



Open Source Wellness: Clinically-Integrated Behavioral Pharmacy Model *(Approved and Funded by American Council on Exercise, 11/2018)*

Abstract

Open Source Wellness (OSW) is a new delivery model for health behavior change: the nation's first "Behavioral Pharmacy," where patients can experientially fill lifestyle prescriptions made by their healthcare providers. OSW is dedicated to transforming the ways in which the transdiagnostic, behavioral underpinnings of physical and psychological health (physical movement, nutrition, stress reduction, and social support) are understood, delivered, and sustained. Representing the next generation of behavioral medicine and operating at the intersection of healthcare and the community, OSW is developing a scalable delivery system for the health practices that underlie individual and population-level health inequities. The current project aims to conduct an evaluation of the first *clinically-integrated* implementation of the Open Source Wellness model in partnership with Hayward Wellness Center (Alameda Health System), and to rigorously assess our feasibility and impact. We will assess objective clinical outcomes (e.g., BMI, blood pressure, HbA1c), self-report behavioral outcomes (e.g., wellbeing, stress, depression, minutes of exercise, servings of fruit and vegetables), and healthcare utilization.

Introduction, Goals and Objectives

Rationale

At nearly 18% of the U.S. GDP, we spend 50% more than any other developed nation per capita on health care services and delivery (Squires & Anderson, 2015), yet our population health outcomes are the worst of any industrialized nation (National Research Council, 2013). Despite the miracles of modern medicine, the U.S. healthcare system has been notably ineffective in the prevention and reversal of chronic diseases such as obesity, diabetes, hypertension, and cardiac disease. The costs of this ineffectiveness are astronomical, and can be measured in dollars of medical spending, (86% of the \$3.2 trillion spent on healthcare is spent on persons with one or more preventable chronic disease) productivity loss, and quality of life (Gerteis et al., 2014). The most proximate cause of (and solution to) these kinds of chronic diseases is behavioral – the transdiagnostic, long-term lifestyle factors that drive health outcomes.

Unfortunately, in most healthcare settings, the best that a physician can do while assessing, diagnosing, and treating any number of chronic conditions is to offer behavioral instructions: "*Exercise more,*" "*Eat healthier,*" and "*Reduce your stress*" are the most common admonitions, and in practice are too-often followed by "*Good luck with that, I'll see you in six months!*" Unsurprisingly, for many patients, this verbal intervention by itself is profoundly

ineffective in changing behavior. Patients without tremendous financial and sociocultural privilege predictably fail to enact these changes in a sustained way (Elder, Ayala, & Harris, 1999), and their preventable, chronic, progressive conditions worsen. *In sum, a “behavioral prescription” without an accessible and effective “behavioral pharmacy” is simply not a viable solution for our patients, providers, insurers, or communities.*

Imagine this:

*A doctor informs a patient that she has pre-diabetes, or obesity, or cardiac disease. Instead of saying: “Eat better, move more, here’s a handout, good luck!” - the physician says: “I’ve written you a different kind of prescription – I think of it as a **Behavioral Pharmacy**. It’s not a class –or a lecture – it’s a community dedicated to wellbeing where members actually cook healthy food, do fun physical movement, and learn stress-reduction together. Once you’ve completed your 3-month membership prescription, which is fully covered by your insurance, they will help you connect with others in your neighborhood who get together to practice – in fact, there are peer-led gatherings in schools, community centers, and even right here in our clinic – and your whole family is always welcome to join you.”*

The Open Source Wellness model is this “behavioral pharmacy” where four trans-diagnostic health behaviors (physical movement, nutritious food, social support, and stress reduction) are delivered (taught and practiced). The core intervention entails four basic practices: movement for all fitness levels (30 min), basic mindfulness meditation (10 min), nutritious family-style meals (plant-based), and facilitated social support and connection, all offered in a format that is affordable, accessible, culturally-relevant, and enjoyable. Our programming is similar in content to the lifestyle change programs that Dr. Dean Ornish has pioneered, studied, and proven profoundly effective across a range of biomarkers and clinical outcomes, including BMI, cholesterol, HbA1c, blood pressure, and depression, as well as behavioral outcomes such as exercise, stress, and functional capacity (e.g., Daubenmier et al., 2007, Koertge et al., 2003, Silberman et al., 2010), particularly with low-income populations (Govil et al., 2009). However, Open Source Wellness operates at a fraction of the cost. Lee and Shepard (2009) calculated the mean cost of Ornish’s cardiac rehabilitation program to be \$9,895 per patient for the 12-month intervention. While still in development, initial estimates for OSW’s program place its cost at \$480 per patient for a 3-month intervention (one “dose”), 1/5th the cost. By developing peer leadership within the program and utilizing para-professional health coaches instead of specialists, we reduce program delivery costs, foster health-related self-efficacy, and build relationships that support sustained lifestyle change.

The community-based version of the Open Source Wellness model was first launched in October 2016, is currently operating in collaboration with the Prevention Institute (Oakland, CA), and accepts referrals from a variety of healthcare providers alongside self-referred individuals. Initial evaluations of that model have shown significant decreases in depression ($p = .01$, $d = .50$), anxiety ($p = .05$, $d = .43$), and stress ($p < .01$, $d = .67$) as measured by the Depression Anxiety and Stress Scale, as well as significant increases in wellbeing (WHO-5, $p = .02$, $d = .50$), social connection (SCS-R, $p = .04$, $d = .53$), and mindfulness, (CAMS-R, $p = .05$, $d = 1.52$).

The clinically-integrated model has been piloted as a program (not a research study) at Hayward Wellness Center, a large primary care clinic (part of Alameda Health System), since October 2017, and all systemic and operational challenges of integration have been addressed and streamlined. The current application seeks support for a research evaluation of the clinically-integrated implementation of the Open Source Wellness (OSW) model in partnership with Hayward Wellness Center (HWC) and Alameda Health System (AHS).

Current Study

The proposed study is a 12-month open trial of the clinically-integrated OSW model, and aims to gather data that will support refinement of the model and clinical partnership prior to a fully randomized controlled trial. It is expected that the clinical implementation will capitalize on several factors known to increase intervention effectiveness in medical settings: warm-handoff or direct referral (Richter et al., 2016), and immediacy of intervention availability post-identification of medical diagnosis or challenges (high motivation to change; Grol & Wensing, 2004). Furthermore, the availability of electronic record data (biomarkers, utilization) offers objective measurement of impact that is unavailable in the community setting.

Study Aims and Hypotheses

Aim 1: To evaluate the impact of the OSW model in promoting health behavior and health outcome change in a clinical setting. It is hypothesized that participants will show improvements in depression, anxiety, stress, health biomarkers (weight, blood pressure, resting heart rate, BMI, HbA1c), wellbeing, and loneliness scores (measures enumerated below).

Aim 2: To evaluate cost efficacy of OSW model. It is hypothesized that participants will show reduced utilization of acute care services (i.e., ER visits and inpatient admissions), and increased engagement in primary care (i.e., decreased no-show rate).

Research Design and Methods

Participants

Participants will be drawn from the Hayward Wellness Center patients. Participants will be referred primary care and specialty providers, using the (already established) clinical workflow and electronic health record integration. Inclusion criteria will include a current diagnosis of diabetes, heart disease, obesity, food insecurity, or depression, as well as an explicit interest in health behavior change, moderate or greater fluency in English, and age of 18 or older. Participants will be excluded if they display active suicidality, psychosis or cognitive impairment (that limits their ability to participate appropriately in OSW activities), or imminently require medical care.

Procedures

The proposed intervention consists of two components.

1. **A weekly, in-person multi-modal Open Source Wellness program implemented on-site at Hayward Wellness Center.** This program will consist of the OSW model as described above: 30 minutes of physical movement, 10 minutes of mindfulness meditation, nutrition education, and a family-style meal. During the meal participants sit in small groups and a health coach facilitates social connection with a focus on health behavior change.

2. **1x1 health coaching in between weekly in-person meetings.** Continuity of relationship fosters increased group cohesion, goal setting and tracking, problem solving, peer support, and accountability over time

Measures

A questionnaire packet will be administered every 4 weeks, and biomarkers (weight, blood pressure, resting heart rate) will be measured weekly.

Medical Data

Participant biomarker data will be drawn from electronic health records, including weight, BMI, resting heart rate, blood pressure, and Hemoglobin A1c (HbA1c).

Utilization data

Utilization data will be drawn from electronic health records and will include acute care usage (ER visits, inpatient admissions and readmissions) and primary care engagement.

Self-Report Measures

5-Item World Health Organization Well-Being Index (WHO-5; Staehr, 1998)

Two-item Food Frequency Questionnaire (Wardle, 2000)

Exercise Vital Sign (Coleman et al., 2012)

Three-Item Loneliness Scale (Hughes et al., 2004)

Patient Health Questionnaire – 9 (PHQ-9; Kroenke et al., 2001)

Generalized Anxiety Disorder – 7 (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006)

Social Connectedness Scale – Revised (SCS-R; Lee, Draper, & Lee, 2001) Due to difficulties understanding and responding to negatively worded items we used a modified version of the SCS-R that includes the 10 positively-worded items.

Data Analysis

For health biomarkers and self-report questionnaires, differences between pre-test and post-test will be assessed with paired sample t-tests. Given that this is an initial evaluation of the clinical model of OSW, alpha will be held at .05, despite multiple comparisons. Utilization data will be used to separately examine acute care and primary care engagement for the 6 months preceding and following participation in the intervention.

Power

Because Ornish's model (Silberman et al., 2010) found moderate effect sizes (Cohen's d 's = .5-.7) and his model utilizes a more intense intervention, an effect size of $d = .4$ was estimated for the current outcomes. A power analysis utilizing this effect size, alpha of .05, and power of .8 would require a sample size of 68. With conservative allowances for attrition given the challenges faced by participants in the study population, this suggests that our sample of 100 should be well powered to detect effects in this range.

Workplan and Timeline

▪ Already completed:

- Developed formal partnership agreements/contract with Hayward Wellness Center (of Alameda Health System). Finalized referral procedures, liability/risk plans and agreements, assessment procedures, data-sharing agreements, and developed relationships with medical directors and clinicians.

- Implemented clinical workflow integration; established triggers for referral/inclusion/exclusion.
- Developed and trained program staff team.
- Launched initial pilot program. Operated OSW program for 5 months; elicited feedback from patients and providers leading to program iteration and improvement. Pilot continues to inform quality improvement until research protocol is implemented.
- **On receipt of funding:**
 - 6/1/18: Submit for IRB approval to launch formal research protocol.
 - 9/1/18 Begin 12-month study period.
 - 9/1/19 Complete study period
 - 3/1/20 Complete healthcare utilization tracking period
 - 3/1/20 Data Analysis and manuscript preparation for behavioral data
 - 6/1/20 Manuscript submission (Conference audiences include APHA and ACLM. Journals TBD)

Budget

The authors are aware that this budget represents a minimalist approach to study funding; however, as researchers, faculty, and cofounders, we are deeply committed to the integrity and completion of this study and are accustomed to operating on tight budgets.

Clinical Site			
Direct Cost	Per Month	Per Year	Total
Site Lead (\$25/hr, 10 hrs/week, 4 weeks)	\$1000		\$12,000.00
4 Coaches (\$20/hr, 5 hrs/week, 4 weeks, 4 coaches)	\$1600		\$19,200.00
Research Coordination (Data analysis, partnership coordination, oversight, training, leadership, 18 months)	\$1200		\$21,600.00
2 interns (Supervised by Site Lead)	\$0		\$0.00
Movement	\$300		\$3,600.00
Food	\$400		\$4,800.00
Administrative Support (\$15/hr, 3 hrs/week, 18 months)	\$180		\$3,240.00
Printing		\$500	\$500.00
Total			\$64,940.00

Implications

The absence of an effective delivery system for basic health behavior change is a massive deficit in our national health care strategy. It is our fundamental belief is that community-based behavioral intervention at sufficient dose can effectively offset massive downstream medical costs, and our purpose is to demonstrate this value through rigorous evaluation of behavioral outcomes, health biomarkers, and healthcare utilization. The Open Source Wellness model is both radically innovative and elegantly simple, and is showing promise as an affordable,

culturally-relevant, scalable delivery system for health behavior change. With high-quality research, we hope to be able to demonstrate replicable outcomes of the program, clarify the health conditions and complications prevented, and offer an analysis of the associated costs offset. Operating at a fraction of the cost of similar programs due to its unique peer-run structure, this model has the potential for dissemination and scaling far beyond the for-profit proprietary programs existing to date. It is our aspiration to learn, refine, and build on this essential first pilot of the clinically-integrated implementation, ultimately offering the field an “open-sourced” model that can empower and uplift health and wellbeing at the national level.

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