Published in final edited form as:

Psychiatry Res. 2020 October ; 292: 113346. doi:10.1016/j.psychres.2020.113346.

Clinical Outcomes from the Texting for Relapse Prevention (T4RP) in Schizophrenia and Schizoaffective Disorder Study

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Abstract

This 6 month randomized control trial investigated whether a novel text-messaging program impacted targeted clinical outcomes in patients with schizophrenia and schizoaffective disorder (SAD). Forty patients were enrolled and completed baseline, 3-month and 6-month assessments. The intervention group received daily symptom check-in text messages, plus, a medication reminder or, inspirational quote text. The control group had treatment as usual. At 6 months the Positive and Negative Syndrome Scale mean positive score was significantly lower and injectable medication compliance was significantly higher in the intervention group. Recovery scores were significantly higher at 3 months. Results suggest that this program may benefit individuals with schizophrenia/SAD who use text messaging. Further investigation in a larger sample appears warranted.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

1. Introduction

Schizophrenia and schizoaffective disorder (SAD) are neurodevelopmental disorders with significant public health impact. Schizophrenia is the fifth leading cause of years lived with disability among men and sixth among women and is responsible for 1% of the global burden of disease (Eaton, 2019). For people with schizophrenia the one-year reported relapse rate ranges between 17-41% (Robinson et al., 1999) and the 5-year relapse rate may be as high as 82% (Robinson et al., 1999). SAD also has a high relapse rate (Angst et al., 1980). Recurrent relapses correlate with poorer treatment response (Emsley et al., 2013) and poorer quality of life (Briggs et al., 2008), accelerate social impairment (Hogarty et al., 1991) and increase the likelihood of having residual symptoms (Shepherd et al., 1989).

Programs that target relapse prevention (Herz and Lambert, 1995) can potentially change the disorder trajectory for those with schizophrenia/SAD. These programs, however, are expensive to implement and so remain unavailable to many patients (Eisner et al., 2013). The increasing use of text messaging provides opportunities to develop relapse prevention programs that are readily accessible to people with schizophrenia/SAD. Nationally, up to 81.4% of people with a serious mental illness report owning a cell phone (Firth et al., 2016), and text messaging has been reported as the second most common use of their phones (Ben-Zeev et al., 2013a).

There has been growing interest in the potential role that technology could play in the detection and management of early symptoms of relapse in schizophrenia. Spaniel (Spaniel et al., 2008) reported a year-long trial of an automated text messaging program where physicians initiated a pre-determined medication increase when early symptoms of relapse were identified. This intervention led to a 60% reduction in the number of hospitalizations among participants.

Granholm and colleagues (Granholm et al., 2012) developed Mobile Assessment and Treatment for Schizophrenia, a text-messaging program that targeted medication adherence, social interaction and auditory hallucinations. Medication adherence improved among those who completed the program and the severity of hallucinations decreased. However, those with more severe negative symptoms, lower functioning, and lower premorbid IQ had a high dropout rate. Participants also found the study-provided phones difficult to navigate.

A study in China found that sending educational and medication-reminder text messages daily to individuals with schizophrenia and a family member/support person increased medication compliance and reduced relapses and hospitalizations. The program, however, relied on the family member/support person being actively involved and neither program content nor the frequency/timing of the text messages could be customized (Xu et al., 2019). Almost 70% of participants required training on cell phone use.

Building on past research, we developed the Texting for Relapse Prevention Program (T4RP) for individuals with schizophrenia/SAD (Ybarra ML, 2019). This is a text-messaging program developed through a collaborative approach involving focus groups with patients, providers, and administrators, which targets early warning symptoms of relapse in those with schizophrenia/SAD. The program is designed for use by those who have a cell

phone and use text messaging. At the start of the program the patient, along with their provider, identifies their top five early warning symptoms of relapse. The T4RP program then sends daily text messages to the patient querying them on one of these five symptoms. The patient responds to symptom check-ins by texting “yes”, “no”, or a numerical response depending on the particular question. If the symptom is present, they receive a follow up text message with a rotation of coping skill suggestions specific to that symptom. If they are asymptomatic, they receive a supportive text message. Additionally, the patient receives, on a daily basis, either a medication-related text message (adherence/coping with side effects) or an inspirational quotation text message. When the patient endorses the presence of a symptom, they are asked about it again on subsequent days, and provided with coping skills targeting the symptom until it resolves. They also continue to receive the daily check-in text message about another of their 5 early warning symptoms. If the patient endorses their preset, individualized threshold of symptoms, the program alerts their provider through either email or text message. The provider contacts the patient within 24 hours to decide on further management. This could include adjusting medication, referral to case management, or problem solving on social stressors.

We posit that T4RP will reduce psychiatric morbidity and institutional rates and promote recovery by promoting self-management of early warning symptoms, medication adherence and by facilitating improved patient-provider communication. Here we report on the impact of the pilot T4RP program on number of hospitalizations, experience of symptoms, medication adherence, empowerment and communication with providers.

2. Methods

2.1 Subjects

This study was a randomized controlled trial (RCT) of the T4RP program involving patients with schizophrenia/SAD attending a hospital-based community psychiatry program. Eligibility criteria included: a chart diagnosis of schizophrenia/SAD; English speaking; capacity to consent; owning and texting on a cellphone; agreeing to retain the same number for the duration of the study; at their personal baseline as assessed by their provider; agreeing to attend the clinic for the duration of the study; and having their provider agree to participate in the study. All providers in the program were eligible to participate and all consented to participate. The study was reviewed and approved by Advarra IRB and the Johns Hopkins School of Medicine IRB.

Over the course of 3 months, all patients attending the clinic with a chart diagnosis of schizophrenia/SAD were assessed by their provider for study eligibility. Potential participants were referred to the study coordinator for confirmation of eligibility, including assessment for capacity to consent (Dunn and Jeste, 2001). Eligible patients were then consented, completed baseline assessments, and were randomly assigned to the control or intervention arm of the study. Participants were randomized by a computer algorithm at a 2:1 ratio for the intervention and control group to maximize the amount of pilot data collected for those in the intervention. Initially, patients were randomized after they consented to take part in the study. After five people were enrolled this methodology was changed to randomize after the baseline survey was completed.

Patients in the intervention met with their providers to select their 5 common symptoms of relapse, their preferred daily timeframe to receive texts, the symptom threshold to alert their provider and their emergency contact information. The provider entered this information into the T4RP online clinical platform. Intervention patients started receiving text messages the day after they were enrolled in the study and continued receiving daily text messages for 6 months. The protocol for the delivery of text messages followed that outlined above. At enrollment, intervention patients were instructed that should they experience a crisis at any point they could text the word “crisis” and they would receive information on the clinic emergency protocol.

Both intervention and control patients continued to attend their regular clinic appointments.

2.2 Measures

Clinical assessments were completed at baseline, 3 months, and 6 months. The study coordinator was trained to complete any clinician-administered scales and entered this data directly into the online study platform. In the presence of the study coordinator, patients completed self-report scales directly into the online system.

Primary clinical outcomes included symptoms of relapse, recovery, and institutionalization. Symptoms of relapse were measured using three scales. The Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987) has three subscales that measure positive symptoms of schizophrenia ($\alpha = 0.55$), negative symptoms of schizophrenia ($\alpha = 0.60$), and general psychopathology ($\alpha = 0.70$). Studies frequently use changes in scores on the positive subscale as an indicator of relapse (Gleeson et al., 2010; Wang et al., 2018). The Montgomery-Asberg Depression Rating Scale (MADRS) measures changes in depressive symptoms during treatment. Items are rated on a scale from 0 to 6 ($\alpha = 0.79$) (Davidson et al., 1986). The Young Mania Rating Scale (YMRS) assesses the presence and severity of manic symptoms ($\alpha = 0.57$) (Young et al., 1978).

Recovery was measured using the Recovery Assessment Scale Revised (RAS-R), a 24-item self-report scale with 5 subscales that measures personal recovery in those with serious mental illness (Corrigan et al., 2004). This scale is sensitive to change over time (Salzer and Brusilovskiy, 2014).

Information on hospitalizations, emergency room (ED) visits and intensive outpatient program (IOP) referrals the year before baseline and for the past 3 months at 3- and 6-month follow-ups was obtained from providers on all study patients.

Posited targeted mechanisms included medication adherence, patient empowerment, and improved patient-provider communication. Medication adherence was measured using the Brief Adherence Rating Scale (BARS), a 4-item scale designed for use in community settings with individuals with schizophrenia/SAD. We compared those with 90% or better medication adherence to those with less than 90% adherence. Depot injection medication adherence rates were measured by comparing the number of injections the patient received to the number they should have received based on the prescribed frequency of delivery of the

depot medication. Those with 90% or better adherence were compared to those with less than 90% adherence.

Patient empowerment was measured with the Boston University Empowerment Scale (BUES) short version, a 25-item self-report scale that measures empowerment among those using mental health services ($\alpha = 0.94$) (Rogers et al., 2010).

To measure patient-provider communication, participants were asked how strongly they agreed or disagreed with five statements that described their relationship with their provider (e.g., “My provider knows who I want involved in my care if my symptoms get worse”). Responses were summed to create a communication “score” ($\alpha = 0.90$).

2.3 Data analyses

Missing data on the BUES scale due to a participant declining to answer some items was replaced with scale mean values. This affected 7 people at baseline and 8 people at 6-month follow-up. One additional person was not included in the baseline BUES scale because there was an internet connectivity issue and their data for this scale were lost. None of the other scales had missing data.

Differences between the intervention and control participants were tested using chi-square tests for dichotomous measures (e.g., medication adherence) or t-tests for continuous measures (e.g., depressive symptomatology). The sample size for this study was determined by the project’s main aims, which were to determine the program’s feasibility and acceptability. As such, it was not powered to detect statistical differences but rather to generate estimates to inform power estimates for a larger trial. Given the exploratory nature of this study, multivariable analyses were not conducted. Also given the pilot nature of the work, a permissive p-value of 0.20 was used to guide differences between the experimental arms (Stallard, 2011).

3. Results

3.1 Study Sample

Twelve hundred and twenty patients were assessed for eligibility, 42 of whom were consented and randomized. The main reason for ineligibility was not using text messaging. One person was randomized to the control group before completing the baseline survey and was censored from analysis as they withdrew when assigned to the control group. Another person was censored post-hoc when their medical record indicated they did not have a diagnosis of schizophrenia/SAD. Of those who completed the baseline survey ($n=40$), 95% ($n=38$) completed the 3-month follow-up and 92% ($n=37$) completed the 6-month follow-up surveys. Two people actively withdrew from the study, one for unknown reasons following their baseline assessment and one after their 3-month assessment due to experiencing an exacerbation of their symptoms. One person remained in the study but, due to scheduling issues, was unable to complete either the 3- or 6-month assessments.

Participants were, on average, 49 years old, 2 in 5 were female, most identified as Black/African American, most were single and two in three had a diagnosis of schizophrenia

(Table 1). The intervention and control groups were balanced on demographic characteristics.

3.2 Clinical outcomes

Symptoms of Relapse: Positive PANSS scores were significantly lower at baseline (M: 16.5 vs. 13.3, $p=0.03$) and at 6-month follow-up (M: 14.3 vs. 11.4, $p=0.03$) for the intervention group. Symptoms of depression and mania were not significantly different between the two groups across the 6-month study (Table 2).

Recovery: Several indicators of recovery were significantly better for those in the intervention group at 3-month follow-up, including personal confidence and hope (M: 25.6 vs. 28.8 $p=0.05$), goal and success orientation (M: 19.8 vs 21.7 $p=0.03$), reliance on others (M: 15.1 vs 16.8, $p=0.03$), and the total score (M: 82.4 vs 90.4, $p=0.04$). Significantly higher scores did not persist through 6 months (Table 2).

Institutionalization.—No significant differences in hospitalizations, emergency room visits, or IOP referrals were noted between the two groups at either follow-up period (Table 2).

Posited mechanisms of change.—Improved oral medication adherence was suggested at both 3 and 6 months for those in the intervention group (69% vs 89%, $p=0.11$). Greater rates of adherence to injectable medications were noted in the intervention group at both 6 months (31% vs 100%, $p=0.02$) and baseline (0% vs 57%, $p=0.09$). Patient empowerment scores were higher in the intervention group over time, particularly at 6-months (Table 2).

4. Discussion

Using text messaging to identify early symptoms of relapse for people who have schizophrenia/SAD has the potential to be a user-friendly and cost-effective intervention. To our knowledge, T4RP is one of the first text messaging-based programs that was developed with significant input from patients and providers. It also is novel because the program tailors the daily check-in messages and coping skills to the early warning signs of the individual. Interactions with the program are simple and use skills (texting) that the target population already has. While the development of self-management apps (Ben-Zeev et al., 2013b; Eisner et al., 2019; Kidd et al., 2019; Palmier-Claus et al., 2013a, b) provides another tool to help patients manage their symptoms, T4RP may be more accessible to this patient population than an app which requires access to a smart phone.

Findings from this study are encouraging. Those in the intervention had fewer positive symptoms than those in the control group at 6 months post-enrollment and their recovery scores were significantly higher at 3 months. Although there was a significant difference in the number of positive symptoms between the two groups at baseline, a consistent decline in symptoms was observed in the intervention but not the control group. It may be that the coping skill messages worked as intended, and empowered patients to enact strategies to address their symptoms. The trend towards higher empowerment scores in the intervention group at both 3 and 6 months is also encouraging.

Medication adherence is important in preventing symptom relapse (Leucht et al., 2012) and impacts mortality rates among those with schizophrenia (Cullen et al., 2013). The significant improvement in adherence to injectable medication and trend towards improved oral medication adherence suggests that this may be a mechanism for change. Individuals in the intervention group received, on average, 3 messages per week that either encouraged them to take their medication or provided simple solutions for common side effects. Previous studies have had success improving medication adherence with daily reminder text messages (Granholtm et al., 2012; Montes et al., 2012; Xu et al., 2019). Findings from the current study suggests that patient education may also influence medication adherence.

Contrary to our hypotheses, hospitalizations, emergency room visits, and IOP referral rates were similar for the intervention and control groups. Perhaps this is because a text messaging program is insufficient, on its own, to affect these large clinical outcomes. It also is possible that were the sample size larger, differences in these rates would be easier to detect.

Patient-provider communication scores were relatively stable for both the groups during the course of the study. This may reflect the baseline level of engagement of patients with providers in this particular clinical setting. Testing the intervention in different types of clinical settings may help further illuminate the impact that T4RP has in this regard.

This study had some limitations. The study sample includes only those people who had a cell phone and used text messaging. In the city where the study was conducted, Medicaid-facilitated phone ownership included unlimited text messaging, which facilitated the inclusion of low-income people in the study. In other settings where this type of subsidy is not available, T4RP may not be appropriate. Also, T4RP requires experience with text messaging so it is not suitable for everyone. This study was a pilot study designed to assess feasibility and acceptability. As such, the sample size was based upon feasibility and was not sufficient to detect statistical differences between the groups. Additionally, the internal consistency for the positive PANSS subscale and the Young Mania Rating Scale in the current study were suboptimal. This perhaps made it more difficult to detect a signal.

Results from the pilot study of the T4RP program are promising, particularly in terms of the posited mechanism for change, improved medication adherence; and the clinical outcome, reduced positive symptoms. Future research that includes multiple sites to determine whether the program impacts patient-provider communication in non-academic settings, and institutionalization in a larger clinical sample appears warranted.

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Highlights

- The program decreased the experience of positive symptoms of schizophrenia
- Medication adherence, especially injectable medication adherence improved
- There was no significant difference in hospitalization rates between the 2 groups

Table 1.

Demographic characteristics of pilot RCT participants

Demographic characteristics	Control (n=12)	Intervention (n=28)	p-value
	M (SD)	M (SD)	
Age	50.1 (14.2)	48.1 (13.2)	0.68
	% (n)	% (n)	
Female	41.7 (5)	42.9 (12)	0.94
Race			0.52
White	16.7 (2)	3.4 (1)	
Black / African American	83.3 (10)	85.7 (24)	
All other	0 (0)	10.8 (3)	
Hispanic			
Ethnicity	0 (0)	3.6 (1)	0.51
Marital status			0.36
Married	8.3 (1)	7.1 (2)	
Divorced	25.0 (3)	17.9 (5)	
Single	58.3 (7)	71.4 (20)	
Widowed	8.3 (1)	3.6 (1)	
Employment status			0.17
Full time	0 (0)	10.7 (3)	
Part time	0 (0)	7.1 (2)	
Not employed	100.0 (12)	82.2 (23)	
Insurance type			0.64
Medicare	66.7 (8)	60.7 (17)	
Medicaid	33.3 (4)	32.1 (9)	
Private insurance	0 (0)	7.1 (2)	
Psychiatric Diagnosis			0.57
Schizoaffective disorder	33.3 (4)	42.9 (12)	
Schizophrenia	66.7 (8)	57.1 (16)	
Participated in intervention development activity	16.7 (2)	35.7 (10)	0.23

Table 2.

Clinical outcomes for the pilot Texting 4 Relapse RCT

Patient characteristics	Baseline (n=40)			3-month outcomes (n=38)			6-month outcomes (n=37)		
	Control (n=13) M (SD)	Intervention (n=28) M (SD)	p-value	Control (n=12) M (SD)	Intervention (n=26) M (SD)	p-value	Control (n=12) M (SD)	Intervention (n=25) M (SD)	p-value
<i>Clinical indicator</i>									
Symptoms of relapse									
PANSS									
Positive	16.5 (4.5)	13.3 (4.0)	0.03	14.3 (4.5)	12.2 (3.4)	0.14	14.3 (3.7)	11.4 (3.5)	0.03
Negative	12.3 (3.7)	13.6 (4.7)	0.37	12.8 (4.0)	13.8 (5.2)	0.55	11.9 (4.6)	14.4 (5.8)	0.21
General	30.3 (8.1)	26.7 (6.5)	0.15	24.8 (7.0)	24.2 (5.2)	0.79	24.5 (6.9)	22.2 (5.3)	0.27
Total	59.0 (13.2)	53.6 (11.2)	0.20	51.8 (10.8)	50.2 (10.0)	0.67	50.7 (10.5)	48.0 (10.3)	0.46
Montgomery-Asberg Depression Rating Scale	9.6 (9.1)	8.1 (7.6)	0.60	8.7 (9.3)	5.5 (7.2)	0.26	6.2 (7.8)	5.4 (7.3)	0.78
Young Mania Rating Scale	5.1 (3.7)	4.1 (2.8)	0.34	2.9 (1.0)	3.0 (0.5)	0.93	3.3 (0.7)	2.6 (0.5)	0.41
<i>Recovery</i>									
Recovery Assessment Scale									
Personal confidence and hope	25.8 (4.0)	27.3 (5.2)	0.38	25.6 (4.0)	28.8 (4.9)	0.05	25.9 (4.1)	26.3 (6.5)	0.86
Willingness to ask for help	12.0 (2.1)	12.6 (2.2)	0.42	12.2 (2.0)	12.8 (1.8)	0.34	12.1 (1.7)	12.1 (2.6)	0.96
Goal and success orientation	19.8 (2.6)	21.0 (3.6)	0.29	19.8 (2.0)	21.7 (2.5)	0.03	20.1 (2.3)	20.8 (4.0)	0.55
Reliance on others	14.8 (2.4)	16.3 (3.2)	0.15	15.1 (1.4)	16.8 (2.5)	0.03	14.5 (2.3)	15.9 (3.5)	0.22
Not dominated by symptoms	9.3 (2.6)	8.6 (2.7)	0.51	9.8 (2.3)	10.2 (2.4)	0.56	9.3 (2.1)	9.9 (2.5)	0.49
Total recovery score	81.7 (10.7)	85.9 (12.1)	0.30	82.4 (9.3)	90.4 (11.3)	0.04	81.9 (10.3)	85.0 (16.8)	0.56
<i>Institutionalization</i>									
Hospitalizations (1+)	15 (2)	11 (3)	0.58	0 (0)	11 (3)	0.21	0 (0)	7.7 (2)	0.31
Psychiatric ER visits	15 (2)	7 (2)	0.33	0 (0)	0 (0)	NC	0 (0)	4 (1)	0.47
IOP referrals	0 (0)	4 (1)	0.49	0 (0)	0 (0)	NC	0 (0)	4 (1)	0.47
<i>Posited targeted mechanisms</i>									
Oral medication adherence (>=90%) *	75% (9)	75% (21)	NC	85% (11)	96% (27)	0.18	69% (9)	89% (25)	0.11
Injectable medication adherence (>=90%) **	0% (0)	57% (4)	0.09	67% (2)	88% (7)	0.43	33% (1)	100% (6)	0.02
Patient Empowerment (BUES)	59.4 (10.1) ***	55.3 (11.6)	0.03	69.6 (5.3)	72.5 (7.1)	0.22	71.0 (4.7)	74.7 (8.1)	0.15
Improving communication between patients and providers	20.3 (4.0)	20.8 (3.7)	0.70	20.1 (3.2)	21.3 (4)	0.21	19.8 (0.3)	19.8 (4.7)	0.99

33 people were on oral medications at baseline, 34 at 3 months, and 36 at 6 months
*
** 10 people were on injectable medications at baseline, 11 at 3 months, and 9 at 6 months
*** 1 control participant's responses were lost due to an internet problem

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