

**Randomized controlled trial of social cognition interaction training
and a therapeutic alliance focused therapy among persons with
Schizophrenia.**

Clinicaltrial.gov ID NCT02380885

Scientific background

Schizophrenia is associated with impairments in both interpersonal and intrapersonal functioning, which in turn, hinders quality of life (QoL). These impairments are so extensive that various clinicians and researchers view them as a major feature of schizophrenia characterized by difficulties in understanding the social environment and the individual's place within it (Penn, Corrigan, Bentall, Racenstein, & Newman, 1997; Stanghellini, 2000). These impairments are relatively non-responsive to antipsychotic medications (Bellack, Schooler, & Marder, 2004) and are reported by patients as their greatest unmet need (Coursey, Keller, & Farrell, 1995; Middelboe et al., 2001). One strong mediator of social functioning impairments in schizophrenia is disturbance in social cognition (i.e., the cognitive processes that underlie social interaction; Couture, Penn, & Roberts, 2006; Brüne, Abdel-Hamid, Lehmkämper, & Sonntag, 2007). The growing recognition of the devastating impact of social cognition deficits in schizophrenia, have generated attempts to develop interventions that target social cognition as a means to improve social functioning and QoL. One such intervention is Social Cognition and Interaction Training (SCIT; Roberts, Penn, & Combs, 2006). SCIT is a manualized, group-based intervention that has demonstrated efficacy in improving social cognition and social functioning in both inpatient and outpatient samples (Combs et al., 2007a; Combs et al., 2009b; Roberts & Penn, 2009; Roberts, Penn, Labate, Margolis, & Sterne, 2010). SCIT was developed to address the three core domains of social cognition that are disrupted in schizophrenia: emotion perception, theory of mind, and attributional style. The major theoretical assumption underlying SCIT is that schizophrenia is associated with a number of social cognitive distortions and impairments. These include jumping to conclusions (Garety, Hemsley, & Wessely, 1991), attribution bias (Bentall, 1994), as well as problems with Theory of Mind (ToM; Frith, 1992) and emotion perception. Because these cognitive impairments are linked to the mental operations underlying social interactions, such as the human ability and capacity to perceive the intentions and dispositions of others (Brothers, 1990), they interfere with social QoL and functioning.

The proposed study assessed both the theoretical assumptions and the effectiveness of the SCIT intervention with persons diagnosed with schizophrenia. The SCIT intervention emphasizes a set of techniques designed to ameliorate the social cognitive deficiencies and biases to promote change. Accordingly, this study will assess both potential mediating processes, such as emotion perception and ToM, that are thought to be limited and distorted by schizophrenia, as well as social functioning and QoL. To test whether any positive change can be attributed specifically to SCIT, we compared its impact to a different intervention, called Therapeutic Alliance Focused Therapy (TAFT). TAFT is based on the system of observing family therapy alliance (Friedlander, Escudero, & Heatherington, 2006) and focuses on the therapeutic alliance. Both interventions (experimental groups) were compared to control group of treatment as usual (TAU).

Method

Research Setting

The current randomized controlled trial (RCT) was an intervention study that assessed the effectiveness of SCIT versus TAFT in a psychiatric community setting in Israel (Clinicaltrial.gov ID NCT02380885). Data were collected between the years 2014 and 2018. Previous studies

derived from this larger project were conducted on the basis of baseline partial samples of the current study (25, 26). Approval for the study was obtained from the ethics committee of the Department of Psychology at Bar-Ilan University, as well as from two psychiatric hospital committees. After receiving a detailed explanation of the study, all research participants provided written informed consent. Data were collected by an experienced mental health practitioner who was trained to administer.

Statistical Analysis:

Analyses were computed using Predictive Analytics SoftWare (PASW, Version 25.0). To test whether the groups differed in their baseline scores on the scales and whether there were differences between participants who did and did not complete Time 2 assessments, two-way ANOVAs were performed. To examine improvement in the outcomes (SQoL, FEIT, Faux Pas task, SSPA, and AIHQ), mixed repeated measures ANOVAs were used with time (pre, post) and group (SCIT, TAFT, and TAU) as factors. A mixed repeated-measures ANOVA allows for an examination of the extent to which participants improved over time regardless of group, as well as whether they improved significantly more over time in one group versus the other (group-time interaction). To assess the overall effect sizes, partial eta squared (η^2) was computed with $\eta^2 = .01$ indicating small, $\eta^2 = .059$ medium, and $\eta^2 = .138$ large effects (37). In case of a significant effect, a paired two-sample t test was conducted for each group comparing preand post-results. Effect sizes of paired tests were reported with Cohen's d (37) with $d = .2$, indicating small; $d = .5$, medium; and $d = .8$ large effects. To examine whether the therapeutic alliance was associated with the change in the research variables, we performed a multiple regression, with the difference in each variable (difference between time 1 and time 2) as the dependent variable, and group (0-SCIT, 1-TAFT) and the four dimensions of the therapeutic as the independent variables.