

Supplementary Online Content

Novotny R, Davis J, Butel J, et al. Effect of the Children's Healthy Living Program on young child overweight, obesity, and acanthosis nigricans in the US-Affiliated Pacific region: a randomized clinical trial. *JAMA Netw Open*. 2018;1(6):e183896. doi:10.1001/jamanetworkopen.2018.3896

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This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix. Supplemental Appendix

The hypothesis for the CHL group-randomized trial was communities that received the intervention would have less obesity in children than control communities or than background trends, as represented by Temporal communities. Therefore, the primary outcomes for the CHL intervention trial are body size variables. Secondary outcomes are the clinical manifestation in Acanthosis Nigricans and intermediate behaviors, including diet, physical activity and sleep. The hypothesis was tested using a hierarchical marginal model of the outcomes that accounted for the complex study design. See reference Wilken et al [1] for a full description of the study design. Briefly, five US Pacific jurisdictions were included in the intervention: the two states of Alaska and Hawaii, the two territories of Guam and American Samoa, and the Commonwealth of the Northern Marianas. Eligible communities were identified in each of the jurisdictions. Two pairs of communities in 4 jurisdictions and 1 pair of communities in Alaska were selected to be randomized to the Intervention or Control groups, after engagement with and agreement of the communities. The remaining eligible communities were used as Temporal communities to monitor trends in obesity over time. Fewer communities were included in Alaska due to the large distances to be covered.

Outcomes were regressed on the following community level variables: indicators for study group (Intervention, Control, Temporal), indicators for time (Baseline, Post-Intervention), and interaction terms between group and time. The intervention effect was tested within the strata of jurisdiction and accounting for the clustering of children within communities. Age and sex were adjusted for at the child level. Ethnicity/race was not adjusted for as it is highly confounded with jurisdiction. However, when the analysis was further adjusted for an indicator for the indigenous status of the child, the results were unaltered. The sample was also weighted to reflect the number of children residing in each community. The purpose of this weighting was to provide estimates of the outcomes that reflected the overall CHL region of underserved children. The number of children assessed across jurisdictions was similar with a ratio of the largest to smallest number of children assessed of 1.35. However, the ratio of the largest to smallest number of children residing in those jurisdictions was 17.4. Therefore, without weighting, the estimates of obesity, for instance, would heavily reflect the smallest jurisdiction of American Samoa rather than the largest of Alaska. Linear regressions were fit for continuous outcomes, and logistic regressions were for dichotomous outcomes. The expected means or proportions with 95% confidence intervals for each study group and each time point were estimated from the model. The test of the intervention was based on a “difference-in-difference” approach. Specifically, the Wald statistic of the interaction term for Intervention versus Control, or Intervention versus Temporal communities was used. As the unit of randomization was community, the degrees of freedom for this test was based on the number of communities (27 for most primary outcomes, 18 for most secondary

outcomes). The model assumptions of normal and homoscedastic residuals were checked for the continuous outcomes. There were violations for four outcomes: waist circumference, screentime, Tayside sleep score, and water intake. Box-Cox transformations were applied to these outcome measures and the test of the hypothesis was performed on the transformed scale. For ease of interpretation, the expected means and 95% confidence intervals are presented in the natural units through back transformation. Specifically, if the outcome was transformed as $f(Y)$, the model provides means M and confidence intervals $M_{\text{low}} - M_{\text{upper}}$ on the transformed scale, we backtransformed the mean as $f^{-1}(M)$ and the confidence interval as $f^{-1}(M_{\text{lower}})$ to $f^{-1}(M_{\text{upper}})$. These analyses were performed using the SAS SURVEYREG procedure for continuous outcomes and SAS SURVEYLOGISTIC procedure for dichotomous outcomes, and statements for STRATA, CLUSTER and WEIGHT.

Reference

1. Wilken LR, Novotny R, Fialkowski MK, Boushey CJ, Nigg C, Paulino Y, Leon Guerrero R, Bersamin A, Vargo D, Kim J, Deenik J. Children's healthy living (CHL) program for remote underserved minority populations in the pacific region: rationale and design of a community randomized trial to prevent early childhood obesity. *BMC Public Health*. 2013;13(1):944. doi: 10.1186/1471-2458-13-944. PubMed PMID: 24107083

| Jurisdiction Information | | | | | |
|---|--|--|---|---|--|
| Name | Alaska | American Samoa | Commonwealth of the Northern Mariana Islands | Guam | Hawaii |
| Geographic coordinates | 64.2008° N, 149.4937° W | 14.2710° S, 170.1322° W | 15.0979 N, 145.6739 E | 13.4443° N, 144.7937° E | 19.8968° N, 155.5828° W |
| Distance from coordinating center (Honolulu, HI) | 3072 miles/North | 2558 miles/Southwest | 3864 miles/West | 3950 miles/West | 0.0 miles |
| US affiliation and land type description | A US state located in the North Pacific Ocean. Consists of the largest land area in the US | US territory located in the South Pacific Ocean. Consists of five islands and two coral atolls: Tutuila, with the Manu‘a Islands, Rose Atoll, and Swains Island. | US commonwealth territory of 15 volcanic islands in the Western Pacific Ocean. Consists of three major inhabited islands: Saipan, Tinian, and Rota. | US territory located in the Western Pacific Ocean. Consists of one island | A US state located in the Central Pacific Ocean. Consists of eight major islands: Hawaii, Maui, Molokai, Lanai, Kahoolawe, Oahu, Kauai, Niihau |
| Population size (2010 census) | 713 985 | 55 519 | 53 883 | 159 358 | 1 360 301 |

eTable 1. Sample Size by Measurement Modules and by Intervention Time Period

| Measurement Modules | Intervention | | Control | | Temporal | | Total |
|-----------------------------------|--------------|--------|---------|--------|----------|--------|-------|
| | Time 1 | Time 2 | Time 1 | Time 2 | Time 1 | Time 2 | |
| Demographic Questionnaire | 1517 | 1343 | 1491 | 1295 | 1321 | 1405 | 8372 |
| Context-Specific Questionnaires * | 1516 | 1345 | 1491 | 1295 | 0 | 0 | 5647 |
| Anthropometry | 1512 | 1309 | 1486 | 1268 | 1319 | 1369 | 8263 |
| Acanthosis Nigricans | 1509 | 1320 | 1479 | 1278 | 0 | 0 | 5586 |
| Food Activity Log | 1343 | 1159 | 1195 | 1067 | 0 | 0 | 4764 |
| Accelerometer | 893 | 701 | 731 | 831 | 0 | 0 | 3156 |

*Acculturation; Screen-Time; Sleep Disturbance

eTable 2. CHL Optimized Intervention of 8 Activities and 6 Behavioral Targets*

| | ↓ SSB | ↑ F/V | ↑ PA | ↑ Water | ↓ Screen | ↑ Sleep |
|--|----------|----------|---------|------------|-------------|------------|
| POLICY- Review Assessment Data & Identify areas for Improvement for Policy & Physical Environment related to 6 CHL behaviors | | | | | | |
| a. Review preschool wellness policy assessment data to identify training needs | X | X | X | X | X | X |
| ENVIRONMENT- Partner and Advocate for Environmental Change | | | | | | |
| a. Support environmental initiatives that relate to the CHL target behaviors | X | X | X | X | X | X |
| SOCIAL MARKETING- Promote the CHL Message | | | | | | |
| a. Support role models to deliver CHL message | X | X | X | X | X | X |
| b. Promote CHL social marketing campaigns | X | X | X | X | X | X |
| CAPACITY BUILDING- Train the Trainers | | | | | | |
| a. Train individuals to lead interactive, hands-on, & family-based sessions (to include gardening) | X | X | X | X | X | X |
| b. Train preschool providers on wellness policy implementation | X | X | X | X | X | X |
| c. Train role models (community champions, adult and youth role models) | X | X | X | X | X | X |
| d. Coalition development | X | X | X | X | X | X |

*↓ - increase, ↑ - decrease, SSB - Sugar Sweetened Beverage Consumption; F/V - Fruit and Vegetable Consumption; PA - Physical Activity; Water - Water consumption; Screen - Leisure screen time; Sleep - Time spent sleeping

eTable 3. Children’s Healthy Living Program Trial Mean Changes in Primary and Secondary Outcomes Between Intervention and Temporal Communities, US-Affiliated Pacific Region, 2012-2015^a

| Child Measure | No. ^b | Temporal | | | | Intervention vs Temporal | |
|---|------------------|------------------------|------------------------|-------------------------|---------|--------------------------|---------|
| | | Time 1 (95% CI) | Time 2 (95% CI) | Diff (95% CI) | P Value | Diff (95% CI) | P Value |
| Anthropometry | | | | | | | |
| Overweight/Obese, % | 7944 | 31.02 (24.41 to 38.51) | 29.75 (21.83 to 39.12) | -1.27 (-28.82 to 26.28) | .84 | -2.63 (-8.58 to 3.32) | .28 |
| BMI z-score | 7944 | 0.64 (0.45 to 0.83) | 0.60 (0.37 to 0.83) | -0.04 (-0.13 to 0.06) | .42 | -0.02 (-0.14 to 0.09) | .68 |
| Waist, cm | 7992 | 52.14 (50.89 to 53.48) | 52.67 (51.03 to 54.49) | 0.54 (-0.14 to 1.21) | .06 | -0.65 (-1.79 to 0.49) | .13 |
| Acanthosis nigricans, % | 5585 | - | - | - | - | - | - |
| Sleep | | | | | | | |
| Sleep, h/d ^c | 7699 | 9.98 (9.69 to 10.27) | 10.07 (9.54 to 10.59) | 0.09 (-0.72 to 0.35) | .59 | -0.02 (-0.53 to 0.49) | .93 |
| Sleep disturbance score ^{1-9c} | 5499 | - | - | - | - | - | - |
| Screen, h/d ^c | 5494 | - | - | - | - | - | - |
| Accelerometer, min/d ^d | | | | | | | |
| Total METs | 2951 | - | - | - | - | - | - |
| Vigorous/Moderate | 2951 | - | - | - | - | - | - |
| Sedentary/Light ^e | 2951 | - | - | - | - | - | - |
| Diet, cups/d | | | | | | | |
| Fruit | 4763 | - | - | - | - | - | - |
| Vegetables | 4763 | - | - | - | - | - | - |
| Water ^c | 4763 | - | - | - | - | - | - |
| Sugar sweetened beverages | 4763 | - | - | - | - | - | - |

Abbreviation: BMI, body mass index; METs, metabolic equivalent tasks.

^aMeans are based on a mixed model with a linear link for continuous outcomes and a logistic link for dichotomous outcomes that accounts for the randomization unit of community and the community clusters within jurisdiction strata, weights for the number of children in each community, and adjusts for child’s age and sex. *P* values are based on a Wald test, with *df* based on the number of communities.

^bNumber of children included in analysis.

^cThe variables were back transformed from the regression model.

^dNumber of minutes per day within bouts of 5 minutes, averaged over 4 to 6 days of accelerometer use.

^eSedentary and light includes sleep activity.

eFigure. Children’s Healthy Living (CHL) Program (a) Acanthosis Nigricans and (b) Screen Time Comparisons Between Intervention and Control Groups With Age and Sex Interaction *P* Values, US-Affiliated Pacific, 2012-2015

