NCT05159622

Trial's Official Title: Water UP at Home

05/18/2022

Study Protocol and Statistical Analysis Plan

This study tested the preliminary effects of an intervention to reduce sugary drinks among low-income, primarily minority parents (n=45)(primary caregivers) and their young children (6 months-3 year olds) compared to a control/comparison group (n=47). The main outcome was behavioral: sugary drink consumption (self-reported oz/day) among parents and among their children (parent-reported oz/day). These outcomes were measured at baseline and immediately after the 12-week intervention. An exploratory aim was intended test if the intervention had a sustained behavioral effect and an effect on body mass index and waist circumference of the parents 12 months after baseline, but due to the pandemic of COVID-19, the team was only able to collect anthropometric data at baseline.

Our mixed methods multi-phase approach included a quantitative component (randomized controlled trial – Aim 1) and a qualitative component (in-depth interviews and focus groups- Aim 2) to test the effects of a behavioral intervention to replace sugary drinks with water at home.

Sample Size Estimation: Based on the effect size of a previous study[38] and on our own proof of concept work[18], a net effect of 6 fl oz/day (SD=1) was hypothesized among adult parents, assuming two-sided α=0.05, power=80%, and a minimum sample size of 60 families. We aimed to recruit at least 38 parents per treatment group (n=76 total parents) to account for up to a 20% loss to follow-up.

Data Collection for Intervention Evaluation

A survey was developed in Spanish to document participants' descriptive characteristics, including sociodemographic (self-reported age and sex for parents and their children), anthropometric (collected by data collectors) and self-reported health variables, as well as change in our behavioral outcomes of interest, which are described in detail below. The survey language was refined and further tested after discussions with the community partners and a professional data collector group. Finally, it was translated into English for use with non-Spanish speakers.

The survey was administered by a professional bilingual (Spanish/English) data collector group that was blinded to treatment randomization. The PI organized a 4-hour training to collect these data with high fidelity. A portion of the training was led by the Exercise Physiology lab at the academic partner's institution; data collectors practiced anthropometric data collection until an acceptable interrater reliability was achieved (>0.90).

Parent beverage consumption was assessed using a modified version of the BEVQ-15 beverage intake questionnaire, an established self-reported survey that assesses habitual consumption (frequency and quantity) of 15 beverage categories in the past month.[39,40] Prior to survey administration, it was tested for comprehension in English and Spanish among parents who were residents of this community, resulting in the following modifications: a) asking separately about bottled, unfiltered tap and filtered tap water; b) including examples such as Tampico®, Sunny Delight ®, *horchatas* (sugary rice- or seed-based beverages) and lemonades made at home or bought at the store in the category of sweetened fruit drink.

Infant/toddler beverage consumption was assessed using a modified version of the BEVQ-PS, which is an established parent-reported survey about habitual consumption (frequency and quantity) of 12 beverage categories for preschoolers, and an open-ended line.[41] Prior to implementation, the instrument was cognitively tested, and the following modifications were made: (a) adding three categories of water: bottled, filtered tap, and unfiltered tap water, (b) adding an energy drink category, per recommendation of the EHS staff, (c) adding separate categories for: formula, toddler milks, breastmilk, and drinkable yogurts. The resulting instrument had 18 drink categories and a space to write-in 'other' beverages.

Anthropometric Measures for Parents: Anthropometric measures were collected at baseline for cohorts 1 and 2 (due to COVID-19 social distancing guidelines, anthropometric data were not collected from cohort 3). Body weight, height and waist and hip circumferences were collected following standard methodology.[42] The average of multiple measures for weight and for height at each time point was used to calculate body mass index (BMI) as kg/m^2.

Theoretical Underpinnings: The following data collection tools were specifically developed for this study to measure parental preferences, community action, perception of household water insecurity as well as psychosocial constructs of parental self-efficacy, susceptibility, and beliefs. Cronbach alphas presented were calculated using data from this study.

Parental preferences for drinking plain water and SSB were assessed via three questions developed for this study: How much do you like to drink: plain water, SSB; how do you feel about replacing a sugary drink with water. Response options were 5-point Likert scales ranging from "Don't like it" to "I like it a lot"; or from "I would hate to replace it" to "I would love to replace it if I could do it".

Community Action (Exploratory Outcome): To explore if participating in a public health nutrition intervention such as this one led to increased willingness to participate in community action, we included the following question: 'Would you participate in a community action to reduce the availability of sugary drinks and increase access to drinking water? 'There were 4 ordered option responses from "not at all" to "yes."

Perception of Household Water Insecurity: To assess if the intervention had any effect on perception of the quality and safety of tap water at home for drinking, the following question was developed: 'Which one of these statements best describes your home's drinking water in the last 3 months?' Response options ranged from 1-4, with 1. "We always have drinking tap water and it is of good quality"; 2. "We have drinking tap water but it is not always good quality"; 3. "Often, we don't have drinking tap water that is good in quality"; 4. "We never have drinking tap water that is good in quality."

Parents' self-efficacy was assessed using a unifactorial scale of 15-questions developed *de novo* to ask about capability/confidence to act to replace SSB with water. The questions were asked as: 'How sure are you that you can…?' Response options were 5-point Likert scales from "totally unsure" to "totally sure." Higher scoring indicated a higher degree of confidence. The scale shows a Cronbach alpha of 0.88.

Parents' perceived susceptibility to health costs associated with SSB consumption was assessed using a unifactorial scale of 10 questions developed *de novo* that asked parents: How much do you agree with the following? Examples included: "Drinking sugary beverages can cause you and your family health problems like diabetes"; "Sugary drinks can negatively affect the developing brain and heart of a child"; "Drinking tap water instead of sugary drinks is part of a healthy diet for my child." Response options were 5-point Likert scales, with higher scores indicating higher level of agreement. The scale shows a Cronbach alpha of 0.83.

Parental beliefs about the health benefits of replacing SSB with tap water were assessed via three close-ended questions developed *de novo* for this study that asked how much parents agreed with the following statements: "Reducing the amount of SSB is good for your child's health"; "Tap water in your community is clean and safe to drink"; "Drinking water instead of SSB is going to improve your health" (Cronbach alpha: 0.53).

Responses on the Likert scales for each item within each construct were summed. Mean scores were then used for each scale.

All data were collected using Qualtrics XM© from all families at baseline and within two months of the end of the implementation period. For the first cohort, data collection occurred in person at the participants' home at a time that was convenient for them. For the second cohort, baseline was collected in person in the same fashion as cohort 1, but follow-up data were

collected remotely via Zoom, due to interruptions caused by the COVID-19 pandemic. For the third cohort, all data were collected remotely. Participants were surveyed in Spanish or English, according to their preference. The survey took approximately 40-60 minutes to complete.

Data Analysis

All survey data were exported from Qualtrics into SAS®9.4. Univariate procedures and frequency distributions were generated to summarize the participants in the comparison (n=47) and intervention (n=45) groups. The two groups were assessed for comparability of baseline characteristics using t-tests and Chi-Square or Fisher's exact tests.

Descriptive Analyses: Frequency and quantity beverage data were used to create daily consumption variables (in fluid ounces per day). Two composite variables were created: composite water and composite SSB. The composite water summed the daily consumption of bottled water, unfiltered tap water, and filtered tap water. The composite SSB was defined as the sum of sweetened fruit drink, soda, flavored milk, sweetened coffee/tea, and sports or energy drinks, as done elsewhere.[39,41,43] Beverage consumption was reported by mean, median and range due to the non-normal distributions of beverage variables. Wilcoxon two-sample nonparametric tests were performed to compare the baseline beverage consumption between intervention and comparison groups due to their non-normal distributions ($p \leq 0.05$).

Intervention Effects: The differences in beverage consumption from baseline to follow-up were calculated by subtracting mean baseline consumption from least-squares mean follow-up consumption. T-tests were conducted to assess which groups (i.e. parents and infants/toddlers in each treatment group) reported changes from baseline to follow-up. Changes in theoretical underpinnings and beverage consumption (SSB, 100% fruit juice, and water) for infants/toddlers and parents were assessed using ANCOVA to examine the least-square means in each experimental group. The least-squares means of follow-up beverage consumption and the p-value for the difference between the groups were reported.

Sensitivity analyses included: 1) restricting the sample to only Hispanic families, and 2) stratifying by implementation cohort to examine any effects based on different implementations and interruption of implementation due to COVID-19. Additional post-hoc analyses included: 1) mean contribution of individual water variables (bottled, tap) to total water consumption, and 2) a count of infants under 12 months reporting 100% fruit juice consumption at baseline, as was seen in formative work.[18] All analyses were conducted using SAS®9.4 software.