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RESEARCH ARTICLE

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The Wellness Incentive and Navigation intervention improved health-related quality of life among Medicaid enrollees: A randomized pragmatic clinical trial

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Abstract

Objective: To examine whether the Wellness Incentive and Navigation (WIN) intervention can improve health-related quality of life (HRQOL) among Medicaid enrollees with co-occurring physical and behavioral health conditions.

Data Sources: Annual telephone survey data from 2013 to 2016, linked with claims data.

Study Design: We recruited 1259 participants from the Texas STAR + PLUS managed care program and randomized them into an intervention group that received flexible wellness accounts and navigator services or a control group that received standard care. We conducted 4 waves of telephone surveys to collect data on HRQOL, patient activation, and other participant demographic and clinical characteristics.

Data Collection/Extraction Methods: The 3M Clinical Risk Grouping Software was used to extract variables from claims data and group participants based on disease severity.

Principal Findings: Our results showed that the WIN intervention was effective in increasing patient activation and HRQOL among Medicaid enrollees with co-occurring physical and behavioral health conditions. Furthermore, we found that this intervention effect on HRQOL was partially mediated by patient activation.

Conclusions: Providing navigator support with wellness account is effective in improving HRQOL among Medicaid enrollees. The pragmatic nature of the trial maximizes the chance of successfully implementing it in state Medicaid programs.

KEYWORDS
longitudinal, Medicaid, motivational interviewing, patient activation, pragmatic clinical trial

1 | INTRODUCTION

Mental and behavioral health conditions (MBHCs), such as anxiety disorders, depression, substance use disorder, and serious mental illness (SMI), affect a significant number of individuals in the United States,[1,2] especially those with low income.[3] Among adults, many of these conditions are more common than diabetes,[4] a leading cause of death in the United States.[5] It is estimated that 19.1 percent of US adults have anxiety disorders and 9.7 percent have mood disorders (ie, major depression, dysthymic, and bipolar disorders),[2] compared

to 7.5 percent with diagnosed diabetes in the same year.[5] Moreover, modifiable behavioral risk factors such as tobacco use,[6,7] physical inactivity,[8] poor diet,[8] and obesity[9] are highly prevalent among adults with MBHCs, further exacerbating their already poor health status. Individuals with MBHCs experience higher morbidity and mortality, and poorer health-related quality of life (HRQOL) compared to those without them, mostly due to preventable co-occurring chronic physical conditions such as cardiovascular disease (CVD) and diabetes.[10,11]

Among low-income Americans, Medicaid is a major source of health insurance coverage for MBHCs. As of March 2018, 67 million individuals were enrolled in Medicaid.[12] Twenty-one percent of adults with any mental illness and 25 percent of adults with SMI were covered by Medicaid in the United States[13] Among Medicaid enrollees with MBHCs, more than half also have co-occurring physical health conditions that require medical attention.[14] These conditions may include cardiovascular disease, diabetes, asthma, and chronic obstructive pulmonary disorder. Medicaid enrollees with comorbid mental and physical health conditions often have worse symptoms, decreased HRQOL, and increased medical costs relative to those with physical health conditions alone.

In 2011, the Centers for Medicare and Medicaid Services (CMS) established the Medicaid Incentives for the Prevention of Chronic Diseases (MIPCD) program through the Affordable Care Act (ACA) to "test the effectiveness of providing incentives directly to Medicaid beneficiaries of all ages who participate in MIPCD prevention programs, and change their health risks and outcomes by adopting healthy behaviors."[15] The goal was to better understand how incentive programs work and thus to promote their wider use among Medicaid programs. In the State of Texas, the Wellness Incentive and Navigation (WIN) study, a 3-year randomized pragmatic clinical trial (ClinicalTrials.gov identifier: NCT02440906), was conducted as one of 10 national demonstration projects in the MIPCD program.

The WIN project targeted Medicaid enrollees with co-occurring physical and behavioral health conditions and tested a behavior intervention consisted of: (a) personal navigators professionally trained in motivational interviewing (MI) to help participants develop and refine wellness goals and strategies and (b) a personal flexible expense account that provided financial support to purchase items and services to implement the wellness strategies. The WIN intervention was designed based on the concept of patient activation, defined as "understanding one's own role in the care process and having the knowledge, skills, and confidence to take on that role." Patients, who are activated, are more likely to engage in more positive health behaviors.[16] Many interventional studies have shown that personal navigators, or health coaches, can increase patient activation and promote better health outcomes across different health conditions and populations, including individuals with SMI.[17-20] MI-based health coaching uses a patient-centered counseling approach, which has been shown to be causally associated with positive behavior and health outcomes.[21]

In this study, we sought to evaluate whether the WIN intervention improved patient activation and health outcomes among Medicaid enrollees with co-occurring physical and behavioral health conditions. We hypothesized that, compared to participants receiving standard care, those enrolled in the intervention receiving support from navigators and flexible spending accounts would have higher patient activation and HRQOL scores at the end of the study. We also hypothesized that patient activation mediated the intervention effect on HRQOL. In other words, we hypothesized that the intervention would lead to increased patient activation, which would in turn lead to improved HRQOL.

2 | METHODS

2.1 | Study design

Full details of the study design and conceptual framework are available in a previously published article.[22] To be eligible for the WIN study, an individual must have the following: (a) a SMI diagnosis (eg, schizophrenia, bipolar disorder, major depressive disorder) alone, (b) diagnosed behavioral health conditions (BHC; eg, anxiety, depression, substance use disorder) coupled with a diagnosed chronic physical health condition (PHC; eg, diabetes, COPD), or (c) all three conditions: a SMI diagnosis, BHC diagnoses, and a chronic PHC diagnosis. Study participants must also reside in the Harris Medicaid managed care service delivery area, which includes Harris (Houston) and adjacent counties (Austin, Brazoria, Fort Bend, Galveston, Matagorda, Montgomery, Waller, and Wharton). We excluded individuals dually eligible for Medicare and Medicaid. We also excluded individuals who had diagnoses of severe cognitive impairment, such as dementia and mental retardation.

To recruit participants, we contacted individuals enrolled in the STAR + PLUS Program who were between 21 and 55 years of age. The STAR + PLUS Program is a Medicaid managed care program for individuals with disabilities severe enough to qualify for Medicaid via Supplemental Security Income (SSI) or Medical Assistance Only (MAO).[23] Initially, 12 349 individuals were identified as meeting the inclusion and exclusion criteria from the Harris SDA Medicaid enrollment files. Among these eligible individuals, 9044 were randomly selected to contact for potential study participation. We successfully contacted 2888 eligible individuals, among whom 1259 agreed to participate in the study.

Participants were randomized to either the intervention or control group. The intervention group received the following: (a) regular meetings with a personal navigator within Medicaid managed care plans professionally trained in MI and (b) a flexible wellness account with a maximum annual fund of $1150 for purchasing necessary items and services. The control group received the usual care provided by Medicaid managed care plans. The usual care in the STAR + PLUS Program included Medicaid health care and long-term services, such as the Day Activity and Health Services (DAHS) and Primary Home Care (PHC) programs.[23] These long-term services

provided support for basic daily activities in patients' homes, modifying homes so that patients could move around safely, short-term care to provide a break for caregivers, etc. Overall, the WIN intervention was implemented for a total of 3 years. Annual telephone surveys, including a baseline survey and three follow-up surveys, were conducted to collect data on the study outcomes.

2.2 | Intervention

The participants in the intervention group were each provided access to a personal navigator who was trained and monitored by the WIN Research Team but employed by one of three Medicaid managed care plans participating in the STAR + PLUS Program (Amerigroup, United, and Molina Health Plans). The intervention group also received a flexible wellness account. The intervention was organized into intake, wellness, and annual review visits. The two initial intake visits were held 1 month apart in the participant's home. After the participant completed a health risk assessment, the navigator worked with the participant to identify health risks and to develop wellness goals and strategies to address selected risks using MI techniques. Then, the participant and navigator chose items and services to purchase for meeting these wellness goals using funds in the flexible wellness account. For instance, one participant identified obesity as a health risk and worked with a navigator to set a wellness goal of 20-pound weight loss. They mutually agreed that the strategies for meeting the goal were to increase physical activity, more walking in this case, and to reduce stress. The navigator then worked with the participant to purchase relevant items and services including walking shoes, books on mindfulness and stress reduction, and yoga classes. The necessary funds, up to a maximum of $1150 annually, were added to the participant's debit card upon approval. The most common wellness goals targeted weight loss, eating habits, sedentary behavior, emotional stress, smoking, arthritis/body pain, and blood pressure.

Following the initial visits, the intervention group received wellness visits which consisted of monthly telephone calls and a quarterly in-person meeting. During the visits, the navigator worked with the participant to review: (a) the health risks, wellness goals, and strategies; (b) self-reported outcomes in meeting the goals; (c) self-reported satisfaction with the strategies used and purchases made; and (d) any requests for new strategies and purchases. Finally, during the in-person annual review visits, the participant completed a new health risk assessment. The navigator and the participant then reviewed current progress and determined whether any changes were required for the selected health risks, goals, and strategies. The control group participated in the baseline and annual surveys for which they received $75 per year. Control group participants also received up to one $10 gift card per month for calling the WIN Project Coordinator to verify and/or update their contact information. Overall, the level of engagement was high among the patients. The monthly calls/visits completion rate ranged from 88.9 to 92.6 percent.

2.3 | Measures

2.3.1 | Health-related quality of life

The primary outcome of this analysis was self-reported physical and mental HRQOL measured with the Short Form-12 (SF-12) health survey version 2. The SF-12 had been validated across many different disease conditions and populations,[24-26] including people with SMI.[26] The survey consisted of 12 questions covering eight functional health and well-being domains: physical functioning (PF), role—physical (RP), bodily pain (BP), general health perceptions (GH), vitality (V), social functioning (SF), role—emotional (RE), and mental health (MH). An algorithm was used to compute the physical component summary (PCS) and mental component summary (MCS) scores from the survey raw scores. The PCS and MCS scores were standardized *T*-scores (mean = 50, SD = 10, possible range = 0-100), with higher scores indicating better health. We accessed HRQOL at baseline and then annually for each of the three study years.

2.3.2 | Patient activation

Patient activation was measured using the Patient Activation Measure (PAM), a 13-question measure characterizing a person's skills, knowledge, and motivation to take control of his or her own health care.[27] PAM is reliable and validated across sex, age, income, education, and racial/ethnic groups.[27] To complete PAM, participants indicated agreement on statements about health care, such as, "Taking an active role in my own health care is the most important factor in determining my health and ability to function," by selecting responses ranging from 1 (strongly disagree) to 4 (strongly agree). Participants' scores were summed, averaged, and converted to an activation score ranging from 0 to 100. Activation scores were then characterized to four possible levels: Level 1 (patient role not important), 47 or lower; Level 2 (lacks confidence/knowledge), 47.1-55.1; Level 3 (beginning to take action), 55.2-67; and Level 4 (staying the course under stress), 67.1 or above.

2.3.3 | Covariates

We controlled for participants' demographics, health status, and census tract poverty in all statistical models. Demographic variables included age (in years), gender, race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, other), and education level (high school or higher vs below high school). Participants' health status was measured using the 3M Clinical Risk Groups (CRGs), a classification system that assigns participants to clinically meaningful health status groups based on inpatient and ambulatory diagnosis and procedure codes, pharmaceutical data, and functional health status.[28] Using CRGs, we classified the participants into three groups: minor chronic conditions, moderate chronic conditions, or major chronic conditions. Census tract poverty was defined as the percentage of

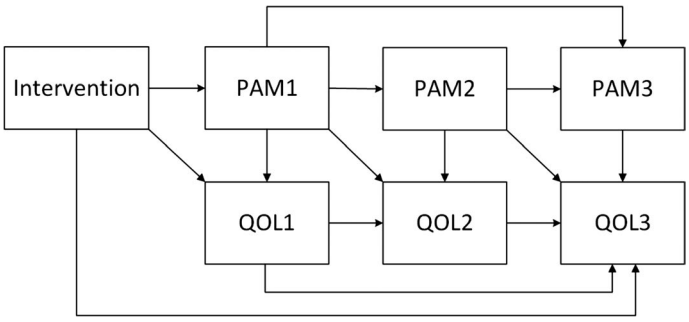

FIGURE 1 Autoregressive mediation model framework. PAM is patient activation measure. QOL is quality of life (PCS or MCS scores). PAM1, PAM2, and PAM3 are patient activation measured at years 1, 2, and 3, respectively. QOL1, QOL2, and QOL3 are health-related quality of life measured at years 1, 2, and 3, respectively

the population living below the federal poverty level in the participants' census tracts.

2.4 | Data analysis

We followed the modified intent-to-treat procedure for the primary analysis.[29] Out of the 1259 enrolled participants, we removed data from 101 participants who had missing values for baseline characteristics and 69 participants who did not participate in any of the follow-up surveys. Data from the 1089 remaining participants were used for this analysis. We first calculated means (SDs) for continuous variables and percentages for categorical variables to describe the participants' characteristics. To examine the intervention effect on SF-12 over time, we conducted longitudinal analysis using the generalized linear mixed models (GLMMs). The outcomes of the study included SF-12 physical and mental scores (PCS and MCS). The primary predictor of interest was the intervention (intervention vs control). Model covariates included gender, race-ethnicity, age, clinical risk groups, education level, census tract poverty level, and the baseline value of the outcome variable. We also tested the interactions between baseline by intervention, baseline by time, intervention by time, and baseline by time by intervention. Backward elimination procedure was used to remove the nonsignificant interaction terms. We used SAS 9.4 for fitting the GLMMs.

In addition to the primary analysis of intervention effect, we also performed longitudinal mediation analysis to examine whether the intervention effect on SF-12 was mediated through patient activation. Considering both longitudinal and contemporaneous mediation, we built 2 separate autoregressive mediation models for the PCS and MCS scores (Figure 1). As seen in Figure 1, PAM1, PAM2, and PAM3 are patient activation measured at years 1, 2, and 3, respectively. QOL1, QOL2, and QOL3 are PCS or MCS scores measured at years 1, 2, and 3, respectively. From the models, we estimated and tested the direct effect (the direct path between intervention and QOL3), total indirect effect (sum of all indirect paths between intervention and QOL3), and indirect effects via patient activation (individual indirect path between intervention and QOL3 that included PAM). Model covariates included gender, race-ethnicity, age, clinical risk groups, education level, and census tract poverty level. The models were developed following the guidelines described in Mackinnon.[30] We used M*plus* version 7 for fitting the autoregressive mediation models.

3 | RESULTS

3.1 | Participant characteristics

We summarized the participants' characteristics in Table 1. Among the 1089 participants included in this analysis, 533 were in the intervention group and 556 were in the control group. The average age of the participants was 44.8 years (SD = 8.9). There were 682 (62.6 percent) women and 407 (37.4 percent) men. The race-ethnic groups included 428 (39.3 percent) non-Hispanic whites, 462 (42.4 percent) non-Hispanic blacks, and 199 (18.3 percent) Hispanics. Sixty-three percent of the participants had high school or higher education. The participants were about evenly distributed in the three eligible diagnostic groups: 32.1 percent in the SMI group, 34.9 percent in the PHC + BHC group, and 33.0 percent in the SMI + PHC + BHC group. The majority (76.2 percent) of the participants were classified as having "severe" health conditions based on the CRG classification system. We did not observe any significant differences in demographic characteristics between the participants in the intervention and control groups, except that there was a higher percentage of non-Hispanic blacks in the intervention group.

3.2 | SF-12 and patient activation scores

The means and standard deviations of the SF-12 and patient activation scores over the course of the study were also summarized in Table 1. At baseline, there were no significant differences between the intervention and control groups regarding the SF-12 PCS (34.1 vs 34.3; $t = 0.30$; $P = .764$) or MCS (36.5 vs 37.5; $t = 1.29$; $P = .198$) scores. However, at Year 3, the intervention group had higher PCS (38.1 vs 34.6; $t = -4.59$; $P < .001$) and MCS (43.7 vs 37.9; $t = -7.10$; $P < .001$) scores compared to the control group. For patient activation, there were no significant differences in the PAM scores between the intervention and control groups at baseline (60.8 vs 61.5; $t = 0.47$; $P = .640$). Both groups experienced an increase in patient activation during the study years. At Year 3, the intervention group had higher PAM scores (67.2 vs 64.8; $t = -2.21$; $P = .027$) compared to the control group.

TABLE 1 Participant characteristics

	Overall N = 1089	Intervention n = 533	Control n = 556	*P*-value
Age (SD)	44.8 (8.9)	45.3 (8.8)	44.3 (9.1)	.070
Sex				
Women	682 (62.6%)	332 (62.3%)	350 (62.9%)	.822
Men	407 (37.4%)	201 (37.4%)	206 (37.1%)	
Race-ethnicity				
Non-Hispanic white	428 (39.3%)	189 (35.5%)	239 (43.0%)	.004
Non-Hispanic blacks	462 (42.4%)	253 (47.5%)	209 (37.6%)	
Hispanics	199 (18.3%)	91 (17.1%)	108 (19.4%)	
Education				
Below high school	403 (37.0%)	180 (33.8%)	223 (40.1%)	.030
High school or higher	686 (63.0%)	353 (66.2%)	333 (59.9%)	
Census tract poverty % (SD)	22.9 (12.5)	23.0 (12.4)	22.7 (12.6)	
Diagnostic group				
SMI	350 (32.1%)	167 (31.3%)	183 (32.9%)	.766
PHC + BHC	380 (34.9%)	185 (34.7%)	195 (35.1%)	
SMI + PHC + BHC	359 (33.0%)	181 (34.0%)	178 (32.0%)	
Clinical risk groups				
Minor	55 (5.1%)	22 (4.1%)	33 (5.9%)	.262
Moderate	204 (18.7%)	95 (17.8%)	109 (19.6%)	
Severe	830 (76.2%)	416 (78.0%)	414 (74.5%)	
PCS (SD)				
Baseline	34.2 (11.3)	34.1 (11.0)	34.3 (11.7)	.764
Year 1	35.4 (11.4)	35.7 (11.4)	35.1 (11.4)	.352
Year 2	36.0 (11.5)	37.1 (11.3)	34.8 (11.6)	.002
Year 3	36.3 (11.5)	38.1 (11.3)	34.6 (11.3)	<.001
MCS (SD)				
Baseline	37.0 (12.5)	36.5 (12.6)	37.5 (12.4)	.198
Year 1	39.9 (12.2)	41.3 (12.2)	38.6 (12.1)	<.001
Year 2	40.1 (12.4)	41.9 (12.3)	38.2 (12.1)	<.001
Year 3	40.7 (12.6)	43.7 (12.3)	37.9 (12.3)	<.001
PAM (SD)				
Baseline	61.2 (16.2)	60.8 (15.7)	61.5 (16.5)	.640
Year 1	63.8 (16.2)	65.0 (16.1)	62.6 (16.2)	.017
Year 2	65.1 (16.9)	66.1 (16.3)	64.0 (17.5)	.058
Year 3	65.9 (17.1)	67.2 (17.4)	64.8 (16.9)	.027

Abbreviations: BHC, behavioral health conditions; MCS, mental component summary score; PAM, patient activation measure; PCS, physical component summary score; PHC, physical health conditions; SD, standard deviation; SMI, serious mental illness.

3.3 | Mixed-effects models for score change

We summarized the model coefficients from the final generalized linear mixed-effects models in Table 2. We also plotted the model predicted PCS, MCS, and PAM scores by group and study year in Figure 2. There was a significant intervention by year interaction in the models for the PCS (Intervention by Year 2: $B = 1.20$, $P = .037$; Intervention by Year 3: $B = 2.70$, $P < .001$) and MCS (Intervention by Year 3: $B = 2.74$, $P < .001$) scores (Table 2). As seen in Figure 2A,B, after controlling for demographic characteristics and health status, the PCS and MCS scores stayed unchanged across time among the participants in the control group. On the other hand, there was a significant increase in PCS and MCS scores among those in the intervention group. In the model for PAM, the intervention by year interaction was not a significant, but the intervention ($B = 2.63$, $P = .009$) and year (Year 2: $B = 1.60$, $P = .025$; Year 3: $B = 2.28$, $P = .002$) main effects

TABLE 2 Effect estimates from the final generalized linear mixed models

Characteristic	*B* Estimate	Standard error	*t*	*P*-value
Model 1: PCS				
Intercept	34.77	1.11	31.24	<.001
Male (vs Female)	0.95	0.46	2.08	.038
Race/Ethnicity —Black (vs White)	1.45	0.51	2.82	.005
Race/Ethnicity—Hispanic (vs White)	1.27	0.63	2.01	.045
Education—High school or Above (vs Below)	0.63	0.46	1.37	.170
Age	−0.08	0.03	−3.11	.002
CRG—Moderate (vs Minor)	0.25	1.10	0.22	.824
CRG—Severe (vs Minor)	−2.20	1.03	−2.14	.033
Census tract poverty	−0.02	0.02	−0.96	.336
Baseline PCS	0.60	0.03	23.68	<.001
Year 2 (vs 1)	0.16	0.41	0.39	.693
Year 3 (vs 1)	−0.41	0.44	−0.93	.354
Baseline PCS by Year 2	−0.02	0.03	−0.69	.487
Baseline PCS by Year 3	−0.08	0.03	−2.83	.005
Intervention	0.91	0.53	1.71	.088
Intervention by Year 2	1.20	0.57	2.09	.037
Intervention by Year 3	2.70	0.63	4.26	<.001
Model 2: MCS				
Intercept	37.04	1.31	28.22	<.001
Male (vs Female)	1.24	0.54	2.29	.022
Race/Ethnicity—Black (vs White)	0.90	0.60	1.49	.138
Race/Ethnicity—Hispanic (vs White)	0.72	0.74	0.97	.331
Education—High school or Above (vs Below)	0.34	0.54	0.63	.529
Age	−0.03	0.03	−1.12	.262
CRG—Moderate (vs Minor)	0.62	1.29	0.48	.631
CRG—Severe (vs Minor)	−0.02	1.20	−0.01	.989
Census tract poverty	0.002	0.02	0.08	.936
Baseline MCS	0.50	0.03	19.45	<.001
Year 2 (vs 1)	−0.35	0.53	−0.66	.510
Year 3 (vs 1)	−0.65	0.54	−1.21	.228
Baseline MCS by Year 2	−0.02	0.03	−0.67	.501
Baseline MCS by Year 3	−0.04	0.03	−1.24	.214
Intervention	3.24	0.64	5.02	<.001
Intervention by Year 2	0.92	0.75	1.23	.220
Intervention by Year 3	2.74	0.77	3.53	<.001
Model 3: PAM				
Intercept	61.42	2.20	27.98	<.001
Male (vs Female)	−1.18	0.90	−1.31	.192
Race/Ethnicity—Black (vs White)	−1.67	1.01	−1.65	.099
Race/Ethnicity—Hispanic (vs White)	−0.39	1.24	−0.32	.751
Education—High school or Above (vs Below)	2.53	0.90	2.82	.005
Age	−0.08	0.05	−1.62	.106
CRG—Moderate (vs Minor)	2.31	2.18	1.06	.290
CRG—Severe (vs Minor)	0.31	2.03	0.15	.878

(Continues)

TABLE 2 (Continued)

Characteristic	*B* Estimate	Standard error	*t*	*P*-value
Census tract poverty	0.06	0.04	1.59	.112
Year 2 (vs 1)	1.60	0.71	2.25	.025
Year 3 (vs 1)	2.28	0.74	3.11	.002
Intervention	2.63	1.00	2.63	.009
Intervention by Year 2	−0.74	1.01	−0.73	.467
Intervention by Year 3	−0.06	1.06	−0.06	.954

Note: Age, census tract poverty, baseline PCS, and baseline MCS were centered at the mean of their values.
Abbreviations: MCS, mental component summary score; PAM, patient activation measure; PCS, physical component summary score.

were significant (Table 2). As seen in Figure 2C, there was an increase in PAM scores for both the intervention and control groups across the study years, and the increase was greater in the intervention group.

3.4 | Longitudinal mediation models

We summarized results from the autoregressive mediation models in Table 3. The fit indices indicated good model fit for both PCS and MCS (RMSEA < 0.05, CFI/TFI > 0.95, and SRMR < 0.05). In the model for PCS, the total indirect effect was statistically significant (*B* = 1.30; SE = 0.44; *P* = .003). We identified two significant indirect paths between the intervention and PCS via patient activation: (a) Intervention→PAM1→PAM3→PCS3 (*B* = 0.06; SE = 0.03; *P* = .048) and (b) Intervention→PAM1→PAM2→PAM3→PCS3 (*B* = 0.03; SE = 0.02; *P* = .049). In the model for MCS, the total indirect effect was also statistically significant (*B* = 2.36; SE = 0.49; *P* < .001). We identified three significant indirect paths between the intervention and PCS via patient activation: (a) Intervention →PAM1→MCS1→MCS2→MCS3 (*B* = 0.11; SE = 0.05; *P* = .017), (b) Intervention→PAM1→MCS1→MCS3 (*B* = 0.12; SE = 0.05; *P* = .020), and (c) Intervention→PAM1→PAM2→MCS2→MCS3 (*B* = 0.08; SE = 0.04; *P* = .024).

4 | DISCUSSION

In this study, we found that the WIN intervention, which utilized navigators trained in MI and flexible wellness accounts, was effective in

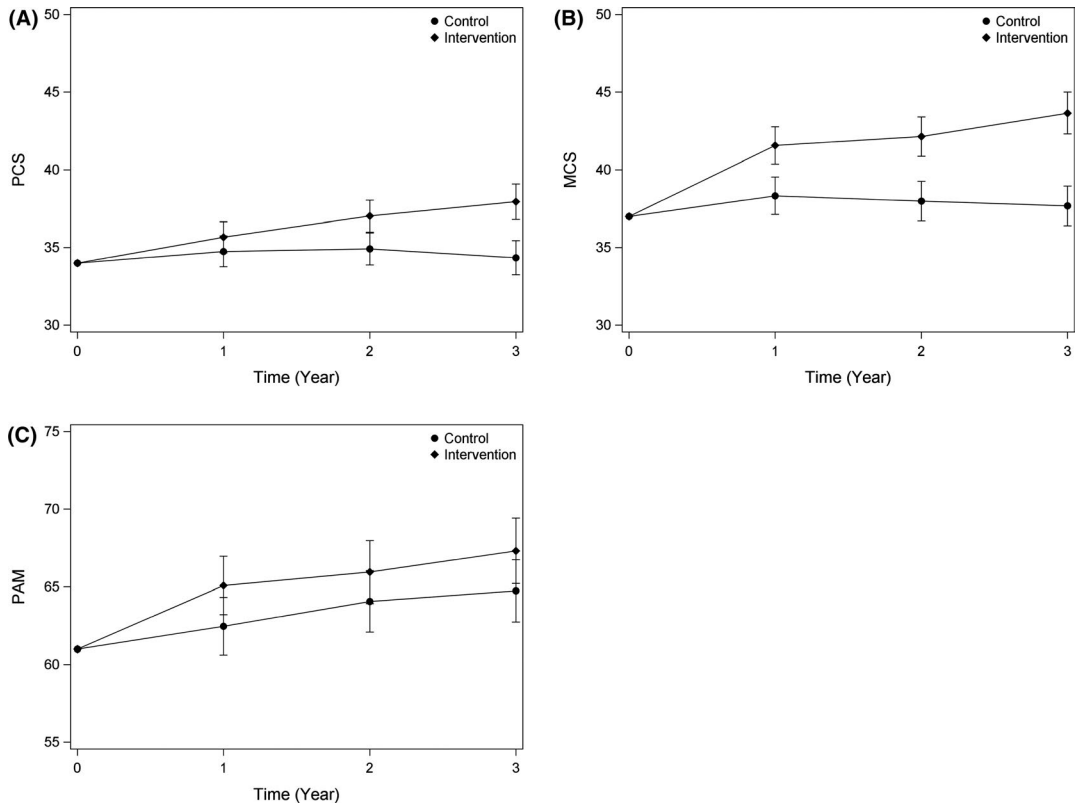

FIGURE 2 Model predicted SF-12 and patient activation scores by intervention group and year. A, Physical component summary (PCS) score. B, Mental component summary (PCS) score. C, Patient activation measure (PAM)

TABLE 3 Standardized path coefficients for longitudinal mediation models

	PCS		MCS	
Effects	**Estimate (SE)**	***P***	**Estimate (SE)**	***P***
Direct effect	3.65 (0.68)	<.001	2.94 (0.62)	<.001
Total indirect effect	1.30 (0.44)	.003	2.36 (0.49)	<.001
Indirect effects via PAM:				
Intervention→PAM1→QOL1→QOL2→QOL3	0.04 (0.02)	.056	0.11 (0.05)	.017
Intervention→PAM1→QOL1→QOL3	0.05 (0.02)	.058	0.12 (0.05)	.020
Intervention→PAM1→QOL2→QOL3	0.03 (0.03)	.265	−0.03 (0.03)	.357
Intervention→PAM1→PAM2→QOL2→QOL3	−0.01 (0.01)	.609	0.08 (0.04)	.024
Intervention→PAM1→PAM2→QOL3	−0.05 (0.04)	.165	−0.01 (0.04)	.697
Intervention→PAM1→PAM3→QOL3	0.06 (0.03)	.048	0.06 (0.03)	.055
Intervention→PAM1→PAM2→PAM3→QOL3	0.03 (0.02)	.049	0.04 (0.02)	.056
Model fit indices				
RMSEA (90% CI)	0.025 (0.000, 0.062)		0.041 (0.009, 0.075)	
CFI	0.999		0.997	
TFI	0.992		0.977	
SRMR	0.016		0.019	

Abbreviations: CFI, comparative fit index; MCS, mental component summary score; PAM, patient activation measure; PCS, physical component summary score; QOL, quality of life (PCS or MCS scores); RMSEA, root mean square error of approximation; SE, standard error; SRMR, standardized root mean square residual; TLI, Tucker-Lewis index.

increasing patient activation and HRQOL among Medicaid enrollees with co-occurring physical and behavioral health conditions. Over the 3 years, the PCS and MCS scores increased for the participants in the intervention group but not for those in the control group. Furthermore, we found that this intervention effect on HRQOL was partially mediated by patient activation.

The WIN intervention was designed to increase patient activation and in doing so to improve HRQOL. There is a growing body of research indicating that more activated individuals have better health outcomes and lower heath care cost, and our study contributes to these findings.[31] Compared to less activated individuals, those with higher activation scores are more likely to engage in healthy behavior such as regular exercise, and avoid high-risk behavior such as smoking. Among people with chronic conditions, those with higher activation scores are more compliant with treatment plans and better at performing self-monitoring and self-management of conditions at home.

The participants in the control group also experienced an increase in patient activation, but not in HRQOL. The reasons for this finding are not entirely clear. The control group participated in annual surveys and received incentives for completing these surveys and for monthly verification of contact information. It is possible that the small financial incentives and the act of asking about patient activation in the annual surveys increased the control group participants' feelings of activation. However, in the absence of any other intervention, HRQOL did not improve.

The success of the WIN intervention suggests that increasing patient activation may be a good strategy for designing intervention that aims to improve long-term health outcomes in this chronically ill and costly population. As a pragmatic trial, the WIN project tested the real-world effectiveness of an intervention for improving health outcomes among Medicaid enrollees. The personal navigators were hired and embedded within Medicaid managed care plans, which are the usual source of care for the intended target population of the intervention. In addition, the unique patient-centered approach used by the intervention ensured its adaptability to individual needs. Although monitored through in-person and telephone meetings, the participants were able to develop personalized wellness goals and decide how to spend the funds in flexible expense account with the help from the navigators. This patient-centered approach to incentives empowered participants by giving them control over what health services they need. Therefore, it can be more cost-effective and responsive than traditional interventions, especially among individuals who need long-term support managing chronic conditions or disabilities.[32,33] The pragmatic nature of the project maximizes the chance of successful implementation of the WIN intervention if Medicaid programs and their participating health plans wish to implement such a program.

There are several strengths of our study. First, as a pragmatic trial, our study produced results that can be generalized and applied in the real-world settings. Second, in this behavioral intervention, we collected 3-year longitudinal data from the participants.

Most behavioral interventions are much shorter in duration, and it is difficult to assess whether behavior change sustains across a long period of time. Also, the findings of this study should be interpreted in the context of its limitations. First, our study participants were a heterogeneous group of patients with different comorbid mental and physical conditions. Future research could evaluate how the intervention components would work among patients with a specific disease such as diabetes. Second, we were unable to evaluate the effectiveness of each intervention component separately due to the pragmatic trial nature of the study design. Nonetheless, our study provided valuable information on how the combination of navigators and flexible wellness accounts could improve patient activation and HRQOL in the context of state Medicaid programs. Third, we did not evaluate the improvement in individual wellness goals because it was financially impossible for the project. There were many wellness goals set by the participants, and many of the goals, such as eating habits and bodily pain, could not be easily measured, tracked, or evaluated individually.

5 | CONCLUSION

The WIN intervention, which combines navigators trained in MI and flexible wellness accounts, is an effective strategy for improving patient activation and health outcomes among Medicaid enrollees with co-occurring physical and behavioral health conditions. Increasing patient activation is the behavior mechanism through which the WIN intervention achieves its effect on HRQOL. Future interventions aiming to improve health outcomes can consider including strategies to promote patient activation.

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CONFLICT OF INTEREST

None.

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REFERENCES

1. Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry*. 2005;62(6):617-627.
2. Harvard Medical School. National comorbidity survey [Internet]. Boston, MA: Harvard Medical School; 2005. https://www.hcp.med.harvard.edu/ncs/index.php. Accessed August 6, 2019.
3. Sareen J, Afifi TO, McMillan KA, Asmundson G. Relationship between household income and mental disorders: findings from a population-based longitudinal study. *Arch Gen Psychiatry*. 2011;68(4):419-427.
4. National Center for Chronic Disease Prevention and Health Promotion. National diabetes statistics report [Internet]. Atlanta, GA: National Center for Chronic Disease Prevention and Health Promotion; 2017. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Accessed August 6, 2019.
5. Stokes A, Preston SH. Deaths Attributable to diabetes in the United States: comparison of data sources and estimation approaches. *PLoS ONE*. 2017;12(1):e0170219.
6. Centers for Disease Control and Prevention. Vital signs: current cigarette smoking among adults aged ≥18 years with mental illness: United States, 2009–2011. *MMWR Morb Mortal Wkly Rep*. 2013;62(5):81-87.
7. Centers for Disease Control and Prevention. Smoking-attributable mortality, years of potential life lost, and productivity losses–United States, 2000–2004. *MMWR Morb Mortal Wkly Rep*. 2008;57(45):1226-1228.
8. Kilbourne AM, Rofey DL, McCarthy JF, Post EP, Welsh D, Blow FC. Nutrition and exercise behavior among patients with bipolar disorder. *Bipolar Disord*. 2007;9(5):443-452.
9. Simon GE, Von Korff M, Saunders K, et al. Association between obesity and psychiatric disorders in the US adult population. *Arch Gen Psychiatry*. 2006;63(7):824-830.
10. Colton CW, Manderscheid RW. Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states. *Prev Chronic Dis*. 2006;3(2):A42.
11. Banerjea R, Sambamoorthi U, Smelson D, Pogach LM. Chronic illness with complexities: mental illness and substance use among Veteran clinic users with diabetes. *Am J Drug Alcohol Abuse*. 2007;33(6):807-821.
12. Centers for Medicare & Medicaid Services. March 2018 Medicaid & CHIP enrollment data highlights [Internet]. Baltimore, MD: Centers for Medicare & Medicaid Services; 2018. https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html. Accessed August 6, 2019.
13. Substance Abuse and Mental Health Services Administration. Reports and detailed tables from the 2015 National Survey on Drug Use and Health (NSDUH) [Internet]. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2015. https://www.samhsa.gov/samhsa-data-outcomes-quality/major-data-collections/reports-detailed-tables-2015-NSDUH. Accessed August 6, 2019.
14. Centers for Medicare & Medicaid Services. Physical and Mental Health Integration [Internet]. Baltimore, MD: Centers for Medicare & Medicaid Services; 2018. https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/program-areas/physical-and-mental-health-integration/index.html. Accessed August 6, 2019.
15. Centers for Medicare & Medicaid Services. Medicaid incentives for the prevention of chronic diseases model [Internet]. Baltimore, MD: Centers for Medicare & Medicaid Services; 2018. https://innovation.cms.gov/initiatives/mipcd. Accessed August 6, 2019.
16. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *J Gen Intern Med*. 2012;27(5):520-526.
17. Terry PE, Fowles JB, Xi M, Harvey L. The ACTIVATE study: results from a group-randomized controlled trial comparing a traditional

worksite health promotion program with an activated consumer program. *Am J Health Promot*. 2011;26(2):e64-e73.
18. Frosch DL, Rincon D, Ochoa S, Mangione CM. Activating seniors to improve chronic disease care: results from a pilot intervention study. *J Am Geriatr Soc*. 2010;58(8):1496-1503.
19. Druss BG, Zhao L, von Esenwein SA, et al. The Health and Recovery Peer (HARP) Program: a peer-led intervention to improve medical self-management for persons with serious mental illness. *Schizophr Res*. 2010;118(1):264-270.
20. Hibbard JH, Greene J, Tusler M. Improving the outcomes of disease management by tailoring care to the patient's level of activation. *Am J Manag Care*. 2009;15(6):353-360.
21. Butterworth SW, Linden A, McClay W. Health coaching as an intervention in health management programs. *Dis Manag Health Outcomes*. 2007;15(5):299-307.
22. Shenkman E, Muller K, Vogel B, et al. The wellness incentives and navigation project: design and methods. *BMC Health Serv Res*. 2015;15:579.
23. Texas Health and Human Services. STAR+PLUS [Internet]. Austin, TX: Texas Health and Human Services; 2019. https://hhs.texas.gov/services/health/medicaid-chip/programs/starplus. Accessed August 6, 2019.
24. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34(3):220-233.
25. Huo T, Guo Y, Shenkman E, Muller K. Assessing the reliability of the short form 12 (SF-12) health survey in adults with mental health conditions: a report from the wellness incentive and navigation (WIN) study. *Health Qual Life Outcomes*. 2018;16(1):34.
26. Salyers MP, Bosworth HB, Swanson JW, Lamb-Pagone J, Osher FC. Reliability and validity of the SF-12 health survey among people with severe mental illness. *Med Care*. 2000;38(11):1141-1150.
27. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health Serv Res*. 2005;40(6 Pt 1):1918-1930.
28. Hughes JS, Averill RF, Eisenhandler J, et al. Clinical Risk Groups (CRGs): a classification system for risk-adjusted capitation-based payment and health care management. *Med Care*. 2004;42(1):81-90.
29. Gupta SK. Intention-to-treat concept: a review. *Perspect Clin Res*. 2011;2(3):109-112.
30. MacKinnon DP. *Introduction to Statistical Mediation Analysis*. Abingdon, UK: Routledge; 2008.
31. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff (Millwood)*. 2013;32(2):207-214.
32. Benjamin AE. Consumer-directed services at home: a new model for persons with disabilities. *Health Aff (Millwood)*. 2001;20(6):80-95.
33. Kodner DL. Consumer-directed services: lessons and implications for integrated systems of care. *Int J Integr Care*. 2003;3(2):e12.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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