A Mobile Application to Improve Procurement and Distribution of Healthful Foods & Beverages in Baltimore City (BUD)

NCT05010018

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A. SIGNIFICANCE

A.1. Changing the food environment to prevent obesity in low-income African Americans

The prevalence of obesity and chronic disease in the US has increased dramatically in recent decades, and is higher among African Americans (AA).[1–5] Obesity greatly increases the risk for chronic disease.[6–8] The diets of low-income urban AAs tend to be high in sugary drinks and high fat foods both of which increase risks for obesity and chronic disease,[9–12] and lack recommended amounts of fruits and vegetables (FV), which are protective for chronic disease.[13–15] While the evidence is mixed, recent reviews conclude that the food access (including availability and price), can influence diet and risk of developing obesity and associated health outcomes,[16–28] and that actions to improve the food environment are justifiable.[29] Low-income minority neighborhoods tend to have greater access to higher-priced nutrient poor foods, obtained at small food stores and carryout restaurants,[30–36] and reduced access to lower-priced nutrient dense foods in supermarkets, which have been shown to reduce health risks.[37–40] Recent studies analyzing price elasticity of fruits and vegetables found that a decrease in price of healthier food has a long-term impact on consumption of these items among low-income individuals.[41,42] In addition, small food store trials have improved access, stocking, and consumption of healthier foods and beverages in these settings.[43–46]

A.2. Access to healthy, affordable foods is a problem for small stores in low-income urban communities

Small independently owned food stores (referred to as corner stores) in low-income settings have low access to affordable healthy foods and beverages to stock in their stores.[47–49] Stocking healthy, affordable foods in small urban stores is impeded by the lack of an adequate distribution network.[50–52] While high-sugar and -fat foods and beverages are commonly delivered directly to these stores by manufacturers/distributors, healthier foods such as fresh produce, milk, and 100% whole wheat bread typically must be obtained by the small store owners themselves at local wholesalers or at grocery stores where availability, selection and quality are often poor, and pricing may be high.[47,49] Those wholesalers who do offer delivery services commonly require a large minimum order cost (e.g., $1000), well beyond what is feasible for corner stores. **Consequently, there is a great need for strategies to increase access to healthier foods in small food stores, in a manner that is cost-effective for the stores and ultimately to consumers.**

A.3. Digital strategies are effective in changing health behaviors and improving health outcomes

Evidence showing impact of digital health interventions used at the patient, provider, and health systems levels has grown dramatically.[53] Digital interventions have been shown to successfully improve health behaviors ranging from diet to smoking cessation[54,55], and health outcomes, including weight loss.[56–59] A strength of digital strategies lies in the near ubiquity of social media/digital communications platforms, which allows for the engagement of peers for driving individual and group-level behavior change.[60] Digital 'networking' to reinforce or drive behavior has been tested on a wide range of strategies from diabetes management in adolescents,[61] to weight reduction [62]and diabetes prevention [63], to increasing consumer spending through group discounts [64]. The BUD application will develop a digital social networking solution to address a critical gap in low-income urban settings in the United States: the lack of affordable supply channels to deliver healthier products to small corner stores. This digital tool will stimulate new supply-side behaviors (e.g., networking among small store owners), while also facilitating the application of proven economic strategies to reduce food costs. BUD represents an innovative interdisciplinary digital strategy that draws upon proven approaches, including collective purchasing[65] and delivery sharing to provide a cost-effective and sustainable solution.

A.4. Need for technologies to improve distribution of healthier foods to small food stores

Despite the proliferation of applications which allow individual ready-to-eat food ordering, digital innovations to improve access to healthy foods are limited in low-income settings. Current online services such as PeaPod and Instacart for supermarket chains and UberEats, OrderUp, and GrubHub for prepared foods are generally unavailable in food deserts.[66–70] Part of this issue relates to delivery challenges. While there are some services that include free delivery to centralized pick-up locations [Virtual supermarket, Books and Bread, etc.], these services are characterized by limited geographic availability and low reach.[71] *More recent entries to online food delivery services such as AmazonFresh are restricted to high-priced items, such as organic fruits and vegetables.* Thus, there is a need to enhance the capabilities of small retail food stores, ubiquitous in low-

income urban settings, that uses technology to enable them to improve their stock and quality of affordable healthful foods. **Specifically, we propose to develop and pilot a mobile web application for an online delivery service of healthy foods from local producers, farmers' markets and existing wholesalers to small urban corner stores in Baltimore.** *Why haven't private businesses already developed delivery apps such as we propose for small food stores located in low-income urban communities? Based on our formative work, we would argue that this gap relates to a kind of systemic bias– expressed in the perception that there is little or no consumer demand for these foods, but our research has shown otherwise.*[72] *The development and successful testing of the BUD app could help resolve this market failure. Once the benefits are shown (e.g., sales, sustainability), we anticipate that the private sector will adopt and improve this solution.*

A.5. Evidence for pass-through of lower prices in urban corner stores

Pricing greatly affects food-purchasing decisions at all levels of the food system, from producers to consumers. The highest price point for delivery is "the last mile", a supply chain term used to describe the last leg of delivery of a product which is often the least efficient and most expensive.[47] Through collective purchasing and delivery we aim to lower the cost of "the last mile." Our previous work supports the notion that cost savings accrued in the last mile will be passed on to consumers.[73,74] Additionally, small urban food stores charge 10-57% more for staple food items than large supermarkets.[75] This proportion may create an economically favorable margin for a pass through of reduced prices to consumers if small stores receive discounts that allow them to practice more competitive pricing. It is common for companies to engage in off-invoice trade promotions; in which manufacturers sell products to accounts below the suggested retail price to create a large enough margin to allow the product to be discounted to consumers.[76] However, documentation of this practice is limited due to a lack of transparency in the industry and varying business practices among companies and accounts. **While data are limited, it appears that small stores will stock healthier foods and beverages if incentivized by reasonable cost, and that there is the potential to expect at least partial pass-through of reduced prices to consumers.** ***Even if cost pass-through does not occur immediately, a successfully distribution app will reduce uncertainty and allow owners to plan and ultimately pass lower costs on to consumers.***

A.6. Evidence for the effectiveness of collective purchasing (and delivery sharing) in food retail

Collective or cooperative purchasing refers to the practice by which individuals or smaller institutions band together to jointly purchase greater quantities at lower prices. Cooperative purchasing has been used extensively by school meal programs, and has been found to reduce costs.[77] A London study examined a growing online grocery purchasing market and the potential for economic, environmental and social cost savings involved in coordinated food delivery throughout the city.[78] The researchers found that shared delivery helped to spread the burden of the "last mile problem". *Furthermore, collective purchasing provides information on aggregate demand over a large number of grocers, which would be less variable than the information at the individual grocer level. Such information can reduce uncertainty about demand and allow corner store owners to plan for restocking in a more cost efficient manner.* **Although limited, available evidence suggests that collective purchasing of food has been successful at improving the retail food environment in some settings. However, this has not been demonstrated in small urban corner stores, nor has the delivery problem been addressed.**

A.7. Summary

There is great need for innovative strategies to improve the distribution of affordable healthful foods and beverages to small food stores in low-income urban communities in cost-effective ways. Digital strategies offer a promising approach, but substantial work is needed to develop a workable app that will be acceptable to wholesalers, producers, and small store owners, yielding an affordable solution for the delivery of healthy foods and beverages – that will ultimately lead to improved access (availability, price) to these products for consumers. **We propose to develop and pilot a working version of the Baltimore Urban food Distribution (BUD) app, which will address these challenges, offering a cost-effective way for small urban food stores to stock a broader range of healthy, affordable products, and will assess the app for feasibility.**

B. INNOVATION

Our study team includes a medical anthropologist community nutritionist (Gittelsohn), a digital health/mHealth expert (Labrique), a health economist (Trujillo), a systems engineer (Igusa), and a biostatistician (Ogburn). Dr.

Gittelsohn has worked on chronic disease prevention in low-income, ethnic minority communities for more than 25 years.[43,73,79–82] His findings, including behavioral, psychosocial, cultural, sociodemographic, and environmental obesity predictors,[83–90] have been used to design culturally- and setting-relevant instruments and interventions at the individual, family and institutional (particularly food retail) levels.[45,79,80,91–93] He has conducted three separate trials aimed at increasing access to healthier foods and beverages in Baltimore corner stores[43,80,94] . These trials successfully increased stocking and sales of healthier foods[43,44,95], increasing purchasing and consumption of these foods among low-income individuals[82], and have been shown to decrease child body mass index (BMI).[94] Dr. Igusa has experience developing web apps for a variety of public health applications including contraceptive decision support[96], systems dynamics modeling of community resilience after natural disasters[97], *a wiki-survey for policy makers considering deployment of autonomous vehicles[98] and a self-evaluation tool for promoting healthy relationships for Native American youth[99]. In each case, he worked with a team of stakeholders[96,97,99] to identify and address design issues, assess and improve usability, and, for the Native American web application, incorporate culturally relevant content.[99] The app that is most closely related to the grant was created by Drs. Igusa and Gittelsohn in collaboration with the Baltimore City Mayor's Office for the purpose of supporting a staple foods ordinance.[100]* Dr. Labrique is Director of the JHU Global mHealth Initiative, and has developed methods for the development, refinement, testing and evaluation of Digital Health technologies, in close collaboration with international agencies such as WHO and UNICEF. His group has developed interoperable software for community health workers, with complementary monitoring and evaluation procedures to ensure high quality, fidelity and impact of these technologies, within the complex ecosystems where they are deployed.[81,101–103]

B.1. First randomized control trial to assess the effectiveness of an app to improve access to healthy foods in low-income communities

While apps and websites have been developed for promoting healthy foods in low-income settings[66,104–106], the impact of these technologies on heathy food access, purchases and intake has not been rigorously examined using randomized controlled trials. We will assess feasibility of the BUD app, and conduct an RCT that tests its impact at the store level. A future clinical trial will assess its impact on consumer behavior and health outcomes. To ensure acceptability, we will use gold-standard systems principles of user-centered design and testing to maximize the fit and user experience of the BUD app. As part of our preliminary formative research, we developed a wireframe model of BUD, working closely with 11 corner store owners, and 7 food distributors/producers. Overall, acceptability and perceived operability was high, but challenges were also identified, such as small stores that operate on a cash-based system, small stores' ability to display and/or provide adequate storage for perishable items such as fresh produce, lack of affordable delivery methods to corner stores for smaller amounts of products, limited variety of products wholesalers and producers carry, and a perceived lack of healthy food demand from consumer. We recognize the challenges faced in implementing a successful BUD app in Baltimore's low-income food environment and will test innovative solutions to overcome these challenges. **We will develop and pilot a working web-based version of the BUD app, and will assess its effectiveness in improving the small store food environment.**

B.2. BUD app will link small urban food stores with local producers and suppliers

To our knowledge, this is the first trial to develop, pilot and carefully evaluate an app to connect small urban food stores located in low-income communities with multiple local producers and suppliers. This will, in turn, improve the healthy food supplier network for small stores. Our team has substantial experience working to improve the urban food environment, and in conducting social marketing, social media and health communications interventions to improve dietary behaviors in low-income ethnic minority populations.[43,73,79,80,82] We have decades of experience operating in the Baltimore business and marketing environment (Gittelsohn), and have worked with local producers previously.[107] Furthermore, we will conduct substantial formative research as part of the app development process, guided by co-investigators with experience in integrating technology into public health research and implementation (Labrique, Igusa), and determining pricing strategies (Trujillo). **The BUD app will allow Baltimore corner store owners to access a wider range of healthy foods and beverages cost-effectively, and will allow efficient planning of food stocks.**

B.3. Use of innovative group purchasing feature to reduce costs

The BUD app will test an innovative group purchasing feature (BuddyUp!), similar to Groupon, to reduce the prices of the foods ordered, and keep delivery costs low by harnessing collective buying power. Wholesalers

and producers will set prices at two levels: 1) individual purchase of smaller quantities commonly ordered by small corner stores; and 2) group purchase of larger quantities at a reduced price. BUD will include a chat feature, which will enable small store owners to communicate with each other to coordinate group purchases. The chat feature will initially support the languages spoken by most Baltimore corner store owners: English, Korean, Spanish, and Mandarin.[108] Both producers and wholesalers have shown excitement about the ability to add BuddyUp! deals to products; in particular, to help promote seasonal produce and storage crops. **The BuddyUp! collective purchasing feature will allow small store owners to purchase relatively small quantities of healthier foods, at an affordable delivery and total cost.**

B.4. Will identify novel, culturally appropriate delivery methods from suppliers to small corner stores

Distributors make the delivery of sugar sweetened beverages and high-fat snacks easy for small store owners. Yet, no such mechanism exists to cover delivery of healthier foods/beverages, such as fresh produce, to corner stores.[49] *Baltimore has 13 food distribution sources, including wholesalers, distributors and warehouse stores. Of these, 4 sources (31%) do not deliver to small stores (Costco, Sam's Club, BJs Wholesale Club, Jetro Cash & Carry). Of the remaining 9 sources, 5 (38%) require substantial minimum purchasing levels beyond what small corner stores can afford (Prima Foods, George J Falter Co, Hearn Kirkwood, Belair Produce Inc., B Greens Co). The remaining 4 sources carry only specialty products (e.g., seafood only, meat only) or do not carry fresh produce (Nino's Food Distribution, Pastore's Wholesale Grocers). Instacart, a grocery delivery service was also considered, but considered impractical in this context due to: 1) Poor consumer reviews (e.g. rotten produce, incorrect foods delivered); 2) Delivery fees which can add up quickly for multiple small orders in a week; 3) Services only offered in English.*

We will explore incorporating at least three different mechanisms for addressing this issue into the BUD app: 1) partner with an existing online delivery service (e.g., Hungry Harvest, UberEats); 2) utilize a suppliers' existing delivery service (if they have one); and 3) small store owners share delivery services between each other through a feature called BuddyLift!.[68,109] The BuddyLift! feature will permit store owners engaged in collective buying to take on the delivery role in exchange for further reduction in price. This feature will be voluntary and any owner placing an order may participate and provide the delivery service. Initial formative research indicates mixed support for the BuddyLift feature, with small store owners enthusiastic about the feature in principle, but expressing concerns about how well the honor system it implies would work. We will work to resolve these challenges during the formative phase of the proposed research, but anticipate that one possible solution will be coordination between store owners through the same language chat feature. Importantly, collective action already exists between the members of some groups of small store owners, such as Korean Americans, making such an approach plausible.

B.5. We will examine the costs/benefits of using the BUD app in relation to sales in small food stores

Led by our economist (Trujillo), we will conduct a financial cost–benefit analysis of the use of the BUD app from the wholesaler, producer and retailer perspectives. We will include in our analysis monthly, and annual totals, including costs at baseline, personnel costs (salaries and benefits), materials and supplies, equipment, and transportation costs, among other items. We will also monetize the time of delivering the intervention and the time devoted to training. We plan to differentiate between initial costs and deployment costs. Initial costs will account for all costs during the pre-implementation phase of the intervention. Post-intervention costs will capture the variable and fixed costs of running the program. We will integrate these templates to estimate the total costs of the intervention and compare these figures to the benefits of the program.[110] Among the potential savings from using BUD, we will include: prices of foods; total net revenues (sales minus discounts); transportation cost of food, transportation costs to buy products; inventory and rotation; financial costs of working capital among other items. Other benefits associated with the BUD are linked with improvement in health and human capital. We would consider these savings broadly using our sample of 190 low-income urban consumers, assessed pre- and post-intervention variation and will monetize outcomes. **We will assess the economic viability of the BUD app, an essential component of feasibility.**

C. APPROACH

C.1. Overview and study design

The overall goal of this R34 application is to develop a stable mobile application to improve access to healthier foods and beverages in small corner corners in low-income urban settings, and to generate preliminary

findings in support of a full-scale clinical trial. The first part of the study will focus on developing a working, mobile accessible version of the BUD app. The second part will employ a randomized controlled trial study design where we will test the app, introduce different features to address identified challenges, and assess feasibility and impact primarily at the store level. Thirty-eight small corner stores located in East Baltimore will be randomized into treatment (n=19 receiving the BUD app) or comparison (n=19). The study will be conducted in seven overlapping phases, over a 33-month period:

Phase 1: Formative research (months 1-5)

Phase 2: BUD app development (months 3-8)

Phase 3: BUD function and usability testing (months 7-12)

Phase 4: Recruitment and baseline data collection (months 10-12)

Phase 5: Randomization, BUD pilot app implementation, process evaluation (months 13-20)

Phase 6: Post intervention data collection (months 21-23)

Phase 7: Data analysis and reporting (months 24-33)

C.2. Study setting and collaborations

The BUD study will take place in low-income areas of East Baltimore. Baltimore City has 633 corner stores, 185 convenience stores, 47 supermarkets, 18 farmers markets, 24 urban farm sites, and 6 public markets.[111] East Baltimore is a largely low income part of the city, representing about a third of the city's area. In East Baltimore there are 12 supermarkets, approximately 168 corner stores, 88 convenience stores, 2 farmers markets, 9 urban farms, and 1 public market.[112] Of corner stores, about two thirds are owned and operated by Korean Americans, roughly 15% are operated by Chinese Americans, and 5% by Hispanic Americans. *Most corner store owners locate their stores in areas not being served by supermarkets. Low income urban food systems throughout the United States have many similarities [72,113–116], including low access to supermarkets/grocery stores[115,117] and high access to small convenience/corner stores, [45,72,118] fast food, [119] and carryout restaurants.[113] These food sources tend to primarily carry foods high in calories, fat, salt and sugar,[120] and lack affordable healthier options. Small independently owned food sources (e.g., corner stores, carryouts) are most common, but these stores often find healthy foods difficult to source, and unhealthy foods easy to obtain.[72,75,80,121–124] Poor healthy food distribution patterns in Baltimore and similar urban food systems are largely due to a distribution gap between small independent food sources and larger wholesalers/distributers.[125]* The BUD research team will partner with various city stakeholders including the Food Policy Director, the Baltimore Food Policy Initiative, and the Baltimore City Health Department (see LOS). In addition, we have obtained strong and detailed letters of support and commitment from 2 wholesalers (including B. Greens, a local wholesaler commonly used by Baltimore corner store owners[126]), 1 produce distributor, 16 East Baltimore corner stores, the Farm Alliance of Baltimore (representing 11 urban farms).

C.3. Additional formative research (Phase 1)

As part of our preliminary studies, we have conducted substantial formative research (i.e., in-depth interviews with 5 distributors, 9 wholesalers, 7 local farmers, 20 corner store owners, and 7 local food system experts). Several key challenges for the BUD app were identified.[124] Delivery challenges include produce spoilage, perceived neighborhood safety, delivery minimums, cost, and scheduling. For example, one local wholesaler does not have a delivery minimum, however, they refuse delivery to areas perceived to be unsafe because of the risk of theft. Other wholesalers offer free delivery with a high minimum, which is difficult for small stores with limited budgets and storage. An additional challenge to app usage is to allow various payment options as many stores and wholesalers/producers prefer to operate on a cash-based system while web-based formats, including BUD, use credit or debit payment systems. Among wholesalers and producers, challenges include varying prices, the effort it takes to input or update products, and integration with current order management processes. Therefore, application design should emphasize convenience and well-constructed design permitting relatively effortless product information updates for wholesalers/producers.

Additional considerations will need to be made to ease use of the application for store owners, including streamlined product pages, working in multiple user languages (*English, Korean, Mandarin, Spanish*), simple return protocol, and product descriptions to inform produce quality.

We will conduct substantial additional formative research to refine the Baltimore Urban food Distribution (BUD) app into an effective mobile app that addresses the challenges described above. In-depth interviews with wholesalers/distributors, local producers and corner store owners (n=16) will be conducted to further explore reactions to *key app features, specifically to the group purchasing (BuddyUp!) and delivery (BuddyLift!) features, to refine these features, add features as needed, and to incorporate recommendations for implementation and usage of the app. This will include assessment of levels and types of subsidies (price reduction, free delivery, etc.) that will be needed to encourage small store owner adoption and maintained use of the app. We will purposively select small store owners of different ethnicities for these interviews, including Korean, Mandarin and Spanish-speaking.* We will explore wholesalers' and producers' willingness to provide discounts based on collective purchasing. We will develop detailed case studies of the ordering and delivery practices of 10 small corner stores *by conducting repeated in-depth interviews. We will also conduct 20 interviews with low income consumers to assess how best to promote targeted foods and beverages*.

One key outcome of the formative work will be to determine the most feasible means of delivering the healthier products to corner stores. Several options will be considered and refined, including the proposed BuddyLift! feature, partnerships with local food delivery services that have expressed interest in operating in low-income neighborhoods such as HungryHarvest, and use of online delivery services such as UberEats.[68,109] Once developed, an improved BUD app graphical user interface (GUI), messages, and survey instruments will be tested in a second round of in-depth interviews with corner store owners and producers/wholesalers (n=16). All interviews will be audio-recorded, transcribed, and translated into English (if needed) for analysis using Atlas-ti 8.4. Research protocol and intervention materials will be reviewed and approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board.

C.4. BUD App Development (Phase 2)

Results from the formative research phase will be incorporated into the development of the BUD mobile app (Aim 1). We will develop the app using Bootstrap 4.0, a multi-platform framework for building web-based apps.[127] While web-based apps are slightly less user-friendly than "native" iPhone and Android apps, they are more versatile in that they will run on all smartphones and laptops. Moreover, adjustments to the system can be more easily accommodated. We will subscribe to an app-based delivery management service (Onfleet) to manage real-time driver pickup and drop off scheduling.[128] With this development and deployment strategy, we will be able to substantially reduce the cost of app development, and by using an app subscription service to handle delivery logistics. The laptop version of the app will be configured as a dashboard so that it can be used by the research team as they monitor the distribution of healthful foods in the Baltimore City low-income neighborhoods. In addition, we will identify and recruit the 38 corner stores in this phase. Technical components of the app will be built using an array of software libraries and methods in the public domain (C.6).

C.5. Multilevel food environment intervention and behavior change framework

Figure 1. BUD app conceptual framework

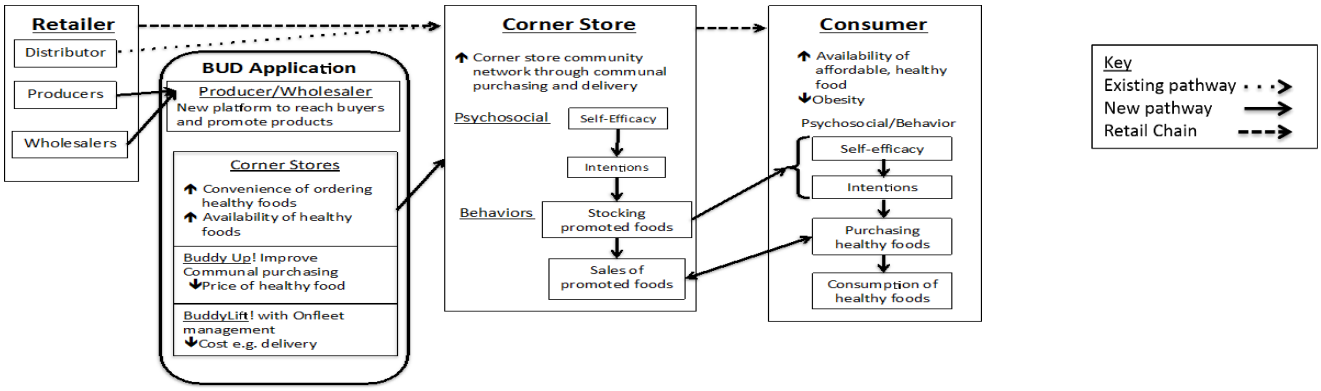


Figure 1 presents the conceptual framework guiding the study, adapted from Social Cognitive Theory and the Social Ecological Model.[129,130] The BUD application addresses physical-environmental factors (e.g. food availability, price) and mediates between the food source (producers, wholesalers) and corner store levels to influence corner store owner stocking of healthier products, and ultimately consumer purchasing. Change in small store owner psychosocial factors (e.g. intentions, self-efficacy) as well as the expected improvements in their access to a broader range of healthier foods and beverages, will result in increased stocking and sales of healthier foods, and lower prices for these foods (if already stocked by a store). Ultimately, we anticipate that consumers who shop at intervention stores will improve their psychosocial factors, and increase purchasing and consumption of healthier foods and beverages, compared to consumers from comparison stores. A long-term outcome to be tested in the subsequent clinical trial is reduction in obesity.

C.6. Description of the Baltimore food Distribution (BUD) application

The BUD app will provide storeowners with a convenient and cost-effective tool for purchasing healthy foods and beverages from local producers and wholesalers. BUD will be linked to Onfleet, an app-based delivery management service that will use product source, destination information, and driver availability to schedule deliveries. BUD will feature an attractive user interface, and have twelve main modules:

Module 1 (Opening the App): Opening the BUD application will direct the user to a main screen that allows app users to choose whether they are producers/wholesalers or corner store owners. The main screen also provides a link to general information about how to use the application.[131]

Module 2 (Producer/Wholesaler Sign Up): Selecting the producer/wholesaler button on the main screen directs the user to either sign in or create an account by completing a series of online forms.[132] On completion, the user is returned to the producer/distributor sign in page.

Module 3 (Uploading Products): A producer/wholesaler can upload products for sale by first selecting the category and completing the Add Product online form (Figure 2).[133,134] Producers/wholesalers can add the product with the price as stated and/or apply a BuddyUp! deal (see Module 7). The wholesaler/producer sets the terms of the BuddyUp! deal, including the amount of the price reduction, minimal amount to be sold, expiration date of deal (optional), distance allowed between small stores participating in the deal, delivery charges and possible discounts (e.g., BuddyLift!).

Module 4 (Updating Products): A producer/wholesaler can make changes to a previously uploaded product (e.g., its price, minimal amount to be sold, etc.) by selecting the product, which opens that products information page, and updating the form.[135]

Module 5 (Add a BuddyUp! Deal): A producer/wholesaler can add BuddyUp! deals to current products, skipping the product information page.

Module 6 (Small Store owner Sign Up): Selecting the store owner button on the main screen directs the corner store owner to either sign in or create an account by completing a series of online forms. After completion, the user is automatically directed back to the store owner sign-in page.[136]

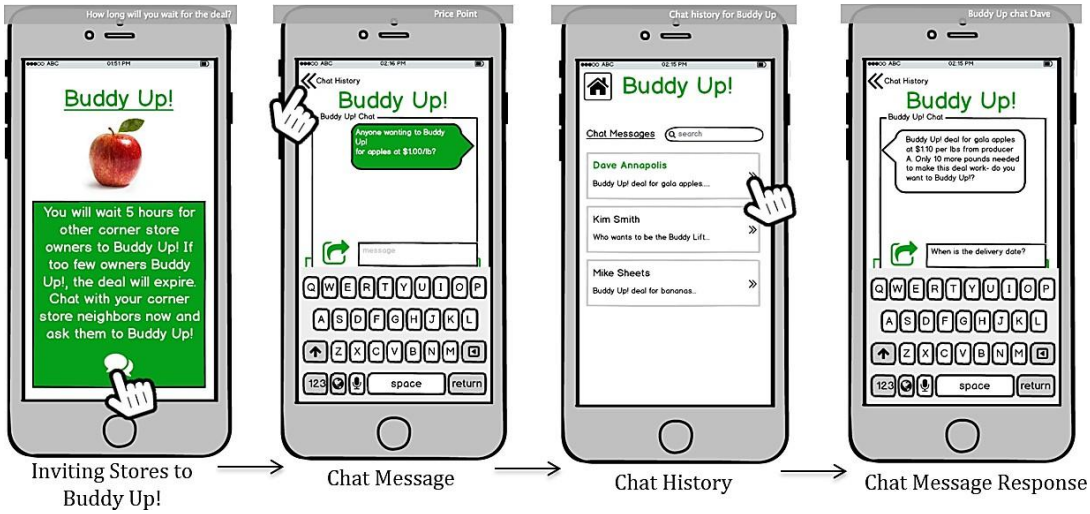
Figure 2: Uploading Products on the BUD App

Module 7 (BuddyUp!): The BuddyUp! feature allows store owners to buy healthy foods at a lower price by facilitating shared purchasing of items in bulk among application users. Selecting the BuddyUp! icon, located on the storeowner home page, directs the user to a page of products currently available for BuddyUp! deals (Note: cost reduction, amount to purchase, delivery distance parameters are set by the wholesaler/producer).[137] After product selection, store owners are prompted though a series of questions to select their quantity and determine the timeframe, or how long they will wait for the deal.

Module 8 (Chat Feature): Once completed, the chat feature can be utilized to prompt and invite other corner storeowners within a pre-specified radius to participate in the deal, share price information and BuddyUp! The chat feature will support communications in English, Korean, Mandarin and Spanish (Figure 3).[138–140]

Figure 3. BuddyUp! Chat Feature

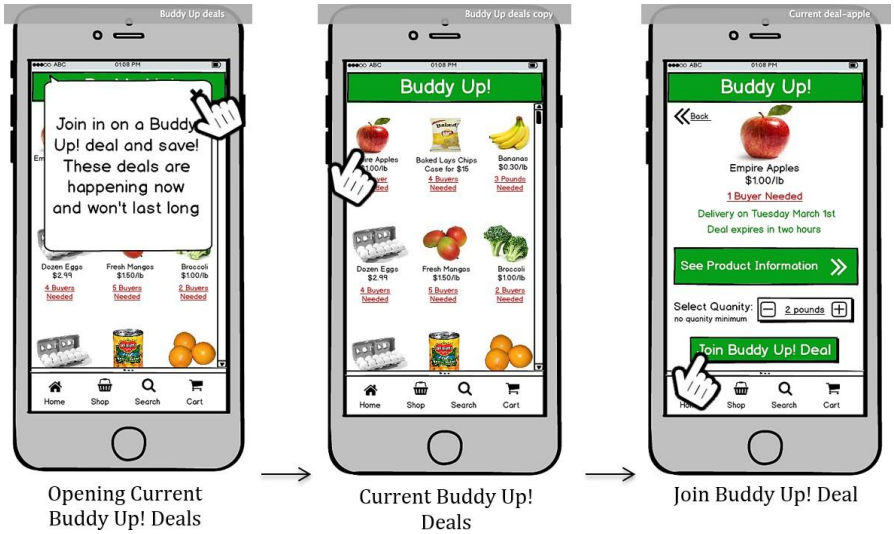
Module 9 (Current BuddyUp! Deals): The BuddyUp! feature also allows store owners to join BuddyUp! deals already in progress. Selecting the "join a BuddyUp! deal" icon, permits storeowners to view the products other storeowners within a specified radius have selected, but need additional participation to complete the deal (Figure 4).



Module 10 (Shopping and Delivery): Store owners can shop for items by category or select the search icon to search for an item by name.[141,142] Once products have been selected (including price), multiple delivery options are offered, including possibly the existing delivery service offered by the supplier, another online delivery partner (e.g., Hungry Harvest), or BuddyLift!

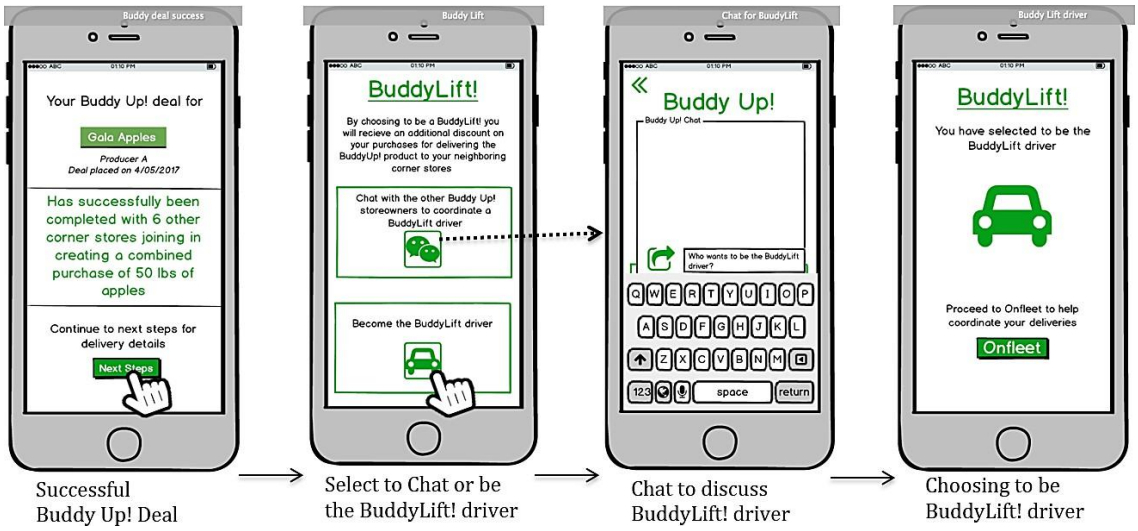
Figure 4. BuddyUp! Deal Feature

Module 11 (BuddyLift!): The BuddyLift! feature offers an additional price reduction for one corner store owner participating in a BuddyUp! deal who agrees to collect and distribute the items in that deal, or on a regular basis (Figure 5) It is possible that some corner stores may form a standing group (similar to informal Korean loan collectives) and alternate pick-up and delivery duties.



Module 12 (User Satisfaction): The BUD app will provide multiple opportunities for users (wholesalers, producers, small store owners) to give feedback on their level of satisfaction with the app, and to provide suggestions for improvement. After their first, third and fifth usage of the app, users will be prompted with a screen asking them to comment on their level of satisfaction with such issues as timeliness, cost, and ease of use. In addition, users will have the ability to provide unprompted comments and suggestions at any time.

Figure 5. BuddyLift! Feature



C.7. BUD Functionality and Usability Testing (Phase 3)

Once the BUD mobile app has been developed, it will be tested for system functionality, stability and usability.

Functionality and Stability: Components of the application will be tested independently and together as a combined application to ensure that expected outputs are produced against specified, prescribed inputs. Scenarios will be developed to 'test' the system on different devices, to ensure consistent software behavior occurs. Functional test scripts and checklists will be developed and applied to ensure all intended system components work as desired and expected. Once basic system tests are complete, we will subject the BUD app to stress testing to ensure, under unfavorable conditions, that the app does not crash – for example, when incorrect sequences are followed, "back" buttons pressed, or "home" buttons inadvertently pressed. Different user-error scenarios will be documented and simulated. Finally, speed and responsiveness of the system will be tested under different connectivity conditions (i.e., wifi, cellular, hotspot).

Usability: We will use client-centered design methods to evaluate and grade the user-friendliness of the interface, evaluate the 'learning curve' of new users, followed by user proficiency testing on days 0, 1, and 3 after training (see C.8). We will also plan repeat user-satisfaction assessments at various time points after deployment to assess whether the system meets the expectations of the end-users. Usability testing will include store owners of different ethnicities, including Korean, Mandarin and Spanish speaking. BUD will be configured to produce multiple outputs, including the capability to collect and store all purchase and delivery service data, including costs and delivery times, in a central server. We will also build a simple survey within the app with rating scales and a text box so that users can provide feedback on any aspect of the BUD program. A SQL (Structured Query Language) database will be used so that the data can be readily accessed using standard statistical packages such as Stata 14.1. We will also allow BUD users to view charts of aggregated quantities, such as trends in produce prices and delivery times. We have identified existing delivery management software (Onfleet), which will allow for stores to coordinate deliveries more efficiently and will alleviate some mentioned challenges. This program-wide information will be continuously updated to keep the users and the research coordinators informed about the program operational status. *Security issues are considered in the Data Safety and Monitoring Plan.*

C.8. BUD Pilot Evaluation (Phases 4)

Detailed sampling rationale, power calculations, eligibility, recruitment and retention information are provided in the PHS Human Subjects and Clinical Trials Information form. We will assess feasibility of the BUD app from the perspective of wholesalers, producers, small store owners and consumers (Aim 2). We will evaluate the impact of use of BUD on corner store (n=38) stocking and sales of healthier foods and beverages (Aim 3), and on a sample of 5 adult customers per corner store (n=190) to assess changes in purchasing and dietary behaviors as part of the pilot (Aim 4). All measures will be conducted at baseline and immediately post-intervention, with additional measures of retail impacts. Several of the instruments described below will be newly developed or adapted as part of the R34 work. *Additional description of these instruments is provided in the Outcome Measures table.*

C.8.1. Wholesaler instrument: Wholesaler impact data will be collected with a Wholesaler Impact Questionnaire (WIQ) that will assess wholesaler characteristics, BUD app usage (# foods uploaded, pricing, use of BuddyUp! option, etc.), and stocking and sales of promoted foods and beverages. This will be completed at baseline, and following each intervention stage, to assess impact (5 times). We have previously collected and reported stocking and sales data from wholesalers successfully with a previously developed instrument.[143] In addition, we will develop new semi-structured questions to assess satisfaction with the BUD app (e.g., ease of use, responsiveness, problem solving, timeliness), as well perceived sustainability.

C.8.2. Producer instrument: A Producer Impact Questionnaire (PIQ) will be conducted to assess producer characteristics (i.e. farm, size, months producing), BUD app usage (FV uploaded, deals offered, sales on the app), producer psychosocial characteristics (self-efficacy, intentions, expectations), and stocking and sales of promoted foods and beverages. This will be completed at baseline, and following each intervention stage, to assess impact (5 times). We will modify an existing instrument used for a pilot trial in Baltimore's urban farms.[107] We will develop additional questions to address user satisfaction and perceived sustainability as described in C.9.1.

C.8.3. Small food store level instrument(s): Impact data for corner stores will be collected with a Store Impact Questionnaire (SIQ) that will assess store characteristics, self-reported BUD app usage, corner store owner psychosocial characteristics (self-efficacy, intentions, expectations), and prices of promoted foods and beverages. This instrument will be completed at baseline, and following each intervention stage, to assess impact (5 times). We will modify a previously developed instrument to conduct these measures.[43,74] *Stocking (availability) of promoted foods will be collected via direct observation at the five time points. Sales of promoted foods will be collected using a tablet PC programmed for the store owner/manager to record unit sales of promoted foods and beverages at the time and point of sale. Detailed description of this software and its feasibility is presented in the Narrative Study Description and Outcome Measures table.*

C.8.4. Consumer-level instruments: The Adult Impact Questionnaire (AIQ) will be a modified version of a survey that we have used in previous studies. This instrument will collect sociodemographic information and food purchasing behavior such as how many times a product was bought and from which type of store (i.e., corner store, grocery store, urban farm, etc.). In particular, we will assess purchasing of promoted products from participating corner stores. Body weight to the nearest 0.1 kg and body composition (% body fat and lean mass) will be measured with Bioimpedance Analysis (BIA) using the Tanita-BIA (Model BF679W). Height to the nearest 1 mm will be measured with a stadiometer (Seca 213). Waist and hip circumference will be measured to the nearest 0.1 cm with a measuring tape. Three measures will be made, and the closest two measures averaged. The AIQ will be performed at baseline and post-intervention (2 times). The Adult Block Food Frequency Questionnaire (FFQ) will estimate adult consumer food intake and nutrient consumption (e.g., total energy intake, total fat, added sugar, sugar sweetened beverage and fruit and vegetable intake). Several studies have validated this instrument.[144,145] Completed FFQs will be analyzed by NutritionQuest (Berkeley, California) and estimates of food patterns and nutrient intakes will be generated. The FFQ will be performed at baseline and post-intervention (2 times). *All consumer measures will take place at the Johns Hopkins Bloomberg School of Public Health in a private office.*

C.8.5. Process evaluation instruments: Process evaluation instruments will be developed to measure the reach, dose delivered, and fidelity of the BUD intervention implementation. The team will develop specific standards for each process evaluation component that will be measured through multiple interventionist data collection forms, as well as through the BUD app itself. We will incorporate both quantitative and qualitative open-ended questions which will permit us to assess user experiences with the BUD app in terms of satisfaction, including challenges and potential solutions. All instruments will be electronic forms developed using REDCap, as we have used for our ongoing multicomponent intervention trial.[146] *See Outcome Measures and Statistical Design Plan for more details.*

C.8.6. Data generated by the BUD application: We will have metrics of all foods and beverages uploaded to the BUD app by suppliers, as well as orders and deliveries to each small store produced by the BUD app. This will include information on level/frequency of user engagement, how many of and which products were delivered, and when. During the appropriate intervention stage, the application will provide the number of times a store participated in the BuddyUp! module, who participated in a BuddyLift! activity, and other associated data, such as prices paid. This information will be stored in a database and will also be updated daily in a web-based dashboard with graphical displays sized for a laptop. We have carefully defined user engagement

variables and system-generated data to be captured and stored by the system for later analysis, including time(s) and duration of sessions, frequency of use and other technical data (battery charge, connectedness). In addition, should formative research indicate this is requested, we will allow select data to be accessible to users (small store owners, producers, wholesalers) in a graphical form, including their own usage patterns of the BUD app (e.g., foods purchased, dates, etc.), and cost savings accrued.

C.9. BUD Pilot App Implementation (Phase 5)

We will pilot the BUD app in 19 intervention corner stores over an 8-month period in East Baltimore. We will select stores only located in East Baltimore for logistical ease, and to keep delivery costs lower. The pilot will be conducted in four stages (2 months each), differentiated by the types of foods and beverages promoted, BUD features activated, and limited subsidy (BUD Credit) provided. During the first weeks of each stage, training of participating corner store owners and producers/wholesalers will take place – focusing on use of the BUD app and any new features, specific foods/beverages and guidance for promotion. Initial training will be followed up by proficiency testing where intervention store owners will be requested to complete certain functions (e.g., enroll in a BuddyUp! deal, fill out a user satisfaction form, etc.). With each subsequent stage, more app features will be made available to users (Table 1). During stage one, the basic BUD app interface will be introduced to corner store owners and low-sugar beverages will be promoted. In stage two, in addition to the basic BUD app interface, the BuddyUp! feature will be introduced to store owners, and fresh fruits and vegetables will be promoted. In stage 3, the BuddyLift! feature will be activated, and low-fat whole grains. Stage four will focus on reinforcement. On the BUD app, promoted items will be highlighted on the homepage (e.g., *Great Deal! Only 1 more buyer needed to get strawberries delivered for just $3/pound! Click here for more information*).

Bundled subsidy: To generate initial engagement and use of the app, we will bundle the app with initial limited subsidies (BUD Credit), which reflects common promotional practices for the introduction of new apps. A subsidy ($100/stage) will be offered for stages 1 and 2 only. The subsidy will only be usable for the products being promoted during that stage. Small store owners will only be able to spend $50/week maximum in order to encourage multiple orders, building familiarity with BUD's functions*. BUD Credit will be usable to pay all or part of any transaction (for example, a corner store owner could use $5 to cover part of the delivery costs of $25 worth of strawberries, or $30 to cover the entire cost).*

Promoting consumer demand: Concurrent with delivery of the BUD app, point of purchase promotions, such as posters and shelf labels promoting BUD healthful foods and beverages will be displayed by study team members at wholesalers and in stores to build consumer demand *for these products. We have developed these materials already through multiple previous trials in corner stores[43], but will refine them based on formative research.* These promotional materials will be provided at both intervention and comparison stores so that we can ascribe impact to the BUD app alone.

Stage 1: Low-sugar beverages (water, unsweetened flavored water). Storeowner training will include how to download the application in the preferred language, sign up, sign in, shop for products, make a purchase, view purchase history, and re-purchase products. Producer and wholesaler training will include: how to download the app, language, sign up, sign in, upload products to sell, and update the status of current products.

Stage 2: Fresh fruits and vegetables. Storeowner training will focus on how to participate in a BuddyUp! deal, and use the chat feature. Producer and wholesaler training will focus on how to add a BuddyUp! deal.

Stage 3: Low-Fat whole grains (e.g., brown rice, 100% whole grain bread, low-sugar granola bars). Storeowner training will focus on how to participate in BuddyLift! using Onfleet management. Producer and wholesaler training will be a booster of stage 1 and 2, if requested. *No subsidy will be provided.*

Stage 4: All previously promoted foods and beverages. Trainings will focus on maintaining engagement with the app, ensuring profitability for small stores and wholesalers/producers. No subsidy will be provided

During the training period at the start of each phase, we will collect interview-based process measures. Rigorous process evaluation will also be conducted at the food delivery, app metrics, and store-levels to measure quality of implementation of the trial according to initial research protocol in terms of reach, dose delivered, and fidelity. Electronic forms will be completed using REDCap, as appropriate.[147] We will conduct

biweekly monitoring and feedback sessions where we consider process indicators in terms of how well we are meeting implementation standards, including consideration of usage statistics generated by the BUD app. We will refine intervention delivery and develop new strategies to improve usage and user satisfaction as needed.

Table 1. Four stages of BUD pilot app implementation

BUD Strategies	Stage 1	Stage 2	Stage 3	Stage 4
Technology	BUD App	BUD App + BuddyUp!	BUD App + BuddyUp! + BuddyLift!	BUD App + BuddyUp! + BuddyLift!
Promoted Foods	Low-sugar Beverages	Fresh Fruits and Vegetables	Low-fat Whole Grains, Snacks	Low-sugar Beverages +FV +Whole Grains, Snacks
BUD Credit	*$100*	*$100*	*$0*	$0

C.10. Post-intervention Data Collection/Feasibility Assessment (Phase 6)

All phase 4 data collection instruments (wholesaler, producer, food store, consumer) will be repeated in Phase 6 to assess change associated with the BUD intervention. We will also conduct in-depth interviews with our 19 intervention corner store owners and participating wholesalers/producers to understand feasibility of the BUD app. This will include questions on acceptability (economic, cultural), operability (challenges, ease in using the app and its functions), and whether they would continue to use the app (perceived sustainability). In addition, we will conduct a follow-up study in 20 small stores in West Baltimore, Philadelphia and Detroit, where we demonstrate the BUD app, and assess feasibility through in-depth interviews. Additional description of feasibility constructs is provided in the Statistical Design Plan.

C.11. Data Analysis (Phase 7)

A detailed description of data analysis procedures, and hypotheses to be tested in relation to each study aim is provided in the Statistical Design Plan section of the PHS Human Subjects and Clinical Trials Information form.

C.12. Study Challenges and Strengths

Challenges: Most small store owners in Baltimore currently use SmartPhones for web access but are relatively inexperienced in making online purchases for their stores. Cultural and language barriers need to be considered throughout the development of the app, which may need to include language options within its user interface and considerations for how to make novel phrases such as “BuddyUp!” appropriate among store owners of different cultural and ethnic identities. Differences in payment preferences will be a challenge. Store owners prefer cash on delivery payment, but some wholesalers are not willing to offer this out of concern for product theft and the safety of their delivery drivers. In the pilot, we will initially subsidize the cost of delivery, as a means of reducing potential barriers of adoption as we measure the efficacy of the intervention. A key challenge is determining which distribution system (e.g., OrderUp, UberEats, Instacart, BuddyLift!, HungryHarvest, among others) will be the most efficient, cost-effective, culturally appropriate and sustainable, either alone or in combination.[67,109] Figuring out this solution is one of the key objectives of the formative research (Aim 1). *Finally, as the app will be piloted in East Baltimore, concerns with potential generalizability to other low income urban settings exists. We have included in phase 6 a qualitative assessment of feasibility in three different urban settings.*

Strengths: While there are apps that connect food sources and consumers, there are no apps that we know of that connect local producers and wholesalers to small urban corner stores. BUD will allow small store owners to connect to a variety of producers and suppliers at once and will allow access healthier products for their stores in an affordable manner. BUD has the potential to offer a sustainable and easy to disseminate solution to the crisis of supply and delivery in low-income urban settings. The R34 proposal is based on substantial previous formative research, including the development and display of a wire frame of the BUD app to multiple types of users. This has allowed us to anticipate many of the challenges that will be faced during the pilot, and to develop strategies to address them.

Statistical Design Plan

The data analysis plan is a series of steps including data entry, data cleaning, exploratory data analysis, and multivariate analysis, led by our biostatistician (Ogburn) and by our economist (Trujillo) for the economic analysis. Data will be managed at JHU and the data manager will review data for quality. Qualitative data will be de-identified, transcribed and translated (if needed) by research assistants, kept on password protected computers, and analyzed using Atlas-ti 8.4. Quantitative data will be de-identified, entered into Microsoft Access databases and analyzed using Stata 14. These data will be collected through direct observation (e.g., availability), electronic point of sale data collection (e.g., sales), surveys (e.g., consumer purchasing), and anthropometry (e.g., BMI). We will look at the change in availability, sales, and purchasing of healthier foods scores from baseline to post-intervention comparing intervention and comparison groups, at the store and consumer levels. Models will control for covariates that predict the outcomes (e.g., store size or consumer age and sex), and standard errors will account for the clustering of repeated measures within stores.

Feasibility analysis (Aims 1 and 2)

In-depth interviews will be analyzed in ATLAS.ti for themes, and used to inform changes to the BUD app and to assess feasibility from the perspective of users. Feasibility analysis will focus on assessing economic and cultural acceptability, operability and perceived/planned sustained use of the BUD app, including barriers and enhancing factors. From the corner store owner/wholesaler/producer perspectives, acceptability will be assessed according to whether the new products are perceived to be in demand, profitable, easy to obtain and store. Operability will be assessed primarily in terms of the BUD app, in terms of whether store owners indicate (and demonstrate) that they can and do continue to use the different features of the app (e.g., BuddyUp, BuddyLift, Buddy Chat, etc.). Perceived sustainability will be assessed in terms of whether store owners (and other users, such as wholesalers, producers) indicate that they plan to continue to use the BUD app, how much, and for what purposes (e,g, which specific foods. Textual data will be coded by trained staff using a codebook. The codebook will emphasize these feasibility constructs. Qualitative analysis will center on providing contextually rich descriptions of each aspect of feasibility, and describing some of the key sources of variation (e.g., by store size, owner ethnicity, etc.). Analysis of the 20 qualitative consumer interviews will focus on identifying those healthier products would be most acceptable to them in terms of demand, cost, taste and other similar characteristics. The analysis will also identify best in-store strategies to promote these foods.

We will conduct a detailed quantitative process evaluation (in terms of reach, dose delivered, and fidelity), and results will serve as additional measures of feasibility, particularly in terms of establishing operability and potential sustainability. Three primary process dimensions will be assessed: reach, dose delivered and fidelity – each will likely have multiple measures – and standards will be set for each measure to monitor quality of intervention implementation. For example, reach will be assessed by the percent of intervention corner stores ever using the BUD App for ordering, and the number of wholesalers/producers who ever put products on the app. The standard could be set at 100%, meaning that each corner stores/wholesaler/producer used the app at least one. Dose delivered will be evaluated as the percent of BUD app trainings successfully completed by corner store owners (out of 18 possible intervention stores) – currently planned at one/phase of the intervention (n=4), # communications with store owners (out of X possible communications, determined by a standard to be set), and delivery of promotional materials to encourage consumer demand (out of X possible deliveries, determined by a standard to be set). Fidelity will be assessed as frequency of usage (e.g., once per week, twice per week) of the BUD App to offer/order foods and beverages by wholesalers/producers/corner store owners, as well as in terms of their use of different features of the app (e.g., BuddyUp, BuddyLift, BuddyChat, etc). We will set standards to monitor quality of intervention implementation for the reach, dose and fidelity measures, and revise these standards based on the experience of the R34 trial for the planned future full-scale trial.

Feasibility will also be assessed via analysis of user satisfaction responses collected during operation of the BUD app, as well as in terms of responses to the open-ended questions that will be part of the process evaluation measures.

Analysis of pilot trial store impact data (Aim 3)

We hypothesize that there will be significantly increased availability (stocking) and sales of healthy promoted foods (whole grain, fruit, vegetable, and low-fat, low-sugar foods) and beverages in intervention stores using the BUD app, as compared to comparison stores. Using direct observation-based stocking data, a healthy food availability index (HFAI)152 will be calculated, and we will initially examine the difference from pre- to

postintervention comparing intervention and control stores. We will also look at change in availability and sales of specific promoted product categories from pre- to post-intervention at each specific phase of intervention. Mixed-effect models, treating the stores as a random effect, will be used to evaluate the effect of the intervention on availability/sales of healthful food and beverage scores comparing corner store intervention and comparison groups, adjusting for covariates, such as store size and food stocking at baseline. We hypothesize that prices of some promoted foods and beverages will decrease given promoted foods/beverages will be subsidized during the first two phases of the intervention, as compared to baseline (if stocked at baseline). Furthermore, we will conduct additional tests to see if a pass-through price effect occurred related to the initial subsidy. Since the subsidy is short term (just phases 1 and 2 of the intervention), relatively small, and intended to generate initial usage of the app, we do not anticipate a significant price effect.

Analysis of pilot trial consumer impact data (Aim 4)

Secondary outcome analyses will include assessment of change in consumer-level variables. From the adult consumer impact questionnaire (AIQ) on purchasing frequency of promoted foods and beverages (i.e. fruit and vegetables, low-fat snacks, low-sugar beverages, whole grain foods), and using the Block FFQ data on the intake of the same products, we will compare the change in purchasing and consumption among consumers of intervention stores to the comparison store consumers. These analyses will be adjusted for potential confounders, such as age, sex, income, participation in food assistance programs, and other household covariates when appropriate. We will use linear mixed-effect models with individual and store random effects to identify potential predictors of participation. We hypothesize there will be a trend toward increased purchasing and consumption of healthy promoted foods and beverages among intervention consumers compared to consumers that are sampled from comparison stores.

Economic analysis (Aim 5)

We will conduct a cost–benefit analysis of the use of the BUD App, from the wholesaler, producer, retailer and consumer perspectives. We hypothesize that the savings promoted by the BUD App will outweigh the costs of developing and implementing the intervention. In other words, we hypothesis that the use of the BUD App will have a high rate of return for the wholesaler as well as retailers and consumers.

Among the potential savings from using BUD, we will include: reduction in prices of foods; increase in total net revenues (sales minus discounts); reduction in transportation cost of food, reduction in transportation costs to buy products; inventory and rotation; financial costs of working capital among other items. Other benefits associated with the BUD are linked with improvement in health and human capital of consumers. We would consider these savings broadly using our sample of 170 low-income urban consumers, assessed pre- and post-intervention variation and will monetize benefits associated to these outcomes. We will separate between short-term and long-term benefits and discount future benefits.

For cost, we will include in our analyses monthly and annual totals, including costs at baseline, personnel costs (salaries and benefits), material and supplies, equipment, and transportation costs, among other items. We will also monetize the time of delivering the intervention and the time devoted to training. We plan to differentiate between initial costs and deployment costs. Initial costs will account all costs during the pre-implementation phase of the intervention. Post-intervention costs will capture the variable and fixed costs of running the program. These costs will include recurrent and capital costs associated to the program. We plan to integrate these templates to estimate the total costs of the intervention and compare these figures to the benefits of the program.110 We will conduct sensitivity analyses to test how robust our results are, in relation to the assumptions of our financial cost model.

Use of Data for Power Calculation for Planned Main Trial

The proposed R34 is expected to provide information needed to power the planned, future RCT. The R34 is designed to provide adequate precision of estimates of the primary outcome(s) of the full trial. We will look at baseline measures of multiple outcomes, and how these change over time. We will examine correlations of outcomes within store over time, between participants (customers) within stores, and within participants over time. We will use these data to assess clustering, permitting us to estimate the ICC, and precision around it, and to modify our main trial sample size estimates as needed. Ultimately, this will address gaps in the research for others who want to perform interventions with similar outcomes.

Power Calculation and Study Design

This is a randomized group-treatment trial, where individual stores will be randomized to two study conditions: 1) usage of a web-based app (BUD) to order healthier food and beverages + in-store point-of-purchase promotional materials + limited subsidies (treatment); or 2) only in-store point-of-purchase promotional materials (comparison). In order to ensure a balanced study design, prior to randomization, we will stratify corner stores by two factors to balance potential confounders: 1) length of time in business at this location (>2 years vs <2years); and 2) store size (0-2 aisles vs 2-4 aisles), and then randomize matched pairs to treatment versus comparison.

We recognize that clustering may occur, given that storeowners will share a change agent (BUD app) with other storeowners assigned to intervention group, and will potentially interact with each other as part of the functioning of the BUD app.153 We will control for baseline covariates of all participating stores that may predict study outcomes.

The feasibility pilot study is powered based on seeing impact at the corner store level. Store eligibility criteria for participation in the trial are as follows: 1) store owner/manager willing to order food through a smartphone or other internet-enabled device; 2) store located in a low-income neighborhood classified as a healthy food priority area in East Baltimore; 3) classified as small food store (< 4 aisles, < 2 cashier); 4) English, Korean, Spanish or Mandarin-speaking; and 5) located >0.25 miles from a supermarket.

Sample size calculations for corner stores were based on the analysis of a simple difference in change in the mean of Healthy Food Availability Index (HFAI) scores.152 We used preliminary impact data from our previous trial (BHCK)80, with a reported mean change in HFAI $\mu(\sigma) = 1.67(5.35)$ and $\mu(\sigma) = 5.65(4.95)$ in the control and intervention groups, respectively. Due to the price incentive features (subsidy, group purchasing discounts) that will be available to BUD stores owners to stock healthier foods and beverages in phases 1 and 2, we estimate that the effect of the BUD intervention will be higher than our previous studies with corner stores. Therefore, we estimated a total sample size of 34 stores (17 per arm) for two-sample comparison of mean assuming a difference in healthy food availability (HFAI) of 6 points, variance of 24, intraclass correlation of 0.0001, type I error of 5% and power level set at 80%. We will increase our store sample size by 2 per treatment arm (n=38) to account for possible loss to follow-up. As mentioned, we will also control for baseline covariance, which will help to increase the power of the study. Some of the potential factors to control for will include store size and baseline HFAI.

The consumer sample size of this feasibility trial is intended to obtain an estimate of effect size and the variance in food consumption, purchasing, and body mass index, in order to plan a larger clinical trial, and to provide evidence of recruitment and retention ability. Therefore, the R34 pilot study is not powered to provide impact at the consumer level (which will be the primary outcomes for the full-scale clinical trial). Consumer eligibility criteria are as follows: 1) frequent consumer of the food store (shop at least once a week); 2) live/work within ¼ mile radius from the store; 3) >21 years old and < 75 years old; 4) live in a household of at least 2 persons. We will use systematic sampling to recruit the consumer study evaluation sample in and around each of the 38 small food stores (5 adult consumers per food store).