ACM-2019-0079-ver9-Emmert-aronson_1P
Type: research-article

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 00, Number 00, 2019, pp. 1–9

DOI: 10.1089/acm.2019.0079

JACM

ORIGINAL ARTICLE

Group Medical Visits 2.0: The Open Source Wellness Behavioral Pharmacy Model

AU1 ▶ Benjamin Emmert-Aronson, PhD,[1] Katherine B. Grill, PhD,[2] Zalak Trivedi, MS,[3]
Elizabeth A. Markle, PhD,[1] and Steven Chen, MD[3]

Abstract

Objectives: The Open Source Wellness (OSW) model was designed to function as a behavioral pharmacy; an affordable, accessible delivery system for a universal *experiential* prescription: MOVE (physical activity), NOURISH (healthy meals), CONNECT (social support), and BE (stress reduction). This study evaluates the OSW model in a billable group medical visit (GMV) format in a federally qualified health center (FQHC).

Intervention: Patients with behaviorally mediated conditions, including cardiovascular disease, diabetes, and depression, as well as poor social determinants of health, such as food insecurity, were prescribed participation in the OSW program by their medical team. Groups met for 2 h each week for 16 weeks to complete 30 min of socially engaging physical activity, 5 min of mindfulness meditation, a 10-min interactive, didactic health lesson, a 5-min nutrition lesson, and 60 min of small-group coaching over a plant-based meal. Paraprofessional health coaches worked with participants in small groups to provide support and create accountability to goals. In addition, participants received a $10 voucher to Food Farmacy, which provided free produce.

Subjects: The sample consisted of 49 patients from the Hayward Wellness Center, an FQHC in Hayward, California. They were mostly women, 59.6%, and racially and ethnically diverse: 23.1% African American, 5.8% Asian, 26.9% Hispanic/Latino, 11.5% Pacific Islander, and 32.7% Caucasian. Participants averaged 59.1 years of age (SD = 10.6).

Outcome measures: Blood pressure and weight were recorded weekly. Demographic and acute care utilization data were drawn from the electronic medical record. Self-report questionnaires assessed diet, exercise, and mood on a monthly basis.

Methods and results: Longitudinal data were analyzed with linear mixed models. Participants ($n = 49$) demonstrated significant increases in daily servings of fruits and vegetables, $b = 0.31$, $p < 0.01$, and exercise, $b = 11.50$, $p < 0.01$, as well as significant reductions in body mass index, $b = -0.10$, $p = 0.05$. Acute care utilization decrease was not statistically significant, $b = -0.07$, $p = 0.14$. Depressed patients ($n = 11$) saw reductions in depression, $b = -1.72$, $p < 0.01$, and hypertensive patients ($n = 24$) saw reductions in systolic blood pressure, $b = -4.04$, $p < 0.01$, but not diastolic blood pressure, $b = 0.04$, $p = 0.95$.

Conclusions: This study demonstrates the effectiveness of the OSW behavioral pharmacy model within a GMV context; pathways for adaptation, spread/scale, and incorporation of this work as a component of the broader health ecosystem and national commitment to health equity are discussed.

AU3 ▶ **Keywords:** behavioral medicine, chronic disease, healthcare delivery, underserved populations

AU2 ▶ [1]Open Source Wellness, San Francisco, California.
[2]California Institute of Integral Studies, San Francisco, California.
[3]Alameda Health System, Oakland, California.

Introduction

AU4 ▶ CHRONIC, PROGRESSIVE, AND preventable health conditions such as diabetes, depression, and hypertension are driving tremendous human suffering and over 85% of health care spending nationally.[1] While the origins of these conditions are multifactorial, all are substantially driven by the *behaviors* and *experiences* that underlie human health and well-being. Savvy health care providers across clinical specialties and patient diagnoses are offering a stunningly consistent set of behavioral prescriptions: ''Exercise more! Eat better! Reduce your stress! Get some social support!'' Unlike the national infrastructure for delivery of medications (i.e., pharmacies), there is lack of an affordable, accessible, and experiential delivery system for behaviors and experiences that drive human health and well-being. For many of the patients most negatively affected by social determinants of health (SDOH), well-intended behavioral prescriptions are essentially a prescription to nowhere, and patients, providers, emergency departments, and health systems bear the brunt of this glaring gap in the health ecosystem.

Open Source Wellness Behavioral Pharmacy

The Open Source Wellness (OSW) model was designed to function as a behavioral pharmacy or an affordable, accessible delivery system for prescriptions that are behavioral and experiential in nature. The model animates clinical, community, housing, and corporate settings as a platform for a universal four-part prescription: MOVE (physical activity), NOURISH (healthy meals), CONNECT (social support), and BE (stress reduction). When patients are given behavioral prescriptions, such as exercise more or eat healthier, this behavioral pharmacy model allows them to experientially fill those prescriptions through socially engaging physical activity, mindfulness meditation, a hearty plant-based snack, and small-group coaching.

The current study evaluates the effectiveness of clinic-based group medical visit (GMV) integration of the OSW behavioral pharmacy model in a federally qualified health center (FQHC) in Hayward, California. The transdiagnostic and collaborative approach integrates downstream clinical care with upstream community-based partnerships to address the behaviors (including physical activity, stress reduction, and nutrition) and SDOH (including food insecurity and social isolation) that drive health outcomes.

Physical health, mental health, and the evidence for behavioral programs

Chronic diseases such as diabetes and cardiovascular disease (CVD) can cause physical pain, disability, and reduced quality of life.[2,3] For patients living with a chronic disease, psychiatric comorbidities such as depression frequently occur. Psychiatric comorbidities complicate treatment by decreasing self-management ability, increasing medical costs, and reducing life expectancy.[3] Even after controlling for blood pressure, glycated hemoglobin (HbA1c), lipids, body mass index, aspirin use, tobacco, alcohol, living alone, and educational level, comorbid clinical depression was found to be a risk factor for mortality in patients with diabetes and cardiac risk.[4]

In recent years, there has been increased interest in teaching these patients behavioral self-management techniques due to the failure of medication alone to sufficiently treat chronic diseases.[2,5,6] Providing group-based educational programs for patients has demonstrated effectiveness across various dimensions of health: improved pain management, decreased depression, increased frequency of exercise, and increased relaxation.[2,7] Such behavioral programs also reduce health care utilization and increase patient self-efficacy: patients gain the knowledge and confidence they need to address health-related issues on their own in between office visits to their primary care provider.[2,6,7]

Nutrition and exercise

Nutrition and exercise programs have demonstrated positive results for patients with chronic diseases. Specifically, patients with diabetes and CVD have benefitted from achieving decreased plasma glucose and weight loss[8,9] as well as decreased overall mortality, decreased disability, and improved quality of life.[10,11] Plant-based (vegan) diets in particular have yielded reductions in HbA1c, low-density lipoprotein cholesterol, and weight that were greater than reductions from following the standard American Diabetes Association nutrition guidelines[12,13] and have acceptable adherence.[14]

Stress reduction

Stress reduction interventions have been shown to have beneficial effects on chronic disease management. A 1-day health education + acceptance and commitment therapy program showed improved HbA1C values 3 months postintervention compared with health education alone.[15] Other studies have shown that participation in a mindfulness program (MBSR, MBCT, MSC, or other mindfulness meditation intervention) resulted in decreased HbA1c, mean arterial pressure, hypertension, blood norepinephrine, depression, anxiety, and stress, as well as improved quality of life in patients with diabetes or cardiac conditions.[16–20]

Social connection

Poor social relationships have been associated with a 29% increase in risk of incident coronary heart disease and a 32% increase in risk of stroke.[21] A lack of social connections is related to decreased happiness and health as well as increased risk for mortality.[22–25] Happiness is negatively correlated with depression, anxiety, and poor health, but positively correlated with social support.[26] These results suggest that behavioral strategies that emphasize social connection are an important addition to patient self-management programs for chronic diseases.

Group Medical Visits

GMVs are gaining more attention as a primary care intervention as the rate of chronic illnesses increases.[27] GMVs offer an interactive setting with increased access to providers, patient agency in their health care, and social support.[28] Patients engaging in GMVs report increased self-efficacy and satisfaction with care and quality of life, as well as improvements in blood pressure, cholesterol, blood glucose, obesity, and HbA1c.[28–30] Increasing patient self-efficacy for disease management is a particularly important component for satisfaction and engagement in continued behavior

change.[30] This work has been especially important within FQHCs for both its economic efficacy and improved patient outcomes.[31–34] More work is needed to understand how to use GMVs in diverse patient populations for optimal primary care and behavior change support.

Objectives and hypotheses

The objective of this study was to evaluate the OSW behavioral pharmacy model for patients with chronic diseases at an FQHC. The current study investigates behavioral, physical, and emotional outcomes of the OSW model using a longitudinal, repeated-measures single-arm design. Participant changes over time were analyzed in regard to (1) fruit and vegetable intake, (2) physical activity, (3) depression, (4) blood pressure, (5) body mass index (BMI), and (6) acute care utilization. It was hypothesized that participants would have increased fruit and vegetable intake and physical activity as well as decreased depressive symptoms, blood pressure, BMI, and acute care utilization following program completion.

Materials and Methods

Participants

The sample consisted of 49 patients from the Hayward Wellness Center (HWC), an FQHC in Hayward, California. HWC is part of the Alameda Health System. The providers from this system referred their patients to a weekly health and wellness GMV run by OSW and HWC staff. English-speaking adult patients were referred to the GMV for a wide variety of behaviorally mediated clinical concerns, such as diabetes, prediabetes, cardiac disease, hypertension, dyslipidemia, obesity, anxiety, and depression. Patients were also referred if they screened positive for food insecurity, as assessed by HWC staff, based on the broad literature linking food insecurity with chronic disease.[35] Exclusion criteria included acute suicidality and inability to participate appropriately in a group setting, both determined by the referring provider. There were no other inclusion or exclusion criteria. This evaluation was approved by the Alameda Health System Institutional Review Board.

Measures

Data were gathered through a combination of biomarkers, the electronic medical record (EMR), and self-report questionnaires. Blood pressure and weight were recorded weekly by HWC staff at the beginning of the GMV on a Welch Allyn Vital Signs Monitor 6000 series and Health O Meter Professional, model 600KL, respectively. Demographic data (i.e., race and ethnicity, age, and gender), medication data (i.e., changes to antidepressant and antihypertensive medications), and acute care utilization were drawn from the EMR. Acute care utilization consisted of emergency department visits and unplanned hospitalizations. The authors examined the number of emergency department visits or days spent in the hospital for 6 months before participants joined the group compared with the 6 months following their graduation from the group. Self-report questionnaires were used to assess diet, exercise, and mood, as follows.

Two-item Food Frequency Questionnaire. This questionnaire asks participants how many servings of fruits and vegetables they have eaten in the past week.[36] It has been validated against longer measures of food intake.[37]

Exercise vital sign. This two-item questionnaire assesses the number of minutes of moderate or vigorous activity engaged in per week.[38] It has been found to have good face and discriminant validity and is more conservative than population-based surveys, potentially reflecting decreased response bias.[38]

Patient Health Questionnaire-9. The Patient Health Questionnaire-9 (PHQ-9) is the most widely used assessment of depression and shows excellent sensitivity and specificity when compared with structured clinical assessments.[39] The PHQ-9 is a reliable and valid measure of both depression and depression severity, demonstrating good internal consistency ($\alpha = 0.83$–0.92), convergent and discriminant validity, and responsiveness to change.[39–41]

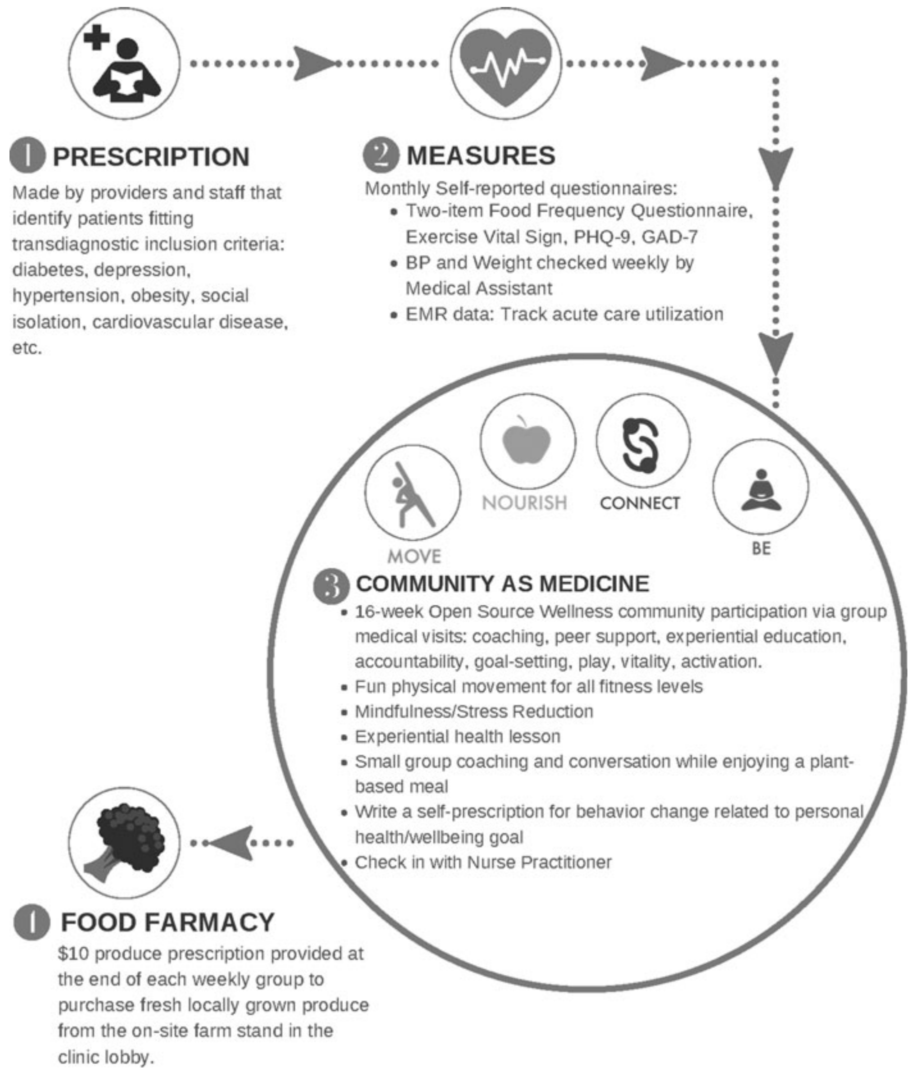
Procedures

As described above, the OSW behavioral pharmacy model is an experiential, accessible, socially rewarding delivery system for fundamental and transdiagnostic behavioral prescriptions: MOVE, NOURISH, CONNECT, and BE (Fig. 1). ◀F1

Patients were referred to the OSW behavioral pharmacy GMV by HWC staff members, including their primary care providers, dietitians, clinical pharmacists, social workers, and medical assistants. Participants joined 4-month cohorts, with a total of 16 weekly 2-h meetings on Thursday afternoons. New participants began a cohort the first week of each month, allowing for overlap between naïve and experienced participants to facilitate building a group culture.

Groups met weekly and consisted of the following structure: 30 min of socially engaging physical activity accommodating various mobility levels, 5 min of mindfulness meditation, a 10-min interactive didactic lesson on varied health topics, a 5-min nutrition lesson, a hearty plant-based snack, and 60 min of small-group coaching.

The mindfulness meditations were led by health coaches and covered a wide variety of practices, including focus on breathing, gratitude, progressive muscle relaxation, and walking meditations. The meals were plant based both because of the data demonstrating health benefits (e.g., eating a plant-based diet led to greater improvements in diabetes than following the American Diabetes Association dietary guidelines[14]) and simplified dietary concerns. Whether participants were vegetarian, vegan, kosher, or halal, etc., a vegan diet would work for them. However, participants were not instructed to follow a specific diet. Instead, general dietary principles (i.e., increasing vegetable consumption and decreasing sugar intake) were discussed and applied. Participants were encouraged and coached to make individual dietary adjustments in ways that were culturally relevant and paced appropriately to their level of motivation and focus on diet. For example, one participant's goal was to change from triple cheeseburgers for lunch to double cheeseburgers, a goal which was supported and applauded. The interactive didactics covered a range of health and well-being topics, including eating healthy on a budget, turning exercise into play, self-care, boundary setting, and habit change. Coaches were internally credentialed and underwent ongoing training and



AU12 ► **FIG. 1.** Open Source Wellness group medical visit patient flow. EMR, electronic medical record;
AU13 ► GAD-7; PHQ-9, Patient Health Questionnaire-9.

weekly supervision. The small-group health coaching expanded on the didactic topic of the day and focused on habit change, motivational interviewing, and social support. A peer leader who had completed his/her own 4-month cohort, applied for, and been accepted to the peer leadership program assisted with supportive coaching as well. Each week, at the end of the small group, participants would write their personal behavioral prescription, describing the behavior change they sought to make that week (e.g., drink one bottle of water instead of one can of soda per day, walk 30 min four times this week, and set a personal boundary in a challenging re-
AU5 ► lationship). Coaches engaged small groups through text messages in between weekly meetings to provide continuity, support, and accountability. Last, a nurse practitioner was part of the group, seeing participants individually throughout the group as well as interacting within the group setting. This allowed for more frequent (weekly vs. every 6 months) medication checks and refills, immunizations, and interdisciplinary team referrals, etc. It was also meant to increase patients' sense of self-accountability toward self-prescribed goals and how they related to their clinical outcomes.

Patients were also given a produce prescription voucher at the end of each weekly session. These produce prescriptions allowed purchase of $10 worth of produce at the Food Farmacy, a farm stand located within the clinic's lobby. This amplified the dose effect of the model by increasing weekly access to vegetables at no cost to the patients. Furthermore, the nutrition lesson incorporated the vegetables available at the Food Farmacy to increase patients' familiarity of taste and confidence in cooking those vegetables at home.

Questionnaire data were collected monthly at the beginning of group sessions by participant self-report. Blood pressure and weight were taken weekly by MAs. There was ◄ AU6
no control group for this open evaluation.

Data analysis

Descriptive data are summarized with means and standard deviations, if continuous, or counts and percentages, if categorical. Age is summarized using mean and standard deviation. Race, ethnicity, and gender are summarized using counts and percentages.

Analysis of longitudinal data presents unique challenges and opportunities not faced in the analysis of cross-sectional data. While additional measurement points offer more nuanced data, allowing for the clear tracking of change over

time, they also violate assumptions of independence of errors, requiring specialized analyses.

Linear mixed models (LMM) were used to account for the longitudinal nature of data as well as to make full use of all available data. This is a particularly strong advantage as listwise deletion of participants' missing data not only dramatically reduces power but also biases parameter estimates.[42] Intercepts for subjects were specified as random effects, allowing for evaluation of the outcome of interest at each assessment point (e.g., blood pressure at pretest and 1, 2, 3, and 4 months) with participants treated as independent. Fixed effects were specified for the outcome variable of interest (i.e., diet, exercise, blood pressure, depression, BMI, and acute care) as well as potential covariates (i.e., gender and minority status, as well as medication changes when assessing blood pressure and depression).

While full group outcomes are reported for completeness, hypertension and depression outcomes were also examined within subgroups. Because participant diagnoses varied widely, many participants were not expected to show changes in both domains (e.g., a participant with hypertension, but normal mood). The hypertensive subset included participants with systolic blood pressure over 130 mmHg at baseline. The depressed subset included participants with a PHQ-9 score of 10 or higher at baseline. In each case, these indicate clinically concerning levels.[39,43] Baseline characteristics were compared between subgroups using chi-square tests for categorical variables and two-sample t-tests for continuous variables. Data were analyzed with R, version 3.3,[44] and R Commander, version 2.3.[45] LMM were estimated using the lme4 package,[46] and *p*-values were estimated using the lmerTest package.[47] The alpha level was set at $p < 0.05$. The authors included data for participants who completed questionnaires at least 2 months after their intake, with 2 months constituting a minimum dose.

Results

Participants

Of the 130 participants who were referred, 49 attended for at least 2 months and filled out questionnaires at least 2 months after their intake. Women constituted the larger proportion of the sample (59.6%). Racially and ethnically the sample was diverse: 23.1% African American, 5.8% Asian, 26.9% Hispanic/Latino, 11.5% Pacific Islander, and 32.7% Caucasian. Participants averaged 59.1 years of age
T1 ► (SD = 10.6; see Table 1). Weekly group size ranged from 8 to 31 participants, with an average group size of 17.5 (SD = 5.5) participants. Reasons for participants not beginning or continuing the group included time conflicts with work or childcare, preferences for one-on-one appointments, and inability to commit to weekly groups.

Table 1. Participant Demographics ($N = 49$)

Demographics			
Race/ethnicity	*Full group,* n *(%)*	*Hypertensive,* n *(%)*	*Depressed,* n *(%)*
African American	12 (24.5)	6 (25.0)	4 (36.4)
Asian	3 (6.1)	0 (0.0)	1 (9.1)
Hispanic/Latinx	14 (28.6)	6 (25.0)	4 (36.4)
Pacific Islander	6 (12.2)	3 (12.5)	0 (0.0)
Caucasian	14 (28.6)	9 (37.5)	2 (18.2)
Total	49 (100)	24 (100)	11 (100)
Gender			
Male	18 (36.7)	13 (54.2)	5 (45.5)
Female	31 (63.3)	11 (45.8)	6 (54.6)
Transgender	0 (0)	0 (0)	0 (0)
Total	49 (100)	24 (100)	11 (100)
	Mean (SD)	*Mean (SD)*	*Mean (SD)*
Age, years	59.1 (10.6)	59.7 (11.6)	58.5 (10.6)

Full group outcomes

Examining the full-group data, $n = 49$, participants demonstrated a significant increase in daily servings of fruits and vegetables, b = 0.31, $p < 0.01$, as well as exercise, b = 11.50, $p < 0.01$. They also saw reductions in depression, b = –0.50, $p < 0.01$, systolic blood pressure, b = –1.68, $p = 0.03$, and BMI, b = –0.10, $p = 0.05$. Changes in diastolic blood pressure and acute care utilization were not significant, b = 0.09, $p = 0.85$, and b = –0.07, $p = 0.14$, respectively, likely due to floor effects. Neither variable was elevated at baseline. Overall acute care utilization decreased by 77%, from 22 ED visits/days of unplanned hospitalizations for the entire ◄ AU7
group in the 6 months before joining the group to five visits in the 6 months following group completion. See Table 2 for ◄ T2
estimated marginal means of outcome variables at each time point.

Subgroup outcomes

There were 11 (22.5%) participants in the depressed subgroup (PHQ-9 ≥ 10), 24 (49.0%) in the hypertensive subgroup (systolic blood pressure ≥130), and six (12.2%) participants in both subgroups. Participants did not differ on race or age by subgroup (hypertensive subgroup: χ^2 (4) = 2.25, $p = 0.69$, t(71) = 0.07, $p = 0.94$; depressed subgroup: χ^2 (4) = 2.79, $p = 0.59$, t(58) = 0.05, $p = 0.95$, respectively). While gender did not significantly differ by either subgroup (hypertensive: χ^2 (1) = 3.14, $p = 0.08$; depressed: χ^2 (1) = 0.36, $p = 0.55$), it is noteworthy that the effect size in the hypertensive subgroup, for this relatively small sample, was large, d = 0.78.

When examining the depressed subgroup, $n = 11$, participants showed a significant decrease in depression, b = –1.72, $p < 0.01$. When examining the hypertensive subgroup, $n = 24$, participants showed a significant decrease in systolic blood pressure, b = –4.04, $p < 0.01$, but not diastolic blood pressure, b = 0.04, $p = 0.95$.

Discussion

Principal findings

This study assessed a behavioral pharmacy model for patients with chronic conditions. In a group-based intervention over the course of 4 months, patients learned and practiced health behaviors related to nutrition, exercise, stress management, and social support. Outcomes include significant changes in health behavior related to nutrition

Table 2. Group Means and Standard Deviations

	Group means and standard deviations					
	Baseline	*1 Month*	*2 Months*	*3 Months*	*4 Months*	p-*Value**
Fruits and vegetables (daily servings)						
Full group, $n=49$	5.19 (0.39)	5.5 (0.36)	5.81 (0.36)	6.12 (0.38)	6.43 (0.43)	<0.01
Hypertensive subgroup, $n=24$	5.25 (0.6)	5.52 (0.55)	5.8 (0.54)	6.08 (0.58)	6.35 (0.65)	0.08
Depressed subgroup, $n=11$	4.22 (0.71)	4.46 (0.65)	4.71 (0.65)	4.96 (0.69)	5.2 (0.78)	0.20
Exercise (minutes per week)						
Full group, $n=49$	82.91 (13.12)	94.41 (12.24)	105.9 (12.14)	117.4 (12.83)	128.9 (14.18)	<0.01
Hypertensive subgroup, $n=24$	82.9 (19.39)	90.39 (18.05)	97.87 (17.79)	105.35 (18.65)	112.84 (20.49)	0.10
Depressed subgroup, $n=11$	64.46 (30.14)	76.84 (28.45)	89.23 (28.31)	101.61 (29.75)	114 (32.54)	0.08
Depression (PHQ-9)						
Full group, $n=49$	6.64 (0.76)	6.14 (0.72)	5.64 (0.72)	5.13 (0.75)	4.63 (0.81)	<0.01
Hypertensive subgroup, $n=24$	6.35 (1.19)	5.79 (1.13)	5.23 (1.12)	4.68 (1.16)	4.12 (1.23)	0.02
Depressed subgroup, $n=11$	14.53 (1.23)[a,b]	12.82 (0.93)[a,b]	11.1 (0.88)[a,b]	9.38 (1.12)[a,b]	7.66 (1.51)	<0.01
Blood pressure (systolic)						
Full group, $n=49$	133.3 (2.37)	131.61 (2.07)	129.93 (2.03)	128.25 (2.26)	126.56 (2.7)	0.03
Hypertensive subgroup, $n=24$	146.06 (2.98)[a]	142.02 (2.5)[a]	137.98 (2.4)	133.94 (2.72)	129.9 (3.35)	<0.01
Depressed subgroup, $n=11$	130.62 (5.44)	129.46 (4.44)	128.29 (4.32)	127.12 (5.14)	125.95 (6.55)	0.58
Blood pressure (diastolic)						
Full group, $n=49$	75.5 (1.35)	75.59 (1.1)	75.69 (1.06)	75.79 (1.25)	75.88 (1.59)	0.85
Hypertensive subgroup, $n=24$	76.87 (1.61)	76.92 (1.22)	76.96 (1.13)	77 (1.39)	77.05 (1.87)	0.95
Depressed subgroup, $n=11$	78.55 (3.98)	78.38 (3.21)	78.21 (3.11)	78.04 (3.74)	77.86 (4.82)	0.91
Body mass index						
Full group, $n=49$	37.15 (1.76)	37.05 (1.76)	36.95 (1.76)	36.86 (1.76)	36.76 (1.76)	0.05
Hypertensive subgroup, $n=24$	41.45 (3.13)	41.36 (3.13)	41.27 (3.13)	41.19 (3.13)	41.1 (3.13)	0.27
Depressed subgroup, $n=11$	42.8 (6.45)	42.93 (6.45)	43.07 (6.45)	43.2 (6.45)	43.33 (6.46)	0.26
Acute care (ER visits or hospitalizations in previous 6 months)						
Full group, $n=49$	0.35 (0.1)	0.28 (0.08)	0.22 (0.08)	0.15 (0.1)	0.09 (0.13)	0.14
Hypertensive subgroup, $n=24$	0.21 (0.1)	0.21 (0.08)	0.21 (0.08)	0.21 (0.09)	0.21 (0.12)	0.99
Depressed subgroup, $n=11$	0.19 (0.12)	0.18 (0.09)	0.18 (0.09)	0.18 (0.12)	0.18 (0.16)	0.96

*p-Value of change over time in linear mixed models, accounting for gender, minority status, and fixed intercept effect of person.
[a]Differs from the full group, $p<0.05$.
[b]Differs from the hypertensive group, $p<0.05$.
AU11 ▶ ER; PHQ-9, Patient Health Questionnaire-9.

and exercise and significant decreases in systolic blood pressure for patients with hypertension, in depressive symptoms in depressed patients, and in BMI for the full group. This was true even after accounting for changes in antihypertensive and antidepressant medications. Consistent with previous research on GMVs, the OSW model offered an interactive setting with increased access to providers, patient agency in their health care, and social support.[28] Patients engaging in the OSW model likewise reported improvements in blood pressure and obesity,[28,29] as well as additional improvements in nutrition, exercise, and mood.

Strengths and limitations

There are several limitations to this research, primarily concerning study design. Foremost, this was a nonrandomized, uncontrolled single-arm design. Without a control group for comparison, it is possible that participant health changes were related to factors other than the intervention. Further investigation is needed, preferably using a randomized design, to determine other potential effects of the model, effect sizes, and the ability to produce sustained changes after program completion. Second, due to significant barriers faced by the patient population (e.g., financial, medical, and interpersonal), a number of patients were lost to follow-up.

A noteworthy strength of the study is its diversity of participants, including individuals from African American, Asian, Hispanic/Latino, and Pacific Island backgrounds. Only 32.7% of participants were Caucasian, and 59.6% were women. Given the diversity of the sample, future studies of the OSW model might investigate ways in which demographic variables moderate program adherence and intervention effects. The use of LMM is also a clear strength, allowing full use of longitudinal data.

One final strength of this study is that it occurred in an FQHC, a safety-net system serving predominantly Medicaid patients and the uninsured, who often have the heaviest burden of disease and face many challenging SDOH. The study had few exclusion criteria and falls strongly on the effectiveness side of the effectiveness/efficacy continuum, increasing external validity and generalizability.

Conclusions

Although more research is clearly indicated, the implications of this early validation are significant. First, this work represents a major advance in integration across the clinic–community continuum, with an integrated partnership between a clinical team and a community-based organization to meet complex patient needs. Within the primary care clinic, the GMV model is a natural application of the behavioral pharmacy, allowing for frequent patient–provider interactions with increased access to care, efficient use of provider time, and an effective billing strategy that is adaptable to fee-for-service or capitated value-based care settings.[48] Utilizing community partners to radically amplify the effectiveness of a single clinical provider, while animating the clinic as a true generator of health, uplifts the transformative potential of GMVs and the patient-centered medical home.[49]

Implications

Success in codifying, adapting, and spreading this methodology represents a substantial contribution to the national commitment to health equity. While acute clinical care will remain necessary, as is future-oriented work on upstream SDOH, the OSW model has the potential to serve as a wedge between disadvantageous SDOH and the corresponding, predictable, negative health outcomes. While employment, transportation, housing, and education cannot be secured for every individual, the most proximal and low-hanging drivers of health and well-being can be potentiated and facilitated.

The current study assessed the clinically integrated OSW model with seamless referral (prescription) and fulfillment of the indicated treatment. However, for many patients, this is the first component of a complete step-down arc within the broader OSW community, which culminates in an entirely peer-led, ongoing maintenance program, currently fully operational. The opportunity at hand is to refine, spread, and radically open source a model for animating clinical and community contexts as platforms for health and well-being such that the treatment, prevention, and management of chronic disease draw not on the overtaxed and often suboptimally effective clinical systems, but rather on the abundant human capital in communities. This affords the opportunity to leverage shared and divergent capacities and work in partnership to create clinical and community cultures of health and well-being for all.

Acknowledgments

The authors are grateful to the staff of the Hayward Wellness Center and Open Source Wellness for their dedicated work on behalf of the most vulnerable, as well as Katherine Goh for her assistance in chart review.

All other aspects of the group medical visit programs were integrated into the health center's operations.

Funding Information ◀AU8

This study was supported by a grant from the American Council on Exercise. Funding for the produce vouchers was ◀AU9 provided through three grants from the Kaiser Permanente Greater Southern Alameda Area Community Benefit Program and the Alameda Health System Foundation's Associate Board Fundraiser.

References

1. Gerteis J, Izrael D, Deitz D, et al. Multiple Chronic Conditions Chartbook. Agency for Healthcare Research and Quality. 2014. Online document at: www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision /mcc/mccchartbook.pdf, accessed February 27, 2019.
2. Marks R, Allegrante JP, Lorig K. A review and synthesis of research evidence for self-efficacy-enhancing interventions for reducing chronic disability: Implications for health education practice (Part III). Health Promot Pract 2005;6:148–156.
3. Holt RIG, de Groot M, Golden SH. Diabetes and depression. Curr Diab Rep 2014;14:491.
4. O'Connor PJ, Narayan KM, Anderson R, et al. Effect of intensive vs standard blood pressure control on depression

and health-related quality of life in type 2 diabetes: the ACCORD trial. Diabetes Care 2012;35:1479–1481.
5. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care 1999; 5–14.
6. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA 2002;288:2469–2475.
7. Center for the Advancement of Health. The Center for Health Studies of Group Health Cooperative of Puget Sound. An Indexed Bibliography on Self-Management for People with Chronic Disease. 1st ed. Washington, DC, 1996. AU10►
8. Goldhaber-Fiebert JD, Goldhaber-Fiebert SN, Tristán ML, Nathan DM. Randomized controlled community-based nutrition and exercise intervention improves glycemia and cardiovascular risk factors in type 2 diabetic patients in rural Costa Rica. Diabetes Care 2003;26:24–29.
9. Boulé NG, Haddad E, Kenny GP, et al. Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. JAMA 2001;286:1218–1227.
10. Thompson PD, Buchner D, Piña IL, et al. Exercise and physical activity in the prevention and treatment of atherosclerotic cardiovascular disease: a statement from the Council on Clinical Cardiology (Subcommittee on Exercise, Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity). Circulation 2003;107:3109–3116.
11. Williams MA, Haskell WL, Ades PA, et al. Resistance exercise in individuals with and without cardiovascular disease: 2007 update: a scientific statement from the American Heart Association Council on Clinical Cardiology and Council on Nutrition, Physical Activity, and Metabolism. Circulation 2007;116:572–584.
12. Barnard ND, Cohen J, Jenkins DJ, et al. A low-fat vegan diet improves glycemic control and cardiovascular risk factors in a randomized clinical trial in individuals with type 2 diabetes. Diabetes Care 2006;29:1777–1783.
13. Barnard ND, Cohen J, Jenkins DJ, et al. A low-fat vegan diet and a conventional diabetes diet in the treatment of type 2 diabetes: a randomized, controlled, 74-wk clinical trial. Am J Clin Nutr 2009;89:1588S–1596S.
14. Barnard ND, Gloede L, Cohen J, et al. A low-fat vegan diet elicits greater macronutrient changes, but is comparable in adherence and acceptability, compared with a more conventional diabetes diet among individuals with type 2 diabetes. J Am Diet Assoc 2009;109:263–272.
15. Gregg JA, Callaghan GM, Hayes SC, Glenn-Lawson JL. Improving diabetes self-management through acceptance, mindfulness, and values: a randomized controlled trial. J Consult Clin Psychol 2007;75:336.
16. Rosenzweig S, Reibel DK, Greeson JM, et al. Mindfulness-based stress reduction is associated with improved glycemic control in type 2 diabetes mellitus: a pilot study. Altern Ther Health Med 2007;13:36–39.
17. van Son J, Nyklíček I, Pop VJ, et al. The effects of a mindfulness-based intervention on emotional distress, quality of life, and HbA1c in outpatients with diabetes (DiaMind): a randomized controlled trial. Diabetes Care 2013;36:823–830.
18. Friis AM, Johnson MH, Cutfield RG, Consedine NS. Kindness matters: a randomized controlled trial of a mindful self-compassion intervention improves depression, distress, and HbA1c among patients with diabetes. Diabetes Care 2016;39:1963–1971.
19. Curiati JA, Bocchi E, Freire JO, et al. Meditation reduces sympathetic activation and improves the quality of life in elderly patients with optimally treated heart failure: a prospective randomized study. J Altern Complement Med 2005;11:465–472.
20. Gotink RA, Chu P, Busschbach JJ, et al. Standardised mindfulness-based interventions in healthcare: an overview of systematic reviews and meta-analyses of RCTs. PLoS One 2015;10:e0124344.
21. Valtorta NK, Kanaan M, Gilbody S, et al. Loneliness and social isolation as risk factors for coronary heart disease and stroke: systematic review and meta-analysis of longitudinal observational studies. Heart 2016;102:1009–1016.
22. Liu L. Social connections, diabetes mellitus, and risk of mortality among white and African-American adults aged 70 and older: an eight-year follow-up study. Ann Epidemiol 2011;21:26–33.
23. Zhang X, Norris SL, Gregg EW, Beckles G. Social support and mortality among older persons with diabetes. Diabetes Educ 2007;33:273–281.
24. Berkman LF, Syme SL. Social networks, host resistance, and mortality: a nine-year follow-up study of Alameda County residents. Am J Epidemiol 1979;109:186–204.
25. Kawachi I, Colditz GA, Ascherio A, et al. A prospective study of social networks in relation to total mortality and cardiovascular disease in men in the USA. J Epidemiol Community Health 1996;50:245–251.
26. Cacioppo JT, Hawkley LC, Kalil A, et al. Happiness and the invisible threads of social connection. The Chicago Health, Aging, and Social Relations Study. In:Eid M, Larsen RJ, eds. *The Science of Subjective Well-Being*. New York, NY: Guilford Press, 2008:195–219.
27. Simon B. Group medical visits: primary care for the next century? Rethinking chronic care. In: *Challenges and Opportunities in Health Care Management*. Cham: Springer, 2015:371–376.
28. Frates EP, Morris EC, Sannidhi D, Dysinger WS. The art and science of group visits in lifestyle medicine. Am J Lifestyle Med 2017;11:408–413.
29. Jaber R, Braksmajer A, Trilling JS. Group visits: a qualitative review of current research. J Am Board Fam Med 2006;19:276–290.
30. Housden L, Browne AJ, Wong ST, Dawes M. Attending to power differentials: How NP-led group medical visits can influence the management of chronic conditions. Health Expect 2017;20:862–870.
31. Geller JS, Orkaby A, Cleghorn GD. Impact of a group medical visit program on latino health-related quality of life. Explore 2011;7:94–99.
32. Wan W, Staab EM, Ham SA, et al. Economic evaluation of group medical visits for adults with diabetes in community health centers. Diabetes 2018;67(Supplement 1):8-OR.
33. Mallow JA, Theeke LA, Whetsel T, Barnes ER. Diabetes group medical visits and outcomes of care in low-income, rural, uninsured persons. Open J Nurs 2013;3:314–322.
34. Gardiner P, Dresner D, Barnett KG, Sadikova E, et al. Medical group visits: a feasibility study to manage patients with chronic pain in an underserved urban clinic. Glob Adv Health Med 2014;3:20–26.
35. Seligman HK, Laraia BA, Kushel MB. Food insecurity is associated with chronic disease among low-income NHANES participants. J Nutr 2010;140:304–310.

36. Wardle J, Parmenter K, Waller J. Nutrition knowledge and food intake. Appetite 2000;34:269–275.
37. Cappuccio FP, Rink E, Perkins-Porras L, et al. Estimation of fruit and vegetable intake using a two-item dietary questionnaire: a potential tool for primary health care workers. Nutr Metab Cardiovasc Dis 2003;13:12–19.
38. Coleman KJ, Ngor E, Reynolds K, et al. Initial validation of an exercise ''vital sign'' in electronic medical records. Med Sci Sports Exerc 2012;44:2071–2076.
39. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16:606–613.
40. Cameron IM, Crawford JR, Lawton K, Reid IC. Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. Br J Gen Pract 2008; 58:32–36.
41. Titov N, Dear BF, McMillan D, et al. Psychometric comparison of the PHQ-9 and BDI-II for measuring response during treatment of depression. Cogn Behav Ther 2001;40: 126–136.
42. Roth PL. Missing data: A conceptual review for applied psychologists. Pers Psychol 1994;47:537–560.
43. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. JACC 2018;71:e127.
44. R Core Team R: A language and environment for statistical computing. R Foundation for Statistical Computing. 2017. Online document at: www.R-project.org, accessed February 27, 2019.
45. Fox J. The R Commander: A basic statistics graphical user interface to R. J Stat Softw 2005;14:1–42.
46. Bates D, Maechler M, Bolker B, Walker S. Fitting linear mixed-effects models using lme4. Stat Softw 2015;67:1–48.
47. Kuznetsova A, Brockhoff PB, Bojesen Christensen RH. lmerTest: Tests in Linear Mixed Effects Models. R package version 2.0–33. 2016. Online document at: www.CRAN.R-project.org/package=lmerTest, accessed February 27, 2019.
48. Jaber R, Braksmajer A, Trilling J. Group visits for chronic illness care: Models, benefits and challenges. Fam Pract Manag 2006;13:37.
49. Miller D. Lessons from the Community-Centered Health Home Demonstration Project: Patient-centered medical homes can improve health conditions in their surrounding communities. Prev Chronic Dis 2016;13:E102.

Address correspondence to:
Benjamin Emmert-Aronson, PhD
Open Source Wellness
227 Fillmore Street
San Francisco, CA 94117

E-mail: ben@opensourcewellness.org

AUTHOR QUERY FOR ACM-2019-0079-VER9-EMMERT-ARONSON_1P

AU1: Please identify (highlight or circle) all authors' surnames for accurate indexing citations.
AU2: Please confirm the correctness of authors' affiliations.
AU3: Keywords have been taken from PDF file. Please check.
AU4: The Publisher requests for readability that no paragraph exceeds 15 typeset lines. Please check for long paragraphs and divide where needed.
AU5: Please check if the edits made in the sentence '' Coaches engaged small groups through text messages in between weekly meetings to provide continuity, support, and accountability'' are OK.
AU6: Please expand MA.
AU7: Please expand ''ED.''
AU8: Please confirm ''Funding Information.''
AU9: Please check if the edits made in the sentence '' Funding for the produce vouchers was provided through three grants from the Kaiser Permanente Greater Southern Alameda Area Community Benefit Program and the Alameda Health System Foundation's Associate Board Fundraiser.'' are OK.
AU10: In Ref. 7, please mention the publisher's name.
AU11: Please define ''ER.''
AU12: Please check the ''sequential order of the numbers (1, 2, 3, 1)'' in Fig. 1.
AU13: Please define ''GAD-7.''