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Cognitive Behavioral Therapy for Social Activation in Recent-Onset Psychosis: Randomized Controlled Trial

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Objective: Negative symptoms largely account for poor outcome in psychotic disorders but remain difficult to treat. A cognitive–behavioral approach to these symptoms showed promise in chronic schizophrenia patients. We explored whether a combination of group and individual treatment focused on social activation (CBTsa) could benefit patients recently diagnosed with a psychotic disorder. ***Method:*** A single-blind randomized controlled trial enrolled 99 participants recently diagnosed with schizophrenia or a related disorder that received treatment as usual (TAU; $n = 50$), or TAU plus CBTsa ($n = 49$). Negative symptoms (Brief Negative Symptom Scale) and social withdrawal (Positive and Negative Syndrome Scale) were primary outcomes. Secondary outcome measures included dysfunctional beliefs (Dysfunctional Attitudes Scale-Defeatist Performance Attitude), stigma Internalized Stigma of Mental Illness Scale (ISMIS), and symptom severity and functioning as measured with the Global Assessment of Functioning (GAF). Outcomes were compared directly posttreatment and at follow-up (6 months posttreatment). ***Results:*** Intention-to-treat analyses showed significant improvement in GAF symptoms ($p = .02$, $d = 0.36$) and a decrease in negative symptoms on trend level ($p = .08$, $d = -0.29$) in CBTsa compared to TAU at posttreatment. These group differences were no longer apparent at 6 months follow-up. Social withdrawal and negative symptoms improved over time in both conditions.

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Conclusions: The current trial showed small positive effects on symptom severity posttreatment but did not demonstrate maintenance of longer-term effects in favor of the CBTsa group. Findings suggest that the treatment duration may have been too short to change dysfunctional beliefs, a potentially important maintaining factor of negative symptom severity. Longer intervention periods in later, more stable stages of the illness when intensive standard treatment has tapered off may yield more beneficial effects.

What is the public health significance of this article?
This study suggests that a cognitive–behavioral approach aimed at social activation might be beneficial in accelerating the initial reduction of negative symptoms in patients recently diagnosed with a psychotic disorder. However, to archive sustained treatment effects, and target defeatist beliefs, additional treatment with a longer intervention period may be necessary.

Keywords: psychosis, CBT, social activation, negative symptoms

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Schizophrenia and related disorders belong to the most disabling and costly disorders worldwide (Salize et al., 2009). Despite extensive treatment, a large proportion of individuals diagnosed with schizophrenia or related psychotic disorders will not return to their premorbid level of functioning (Horan et al., 2012). Negative symptoms largely account for poor functional- and clinical outcome (Fervaha, Foussias, Agid, & Remington, 2014; Kirkpatrick, Fenton, Carpenter, & Marder, 2006; Lang, Kösters, Lang, Becker, & Jäger, 2013; Milev, Ho, Arndt, & Andreasen, 2005) and have long been considered to be highly treatment resistant (Kirkpatrick et al., 2006). A recent meta-analysis showed statistically significant beneficial effects of various psychological interventions directed at negative symptoms; however, results were not considered to be clinically significant (Fusar-Poli et al., 2015). These findings are in line with a meta-analysis by our group, which showed only a marginal effect of cognitive–behavioral therapy (CBT) on negative symptoms (Velthorst et al., 2015). Both studies recommend further research on interventions for negative symptoms.

Based on the favorable effects that CBT exerts on positive symptoms, Beck and colleagues developed and investigated the efficacy of a new CBT approach focused on negative symptoms (Grant, Huh, Perivoliotis, Stolar, & Beck, 2012). In their approach, Beck and colleagues argued that negative symptoms are not solely the consequence of neurocognitive impairments but are amplified by feelings of stigmatization, dysfunctional beliefs and negative expectations, which may negatively impact treatment. For example, individuals who experience diminished concentration and poorer functioning as a consequence of their psychosis may become demoralized, in turn reinforcing feelings of incompetence, inactivity, and avoidance behavior (Beck, 2008). Support for this assumption stems from a recent meta-analysis that showed a relationship between defeatist performance beliefs and functional outcome (Campellone, Sanchez, & Kring, 2016). Negative expectancies and dysfunctional beliefs are particularly well suited for a cognitive–behavioral approach. In their trial Beck and colleagues targeted a chronic schizophrenia population with severe negative symptoms, with the primary aim of helping patients overcome isolation and inactivity, thereby improving quality of life (Grant et al., 2012). The authors found that participants treated with CBT showed more improvement in global functioning and in avolition/apathy (a subdomain of negative symptoms as measured with the Scale for the Assessment of Negative Symptoms [SANS; Andreasen, 1989]) compared to patients in the standard treatment condition. In an effort to increase feasibility and cost-effectiveness, Staring et al. explored whether a shortened, 6-month version of the protocol could also reduce negative symptoms. Their open pilot study showed promising results (Staring, Ter Huurne, & van der Gaag, 2013).

Despite favorable effects of these two studies, thus far the intervention has only been tested in more chronic stages of schizophrenia and related disorders, although social withdrawal is also prominent in the early phase of the illness. Importantly, early intervention is thought to be essential to improving illness course and functional outcome (Harrison et al., 2001; Verma, Subramaniam, Abdin, Poon, & Chong, 2012). Therefore, in the present randomized controlled trial study we aimed to examine whether a CBT approach based on the manual of (Staring, Ter Huurne, & van der Gaag, 2013) would also benefit individuals recently diagnosed with schizophrenia or a related psychotic disorder.

In the treatment manual by Staring et al., the number of sessions were reduced from 50 (Grant and colleagues) to 16–20 sessions (Staring, Ter Huurne, & van der Gaag, 2013). For the purpose of the present study, we slightly adapted this shortened manual to meet specific needs of young individuals in the early stages of the illness. For example, our treatment approach consisted of group- and subsequent individual sessions to combine advantages of group processes (such as practicing skills together and sharing experiences) and peer interaction with individual CBT. During the group sessions, buddy couples were formed to stimulate peer support and generalization of skills to everyday life. Moreover, we adapted the treatment manual to target social withdrawal specifically. Recent studies suggest that social withdrawal is not only a strong predictor of conversion in those at ultrahigh risk for developing a first psychotic episode (Lyngberg et al., 2015; Velthorst et al., 2009) but is also strongly associated with poorer prognosis and poorer quality of life after illness onset (Mäkinen, Miettunen, Isohanni, & Koponen, 2008).

In sum, we aimed to investigate whether CBT focused on social activation (CBTsa) is more effective in reducing negative symptoms and social withdrawal in particular, compared to treatment as usual (TAU) in individuals recently diagnosed with a psychotic disorder. Furthermore, we explored whether CBTsa reduces dys-

functional beliefs and stigma, and whether CBTsa is associated with greater improvement in overall functioning compared to TAU.

Method

Trial Design

The current study was designed as a multisite randomized controlled trial (RCT) in which CBTsa was compared to TAU in alleviating social withdrawal in participants with a recent onset psychotic disorder. Measurements were conducted at baseline (t_0), at first follow-up directly posttreatment (t_1), and at second follow-up, 6 months posttreatment (t_2). The experimental CBTsa intervention consisted of eight group sessions and six individual sessions over the course of a maximum of 3 months. The study was approved by the local ethics committee of the Academic Medical Center (NL51493.018.14), and by the local ethics committees of the other participating institutes.

Study Participants

Participants were recruited from four early psychosis treatment centers in the Netherlands and one general mental health service in the Netherlands: Arkin Psychiatric Institution in Amsterdam; Early Psychosis Department of the Academic Medical Center (AMC) in Amsterdam; Altrecht ABC Team in Utrecht; Centrum First Psychosis Parnassia in The Hague; and InGeest outpatient psychiatric service in Amsterdam.

To be eligible to participate in the study, participants had to be between 18 and 36 years old and diagnosed with *DSM–IV–TR* (American Psychiatric Association [APA], 2000) schizophrenia or a related disorder with onset of their first psychotic episode <4 years prior to inclusion. Diagnosis was confirmed with the *Structured Clinical Interview for DSM Disorders* (First, Spitzer, Gibbon, & Williams, 2002). Patients with a comorbid diagnosis of bipolar disorder or autism spectrum disorder were not included in this study. Only participants with at least a mild level of social withdrawal behavior, defined as a score of ≥3 on apathy/social withdrawal as measured with the negative scale of the Positive and Negative Syndrome Scale (PANSS; Kay, Opler, & Lindenmayer, 1988), or ≥2 on the social isolation items of the Brief Negative Symptom Scale (BNSS; Kirkpatrick et al., 2011) were included. The experience of positive symptoms was not an exclusion criterion. However, individuals were not eligible when negative symptoms were primarily the result of hallucinations or delusions (e.g., withdrawal due to paranoid delusions). To determine whether negative symptoms were primarily caused by positive symptoms, during an initial screening session patients were explicitly asked whether their reduced social engagement was related to the hearing of voices or other psychotic experiences.

Procedure

After determining eligibility, participants who agreed to be contacted by a researcher of the study were provided verbal and written information about study procedures, and written informed consent was obtained before baseline measurements were administered. Four psychologists with a master's degree in clinical psychology and four master students with a bachelor's degree in clinical psychology, who were blind to treatment allocation, carried out assessments. Assessors received extensive training prior to inclusion by certified trainers (Eva Velthorst and Frederike Schirmbeck) for the PANSS, BNSS and GAF. The training consisted of three training-videos for the PANSS, provided by the AMC as part of their clinical training program and three trainings videos for the BNSS provided by the original authors Dr. Kirkpatrick and Dr. Strauss. For all videos gold standard scores and scoring rationales were provided. Prior to assessment, all raters participated in a consensus training and fulfilled the criteria of interrater reliability >0.8. Ongoing weekly supervision was provided to ensure consensus across raters.

If blinding was broken, another researcher still blind to the condition carried out the assessment. Subjects were randomly assigned per site by a researcher not involved in the research team to either the CBTsa condition or TAU by block-randomization (www.randomizer.org), sequencing participant assignments by block to insure an equal number of individuals in each intervention arm.

Sample Size Calculation

Sample size calculation was based on the study of Grant et al. (2012), which found a larger mean reduction in avolition-apathy of the CBT condition compared to standard treatment of $d = -0.66$ (Grant et al., 2012). Based on this result, and upon the commonly held assumption that recent onset subjects are more likely to change than the more chronic population, we estimated to find an effect size of (at least) .66 in our study. With an alpha of 0.5; power = 80%; effect-size .66 and taking into account an expected dropout rate of 20%, analyses resulted in 72 + 20% = 87 participants = 44 per group. Because of our multicenter design we also accounted for a variance inflation factor, therefore we calculated the intraclass correlation coefficient (ICC) of the PANSS negative symptom scores of a study targeting a similar population and setting (Genetic Risk and Outcome of Psychosis study), in which four centers participated. The ICC in this study was .146. Following the literature, we then used the following formula:

$1 + (m-1) \times \text{ICC}$ (m = number of participating centers). For our study, this meant that we had to increase the sample size (87) by a factor of: $1 + (3-1) \times .146 = 1.292$, resulting in a total estimated sample size of: $1.292 \times 87 = 112$ individuals (56 per condition).

Primary Outcome

The BNSS, a scale primarily designed to assess (change in) negative symptoms in clinical trials (Kirkpatrick et al., 2011), was used to assess the primary outcome negative symptoms. The Dutch translation was conducted by coauthors in agreement with original authors (Staring, Velthorst, et al., 2013). The BNSS constitutes 13 items that can be rated in a 30-min interview, assessing clinically meaningful negative symptoms in five subdomains: blunted affect, alogia, a-sociality, anhedonia, avolition, and a separate item that measures lack of distress/dysphoria. Sample items of the subdomain "a-sociality" (of main interest in the present study) include, "When you spent time with . . ., did you contact them or did they contact you? How often do you talk to them about private,

personal things?", or "Some people like to be by themselves; others like to be around other people. What do you prefer?"

Reliability analyses indicate that the BNSS has excellent internal consistency and temporal stability (Kirkpatrick et al., 2011). In the current study, Cronbach's alpha of the BNSS total score was 0.81.

Group differences in negative symptom severity, particularly social withdrawal were additionally explored by means of the PANSS (Kay et al., 1988). The PANSS has been translated into Dutch by Linszen, de Haan, Kuipers and Dingemans, AMC Department of Psychiatry (1995). Two subdomains of negative symptoms have been confirmed in two large Dutch cohorts (Liemburg et al., 2013). For our study purpose, PANSS negative symptom scores were measured with the subdomain 'social emotional withdrawal,' which comprises active and passive social withdrawal and- avoidance behavior.

Secondary Outcomes

Global Assessment of Functioning (GAF) was administered using the two functioning (GAF-F) and symptoms (GAF-S) subscales (Jones, Thornicroft, Coffey, & Dunn, 1995). The Dutch version of the GAF is part of the *DSM–IV–TR* (APA, 2000) and has been validated in Dutch patients (Havenaar et al., 2004). The two subscales are rated on a scale from 1 to 100 and measure the current level of symptoms and functioning in the last month. For the GAF subscales, a score between 1 and 10 signifies "a persistent danger of severely hurting self or others (e.g., recurrent violence)/ persistent inability to maintain minimal personal hygiene," whereas a score between 91 to 100 indicates "no symptoms/ superior functioning in a wide range of activities." It is a widely used and valid measurement of functioning.

Dysfunctional beliefs were measured with the Dutch version of the Dysfunctional Attitudes Scale-Defeatist Performance Attitude (DAS-DPA). The scale is a 15 item measure (Beck, Grant, Huh, Perivoliotis, & Chang, 2013) assessing the beliefs of one's ability to perform tasks and the likelihood of success, derived from the 40-item Dysfunctional Attitude Scale (DAS; Weissman & Beck, 1978). Translation was conducted by A. B. P. Staring, in agreement with the original authors (i.e., Beck and Grant; Staring, Ter Huurne, & van der Gaag, 2013). Items are rated on a 7-point Likert scale, ranging from 1 (*agree totally*) to 7 (*disagree totally*), with lower scores representing higher dysfunctional beliefs. Questions include, "It is difficult to be happy unless one is good looking, intelligent, rich and creative", and "People will probably think less of me if I make a mistake." Cronbach's alpha in the current study was 0.90.

Feelings of stigma were measured with the Internalized Stigma of Mental Illness Scale (ISMI; Boyd Ritsher et al., 2003), translated and validated in Dutch by Brohan et al. (2011). The 29-item questionnaire is rated on a 4-point Likert-type scale, ranging from 1 (*strongly agree*) to 4 (*strongly disagree*). It contains five subscales: alienation, stereotype endorsement, perceived discrimination, social withdrawal, and stigma resistance. For this study, a sum-score of the scales alienation, stereotype endorsement, perceived discrimination and social withdrawal was used (Cronbach's alpha = .91). A sample question of alienation includes, "People without mental illness could not possibly understand me," and of perceived discrimination: "Nobody would be interested in getting close to me because I have a mental illness".

Treatment Conditions

CBTsa. Participants randomized to the CBTsa condition received eight group sessions of 1 hour/twice a week followed by six weekly individual sessions of 45 min. Treatment was delivered at each of the four recruitment sites over a period of 3 months. The overall aim of the treatment was to modify dysfunctional beliefs and to increase engagement in constructive social activity in individuals with prominent negative symptoms. The primary focus was to help participants become more active in reaching personal social goals.

Group sessions. During the first session of the group therapy, psychoeducation with a focus on negative symptoms (e.g., anhedonia, lack of energy, cognitive deficits, problem in social interaction and social withdrawal) was provided. Patients were asked to share their experiences and to define their individual social goals (e.g., [re] connect with friends, [re] engage in team sport) aimed to increase social interaction. To promote peer support as one of the major components of the group-based intervention part, buddy couples were formed. These couples worked together during sessions and were encouraged to support each other between sessions in completing their homework (e.g., by sending reminders). At the start of the second session, goals with the highest personal value were selected and divided into smaller steps necessary to reach these goals. Participants were asked to rate which obstacles in reaching their goals they anticipated. Emphasis was placed on dysfunctional beliefs regarding one's own cognitive functioning, skills, or the expected (lack of) pleasure or social devaluation (e.g., "I cannot enjoy things anymore," "I am unable to concentrate and memorize anything and will not be able do have an interesting conversation"). Psychoeducation during this session was specifically focused on the cognitive model of negative symptoms, emphasizing the role of dysfunctional beliefs, avoidance behavior, and demoralization. Subsequent sessions focused on challenging anticipated and experienced obstacles using standardized material such as cognitive restructuring worksheets, role-plays, and on-site behavioral experiments. Specific actions to reach one's personal goal were planned in detail during the sessions, and the participant was asked to carry out that step before the next planned session as homework assignment. At the start of each following session, homework assignments were discussed. To maximize a sense of personal efficacy, each failure of the patient to execute a new behavior was interpreted as the therapist's fault (e.g., due to insufficient preparation or setting goals too high). The underlying idea is that small successes are prerequisite to the experience of hope and personal efficacy. To facilitate engagement and generalization of learned skills to daily functioning, participants were encouraged to actively participate in discussions, role-plays and behavior experiments.

Individual sessions. Individual therapy sessions were aimed at the continuation of social activation and achievement of personal goals through a personalized focus on the person's main dysfunctional beliefs and associated behaviors, and countering obstacles to these goals. Rather than providing a session-by-session protocol, the treatment manual provided material for psychoeducation and interventions that could be used if needed.

Intervention tools were based on different elements of demoralization (e.g., cognitive techniques used to investigate dysfunctional beliefs and behavior, such as Socratic dialogue, behavioral and cognitive experiments; dimensional evaluation of negative or stereotype self-image etc.; cognitive imagery techniques (imagining the steps needed to achieve new goals); and behavioral techniques (activity scheduling, exposure to new situations that trigger anxiety etc.). The choice for a particular combination of the above-mentioned techniques was based on the individual needs and goals.

Treatment Fidelity and Adherence

To ensure treatment fidelity and adherence to treatment, therapists received extensive training by A. B. P. Staring (adaptor of the original manual of Grant at al. (Staring et al., 2010) and were supervised by C. J. Meijer and F. Schirmbeck throughout the study. Feasibility of the treatment and treatment manual proved to be good in the pilot study of Staring et al. (Staring, Ter Huurne, & van der Gaag, 2013). MSc level psychologists provided the group and individual CBT sessions. To ensure treatment implementation, adherence to the manual and coherence across sites, sessions were routinely monitored by videotapes (group sessions) and audiotapes (individual sessions). In addition, on-site and telephone supervises were provided. Treatment receipt and enactment was promoted by active participation during sessions, on-site exercises including cognitive and behavioral experiments and homework assignments, which were discussed at the beginning of the following session to ensure understanding and application of learned skills.

TAU

Every participant in the TAU condition received either inpatient treatment, day-treatment or outpatient treatment at one of the collaborating (local community) mental health centers. Across sites, TAU consisted of early intervention programs where patient's symptoms, functioning and medication use are monitored for 3 years. At minimum, treatment as usual consisted of antipsychotic medication and supportive therapy. In addition, TAU could involve psycho-education, family support, physical health care, psychomotor therapy and vocational therapy. The latter includes individual placement and support (IPS), intended to support patients in their efforts to achieve employment and reintegration. Participants in the TAU condition were not allowed to receive any form of CBT or any intervention that was specifically focused on social activation. The teams of the participating psychiatric services included psychiatrists, psychologists, psychiatric nurses and social workers.

Data Analyses

For data analyses, SPSS 22 was used. All treatment effects were analyzed on an intention to treat basis using a (generalized) linear mixed model, the recommended approach to longitudinal designs as estimates are based on all available data. To determine treatment effects the primary (BNSS, PANSS) and secondary (ISMI, DAS-DPA, GAF) outcome measures were entered as dependent variables, assessment time, treatment condition and Treatment × Time interactions were included as fixed effects in the model. Assessment time was included as a categorical variable. The intercept was treated as random effect. Mixed effects models use full information maximum-likelihood estimation to adjust the likelihood function so that each case contributes information on the variables that are observed.

Analyses were conducted over time (i.e., overall assessment points) and were repeated for baseline posttreatment effects and baseline follow-up effects. Because of between-groups differences at baseline and significant associations with most outcome variables, all analyses were controlled for gender, relationship status, and recruitment site by including these variables as covariates to the model.

For exploratory purposes all analyses were repeated using a (a) "per protocol" approach, including only those individuals that completed at least 65% of the therapy sessions, as well as a (b) "completer" approach, including only those individuals with outcome data available at all time points. We used a two-tailed significance level of $p < .05$. Cohen's d effect sizes were computed for significant effects.

Results

Sample Characteristics

Figure 1 presents the participant flowchart of the study. Of the 305 individuals screened for eligibility, 99 were randomized to one of the two conditions.

Of the complete study sample, 20.3% presented with active delusions and 32.3% with active hallucinations with mild to moderate severity. Average positive symptom severity of our sample was relatively low ($M = 11.3$, $SD = 3.4$). Mean negative symptom severity at baseline was considerably higher ($M = 17.8$, $SD = 5.5$) with 76.8% reporting moderate to severe social withdrawal and 37.4% with moderate to severe emotional withdrawal. Overall baseline average depression scores on the Calgary Depression Scale were relatively low ($M = 2.8$, $SD = 2.9$), with 15.5% of our sample scoring ≥6, indicating clinically relevant depressive symptoms (Addington, Shah, Liu, & Addington, 2014). Fifty-one percent of the participants presented with serious symptoms of schizophrenia (GAF-S ≥ 50) and 80.2% with serious impaired functioning (GAF-F ≥ 50). See Table 1 for demographical and clinical information. Baseline scores on relevant outcome measures by condition are described in Table 1.

Loss to Follow-Up

Dropout rates did not differ between the CBTsa (20.4%) and TAU (30%) condition at follow-up ($\chi^2 = 1.206$, $p = .272$). Individuals who dropped out of the study did not significantly differ from those who completed the study in age, ethnicity or years of education. However, dropouts included a higher percentage of women ($\chi^2 = 6.093$, $p = .014$). No significant differences were found in terms of severity of positive, negative or depressive symptoms, or functioning. Group-wise comparisons of dropouts and individuals who completed the study also did not show any significant differences, apart from a higher dropout-rate of women in the CBTsa condition ($\chi^2 = 4.421$, $p = .035$).

Adherence to the Intervention

Of those randomized to the CBTsa condition, 7 individuals (14.3%) did not start with the group training and were lost pre-

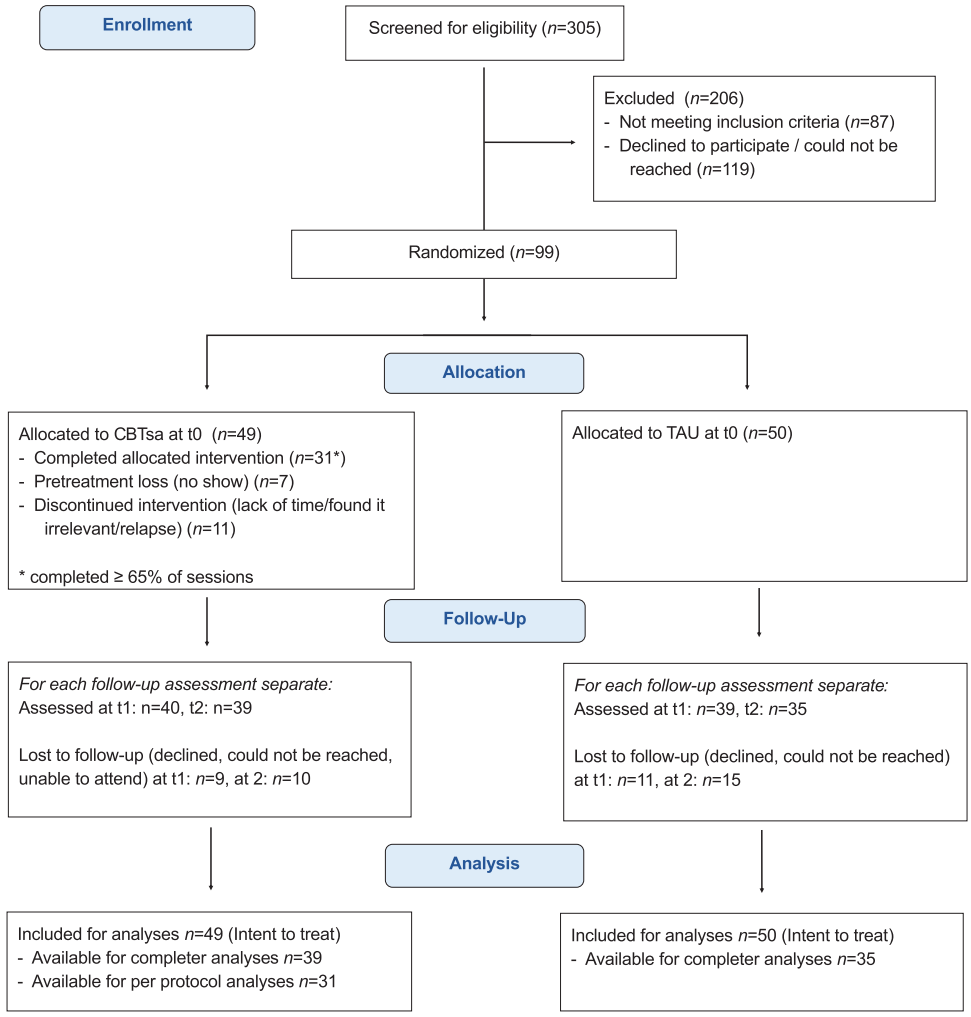

Figure 1. Flow of the participants through the trial. See the online article for the color version of this figure.

treatment. Another 11 of the remaining 42 (26.2%) were defined as noncompleters, adhering to less than 65% of the trainings sessions. Of these, five were lost during the first half of the group training, another five were lost at the end of the group training and did not start with individual therapy and one attended only 50% of group and individual sessions. The average number of followed CBTsa-group sessions among patients who started treatment was 6.7 (SD = 1.9); range = 1–8, and of individual sessions 4.0 (SD = 2.5); range = 0–6.

Intent-to-Treat Analyses

ITT results are shown in Table 2. Significant time effects revealed an overall decrease in most outcome variables in both conditions over the total assessment period. No overall Group (2) × Time (3) interaction effects were apparent. Baseline-posttreatment analyses showed that compared to TAU, the CBTsa group showed a slightly steeper decrease in negative symptoms as measured with the BNSS between t0 and t1: $z = 1.74$, $p = .082$, $d = -0.29$. However, this difference leveled out at follow-up. Also, a significant Group (2) × Time (2) interaction effect was found for GAF symptoms: $z = -2.33$, $p = .024$, $d = 0.36$ at post treatment. Compared with TAU, patients randomized to the intervention group showed a faster decrease in overall symptom severity at posttreatment. This difference was no longer apparent at follow-up. No other significant Group (2) × Time (2) interaction effects were found at posttreatment or follow-up. Figure 2a and 2b display the overall course of BNSS and GAF-S symptom scores.

Per Protocol and Completer Analyses

For exploratory purposes, analyses were repeated using a "per protocol" and "completer" approach. As can be seen in Supplementary Tables S1 and S2 in the online supplemental material, findings were similar to those resulting from the ITT analyses.

Discussion

In the present study, we aimed to investigate the effectiveness of a CBTsa intervention on negative symptoms, dysfunctional beliefs, and general functioning in individuals with a recent onset psychosis. There was a slight trend showing a steeper decrease in

Table 1
Demographical and Clinical Information of the Experimental and Control Condition at Baseline

Demographic information	CBTsa (n = 49) *M* (*SD*)	TAU (n = 50) *M* (*SD*)
Age	25.14 (4.47)	25.72 (4.44)
Sex ratio male/female	37/12	43/7
Ethnicity % minority	69.4	51.0
Diagnosis according to *DSM IV-TR*		
Schizophrenia disorder	29	34
Schizoaffective disorder	7	3
Psychotic disorder NOS	10	9
Other psychotic diagnosis	4	4
Current cannabis use %	25.5	17.0
Antipsychotic medication %	85.4	98.0

Note. CBTsa = cognitive–behavioral approach aimed at social activation; TAU = treatment as usual; NOS = not otherwise specified.

negative symptoms and significantly larger decrease in overall symptom severity in the intervention group compared to the TAU group posttreatment. However, these effects were small and between-groups differences at post treatment were not maintained at 6 months follow-up. These findings correspond to the small effects found in the meta-analysis of Fusar-Poli et al. (2015) and Velthorst et al. (2015). We found no significant differences in the reduction of measures of social withdrawal or dysfunctional beliefs between conditions. Overall, our study could not support earlier favorable findings of social activation CBT compared to TAU on negative symptoms as observed in chronic patients with schizophrenia in the study of Grant et al. (2012).

Contrary to the lack of improvement in avolition/apathy in TAU observed in Grant et al. (2012), our results showed significant time effects in both conditions with improvement on most measures of negative symptoms. These inconsistent findings could be due to differences in sample characteristics. In a study by Chang et al. (2011) patients with a first-episode schizophrenia spectrum disorders showed substantial reduction of primary negative symptoms in the initial year of treatment after first admission. The authors concluded that contrary to the persistence of negative symptoms in the later stages of the illness, severity of negative symptoms fluctuates considerably in the first year after psychotic manifestation.

Significant improvement in negative symptom severity in both study conditions may also suggest that standard treatment offered by early intervention psychosis teams in the Netherlands already has an effect on the severity of negative symptoms. One of the characteristics of standard treatment in early psychosis programs concerns the focus on reintegration, such as IPS. Although not specifically targeting psychopathology, a randomized controlled trial showed significant effect of IPS on negative symptoms (Hoffmann, Jäckel, Glauser, & Kupper, 2012). Hence, this behavioral approach might provide patients with the means they need to participate in work and education and in turn gives them opportunities to engage in social contact and experience rewarding and meaningful social interactions.

Despite the lack of sustained differential treatment effects, we did find some positive effects of CBTsa directly posttreatment regarding overall symptom severity, and more specifically in the

Table 2
Intent-to-Treat Analyses of Primary and Secondary Outcome Measures Directly After End of Treatment (Post), 6 Months Posttreatment (Follow-Up), and for the Overall Period (Over Time)

Measure	Baseline		Posttreatment				Follow-up				Over time	
	CBTsa (n = 49)	TAU (n = 50)	CBTsa	TAU	T p-value	G × T p-value	CBTsa	TAU	T p-value	G × T p-value	T p-value	G × T p-value
BNSS a-sociality	5.4 (4.9–6.0)	5.9 (5.4–6.5)	4.3 (3.6–4.9)	4.6 (4.0–5.3)	<.001	.772	4.1 (3.5–4.7)	4.3 (3.7–5.0)	<.001	.788	<.001	.640
BNSS Negative symptoms	29.9 (26.6–33.2)	28.3 (25.1–31.5)	22.0 (18.6–25.5)	24.6 (21.1–28.0)	<.001	.082	23.2 (19.7–26.7)	22.7 (19.0–26.3)	<.001	.546	<.001	.583
PANSS Social emotional withdrawal	9.6 (8.9–10.4)	9.5 (8.8–10.3)	7.5 (6.7–8.2)	7.4 (6.6–8.1)	<.001	.866	7.1 (6.3–7.9)	7.2 (6.3–8.0)	<.001	.754	<.001	.764
GAF symptoms	45.6 (41.9–49.3)	47.8 (44.0–51.5)	54.3 (50.2–58.3)	49.5 (45.5–53.6)	<.001	.024	52.1 (48.0–56.2)	52.9 (48.6–57.2)	.004	.671	.002	.549
GAF functioning	41.5 (38.3–44.7)	41.7 (38.4–44.9)	49.0 (45.4–52.5)	48.8 (45.3–52.3)	<.001	.997	50.8 (47.2–54.4)	51.3 (47.6–55.1)	<.001	.979	<.001	.878
DAS-DPA	70.8 (65.6–75.9)	73.3 (68.2–78.5)	75.9 (70.4–81.3)	73.1 (67.6–78.5)	.112	.389	74.4 (69.1–79.7)	75.7 (70.1–81.3)	.169	.701	.156	.664
ISMI Stigma	51.3 (47.6–55.0)	49.1 (45.2–52.9)	50.3 (46.3–54.4)	45.3 (41.2–49.4)	.560	.384	46.5 (42.7–50.4)	46.4 (42.2–50.5)	.017	.449	.022	.582

Note. CBTsa = cognitive–behavioral approach aimed at social activation; TAU = treatment as usual; NOS = not otherwise specified; PANSS = Positive and Negative Symptoms Scale; BNSS = Brief Negative Symptoms Scale; GAF = Global Assessment of Functioning Scale; DAS-DPA = Dysfunctional Attitudes Scale-Defeatist Performance Attitude; ISMI = Internalized Stigma of Mental Illness Scale; T = time effects; G × T: Group × Time interactions on outcome variables: p values. Values given as estimated marginal means (95% confidence interval) of the intention-to-treat linear mixed model. Analyses are controlled for gender, relationship status, and recruitment site.

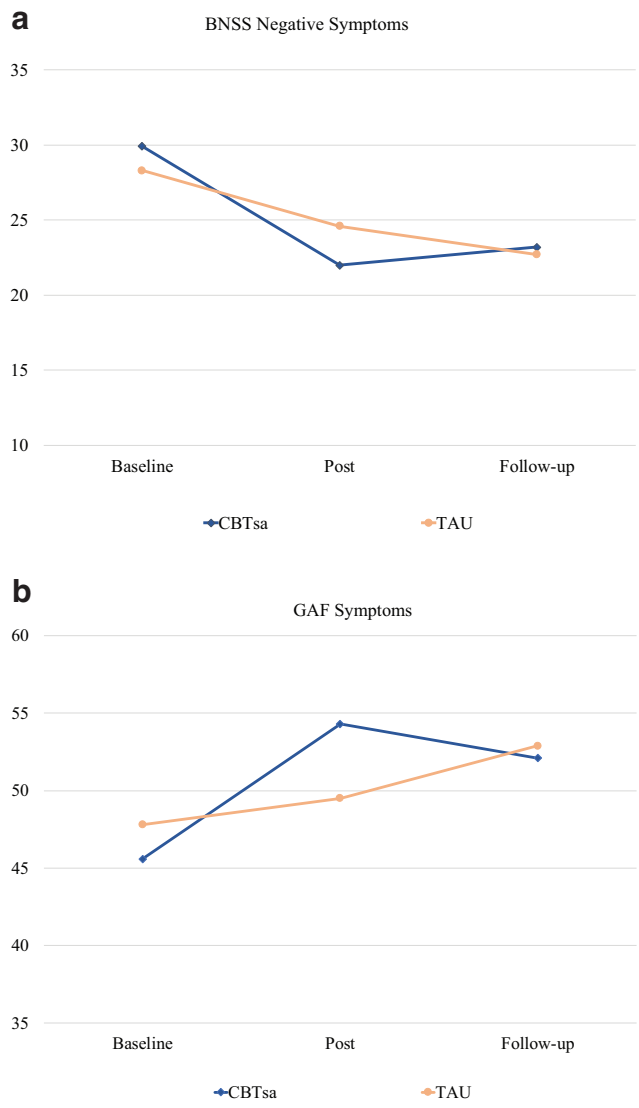

Figure 2. Estimated marginal means of Brief Negative Symptom Scale and Global Assessment of Functioning Symptom subscale as a function of treatment group in the intent-to-treat sample. CBT = cognitive–behavioral therapy. See the online article for the color version of this figure.

decrease of negative symptoms. These results may indicate that CBTsa shortly after first admission may be beneficial in accelerating the reduction of symptoms.

However, as mentioned previously, the beneficial effect of CBTsa was no longer apparent at follow-up. Furthermore, 6 months after the end of treatment participants in both the intervention and TAU group reported remaining clinically relevant negative symptoms.

One important factor that may help explain the lack of a favorable effect in longer term improvements of negative symptoms in the CBTsa condition was our inability to establish a positive change in the proposed working mechanism; minimizing dysfunctional beliefs and/or (self) stigma. Based on the cognitive model of negative symptoms, we assumed that defeatist beliefs play a central role in the development and maintenance of negative symptoms, specifically social withdrawal. Accordingly, in their pilot study, Staring et al. found that a reduction in dysfunctional beliefs partially mediated the observed change in negative symptoms after CBT treatment (Staring, Ter Huurne, & van der Gaag, 2013). This finding was recently supported by Granholm and colleagues (Granholm, Holden, & Worley, 2018).

It may be that our shorter treatment protocol was not intensive enough to ensure a sustained differential effect and improvements in the proposed working mechanism defeatist beliefs. The studies that showed successful improvement all had a significantly longer treatment duration (Granholm et al., 2018; Morrison et al., 2014; Staring, Ter Huurne, & van der Gaag, 2013). Furthermore, a substantial number of participants in the CBTsa condition were lost during or at the end of group therapy before individual sessions started and could therefore not benefit from individual work on dysfunctional beliefs and activation plans. Lincoln et al. (2017) recently emphasized that individualized treatment planning is needed to increase the effectiveness of approaches aiming to reduce negative symptoms. Based on these findings, it may be advisable for future studies to start with more individual sessions, personal attention, and practice. Subsequently, in a second step—when more familiar with the content of CBTsa and a personal case formulation—participants may be more prone to benefit from 'peer support' groups. Furthermore, because psychotic disorders often have an episodic course, and studies indicate that psychotherapy treatment gains decline over time, some patients may need access to booster sessions and additional psychotherapy to manage symptoms and sustain treatment gains or further improve them over time. Fowler et al. (2018) recently reported promising results of an RCT investigating the effect of social recovery therapy at four early intervention services in the United Kingdom. In contrast to our study, their approach not only had a longer treatment duration (9 months), but also focused extensively on the inclusion of family members, employers, and education providers. This integrative approach with a stronger focus on the close environment of the patient may be needed to establish an enduring positive treatment effect. Future research targeting defeatist beliefs and negative symptoms should address these limitations.

Finally, sustained additive effects of CBT targeting negative symptoms may be more likely in more chronic patient groups that show enduring negative symptoms and dysfunctional beliefs.

Our study should be considered in the context of some limitations. First, we did not meet our recruitment target (n = 112) and a considerable number of participants were lost to follow-up. Because of the substantial number of pretreatment loss and noncompleters in the intervention condition, we chose a liberal criterion of at least 65% of attended sessions to define completers. Regardless, dropout rates may have contributed to insufficient power in the per protocol analyses. However, dropout rates were comparable to those in the meta-analyses of Fernandez, Salem, Swift, and Ramtahal (2015), who reported average weighted dropout rates from CBT of 15.9% pretreatment and 26.2% during treatment. Second, more women were lost to follow-up in the CBT condition, which might have influenced outcome of the completer analyses. However, no differences were found between the ITT and completer analyses.

Third, current cannabis abuse was not included as a covariate due to too many missing values. It would be interesting to further

investigate the effect of CBTsa in better-powered studies—potentially with different, more sensitive measures.

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