CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

What are the health benefits of a community based exercise and health education program for underserved Latinas?

AUTHOR

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CLINICAL SCENARIO

The Latino community has a higher need for healthcare due to the prevalence of obesity, diabetes mellitus type 2, and hypertension. These three chronic conditions put the Latina community at a higher risk of co morbidities, such as end stage kidney disease and cardiovascular disease. Furthermore, mortality increases when diagnosed with one or more of these conditions. In the United States, 20.8% of deaths in the Hispanic community are caused by heart disease, 5% by cerebrovascular diseases, and 4.5% by diabetes mellitus. The high prevalence of these chronic conditions, is due in part to multiple preventable factors common among Latinos such as diets low in fruits and vegetables, high sedentary rates, and an elevated prevalence of smokers. The high rates of life threatening diseases and risk factors make affordable health care a vital tool for management of chronic diseases; yet data show that a larger percentage of the Latino population remain uninsured when compared to the national average. Currently the Latino community comprise 8.9% of the total United States' population, and the need for effective, low cost chronic disease management and prevention programs for this community will only continue to grow as the Latino population grows.

This CAT is meant to investigate the efficacy of wellness programs for delivering preventive care, thereby addressing disparities in disease prevalence and access to health care. The secondary goal of this CAT is to provide a preliminary assessment of the efficacy of Amigas en Salud, by researching the outcomes of programs based on similar principles and interventions.

SUMMARY OF SEARCH

Twenty-five studies were located that met the inclusion and exclusion criteria. Ten of these were selected due to their similarity to Amigas en Salud. This group of studies included 1 systematic review, 6 RCTs, and 3 prospective cohort studies. Three studies were reviewed and discussed due to their superior quality, their use of an intervention that best matched Amigas en Salud, and their use of a variety of outcome measures.

The following statistically and clinically significant health benefits were gained from exercise and health awareness programs for Latinas: improved physical activity, improved physical fitness, decreased HbA1c, decreased insulin resistance, and improved diet. Additional statistically significant findings were decreased LDL.

Due to the variation in interventions across the three papers, there was no consistent outcome found in all of them. Specificity of intervention appears to be an important factor that determines the resulting outcome.

These three papers presented important keys to creating a wellness program including: Social Cognitive Theory as a framework, with special attention paid to addressing barriers; lay health advisors; collaboration with the community; ensuring low attrition through phone calls, home visits, and rewards; and an interactive education model.

CLINICAL BOTTOM LINE

Evidence suggests that a community based exercise and health education program for Latinas can meaningfully affect physical fitness, physical activity, Hb1Ac, insulin resistance, and diet.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy					
Patient/Client Group	<u>I</u> ntervention 1	<u>I</u> ntervention 2 *	<u>O</u> utcome(s)		
Latin* Hispanic* Underserved	Exercis* Zumba Aerobic exercise* Physical exercise Run* Walk* Bike OR cycling Swim*	Education, "health education" Diabetes Hypertension Domestic Violence Sexual health Obesity Body mechanics Self defence Nutrition Women's health Sexually transmitted infection Sexually transmitted diseases End Stage Kidney Disease Mental Health Stress management Health literacy	Body mass index BMI Weight Waist circumference Resting heart rate Blood pressure Systolic diastolic Hemoglobin A1c glucose Lipid* Cholesterol Triglycerides LDL HDL Insulin Diet nutrition knowledge Quality of life Depression Percent body fat Habit*		

^{*}As I don't have a comparison group, I changed the "C", to a second "I" so as to include the education portion.

Final search strategy: I used multiple searches so as to ensure inclusion of all relevant articles. These searches are included below.

- 1. (Underserved AND (Latin* OR Hispanic*)) AND (Exercise OR Zumba OR Aerobic exercise OR Physical exercise OR Run* OR Walk* OR Bike OR Swim*) AND (Education AND (Diabetes OR Hypertension OR Domestic Violence OR Sexual health OR Obesity OR Body mechanics OR Self defence OR Nutrition OR Women's health OR Sexually transmitted infection OR Sexually transmitted diseases OR End Stage Kidney Disease OR Mental Health OR Stress management OR Health literacy)) AND (Body mass index OR BMI OR Weight OR Waist circumference OR Resting heart rate OR Blood pressure OR Systolic OR diastolic OR Hemoglobin A1c OR glucose OR Lipid* OR Cholesterol OR Triglycerides OR LDL OR low-density lipoproteins OR HDL OR "high density lipoproteins" OR Insulin OR Diet OR nutrition* assessment OR knowledge OR Quality of life OR Depression OR Percent body fat OR Habit*)
- 2. To broaden search: Modified to "underserved" for population:

Underserved AND (Exercise OR Zumba OR Aerobic exercise OR Physical exercise OR Run* OR Walk* OR Bike OR Swim*) AND (Education AND (Diabetes OR Hypertension OR Domestic Violence OR Sexual health OR Obesity OR Body mechanics OR Self defence OR Nutrition OR Women's health OR Sexually transmitted infection OR Sexually transmitted diseases OR End Stage Kidney Disease OR Mental Health OR Stress management OR Health literacy)) AND (Body mass index OR BMI OR Weight OR Waist circumference OR Resting heart rate OR Blood pressure OR Systolic OR diastolic OR Hemoglobin A1c OR glucose OR Lipid* OR Cholesterol OR Triglycerides OR LDL OR low-density lipoproteins OR HDL OR "high density lipoproteins" OR Insulin OR Diet OR nutrition* assessment OR knowledge OR Quality of life OR Depression OR Percent body fat OR Habit*)

3. Broadening intervention and narrowing population:

(Underserved AND (Latin* OR Hispanic*) AND women) AND (Exercise OR Zumba OR Aerobic exercise OR Physical exercise OR Run* OR Walk* OR Bike OR Swim*) AND (Body mass index OR BMI OR Weight OR Waist circumference OR Resting heart rate OR Blood pressure OR Systolic OR diastolic OR Hemoglobin A1c OR glucose OR Lipid* OR Cholesterol OR Triglycerides OR LDL OR low-density lipoproteins OR HDL OR "high density lipoproteins" OR Insulin OR Diet OR nutrition* assessment OR knowledge OR Quality of life OR Depression OR Percent body fat OR Habit*)

Then: (Underserved AND (Latin* OR Hispanic*) AND women) AND (Education AND (Diabetes OR Hypertension OR Domestic Violence OR Sexual health OR Obesity OR Body mechanics OR Self defence OR Nutrition OR Women's health OR Sexually transmitted infection OR Sexually transmitted diseases OR End Stage Kidney Disease OR Mental Health OR Stress management OR Health literacy)) AND (Body mass index OR BMI OR Weight OR Waist circumference OR Resting heart rate OR Blood pressure OR Systolic OR diastolic OR Hemoglobin A1c OR glucose OR Lipid* OR Cholesterol OR Triglycerides OR LDL OR low-density lipoproteins OR HDL OR "high density lipoproteins" OR Insulin OR Diet OR nutrition* assessment OR knowledge OR Quality of life OR Depression OR Percent body fat OR Habit*)

4. After reviewing my results from the above searches, I found that many of the papers were on web-based interventions or were population surveys. Furthermore, I decided to narrow the number of papers I included in the top 10 below, by searching for interventions that were most similar to the Amigas en Salud structure (discussed below). As this decreased the number of studies included from my database searches, I supplemented my findings with the resources provided by Ickes et al's systematic review.

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
Cochrane	10	25 satisfied my inclusion and exclusion
Pubmed	41	criteria.
* Number of results are for search strategy #2.	19	5 of these studies were selected that were most similar to Amigas en Salud due to population (>80% Latinas) and intervention (both exercise and educational portion). In addition to the 5 selected from this search result, I selected 5 that were identified in Ickes et al's systematic review. These 10 are discussed in the table below.

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria

- Randomized controlled trials, controlled trials, uncontrolled trials, case studies, systematic reviews
- Published up to September 2014
- An intervention that included a physical exercise component AND an education component.
- The majority of participants were Hispanic women.
- · Measured a health related outcome.
- · Published in English or Spanish

Exclusion Criteria

Exclusion criteria:

- Abstracts, conference proceedings, letters to the editor, dissertations, narrative review articles.
- Web-based interventions or media campaign intervention.

RESULTS OF SEARCH

A total of __10__ __ 10 relevant studies were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) and Downs and Black
Quality Assessment Rating Scale

Author (Year)	Study quality score**	Level of Evidence	Study design
Khare, M et al (2014) ⁵	20/31	2B	RCT
Ockene, I et al (2012) ⁶	24/31	2B	RCT
Staten, L et al (2005) ⁷	20/31	2B	Prospective cohort study
Ziebarth, D et al (2012) ⁸	17/31	2B	Prospective cohort study
Hayashi, T et al (2010) ⁹	20/31	2B	RCT
Ickes, M et al (2012) ¹⁰	9/11 (AMSTAR)	2A	Systematic Review
Philis-Tsimikas, A et al (2004) ¹¹	20/31	2B	RCT
Kim, S et al (2004) ¹²	18/31	2B	Prospective cohort study
Olvera, N (2010) ¹³	21/31	2B	RCT
Hovell, M et al (2008) ¹⁴	26/31	1B	RCT

^{**}Unless indicated, the Downs and Black Quality Checklist was used to assess quality of study. AMSTAR was used for the systematic review, as it was a more appropriate quality assessment.

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- Ockene IS, Tellez TL, Rosal MC, et al. Outcomes of a Latino Community-Based Intervention for the Prevention of Diabetes: The Lawrence Latino Diabetes Prevention Project. Am. J. Public Health 2012;102(2):336-342. doi:10.2105/AJPH.2011.300357.
- Olvera N, Bush JA, Sharma S V, Knox BB, Scherer RL, Butte NF. BOUNCE: a community-based mother-daughter healthy lifestyle intervention for low-income Latino families. *Obesity (Silver Spring)*. 2010;18 Suppl 1:S102-4. doi:10.1038/oby.2009.439.
- Hovell MF, Mulvihill MM, Buono MJ, et al. Culturally tailored aerobic exercise intervention for low-income Latinas. *Am. J. Health Promot.* 22(3):155-63. doi:10.4278/ajhp.22.3.155.

I chose the above 3 for a number of reasons: they had the highest quality scores, they had an intervention that best matched Amigas en Salud (so as to be able to draw comparisons), and they offered multiple outcome measures for both physiological changes and education/mental changes. I considered many other studies to include, especially the systematic review, but I felt that the overall quality of the studies and detail that was given in the chosen three could not be sacrificed for a systematic review that was simply summarizing the impact of different physical activity interventions.

The BOUNCE study by Olvera et al, was especially pertinent to my research, as it was an intervention for mothers and daughters. Amigas en Salud offers free childcare and allows children that are interested to participate in Zumba and the tutorials. Furthermore, the exercise intervention in Hovell et al and Olvera et al's research was Latin dance or Zumba. Under the impact of this particular intervention is important, as it is the form of exercise Amigas en Salud offers, and different forms of physical activity have the potential to affect attrition rates and physiological changes.

Ockene et al's study was selected as it focused on Diabetes prevention and measured A1C as one of its outcomes. Amigas en Salud offers Diabetes education, as many of the participants either have risk factors or have already been diagnosed with Diabetes. Although the exercise intervention is not Zumba, the study includes a walking goal assessed with pedometers. Amigas en Salud recently purchased pedometers for each of the participants, and I plan on giving them the same walking goal of 4,000 steps per day this weekend.

All of these studies will give an idea of the impact that Amigas en Salud has on its participants.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of Outcomes of a Latino Community-Based Intervention for the Prevention of Diabetes: The Lawrence Latino Diabetes Prevention Project by Ockene et al, 2012 ⁶

Aim/Objective of the Study/Systematic Review:

Assess the efficacy of a community-based program that was culturally tailored to promote weight loss and prevent diabetes in the underserved Latino community.

Study Design

- Randomized Control Trial. The study indicated blinding of data collector for blood pressure, dietary
 assessments, and physical activity assessments, but there was no mention of blinding for other data
 collection methods and data analysis.
- Subjects were randomly assigned using a randomized block design to one of two groups: "lifestyle intervention care" (n=162) or "usual care" (n=150).
- Before randomization, subjects participated in a baseline assessment. Follow up assessments were conducted at 6 months and 1 year. No assessments were conducted beyond program completion. Outcome measures included a variety of physiologic and behavioural indices (discussed in detail below).
- The program was designed using the Social Cognitive Theory and patient centered counselling.

Setting

Community setting: Subjects participated in assessments and the interventions at Lawrence Senior Center and YWCA both of which are centrally located.

Participants

- Six hundred and thirty seven of the 949 people interested were not included in the study due to exclusion criteria, inability to recontact, or refusal to participate. One hundred sixty two of the participants were allocated into the intervention group and 150 participants were allocated to the usual care group (total 312 participants).
- The majority of participants (78%) were recruited from the Greater Lawrence Family Health Center (GLFHC). Other recruitment methods were radio, television, and newspaper announcements and contacting physicians. The demographics of the participants were: average age of 52 years (range 25-79 years), less than 50% were employed, 74% were female, and 59% had less than a high school degree. The control and intervention groups were analogous in likelihood of developing diabetes, body weight, HbA1c levels, physical activity level, and fasting glucose.
- At the end of the program, there was a 94% completion rate, 142 participants were reassessed in the usual care group and 147 were reassessed in the intervention group. Reasons for attrition and exclusion of data included: unable to recontact, relocation, no time, medical condition, bariatric surgery, and incomplete laboratory results. The demographics of those who dropped out were primarily male, had greater HOMA-IR, had greater caloric intake, and had decreased systolic blood pressures.

Intervention Investigated

Control: Usual Care

No explanation of what "usual care" entailed in paper. No additional papers located outlining the parameters of this group.

Experimental: Lawrence Latino Diabetes Prevention Project

- The experimental group consisted of a mix of individual (n=3) and group sessions (n=13), lasting between 30 minutes to an hour and a half, distributed over the 12 months. Group sessions took place in the community center and individual sessions were held in the participants home. Makeup sessions were scheduled as needed.
- The foundation of the intervention was in the Social Cognitive Theory (SCT) and patient-centered counselling. These methods were used to educate participants on diabetes, nutrition, and physical activity and promote behavioural changes. The intervention was culturally tailored by using Spanish in all interactions, recommending dietary changes based on the Hispanic diet, addressing beliefs about diabetes using a 'telenovela' format, and visually adapting informational materials to address low literacy levels in this population.
- As part of the SCT, the instructors used goal setting and self-monitoring, providing participants with worksheets to record daily activity. The following goals were set for the participants: increased whole grain and vegetable (low in starch) intake; decrease sodium, saturated fat, serving size, and processed carbohydrates and starches; walk an additional 4000 steps a day (as measured by pedometers).
- Each session was formatted as follows: weight taken, discussion of progress towards goals discussed, discussion of barriers, healthy meal provided. Trained, Latino community members (lay health advisors) led the sessions.
- To prevent high attrition rates, transportation and reminder calls were used.

Outcome Measures

All measures taken at baseline and at the 12 month follow up in the Lawrence Senior Center. All questionnaires were offered in Spanish and English. Limited information was provided on who was taking the outcome measures.

Primary outcome:

• Hemoglobin A1c was assessed with Primus Diagnostics boronate affinity high-performance liquid chromatography. Sample was assessed Dr. Randie Little's Diabetes Diagnostic Laboratory.

Secondary outcomes:

- BMI: A standardized procedure was developed to assess height and weight, which were then used to calculate BMI.
- Insulin resistance was calculated using the homeostasis model assessment (HOMA-IR) and fasting glucose and insulin levels.
- Blood pressure: Blinded personnel took the average of 2 Dinamap XXL readings, for an estimate of the participants blood pressure.
- Analysis of concentrations of glucose, high-density lipoproteins, total cholesterol, and triglycerides. The Cobas Mira Autoanalyzer was used. From these findings, LDL was deduced.
- Three, 24-hour diet recalls in a period of three weeks by blinded dietitians. The data was analyzed by the University of Minnesota's Nutrition Coordinating Center's Nutrition Data System for Research software.
- Three, 24-hour physical activity recalls in a period of three weeks. This assessment was validated against accelerometers and questionnaires in a previous study.
- Center for Epidemiological Studies- Depression Scale (CES-D)
 - Cut off score is greater than or equal to 16
 - o .95 sensitivity, .29 specificity for general population
 - o Range: 0-42
 - Adequate test-retest reliability
- Short Form-12 (SF-12) was used for quality of life.
 - Range: 0-100
 - Excellent test-retest reliability
 - o No floor or ceiling effects reported in general population
- · Cost per participant in the intervention group was tracked throughout the program.

Main Findings

The effect of the intervention when compared to usual care showed the following significant improvements:

- Increased weight loss
 - o The mean difference in weight loss was -2.5 lbs in favor of the intervention group.
 - \circ 95% CI = -4.25 to 0.75 lbs
 - \circ P = .004
- Decreased BMI
 - The mean difference in weight loss was-0.46 kg/m² in favor of the intervention group.
 - \circ 95% CI = -0.76 to 0.14 kg/m²
 - \circ P = .004
- Reduced HbA1c
 - o The mean difference in HbA1c is −0.07 in favor of the intervention group.
 - \circ 95% CI = -0.10 to -0.04
 - o P= 009
- Improved insulin resistance
 - o The mean difference in insulin resistance is −0.28 in favor of the intervention group.
 - 95% CI= -0.76 to 0.20
 - o P = .03
- Reduced caloric intake from fat
 - o The mean difference of caloric intake from fat is −1.77% in favor of the intervention group.
 - 95% CI=-3.48 to -0.08%
 - o P= .04

Results that were not statistically significant

- Reduction in percentage of calories from saturated fat
 - $_{\circ}$ The mean difference in caloric intake from saturated fat is -0.59% in favor of the intervention group.
 - \circ 95% CI = -1.28 to 0.07
 - o P=.08
- Increase in dietary fiber intake
 - The mean difference in caloric intake from dietary fiber is 1.98% in favor of the intervention group.

- \circ 95% CI = -0.16 to 4.01%
- \circ P=.07

Additional findings:

- Both the intervention and usual care groups had fewer depressive symptoms after the intervention when compared to baseline_as seen by the lower scores on the CES-D. However, there was no significant benefit seen in the intervention group when compared to the control group.
- There was no significant change in the quality of life as measured by the SF-12 assessment.
- There was an association noted between weight loss and attendance. Threshold of 7/16 session, with less than 7 sessions associated with .13 lbs weight loss, and more than 7 sessions associated with 4.75 (p=.02). The average number of sessions attended was 8 total and 6-group session.
- Change in weight was the only factor that was found to influence HbA1c using the Sobel-Goodman test.
- No adverse events occurred in either group.
- Cost per participant was \$661.
- Feedback showed primary barriers to changing diet as
 - Lack of willpower (55%)
 - Stress (34%)
 - Food environment (30%)
 - Knowledge (18%)
- · Primary barriers for exercise change:
 - o Time (48%)
 - Weather (38%)
 - Physical illness or disability (29%)
 - o Fatigue (27%)
 - Lack of motivation (29%)

Original Authors' Conclusions

"In conclusion, this tailored intervention program developed and tested for a target population of low-income Caribbean Latinos at elevated risk for diabetes produced a modest but significant degree of weight loss associated with significant improvement in insulin resistance and HbA1c." (Ockene et al, 2012, p. 341)

Critical Appraisal

Validity

- 24/31 on the Downs and Black Quality Checklist. Quality of this study is diminished secondary to the lack of subject blinding to intervention and randomised assignment.
- The paper did not include an explicit discussion of the "usual care" group, blinding, or psychometric properties of all outcome measures. The lack of information provided, makes assessment of confounding variables and thus internal validity difficult.
- Due to lack of information, a full assessment of bias is not possible. However, possible sources of bias include selection, measurement, and analysis bias due to lack of blinding.

Interpretation of Results

- There is evidence that a culturally tailored, community based program using SCT and patient-centered care principles for diabetes prevention improves weight loss, HbA1c, insulin resistance, and diet.
- This method of intervention had no significant impact on depressive symptoms, physical activity, and fasting blood glucose when compared to the usual care group.
- The lack of improvement in physical activity level may be attributed to the low emphasis on exercise and/or unavailable exercise space in neighbourhoods.
- The lack of long term follow up provides only the short term effects of a community based program, with no information of whether this temporary program can have a long term effect on the participants health.
- The incorporation of the community in the program design, allowed for low attrition and an effective intervention.
- Useful information on how to create and implement a community based program that is specific to the Latino community.
- (2) Description and appraisal of BOUNCE: a community-based mother-daughter healthy lifestyle intervention for low-income Latino families by Olvera et al, 2010^{13}

Aim/Objective of the Study/Systematic Review:

To assess the effectiveness of a Latino, family based program, BOUNCE (Behavior Opportunities Uniting Nutrition, Counseling, and Exercise), in increasing fitness and activity levels through education and exercise. The secondary aim was to see the programs effect on diet.

Study Design

- Parallel group assignment, with a control and an intervention group.
- Theoretical framework was Bandura's Social Cognitive Theory.
- No discussion of blinding.
- Cluster randomization used to decrease risk of contamination between groups. The two clusters were the two different schools from where the participants were recruited.
- Subjects participated in a baseline assessment and a follow up assessment (at 12 weeks). No
 assessments were conducted beyond program completion. Outcome measures included a variety of
 physiologic and behavioural indices.

Setting

Community setting: Intervention and assessments took place in community locations like: parks, schools, grocery stores, and community centers.

Participants

- Subjects were recruited from 2 elementary schools (third through sixth grade) in the same district.
 Schools were matched to decrease variability: similar percentage of Latino students enrolled, similar
 percentage of students on discounted or free lunch plans, and both in an urban setting. The methods of
 recruitment were flyers mailed home to the students' families and information sessions at the schools.
 There was no discussion of how they decided which homes to send flyers to or how many total flyers
 were distributed.
- Seventy-seven percent of the families who expressed interest met inclusion criteria and were incorporated into the study.
- There were 46 mother-daughter pairs. Twenty-six pairs from one school were allocated to the experimental group and 20 pairs from the other school were allocated to the control group. Over the course of the intervention, 11 (24%) of the mother-daughter pairs dropped out, leaving 18 in the experimental group and 17 in the control group. The reasons for dropping out included: religion, health, and job schedule. There were no differences in demographic markers between those who dropped out and those who completed the study.
- The demographics of the majority of the participants were: daughters born in the United States (82%), mothers born in Mexico or Central America (100%), low acculturation in daughters and mothers (85% and 62%, respectively), less than 8 years of education for mothers (68%), unemployed (75% of mothers), and overweight (66% of daughters and 88% of mothers). The average child's age was 9.9 years old (+/- 1.1) for the experimental group and 10.4 years old (+/- 1.1) for the control group. All subjects were screened for medical issues, and excluded if any were present.
- There were no significant differences between groups at baseline for: the demographic markers listed above and BMI (23.6 kg/m² +/-4.2 in the experimental group, 21.8 kg/m² +/-3.2 in the control group, p = .574). However, there was a significant difference in the age of the mothers. The mothers in the experimental group were on average 33.3 years old (+/-4.6 years), while the control group mothers were younger at 38.2 years old (+/-10.6 years).

Intervention Investigated

Control

The control group participated in a 45-minute session on Fridays where they were given educational materials on nutrition and some counselling topics. These classes were led by a child psychologist, licensed counselor, registered dietician, nutrition educator, and trained fitness specialists. After the class there was an intermittent, light aerobic activity, like samba, salsa, hip-hop dance, or team sports for 45 minutes. They also incorporated resistance training with bands. The control group lasted for 12 weeks with 1 session a week.

There was no mention of how the intensity was assessed, how intermittent exercise was defined, and the specific class content.

Experimental

The intervention group participated in exercise three times a week for 45 minutes. The exercise was followed by either a nutrition session (twice a week) or a behavior counselling session (once a week), each 45 minutes. The intervention lasted for a total of 12 weeks.

The BOUNCE curriculum was designed and taught by experts in diet, nutrition, health education, exercise physiology, behavioral psychology, and physical education after an extensive review of the current literature. Bilingual Latinos translated the materials into Spanish. Pilot testing was used to determine the format of the following areas: nutrition, exercise, and self-esteem classes; exercise preferences; and timing of program. From the pilot testing they constructed the following intervention:

• <u>Goals of nutrition education:</u> reduce drinks high in sugar while increasing water intake; decrease amount of saturated fat in diet; assist in developing nutritious strategies when eating. All concepts

- discussed were then practiced with interactive activities like games, food preparation, a tasting, etc.
- <u>Goals of the behavioral component</u>: promote a positive body image to improve acceptance of self; address perceptions related to exercise, weight, and food; teach subjects useful strategies when confronted by a challenge. This intervention also consisted of strategies for creating behavioral change. These strategies included addressing triggers that prompt eating; goal setting; rewards planning; and role modelling (concepts inspired by the Social Cognitive Theory). Intervention strategies included use of journaling, trust exercises, collages, etc.
- The <u>exercise portion</u> was at a moderate to vigorous intensity. Two of the sessions included aerobic conditioning (in the form of hip hop, salsa, step aerobics, etc) and resistance training using bands or body weight. The third session of the week was a team sport activity or free play. All three sessions included a warm up and cool down, each for 5 minutes.
- Throughout the program, participants were given "take home challenges" where they would try something they learned and journal about the experience.
- Handouts were given at the end of sessions.

Sample of curriculum from first 4 weeks:

Week 1:

- 1. Nutrition: Heart healthy cooking with demonstration of a sample meal (brown rice, bean soup, and tuna salad)
- 2. Counseling: Explanation of the program, introductions
- 3. Exercise: Hip-hop dance, Latin dance

Week 2:

- 1. Nutrition: Food pyramid, hand washing, low fat quesadilla recipe
- 2. Counseling: Women's health issues; developmental milestones; relationship among obesity, diabetes, and some cancers
- 3. Exercise: Hip-hop dance, Latin dance, Kickboxing/sports

Week 3:

- 1. Nutrition: Alternatives to drinks high in sugar, how to make a fruit smooth
- 2. Counseling: Discussing the choices each person has in her health
- 3. Exercise: Hip-hop dance, Latin dance, Kickboxing/sports

Week 4:

- 1. Nutrition: Healthy snacking, fruit and vegetable salsa cooking demonstration
- 2. Counseling: Setting goals, and identifying cues, resources, and barriers that impact one's ability to achieve said goals.
- 3. Exercise: Hip-hop dance, Latin dance, Kickboxing/sports. Introduction to strength training.

<u>Other topics included</u>: benefits of fiber, attitudes towards food, portion control, triggers for overeating (like negative emotions), normal BMI, understanding food labels, calorie counting, self esteem, benefits of calcium, healthy fats, positive parenting strategies (mother-daughter communication), etc.

Outcome Measures (Primary and Secondary)

All measures were taken at baseline and at the end of the intervention at 12 weeks. There was no mention of who was collecting the measurements and whether they were blinded. Exact location was unspecified. There was no discussion of the psychometric properties of these tests.

Primary outcomes:

- · Physical fitness:
 - o Daughters: The 20-Meter Endurance Shuttle Run Test determined the daughters' fitness level.
 - Mothers: Rockport Walk Test determined the mothers' fitness level. The mothers walked 1 mile, with the following information collected: speed, body weight, age, heart rate at the end of exercise (one minute heart rate using palpation of radial artery), and peak oxygen consumption.
- · Activity level
 - Daughters: Activity level was measured with accelerometers. Accelerometers were used for 2 consecutive days in the first week and last week. This data was then used to determine their activity level with a cut off point of 1,500 counts/minute between moderate and vigorous activity level.
 - Mothers: The University of Houston Non-Exercise Physical Activity Rating was used to determine activity level over the last month. The scale is from 0 (sedentary) to 7 (vigorous activity).

Secondary outcomes:

- Daughters' diet: The School Physical Activity and Nutrition survey was used.
- BMI (age and gender specific): Height with a stadiometer and weight measured with a scale (Tanita).
 Obesity was determined by percentile for daughters (greater than or equal to 85th percentile) and by a

BMI greater than or equal to 25 for the mothers.

Main Findings

Primary significant finding:

- The daughters in the experimental group had higher physical fitness scores post intervention as measured by the 20 Meter Shuttle Run. This increase was statistically and clinically significant when compared to the control group.
 - Experimental group increased from 14.2 laps (+/- 4.9) to 20.7 laps (+/-8.4)
 - Effect of intervention when compared to the control group:
 - Cohen's d: .78, which is considered a large effect by authors
 - F: 4.49
 - p: .044

Secondary findings:

- There was a non-significant reduction in the caloric intake of high fat foods.
 - Cohen's d:.40
 - p: .260
 - F: 1.32
- There was a non-significant reduction in the caloric intake of sweetened beverages.
 - Cohen's d: .36
 - p: .312
 - F: 1.06
- There was a non-significant increase in the intake of fruits/vegetables.
 - Cohen's d: .34
 - p: .343
 - F: .93

No significant difference from baseline after the program:

- There was no difference in both the EG and CG daughters for average daily counts per minute or MVPA post intervention.
- There was no difference in BMI in both the EG and CG mothers post intervention when compared to baseline values.
- There was no difference in EG or CG mothers post intervention for physical fitness or physical activity levels.

Original Authors' Conclusions

"Consistent with previous studies, a significant increase in physical fitness was observed in daughters participating in the EG compared to those in the CG. The effect of the BOUNCE intervention on Latino girls' physical fitness is significant given that youth fitness scores can predict adult fitness levels... the BOUNCE intervention has several unique features including an innovative approach that takes advantage of natural interactions occurring across generations of women such as Latino mother-daughter pairs and the utilization of community resources." (Olvera et al, 2010, p. 104)

Critical Appraisal

Validity

- 21/31 on the Downs and Black Quality Checklist. Quality of this study is diminished secondary to lack of information provided on the intervention in the experimental group and the control group; no mention of adverse events; subjects, data collectors, and investigators were not blinded to the intervention or randomization; confounding variables were not evenly distributed between groups (mothers were younger in the experimental group); no discussion of the outcome measures' psychometric properties; no power analysis.
- Limited information was provided on the specifics of the control group condition, how exercise intensity was assessed in the control and exercise group, and blinding. This makes a full assessment of confounding variables and bias difficult. However, possible sources of bias include selection, measurement, and analysis bias due to lack of blinding.
- Although, the cluster randomization to limit contamination does bolster the internal validity, the likelihood of multiple forms of bias, increased contact with health care providers in the exercise group when compared to the control group, and the differences in age of mothers at baseline makes the internal validity limited.
- The external validity appears to be limited secondary to the small sample size.
- The paper did not include a detailed description of the BOUNCE intervention protocol, which was gathered from a previous paper published by Olvera, et al.

Interpretation of Results

· There is evidence that a Latino mother-daughter wellness program with exercise three times a week

and counselling sessions on a variety of behavioural and nutrition topics can create statistically and clinically significant changes in the physical fitness of daughters. The magnitude of the effect this intervention had was large, indicating clinical significance.

- This intervention had no statistically significant impact on physical activity level and diet in both mothers and daughters, and physical capacity among mothers.
- As physical activity level assessments for the daughters were only taken for two days and self-report assessments were used for the mothers, it may not represent their overall activity level.
- The lack of long term follow up provides only the short term effects of a community based program, with no information of whether this temporary program can have a long term effect on the participants fitness level.
- The control group received some health education and exercise a week, decreasing the quality of the control and perhaps creating type II error.
- (3) Description and appraisal of Culturally Tailored Aerobic Exercise Intervention for Low-income Latinas by Hovell et al, 2007^{14}

Aim/Objective of the Study:

Assess the efficacy of "a culturally tailored intervention based on operant learning theory and applied behavior analysis that targeted vigorous exercise in a community sample of low-income, largely monoingual spanish-speaking immigrant Latinas" (Hovell, 2007, p.155)

Study Design

- Randomized Control Trial with 3 repeat measures at baseline, program completion (6 months), and follow up (12 months).
- Block randomization divided subjects into either the exercise intervention group (n=75) or the home safety conditions group (n=76). The project staff and coordinator were blinded to group assignments.
- Primary outcome measures assessed physical activity and aerobic capacity. The data collectors were blinded.

Setting

Community setting: Intervention and assessments occurred at a "store front" exercise site and a community clinic that were near each other. (Hovell et al, 2007, p. 155)

Participants

- Recruitment involved door-to-door advertising and presentations at the following locations: schools, retail outlets, and clinics.
- If participants met the inclusion criteria, they partook in a medical examination with testing of fasting glucose, insulin and lipid panels. Less than 24 people were excluded due to hypertension, hypercholesteremia, history of MI, history of stroke, morbid obesity knee pain or back pain. Those excluded were given educational materials and referrals.
- A total of 151 Latinas were recruited. After baseline measurements were taken, block randomization divided the women into either the intervention (n=75) or control group (n=76).
- The demographics of the majority of the participants were: average age of 31.36 years old (range of 18-55 years old), married with children (69.5%), home-makers (62.9%), born in Mexico (96.7%), mean education of 8.52 years (SD: 3.58), did not graduate from high school (76.9%), Spanish speaking only (59%), lived in the US for 9.5 years (range of .5 to 36 years), Acculturation Rating Scale for Mexican-Americans score of 1.65 (signifying highly unacculturated), family income between 10,000-19,000 (51%), without health insurance (81.1%), low physical activity levels (76.8% did not partake in vigorous activity, 82.1% did not walk for exercise), and overweight or obese (27% and 23.2%, respectively). A minority of subjects had a positive family history for type II diabetes (24.5%), hypercholesterolemia (12.6%), hypertension (25.3%), heart attack or stroke (14.6%). ACSM exercise recommendations (>150 minutes of moderate PA a week) were met by 16.4%.
- The control and intervention group had statistically similar demographics.
- Ninety-one percent of the participants were at the 12-month follow up. Attrition was attributed to schedule conflicts, domestic violence, relocating, unsupportive spouse, illness, and pregnancy. The 13 dropouts were similar in physical level and fitness to those participants (n=138) who completed the study. There was no further data or discussion on demographic characteristics of dropouts.

Intervention Investigated

Control

The control group served as a "partial control" for attention effects. They met for 90 minutes, during 18

sessions, over six months (fewer sessions than the intervention group). During these sessions Spanish-speaking health educators discussed home safety and disease prevention. Examples included prevention of: tuberculosis, smoking, crime, poisoning, etc. None of the topics discussed diet, exercise or cardiovascular disease. Raffle tickets were given as rewards for attendance and a prize was given during each session (example prize: fire extinguisher).

Experimental

The experimental group involved an exercise and education component.

- For 6 months, participants attended 3, 90-minute aerobic dance sessions a week. The program offered morning and afternoon sessions (each with 15-30 attendees), for the convenience of the participants. Staff was present to assess and give feedback on intensity, body alignment, and movements to all participants. There was 1 staff member for every 5 participants.
- Each session involved a warm up (stretching) and a cool down (core strengthening) each 10 minutes. The aerobic exercise was low-impact aerobic dance, led by a bilingual Latina, with salsa and merengue music used. Initially, the aerobic portion was 10 minutes. This increased by 3 minutes each week, until the aerobic portion was 40 minutes in length. At this point the instructor increased the intensity.
- In order to ensure a vigorous exercise level, each session a randomly chosen subsample of the participants' heart rates were monitored with the Polar Heart Watch. These participants were then given feedback, so as to maintain greater than or equal to 70% of their maximum heart rate as predicted by their age. At the end of the aerobic portion, all participants assessed their own heart rates.
- The educational component focused on exercise and diet for 30 minutes. Specific topics included: hydration, posture, safety, footwear and attire, injury prevention and treatment, benefits, heart-healthy diet, importance of a warm-up and cool down, and the benefits of exercise. These sessions were in Spanish, culturally tailored, and at a low literacy level. Sessions emphasized behavioral skills and involved skits, cooking, stories, and role-play to demonstrate and practice the new skills. Expert psychologists trained all educators.
- During the third session of every week, there was a discussion about barriers and misconceptions. These included time management, transportation, and spousal support.
- The intervention group, like the control group, got raffle tickets and rewards for their attendance. If a participant attended all 3 sessions that week, a five-dollar grocery store certificate was given.
- To limit attrition the following strategies were used: comadre (exercise buddy) for encouragement; telephone calls made to participants after an absence; if there were 3 consecutive absences a home visit was done to give educational materials, to discuss barriers, and help problem-solve.

Outcome Measures (Primary and Secondary)

All outcome measures were single-blinded taken on 3 different occasions: at baseline, 6 months, and 12 months.

Primary outcome measures:

- 1. Fitness: graded treadmill protocol until exhaustion
 - a. Maximal oxygen uptake with True Max 2400 Metabolic Measurement cart. Reading taken continuously to find highest value. Max uptake was when respiratory exchange ratio was over 1.05 and heart rate was greater than or equal to 90% of maximum heart rate. If these criteria weren't met, the subjects performed the test again within 48-72 hours (n=5).
 - They assessed test-retest reliability to be .85.
 - b. Heart rate (with Polar wireless monitor) assessed every 2 minutes.
 - c. Blood pressure assessed every 2 minutes.
 - d. Rate of Perceived Exertion (RPE) assessed every 2 minutes, using Borg's 20 point scale.
- 2. Physical Activity (PA): PA was assessed in an interview with a Spanish-speaking staff member, where they discussed current levels, mediators, facilitators, demographics, and family history. Specifically, they were asked to recall their PA and duration of PA in the last 7 days with a list of 23 exercises provided (the Project GRAD survey was modified to be more culturally appropriate for Latinos). The level of intensity was quantified by metabolic expenditure with reference activities for each level.
 - MET values of >6 were considered vigorous activity; values of 3-6 were considered moderate activity.
 - Intraclass correlation for this survey is .77.

Secondary outcome measures:

- 1. Blood was taken by a phlebotomist after a 12 hour fasting period. The following levels were assessed: HDL, LDL, triglycerides, insulin, and glucose. The samples were assessed by Smith-Kline lab that was blinded to group assignment. A randomly selected retest was performed on 10% of the participants' samples.
- 2. Blood pressure: Participants stayed seated for 5 minutes in a controlled environment. After which the Hypertension Detection and Follow up Program protocol was used: 3 measurements, with 1-minute rest in between on the left arm. The average was then calculated.

3. Anthropometrics:

- a. BMI calculated with the nomogram (by Nieman). Weight taken with the Precision dial health scale.
- b. Body composition was calculated using 2 skin fold measurements with Lange calipers at 7 locations and the skin-fold equation by Pollock et al.
- 3. A sign in sheet was used to track attendance.
- *Cash was awarded post assessment and at the follow up (\$25 and \$50, respectively).

Main Findings

Data was skewed, and normalization was not feasible. Non-parametric statistical analysis was used and clinical significance was not addressed.

Primary findings:

Physical activity

1. Exercise group:

- There was increased vigorous activity and walking from baseline to 6 months, p< .001.
- There was then a decrease in vigorous activity and walking from 6 months to 12 months, but values were still higher than at baseline, with p = .013 and p = .011, respectively.
- The number of participants that met the ACSM guidelines for physical activity increased from 19.1% at baseline to 63.2% at the 6-month follow-up. At the 12 month follow up the percentage had decreased to 38.2%.

2. Control group:

- There was increased vigorous activity and walking in the control group from baseline to 6 months, p=.001 and .022 respectively.
- The number of participants that met the ACSM guidelines for physical activity increased from 13.6% at baseline to 16.7% at the 6-month follow-up. At the 12 month follow up the percentage had decreased to 15.2%.

3. Comparison:

- Vigorous activity was significantly higher in the exercise group at 6 months and 12 months when compared to the control group, with p <.001. Walking was significantly higher at the 6 month follow up (p=.023), but this was lost at the 12 month assessment.
- 4. No change in moderate activity level for the exercise and control group (p: .310 and .411, respectively)

Physical fitness:

- 1. Exercise group: VO_2 max increased (t(56) = 7.454, p<.001). Some decline in fitness occurred at the 12-month follow up (t(56) = -5.965, p<.001), but it remained higher than the control group (p<.001).
 - Vo_{2max} increased by 16.9% from baseline to 6 months.
- 2. Control group: No significant change over time in VO_{2max}
 - Vo_{2max} increased by 3% from baseline to 6 months.

Secondary findings:

Risk factors for CVD:

- 1. Exercise group:
 - A significant percentage decreased their risk of cardiovascular disease by having LDL measures below 100 mg/dL.
 - At post-test, the percentage of participants that were in a lower-risk category (LDL<100-mg/dL) increased from 33% at baseline to 51% (p=.041).
 - HDL and the cholesterol ratio didn't change.

2. Control group:

- A significant percentage decreased HDL (1.74 to 1.69, logged mean; t(59)= -5.635; p<.001) initially.
- HDL increased at 12 months (1.71, logged mean; t(59)=-2,259; p=.028).
- Increase in cholesterol ratio at 6 months (.65 to .67, logged mean; t(59) =-3.170, p=.002).
- From baseline to 6 months, there was an increase in the percentage of participants that had increased risk of cardiovascular disease (HDL below 60mg/dL) increased from 71% to from 71% to 85% (p:.041).
- 3. <u>Comparison</u>: The experimental group had lower HDL and a better (lower) cholesterol ratio at 6 months when compared to the control group (p=.023 and p=.003, respectively), but that significance was lost at the 12 month follow up.
- 4. <u>No significant findings between groups</u> for changes in blood pressure, blood glucose, body fat percentage, low-density lipoproteins, and triglycerides.

Attendance

- Intervention group: Average sessions attended: 50.33 (SD: 22.96), 65.76% of total sessions
- Control group: Average sessions attended: 8.87 (SD=5.40), 55.43% of total sessions were

Original Authors' Conclusions

"The major finding of this study was that a culturally tailored aerobic dance program can increase vigorous

activity, walking, and cardio respiratory fitness in low-income, sedentary, overweight Latinas who face enormous cultural, social and environmental barriers to routine physical activity." (Hovell et al, 2007, p. 160)

"One interpretation of results is that the intervention was powerful, enough to generate substantial adoption and to support women's physical activity during the intervention, but not to change the larger environmental and social contexts that contribute to low levels of physical activity in this group." (Hovell et al, 2007, p. 161)

Critical Appraisal

Validity

- 25/31 on the Downs and Black Quality Checklist. Quality of this study is diminished secondary to absent CI assessment, absent effect size, lack of participant blinding, randomization was not concealed from participant, no demographic information provided on dropouts, and absent power assessment.
- As the data were highly skewed (towards inactivity and low fitness levels) and the data could not be normalized, the researchers used non-parametric testing. Overall, the data presented are not easily interpretable, and clinical significance cannot be deduced.
- The investigators addressed bias by blinding data collectors, thereby improving internal validity. They further improved internal validity by addressing the confounding variable of non-specific attention.
- Although the subject demographics reflect population demographics and it takes place in a community setting, external validity is limited due to the highly regulated and subject specific intervention.

Interpretation of Results

- There is statistically significant evidence that this culturally tailored, community based exercise and education program, using rigorous exercise guidelines and monitoring, improves physical activity and physical fitness, and decreases cardiovascular disease risk factors.
- The data show that this intervention created results in fitness and vigorous exercise levels beyond the end of the program, implying a behavioral change that was maintained beyond the support of the program.
- This method of intervention had no impact on: blood pressure, blood glucose, body fat percentage, lowdensity lipoproteins, and triglycerides.
- As the effect size was not adequately assessed, the reader cannot assume clinical significance.

IMPLICATIONS FOR PRACTICE and FUTURE RESEARCH

<u>Implications for Practice:</u>

The evidence reviewed in this clinical appraisal supports community-based exercise and health education programs for underserved Latinas to increase physical fitness, increase activity levels, improve diet, and reduce LDL and A1c levels. The evidence supports the presence of existing wellness programs with a similar framework and target population, as well as helps guide future wellness programs for the Latina population.

These programs can be models for future, successful community based wellness programs. Emphasis should be put on a curriculum founded in evidence and synthesized by an interdisciplinary team of experts; a thorough assessment of the population using the Social Cognitive Theory as a framework; lay health advisors and peer support; collaboration of a university and community organizations; focus groups to assess the community's needs and alter the program accordingly; aggressive attrition prevention; community setting for the intervention; assessment of heart rate to ensure vigorous exercise levels; interactive education through roleplaying, etc; and use of a progressive aerobic intervention for sedentary adults.

The feasibility of implementing similar programs is limited secondary to the following factors: high cost, need for participant transportation, need for a supportive University, high frequency of classes offered, need for aggressive and frequent methods to address attrition, and the need for trained staff to ensure a vigorous exercise program. The sum of these factors implies that the likelihood of these programs' sustainability in a community setting, without research funding, is low.

Of note, all of the studies included rigorous exclusion criteria, reducing the risk of an adverse event secondary to cardiovascular disease, diabetes, and hypertension. Yet, this high-risk population is in need of an exercise and health education intervention more than their healthier counterparts. So as not to exclude this high-risk population, the staff and participants of wellness programs should be educated on monitoring their health and safety throughout the exercise intervention.

Implication for Amigas en Salud:

Amigas en Salud, an exercise and health education program in North Carolina, attempts to address physical activity, physical fitness, diabetes, cardiovascular health, and diet, as the above programs have. However, its efficacy cannot be determined from the current research due to dissimilarities in its intervention. Namely, the intervention frequency is significantly lower, at once a week, due to limited funding and resources. This was

addressed by offering a "Step Challenge" where participants were encouraged to walk over 3,000 steps a day, as measured by pedometers and by offering discounted YMCA memberships. Furthermore, Amigas en Salud has not incorporated lay health advisors into the program at this point, as experts in their respective fields lead all presentations. There is a scarcity of community based exercise and health education programs in North Carolina, and Amigas en Salud is the only one targeting Latinas in Chapel Hill. This information will assist in educating Amigas en Salud participants and future donors in the benefits of community based exercise and health education programs. It has also been instrumental in informing the directors of Amigas en Salud in effective intervention methods, allowing for the program to evolve into a more beneficial program. For example, plans have begun to educate the current participants to be lay health advisors. The aim is for them to lead educational sessions in their neighborhoods to reach a larger community by 2016.

Implications for policy:

It is clear that beyond implementing wellness programs for preventative care, a policy level change must occur. This will bolster access to community resources and alter societal norms; thereby, causing wide spread change among Latinos and the population at large.

Implications for research:

- Key points for future research include the need to specifically address both diet and exercise in wellness programs, a long term follow up to assess maintenance of behavior change, and outcome measures with excellent psychometric properties.
- The need for an assessment of long-term maintenance and change in future research is seen in all three of the assessed articles. This will determine the need for sustainable community programs that will continue to provide support to participants.
- As found in Olvera et al's study, future research should use accelerometers for 7 days in a row to assess physical activity and have a control group that accounts for the effect of non-specific contact while being dissimilar to the intervention group.¹³
- In order to better assess changes in body composition, Hovell et al suggests the use of densitometry.

 The investigators also recommend that future interventions should have a longer intervention period (>6 months) and that they directly address diet through role-playing, reinforcement, modeling, etc.
- For all research, in order to better assess clinical significance, effect size should be calculated.
- Future research should not have rigid exclusion criteria of higher risk Latinos, and instead use extensive safety precautions to reduce the risk of adverse events.

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