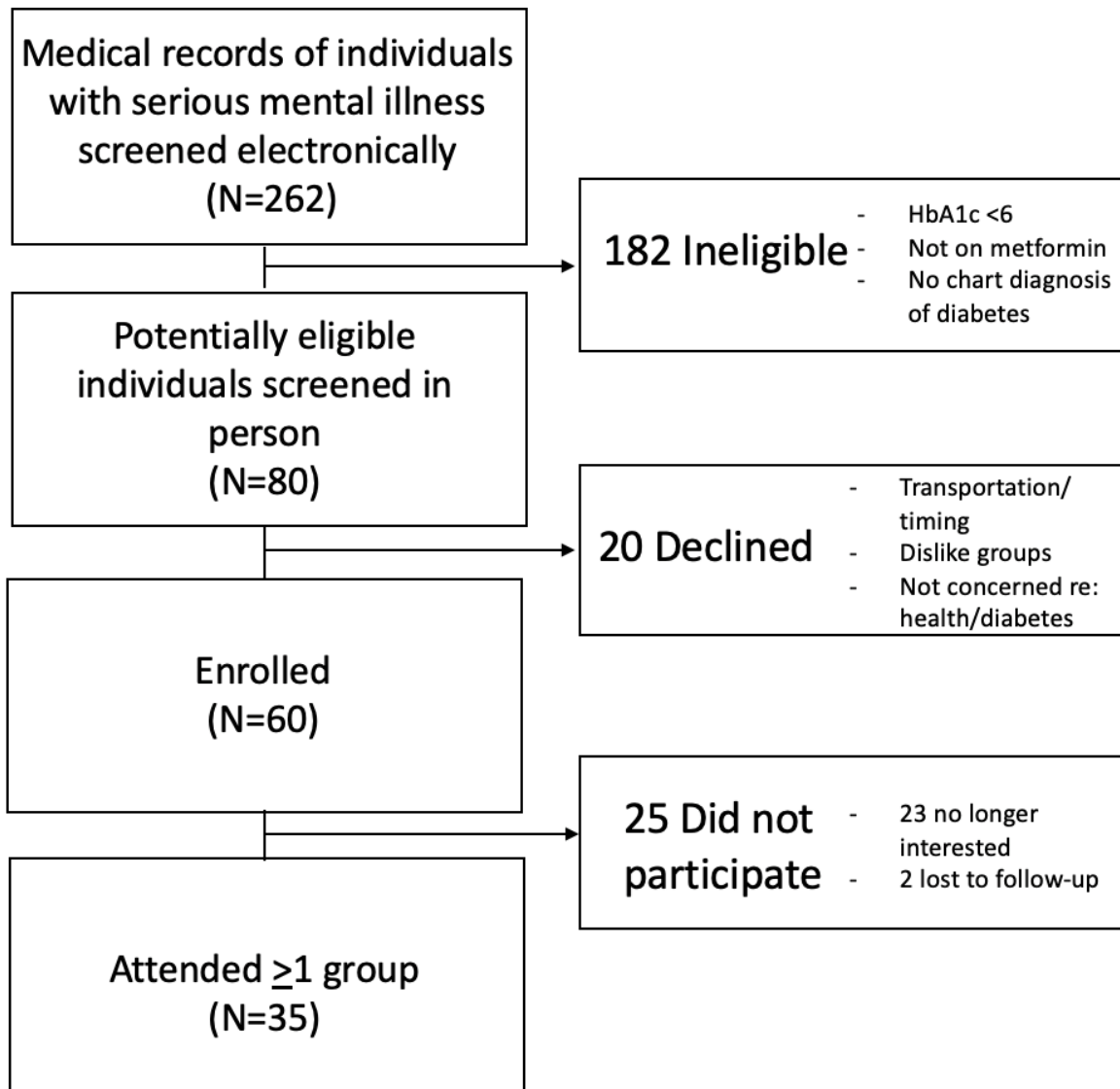


**Intervention**

The intervention was modeled after the Diabetes Prevention Program (1).

Online Curriculum - <https://www.cdc.gov/diabetes/prevention/resources/curriculum.html>

**Consort Diagram**



**Assessments**

Assessed at baseline:

- Clinical Global Impressions Scale (CGI) (2)

Measured weekly:

- Weight

- Systolic and diastolic blood pressure
- Step count

Measured at baseline and week 16:

- Lipid panel
- A1C

Assessed at weeks 1, 4, 8, 12, 16:

- Short Diabetes Knowledge Instrument (SDKI) (3)
- Summary of Diabetes Self-Care Activities (SDSCA) (4)
- Problem Areas in Diabetes (PAID) (5)

**Results**

There were no significant differences between participants who enrolled and attended at least one group versus those who enrolled but attended no groups ( $p's > 0.05$ ). However, we have low power to detect between group differences. Those who attended any groups were more likely to be non-white, more likely to be treated with an antipsychotic medication, more likely to be treated with olanzapine, and more likely to be treated with metformin and insulin and have a greater HbA1c than those who enrolled and attend none of the intervention.

**Baseline Characteristics of Study Participants**

	Attended no groups N = 25	Attended 1 or more groups N = 35
Age, years - M (SD)	56.9 (12.2)	52.9 (10.9)
Female - N (%)	10 (40)	8 (22.9)
Race/Ethnicity		
White	16 (64)	16 (45.7)
African American	5 (20)	12 (34.3)
Other race	3 (12)	7 (20)
Hispanic	1 (4)	3 (8.6)
Clinical Global Impression-Severity M (SD)	4.9 (1)	4.8 (0.9)
Treatment - N (%)		
Any antipsychotic	12 (75)	34 (97.1)
Clozapine	8 (50)	14 (40)
Olanzapine	1 (6.2)	8 (22.9)
Mood stabilizer	4 (25)	12 (34.3)
Antidepressant	6 (37.5)	10 (28.6)
Metformin	6 (37.5)	23 (65.7)
Other oral diabetes medication	3 (18.8)	12 (34.3)
Insulin	2 (12.5)	9 (25.7)
Disease status - M(SD)		
BMI		33.3 (3.8)
Systolic blood pressure, mmHg		127 (13)

	Attended no groups N = 25	Attended 1 or more groups N = 35
Diastolic blood pressure, mmHg		81 (11)
HbA1c, %	6.5 (1.1)	7.5 (1.6)
Total cholesterol, mg/dL	168 (41)	160 (39)
HDL, mg/dL	41 (14)	38 (15)
Average steps		5028 (4467)
Diabetes Self Care (SDSCA) <sup>a</sup> – M (SD)		
General diet		3.5 (2.5)
Specific diet		3.2 (2.1)
Exercise		2.7 (2.5)
Foot care		4 (1.4)
Diabetes distress (PAID) <sup>b</sup> – M (SD)		41.8 (21.1)
Diabetes knowledge (SDKI) <sup>c</sup> – M (SD)		7.2 (2.7)

<sup>a</sup> Summary of Diabetes Self-Care Activities Measure: multidimensional assessment of diabetes self-management, number corresponding to days per week activity is performed, range 0-7

<sup>b</sup> Problem Areas in Diabetes: 20-item questionnaire to query diabetes-related psychosocial distress, items rated from 1 ("no problem") to 6 ("serious problem"), score range 20-120

<sup>c</sup> Short Diabetes Knowledge Instrument: score range 0-13 with higher scores indicating greater knowledge

#### Data from baseline to end of treatment (week 16), n=35

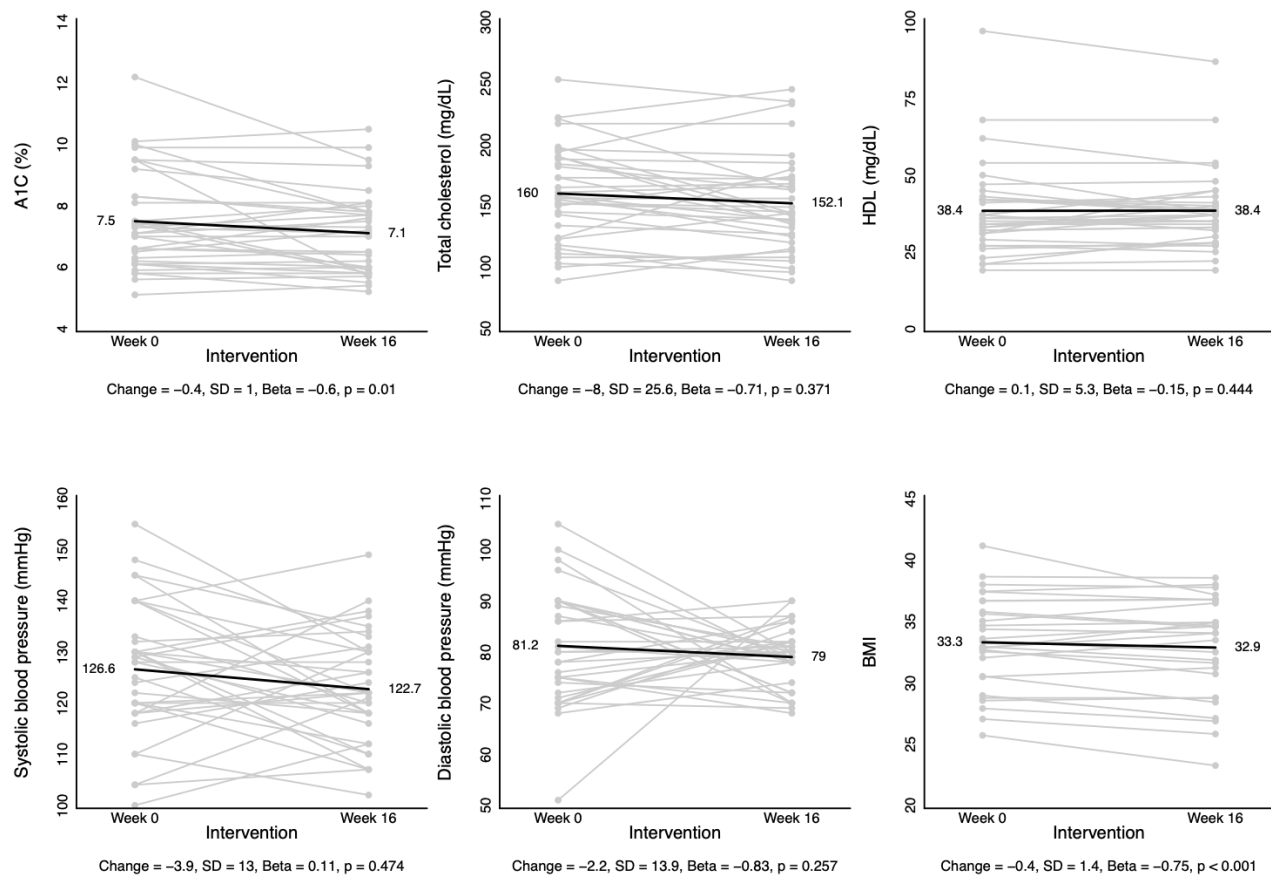
Variables	Baseline (SD)	End of Treatment (SD)	Change	Estimated population effect $\beta$ (SD)	p-value
<b>Physiologic measures</b>					
HbA1c, %	7.5 (1.6)	7.1 (1.4)	-0.4	-0.6 (0.26)	0.01*
HbA1c, % (baseline $\geq$ 6.5%, n=24)	8.2 (1.5)	7.6 (1.3)	-0.6	-0.63 (0.25)	0.008*
Weight, lbs	220.3 (40.9)	217.7 (42.6)	-2.6	-4.11 (0.91)	0.001*
BMI, kg/m <sup>2</sup>	33.3 (3.8)	32.9 (4.1)	-0.4	-0.75 (0.17)	<0.001*
Total cholesterol, mg/dL	160 (39.2)	152.1 (39.3)	-7.9	-0.71 (2.17)	0.371
HDL, mg/dL	38.4 (14.9)	38.4 (12.7)	0	-0.15 (1.07)	0.444
HDL, mg/dL (baseline $\leq$ 40 mg/dL, n=22)	30.4 (5.5)	32.8 (6.6)	2.4	1.94 (0.89)	0.013*
Systolic blood pressure, mmHg	126.6 (12.9)	122.7 (10.8)	-3.9	0.11 (1.73)	0.474
Systolic blood pressure, mmHg (baseline $\geq$ 130mmHg, n=10)	141.8 (6.8)	128.9 (9.7)	-12.9	-3.43 (2.42)	0.081
Diastolic blood pressure, mmHg	81.2 (11.2)	79 (5.9)	-2.2	-0.83 (1.26)	0.257
Diastolic blood pressure, mmHg (baseline $\geq$ 80mmHg, n=17)	90.6 (6.2)	78.5 (5.4)	-12.1	-7.82 (1.66)	<0.001*

Variables	Baseline (SD)	End of Treatment (SD)	Change	Estimated population effect $\beta$ (SD)	p-value
Steps per day	5028 (4467)	5787 (4976)	759	0.12 (3.83)	0.488
<b>Diabetes knowledge &amp; self-care</b>					
Diabetes knowledge (SDKI)	7.2 (2.7)	8.5 (2.7)	1.3	1.75 (0.42)	<0.001*
General diet self-care, days	3.5 (2.5)	4.6 (1.9)	1.1	1.21 (1.21)	0.003*
Specific diet self-care, days	3.2 (2.1)	4 (1.4)	0.8	0.96 (0.32)	0.001*
Exercise self-care, days	2.7 (2.5)	4.1 (2.4)	1.4	1.09 (0.5)	0.015*
Foot self-care, days	4 (1.4)	4.2 (1.4)	0.2	0.28 (0.25)	0.129
Diabetes distress (PAID)	42 (21)	37 (18)	-5	-1.76	0.223

Note: A1C for participants who enrolled but attended no groups did not significantly change after four months: 6.5 (1.1) at baseline to 6.4 (0.8) at 16 weeks,  $\beta = -0.46$  (0.47),  $p = 0.156$ .

\*Comparisons considered significant at  $p < 0.022$

### Physiologic measures from baseline to week 16, n=35



**Diagnostic results for mixed effects models (Kolmogorov-Sminorv test for normality of residuals and R<sup>2</sup>)**

Outcome	Distribution of residuals	R <sup>2</sup>
Diabetes knowledge	D = 0.06, p = 0.852	0.63
Summed likert scores for stress due to diabetes	D = 0.11, p = 0.595	0.20
Average days spent on general diet self-care	D = 0.07, p = 0.852	0.42
Average days spent on specific diet self-care	D = 0.05, p = 0.852	0.50
Average days spent on exercise self-care	D = 0.07, p = 0.852	0.39
Average days spent on foot self-care	D = 0.06, p = 0.852	0.59
HDL	D = 0.09, p = 0.497	0.84
LDL	D = 0.07, p = 0.852	0.58
Total cholesterol	D = 0.08, p = 0.709	0.45
Triglycerides	D = 0.15, p = 0.013*	0.50
Systolic blood pressure	D = 0.03, p = 0.852	0.31
Diastolic blood pressure	D = 0.05, p = 0.709	0.24
Weight	D = 0.11, p < 0.001*	0.98
A1C	D = 0.12, p = 0.094	0.40
Average steps per day	D = 0.14, p < 0.001*	0.83
BMI	D = 0.12, p < 0.001*	0.95

\* Significant at p < .05 following Benjamini & Hochberg (1995) correction.

Four outcomes had tests indicating unusual distributions for residuals (see summary below of these flagged residuals and whether these represented over- or under-estimations). In these cases, we examined the distribution of residuals and flagged residuals that exceeded  $\pm 2$  standard deviations. We then refit the data using a variant of the mixed effects model robust to outliers, in which data are assumed to follow a student t distribution rather than a normal distribution (6). In all cases the significance and direction of effects did not change even when using the robust statistical approach, suggesting results were not affected by outliers/excessive variability.

- Triglycerides: 4 subjects had flagged residuals (1 was underestimated, 3 were overestimated), at 0, 8, 16, and 32 weeks.

- Weight: 8 subjects had flagged residuals (4 were underestimated, 4 were overestimated), at pre-intervention, and 1, 3, 13, and 32 weeks. Notably, one subject was consistently underestimated at all time points.
- Average steps per day: 2 subjects had flagged residuals (1 was underestimated, 1 was overestimated), over weeks 2, 4, 5, 6, and 16.
- BMI: 7 subjects had flagged residuals (3 were underestimated, 4 were overestimated), at pre-intervention and weeks 1, 3, 4, and 32. Notably, one subject was initially underestimated but his/her improvement was also underestimated.

## Citations

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