“Improving Adherence to Cognitive Rehabilitation”

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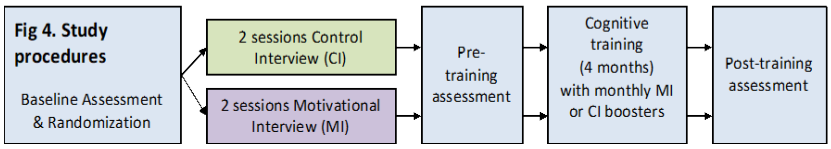
Study Protocol:

This is a randomized, controlled trial investigating whether adding a brief motivational interviewing intervention to a cognitive rehabilitation training program can improve program outcomes in individuals with schizophrenia spectrum disorders. Primary outcome is cognitive rehabilitation treatment adherence. We will also examine potential mediators (increases in intrinsic motivation) and moderators (baseline variables) of the effects of MI on cognitive rehabilitation outcomes.

Approximately 120 individuals with psychotic spectrum diagnoses will be recruited. Following written informed consent and baseline assessment, they will be randomized (1:1) into one of two conditions: Motivational Interview (MI) or sham Control Interview (CI). Refer to Tables 1 and 2 for study intervention components. All participants will be invited to participate in 4 months (up to 50 sessions) of computerized cognitive rehabilitation training. Computerized cognitive training task performance and intrinsic motivation for training will be assessed at the beginning of cognitive training and at the end of each month of training. An additional assessment of cognition and functional capacity will be conducted at the midpoint (end of 2 months) of the cognitive training. All participants will also receive MI or CI booster sessions at the end of the first, second, and third month of training. At the conclusion of the 4-month cognitive training period, participants will once again undergo comprehensive assessments. Please refer to Figure below for study schematic. We anticipate that length of study participation for individual participants will be approximately 5 months.

Table 1. MI Intervention Elements
MOTIVATIONAL INTERVIEW (MI) SESSIONS Note: throughout both MI sessions, interviewer uses common MI techniques including open-ended questions, affirmations, reflections, summaries, asking permission, rolling with resistance, expressing empathy, supporting self-efficacy, etc.
MI Session 1 (~45-60 min)
Opening remarks, focus of sessions on cognitive impairments
Open-ended discussion about participant's cognitive problems and their impact
Personal feedback on neurocognitive and functional ability task performance (MCCB, MMAA, PAOFI)
Information on schizophrenia, cognitive impairments and methods to improve cognition
Description of the cognitive training program, including principles and mechanisms
Participant ratings (1-10) of importance of cognitive training and confidence in ability to learn, to assess motivation and promote change talk
Ending interview 1 (summary, perceived impact, readiness for change)
MI Session 2 (~45-60 min)
Summary of previous session's content, emphasizing motivation to change (i.e. improve cognition)
Hands-on demonstration of cognitive training program
Constructing a decisional balance for participating in cognitive training, collaboratively problem-solving potential obstacles; filling out checklist to select reasons participants may want to do cognitive training
Filling out and discussing the patient's change plan (as pertains to cognition), highlighting cognitive training goals, identifying and collaboratively problem solving around obstacles, and eliciting level of commitment for change (i.e. improving cognition)
Ending interview 2 (summary of decisional balance and change plan)
Monthly MI Boosters (~ 20-30 min each)
Open-ended discussion of participant's views of how the training is progressing (whether helpful, perceived barriers, perceived progress, etc).
Personal feedback on cognitive training task progress since last assessment
Participant ratings (1-10) of importance of continuing cognitive training and confidence in ability to learn (to assess motivation and promote change talk)
Constructing a decisional balance for participating in cognitive training, collaboratively problem-solving potential obstacles; filling out checklist to select reasons participants may want to continue to attend cognitive training
Ending MI Booster (summary, readiness to change/continue training, decisional balance, change plan)

Table 2. CI Intervention Elements
CONTROL INTERVIEW (CI) SESSIONS Note: throughout both CI sessions, interviewer presents self as expert providing feedback to participant; interviewer avoids open-ended questions, affirmations, reflections, summaries, expressing empathy, etc.
CI Session 1 (~45-60 min)
Opening remarks, focus of sessions on finding out how the participant best learns new information
Completing learning style questionnaires (Achievement Motivation Profile)
Ending interview 1 (participant informed that s/he will receive feedback on learning styles during 2nd interview session)
CI Session 2 (~45-60 min)
Opening remarks (explanation of information provided by learning style questionnaires and how it may be helpful)
Personal feedback on learning styles inventories (Achievement Motivation Profile)
Description of the cognitive training program, including principles and mechanisms
Hands-on demonstration of cognitive rehabilitation program
Ending interview 2 (summary of learning styles and opportunity for questions)
Monthly Sham CI Boosters (~ 20-30 min each)
Review of individual training exercises, soliciting participant opinion of whether they like or do not like specific tasks and how they might change the training
Interventionist provides rationale for presence/types of training tasks included and current training structure (emphasis on why current training should not be modified)



Data Analysis for primary aim:

Treatment adherence. Differences between MI and CI conditions on the total number of sessions attended over the 4 month cognitive rehabilitation (CR) phase were compared using Wilcoxon rank-sum test. As the total number of sessions attended followed a Poisson distribution, and as a considerable portion of the participants did not attend any sessions, zero-inflated Poisson (ZIP) model was built to evaluate treatment adherence, with the probability of not attending any sessions based on results of a logistic regression, and the number of sessions attended between conditions based on results of a Poisson regression.