The Healthy Children, Strong Families 2 (HCSF2) Randomized Controlled Trial Improved Healthy Behaviors in American Indian Families with Young Children

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ABSTRACT

Background: American Indian (AI) families experience a disproportionate risk of obesity due to a number of complex reasons, including poverty, historic trauma, rural isolation or urban loss of community connections, lack of access to healthy foods and physical activity opportunities, and high stress. Home-based obesity prevention interventions are lacking for these families.

Objective: Healthy Children, Strong Families 2 (HCSF2) was a randomized controlled trial of a healthy lifestyle promotion/obesity prevention intervention for AI families.

Methods: Four hundred and fifty dyads consisting of an adult primary caregiver and a child ages 2 to 5 y from 5 AI communities were randomly assigned to a monthly mailed healthy lifestyle intervention toolkit (*Wellness Journey*) with social support or to a child safety control toolkit (*Safety Journey*) for 1 y. The *Wellness Journey* toolkit targeted increased fruit/vegetable (F/V) intake and physical activity, improved sleep, decreased added sugar intake and screen time, and improved stress management (adults only). Anthropometrics were collected, and health behaviors were assessed via survey at baseline and at the end of Year 1. Adults completed surveys for themselves and the participating child. Repeated measures analysis of variance was used to assess change over the intervention period.

Results: Significant improvements to adult and child healthy diet patterns, adult F/V intake, adult moderate-to-vigorous physical activity, home nutrition environment, and adult self-efficacy for health behavior change were observed in *Wellness Journey* compared with *Safety Journey* families. No changes were observed in adult body mass index (BMI), child BMI z-score, adult stress measures, adult/child sleep and screen time, or child physical activity. Qualitative feedback suggests the intervention was extremely well-received by both the families and our community partners across the 5 participating sites.

Conclusions: This multi-site community-engaged intervention addressed key gaps regarding family home-based approaches for early obesity prevention in AI communities and showed several significant improvements in health behaviors. Multiple communities are working to sustain intervention efforts. This trial was registered at clinicaltrials.gov as NCT01776255.
Curr Dev Nutr 2019;3:nzy087.

Introduction

American Indians (AI) experience severe health inequities, including high rates of cardiovascular disease, type 2 diabetes, and cancer, that are due in part to high rates of obesity (1, 2).

Keywords: childhood obesity, American Indian, nutrition, physical activity, stress, sleep, prevention, family-based intervention

Manuscript received July 5, 2018. Initial review completed September 13, 2018. Revision accepted November 9, 2018. Published online November 16, 2018.

Primary work was conducted in the Department of Family Medicine and Community Health, School of Medicine and Public Health, University of Wisconsin, Madison, WI.

Supported by NIH NHLBI R01HL114912 to AKA. The trial was registered at clinicaltrials.gov as NCT01776255.

Author disclosures: EJT, RJP, KAC, KK, TP, and AKA, no conflicts of interest.

Published in a supplement to *Current Developments in Nutrition*. This article appears as part of the supplement "Proceedings of the First and Second Annual Conferences on Native American Nutrition," sponsored by the Shakopee Mdewakanton Sioux Community's Seeds of Native Health campaign through a gift to the University of Minnesota. The guest editors of the supplement, Treena Delormier and Mindy Kurzer, have no conflicts of interest. The opinions expressed in this publication are those of the authors and are not attributable to the sponsors or the publisher, Editor, or Editorial Board of *Current Developments in Nutrition*.

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Abbreviations used: AI, American Indian; FNPA, Family Nutrition and Physical Activity screener; F/V, fruits/vegetables; HCSF, Healthy Children, Strong Families; HCSF2, Healthy Children, Strong Families 2; MVPA, moderate-to-vigorous physical activity; SSB, sugar-sweetened beverage.

Moreover, evidence suggests disparities in obesity begin early in life; AI preschool obesity rates are the highest nationally (21%) and continue to increase despite decreases observed for other population groups (3, 4). As with other minority communities, the reasons for these disparities are complex and include poverty, racism, historic trauma, rural isolation or urban loss of community connections, insufficient healthcare services, lack of access to healthy foods and physical activity opportunities, and high stress levels (5–7). AI children also have approximately twice the levels of food insecurity and type 2 diabetes in comparison to the averages for all US children of similar ages (8–10).

The high rate of obesity during early childhood represents a vital window for promoting healthy habits. Diet and physical activity are commonly identified as key obesity prevention targets (11), but other factors, such as sleep and stress, have been implicated in increasing the likelihood of weight gain (12, 13). In fact, both maternal and child-level stress are associated with an increased likelihood of overweight and obesity in children (13, 14). However, coping responses to stress can be modified to diminish the potential negative effect (15–17), suggesting stress should be considered when designing obesity interventions (9). With regards to sleep, short sleep duration has been associated with obesity in people of all ages, with evidence strongest for children and young adults (18). For young children, the majority of decisions regarding food, activity, and sleep behaviors are significantly influenced by parents/caregivers, highlighting the importance of the family context in understanding and mitigating obesity risk (19, 20). However, previous reviews of best practices in obesity prevention showed a limited number of interventions in the home environment (21–24), with very few interventions conducted in AI communities (25) or targeting children ages <5 y (26). In addition, neither stress nor sleep has been addressed in interventions for AI families with young children.

Despite facing significant health disparities, AI communities are reviving traditional culture and language, and many AI community-based health programs seek to improve the health of their people by utilizing this resiliency. This interest in and commitment to community health and well-being enabled the research team to successfully partner with multiple AI communities in Wisconsin to test the efficacy of the Healthy Children, Strong Families (HCSF) toolkit, which addressed diet and physical activity targets, to prevent obesity and improve related health behaviors within the family context (27). Based on positive results in HCSF and to address the gap in home-based interventions targeting a wider range of obesity risk factors (28), the HCSF intervention was expanded to also address stress and sleep and to include new social support mechanisms to support families to make healthy behavior changes (29, 30). The objective of the Healthy Children, Strong Families 2 (HCSF2) randomized controlled trial was to test the efficacy of the expanded intervention to mitigate obesity risk in both urban and rural AI families. The research team partnered nationally with 4 reservations and 1 urban site serving AI patients to conduct this trial; sites were selected to include a range of geographic conditions (extreme rural to urban) and involved communities with whom the research team had working relationships. An urban site was selected because although the majority of people who identify as AI report living outside of reservations, most federal-level surveys and smaller obesity prevention studies that include AI participants are reservation based. Consequently, little is known about obesity risk involving AI families in urban areas (31). We hypothesized the HCSF2 intervention would improve obesity-associated health behaviors and improve or maintain weight status in AI children and adults compared with a child safety focused toolkit control. This article presents results after Year 1 of the HCSF2 randomized controlled trial. The trial was registered at clinicaltrials.gov as NCT01776255.

Methods

Design

HCSF2 employed a modified crossover design whereby adult/child dyads were randomly assigned to an obesity prevention intervention (*Wellness Journey*) or an active control group focused on child safety (*Safety Journey*). The study design has been fully described previously (29). Briefly, a sample size of 450 dyads was determined based on changes in adult BMI (measured in kg/m^2) and child BMI z-score (primary outcomes) to detect an effect size of 0.28 at a significance level of 0.05 with power 0.76–0.81, assuming 10–20% dropout at Year 1 (27, 29). Stratified randomization by study site was used to balance study arms on child weight status ($\geq$85th BMI percentile compared with <85th percentile) based on child height and weight obtained at the pre-enrollment visit using the randomization module of the REDCap database application (32). Randomization was conducted by a centralized study coordinator after baseline enrollment data were collected by local site coordinators at each study site. Site coordinators were not blinded to study arm for the postintervention/Year 1 data collection due to in-person delivery of intervention Lesson 1 and administration of the *Wellness Journey* Facebook group. Data input and analysis were conducted by study personnel who were blinded to group assignment. After Year 1, dyads switched arms so that all families received both *Journeys* for 1 year. Dyads randomly assigned to the *Wellness Journey* first continued to receive social support throughout Year 2; therefore, HCSF2 was not a true crossover design. This decision was made with community-based participatory research principles and was based upon community desires to ensure all families had access to the *Wellness Journey* intervention. For this reason, we report the results of Year 1 as the randomized controlled trial of the *Wellness Journey* compared with the *Safety Journey*.

Participants

Staggered recruitment occurred at 4 tribal reservations (1 in the northeastern US, 2 in the upper Midwest, and 1 in the northern mountain region) and 1 southwestern urban clinic serving a primarily AI population. Primary recruitment strategies included informational flyers sent home with children in tribal-based childcare/Head Start and active outreach by community-based site coordinators. Exclusion criteria were minimal to support the inclusiveness valued by the participating communities and the underlying philosophy of our research program. Inclusion criteria were an adult enrolling themselves and a dependent child aged between 2 and 5 y, and a working cell phone to receive text messages. The adult or child were not required to be AI and the adult did not have to be the biological parent of the child. All study protocols were approved by the University of Wisconsin Institutional Review Board, local tribal councils, and tribal Institutional Review Boards, when requested. Adults provided written consent for themselves and their participating child.

Intervention

The *Wellness Journey* toolkit consisted of 12 monthly mailed healthy lifestyle lessons, items, and children's books addressing 6 intervention targets: increase fruit and vegetable (F/V) consumption, decrease sugar consumption, increase physical activity, decrease screen time, improve sleep habits, and decrease stress (adult only). Each monthly toolkit included (*1*) printed educational lessons with information and suggestions for activities, (*2*) supportive items (e.g., measuring cups, recipes, pedometers, games), and (*3*) a children's book relating to one of the intervention targets to foster family interaction. *Wellness Journey* adult participants were supported by social media engagement via 2 weekly text messages and invitation to an optional, site-specific Facebook group where intervention targets were discussed. The *Safety Journey* consisted of 12 monthly mailed safety newsletters and related materials (e.g., safety reflectors for biking, cabinet safety locks). Both the original HCSF and expanded HCSF2 toolkits were developed and tested collaboratively with Extension specialists, content experts, tribal wellness staff, and AI community members, with specific attention to literacy level and the cultural and social relevance for different tribes of the lesson materials, activities, goals, and incentives (29, 33).

Outcomes

Physical measurements (height, weight, and waist circumference) were collected according to standardized protocols and converted to age- and sex-specific BMI percentiles for children (34) and adult BMI for adults (35). Adult participants who were pregnant were excluded from weight and waist circumference measurements and provided self-reported prepregnancy weight ($n = 27$). Health behaviors related to the intervention targets were measured: participating adults completed a packet of validated self-report surveys that assessed adult and child diet (36, 37) and physical activity (38, 39), family home environment (40) [with two validated questions on food security (41)], adult stress and other psychosocial measures (42, 43), and adult cultural identity (44). The research group created or adapted additional surveys to assess adult and child health history, sleep, screen time use, social media use (adult only), and readiness to change health behaviors (adult only). All measures (i.e., anthropometrics and surveys) were completed at baseline and after Year 1, with adults completing all surveys for themselves and the participating child. Families were given a $50 gift card for each data collection visit. In addition, each participating family was mailed a letter summarizing the baseline results for themselves and their child along with information for follow-up, if desired.

Qualitative participant feedback

We employed two methods to assess acceptability and utility of the intervention among participating families. First, upon study completion, participating adults were asked 2 open-ended questions, "What have you and your child found to be most useful/least useful about the mailed *Wellness Journey* toolkits?" Second, after study completion, we conducted 5 focus group sessions involving ~5–7 adult participants per session ($n = 15$ total from 2 rural sites, $n = 20$ total from the urban site) regarding their experience with the intervention and support and barriers to making healthy lifestyle changes. A focus group discussion guide was developed before the sessions to ensure consistency, and sessions were moderated by community site coordinators and study staff. Discussions were transcribed by a third-party and analyzed for major themes using an inductive approach (45).

Statistical analyses

Analysis of continuous variables was conducted using repeated measures analysis of variance with study arm (*Wellness Journey* compared with *Safety Journey*) as the between subjects factor. Due to the large number of diet variables produced by the screener, the multivariate technique of principal component analysis was used to determine optimal groupings of variables to maximize the amount of variance explained through such combinations (46, 47). Additional weighting using oblique rotation was applied to maximize the correlation of components with their constituent variables and to reduce the correlation with nonconstituent variables. The method of Trude et al. (48) was used to construct the dietary pattern scales. All analyses were performed using SPSS v.23 (IBM Statistics) with significance set at $P < 0.05$.

Results

During recruitment, 659 adults completed interest forms and 527 participated in the initial screening. Twenty-five failed the initial screen, resulting in 502 eligible participants. Of these, we were unable to collect complete baseline data on 52 families, resulting in 450 adult/child dyads enrolled (100% of recruitment goal). Baseline data were collected between February 2013 and April 2015, and Year 1 data between February 2015 and April 2017. At the end of Year 1, dropout was 16.4% and did not differ by study arm. Dropouts refer to families who failed to complete the Year 1 data collection visit, who voluntarily withdrew from the study, or for whom mailed materials were returned; dropout was attributed primarily to unavoidable circumstances (e.g., relocation, incarceration, loss of custody). At baseline, mean child age was 3.3 ± 1.1 y (50.2% female), with 39.8% overweight/obese; mean adult age was 31.4 ± 8.4 y (94.7% female), with 82% overweight/obese. Among all families, 57% reported family income <$20,000/year, with a high prevalence of reported household food insecurity (61%). Baseline demographics by study arm, *Safety Journey* compared with *Wellness Journey*, are shown in **Table 1**. Baseline variables and predictors of weight status have been reported in detail elsewhere (49) and did not differ between study arms at baseline.

Healthy lifestyle outcomes

Diet.

At baseline, 6 patterns were determined for adults ('fast food', 'healthy food', 'sweets', 'cereal and milk', 'animal protein', 'other') that explained 82.5% of the model variance and 4 for children ('nonhealthy foods', 'healthy foods', 'nonhealthy beverages', 'healthy beverages') that explained 56% of the model variance. Comparable categories were significantly correlated between adult and child data (e.g., adult 'fast food' with child 'nonhealthy foods', $r = 0.519$, $P < 0.05$; adult 'healthy foods' with child 'healthy foods', $r = 0.543$, $P < 0.05$). When the food patterns were combined to create an overall healthy diet pattern variable, the *Wellness Journey* group had a significantly greater post-intervention improvement compared with the *Safety Journey* group for both adults (−0.02 ± 0.76 to 0.20 ± 0.68 [change of +0.21] for *Wellness*

TABLE 1 Selected participant demographics by study arm at baseline (*Safety Journey* compared with *Wellness Journey*)[1]

	Safety Journey (*n* = 225 dyads)	*Wellness Journey* (*n* = 225 dyads)
Adult age, y (mean ± SD)	31.3 ± 9.1	31.4 ± 7.8
Child age, mo (mean ± SD)	44.1 ± 13.2	45.9 ± 12.8
Adult sex, female (n, %)	213, 94.7%	213, 94.7%
Child sex, female (n, %)	111, 49.3%	115, 51.1%
Adult education (n, %)		
High school equivalent or less	86, 38.2%	83, 36.9%
Some college or associate degree	115, 51.1%	120, 53.3%
College degree or postgraduate	24, 10.7%	22, 9.8%
Family income (n, %)		
<$5,000	63, 28.4%	69, 31.7%
$5,000–19,999	63, 28.4%	61, 28.0%
$20,000–34,999	49, 22.1%	45, 20.6%
≥$35,000	47, 21.2%	43, 19.7%
Adult Race (n, %)		
AI/AN	177, 78.7%	191, 84.9%
White	42, 18.7%	35, 15.6%
Other	6, 2.6%	5, 2.2%
Adult Ethnicity, Hispanic/Latino (n, %)	30, 13.3%	21, 9.3%
Child Race (n, %)		
AI/AN	190, 84.4%	200, 88.9%
White	44, 19.6%	45, 20%
Other	14, 6.2%	10, 4.4%
Child Ethnicity, Hispanic/Latino (n, %)	46, 20.4%	34, 15.1%
Adult BMI, kg/m^2 (mean ± SD)	31.8 ± 7.0	32.3 ± 8.7
Child BMI percentile (mean ± SD)	72.2 ± 26.7	69.9 ± 27.0

[1]AI/AN, American Indian/Alaska Native.

Journey and 0.05 ± 0.65 to 0.04 ± 0.62 [change of −0.005] for *Safety Journey* at baseline and Year 1, respectively; $P = 0.009$) and children (−0.01 ± 0.72 to 0.15 ± 0.70 [change of +0.16] for *Wellness Journey* and 0.05 ± 0.63 to 0.05 ± 0.07 [change of +0.007] for *Safety Journey* at baseline and Year 1, respectively; $P = 0.008$).

Adults in the *Wellness Journey* reported a significant increase in servings/wk (7 d) of F/V from 16.2 ± 12.0 to 18.5 ± 14.0 compared with baseline and Year 1 values for *Safety Journey* adults of 16.1 ± 13.4 and 14.9 ± 10.2 ($P = 0.007$). There were no significant intervention effects for adult sugar-sweetened beverage (SSB) intake. *Wellness Journey* children had a nonsignificant mean increase in F/V servings/wk of 1.6 (18.0 ± 12.1 to 19.6 ± 13.3) compared with 0.6 (15.4 ± 10.4 to 16.0 ± 9.8) in *Safety Journey* children, as well as a decrease of 1.2 servings/wk of SSB (9.8 ± 10.4 to 8.6 ± 8.9) compared with no change in *Safety Journey* children (8.0 ± 8.5 to 8.1 ± 8.5).

Physical activity, screen time, and sleep.

Adults in the *Wellness Journey* self-reported a significant increase in 15-min bouts of moderate-to-vigorous physical activity (MVPA) compared with adults in the *Safety Journey* (3.60 ± 3.79 to 4.91 ± 3.78 for *Wellness Journey* and 3.85 ± 3.65 to 3.90 ± 3.51 for *Safety Journey* at baseline and Year 1, respectively; $P < 0.001$). There were no significant differences between study arms for child physical activity, adult/child screen time, or adult/child minutes of weekday and weekend sleep (**Table 2**). Child total sleep time among all participants was significantly below national norms (50).

Weight status.

There was no difference between *Wellness* or *Safety Journey* groups for adult BMI or child BMI z-score after Year 1; values are listed in Table 2. However, child BMI z-score was stable with a trend towards a decrease in the *Wellness Journey* group (nonsignificant). In addition, food secure *Wellness Journey* children had a loss of −0.07 BMI z-score, whereas food insecure *Wellness Journey* children had a gain of 0.12 BMI z-score (nonsignificant).

Psychosocial factors (Table 3).

Wellness Journey adults reported significant increases in readiness to change the following health behaviors compared with *Safety Journey* adults: increase physical activity ($P = 0.019$), increase F/V consumption ($P = 0.037$), decrease screen time ($P < 0.001$), and obtain adequate sleep ($P = 0.012$), with a trend for decreased added sugar ($P = 0.074$). *Wellness Journey* families also had a trend toward significant improvement in the family environment for nutrition-related behaviors compared with *Safety Journey* families ($P = 0.057$) as assessed by the Family Nutrition and Physical Activity Screening Tool (FNPA) (40). Changes in self-rated quality of life and perceived stress, assessed in adults only, were not significantly different between *Wellness Journey* and *Safety Journey* adults.

Qualitative outcomes: family response to intervention

Results from 5 focus groups and from written participant feedback forms indicated a high level of satisfaction with the intervention, including the Facebook and text message components. *Wellness Journey*

TABLE 2 Health behaviors at baseline and after Year 1 for *Safety Journey* and *Wellness Journey* families[1]

	Safety Journey, Baseline	*Safety Journey*, Year 1	*Wellness Journey*, Baseline	*Wellness Journey*, Year 1	*P* value
Adult					
MVPA, 15- min bouts per week	3.85 ± 3.65	3.90 ± 3.51	3.60 ± 3.79	4.91 ± 3.78	0.001
Screen time, total min/d	173.52 ± 157.6	157.61 ± 157.2	198.91 ± 209.8	161.88 ± 165.2	0.305
Weekday sleep, h	8.00 ± 1.42	8.13 ± 1.46	8.04 ± 1.57	8.16 ± 1.46	0.660
Weekend sleep, h	8.66 ± 1.50	8.49 ± 1.48	8.48 ± 1.62	8.54 ± 1.54	0.181
SSB intake, servings/wk	13.3 ± 11.7	12.1 ± 10.8	15.2 ± 13.3	13.02 ± 11.8	0.472
F/V intake, servings/wk	16.1 ± 13.4	14.9 ± 10.2	16.2 ± 12.0	18.5 ± 14.0	0.007
BMI, kg/m^2	31.64 ± 6.94	31.54 ± 6.70	32.64 ± 9.05	32.96 ± 9.29	0.46
Child					
Physical activity score	24.19 ± 3.40	24.22 ± 3.60	24.03 ± 3.87	24.11 ± 4.07	0.950
Screen time, total min/d	122.91 ± 115.0	119.60 ± 126.3	124.35 ± 116.8	109.07 ± 95.3	0.319
Weekday sleep, h	10.16 ± 1.08	10.14 ± 0.97	10.08 ± 1.08	10.10 ± 0.87	0.422
Weekend sleep, h	10.26 ± 1.07	10.19 ± 1.14	10.27 ± 1.14	10.25 ± 1.06	0.656
SSB intake, servings/wk	8.0 ± 8.5	8.1 ± 8.5	9.8 ± 10.4	8.6 ± 8.9	0.209
F/V intake, servings/wk	15.4 ± 10.4	16.0 ± 9.8	18.0 ± 12.1	20.0 ± 13.3	0.414
BMI z-score	0.80 ± 1.11	0.80 ± 1.10	0.78 ± 1.06	0.76 ± 1.04	0.513

[1]Values are mean ± SD unless otherwise noted. F/V, fruits/vegetables; MVPA, moderate-to-vigorous physical activity; SSB, sugar-sweetened beverage. Child physical activity score was determined from the Netherlands Physical Activity Questionnaire for Young Children, with a higher score indicating higher activity. Sample sizes ranged from 172 to 199 for *Safety Journey* and 176 to 199 for *Wellness Journey*, depending on the variable. The *P* value indicates significance of the time by group interaction term as determined by repeated measures analysis of variance, with intervention arm/group as the between subjects factor.

families reported spending more time together as a family reading and doing activities after the HCSF2 intervention. Parents reported they appreciated receiving the materials by mail because it got their child excited to receive a package, which facilitated child engagement with the lessons. Moreover, mailed lessons allowed them to learn at their own pace without requiring them to attend a meeting or class. Getting a book with every lesson was especially appreciated, and parents reported spending more time reading with their child, particularly on health-related topics. Participants also related high satisfaction with the *Safety Journey* and may not have distinguished between the two *Journeys*. Saturation in themes was reached with the 5 focus groups.

When asked at the end of Year 1 how long they spent reviewing the lessons each month, 38.9% of participants said 30 min or more, 40.9% said 15–30 min, and 20.2% said 5–15 min. When asked how much time they spent doing the activities described in the lessons, 49.0% said 30 min or more, 34.8% said 15–30 min, 15.2% said 5–15 min, and 1% said they did not do the activities. An open-ended question on the feedback form asked if there was anything preventing healthier choices; 41% of participants who responded said "time"; 18% said "money"; and 41% identified some other issue, such as physical limitations, uncooperative family members, old habits, and lack of willpower. Multiple participants requested opportunities to connect

TABLE 3 Psychosocial factors at baseline and after Year 1 for *Safety Journey* and *Wellness Journey* families[1]

	Safety Journey, Baseline	*Safety Journey*, Year 1	*Wellness Journey*, Baseline	*Wellness Journey*, Year 1	*P* value
Readiness to Change					
Increase physical activity	3.63 ± 1.05	3.70 ± 1.01	3.63 ± 1.08	4.04 ± 0.83	0.019
Increase fruits/vegetables	3.82 ± 0.90	3.98 ± 0.88	3.90 ± 0.90	4.31 ± 0.68	0.037
Decrease screen time	3.07 ± 1.31	3.28 ± 1.31	3.01 ± 1.29	3.73 ± 1.18	<0.001
Decrease sugar intake	3.72 ± 1.11	3.85 ± 1.10	3.70 ± 1.18	4.15 ± 0.90	0.074
Manage stress	3.60 ± 1.06	3.75 ± 1.03	3.70 ± 1.10	3.88 ± 0.94	0.689
Obtain adequate sleep	3.62 ± 1.08	3.67 ± 0.99	3.60 ± 1.08	3.96 ± 1.00	0.012
Adult Perceived Stress (PSS)	16.20 ± 6.04	14.60 ± 6.66	16.48 ± 6.33	15.02 ± 6.56	0.826
Adult SF-12 Score					
Physical health component	50.31 ± 7.42	49.85 ± 7.67	48.53 ± 8.52	48.52 ± 8.85	0.567
Mental health component	46.82 ± 9.21	48.71 ± 9.82	46.66 ± 10.44	48.87 ± 9.84	0.767
Home Environment (FNPA)					
Total score	61.33 ± 7.41	62.84 ± 7.13	61.72 ± 7.55	64.20 ± 6.50	0.136
Nutrition domain	3.21 ± 0.38	3.24 ± 0.34	3.23 ± 0.35	3.32 ± 0.31	0.057
Physical activity domain	2.89 ± 0.47	3.03 ± 0.45	2.92 ± 0.50	3.08 ± 0.43	0.539

[1]Values are mean ± SD. Sample sizes ranged from 172 to 199 for *Safety Journey* and 176 to 199 for *Wellness Journey*, depending on the variable. The *P* value indicates significance of the time by group interaction term as determined by repeated measures analysis of variance, with intervention arm/group as the between subjects factor. FNPA, Family Nutrition and Physical Activity Screening Tool; PSS, Perceived Stress Scale; SF-12, 12-item Short Form Health Survey.

with other families participating in HCSF2 in a "real world" setting, highlighting that social and environmental supports are needed to reinforce family learning to make and sustain healthy lifestyle behaviors. There was variability in social media engagement among sites, with the urban site being much more engaged than the rural sites; this difference may be due to Facebook bullying that community partners have anecdotally reported to occur in smaller communities. Participants indicated the most useful posts were about recipes and expressed a desire to learn more about how to cook with F/V and how to preserve food (freezing/canning). Text messages were consistently reported to be helpful as a reminder to stay on track, and participants also liked the motivational messaging. **Table 4** details representative participant focus group comments by theme.

Discussion

Healthy Children, Strong Families 2 is the first trial of a family-based healthy lifestyle intervention for AI families with young children and represents one of the largest obesity prevention intervention trials involving AI participants. Our approach was novel for the use of a home-delivered healthy lifestyle intervention aimed at both adults and young children, which promoted family interaction and early health literacy and was highly acceptable to families. Moreover, HCSF2 is the first obesity prevention trial to include both urban and rural AI families. This factor is significant, as we previously demonstrated significant differences between urban and rural families in this sample with regards to food insecurity, diet patterns, and obesity (51). The significant changes in some key health behaviors and readiness to change these behaviors seen in families after participating in the HCSF2 *Wellness Journey* are encouraging and are similar to other low-intensity interventions (52, 53).

After the intervention, we observed significant improvements in adult and child diet patterns, adult F/V intake, and in the home nutrition environment. Nonsignificant but important improvements in child F/V intake and SSB consumption also were observed. For diet variables, we used a method previously employed in AI communities (48) to look at overall diet patterns among participants. The construction of dietary patterns using this method depends on the foods included in the model, and the resulting value is more difficult to interpret than standardized measures, such as the Healthy Eating Index (54). For this reason, data on specific food groups that were targets of the intervention (i.e., F/V, SSBs) are also reported in addition to the diet pattern scores, as these specific foods are easier to interpret in servings per week. Given the potentially small biological significance of the observed changes (e.g., increase of approximately one-third of a serving of F/V per day for *Wellness* adults), the principal component analysis method was employed to provide an indication of change in broader dietary patterns that may not be captured at the individual food or food group level.

In addition to health behavior changes, we observed significant improvements in readiness to change multiple health behaviors for the *Wellness Journey* families. Previous work suggests this variable is associated with significant levels of subsequent behavior change (55–57). Families were highly engaged with the HCSF2 intervention materials as evidenced by comments at the end of study surveys and focus groups. This high level of engagement may partially explain the increase in both health behaviors and in the readiness for health behavior change. Similar to HCSF, families in HCSF2 reported spending more time together as a result of the intervention (27). This significant increase in readiness to change health behaviors among families receiving the intervention may indicate that additional behavior change could be expected beyond the Year 1 timeline reported here.

Maintenance of weight status (i.e., prevention of weight gain or weight status crossing) or weight loss were hypothesized outcomes as a result of study participation. Importantly, child weight status was stable during Year 1 of the intervention, with a trend for a decreased BMI z-score in *Wellness Journey* children. Of note, HCSF2 was not designed as a weight loss study: current weight status was not an inclusion/exclusion criterion for the study, and 60% of the children were within normal weight range at baseline. The *Wellness Journey* therefore emphasized health and wellness rather than focusing on weight. Moreover, recent evidence suggests BMI may not be a sensitive indicator of adiposity in overweight and obese children (58) or an appropriate marker of changes in body fat over time (59). Other methods, such as dual X-ray absorptiometry, may be more accurate but are difficult to implement in community-based research studies due to cost, participant burden, and geographic distribution of study sites. Less expensive methods, including skinfold thickness and waist circumference, are subject to large error in pediatric populations (59, 60). Biomarkers of both body composition and diet intake that can be used within community research settings are needed to overcome limitations of commonly used approaches.

A home-based obesity prevention intervention for Latino preschoolers reported by Taverno Ross and colleagues detailed very similar findings to ours, with no changes in adult or child weight parameters despite significant improvements in adult and child health behaviors (52). Another study, the CHILE multi-level obesity prevention trial targeting preschool AI and Hispanic children in Head Start settings, found no changes in BMI z-score after a 2-y intervention (61); although this study included a family engagement component, adult-level variables were not assessed. Other studies have shown reductions in BMI percentile in older children after a family focused obesity intervention (62). Of note, the US Preventive Services Task Force recommends a total of 26 or more high-intensity clinical contact hours over a period of 2 to 12 mo for successful weight loss to occur in children (63). In light of this recommendation, the behavior changes seen in HCSF2 are reasonable given the intervention intensity as well as the severe resource constraints of many AI families and communities that might prevent access to high-intensity clinical contact.

Specific to resource constraints, our findings of considerable food insecurity and poverty among HCSF2 families reflect the difficulty of making healthy lifestyle changes within significantly economically challenged communities. In particular, food insecurity was associated with less optimal diet patterns in HCSF2 families (51) and in other populations (64), and in other health-related behavior changes in response to the intervention. Other issues include the importance of community support for healthy behavior change among families, as multi-component interventions (65–67) have been shown to be more successful than individual interventions. A review of 3 AI multi-level environmental interventions revealed that AI chronic disease prevention strategies appeared to be successful when they functioned at multiple levels, including environmental and individual levels, and

TABLE 4 Themes and sample participant comments from focus group sessions

Families reported meaningful benefits from HCSF2 participation.	• I have grown to love this program because this program has been there for me when I had no clue of what to do or know to go about life. This program has helped me to be a better parent to my children and it has bettered my view of life. It has given me a very good chance to have a great recovery from alcohol. It helped me to figure out what to do with my children. It has given me great ideas about how to recap my connection with my children. It up lifted my spirit knowing that I'm not the only one with many problems. But this has given my outlook in life back to me. I thank you for the support in everything that this program has given to me and my child. I feel so much better within myself. And so does my child. This program has given me and taught me many things that I have lost when I was a drunk. So thank you for helping me out to be a better person and showing me a different and a healthier life style. • I learned a lot and this program helped keep me motivated to stay eating healthy and be more physically active. I now eat veggies every day and I cook dinner more and watch a lot less TV and actually we don't even watch TV more than 2 times a week. • I want to say I am glad I got to participate in this program. It has been a lot of fun, we all learned from it, and it brought us closer together as a family. Thanks to this wonderful program, we have many new activities/games for the summer. We have new recipes that are healthy, the kids can help with, and that we actually like! This program has not only helped my partner and me, but my youngest too! Both boys and I have learned so much! Thank you for helping us become closer and grow as a family. • We loved how activities kept us active and always having something to do. My daughter always liked getting the mail from HCSF. Keeps her super busy with things to do and cook! Mmmm! Thank you so much!
Intervention materials were well-received.	• Good choices on books…we enjoyed reading them together…and my daughter was engaged and asked questions. • My daughter loved playing all the games; we would talk about the lesson, and then play the game. She also loved the cooking and being able to help. • I found this program to be very helpful and I loved all the information I received, the fun activities to do, and all the recipes to try.
Families reported commitments to making healthy choices for their family and desire to serve as positive role models.	• So, I wanted to teach them how not to eat all that junk food, and to replace it with healthy foods and then the activities for them. • The program was a nice reminder that it's important for me to be the role model for my kids – but also that they help keep me on track…like they ask before they eat things 'is this healthy?' and they ask for water or milk instead of pop when we go out. • You have to think of them and their future. I think the name of the program is good, "Healthy Children, Strong Families" because if I'm not teaching them good habits now, what will their family look like in the future? • I am very pleased with this program. It taught me a lot about healthy habits…it was hard at times when I realized that I needed to change and work on being healthier without using any excuses or blaming others. • Now I know to make sure that half their plate is for fruits and vegetables… and they are eating them, so that's one thing I like. • It was like very small, little steps, even with the healthy food, the eating healthy and cooking using fresh vegetables…you weren't asking us to change everything all at once. And it was fun to have the kids help decide new things they want to try when we're at the grocery store.
Families are setting limits for screen time and recognizing the link between screen time, sleep, and the amount of food advertising on TV.	• What really helped me about the sleep schedule was actually being thoughtful about transition time…so we start winding down and turn off everything so we have time to brush teeth and get out our books and generally have quiet time so we're all ready for bed. • We were more aware that you have these commercials coming on – for food, for McDonald's, so you have the urge to go there…and the kids want to stop there when you're out driving around. I think turning off the TV has helped us avoid that. • The Sleep Tight lesson…it helped me a lot, getting my kids to go to bed, because I have one that doesn't really like to follow bedtime rules and routines, but that lesson really helped and now he goes to sleep with no problem.
Families face significant challenges to healthy lifestyles, including the high cost of food and stress.	• It's hard to change to eating healthy meals because healthy foods are expensive. • Hard to afford consistent supply of fruits and veggies in the house, especially at the end of the month. • I'm just used to being stressed out all the time. • It is always harder to make healthy lifestyle choices when I am sleep-deprived or have a lot of work to do. • We had a rough situation the past few months that have made it difficult.

when local stakeholders were engaged (68). Although not specific to AI communities, another recent study indicated that communities with high levels of community-based programs and policies supporting healthy behaviors were associated with lower BMI in children (69). Given the scope of this HCSF2 trial in 5 states, it was not possible to implement both home- and community-based approaches during the intervention. However, this represents an important future direction.

HCSF2 revealed promising healthy behavior changes, improved caregiver readiness to change, and resulted in a highly acceptable toolkit that led to positive family engagement. This work adds to the limited literature regarding home- and family-based obesity prevention interventions for young children in AI communities. Moreover, the inclusion of both adults and children, the geographic distribution of study sites from extreme rural to urban, the comprehensive intervention targets, and the high engagement of community partners throughout all phases of the project, and of families during the intervention, represent significant strengths of HCSF2. Limitations include the lack of objective measures of health behavior (e.g., accelerometry rather than physical activity surveys), and possible contamination from implementing a randomized trial in small communities. Other limitations include potential participant bias, as the local site coordinator was often personally known to the rural participants, and response bias, as survey packets were sometimes completed by participants in the presence of the site coordinator. However, >60% of the total number of families with children in the target age range were recruited from some of the rural communities, which may have minimized potential selection bias.

Future interventions for AI families with young children need to address both individual- and community-level support for change, particularly in addressing food insecurity and the role of historic and current trauma. Most of the participating communities are continuing to work on childhood obesity prevention, with one community implementing individual sleep and healthy behavior interventions; another working on community-wide policy, system, and environmental changes to support families; and the urban site working to sustain the program by continuing to provide intervention materials (e.g., toolkit lessons, books) in the clinic. The intervention team is also actively working on creative ways to disseminate the materials to communities to support additional families on their journey towards health based on the promising findings of the HCSF2 trial.

Acknowledgments

The authors' contributions were as follows—AKA, RJP, KAC, and TP designed the research; AKA, KAC, and EJT conducted the research; RJP and KMK analyzed the data; AKA and EJT wrote the paper; AKA had primary responsibility for the final content. All authors have read and approved the final manuscript.

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