Woolford Susan J (Orcid ID: 0000-0003-4431-0652)
Resnicow Kenneth (Orcid ID: 0000-0003-1416-9627)

Cost-Effectiveness of a Motivational Interviewing Obesity Intervention vs. Usual Care in Pediatric Primary Care Offices

Susan J. Woolford, MD, MPH[1, 2], Kenneth Resnicow, PhD[1], Matthew M. Davis, MD, MAPP[3], Lauren P. Nichols, MPH[1], Richard C. Wasserman, MD, MPH[4], Donna Harris, MA[5], Achamyeleh Gebremariam, MS[1,2], Laura Shone, DrPH, MSW,[5] Alexander Fiks, MD, MSCE, FAAP,[5] Tammy Chang, MD, MPH, MS[1,6]

Affiliations:
[1]University of Michigan, Ann Arbor, MI, United States, [2]Susan B. Meister Child Health Evaluation and Research Center, Ann Arbor, MI, United States, [3]Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, IL, United States, [4]Larner College of Medicine, University of Vermont, Burlington, VT, United States, [5]American Academy of Pediatrics, Itasca, IL, United States, [6]Institute for Healthcare Policy and Innovation, Ann Arbor, MI, United States

Correspondence: Susan J. Woolford, MD, MPH
300 NIB, Room 6D20 (Campus Box 0456)
Ann Arbor, MI 48109-5456

Phone: 734-615-8214 (Fax: 734-764-2599) **Email:** swoolfor@med.umich.edu

Short Title: Cost-Effectiveness of Primary Care MI Intervention

Funding Source: NIH 5R01HL085400 - BM12: Brief Motivational Interviewing to Reduce Child BMI

Additional infrastructure funding was provided by the American Academy of Pediatrics and the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under UA6MC15585 - National Research Network to Improve Children's Health and U5DMC39344 - Pediatric Research Network Program. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA/HHS, or the U.S. Government.".

Financial Disclosure: All authors have indicated they have no financial relationships relevant to this article to disclose.

Conflict of Interest: All authors have indicated they have no potential conflicts to disclose.

Word Count: Main manuscript 4383; Abstract 200

Abbreviations: Incremental Cost Effectiveness Ratio (ICER) Body Mass Index (BMI); Motivational Interviewing (MI); Pediatricians and nurse practitioners (PCPs); Registered Dieticians (RDs); Pediatric Research in Office Settings (PROS), American Academy of Pediatrics (AAP), Brief Motivational Interviewing to Reduce Body Mass Index (BMI^2), Behavioral Therapy (BT), Digital Versatile Disc (DVD), Childhood Obesity Intervention Cost-Effectiveness Study (CHOICES), Study of Technology to Accelerate Research (STAR) Electronic Health Record (EHR)

Clinical Trial registry name and registration number: Brief Motivational Interviewing to Reduce Child Body Mass Index - NCT01335308

What's Known on This Subject

Obesity is a public health problem that is associated with significant social and economic costs. Prior work has largely focused on costs associated with tertiary care treatment and community-based interventions. Little is known about the costs and cost-effectiveness of interventions to address childhood obesity in the primary care setting.

What This Study Adds

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/oby.23560

This study presents the costs and incremental cost-effectiveness ratio, from the societal perspective, of the Brief Motivational Interviewing to Reduce Child BMI primary care intervention. It shows that this approach is effective and associated with low costs and incremental cost-effectiveness ratio, taking a societal view (i.e., including costs such as food).

How This Study Impacts Research or Clinical Practice

Further work should explore dissemination of brief motivational interviewing training for primary care providers and registered dietitians to reduce BMI in children.

Key words: Incremental cost-effectiveness ratio, childhood obesity, primary care, motivational interviewing

Contributors' Statement Page

Dr. Woolford participated in conceptualizing and designing the study. She drafted the initial manuscript and reviewed and revised the manuscript.

Dr. Resnicow participated in conceptualizing and designing the study. He participated in conducting the analyses and reviewed and revised the manuscript.

Dr. Davis participated in conceptualizing and designing the study. He participated in conducting the analyses and reviewed and revised the manuscript.

Lauren Nichols made a substantial contribution to the interpretation of the data, drafting the article and also providing the final approval.

Dr. Wasserman participated in conceptualizing and designing the study and also reviewed and revised the manuscript.

Donna Harris participated in conceptualizing and designing the study and also reviewed and revised the manuscript.

Achamyeleh Gebremariam made a substantial contribution to the analysis and interpretation of the data and contributed to reviewing and revising the manuscript.

Dr. Laura Shone made substantial contributions to revising the study and reviewing and revising the manuscript.

Dr. Alexander Fiks made substantial contributions to revising the study and reviewing and revising the manuscript.

Dr. Chang made a substantial contribution to the design of the study, drafting the article and also providing the final approval.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

ABSTRACT

Objective: To assess the incremental cost-effectiveness ratio (ICER) of a 2-year, motivational interviewing (MI) intervention versus usual primary care.

Methods: A national trial was implemented in the Pediatric Research in Office Settings (PROS) network of the American Academy of Pediatrics to evaluate MI vs. usual care for children (2- through 8-years old; baseline BMI 85^{th}-97^{th} percentiles). Healthcare utilization, food costs, provider fees, and training costs were assessed, and sensitivity analyses conducted. Primary outcome was the ICER, calculated as cost per-unit-change in BMI percentile for intervention versus usual care.

Results: At 2 years, 72% of enrolled parent/child dyads were retained; 312 children were included in the analysis. Mean BMI percentile point change was -4.9 and -1.8 for the intervention and control respectively, yielding an incremental reduction of 3.1 BMI percentile points (95% CI: 1.2, 5.0). The intervention cost $1,051/dyad ($658 for training DVD development). Incorporating healthcare and non-healthcare costs, the intervention ICER was $363 (range from sensitivity analyses: cost-saving, $3159) per BMI percentile point decrease/participant over 2 years.

Conclusions: Training pediatricians, nurse practitioners, and registered dieticians to deliver MI-based interventions for childhood obesity in primary care is clinically effective and acceptably cost-effective. Future work should explore this approach in broader dissemination.

INTRODUCTION

Obesity is a public health problem associated with multiple comorbidities and significant social and economic costs.[1-3] While a large proportion of the sequelae and associated costs of obesity occur during the adult years, a number of comorbidities emerge during childhood that result in higher health care costs among children with obesity than among their healthy weight peers.[4-10] It is imperative to find cost-effective ways to address obesity.

Primary care providers, including pediatricians and nurse practitioners, represent the front line of pediatric obesity prevention and treatment. Expert Committee Recommendations endorsed by the American Academy of Pediatrics (AAP), outline a staged treatment approach starting in the primary care setting prior to considering other more intensive, and presumably, more expensive and less convenient options such as referral to multidisciplinary care.[11]

While few primary care initiatives have proven successful in treating pediatric obesity, a prior trial (the Brief Motivational Interviewing to Reduce Child BMI (BMI^2) intervention), showed statistically and clinically significant decreases in BMI over two years among children 2 through 8 years of age (at baseline).[11-13] The BMI^2 study, described in detail elsewhere,[13,14] was a three-arm trial designed to test two approaches to motivational interviewing (MI) compared to a usual care control arm. Briefly, all participating primary care pediatricians and nurse practitioners (hereafter described as PCPs) along with one staff person per clinic received a half-day study orientation session, which included an overview of current treatment guidelines. One intervention arm included pediatricians and registered dietitians (RD) (the “PCP/RD Intervention” group) and both received an additional 1.5 days of in-person training in MI and Behavior Therapy (BT) as well as an interactive Motivational Interviewing DVD training system focusing on pediatric obesity developed for this study. Children in the PCP/RD intervention group were offered four in-person counseling sessions delivered by PCPs over two years plus 6 MI-based counseling sessions (by phone or in person) with an RD over the 2 years.[13,14] The other intervention arm was a PCP-only intervention group that received visits with the MI-trained PCPs, without RD visits. The “PCP/RD” intervention led to a statistically and clinically significant mean reduction in BMI compared to those who received usual care.[13] Meanwhile, there were no statistically significant differences in BMI outcomes between the PCP-only group and the usual care controls, which is likely due to there being an insufficient dose of the intervention.[13] Therefore, as the PCP-only intervention was dominated by usual care, only the PCP/RD intervention is included in this cost-effectiveness analysis.[13]

In an effort to inform the process of improving the treatment of obesity in pediatric primary care and to assist decision makers faced with the allocation of funds related to pediatric obesity, the objective of this analysis was to evaluate the incremental cost-effectiveness ratio (ICER) of the BMI^2 intervention from a societal perspective over a two-year period, comparing the PCP/RD intervention group to a concurrent usual care group. The societal perspective aims to include a broad array of costs beyond those associated with healthcare (e.g., productivity costs including time away from work and consumption costs including food costs).[15]

PATIENTS and METHODS

Child anthropometrics and parent-reported survey data were collected as part of the 2-year national randomized controlled trial to test the use of MI vs. usual care among the parents of children who, at baseline, were 2 through 8 years old and had BMI measurements between the 85th and 97th percentiles for age and sex (Centers for Disease Control and Prevention).[16] All practices were recruited from the PROS (**P**ediatric **R**esearch in **O**ffice **S**ettings) network (www.aap.org/pros), the primary care practice-based research network of the American Academy of Pediatrics. The design of this intention to treat analysis, included 645 total parent/child dyads in all three groups of the study at baseline, with a total of 457 dyads (71%) followed to study conclusion at the end of 2 years. The usual care control group included 11 practices; n=198 parent/child dyads, with 158 dyads (80%) retained and the PCP/RD group included 15 practices; n=235 initial dyads, with 154 dyads (66%) followed to study conclusion. Thus, for these two groups (PCP/RD and usual care), 312 (72.1%) of the original 433 dyads were retained at 2 years and were included in this analysis (even if participants did not have complete data at all time points). Of note, this degree of attrition was not unexpected. Attrition from pediatric weight management interventions, which are typically 3 to 12 months long, ranges from 27 to 73%.[17] For the BMI^2 study, the overall attrition rate was 29% over 2 years. As the study occurred during implementation of the Affordable Care Act, participants could have had changes to their insurance coverage or their families and may have faced challenges in continuing care with the same PCP.

For this study we conducted a cost-effectiveness analysis which is a way to consider the marginal cost (in monetary terms) and the marginal benefit (expressed as natural units BMI units in this case) of an intervention in comparison to an appropriate alternative.[18] To achieve this, we calculated the Incremental Cost Effectiveness Ratio (ICER). The ICER provides a measure of additional cost for each additional unit-gain of effectiveness delivered by the intervention.[18] The ICER was calculated as cost per unit-change in age- and sex-specific BMI percentile from baseline to two-year follow-up. Survey data collected at baseline and at the end of years one and two included the following items regarding costs:

a) Parent-reported healthcare utilization for the child over the previous 12 months including out-of-pocket prescription costs, healthcare visits, and missed work related to healthcare encounters of any kind (Example question: "Over the past 12 months about how many of the following health care visits has your child had: Emergency Department visits, Sick visits for a new illness or problem, Sick visits for a chronic illness or problem, Checkup visits not including visits for this study"). Categorical response choices were provided only in one instance (for out-of-pocket prescription medications) to assist respondents in estimating broad strata of their cost burden. No tools were provided to aid recall and no electronic records were used to capture costs. Parent reports of patients' healthcare visits were used to calculate healthcare utilization costs as described below.

b) Parent-reported food costs (including dining out costs, grocery costs) were collected via open ended questions asked annually (i.e., In a typical week how much do you spend on groceries for the whole household? $___________; of note, no cost strata were provided)

In addition, missed work for study-related visits was assessed using attendance records for in-person PCP and RD sessions. PCP and RD reimbursement were obtained from administrative study data. Furthermore, costs of educating PCPs in MI to deliver the intervention (including costs of in-person training and costs of producing the training DVD) were calculated. The costs included in each analysis are indicated in Table 1.

The measure of efficacy, mean change in age- and sex-specific BMI percentile from baseline to two-year follow-up, was obtained from a mixed-effects regression with children nested within their practice, to control for cluster randomization effects. The study was powered to detect a 3-

point difference in BMI percentile between groups, with an assumed standard deviation for BMI percentile between 4 and 6: power of 0.80 and 2-tailed α of .05.[13] For this cost analysis we only included those participants for whom we had cost data and used all available data (even if they did not have complete cost data for each time point).**Analysis**

The ICER for the PCP/RD intervention compared with usual care was calculated using the equation in Figure 1.

(Figure 1)

Annual expenditures for eating out and for groceries were calculated from the survey data described above for the year before baseline, for year 1 and for year 2. The difference between the annual costs for year 1 compared to the baseline year was calculated and similarly the difference between the year 2 costs and baseline was calculated. These costs were summed to represent dining out and grocery costs per participant over the 2-year intervention.

As noted above, monthly out-of-pocket prescription costs were collected from survey data at baseline, and at the end of years 1 and 2. Parents selected their perceived cost burden for prescriptions from the following strata $0, $1-30, $31-60, $61-90 and more than $90 per month. We used the midpoints of these strata ($0, $16, $46, $76, $90) to estimate the out-of-pocket monthly costs for parents. Differences from baseline were calculated as described above.

Emergency visits, sick visits for new problems, sick visits for chronic problems, and routine check-ups (excluding study visits) were summed and averaged over the number of respondents at each time point to obtain the mean number of visits in the previous 12 months in each study group. To obtain a cost estimate for utilization frequency in each setting, the number of visits was then multiplied by national expenditure data from the 2013 Medical Expenditure Panel

Survey (MEPS).[19] To account for wages related to missed work among parents as they accompanied their children to medical visits and study related visits, the visit frequencies (from parent self-reported medical visits and from data collected regarding in-person study visit attendance) were multiplied by the average hourly wage plus 30% for fringe benefits x 4 hours (corresponding to a half-day of missed work per visit) based on 2013 Bureau of Labor Statistics data for all occupations (thus these estimates were not profession specific).[20] These values were aggregated to reflect costs per participant per 2 years of intervention. Finally, all cost data (both for our study and for all referenced studies) were adjusted for inflation to 2019 U.S. dollars. We used personal consumption expenditure indexes available from the Bureau of Economic Analysis (www.bea.gov)[20] to inflate dining cost, grocery cost and healthcare visit costs. Out-of-pocket costs and time costs were inflated using the consumer price index for medical care (www.bls.gov).[21] Discounting (which is a way to make comparisons when dealing with cost effectiveness analyses that span a long period of time) was not used due to the duration of the study (2 years).

We estimated the ICER from the societal perspective, and thus included variables that would pertain to the implementation of the intervention in real-world settings that consider food costs and parents' missed work, in addition to expenditures for medical encounters and prescriptions. Transit costs were not included as data on ZIP codes were not available. Families received a $20 gift card and small toys at baseline and again at the 1-year height/weight measurement. At the 2-year measurement, they received a $20 gift card. The total value of their incentives totaled ~$96/family. PCPs received $50 for each in-person MI visit; RDs received $35 for each phone visit.

To address potential uncertainty regarding the costs assessed in this study, we conducted a one-way sensitivity analysis to examine uncertainty one factor at a time (using the lower and upper bounds of year 2-to-year 0 change). The factors, varied one at a time, were: dining costs, grocery costs, out of pocket prescription costs, number of ER visits, number of new sick visits, number of chronic sick visits, checkup visits, number of missed workdays – study-related, and number of missed workdays – other. Furthermore, we conducted a probabilistic sensitivity analysis, which allowed us to vary multiple variables at the same time using random draws from each of the distributions, and to obtain percentile-based 95% confidence intervals for the ICER. From these calculations, a cost-effectiveness acceptability curve was generated. All analyses were preformed using Stata/SE version 15 and TreeAge Pro version 2021.

RESULTS

Sample Description – This analysis was performed on data from 312 participants; 158 in the usual care control group and 154 in the PCP/RD group, for whom baseline, 1-year and 2-year follow-up BMI data were complete. The largest proportion of the cohort was white (60% White, 22% Hispanic, 7% Black, and 6% Asian) and approximately two-thirds (68%) reported an annual household income at or above $40,000. Details of the sample have been previously reported.[13,14]

Effectiveness of the MI Intervention: ***Change in BMI Percentile*** – There was a mean reduction in BMI for both the MI intervention (PCP/RD) and the control (usual care) groups, but the reduction for the MI intervention group was statistically significantly larger than for the control group (4.9 vs. 1.8; *P*=0.02). The net difference between these groups was 3.1 BMI percentile points (95% CI: 1.2, 5.0).[13]

Costs – The cost of the PCP/RD intervention (i.e., training costs for PCPs and clinic staff – not including incentives for children/families or PCPs, practice/practitioner reimbursements) per participant for 2 years was $1,051. This included the cost to produce the training DVD which was $154,700 ($658/per participant) and constituted 63% of the overall direct costs related to the intervention. Given that the training DVD has already been produced and is available for continued use, cost-effectiveness was calculated with and without DVD costs. The average costs for usual care visits reported by parents were $146 per participant. Changes in average health care costs (including study-related visits) and societal costs (i.e., food, missed work for medical visits) after two years of the study compared to costs reported at baseline (for the year prior to study enrollment) for children enrolled in the PCP/RD intervention group were $2,013 and for the usual care group were $886 (Table 2). Of note, for the intervention group the eating out costs decreased while grocery costs increased.

Incremental Cost-Effectiveness Ratio – From a societal perspective that accounts for the costs of parents' self-reports of missed work (for medical visits and study visits), the ICER of the intervention compared with usual care was $363 per BMI percentile point decrease, per participant, over 2 years. Considering a health care perspective (i.e., not considering costs for food or missed work), the ICER of the intervention compared with usual care was $284 per percentile point decrease in patient BMI, per participant, over 2 years (range: $50, $1,553). When excluding costs of DVD production and other training costs, the incremental cost effectiveness ratio for the steady state was $72 per BMI percentile point decrease, per participant, over 2 years (Table 3).

Sensitivity Analyses – The results of the 1-way sensitivity analysis are presented in Figures 2a and 2b. The change in grocery costs impact the ICER the most, followed by parent-reported dining costs, number of checkup visits and number of missed workdays due to study-related visits. The results of the probabilistic sensitivity analysis for the ICER with DVD cost included are presented in Table 3 and show a range from cost-saving (i.e., a negative value) up to a cost of $3,159 per BMI percentile change. For the ICER without DVD cost, the range was cost-saving to a cost of $2,276 per BMI percentile change. The cost-effectiveness acceptability curve (Figure 3) indicates that for low willingness to pay the usual care strategy is more acceptable than the intervention.

DISCUSSION

Our analysis suggests that the BMI^2 intervention in primary care settings costs $1,051 per participant over two years and has an ICER of $363 per percentile point decrease in patient BMI per participant over 2 years when considered from the societal perspective and $284 from the health care perspective. Excluding the development and production of the DVD (a one-time expenditure) yielded a per-participant cost of $393 and an ICER of $72 per BMI-percentile decrease. This level of investment appears modest, given the severity of adverse health outcomes related to childhood obesity. As this is among the first studies of which we are aware, to provide a formal assessment of cost-effectiveness for the treatment of childhood obesity delivered mainly via primary care practice visits for this age group, a direct comparison with equivalent approaches is not possible.

However, there is a growing body of literature regarding costs for obesity interventions in pediatric primary care and for obesity treatment interventions in other clinical settings that may offer a sense of the spectrum of cost-effectiveness estimates. For example, a recent analysis of a primary care intervention consisting of MI delivered via 4 in-person and 3 telephone visits by pediatric nurse practitioners significantly decreased television viewing and unhealthy eating practices among children 2-6 years old.[22] However, the intervention did not achieve a significant change in BMI. Costs for children in the intervention group were found to be $296 per child and costs for children in the usual care group of the study were $72, yielding an incremental cost of $224 for the intervention with no significant change in BMI.[22] This suggests a potentially promising approach at modest cost, though in the absence of a statistically significant decrease in BMI, a cost-effectiveness analysis was not possible. A more intensive intervention, such as the BMI^2 approach reported here, may be needed to affect obesity in clinically and statistically significant ways.[23]

In contrast, a 6-month family-based intervention for 8- to 12-year-olds, led to a significant decrease in the severity of excess weight (measured in 'percent BMI over the 50th percentile') at 12-month follow-up, with reported costs of $1,608 ($934 payer costs + $675 participant costs) per family, and a child cost-effectiveness ratio of $232 per "percent over BMI" (calculated by comparing the participant's BMI with the BMI at the 50th BMI percentile for child age and gender).[24] Comparisons between the outcomes of this 6-month study and BMI^2 are difficult to make, as it was a multidisciplinary intervention not offered in the primary care setting, and the measurement assessed was percent BMI over the 50th percentile at 12-month follow-up as opposed to change in BMI percentile at 2-year follow-up in our study. Similarly, "percent over BMI" was the measure used in a recent family-based intervention for 2- to 5-year olds with obesity/overweight and their parents, delivered via 17 group sessions in primary care offices over the course of 2 years.[25] It showed an ICER compared to the control group of $129 for a 1% decrease in "percent over BMI" at 24-month follow-up.[25] While "percent over BMI" is not directly comparable to the measures used in the current study, it does provide an indication of the ICER of other pediatric obesity interventions.

Though bariatric surgery is not a clinically appropriate treatment option for most patients in the age group included in the BMI^2 study, the costs of bariatric surgery warrant mentioning as patients who go on to become adolescents or adults with severe obesity may be considered candidates for invasive interventions such as surgery. The two most common procedures among adolescents, the Roux-en-Y gastric bypass and the sleeve gastrectomy, have a mean surgical cost of $27,001 ($17,234 to $37,810) and $25,534 ($14,360 to $37,691) per patient, respectively, not including other health or societal costs, or the additional costs associated with complications.[26] One study of bariatric surgery costs, reported average per patient costs of $28,260 and an average decrease in BMI of 13.2 BMI units, yielding surgical intervention costs of $2,141 per BMI unit (kg/m^2) reduced.[27] However, without costs per BMI percentile change, direct comparisons are not possible with our findings.

In light of the broad range of possible approaches to obesity prevention and treatment, the consideration of costs in a wider context is necessary. To explore the cost-effectiveness of obesity interventions more broadly (including clinical, school-based, early childhood, community, and policy efforts), Gortmaker et al initiated the Childhood Obesity Intervention Cost-Effectiveness Study (CHOICES).[28,29] This work illustrates how cost-effectiveness analyses may be used to understand the practical impact on population focused interests at the national level. For example, a microsimulation model of a national implementation of the Study of Technology to Accelerate Research (STAR) trial was performed. This trial using electronic health record (EHR) decision support tools for primary care providers with self-guided behavior change support for parents of 6- to 12-year-olds with obesity resulted in a smaller increase in

BMI over time among the intervention group compared to usual care patients.[30] The simulation projected the potential effects of the STAR intervention, if used by all PCPs with EHRs in the US over the course of 10 years, and estimated costs of $255 per BMI unit reduced.[31] In another CHOICES study, lower costs were projected for large-scale public policy efforts such as an excise tax on sugar-sweetened beverages, which has an estimated cost of $3.00 per BMI unit reduction.[32] While direct comparisons with our findings are not possible because of different measures of impact on BMI, these interventions do provide a helpful context for understanding the similarly modest cost-effectiveness ratio that we found.

The cost for interventions to treat obesity among adults may also be helpful when considering our results. In a meta-analysis of commercial weight loss strategies, Finkelstein and Kruger assessed the cost-effectiveness of two lifestyle programs (Weight Watchers and Vtrim), one meal replacement program (Jenny Craig) and three medications (Qsymia, Lorcaserin, and Orlistat).[33] They found the most favorable ICER was for Weight Watchers with a mean cost per kilogram of weight loss of $155 (95% CI: $110-$218) relative to a low-cost control intervention. The least favorable intervention was Orlistat, with a mean cost per kilogram of weight loss of $546 (95% CI: $390-$736).[33]

Of note, our findings indicate a decrease in health care visits for children in the intervention group. This finding may be attributable to parents' questions being answered during the study-related visits which would obviate the need for additional visits to discuss other health concerns. Alternatively, it is possible that frequent contact with a health care provider offers some reassurance and supports the worried well, thereby decreasing additional health care utilization. Exploring this issue fully was beyond the scope of the study, and further research is warranted to examine this question and to elucidate the mechanisms by which changes in visit frequency may be related to an intervention such as BMI[2]. In the longer term, we hypothesize that interventions like the one studied may improve lifestyle habits, leading to a lower BMI percentile and better health status with an associated decreased need for healthcare services.[34]

Our findings must be considered in light of certain study limitations. It is possible that the value of a change in BMI percentile may differ based on the patient's initial BMI percentile. Our ability to explore this question in the current study was limited by our sample size. In addition, participant dropout may not have been at random and could have led to a smaller denominator and higher ICER if those with less favorable changes in BMI were more likely to leave the study. Missing data were not imputed and were as high as 15% at Year 1 for dining costs and out-of-pocket prescription costs. Participant costs were not objectively obtained but were from self-report at baseline, and the end of year 1 and year 2, which may have led to recall errors and may have impacted the accuracy of our estimates, including the accuracy of parental report of emergency department visits and medication use. However, we are unaware of any literature that would lead us to expect a systematic bias in parent reporting of these events and costs that would differ by intervention versus control groups. An additional limitation is that the number of family members was not collected at any time point, and change in cost for food was collected at the family level. For families with more than one child, or with shifting family structures and dietary preferences over time unrelated to the intervention, estimates reported here may not reflect the incremental cost change attributable to the specific child enrolled. However, this should affect both the control and intervention arms similarly, which may mitigate this concern. Furthermore, in the absence of data regarding parental occupations, we utilized the Bureau of Labor statistics "all-occupations" data; higher or lower wages for parents may have affected estimated costs and the ICER, in ways that are not possible to predict. Finally, this study was conducted at PROS offices, which are well suited to conducting such interventions, and findings may differ in other practice settings.

While we attempted to oversample among minority families, our sample size did not allow us to conduct analyses to determine whether the ICER differed by SES, race, gender, or ethnicity. This remains a priority we plan to address in future studies. As it is possible that a population with greater diversity may have a greater sensitivity to the costs associated with participation, efforts may be needed to further minimize the costs borne by families. While not large enough to impact the ICER of this study in a substantial way, grocery costs did increase among the intervention group. Though we did not ask families about reasons for change in their food costs, the cost of healthy foods is an oft-cited barrier to making healthy changes.[35,36] In addition, parents frequently express concern about children not eating fresh fruits and vegetables which can lead to these costly foods being wasted.[37] In order to increase the uptake of this intervention, it may be helpful to counsel parents on economical approaches to healthy food options.

In summary, our findings offer an assessment of the costs associated with an effective MI intervention for treating pediatric obesity in the primary care setting and may present a benchmark upon which future analyses could be assessed. Educating PCPs and registered dietitians to deliver MI-based interventions to address childhood obesity in primary care is effective and is associated with modest costs in the context of primary care-based weight management interventions for children. Further research is warranted to examine whether MI training for PCPs (and possibly medical students and residents) offers a longer-term opportunity for a cost-effective impact on obesity, as the durability of MI training may continue to favorably affect children's BMI trajectories over time and may also be amortized over an increasing number of children in a PCP's practice who develop obesity. Indeed, broadly disseminating the MI training materials may be a means of helping PCPs adopt approaches similar to those used in BMI^2, which without the curriculum development costs, offer the potential of an improved ICER. Moreover, in light of improvements in technology and the widespread use of video conferencing platforms implemented since the BMI^2 trial was conducted, it is possible that training costs could be much lower for future iterations of similar interventions.

Acknowledgements: The authors would like to thank the practices, children, and families who participated in the study, and Alexander Fiks, MD, MSCE, FAAP, Laura Shone, DrPH, MSW and Donna Harris, MA of the PROS Network for their dedicated assistance in the review and preparation of this manuscript.

REFERENCES

1. Dietz WH. Health consequences of obesity in youth: childhood predictors of adult disease. *Pediatrics.* Mar 1998;101(3 Pt 2):518-525.

2. Schwimmer JB, Burwinkle TM, Varni JW. Health-related quality of life of severely obese children and adolescents. *JAMA.* Apr 09 2003;289(14):1813-1819.

3. Finkelstein EA, Graham WC, Malhotra R. Lifetime direct medical costs of childhood obesity. *Pediatrics.* May 2014;133(5):854-862.

4. Woolford SJ, Gebremariam A, Clark SJ, Davis MM. Incremental hospital charges associated with obesity as a secondary diagnosis in children. *Obesity (Silver Spring).* Jul 2007;15(7):1895-1901.

5. Woolford SJ, Gebremariam A, Clark SJ, Davis MM. Persistent gap of incremental charges for obesity as a secondary diagnosis in common pediatric hospitalizations. *J Hosp Med.* Mar 2009;4(3):149-156.

6. Hampl SE, Carroll CA, Simon SD, Sharma V. Resource utilization and expenditures for overweight and obese children. *Arch Pediatr Adolesc Med.* Jan 2007;161(1):11-14.

7. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff (Millwood).* Sep-Oct 2009;28(5):w822-831.

8. Must A, Strauss RS. Risks and consequences of childhood and adolescent obesity. *Int J Obes Relat Metab Disord.* Mar 1999;23 Suppl 2:S2-11.

9. Ciba I, Widhalm K. The association between non-alcoholic fatty liver disease and insulin resistance in 20 obese children and adolescents. *Acta Paediatr.* Jan 2007;96(1):109-112.

10. Must A, Jacques PF, Dallal GE, Bajema CJ, Dietz WH. Long-term morbidity and mortality of overweight adolescents. A follow-up of the Harvard Growth Study of 1922 to 1935. *N Engl J Med.* Nov 05 1992;327(19):1350-1355.

11. Barlow SE. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics.* Dec 2007;120 Suppl 4:S164-192.

12. Davoli AM, Broccoli S, Bonvicini L, et al. Pediatrician-led motivational interviewing to treat overweight children: an RCT. *Pediatrics.* Nov 2013;132(5):e1236-1246.

13. Resnicow K, McMaster F, Bocian A, et al. Motivational interviewing and dietary counseling for obesity in primary care: an RCT. *Pediatrics.* Apr 2015;135(4):649-657.

14. Resnicow K, McMaster F, Woolford S, et al. Study design and baseline description of the BMI2 trial: reducing paediatric obesity in primary care practices. *Pediatr Obes.* Feb 2012;7(1):3-15.

15. Newmann PJ, Sanders GD, Russell LB, Siegel JE, Ganiats TG. *Cost-Effectiveness in Health and Medicine*. 2nd Edition. New York, NY: Oxford University Press; 2017

16. Kuczmarski RJ, Ogden CL, Grummer-Strawn LM, et al CDC growth charts: United States. Adv Data. 2000;(314):1–27pmid:11183293

17. Skelton JA, Beech BM. Attrition in paediatric weight management: a review of the literature and new directions. Obes Rev. 2011;12: e273–e281.

18. Carr SM, Lhussier M, Forster N, et al. An Evidence Synthesis of Qualitative and Quantitative Research on Component Intervention Techniques, Effectiveness, Cost-Effectiveness, Equity and Acceptability of Different Versions of Health-Related Lifestyle Advisor Role in Improving Health. Southampton (UK): NIHR Journals Library; 2011 Feb. (Health Technology Assessment, No. 15.9.) Appendix 13, Use of ICERs in the analysis of cost-effectiveness

19. Mirel L, Carper K. Trends in Health Care Expenditures for Children under Age 18: 2001, 2006, and 2011 2014; https://meps.ahrq.gov/data_files/publications/st428/stat428.shtml. Accessed November 21, 2017.

20. Bureau for Ecoomic Analysis Accessed March 8, 2020

21. Bureau of Labor Statistics. Occupational Employment Statistics. http://www.bls.gov/oes/tables.htm. Accessed March 8, 2020.

22. Wright DR, Taveras EM, Gillman MW, et al. The cost of a primary care-based childhood obesity prevention intervention. *BMC Health Serv Res.* Jan 29 2014;14:44.

23. Frohlich G, Pott W, Albayrak O, Hebebrand J, Pauli-Pott U. Conditions of long-term success in a lifestyle intervention for overweight and obese youths. *Pediatrics.* Oct 2011;128(4):e779-785.

24. Epstein LH, Paluch RA, Wrotniak BH, et al. Cost-effectiveness of family-based group treatment for child and parental obesity. *Child Obes.* Apr 2014;10(2):114-121.

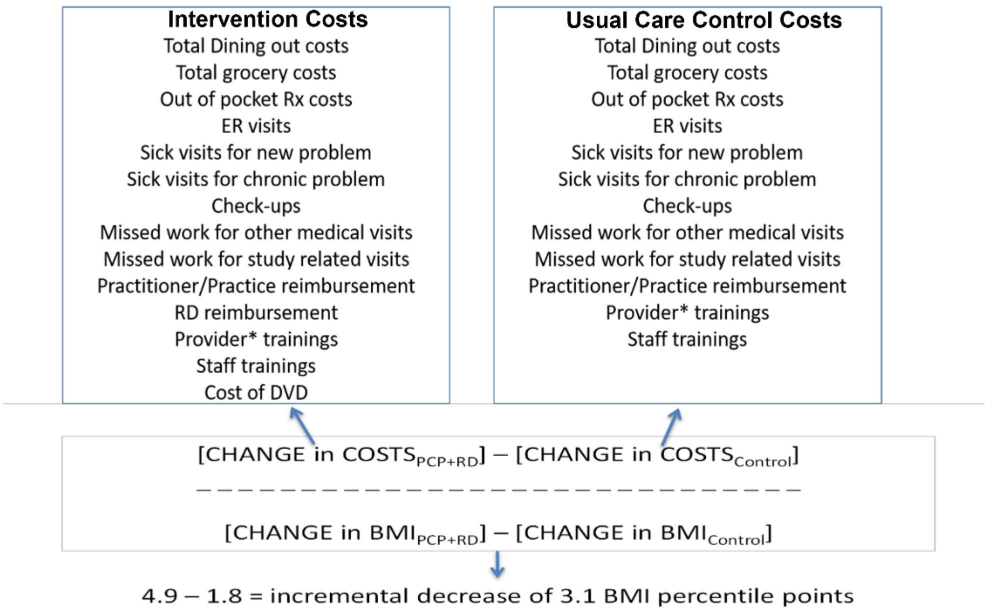
25. Quattrin T, Cao Y, Paluch RA, Roemmich JN, Ecker MA, Epstein LH. Cost-effectiveness of family-based obesity treatment. Pediatrics. 2017; 140(3):e20162755

26. Klebanoff MJ, Chhatwal J, Nudel JD, Corey KE, Kaplan LM, Hur C. Cost-effectiveness of Bariatric Surgery in Adolescents With Obesity. *JAMA Surg.* 2017;152(2):136–141.

27. Bairdain S, Samnaliev M. Cost-effectiveness of Adolescent Bariatric Surgery. *Cureus*. 2015;7(2):e248.

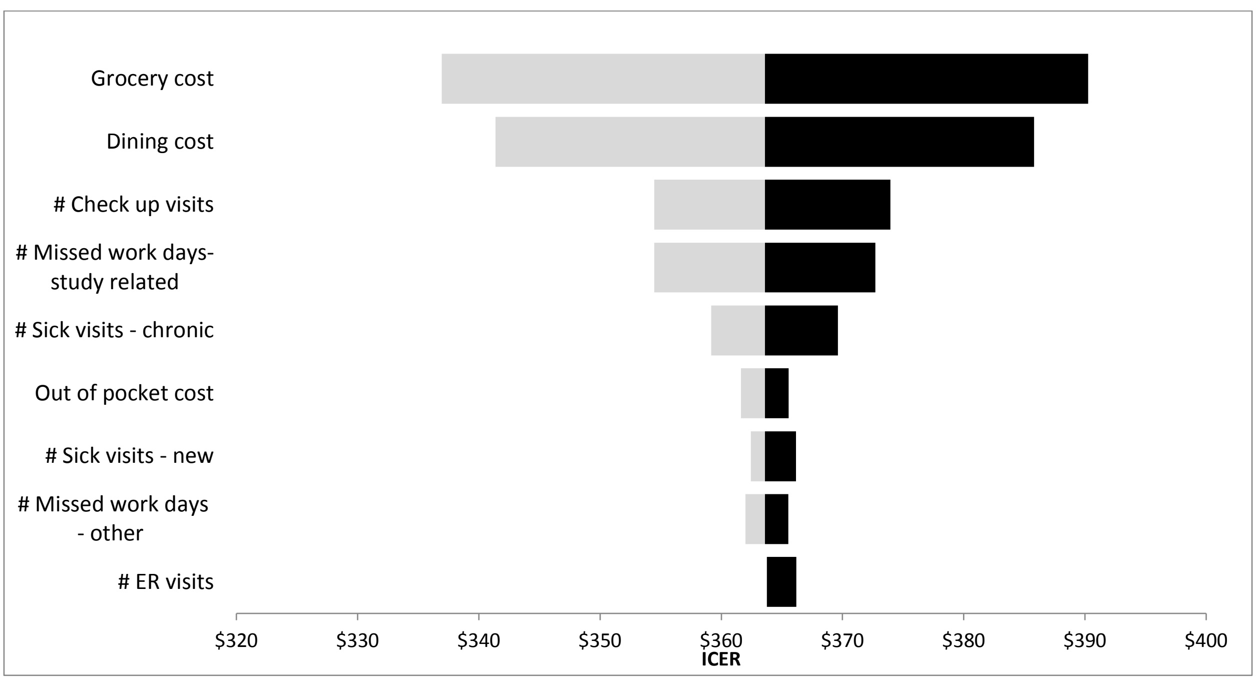
28. Gortmaker SL, Long MW, Resch SC, et al. Cost Effectiveness of Childhood Obesity Interventions: Evidence and Methods for CHOICES. Am J Prev Med. 2015 Jul;49(1):102-11. doi: 10.1016/j.amepre.2015.03.032.
29. CHOICES project. https://choicesproject.org/ Accessed on September 30, 2019
30. Taveras EM, Marshall R, Kleinman KP, et al. Comparative Effectiveness of Childhood Obesity Interventions in Pediatric Primary Care: A Cluster-Randomized Clinical Trial. JAMA Pediatr. 2015;169(6):535-542.
31. Sharif M, Franz C, Horan CM, et al. Cost-Effectiveness of a Clinical Childhood Obesity Intervention. Pediatrics Nov 2017, 140 (5) e20162998
32. Gortmaker SL, Claire Wang Y, Long MW, et al. Three Interventions That Reduce Childhood Obesity Are Projected to Save More Than They Cost to Implement. Health Affairs, 34, no. 11 (2015):1304-1311.
33. Finkelstein, E.A. and Kruger, E. (2014), Meta- and cost-effectiveness analysis of commercial weight loss strategies. Obesity, 22: 1942-1951. https://doi.org/10.1002/oby.20824
34. Edwards CH, Aas E, Kinge JM. Body mass index and lifetime healthcare utilization. BMC Health Serv Res. 2019 Oct 15;19(1):696. doi: 10.1186/s12913-019-4577-0. PMID: 31615572; PMCID: PMC6794833.
35. Drewnowski A, Specter SE. Poverty and Obesity: The Role of Energy Density and Energy Costs. The American Journal of Clinical Nutrition. 2004;79(1): 6–16.
36. Drewnowski A, Eichelsdoerfer P. Can Low-Income Americans Afford a Healthy Diet? Nutrition Today. 2010;44(6): 246-249.
37. Daniel C. Economic Constraints on Taste Formation and the True Cost of Healthy Eating. Social Science & Medicine. 2016;148:34-41.

Figure 1: Cost Analysis Equation with Societal View



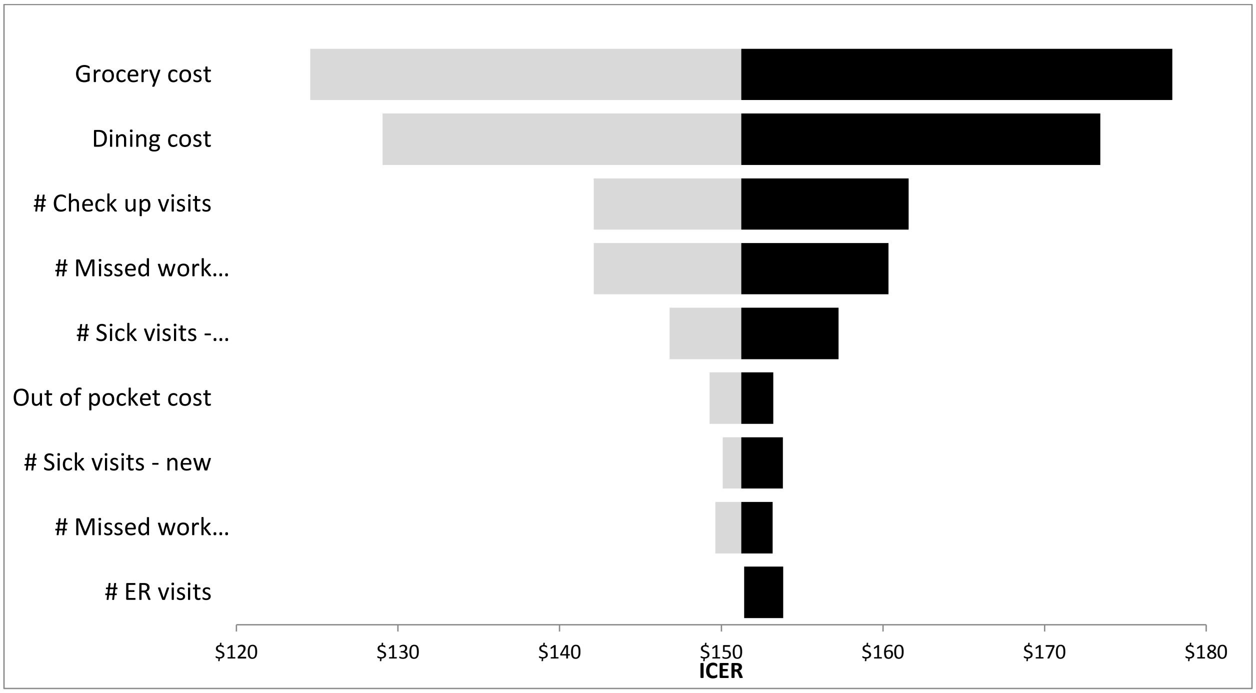
*For usual care group, PCP = Pediatricians/nurse practitioners; for intervention group, PCPs = Pediatricians and registered dietitians

Figure 2a: Tornado diagram for 1-way sensitivity analysis: *with DVD cost*



Base case ICER $363

Figure 2b: Tornado diagram for 1-way sensitivity analysis: *without DVD cost*



Base case ICER $151.

Figure3: Cost-effectiveness Acceptability Curve

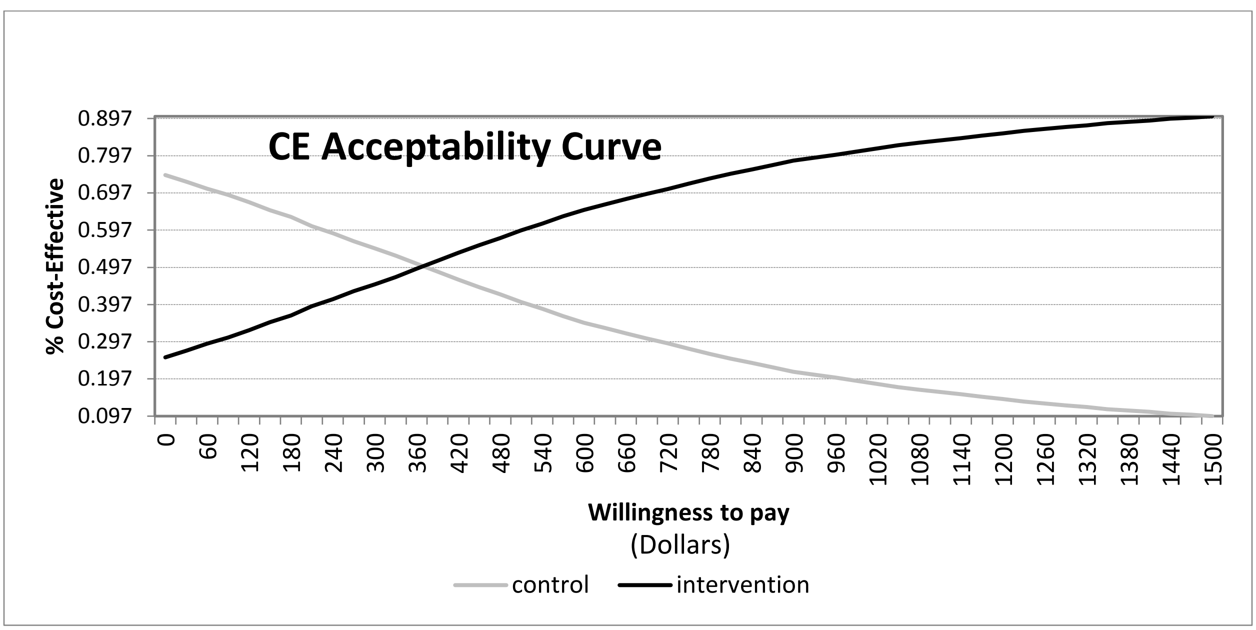


Table 1: Overview of Variables used in the Analyses for this Study

Input variables	Source	Data obtained	Other source of Cost data	Analyses in which cost is included*	Converted to annual costs
Costs to family for dining out costs	Annual Parent Survey	weekly estimate		SPI; SPUC; SSI; SSUC	X by 52
Costs to family for groceries	Annual Parent Survey	weekly estimate		SPI; SPUC; SSI; SSUC	X by 52
Out of pocket costs to family for index child's prescriptions	Annual Parent Survey	Monthly estimate		SPI; SPUC; SSI; SSUC; HCPI; HCPUC	X by 12
Number of ED Visits by index child	Annual Parent Survey	Annual estimate	MEPS	SPI; SPUC; SSI; SSUC; HCPI; HCPUC	# of visits X cost estimate from MEPS
Number of Sick Visits by index child for New Problems	Annual Parent Survey	Annual estimate	MEPS	SPI; SPUC; SSI; SSUC; HCPI; HCPUC	# of visits X cost estimate from MEPS
Number of Sick Visits by index child for Chronic Problems	Annual Parent Survey	Annual estimate	MEPS	SPI; SPUC; SSI; SSUC; HCPI; HCPUC	# of visits X cost estimate from MEPS
Number of visits by index child for Check-ups	Annual Parent Survey	Annual estimate	MEPS	SPI; SPUC; SSI; SSUC; HCPI; HCPUC	# of visits X cost estimate from MEPS
Number of days of missed work by parent[s] for other medical visits for index child	Annual Parent Survey	Annual estimate	BLS hourly wage data	SPI; SPUC; SSI; SSUC	# of hours missed X mean hourly wage from BLS
Number of days of missed work for study related visits for index child	Study Admin data**	Number of in-person study visits recorded	BLS hourly wage data	SPI; SPUC; SSI; SSUC	# of hours missed X mean hourly wage from BLS
Incentives	Study Admin Data**				

Reimbursement to Practitioner/ Practice	Study Admin Data**			SPI; SPUC; SSI; SSUC; HCPI; HCPUC	
Reimbursement to RD	Study Admin Data**			SPI; SSI; HCPI;	
Costs to the study to train PCPs and staff	Study Admin Data**			HCPI, HCPUC	
Costs to the study to develop study training DVD	Study Admin Data**			HCPI	

*SPI – Societal Perspective for PCP/RD intervention; SPUC – Societal Perspective for usual care;
HCPI – Health Care Perspective for intervention group; HCPUC – Health Care Perspective for usual care group
SSI – Steady state for intervention group; SSUC – Steady State for usual care group

**Study Administrative Data – Refers to documentation by the research team of study related expenses and number of visits attended by participants.

Table 2. Costs of BMI[2] intervention over 2-year study period, per participant

	Usual Care group (n=158)	PCP/RD Intervention group (n=154)
Differences in Aggregate Yearly Costs per participant (Year 2 Versus Baseline Year)		
Dining out costs	$345.65	-$473.23
Grocery costs	$973.39	$1,528.02
Out of pocket Rx Costs	-$43.68	-$43.43
ER visits	-$140.93	-$235.32
Sick visits for new problem	-$353.42	-$644.67
Sick visits for chronic problem	-$90.87	-$323.67
Check-ups	-$58.71	$119.37
Missed work – other medical visits	-$66.47	-$57.98
Missed work – study related visits	-$4.04	$496.81
Cost of Study-Related Payments		
Practitioner/Practice Reimbursement	$179.75	$425.39
RD Reimbursements		$171.12
Costs of Educational Program		
PCP trainings* **	$101.85	$280.15
Staff for trainings	$43.87	$112.25
Cost of DVD production		$658.30
TOTAL	**$886.38**	**$2,013.11**

* Includes expenses for roundtrip airfare, hotel rooms, miscellaneous travel expenses and meals/snacks at hotels for each PCP/RD who underwent training, distributed across all children in the Intervention group

** For usual care group, PCP = Pediatricians/nurse practitioners; for intervention group, PCPs = Pediatricians and registered dietitians

Table 3: Probabilistic Sensitivity Analysis

Incremental Cost Effectiveness Ratio (ICER) with 95% CI

	ICER-societal perspective	Base case	ICER Results	
BMI %ile	with DVD	$363	CS	$3,159
	Without DVD	$151	CS	$2,454
Excluding training cost	with DVD	$284	CS	$2,809
	Without DVD	$72	CS	$2,276

CS: Cost saving