IN-HOME OBESITY PREVENTION TO REACH LOW-INCOME INFANTS

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A. SPECIFIC AIMS

More than 40% of children enrolled in federally funded programs are overweight or obese by age 5.[1-4] This is concerning because obese children have a 70% chance of becoming obese adults.[5,6] Unfortunately, extant obesity efforts have had a limited impact among low-income underserved children, in part because of limitations inherent to existing programs: 1) short duration and low intensity; 2) late timing of implementation, when children are already overweight or obese; 3) delivery methods limiting their accessibility and sustainability; and 4) failure to address barriers such as a lack of culturally competent and in-language services, poverty, housing instability, and access to care, which interfere with healthy lifestyle changes. *To address these gaps, we have integrated simple, evidence-based nutrition and physical activity components as part of the services already delivered by our home visitation partner, Healthy Families America, with the long-term goal to deploy these efforts to Home Visitation Programs (HVPs) nationwide.* Annually, over 500 publicly and privately funded HVPs provide nationwide services to more than 650,000 low-income, underserved infants and their families. The home visiting structure is not only an unparalleled model for scalable and sustainable childhood obesity prevention, but it also provides a unique opportunity to understand factors related to the intergenerational transmission of obesity in families who are most at risk.

Over the last four years, our transdisciplinary team of researchers, home visiting stakeholders, families, and community stakeholders (hereafter referred as the *COPE team*), has integrated evidence-based nutrition and physical activity components into an engaging module that we call **COPE**: **C**hildhood **O**besity **P**revention @ hom**E** /*Contrarrestar Obesidad: Programa para niños En casa*. COPE is delivered in English and Spanish as an *enhancement module* to the services of our HVP partner. Our pilot work supports the successful integration, feasibility, and preliminary efficacy of COPE.

The proposed study builds upon the momentum, resources, and research infrastructure of our pilot work to test the larger-scale and sustained impact of COPE on infant's and mothers' obesity outcomes, and to study key mechanisms of maternal and social transmission on infants' obesity risk. Specifically, 300 low-income mothers/infants enrolled in Healthy Families America HVP will be recruited and enrolled in the study, for an effective final sample of 200 mothers/infants. Based on standard HVP procedures, mothers/infants will be matched to highly trained home visitors (nurses) based on their ethnicity/race and language preferences. Home visitors, in turn, will be randomly assigned to deliver the standard HVP curriculum only or the standard HVP curriculum + COPE as part of their weekly home visits for two years of HVP services. Comprehensive assessments of mothers/infants will be conducted at enrollment and after 6 and 12 months of intervention.

Specific Aim 1 (maternal and infant outcomes). Test the direct effects of COPE on infants and mothers' weight, metabolic risks, diet/energy intake, and physical activity. This will be accomplished by comparing changes in body weight, metabolic markers, and eating and activity-related behaviors between infants/mothers across study arms (HVP only vs. HVP+COPE). These results will indicate whether HVP is an effective infrastructure for primary and secondary obesity prevention.

Specific Aim 2 (maternal transmission). Test whether breastfeeding and maternal diet and activity, feeding practices, and food insecurity mediate the effect of COPE on infants' outcomes. This aim will test mechanisms of maternal transmission on infants' obesity risks.

Specific Aim 3 (social transmission). Aim 3 is two-pronged. **Aim 3a** tests the direct effect of HVP+COPE (vs. HVP only) on the characteristics of the social and community networks that surround mothers and infants (i.e., the density, composition, and quality of "health support networks"). **Aim 3b** tests whether the characteristics of social networks mediate the effects of COPE on maternal and infant outcomes. These findings will indicate if HVP obesity prevention efforts can alter and/or activate social network mechanisms.

Secondary Aim. Conduct a real-life economic analysis (costs, cost-savings, and non-monetary benefits) of integrating COPE into existing HVPs.

This proposal addresses the impetus to develop interventions targeting at-risk infants before obesity is established. Although maternal-infant interventions are much-needed, they present implementation and dissemination challenges, including limitations on compliance and retention, and limited potential for scalability and sustainability. Our proposed strategy overcomes these challenges through an innovative solution that merges evidence-based nutrition and activity components into an existing, ongoing federally-funded infrastructure. *The proposed research is timely as the Institute of Medicine, the United States Department of Agriculture (USDA), and Health and Human Services (DHHS) extend their recommendations to address key factors influencing obesity risk in children from birth to 24 months of age.*
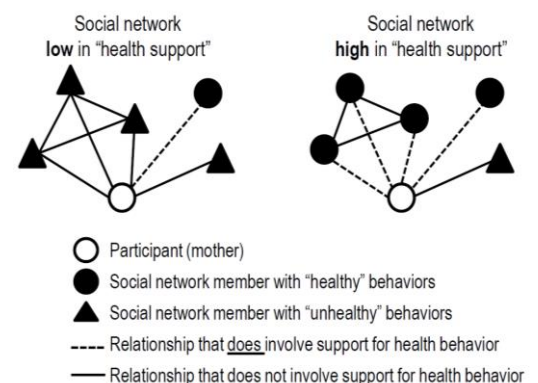
B. SIGNIFICANCE

B.1. Scientific premise and impact. The proposed study tests whether delivering in-home obesity prevention as part of an ongoing, sustainable service delivery system (home visitation programs, HVPs) is an effective approach for primary (infants) and secondary (mothers) obesity prevention among low-income, underserved families. This research is poised to have a substantial impact because the delivery modalities of current obesity efforts disproportionally restrict the reach and engagement of children who are most at-risk for obesity, and limit the development and generalization of healthy habits in families' home environment. Our proposed strategy overcomes these challenges through an innovative and potentially cost-effective solution that merges evidence-based key nutrition and activity components into an ongoing federally funded HVP. Our focus on understanding maternal and social determinants of intervention effects increases the significance, innovation, and impact of this research by identifying key determinants that can be leveraged to prevent childhood obesity in infancy. This work will inform maternal and child health public policy initiatives that seek to address the intergenerational transmission of obesity efforts. If effective, this intervention can be readily disseminated to other HVPs sites nationwide.

B.2. Focus on underserved segments of the population. Although a recent nationally representative study found a decline in obesity for children ages 0-5, this was not true for low-income and non-white children.[10] In fact, 40% of low-income children enrolled in federally-funded programs are overweight or obese by age five.[1-4] In Los Angeles (LA) County there is a strong, positive association between the prevalence of childhood obesity and economic hardship.[11] Sadly, even the most successful obesity strategies have had limited impact among economically disadvantaged families, partly because of their failure to address factors which profoundly affect the ability of at-risk families from diverse racial and ethnic backgrounds to adhere to lifestyle changes in real-world settings.[12,13] Initiating and maintaining healthy habits is ubiquitously difficult, especially for families who face a multitude of barriers such as a lack of access to linguistically and culturally competent services, poverty, housing instability, and food insecurity. *These challenges highlight the dire need to re-conceptualize obesity prevention as an integral component of universal care, embedded in a comprehensive system of child and maternal health services.*

B.3. Focus on infant/maternal transmission. Rapid weight gain during the first 4-6 months of life has been associated with greater odds of child overweight at age 4-7y,[14-16] and in adolescence.[14,17-20] Yet, most obesity programs focus on school-aged children, when many youth are already overweight or obese, and only a few studies have focused on modifying obesity-risk factors in infancy. Child-**feeding practices** and early nutritional experiences play a key role in shaping children's health behaviors and weight outcomes.[21-24] For example, in a sample of 718 parents of children ages 3-5y, parents with an indulgent feeding style had children with a higher BMI,[25] a finding that has been replicated in 177 Head Start families.[26] Another potential mechanism by which maternal factors might mediate infant outcomes is via **breastfeeding**. In developed countries, some studies suggest that breastfeeding is protective for childhood obesity.[27-30] However, not all studies support this view.[31-36] These mixed findings suggest that a range of maternal factors, including mothers' feeding practices,[37-41] mother's energy intake and diet, food insecurity (as it relates to diet), and physical activity may impact child obesity outcomes.[42-50] Positive changes in maternal health behaviors and food security are not only beneficial for mothers' health, but are also a promising approach to address intergenerational transmission of obesity risk and health disparities. *The proposed research represents a unique opportunity to test the impact of key maternal mechanisms on obesity transmission and whether a comprehensive approach to maternal/infant health can alter children's weight trajectories.[51]*

B.4. Focus on social transmission. Despite evidence that obesity is influenced by social networks and social-ecological systems, which extend beyond parent-child context, few childhood obesity initiatives have translated these concepts into practice. Families are embedded in social networks and communities that influence their health behaviors and practices through several mechanisms, in particular via social influence and social support.[52-59] These social factors can ultimately promote or impede behavior change and maintenance.[60-62] Drawing on social influence and social network theories, as well as innovative "network-mediated interventions" that have been successfully applied in other areas of public health,[60,62] the promotion of maternal and infant health behaviors to prevent childhood obesity ideally involves *enhancing*

Social network **low** in "health support"

Social network **high** in "health support"

○ Participant (mother)
● Social network member with "healthy" behaviors
▲ Social network member with "unhealthy" behaviors
---- Relationship that <u>does</u> involve support for health behavior
—— Relationship that <u>does not</u> involve support for health behavior

Figure 1. Social network characteristics relevant to healthy behavior change

families' social networks so that they support behavior change (***Figure 1***). The intervention goal is to alter and enhance mothers' social networks so that they provide greater (a) *healthy social influence*, with a larger proportion of individuals in their network who engage in the desired health behaviors and so provide healthy behavior norms, modeling, cues, and opportunities;[63-65] and (b) *health-relevant social support*, with an increase in the density of relationships that encourage and support healthy behaviors.[66,67] Obesity prevention initiatives that explicitly target families' social networks (i.e., their connections to people and organizations) by creating opportunities for *meaningful, health-supportive relationships to be fostered and maintained*, will help to promote healthy behavior change, and has the potential to improve the reach, effectiveness, adoption, implementation, and maintenance of family-based interventions.[62,68]

B.5. Focus on sustained implementation and high intervention dosage. Obesity researchers and public health decision makers have argued against "diets" and promoted the development of healthy habits for life. Yet most (if not all) obesity intervention and prevention programs are generally short-lived (8-12 weeks). We believe that the short delivery and low intensity of obesity interventions greatly decreases their potential impact. Specifically, the short implementation of interventions/programs is inadequate to cover pivotal feeding and eating-related developmental transitions that are not only critical for the development of healthy eating habits, but also highly challenging for children and parents (e.g., transition from breast milk, to pureed foods, to solid foods).[69] Furthermore, the greatest challenge of healthy lifestyle interventions is not to initiate healthy practices in families, but to help them maintain healthy behaviors for a prolonged period of time. *Even when obesity interventions directly plan or address this as part of their curriculum, the maintenance phase rarely (if ever) exceeds a few weekly one-hour sessions. This timeline is arguably insufficient to ensure mastery of learned skills into lifelong healthy habits.*

B.6. Focus on home visitation programs: an untapped opportunity to address childhood obesity.

Figure 2. Scientific Premise & Impact of COPE.

Consistent with a capacity building approach, we aim to extend the existing curriculum and mission of HVPs to address the important gaps reviewed above (see also ***Figure 2*** and *our concept paper*[70]). The outcomes of the proposed research combined with our HVP partnership is likely to have national implications. Over 500 publicly and privately funded HVPs provide services to more than 650,000 low-income, underserved children and their families in the U.S. annually. HVPs are embedded in a comprehensive system of child and maternal health service that is designed to promote optimal child development and prevent adverse outcomes.[71-75] Randomized controlled trials (RCTs) show that high-quality HVPs can effectively improve children's physical and psychosocial health such as birth outcomes, breastfeeding, immunization rates, and overall cognitive and social development.[75-93]

Although some HVPs provide basic information on infant nutrition, there has *been no comprehensive, and sustainable effort to address childhood obesity prevention, nutrition, and physical activity as part of their services.* This may be because the initial focus of HVPs, 40 years ago, was to decrease the incidence of low birth weight.[94,95] The current high prevalence of overweight and obesity among HVPs children is likely to prompt a new national mandate that HVPs address childhood obesity prevention as a part of their services. This highlights the pressing need to re-conceptualize the mission and capabilities of HVPs to address obesity prevention for <u>all children</u>. The HVP structure is ideal to address obesity prevention among underserved families for many reasons (see also [70]):

a. HVPs have been in place for more than 40 years, with $1.5 billion annual investment from the Affordable Care Act,[96] which speaks to the sustainability of the services provided.

b. They provide culturally and linguistically tailored in-home services, which removes barriers to accessing the program (e.g., transportation, childcare), promotes the generalization of skills to the home environment, and enables ethnically and racially diverse families to access culturally competent health services.

c. HVPs have existing partnership with Women, Infants and Children (WIC) programs nationwide.

d. HVPs already address many barriers to healthy lifestyles such as unemployment, family conflict and violence, housing instability, and neighborhood characteristics.

e. The free and voluntary weekly home visits begin during pregnancy or shortly after birth, and continue until the child reaches 2-5 yo, depending on the HVP model. The extensive timeframe for service delivery makes it possible to reinforce health knowledge, skills, and behavioral habits.

f. Support, referral, and advocacy is central to the HVP model of delivery, facilitating families' development of social and community networks that support health outcomes.

g. The widespread presence of HVPs across the US, and established infrastructures in nationwide urban and rural areas,[80,91,97,98] are critical for the scalability of services across the United States.

h. The model is likely to be cost-effective as obesity prevention would be delivered as part of an existing infrastructure, with the potential to improve child health and reduce societal costs.

B.7. Feasibility of delivering obesity prevention as part of HVPs' services. Over the last four years, our transdisciplinary COPE team has integrated established nutrition and physical activity components and activities[9,99-104] into a culturally sensitive, language specific, and community-forming model of implementation that we call COPE (see *Intervention arms* below). COPE *does not* target weight loss; rather it focuses on preventing the development of childhood obesity through the promotion of healthy behaviors in all mothers and infants/children from diverse racial and ethnic backgrounds, regardless of weight status.

Drs. Salvy & de la Haye secured two pilot grants (CTSI [Salvy, #8UL1TR000130] and NIH Johns Hopkins Global Obesity Prevention Center [de la Haye, # 5U54HD070725-03]) and completed the following activities:

1. Obtained *IRB* approval and developed all study material.
2. Consolidated our partnership with Cyd Wessell, the National Director of *Healthy Family America* (see letters of support), laying the groundwork to enable the dissemination of COPE to other sites nationwide.
3. Publish the *concept paper* outlining the rationale and scientific premises underlying our initiative (see [70])
4. *Manualized* evidence-based nutrition and activity guidelines into educational material and hands-on activities that are culturally sensitive (e.g., recipes adapted to families' preferences) and community engaging (e.g., leveraging resources and social networks endogenous to the community through community gardening and communal cooking activities) to meet the needs and desires of HVP families.
5. *Trained home visitors* to implement COPE using science-based content and social-experiential approaches to elicit change talk and patient-centered goals; trained recruitment and data collection staff.
6. *Integrated COPE into the curriculum* of our HVP partner in Antelope Valley (a chapter of Healthy Families America in Antelope Valley, CA), and delivered the module in English and Spanish.
7. Evaluated recruitment procedures and retention rates, and documented characteristics of the families' social networks that could be targeted to optimize healthy changes.
8. Enrolled our target pilot sample of 50 HVP mothers/infants and randomized families to receive HVP curriculum with or without COPE for 6 months to test the *feasibility* of integrating COPE into HVP services (see *Preliminary findings* below).
9. Formed our *COPE Community Advisory Board* (families, Antelope Valley Partners for Health home visitors, stakeholders, physicians), which provides feedback on the project every 6 months.
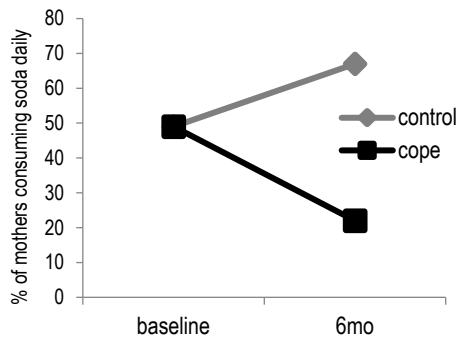
Preliminary data: Baseline characteristics and social networks. Mothers (average age = 25 years) in our pilot sample were 70% Hispanic/ Latino, 13% African American, 8% White, 5% American Indian/Alaskan, and 4% mixed/other race. All were low-income and were receiving federal support through WIC. Mothers' social connections were predominantly family and household members, who were the key providers of health-related support. Mothers were somewhat socially isolated from their broader community: they reported few connections to same-age friends, spouses/romantic partners (<50%), or other (non-family) community members. Specific characteristics of mothers' social networks were identified as potential barriers to healthy behavior change. For example, having a larger proportion of social ties who were female or who lived in the same household, and a smaller proportion of friends, was associated with poorer health indicators (i.e., greater gestational weight gain, pre-pregnancy and baseline BMI; greater soda intake; and less fruit and vegetable intake). *These findings have informed the proposed study design, which aims to alter and enhance mothers' social networks so that they are more supportive of healthy behavior change. For example, the proposed intervention will foster new social connections to peers in their community who can provide support and serve as healthy role models.*
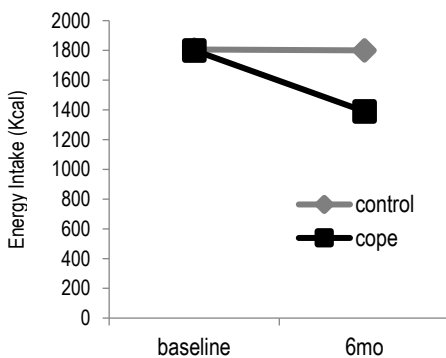
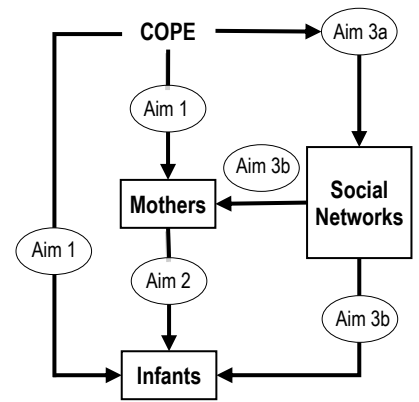**Figure 3.** Effects of COPE on maternal energy intake.

Preliminary data: infant and mother outcomes. To date, our pilot study has collected and processed outcome measures among 25 children and mothers who have completed 6 months of intervention. Children's weight velocity was 18% lower in COPE than in the control group (0.61 $\pm$ 0.1 kg/month vs 0.75 $\pm$ 0.1 kg/month), although this difference was not statistically significant. Interestingly, there were no group differences in infants' energy intake at baseline or at 6-month, which raises the possibility that maternal factors, such as breastfeeding and maternal diet account, at least in part, for infants' weight trajectories. This hypothesis will be tested in the proposed study. As part of this pilot study, we also assessed maternal energy intake (***Figure 3***) and consumption of sugar-sweetened beverages (***Figure 4***) as we hypothesize that these variables impact children's obesity outcomes (as outlined in *Aim 2*). Mothers' food intake was assessed via 24-hour food recalls and converted into energy intake (Kcal) by a research assistant blind to group assignment. These preliminary trends that suggest an improvement in maternal dietary intake in COPE vs. control are promising.

Figure 4. Mothers' soda consumption.

B.8. Theoretical Framework. Our overarching model promotes maternal healthy weight, healthy family behaviors and home environment, and supportive family and community social networks, as key pathways affecting child outcomes during the important developmental period of infancy/early childhood.[105,106] This theoretical framework and underlying scientific premise informs our specific *intervention model* (***Figure 5***). Our approach is based on the *Ecological Systems Theory*, *Family Systems Perspective* and on the *Life Course Perspective*. These frameworks provide the rationale for targeting the maternal and social mechanisms to initiate, reinforce, and maintain healthy behaviors in infancy/early childhood. The *Ecological Systems Theory* and *Family and Community Systems* perspective emphasize the need to consider the impact of individual, family, community, and societal factors on health and social outcomes.[107] Social networks, which include parent-child dyads as well as other family, friends, and important individuals and organizations, exert

Figure 5. Intervention model.

influence on obesity and related behaviors that should be harnessed.[108] Finally, the *Life Course Perspective* underpins our focus on the intergenerational transmission of health behavior, the importance of intervening during critical life stages, and addressing differential exposures to risk / protective factors at key points across the lifespan contribute to health disparities.[109-113]

B.9. Innovation. This study is both theoretically and clinically innovative in:
1. Focusing on primary prevention of childhood obesity by targeting infancy to promote the development of healthy habits for life in culturally sensitive ways.
2. Using an existing infrastructure that is providing culturally-, family-, and community- oriented services to a high-risk segment of the population to address the limitations of current childhood obesity efforts, and focusing on scalability, sustainability and cost effectiveness, all of which are critical issues to consider for the delivery of health services.
3. Testing key social and maternal mechanisms in the intergenerational transmission of obesity, and thus evaluating whether changes maternal behavior and social networks affect infant outcomes and ultimately contribute to childhood obesity prevention.
4. Providing weekly in-home obesity prevention to optimize the generalization of skills and behaviors in the family environment, and to modify the home environment.

C. APPROACH
This research is designed to integrate and leverage our team's expertise (***Table 1***), as detailed in the *Personnel Justification* section, *Multiple PI Plan,* and *Biosketches*.

C.1. Design overview. *Table 2* depicts the logic model of the proposed study, and demonstrates its scientific rigor. Healthy Families America home visitors (see *Intervention arms* below for their qualifications) will be randomized to deliver the HVP curriculum with or without COPE for 12 months (standard HVP duration). Mothers/infants will be recruited and enrolled on a rolling basis over 24 months (study months 6-30), and

matched to a home visitor based on race, ethnicity and language preferences. Assessment of mothers and infants will be conducted by *assessment workers* (who are blind to study assignment) at enrollment, and after receiving 6 and 12 months of services. **

Table 1. Expertise of team members	Salvy	de la Haye	HFA	Chandler-Delaney	Goran	Chou	Galama
Infants and early childhood obesity/nutrition	x		x	x	x		
Home visitation services			x				x
Family-based behavioral obesity interventions	x						
Underserved, racial/ethnic populations and culturally/linguistically tailored interventions			x	x	x		x
Multilevel interventions for behavior change	x	x					
Social network measurement and analysis		x					
Longitudinal modeling of multilevel data		x				x	
Cost analyses of childhood prevention efforts							x

The assessment of participants after they ceased to receive services for a given period of time (i.e., "true" follow-up) is impossible because of the ongoing nature of HVP services. We believe that asking home visitors to withhold the delivery of the COPE material to allow for a "no COPE" period would be unrealistic in terms of potential contamination, and also create an uncomfortable situation for families and HVP staff.

Table 2. Logic Model COPE
SITUATION: More than 40% low-income children enrolled in federally funded programs are overweight or obese by age 5. Obesity efforts have limited impact among underserved, low-income children, at risk for obesity.

INPUTS	OUTPUTS	OUTCOMES
• Existing HVP infrastructure • Funding • Evidence-based nutrition, activity, and behavioral components; Research and education expertise; Pilot study evidence • Partnership (academia, service systems, stakeholders, families, community organizations) • Community Advisory Board (CAB) • Training and intervention curricula • Input from childhood obesity experts	**ACTIVITIES** Implementation of COPE: Nutrition, Physical activity, Psychosocial Support and Behavioral Change, Healthy home environment, Support and Community Connectedness, Social-experiential activities **PARTICIPANTS** • 200 mothers/infants enrolled in HVP • Home visitors, directors and stakeholders	**SHORT AND MEDIUM TERM** • Healthier infant feeding practices and breastfeeding; Healthier home environment; Healthier diet and physical activity for mothers and infants; Social connections supporting health; Improvement in child diet and physical activity **LONG-TERM** • Lowered obesity incidence and health disparities among children involved in HVPs; Reduced costs of obesity and related diseases

ASSUMPTIONS	EXTERNAL FACTORS
• Personal, family and structural factors influence the outcomes of childhood obesity prevention. • HVP infrastructure provides a scalable, sustainable, cost-efficient delivery model for obesity prevention. • Combining didactic and social experiential learning is necessary to engage and mobilize families and children. • Supportive social networks are pivotal to sustain healthy change	• Underserved families lack access to opportunities and resources that facilitate healthy behaviors (e.g., poverty, food deserts). • Social and community contexts can support or create barriers to healthy behaviors. • HVPs do not currently address childhood obesity, and home visitors are not trained to address obesity risks.

| EVALUATION AND OUTCOMES: *Aim 1* (maternal and infant outcomes). Test the direct effects of COPE on infants and mothers' weight, metabolic and behavioral trajectories. *Aim 2* (maternal transmission). Test the hypothesis that mothers' weight, diet and behavioral outcomes (activity, feeding practices, and food insecurity) mediate the effect of COPE on infants' outcomes. *Aim 3 (social transmission)*. *Aim 3a* tests the direct effect of COPE on maternal networks. *Aim 3b* tests whether the characteristics of maternal networks mediate maternal and infant outcomes. *Secondary Aim.* Conduct a real-life economic analysis (costs, cost-savings and non-monetary benefits) of integrating COPE into existing HVPs. **DELIVERABLES:** Scientific/academic (journals and conferences) and non-academic outlets (online media; meeting with stakeholders). |

C.2. Technical merits of our study approach. Our formative and pilot work made it possible to refine issues related to the technical merit and scientific rigor of our study approach. ***Intervention dosage.*** By providing our program components via *weekly in-home* services initiated in infancy and maintained for a *sustained period of time (12 months)*, we resolve many limitations of existing obesity prevention programs. The proposed model of delivery makes it possible to: (1) cover key child developmental periods for healthy eating and activity; (2) deliver the material gradually, over a sustained period of time, to avoid burdening families and home visitors; (3) guide parents to implement changes in their homes to promote generalization and address ecologically relevant cues related to habit formation, (4) and ensure that the skills and knowledge gained are reinforced and mastered to promote long-term maintenance. ***Treatment fidelity.*** Intervention fidelity encompasses integrity (interventions are implemented according to established procedures) and differentiation (interventions are distinct from one another).[114] Our preliminary findings suggest that our strategies are effective in preserving integrity and differentiation: (1) Comprehensive assessment of the standard HVP curriculum to avoid content overlap. (2) Home visitors

complete rigorous training to learn the HVP curriculum and meet the requirements of Healthy Families America (the HVP model we are partnering with). They receive weekly supervision to review progress and address issues. (3) Home visitors delivering COPE receive a 2-day initial training and annual refresher courses from Dr. Salvy and the onsite Health Families America dietitian and nutritionist, with scripted manuals and materials. Dr. Salvy further reviews 25% of the sessions to monitor fidelity. (4) Weekly supervisions (home visitors) and bi-annual focus groups (families, home visitors, and Community Advisory Board) are conducted to review progress, dosage and timing of delivery, and provide the opportunity to resolve problems or issues encountered. (5) Intervention components are delivered in the home or at specified community-run settings (e.g., community garden), and meetings and supervisions with home visitors implementing different arms are held on separate days (at Antelope Valley Partners for Health) to minimize the risks of contamination. COPE supervision is embedded in the weekly supervision home visitors already receive to monitor their services. ***Potential burden or weakening of HVP curriculum****.* Potential concerns related to adding material to the existing HVP curriculum include (1) diluting or weakening HVPs' outcomes in other areas (e.g., parenting skills, maternal depression), and (2) increasing the burden on HVP staff and families. Our formative evaluation and pilot work indicate that these concerns are unfounded. COPE was designed collaboratively with our HVP partners (who are experienced in integrating new enhancement modules into the HVP curriculum) so that it would complement other program goals. For instance, home visitors report that COPE cooking and tasting activities are used to strengthen mother-child bonding and parenting skills (a standard HVP benchmark area). HVP directors also found no differences between HVP+COPE and HVP only families on HVPs' benchmark areas set by the Health Resources and Services Administration (i.e., maternal and newborn health; child abuse and neglect and emergency department visits; crime or domestic violence; family economic security; and coordination and referrals for other community resources and support). Concerns that COPE may overly burden families and lead to greater attrition was also not supported, as the dropout rate was considerably *lower* among mothers in the HVP+COPE group than among mothers in the HVP only group in our pilot study. These findings suggest that the addition of COPE does not weaken other HVPs' targeted outcomes, or overly burden families and home visitors. We will continue to monitor these outcomes throughout the implementation.

C.3. Participants. Participants will be low-income mothers/infants (6mo at enrollment) *who are already receiving services from our HVP partner* (**Figure 6**). Thus, study enrollment does not require that we recruit more families than our HVP partner is already enrolling. Mothers are enrolled in HVP services through outreach and screening pre-partum, in English or Spanish, at community health centers and hospitals. In order to be eligible mothers must meet a number of (but not all) risk criteria (e.g., low-income, housing instability). Enrolled mothers are matched to a home visitor (nurse) based on culture and language. ***Recruitment***. Assessment workers (distinct from home visitors delivering services) who enroll families into services will introduce the study to mothers and obtain written consent. They will clarify with mothers that their refusal to participate in the study will not affect their receipt of any other services provided by the HVP. In our experience, families feel comfortable refusing if they are not willing to participate. Mothers/infants will be ineligible if they have any of the following conditions: eating disorders (e.g., bulimia nervosa), schizophrenia, and obesity-related syndrome (e.g., Prader Willi). Participants enrolled in a weight-loss program will be ineligible. Based on our pilot work, we expect to recruit 70% Hispanic/Latino, 13% African American, 8% White, 5% American Indian/Alaskan, 4% mixed race.

Figure 6. Enrollment flow

Retention. We have learned a great deal about retention through our pilot work. For instance, most attrition from HVP services occurs in the first six months of services. Therefore, to maximize retention, mothers will be invited to participate in the study *after six months of home visits*. The unique relationship between home visitors and mothers facilitates subsequent retention, as many of these mothers are socially isolated and home visitors are important confidants and supports. We will use multiple strategies that are effective for high-risk populations to further retain the study sample: (1) gift cards of $25 at each data collection, with all incentives paid after each assessment; (2) frequent contacts to maintain engagement and foster open communication; (3) quarterly newsletters to update subjects about study activities; (4) acknowledging birthdays and milestones; (5) reminder phone calls the day before the weekly visits and assessment sessions. ***Randomization***. Randomization will be at the level of home visitors, who deliver the HVP (cluster randomization). Home visitors who serve mothers that are participating in the proposed study will be randomly assigned to deliver either HVP only or HVP+COPE. Potential concerns with randomizing by home visitors are feasibly addressed in this study. First, the likelihood of
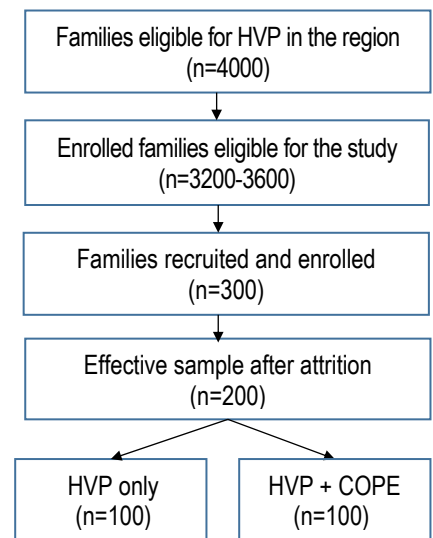
bias is reduced due to the homogenous population enrolled in HVPs (e.g., income, ethnicity/race). Second, to reduce contamination, the training and supervisions of home visitors assigned to each arm will be held on separate days. All analyses will control for home visitor work experience (number of years in HVP).

C.4. Intervention Arms (*Table 4)*.

    HVP curriculum. Our HVP partners are two of 400 nationwide *Healthy Families America* (HFA) sites/chapters, housed at Antelope Valley Partners for Health and the Antelope Valley Children's Bureau. The HFA model meets the DHHS criteria for an "evidence-based early childhood home visiting service delivery model" (See http://homvee.acf.hhs.gov). HFA services begin prenatally and continue until children are 2-5yo depending on the HVP model. The curriculum focuses on strengthening parent-child relationships and family functioning, promoting positive child

Table 4. Interventions components	HVP	COPE
Maternal/infant health	x	
Child physical and social development	x	
Crime and domestic violence	x	
Child abuse and neglect	x	
Family economic stability	x	
Breastfeeding	x	x
Maternal nutrition		x
Physical activity and play		x
Infant nutrition/feeding practices		x

development, and linkage to community resources (e.g., medical providers, financial/housing assistance, childcare, substance abuse treatment, community programs). **HFA accredited home visitors** (Nurses) are matched to families on cultural background and language (English or Spanish), to provide culturally sensitive services. Home visitors are selected because of their personal characteristics (e.g., non-judgmental, compassionate, ability to establish a trusting relationship), their experience working with culturally diverse communities, and their skills to do the job. HFA home visitors are expertly trained and experienced in handling situations encountered while working with at-risk families. They receive training in cultural competency, substance abuse, reporting child abuse, domestic violence, and linkage to services in their community. Home visiting staff also receive intensive training specific to their role (e.g., identifying at-risk families, standardized assessments, phlebotomy, mental health referrals, promoting preventive health care, utilizing creative outreach efforts, establishing and maintaining trust with families, building upon family strengths, developing individual family support plans, teaching parent-child interaction, managing crises). Staff also receive weekly supervision, ongoing developmental training, and have limited caseloads (10-15 families) to meet their families' needs.

    COPE is a culturally sensitive, language specific, and community-forming model of implementation to deliver key nutrition, activity and feeding practice components as part of HVP services in a way that is engaging for families. COPE key components are summarized in **Table 4**, and outlined in detail below. Although mothers/infants are the focus of HVPs and COPE, visits are delivered in the home and, as is standard practice with HVPs, will engage other household members if possible (e.g., spouse).

1. Maternal nutrition. Home visitors teach mothers to prepare and store foods they receive from *WIC* and the *Food Bank*, and to gradually build healthier nutrition and activity goals congruent to their cultural practices and ethnic specific food palate: (a) increasing intake of vegetables and fruits (≥5 servings/day of fruits and vegetables) and integrating nutrient-dense ingredients in their families' meals/recipes; (b) limiting intake of high-saturated fat and sugar in modifying families' favorite recipes (the material is adapted to families' cultural and personal preferences); (c) eliminating sugar-sweetened beverage intake, supported by the provision of information and activities on sugar content, long-term effects of high sugar consumption, importance of drinking water, and impact of advertising;[115-121] (d) teaching healthy portion sizes using different visual activities. *2. Infants/young children nutrition*. The curriculum promotes sustained breastfeeding for the first two years and the gradual integration of complementary feeding (pureed and age-appropriate solid foods) that support healthy eating for infants. Mothers learn about feeding/eating developmental stages and transitions, and healthy feeding[7-9,122] practices to promote: (a) responsiveness to child hunger and fullness cues; (b) the consumption of nutrient-dense foods (as opposed to energy-dense); (d) the transition to structured schedule for meals/snacks from complementary feeding; and (d) the use of non-food related child soothing techniques. Mothers also learn strategies to address neophobia,[123,124] such as repeated multi-sensory (i.e., smell, touch, taste) exposures to nutrient-dense novel foods,[125] gradual texture shaping, parents/caregivers modeling, and involvement of children in food selection and preparation; and strategies to handle meal-related tantrums (e.g., redirection, positive reinforcement of appropriate behaviors).[126,127] *3. Maternal/child physical activity.* Although there is no unequivocally accepted guidelines for the number of minutes children 0-2yo should be active each day,[128] the DHHS has summarized recommendations from the National Association for Sport and Physical Education, the American College of Sports Medicine, and the National Institutes of Health: (a) daily planned physical activities, including tummy time, that safely support the infant's developmental milestones (e.g. head and neck self-support, rolling, floor sitting, kicking, crawling, reaching and grasping for objects, etc.); (b) engage in 30

minutes of supervised but *unstructured* physical activity each day; and (c) avoid being sedentary for more than 60 minutes at a time, except when sleeping. The American Academy of Pediatrics (A.A.P.) Expert Committee further suggests limiting screen time.[129] COPE is premised on the above guidelines in addition to CDC guidelines for adults (150 minutes of moderate intensity physical activity/week). COPE teaches parents to make activity/play a daily habit for their entire family by exploiting lifestyle activities (e.g., taking the stairs, walking to the shop). Home visitors help parents design activities around their local environment, schedule, and preferences, and to optimize their use of safe spaces. Parents are provided with information about resources and free group activities conducive to physical activity (e.g., parks, walking clubs, outings, etc.), and classes they can take with their children and with other HVP families. The curriculum emphasizes the importance of parents co-engaging in activities with their children to set a good example through modeling and to provide opportunities for their children to be physically active.

COPE delivery format. Our formative work and pilot research indicates that didactic and experiential approaches are needed to help families adopt behaviors that will promote their child's health.

1. Didactic education focuses on in-home individualized coaching to help mothers implement changes in their "natural environment". A strong emphasis is placed on *gradual goal setting* in which mothers set objectives for their own and/or their children's weekly activity and diet (e.g., decreasing by "x" the number of sugar-sweetened beverages) and on *parent modeling* healthy behaviors (i.e., co-engaging in healthy behaviors with their children). Parents are taught *behavior management and cognitive-behavioral strategies* to change cues in their home environment. Mothers receive individual coaching to gradually eliminate high-energy dense foods from the home environment, and to modify the home to make it more conducive to exercising (e.g., removing computer/televisions from sleeping areas).[129] *2. Social experiential activities* (**Table 5**) were selected in response to: our theoretical framework that emphasizes social network influences; our pilot work that highlights existing social network barriers to behavior change; and families' desire to learn through hands-on, social activities. These activities are already built into the service infrastructure at Antelope Valley Partners for Health, are integrated across all key content areas of COPE, and will be promoted to participants in the intervention arm (but not to participants in the control arm) by their home visitor. Participation by study participants will be monitored and recorded by activity staff. One central purpose of the communal activities is to foster new, yet sustainable social and community connections that will provide increased healthy behavior role models and social support for mothers. This will be achieved through activities that provide a context for repeated social connection among consistent groups of COPE participants in their neighborhoods, and through activities designed to foster group learning, discussion, and shared experiences that are aligned with the individual didactic learning in home. These social activities are similar to those delivered as part of the *National Institute of Food and Agriculture's Expanded Food and Nutrition Education Program*.[130]

Table 5. Description of COPE experiential and communal activities	
Communal cooking	Advance meal preparation to promote home cooking using foods from WIC/food bank, and decrease reliance on fast-food. Gatherings are lead by Nadia Sigaran (Site Culinary Program Coordinator) and take place in the Wellness Homes operated by our partner (Resources & Environment section).
Community gardening	Mariposa master gardeners teach parents/children gardening techniques (planting, growing and harvesting fruits and vegetables). Gardens are located on Wellness Homes' grounds. Families tend local gardens with other families.
Food management	Classes to improve food resource management practices such as purchasing, selecting, or otherwise obtaining; preparing; and storing foods to increase sustained availability of healthy foods throughout the month. This material is delivered in local grocery stores and markets.
Mobile food demos	Food demonstrations hosted in neighborhood farmers markets to provide convenient and accessible cooking and food preparation demonstrations using fresh products from local farmers markets.

C.5. Measurements. HVP *Assessment Workers* (registered nurses who can draw blood) who enroll families into standard HVP services, have been trained to screen and recruit eligible families for the proposed project. They will administer the assessments (English or Spanish; **Table 6**) in the families' homes or at the HVP clinic (as needed) at baseline/enrollment, and after 6mo and 12mo of services. *Home visitors* will be trained to gather interim (objective) weight measurements for the purpose of generating more frequent data points, triangulated with the assessment workers' measurements.

Medical and family history. A thorough family history and physical examination will be conducted at baseline. We will collect demographic data, including socioeconomic status (education, income, eligibility for SNAP).

Infant growth & waist trajectories. Weight will be measured on a digital scale (Tanita) accurate to the nearest 5g. Length will be measured to the nearest 0.1 cm using an infanto-meter using the standardized WHO approach,

Table 6. Assessment time points (month of intervention) and key measures	Baseline	3	6	9	12	15	18
COVARIATES							
Demographics, household composition, medical history, post-partum depression, activity readiness	X						
MOTHERS							
Weight/height, waist circumference	X	X	X	X	X	X	X
Blood and vitals	X						X
24h diet & activity recall	X		X				X
Feeding and food insecurity	X		X				X
Social support and networks	X		X				X
Home environment	X		X				X
INFANTS							
Weight/length, waist circumference	X	X	X	X	X	X	X
Blood (finger prick)	X						X
24h diet & activity recall (from mother)	X		X				X

including use of staff training modules. Weight and length will be used to calculate weight-for-length and weight-for-age z-scores (WHO Standards), as recommended by the CDC for children <24 mos. Infant growth rates will be examined as the change in WLZ from baseline to follow up (12mo) Waist circumference will be measured at the umbilicus (nearest 1-mm) using a non-stretch measuring tape.

Infant diet & activity. To fully capture *infants' diet* (e.g., breastfeeding, use of formula, fruits/ vegetables, fat/sugar intake), we will use multiple tools. *Diet recall.* .Mothers will be interviewed about their *infants'* intake of fruits, vegetables, friend foods, and sugared beverages. Mothers will complete items from the *Diet and Behavior Questionnaire (DBQ)*[132] of the National Health and Nutrition Examination Survey to capture breastfeeding/feeding history and introduction to formula and solid foods. *Infants' activity.* Because of validity issues related to accelerometry in infants/young children, we opted to capture time engaged in sedentary activities and structured/unstructured physical activity. Mothers will report their child's activities (e.g., tummy time,).[133-135]

Infants and maternal biomarkers for metabolic risks. Blood will be drawn at the Antelope Valley Partners for Health office by Assessment workers with phlebotomy certification, at baseline for mothers only. *Mothers*: Blood will be drawn by Assessment Workers who will make a maximum of 3 attempts to draw the blood during the first visit. If the first attempt is not successful, mothers will be invited to return on another day for a second (and final) attempt. Plasma will be stored at -70°C for analysis. Biomarkers of type 2 diabetes risk, lipids, and inflammatory markers. CRP will be measured using the Millipore Multiple assay kit at the USC DORI Core Laboratory. Lipids will be assayed using Vitros Colorimetric assays (Johnson & Johnson Clinical Dinostics Rochester, NY) for cholesterol, triglycerides and HDL-cholesterol. Sitting blood pressure (mothers) using auscultation and heart rate will be measured on the right arm after a 5-minute rest. Three readings of blood pressure and heart rate will be obtained and the average of the last two last will be recorded.

Maternal weight & waist circumference. Weight and height will be measured by Assessment Workers in participants' homes using an electronic scale (Model BWB-800S, Tanita, Portage, MI) and stadiometer (Model PE-AIM-101, Perspective Enterprises) according to standard procedures.[140] Subjects will remove shoes, belts, and heavy outerwear and empty pockets. We will measure height in duplicate and if measurements are not within 0.5 cm, we will obtain a third measurement. The mean of all measurements will be used to calculate BMI. Waist circumference will be measured at the umbilicus to the nearest 1 mm using a non-stretch measuring tape. Maternal obesity prior to pregnancy will be derived from pregravid BMI (recall during pregnancy at recruitment). Gestational weight gain will be defined as the last weight obtained before delivery minus the pregravid recalled weight or the weight recorded at the first prenatal visit during the first trimester using electronic medical record data.

Maternal diet & activity. Mothers' dietary intake and activities will be assessed using several items from NHANES (2017), including intake of fruits and vegetables, fried foods, and sugary-sweetened beverages, and time mothers engage in moderate physical activity.

Maternal social networks & support. Using egocentric social network methods[141] and EgoWeb software (http://www.rand.org/methods/egoweb.html, developed with PI de la Haye), we will assess the characteristics of the social actors (people, organizations) and relationships that surround mothers.[142,143] Using standard name generator items,[143,144] participants are asked to identify 20 important adults in their lives, and then report on the attributes of each person (demographics, health attributes/behaviors) and types of relationships they share. Relationship characteristics of interest include how they know the person (e.g., family, friend from a community program, etc.), frequency of interaction, and provision of support for health behaviors (e.g., encouragement for or co-engagement in specific behaviors)[52,53,145]. *Social Support measures from the PROMIS database* will be used to assess emotional and instrumental support, and social isolation. Egocentric network data is used to compute network composition variables (e.g., proportions of family/friends in the network), and variables that represent

important network structures (e.g., sparse or dense support). Respondents will also be asked about health-related relationships (e.g., information seeking, support) they have with community organizations. Social network analysis (SNA) will be used to compute summary statistics for each mother's network, such as the proportion of network members that engage in regular exercise or that provide health-relevant support, and the density of supportive relationships.[147]

Maternal food insecurity. The U.S. Adult Food Security Survey Module[148] is an 18-item, three-stage design with screeners. Each stage consists of characteristic conditions and experiences of food insufficiency to meet the basic needs of household members, and of the behavioral responses of household members to these conditions. We will test if scores mediate the effect of COPE on infants' outcomes, as energy intake and weight are related to food insecurity.[42-50]

C.6. Analytic Plan.

General strategy. Three waves of data will be collected (baseline/enrollment, 6 and 12- months of intervention). Analyses will be carried out according to the intention-to-treat rule consistent with standard practice in most clinical trials. We will conduct standard statistical diagnosis and descriptive statistics of demographic and background variables, and examine frequencies for reasonableness, sparseness (categorical data) and non-normality (continuous variables) of the data. Missing data will be addressed using multiple imputation and/or full information maximum likelihood estimation. Psychometric properties of the study scales will be investigated to ascertain appropriate validity and reliability. Preliminary analyses will test group equivalence on baseline characteristics. Categorical methods of analysis (e.g., cross tabulations, chi-square) will be used for discrete data while *t*-tests will be used for continuous data to test the comparability of the prevention arms. Factors found to be different at baseline will be adjusted for in subsequent analyses. The following *covariates* will be entered in all analyses: home visitor, home visitor experience (years), number of visits, household composition, race/ethnicity, acculturation, mother's age, medical history/gestational diabetes, post-partum depression.

Social network analysis (SNA). Network data will be analyzed using SNA packages in R (e.g., SNA, igraph) to produce visualizations and statistics that summarize the characteristics of each mothers' network. We will compute the following network statistics: the proportion of network members that provide specific types of health relevant support, and that engage in specific health behaviors; and the density of supportive relationships within each network (i.e., the number of supportive relationships among network members that are reported, as a proportion of the total number of possible supportive relationships where all network members provide support).[149,150] These statistics will be computed for each assessment period (as well as change statistics across periods), and included in the analyses, as described below.

Statistical Models Aims 1-3. Our conceptual model includes three types of variables: Intervention arms (HVP vs. HVP+COPE) and covariates, mediators, and outcome variables. We will use multiple statistical procedures tied to the analytic objectives of each of our specific aims, including generalized linear modeling, path analysis and structural equation modeling (SEM) approaches. To control for potential cluster effect due to home visitors as families are nested with visitor, statistical models will be developed based on multilevel path analysis to test direct and indirect (or mediational) effects hypothesized in the model.[151,152] The models involve two levels with mothers or children as Level-1 units and visitors as Level-2 units treated as a random effect. With multilevel path modeling approach, the covariance matrix to be analyzed can be properly decomposed into individual- and group-level covariances to account for the clustering effect due to visitor nesting effect of the data. The multilevel path model can involve all variables from the family level in the analysis. The model can also incorporate distal predictors and mediators from the visitor-level (Level-2) and outcomes from family-level (Level-1) data. The aims of the proposed study focus on the Level-1 units. Following Bentler-Weeks[153] modeling notation, the path model can be expressed as: $\eta=\beta\eta+\gamma\xi$, with all exogenous (distal) variables defined as ξ and all endogenous (mediators and final outcomes) variables as η. The parameters in β and γ matrices can be specified according to the hypotheses of each Aim. Models to be developed are discussed in greater detail below for each Aim. Mplus software[154] will be used model estimation and evaluation.

Aim 1 (maternal/infant outcomes). Change in weight-related outcomes over the 2-year implementation is the primary outcome comparison. We will use multilevel regression models adjusting for clustering effect of home visitors to compare differences in the main outcomes across time by intervention arm. Regression model can be treated as a special case of path model without mediators. These regression models will include all participants, who have at least 2 measurements, regardless of when the measurements are taken, increasing the follow-up of study participants and statistical power. Specific measures relevant to Aim 1 are maternal and children weight-related measures. These models will allow the evaluation of intervention effects on, for example, child growth trajectory and activity, and mother BMI, metabolic, and behavior outcomes. Investigation of the main effects of COPE on outcomes will be conducted at each follow-up. Baseline outcome measures will be treated as covariates to control for potential

baseline differences. Effects of COPE will be evaluated first at each follow-up assessment point. Longitudinal analyses with all follow-up points (6 and 12 months) will then be conducted to examine profiles across time to investigate the effects of program conditions on trends of outcome measures.

Aim 2 (maternal transmission). To estimate the mediational effects of maternal transmission, multilevel path models will be developed and evaluated per our hypotheses. The model specification will be guided by our conceptual model treating Intervention program as the distal variables along with demographic variables to affect mother's weight, diet and behavior as mediators, which in turn may influence infants' outcome. While the intervention program will be at the Level-2 unit, all other variables included in the multilevel path models will be Level-1 variables obtained from mothers and children. Using breastfeeding and maternal diet on infants' weight trajectories as an example, the mediation mechanism of maternal transmission can be expressed by the process: COPE→ breastfeeding * maternal diet→ weight. The path model will allow the test of both the direct effect of COPE on infant weight trajectory and its indirect effect on through breastfeeding and maternal diet.

Aim 3 (social transmission). A multilevel path model similar to the one described in Aim 2 will be specified. Mediators can be specified in a process to more appropriately represent the mechanism of social transmission. For example, the model can contain a sequence of influences such as: COPE→ density of social network support→ maternal outcomes→ infant outcome. A direct effect of social network on infants' outcomes can also be specified to investigate if social network has direct and indirect effect on infants' outcomes.

Power Analysis Aims 1-3 (Figure 7). A total of 30 home visitors will be recruited and randomized to HVP or HVP+COPE. With an average of 13 families served by each visitor, a total of 300 families will be invited to participate in the proposed study over 12 months. Based on our pilot work and existing HVP data,[94,95,155-157] we expect a retention rate of 75% of families, which will result in a final sample of 200 mothers/infants. We have calculated power using G*Power[158] based on an effective sample of N=200 for the main weight related outcomes with the design of repeated measurement. All tests use a two-sided alpha level of .05. Our pilot study showed a small to medium effect size of .4 (Cohen's *d*) on our main outcome of children's weight velocity and smaller effect on energy intake at 6 months post-test. No previous study has investigated the long-term (12 months) delivery of in-home obesity prevention on 0-2yo children's growth trajectory, diet and activity. However, an in-home

intervention compared to outpatient pediatric counseling resulted in a large effect size of 1.64 (Cohen's *d*) for changes in zBMI at 12 months, among obese 2-5yo children.[159,160] To account for potential large clustering effect at the home visitor level, we assume the intraclass correlation (ICC) of .05 to .1 [161] with inflation factors $(1+(n-1)*ICC)$ of 1.4 to 1.8, respectively.[162] After taking inflation factor into account, our proposed sample size of 200 will have enough power to detect medium effect sizes based on Cohen's *f*[163] between .17 and .20. More comprehensive path model will be specified in each aim for model evaluation and hypothesis testing. We are aware of the sample size limitation and will be cautious in the number of variables and the size of the model involved. We used the hypothesis-testing framework of RMSEA[164] to estimate

Figure 7. Required sample size by effect size

power of model fitting in our study. With α = .05, a null hypothesis RMSEA of .00 (almost exact fit for path model), an alternative hypothesis RMSEA of .08 (criterion of not acceptable models) and degrees of freedom (size of the model) ranging from 10 to 15, the range of statistical power for a sample size of 300 is between .83 and .93. We will have sufficient power to detect small to medium effect of a set of pre-selected parameters associated with mediators and outcomes with sample size of 200.[165]

Secondary Aim (Real-life economic analysis). We will document the costs of adding COPE to HVP's services through cost logs and interviews with HVP directors. We will consider the costs of labor (the time home visitors spent in training and in administering COPE, times their wage rate) and of materials (training and intervention manuals for home visitors), and evaluate how these costs can be absorbed through the ongoing funding from the Affordable Care Act. We will calculate infants and mothers' weight, metabolic, and behavioral trajectories and how they differ by child gender, household structure, and other observables. These analyses will be conducted at two levels. First, we will calculate the cost-effectiveness of HVP+COPE (vs. HVP only) by comparing the cost of adding COPE per unit of improvements in weight, metabolic, or behavioral outcomes with the cost per unit of improvement in these outcomes vs. alternative obesity programs with similar aims (e.g., prevention delivered in outpatient settings). This will provide a measure of the effectiveness of COPE vs.
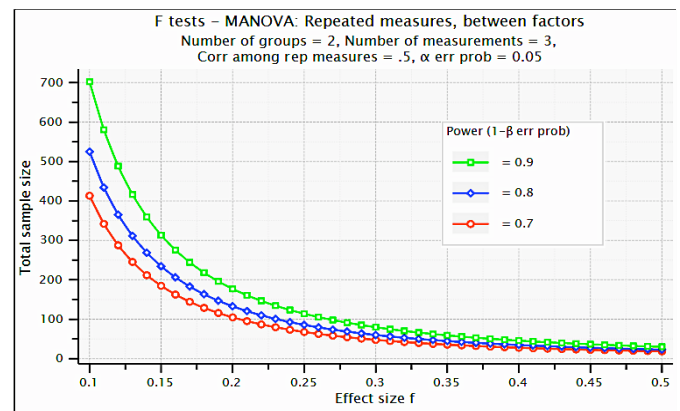
alternative interventions. We will rely on an extensive review of the literature to obtain estimates of costs and improvements associated with such alternative programs. Second, in the absence of long-term data, simulation models are often used to predict long-term outcomes and/or evaluate the cost-effectiveness of healthcare interventions. We have developed a simulation model to predict BMI trajectories and associated medical expenditures over the life cycle (e.g., [166]). The model utilizes data from the Medical Expenditure Panel Survey (MEPS) to model yearly changes in BMI and healthcare costs associated with each possible initial BMI state. The model was validated using data from the National Health and Nutrition Examination Survey (NHANES). This work shows that reducing by 10% the risks of overweight/obesity (BMI ≥ 85th percentile) in ages 2-18 is associated with reductions in direct medical costs between $2,830 (men) and $3,000 (women) in adulthood. Reducing obesity risks by 25% is associated with savings of $5,860 and $6,022 in adult men and women respectively. We will use this model to predict reductions associated with long-term BMI and medical care expenditures over the life cycle and compare these to costs associated with COPE.

C.7. Timeline

Table 7. Timeline of planned research activities

Research Task	Month of Study									
	6	12	18	24	30	36	42	48	54	60
Convene weekly research meetings (key personnel)										●
CAB meetings	●	●	●	●	●	●	●	●	●	●
In-person training of home visitors and refresher courses	●	●		●		●				
Delivering COPE as part of HVP services								●		
Recruitment /enrollment /baseline assessment										
33% sample			●							
66% sample				●						
100% sample					●					
Assessments (based on rolling enrollment)										
6-month assessment						●				
18-month assessment								●		
Data entry and data cleaning										
Interim analyses and preliminary reports and publications								●		
Manuscript preparation and research dissemination										●
Clinical and community dissemination										●

C.8. Deliverables. The most appropriate scientific outlets will be journals dedicated to obesity (International Journal of Obesity, Pediatric Obesity) and general nutrition and public health (Pediatrics, American Journal of Public Health, American Journal of Clinical Nutrition). We will also target specialized (Obesity Society, International Network for Social Network Analysis) and general conferences. Study findings will be disseminated to our HVP partners, Community Advisory Board and key stakeholders, and utilized to refine our existing curriculum and protocol for future dissemination.

PROTECTION OF HUMAN SUBJECTS

A. Participants
This comparative effectiveness research involves the enrollment of 300 mothers/infants for a final effective sample of 200 mothers and their infants (age 6mo at enrollment).

Inclusion of women. Women are represented by mothers and female infants, which will be about half of the infant sample. Based on our projected effective sample of 200 mothers and their 200 infants (N=400), we anticipate that 75% of our sample will be women (100 children + 200 mothers = 300).

Inclusion of racially and ethnically diverse families. The families enrolled in the Home Visiting Program (HVP) from which the sample is drawn is culturally, racially and ethnically diverse, reflecting the population of low-income families enrolled in home visiting services in the Antelope Valley, CA area. Based on our HVP partner (Healthy Families America site in Southern California: Antelope Valley Partners for Health and Children's Bureau) clients' demographics and on our pilot work, we anticipate the following ethnic and racial distribution: 70% Hispanic/ Latino, 13% African American, 8% White, 5% American Indian/Alaskan, and 4% mixed/other race.

It is important to note that Health Families America (HFA) home visitors are matched to families based on language and cultural background. Home visitors are rigorously trained to understand, acknowledge, and respect families' cultural differences. Home visitors are selected because of their personal characteristics (i.e. non-judgmental, compassionate, ability to establish a trusting relationship, etc.), their experience working with culturally diverse communities, and their skills to do the job.

Inclusion of children. Infancy and early childhood are important developmental periods given that nearly one-third of American children two years and older are already overweight or obese[167-169] and these rates are even higher among low-income children of color. Once obesity is established, it is difficult to reverse,[170] and obesity in childhood and adolescence are independent risk factors for adult obesity.[6] Children develop eating and activity habits in the context of their family, and parents influence the child's health trajectories through their own behaviors (e.g., modeling) and through the shared family environment. This proposal addresses the impetus to develop interventions targeting at-risk infants before obesity is established, to avoid the significant public health implications associated with obesity by reducing lifelong health struggles for at-risk individuals and reducing financial burdens for the society as a whole. The services and obesity module being evaluated in this proposed research involve the provision of home visiting services to infants/children and their mothers. Therefore, a number of the outcomes that will be measured as part of the proposed research will involve children. Specifically, children will be represented by the 200 infants that will be the offspring of the mothers, as well as mothers who are 18 years of age or younger. A significant proportion of mothers enrolled in home visiting services (50%) are ≤18 years of age. Based on our pilot data, we expect the total number of participants ≤18 years of age at enrollment will be: 200 infants + 100 mothers = 300.

The research team is well trained and experienced in conducting research in children. Dr. Salvy (MPI) is a Clinical Psychologist with expertise in pediatric and child psychology, and she has been a member of the children's Institutional Review Board (IRB) for several years at the Women and Children's Hospital in Buffalo, NY. She will ensure the quality of the treatment implementation. The involvement of minors as participants in this research is in compliance with all subparts of 45 CFR Part 46 as well as with Federal laws and regulations.

Sources of materials. Data will be used specifically for research purposes and held in strict confidence. Data from human subjects include:
- Clinical evaluation and medical history via questionnaire/interview;
- Demographic information, via questionnaire (mothers)
- Anthropometry: body weight, waist circumference, height (mothers/infants)
- Blood pressure (mothers) and blood samples (mothers/infants);
- Variables derived from dietary intake, via recall interviews (mothers as respondents for themselves and for their infants);
- Physical activity via interview/recall (infants) and accelerometers (mothers);
- Social networks and support via questionnaires (mothers);
- Maternal feeding style & practices via questionnaire (mothers);
- Maternal food insecurity via questionnaire (mothers);

Records. Mothers' pre-pregnancy weight and infants' birth weight will be obtained from our HVP partner. All other data used for this study will be collected during the implementation of the study protocol.

B. Potential Risks/Adverse Events and Procedures Used to Minimize the Risks
For purposes of monitoring and reporting adverse events, the following definitions will be used:

Adverse event (AE): any untoward medical occurrence that may present itself during treatment or administration of an intervention, and which may or may not have a causal relationship with the treatment. Adverse events could arise from the study (e.g., breach of confidentiality) or could arise because of the population under study (e.g., a mother reports extensive use of drugs).

Serious adverse event (SAE): Any medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalizations; creates persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Such an event could include suicidal ideation or attempted drug overdose or withdrawal, etc.

Adverse events monitoring. Each participant (mother and infant) will be evaluated for any adverse events. All events will be graded by their attribution (unrelated to protocol; or possibly, probably, or definitely related to protocol). Any event reported to the Principal Investigators or to designated research associates by the subjects or Antelope Valley Partners for Health nursing and medical staff, which also meets the event criteria, will be carefully documented in a report submitted to the IRBs. The report will include a description of the event; when and how it was reported; any official charts, records, or documentation to corroborate the event or the reporting of the event; and an action plan to prevent future occurrences. All adverse events will be graded as mild, moderate, or severe. Any severe and/or unanticipated adverse event will be immediately reported to the IRBs (within 48 hours of occurrence or recognition) and NIH. All adverse events will be summarized annually and submitted to the IRBs and NIH. Any action resulting in a temporary or permanent suspension of this study (e.g., IRB actions) will be reported to the NIH.

Physical risks. There are minimal physical risks added from participating in this study. All lifestyle dietary and physical activities suggested are in line with national guidelines. Recommended physical activities are low impact and unlikely to create discomfort for participants.

Psychological risks. Though none of the questionnaires contain items that are particularly sensitive, personal, or potentially upsetting, it is possible that a participant may become upset thinking about some of the questions or topics in this study. Trained assessors will be conducting the assessment sessions to address any potential incident. All participants will be informed that they are free to refuse to answer any particular questions or questionnaires. They will also be informed that they can withdraw from the study at any time without penalty. Staff will immediately report any AEs connected to the implementation of the intervention to Drs. Salvy and de la Haye who will keep a log of AEs and SAEs. Drs. Salvy and de la Haye will file a written report within 24 hours of being notified to the IRB, whether the event relates to the project or not. As part of this process, members of the IRB committee review the event and determine whether the event is directly related to project procedures so that it can be determined whether procedures need to be modified to avoid a similar AE in the future. Whether the event is related to the project, we will keep a log to provide information about all AEs in annual progress reports to the IRB and NIH. Drs. Salvy and de la Haye will monitor outcomes for AEs, and outcome information will be entered into a log for inclusion in reports to the IRB and NIH.

Social risks. There are no social risks for participating in this study.

Legal/other risks. None.

Postpartum depression. The Edinburgh Postnatal Depression Scale (EPDS)[171] is used to assess *postpartum depression* at enrollment into home visiting services. Maternal depression will be assessed again prior to study enrollment. Mothers who show signs of severe postpartum depression will be closely monitored and provided additional referrals and resources as needed. The Safety Officer, Dr. Paul Round, is a physician at the Antelope Valley Clinic. Dr. Round oversees the physical and psychosocial safety and well-being of families enrolled in home visiting services. The decision to include/exclude mothers with postpartum depression will be taken on a case-by-case basis with the counsel of one of the PI (Dr. Salvy, Psychologist), Antelope Valley Partners for Health directors, the Safety Officer (Dr. Round, DO) and our CAB (which includes mental health professionals and Dr. Paul Simon, MD). We believe that some mothers may benefit from engaging in positive and reinforcing activities such as cooking and lifestyle activities. Physical activity has been shown to improve moods and alleviate symptoms of depression.

Trauma and domestic violence. If we suspect that mothers are victims of intimate partner violence, either through completion of the questionnaires or through mother report or staff observation, we will implement the following procedures: (1) we will make mothers aware of resources available to them in their communities, such as shelters; (2) we will work with mothers to develop a safety plan for addressing violence and seeking shelter; (3) we will ascertain risk to the child. If we suspect that the child has been abused or witnessed domestic violence, we will make a report to child protective services. We will work closely with the home visitor and our HVP partner to coordinate efforts in the best interests of the mother and child. Mothers who are victims of domestic violence will not be dropped from the study.

Suicidal behavior. As we will be measuring depression in mothers, we will potentially identify participants who are suicidal. We follow the Substance Abuse and Mental Health Services Administration SAFE-T: Suicide Assessment Five-Step Evaluation and Triage approach to determining risk and clinical response. The five steps are Identify Risk Factors, Identify Protective Factors, Conduct Suicide Inquiry, Determine Risk Level/Intervention, and Document (which includes intervention and follow-up). As per Practice Guidelines, we will estimate suicide risk as Low, Moderate, or High. All potentially suicidal mothers will be provided an emergency plan with numbers to call, including local hospital emergency rooms, suicide hotlines, and home visitor contacts. Each plan will be individually tailored to the needs and resources of the mother. Family members will be incorporated into the plan. We will be available to home visitors and our HVP partner to work with them as to how to proceed if their clients present with suicidal behavior. Home visitors also have ready access to supervisors in their agencies to help them respond to mental health needs, and some of the agencies run separate mental health programs, thereby providing additional resources for home visitors in conjunction with project staff. Mothers who experience psychiatric emergencies such as suicidal behavior will not be dropped from the study.

Alternative treatments. Parents who do not want to receive the nutrition and physical activity module (i.e., COPE), will receive the standard home visitation program curricula.

C. Recruitment and Retention

Participant recruitment. Low-income mothers and their infants (N=300, for a final effective sample of 200) will be participants in the study. Active participants will be low-income mothers and their infants (6mo-old at enrollment) drawn from mothers who are enrolled in HVP services at the Healthy Families America site/chapter in Antelope Valley, CA. Home visitors providing the HVP services will introduce the study to mothers, and study Assessment Workers will obtain written consent. Home visitors will clarify with mothers that their refusal to participate in the study is not affecting the services they provide. In our experience from our pilot research, families feel comfortable to refuse if they do not wish to participate. Of note, 90% of families receiving *Healthy Families America* HVP services choose to enroll in enhancement studies when offered (i.e., when a module is added to the core curriculum and evaluated). These rates are consistent with our pilot work.

Inclusion/exclusion criteria. Participants will be ineligible if either parent and/or child have a Dx of eating disorders (e.g., Anorexia Nervosa), Schizophrenia or Obesity-related syndrome (e.g., Prader Willi). Participants enrolled in a weight-loss program will be ineligible.

Retention. Using conservative estimates, we anticipate that 25% of mothers enrolled will drop out of home visiting services over the 12-month study. Consequently, we will oversample at enrollment (N=300) to ensure an effective sample of 200 mothers and infants. We have learned a great deal about retaining mothers through our prior pilot studies. We attribute retention in part to our persistent efforts and abilities of the HVP home visitors, but also believe that there are unique features of home visited mothers that facilitate retention in a research study. For example, many of these mothers are socially isolated, and opportunities to exchange with their home visitor can be highly rewarding for mothers. We will use multiple strategies to retain the sample over the 12months of the implementation and assessments. We will rely on approaches widely used in studies of high-risk populations: (1) a gift card in the amount of $25 at each data collection, with all incentives paid after each assessment/data collection *regardless of whether they complete the study*; (2) frequent contact with participants to maintain engagement because we believe that open communication between the team and participants is critical; (3) quarterly newsletters to update participants about study activities; (4) acknowledging birthdays; (5) participants are given a reminder phone call the day before the weekly visits and assessment sessions (or on Fridays for Monday assessment sessions).

Informed consent procedure. Informed consent, approved by the appropriate IRB, will be obtained by Antelope Valley Partners for Health assessment workers who are trained by our research team. All mothers that are enrolled in HFA's HVP services by Antelope Valley Partners for Health and Children's Bureau will receive a detailed explanation of the protocol, including any potential benefits and risks (in English or Spanish). Mothers will be required to sign the consent form (in Spanish or English) and provide consent for their infants. Only participants from whom consent is obtained will be involved in the study. Signed consents will be kept in the participants' files in locked filing cabinets. Each participant will receive a copy.

Waiver. No waiver or modification of consent is being requested from the IRB.

D. Protection Against Risk

Safety reviews. The PIs will review the safety and progress of this study on a monthly basis. The PIs and the IRBs will review this protocol on a continuing basis for subject safety and include results of the review in the annual progress reports submitted to NIH. The annual reports will include a list of adverse events and address: *1)* whether adverse event rates are consistent with pre-study assumptions; *2)* reasons for dropouts from the

study; *3)* whether all participants met entry criteria; and *4)* whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study.

It is also important to note that Healthy Families America home visitors are expertly trained and experienced in handling situations they encounter while working with at-risk families. All home visitors receive extensive training in cultural competency, substance abuse, reporting child abuse, domestic violence, drug-exposed infants and children, and linkage to services in their community. Home visiting staff further receive intensive training specific to their role (i.e., assessment, home visitation, identifying at-risk families, completing standardized assessments, phlebotomy, mental health referrals, promoting preventive health care, securing medical homes, immunizations, utilizing creative outreach efforts, establishing and maintaining trust with families, building upon family strengths, developing individual family support plans, determining the safety of the home, teaching parent-child interaction, managing crisis situations, etc.). Staff further receive weekly supervision, ongoing developmental training, and have limited caseloads (10-15 families) to meet families' needs.

Monitoring plan. The study's data safety and monitoring plan will entail several components, overseen Principal Investigators (Drs. Salvy and de la Haye):

1. All *University of Southern California (USC) and University of Alabama at Birmingham IRB policies and continuous reporting requirements* will be followed in conducting the proposed study. Any actions taken by the IRB as part of its continuing review will be immediately reported to NIH.

2. The PIs will implement and monitor procedures to ensure that each mother provides *informed consent* and that all *data remains confidential*. This will also include a rigorous data management protocol to optimize data entry, accuracy/checking, and retrieval. Data will be stored in password-protected files accessible only to the investigators and staff under their supervision. In the database, only an ID code number will identify subjects. A list linking names and other identifiers with their ID codes will be stored in a separate file with a separate password. All original paper surveys and case report forms will be stored in locked file cabinets. The PIs will review all data collection forms for completeness and accuracy of the data and for protocol compliance. In the case of a breach of confidentiality or other adverse event, the Principal Investigators will report the event to the IRB and the appropriate NIH officials, and appropriate procedural changes will be implemented to prevent future breaches or adverse events.

3. An *internal committee* comprised of the projects' Principal Investigators (Dr. de la Haye will serve as the chair of the committee and Dr. Salvy will act as clinical training and supervisor chair) and the On-Site Project Director (Michelle Kiefer at Antelope Valley Partners for Health) will meet quarterly to assess: participant recruitment, accrual, and retention; data quality and timeliness; participant risk versus benefit; and the development of external conditions that could potentially affect the study. Significant problems or adverse events will be reported immediately to the USC and UAB IRBs, NIH, or FDA (if relevant).

4. As part of their training for the study, all personnel who will interact with subjects will receive instruction in the completion of an *adverse event reporting form*. In response to any adverse event, these forms will be completed promptly and returned to the corresponding study team supervisor, who in turn will report the information to the Principal Investigators.

5. An external *Data Safety Monitoring Board* (DSMB), not connected to USC, UAB or the research project, will convene twice annually, via teleconference, to review the progress of the study, ensure adequate recruitment of minority subjects, and to monitor safety concerns. Key members of the research team will co-participate in the conference calls. The DSMB will consist of five to-be-named individuals from outside USC: (1) a home visitation program consumer (parent, most likely a mother) (2) a child services advocate; (3) a layperson; (4) a home visitation program stakeholder; (5) a health disparities researcher and (6) a mental health professional. The DSMB will meet by phone conference two times within each of the project's 5 years. Their function will be to review the progress of the study, ensure adequate recruitment of minorities into the sample, and monitor the study with respect to the safety and well-being of the research patients.

6. Safety officer. Dr. Paul Round, DO is a pediatrician at the Antelope Valley Community Clinic. Dr. Round will serve as safety officer on this project to ensure the protection, safety and satisfaction of mothers and staff throughout the many facets of the project. Dr. Round will serve as contact-person to family participants, service providers, and all project staff to report problems or areas of concern regarding project implementation for resolution with investigators.

Additional protections for pregnant women, human fetuses, and neonates involved in research. This study involves parents and their infants (6mo at enrollment). This research does not involve women who are pregnant. If a mother becomes pregnant during the study, she will continue to receive HVP services, but she will not be involved in the study.

Potential benefits of the proposed research to human subjects and others. The potential benefits of this study include better management of postpartum weight-loss among mothers involved in home visitation programs and healthier growth trajectories for their infants. This study will also help researchers and professionals understand how home visitation programs can be used as a vehicle for early childhood obesity prevention. Participants will benefit by receiving a nutrition and physical activity module at no cost. Thus, the benefits of this project to the individual and society greatly outweigh the risks.

Importance of the knowledge to be gained. HVPs serve at-risk families, including low socioeconomic status (SES) and minority families, who are also at the highest risk of obesity. HVPs currently address multiple areas of mother and child health and development,[71,72,74,75,172] but they have yet to be tested as a viable and effective infrastructure for obesity prevention in early childhood. The proposed study seizes an untapped opportunity to test this potentially cost-effective, scalable and sustainable model of obesity prevention. This represents a unique opportunity to test an innovative model of care for childhood obesity. Findings will inform health policies at local, state, and federal levels, as home visitation programs are already implemented in many U.S. urban and rural areas and serve a large proportion of low-SES and minority families. Building a healthy lifestyle intervention into this infrastructure makes it possible to reach families who are most at risk for poor nutrition, a first step toward decreasing disparities. This research is particularly timely with stable funding for HVPs from the Affordable Care Act.[91]

Risk-to-benefit ratio. The risks to the participants are minimal and procedures are in place to reduce the risk and minimize the impact of adverse events. The potential gains of this project, including the adoption of healthier behaviors for mothers and their infants, healthier growth trajectories for children at high-risk for overweight/obesity, and the evaluation of a model for obesity prevention through existing home visitation programs, outweigh the risks.

E. ClinicalTrials.gov Requirements

The project will be registered in ClinicalTrials.gov no later than 21 days after the first subject is enrolled. Reporting of summary results information (including adverse events) will be reported no later than 1 year after the completion date. The ClinicalTrials.gov registry number (also known as NCT number), brief lay public title, and a certification that all required submissions to ClinicalTrials.gov were completed will be provided in progress reports. The PIs (Dr. Salvy at UAB and de la Haye at USC) will assume responsibility for these aspects of the trial.

MINORS AS RESEARCH SUBJECTS

The research team is well trained and experienced in conducting research in children. Dr. Salvy (MPI) has been trained in Pediatric and Child Psychology and she has been a member of the children's Institutional Review Board (IRB) for several years at the Women and Children's Hospital in Buffalo, NY. She will ensure the quality of the treatment implementation. The involvement of minors as participants in this research is in compliance with all subparts of 45 CFR Part 46 as well as with Federal laws and regulations.

INCLUSION OF WOMEN AND MINORITIES

Women are represented by mothers and female infants, which will be about half of the infant sample. Based on our projected effective sample of 200 mothers and their infants (N=400), we anticipate that 75% of our sample will be women (100 infants/children + 200 mothers = 300). The families enrolled in the Home Visiting Program (HVP) from which the sample will be drawn is diverse, reflecting the population of low-income families enrolled in home visiting services in the Antelope Valley, CA area. Based on our HVP partner (two Healthy Families America sites in Southern California: Antelope Valley Partners for Health and Children's Bureau) clients' demographics and on our pilot work, we anticipate the following ethnic and racial distribution: 70% Hispanic/ Latino, 13% African American, 8% White, 5% American Indian/Alaskan, and 4% mixed/other race. It is important to note that Health Families America (HFA) home visitors are matched to families based on language and cultural background. Home visitors are rigorously trained to understand, acknowledge, and respect families' cultural differences. Home visitors are selected because of their personal characteristics (i.e. non-judgmental, compassionate, ability to establish a trusting relationship, etc.), their experience working with culturally diverse communities, and their skills to do the job.

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