The Children's Healthy Living (CHL) Center of Excellence

CHL STUDY DESIGN

Vol. 1 Individual-Level Data for the CHL Community Randomized Trial and FAS Prevalence Study

Developed by the CHL Data Work Group

for use in the CHL Pacific Region

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The Children's Healthy Living (CHL) Program

The Children's Healthy Living (CHL) Center of Excellence is a partnership among the remote Pacific jurisdictions of Alaska; American Samoa; Commonwealth of the Northern Mariana Islands (CNMI); the Freely Associated States of Micronesia (FAS) which includes the Republic of the Marshall Islands (RMI), Republic of Palau, Federated States of Micronesia (FSM); Guam; and Hawaii to study childhood obesity among Pacific children, ages 2 to 8 years. The program is sponsored by the United States Department of Agriculture (USDA), Agriculture and Food Research Initiative.

Figure 1 illustrates CHL's model to influence multiple aspects of the environment to promote healthy food intake and physical activity in young children ages two to eight years old. CHL aims to prevent early childhood obesity in the United States Affiliated Pacific.

CHL Program Objectives

To address the child obesity epidemic in the Pacific, the CHL Program has the following objectives:

1) Conduct program/data inventories and situational analysis;

2) Train 22 professionals and para-professionals in obesity prevention;

3) Develop a Pacific food, nutrition, and physical activity data management and evaluation system**,** using assessment data, and aggregate, display and communicate available data pertinent to young child obesity;

4) Develop and conduct a community-based environmental intervention to prevent, maintain, or reduce young child overweight and obesity;

5) Evaluate the environmental intervention; and

6) Incur at least one obesity prevention policy change per jurisdiction.

Figure 1. CHL Conceptual Model

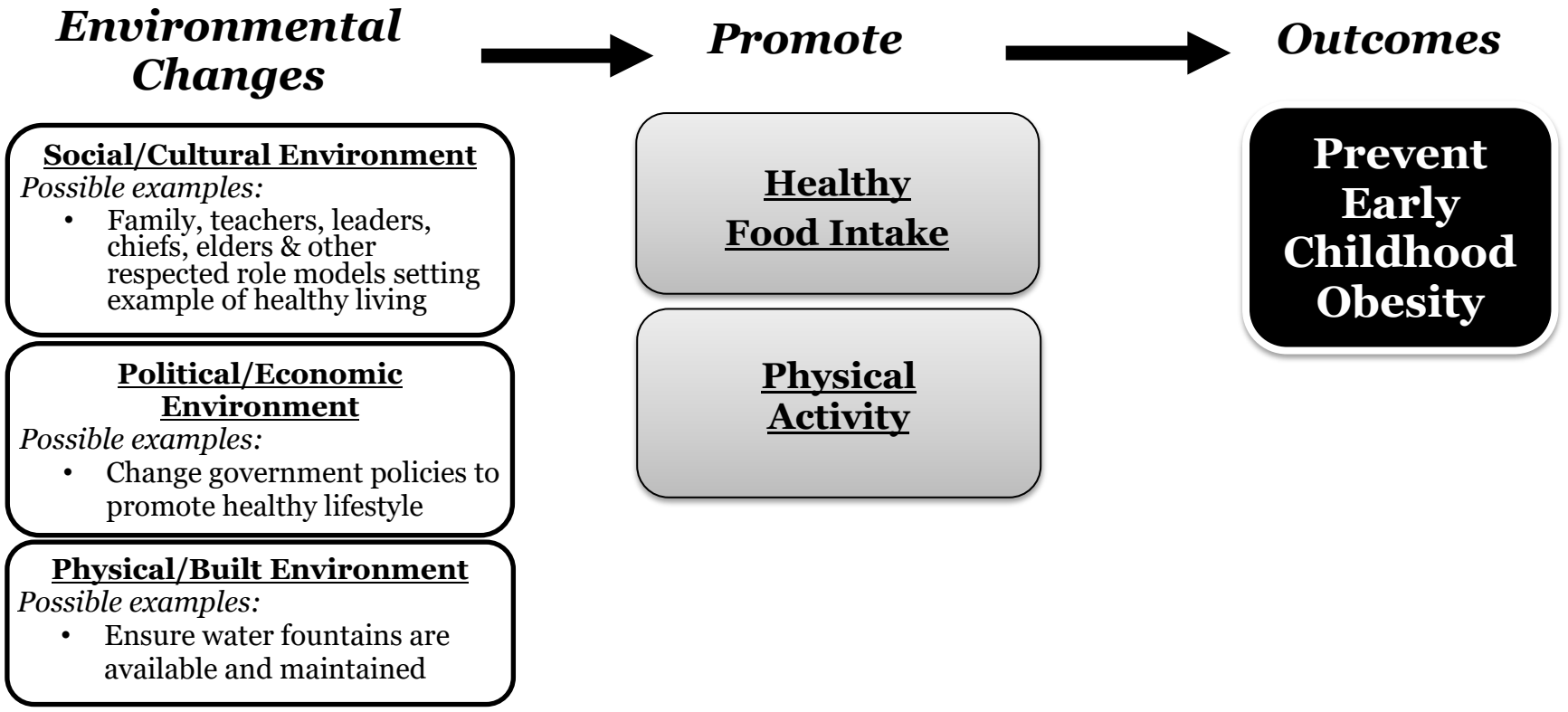

Figure 1. The Children's Healthy Living Program Model to Influence Multiple Aspects of the Environment to Promote Healthy Food Intake and Physical Activity in Young Children (2 -8 years) as a Method to Prevent Early Childhood Obesity in the U.S. Affiliated Pacific

CHL Study Design

The Children's Healthy Living Program Community Randomized Trial was designed to test the intervention by comparing intervention with non-intervention communities on the prevalence of obesity in the U.S.-affiliated Pacific region collected at Time 1 (baseline), Time 2 (follow-up), and Time 3.

Objectives of the CHL Community Randomized Trial and the FAS Prevalence Study

Community Randomized Trial

We are assessing behaviors and anthropometry of children in communities over time as indicators of whether the intervention led to change. Data has been collected at three time points – Time 1, Time 2 (post-intervention - about 24 months after baseline measurement), and Time 3 at the end of the CHL community randomized trial.

Objectives for the Community Randomized Trial

- Measure 2 to 8-year-old children at Time 1 and Time 2 in selected communities to track behaviors and anthropometry that indicate healthy eating, physical activity, and BMI.
- Decrease the prevalence of young child overweight and obesity by 5%, or a reduction in 0.08 of BMI z-score;
- Decrease the functional outcomes of young child overweight and obesity –
    - decrease acanthosis nigricans by 5%,
    - and increase sleep by 15 min/day;
- increase moderate to vigorous physical activity by 10 min/day
- and decrease sedentary behavior (screen time) by 10 min/day;
- increase healthy eating (fruit and vegetable intake by 1 serving/day),
- increase water intake by ½ cup/day;
- decrease sweetened beverage intake by ½ cup/day,
- Develop a Pacific food, nutrition and physical activity data management and evaluation system

Objectives for the FAS Prevalence Study

- Provide a jurisdiction-specific prevalence of overweight/obesity and related exposures.
- Measure 2 to 8-year-old children at one time point in selected communities to track behaviors and anthropometry that indicate healthy eating, physical activity, and BMI.

CHL Study Design Overview

Figure 2. CHL Study Design Schematic

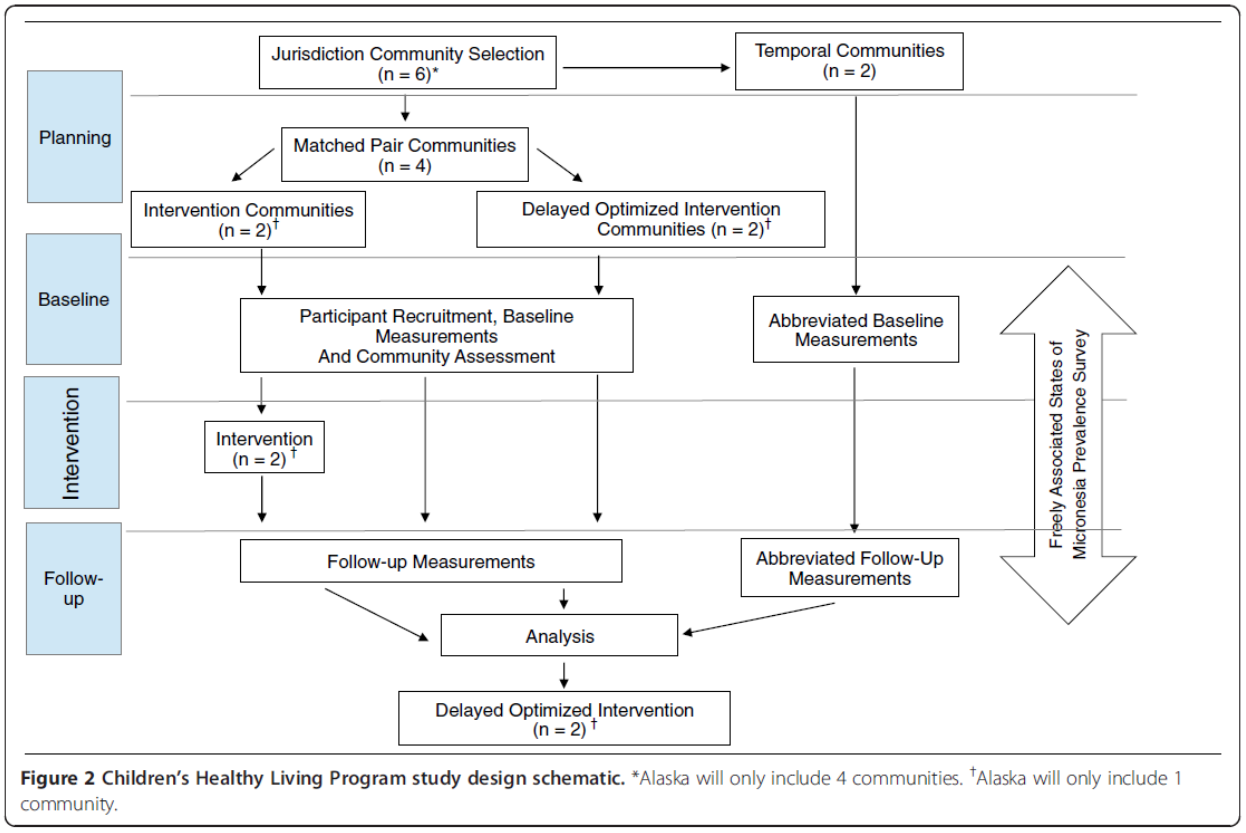

Figure 2 Children's Healthy Living Program study design schematic. *Alaska will only include 4 communities. †Alaska will only include 1 community.

Community / Site Selection

Communities were identified in Alaska, American Samoa, CNMI, Guam and Hawaii using the 2000 U.S. Census tract data, since 2010 data was not available at the census tract level (U.S. Census Bureau) in 2011 when sites were selected. In the FAS, 2010 country census data were used to inform selection of sites for prevalence survey data collection (Economic Policy, Planning, and Statistics Office of the Republic of the Marshall Islands, 2012; FSM Division of Statistics, 2010; Republic of Palau Office of Planning and Statistics, 2005). The CHL team first selected communities based on initial eligibility criteria and then considered additional selection criteria. Based on the following criteria, communities in each of the jurisdictions were selected to participate in the intervention trial.

Community eligibility criteria:

- population size of >1000,
    - Except for FAS
- >25% of the population of indigenous/native descent
    - Except 15% in **Alaska** due to no census tract with a population of more than 1000 having more than 25% indigenous/native,

and

- >10% of the population under age 10 years
    - (based on combining census tract data groups of < 5 years of age and 5 – 9 years of age)
    - to have sufficient population size for CHL target of 2 to 8 year olds.

Additional selection criteria:

- adequate settings for sampling and measuring children (e.g., schools);
- reasonable accessibility for the CHL team
    - (e.g., isolated communities that would require substantial travel logistics were excluded);
- community cohesiveness (Swinburn et al., 2007)

Additional selection criteria for intervention and delayed optimized (comparison) communities:

- evidence that children live and go to school in the same community
    - (i.e., not a commuter community),
- ensuring that the measured children have an opportunity to be exposed to the intervention;
- a minimal risk of contamination between matched-pair communities;
- sufficient settings for intervention (e.g., community centers, parks, churches, and stores)

Additional selection criteria for FAS:

- scheduled air or boat service, and geographical representation.

A list of all eligible communities was created for each of the jurisdictions based on the above criteria. The communities were matched to form pairs based on the following factors:

- percentage in poverty and population density (both from the U.S. census),
- distance from urban centers,
- and percentage overweight/obesity, when available.

In American Samoa, CNMI, Guam and Hawaii, four communities were selected (two matched-pairs), while two communities were selected (1 matched-pair) in Alaska due to large distances between sites (see Figure 2).

In each pair, one community was randomly assigned to intervention and the other to a delayed optimized intervention (community will receive intervention at the end of the main trial). Randomization to intervention, in general, produces study groups that are comparable with

respect to confounding variables (Friedman, Furberg, & DeMets, 1998). A statistician who was not part of the CHL team performed the randomization. The **delayed optimized intervention communities** will be called **comparison communities** in this CHL Data Dictionary.

Two additional non-matched communities (third and fourth for Alaska and fifth and sixth for other jurisdictions) were selected from the eligible list of communities to serve as temporal indicators of anthropometry status (see Figure 2). Generally, the communities selected for temporal assessment had been considered to participate as a matched pair; however, they often did not match another eligible community well or they had less community cohesiveness, which was not as important for a community providing prevalence information only. The temporal communities will not receive the intervention program as part of the CHL trial and early dissemination phase.

In the FAS region, the prevalence survey was intended to provide representative samples for each of 6 jurisdictions: Chuuk, Kosrae, Pohnpei, Yap, Palau and the RMI (n=200 children per location). To achieve geographic representation, the main population centers/islands were divided into sectors for sampling, with the number of children recruited in each sector proportional to number of children in the sector based on country-specific censuses. For the jurisdictions of Yap and RMI, a remote island was additionally sampled. Each FAS jurisdiction has a majority indigenous population and a relatively young population, and therefore meets the CHL criteria of >25% of the population of indigenous/native descent and >10% of the population under age 10 years. Availability of scheduled air or boat service was an additional selection criterion for sampling sectors in the FAS.

Thus, in total, four communities in Alaska and six communities in each of the remaining four CHL intervention jurisdictions were selected for a total of twenty-eight communities across the CHL region for participation in the CHL community intervention trial: 9 matched pairs (18 sites total) and 10 temporal sites.

A cross-sectional sample of children in each of the CHL intervention communities is being assessed for outcomes at Time 1 and Time 2 around 24 months from baseline. Additionally, the outcomes are being assessed once in the FAS region to provide prevalence information.

The intervention does not explicitly target the assessed children; they serve as representatives of their communities. Children who participate at both time points provide repeated measures and serve as an embedded longitudinal sample.

Power and sample size calculations

The process for sample size and power estimation was described in Wilken [*sic*] et al., 2013). Sample size estimates were based on the need for a sufficient number of communities and children in each of the five jurisdictions to ensure adequate statistical power to detect meaningful differences between intervention arms in overweight and related outcomes (listed

previously) overall and for select outcomes within jurisdictions. The effect size, Cohen's *d,* (Cohen, 1988) was calculated based on an analysis of 2,000 simulated data sets with children clustered within community clustered within jurisdiction. The intervention effect was tested based on an *F* test of the interaction term of intervention group and time from a mixed model of the outcomes, accounting for the clustering in a group-randomized trial (GRT) by adjusting the test degrees of freedom to the number of communities (Hsieh, 1988). The calculations assume a minimum *n* or sample size of 150 children with anthropometry and a minimum *n* of 100 children with accelerometry and food and activity logs in six communities in four jurisdictions and in two communities in Alaska; this assumption is conservative as the goal is a sample size of 180 children per community.

An expected correlation for communities within jurisdictions was low with an estimate of the interclass correlation coefficient (ICC) that varied between 0.02 to 0.04. We assumed a critical level of 0.05 (two-sided), a power of 80%, and a constant sample size at Time 1and Time 2 (around 24 months). The respective effect sizes for an ICC of 0.02 and 0.04 are modest at 0.26 and 0.35 for outcomes with n=150. Using means and variances for the outcomes from previous research (de Silva-Sanigorski , 2010; Murray et al., 2004; Westerlund, Ray, & Roos, 2009), the minimum detectable differences for the two ICC values were 0.09 and 0.12 for BMI z-score, 21 and 28 minutes of television viewing, and 11 and 15 minutes of sleep. The respective effect sizes for an ICC of 0.02 and 0.04 are also modest at 0.31 and 0.42 for outcomes with n=100. Using means and variances for the outcomes from previous research (de Silva-Sanigorski , 2010; Murray et al., 2004; Ludwig, Peterson, & Gortmaker, 2001; Vorwerg, Petroff, Kiess, Bluher, 2013), the minimum detectable differences for the two ICC values were 0.50 and 0.67 servings of vegetables, 0.45 and 0.61 servings of fruits, 0.45 and 0.60 servings of water, 0.34 and 0.46 servings of SSB, and 33 and 45 minutes of PA with metabolic equivalent values (METs) > 3, based on accelerometry.

Measures Overview

The CHL study design was to collect data on body size, functional outcomes of obesity, food intake, physical activity, lifestyle behavior which includes screen time, and demographics. These are measured through anthropometry, food and activity logs, questionnaires, and visual inspection (of the neck).

The following study outcomes were measured for children across jurisdictions using a common methodology:

Body size:

Body size measures included weight, height and waist circumference and the resultant calculations of BMI, percent overweight and obese. Trained staff in all jurisdictions **used standardized instruments, such as c**ommon scales for weight, stadiometers for height, and tape measures for waist circumference. Body size outcomes include overweight, defined as the 85th - 94th percentile for BMI (weight, kg/height, m2) and obesity, defined as greater than or equal to the 95th percentile for BMI (Centers for

Disease Control and Prevention, 2009), BMI Z-score and waist circumference. . During training sessions on anthropometry, inter- and intra-person reliability of each measurement, as well as agreement to a expert measurer, were determined. We followed guidelines by Zerfas to assess agreement (1986).

Functional outcomes of obesity

Functional outcomes of obesity (Ropka, 2002) included sleep quality and duration, both as minutes per night from the accelerometer and self-reported average duration, and presence of Acanthosis nigricans as an indicator of insulin resistance/pre-diabetes.

Dietary intake:

Information about food and beverage intakes and daily activities of children participating in CHL was collected using the dietary record method for Time 1 and Time 2. Time 1 included "other activities while eating" and activities of daily living. Time 2 included only the "other activities while eating." This method is useful when detailed information is recorded. The dietary record administered at time one for the intervention jurisdictions and at time one for the prevalence jurisdictions included collection of physical activity; thus, the tool was referred to as the "food and activity log" or FAL. The FAL was based on the Food and Physical Activity record used for Dr. Novotny's study Pacific Kids DASH for Health and the dietary records used in the dietary data collection conducted by Dr. Boushey as part of the CoASTAL cohort. Parents were asked to complete two days of food and activity logs (FAL) at baseline. Parents/caregivers were asked to complete the FAL for their children on two randomly assigned non-consecutive days, which included weekdays and weekend days, between visit 1 and 2. Assignment of recording days was based on the day of the child's first visit (Monday – Sunday). Standard techniques were used to improve accuracy of information recorded in the FAL. Parents/caregivers were instructed in record keeping techniques with the aid of food models, service ware, and utensils and were provided a tool kit of calibrated utensils (i.e., measuring cups and spoons); the FAL; and a zip-top bag in which to place food wrappers, labels, and packages (WLP) and school/childcare menus. CHL staff followed-up with reminder telephone calls. During visit two, research staff reviewed the FAL with the parents (e.g., for completeness of food entries, portion size estimation, food preparation methods, accuracy of recording data). These logs were used to estimate dietary intake over the two randomly assigned days. The information gathered in "real time" was used to measure progress toward the CHL objectives of increasing fruits and vegetables and water; and reducing sugar-sweetened beverages. From two 24-hour periods, the data will estimate foods and beverages and amounts each child consumes and will estimate prevalence of dietary patterns in the region.

Food and Activity Log (FAL):

The data fields within the FAL completed by the parent/caregivers included time (or time of eating occasion), detailed description of food and beverages, amount (or amount consumed), place prepared, place eaten, and other activities while eating. Extensive instructions were embedded in the FAL for all of the fields. In addition, a section for logging down recipes was included for parents/caregivers to describe homemade recipes.

Additional data collected in the FAL for Freely Associated States (FAS):

The FAL used for the FAS jurisdictions differed from the FAL used in the intervention jurisdictions study. Unique to the FALs used in the FAS with regard to data collection was the request to provide source information for all foods and water used as single items and as ingredients in prepared dishes. Examples of sources were provided in the FAL and shown below in Table 1. The FAL for the FAS jurisdictions included an additional portion size estimation aid for fish. Pictures of fish were included in the FAL representing three portion sizes by whole fish and cut pieces of fish. The additional aids for estimating fish intake were provided due to the importance of fish in the diet among the FAS jurisdictions.

Table 1: Examples of Source of Food on FAL in FAS

Purchase	**Communal/gift/donation**	**Local labor or self-labor**
Supermarket	Food bank / food pantry	Fishing
Restaurant	Field trip	Hunting
Road side stand / stall	Church gathering	Home garden
Convenience store	Government assisted	Personal farm
Grocery store	Gift from friend/relative	Community garden
Farmers' market	USDA Commodities	Commercial farm
Lunch wagon / food wagon	Funeral	Ocean gathering
Fish markets	Traditional event	Animal husbandry
Merchant/Cargo		Specify: non-purchase

Physical activity:

We measured physical activity with several strategies with which we have experience – accelerometers and physical activity logs.

We developed 24-hour activity logs to measure physical activity of children in the PacDASH study, which were successfully pilot-tested for children aged 3-5 years. At Time 1, parents/caregivers were asked to complete the FAL for their children on two randomly assigned non-consecutive days when food intake was recorded, which included weekdays and weekend days, between visit 1 and 2. Assignment of recording days was based on the day of the child's first visit (Monday – Sunday). In addition to recording the "other activities while eating," parents/caregivers were asked to record all activities for the child for the two assigned days which emphasized waking up and activities all the way through going to bed at the end of their day (i.e., activities of daily living). These activity logs provided us with the type and duration of each activity of their child. Trained CHL staff assigned a metabolic equivalent (MET) that reflected the energy expenditure for the child's activity (Ridley, Ainsworth, & Olds, 2008), and a 24-hour METs could be computed. Completion of the FAL

for Time 1 included “other activities while eating” and activities of daily living. Time 2 included only the “other activities while eating.”

Children were asked to wear accelerometers for six days in this study. In Year 1 of CHL, we pilot tested Actical accelerometers as a method to measure physical activity in young children to be used in the full study. Based on our successful CHL Physical Activity Pilot results, we used accelerometry at all sites (Nigg et al., 2012; Ettienne-Gittens et al., 2012, submitted). The CHL Coordinating Center (CCC) trained staff at each jurisdiction on use of the accelerometers before measurement began.

Food and Activity Log (FAL):

At Time 1, the activity data fields within the FAL completed by the parent/caregivers included start time, activity (or a description of the activity completed), and end time. Extensive instructions were embedded in the FAL for all of the fields. At Time 2, the activity data fields within the FAL were removed and only the “other activities while eating” was included.

PacTrac 3: Data Entry Application:

The Pacific Tracker 3 (PacTac3) database and web application is a modification of the MyPyramid Tracker developed by the U.S. Department of Agriculture’s (USDA) Center for Nutrition Policy and Promotion and the PacTrac2 modification by the UH Cancer Center and the Human Nutrition, Food and Animal Science (HNFAS) department. PacTrac2 modified the MyPyramid Tracker for collection of dietary data in the Pacific islands. Two modifications had been made to the existing MyPyramid Tracker: 1. The addition of a function to save entered data and allow data to be accessed at a later date. 2. The addition of foods specific to the diets of the Pacific Islands’ populations. PacTrac2 was modified for use in CHL and was designated as PacTrac3. This tool was used to input and analyze data collected from the food records. Pac Trac 3 generates two data tables that can be used for data analysis. The “heh” table includes derived food groupings, energy, and nutrients based on information recorded on the Food and Activity Log (FAL) and entered by CHL staff into PacTrac3. The heh file has one or two record days along with the dates of each record day per CHL ID. The “hei” table contains the names of the foods and beverages recorded on the FAL by the parents or caretakers. There is one data row per food/beverage entered associated with the user ID, record date, record time, and other relevant variables. The University of Hawaii Cancer Center’s Nutrition Support Shared Resource (NSSR) Food Composition Table (FCT) was used in PacTrac3.

Other questionnaires:

Parents / caregiver respondents for the children completed questionnaires about demographics, lifestyle measures and culture. Lifestyle measures included food security and food expenditures (USDA, 2008). In addition, parents/caregivers completed standardized questions about screen time, regarded as sedentary behavior and a lifestyle measure (Haas & Nigg, 2009).

Table 2 displays an overview of all the measures used for CHL, and the frequency of their use. The community level measures are described in Volume 2 of the CHL Data Dictionary.

Table 2: The Children's Healthy Living (CHL) Program Individual-level Measures

Individual level measures				Assessed in matched-pair communities			Assessed in temporal communities			Assessed in FAS†
Category	**Measurement**	**Measurement tools**	**completed by**	**Time 1**	**Time 2**	**Time 3**	**Time 1**	**Time 2**	**Time 3**	
Demographic	Demographic[15,43-48]	Questionnaire	Surrogate*	X	X	X	X	X	X	X
Anthropometry	Height	Stadiometer	Staff	X	X	X	X	X	X	X
	Weight	Portable Scale	Staff	X	X	X	X	X	X	X
	Waist circumference	Circumference Tape	Staff	X	X	X	X	X	X	X
Diet	2 d# Food intake[61,62]	Food & Activity Log	Surrogate*	X	X	X			X	X
Physical Activity (PA)	6 d PA[66]	Accelerometer**	Child	X	X					X
	2 d# Activity Log [62]	Food & Activity Log	Surrogate*	X						X
Sedentary behavior (SB)/Screen Time (ST)	6 d SB/ST[66]	Accelerometer**	Child	X	X					X
	2 d# Activity Log[62]	Food & Activity Log	Surrogate*	X	X					X
	Usual SB/ST[52]	Questionnaire	Surrogate*	X	X	X			X	X
Sleep	6 d Sleeping[66]	Accelerometer**	Child	X	X					X
	2 d# Activity Log[62]	Food & Activity Log	Surrogate*	X	X					X
	Sleeping behavior[53]	Questionnaire	Surrogate*	X	X	X			X	X
Acanthosis Nigricans	Presence/Severity[67]	Visual observation/ assessment form	Staff	X	X	X			X	X
Culture	Language/culture[49-51]	Questionnaire	Surrogate*	X	X	X			X	X

†FAS = Freely Associates States of Micronesia.
X = indicates measurement completed.
*Surrogate reporter = parent/caregiver.
**A minimum of 100 children in each matched-pair community and FAS jurisdiction will wear an accelerometer.
#Randomly assigned non-consecutive days.

Frequency of measurements

The initial Time 1 measurement period for **individual** measures was between October 2012 through February 2014 to complete measurement in all five jurisdictions. The Time 2 measurement period was between January 2015 – October 2015. The Time 3 measurement period was between January 2019 – October 2020.

In FAS for the prevalence study, measurement began in October 2013 and may continue through early 2015.

Note in the temporal communities we had an abbreviated set of individual level measures, including height, weight, waist circumference and demographics.

Data Collection Visit Protocol

Measurements were taken in either a school or preschool setting (e.g., Head Start), or in a community-based setting (e.g., community recreation center or a community event) at Time 1, Time 2 (about 24 months), and Time 3.

Intervention and Comparison Communities

Parents of two to eight-year-old children were approached to learn about the study, to participate in an informed consent process and sign a consent form, to answer screening questions, and to receive instructions about completing the forms. Staff reviewed the forms for completeness as they were turned in and asked the parent to complete unanswered questions, if they were willing. All of the aforementioned may have happened at one time or over two occasions. Staff also provided training on how to complete a Food and Activity Log, using food models, etc. to demonstrate. Also, parents learned how to re-apply a wrist band and accelerometer, in the event it came off during the 6-day wearing period for the child. Parents were asked to notice if their child was still wearing the accelerometer at home and to put it back on, if the child was willing. Parents also kept a food log on their child for two days as well as an activity log for the same two days. One week after the child began to wear the accelerometer, parents sat with CHL staff to review their child's food and activity logs, and document receipt of the record.

After receiving the child's assent, the anthropometry measures and the screening for acanthosis nigricans took place. Children in the intervention and comparison communities were asked to wear an accelerometer for 6 days. CHL staff asked for the child's assent and choice of wrist band before placing the accelerometer.

The protocol called for two visits by participants in intervention and comparison communities. However, for some circumstances, participants only had to attend one visit.
The circumstances for one visit were when accelerometers were not used. After a certain number of participants wore accelerometers, they were not used in every measurement event. Also, in community events without an organization group leader who could help with follow up of retrieving accelerometers, measurement events could be held without using accelerometers.

When Food and Activity Logs (FAL) were used, but no accelerometer, sometimes participants returned their FAL by mail or to another collection site. Participants asked to return items by mail were given stamped addressed large envelopes to send their FALs back. Phone follow-up occurred as needed. In some circumstances after a certain number of participants had already completed Food and Activity Logs, the measurement package in intervention and comparison communities did not collect FAL data from participants.

Temporal Communities

Parents of 2 to 8-year-old children were approached to learn about the study, to participate in an informed consent process and sign a consent, and to receive instructions for the demographics form. Staff reviewed the form as it was turned in and asked parents about any incomplete sections. The aforementioned happened at one time or over two occasions.
Their child may have been measured with the parents present or at a different time in their classroom.

Study Sample

Table 3 shows the sample size goals for each intervention, comparison, and temporal community in the jurisdictions. The projected sample size for the individual level measurements will be the same at Time 1, Time 2, and Time 3.

The total proposed sample size for anthropometry measures for CHL was 4100 children for the cross-sectional samples at Time 1 and Time 2.

Table 3: Frequency and Sample Size Goals for CHL Measurement

Frequency and Sample Size Goals for CHL Measurement						
		n size for each community		Individual Measures		
		Time 1 and 2	Time 3	Time 1	Time 2	Time 3
American Samoa, CNMI, Guam, and Hawaii						
Intervention community 1	**Matched pair 1**	150	50	✓	✓	✓
Comparison 1		150	50	✓	✓	✓
Intervention community 2	**Matched pair 2**	150	50	✓	✓	✓
Comparison 2		150	50	✓	✓	✓
Temporal	**2 communities**	150	50	✓ Abbreviated	✓ Abbreviated	✓ Abbreviated
Alaska						
Intervention community 1	**Matched pair 1**	200	50	✓	✓	✓
Comparison 1		200	50	✓	✓	✓
Temporal	**2 communities**	200	50	✓ Abbreviated	✓ Abbreviated	✓ Abbreviated
FAS: Pohnpei, RMI, Palau, Yap, Chuuk, Kosrae						
All FAS Communities		200		✓		

Table 4: Number of Participants Consented* at Time 1 and Time 2 for CHL Community Randomized Trial and FAS Prevalence Study.

Number of Participants Consented at Baseline for CHL Community Randomized Trial and FAS Prevalence Study			
	Time 1	**Time 2**	**Time 3**
	# Consented	**# Consented**	**# Consented**
Alaska	713	782	**238**
American Samoa	978	950	**323**
CNMI	924	1,001	**338**
Guam	885	908	**270**
Hawaii	988	1,039	**308**
	4592	5684	**1477**
Pohnpei	211	-	**-**
RMI	218	-	**-**
Palau	214	-	**-**
Chuuk	232	-	**-**
Yap	205	-	**-**
Kosrae	207	-	**-**
FAS Prevalence Data (total)	1,287	-	**-**
CHL Total	**5,775**	**5,684**	**1,477**

***Note: The number of participants consented reflects a raw number of participants available in the dataset. Please refer to the Consort Diagram for official participant numbers for those included in the CHL study.**

Recruitment

Participant recruitment goals
In order to meet sampling goals for children between the ages of 2 – 8 years, recruitment activities involve schools and other community venues and activities. Recruitment sites consisted of Head Starts, pre-schools/day cares, kindergartens, WIC sites, community health centers and other appropriate venues (e.g., parks and community recreation centers). Recruitment efforts, led by CHL staff in each jurisdiction, involve close collaboration with community liaisons (e.g., teachers, school staff, program directors, matai, mayors) to enhance participation and retention throughout the measurement protocol. The teams in all jurisdictions tailored the recruitment strategies to work effectively with the stakeholder organizations while meeting recruitment goals of CHL.

Screening and Eligibility Criteria

Those who attended a measurement event and agreed to informed consent were asked a series of screening questions to confirm their child's eligibility. Eligibility criteria were selected for the purpose of an obesity prevention and management intervention trial. Parents of potential participants were asked to complete a screening with study staff to confirm the health status of the child. The screening questions for study inclusion are in the appendix.

Eligibility Criteria:
The participating children will be

- 2-8 years old,
- healthy with no known cardiovascular disease, pulmonary or metabolic disease signs and/or symptoms;
- no known disease or joint problems or injuries that would be exacerbated by physical activity.
- The child will be stable in the use of any prescribed medications.
- The child will live in the selected community.

Exclusion Criteria:

1. Children outside the age group (under two or over eight years)
2. Known orthopedic, psychological or neurologic impairments that prevent physical activity
3. Presence or history of any metabolic or chronic health problems known to affect intermediary metabolism (e.g. untreated thyroid disease, cancer, hepatic disease, renal disease, diabetes, cardiovascular disease, hypertension)
4. Irregular use of prescription or over-the-counter medications known to affect appetite, food intake or intermediary metabolism (e.g. appetite suppressants, lithium, antidepressants, etc.)

Reference:

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