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Healthy Children, Strong Families 2: a randomized controlled trial of a healthy lifestyle intervention for American Indian families designed using community-based approaches

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Abstract

Background/Aims—Few obesity prevention trials have focused on young children and their families in the home environment, particularly in underserved communities. Healthy Children, Strong Families 2 (HCSF2) is a randomized controlled trial of a healthy lifestyle intervention for American Indian children and their families, a group at very high risk of obesity. The study design resulted from our long-standing engagement with American Indian communities, and few collaborations of this type resulting in the development and implementation of an RCT have been described.

Methods—HCSF2 is a lifestyle intervention targeting increased fruit and vegetable intake, decreased sugar intake, increased physical activity, decreased TV/screen time, and two lesser-studied risk factors: stress and sleep. Families with young children from five American Indian communities nationwide were randomly assigned to a healthy lifestyles intervention (*Wellness Journey*) augmented with social support (Facebook and text messaging) or a child safety control group (*Safety Journey*) for one year. After Year 1, families in the *Safety Journey* receive the *Wellness Journey*, and families in the *Wellness Journey* start the *Safety Journey* with continued

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Declaration of Conflicting Interests

The authors declare that there are no conflicts of interest.

wellness-focused social support based on communities' request that all families receive the intervention. Primary (adult body mass index and child body mass index z-score) and secondary (health behaviors) outcomes are assessed after Year 1 with additional analyses planned after Year 2.

Results—To date, 450 adult/child dyads have been enrolled (100% target enrollment). Statistical analyses await trial completion in 2017.

Lessons Learned—Conducting a community-partnered randomized controlled trial requires significant formative work, relationship building, and ongoing flexibility. At the communities' request, the study involved minimal exclusion criteria, focused on wellness rather than obesity, and included an active control group and a design allowing all families to receive the intervention. This collective effort took additional time but was critical to secure community engagement. Hiring and retaining qualified local site coordinators was a challenge but was strongly related to successful recruitment and retention of study families. Local infrastructure has also been critical to project success. Other challenges included geographic dispersion of study communities and providing appropriate incentives to retain families in a two-year study.

Conclusions—This multi-site intervention addresses key gaps regarding family/home-based approaches for obesity prevention in American Indian communities. HCSF2's innovative aspects include substantial community input, inclusion of both traditional (diet/activity) and lesser-studied obesity risk factors (stress/sleep), measurement of both adult and child outcomes, social networking support for geographically dispersed households, and a community selected active control group. Our data will address a literature gap regarding multiple risk factors and their relationship to health outcomes in American Indian families.

Keywords

childhood obesity; diet; physical activity; stress; sleep; social support; community based participatory research

Background

Obesity disproportionately burdens American Indian populations compared to the general US population.¹ Our previous research in Wisconsin American Indian communities showed 46% overweight/obesity in children ages 3–8 years^{2, 3} and even higher prevalence (>70%) in their primary caregivers.² Once obesity is established in early childhood, it increases the likelihood of obesity in later life and greatly increases future chronic disease risk.⁴ However, few obesity prevention trials have focused on the vulnerable early childhood period or on families, particularly in underserved communities.⁵

For the past decade, we have worked in community based participatory research partnerships with four Wisconsin tribes on childhood obesity prevention.^{6–9} We collaboratively designed and pilot tested a randomized trial of a home-visiting vs. mailed-only healthy lifestyle toolkit for American Indian families with children ages 2–5 years, Healthy Children Strong Families (HCSF1)^{10, 11}, which was funded as part of a collection of studies addressing the lack of randomized controlled trials in American Indian communities.¹² In the first trial, HCSF1, both the mailed-only and home-visiting groups demonstrated improvements in child

weight in overweight/obese children, adult and child screen time, added sugar and fruit/vegetable intake in children, and adult self-efficacy for diet and activity change.¹³ However, we found home-visiting was logistically difficult, expensive, and did not provide significant additional benefit.

Here we describe the collaborative development of the Healthy Children Strong Families 2 (HCSF2) randomized controlled trial, which was based on lessons learned from HCSF1. We discuss study design issues and the rationale for addressing these challenges in the context of community-engaged research. The trial is registered at clinicaltrials.gov (NCT01776255).

Research Design and Methods

Our previous work suggests American Indian caregivers have low recognition of overweight or disease risk in young children,¹⁴ often viewing heavier children as healthy or “the norm”. We also found high prevalence of overweight, obesity, and early cardiovascular disease risk factors in these children.³ Moreover, our work with community advisory boards suggested adults were far more willing to talk about their children’s health rather than their own health. Therefore, we chose to focus on young children and a primary caregiver, and the pilot communities chose the name “Healthy Children, Strong Families” to express the more holistic community views of health. This name notably avoids use of “overweight” or “obesity”, which are more stigmatizing and not appropriate given the low proportions of children perceived as overweight. These decisions were critical to facilitate recruitment and retention of families, which can be challenging in American Indian communities.

Study design

HCSF2 is a randomized controlled trial of an enhanced version of the HCSF1 toolkit (*Wellness Journey*) vs. an active control (*Safety Journey*) (Figure 1). Inclusion criteria included enrolling a child 2–5 years old and having a working cell phone. Exclusion criteria were minimal due to the communities’ value for inclusion in community projects. Dyads were randomized between starting in the *Wellness* or *Safety Journeys*, stratified by tribal site and child weight status (overweight vs. healthy weight).¹⁵ Randomization was conducted by the REDCap²¹ data management system (Research Electronic Data Capture data management system) using a permuted block strategy prepared by the study biostatistician.

A priority of participating communities was that all families receive the intervention, which has been previously described regarding community-engaged research in tribal communities and necessitates alternatives to the standard RCT.¹⁶ Most RCTs to date in American Indian communities have involved more discrete geographic regions, where differences in tribal-specific practices were not significant¹⁷. However, substantial differences in geography, language, culture, and traditions among our partner communities across the country suggested control communities would not be possible for HCSF2. A wait-list control group also was considered, but was deemed likely to result in high dropout, particularly in small American Indian communities where some family members may be receiving the intervention while others are waiting. Families who received the intervention also could easily pass on intervention materials to waiting families, resulting in study contamination. In HCSF1, we addressed the request for all families to receive the intervention by delivering an

identical wellness toolkit but through different modalities.¹¹ Seeking a more robust design for HCSF2, the research team designed an active control group, allowing for Year 1 to function as a traditional RCT. However, an additional year was included to allow all families to participate in both *Journeys*. After Year 1, families in the *Safety Journey* receive the *Wellness Journey*, while families who were first randomized to the *Wellness Journey* enter the *Safety Journey* but continue to receive social support via wellness-related text messages and Facebook content (Figure 1). To our knowledge, this design has not been reported in the literature. For this reason, primary outcomes will be assessed after Year 1, but additional analyses are planned after Year 2 to assess the effects of continued social support despite cessation of the wellness-related mailings (see ‘Statistical considerations’).

Site selection

In choosing American Indian communities to approach for the project, Drs. Adams and Parker selected communities with whom they were currently working or where they had close relationships with community members or wellness staff. Initially, six communities were selected as potential sites; due to changes in leadership, five communities enrolled participants. Each selected community vetted the final study design and provided input, and significant effort was made to take a broad American Indian value- and knowledge-based approach to expand its relevance across regions. Key stakeholders included administrators from tribal clinics, community health programs, schools, colleges, and early child development programs. The University of Wisconsin Health Sciences Institutional Review Board approved this study and serves as the IRB of record for four participating sites; one site approved this study through its own IRB.

Development of enhanced Wellness Journey toolkit

The original toolkit (from HCSF1) targeted four healthy lifestyle behavioral changes: 1) increasing fruit and vegetable intake, 2) decreasing added sugar intake, 3) increasing physical activity, and 4) decreasing TV/screen time. After pilot testing, we worked with our community partners (including tribal wellness staff and community advisory boards) to develop additional lessons targeting 5) stress and 6) sleep in recognition of these emerging obesity risk factors. Initial testing informed development of these lessons; for example, review of dietary records collected during pilot testing indicated high levels of late-night snacking for participating children, suggesting the need to address healthy sleep routines. Each *Wellness Journey* lesson includes a children’s book related to the topic and items to support behavior change (e.g., pedometers, apple corers, measuring cups, exercise DVDs). We chose the toolkit method because pilot testing showed high levels of acceptability and ease of toolkit use in American Indian families. Lesson topics are listed in Table 1 and are delivered monthly by mail starting with Lesson 1 (*Starting the Journey*).

Creation of the Safety Journey curriculum

National data and feedback from community partners revealed American Indian children are disproportionately affected by unintentional injuries for a variety of reasons including poverty, substandard housing, limited access to emergency medical services, and low engagement with primary prevention strategies. Therefore, child safety was chosen as the focus for the active control group, particularly for its lack of relationship to the primary

study outcomes. A similar approach was used by Walters et al., who used a family cohesiveness curriculum as a control condition to a cardiovascular prevention intervention in American Indian communities¹⁸. Academic and tribal researchers, tribal community members, tribal wellness staff, and national child safety experts collaborated to develop a comprehensive culturally-informed child safety curriculum. The *Safety Journey* addresses home safety, choking/suffocation, poison control, stranger danger, bike/pedestrian safety, weather safety, water safety, animal safety, car safety, Halloween safety, ATV use, fire safety, and cold weather safety. The *Safety Journey* curriculum is delivered through monthly mailings that also contain books and materials to support safe behaviors, such as bike reflectors and outlet covers. The development and content of this curriculum have been described in detail elsewhere (*Berns et al., under review*).

Hiring local community coordinator

The study partners decided employment of a local community member as the project coordinator at each site would best support community based participatory research principles.¹⁹ A standard job description was sent to each participating community to provide guidance regarding minimum qualifications and job duties. An initial problem encountered was that each tribe had a different hiring process, and the Memorandum of Understanding we adopted did not stipulate which party had the final say in applicant selection. At two sites, the tribe had a formal process and screened approximately 10–15 potential applicants. At other sites, the process was informal: a person identified as a good candidate was screened and interviewed, particularly for cases where a large applicant pool was not present. Most sites expressed the preference for a female coordinator because of the collection of sensitive measures (e.g., weight, waist circumference) from female participants, which further limited the applicant pool. Efforts were made to hire American Indian coordinators who were well known to the community to facilitate participant recruitment and enrollment. After hiring, local coordinators were trained in-person by the central study coordinator on all research protocols.

Social networking support

The benefits of cell phone messaging and social networking to support behavior change and improve health outcomes are being increasingly recognized.^{20–25} Our prior work revealed nearly all American Indian families use text messaging and regularly access the Internet for social networking, and the feasibility of technology-related health interventions in American Indian communities has been demonstrated previously.^{26–28} Therefore, the *Wellness Journey* is supported by both a text messaging campaign and community-specific Facebook pages for the adult participant to create a “virtual community” to enhance social support for lifestyle change. Several of the participating communities are small, and focus groups indicated Facebook is often used negatively such as for fighting or bullying. Our invitation-only, site-specific group pages were monitored by the central study coordinator to mitigate any potential misuse. The central coordinator posts information to all sites in support of lesson materials (e.g., healthy recipe ideas, sleep tips), and local site coordinators post community-specific information (e.g., announcement of local wellness events). Adult participant interaction with the Facebook page is tracked (e.g., number of “likes”) as a measure of engagement. Text messaging is managed by a mobile research and communications

technology company, TargetMobi (Milwaukee, WI), and messages are sent twice weekly on relevant topics to one cell phone per study dyad.

Outcome measures

Measures are collected for both the enrolled child and adult by trained site coordinators at WIC visits, Head Start centers, tribal college/administration buildings, or clinics, depending on the site. All surveys are completed by the adult for themselves and the participating child. Measurement tools were selected to minimize participant burden (e.g., surveys rather than accelerometers to assess physical activity), to align with the qualifications of the survey administrator (e.g., generalized stress measures rather than depression surveys because the study coordinators were not qualified to refer for follow-up counseling or emergency services), and special consideration was made to use tools that had been validated for young children or in American Indian communities. Table 2 lists the included measures and the schedule for data collection.

Study management

Study management is primarily conducted through the coordinating center at the University of Wisconsin, Madison. Tracking of all participant data and schedule management for mailing intervention materials are performed through REDCap, and all intervention materials are mailed from Madison. This approach minimized the burden on local site coordinators, ensured consistency in mailing and tracking participants, and mitigated any potential disruptions if site coordinator turnover were to occur. The entire team meets bi-monthly via videoconferencing to facilitate relationship development among team members and to provide ongoing training/support for the local coordinators. Blinding of outcome assessors was not possible because measurements were taken by site coordinators, the only project employees available at our remote study sites. However, data entry was conducted by two blinded research staff, and an independent data oversight committee carefully monitors the analytical approach to ensure study ethics.

Statistical considerations

The effect of the HCSF2 intervention will be evaluated by comparing Year 1 outcomes for the *Wellness Journey* group against the *Safety Journey* group. A sample size of 450 adult/child pairs was based on changes in adult body mass index (BMI) observed in pilot testing to detect an effect size of 0.28 at a two-tailed 0.05 level with power 0.76–0.81 under the assumption of 10–20% Year 1 drop-out. The study has the same power to detect the effect size of 0.28 at a two-tailed 0.05 level for changes in child standardized BMI (zBMI). The effect size of 0.28 represents a mean change of 0.64 for adult BMI and 0.25 for child zBMI. Statistical analyses of outcome data await trial completion in 2017. Data will be analyzed with intention to treat by including all randomized dyads according to randomization, and missing data will be imputed using multiple imputation. The primary comparison will be supplemented by analysis of covariance (ACOVA) for BMI/zBMI at Year 1 with randomization and BMI/zBMI at baseline as model terms. Healthy behaviors and self-efficacy for behavior change from baseline to Year 1 will be analyzed as secondary outcomes using two-sample t-test or Wilcoxon rank sum test, supplemented by ANCOVA. We also will investigate the differential effectiveness of the intervention across different

communities by developing exploratory regression models for outcome measures that include interaction terms between the intervention (*Wellness Journey*) and baseline family characteristics and study site. The secondary comparison of the *Wellness* vs. the *Safety Journey* will be based on a two-sample test of the change from baseline to Year 2 to test the effect of social networking under the assumption that the *Journeys* have the same effects regardless of the order in which they are applied. Finally, as a subgroup analysis, we intend to analyze participants by weight status at baseline to increase the clinical applicability of our findings and to determine if participants are crossing weight status group (e.g., normal weight to overweight).

Results

Recruitment was staggered by site from February 2013 to April 2015. Primary recruitment sites included Head Start centers, social service centers, and tribal clinics. Informational flyers also were distributed among community spaces. Community site coordinators collected 659 interest forms, and 527 participants were screened during the recruitment phase. Twenty-five participants failed screening (e.g., child not in targeted age range, moving out of area, no cell phone, or declined to participate), leaving 502 eligible participants. Of these participants, we were unable to collect baseline data on 52 families to enroll them in the study. To date, 450 adult/child (age 2–5 years) dyads have been enrolled from five communities (four rural and one urban site), representing 100% of our target enrollment. We anticipate project completion in March 2017 and will present study findings to each community along with dissemination to the wider academic community. As of October 2016, each community has received a summary of their participating families' baseline data, each family has received portions of their individual baseline data, and each community will participate in the review and revision of any resulting study manuscripts in alignment with community based participatory research principles.

Lessons Learned

Here we describe lessons learned in the development and implementation of the trial. These and additional lessons related to community-based work are summarized in Table 3.

Incentives

Previous work in American Indian communities and ongoing feedback suggested incentives were an important component to increase retention. Community partners suggested Wal-Mart® gift cards would be desirable; one site did not have a local Wal-Mart®, and gift cards to a local grocery store are provided instead. All families receive a \$50 gift card after completing testing at baseline, 12 months, and 24 months (\$150 total). Families randomly selected to complete dietary recalls receive an additional \$25 gift card at each time point (n=25 per community). Lesson-specific incentives, such as cooking utensils, balls, books, games, and pedometers, are included in each mailed lesson for the *Wellness Journey*. Safety-focused incentives, including bike reflectors, outlet covers, and books, are provided during the *Safety Journey*. Although small gifts for the child (<\$10) are provided at the 6-month and 18-month visits, gift cards are not given because these visits are significantly shorter (compared to baseline, 12 months, and 24 months). We found that fewer participants showed

up for these study visits or many who did were under the impression they were receiving a gift card, and other studies have cited misunderstanding of incentives as a barrier to retention.²⁹

Social networking

An unexpected finding from the study has been the benefits of Facebook for promoting participant retention. The central and local site coordinators spend a large proportion of their time scheduling participant visits. We found that many participants screen phone calls and are difficult to reach by phone. Moreover, many participants in low-income communities have periodic disruptions of their cell phone service or change their number for a variety of reasons. However, we have been successful in reaching difficult-to-schedule participants through Facebook messaging, which would not have been possible without the creation of site-specific group pages. Participant feedback on the use of Facebook has been positive. Feedback on the weekly text messages has been mixed; with cell-phone number turnover and loss of service common in many rural communities, the challenges of phone-based intervention approaches should be considered in the future.

Site coordinators

We have discovered that the local site coordinators are crucial to the success of this project, as they are responsible for recruitment, retention, and data collection. For this study, the five coordinators were hired, housed, and managed in different ways. For example, one was hired through and housed in the tribal clinic, while another was hired through the early childhood education unit. Being associated with a unit that was already functional was critical for timely completion of job duties. For example, one coordinator was already working part-time in the tribal clinic and had access to office space, a phone, and a computer. At another site, it took months to secure these essentials for the study coordinator, making it very challenging to launch the project there. Another lesson was that some tribes required the site coordinator to be hired as tribal staff, which enhances tribal infrastructure. This approach was often slower, complicated by the distance between the research team and sites that would have allowed for in-person meetings. Some of the issues could be attributed to the lack of clarity in the Memorandum of Understanding regarding the hiring process. Future studies should articulate a defined protocol for hiring a site coordinator and the entity that has the ultimate authority in hiring and in local supervision.

Community based participatory research with American Indian communities

Maintaining an intervention for two years is difficult, especially in tribal communities where infrastructure may not exist to support the project. Moreover, the inclusion of diverse communities nationwide (5 states) strengthened the study but presented challenges associated with the large geographic spread. Other studies in American Indian communities have reported similar challenges that also resulted in changes to the study design, including a decrease in planned follow-up time after a lag in recruitment.²⁶ We learned that conducting a multisite randomized trial using community-engaged approaches requires flexibility in several different areas. For example, it was important to engage in discussions with more potential sites than we needed because of likely dropout during the early stages of project planning. In addition, every site presented a different challenge that was associated with the

study design. For example, a different number of care-giver child dyads were recruited at each site, two sites experienced coordinator turnover mid-project, and we had to be flexible with which sites started first due to lack of readiness in communities that were initially targeted with the staggered enrollment. Multiple studies conducted in American Indian communities have confirmed the importance of tribal support in ensuring project success^{30, 31}, which can be challenging when tribal elections are held every 2 years. During a 5-year grant, this could potentially include 3 cycles of tribal council members from whom the researchers must earn trust and support.

Discussion

We have described the methods and study design issues of an innovative intervention to promote health in American Indian families with young children, Healthy Children, Strong Families 2, the first national family-based obesity prevention project in American Indian communities. HCSF2 has the following strengths:

Healthy Children, Strong Families 2 utilized a home-based approach. Other RCTs have been successfully implemented in American Indian communities in schools^{30, 32}; another study focused on the health care setting but included home-focused elements.³³ However, HCSF2 is the first to target both adults and children primarily within the home in recognition of the critical importance of family dynamics in promoting wellness. HCSF2 supports families in multiple ways by increasing internal resiliency to outside obesogenic forces and is unique in providing tools for change rather than just an educational lesson. Toolkits containing lessons, children's books, and healthy lifestyle reinforcers (e.g., cooking supplies, exercise DVDs) are mailed monthly; participant feedback from previous focus group testing has indicated the excitement produced by a child receiving a monthly package in the mail has enhanced engagement and behavior change.¹³

Another strength is the focus on the early childhood period when health habits are developing. This focus addresses key gaps regarding family/home-based approaches for American Indian children, who are at particularly high risk for developing obesity and associated chronic diseases. Moreover, our approach considers traditional determinants of obesity risk, such as diet and activity, but also novel risk factors for obesity, namely stress and sleep. Data on these factors and their relationship to health outcomes are lacking for this population, and few interventions have addressed these important determinants of health risk.

HCSF2 is the first study, to our knowledge, to evaluate the use of social support for healthy lifestyle change in American Indian communities (text messaging and Facebook). These platforms allow for information exchange for both individual and community support, which is particularly relevant for geographically dispersed and economically limited households. Other aspects of the participating communities have been instrumental in this study: HCSF2 was designed and implemented with strong community engagement, which was critical to study success thus far. Initial testing of intervention materials in the HCSF1 trial indicated feasibility and community acceptance, and this successful pilot testing significantly informed the development of HCSF2. Finally, we feel this study was strengthened by the

inclusion of a diverse sample of urban and rural families in 5 states across the county, representing a unique contribution to the literature.

Conclusion

We have addressed the HCSF2 study design and the challenges our research team encountered. We also describe the solutions we employed to overcome these problems during the implementation of this large randomized trial of a healthy lifestyles intervention in diverse American Indian communities across multiple states. A review of 165 studies in underserved populations found similar barriers and challenges, but very few randomized trials have been conducted in American Indian communities.³⁴ The findings from this study may help future researchers understand the complexity and sensitivity needed when working with tribal or other underserved communities, including significant formative work, relationship- and trust-building, extensive planning, a high degree of flexibility, and respect for tribal or community-specific protocols. We are optimistic that data generated from this randomized controlled trial will significantly enhance our understanding of early child health in the context of American Indian families and strengthen the ability of researchers to effectively partner with tribal and other diverse communities to promote health and wellness.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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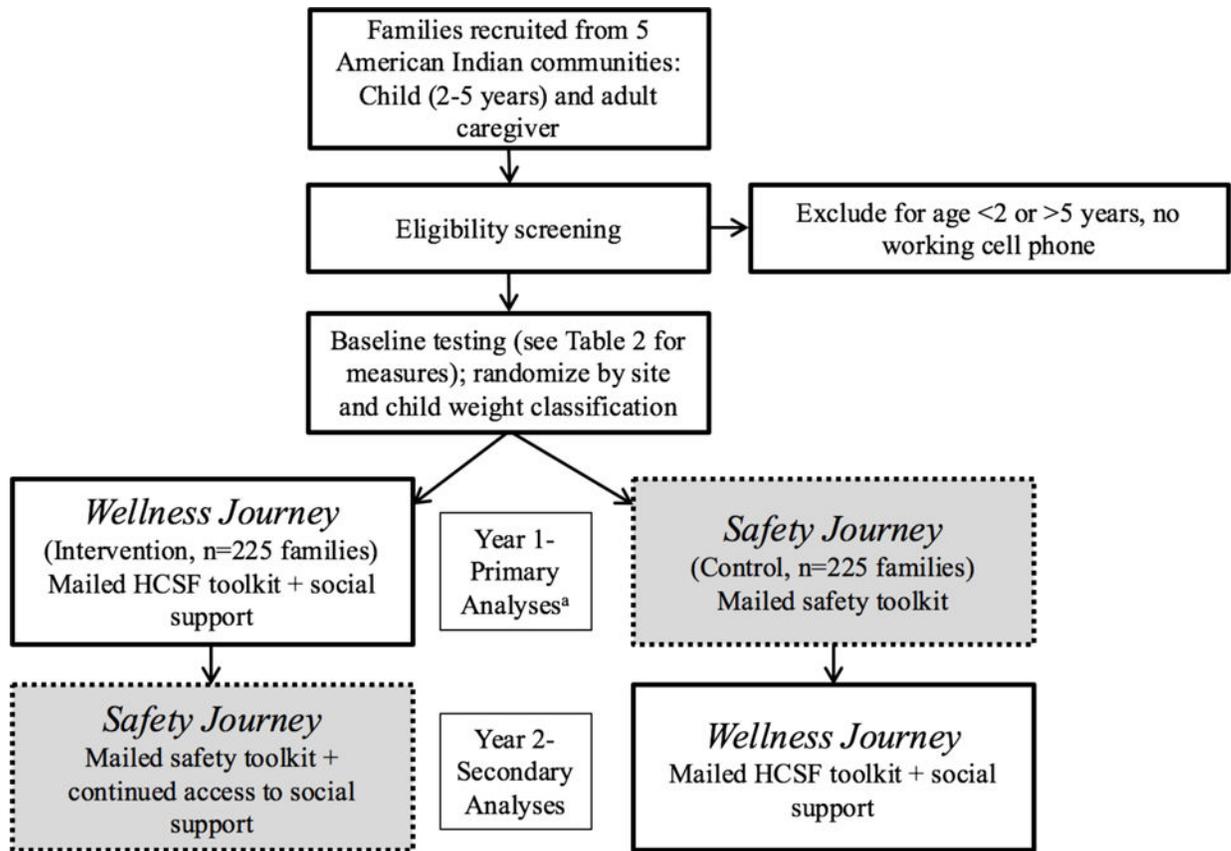


Figure 1. Healthy Children, Strong Families 2 study design

^aAfter Year 1, families cross-over into the other *Journey*. Outcome measures are assessed at baseline, 6 months, 12 months (corresponding to the end of Year 1), 18 months, and 24 months (corresponding to the end of Year 2) as listed in Table 2. Families who randomize into the *Wellness Journey* first continue to receive the associated social support (cell phone text messaging and access to private Facebook group) after switching to the *Safety Journey* at the end of Year 1. Families who randomize into the *Safety Journey* first receive social support at the end of Year 1 when crossing into the *Wellness Journey*. Because of this design, the primary analyses of the effectiveness of the intervention will be comparison between groups of outcomes assessed at the end of Year 1.

Table 1

Healthy Children Strong Families 2 monthly *Wellness Journey* mailed topics, including intervention target and associated book(s)/incentives

Lesson	Book	Incentive
<i>Starting the Journey (1–6)^a</i>	Through the Eyes of the Eagle ^b	Balloons, disposable camera
<i>Naturally Sweet & Nutritiously Delicious (2)</i>	The Very Hungry Caterpillar	Apple slicer, game, recipe cards
<i>Fun Family Fitness (3)</i>	Knees Lifted High, Little Running Deer Meets Robert	Pedometers, sidewalk chalk, magnifying glass, jump rope, game cards
<i>Sleep Tight (6)</i>	Little Beavers Go To Bed	Glow in the dark stickers, coloring book, stuffed animal
<i>Maintaining Harmony (5)</i>	Calm Down Time	Yoga Kids DVD, stress ball, relaxation cards
<i>On Track Snacks (1,2,4)</i>	Tricky Treats, Gregory the Terrible Eater	Game, recipe cards
<i>Suspending Screen Time (3,4)</i>	The Berenstain Bears and Too Much TV	Move Cube with activity cards
<i>Juicing the Benefits (2)</i>	Eating the Alphabet: Fruits & Vegetables from A to Z	Measuring spoons, game
<i>Healthy Adventures (3,5)</i>	Oh The Things You Can Do That Are Good For You	RezRobics DVD, stickers, beach ball
<i>Gifts from the Land (1)</i>	Plate Full of Color	Seed packets, recipe cards
<i>Fruitful Foods (1)</i>	I Will Never Not Ever Eat a Tomato	Dinner set (child sized divided plate, bowl, cup)
<i>Fast Lane to Health (1,2,5)</i>	The Berenstain Bears and Too Much Junk Food	Game, recipe cards
<i>Maintaining a Healthy Balance (1–6)</i>	HCSF Cookbook and Brag book	

^a Intervention targets: (1) Increase fruits and vegetables, (2) Decrease soda/sweetened drinks and added sugar intake, (3) Increase physical activity, (4) Decrease TV/screen time, (5) Manage stress, and (6) Develop healthy sleep habits.

^b Reference citations for books used in the lessons are provided as Supplementary Material (Little Running Deer Meets Robert, Little Beavers Go to Bed, and the HCSF Cookbook are self-published by the research team).

Table 2

Timeline for measurement of primary and secondary outcome variables

	Base	6 m	12 m	18 m	24 m
Primary Outcomes					
Adult BMI and child zBMI based on height and weight ¹⁵	A+C	C	A+C	C	A+C
Secondary Outcomes					
Medical history survey (developed by research team)	A+C		A+C		A+C
Waist circumference	A+C	C	A+C	C	A+C
Diet screeners: based on NHANES 2009–10 for adults ³⁵ and on the 2010 National Youth Physical Activity and Nutrition Survey for children ³⁶	A+C		A+C		A+C
24-hour dietary recall	A+C		A+C		A+C
Screen time survey (developed by research team)	A+C		A+C		A+C
Physical activity surveys: Godin Leisure-Time Exercise Questionnaire for adults ³⁷ and Netherlands Physical Activity Questionnaire for children ^{38, 39}	A+C		A+C		A+C
Sleep survey based on Child Sleep Habits Questionnaire ^{40, 41} and the Pittsburg Sleep Quality Index ⁴²	A+C		A+C		A+C
Family activity and environment with Family Nutrition and Physical Activity Survey ⁴³ with 2 validated questions on food security from the USDA Household Food Security Survey ⁴⁴	A	A	A	A	A
Psychosocial measures: Physical Activity and Nutrition Self-Efficacy Scale ⁴⁵ , Perceived Stress Scale (PSS) ⁴⁶⁻⁴⁸ , SF-12	A		A		A
Social network use (developed by research team)	A		A		A
Cultural Identity: A 6-item measure of acculturation ⁴⁹		A			
Control Behaviors					
Safety survey (developed by the research team)	A		A		A

A, adult; C, child; m, months.

Table 3

Lessons learned from community engagement using community-based participatory research approaches

Component	Example
<i>Study design</i>	<ul style="list-style-type: none"> • Development of active control group (<i>Safety Journey</i>) per community request that no families be in a passive control group • Designed to allow all families to benefit from both <i>Journeys</i> • Very few inclusion criteria to allow the most families to participate • Hiring of community-based site coordinators to strengthen engagement • Working with tribal IRB, tribal councils, and other stakeholders to obtain study approval • Provision of incentives that are useful to participants
<i>Wellness toolkit</i>	<ul style="list-style-type: none"> • American Indian-focused materials included (e.g., use of the American Indian-authored and illustrated Eagle Book Series, RezRobics DVD) • Focus on traditional foods throughout lesson materials (e.g., recipes utilizing wild rice, berries, etc.) • Creation of sleep book, <i>Little Beavers Go To Bed</i>, by study team after difficulty finding books that illustrate healthy sleep routines; illustrated by American Indian artist
<i>Social support</i>	<ul style="list-style-type: none"> • Partners shared that negative interactions can sometimes occur through Facebook; a private, by-invitation monitored Facebook group was therefore created • Focus group participants suggested text message content and timing preferences; text messages are sent twice a week with content reflecting intervention targets
<i>Measures</i>	<ul style="list-style-type: none"> • American Indian-specific cultural survey included in outcome measures
<i>American Indian cross-cultural considerations</i>	<ul style="list-style-type: none"> • Both urban and rural communities included • Efforts to use animals in lesson materials that are not specific to one group, tribe, or community • Inclusion of foods in cookbook that reflect traditional foods from different regions • Inclusion of healthy recipes for cross-cultural foods (e.g., chili).