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DEVELOPMENT

Evaluation of *¡Vivir Mi Vida!* to improve health and wellness of rural-dwelling, late middle-aged Latino adults: results of a feasibility and pilot study of a lifestyle intervention

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Aim: The aim of this study was to determine the feasibility and efficacy of a culturally tailored lifestyle intervention, *¡Vivir Mi Vida!* (Live My Life!). This intervention was designed to improve the health and well-being of high risk late middle-aged Latino adults and to be implemented in a rural primary care system. **Background:** Rural-dwelling Latino adults experience higher rates of chronic disease compared with their urban counterparts, a disparity exacerbated by limited access to healthcare services. Very few lifestyle interventions exist that are both culturally sensitive and compatible for delivery within a non-metropolitan primary care context. **Methods:** Participants were 37 Latino, Spanish-speaking adults aged 50–64-years-old, recruited from a rural health clinic in the Antelope Valley of California. *¡Vivir Mi Vida!* was delivered by a community health worker-occupational therapy team over a 16-week period. Subjective health, lifestyle factors, and cardiometabolic measures were collected pre- and post-intervention. Follow-up interviews and focus groups were held to collect information related to the subjective experiences of key stakeholders and participants. **Findings:** Participants demonstrated improvements in systolic blood pressure, sodium and saturated fat intake, and numerous patient-centered outcomes ranging from increased well-being to reduced stress. Although participants were extremely satisfied with the program, stakeholders identified a number of implementation challenges. The findings suggest that a tailored lifestyle intervention led by community health workers and occupational therapists is feasible to implement in a primary care setting and can improve health outcomes in rural-dwelling, late middle-aged Latinos.

Key words: community-based research; community health worker; Latino; lifestyle intervention; occupational therapy; rural

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The number of Latino older adults in the United States is expected to surpass 14 million by the year 2050 (Vincent and Velkoff, 2010), which corresponds to a 550% increase from 2017. This demographic trend forebodes significant healthcare challenges given the high prevalence of chronic conditions such as obesity and diabetes in this population (Daviglus *et al.*, 2012). Despite the high rate of disease, Latino elders have lower mortality rates than other ethnic groups. Unfortunately, this extended longevity in combination with high prevalence of chronic conditions results

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in more years per capita in which disease or disability is present (Hayward *et al*., 2014).

Compounded by the aforementioned healthcare challenge, Latinos in rural communities comprise 9.3% of the total US population (Housing Assistance Council, 2012) and, relative to urban-dwelling Latinos, experience additional health inequities such as greater prevalence of hypertension and type 2 diabetes (Koopman *et al*., 2006; Bale, 2010). These disparities stem from risk factors found in rural communities such as decreased health service availability and accessibility (Lutfiyya *et al*., 2012; 2013), shortages of healthcare professionals (Weinhold and Gurtner, 2014), economic disadvantages (Lutfiyya *et al*., 2013; Weinhold and Gurtner, 2014), and environmental barriers that impede physical activity (Swenson *et al*., 2005).

Interventions that utilize specialized strategies and adaptations have been proposed to effectively reach rural-dwelling individuals and address their unique health-related barriers. Examples of these recommendations include building local partnerships to support implementation, offering telemedicine, accommodating long-distance travel, integrating services into primary care, seeking aid from 'natural helpers' in the community, and broadening providers' skillsets to make up for service shortages (Chipp *et al*., 2008; Lutfiyya *et al*., 2012; Calancie *et al*., 2015). Community-based lifestyle interventions that are both designed for delivery in a rural setting and sensitive to Latino culture, though not great in number, have successfully achieved such outcomes as enhanced glycemic control and engagement in health behaviors (Goldhaber-Fiebert *et al*., 2003; Sanchez *et al*., 2014).

Despite promising results for culturally sensitive, rural community-targeted interventions, efficacy has not been studied through the lens of patient-centered outcomes. Such outcomes were recognized as a priority in the Patient Protection and Affordable Care Act of 2010 and commonly incorporate psychosocial concerns that reflect individuals' preferences, feelings, needs, and functional status (Rubenfeld, 2003). Examples of patient-centered outcomes include activity participation, sleep quality, stress, and symptom management. Use of such outcomes complements conventional physiological measures (Verhoef *et al*., 2005). Patient-centered outcomes not only correlate with traditional, objective outcomes such as cardiovascular risk profile (De Smedt *et al*., 2013) and cognitive functioning (Scullin and Bliwise, 2015), but also provide a more complete picture of health and well-being.

In this study, the feasibility and efficacy of a culturally tailored lifestyle intervention, *¡Vivir Mi Vida!* (*¡VMV!*; Live My Life!), intended to improve the health and well-being of high risk 50–64-year-old Latino adults, was pilot tested. This activity-centered intervention was delivered by partnered community health workers (CHWs) and occupational therapists (OTs) within the context of a primary care system. A preliminary qualitative needs assessment resulted in identification of a set of patient-valued health domains and health promotion strategies that informed *¡VMV!* module construction (Schepens Niemiec *et al*., 2015). *¡VMV!* was then adapted by incorporating strategies for rural healthcare delivery such as a strong reliance on home-based sessions, use of telemedicine, and a focus on local resources and supports. It was hypothesized that the adapted intervention would be feasible to administer and improve both physiologic and patient-centered health-related outcomes in the target population. In addition, it was hypothesized that key stakeholders – including intervention supervisors, CHWs, assessors, and the partnering community wellness organization administrator – would be satisfied with the program and view it as practical to implement in their community.

Method

Design

Study procedures were approved by the University of Southern California (USC) Institutional Review Board. The design entailed a one-arm, feasibility and pre-post pilot efficacy study of the rural-adapted program in the Antelope Valley of California during 2016. Antelope Valley is located in northern Los Angeles County and comprises the western tip of the Mojave Desert.

Participants & setting

A total of 40 eligible participants were recruited between February and March 2016 through randomized selection of referred patients listed as potentially eligible by the partnering health clinic (Antelope Valley Community Clinic [AVCC]), as

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well as through community information booths, word-of-mouth, and flyers. Inclusion criteria limited enrollment to individuals who were 50–64-years-old, Latino, fluent in Spanish (to facilitate group session interactions), available by phone, and oriented to person, place, and time. In addition, participants were required to have visited AVCC during the past year, with self-reported capacity to complete a 16-week intervention and no plans to move outside of Antelope Valley within six months. The decision to target late middle-aged adults was based on: (a) recent theory, which emphasizes healthy aging as a continuous process throughout the lifespan (Hansen-Kyle, 2005); (b) the desirability of instilling sound health habits during a temporal window that precedes major health declines experienced in older age (Sudano and Baker, 2006); and (c) indications that Latino adults in this age group are willing to undertake health-promoting lifestyle changes (Osuna *et al*., 2011; Schepens Niemiec *et al*., 2015).

Procedure

Greater detail of all study procedures can be found in (Schepens Niemiec *et al*., In Press). With support from AVCC, this community-based participatory research was conducted in partnership with Antelope Valley Partners for Health (AVPH), a community wellness organization located in Antelope Valley. AVPH supplied two CHW interveners who were Spanish-English bilingual. The USC research team provided two bilingual intervener supervisors: a treating OT and senior *promotor* (ie, a CHW who has deep ties to the Latino community, specialized cultural knowledge, and shared lived experiences; Latino Health Access *et al*., 2011). The USC team led 12- and 40-h training workshops for the assessors and intervening CHWs, respectively.

Participants were screened for eligibility primarily by telephone and subsequently consented and enrolled in person. Using schedule availability, individuals were allocated to one of four intervention groups ($n = 10$ per group; two groups per CHW). Assessments took place at baseline (pretest) and post-intervention (posttest).

Data collection & instruments

Table 1 summarizes the tools/indices and study variables used to evaluate intervention efficacy. Assessors collected data at each time point (unless otherwise noted) typically at participants' homes. All pre-existing assessments had been validated for Latino populations and were available in Spanish. The primary patient-centered outcomes consisted of sub-scores on the Measure Yourself Medical Outcome Profile 2 (MYMOP2; Paterson, 1996). MYMOP2 is a patient-centric questionnaire that requires respondents to identify one or two current and personally bothersome symptoms. Participants rate symptom severity, as well as how much each symptom interferes with daily activities and well-being. The MYMOP2 produces an overall profile score as well as sub-scores of symptom severity, general well-being, and impact of symptoms on daily activity. Secondary outcomes ranged from lifestyle factors (eg, physical activity engagement) to cardiometabolic measures (eg, cholesterol level). Comorbidity information was collected via self-report and from AVCC electronic medical records. Assessors entered self-reported data obtained orally and cardiometabolic measurements into Research Electronic Data Capture (REDCap) – a web-based application to support data collection (Harris *et al*., 2009).

Intervention

As described in Schepens Niemiec *et al*. (In Press), *¡VMV!* integrated theoretical constructs from (a) OT Lifestyle Redesign® – holistic wellness, habits and routines, and participation in culturally defined activities (Carlson *et al*., 1998; Clark *et al*., 2015); and (b) social cognitive theory – self-efficacy, self-regulation, social support, and outcome expectations (Bandura, 1986; 2004). Intervention delivery was also underpinned by behavior change techniques such as goal-setting, building social support, acknowledging past successes, and educating individuals about the consequences of behavior (Michie *et al*., 2011).

¡VMV! utilized CHWs as frontline interveners who were supervised by a senior *promotor*-OT team. The supervising *promotor* educated the CHWs about community health outreach, provided community resources and supports for participants, and assisted the CHWs in delivering content in a culturally sensitive and understandable manner. The OT held a dual role as a supervisor and clinical interventionist. As a supervisor, the OT facilitated the CHWs' use of health behavior change techniques and guided the CHWs in grading and adapting participants' activities to support long-term goal

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Table 1 Overview of study variables and data collection tools/procedures used to evaluate intervention efficacy

Category	Variable(s)	Method of measurement	Description	References
Background and demographics[a]	Age, country of birth, employment status, ethnicity, household income, living arrangement, marital status, race, sex, smoking status and behavior, years living in United States, years of schooling	Study-specific demographic/ background questionnaire	–[a]	–
Anthropometrics	Weight	Standard weight scale	–	–
	Height[b]	Stadiometer	–	–
	Waist and hip circumference	Measuring tape	–	–
Patient-centered measures	Patient-centered outcomes (primary outcome)	Measure yourself medical outcome profile (MYMOP2)	Symptom severity, symptom interference with daily activities, and well-being	Paterson, (1996), Paterson *et al*. (2000), Polus *et al*. (2011)
	Social health satisfaction	Satisfaction with participation in social roles – short form 7a and Satisfaction with participation in discretionary social activities – short form 7a	Satisfaction with performing usual social roles and activities	Cella *et al*. (2010)
	Sleep disturbance	Pittsburgh sleep quality index (PSQI)	Global sleep quality, sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications, and daytime dysfunction	Backhaus *et al*. (2002), Cole *et al*. (2006)
	Stress	Elo *et al*.'s single item stress index	General level of stress 'these days'	Elo *et al*. (2003)
	Patient activation[c]	Patient activation measure 13-item short form (PAM-13)	One's knowledge of, skills in, and confidence in health self-management	Hibbard *et al*. (2005)
Lifestyle	Dietary intake	Block 2005 food frequency questionnaire Spanish version	Usual and customary intake of a wide array of nutrients and food groups	Centers for Disease Control and Prevention (2015)
	Physical activity engagement	International physical activity questionnaires (IPAQ)	Vigorous activity, moderate activity, walking, and time spent sitting	Craig *et al*. (2003)
Clinical health	Comorbidity[c,d]	Charlson comorbidity index calculated from electronic medical record diagnoses	Comorbidity status	Charlson *et al*. (1987)
	Hemoglobin A1c	Afinion meter (Alere, Inc., Waltham, MA, USA)	Non-fasting	–
	Lipid profile	Cholestech meter (Alere, Inc.)	Non-fasting	–
	Blood pressure	Digital blood pressure monitor	Seated and resting	
Disease risk	Coronary heart disease risk[d]	Framingham risk score LDL points total	–	Wilson *et al*. (1998)
	Diabetes risk[c]	European prospective investigation into cancer and nutrition diabetes risk score (EPIC)	–	Schulze *et al*. (2007)

[a] Measurement tool is self-explanatory.
[b] Assessed only at baseline.
[c] Assessed only at posttest.
[d] Calculated from other collected variables.

attainment. As part of the OT's clinical role, she reviewed health information from the electronic medical record, concatenating it with treatment; monitored participants' activity participation, and discussed with individuals integration of healthful routines. Digital communication was established between the CHW-OT team and participants' primary care physicians to report health-related updates. The senior *promotor* and OT held weekly supervisory sessions with the CHWs to discuss participant cases, implementation challenges, and forthcoming sessions.

The first intervention session included a home visit with a CHW, combined with a telemedicine OT consultation. During this session, the participant created a personalized health action plan (HAP), which was revisited at subsequent sessions. CHWs led weekly visits (including seven one-on-one home sessions, two group sessions held at local community facilities, and two telephone check-ins) over 16 weeks. In addition, the OT provided two 20-min telephone consultations to discuss individually experienced wellness facilitators, as well as troubleshoot barriers to health-related goals.

CHWs were provided with a structured manual, supplemented with a picture-based flip-over booklet and demonstration tools. Participants were given health-related materials and tools throughout the program such as a Garmin Vivofit activity monitor and a measuring cup. Overarching modular topics included healthy eating and physical activity, healthcare navigation, chronic disease management, and mental well-being.

Data analysis

All analyses were organized using a rubric that addresses pilot interventions' feasibility based on scientific merit (efficacy results) and study processes, resources, and management (Thabane *et al.*, 2010). Given 10% attrition, use of a two-tailed test with $\alpha = 0.05$, and an effect size of 0.454, a sample size of 40 was required to achieve 80% power for detecting change on a continuous outcome variable. Similar interventions (Parikh *et al.*, 2010; Koniak-Griffin *et al.*, 2015) suggested an effect size of 0.454 would be appropriate for examining efficacy. Wilcoxon signed rank tests were used to compare pre- and post-intervention scores on primary and secondary outcomes. Statistical analyses were performed using SAS 9.4 for windows (SAS, Cary, NC, USA).

Feasibility evaluation & analysis

Feasibility was assessed using a mixed-methods process evaluation that considered viewpoints of participants, stakeholders, and the study team. Immediately after the posttest, assessors queried each participant about program feasibility and acceptability using a semi-structured interview guide and Likert-style survey. In addition, all participants were invited to attend one of two focus groups – led by experienced qualitative researchers who were unrelated to the study – to further discuss their intervention experiences. A research assistant took detailed field notes during these groups. Slightly less than one-half of the participants attended the groups ($n = 7$ and $n = 8$), which resulted in sizes optimal for group interaction (Patton, 2001). In addition, stakeholders (ie, intervention supervisors, CHWs, assessors, and AVPH administrator) were queried using semi-structured interviews. All interviews and focus groups were audio-recorded.

Fidelity of intervention delivery by the CHWs was assessed by the supervising OT using a study-specific index that listed theoretically postulated core content and processes comprising *¡VMV!* (Schepens Niemiec *et al.*, In Press for details). Intervention elements such as culturally sensitive delivery of materials or attention to a participant's personal support system were rated as 'completed,' 'not completed,' 'unsure,' or 'not applicable.' The OT applied the fidelity index during two individual and two group sessions per CHW, as well as during two audio-recorded individual sessions (randomly selected, but contingent upon participant permission). Finally, feasibility was assessed through recruitment logs, daily correspondences, attendance reports, and adverse event logs.

Focus group and interview audio recordings were transcribed, and translated to English as necessary. Using Dedoose (Version 7.5.9) web application for qualitative data (SocioCultural Research Consultants, 2017), a surface-level content analysis (Berg, 2001) was conducted to identify themes specific to feasibility. This type of analysis permits classification of qualitative information using a predetermined coding scheme. Two research team members generated codes independently, which were later checked by a third member and stored in a master codebook. Analysts documented decision pathways for purposes of maintaining an audit trail of analytic memos.

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Quantitative data resulting from participant interviews and supplemental sources (eg, attendance logs) were summarized via descriptive statistics. Because the present study did not involve comprehensive qualitative procedures, alternative in-depth analyses methods were not warranted. Thabane and colleagues' (2010) recommended organizational structure and rubric for evaluating pilot studies served as overarching themes under which both quantitative and qualitative information was filed. Doing so enabled efficient integration of mixed-methods data that are easily compared across studies that have used a similar thematic scaffold.

Results

Study sample

Table 2 describes characteristics of participants who completed post-testing ($n = 37$). Age ranged from 50.7 to 64.9 years. Most participants were female ($n = 34$, 91%), born outside of the United States ($n = 36$, 97%), non-smoking ($n = 28$, 76%), and/or unemployed ($n = 28$, 76%). The mean body mass index (32.1 ± 6.5) fell within the range of *Class I obesity* (Nuttall, 2015). All participants reported an income of less than US$24 000/year. Information on comorbidities was collected from complete electronic medical record data ($n = 27$) and self-report questionnaires ($n = 33$). Of participants with electronic medical record data, more than half were diagnosed with pain ($n = 21$, 78%), dyslipidemia ($n = 18$, 67%), diabetes ($n = 15$, 56%), and gastrointestinal/liver disease ($n = 14$, 52%). Charlson comorbidity indices for those with electronic medical record data ranged from 0 (44%) to 4 (4%), with a mean score of 1.1 ± 1.2. Common self-reported conditions included dyslipidemia ($n = 18$, 55%), arthritis ($n = 14$, 42% versus 11% in electronic medical records), diabetes ($n = 13$, 39%), depression ($n = 12$, 36% versus 19% in electronic medical records), and hypertension ($n = 12$, 36% versus 18% in electronic medical records).

Table 2 Characteristics of pilot study participants at pretest ($n = 37$) who completed post-testing

Characteristic	*M* ± SD or *n* (%)
Age (years)	58.2 ± 4.8
Sex: female	34 (91.1%)
Birthplace	
United States	1 (2.7%)
Mexico	24 (64.9%)
Other	12 (32.4%)
Education level	
< High school	20 (54.1%)
High school degree	13 (35.1%)
Some college, business, or trade	4 (10.8%)
College graduate +	0
Household income	
⩽ US$999/month	22 (62.9%)
US$1000–1999/month	13 (37.1%)
Years in United States	
⩽ 20 years	8 (22.2%)
> 20 years	28 (77.8%)
Relationship status	
Married/committed	23 (62.2%)
Single/widowed/divorced	14 (37.8%)
Living status	
Alone	4 (10.8%)
With others	33 (89.2%)
Employed	
No	28 (75.7%)
Yes (*M* hours/week)	9 (24.3%) [23.2]
Smoking status	
Current	0 (0%)
Former	9 (24.3%)
Never	28 (75.7%)
Insurance	
Medi-Cal	33 (89.2%)
Private or other	4 (10.8%)
Emergency room visit past 12 months	
No	20 (55.6%)
Yes	16 (44.4%)
Hospitalized past 12 months	
No	27 (75.0%)
Yes	9 (25.0%)
Body mass index (kg/m^2)	32.1 ± 6.5

Scientific feasibility

No intervention-related adverse events occurred. Patient-centered outcomes improved significantly ($P \leqslant 0.01$) from pretest to posttest (Table 3) for the overall MYMOP2 profile score and subscales (ie, symptom severity, symptom impact on activity, and well-being), with all effect sizes medium-to-large (0.50–1.06). Results for secondary outcomes are presented in Table 4. Participants improved significantly for the patient-centered outcomes of stress, satisfaction with social roles, and satisfaction with social activity (effect sizes = 0.39–0.45). Relative to clinical health, participants' systolic blood pressure improved ($P = 0.006$). Other outcomes such as weight, HbA1c, cholesterol level, and diabetes and cardiovascular disease risk did not change. Regarding lifestyle behaviors, intake of sodium and saturated fat decreased significantly

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Table 3 Measure yourself medical outcome profile (MYMOP2) scores from pretest to posttest

	Pretest			Posttest				
Outcome	*n*	*M*	SD	*n*	*M*	SD	*P*[a]	Effect size (*d*)[b]
MYMOP2 profile	36	4.7	1.2	37	3.5	1.4	< 0.0001	–0.95
Symptom 1 severity	36	5.1	1.3	37	3.7	1.9	< 0.0001	–1.04
Symptom 2 severity	25	5.2	1.5	26	3.7	2.0	0.005	–0.92
Activity impact	29	4.8	1.9	30	3.7	1.7	0.008	–0.74
Well-being	31	4.2	1.7	34	3.3	1.6	0.01	–0.49

A decrease in scores is considered improvement.
[a] Wilcoxon signed rank test.

Table 4 Changes in secondary outcomes from pretest to posttest

Outcome	Pretest [*M* (SD)]	Posttest [*M* (SD)]	*P*[a]	Effect size (*d*)
Weight (kg)	79.5 (17.9)	78.8 (16.6)	0.25	–0.04
Waist (cm)	105.5 (12.1)	104.4 (12.1)	0.12	–0.09
Hips (cm)	116.8 (13.2)	115.6 (13.1)	0.41	–0.09
Blood pressure				
Systolic	130.5 (16.7)	122.6 (16.4)	**0.006**	–0.47
Diastolic	76.3 (10.7)	74.6 (8.8)	0.31	–0.16
HbA1c among diabetics[b]	7.8 (1.7)	8.4 (2.5)	0.25	0.30
Cholesterol[c]				
Triglycerides	207.9 (103.1)	198.9 (71.9)	0.47	–0.15
HDL	47.0 (10.1)	42.1 (10.1)	0.07	–0.42
LDL	98.9 (27.7)	99.0 (35.6)	0.66	–0.03
Total	184.8 (30.7)	180.4 (40.5)	0.61	–0.20
Coronary heart disease risk[d]	0.09 (0.06)	0.10 (0.07)	0.63	0.07
Diabetes risk[e]	560.2 (117.2)	586.3 (71.4)	0.21	0.20
Stress	3.2 (1.5)	2.6 (1.4)	**0.02**	–0.39
Sleep disturbance	8.9 (4.9)	7.4 (4.5)	0.07	–0.30
Physical activity engagement				
MET (minutes/week)	2801.2 (3677.5)	2013.4 (3235.0)	0.25	–0.21
Health enhancing activity	1.9 (0.9)	1.8 (0.8)	0.90	–0.03
Social roles satisfaction	21.8 (7.6)	25.1 (7.6)	**0.001**	0.43
Social activity satisfaction	19.6 (6.0)	22.2 (7.2)	**0.002**	0.43
Daily dietary intake				
Sugar (g)	78.8 (44.9)	63.7 (35.3)	0.07	–0.31
Sodium (mg)	3120 (1741)	2168 (925)	**0.0001**	–0.51
Saturated fat (g)	22.3 (11.6)	14.8 (6.1)	**<0.0001**	–0.59
Vegetables (servings)	2.3 (1.7)	2.1 (1.3)	0.50	–0.13
Fruit (servings)	1.1 (0.8)	1.4 (1.0)	0.24	0.30
Patient activation	–	73.4 (19.0)	–	–

HDL = high density lipoprotein; MET = metabolic equivalent; *n* = 36–37, unless otherwise indicated.
[a] Wilcoxon signed rank test with significant values bolded.
[b] Of participants diagnosed as diabetic (*n* = 18), HbA1c was available for 11 participants at pretest, 18 at posttest and 11 for both time-points.
[c] Cholesterol values were available for 15 participants at pretest, 28 at posttest, and 14 for both time-points.
[d] Coronary heart disease risk scores are the 10-year congenital heart disease risk; values were available for 15 participants at pretest, 28 at posttest, and 14 for both time-points.
[e] Diabetes risk scores of 534–585 and 586–657 are associated with 3.0–4.9% and 5.0–9.9% incidence of diabetes within five years, respectively; values are calculated only for non-diabetics and were available for 16 participants at pretest, 17 at posttest, and 16 for both time-points.

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($P \leqslant 0.0001$) and sugar consumption showed a marginally significant reduction ($P = 0.07$), but no significant changes were noted for physical activity engagement. Reductions in systolic blood pressure were associated with reduced intake of sodium ($r = 0.43$, $P = 0.01$) and saturated fat ($r = 0.43$, $P = 0.01$); data not shown.

Process feasibility

Recruitment, retention, & adherence

Recruitment and retention data are presented in Figure 1. A total of 74 potentially eligible individuals were screened: 14 failed to meet inclusion criteria, eight declined participation, and 12 were excluded for other reasons such as unresponsiveness to repeated telephone messages. In all, 37 participants (93%) completed post-testing. Participant adherence was defined as percent completion of all possible intervener contacts ($n = 15$) – including individual, group, telephone, and OT sessions – within the 16-week program. We operationalized 'successful' adherence as $\geqslant 75\%$ completion of all contact opportunities based on a similar study (de Heer *et al.*, 2015). Adherence averaged 77% for all session types, 88% for individual sessions, 61% for group sessions, and 76% for telephone check-ins. Participants received an average of two of the three intended OT consultations.

Fidelity

With $\geqslant 80\%$ integrity constituting 'high' and $\leqslant 50\%$ representing 'low,' session fidelity (Perepletchikova and Kazdin, 2005) the CHWs delivered the majority of *¡VMV!* with high fidelity (when items were applicable). Nine of the 12 fidelity

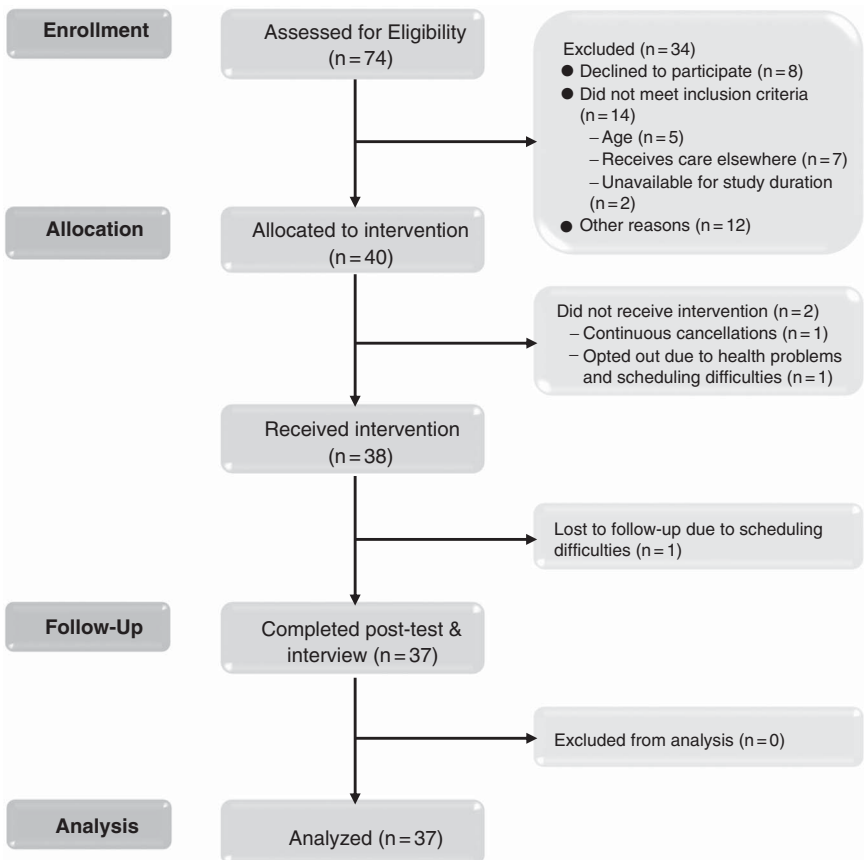

Figure 1 Recruitment and retention of participants

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items the OT reviewed were rated as performed properly ⩾85% of the time. The OT noted that the CHWs engaged in participant-skill building only 71% of the time. One area in need of improvement was the CHWs' confidence and ability to deliver the intervention fluently in Spanish (Spanish was their second language); the OT rated this as occurring only 20% of the time. In addition, the CHWs did not utilize motivational interviewing techniques in any of the reviewed sessions.

Implementation alterations

Over the course of the study, the team made three major alterations to *¡VMV!*. First, although the intervention was originally designed to be delivered by *promotores*, the limited supply of qualified personnel in the targeted rural area made it necessary to broaden intervener eligibility more generally to Spanish-speaking CHWs. To prevent this change from compromising the program's cultural sensitivity, our *promotor* devoted more attention during supervisory sessions to guiding the CHWs in delivering *¡VMV!* in a culturally competent manner. The second alteration occurred shortly after the onset of implementation and consisted of allowing participants to schedule make-up sessions outside of the intended sequence of intervention modules or to attend alternate group sessions when experiencing scheduling conflicts. Finally, the intervention manual was originally in English. Based on feedback from the CHWs during their training, we generated a certified translation of the manual so that the CHWs could more easily conduct sessions in Spanish. Other, more minor modifications are noted below in the discussions of implementation barriers and resource and management feasibility.

Implementation facilitators & barriers

The following implementation facilitators were noted by CHWs: (a) adjusting supervisory meetings to provide more review of content for upcoming sessions; (b) having the supervising OT available to discuss health-related issues that fell outside of the CHWs' scope of practice; and (c) conducting individual sessions in participants' homes. Participants strongly endorsed the last item, stating that in-home sessions reduced the need to travel, making it easier for them to engage in program activities. Though some participants viewed in-home sessions as affording privacy that fostered trust, confidence, and more intimate interactions, others equally valued group sessions as an opportunity to receive peer support. Participants also shared that simply knowing that someone cared about them provided them with needed encouragement to carry out health behaviors. Finally, participants described that CHWs' demonstrations and activities (eg, measuring food portions, reading nutritional labels) were very helpful.

Implementation barriers largely revolved around resource limitations (see *Resource Feasibility*); however, process-related issues were also noted. The CHWs felt that the required computerized session documentation was too challenging, including the volume of data they were obligated to record and the process of uploading image captures of handwritten forms. To lessen this burden, the documentation process was streamlined mid-intervention. The CHWs also expressed feelings of being overloaded due to issues such as scheduling difficulties, partly stemming from packed caseloads, and having to spend time on evenings and weekends to offset laggard notes. In addition, they articulated uneasiness in covering topics outside of their comfort zones such as *money management* or *grief*; topics that are commonly addressed by OTs but not by CHWs. Finally, participants reported some process-related implementation barriers: (a) difficulty attending groups due to transportation challenges; (b) limited time to delve into intervention topics because the program was short; and (c) trouble activating and using the Garmin Vivofit activity monitors given to them in week 4, due to not having a computer or smartphone.

Satisfaction, acceptability, & adoption

On a 0–10 scale, participant satisfaction with the overall *¡VMV!* experience was high ($M = 9.4 \pm 1.8$); 81% of respondents rated the program as 10. When asked about the acceptability of different intervention components, participants responded almost exclusively with highly positive feedback (Table 5). One participant stated, 'They explain everything very meticulously and you learn, like the program is named, how to live your life individually and how to start trusting in yourself, in people, and […] live day by day.' They expressed

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Table 5 Descriptive statistics for participant satisfaction survey post-intervention ($n = 37$)

Survey item (0–10 scale)	Mean rating	SD
Handouts were helpful	9.4	1.2
Picture cards were helpful	9.7	0.9
Health action plan was helpful	9.5	1.3
Demonstration tools were helpful	9.7	0.7
Community health worker's ability to instill understanding	9.9	0.5
¡Vivir Mi Vida! met your health needs	9.8	0.5
¡Vivir Mi Vida! met health needs of the Hispanic community	9.8	0.6
Overall experience in *¡VMV!*	9.4	1.8

intense appreciation for *¡VMV!*, with many describing the provision of the program as a 'gift from God' to the community. One individual suggested making *¡VMV!* the focal point of a community health program: 'I would like for there to be an institution that has programs like this, but in the center it would be *¡Vivir Mi Vida!*.' Participants' willingness to adopt healthier lifestyles on a more long-term basis was also promising. One participant noted, 'I can utilize what I learned here for the rest of my life, because you stay with it for the rest of your life.'

Though not to the same degree as participants, the stakeholders also disclosed high satisfaction with *¡VMV!*. For example, the CHWs felt that *¡VMV!* offered social and emotional support that was much needed in the rural population. The AVPH administrator said that her organization was eager to adopt health programs for older people, including *¡VMV!*, because seniors in Antelope Valley are in dire need of support for their well-being.

Resource feasibility

The feasibility of *¡VMV!* was chiefly dictated by the level of available resources (ie, time, space, equipment/materials, budget, and personnel). Accordingly, stakeholders' and participants' views about implementation barriers often focused on resource limitations. The CHWs expressed that the time needed to travel between participants' homes was burdensome due to Antelope Valley's vastness. Stakeholders all stated a desire for more time – for session and program length – to cover a greater range and depth of content; participants echoed this request. The *promotor* and OT supervisors pointed out that supervisory meetings, designed to assist CHWs in intervention delivery, were oftentimes cut short or canceled due to priority being placed on the CHWs' completion of participant sessions and documentation. The OT noted that this lack of time to communicate with the CHWs hindered her ability to provide an adequate level of informed support and intervention individualization.

With regard to space, the CHWs raised no concerns about securing a central location for group sessions. However, some participants indicated that having closer venues for group meetings would have been preferable due to the lengthy travel requirements for those living in outlying communities and/or relying on public transportation. The stakeholders and project management team alike expressed frustrations with equipment, including technological complexity of the physical activity monitors that were given to participants; videoconferencing using study laptops, which was often impeded by unreliable Wi-Fi signals, thus requiring communication via phone; and necessity to share certain equipment and materials among multiple personnel.

Budgetary and personnel resources were closely linked. Limited funding hampered implementation feasibility by posing personnel challenges in meeting the deadline for intervention completion, which resulted in the CHWs having heavy caseloads. Accordingly, during implementation, we discovered the need for a third CHW intervener to ensure the full dosage of intervention delivery. Having a third intervener proved necessary after one of the CHWs required a short leave of absence, and when participant schedules did not align with the availability of the two primary interveners. Given budgetary constraints and shortages of Spanish-speaking personnel at AVPH, we allowed the supervising *promotor* to serve as a back-up intervener. Nevertheless, the AVPH administrator discussed difficulties with not having additional AVPH staff cross-trained as a back-up for the CHWs, which limited program flexibility.

Management feasibility

Managing the overall project and intervention from a distance without an onsite project coordinator was particularly challenging. For example, communication with community partners occurred

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primarily through long email chains and phone texts, sent from multiple study team members. AVPH stakeholders voiced frustration with this system, stating that the messages they received were overwhelming in number and were occasionally overlapping or contradictory. In response, communication was streamlined by splitting up responsibilities among our study team and limiting the number of sent messages. Bi-weekly phone check-ins with the AVPH administrator were also arranged to ensure the project was running smoothly for both AVPH and USC personnel. Importantly, the AVPH administrator brokered contact between the study team and administration at AVCC. The pre-established relationships with community partners greatly enhanced the ease of completing mandatory processes such as obtaining institutional agreements and human subject authorizations.

Discussion

The study findings uphold the viability of implementing a CHW/OT-led lifestyle intervention for rural-dwelling, late midlife Latinos. In support of the intervention's *scientific feasibility* related to efficacy, a number of positive changes – typically reflecting large effect sizes – in psychosocial patient-centered outcomes were found including symptom severity, perceived impact of symptoms on daily activity, general well-being, satisfaction with social roles, satisfaction with social activities, and stress. Although there is some evidence demonstrating similar positive effects of lifestyle interventions led either by OTs or CHWs (Clark *et al*., 1997; 2012; Viswanathan *et al*., 2010), these results support adoption of a hybrid CHW-OT intervention approach.

Intervention recipients' systolic blood pressure declined significantly, an outcome not routinely produced from Latino-tailored lifestyle interventions (Rosal *et al*., 2011; O'Brien *et al*., 2015). Because systolic hypertension increases with age, maintaining its level within healthy ranges becomes increasingly important for cardiovascular disease prevention in persons 50 years and older (Chobanian *et al*., 2003). Notably, the magnitude of systolic blood pressure reduction recorded in the present study was also clinically meaningful, as similar improvements have been associated with reduced risk of cardiac disease or mortality in medication-based trials (Chobanian *et al*., 2003). Though in a future trial plans will be made to test the precise mechanisms by which the intervention may have reduced blood pressure, it is postulated that participants' reduced intake of sodium, saturated fat, and sugar played an important role (Hall, 2009; Chen *et al*., 2010; He *et al*., 2013). Moreover, intervention elements focusing on mental health, stress reduction, self-efficacy, and social support may have enhanced this effect, a possibility consistent with previous reports on the cardiovascular benefits of psychosocial interventions (Linden *et al*., 1996; Rainforth *et al*., 2007). Together, evidence points to the need to further explore lifestyle interventions that reach beyond a focus on diet and exercise and extend to psychosocial factors that may positively influence both physiological and mental well-being.

Other physiological parameters did not improve, and coronary heart and diabetes disease risk remained the same. These results are consistent with other CHW-led programs that have shown modest effects at best on cardiometabolic indicators (Rosal *et al*., 2011; De Heer *et al*., 2015). One explanation for these findings is that the 16-week intervention did not uniquely target any single disease or delve deeply into physical activity or diet, which is uncharacteristic of traditional lifestyle interventions. However, the intervention was designed to promote holistic wellness as recommended for rural healthcare efforts, in which multiple, targeted services are less practical or feasible (Chipp *et al*., 2008). In this regard, cardiometabolic parameters associated with certain diseases (eg, HbA1c levels) or specific health behaviors may be difficult to alter through a generalized intervention. Further investigation is warranted to determine the impact that adaptations made to improve the practicality of lifestyle interventions for implementation in a rural primary care context have on the intervention's potential to produce desired health outcomes.

One aspect of *¡VMV!* that proved unfeasible was use of the Vivofit activity monitor. The CHWs described the tracker as 'too high-tech' for the target population, resulting in only one participant utilizing it. In other CHW-led programs, incorporating strategies such as providing low-tech pedometers with a goal of 10 000 daily steps (Koniak-Griffin *et al*., 2015) or linking participants

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to community-based physical activity resources such as walking groups (De Heer *et al*., 2015) resulted in significantly increased physical activity. In planning the next iteration of *¡VMV!*, our team will more appropriately tailor physical activity strategies to the target population.

Another possible reason for the lack of effect for cardiometabolic indicators is that the four-month program length was too short to affect changes in these parameters. For instance, in one prior study, significant changes in HbA1c levels were not observed until completion of a six-month, *promotor*-delivered, diabetes-focused program (Lujan *et al*., 2007). In a further study, Ockene *et al*. (2012) reported improvements in weight and HbA1c following a lifestyle intervention for Latinos, although their program lasted a full year. Our preliminary findings justify consideration of an extended intervention and assessment period in a future clinical trial.

The *process feasibility* of *¡VMV!* is promising. The desired number of intervention participants were efficiently recruited in a one-month time period with assistance from the primary care partners. Moreover, the study demonstrated 77% participant adherence to the program and 93% retention of individuals to the time of post-testing. These numbers are successful, given anecdotal reports of 50% no-show rates for general community programs at AVPH. *¡VMV!* was delivered with high fidelity, though in future efforts the training workshop and CHW supervision meetings will be bolstered to address areas of concern. For instance, the CHW's underutilization of motivational interviewing may be remedied by expanding the training component that is dedicated to introducing and utilizing the techniques. Nonetheless, the systematic assessment of intervention delivery fidelity featured in this pilot study reveals that the CHWs have full capacity to deliver the core components of a complex OT-CHW intervention with high fidelity.

Participants were extremely satisfied with *¡VMV!*. Key stakeholders also found the program to be acceptable and worthy of adopting, but pointed out aspects that could be improved. For example, the OT and the AVPH administrator requested that in future efforts attempts be made to more fully integrate *¡VMV!* into the ongoing services offered through patients' primary care institutions (eg, establishing clear expectations for collaboration and reciprocal communication between the primary care and CHW-OT teams regarding treatment and outcomes). Interveners and participants alike experienced difficulties with Wi-Fi during the intervention. Because the Wi-Fi landscape continuously changes, verifying coverage before study initiation will be useful in future applications, and 'offline' solutions, such as using carbon copy paper to capture treatment notes instead of requiring CHWs to upload digital copies, need to be implemented when indicated.

Among all levels of the process evaluation, the team's ability to improvise emerged as a common theme that facilitated implementation. Whether addressing adherence by allowing participants to make up missed treatment sessions or streamlining treatment documentation so that CHWs could complete their notes with less difficulty, the ability to undertake in-stream adaptations proved critical. In cases where the team was less adaptable, process feasibility suffered. As an example, because having prearranged groups for each CHW before initiating the intervention was adhered to, the time between pretesting and the first treatment session was unusually long ($M = 22$ days). Indeed, the success of community-based participatory research hinges on the flexibility with which teams approach and execute process elements (Cook, 2008).

The assessment of the *resource feasibility* and *management feasibility* of *¡VMV!* revealed the need for slight reconfiguration of time and personnel. Travel time frequently presents an obstacle for rurally situated home health service providers and patients (Buzza *et al*., 2011), as was the case in this study. During planning stages, the amount of time required for CHWs to travel among participants' homes was underestimated, resulting in a failure to anticipate how this would impact scheduling and caseloads. Future efforts will require strategizing with community partners to identify practical solutions to resource and management shortcomings, discussing strategies such as reducing intervener caseloads, increasing the number of telehealth sessions, and hiring an onsite project coordinator.

Strengths & limitations

This study had multiple strengths. The intervention features a pioneering collaboration between OTs and CHWs within primary care. Though each field of practice is independently emerging as a contributor to this healthcare

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context (Brownstein *et al.*, 2011; Donnelly *et al.*, 2013), their co-involvement as a partnered team brings an important, reciprocal skillset to the intervention equation that has not yet been studied. In addition, *¡VMV!* is qualitatively distinct from other lifestyle interventions for rural-living Latinos (Brown *et al.*, 2002; Walker *et al.*, 2009; Fahs *et al.*, 2013; Hu *et al.*, 2014; Lilly *et al.*, 2014). It is based on a holistic approach to healthy lifestyle, thereby moving beyond the traditional focus on dietary intake and exercise to encompass pressing daily concerns such as social relationships, mental health, sleep, and stress management. Finally, including patients and all ranks of stakeholders in the development and implementation process of *¡VMV!* (Schepens Niemiec *et al.*, 2015) provides a more realistic view of program roll-out in a real-life context.

Despite its strengths, the study also had several limitations. The pretest-posttest design did not include a control group, which leaves study results, particularly for the MYMOP2, susceptible to regression to the mean or other threats to causal inference. Long-term follow-up assessment was not included; however, the team is currently preparing a 12-month follow-up study of the same intervention participants. A small sample was drawn from one primary care facility. A future study will feature a multi-site trial with more participants to improve generalizability. Group session attendance was low in comparison to individualized sessions. A wider variety of locations and time slots for group sessions will be available to participants in a future trial to improve adherence. Use of deductive methods for content analysis of feasibility data – using predetermined thematic categories – limited the richness of data extracted from the interviews. More in-depth interviews with detailed qualitative analysis is warranted. Finally, change in self-reported health outcomes may have been over- or underestimated, owing to recall and social desirability biases.

Conclusion

The *¡VMV!* lifestyle intervention is feasible to implement and shows potential to improve a variety of health and wellness outcomes in late middle-aged Latino patients from a rural community. This study is significant because it serves as a springboard to change clinical practice in primary care. Unlike other interventions, *¡VMV!* combined the specialties of CHWs and OTs to encourage a hard-to-reach patient population to incorporate general healthy lifestyle changes into their daily routines. Although a number of challenges arose which can potentially be minimized through programmatic tweaks, this study demonstrated one way in which CHWs and OTs can effectively collaborate to address the health needs of underserved populations within rural primary care. Given the promise that *¡VMV!* shows, and the health risks that present in rural-living Latinos, a future randomized controlled trial is warranted to further investigate the efficacy of this lifestyle intervention.

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Conflicts of Interest

None.

Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the University of Southern California Institutional Review Board and with the Helsinki Declaration of 1975, as revised in 2008.

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