Metacognitive and Insight Therapy for Persons With Schizophrenia (RCT MERIT)

Clinicaltrial. gov ID NCT03427580

Background: Updated approaches to psychotherapy with people with schizophrenia emphasis reflective processes as both mechanism of change toward recovery, as well as desirable outcome essential to the experience of the self in a coherent integrative manner (Hasson-Ohayon & Lysaker, 2021). This emphasis is based on extensive research showing that people with schizophrenia often show challenges in experiencing themselves in a coherent meaningful way as agents in the world that are connected to others (e.g. Lysaker, Hamm, Bethany & Lysaker 2019; McCarthy-Jones et al., 2013). Although the need to address these deficits of the self-experience in treatment was already argued more than a century ago and has a long history, (Kraepelin, 1896; Bleuler, 1911; Jaspers, 1923), it is only recently that evidenced based and theory driven reflective approaches to psychotherapy with people with schizophrenia have emerged. One of these approaches, Metacognition Reflection and Insight Therapy (MERIT, Lysaker & Klion, 2017) have been applied in different psychiatric settings and was tested for its effectiveness. Randomized controlled trials (Vohs et al., 2018, de Jong et al., 2019), open trials (Bargenquast & Schweitzer, 2014; de Jong et al., 2016), session by session assessment of change (Lavi-Rotenberg et al., 2020), qualitative studies (de Jong et al., 2019; Lysaker et al., 2015) and a series of case studies (e.g. Cohen-Chazani et al., 2021, Arnon-Ribenfeld et al., 2018; Hasson-Ohayon et al., 2017; Igra et al., 2020) support its effectiveness in improving different dimension of metacognition and selfexperience such as mastery and self-reflection. Interestingly, in few case studies reliable change index showed also improvement in general symptoms of distress (Arnon-Ribenfeld et al., 2018; Igra et al., 2020) as well as in psychotic symptoms (Cohen-Chazani et al., 2021) and descriptive reports showed improvement in negative symptoms and functioning (Hillis et al., 2015; van Donkersgoed et al., 2016). However, no systematic evaluation of change in symptoms of psychosis was carried out and it is not clear whether MERIT contribute to parallel improvement in both metacognition and symptoms. In an attempt to broaden the literature on the effectiveness of MERIT the current study assesses changes in both metacognitive abilities as well as in

symptoms among people diagnosed with schizophrenia. Evidently, associations between metacognition and symptoms were subject to previous studies that showed better metacognition is related to decreased level of symptoms (e.g. Hasson-Ohayon et al., 2018; Lysaker et al., 2005; Nicolo et al., 2012) and meta-analysis further support this (Arnon-Ribenfeld et al., 2017). Of note, it was suggested that this association is mediated by interpersonal functioning (Brune, 2006; Salvatore et al., 2008) so that metacognition leads to better social relationships and this results in less withdraw, distress and additional symptoms. Thus, it might be that during MERIT, improvement in metacognition will be accompanied with improvement in symptoms, interpersonal functioning and general quality of life. This research question, addressed in the current study, was examined in the unique context of covid-19 pandemic. Half time of the duration of the current reported trial took place under conditions of quarantine and gathering limitations. As previously reported (Hasson-Ohayon & Lysaker, 2021) adaption to online meetings were done when possible and content in therapy naturally included coping with the pandemic and related stress. Thus, the current study also seeks to explore whether under these unique circumstances that included both high pandemic related distress of patients as well as often online meetings, MERIT will result in improvement in metacognition, symptoms and quality of life for people diagnosed with schizophrenia. A delayed randomized controlled trial was applied to answer this question, in an outpatient university community clinic.

Method: The study used a delayed randomized controlled trial design and session-bysession assessment to examine the therapeutic benefits of 24 sessions of MERIT delivered in a community clinic at Bar-Ilan University (Clinicaltrial.gov ID NCT03427580). The clinical trial was advertised in rehabilitation centers, mental health centers and in relevant internet sites and Facebook groups. Participants approached the clinic voluntarily, seeking therapy due to psychological challenges. Participants were offered 24 sessions of MERIT in reduced fee, as part of the research trial. All participants were screened on the telephone by clinical or

rehabilitation psychologists. Participants that aligned with inclusion criteria were invited to an intake meeting. They signed an informed consent form describing the study design and purposes, and completed baseline assessment. After completing the intake participants were randomized for immediate or delayed intervention. Participants in the immediate intervention received 24 weekly sessions of MERIT and were assessed after treatment. Participants in the delayed intervention group had a six month wait period and were assessed before and after waiting, then they were offered 24 sessions of MERIT and were assessed after treatment.

Statistical analysis: In order to examine the therapeutic benefits of MERIT, the outcome measures (metacognition – MAS-A) will be analyzed by means of repeated measures of multivariate analysis of variance (MANOVA). We will use group (MERIT\ Control) as between subject factor and time (T1\T2) as within subjects' factor. In addition, reliable change index (RCI; Jacobson & Traux, 1992) of the outcome measures will be computed for each participant that completed MERIT (from both groups).