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## A Healthy Lifestyle Intervention for Middle-Aged and Older Schizophrenia Patients with Diabetes Mellitus: A 6-Month Follow-Up Analysis

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### 1.1 Introduction

People with schizophrenia are about twice as likely to develop diabetes mellitus as the general population. (Stroup et al., 2003; Lamberti et al., 2004; Citrome, 2005; Gough, 2005; Holt, 2005; Susce et al., 2005) Prevalence estimates range from 15 to 18% in persons with schizophrenia, increase with age, and are as high as to 25% in some studies (Lamberti et al., 2005). These estimates are concerning because diabetes is a disorder that requires both medical monitoring by a qualified provider and active self-management on the part of the patient for optimal management. Unfortunately, the complexities of diabetes self-management (i.e., careful balance between diet, physical activity, and in some cases, medication), may pose unique problems for patients with schizophrenia. Therefore it is important that diabetes management and education programs be tailored for this group.

Few if any researchers have examined the efficacy of diabetes management interventions in this population. We reported results from a 24-week diabetes management intervention in middle-aged and older adults with schizophrenia and type 2 diabetes mellitus. (McKibbin et al., 2006) In the prior study, participants were randomly assigned to receive either a group-based healthy lifestyle intervention (i.e., Diabetes Awareness and Rehabilitation Training; DART) each week for 24 weeks or a Usual Care plus information condition (i.e., Usual Care + Information; UCI). Analysis of outcomes from 57 subjects revealed that the DART group

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Conflicts of Interest. The authors have no conflicts of interest to disclose.

Contributors. Dr. McKibbin assisted with study design, intervention development, data analysis and interpretation, and wrote the first draft of the manuscript. Dr. Golshan assisted with the study design and interpretation and assisted with the revision of the manuscript. Ms. Griver assisted with the intervention development and revision of the manuscript. Ms. Kitchen assisted with manuscript revision and preparation for resubmission. Mr. Wykes assisted with the literature review and revision of the manuscript. All authors contributed to and have approved the final manuscript.

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showed greater improvements in weight, waist circumference, diabetes knowledge, diabetes self-efficacy, and self-reported physical activity than the UCI group. No improvements were noted in fasting glucose and glycosylated hemoglobin (A1C).

Although this study shows promise for the use of diabetes management interventions in persons with schizophrenia, little is known about the duration of treatment gains in this population. Therefore, the purpose of this study is to evaluate treatment outcomes at 6-month after completion of the intervention. We hypothesized that, at the 12-month follow-up assessment (i.e., 6 months after intervention completion), DART participants would show greater improvement in physical (i.e., weight, waist circumference, A1C), behavioral (i.e., energy expenditure) and psychosocial parameters (i.e., diabetes knowledge) than participants in the UCI participants.

## 2.1 Methods

### 2.1.1. Study Design

A randomized pre-test, post-test control group design was used to test the feasibility and efficacy of DART. The intervention was implemented in board-and-care and community clubhouse settings in San Diego County. Participants were evaluated at baseline, six-months, and at 12-months. Baseline and 12-month assessment time-points were used for this follow-up analysis.

### 2.1.2. Intervention Conditions

Diabetes Awareness and Rehabilitation Training (DART) comprised a 24-week intervention with three modules: (1) Basic Diabetes Education; (2) Nutrition; (3) Lifestyle Exercise. Each module contained 4 90-minute manualized sessions. Participants met in groups with 6 to 8 of their peers and one diabetes-trained mental health professional. Concrete behavioral-change strategies were used including self-monitoring (e.g., pedometers), modeling, practice (i.e., healthy food sampling), goal setting and reinforcement (i.e., raffle tickets). Simple guidelines were provided such as switching from regular to diet soda and eating slowly.

The Usual Care plus Information (UCI) condition consisted of usual care provided by the participants' providers and three brochures from the American Diabetes Association relevant to diabetes management (i.e., basic diabetes education, nutrition, exercise).

### 2.1.3. Subjects

This study included participants who returned for assessments 6 months after completion of their intervention program. The parent study is detailed elsewhere. (McKibbin et al., 2006) In brief, participants were included if they were age 40 or older, had provider-confirmed diagnoses of schizophrenia or schizoaffective disorder and a provider-confirmed diagnosis of diabetes mellitus, were ambulatory, and had provider approval to participate in lifestyle exercise (e.g., walking). Participants were excluded if they were unable to complete the assessment battery or if they had a diagnosis of congestive heart failure.

### 2.1.4. Procedures

The University of California San Diego (UCSD) Institutional Review Board reviewed and approved this study. All participants were contacted via telephone and invited to take part in the 6-month, follow-up assessment. There was no other contact between the investigators and the participants between the end of the intervention trial and the 6-month follow-up time point. After providing informed consent, participants completed a 90-minute interview with a trained interviewer who was masked to treatment assignment. Within one week, a

phlebotomist completed anthropometric measurements and a blood draw. All participants received \$20 for the follow-up visit.

### 2.1.3. Instruments

Psychiatric symptom severity was evaluated with the 30-item Positive and Negative Syndrome Scale (PANSS). (Kay et al., 1988) Depressive symptom severity was measured using the 28-item Hamilton Depression Rating Scale (HAM-D) (Hamilton, 1969) and cognitive functioning was measured using Mattis' Dementia Rating Scale (DRS). (Mattis, 1973) Diabetes knowledge (DK) was measured with the first 14 items of the Diabetes Knowledge Test. (Fitzgerald et al., 1998) The percent correct was calculated to yield a knowledge score. Body Mass Index (BMI) was calculated from height and weight as kilograms per square meter measured at awakening, after a 10-hour fast, in light clothing. Waist circumference was measured with a measuring tape at a level midway between the lower rib margin and iliac crest with the tape in horizontal position (World Health Organization, 1998). Finally, 12-hour fasting blood samples were also obtained and assayed for A1C by the UCSD General Clinical Research Center using established protocols.

### 2.1.4. Statistical Analysis

Distributions of all variables were first examined and transformations conducted as necessary. Untransformed means and standard deviations, however, are presented for clarity of interpretation. Baseline group differences on all sociodemographic, clinical, outcome variables were also examined using t-tests and chi-square analyses. Alpha was set to  $p < .05$ . To test our hypothesis, the independent variables group (DART vs. UCI) and time (baseline vs. 12-months) were entered into a mixed-model analysis of variance (ANOVA). Alpha was set to  $p < .05$  for all outcomes and tests were two-tailed.

## 3.1. Results

A total of 52 of the original 64 subjects (i.e., those randomly assigned to treatment condition) completed both baseline and 12-month assessments. Participants did not complete the follow-up assessment due to inpatient hospitalization ( $n=2$ ), inability to complete the follow-up assessment ( $n=1$ ), psychiatric decompensation ( $n=1$ ), lack of interest ( $n=1$ ), moved out of the area ( $n=5$ ), or moved/lost contact ( $n=2$ ). The attrition rate was identical in both conditions over the 12-month study (i.e., 18.7%). Analysis of baseline demographic characteristics, presented in Table 1, showed that groups were similar on all demographic and clinical characteristics. Groups were also similar on all outcome measures at baseline. All participants were receiving treatment for diabetes.

Results of mixed-model analysis showed that the DART group experienced significantly greater improvement in BMI and waist circumference from baseline to the 12-month follow-up assessment (i.e., six months after the treatment had ended) than did the UCI group. DART participants reduced their BMI by approximately 1 point while UCI participants increased, on average, by about one-half point. DART participants experienced approximately 5 pounds of weight loss (i.e.,  $M = 5.7$ ,  $SD = 12.8$ ) while UCI participants gained 7 pounds on average (i.e.,  $M = 7.0$ ,  $SD = 10.6$ ). Neither change in BMI nor waist circumference was associated with baseline antipsychotic type or diabetes treatment type (i.e., diet only, oral glucose control agent, insulin) or changes in antipsychotic treatment or diabetes treatment type. More specifically, there were few changes in antipsychotic treatment type at 6-months and no change in antipsychotic treatment type between 6-months and 12-months post-baseline. Groups were also similar on antipsychotic treatment type at baseline and at the 6-month and 12-month follow up assessments. Similarly, few changes in diabetes treatment type occurred from baseline to 6-months and 12-months for either the

UCI or DART groups. Again, there were no group differences between groups on diabetes treatment type at any assessment time point.

A significant group by time interaction was also found for diabetes knowledge. Specifically, greater improvements in diabetes knowledge from baseline to 12-month follow-up assessment for DART as compared to the UCI participants. DART participants showed an increase in knowledge from about 50% correct to 60% correct at the 12-month follow-up assessment. No group by time interaction was found for A1C or energy expenditure.

## 4.1 Discussion

Our previous work (McKibbin et al., 2006) showed that a 24-week, group-based, diabetes management intervention designed for middle-aged and older patients with schizophrenia and schizoaffective disorder and type 2 diabetes resulted in significant health-related improvements. The current follow-up study not only showed that participants retained some knowledge that they had gained over the course of treatment, but also that they experienced sustained improvements in anthropometric outcomes (i.e., weight/BMI and waist circumference). At the 12-month assessment, participants in our DART condition lost approximately 5 pounds whereas our control condition gained approximately 7 pounds on average - a 12 pound group difference at intervention end. This is notable because even modest weight loss (5% to 10% under baseline) has been associated with improved insulin action, decreased fasting blood glucose, decreased need for diabetes-related medications (Olefsky et al., 1974; Goldstein, 1992; Williams and Kelley, 2000; Torgerson et al., 2004) and reduced risk for cardiovascular disease (Wing & Marquez, 2008). Approximately 40% of DART participants lost 5% or more of their baseline body weight compared to 15% of UCI participants.

Our findings appear consistent with other weight management studies in younger seriously mentally ill showing sustained improvements weight and body mass index over 38 weeks and 52 weeks post-intervention. (Melamed et al., 2008; Chen et al., 2009; Chwastiak et al., 2009) Comprehensive lifestyle therapies in the general community, however, have shown weight loss of 2 to 10 kilograms (i.e., 4 to 22 pounds) over 10 to 20 weeks, but weight regain over a one-year period. (Hensrud, 2001)

Although, we did not find significant improvement in A1C in our previous work, we expected that continued improvement in A1C would be observed if given time to manifest. It is possible that we did not achieve significant improvements in A1C over the follow-up period because our sample had reasonably good values at the baseline assessment. This is a noted limitation of our sample. It is also possible that our intervention was not of significant duration or intensity to achieve A1C benefits in a fairly well controlled sample. Menza et al.'s, (Menza et al., 2004) 52-week study did show significant reductions in A1C in younger participants. Additionally, results from a meta-analysis (Norris et al., 2002) showed, for follow-up periods, greater than 4 months, that a 1% decrease in A1C was achieved for each 23.5 hours of contact time between care providers and nonpsychiatric samples. Interventions of longer duration or the inclusion of maintenance sessions may be useful for achieving additional improvements in A1C levels.

Future research should examine diabetes management interventions in larger samples persons with schizophrenia and type 2 diabetes. Further investigations should also test interventions of longer duration, that include longer follow-up, and samples of participants with poor glucose control to determine whether interventions can achieve metabolic improvements and maintenance of treatment gains in obesity, central adiposity, and diabetes knowledge in patients with serious mental illness.

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**Table 1**  
Baseline Sociodemographic and Clinical Characteristics for Participants Who Returned for the 12-month Assessment (n = 52).

Characteristic	Usual Care + Information		Usual Care + Information		Test (df)
	M	SD	M	SD	
Age +	55.6	8.7	52.4	8.6	t = 1.30 (50)
Education in Years	12.2	1.8	12.3	2.7	t = 0.00 (50)
Gender	N	%	N	%	$\chi^2 = 0.00$ (1)
Male	16	61.5	16	61.5	
Female	10	38.5	10	38.5	
Ethnicity	N	%	N	%	$\chi^2 = 2.80$ (1)
Euro-American	18	69.2	12	46.2	
Other	8	30.8	14	53.8	
Diagnosis	N	%	N	%	$\chi^2 = 1.98$ (1)
Schizophrenia	23	88.5	19	73.1	
Schizoaffective	3	11.5	7	26.9	
Neuroleptic	N	%	N	%	$\chi^2 = 0.44$ (1)
Low metabolic liability	18	69.2	19	73.1	
High metabolic liability	8	30.8	7	26.9	
Diabetes Treatment	N	%	N	%	$\chi^2 = 2.30$ (3)
Diet Only	3	11.5	4	15.4	
Oral agent	18	69.2	19	73.1	
Insulin Only	1	3.8	2	7.7	
Oral agent and insulin	4	15.4	1	3.8	

+ square root transformation



**Table 2**  
**Means and Standard Deviations for Outcomes by Time and Treatment Group (n = 52)**

Outcome	Usual Care + Information		DART		F (1,50)
	Baseline M ± SD	12-month M ± SD	Baseline M ± SD	12-month M ± SD	
Body mass index <sup>+</sup>	32.6±6.0	34.0±6.6	33.9±6.9	32.9±5.9	10.40 <sup>***</sup>
Waist circumference	45.1±4.2	46.0±4.7	45.9±7.0	45.0±6.5	6.60 <sup>*</sup>
Glycosylated hemoglobin	6.8±2.0	7.9±3.6	7.3±2.7	6.9±2.0	0.44
Diabetes knowledge	0.5±0.2	0.5±0.2	0.5±0.2	0.6±0.2	10.86 <sup>***</sup>
Energy expenditure <sup>^</sup>	3290.1 ±4951.6	2148.3 ±2681.6	1942.0 ±2326.7	2799.9 ±3241.5	1.23

<sup>+</sup> square root transformation.

<sup>^</sup> log transformation

\*  $p < .05$ .

\*\*\*  $p < .01$ .