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Cost Effectiveness of Lay Health Worker Delivered Interventions to Promote Colorectal Cancer Screening: A Randomized Trial

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Abstract

Background: Colorectal cancer screening rate among Hispanics is low.

Objective: To assess the cost effectiveness of lay health worker delivered interventions to increase colorectal cancer screening among low income Hispanics in Texas.

Methods: The randomized trial compared two lay health worker-delivered interventions, a small media print intervention and a tailored, interactive multimedia intervention delivered on a touch screen tablet. Twenty-six colonias (neighborhoods) were randomly selected among 1,113 colonias in the Lower Rio Grande Valley of Texas. Eight colonias were assigned to the control group (204 participants), nine colonias to the small media print intervention (236 participants) and nine colonias to multimedia (216 participants). Participants completed a baseline interview prior to the intervention. Screening status was determined with a 6-month follow up interview and medical chart review. Intervention resources were tracked prospectively and weighted with local prices. Outcomes were assessed with "intention to treat" methods and uncertainty was examined with nonparametric bootstrapping.

Results: The small media print intervention average cost was more ($46 vs. $39) but may yield a slightly larger (13.5% vs. 10.2%) screening rate compared to the multimedia intervention. The cost per additional person screened for the small media intervention was $1,643 from the payer plus participant perspective and $1,187 from the payer perspective.

Conclusion: Lay health worker delivered interventions using small media and an interactive tablet delivered program were relatively expensive given the low impact on screening. Traditional small media print interventions, while more costly, can result in slightly higher screening rates.

Keywords: Colorectal neoplasms; Cost effectiveness analysis; Intervention studies; Early detection of cancer

Abbreviations: SMPI: Small Media Print Intervention; TIMI: Interactive Multimedia Intervention; CRC: Colorectal Cancer; CRCS: Colorectal Cancer Screening; IM: Intervention Mapping; LHW: Lay Health Worker; SMI: Small Media Intervention; ICERs: Incremental Cost-Effectiveness Ratios; WTP: Willingness to Pay; CEAC: Cost Effectiveness Acceptability Curve; CI: Confidence Intervals; CDC: Centers for Disease Control and Prevention

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Introduction

CRC (Colorectal cancer) was the third leading cancer killer in the US. In 2014, there were approximately 136,830 new cases of CRC and 50,310 deaths due to the disease [1]. In Texas, it was the third most common cancer and there were approximately 9,760 new cases and 3,430 deaths due to the disease in the year 2014 [2].

Direct and indirect costs associated with colorectal cancer added up to nearly $1.2 billion in the past decade for Texas, making it one of the costliest cancers. With proper screening and early detection, nearly 90% of all colorectal cancer cases and deaths could be prevented. Five-year relative survival rates for patients diagnosed at local, regional, and distant stages of CRC were 90%, 70%, and 13%, respectively, indicating a high probability of survival with early detection [1]. The overall incidence and mortality for CRC are greater among non-Hispanics yet discrepancy in mortality reduction overtime exists. While CRC mortality rates have declined over all ethnic groups, 4.7% per year (from 2002 to 2004), the rate of decrease is much lower in Hispanics 0.9% per year (from 1995 to 2004) [3]. This lower rate of decline among Hispanics is an alarming disparity and may be an indication of lower rates of screening and follow-up among Hispanics than other groups. Hispanics were more likely to be diagnosed at a later stage than non-Hispanic whites. Hispanics had lower usage rates of CRCS (colorectal cancer screening) tests and had associated vulnerabilities such as lack of access, limited English fluency, and acculturation [2, 4]. The Texas-Mexico border is one of the areas with the largest Hispanic populations in the United States. In the 32 Texas counties closest to Mexico, commonly known as the border region, approximately 81% of the population was Hispanic which equals about 1.7 million people. This region was known for having high unemployment rates (9.9% versus the state's rate of 5.3%), increased poverty rates (33.9% versus the state's rate of 16.7%), limited availability and access to education and healthcare, and an underdeveloped infrastructure [5-7].

Because of this combination of socioeconomic factors, community health status is considerably poorer than in other parts of the state and country. Approximately 22% of the state's Medicaid recipients reside in the border region, while the border population is only about 10% of the state's total population. In terms of availability of health care professionals compared to the rest of the state, the ratio of the population to direct care physicians and general/family care physicians is about 1.7 and 1.5 times, respectively [7]. A majority of border inhabitants live in *colonias* which are unincorporated communities along the border, generally characterized by lack of physical infrastructure. Since most Hispanics in the border region are recent immigrants, factors associated with migration such as language barriers, poverty, acculturation, and cultural/societal issues also played into their propensity for disease burden [8].

Screening for colorectal cancer among Hispanics in the U.S. remains low compared to screening rates in other ethnic groups [2, 9]. There exists a great disparity in CRC test use among Hispanic population of the U.S. compared to the Non-Hispanic population [10] and among states; Texas has the lowest CRC test utilization by Hispanic populations [11]. Hispanics living in the Texas-Mexico border region are a unique population that would likely benefit from interventions to promote healthy behaviors such as the one presented here.

Several studies support the cost-effectiveness of colorectal cancer screening interventions; few, if any, studies have been conducted to assess the cost-effectiveness of CRCS promotion interventions among Hispanics such as those living in the border region [12-14]. Given the unique population and considerations taken in developing the intervention to fit their needs, it is important to assess cost-effectiveness of these alternative screening promotion methods to inform decision-makers at the government or program level.

Method

Intervention overview

An IM (Intervention Mapping) approach was used to identify the particular determinants of colorectal cancer screening in this population through structured questionnaires, focus groups, and environmental analysis. Intervention Mapping was used to develop program objectives and two theory-based interventions to increase CRCS in this population [15]. More details about the interventions are available in the outcomes paper [16]. A brief overview follows. The TIMI was delivered via a touch-screen tablet computer that participants could use after a brief instruction by a LHW (lay health worker). It was tailored by gender, language, knowledge of CRCS, perceived risk of CRC, and readiness to obtain CRCS based on Stage of Change from the Transtheoretical Model. The SMI (small media intervention) consisted of an informational flipchart and video that was also delivered by a LHW. Participants had the option of Spanish or English language. The third group was a no intervention control group that received the baseline and follow-up surveys.

The trial had three arms: no intervention (control), promotora-delivered small media print intervention (usual care), and promotora-delivered TIMI intervention. The unit of randomization was colonias in Hidalgo and Cameron counties, Texas. There were nine randomly-selected colonias per intervention arm and eight colonias in the control group for a total of 26 colonias. Within colonias, 26 people were randomly selected to participate in the trial for a total of 656 participants **(Figure 1)**. All participants completed a baseline interview with an interviewer **(Table 1)**; and those assigned to intervention arms were contacted by a LHW to schedule an intervention session. Participants were contacted approximately six months from baseline to complete a follow-up interview. At this time, compliance with screening guidelines were ascertained and confirmed through self-report and by medical chart review. Data for the cost-effectiveness analysis was collected and analyzed throughout the trial from 2007 to 2009. Study approval was obtained from the Committee for the Protection of Human Subjects at the University of Texas Health Science Center at Houston.

Effect estimation

The overall cost-effectiveness of colorectal cancer screening has been well supported in prior studies. This study focused on the

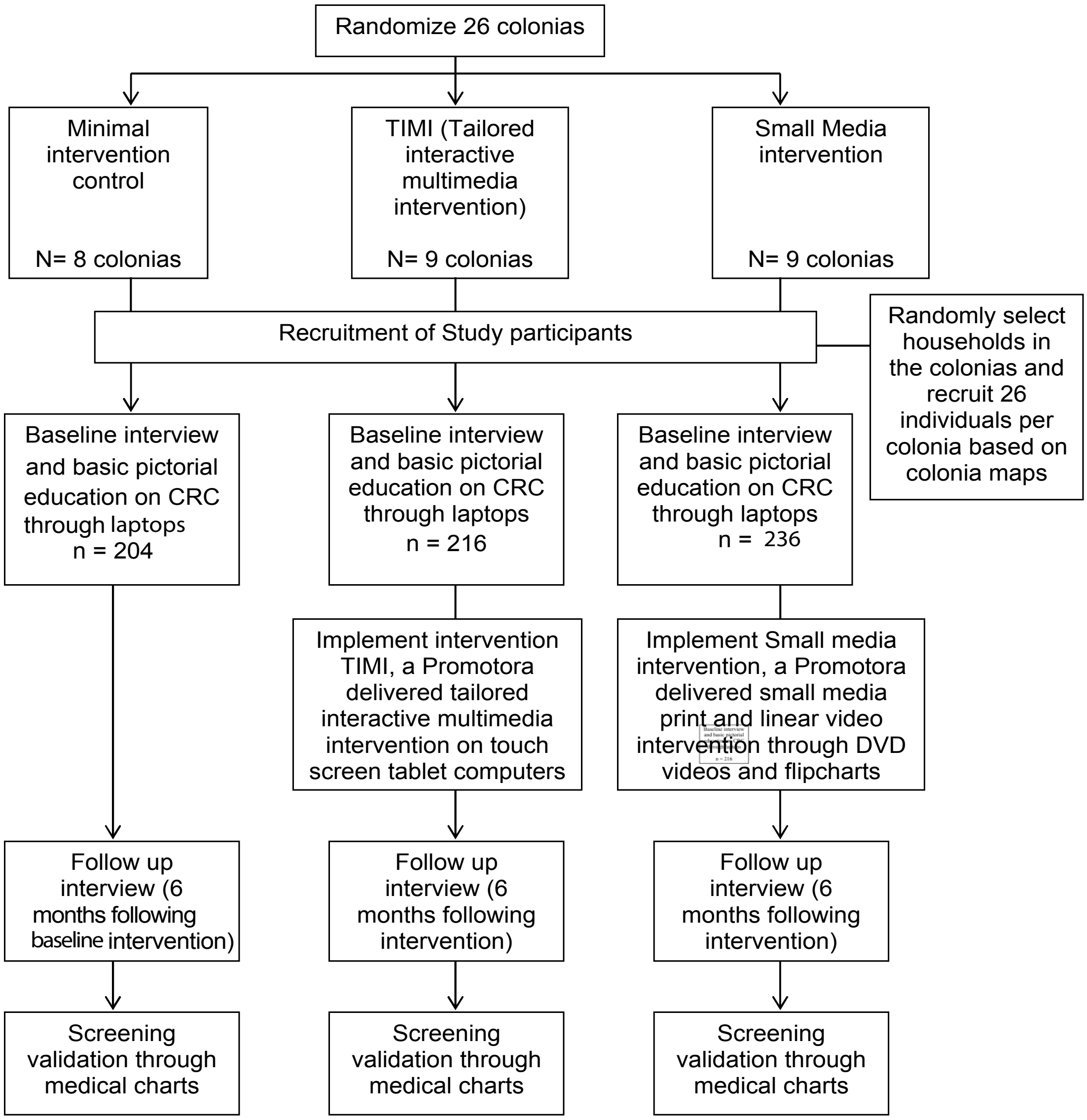

Figure 1 Study flowchart.

intermediate outcome of screening compliance, or percentage of people screened for CRC in each group. The screening adherence rates six months post intervention for the two intervention groups were compared with the control group and with each other.

Cost estimation

Costs were estimated from the payer and participant perspectives for each intervention group and summarized by major activity. The material and time cost for each project activity was determined by prospective micro costing, where the resource use was tracked and weighted with local prices. Costs incurred in the control group were excluded because they were research related. The cost data of intervention groups were gathered from the following sources [17-19]:

- Personnel time logs for time spent in minutes for each task of the project activities which included encounter forms, training logs, and follow-up forms
- Participant time log data for determination of intervention participation
- Purchase orders and invoices for materials used in the project-DVD players, touch screen laptops, flipcharts, and other supplies
- Estimation of overhead costs as a percentage of the direct cost

Total cost was computed as the sum of the direct cost for each activity plus the overhead cost. Overhead cost was estimated at 35 percent of direct cost, based on studies of screening promotion [5]. Average cost per participant was calculated by dividing the total cost for each intervention by the number of participants in each intervention group. Development cost of the tailored intervention was not included in the analysis as it was considered a “sunk cost”. Research costs were excluded from the

Table 1: Baseline characteristics of study participants.

	Overall (%)	Control (%)	Small Media (%)	TIMI (%)
	N=656	N=204	N=236	N=216
Age				
50-59 years	48.0	41.4	51.5	50.9
60-69 years	31.6	34.0	28.5	32.9
70 years old and over	20.1	24.6	20.0	16.2
Sex				
Female	69.4	69.1	69.5	30.6
Male	30.6	31.1	30.5	69.4
Hispanic Origin				
Mexican American, Mexican, or Chicana	99.4	99.0	100.0	99.5
Birthplace				
Born in Mexico	66.2	66.2	76.6	55.1
Born in U.S.	33.4	33.3	23.5	44.4
Years in U.S.				
Less than 11 years	5.2	86.7	83.8	92.6
11-19 years	7.2	8.4	9.4	3.7
More than 20 years	87.0	4.9	6.8	3.7
Education				
12 years or more	10.1	8.9	12.6	8.8
6-11 years	43.4	41.9	40.7	49.3
1-5 years	38.0	40.4	40.3	34.4
None	7.5	8.9	6.5	7.4
Married	63.5	60.1	66.4	63.4
Health Insurance (More than one may apply)				
None	51.1	40.2	55.1	57.0
Medicaid	27.0	31.4	26.8	23.1
Medicare	31.6	40.2	27.2	28.2
Private	5.9	4.4	7.4	6.0
Income (yearly)				
< $5,000	40.7	43.0	42.4	44.0
$5,000-9,999	22.7	29.0	23.5	24.6
$10,000-19,999	18.3	16.1	21.7	19.8
$20,000 or more	10.7	11.9	12.5	10.2
Aware of CRCS	63.4	65.7	59.1	66.2
Not all subgroups under each category are reported.				

analysis. All costs were valued in 2008 U.S. dollars, the year that data collection was initiated.

Description of costs according to project activities

Training cost of promotoras: The cost of training promotoras was comprised of:

1. The training time cost of a health educator
2. Training time cost of the promotoras
3. Food cost for training.

The number of minutes spent training the promotoras to deliver the intervention in each intervention group was multiplied by the adjusted salary per minute of the trainer and evenly spread among the participants of the TIMI group and small media group to get a training time cost of $0.82 per person in the TIMI group and $0.43 per person in the small media group.

The number of minutes spent in receiving training was multiplied by the adjusted wage rate of the promotora in each intervention group and evenly spread among the participants to get a per person cost of $0.36 in the TIMI group and $0.19 in the small media group. The cost of food provided to the promotoras during training sessions for both intervention groups was spread among the participants of each group to get a per person cost of $0.73 for TIMI and $0.67 for the small media group. The total training cost summed up to $1.91 per person in the TIMI group and $1.29 per person in the small media group.

Intervention delivery cost: The cost of administering the intervention was comprised of:

1) Amortized cost of equipment

2) Personnel time cost

3) Participant time cost

The equipment used was calculated as $35.72 using 3% interest rate and a useful life of four years. This cost was multiplied by the number of laptops used and by the number of months of TIMI delivery to get a total TIMI equipment cost of $2.48 per person. In the small media group, the cost of three DVD players was $326.86 and a per person equipment cost of $1.39. The Personnel cost was calculated by multiplying the adjusted salary per minute by the number of minutes spent delivering the intervention to the participant. The participant time cost for the small media and the TIMI groups was calculated by multiplying the US federal minimum wage rate ($6.55 per hour) by the number of minutes spent in viewing the small media intervention through flipcharts and DVD players or the multimedia intervention on the touch screen laptops respectively.

Overhead cost: Overhead cost was calculated by multiplying direct costs for each group with a hypothetical overhead rate of 35% [20] and adding the administrative cost. The administrative cost was comprised of personnel time cost for assigning households, preparing paperwork, reviewing paperwork and ordering supplies. The initial planning component of recruitment to identify prospective households to intervene was considered a part of the administrative cost. The administrative cost was calculated by multiplying the number of minutes spent by the adjusted salary per minute of the respective personnel. The total administrative cost was spread amongst all 656 participants of the intervention and control groups to get a cost of $0.79 per person. The cost of supplies was $0.30 per person for the small media group; comprised of the total cost of three flipcharts, three easels and three DVDs for showing information on CRCS to the participants. There were no supplies needed for the TIMI group.

Cost-effectiveness analysis

The cost-effectiveness analysis was conducted alongside a randomized controlled trial over the course of six months. The ICERs (incremental cost-effectiveness ratios) represented the additional cost per additional person screened for CRC stepping up from the no intervention control group to the tailored intervention group and then to the small media intervention group. ICER was computed by dividing the incremental cost by the incremental percent of people screened in each group. The sensitivity of the incremental cost-effectiveness ratios was assessed by tracking changes in the ICER with changes in the assumptions regarding the overhead rate and participant wage rate on the intervention cost. In addition to the intervention cost, the base case scenario included the promotora training cost and 35% overhead. The changes in ICER were observed with 40% and 30% overhead rates and by varying the participant wage rate to a minimal rate of $1 per hour. Costs and effects were not discounted because the follow-up period was not greater than one year.

Statistical uncertainty in the cost and effect estimates was assessed with nonparametric bootstrapping [21-24]. Replicates of cost and effect were obtained and plotted on the cost-effectiveness plane by sampling cost and screening outcome for all the cases with replacement one thousand times (see description of methods in supplement). The probability that one intervention was cost-effective compared to another alternative can be identified from the cost-effectiveness plane given the payer's maximum WTP (willingness-to-pay). A CEAC (cost-effectiveness acceptability curve) was generated by proposing several alternative levels of WTP. A net benefit regression analysis was used to confirm the bootstrap analysis of uncertainty (data not included).

The missing values of some direct cost variables were imputed using simple linear regression models [25]. The screening compliance for each participant, a binary variable, was obtained from the randomized trial. The analysis was done with Stata 12 statistical software.

Results

Table 2 shows a breakdown of the estimated costs by study group. For the small media intervention, the average cost was $45.69 and the standard deviation was $24.23. The average cost for implementing the TIMI was $39.15 and the standard deviation was $25.08. The variability in cost was primarily due to the time cost of both subjects and staff during the intervention delivery; more time was required to complete the small media intervention. For the small media, about 80 percent of the direct cost was for intervention delivery, compared to 72 percent for the TIMI.

Estimates of the base case incremental cost-effectiveness analysis are presented in **Table 3**. The screening compliance in the no intervention control group was 10.8% compared with 13.6% in the small media group and 10.2% in the TIMI group. The randomized trial did not yield statistically significant differences

Table 2: Cost of interventions.

Cost elements	Control($) n=204	TIMI($) n=216	Small Media($) n=236
Training	-	410.15	302.86
Equipment	-	535.83	326.88
Intervention delivery time (staff)	-	2,811.78	4,053.50
Intervention viewing time (participant)	-	1,560.43	2,218.59
TOTAL DIRECT COST	-	6,137.66	7,797.17
Overhead (35% of Direct cost+Admin+Supplies)	-	2,319.40	2,986.77
TOTAL COST	0.00	8,457.06	10,783.94
Cost per person	**0.00**	**39.15**	**45.69**
Standard deviation	0.00	25.08	24.23

in screening rates [16]. For the economic evaluation, the point estimates represent the "best" available estimate of program effects and costs. The mean ICER was $1,643 moving from no intervention to the small media intervention, whereas the TIMI had a negative effect compared to both the control group and the small media intervention. If we exclude participants' time cost receiving intervention, average cost per person was $33, which yields a mean ICER of $1,187 from payer's perspective. The TIMI was less costly and less effective than the small media intervention.

The sensitivity analysis for overhead rates is presented in **Table 4**. The average cost and the incremental cost effectiveness ratios showed relatively small changes in response to alternative assumptions regarding the overhead rate. Varying the participant wage rate from the minimum wage to $1 per hour, had an important effect on the average cost from payer plus participant perspective, but did not fundamentally alter the relative cost-effectiveness of the interventions.

Bootstrap analysis

The joint density of ΔC (difference in cost) and ΔE (difference in effect) when comparing the no intervention control group to the small media intervention along with the 95% CI (Confidence Intervals) for ICERs are summarized in **Figures 2 and 3**.

The bootstrapped mean differences for cost and effectiveness per participant showed that the small media intervention had an added cost with a positive effect compared with no intervention control as most of the simulations fell in the northeast quadrant of the cost effectiveness plane. A CEAC was constructed by calculating the proportion of the 1,000 bootstrap replicates that were cost-effective for a range of WTP values **(Figure 4).** The CEAC showed that if the WTP was less than $400 per additional person screened, no intervention was cost-effective; but the probability of small media being cost-effective increased rapidly between $400-$3,000 WTP and reached nearly 80% if the payer and participant were willing to pay more than $4,000. The small media intervention had a higher probability of being cost-effective from a payer's perspective compared to payer plus participant perspective, especially in the range of $230-$4,000. The net benefit regression analysis results were the same as the bootstrap results, data not included.

Discussion

Comparing the no intervention group with the small media intervention, the cost effectiveness ratios demonstrated an added cost of the intervention with a positive effect on the screening rate. In contrast, comparing the no intervention with the TIMI resulted in a lower screening rate and higher cost. This finding was unexpected given that culturally tailored video and audio educational messages had worked best for overcoming internal barriers of low education, lack of knowledge about CRC, embarrassment and fatalistic beliefs and promoting screening compliance among underserved and protected ethnic populations [26]. Additionally, since the video was tailored to the individual's needs and interests, the time of delivery theoretically could have been shorter since they would not be receiving information that was not needed. It was likely that difficulties with delivery of the TIMI intervention due to technical difficulties (problem with passwords, slow start-up, etc.) contributed to the increased cost as well as lack of effectiveness [27].

Geller et al. found that implementing a pilot test of a tailored intervention based on the Transtheoretical model via the computer tablet in five primary care practices in rural Vermont enhanced patient and provider discussion about CRCS and positively influenced patients' intentions to get screened [28].

Table 3: Cost-effectiveness results.

Group	Total cost $	Incremental cost $	Total effect %	Incremental effect %	Cost effectiveness $	ICER $
Payer plus Participant's Perspective						
Control	0.00	-	10.78	-	-	-
TIMI	39.15	-	10.20	-		dominated
Small Media	45.69	45.69	13.56	2.78	337	$1643
Payer's Perspective						
Control	0.00	-	10.78	-	-	-
TIMI	29.40	-	10.20			dominated
Small Media	33.00	33.00	13.56	2.78	243	$1,187

Table 4: Sensitivity analysis: overhead rate.

GROUP	Overhead rate %	Total cost $	Incremental cost $	Total effect %	Incremental effect %	ICER $
Control	30	0.00	-	10.78	-	-
TIMI		35.50	-	10.20	-	dominated
Small Med		44.04	44.04	13.56	2.78	1,584
Control	35	0.00	-	10.78	-	-
TIMI		36.84	-	10.20	-	dominated
Small Med		45.69	45.69	13.56	2.78	1,644
Control	40	0.00	-	10.78	-	-
TIMI		38.17	-	10.20	-	dominated
Small Med		47.35	47.35	13.56	2.78	1,703

The authors suggest testing this intervention in a randomized controlled trial in order to measure the actual screening outcome.

Khankari et al described a pilot study conducted by a physician among 154 eligible patients in a federally qualified health center in Chicago serving indigent low income population of African American and Hispanic origin [29]. The intervention aimed at increasing provider recommendation and patient completion of CRCS one year after delivery. The study identified patients above 50 years of age and non-adherent with CRCS from the clinic's database; sent a physician letter to eligible participants inviting them to the clinic to collect their CRCS referrals and discuss CRCS with their doctor along with printed brochures from the CDC (Centers for Disease Control and Prevention) "Screen for Life" campaign in English and Spanish to provide basic information on CRCS. The pre and post intervention screening adherence rates were compared and a cost effectiveness analysis of the intervention was conducted. The time cost of physicians and medical assistants for intervention delivery and the mailing cost of letters and brochures to participants were calculated. The authors found that the screening rates increased from 11.9% to 27.9% and the physician recommendation increased from 31.6% to 92.9% post intervention and the ICER per additional person screened was $106. The authors recommend implementing this low cost intervention in minority populations for CRCS promotion and suggested testing the intervention at multiple sites in a randomized trial design with the use of multimedia tools for patient education. Although the pilot study found increased screening compliance and the intervention appeared to be cost effective, the validity of the results was unclear due to possible patient selection bias.

Larkey and Gonzalez conducted a randomized pilot intervention to test two methods of CRCS and healthy behavior promotion among Latinos in Arizona [30]. Participants over 18 years of age and identified as Latino were recruited from churches, community centers and senior citizen centers; randomized to intervention arms of either "Story Telling" or "Numeric risk" group. The health educators in both intervention groups presented basic information in English and Spanish on risk factors for cancer and CRC, screening guidelines and options, impact of early detection of CRC during face to face interviews and collected post intervention survey responses. Data on intentions to get screened and encouraging others for CRCS was collected for adults over age 50. In both the "story telling" group and the "numeric risk" group fear and risk perception decreased after intervention and intention to get screened for CRC increased by equal values. The authors suggest implementing the method of "story telling" in the Latino population for risk communication and conducting future research trials on improving CRCS behavior. Our intervention

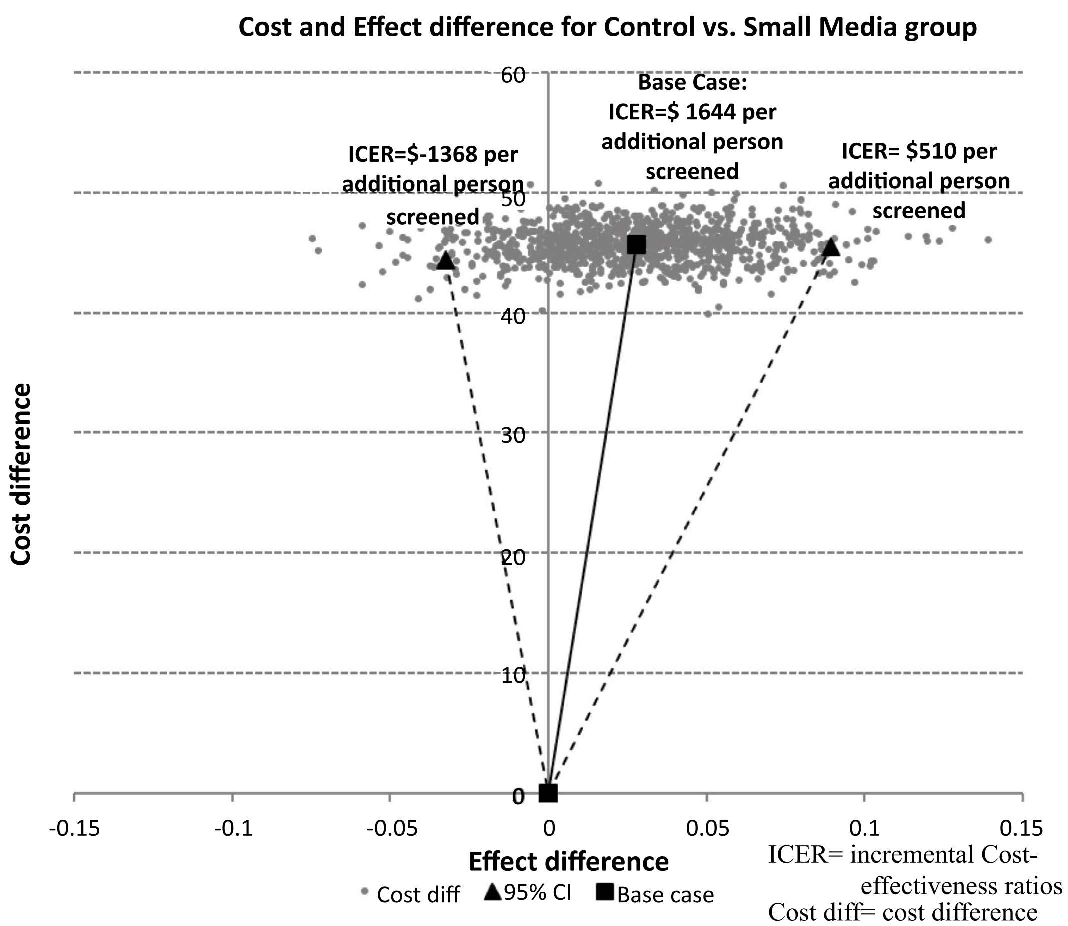

Figure 2 Cost and effect differences when moving from no intervention control to small media group.

utilized a story telling format (novella) that was well received by participants. However, CRCS access was likely an important barrier to completion of screening [16]. Additional studies are needed to assess both the effectiveness and cost effectiveness of both tailored and targeted small media interventions.

The limitations of the study included self-report of time spent in intervention delivery by the promotoras although time logs were used on a daily or weekly basis. The overhead cost was calculated as a percent of the direct cost instead of exact measurement. However, the sensitivity analysis showed that a range of values for the overhead rate had little effect on the cost-effectiveness results. Due to the difficulty of separating the direct cost of recruitment from research costs associated with the trial, recruitment was only considered as part of the administrative cost of planning the intervention and may be partially captured

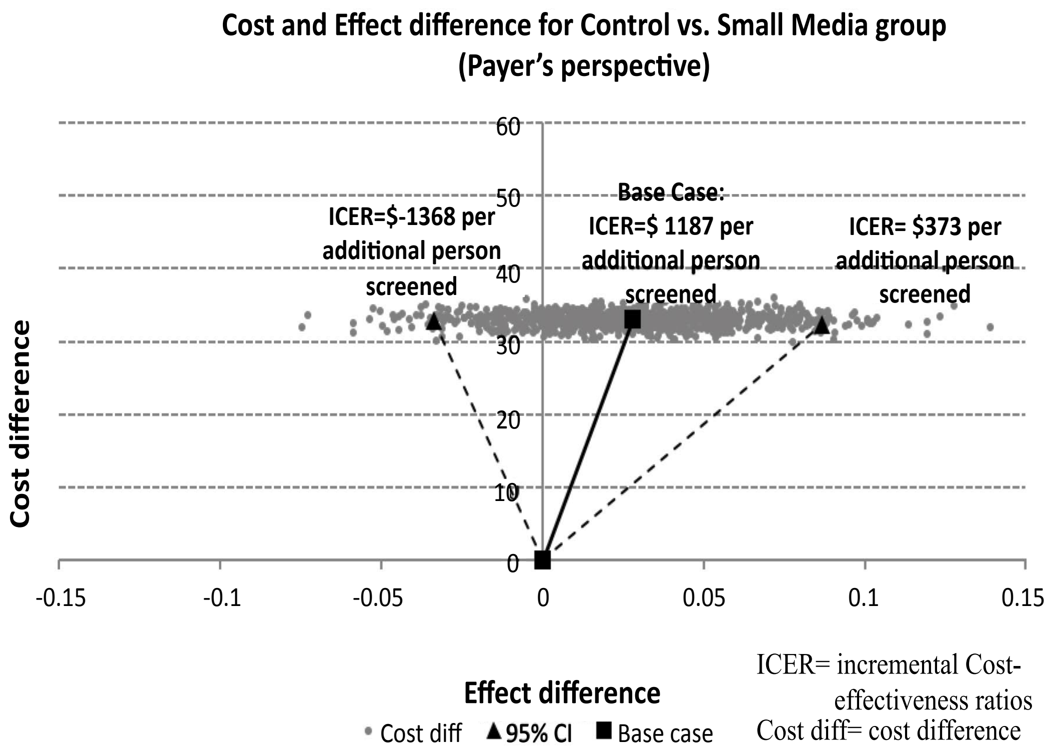

Figure 3 Cost and effect differences when moving from control to Small media group (payer's perspective).

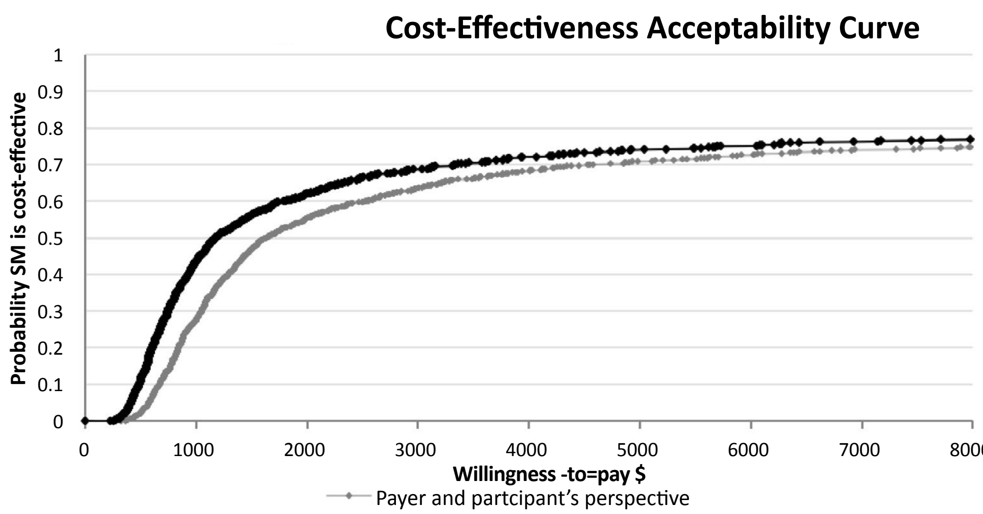

Figure 4 Cost-effectiveness acceptability curve showing the probability that small media was cost-effective compared to control group over a range of values for the maximum acceptable WTP.

in the overhead estimate. Recruitment can be especially costly when reaching out to a low income isolated community [31].

The results suggest that implementing a culturally tailored colorectal cancer screening promotion intervention through LHW for low-income underserved Hispanic populations in the Texas-Mexico border may lead to a modest increase in CRCS completion. However, the cost per additional person screened was substantial. The simpler intervention using small media and descriptive flipcharts may produce better results compared to the more technically advanced multimedia intervention. A qualitative study [27] found that the small media intervention may have involved a greater amount of communication between the promotora and the participants as compared to the tailored intervention. This qualitative report also found that the technology at the time of the trial may have been a barrier because some promotoras had problems using the equipment. It is likely that newer platforms including I-pads or other mobile devices with more "user friendly" features may be more effective. Finally, low income communities on the Texas Mexico border generally have low access to health care services, including cancer screening. Boosting the screening rate is all the more challenging under these circumstances and may require a systemic change in the health care access.

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