

# The Long-Term Effects of Cellular Telephone-Delivered Telephone Intervention Problem Solving (TIPS) for Schizophrenia Spectrum Disorders (SSDs): Rationale and Design

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## Introduction

Medication adherence is a significant problem among persons with schizophrenia spectrum disorders (SSDs=schizophrenia and schizoaffective disorder). As many as 74% of persons with SSDs do not fully adhere (take less than 80% of doses) (1) to prescribed medications. Low adherence leads to poor symptom management and hospitalization for many persons; these hospitalizations account for most of the nearly \$80 billion annual cost of SSD treatment in the United States (2, 3). An extensive body of literature suggests that face-to-face problem-solving interventions have a significant impact upon medication adherence in this group, even while such interventions are not specifically focused upon medication adherence. Unfortunately, these interventions are expensive and ill-suited for community implementation (4-12). Communities with face-to-face problem-solv-

ing programs generally offer them to only a few of the most severely ill persons due to cost and personnel constraints. This situation means the majority of outpatients with SSDs lack access to problem-solving interventions that have been shown to increase adherence. Thus, there is a need for exploration of alternate delivery methods for problem solving.

Building upon our prior research (13-16), we are conducting a study to examine a cost-effective and time-efficient delivery method for *adherence-focused* problem solving. Telephone Intervention Problem Solving (TIPS) uses telephone contact to remind persons with SSDs to take their medications and problem solve adherence-related difficulties. TIPS (in its original form; e.g., no face-to-face contact with the TIPS provider) can be added to usual care for SSD outpatients at an average cost of less than \$240.00/year (17). In four previous studies (13-16), we demonstrated that TIPS is feasible, acceptable to persons with SSDs, and that TIPS significantly improved three-month psychiatric medication adherence compared to usual care.

Our first study (13) evaluated the feasibility and acceptability of TIPS via landline. Of eligible participants, 76% agreed, but 20% of eligible persons could not participate due to lack of telephone access. The retention rate was 83%. During the three-month study period, more than 150 TIPS calls were provided and 67% of scheduled calls were completed. No significant associations were found between numbers of missed calls and any sociodemographic or illness variables examined. No participant reported a worsening of symp-

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toms as a result of, or during, TIPS; no participant expressed suicidal or homicidal ideation; and, no participant experienced any psychiatric or other emergency during TIPS.

In a follow-up study (14), we examined the effect of rapport on TIPS responses. A convenience sample of twenty inpatients with SSDs, aged 18–78 years, was recruited and, while they were still hospitalized, experimental participants attended two face-to-face meetings with the TIPS provider to establish rapport. Control participants had no contact with the TIPS provider while hospitalized. A psychiatric nurse provided weekly TIPS to all participants for six weeks after discharge using the same protocol as reference #13. Repeated measures ANOVA revealed that experimental participants conversed significantly longer than controls during Weeks 1 through 3 ( $F[1, 7]=8.49, p=0.02$ ), and were almost twice as likely as controls to make a feeling statement (odds ratio=1.85,  $p=0.07$ ) (14). Since participants who converse longer and share their feelings have more opportunities to benefit from the TIPS intervention, TIPS was modified to include a face-to-face meeting with the TIPS provider and experimental participants to establish rapport.

We next examined the effect of TIPS (provided by landline) upon medication adherence (15). Twenty-nine community dwelling persons with SSDs were randomly assigned to weekly TIPS or usual care for three months. Repeated measures ANOVA yielded a statistically significant mean effect for group ( $F[1, 20]=5.47, p=0.0298$ ), indicating a significant difference in psychiatric medication adherence as averaged across all three months of the study (15).

*These preliminary results show great promise* for TIPS to significantly improve psychiatric medication adherence in SSDs. Studies 13–15 provided TIPS via landline telephone, and up to one-third of persons were ineligible due to lack of telephone access or lost landline telephone service during the studies. In order to provide this proven treatment with promising effects on medication adherence to as many people as possible, we next explored providing TIPS via cellular telephone (16). Because of the unstable living environment of many persons with SSDs, we examined the feasibility of providing TIPS via cellular telephone. An additional purpose of the study (16) was to develop procedures for TIPS provider training to enhance the adoption of TIPS in community settings. If the feasibility of cellular telephone use, and of TIPS training procedures, can be demonstrated, the availability and adoption of TIPS would be greatly increased, allowing us to offer this proven intervention to large numbers of persons with SSDs and greatly increasing its impact.

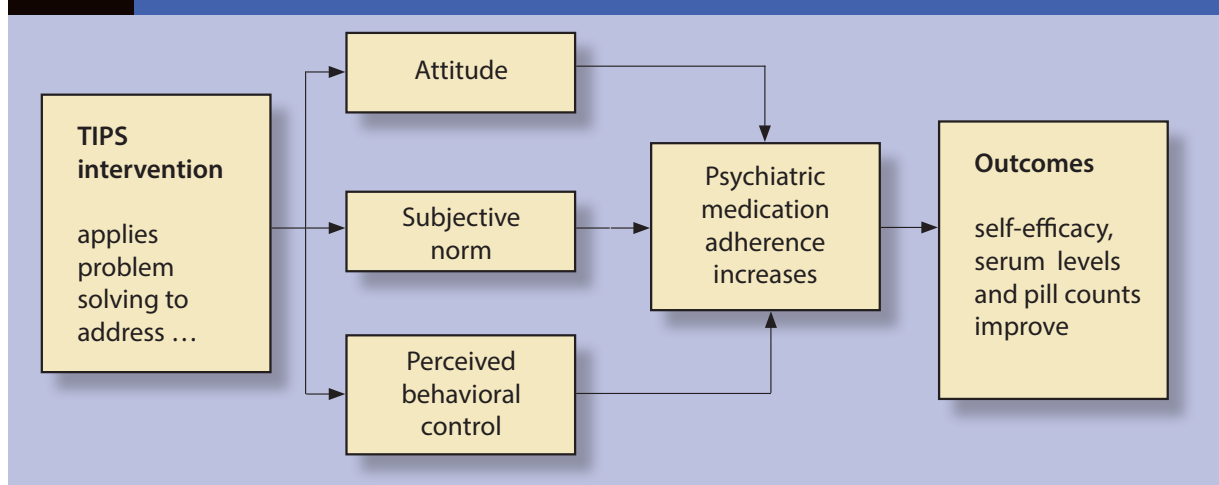
This study (16) established TIPS feasibility via cellular telephone. Of eligible persons, 100% agreed to participate. Ten outpatients with SSDs were provided previously activated basic cellular telephones (not smartphones) with five

months of unlimited local calling. Eight participants had never used a cellular telephone before. Participants were instructed on telephone use and given a written instruction sheet. Subjects received a weekly TIPS call for five months. Nine subjects completed the five-month study. All subjects had robust cellular telephone signals during the study, and very few telephone problems were reported. *These preliminary data indicate* that most persons with SSDs can use cellular telephones with few problems, suggesting this is a viable mechanism for TIPS delivery.

*In summary*, we have successfully conducted four studies of TIPS for persons with SSDs that support the feasibility and effectiveness of our intervention. None of our prior work limited enrollment to persons with known adherence problems. The studies ranged from six weeks to five months in length, with an average recruitment rate of 82.25% and an average retention rate of 84.75%. Over the course of the studies, over 485 TIPS calls were safely provided. No participants experienced worsening symptoms as a result of TIPS, nor were any suicidal, homicidal, psychiatric or other emergencies identified during TIPS. Our work consistently shows the feasibility and acceptability of this delivery method and documents statistically significant improvement in psychiatric medication adherence over usual care, even without limiting participants to persons with known adherence problems (15). These promising results support further study of TIPS in this group. The next logical step is to examine the long-term effectiveness of TIPS.

## Methods

This paper reviews the rationale and design of our current study. This randomized controlled trial will test the effect of cellular telephone-delivered TIPS upon medication adherence, medication self-efficacy and symptom management in outpatients with SSDs over nine months. A computer-generated random number table will be used to randomly assign participants to TIPS or treatment as usual (TAU) in a 1:1 ratio. In order to ensure consistent telephone access, all participants will be provided a basic cellular telephone (not a smartphone) with unlimited local calling upon study enrollment. One hundred and twenty-eight participants will be randomly assigned to treatment as usual *plus weekly cellular telephone-delivered TIPS* or TAU. TAU includes medication follow-up appointments with a psychiatrist at a community mental health center approximately every 4–6 weeks along with case management appointments approximately every 6–8 weeks. In addition, TAU participants will have personal use of the study-provided cellular telephone for nine months but no intervention. Study-provided cellular telephones are used only to schedule the 3-, 6-, and 9-month follow-up appointments for TAU participants.

**Figure 1** Hypothesized Results of TIPS Based Upon the Theory of Planned Behavior

We hypothesize that experimental participants will have significantly higher serum psychiatric medication levels, higher pill count psychiatric medication adherence, higher scores on the medication adherence rating (MARS) scale, higher scores on the medication adherence self-efficacy scale (MASES), and lower Positive and Negative Syndrome Scale (PANSS) scores than those not receiving TIPS.

## Setting

The sample will be selected from persons receiving outpatient care at a community mental health agency (CMHA) located in a rural area in the Southeastern United States. The CMHA is a regional, not-for-profit integrated system providing outpatient services to 650+ SSD outpatients: 61% male, 59% Caucasian. The site was chosen for adequate numbers of potential participants. The site does not provide services to persons under age 18. Approximately 10% of SSD outpatients at the CMHA attend day treatment support programs, where medication education, social support and living skills are provided in a group setting for three hours daily. Persons receiving day treatment services will not be excluded from the study; however, their attendance records and services received will be examined as potentially affecting outcomes. In addition to university IRB approval, signed letters of agreement and institutional consents will be obtained before participants are recruited or data are collected.

## Sample

The sample will be selected from persons with SSDs aged 18–68 years, receiving outpatient care at the CMHA and meeting the following criteria: Inclusions: 1) a chart diagnosis of schizophrenia or schizoaffective disorder, any subtype, according to the criteria established in the *Diagnostic and Statistical Manual of Mental Disorders, 5th edition* (18); 2) English speaking; and, 3) the ability to give consent.

We will document the participant's basic understanding of the study's purposes and procedures using an assessment of research consent capacity developed at the Maryland Psychiatric Research Center (19, 20). Exclusions: 1) a chart diagnosis of coexisting mental retardation, neurological disorders or head injury; 2) exposure to TIPS in prior studies; and, 3) receipt of services from an Assertive Community Treatment (ACT) team. Persons receiving ACT services receive numerous additional treatments and clinical contacts above usual care, including telephone contacts that would preclude examination of TIPS-related outcomes.

We will meet with potential participants in a private office at the recruitment site to verify inclusion and exclusion criteria. Following these verifications, we will document the participant's basic understanding of the study's purposes and procedures using the Evaluation to Sign Consent (ESC), an assessment of capacity to give consent for research developed at the Maryland Psychiatric Research Center (19, 20) and used in our prior work (16, 21, 22).

## Treatment Groups

### Telephone Intervention Problem Solving (TIPS)

#### Conceptual Framework

The Theory of Planned Behavior (TPB) (24) will guide our study. TPB (24) states that adherence intent is determined by individual attitude, subjective norm and perceived behavioral control (operationalized as self-efficacy) (25). Attitudes reflect beliefs and values about perceived outcomes associated with adherence. Subjective norm reflects the extent to which significant others (family, caregivers) encourage adherence. Perceived behavioral control (self-efficacy) reflects the perceived ease or difficulty of overcoming adher-

**Figure 2** TIPS protocol

Protocol Item	Common Barrier identified in our prior work (13-16) and its relationship to adherence	Example problem-solving response	Concepts from the Theory of Planned Behavior
<b>1</b> Are you taking your medication as prescribed? Have you missed any doses at all?	Forgetting limits number of doses taken (13-16).	It might help to have someone remind you every day.	Subjective norm: significant others encourage adherence.
<b>2</b> Do you know when your next appointment is scheduled?	Misplacing appointment card (missed appointments are associated with poor medication adherence) (33).	Try placing a reminder note in a prominent location.	Perceived behavioral control: perceived ease or difficulty of overcoming adherence barriers (self-efficacy).
<b>3</b> Have you had any symptom(s) since we last talked? (Nonadherence-related symptoms specific to individual participant collected at baseline.)	Psychotic symptoms (symptoms are associated with poor medication adherence) (33).	Explain benefits of medication upon symptoms.	Attitudes: beliefs/values about adherence-associated outcomes.
<b>4</b> Have you had any cravings for alcohol or other drugs this week that you've found uncomfortable?	Substance use is associated with poor medication adherence (33).	Educate about negative effects of substances upon medication adherence/efficacy.	Attitudes: beliefs/values about adherence-associated outcomes.
<b>5</b> How have you been getting along with others this week?	Conflict in the environment can contribute to poor medication adherence (34).	Problem solve options to improve interpersonal interactions.	Subjective norm: significant others encourage adherence.
<b>6</b> Do you have any questions about anything this week?	Common questions concerned medication side effects; concerns over side effects are associated with poor medication adherence (33).	Teaching about expected side effects and ways to reduce their impact.	Attitudes: beliefs/values about adherence-associated outcomes.

ence barriers and level of confidence in one's ability to do so (26). TIPS addresses each of these determinants of adherence intent. During TIPS intervention, the value of adherence is expressed and reinforced (subjective norm), participants are educated about adherence benefits (attitude) and assisted to problem solve identified adherence barriers (perceived behavioral control/self-efficacy). See Figure 1.

Individualized adherence barriers identified in our prior work (13-16) include attitudes toward illness, undesirable medication side effects, lack of transportation, psychiatric symptoms, memory impairments, and substance use. In prior studies, over half of participants reported adherence barriers; most commonly, memory and cognitive deficits. TIPS provides a format for the provider to offer problem solving to mitigate the effects of these problems upon adherence.

TIPS follows a protocol manual developed by the PI that addresses medication adherence and related issues in a problem-solving format. The TIPS protocol consists of three open-ended questions and three specific queries. See Figure 2 for a list of protocol items, along with commonly identified barriers and related concepts from TPB. Based upon literature and our prior studies of common problems faced

by community-dwelling persons with SSDs (13, 14, 16), the specific queries address medication adherence, psychiatric symptoms and substance use. The interventionist will respond to participant concerns by guiding them through the problem-solving process originated by D'Zurilla and Nezu (23) and adapted for SSDs by Liberman, Eckman, and Marder (8):

- identify the problem
- generate/discuss solutions
- select a solution
- plan to implement the solution
- follow-up on effectiveness of chosen solution.

### Example Interaction

The following example from the TIPS manual illustrates specifically how the problem-solving process will be applied using principles from the Theory of Planned Behavior (24). The example problem of forgetting is illustrated here because forgetting was the most commonly reported adherence problem in prior studies (13-16). The complete TIPS manual is available from the first author.

TIPS will be provided weekly via cellular telephone for nine months by a doctorally prepared psychiatric nurse interventionist who provided TIPS in two prior studies (15, 16). An eight-hour TIPS review session will be conducted before any TIPS interventions, and the interventionist will

take a TIPS knowledge test. Remediation will be provided for items missed and testing will be repeated until the interventionist scores 100%. TIPS intervention will begin within one week of study enrollment.

At least two hours of supervision will be conducted

**Example Interaction from TIPS Manual—Protocol Item #1: Missing Medication Doses**

Nurse	Participant	Concepts from Theory of Planned Behavior
<b>Step 1—Identify the problem</b>		
Nurse: Have you missed any medication doses at all in the past week?	Participant: I think I forgot yesterday.	
Nurse: It's very important to take your medicine every day to help your symptoms.	Participant: OK.	1-Subjective norm: significant others encourage adherence. 2-Attitudes: beliefs/values about adherence-associated outcomes.
<b>Problem: Forgetting medication Step 2—Generate solutions/discuss solutions</b>		
Nurse: Let's talk about what else might help. Can you think of anything that might help you remember to take your medicine?	Participant: Sometimes my mom reminds me.	1-Subjective norm: significant others encourage adherence.
Nurse: That's a good idea; it might help to have someone remind you every day. Can you think of anything else?	Participant: Not really.	Perceived behavioral control: perceived ease or difficulty of overcoming adherence barriers (self-efficacy).
Nurse: Do you think it might help if you put the medicine in the bathroom? Then you could take it right after you go to the bathroom in the morning.	Participant: I could do that.	Perceived behavioral control: perceived ease or difficulty of overcoming adherence barriers (self-efficacy).
<b>Problem: Forgetting medication Step 3—Select solution</b>		
Nurse: We have talked about having someone remind you or keeping your medicine in the bathroom. Which of these things would you like to try this week?	Participant: Can I do both of them?	Perceived behavioral control: perceived ease or difficulty of overcoming adherence barriers (self-efficacy).
Nurse: Yes, good idea.	Participant: OK.	
<b>Problem: Forgetting medication Step 4—Plan implementation</b>		
Nurse: So you are going to take your medicine in the bathroom after getting up every day, and ask your mom to remind you about it.	Participant: OK.	1-Subjective norm: significant others encourage adherence.
Nurse: What would be a good way to remember to do this?	Participant: I can put the medicine in there right now.	2-Attitudes: beliefs/values about adherence-associated outcomes.
Nurse: OK, you can put the medicine in there now, I will hold on.	Participant: I can talk to my mom too because she's home now.	1-Subjective norm: significant others encourage adherence.
<b>Step 5—Follow-up effectiveness of chosen solution</b>		
Nurse: (When participant returns.) That's good, next week when I call I will ask how these things worked for you.	Participant: OK.	

with the TIPS interventionist each week. The interventionist will log each intervention using the documentation form provided in the TIPS manual. Twenty percent of TIPS logs will be randomly reviewed weekly, and a fidelity form will be completed. The fidelity form provides an objective measure of the provision of each aspect of TIPS, from 1 (none of the time) to 5 (all of the time). Remediation will be provided for any area scored below 4 (most of the time) by: 1) identifying concerns/questions; 2) item-by-item discussion; and, 3) feedback/clarification. Supervision will be organized as follows: 1) identification of problems or questions by the interventionist; 2) discussion of issues raised by the interventionist, with feedback and clarification; 3) discussion of fidelity forms completed on 20% of randomly selected TIPS interventions; 4) provision of feedback on degree of interventionist's fidelity; and, 5) immediate remediation of identified fidelity deficits. These plans ensure correct TIPS implementation, increasing replicability and the likelihood of detecting significant treatment effects.

### **Treatment as Usual (TAU)**

Sixty-four participants will be randomly assigned to receive TAU only during the study, which includes medication follow-up appointments with a psychiatrist at the CMHA approximately every 4–6 weeks and case management appointments approximately every 6–8 weeks. In addition, TAU participants will have personal use of the study-provided cellular telephone for 9 months but no intervention. Study provided cellular telephones are used only to schedule the 3-, 6-, and 9-month follow-up appointments for TAU participants.

### **Outcomes**

The outcome of medication adherence will be operationalized by pill count, serological measurement and self-report on the Medication Adherence Rating Scale. The outcome of medication self-efficacy will be operationalized by self-report on the Medication Adherence Self-Efficacy Scale. The outcome of psychiatric symptoms will be operationalized as the score on the Positive and Negative Syndrome Scale.

### **Pill Counts**

A blinded Research Assistant (RA) will perform pill counts of psychiatric medication in all participant homes at baseline (within one week of recruitment) and every three months. Based upon the medications most commonly prescribed in prior studies, we anticipate most participants will be prescribed one of the following: risperidone, haloperidol, clozapine, prolixin, olanzapine, aripiprazole, quetiapine, and

ziprasidone; however, being prescribed another antipsychotic medication (e.g., Saphris) will not preclude participation. A measure of adherence will be generated by dividing the number of pills missing from the bottle(s) by the number of pills prescribed within the time period covered by the current prescription. Participants will be compensated with a \$5.00 gift card after each pill count.

### **Serological Measures**

Blood specimens will be collected at the recruitment site at baseline (within one week of recruitment) and every three months on all participants for assessment of serum medication levels. Transportation will be provided and participants will receive remuneration in the amount of \$10.00 for the time and discomfort involved in specimen collection.

### **Medication Adherence Rating Scale (MARS)**

The MARS (27) will be used to measure self-reported medication adherence. Participants will complete the MARS at the outset of the study and quarterly thereafter. The MARS contains ten items measuring medication adherence behaviors, specific attitudes toward medication and the presence of negative side effects. Higher scores indicate better adherence. Cronbach's alpha for the MARS has been reported as 0.60–0.75 (28). Test-retest reliability after two weeks was 0.72 (27). The MARS was selected since, unlike the MASES (see below), it has been previously used in persons with SSDs. In addition, the brevity of the MARS is desirable to reduce participant time burden. We plan to examine correlations between the MARS and our objective serum medication levels at the conclusion of the study.

### **The Medication Adherence Self-Efficacy Scale (MASES)**

The MASES will be used to measure confidence in one's ability to adhere to prescribed medications (self-efficacy). Participants will complete the MASES at the outset of the study and quarterly thereafter. The MASES (29) is a 26-item self-report scale that measures patients' level of certainty (not at all sure=1; somewhat sure=2; or, very sure=3) that they will be able to adhere to prescribed medications in a variety of common situations (e.g., when busy, when in public, and when traveling). Items are summed and the mean calculated. Scores range from 1–3, with higher scores indicating higher medication self-efficacy. Cronbach's alpha for the MASES was 0.95 and one-week test-retest reliability was 0.4 (29). The MASES was designed to measure medication adherence self-efficacy in hypertensive African Americans and to our knowledge this project will be the measure's first use in SSDs. We chose the measure for several reasons. Based

upon prior work, we estimate that nearly 50% of our participants will be African American (16). Both hypertension and SSDs are chronic illnesses that necessitate daily medication management to prevent disability and illness exacerbations. Finally, there exists no medication-adherence self-efficacy measure specifically designed for persons with SSDs.

### Positive and Negative Syndrome Scale (PANSS)

The PANSS will be used to assess symptoms, and will be completed by the blinded RA at each measurement point. The PANSS (30) is a 30-item Likert-type scale that measures schizophrenia symptoms. Cronbach's  $\alpha$  were 0.73 on the positive subscale, 0.83 on the negative subscale, and 0.87 on the general subscale. Internal reliability coefficients ranged from 0.70–0.85 (31). Before administering the PANSS, the RA will complete training designed by the developer, scoring training tapes until a 0.80 intraclass correlation coefficient is achieved. Participants will be compensated with a \$10.00 gift card after completion of the PANSS.

### Sociodemographic Variables

Data regarding sociodemographic characteristics, living arrangements, and prescribed medications will be collected initially and data on living arrangements and prescribed medications will be updated at three and six months to reveal factors that could affect responses to TIPS.

### Data Analysis Plan

Data analysis will begin with data plots and basic descriptive statistics, such as frequency distributions, means and standard deviations, appropriate for the level of measurement of the variables. The two groups will be compared for pre-treatment equivalence on sociodemographic characteristics, initial PANSS, MARS and MASES scores and number, type and dosage of prescribed medications. In the analysis, expected mean squares will be calculated and the appropriate combination will be used for hypothesis tests with specific functions of the repeated measures. General linear model mixed models analyses in SAS (GLIMMIX and MIXED procedures) will be used to examine the effects of: 1) time; 2) intervention; and, 3) time by intervention interaction. All analyses in this study will be considered intent-to-treat analyses in order to guard against statistical bias, maintain a balanced design, and to assure the validity of the statistical tests assured by the randomization scheme. Level of statistical significance set at 0.05. Our prior work (15) indicated effect sizes ranging from medium to large (32). The power calculation indicates that there is at least 80% power for  $\alpha=0.05$ , and medium effect size, for  $n=64$  for within-

between-subject, within-subject, and between-subject effects.

### Conclusions

In addition to testing the long-term effect of TIPS, this study will provide additional information on the responses to our cellular telephone delivery method. We believe this information will be critical as we continue to explore a variety of cellular telephone technologies to provide needed interventions to persons with SSDs in a feasible, economical way.

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