed. This was done to avoid overestimating the frequency of SGs. We analysed continuous outcome variables using a linear mixed effects models framework, using a first autoregressive covariance structure, or with t-tests. Analyses of nominal scale variables were conducted using Chi² tests (between-group).

As for diagnostic assessments, the reported estimates are based on the group ($n = 40$) who received immediate treatment and analysed using McNemar's test of change. Effect sizes were calculated using Cohen's d based on pooled standard deviations. Reversal of a SG was defined as a 50% increase in symptoms after the occurrence of the SG. Consistent with the SG literature, the SG is denoted N, the assessment prior to that is denoted N-1, the assessment point immediately following the SG is denoted N+1, and the assessment point after that N+2.

There was no data loss at pre-treatment; 79 of 81 (98%) participants completed assessments at post-treatment. At six-month and 1-year follow-ups, 74 (91%) and 75 (93%) of the participants completed assessments, respectively. During the treatment phase the 81 participants received one assessment per each of the 12 weeks of treatment. 697 (78%) of these 12 times 81 = 891 possible assessments were completed. In the time provided to complete all 12 modules, which was fixed to 12 weeks, participants on average, completed 8.1 modules ($SD = 3.9$). After treatment completion, we assessed whether participants taking psychotropic medication had remained stable in this regard during the treatment period. Four participants had changed their medication, but none of these exhibited a SG. Thus, medication change did not affect the frequency estimate of SGs, and therefore no participant was excluded from the analyses.

Within-group effect sizes were large on the primary outcome measure HAI at post-treatment ($d = 1.69$; 95% CI = 1.33–2.05) and follow-ups (6MFU $d = 1.92$, 95% CI = 1.53–2.29; 1YFU $d = 1.80$, 95% CI = 1.42–2.16) compared to baseline. Improvements were also large on the complementary health anxiety measures. The pre-post-treatment d s of the IAS and the WI were 1.56 (95% CI = 1.20–1.91) and 1.23 (95% CI = 0.88–1.56), respectively. The corresponding estimates at six-month follow-up were 1.66 (95% CI = 1.29–2.02) and 1.47 (95% CI = 1.10–1.81). At 1-year follow-up, the large effect sizes were maintained on the IAS ($d = 1.73$, 95% CI = 1.35–2.08) and the WI ($d = 1.47$, 95% CI = 1.11–1.81).

Effects were also strong in terms of clinician assessment of severe health anxiety (hypochondriasis) diagnosis after treatment. At post-treatment and six-month follow-up respectively, 67.5% and 80.0% of the participants were treatment responders, as they no longer met diagnostic criteria for severe health anxiety, a significant reduction from baseline ($p < .001$).

Sudden gains in health anxiety

During the treatment phase (between week 1 and week 11), thirteen (16%) participants experienced one SG in terms of health anxiety improvement. SHAI data were missing for 180 occasions across 48 (59.26%) of the patients. Based on Little's Missing-Completely-At-Random (MCAR) test (Little & Rubin, 1987), data was missing completely at random ($\chi^2_{(232)} = 226.93$, $p < .58$).

The median session of SGs occurred from session five to six; the average SG occurred midway through the treatment ($M_{(week)} = 5.23$; $SD = 3.14$). Three (23%) and two (15%) SGs occurred from session two to three and nine to ten respectively. In every other session, one patient had one SG. Figure 2 presents the average SG pattern on the SHAI, i.e. means from the three pregain and post gain sessions, among the participants with a SG. The size of the average SG was 9.62 ($SD = 3.31$). As displayed in Table 1, SG status was unrelated to initial symptom status, age, number of completed modules, gender, duration of severe health anxiety, and treatment credibility ratings at baseline. There was one SG reversal showing first a decrease of SHAI scores from 16 to 9, followed by an increase to 15 in the subsequent session. As participants in the waiting list control condition ($n = 41$) also completed assessments in the same fashion as the group receiving treatment, we examined whether SGs may also occur spontaneously without treatment. One of these patients experienced a SG from session two to three (9 points on the SHAI).

Association of treatment outcome and sudden gains

Figures 3 and 4 display the course of improvement on the HAI and SHAI respectively for those with SG compared to those without. At post-treatment, mixed effects models analyses showed a significant interaction effect of group (sudden gainers vs. non-sudden gainers) and

time on all measures of health anxiety ($F_{(1, 77-78)} = 6.2-12.0, p < .02-.01$), indicating superior improvements in the sudden gains group. These interaction effects were maintained at follow-ups, i.e. modelling time as baseline, six-month and 1-year follow-up assessments ($F_{(2, 147-167)} = 5.6-7.0; p < .01-.001$). On average, sudden gainers made a total improvement of 17.0 ($SD = 7.43$) points on the SHAI from baseline to post-treatment. Of this overall improvement, 56.56% were achieved through SG. The between-group effect size at post-treatment on the HAI (sudden gainers vs. non-sudden gainers) was $d = 1.04$ (95% CI = 0.42–1.65), indicating a large effect of SG. At six-month follow-up, the effect size remained large ($d = 1.17$, 95% CI = 0.54–1.78) and was still in the large range one year after treatment completion ($d = 0.91$, 95% CI = 0.29–1.51). Among the three subgroups (sudden-gainers, gradual gainers and non-gainers), only the non-gainers were significantly improved from post-treatment to six-month and 1-year follow-ups ($F_{(1, 15)} = 13.1-9.6; p < .02-.01$).

Sudden gains vs. gradual gains

To obtain a more precise estimate of the effect of the suddenness of gains, we conducted analyses comparing sudden gainers to gradual gainers only. Mixed effects models analyses showed that the interaction effect of group and time on the primary outcome measure HAI was significant across all assessment points, indicating larger improvements in the sudden gains group ($F_{(3, 169)} = 3.2, p < .03$). The average time for achieving a gradual gain was 4.1 weeks ($SD = 2.7$), which was not significantly different from the average time that SGs occur ($t_{(61)} = 1.2, p < .25, d = 0.39$, 95% CI = $-0.22-1.00$). Sudden gainers were also significantly more improved on the secondary health anxiety measure IAS ($F_{(3, 182)} = 3.8, p < .02$) but not on the WI ($F_{(3, 174)} = 2.3, p < .09$).

Discussion

This study is the first to investigate SGs in the treatment of severe health anxiety and provides the first report on SGs in CBT delivered via the internet. Of 81 participants receiving internet-based CBT, 13 (16%) experienced one SG in terms of health anxiety (SHAI) at some time during the 12 weeks of treatment. SGs occurred throughout treatment with increased frequencies around session 3 and 10. In line with most other SG studies, experiencing SGs was associated with larger improvements. In our study, this advantage was maintained one year after treatment completion.

In line with a previous study (Greenfield et al., 2011), individuals with SGs surpassed gradual gainers with regards to their overall improvement on the primary outcome. It is possible that the suddenness of a gain may be more rewarding, encouraging participants to become more engaged in treatment, which might then produce better long term outcomes. Furthermore, it is interesting to note that there was no difference in time for achieving SGs and gradual gains. Although we can only speculate, it is possible that aspects of the treatment protocol that are the same for all participants might trigger improvements in general, whereas other treatment characteristics, such as the patient-therapist relationship or other, not yet identified and unique patient variables might lead to either a gradual gain or SG.

Compared to previous studies on SG in face-to-face treatments of anxiety disorders (see Aderka et al., 2012b, for a review), the proportion of individuals with SGs in this study was comparable to those with SGs during CBT for social anxiety disorder (15–22%; Hofmann et al., 2006), but lower than those in the treatments for generalized anxiety disorder (Present et al., 2008), panic disorder (Clerkin et al., 2008), and post-traumatic stress disorder (Doane et al., 2010). These studies reported that 34–52% of individuals experienced SGs. The between group effect size at post-treatment (SG vs. no SG) of $d = 1.04$ in the present study is in the

same range as in the mean d of 0.75 across CBT studies found in the meta-analysis (Aderka et al., 2012a).

One possible reason for the somewhat lower SG frequency may be related to the outcome measure. Although the SHAI scale is generally sensitive to change, some of the items are less related to specific behaviours or thoughts that are easy to assess on a weekly basis but are perhaps more reflective of general predispositions, such as “I usually feel at high risk for developing a serious illness”. One could speculate that it is more difficult to achieve SGs when using a scale that entail such items, as participants might be inclined to use a longer time period than the prescribed one week when making assessments of their current health anxiety.

Consistent with Greenfield and colleagues (2011), the suddenness of gains seems to reflect an important process, because participants making gradual gains were relatively more symptomatic at post-treatment and follow-ups. Taken together with the fact that there was only one reversal of a SG, this indicates that SGs in internet-based CBT for severe health anxiety are not merely an expression of large fluctuations in symptom levels, but actually a stable pattern of responding accounting for more than half of the long-term improvement in individuals experiencing them.

Our results are clinically useful because they can be used to inform patients’ possible trajectories of improvement during therapy. For instance, this information might be used to predict a patient’s treatment response based on his/her individual rate of improvement. The findings also suggest that the improvement patterns in internet-based CBT resemble those of face-to-face CBT, possibly reflecting common mechanisms in both modalities. It is further possible that inducing SGs might lead to better treatment response. As a potential explanation, it has been suggested, that SGs are preceded and caused by changes in cognitions (Tang, DeRubeis, Bebermann, & Pham, 2005). Although there is some support for this assumption coming from treatment studies for depression (e.g. Tang & DeRubeis, 1999; Tang et al., 2005), cognitive change was not predictive of SGs in studies examining behavioural activation (Hunnicut-Ferguson, Hoxha, & Gollan, 2012) or supportive-expressive therapy for depression (Andrusyna, Luborsky, Pham, & Tang, 2006) or CBT for social anxiety disorder (Hofmann, Schulz, Meuret, Moscovitch, & Suvak, 2006; Bohn, Aderka, Schreiber, Stangier, & Hofmann, 2013). It is possible that SGs are more likely to emerge as treatment mediators in interventions that place a relatively great focus on modifying maladaptive beliefs, such as CBT for depression as compared to other treatments, such as those that are focused on an exposure-extinction paradigm. We did not assess cognitive change in our study. Therefore, it remains uncertain whether cognitive changes preceded or mediated SGs. Identifying the mechanism of treatments with and without SGs is clearly an important area for future research.

The limitations of this study include the following: First, we did not conduct diagnostic assessments at one-year follow-up, making it impossible to associate SG with diagnostic status. However, the primary outcome HAI has been shown to possess good psychometric qualities, including good discriminant validity and convergent validity with clinician-administered measures. Second, because participants could apply through referral as well as through self-referral, caution is warranted when applying the conclusions to patient populations in somatic medical settings. Patients participating in ICBT may be more computer-educated, particularly open for novel treatment approaches and motivated by the technological framework. However, recent evidence suggests that such differences may be overestimated, as patients who seek Internet-based treatment are rather similar to general clinical psychiatric outpatient populations (e.g., Wootton, Titov, Dear, Spence, & Kemp, 2011). Third, since there was data loss in the data set, there is a risk that we might have

underestimated the proportion of SG, as a SG occurring in an instance with data loss might have been misclassified as a gradual gain. However, it should be noted that we observed significant between group differences despite the missing data and also that attrition rates were generally low. Fourth, patients with severe health anxiety have a strong bias in terms of interpretation of bodily symptoms. This may affect a subset of self-assessments. However, there is no reason to assume that it impairs the validity of their self-related assessments in general. In our own data, this notion is supported by strong associations between self-assessment and clinician-administered measures. Fifth, the proportion of individuals with SG in our sample was lower than in other studies. Because there is currently no other study on SGs in the treatment of severe health anxiety available for comparison, it may be speculated that these differences are related to our specific sample or the treatment administration method (online vs. in person). For example, it might be possible that the administration methods of the questionnaires (online vs. paper and pencil) might account for differences in SG between the current study and other studies. However, previous studies (Carlbring et al., 2007; Hedman et al., 2010) indicate that the difference between paper and pencil vs. online administration is small, and online measures offer similar psychometric properties.

In spite of these limitations, we view the findings of this study as important, as they suggest that SGs are associated with large and enduring treatment effects during internet-delivered CBT for health anxiety. It is also of clinical importance as it suggests that the process of improvement in guided internet-based CBT is similar to face-to-face CBT.

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Figure 1. Description of Session Content

Note: Reproduced with kind permission of the British Journal of Psychiatry(cf. Hedman et al., 2011). Abbreviations: CBT, Cognitive behaviour therapy.

Figure 2. The average sudden gain pattern among participants making a sudden gain on the SHAI

Note: N, the average score in the pregain session; N-1, score in the session prior to the pregain session; N+1, score in the session immediately following the sudden gain.

Abbreviation: SHAI, Short version of the Health Anxiety Inventory

Figure 3. Improvement course on the primary outcome measure HAI for sudden gainers compared to non-sudden gainers including its subgroups of gradual gainers and non-gainers
 Note: The number of participants in the respective arms were: Sudden gainers, $n = 13$; Non-sudden gainers, $n = 68$. Non-sudden gainers comprised the subgroups Gradual gainers, $n = 50$, and Non-gainers, $n = 18$. Abbreviations: HAI, Health anxiety inventory; Pre, pre-treatment, Post, post-treatment, 6MFU, six-month follow-up; 1YFU, 1-year follow-up. Note: error bars represent 95% CIs.

Figure 4. Improvement course on the SHAI for sudden gainers compared to non-sudden gainers including its subgroups of gradual gainers and non-gainers

Note: The number of participants in the respective arms were: Sudden gainers, $n = 13$; Non-sudden gainers, $n = 68$. Non-sudden gainers comprised the subgroups Gradual gainers, $n = 50$, and Non-gainers, $n = 18$. Abbreviations: SHAI, short version of the Health anxiety inventory; Pre, pre-treatment, Post, post-treatment, 6MFU, six-month follow-up; 1YFU, 1-year follow-up. Note: error bars represent 95% CIs.

Table 1

Overview of the participants on demographic and clinical variables

		Health anxiety Sudden gainers		Health anxiety Non-sudden gainers		Statistics SG vs. non-SG
		n = 13	n = 68	n = 50	n = 18	
Age	Mean age (SD)	40.3 (7.5)	38.8 (9.9)	39.2 (9.0)	37.7 (12.5)	$t_{(79)} = 0.55, p > .5$
Gender	Women (%)	10 (77%)	50 (74%)	38 (76%)	12 (67%)	$\chi^2_{(1)} = 0.65, p > .8$
	Men (%)	3 (23%)	18 (26%)	12 (24%)	6 (33%)	
Severe Health Anxiety	Mean duration in years (SD)	13.3 (13.0)	17.9 (13.6)	16.5 (12.7)	22.2 (15.7)	$t_{(79)} = 01.25, p > .2$
Employment	Working full time (%)	13 (100%)	50 (74%)	38 (75%)	14 (74%)	$\chi^2_{(3)} = 4.42, p > .2$
	Unemployed	0 (0%)	11 (16%)	9 (18%)	2 (11%)	
	Sick leave	0 (0%)	6 (9%)	3 (6%)	3 (16%)	
	Disability pension	0 (0%)	1 (1%)	1 (2%)	0 (0%)	
Adherence	Mean completed modules (SD)	9.5 (2.2)	8.7 (3.5)	8.8 (3.6)	8.3 (3.4)	$t_{(79)} = 1.32, p > .1$
HAI Pre-Treatment	Mean (SD)	102.5 (21.1)	107.1 (19.1)	105.0 (18.9)	113.0 (21.4)	$t_{(79)} = 0.78, p > .4$
HAI Post-Treatment	Mean (SD)	45.0 (18.0)	71.2 (26.2)	62.3 (22.6)	96.0 (18.6)	$F_{(1, 77)} = 12.0, p < .001$
HAI 6MFU	Mean (SD)	38.1 (10.7)	67.0 (26.4)	62.0 (25.7)	83.9 (22.9)	$F_{(2, 151)} = 7.5, p < .001$
HAI 1YFU	Mean (SD)	43.5 (17.3)	67.3 (27.5)	65.2 (29.6)	72.4 (19.4)	$F_{(3, 216)} = 4.8, p < .01$

Abbreviations: SG, sudden gainers; HAI, Health anxiety inventory; Pre, pre-treatment, Post, post-treatment, 6MFU, six-month follow-up; 1YFU, 1-year follow-up