A Hybrid Effectiveness-Implementation Study on Weight Gain Prevention among 2-1-1 Callers

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A Hybrid Effectiveness-Implementation Study on Weight Gain Prevention among 2-1-1 Callers.

Short Title: Core Research: HH/HF in 2-1-1 systems

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BACKGROUND & SIGNIFICANCE

Importance of Weight Gain Prevention and Diet Quality in Cancer Prevention.

It is now well-established that obesity and excess weight increase the risk of cancer (i.e., colorectal and post-menopausal breast cancer), as well as other chronic diseases including diabetes, stroke, coronary heart disease, and arthritis.[1-6] The World Cancer Research Fund and the American Institute for Cancer Research state "maintenance of a healthy weight throughout life may be one of the most important ways to protect against cancer" (p.8).[7] Unfortunately, adults generally gain weight as they age.[8-11] A prospective study of weight gain in over 120,000 adults reported an average increase of .8 pounds per year.[12]

Weight gain prevention centers on balancing calories consumed with calories expended.[13] Portion control and reduced consumption of sugar-sweetened beverages and fast food are integral to healthy eating patterns, as is increased consumption of fruits and vegetables.[13] Estimates of the energy gap responsible for the current obesity problem range from 100 to 400 excess calories per day.[13] Thus, relatively modest changes in daily caloric intake could help ameliorate the obesity epidemic. Despite this, a review of weight gain prevention interventions documents a dearth of rigorous community-based trials (most studies emphasize weight loss) and concludes there is an urgent need for such research.[10]

Food choices that align with the US Dietary Guidelines for Americans are associated with better diet quality and can facilitate weight control. The Healthy Eating Index, (HEI) is a scoring metric that can be used to assess overall diet quality in relation to adherence with the Dietary Guidelines.[14] We previously reported that better diet quality as measured by the HEI was associated with lower weight in a racially diverse (39% African American) population of community-dwelling adults.[15] In other research, in a phone and mail-based intervention, diet quality was associated with modest weight loss at one year of follow-up (~ -1 unit BMI). Importantly, intervention-associated improvements in diet quality contributed to sustained weight management over two years. Compared to baseline, after two years of follow-up HEI diet quality scores continued to be significantly improved (+6.6) and contributed to sustained improvements in BMI.[16]

Rationale for Intervening through Home Food Environments.

Ecologic models of healthy eating and weight gain prevention acknowledge that influences at multiple levels (e.g., individual, interpersonal, organizational, community and policy) synergistically shape behavior.[17-19] These models highlight behavioral settings, such as homes and worksites.[20-22] We believe the home is an especially important setting given that 68.4% of calories still come from foods prepared at home.[23] Research shows that food availability in the home is associated with dietary quality and/or weight;[24-32] as are food shopping and food preparation, family meals, serving of non-home food sources (e.g., fast food) and eating while watching TV.[27,33-39] Social aspects of the home food environment are also influential. Family support can increase healthy eating, but family food preferences can do the opposite.[31,40,41] Despite its important role in weight-related behaviors, few interventions have focused on the home environment and the Emory Prevention Research Center (EPRC) has developed one of the only home environment interventions to focus on weight gain prevention in adults.[42,43] An intervention focused on the more proximal environment of the home, if

scalable, has the potential to be impactful as a stand-alone intervention, but also as one component of a multi-level approach to combatting the obesity epidemic.

Relevant Prior Work: Healthy Homes/Healthy Families Intervention (HH/HF)
After a series of qualitative and quantitative studies to understand how home, faith and work settings influenced healthy eating, physical activity and tobacco use conducted from 2004 to 2010,[32,44-50] the EPRC Community Advisory Board (CAB) prioritized obesity prevention through home environments as the focus of our intervention research. Using Community Based Participatory Research (CBPR) in collaboration with our CAB in SW GA, we developed and tested the HH/HF intervention, which was originally delivered through home visits and telephone calls. The intervention involves a tailored home environment profile and a health coach working with participants to select and implement a series of healthy actions to create a home environment more supportive of healthy eating and physical activity (see Table 1). Healthy actions were selected based on an extensive review of the literature to identify features of the home associated with dietary behavior and/or weight-related outcomes.

Table 1. Sample of Healthy Actions for HH/HF intervention

Healthy Eating Actions
Always have a low calorie beverage available instead of sugar soda and/or sweet tea.
Identify one unhealthy food or drink and do not allow it in the home.
Bring home fresh vegetables and fruits at least once a week and make them easy to see and grab.
Establish rules that limit eating while watching TV.
Healthy Physical Activity Actions
Keep at least one piece of exercise equipment or aid in a visible location and commit to using it once a week.
Identify and commit to walking to a place in your neighborhood at least once a week.
Establish a rule for screen free hours/days and use the time for exercise.

Feasibility/Acceptability Study. We collaboratively designed an intervention and pilot tested it in three counties in SW GA.[51] The intervention was delivered by local staff, managed by Horizons Community Solutions. The study was quasi-experimental in design with 90 households completing data collection at baseline, two and four months. Participants in two counties were in the intervention group and participants in a third county were in the comparison group. The intervention was six weeks, with two home visits and two phone calls. The intervention resulted in numerous changes to the home environment among intervention group participants relative to comparison group participants. Those in the intervention group improved their home food inventory, purchased fruits and vegetables more often, improved meal preparation methods, decreased meals with the TV on, and increased family support for healthy eating. Although not powered to detect dietary outcomes, we observed a significant decrease in percent energy intake from fat, and positive trends for fruit and vegetable consumption and weight. While we saw changes in the home activity environment, there were no changes in level of moderate/vigorous physical activity. Focus groups with participants after the intervention suggested they would like a longer intervention; participants commented they were just starting to make changes when the intervention ended.

Efficacy Trial. Given positive results in changing the home environment and promising trends for the weight-related behaviors, we modified the intervention through a series of CAB work group meetings to refine and expand the list of healthy actions, and then conducted a RCT in collaboration with our CAB and three Federally Qualified Health Centers (FQHC) in SW GA. As in the pilot, baseline data were used to generate a tailored home environment profile showing areas in need of improvement (e.g., too many high fat/salty snacks) and positive aspects of the home environment (e.g., family never eats in front of the TV). Coaches, again hired and supervised by Horizons, used the home environment profile to guide participants in choosing six healthy actions over the course of the intervention (three related to the food environment and three focused on the activity environment). The chosen healthy actions were recorded on a family contract which was signed by the participant and coach. Based on the healthy actions chosen, participants received supportive materials via mail (e.g., portion size plate) and tips for implementation and overcoming challenges from the coach. The intervention was delivered through three home visits and four coaching calls over 16 weeks. Control participants received three mailings of educational material at six week intervals. The intervention was delivered by health coaches who resided in SW GA and had at least a high school education, and experience in social or customer service.

Providers from three FQHCs referred overweight and obese female patients to the study. Eligible participants were women, ages 35 to 65, lived with at least one other person, and lived no further than thirty miles from the referring clinic to facilitate home visits. Data collection was fairly extensive; study participants were asked to complete three baseline and two six and 12 month follow-up telephone interviews each, and wear an accelerometer at baseline and at six months follow-up. Of the 349 randomized into intervention or control, 82.5% completed six month data collection and 76.8% completed 12 month data collection. At baseline, six months and 12 months, participants completed two 24 hour dietary recalls (one weekday and one weekend day).[52] Dietary data were collected and analyzed using Nutrition Data System for Research (NDSR) software version 2010.[53-55] Physical activity was measured using the 7-day Physical Activity Recall (PAR)[56] and through accelerometers worn for seven days (ActiGraph 3X+) at baseline and six months post-baseline.

In terms of *primary outcomes*, we documented sustained reductions in caloric intake among intervention participants relative to control participants over a 12-month period, as well as sustained improvements in dietary quality as measured by the HEI and numerous positive changes to the home food environment. Daily energy intake decreased significantly more for the intervention than control group at six months (-274 Kcal versus -69 Kcal) and twelve months (-195 Kcal versus -76 Kcal), and was significant in longitudinal intent to treat analyses (p=.03). In terms of diet quality, the HEI score increased significantly more for participants in the intervention group compared to those in the control group at six months and was significantly different in longitudinal intent to treat analyses (p = .02). Although assessed through self-report with a relatively short timeframe for weight gain prevention, at 12 months post-baseline, 82.6% of intervention participants had not gained weight compared to 71.4% of control participants (p = .03). No change was observed for either objective or self-reported physical activity, although we again documented some changes to the home activity environment. Table 2 shows significant home food environment outcomes that correspond to the healthy actions promoted by HH/HF. The outcome results were published in the *American Journal of Public Health*.[42]

Table 2. HH/HF RCT Results for Home Food Environment Outcomes

Home Food Environment Outcome	Change from BL to Six Month F-UP	Intent to treat analyses (Baseline to 12 Month F-UP)+
Unhealthy drinks in the home	X	X
Unhealthy snacks in the home	X	X
Frequency of fruit shopping	-	X
Frequency of vegetable shopping	-	X
Family eating in front of TV	X	X
Healthy food preparation	X	X
Healthy food serving practices	X	X
Family meals from non-home sources	X	X
Family support for healthy eating	X	-
Telling others your weight	-	-

x-SIGNIFICANT CHANGE IN DESIRED DIRECTION at p<.05. p-values for change between two time points results from independent t-tests and regression analyses; p-values for the ITT analysis are from growth modeling and refer to the significance of the interaction term of group and time

Adaptation for 2-1-1 Delivery and Feasibility/Acceptability Study (IRB #86129 & #92840). With scalability in mind, we next obtained funding from NCI to adapt the intervention for telephone delivery with 2-1-1 callers. Given successful history with 2-1-1 in our smoke-free home research which involved telephone delivery and mailed materials, we partnered with United Way of Greater Atlanta 2-1-1 for this adaptation pilot study from 2016 to 2018. We formed a Steering Committee to help adapt the intervention for urban households living in disadvantaged neighborhoods within the metro area.

In this recently completed one-arm study, we learned that telephone delivery is feasible, with comparable results in terms of changes in the home food environment and changes in the expected direction for eating and weight-related outcomes. Atlanta 2-1-1 introduced the study to callers and conducted a brief eligibility screener. If callers were interested in learning more, 2-1-1 line agents took their contact information and provided names and contact information to the EPRC via a secure website. Over a 3 month period, they provided 265 names. EPRC staff then screened, consented, enrolled, and collected baseline data on 101 of the 2-1-1 callers. Eligibility criteria were broad to make it easy for 2-1-1 to identify interested callers and because of the focus on healthy eating and weight gain prevention which applies to almost everyone. Core components of the HH/HF intervention remained the same as in the larger trial, but delivery took place over three months instead of five, and was reduced to six phone calls (no home visits) delivered at two week intervals over three months, with text messages tailored to barriers mentioned on the calls delivered on the off-

weeks. We did not include the physical activity actions given null results in both the earlier pilot and the main trial.

The majority of participants were African American (82%) and female (74%), with more men participating than expected. Close to half of the participants were unemployed (48%), and just 14% were college graduates with 10% not finishing high school. All participants reported annual household incomes < $25,000. Typical household size was 2.8 members, and less than half had children in the household (45%). The mean age was 44, and 44% received SNAP benefits. Of the 101 completing baseline data collection, 75% completed the first coaching call, and 51% completed at least four of the six calls. Sixty percent were reached for follow-up one month post-intervention. Outcome measures consisted of the home environment survey used in our prior studies and two 24 hour dietary recalls at baseline and four months. Although not powered to detect change, we observed a significant increase in HEI scores[14,57] (from 54.5 to 58.9), decreases in Kcal of 203 per day from pre to post, and decreases in self-reported weight of 4 pounds. Consistent with one or both prior evaluations of the HH/HF intervention, we documented significant changes in household food inventories, food shopping behavior, food preparation, family meals from non-home sources (e.g., not eating out or getting take out), and less eating with the TV on. Moderator analyses did not justify targeting the intervention to a specific subpopulation of callers. These results, which documented the feasibility of partnering with 2-1-1 to identify low-income individuals interested in a healthy eating/weight gain prevention intervention, combined with the potential reach of 2-1-1, position us for the current research project.

Potential Reach of Regional 2-1-1 Infrastructure. In Georgia, the 2-1-1 infrastructure consists of nine United Way agencies. United Way of Greater Atlanta 2-1-1 is the largest by far and is the first 2-1-1 in the U.S. and is today one of the busiest in the country. In 2017, they received close to 500 contacts per day (167,434 total). They cover the Atlanta metro area and also have contractual arrangements with several other 2-1-1s in the state to take their calls as the Atlanta 2-1-1 is staffed 24/7. United Way of Central Georgia and United Way of the Chattahoochee Valley 2-1-1s cover much of the west central region of GA and have arrangements with Atlanta 2-1-1 for call coverage. Macon 2-1-1 had 5,137 contacts in 2017 and Columbus 2-1-1 had 10,330. United Way of Albany 2-1-1 is a stand-alone 2-1-1 and takes calls from 12 counties in SW GA. They received 2,285 contacts in 2017. All four of these 2-1-1s will participate in the **effectiveness-implementation study with United Way of Greater Atlanta 2-1-1 (UWGA 2-1-1)** serving as the main recruitment site.

GOALS/AIMS

We plan to conduct a **hybrid-implementation effectiveness** trial to evaluate a weight gain prevention intervention for delivery through 2-1-1s. Our specific aims for the research project are:

> **Aim 1**. Conduct a hybrid effectiveness implementation trial to assess the impact of a telephone-based home food environment intervention on weight-related dietary behaviors among 2-1-1 callers.
> **Aim 2**. Assess implementation and scale-up feasibility of an intervention delivery model to reach low income populations through a regional 2-1-1 system.
> **Aim 3**. Conduct a cost-effectiveness analysis of delivering a weight gain prevention intervention to 2-1-1 callers through a regional 2-1-1 infrastructure.

This IRB protocol focuses on Aim 1 – the hybrid effectiveness implementation trial, Aim 2 – assessing implementation and scale up feasibility of an intervention; and Aim 3, cost-effectiveness analysis of delivering the intervention.

STUDY DESIGN

EPRC Research Team

The research team will be led by **Dr. Michelle Kegler**. Co-investigators include: Drs. Cam Escoffery, Regine Haardörfer, David Howard, Terry Hartman, and Alexandra Morshed. Day-to-day oversight of the project and data collection will be managed by Lucja Bundy. Shade Owolabi will serve as the intervention coordinator to supervise intervention delivery on the project.

Primary Organizational Partners
Horizons Community Solutions, based in Albany, GA, will be a primary partner in the proposed research. In addition, we will partner with four United Way 2-1-1 organizations (United Way of Greater Atlanta 2-1-1 (UWGA 2-1-1), United Way of Central Georgia 2-1-1, Chattahoochee Valley 2-1-1 in Columbus, and United Way of Southwest Georgia (SWGA)). This research is funded by the Centers for Disease Control and Prevention. A subcontract with Horizons Community Solutions and two fee-for-service agreements with UWGA 2-1-1 and United Way of SWGA have been established.

Setting and Location
Study procedures, including informed consent and data collection, will be done over the telephone from the offices of the Rollins School of Public Health, Emory University, or home offices (due to COVID-19, CITI certified staff have been approved to carry out research activities at home). Recruitment and preliminary screening will occur at UWGA 2-1-1 and United Way of SWGA. Day-to-day operations of the project and oversight of data collection will be conducted by a Sr. Associate Director of Research Programs with support from staff and graduate research assistants. The intervention will be delivered jointly by Emory and Horizons staff. Process evaluation interviews with 2-1-1 leaders and staff and intervention arm participants will be conducted by Horizons staff and Emory staff and students.

Population
The study population will consist of 2-1-1 clients/callers. To be eligible for participation in the **hybrid-effectiveness implementation trial (aim 1)**, participants must be: 18 to 70 years of age, able to speak English, and self-report BMI of 20 and above. Pregnant women will be excluded and only one member per household will be enrolled.

For the **assessment of implementation study (aim 2)**, we will recruit up to 18 2-1-1 and Horizons leaders/staff selected for a one-time semi-structured interview. Interviews assessing implementation, costs, and potential scalability will be conducted with Horizons staff; interviews with 2-1-1- staff will focus on the organizations as study referral agencies. We will also conduct interviews with intervention participants via a one-time semi-structured interview. We will use two different interview guides (with different participants) to ensure coverage of all of our process evaluation questions. The first interview guide will be used for up to 45 participants with the goal of five participants per healthy action; The second interview guide will be used with a total of 35 participants with equal representation by food secure and food insecure participants who chose one of the following healthy actions: bring home fresh FV at least once a week and make them easy to see and grab; identify one unhealthy food or drink and do not allow it in the house; always have a low-calorie beverage available instead of sugar soda or sweet tea.

Community participation
The EPRC has a long history of engagement with its diverse and active CAB. The CAB was established in 2004, building on board membership of the SW Georgia Cancer Coalition, renamed Horizons Community Solutions three years ago, that represented a group of concerned citizens and community leaders who had organized around cancer prevention and control. Our community partners advise on all phases of the research including study design, implementation, translation, and dissemination activities.

Recruitment for the Hybrid-effectiveness implementation trial (Aim 1).
Recruitment will occur either by phone, web, text messaging, or via flyer distribution. Flyers (or IRB approved flyer content) may be distributed by any of the four United Way 2-1-1 organizations (United Way of Greater Atlanta 2-1-1, United Way of Central Georgia 2-1-1, Chattahoochee Valley 2-1-1 in Columbus, United Way of SWGA). Flyers will contain the Atlanta 2-1-1 and United Way of SWGA contact information for those interested in the study. The flyer content is included for review prior to production of flyers. In addition, 2-1-1 organizations may use social media and work with local media, such as TV and radio stations, in promoting the study. Content shared with the media will be consistent with that included in the approved flier and interested individuals will contact their local 2-1-1 as outlined below.

Phone/Text method: Line agents, called Community Connections Specialists at the Atlanta 2-1-1 and United Way of SWGA will answer incoming calls and texts at random, which will reduce systematic selection bias. After fulfilling service requests for those being recruited via text, a line agent will text participants a canned statement and the link to the screener for them to complete on their own (canned statement is included for review). After fulfilling service requests for those being recruited over the phone, a line agent will screen and invite callers to obtain more information on the study. A quick screening question at the beginning of our 2-1-1 version of the recruitment script will facilitate efficiency in recruitment (i.e., only those who report interest in participating in a study on making homes more supportive of healthy eating of 5 or more (on a scale of 0-10) will continue to full eligibility screener). Eligible and interested callers will provide their contact information (name and telephone number) and be referred to Emory research staff for further screening and enrollment. Atlanta 2-1-1 line agents also answer calls for the Macon and Columbus 2-1-1s. We anticipate recruiting a large proportion of the sample from these two 2-1-1 regions (approx. 40%), 20% from United Way of SWGA, and 40% from metro-Atlanta 2-1-1.

Flyer/Web method: Participating 2-1-1 agencies will have the option of creating a study information flyer for distribution (in-person or on their website). Content of this flyer includes information on study involvement, length, compensation, eligibility criteria, and study PI. Callers will have several different options (phone, text, or web link) to be connected to their local agency for preliminary screening.

We expect that 80% of callers will be eligible and based on our feasibility study, 50% will be reachable and interested in the research. We anticipate approximately 1700 callers will be referred to enroll **800** participants. Emory research staff will contact callers to describe the research activities in more detail, confirm eligibility, obtain verbal consent, and enroll them in the study. Participants will provide contact information for themselves and a person who can always locate them to aid in retention, and complete the baseline survey on the call. Following the completion of the baseline survey, we will call them two more times, to complete two dietary recalls. That will conclude their requirements for enrollment into the study. Both 2-1-1 and Emory versions of the eligibility screeners are included for review.

Recruitment for the assessment of implementation study (aim 2).
2-1-1 and Horizons leaders and staff and intervention arm participants will be selected for semi-structured interviews.

The following protocol will be used to recruit 2-1-1 and Horizons leaders and staff:

1. An introductory email notification and up to five reminders will be sent to selected 2-1-1 and Horizons leaders/staff inviting them to participate in interviews. Potential participants will be identified by the Directors overseeing the centers and/or have a study-related role. The email invitation will include a description of the study, study procedures, compensation for completing the semi-structured interview, etc. An opt-out option with instructions will be provided in the email notification and no further contact will be made with those who remove themselves from further participation.
2. Those who are interested in participating will be fully informed about the study procedures and consented to participate via telephone. The IRB-approved consent statement will describe the purpose of the study, risks and benefits, and selection criteria. Participants will be informed that they have a right to withdraw from the study at any time. Information collected prior to withdrawal will remain in the study. All correspondence will contain the PI's email address and phone number for invited participants to use if they have questions.
3. Research staff will then conduct the semi-structured interview by telephone with consented participants.
4. Participants will receive $40 for completing the interview.

The following protocol will be used to recruit participants for the process evaluation among intervention arm participants:

1. An introductory letter will be sent to eligible participants from the HH/HF hybrid-effectiveness implementation trial inviting them to participate in interviews. Eligible participants include study participants (from Aim 1) who have expressed interest in being contacted for a follow-up interview during their last study survey. The letter will include a description of the study, study procedures, compensation for completing the semi-structured interview, contact information for study staff, etc.
2. Ten days after mailing the letter, identified participants from the HH/HF hybrid-effectiveness implementation trial will then be contacted via telephone and will be told about the study, study

procedures, compensation for completing the semi-structured interview, etc.
3. Those who are interested in participating will be fully informed about the study procedures and consented to participate via telephone. The IRB-approved consent statement will describe the purpose of the study, risks and benefits, and selection criteria. Participants will be informed that they have a right to withdraw from the study at any time. Information collected prior to withdrawal will remain in the study. All correspondence will contain the PI's and study coordinator's email address and phone number for invited participants to use if they have questions.
4. Study staff and students will then conduct the semi-structured interview by telephone with consented participants.
5. Participants will receive $40 for completing the interview.

Field Methods for hybrid-effectiveness implementation trial

To answer our effectiveness and implementation research questions, we will conduct an RCT with follow-up at four months and nine months post-baseline. The four-month post-baseline follow-up will document short-term outcomes and process data such as acceptability of the intervention. The nine-month post-baseline follow-up will assess maintenance of home food environment and dietary changes. Participants will be recruited by United Way of Greater Atlanta 2-1-1 and United Way of SWGA. EPRC staff will obtain informed consent and enroll participants and collect data at baseline and follow-up. Horizons Community Solutions staff will deliver the intervention to participants recruited from outside the Atlanta area and EPRC staff will deliver the intervention to callers from the Atlanta area.

Data Collection Procedures. The telephone interviews will be conducted by trained Emory research staff and graduate research assistants. All data collectors will be blind to group assignment and have no interactions with any intervention delivery related tasks, including mailings. At follow-up, if data collectors are unable to reach participants with the established telephone-based collection protocol, data collectors will text and email participants a unique survey link designed using REDCap for them to complete their home environment survey. A final attempt to collect data will be made via mail. Participants will receive a paper copy of the home environment survey asking them to complete it and mail it back.

Data collectors will be responsible for confirming eligibility of all interested participants referred by 2-1-1 and conducting informed consent to participate in the study. Once verbal informed consent has been documented, the baseline interview will be conducted. Two unscheduled dietary recalls will follow to ensure completion of a weekend and weekday recall for each participant. Similar procedures will be executed for follow-up data collection #1 and #2. Please see table below for data collection and payment schedules.

	Recruitment & Screening	Informed consent	***Interview 1*** Home Environment Survey	***Interview 2*** Dietary Recall 1	***Interview 3*** Dietary Recall 2
Baseline	X	X	$40		
			X	X	X
Follow-up 1 (4-months post-baseline)			$20	$20	
			X	X	X
Follow-up 2 (9-months post-baseline)			$20	$20	
			X	X	X

Dietary recalls will be administered using NCI's web-based application, ASA24. Although this user-friendly application is intended for self-administration, we have also established protocols to aid in researcher-guided telephone-based collection. Additionally, data collectors will be trained on proper probing techniques to ensure all foods, drinks, supplements, and home-made food item ingredients are included. If data collectors are unable to reach participants with the established telephone-based collection protocol at follow-up, data collectors will share the ASA24 study link, username, and password via a text message or an email for participants to complete their 24-hour dietary recalls on their own. **All** participants will receive a copy of their home environment profile and a list of healthy actions at the end of the study.

Baseline and Follow-up Outcome Measures

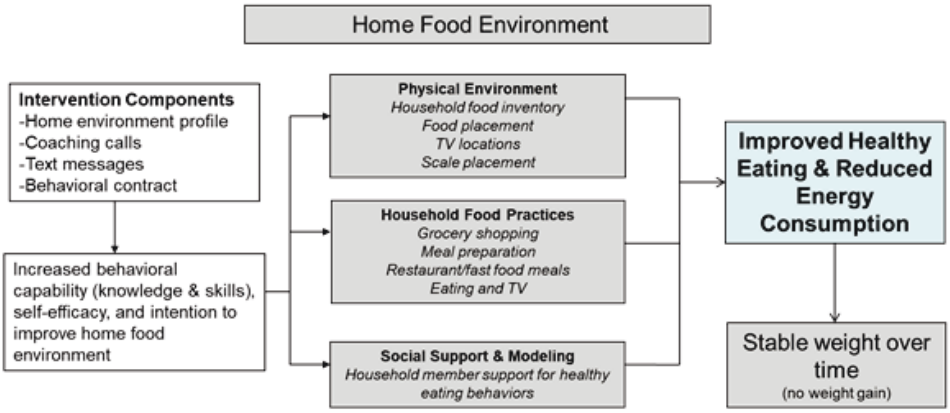
Primary and Secondary Outcomes/Theoretical Mediators. Our primary outcome will be the USDA Healthy Eating Index (HEI)[14] calculated from two telephone administered 24-hr dietary recalls (one weekday, one weekend day), which will be administered at baseline, four-months, and nine-months post-baseline to estimate total energy intake. Interviewer-administered 24-hr recalls are regarded as the best methodology to measure short-term changes in food intake because they provide high-quality and relatively unbiased dietary data.[58] Assessment of dietary intake will be conducted under the supervision of Terry Hartman, PhD, MPH, RD. The respondent will be asked to recall all foods and beverages consumed over the previous day, and at each time point two days will be used to estimate average intake. A computer-directed interview process will guide the respondent through several passes to facilitate accurate recall (e.g., meal-based quick list, meal gap review, detailed pass, commonly forgotten foods, final review). Our team used 24-hr dietary recalls in the original trial for HH/HF and the 2-1-1 feasibility study.

Secondary outcomes will include Kcal per day, self-reported weight, and changes to the home food environment, collected at baseline, four-months, and nine-months post-baseline. Covariates include demographic characteristics (e.g., education, income, household composition), as well as food insecurity and depression. We will also collect data on acceptability, relevance and satisfaction from participants.

Randomization

Participants will be randomized within site (i.e., Atlanta, Albany, Macon, Columbus) using a random number generator with balanced blocks of 10. To accommodate rolling enrollment, the lead statistician or Associate Director of Research Projects will receive participant IDs in meaningful time intervals (e.g., weekly) and communicate their group assignment to the intervention Coordinator.

Figure 4. Conceptual Model of Healthy Homes/Healthy Families Intervention



Intervention Condition

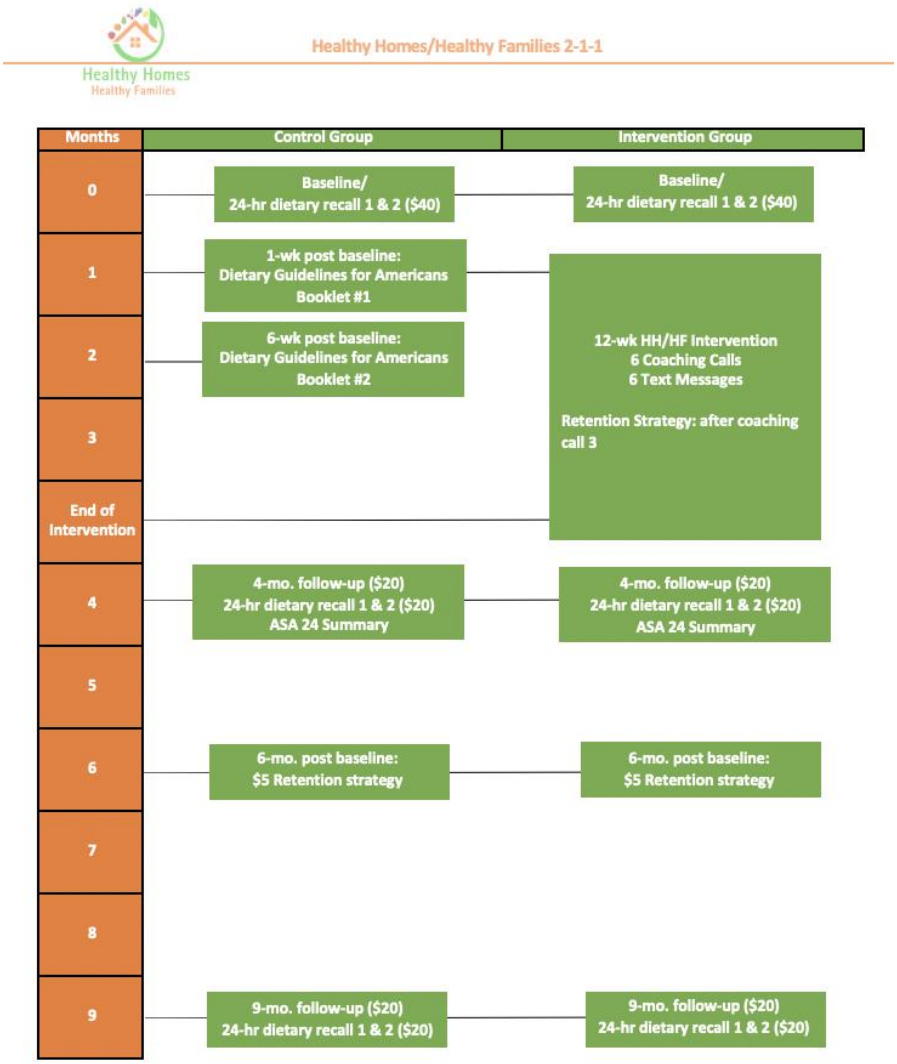
The intervention is designed to target home-based environmental determinants of dietary behaviors (Figure 4). The intervention is grounded in empirical research showing associations between environmental factors and behaviors. The intervention is also informed by Social Cognitive Theory and the Social Ecological Framework,[17,59] both of which posit reciprocal influences between individuals and their environment. Intervention strategies are also informed by coaching, goal-setting theory, and motivational interviewing.[60-63] Our coaching approach is adapted from Heimendinger's 5-stage model (discover, connect, create, design, activate).[60] Additionally, the coaches will use

Table 3. Intervention Delivery Schedule

Timing by Week	Type of Contact	Description
0	Recruitment, consent, baseline data collection	Home environment profile generated and mailed, with other intervention materials (family contract, healthy actions, stickers)
1	Call	***Coach call to review profile and select healthy action 1***
2	Text/email message	Reinforce actions with tips
3	Call	Reinforce progress/problem-solve challenges
4	Text/email message	Reinforce actions with tips
5	Call	***Coach call to select healthy action 2***
6	Text/email message	Reinforce actions with tips
7	Call	Reinforce progress/problem-solve challenges
8	Text/email message	Reinforce actions with tips
9	Call	***Coach call to select healthy action 3***
10	Text/email message	Reinforce actions with tips
11	Call	Reinforce progress /problem-solve challenges
12	Text/email message	Reinforce actions with tips

key aspects of motivational interviewing, such as reflective listening and rolling with resistance.[64,65] Immediately after a participant completes baseline data collection, we will generate the home environment profile via a secure web-based application and send it along with the other intervention materials (i.e., family contract, healthy action checklist and stickers). The home environment profile presents tailored baseline data in a user-friendly format that helps participants identify aspects of their home environment that facilitate or hinder eating healthy. Tailoring is based on the household food inventory, frequency of grocery shopping for fruits and vegetables, frequency of purchasing fast food/restaurant food for family meals, food preparation and serving practices, eating in front of the TV, and weight monitoring.

The intervention will be delivered over 12 weeks with weekly contact alternating between phone and text/e-mail contact (see Table 3). The Coach will contact the participant one week after baseline data collection to review the home environment profile and select the first healthy action. On the first call, the Coach will review the profile, then present a list of low-cost "healthy actions" that target possible environmental changes to make in the home. Using a series of open-ended questions, the coach guides the participant to select a healthy action to work on. This will be followed at weekly intervals by text/e-mail check-ins to reinforce progress and problem-solve challenges. Additional healthy actions are added in future calls, for a total of three healthy actions across three months. The participant will document the selected healthy actions on a family contract with stickers and their signature. The coaching calls, text messages and intervention materials are designed to increase behavioral capability, self-efficacy and behavioral intention to improve the home food environment for healthy eating and weight gain prevention. Participants will receive three seasonings, one portion size plate, and a magnetic grocery list pad after completing their 3rd coaching call.



Control Condition. Participants in the control condition will receive two mailings on healthy eating, the first from the *Dietary Guidelines For Americans 2015-2020- Eight Edition* and the second from *Choose MyPlate*.[66,67] Additionally, both mailings will include a food diary from the Centers for Diesease Control and Prevnetion.[68] Mailings will be sent to participants one and six-weeks post-baseline. These materials focus on the same dietary outcomes we are targeting, but without the home environment emphasis. We will also send control group participants their home environment profile with a list of healthy actions upon completion of the study.

Field Methods for the assessment of implementation (aim 2)

Participant surveys, completed one month after the intervention will include a number of process evaluation questions. We will ask about receipt of mailed materials, usefulness and relevance of materials, and satisfaction with the coaching calls. Coaches will also complete coaching logs to document goals set and barriers faced or anticipated. Semi-structured interviews will be conducted with four staff at each 2-1-1 (e.g., United Way Director, 2-1-1 director, line agent/resource manager and line agent/community connections specialist) (n=16) and with the Horizons coach and supervisory staff (n=2) via telephone or Zoom. Semi-structured interviews will also be conducted with intervention arm participants based on each of the eight healthy actions (n=45) and based on participants' food security status (n=35) via telephone or Zoom for a total of 80 interviews. Semi-structured interview guides for 2-1-1 and Horizons leaders and staff will cover topics to adoption, adaptation, acceptability, relevance, and maintenance. Semi-structured interview guides with intervention arm participants will cover topics related to barriers and facilitators to healthy action progress and maintenance, barriers and facilitators to healthy food access and healthy eating, and suggestions for program changes or improvements. Interviews will be recorded and transcribed verbatim. All interviews will be conducted by personnel not directly involved in other aspects of the study, to minimize social desirability bias. All study procedures, including the interviews, will occur by telephone. 2-1-1 and Horizons leaders and staff who complete the semi-structured interview will receive a $40 gift card in appreciation of their time. Intervention arm participants who complete the semi-structured interview will also receive a $40 e-gift card and/or mailed gift card.

Field Methods for cost-effectiveness study (aim 3)

We will collect program delivery tracking logs, partners' estimated time and costs as part of the cost-effectiveness analysis. We will also include data on call attempts for recruitment, program delivery, frequency and outcome of call contacts, etc. Participant surveys, completed one-month post intervention implementation, will include a number of process evaluation questions that will be used to assess implementation (from aim 1). These data sources will be used for the purposes of program document review to answer evaluation questions.

INFORMED CONSENT PROCESS

We will use an IRB approved informed consent prior to conducting any study procedures. Since all of the study procedures are telephone-based and we will not have any physical contact with participants, the informed consent process will also occur by telephone. Personnel working remotely from home, will document the date and time of consent and provide their signature using the REDCap electronic-consent feature that implements consent forms through an online survey. This will allow us to keep confidential participant data paper-less and securely saved on Emory's servers. A waiver of written consent document that will be constructed in REDCap has been uploaded for approval.

During the informed consent process, we will describe the purpose of the study, procedures, risks and benefits to participating, compensation, and how confidentiality will be maintained. Since contact information for study PI and Project Coordinator will be provided, a hard copy of the consent form will be mailed to all participants who request it.

POTENTIAL RISKS/DISCOMFORTS TO STUDY PARTICIPANTS AND MEASURES TO PREVENT OCCURRENCE

We will not be discussing any sensitive topics and we do not expect any of the telephone calls, survey questions, or print materials to cause any harm or distress. The primary risk in this study is a loss of privacy or breach of confidentiality. We will take standard measures to protect all participants' confidentiality, as described in the Confidentiality section below. The proposed protocol contains minimal risk so no adverse events are expected. However, should any adverse event occur, the study staff would immediately alert the Principal Investigator (PI), who will have the responsibility of informing Emory IRB.

There are two potential risks for participants in the assessment of implementation study (aim 2), though it is important to stress that the overall risk is judged to be very low. First, study participants may experience risks

related to loss of privacy or breach of confidentiality. Additionally, when participating in the semi-structured interview, they may be hesitant or uncomfortable responding to questions regarding intervention implementation, relevance, barriers experienced, etc. They will be interviewed by staff not directly involved with intervention delivery. We will provide the maximum possible protections so that all participant information is protected and participants understand their rights, data purpose, use, and storage. We will ensure that participants are aware their responses are optional and that they have the right to withdraw from the study at any time without penalty or loss of benefits. Participation will not be disclosed to their organization or anyone outside the research team. All responses will remain confidential and not be shared with anyone except the project staff.

BENEFITS

Participants may benefit from improving their home food environment and/or eating healthier as a result of our intervention materials and contact with health coaches. With participants' help, future 2-1-1 clients and their families may benefit from an intervention that is designed to help them improve their home food environment.

COMPENSATION

Participants will receive a $40 reloadable gift card (ClinCard) as compensation for completing their baseline data collection (home environment survey and two dietary recalls). An additional $40 will be loaded to the participant's reloadable gift card after the completion of follow-up 1 and follow-up 2 (HES with 2 dietary recalls at 4-months and 9-months post-baseline). We will also load $5 to their reloadable gift card if they respond to a text message confirming their contact information at 6-months post-baseline, as a retention strategy. If unable to reach them via text we will mail them a postcard that they will have to initial, confirming their contact information is the same (postcard is included for review). Once we receive the postcard we will load $5 to their reloadable gift card. The total amount that participants are eligible to receive is $125, if they complete all parts of this study.

2-1-1 and Horizons leaders and staff in the assessment of implementation study will receive a $40 Amazon e-card as compensation for taking part in the interview, and intervention arm participants will receive a $40 Amazon e-gift card or other gift card (e.g., Walmart) as compensation for taking part in the interview (aim 2).

DATA MANAGEMENT AND MONITORING

All study staff, including the PI, will participate in the monitoring of participant data. The proposed protocol contains minimal risk so no adverse events are expected. However, should any adverse event occur, the study staff member who discovered the adverse event would immediately alert the Principal Investigator, who will have the responsibility of informing the Emory IRB. The PI will meet regularly with study staff to ensure that data security is maintained and data analysis is handled as outlined above. Each study participant will be assigned an ID number and surveys will be identifiable via assigned IDs only. A separate Excel database will link identification codes with participants' names. Coaches will upload and store all electronic files, including audio-recordings, on a secure, password protected network drive that is backed up by the RSPH Office of Information Technology.

Data for intervention delivery will be collected via the HHHF Application, a secure electronic intervention delivery application which is hosted on Amazon Web Services (AWS). AWS is a secure cloud services platform, offering database storage, content delivery, and is a more cost-efficient but equally secure platform to host such web-based applications. We have first-hand experience working with AWS and are hosting another web-based application there currently. All other data sources will include hard-copy interview guides with responses, audio files, and tracking logs. All of the electronic files (including data from REDCap) will be stored on the secure network drive and hard-copy files will be locked in a filing cabinet in a locked office only accessible to approved research staff and faculty. While working from home, we are implementing paper-less methods of data collection and tracking.

DATA ANALYSIS

Data Analysis Plan for the hybrid-effectiveness implementation trial
All dietary recalls will be collected, processed, and analyzed using the most recent version of ASA24 that prompts for food description details and automatically codes and calculates nutrient intakes using the USDA Food and Nutrient Database for Dietary Studies.[69] The ASA24 provides values for total energy, nutrients and nutrient ratios, foods and food groups, and can be used to calculate the HEI to assess diet quality. The ASA24 program provides a daily total for energy intake and other nutrients (e.g., total fat) and food groups (e.g., fruits and vegetables). We will use the average of one weekday and one weekend day to estimate usual short-term diet at each time point.

We will assess continuous outcomes for normality and transform them if assumptions are not met. We will assess missingness of data by conducting logistic regression analyses with reached/not reached for follow-up as the outcome to see if those who were not reached were statistically significantly different from those who were not reached.[70] Predictor variables will include demographics and other baseline variables such as BMI. For all outcome variables, we will also investigate any outliers and will decide on exclusion if they are unusually high (beyond 3 SD) or impossible values. However, we will make strong efforts to reduce outliers through rigorous data quality control.

To assess the effectiveness of the HH/HF in the 2-1-1 population we will conduct traditional RCT analyses, using both complete case and intent-to-treat data (all participants). We will first assess statistical significance of change between baseline and each follow-up points with appropriate bivariate tests (e.g., independent t-tests, Wilcoxon-Mann-Whitney tests, chi-square tests of independence). We will use growth modeling as the intent-to-treat analysis as it allows for modeling of all available data without the need for multiple imputations based on the assumption of data missing at random.[71,72] Hence, we will include any variables identified as being related to missingness into these models as covariate. We will utilize multiple imputation if there are issues with missing data for individual covariates.[73] In general, growth models will include time (calculated as time elapsed between the measurement point and baseline date) and an interaction effect between time and group assignment. We will assess the intraclass correlation (ICC) due to clustering in 2-1-1 call centers, but based on our previous research, ICCs are expected to be very small (< 1%) and we therefore do not anticipate the need to adjust for clustering. However, if the need arises, we will adjust for clustering using three-level modeling with Bayesian estimators due to the small number of clusters.

Furthermore, we will test differences in intervention effectiveness, i.e., conduct moderator analyses, for demographics/household characteristics, and baseline BMI using growth modeling with interaction effects between group assignment and the moderators of interest. Finally, we will use Structural Equation Modeling to assess changes to the home food environment as mediators as indicated in Figure 4. Data cleaning and analyses will be conducted using SAS 9.4 and Mplus 8.

We will also use the addresses of HH/HF study participants to investigate the relationship between food desert residence and primary and secondary outcome variables such as diet quality and household food inventories. To do so, participants' addresses will be geocoded using ArcGIS 10.8.2 and assigned to 2010 census tract data. These data will then be joined with USDA's Food Access Research Atlas dataset, which includes census tract-level information on food access. Using participant's census tract as an objective indicator of food access de-identifies participants' home locations.

Data Analysis Plan for the assessment of implementation study (aim 2)
Descriptive analyses will be run on survey and coaching log/web analytic data to characterize the process measures and program implementation. Regarding data from 2-1-1 and Horizons leaders and staff, we will conduct analyses pooled across sites and by individual sites (i.e., the four 2-1-1s and Horizons versus EPRC) to understand variations in promotion, recruitment, and implementation. We will also develop a codebook based on evaluation questions and emergent themes from the transcripts. Two analysts will double code each transcript and resolve discrepancies through discussion. NVivo will be used for qualitative data analysis and management. We will then generate code reports using NVivo to facilitate identification of themes and develop matrices to aid in identifying themes and patterns across key categories such as type of 2-1-1 organization (e.g., Atlanta versus Macon/Columbus versus Albany), which differ in terms of staffing structure and organizational and community context. A similar approach will be taken for the analysis of qualitative data from intervention arm participants. The process evaluation data from program participants will be triangulated with the staff interviews to assess multiple stakeholders' perspectives.

Data Analysis Plan for the cost-effectiveness analysis (aim 3)
We will conduct a cost analysis and a cost-effectiveness analysis of the intervention, focusing on effects associated with improvements in diet (i.e., fruit and vegetable consumption, fewer empty calories) and avoidance of weight gain (relative to controls). The analysis will be conducted from the societal perspective and assume a lifetime horizon. We will use estimates of effectiveness of the intervention based on the analysis described above. In the baseline analysis, we will assume that behaviors persist for participants remaining lifetime. We will test the sensitivity of results to reasonable assumptions about effect durability, but most studies linking dietary behaviors to health outcomes in the literature focus on binary classifications of behaviors rather than exposure time. We will build a model that tracks participants from the beginning of the intervention to death. The analysis will conform to Panel on Cost-Effectiveness in Health and Medicine standards for conducting cost-effectiveness analyses.[68]

Direct intervention costs. We will estimate the costs of program delivery in the intervention group. We will not consider costs associated with the evaluation of the intervention. Project staff will be asked to keep time logs to document time spent on developing and delivering the intervention. We will value staff time based on their wages, which are included in the grant budget. For staff who are hired on a full-time basis, we will make a reasonable assumption about the share of time they spend on intervention delivery versus research and value it accordingly. **Indirect costs**. We will record the length of time participants spend on the phone with their Coach and value time using the median US wage. Use of a wage to value time costs is appropriate even for individuals who are not employed because it reflects the opportunity cost of forgone leisure time. **Cost-offsets**. We will focus on the impact of the intervention on fruit and vegetable consumption and obesity. We will follow the methods of Rahkovsky and Gregory to estimate cost-offsets from changes in fruit and vegetable consumption.[69] They estimate the relationships between food prices and non-high density lipid cholesterol and use their results to predict the impact of interventions to change the consumption of various types of food groups (e.g., vegetables, whole grain products) on cardiovascular disease-related spending. We will use estimates from the nutritional epidemiology literature and estimates of disease-attributable costs, some of which we have estimated,[70] to predict the impact of dietary changes on cancer- and diabetes-specific costs. We will use a similar approach to estimating cost-offsets from reductions in obesity that occur independently of dietary improvements.

Cost-effectiveness. In the event cost-offsets are lower than the direct costs of the intervention (i.e., it is not cost-saving), we will calculate the incremental cost-effectiveness ratio associated with improvements in health status due to the intervention. The numerator of the ratio is the change in per participant costs between the two groups, including the direct costs of the intervention, indirect costs, and cost offsets. The denominator is the change in quality-adjusted life years.

TRAINING OF THE STUDY TEAM

Intervention staff at both the EPRC and Horizons will include staff who participated in conducting our prior studies on HH/HF. They and newly hired coaches will undergo a two-day in-person training with built-in practice sessions with original program developers and intervention staff. Post-training practice sessions will continue until interventionists are well-versed in interpreting the home environment profile, delivering coaching calls with appropriate tips and goals, and providing effective reinforcement contacts (via text and phone) to reinforce healthy actions and problem-solve challenges. All participant interactions will be audio-recorded until five consecutive coaching sessions and reinforcement calls are delivered successfully. Tailored written and verbal feedback will be provided on all recorded sessions for improvement and audio-recordings will continue for 10% of subsequent calls throughout the duration of the study. Monthly/quarterly group booster training sessions will be held via telephone with all intervention staff to review feedback. Similar processes will be used to train data collection staff with intensive in-person training to be provided by our seasoned study coordinator. Training topics will include item-by-item review of baseline and follow-up surveys, data collection techniques, multiple call attempt tips, and accurate data documentation will be emphasized. Baseline and follow-up survey data will be documented on hard copy and entered into the HH/HF web-based application to generate the home environment profiles. All hard copy survey data will be reviewed for completion (against an

audio recording, if available), and feedback will be provided to data collectors as needed. All hard copy data will be double-entered into an SPSS database to ensure accurate data entry. ASA24 data downloads will also be reviewed regularly and responses requiring revisions will be reviewed by Dr. Hartman and study faculty. All data collection interactions will be audio-recorded until 5 successful surveys and dietary recalls have been documented with 10% of recalls being recorded thereafter. Ongoing quality control of dietary recall recordings will continue throughout the duration of the study with provision of individual and general group feedback by the study coordinator as needed. All study team members have completed (or will complete once identified) the necessary CITI certifications to maintain human subject protections.

PLANS FOR MONITORING THE STUDY FOR SAFETY

Only authorized study staff will have access to surveys, audio files, transcripts, datasets, information that links identifiers to subjects, and any other information provided. As previously mentioned, all data will be transmitted and saved on a secured research network server of RSPH that can only be accessed by study staff.

All study staff, including the PI, will participate in the monitoring of participant data. The proposed protocol contains minimal risk so no adverse events are expected. However, should any adverse event occur, the study staff member who discovered the adverse event would immediately alert the PI, who will have the responsibility of informing the Emory IRB. The PI will meet regularly with study staff to ensure that data security is maintained and data analysis is handled as described.

CONFIDENTIALITY

Confidentiality of participant data will be protected at all times. The following procedures will take place:

a) All study personnel will be thoroughly trained on how to maintain confidentiality.
b) Each participant will be assigned a unique ID number. We will use each participant's ID number instead of his/her name whenever we can, including the surveys and during data analysis. Once the data is exported from the HH/HF Application, we will ensure that all personally identifying information, such as names, will not be stored in the same electronic data file as other study data.
c) Contact information obtained from participants will be kept on a secure network server. No hard copies of data will be stored.
d) All data collected will be backed-up on a secure "Research" drive and will only be accessible to CITI certified study staff.
e) Participant names and other facts that might identify a specific participant will not appear when we present this study or publish its results.
f) We will use digital recorders and files will be stored electronically on a secure and password protected "Research" drive. Audio files will be deleted once the study procedures and data analyses are complete, or three years after transcription (whichever comes first).

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