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Personalizing Interventions Using Real-World Interactions: Improving Symptoms and Social Functioning in Schizophrenia with Tailored Metacognitive Therapy

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Abstract

Objective: When clients' lives are not reflected in therapy, they struggle to apply the skills learned in treatment to everyday situations. In this pilot study, we determined if using clients' real-world interactions in therapy could effectively target metacognitive capacity—yielding improved symptoms and social functioning—by tailoring treatment to focus on issues faced by clients in daily life.

Method: Using a randomized controlled trial design, schizophrenia subjects with metacognitive deficits completed 24 sessions of: 1) Standard Metacognitive Reflection and Insight Therapy (MERIT); or 2) Tailored MERIT. Real-world interactions were captured via the Electronically Activated Recorder (EAR), a smartphone application that passively records audio in daily life. All subjects wore the EAR; however, real-world interactions were only used to personalize sessions in Tailored MERIT.

Results: Feasibility and acceptability were shown; those in Tailored MERIT wore the EAR 84% of their waking hours and reported minimal burden. When compared to Standard MERIT, Tailored MERIT participants showed large pre-post reductions in negative metacognitive beliefs and disorganized symptoms. Small, but non-significant, improvements in social functioning were also observed.

Conclusions: Compared to an evidence-based benchmark, we observed that real-world interactions can be used to tailor metacognitive therapy and improve outcomes in schizophrenia. Tailored MERIT has the potential to impact practice by personalizing treatment to account for individual variations in environment and lifestyle—aligning with the Precision Medicine Initiative

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—in a way that is not possible with current therapy. This is particularly salient in schizophrenia, where limited insight and cognitive deficits often make subjective reporting unreliable.

Keywords

schizophrenia; social functioning; metacognition; psychosocial therapy; ecological momentary assessment

Introduction

We all approach the world in unique ways. Differences in our approach—sometimes subtle, sometimes clear-affect how we interact with other people. Those with schizophrenia exhibit large deficits in their ability to interact with others. This ability is frequently referred to as social functioning, a construct that also consists of the size of one's social network and the quality of relationships within that network (Bowie & Harvey, 2008; Green et al., 2015). Poor social functioning has important ramifications in schizophrenia; it is often cited by clients as the most distressing aspect of their disorder and is linked with increased suicidal ideation and poor illness progression (Bellack et al., 2007; Harvey et al., 2007; Lyu & Zhang, 2014). Thus, there is a need to develop treatments that can reduce symptoms and target underlying mechanisms of social functioning. One potential mechanism is metacognitive capacity-a process that is disrupted in schizophrenia and is characterized by one's ability to make sense of the world via awareness of their own and others' emotions (Lysaker & Klion, 2017; Lysaker, Minor, et al., 2020). Metacognitive capacity is a form of metacognition that goes beyond 'thinking about thinking' to include our understanding of how thoughts, feelings, and past experiences can be integrated to make sense of our surroundings. When understanding is lacking, low metacognitive capacity limits social functioning by affecting one's grasp on how a multitude of factors-thoughts, feelings, connections between events-fit together during social interactions. This can adversely impact how those with schizophrenia approach and understand the world around them.

Metacognition Reflection and Insight Therapy (MERIT) is a psychosocial therapy that aims to change how people with schizophrenia approach the world (Lysaker & Klion, 2017). In MERIT, metacognitive capacity is viewed hierarchically and individual sessions are designed to 'meet' clients at their current capacity. Therapists seek to form a consultative alliance, with the overarching goal of improving metacognitive capacity by changing the client's understanding of how they view themselves and the world around them. Sessions focus on specific interactions and how a clients' thoughts, feelings, and motivations may change over the course of that interaction and be informed by past interactions. This integrative process—where clients learn to synthesize information from multiple sources (e.g., situational context, past experiences) by reflecting on how they view themselves and others in social situations—is essential to developing and sustaining social relationships. Thus, MERIT is uniquely suited to reduce symptoms and improve social functioning. Recent clinical trials and case studies have illustrated MERIT's effectiveness in schizophrenia by showing how clients exhibit decreases in psychotic symptoms and gains in social

functioning following participation in MERIT (Bargenquast & Schweitzer, 2011; Buck & George, 2016; De Jong et al., 2018; Lysaker, Gagen, et al., 2020).

MERIT's effectiveness may be hindered, however, by the limitations of standard therapy. In psychosocial interventions, it is vital that content discussed in sessions is relevant to client's actual experiences. Subjective stimuli (i.e., client identified social situations) typically serve as core elements for clients to practice skills in sessions. In most cases, social interactions discussed in therapy rely solely on a client's retrospective report. By definition, people with metacognitive dysfunction have difficulty understanding the complexities of their interactions (Bright et al., 2018; James et al., 2018; Lysaker & Dimaggio, 2014). This can make it impractical for these clients to generate relevant examples in sessions. When generated, other impairments common to schizophrenia (e.g., cognitive deficits, poor insight) often make subjective stimuli unreliable and difficult for people to reflect upon (Dimaggio & Lysaker, 2015; Minor & Lysaker, 2014). Thus, a significant issue that may limit the effectiveness of MERIT and other therapies is obtaining accurate content for therapy sessions that can be applied to a client's real-world experiences.

Addressing the issue of creating relevant content to target metacognitive capacity requires using clients' real-world interactions to tailor interventions. Without tailored interventions, therapists will remain unable to personalize therapy to the unique obstacles clients face —making it difficult for those with schizophrenia to maximize metacognitive gains. In recent years, portable technologies have evolved as an objective measure of social behavior (Ben-Zeev et al., 2016; Insel, 2015; Kwapil et al., 2012). Many ambulatory methods (e.g., digital phenotyping, ecological momentary assessment) increase ecological validity and offer valid accounts of social functioning but are not designed to dissect interactions with the complexity needed to assess metacognitive capacity. Even if they could systematically capture metacognitive dysfunction requires therapists to go beyond the client's perspective of their social behavior: it necessitates collecting concrete accounts of social behaviors in a client's everyday environment so that therapists can use these as examples by which to promote metacognitive capacity.

A methodology that has exhibited great promise for providing observations of real-world social behaviors is the Electronically Activated Recorder (EAR; Abel et al., in press; Robbins et al., 2018; Robbins et al., 2019). The EAR is a computer-based application that can be paired with widely-used smartphone technology to collect behavioral samples at pre-programmed intervals using audio recordings (Mehl et al., 2012; Mehl, 2017). It offers a novel solution to the issue of clients being the sole reporters of their behaviors outside of session by providing therapists with concrete examples of real-world social interactions. This addresses two significant problems for MERIT therapists: 1) clients with schizophrenia who cannot generate examples now have social interactions to discuss in session; and 2) those with cognitive deficits who struggle to accurately recall details of their interactions now have objective recordings they can listen to and share with therapists. Thus, the EAR may add more opportunities to reflect on clients' experiences. During sessions, clients and therapists can jointly use recordings to stimulate a client's understanding of how a multitude of factors—thoughts, feelings, connections between events—fit together to form

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representations of the mental states of themselves and others by using specific interactions from the client's life as a foundation for developing these abilities. By tailoring MERIT using EAR audio recordings, this study's primary goal was to create a novel, personalized intervention that targets metacognitive deficits to reduce symptoms and improve social functioning.

Study Objectives and Hypotheses

In this pilot study, our central objective was to test whether using clients' real-world interactions to tailor therapy would target metacognitive capacity more effectively-yielding reduced symptoms and improved social functioning. To accomplish this objective, the EAR was implemented to tailor MERIT. Subjects with schizophrenia and metacognitive deficits were randomized to 24 sessions of: 1) Standard MERIT; or 2) Tailored MERIT. Our aims were to determine Tailored MERIT's feasibility, acceptability, and effectiveness using a randomized controlled trial (RCT) design. Regarding feasibility, we expected that subjects would wear the EAR for at least 70% of their waking hours. This is in line with previous EAR assessment studies (Manson & Robbins, 2017; Minor et al., 2020) and would provide approximately 1.5 hours of audio data each week from which to select social interactions. To measure acceptability of the EAR, we hypothesized that participants, particularly those in Tailored MERIT, would rate wearing the EAR as being low in burden and having minimal impact on behavior. To test effectiveness, we expected improvements in metacognition, psychotic symptoms, and social functioning when comparing Tailored MERIT to Standard MERIT. By bridging novel technology and psychosocial therapy, this study sought to target metacognitive capacity in a new way. If successful, Tailored MERIT has the potential to improve clinical practice by personalizing treatment to account for individual variations in environment and lifestyle-aligning with the Precision Medicine Initiative (see Ashley, 2015)—in a way that is not possible with traditional therapy. This is particularly salient in schizophrenia, where limited insight and cognitive deficits often make subjective reporting unreliable.

Methods

Participants

Participants were recruited from a local community mental health center and a volunteer registry. To be included in the study, participants had to: a) exhibit metacognitive dysfunction at baseline (defined as one standard deviation or more below the general population mean); b) have a schizophrenia-spectrum disorder diagnosis (confirmed using the Mini International Psychiatric Interview; Sheehan et al., 1998; see Supplemental Methods for more information); c) be 18–60 years old; d) demonstrate English fluency; e) have no change in outpatient status in the 30 days prior to baseline testing; f) be able to provide informed consent; g) exhibit no current substance dependence; and h) have no documented intellectual disability. In total, 64 participants were assessed for eligibility, 34 were randomized to one of the two MERIT conditions, and 27 received the allocated intervention (i.e., 7 people dropped out between randomization and session one). Of the 27 who received the intervention, 20 completed a follow-up session to assess changes from preto post-intervention (Standard MERIT n = 8, Tailored MERIT n = 12; see Figure 1 for more

information). All participants signed informed consent documents prior to engaging in study procedures and protocols were approved by local institutional review boards.

Therapists

Therapists for this study consisted of five doctoral graduate students with 1 year of experience administering MERIT to people with schizophrenia-spectrum disorders. All therapists had been trained and supervised in MERIT with a study co-author who created MERIT (PHL) (Lysaker & Klion, 2017) and weekly supervision occurred with co-authors (KSM, PHL). Therapists were assigned to a participant once all pre-intervention measures were completed and randomization had occurred. Each therapist saw participants in both Standard and Tailored MERIT conditions and, once assigned to a participant, the therapist remained with them until the participant completed the study or dropped out. Therapists were primarily female (60% compared to 40% male); Caucasian (60% compared to 20% African-American, 20% Middle Eastern); in their mid-twenties to early thirties; and met with an average of 5.4 unique participants (with a mean of 4.0 study completers).

Examiners

Study examiners were three doctoral graduate students who had worked with people with schizophrenia-spectrum disorders for 1 year. For interview-based measures, training consisted of watching interviews and practicing administration of items with study staff. Examiners also had to exhibit good inter-rater reliability (κ 0.75) prior to conducting interviews independently. In weekly consensus meetings, examiners presented challenging cases to the study team and interview-rated scores were decided on as a group. Examiners were mostly male (67% compared to 33% female), Caucasian (67% compared to 33% African-American), and completed assessments with a mean of 11.3 unique participants (or 6.7 study completers).

Procedures

Upon meeting eligibility criteria and completing baseline assessments, participants were randomized to 24 sessions of Standard MERIT or Tailored MERIT. Selecting a sufficient number of MERIT sessions was important given that metacognitive capacity is relatively stable compared to many other psychological constructs. A duration of 24 sessions (e.g., around six months) was selected in consultation with the creator of MERIT because it balanced a strong enough 'dose' for effects to occur while also being moderate enough in duration to be implemented in community mental health settings. Although subjects could not be blinded to condition (i.e., audio files were used during Tailored MERIT), personnel gave general descriptors of MERIT during recruitment and did not refer to "tailored" or "standard" MERIT with participants. Participants were also asked to avoid discussing details of therapy during assessments or at their treatment center to avoid biasing examiners or potential participants.

The general goals of MERIT were similar across conditions. During sessions, the therapist and client engaged in joint thinking and reflecting about the client's life. Within these reflections, clients selected interactions from their life to discuss in session. The overarching goal was for the client to organize thoughts and form an integrated understanding of their

life and how they approach the world. However, Tailored MERIT clients and therapists used recent, real-world interactions as stimuli for developing metacognitive capacity in session— whereas Standard MERIT clients and therapists relied on subjective stimuli (see Figure 2). Regardless of condition, all clients engaged in MERIT and wore a locked iPod Touch with the EAR application for two days after each session. This strategy was implemented to control for effects of the EAR itself (i.e., it allowed us to examine integrating the EAR in therapy rather than general EAR awareness). Although Hawthorne effects could still occur, past studies show that participants acclimate to the EAR after a few hours and report it has minimal effects on behavior (Abel et al., in press; Mehl et al., 2012; Minor et al., 2018). In total, approximately two hours of audio was collected each week, with 5 minute recordings at 90 minute intervals from 6:00am to midnight.

Standard MERIT.—Participants in this condition received MERIT as it was designed. The therapist allowed the client to set the agenda and interjected when appropriate. Participants selected past interactions from memory to discuss in session. Therapists worked with them in session to understand details of these interactions, including how the client's thoughts, feelings, and knowledge of their mind and the mind of others changed during the interaction. When participants could not generate examples of past interactions or generated incomplete examples, therapists worked with them to think about important periods in their life or asked clarifying questions to try to obtain further details. Prior to sessions, participants worked on an unrelated activity (i.e., Sudoku) for 20 minutes in a separate room from the therapist to standardize the time frame across conditions (i.e., comparable length to audio file reviews in Tailored MERIT).

Tailored MERIT.—Participants and therapists in Tailored MERIT listened to participant audio files prior to sessions. Participants listened to files on head-mounted microphones and deleted any files that they did not want therapists to hear prior to therapists accessing them. Participants were instructed to listen for any interactions that they might want to discuss in that day's session. As subjects reviewed files, therapists also cued interactions from that or a previous week for use in session. Participants and therapists were typically in separate rooms when listening to files. During sessions, participants still selected interactions to discuss and therapists clarified understanding. The major difference from Standard MERIT was that participants could now select interactions from audio files and therapists could play or discuss files to promote shared understanding. For example, the therapist might play an audio recording of a client's recent social interaction with a friend to open a dialogue on the client's self-reflections at different points of the interaction. Further, participants and therapists could use audio files as a reference point to past interactions (e.g., therapists could connect the participant's emotions during the interaction to a similar experience from the participant's past; participants could reflect on how their understanding of the friend's thoughts at the start of the interaction connected to a previous interaction with that friend). Recorded interactions were identified quickly via .wav files; the review process typically took between 15-30 minutes each week.

EAR Procedures.—Participants in both MERIT conditions wore the EAR following pre-post assessments and after each therapy session. At each time point, participants wore

the EAR for two consecutive days after a session (e.g., if a session occurred on Monday, they wore the EAR on Tuesday and Wednesday) for a total of approximately 50 days over the course of the study. Two-day intervals were selected because this time frame has exhibited good temporal stability (Mehl & Robbins, 2012), convergence with four-week intervals (Mehl et al., 2012), and provided ample social interactions for use in therapy in our team's pilot work. Further, a recent assessment study from our group demonstrated that this two-day recording interval captured an average of >6 social interactions in people with schizophrenia (Abel et al., in press).

Participants were unaware of when the EAR would record but were told that recordings would occur approximately five percent of the time on days the EAR was worn. Before leaving with the EAR, participants were made aware that they could listen to and delete any recordings before our team accessed them. Additional safeguards to protect confidentiality included: a) subjects were instructed to remove the EAR in settings they did not wish to be recorded; and b) a sign was placed on the protective case of the iPod Touch to alert third parties of the EAR (i.e., "This device is being used for research purposes. It records nearby surroundings at various intervals and may record your voice"). Upon reviewing recordings, participants only deleted 1–2% of files, which is consistent with past EAR studies (Minor et al., 2018; Robbins et al., 2014).

Measures

Feasibility.—Recordings from pre-post assessments were used for feasibility analyses. At each time point, research assistants coded audio files (yes/no) to denote if participants wore the EAR. Files were rated using a standardized coding system, the Social Environment Coding of Sound Inventory (Mehl et al., 2007; see Kaplan et al., 2020). To rate files, research assistants used .wav charts and listened for ambient noise (e.g., breathing, movement) that indicated the EAR was being worn. Frequency scores were then calculated for each participant to illustrate how often they wore the EAR during their waking hours across pre-post assessments.

Acceptability.—Self-report questions from the EAR Experiential Questionnaire (Mehl et al., 2001) were administered pre-post intervention to assess acceptability of wearing the EAR. Questions focused on: how uncomfortable participants were wearing the EAR; if the EAR impeded daily activities; if it changed their behaviors or others' behaviors; and how typical days were that the EAR was worn. Each question was rated on a 1 (not at all) to 5 (a great deal) scale. Across pre-post time points, responses were averaged for each condition.

Metacognition.—The Metacognitive Beliefs Questionnaire-Brief (MCQ-30; Wells & Cartwright-Hatton, 2004) is a 30-item, self-report measure (e.g., 'I am aware of the way my mind works when thinking through a problem', 'I think a lot about my thoughts'). It uses a 1 (do not agree) to 4 (agree very much) scale (higher scores indicate greater unhealthy metacognitive processes) and has five subscales (lack of cognitive confidence, positive beliefs about worry, cognitive self-consciousness, negative beliefs about uncontrollability, need to control thoughts). Good internal consistency was shown here for pre- ($\alpha = .900$) and post-assessments ($\alpha = .899$).

Social functioning.—In this study, we used a primary (Global Functioning: Social Scale; GF: Social; Auther et al., 2006) and a secondary (Interpersonal Relations subscale from the Quality of Life Scale; QLS-IR; Heinrichs et al., 1984) interview-rated scale to assess social functioning. GF: Social is a clinician-rated, interview-based measure that ranges from 1 (extreme social isolation) to 10 (superior functioning in a wide range of social/ interpersonal activities). The QLS-IR contains 8 items and scores range from 0 to 6; increasing scores represent better functioning. Both measures have demonstrated strong psychometric properties (Cornblatt et al., 2007; Gupta et al., 2000) and have been used in past studies to measure social functioning in schizophrenia-spectrum samples (Abel & Minor, 2021; Fulford et al., 2020; Minor et al., 2016).

Symptoms.—The Positive and Negative Syndrome Scale (PANSS; Kay et al., 1987) is a widely-used interview-rated measure. It has 30 items ranging from 1 to 7 (higher scores indicate greater symptom severity). In past studies, it has exhibited good internal consistency (Kay et al., 1987), interrater reliability (Lysaker et al., 2013), and predictive validity (Bell et al., 1992). Here, we used the total score and five factor scores (see Bell et al., 1994): 1) positive (hallucinations, delusions, unusual thought content, somatic concerns, suspiciousness, grandiosity); 2) negative (passive social withdrawal, emotional withdrawal, blunted affect, lack of spontaneity, poor rapport, disturbances of volition, preoccupation, motor retardation); 3) cognitive (difficulty in abstract thinking, stereotyped thinking, conceptual disorganization, lack of insight, tension, poor attention, mannerisms/ posturing); 4) hostility (excitement, hostility, poor impulse control, uncooperativeness); and 5) depression (depression, anxiety, guilt, active social avoidance).

Analyses

Analyses were conducted in four parts. First, study completers/non-completers and participants in Standard/Tailored MERIT were compared on demographic and baseline clinical data using chi-square analyses, one-way ANOVAs, and independent *t*-tests. Second, feasibility was measured across conditions by calculating how often participants wore the EAR during their waking hours. Pre-post intervention adherence was averaged for each participant and conditions were compared using an independent *t*-test. Third, acceptability was assessed by first averaging pre-post intervention responses for each participant. Then, acceptability in Standard and Tailored MERIT conditions was compared using independent *t*-tests. Finally, changes in clinical data from pre-post intervention were compared using a series of analysis of covariance (ANOVA) tests. In each ANOVA, time (pre-, post-intervention) and condition (Standard MERIT, Tailored MERIT) were independent variables and the clinical outcome (e.g., social functioning, overall symptoms) was the dependent variable. For all analyses, one-tailed significance tests were used for hypothesized outcomes and two-tailed significance tests were used for non-directional analyses. Effect sizes used Cohen (1992) guidelines for small, medium, and large effects.

Results

Demographic and Pre-Intervention Comparisons

Study completers and non-completers did not exhibit significant differences in age (Completers mean = 44.25, SD = 10.95; non-completers mean = 47.60, SD = 7.84), sex (Completers male/female = 9/11; non-completers male/female = 6/8), race (Completers African-American/Caucasian = 15/5; non-completers African-American/Caucasian = 8/6), marital status (Completers never married = 60%; non-completers never married = 43%), or education (Completers high school or greater = 70%; non-completers high school or greater = 71%; all p's > 0.10). Differences were not observed at baseline for metacognition (Completers mean = 75.10, SD = 16.27; non-completers mean = 76.71, SD = 15.51), social functioning (Completers mean = 5.60, SD = 0.60; non-completers mean = 6.14, SD = 1.56), or symptoms (Completers mean = 59.70, SD = 12.06; non-completers mean = 64.21, SD = 10.84; all p's > 0.10). This suggests that those who completed the study were similar to those who did not.

When study completers were compared by condition, participants did not significantly differ in age, sex, race, or marital status. There was a trend level difference across conditions in education, with participants in the Tailored MERIT condition reporting a greater frequency of high school or greater achievement. No significant differences were reported in any pre-intervention clinical variable (see Table 1).

Feasibility

Across pre- and post-intervention time points, participants wore the EAR for the majority of their waking hours. Those in the Tailored MERIT condition wore the EAR for approximately 84% of their waking hours and participants in the Standard MERIT condition wore it approximately 72% of the time. No significant group differences were observed, t(18) = -1.61, p = 0.125, d = 0.69. Our hypothesis that participants would wear the EAR for at least 70% of their waking hours was supported (mean across conditions = 79.29%, SD = 17.60).

Acceptability

Participants in both conditions reported high levels of acceptability in regard to wearing the EAR. Those in Tailored MERIT reported low levels of discomfort, a lack of impediment to their daily activities, and minimal changes to their behavior or in others' behavior. They also rated the days that they wore the EAR as being highly typical. No differences between Tailored MERIT and Standard MERIT were observed for any responses (Table 2). Significant differences were not observed for either condition when pre- and post-intervention variables were compared. Our hypothesis that MERIT participants would rate the EAR as acceptable was supported.

Preliminary Effectiveness

Consistent with hypotheses, we observed significant differences across conditions in one metacognitive subscale and one symptom subscale. On the metacognition scale, those in the Tailored MERIT condition exhibited fewer negative beliefs about the uncontrollability of

their thoughts compared to the Standard MERIT condition from pre- to post-intervention, F(2,19) = 5.22, p = 0.018, d = -1.04. Regarding symptoms, Tailored MERIT participants demonstrated reduced disorganized symptoms from pre to post-intervention compared to those in Standard MERIT, F(2,19) = 3.08, p = 0.048, d = -0.80 (see Table 3).

Contrary to hypotheses, no group differences were observed in overall social functioning, F(2,19) = 0.64, p = 0.218, d = 0.37, metacognition, F(2,19) = 0.68, p = 0.365, d = -0.38, or symptoms, F(2,19) = 1.07, p = 0.158, d = -0.47. A second social functioning measure, the QLS-IR, also showed no significant group differences on the overall scale (see Supplemental Table 1). For all constructs, those in Tailored MERIT showed overall improvements in the small to medium effect size range compared to Standard MERIT. No significant differences by condition were found for metacognition or symptom subscales outside of those listed above; those in Tailored MERIT did show significant gains on the Sociosexual Relations item on the QLS-IR.

Discussion

This study's primary goal was to determine if tailoring an evidence-based metacognitive therapy using clients' real-world interactions was feasible, acceptable, and effective. Three main findings emerged. First, Tailored MERIT demonstrated feasibility in a schizophrenia population. Participants in Tailored MERIT wore the EAR over 80% of their waking hours, which provided therapists and clients with several options when selecting social interactions to personalize therapy sessions. Second, acceptability was shown in Tailored MERIT. Participants reported that wearing the EAR was not burdensome and had no substantial effect on their behavior. Third, effectiveness was exhibited in some metacognitive and symptom domains when comparing pre-post performance in Tailored MERIT to Standard MERIT. Although small effects were also found for social functioning, these did not reach the level of statistical significance. This suggests that using real-world interactions engaged the intervention target but did not significantly improve social functioning more than standard treatment in this initial pilot study.

This is the first time the EAR has been used to personalize therapy by collecting real-world interactions. A critical question was whether people—particularly those with psychotic disorders—would adhere to wearing the EAR on a weekly basis for six months. High levels of adherence are a necessary component of tailoring therapy because they increase the likelihood of providing clients and therapists with multiple social interactions to use during sessions. Pre-post intervention data showed strong evidence of feasibility: participants in both conditions wore the EAR over 70% of their waking hours (84% in Tailored MERIT), with little change between pre-post time points. These findings aligned with past EAR assessment studies (Manson & Robbins, 2017; Minor et al., 2020) and show that asking people to wear the EAR for extended periods is a viable strategy. Our group has also shown that having participants wear the EAR for two days yields enough data to select social interactions, as a recent study found that our strategy resulted in a mean of >6 recorded interactions per week in those with schizophrenia (Abel et al., in press).

Regarding acceptability, a question going into this study was whether the EAR would present undue burden or severely impact observed behaviors. Acceptability was high on both fronts. Participants reported that the EAR introduced minimal burden; further, approximately 75% of those who started therapy, and 80% who began Tailored MERIT, completed the trial. Participants also reported that the EAR had little impact on their behavior, the behavior of others, and rated the days that the EAR was worn as highly typical. These findings, paired with high levels of EAR adherence, suggest that the EAR collects representative real-world interactions. Two aspects of our study may have contributed to the high acceptability found here. First, partnering with clients to let them control their data may have increased EAR adherence. This is a common approach in EAR studies (Abel & Minor, 2021; Robbins et al., 2011; Robbins et al., 2014) and allows participants to listen to and delete files that they do not want to share with our team. Consistent with other studies, approximately 1% of files were deleted in this trial (Minor et al., 2018; Minor et al., 2020; Robbins et al., 2014). Second, not providing recording times to participants likely minimizes social desirability biases and limits the impact of the EAR on participants' behavior. Future studies should use both strategies to increase acceptability. Holding focus groups with clients and therapists to determine which aspects of using real-world interactions in therapy were beneficial or could be improved is also recommended.

A third question in this pilot trial centered on the preliminary effectiveness of Tailored MERIT. When compared to Standard MERIT, those in Tailored MERIT showed large effect size improvements in negative metacognitive beliefs and disorganized symptoms. In both instances, the implementation of real-world interactions may have enhanced MERIT's strengths. Regarding reduced negative metacognitive beliefs, MERIT's focus on how clients' approach the world around them is designed to increase their feelings of control—a key component of this construct. One issue for people with schizophrenia, however, is that many have problems identifying relevant situations where they feel a lack of control. Using real-world interactions addresses this issue by providing directly applicable situations as stimuli to work through in sessions. This allows clients and therapists to work together on a recent problem throughout the session rather than spending valuable time trying to generate content.

Integrating real-world interactions within a MERIT framework also reduced disorganized symptoms. This is encouraging, as disorganized symptoms are a long-standing problem that have been described as one of schizophrenia's most underexplored aspects (Beck et al., 2011). Past research has shown clear links between metacognition and disorganized symptoms (Minor et al., 2015; Minor et al., 2019); MERIT's focus on organizing clients' thoughts about themselves and others into cohesive, meaningful narratives aligns well with boosting organized communication. One explanation why implementing real-world interactions further enhances this goal centers on the objective nature of these stimuli. Real-world interactions provide direct examples of how clients communicate with other people. This allows both the client and the therapist to develop a shared understanding of the situation being discussed and how the client reacts at different points of the interaction. Through shared understanding, metacognitive capacity may be targeted more effectively—and disorganized symptoms further reduced—by jointly focusing on the client's thoughts, feelings, and actions during interactions. To further test Tailored MERIT's impact, future

clinical trials should recruit larger groups with moderate to severe disorganization and determine if Tailored MERIT can be a useful intervention for improving disorganized symptoms.

Despite these two significant findings, overall observations were mixed when comparing Tailored MERIT to Standard MERIT—with those in Tailored MERIT showing small to medium improvements in social functioning, symptoms, and metacognition. We were particularly surprised that improvements in social functioning were not more robust. A potential explanation is related to the length of the intervention. MERIT is designed as a long-term therapy and most reports showing improvements in social functioning focus on clients who have been in therapy for a year or longer (Buck & George, 2016; van Donkersgoed et al., 2016). Thus, it is possible that the 24-week period was not long enough to observe a larger impact in social domains. Regarding metacognitive outcomes, our metacognition measure uses a broad conceptualization of this construct. Although metacognitive capacity is a form of metacognition, measures that directly assess it might demonstrate greater change. Thus, future studies should use measures that directly assess constructs and focus on dose-response relationships of Tailored MERIT on social functioning to determine the ideal intervention length for maximizing social benefits.

Another reason why Tailored MERIT's effectiveness may have been less pronounced is due to the high bar of comparison for the "control" condition (i.e., larger differences may have occurred with 'treatment as usual' in place of Standard MERIT). However, we felt it was vital to test Tailored MERIT against its closest possible comparison to measure how introducing real-world audio files impacted treatment outcomes. Although personalized interventions have many benefits over "one size fits all" approaches, there is a time cost to personalizing sessions. By comparing Tailored to Standard MERIT, we were able to ensure that both interventions targeted metacognitive capacity and illustrate the small to large benefits of implementing real-world interactions into therapy. Larger superiority trials should be conducted to confirm findings from this study and determine the extent of improvements shown by those receiving Tailored MERIT.

The use of real-world audio files to tailor an evidence-based therapy is a strength of this study. However, limitations also exist. First, this study's pilot nature led to small sample sizes. Although small to medium effects were observed here, we were only adequately powered for medium to large effects (d = 0.65). Estimated power, based on sample/effect sizes for primary constructs, was also low (0.31–0.58). Our small sample also prevented us from modeling or controlling for therapist effects. This is important given that some therapists may have expected Tailored MERIT to outperform Standard MERIT. For this pilot, our goal was to determine if enough signal was provided to conduct follow-up trials. Although we believe future trials are warranted, it is critical that these studies also control for therapist effects using larger samples. Second, the EAR may present privacy concerns. Although mitigation strategies were noted for participants, concerns also extend to third parties. To address this issue, we included a sign on the EAR device to alert third parties that their voice may be recorded. Participants were also encouraged to answer any questions about the EAR and explain files can be deleted if concerns persisted. Third, scalability is a concern for expanding Tailored MERIT to new communities. In its current iteration, we

were able to identify relevant interactions within 15–30 minutes prior to sessions. Although clients often spend significant time generating details about interactions in MERIT, a future goal is to reduce file review time using artificial intelligence to find interactions faster. Past studies have shown that machine learning and other voice identification approaches can be used to reduce background noise to isolate and identify subjects (Dubey et al., 2016). Our ultimate goal is to fully automate the tailoring process for future trials. Applying artificial intelligence approaches is an essential step to increase the efficiency of personalizing MERIT.

In sum, Tailored MERIT appears to be a feasible and acceptable intervention for people with schizophrenia. Those in Tailored MERIT wore the EAR over 80% of their waking hours, had high completion rates, and reported minimal impact of the EAR on behavior. Effectiveness findings were mixed. Compared to Standard MERIT, those in Tailored MERIT showed large reductions in negative metacognitive beliefs and disorganized symptoms. Although other areas did not reach statistical significance, small to medium gains in social functioning, metacognitive capacity, and symptoms were found. Future trials with larger samples should test if our strategy of implementing real-world social interactions to personalize therapy engages metacognition and improves social functioning. Trials should also focus on increasing scalability by using artificial intelligence to reduce the time needed to identify real-world social interactions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix

Appendix

Appendix Table 1.

Data Transparency.

No outcome results have been previously published from this clinical trial. There is one paper that is currently under review that contains baseline data from this trial; this paper tested how social functioning, as measured by the Electronically Activated Recorder, differentiated people with schizophrenia from healthy controls.

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Public Health Significance

This pilot study shows that tailoring a metacognitive intervention to improve social functioning and symptoms is both feasible and acceptable for schizophrenia. Compared to standard metacognitive therapy, our tailored intervention—which uses real-world interactions to personalize therapy sessions—led to reduced negative metacognitive beliefs and disorganized symptoms.





Figure 1. Consort Flow Diagram for Study



Figure 2.

Illustration of how the Electronically Activated Recorder (EAR) is implemented across conditions.

Baseline Participant Demographic and Clinical Data

	Standard MERIT $(n = 8)$	Tailored MERIT $(n = 12)$	
	n, %	n, %	Test of significance
Sex			$\chi^2 = 0.14$
Male	4, 50.0%	5, 41.7%	
Female	4, 50.0%	7, 58.3%	
Race			$\chi^2 = 0.00$
African American	6, 75.0%	9, 75.0%	
Caucasian	2, 25.0%	3, 25.0%	
Education			$\chi^2 = 2.54$
< High School	4, 50.0%	2, 16.7%	
High School or Greater	4, 50.0%	10, 83.3%	
Marital Status			F = 0.31
Never Married	5, 62.5%	7, 58.3%	
Divorced	2, 25.0%	5, 41.7%	
Married	1, 12.5%	0, 0.0%	
	M (SD)	M (SD)	
Age	45.88 (8.81)	43.17 (12.43)	<i>t</i> = 0.53
Total Symptoms: Baseline	62.88 (8.63)	57.58 (13.84)	t = 0.96
Social Functioning: Baseline	5.38 (0.74)	5.75 (0.45)	t = -1.41
Metacognition: Baseline	78.00 (16.73)	73.17 (16.39)	t = 0.64

Note. MERIT = Metacognition Reflection and Insight Therapy.

Table 2.

Feasibility and Acceptability Data Across Groups

	Standard MERIT $(n = 8)$	Tailored MERIT $(n = 12)$	
Feasibility Data	M (SD)	M (SD)	Test of significance
Adherence ^a	71.83% (22.42)	84.26% (12.15)	t = -1.61
Acceptability Data ^b	M (SD)	M (SD)	
Uncomfortable with EAR	1.75 (0.93)	1.50 (0.67)	<i>t</i> = 0.71
Impedes daily activities	1.50 (0.60)	1.75 (0.89)	t = -0.69
Changes your behavior	2.06 (1.48)	1.54 (0.66)	t = 0.94
Changes others behavior	2.25 (1.75)	1.71 (0.69)	t = 0.83
Typicality of days measured	3.56 (1.05)	4.21 (0.94)	t = -1.44

Note. EAR = Electronically Activated Recorder.

 a Adherence is defined as the percentage of one's waking hours where the EAR was worn.

b All acceptability data uses the following scale: 1 = not at all, 2 = between not at all and somewhat, 3 = somewhat, 4 = between somewhat and a great deal, 5 = a great deal.

Table 3.

Pre-Post Differences in Clinical Variables Within and Across Groups

	Pre M (SD)	Post M (SD)	Pre M (SD)	Post M (SD)	F	d	d [95% CI]
Social Functioning	5.38 (0.74)	5.25 (0.71)	5.75 (0.45)	6.00 (1.41)	0.64	0.218	0.37 [-0.54, 1.27]
Metacognition	78.00 (16.73)	79.38 (19.03)	73.17 (16.39)	70.42 (11.74)	0.68	0.216	$-0.38\left[-1.28, 0.53 ight]$
cc	16.63 (3.50)	15.63 (2.67)	15.00 (4.35)	15.33 (3.39)	0.58	0.228	$-0.35 \left[-1.25, 0.55\right]$
PB	14.38 (5.29)	14.75 (6.09)	14.08 (4.17)	13.17 (3.21)	0.88	0.181	-0.42 $[-1.33, 0.48]$
CSC	15.25 (3.28)	16.13 (4.36)	14.83 (3.46)	14.08 (3.06)	2.13	0.081	-0.67 [1.58, -0.25]
NB	13.13 (3.87)	15.25 (4.33)	13.58 (3.55)	12.17 (1.95)	5.22	0.018	-1.04 [-1.99, -0.09]
NTC	18.63 (3.70)	17.63 (4.03)	15.67 (3.77)	15.67 (2.81)	0.54	0.236	0.34 [-0.57, 1.24]
Symptoms	62.88 (8.63)	63.19 (9.71)	57.58 (13.84)	53.67 (13.71)	1.07	0.158	-0.47 $[-1.38, 0.43]$
Positive	15.00 (2.07)	15.50 (3.34)	10.50 (3.50)	11.33 (4.29)	0.05	0.410	0.10 [-0.79, 1.00]
Negative	14.50 (2.67)	13.94 (3.36)	16.83 (7.09)	16.00 (6.49)	0.02	0.442	-0.06 $[-0.96, 0.83]$
Cognitive	14.25 (5.18)	14.13 (5.11)	14.58 (3.96)	11.83 (3.35)	3.08	0.048	$-0.80 \left[-1.73, 0.13\right]$
Hostility	6.88 (3.27)	8.13 (2.90)	6.83 (3.01)	6.17 (2.17)	2.03	0.086	$-0.65 \left[-1.57, 0.27\right]$
Depression	12.25 (2.55)	11.50 (3.42)	8.83 (3.90)	8.33 (5.10)	0.04	0.421	0.09 [-0.80, 0.99]

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Note. CC = Lack of cognitive confidence, PB = Positive beliefs about worry, CSC = Cognitive self-consciousness, NB = Negative beliefs about uncontrollability, NTC = Need to control thoughts.