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# Adapting and RE-AIMing a heart disease prevention program for older women with diabetes

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## ABSTRACT

Coronary heart disease is a pervasive public health problem with a heavy burden among older women. There is a need for developing effective interventions for addressing this problem and for evaluating the dissemination potential of such interventions. A multiple-behavior-change program originally designed for men with heart disease was adapted for women at high risk of heart disease in two randomized clinical trials—the Mediterranean Lifestyle Program and ¡Viva Bien!. Results from these two trials, including readiness for dissemination, are evaluated using the RE-AIM framework in terms of Reach, Effectiveness, Adoption, Implementation, and Maintenance. Program adaptations produced relative high reach as well as consistent and replicated effectiveness and maintenance, and were adopted by a high percentage of primary care offices and clinicians approached. We discuss key findings, lessons learned, future directions for related research, and use of RE-AIM for program development, adaptation, scale-up, and evaluation.

## KEYWORDS

Coronary heart disease, Diabetes, Latino, RE-AIM, Evaluation

**ClinicalTrials.gov Protocol IDs**
NCT00142701 (CHDRISK); NCT00680849 (MLP); NCT00233259 (¡Viva Bien!)

**Implications**

**Practice:** Having a consistent set of criteria or implementation factors against which to judge programs and to guide adaptation can be helpful in balancing fidelity and adaptation, and in planning for dissemination.

**Policy:** Implementation science frameworks such as RE-AIM can be used to help plan, select, and adapt evidence-based interventions for older populations and contexts.

**Research:** Applications such as RE-AIM can be used to create replicable programs that are effective across diverse settings and older populations.

Coronary heart disease (CHD) is a pervasive problem in terms of overall incidence and mortality rates in western society [1, 2]. Diabetes confers an increased risk of functional limitations and heart disease mortality in middle-aged and older adults, especially postmenopausal women [3, 4]. Among those with diabetes, older women have a poorer survival prognosis than men after a myocardial infarction, including a 1.4 times higher risk of in-hospital death [5]. Despite the incidence and mortality rates of CHD in women, older women with diabetes, including Latinas, remain a largely understudied group. A comprehensive lifestyle program addressing CHD risk factors would be of enormous benefit to such persons, yet CHD risk-prevention research with older women and Latinas is very limited [6].

In the early 1990s, Ornish [7] successfully intervened simultaneously on a combination of heart-disease factors to reverse CHD. The Ornish comprehensive lifestyle program consisted of a very low-fat (<10% of calories from fat) diet, smoking cessation, stress-management training, moderate exercise, and group support. Angiographic results of the randomized Ornish Lifestyle Heart Trial found that the average percent diameter stenosis regressed from 40.0% to 37.8% in the experimental group and progressed from 42.7% to 46.1% in controls ($p<.001$).

The Ornish program, as well as other in-person multiple-risk-factor intervention trials [8, 9], improved behavioral, psychosocial, quality of life, and biologic heart disease risk factors. But questions remained about the dissemination potential of this intervention. Can the costs and burden required for this intense intervention be reduced without sacrificing significant and lasting lifestyle change in high-risk populations? In a series of randomized clinical trials [9–12], we adapted the Ornish program–which was efficacious for men with CHD–for older women with type 2 diabetes at risk of CHD, and answered questions about (a) the feasibility of recommending such a restrictive diet; (b) adherence to treatment recommendations and techniques to increase adherence in less closely supervised contexts; and (c) public health concerns related to the intensity, cost, reach, generalizability, time demands, and extreme lifestyle changes

called for in this intervention. Our intent was to adapt the Ornish intervention to make it more broadly applicable and disseminable without reducing effectiveness. Furthermore, evaluating the effectiveness of intervention adaptations for both European American women and Latinas would expand generalizability, an important demonstration in evaluating dissemination potential.

The purpose of this paper is to (a) describe the steps taken to adapt the Ornish program for older women and Latinas in our Mediterranean Lifestyle Program (MLP) and ¡Viva Bien! trials; (b) evaluate the readiness of the intervention for dissemination based on the RE-AIM framework [13–15]; and (c) present key findings, lessons learned, and future directions for program development, evaluation, and improvement. RE-AIM is an acronym for dimensions of Reach (percentage and representativeness of potential participants who take part in an intervention), Effectiveness (impact of the intervention on multiple outcomes), Adoption (participation rate and representativeness of intervention settings and staff), Implementation (consistency of delivery of intervention content and costs), and Maintenance (long-term intervention effects and continuation of the intervention by organizations). RE-AIM has provided a useful structure for assessing the potential impact of interventions in real world settings [13, 14].

## METHODS

### Adaptation of the Ornish program

We first adapted the Ornish Lifestyle Heart Trial [7] in a randomized pilot ($n$=28) trial (the Women's Lifestyle Heart Trial [WLHT]) [16] to determine whether the substantial cardiovascular benefits among men reported in Ornish could be replicated in postmenopausal women with CHD. The WLHT combined the Ornish [7] approach with our research group's previously successful diabetes self-management work stressing self-efficacy and problem solving [17]. As in Ornish, the WLHT intervention began with a 1-week retreat, which was followed by 4-h twice-weekly meetings to establish and practice healthful behavior changes in diet, physical activity, stress management, smoking cessation, and social support. Similar to Ornish, the WLHT emphasized proximal sources of support (e.g., significant other, family, friends), which would be expected to produce sizeable short-term effects compared with a control condition but did not explicitly incorporate strategies to promote health behavior maintenance or to explicitly address more distal sources of social support for behavior change, such as worksite, media, neighborhood, or community organization support. The WLHT demonstrated that the Ornish program was feasible and effective in a sample of women who had CHD [10]. Based on these promising results, we again modified the intervention and conducted two randomized clinical trials to test the program's effectiveness in women with type 2 diabetes who were at high risk for CHD, but who did not have CHD. In the first of these trials, the MLP, significant changes in the targeted behaviors of diet, physical activity, stress management, smoking cessation, and social support were achieved with a lower-intensity Ornish-type intervention [11, 12]: The retreat was shortened from 1 week to 2½ days; meetings were held on a fading schedule over 24 months and were facilitated by lay leaders once established by professional leaders, and the less-restrictive Mediterranean-style diet was recommended.

In the second of these trials, the ¡Viva Bien! study [9], we showed that the MLP intervention could be effectively adapted for Latinas with type 2 diabetes who received health care from a large health maintenance organization (HMO) or community health center. The less intense version of the Ornish program reduced costs, was more appropriate for high-risk women who did not have CHD, and promoted the use of all sources of social support.

### Settings and samples

The MLP was evaluated in a clinical trial that randomly assigned 279 women to either (a) usual care from their health providers ($n$=116) or (b) usual care plus MLP ($n$=163). All participants were recruited from primary care practices in Oregon. Details of participant recruitment have been described previously [18].

¡Viva Bien! participants were assigned randomly to (a) usual care within their HMO or community health center ($n$=138) or (b) usual care plus the ¡Viva Bien! intervention ($n$=142). The study recruited older Latinas with type 2 diabetes who received their medical care from 19 clinics associated with Kaiser Permanente Colorado in the Denver metropolitan area or from the Salud Family Health Center (Salud) in Commerce City near Denver [19]. A woman was eligible if she identified as Latina, was 30–75 years old, had been diagnosed with type 2 diabetes for at least 6 months, lived independently, had a telephone, was literate in either English or Spanish, and lived near the intervention site.

Procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000 and approved by the IRBs of the host institutions. All persons gave their informed consent prior to their inclusion in these studies.

### Measures

(a) RE-AIM measures are summarized in Table 1. This evaluation approach offers a practical way to evaluate the intervention on dimensions of Reach, Effectiveness, Adoption, Implementation, and

**Table 1** | RE-AIM guidelines for developing, selecting, and evaluating programs and policies intended to have a public health impact

| RE-AIM element | Guidelines and questions to ask |
|---|---|
| Reach, % and representativeness of participants | Can the program attract large and representative percent of target population? Can the program reach those most in need and most often left out (i.e., older adults, the poor, low literacy and numeracy)? |
| Effectiveness: Impact on key outcomes, quality of life, unanticipated outcomes, and subgroups | Does the program produce robust effects, and across sub-populations? Does the program produce minimal negative side effects and increase quality of life or broader outcomes? |
| Adoption, % and representativeness of settings and staff that participate | Is the program feasible for most real-world settings (costs, expertise, time, resources, etc.)? Can it be adopted by low-resource settings and typical staff serving high-risk populations? |
| Implementation: Consistency and cost of delivering program and adaptations made | Can the program be consistently implemented across program elements, different staff, time, etc.? Are the costs—personnel, up-front, marginal, scale-up, equipment—reasonable to match effectiveness? |
| Maintenance: Long-term effects at individual and setting levels, modifications made | Does the program include principles to enhance long-term improvements (i.e., follow-up contact, community resources, peer support, ongoing feedback)? Can the settings sustain the program over time without added resources and leadership? |

Maintenance, with implications for policy, research, and practice.

(b) Primary outcome measures.

Behavioral measures were as follows: (a) daily fruit and vegetable intake (NCI fruit and vegetable scan [20] and Food Frequency Questionnaire [FFQ; 21] in the MLP, and FFQ ¡Viva Bien!), with the criterion set at greater than or equal to five servings a day; (b) percent of calories from saturated fat (FFQ in both studies), with the criterion set at less than 10%; (c) physical activity (frequency/week of moderate physical activity measured by the CHAMPS Activities Questionnaire for Older Adults [22] in the MLP and days/week of physical activity measured by the International Physical Activity Questionnaire [23] in ¡Viva Bien!), with the criterion set at 5 days or more per week; minutes/day of stress-management practice (measured by a 7-day self-monitoring diary for both studies), with the criterion set at 5 min or more per day; and smoking status (self-reported smoker or nonsmoker), with the criterion set at nonsmoking.

Quality of life was measured by the Medical Outcome Study short form general health survey [24] in the MLP and by the Centers for Disease Control and Prevention Healthy Days instrument [25] in ¡Viva Bien!. The criterion for "healthful" quality of life was set at 50 for the physical health scale and 42 for the mental health scale, with higher scores indicating better health. The Healthy Days criterion was set at 15 or more healthy days per month because a cutoff point of 14 unhealthy days is regarded as a meaningful demarcation corresponding to the upper 10–15% of distribution of the general population for this index.

### Analyses

To provide a common metric for the two studies, all variables were recoded to reflect "proportion of criterion met." Values meeting or exceeding criterion were coded 1.00; all other values were coded within a range from 0 to 0.99. Once the proportions were calculated, the mental and physical health scales were averaged for analysis. Because the two studies targeted multiple behavioral outcomes, a multi-behavioral index score also was created as the mean of the five proportionalized behavioral outcomes.

Descriptive statistics were computed to assess reach, adoption, and implementation in the two studies. Repeated measures MANCOVA models across four time points (baseline and 6, 12, and 24 months) were conducted to document effectiveness and maintenance, focused on primary outcomes of behavioral change and quality of life. Age was covaried because it was found in univariate analyses to be significantly correlated with different behaviors at multiple time points.

## RESULTS

### Reach

*Recruitment*–Recruitment statistics and characteristics of the recruited samples are presented in Table 2. The percent of those eligible and invited who agreed to participate and began the program was 51% (279/544) in the MLP and 41% (280/680) in ¡Viva Bien!. Both studies drew relatively diverse samples of older women, average age around 60 years, with the exception of all being Latina in the ¡Viva Bien! study. There was substantial variability on most

**Table 2** | Reach: recruitment results and participant/nonparticipant characteristics from two studies (MLP and ¡Viva Bien!) of older adults

| | MLP | ¡Viva Bien! | | |
|---|---|---|---|---|
| Recruitment statistics | | | | |
| Letters mailed | 1162 | 7,945 | | |
| Declined postcard | 184 (184/1,162=16%) | 1,338 (1,338/7,945=17%) | | |
| Calls attempted | 978 (978/1,162=84%) | 6,607 (6,607/7,945=83%) | | |
| Successful calls | 850 (850/978=87%) | 4,045 (4,045/6,607=61%) | | |
| Eligible | 544 (544/850=64%) | 680 (680/4,045=17%) | | |
| Agreed to participate | – | 414 (414/680=81%) | | |
| % Eligible agreeing to participate who began program | 279 (279/544=51%) | 280 (280/680=41%) | | |
| | MLP | | ¡Viva Bien! | |
| | Nonparticipants | Participants | Nonparticipants | Participants |
| | Mean (SD)/% | Mean (SD)/% | Mean (SD)/% | Mean (SD)/% |
| Recruited sample | | | | |
| Age (years) | 61.7 (7.7) | 60.9 (8.0) | 58.7 (8.7) | 57.0 (10.1) |
| BMI (kg/m$^2$) | 33.3 (7.4) | 34.4 (7.7) | 32.9 (6.8) | 33.9 (7.5) |
| Years with diabetes | 10.2 (8.7) | 8.5 (7.8) | 9.2 (5.7) | 9.6 (8.4) |
| % Smoker | 5.8% | 4.8% | 16.7% | 9.2% |
| % Prefer Spanish | – | – | 9.5% | 15.2% |
| Type of glucose-lowering medication | | | | |
| None or oral only | 30.2% | 44.1% | 55.6% | 69.9% |
| Insulin | 13.2% | 12.6% | 44.4% | 30.2% |

personal characteristics, but a sizable percent of participants in both studies was relatively poor (43–54% reported annual family incomes less than $30,000) and less well educated (35–53% had a high school education or less). The vast majority was considerably overweight (body mass index in both samples averaged around 35 kg/m$^2$) and had chronic illnesses besides diabetes.

*Characteristics of participants vs. those who declined*–In the MLP study, participants and nonparticipants did not differ on self-reported age, BMI, age diagnosed with diabetes, type of diabetes medication, or percent of smokers, however, participants tended to have fewer years taking medication and fewer years diagnosed with diabetes (Table 2).

In the ¡Viva Bien! study, among those eligible, the only significant differences found between participants and nonparticipants were that smokers were more likely to decline participation than nonsmokers, and nonparticipants tended to have a lower body mass index.

### Effectiveness and maintenance

As can be seen in Table 3, in general, there were short-term and moderately large, consistent improvements in both studies on most health behavior outcomes for the intervention condition relative to the enhanced usual care control condition.

*Robustness of results*–The intervention proved to be equally effective across all subgroups of participants, including those most vulnerable, such as those with less formal education or income. Because age was a significant independent predictor of some behavioral outcomes, with older participants engaging in more healthful behaviors than younger, age was covaried in analyses of these outcomes; age did not moderate treatment effects.

*Quality of life*–Neither study significantly affected quality of life. Repeated-measures MANCOVAs produced nonsignificant treatment×time interactions for quality of life from baseline to 24 months in both studies.

### Adoption

The intervention programs had very high levels of adoption/acceptance among primary care settings and physicians within those settings. The community-based MLP study had an 83% setting-level physician office participation rate, and, within those settings, 70% (54 out of 79 approached) of physicians took part. In the ¡Viva Bien! study, two health-care settings, an HMO and a community health center, were approached, and both participated. Once this participation was arranged, all primary care clinics approached, and all physicians within these clinics referred their patients to the study.

### Implementation

Table 4 summarizes implementation results. Staff delivered the program with high fidelity, but participant attendance at the weekly sessions declined over time. The costs both per participant and per unit reduction in different outcomes

**Table 3** | Effectiveness and maintenance: short-term and longer-term intervention effects in two studies of older adults

| | Time 1 (baseline) mean (SD) | Time 2 (6 month) mean (SD) | Time 3 (12 month) mean (SD) | Time 4 (24 month) mean (SD) | Time × Tx group interaction $F$; $p$ | Age $p$ |
|---|---|---|---|---|---|---|
| Fruit/veg intake | | | | | | |
| MLP | | | | | 1.7; 0.18 | 0.13 |
| Control | 0.83 (0.23) | 0.82 (0.25) | 0.83 (0.25) | 0.82 (0.25) | | |
| Intervention | 0.82 (0.25) | 0.86 (0.23) | 0.89 (0.20) | 0.87 (0.20) | | |
| ¡Viva Bien! | | | | | 6.7; <0.001 | 0.34 |
| Control | 0.63 (0.30) | 0.62 (0.28) | 0.65 (0.28) | 0.68 (0.28) | | |
| Intervention | 0.68 (0.29) | 0.80 (0.25) | 0.76 (0.26) | 0.78 (0.23) | | |
| Sat fat intake | | | | | | |
| MLP | | | | | 15.7; <0.001 | <0.01 |
| Control | 0.69 (0.29) | 0.75 (0.27) | 0.74 (0.28) | 0.73 (0.28) | | |
| Intervention | 0.65 (0.28) | 0.89 (0.19) | 0.86 (0.16) | 0.82 (0.22) | | |
| ¡Viva Bien! | | | | | 2.5; 0.06 | <0.01 |
| Control | 0.82 (0.19) | 0.87 (0.15) | 0.88 (0.16) | 0.86 (0.16) | | |
| Intervention | 0.80 (0.21) | 0.96 (0.10) | 0.93 (0.12) | 0.92 (0.15) | | |
| Physical activity | | | | | | |
| MLP | | | | | 9.1; <0.001 | 0.50 |
| Control | 0.57 (0.44) | 0.61 (0.41) | 0.57 (0.43) | 0.44 (0.47) | | |
| Intervention | 0.54 (0.43) | 0.88 (0.27) | 0.79 (0.36) | 0.72 (0.41) | | |
| ¡Viva Bien! | | | | | 2.1; 0.10 | 0.56 |
| Control | 0.66 (0.40) | 0.78 (0.34) | 0.78 (0.34) | 0.88 (0.26) | | |
| Intervention | 0.68 (0.40) | 0.84 (0.30) | 0.82 (0.31) | 0.85 (0.31) | | |
| Stress mgmt practice | | | | | | |
| MLP | | | | | 16.3; <0.001 | 0.60 |
| Control | 0.44 (0.47) | 0.50 (0.47) | 0.42 (0.48) | 0.43 (0.47) | | |
| Intervention | 0.40 (0.47) | 0.82 (0.37) | 0.74 (0.43) | 0.72 (0.43) | | |
| ¡Viva Bien! | | | | | 5.1; 0.002 | 0.003 |
| Control | 0.45 (0.43) | 0.49 (0.42) | 0.56 (0.41) | 0.56 (0.39) | | |
| Intervention | 0.39 (0.43) | 0.59 (0.40) | 0.60 (0.41) | 0.62 (0.41) | | |
| Smoking status | | | | | | |
| MLP | | | | | All $\chi^2$=NS | 0.36 |
| Control | 0.90 (0.31) | 0.90 (0.31) | 0.90 (0.30) | 0.90 (0.31) | | |
| Intervention | 0.91 (0.28) | 0.93 (0.25) | 0.92 (0.28) | 0.93 (0.25) | | |
| ¡Viva Bien! | | | | | all $\chi^2$=NS | <0.01 |
| Control | 0.87 (0.33) | 0.92 (0.27) | 0.91 (0.29) | 0.91 (0.29) | | |
| Intervention | 0.91 (0.29) | 0.92 (0.27) | 0.91 (0.29) | 0.94 (0.24) | | |
| Behavioral index[a] | | | | | | |
| MLP | | | | | 30.9; <0.001 | <0.05 |
| Control | 0.68 (0.18) | 0.72 (0.16) | 0.70 (0.17) | 0.69 (0.19) | | |
| Intervention | 0.67 (0.18) | 0.88 (0.14) | 0.84 (0.16) | 0.81 (0.18) | | |
| ¡Viva Bien! | | | | | 6.8; <0.001 | <0.001 |
| Control | 0.69 (0.20) | 0.74 (0.17) | 0.76 (0.17) | 0.78 (0.16) | | |
| Intervention | 0.69 (0.18) | 0.81 (0.21) | 0.78 (0.23) | 0.82 (0.16) | | |
| Quality of life | | | | | | |
| MLP | | | | | 0.6; 0.63 | 0.47 |
| Control | 0.86 (0.12) | 0.87 (0.12) | 0.86 (0.13) | 0.85 (0.13) | | |
| Intervention | 0.86 (0.11) | 0.87 (0.12) | 0.86 (0.12) | 0.87 (0.12) | | |
| ¡Viva Bien! | | | | | 1.3; 0.28 | <0.05 |
| Control | 0.71 (0.43) | 0.75 (0.41) | 0.68 (0.43) | 0.81 (0.43) | | |
| Intervention | 0.66 (0.44) | 0.72 (0.41) | 0.82 (0.36) | 0.72 (0.43) | | |

MANCOVA results are presented in the last two columns of the table. Presented first is the time × treatment group interaction $F$ and significance ($p$) values, then the significance ($p$) values of the age covariate. Chi-square analyses were used for smoking outcomes, which were dichotomous. Note: Behavioral variables were recoded to reflect the proportion of criterion met (see text)

[a] The behavioral index is the mean of five independent behavioral variables that were recoded to reflect the proportion of criterion met, with higher numbers indicating more healthful behaviors (see text): daily fruit and vegetable intake, percent saturated fat intake, weekly exercise, weekly self-monitored stress-management practice, and smoking status

were moderate, especially given the intensity of the program. Costing and the economic outcomes are presented in more detail in Ritzwoller et al. [26, 27].

**Table 4** | Implementation: attendance, retention, and intervention costs from two studies (MLP and ¡Viva Bien!) of older adults

| | MLP, % or $ | ¡Viva Bien!, % or $ |
|---|---|---|
| Attendance (intervention participants only) | | |
| 0–6 Months | 54% | 65% |
| 6–24 Months | 31% | 47% |
| Retention | | |
| 6 Months | 88% | 78% |
| 12 Months | 83% | 70% |
| 24 Months | 85% | 61% |
| Costs of intervention delivery | | |
| Recruitment costs/ participant | $ 990[a] | $ 263 |
| Intervention cost/ participant | $1,058[a] | $3,045 |
| Cost per unit reduction in | | |
| Hemoglobin A1c | $4,592[a] | $5,076 |
| Body Mass Index | $2,839[a] | $5,076 |

[a] Costs of the Mediterranean Lifestyle Program (MLP) were adjusted for inflation (.58%) from the year 2000 to compare with the ¡Viva Bien! program. MLP costs are underestimates because cost data were captured retrospectively and likely omitted some labor, technology, and supply expenses associated with the intervention

### Maintenance

*Individual level*–As shown in Table 3, long-term intervention effects were generally present, but the differences between intervention and control conditions were usually less at 24-month follow-up than at the post-intervention assessments at 6 and 12 months.

*Setting level*–Although it was not a condition of participation, no practice continued the intervention through their own resources after the study was over, despite the generally encouraging results and positive patient feedback and satisfaction, likely because there was not a business model or reimbursement from payers for providing the program.

## DISCUSSION

We employed the RE-AIM framework to help us consider and address translation and adaptation issues important for public health impact, and to increase the likelihood that the MLP and ¡Viva Bien! programs would be replicated, be widely adopted, and reach older women at risk for CHD. Consistent with this theme issue, this paper evaluated the adapted programs on each of the RE-AIM dimensions and considered implications for older adults. Below and in Table 5, we summarize lessons learned on each of the key RE-AIM dimensions as well as future anticipated directions.

*Reach*–These programs demonstrated good reach despite their intensity. An important caveat is that participants did not have to pay for the programs. Our results demonstrate that it is possible to recruit, engage, and retain older women with lower SES, Latinas, and those with multiple chronic illnesses. Our clinical impression is that the women in these programs formed strong social bonds. Social connectedness (e.g., meeting with other women like them) was an important part of the program. Older women at high risk for CHD made the time necessary for intensive lifestyle change, but it remains to be seen whether they would or could pay for such a program. Future research should investigate the attractiveness of this program with other cultural groups, and whether offering the program through community organizations serving older adults or those with diabetes, would enhance its reach and increase the sustainability of one of the key strengths of the program, social connectedness.

*Effectiveness*–Results indicate that older women, despite facing many social–environmental and illness challenges, were able to make significant, consistent, moderate improvements in multiple behaviors. The interventions were effective for the highest-risk subgroups as well as other participants and for older as well as more middle-aged participants. The MLP and ¡Viva Bien! programs did not produce improvements in health-related quality of life, but they also did not produce any negative side effects or decrements in quality of life despite their intensity and time demands. Future studies could examine whether a less intense program could be as effective and if adding real-time self-monitoring strategies might enhance effectiveness.

*Adoption*–This RE-AIM dimension was not fully tested. The clinics and physicians offering this

**Table 5** | Lessons learned and future anticipated directions

| RE-AIM dimension | Key findings | Lessons learned | Future directions |
|---|---|---|---|
| Reach | High, given intensity | Is attractive to women at risk | Reduce intensity and number of sessions |
| Effectiveness | Consistent moderate behavioral effects | Robust effects: older women made multiple changes | Add real-time self-monitoring |
| Adoption | High rates, both studies | PCPs like it; no cost to them, does not interfere | Need to acquire sponsors or reimbursement |
| Implementation | High across staff; attendance moderate | Supervision pays off; highly paid professional staff | Add mobile technologies |
| Maintenance | Good for 24 months individual; no continuing adoption | Social environment critical | Add more social media |

service as a free supplement to their usual care were glad to support it and refer patients, but they did not have to pay for it or to integrate it with the rest of the patient's primary care. In other words, the high physician acceptance represented "research adoption" rather than "clinical adoption," in which health plans or clinics would have to cover costs of the programs. We note that Dr. Ornish has been able to persuade a number of hospitals to fund his even more intensive and costly CHD reversal program. Future research could explore whether acquiring sponsors or reimbursement would increase adoption. In addition, effectiveness trials to study adoption of the program in both clinical and non-clinical settings is an important future step.

*Implementation*–The implementation measures were relatively few for MLP and ¡Viva Bien! because much of the intervention was conducted by research staff who followed detailed protocols. The program components were delivered consistently to all participants who attended the various sessions. RE-AIM includes costs under Implementation, and relatively comprehensive cost data (including costs for promotion and recruitment, replication costs, and sensitivity analyses) have been collected in both the MLP and ¡Viva Bien! and detailed elsewhere [26, 27]. Depending on one's perspective, the costs from health plan/payer and patient perspectives were somewhat less than we initially anticipated, given the intensity of the program. The MLP and ¡Viva Bien! interventions are not inexpensive, but they are certainly much less expensive than "downstream" expenditures such as surgical procedures and even some medications to prevent or manage CHD.

Future research is needed to determine whether mobile technologies could help reduce costs and enhance implementation. In addition, developing a training and certification program that would promote implementation within existing programs, such as public recreational centers, community health education programs, senior centers, or state public health departments, as well as clinical settings, would increase the potential for implementation and sustainability of the program.

*Maintenance*–Individual-level maintenance of behavior changes across multiple risk factors was good out to 6–12 months, then showed some relapse at 24 months, likely due to pervasive environmental influences. The addition of social media might promote maintenance, a ripe area for future research.

The biggest disappointment from a RE-AIM perspective is that, like much randomized controlled research, the implementation sites did not maintain the program after research funding was withdrawn. Sustainability was not the goal of this program and should not have been expected, as materials, staff training, and other required resources and technical assistance were not provided to sites. Setting-level maintenance is viewed as a next stage of this research. More generally, setting-level maintenance is the least frequently reported RE-AIM dimension and one of the focal points for future research [13, 14].

One limitation of this report is its largely retrospective viewpoint. Although key concepts such as reach and likelihood of implementation in real-world settings were directly used in adapting both the MLP and ¡Viva Bien! from the Ornish program, the full RE-AIM model was not prospectively tested in either study. Strengths include the detailed use of a translation science framework, replication and lessons learned from two reasonably large randomized controlled trials on a relatively neglected group of real-world older primary care patients, long-term data on multiple health behaviors across studies, and detailed discussion of the important and underreported issues of reach, costs, and sustainability.

In conclusion, program adaptations produced relatively high reach among older women with high risk of cardiovascular disease as well as consistent and replicated effectiveness and maintenance, and the programs were adopted by a high percentage of primary care offices and clinicians approached. Future research applying implementation science models such as RE-AIM is indicated, especially when they can be used consistently throughout the phases of program planning, design, implementation, adaptation, maintenance, and reporting [28].

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