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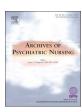
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## What Works in a Nurse Led Self-Management Program for Patients with Serious Mental Illness (SMI) and Diabetes (DM)

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#### ABSTRACT

Objective: To develop a deeper understanding of "how" a nurse led self-management intervention in a successful randomized controlled trial (RCT) for individuals with both serious mental illness (SMI) and diabetes (DM) influenced health outcomes and the lives of the participants.

*Methods*: In depth interviews, were conducted with a sample of 10 participants who received the self-management intervention in the RCT. Interviews were audiotaped, transcribed verbatim, and analyzed using content analysis, with an emphasis on dominant themes.

Results: The mean age of the respondents was 53.9 years (SD = 5.6); 6 (60%) were women and the mean level of education was 12.4 years (SD = 2.4). Transcript based analysis generated 3 major mechanisms of action that led to improved self-management of their SMI and DM: (Colton & Manderscheid, 2006) positive group experience, (Osborn et al., 2008) increased health knowledge, and (Newcomer, 2005) increased self- confidence.

Conclusions: Developing complex interventions for testing in RCTs of individuals with SMI and other comorbid conditions is of increasing importance in healthcare planning for this vulnerable population. Using qualitative methods to explore mechanisms of action underlying quantitative outcomes, can enrich our understanding of processes relevant for individuals with SMI and comorbid conditions.

#### Introduction

Adults with severe mental illness (SMI), such as schizophrenia and bipolar disorder are estimated to die, on average, 25 years earlier than the general population (Colton & Manderscheid, 2006). Much of the premature mortality among individuals with SMI is due to medical comorbidities, such as diabetes (DM) which is more common among people with SMI as compared to the general population (Osborn, Wright, Levy, et al., 2008). This is facilitated by a variety of factors including sedentary life style, poor diet and the metabolotoxic effect of many psychotropic medications (Newcomer, 2005; Osborn et al., 2008). The Institute of Medicine (Institute of Medicine Committee on Crossing the Quality Chasm, 2006) has called for improvements in health care for individuals with SMI and medical comorbidity. A recent review on integrated general medical and psychiatric self-management interventions in people with SMI suggest that they are effective in improving health outcomes (Whiteman, Naslund, DiNapoli, et al., 2016). However, how best to implement self-management approaches is not entirely clear and self-management training is under-used in clinical settings (Whiteman et al., 2016). Qualitative research that elicits input from individuals with SMI and medical comorbidity may offer insight into the patient engagement component of self-management interventions and help with future scale-up.

The current investigators recently completed a prospective, 60-week, randomized controlled trial (RCT) that assessed *Targeted Training in Illness Management (TTIM)* vs. treatment as usual (TAU) in 200 individuals with SMI-DM. The TTIM intervention was led by a nurse educator who delivered a curriculum of content focused on enhancing self-management of SMI and comorbid DM. (Table 1). The nurse educator role was conceptualized as the TTIM "content expert." To enhance program effectiveness, trained peer educators, patients with both SMI and DM, provided complementary support and structure as "experiential experts" in SMI and DM self-management. A characteristic feature of TTIM was having a nurse educator provide information on the "how-to" of self-management, which the peer educator could expand on in terms of barriers and facilitators to success. The interaction between

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Table 1
Topics and Health Behaviors Covered in in the 12-week TTIM Intervention Sessions with Patients.

Session	Topic(s)
1	Orientation and introductions, Emphasize ground rules, Establishment of a therapeutic relationship, Discuss facts and misconceptions about SMI, An introduction to DM
2	The challenge of having both SMI and DM, Stigma of SMI and strategies to cope with stigma, Relationship of SMI symptoms and functioning in response to stress and
	DM, An introduction to personal goal-setting
3	Personal SMI profile (what does worsening illness look like for you), Triggers of SMI relapse, Personal action plan for coping with SMI relapse
4	Diabetes complications and benefits of change, Blood sugar monitoring, Symptoms of high/low
5	Problem-solving skills and the IDEA approach (Identify the problem, Define possible solutions, Evaluate the solutions, Act on the best solution), Talking with your
	medical and your mental health care providers, Role play of communication with care providers
6	Nutrition for best physical and emotional health, Reading labels
7	Replacing unhealthy sugar and fat, Substance use and its effects on SMI and on DM, Problem-solving to feed your body healthfully
8	Effects of exercise on physical and emotional health, The importance of daily routine and good sleep habits
9	Medications and psychological treatments for SMI, A personal care plan to take care of the mind & body
10	Social supports and using your available supports, Types of physical activity and your community
11	Taking care of your feet, Staying on track with medication treatments
12	Illness management as a life-style, Acknowledgement of group progress, Setting the stage for ongoing Illness management and recovery

nurse educators, peer educators and patients, was a key feature of the TTIM intervention.

The study was conducted in the primary care setting of a safety-net health system and evaluated effects on SMI symptoms, functioning, general health and DM control. As in the chronic disease/long term condition paradigm of disease management, TTIM stressed the self-management approach to SMI and DM. Psycho-education, problem identification/goal-setting, behavioral modeling, and care linkages, all emphasized the patient's central role in managing their chronic medical and mental illnesses (Lorig, 2015; Mueser, Corrigan, Hilton, et al., 2002; Wagner, Austin, Davis, et al., 2001).

In step 1 of the TTIM intervention, 12 weekly group format educational sessions (Table 1) were delivered by a nurse educator, assisted by a peer educator. Sessions were also manualized and included handouts that reinforced the material delivered in the group sessions. In step 2, during the 48 weeks following the group sessions, participants had brief telephone maintenance sessions with the nurse educators. Telephone sessions occurred every other week for the first three months, and monthly thereafter. A more comprehensive description of the nurse's role in the TTIM intervention can be found elsewhere (Lawless, Martin, Kanuch, et al., 2016).

Results of the study revealed a greater improvement at 60-weeks in TTIM vs. TAU in psychiatric illness severity (p=0.0008), depression (p=0.0156), functioning (p=0.0031), and DM knowledge (p<0.0002). While both TTIM and TAU groups had similar 60-week improvement in HbA1c (a biological marker of diabetes control), in a post-hoc analysis of the sub-set of patients with good to fair baseline HbA1c (> 50% of the entire sample), TTIM participants had minimal HbA1c change over 60-weeks, compared to TAU who had worsening HbA1c. Of 84 participants who responded to a survey on TTIM acceptability, 98% (N=82) strongly agreed or agreed that TTIM was useful to them. Most (95%, N=80) strongly agreed or agreed that TTIM covered most of the important issues (Sajatovic, Gunzler, Kanuch, et al., 2016).

While these quantitative results of the RCT provided information on whether the TTIM intervention had an influence on patient health outcomes, we went beyond the question "Can the intervention influence outcomes?" to ask questions from the patients' perspective: "How did the intervention influence outcomes and how did it influence the lives of the study participants?" In the following qualitative analysis we describe patients' responses to these two questions and discuss how our findings can inform and enrich our understanding of the processes that impact the outcomes of this RCT and how these insights may help inform future work in chronic illness management among people with SMI.

#### Methods

Sample and setting

Participants (N=10) from the RCT, who participated in the TTIM arm of the study, were recruited for the present qualitative study. For qualitative research, this sample size is within the recommended number of 5–25 individuals who have all experienced the same phenomena (Polkinghorne, 1989). Inclusion criteria included having schizophrenia, schizoaffective disorder, bipolar disorder or major depressive disorder confirmed by the Mini-International Neuropsychiatric Interview (MINI) (Sheehan, Lecrubier, Sheehan, et al., 1998), having Type 2 DM, being age  $\geq$  18, being able to communicate in English, and being able to provide written, informed consent. A sampling grid designed to ensure variability in psychiatric diagnosis, gender, age, and race/ethnicity, was used in the recruitment of these 10 TTIM participants. The study was approved by the Institutional Review Board of the participating institution. All participants provided written informed consent.

The mean age of the respondents was 53.9 years (SD = 5.6); 6 (60%) were women and the mean level of education was 12.4 years (SD = 2.4). Four (40%) identified themselves as African-American, 4 (40%) as Caucasian, and 2 (10%) as Hispanic. Eight (80%) had major depression, 1 (10%) had schizophrenia or schizoaffective disorder, and 1 (10%) had bipolar disorder. The mean duration of SMI was 20.2 years (SD = 13.4) and the mean duration of DM was 11.5 years (SD = 9.3).

#### Study design

In this cross-sectional qualitative study, a thematic analytical approach was used to develop a deeper understanding of how the intervention influenced quantitative outcomes and how it influenced the lives of the study participants (Strauss, 1988). In this approach researchers move their analysis from a broad reading of the data toward discovering patterns and developing themes.

#### Qualitative data collection and analysis

Qualitative methods, consisting of focused in-depth interviews, with 10 participants in the TTIM intervention group, were used to elicit responses about their perceptions of the intervention at the 13th-week follow-up point of the trial. In in-depth interviews, the goal is to explore a topic more openly, and to allow interviewees to express their opinions and ideas in their own words (Marshall & Rossman, 2006). Therefore, participants were given as much latitude as possible to describe their lived experience of being part of this study. A topic guide was used to focus the discussion on main topics, and specific topic-related questions. For example, under the topic, "how the TTIM program influenced

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