

The long term effectiveness of Telephone Intervention Problem Solving (TIPS).

PI Lora Humphrey Beebe, PhD, PMHNP-BC

Team members:

Kathleen D Smith, PhD, interventionist;

Abbas Tavakoli, PhD, statistician, University of South Carolina

Dawn Velligan, PhD, consultant, University of San Antonio

Organization: University of Tennessee Knoxville

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Structured abstract

Purpose. We conducted a randomized controlled trial to determine the effect of weekly telephone intervention-problem solving (TIPS) upon self-reported medication adherence (Medication adherence rating scale-(MARS¹), medication adherence self-efficacy,(MASES² scores), objective measures of medication adherence (pill counts and serum antipsychotic medication levels) and symptoms (PANSS³) scores in stable outpatients with schizophrenia spectrum disorders (SSDs) for nine months.

Scope. Problem solving has long been among the most effective treatments to improve psychiatric medication adherence but persons with SSDs have limited access to problem solving interventions. Our TIPS intervention increases access to this proven treatment.

Methods. RCT. Participants were randomized to receive weekly TIPS or a control condition of usual care for nine months. We approached a convenience sample of 295 potential participants (approximately 6 persons/week) over 13 months, to obtain descriptive data on 185 persons with SSDs.

Results. 140 participants completed at least one measure at three months, 105 completed at least one measure at six months and 119 completed at least one measure at nine months. Fifty eight participants completed data measures at all four measurement points (baseline, 3,6, and 9 months).TIPS was associated with improvements in subjective and objective medication adherence and symptoms at 3, 6 and 9 months; and with improved medication adherence self-efficacy at 3 and 6 months.

Keywords. Keywords: schizophrenia, outpatient, community, treatment, telephone

Purpose

We conducted a randomized controlled trial to determine the effect of weekly telephone intervention upon self-reported medication adherence (MARS¹ scores, medication adherence self-efficacy,(MASES² scores), objective measures of medication adherence (pill counts and serum medication levels) and symptoms (PANSS³) scores in stable outpatients with SSDs for nine months.

Scope.

Background. Problem solving has long been among the most effective treatments to improve psychiatric medication adherence but persons with SSDs have limited access to problem solving interventions. Our TIPS intervention increases access to this proven treatment. We have successfully conducted four studies of TIPS for persons with SSDs and one study examining family perspectives. These studies that support the acceptability, feasibility and effectiveness of TIPS to both patients and families. The TIPS studies ranged from 6 weeks to 5 months length, with an average recruitment rate of 82.25% and an average retention rate of 84.75%. Over the course of the TIPS studies, over 485 TIPS calls were safely provided. No participant experienced worsening symptoms as a result of TIPS, nor were any suicidal, homicidal, psychiatric or other emergencies identified during TIPS. Our family focus group identified perceived needs that TIPS can be expected to meet efficiently and effectively⁴⁻⁸

Context This body of work demonstrated the feasibility and acceptability of this delivery method to both patients and families, and documented improvement in psychiatric medication adherence over usual care.⁶ The project reported herein examined the long term effectiveness of TIPS.

Setting. The study was conducted at the Helen Ross McNabb Center, (HRMC) a regional, not-for-profit integrated system providing outpatient services to 650+ SSD outpatients, 61% male, 59% Caucasian. The site was chosen for access to participants identified as target populations by AHRQ, including vulnerable persons, low income persons and persons with chronic diseases.

Participants The 185 outpatients completing baseline measures ranged in age from 19-75 years with an average age of 46 years (SD 13.0). A majority of participants were males (n = 102, 55.1%) with schizoaffective disorder (n = 129, 69.7%). Most were Caucasian (n = 116, 62.7%) and the remainder were African American (n = 66, 35.7%) and Asian (n = 3, 1.6%). Most participants were living with family when study measures were completed (n = 100, 54.1%). The remainder lived alone (n = 70, 38.4%) or with paid caregivers (n = 15, 7.6%). Self-reported educational levels were: 81 graduated high school (43.8%), 53 did not graduate high school (28.6%) and 44 completed some post high school education (23.8%). The following characteristics were not significantly associated with adherence measures at baseline: age, diagnosis, gender, race, living arrangement, educational level, typical versus atypical antipsychotic medication.

Incidence. About 100,000 persons will be diagnosed with schizophrenia this year in the US alone.

Prevalence. Schizophrenia is present in approximately 1.1% of the population over the age of 18 years. As many as 74% of persons with SSDs do not fully adhere (take 80% of doses) to prescribed antipsychotic medications.⁹

Methods.

Study design. RCT. Participants were randomized to receive weekly telephone intervention or a control condition of usual care for nine months. We approached a convenience sample of 295 potential participants (approximately 6 persons/week) over 13 months, to obtain descriptive data on 185 persons with SSDs.

Data collection. Once diagnosis was verified, capacity to consent was documented and informed consent was obtained, we collected, via record review, data on sociodemographic characteristics, living arrangements, prescribed medications, and length of illness. The PANSS, MARS, and MASES were administered at baseline. After TIPS began, we conducted quarterly record reviews to collect information regarding living arrangements and medication changes, administered the MARS, PANSS and MASES quarterly, and conducted quarterly in-home pill counts in all participant homes. Baseline serum medication levels were obtained within one week of study recruitment and quarterly thereafter.

Interventions. TIPS. Ninety three participants were randomly assigned to receive treatment as usual plus weekly TIPS for 9-months. TIPS was provided by the K. Smith, TIPS provider in prior work. Before conducting any telephone intervention, K. Smith reviewed the TIPS training along with the PI. TIPS interventions began within one week of study enrollment.

TIPS followed a protocol manual developed by the PI that addresses medication adherence and related issues in a problem-solving format. The protocol consisted of three open-ended questions and four specific queries. Based upon literature and our prior studies of common problems faced by community dwelling persons with SSDs,^{4,10,11} the specific queries addressed medication adherence, psychiatric symptoms and substance abuse. The inclusion of open-ended questions encouraged participants to discuss concerns of importance to them. K. Smith responded to

concerns by guiding participants through the problem-solving process originated by D'Zurilla & Nezu¹² and adapted for SSDs by Liberman, Eckman, and Marder.¹³

- Identify the problem
- Generate/discuss solutions
- Select a solution
- Plan to implement the solution.
- Follow up on effectiveness of chosen solution

TIPS calls were scheduled for a specific day and time according to participant preference (morning, afternoon or evening) and initiated by K. Smith, who asked for the participant by name. The TIPS manual was followed each time a participant was called; responses were recorded by hand.

Measures.

Pill counts. The research assistant performed monthly pill counts of psychiatric medication in all participant homes. For purposes of this project and based upon the medications most commonly prescribed to participants in our prior studies, we define psychiatric medications as: risperidone, haloperidol, clozapine, fluphenazine, olanzapine, aripiprazole, quetiapine, and ziprasidone. . A measure of adherence was 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 prescription.

Serological measures. Were collected at HRMC quarterly. Transportation was provided and participant remuneration in the amount of \$10.00 was provided for the time and discomfort involved in specimen collection.

Self-report: The Medication Adherence Rating Scale. The MARS¹ was used to measure self-reported medication adherence. Participants completed the MARS at baseline and quarterly thereafter. The MARS was chosen for cost and time savings and because it permits examination of medication adherence concurrent with the theory of planned behavior. The scale contains 10 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 0.60-0.75.¹⁴ Test-retest reliability after 2 weeks was 0.72.¹

Medication adherence self-efficacy: Self report

The Medication Adherence Self Efficacy Scale (MASES). The MASES was used to measure the theoretical construct of perceived behavioral control, that is, confidence in one's ability to adhere to prescribed medications (self-efficacy). Participants complete d the MASES at baseline and quarterly thereafter. The MASES² 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 (for example, when busy, when in public, and when travelling). 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 0.4.² The MASES was designed to measure medication adherence self-efficacy in hypertensive African Americans and to our knowledge this was the measure's first use in SSDs.

Psychiatric Symptoms:

Positive and Negative Syndrome Scale (PANSS). The PANSS³ is a 30-item Likert-type scale that measures schizophrenia symptoms. Cronbach's α 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 0.70-0.85.¹⁵ Before administering the PANSS, study personnel completed training designed by the developer, scoring training tapes until a 0.80 intraclass correlation coefficient was achieved.

Additional measures:

Sociodemographic variables. Data regarding sociodemographic characteristics, living arrangements, length of illness, and prescribed medications was collected at baseline and data on living arrangements and prescribed medications was updated during the 3- 6- and 9-month record reviews.

Limitations. Results were not statistically significant, likely due to the sample size. Our plans called for a final sample of 128 participants, providing 80% power for alpha 0.05 and medium effect size; however budget constraints prohibited recruitment to replace all noncompleters, with the result that our final sample did not reach 128. Our final sample of participants completing all study measures was 58. While we were unable to query noncompleters as to their reasons due to time and resources constraints, the high numbers of completers of our noninvasive measures (pill counts and questionnaires) as compared to the much lower completion rate for serum measures suggests that, despite remuneration and the provision of transportation, serum draws were aversive and unlikely to be competed versus other measures of adherence.

Results.

Principal findings. Sample. The 185 outpatients completing baseline study measures ranged in age from 19-75 years with an average age of 46 years (SD 13.0). A majority of participants were males (n = 102, 55.1%) with schizoaffective disorder (n = 129, 69.7%). Most were Caucasian (n = 116, 62.7%) and the remainder were African American (n = 66, 35.7%) and Asian (n = 3, 1.6%). Most participants were living with family (n = 100, 54.1%). The remainder

lived alone (n = 70, 38.4%) or with paid caregivers (n = 15, 7.6%). Self-reported educational levels were: 81 graduated high school (43.8%), 53 did not graduate high school (28.6%) and 44 completed some post high school education (23.8%). The following characteristics were not significantly associated with adherence at baseline: age, diagnosis, gender, race, living arrangement, educational level, typical versus atypical antipsychotic medication. Serum antipsychotic medication level was significantly negatively correlated with PANSS scores, and significantly positively correlated with MARS and MASES scores at baseline. Pill count antipsychotic adherence was significantly positively correlated with MARS and MASES scores, and significantly negatively correlated with PANSS at three months.

Three month follow up. T tests were conducted to examine differences in scores on the PANSS, MARS and MASES between groups at three months. PANSS scores for experimental participants averaged 79.7 (SD 9.6) at baseline and 74.3 (SD 8.6) after three months; control participants averaged 79.4 (SD 8.8) at baseline and 75.4 (SD 16.6) after three months. MARS scores for experimental participants averaged 7.2 (SD 1.9) at baseline and 7.4(SD 1.9) after three months; control participants averaged 6.9 (SD 1.9) at baseline and 6.8(SD 2.2) after three months. MASES scores for experimental participants averaged 2.5 (SD 0.43) at baseline and 2.4(SD 0.46) after three months; control participants averaged 2.4 (SD 0.42) at baseline and 2.5 (SD 0.58) after three months. Symptoms were lower and self-reported medication adherence was higher in experimental participant after three months, but differences were not statistically significant. Medication adherence self-efficacy was essentially unchanged over the three month follow up period in both groups.

Six month follow up. T tests were conducted to examine differences in scores on the pill count and serum antipsychotic levels between groups at six months. Pill counts scores for psychiatric medications for experimental participants averaged 67.4% (SD27.1) at baseline and 68(SD 26.1) after six months; control participants averaged 68(SD24.9) at baseline and 68.9(SD 29.5) after six months. 54.7 % of experimental participants had serum antipsychotic levels within therapeutic range at baseline- the percentage was unchanged at six months; 46.2 % of controls had serum antipsychotic levels within therapeutic range at baseline- 32.7% remained within therapeutic range after six months.

Analysis of nine month follow up data is ongoing

Outcomes. Experimental participants had improvements in subjective and objective medication adherence (MARS scores and pill count adherence) and symptoms (PANSS scores) at every follow up point (3, 6 and 9 months) ; and improved medication adherence self-efficacy (MASES scores) at two follow up points (3 and 6 months). Serum antipsychotic levels remained in therapeutic range for 54.7% of experimental subjects through six months of follow up, whereas only 32.7% of control participants had therapeutic serum antipsychotic levels over the same time period.

Discussion. Our research group completed this investigation as planned and on time, meeting all targets for recruitment and data collection. In spite of the known challenges of research studies in persons with SSDs, our recruitment and data collection efforts were very successful: we recruited 185 persons in 13 months. Retention rates were as follows: 76% of participants completed at least one measure at three months; 57% of participants completed at least one measure at 6 months and 64% of participants completed at least one measure at 9 months. Thirty

one percent of participants had a complete data set- all measures completed at all four measurement points (baseline, 3,6, and 9 months).

As in prior work, TIPS was well received, feasible and acceptable to participants. During the nine month study, 92 persons were assigned to receive weekly ITPS calls. Of that number, 10 dropped out and 6 more were excluded because they received TIPS for less than one month. The 76 remaining participants received 2424 weekly TIPS calls, for a call completion rate of 93%. No participant experienced worsening symptoms as a result of TIPS, nor were any suicidal, homicidal, psychiatric or other emergencies identified during TIPS.

We will address the following identified limitations in future studies: the budget allotted to provide telephones and service necessitated that we close recruitment early, prohibiting us from recruiting replacements for participants who dropped out of the study and reducing statistical power due to smaller than anticipated sample size. While we did not query participants as to their reasons for drop out, completion rates for pill counts, questionnaires and serum medication levels indicate that serum medication levels were aversive and subjects often completed all measures with the exception of serum medication levels. Further, some psychiatric medications (e.g. lurasidone) had no serum test available at the time of the study. In future work, we will consider increasing remuneration or using an alternative, objective adherence measure such as pharmacy refill records rather than serum medication levels.

Conclusions

Significance. This study adds to the knowledge concerning SSDs and TIPS in several ways:

- Demonstrated recruitment success
- Demonstrated our ability to complete a large percentage of weekly TIPS calls

- Lessons learned regarding study retention
- Further evidence of the safety of TIPS
- Adds to the literature on the use of the MARS in persons with SSDs
- pilot information on the use of the MASES in persons with SSDs
- Long term data on TIPS impact upon subjective and objective medication adherence and symptom levels

Implications. This cost effective, time efficient, proven treatment with high acceptability and low risk has the potential to support substantial improvement in symptom control and adherence in SSDs. Our goal is to see TIPS implemented on a large scale. To that end, we propose a follow up investigation of the effects of TIPS when provided by mid-level providers (BSN nurses) as well as by providers in non-nursing disciplines (Bachelor's degree in social work). Using mid-level providers and non-nurses will further reduce costs and increase the likelihood of TIPS implementation with as many SSD persons, as possible.

List of publications and products

Beebe, L.H. (2015). The long term effectiveness of telephone intervention problem solving (TIPS) for schizophrenia spectrum disorders (SSDSs). *Schizophrenia Bulletin*, 41(Suppl 1), S301.

Beebe, L.H., Smith, K., & Phillips, C. (in press). Effect of a telephone intervention upon self-reported medication adherence and self-efficacy in outpatients with schizophrenia spectrum disorders (SSDs). *Issues in Mental Health Nursing*.

Beebe, L.H., Smith, K. & Phillips, C. (in press). Descriptions and correlates of medication adherence, attitudes, and self-efficacy in outpatients with schizophrenia spectrum disorders (SSDs). *Archives of Psychiatric Nursing*.

In preparation:

1-Effect of a telephone intervention upon measures of psychiatric and nonpsychiatric medication adherence in outpatients with schizophrenia spectrum disorders (SSDs) . A report of six month outcome measures

2-Telephone Intervention –Problem Solving for persons with schizophrenia spectrum disorders: results of a 9-month RCT.

3-Problems in community living identified by stable persons with schizophrenia spectrum disorders receiving 9 months of weekly telephone intervention

4-Pilot study of the first use of the MASES in persons with SSDs

Poster presentations

Beebe, L.H., Phillips, C. & Green, A.M. (2015). Monitoring Recovery During home visits to Persons with Schizophrenia Spectrum Disorders: The Student role in Interdisciplinary research. Poster presentation. Annual conference of the International Society of Psychiatric Nurses, March 24-28, 2015, Seattle WA.

Beebe, L. H. (2015). The long-term effectiveness of telephone intervention problem Solving (TIPS) for schizophrenia spectrum disorders (SSDs). Poster presentation. International Congress of Schizophrenia Research, March 28–April 1, 2015, Denver, CO.

Foster, T., Carey, A., & Beebe, L.H. (2015, April 10). The Student Role on the Research team: Experiences and Lessons Learned. Poster presented at the Annual meeting of the Tennessee Chapter of the American Psychiatric Nurses' Association, Knoxville Tn.

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