Sugar Champ: Pilot Social Network Intervention to Reduce Intake of Sugary Drinks

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JHM IRB - eForm A – Protocol

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1. Abstract

The 1.2 million households living in public housing are disproportionately affected by obesity, where prevalence is estimated at 50%. An ecologic framework hypothesizes that this disparity is related, in part, to social and environmental factors within these neighborhoods that influence residents' lifestyles. Social networks and the built environment may work together to promote or inhibit lifestyle behaviors; however, combined social network-built environment interventions have not previously targeted changes in diet. We hypothesize that an intervention that combines a social network approach with strategies that address public housing residents' challenges related to the built environment will improve dietary habits. Our overall aim is to develop a combined social network-built environment intervention to reduce intake of beverages high in added sugars and to pilot test the intervention among residents of public housing developments in Baltimore, MD.

2. Objective

Objective: **To develop a combined social network-built environment intervention to reduce intake of beverages high in added sugars and to pilot test the intervention among residents of public housing developments in Baltimore, MD.**

Hypothesis 1: A combined social network-built environment intervention will be feasible and acceptable in promoting reduced intake of beverages high in added sugars.

Hypothesis 2: A combined social network-built environment intervention promoting reduced intake of beverages high in added sugars will alter diet among public housing residents.

3. Background

Ecologic Framework of Obesity. Over one-third of U.S. adults are now obese, a condition linked to increased risk of type 2 diabetes mellitus (T2DM), cardiovascular disease, and cancer. An ecologic framework hypothesizes that macro- and micro-level elements of the built and social environments influence obesity. This framework is supported by evidence that links neighborhood factors with obesity.

Public Housing and Obesity. The U.S. House Ways and Means Committee estimates that 1.2 million households reside in public housing, which are often located in neighborhoods that have a confluence of negative environmental factors including low socioeconomic status (SES), limited access to grocery stores, and few safe places to exercise. As compared to the general population, the obesity epidemic disproportionately impacts adults living in public housing, where 20% have hemoglobin A1c ≥6.5% and over 50% are obese. The 10-year outcomes from the "Moving to Opportunities" demonstration project suggested that public housing residents who had the opportunity to move to a higher SES neighborhood had a reduced prevalence of T2DM and extreme obesity as compared to residents who did not have this opportunity. This evidence implies that

living in low-SES public housing confers an increased risk of obesity and T2DM to its residents, and there is a critical need to design and test interventions that decrease the burden of T2DM and obesity among this population.

Built Environment and Obesity. Many studies have described environmental factors associated with obesity. For example, proximity to grocery stores, exercise facilities, and parks has been associated with lower body mass index (BMI). The availability of grocery stores and recreation facilities tends to be limited in low-SES neighborhoods, which results in poor access to healthy foods and exercise. Interventions have attempted to address food access disparities in Baltimore. Local stores increased their stocking of healthy foods and used point of purchase materials to promote these items, which increased purchasing of promoted foods but had no effect on consumers' healthy eating habits. Addressing access alone seems insufficient to change behavior.

Social Networks and Obesity. An individual's social networks can influence behaviors through social influence such as social norms and behavior modeling. The potential for social networks to promote behavior change has been studied in smoking cessation, where clusters of people simultaneously stop smoking. Social network interventions with drug users have successfully increased HIV risk reduction behaviors such as using clean needles and condoms. Obesity has been associated with social networks among adolescents and Framingham Heart Study participants. Mathematical simulations have illustrated the spread of obesity through social networks and how social networks might be used to mitigate the obesity epidemic. While these studies show the diffusion of obesity, social network interventions have yet to be used to target lifestyle change. It has been postulated that social networks may interact with the built environment to influence health behaviors. Therefore, an intervention that uses a social network approach in combination with strategies that address residents' challenges related to their built environment could improve diet, eating, and exercise habits that may result in weight loss and decreased risk or improved control of T2DM.

Preliminary Work. In 2011, we completed focus groups with Baltimore public housing residents exploring perceptions of health and community. Potential facilitators of behavior change included support from family members and cohesion among neighbors in housing courts; however, individuals reported limited access to fresh foods and safe areas for recreation. We completed a cross-sectional survey characterizing the personal diet, eating, and exercise habits and the perceptions of these habits among the social networks of over 350 adults living in Latrobe Homes and Gilmor Homes public housing developments in September 2015. We captured data on perceptions of the built environment along with observer ratings of the community environment and geographic information system (GIS) data. While analyses are ongoing, preliminary results show that over 50% are obese (BMI ≥30 kg/m2) and proportion with self-reported diabetes mellitus is 20%. We found that the median added sugar intake was 21.1 tsp per day as compared to the 6 to 9 tsp per day recommended by the American Heart Association. In multivariate models, individuals who perceived a greater proportion of their social networks drank sugar-sweetened beverages or ate sweets daily had significantly higher added sugar intake. We used this prior study to inform the development of a social network-built environment intervention to reduce added sugar intake among public housing residents, which will be tested in this pilot study.

The study team has prior experience conducting focus groups and a cross-sectional survey among public housing residents in Baltimore City, and has a long-term relationship with the Housing Authority of Baltimore City to conduct this research.

4. Study Procedures

a. Study design

We will conduct a 6-month non-randomized trial of the social network intervention described below. This will be a single arm trial in which we compare the outcomes of interest pre- and post- intervention. We have elected to use a pre-post design in this pilot study, given the preliminary nature of this work. We will adapt an HIV risk reduction social network intervention to create a new social network intervention targeting reduction in intake of added sugars. Our primary outcomes will be to test the acceptability and feasibility of the intervention and its components as well as estimate the likely effect of the intervention.

In the intervention, individuals will be recruited and trained to be "Peer Educators" who will participate in group sessions and then communicate this information with members of their social network ("Sidekick") and work to make changes to reduce intake of added sugars together. Given the frequent intake of sugar-sweetened beverages (SSB) in this population, the intervention will focus on reducing added sugar intake through the reduced consumption of SSB. Peer Educators will participate in 6 core group sessions over a 6-week period as well as 3 additional booster sessions over the subsequent 3 months after completing the core curriculum. All sessions will be delivered by a facilitator and assistant facilitator using a guide (Appendix A). All groups will be held in a room in each public housing development's administrative building. Participants will receive a healthy meal or snack during each group session. We anticipate each group will last approximately 90 minutes.

We will recruit participants from Latrobe Homes and Gilmor Homes. We will recruit a total of 24 overweight Peer Educators along with 24 of their social network members (12 Peer Educators from Latrobe and 12 Peer Educators from Gilmor). We will require that both Peer Educators and Sidekicks consume sugar-sweetened beverages at least twice a day. We will require that the Peer Educator and Sidekicks have had in person contact at least once during the past month, which suggests a more significant relationship. We will not require Sidekicks to live in the housing development, as many individuals' social networks extend beyond their immediate neighborhood.

We will mail an invitation (Appendix B) to all overweight respondents daily that participated in our prior survey and agreed to be contacted for future research directing them to call our study office if they are interested in participating. These individuals will be eligible to be Peer Educators. Only one person per household will be eligible to be a Peer Educator. We will use a telephone script to handle all calls generated from this letter (Appendix C). If we do not meet our recruitment target through the letter, we will contact participants via telephone or doorknocking from our previous survey in these communities who agreed to be contacted for future research studies. We will make two telephone or door-knocking attempts before considering the individual a non-responder. We will use the same telephone screening script to recruit these participants. If we have not met our recruitment target after exhausting two contact

attempts, then we will mail a letter (Appendix B) to all other residences in Latrobe and Gilmor Homes to identify additional Peer Educators. We will use a telephone script to handle all calls generated from this letter (Appendix C). If we still do not meet our recruitment target through the letter, we will contact these other households in Latrobe and Gilmor Homes via a single doorknocking attempt using the telephone screening script to recruit these participants. To address privacy issues during recruitment, all participants who are contacted or approached for recruitment will be assured that the research staff at Johns Hopkins will be the only ones to see their information, and that the information we collected will be kept private and be used only for the research study we are discussing. If the potential participant chooses not to enroll in the study or does not qualify to be in the study, then his/her information will be destroyed. Each Peer Educator will be responsible for recruiting one member of their social network to be his/her Sidekick.

Peer Educators will give their potential Sidekicks an invitation (Appendix D) describing the study, the roles of Peer Educators and Sidekicks, and directions on how to contact study staff for screening. We will use a telephone script to handle all calls generated from this letter (Appendix E). To address privacy issues during recruitment, all participants who are contacted or approached for recruitment will be assured that the research staff at Johns Hopkins will be the only ones to see their information, and that the information we collected will be kept private and be used only for the research study we are discussing. If the potential participant chooses not to enroll in the study or does not qualify to be in the study as a Sidekick, then his/her information will be destroyed.

Peer Educators and Sidekicks will complete a baseline study visit for data collection, along with 3- and 6-month follow up visits for data collection (Appendices F-H). At baseline and 6-month follow up, data collection will include a survey that has individual-level questions, biometric measurements, and an egocentric social network inventory.

- Individual-level questions:
    - Demographics including age, gender, race/ethnicity, and address
    - Dietary content with brief food frequency questionnaire using the 5-Factor NHIS screener
    - Modified 3-Factor Eating Questionnaire R18 Biometric measurements:
    - Height using rafter square method where respondents remove their shoes and stand on a smooth surface with their heels and shoulders against a wall. Interviewer will then place a rafter square on the respondent's head, mark the height on a wall, and then measure it in inches (to the nearest quarter inch) using a tape measure.
    - Weight on portable scale
    - Blood pressure via automated sphygmomanometer Egocentric social network inventory:
    - At baseline, each study participant will begin by listing 10 people he/she knows and has had contact with sometime during the past year. Only first names or initials of these alters will be recorded, so they are not identifiable to the research team and will not be sought out as research subjects. The ego will then answer questions regarding the natures of his/her relationship with these alters and list characteristics of each alter including demographics, socioeconomic status, body

size via pictogram, as well as lifestyle behaviors. Finally, we will assess for ties among these alters.

- At 3- and 6-months, we will repeat questions on body size via pictogram, lifestyle behaviors, and ties among these alters of the 10 original alters named at baseline. We will also ask each study participant to list up to 5 additional people who have become a part of their social network over the last 3 and 6 months, respectively. The ego will then answer questions regarding the natures of his/her relationship with these alters and list characteristics of each alter including demographics, socioeconomic status, body size via pictogram, as well as lifestyle behaviors.

At 6 months, we will also ask questions regarding satisfaction with the intervention. At 3 months, an abbreviated survey will be conducted that includes only individual-level questions, biometric measurements, and satisfaction with the intervention. Study visits will be held either in the administrative building of the public housing developments or during home visits based on participant preference. Two data collectors will be present during surveys administered in the respondent's home. The survey will be administered in-person by trained research assistants. During the intervention, we will also collect sheets on which the Peer Educators and Sidekicks track their SSB intake (Appendix N).

Informed consent will be obtained from each participant during the baseline study visit for data collection. In particular, residents will be advised of the voluntary and confidential nature of participation. Residents will be asked questions about the study procedures to test their understanding and will be given materials, written at <5th grade level, to read and take home. They will also be provided the contact information of the principal investigator. We will emphasize that their participation in the study will not affect their clinical care.

All survey responses will be collected on password protected laptop computers and entered into the EgoNet software. EgoNet facilitates the collection of survey and egocentric social network data. The data is immediately stored onto the laptop's hard drive. At the end of each day, all data will be transferred to a secure network share drive on the password protected desktop computer in a study investigator's office (Dr. Gudzune). Once successful download is confirmed, the data will be erased from the laptop computer. Data will not be stored on servers external to the institution.

b. Study duration and number of study visits required of research participants.
Study duration will be 6 months. Peer Educators will be required to attend 6 core sessions and 3 booster sessions for the intervention. Peer Educators and Sidekicks will complete a baseline study visit for data collection, along with 3- and 6-month follow up visits for data collection. Study visits will be held either in the administrative building of the public housing developments or during home visits based on participant preference.

c. Blinding
Not applicable

d. Justification of why participants will not receive routine care or will have current therapy stopped.

Not applicable

e. Justification for inclusion of a placebo or non-treatment group.
Not applicable

f. Definition of treatment failure or participant removal criteria.
Not applicable

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely. Not applicable

5. Inclusion/Exclusion Criteria

For Peer Educators to participate in the pilot, one of their social network members ("Sidekicks") who consume foods with added sugars daily must also enroll. Peer Educators and Sidekicks must be at least 18 years old and consume sugar-sweetened beverages at least twice daily. Peer Educators must have a BMI $\geq$25 kg/m^2.

We will exclude subjects with any underlying medical conditions that could seriously reduce their life expectancy, their ability to participate in the trial, or for which dietary change may be contraindicated and/or require medical supervision by a physician such as medication-dependent diabetes mellitus, cancer or malignant tumor, lung disease requiring supplemental oxygen, dementia or cognitive impairment, angina, or diagnosis in the last 12 months of myocardial infarction, congestive heart failure, transient ischemic attack or stroke, liver disease or kidney disease. We will also exclude women who are pregnant or breastfeeding. Only one person per household will be eligible to be a Peer Educator, and additional eligible household members can participate as a Sidekick.

6. Drugs/ Substances/ Devices

Not applicable

7. Study Statistics

a. Primary outcome variables.

Our feasibility outcomes will include recruitment and retention rates, as well as program attendance. Our acceptability outcomes will include participant satisfaction with the intervention and willingness to recommend that a friend participate as a Peer Educator. Our effect outcome will be change in intake in added sugars among Sidekicks using the relevant elements in the NHIS 5-factor screener. With a sample size of 24, the minimal detectable intervention effect is reduction of added sugar intake by 16.1 tsp per day (assuming a type I error of α=0.05 (two-tailed), 80% power, and assuming SD of outcome of 19 based on our prior survey). Of note, a 12 oz can of soda has approximately 10 teaspoons of added sugars and a 20 oz bottle has approximately 17 teaspoons.

b. Secondary outcome variables.

Our secondary outcome will be change in intake in added sugars among Peer Educators using the NHIS 5-factor screener. We will also examine change in cognitive restraint related to intake of foods high in added sugars using elements modified from the Three-Factor Eating Questionnaire R18. We will also examine weight change both Sidekicks and Peer Educators.

c. Statistical plan including sample size justification and interim data analysis.
We will conduct descriptive analyses comparing pre- and post-intervention. We will examine feasibility and acceptability outcomes with t-tests and Chi Square tests. We will compare the values of the Sidekicks' intake of added sugars before and after intervention with a paired, two-tailed ttests. We will use paired, two-tailed t-tests to compare Peer Educators' intake of added sugars, Sidekicks' weight, and Peer Educators' weight before and after the intervention. If our outcomes are not normally distributed, then we will use Wilcoxon signed-rank tests in lieu of t-tests.

d. Early stopping rules.
Not applicable

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency. Risks related to the intervention include time required for participation in the group-based training sessions for the Peer Educators. The group sessions that will be used for Peer Educator training involves group discussions where individuals may feel uncomfortable and there is a risk of group members disclosing information about other members to people outside the group. In addition, making dietary changes may also pose risks such as needing to adjust the dose of certain medications (e.g., hypoglycemic agents) or may be inappropriate for people with certain medical conditions.

Risks related to the data collection include loss of confidentiality, and potential discomfort, boredom or inconvenience from answering survey questions and undergoing measurements of height, weight and blood pressure. There are also risks related to interview location. We have plans in place to address occurrence of 1) uncontrolled hypertension and 2) participant medical illness, medical concerns or needs for medical services.

b. Steps taken to minimize the risks.
We will minimize risk of group discussions by advising participants that by agreeing to be in this study, they are agreeing not to talk about any personal details that other peer educators share in the group. Participants will be informed that they do not have to participate in any group discussion where they feel uncomfortable and can leave the session at any time. We will attempt to minimize the risk of dietary change by excluding participants who have medical conditions that require specific dietary requirements or conditions associated with decreased life expectancy (as listed in eligibility criteria above). We will advise all participants to talk with their doctor about making dietary changes before participating in this program. If patients do not have a primary care provider, then study staff will provide a resource listing for primary care clinics and safety-net clinical facilities to establish primary care. In addition, we will encourage all participants to follow up regularly with their doctor during the study period or if any symptoms should occur, as lifestyle changes can often result in the need to adjust the dose of medications.

There is a risk of the loss of confidentiality of medical information. We will ensure protection of the data and any personal health information. Only the study team will have access to patient's identifying information. Each participant will be assigned an identification (ID) number at the time of recruitment. The database that links the ID with the participant will only be accessible by the principal investigator. Data will be stored on the Johns Hopkins Department of Medicine Network Drive, which is password- protected and backed-up each night. If a participant changes his/her mind and does not wish to complete the study s/he may withdraw at any point.

There is a risk of potential stress, discomfort, boredom or inconvenience from answering survey questions and undergoing biometric measurements. Participants will be informed that they do not have to answer any questions that they do not wish or have their blood pressure, height, or weight measured.

There are risks related to interview location. Interviews will occur either at the public housing developments' administrative buildings or in the participant's home, depending upon participant preference.

Interviews in the administrative or community building(s). To ensure participants' privacy, we will conduct interviews in a private room or private screened booth in a conference room. We will play background music to decrease risk of others overhearing the interviews.

Interviews in the participant's home. To ensure the safety of our research assistants during data collection, we will require two data collectors to attend all home interviews. Research assistants will also be trained in safety procedures, and will be encouraged to halt interviews if they have concerns for their personal safety. There is also the potential for a member of our research team to encounter a potential emergency situation that is not related to study participation (e.g., dehydration, environmental risk, medical emergency). We refer to such events as "alerts" and have procedures for their management, which are outlined in Table 2.

Table 2. Proposed algorithm for home emergencies

Alert	Action
Medical emergency <u>Examples:</u> - Chest pains - Excessive bleeding - Fall and cannot get up - Difficulty breathing	- If situation occurs within the home, then staff person calls 911 immediately, and stays with participant until help arrives. - JHU research coordinator (RC) and PI are informed within 24 hours of the event. Research staff member completes Protocol Alert Reporting Form (Appendix H) and gives to JHU RC/PI. - RC then contacts individual as a follow-up within two days.
Evidence of physical abuse <u>Examples:</u> - Participant or other person in household states to research staff that abuse occurs - Research staff observes physical evidence (e.g., black eye, black and blue marks on arms/legs)	- Research staff member informs participant that a RC/PI will contact him/her later that day. Staff member informs RC/PI immediately upon completion of interview. Research staff member completes Protocol Alert Reporting Form (Appendix H) and gives to JHU RC/PI. - RC/PI contacts participant to obtain further information. Participant is strongly encouraged to call his/her physician and/or Baltimore City Social Services (Adult or Child Protective Services as appropriate)(phone number will be provided). - Based on the situation, the RC/PI may notify Adult or Child Protective Services. RC (or designate) completes Alert form.

Extreme home hazards Examples: -Exposed electrical -External door missing or cannot be locked -Ceiling, floors caved in -No temperature control in extreme weather conditions -Major infestation	- JHU research coordinator (RC) and PI are informed within 24 hours of the event. Research staff member completes Protocol Alert Reporting Form (Appendix H) and gives to JHU RC/PI. -RC/PI will notify HABC service coordinator or maintenance staff of situation.

We address the protections against the additional risks below:

1) Plan for occurrence of uncontrolled hypertension. During blood pressure assessment, we may discover that a subject has uncontrolled hypertension. We will develop a blood pressure safety alert algorithm to handle this scenario. Data collectors will be instructed to complete the algorithm after every blood pressure measurement. We will specify blood pressure ranges for various levels of adequate and inadequate control based on current guidelines from the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7). Based on the blood pressure level, the algorithm will indicate advice that the data collectors/project staff should provide the participant and will also indicate questions that they should ask the participant when an abnormal value is obtained. Research staff will complete the Protocol Alert Reporting Form (Appendix I). Dr. Gudzune, the study physician, will be available to the data collectors and study staff to assist in this algorithm. We anticipate that the some of our participants will not have access to a primary care provider. We plan to provide participants with a resource listing for primary care clinics, safety-net clinical facilities and urgent care centers in their area. If an emergency arises we will call 911. Table 3 provides additional details on our proposed blood pressure safety alert algorithm. We will provide each participant with a letter documenting their biometric values (including blood pressure) that they can share with their healthcare provider (Appendix J).

Table 3. Proposed algorithm for elevated blood pressure

Blood Pressure	Control	Advice	Check
SBP ≤139 DBP≤ 89	Adequate	N/A	Compliance with diet and medications (if prescribed)
SBP 140-159 DBP 90-99	Inadequate Stage I hypertension	Advise to discuss with physician at next scheduled visit	Compliance with diet and medications (if prescribed)
SBP 160-179 DBP 100-109	Inadequate Stage II hypertension	Advise to make an appointment to see physician for repeat blood pressure check in 7 days	Make sure participant has taken daily medication (if prescribed), if they have not taken meds then advise to do so
SBP ≥180 DBP ≥110	Inadequate Stage II hypertension	Call study physician to discuss	Refer to emergency department

2) Plan for occurrence of participant medical illness, medical concerns or need for medical services during the study. We anticipate that the some of our participants will not have access to a primary care provider and may look to the study staff for help with personal or family medical concerns or illness. If these concerns arise during the study, we plan to provide participants with a resource listing for primary care clinics, safety-net clinical facilities and urgent care centers in their area (Appendices K & L). If an emergency arises we will recommend calling 911. We will also have a list of social services resources for residents who report issues with food insecurity (Appendices K & L).

c. Plan for reporting unanticipated problems or study deviations.
Unanticipated problems or study deviations will be reported to the IRB, the NIH, and if applicable to all study participants in a letter.

d. Legal risks such as the risks that would be associated with breach of confidentiality. None

e. Financial risks to the participants.
None

9. Benefits

Participants may benefit from participating in the training to increase their knowledge about healthy diet. This study will provide benefit to society at-large, as our results will fill an important gap in the medical literature to understand how social networks may help facilitate lifestyle change and alter the development of obesity, which is now an epidemic in the U.S. We believe that the risks to subjects are low and reasonable given the knowledge to be gained.

10. Payment and Remuneration

We will offer all participants an incentive to complete the baseline and follow up assessments ($50 for baseline and 6-month assessments; $25 for 3-month assessment). Total possible compensation for data collection is $125. In addition, we will offer Peer Educators an additional $300 incentive to compensate them for the time required to attend the training sessions. We will require that Peer Educators attend at least two-thirds of all sessions (at least 6 out of the 9 sessions) to be eligible for this compensation. This additional compensation will be distributed during the final booster session. For Peer Educators eligible for this compensation that do not attend the final booster session, the study team will attempt to contact the Peer Educator to arrange a time to personally deliver the gift card to them.

11. Costs

There are no costs to participants. Participants who require a letter of excuse from work or school will be provided with a signed letter explaining that they participated in a medical study at Johns Hopkins with the appropriate date and time of participation (Appendix M).