**Additional File - Extended information SPIRIT Checklist**

The Baltimore Urban food Distribution (BUD) App: Study protocol for a food systems intervention

2b. Trial registration

**Table 1. World Health Organization Trial Registration Data Set**

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| **Data category** | **Information** |
| Primary registry and trial identifying number | This trial will be registered on ClinicalTrials.gov, the registry for the Centers for Disease Control. Once registration is complete, this protocol will be updated. |
| Date of registration in primary registry | Please see above. |
| Secondary identifying numbers | Johns Hopkins Bloomberg School of Public Health Institutional Review Board: *To Be Determined* |
| Source(s) of monetary or material support | National Institutes of Health- National Heart, Lung, and Blood Institute |
| Primary sponsor | National Heart, Lung, and Blood Institute |
| Secondary sponsor(s) | N/A |
| Contact for public queries | Dr. Joel Gittelsohn, Professor, jgittel1@jhu.edu, 410-955-3927, 615 N. Wolfe Street, Room W2041, Baltimore, MD 21205, Johns Hopkins University, Bloomberg School of Public Health |
| Contact for scientific queries | Dr. Joel Gittelsohn, Professor, jgittel1@jhu.edu, 410-955-3927, 615 N. Wolfe Street, Room W2041, Baltimore, MD 21205, Johns Hopkins University, Bloomberg School of Public Health |
| Public title | Using a Web-based Application to Increase Availability of Healthy Foods and Beverages in Low Income Urban Areas |
| Scientific title | [A Web-Based Application to Improve Procurement and Distribution of Healthful Foods & Beverages in Low Income Urban Communities](https://phirst.jhsph.edu/sph/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b33AE602EB7039C41A02FE34D832B5B2C%5d%5d) |
| Countries of recruitment | United States of America |
| Health condition(s) or problem(s) studied | Healthy adult volunteers, Improving healthy food access, Prevention of obesity |
| Intervention(s) | The Baltimore Urban food Distribution (BUD) application is a web-based software application connecting urban corner stores to local producers and wholesalers with the goal of increasing the availability of healthy food in healthy food priority areas. BUD will be implemented as a randomized controlled trial involving 19 intervention corner stores who will use BUD and 19 control corner stores with no treatment. Intervention stores will use the BUD application for 8 months and then provide feedback. |
| Key inclusion and exclusion criteria | Ages eligible for study: 21-75 years old |
| Inclusion criteria:  Inclusion criteria for wholesalers and producers:   * Provide service to Baltimore City (e.g., for producers, this could mean participating in Baltimore City-based farmers markets) * Willing to use the BUD app, including posting and maintaining data on a minimum number of products * Willing to participate with delivery services arranged   Inclusion criteria for consumers (community members):   * Regular customers of the store (purchase food items at least once a week in the store) identified by the small food store owner/manager enrolled in the study * Adult (between 21 years old and 75 years old) * Live/work within a 1/2 mile radius from one of the 38 small food stores participating in the study * Live in a household of at least 2 persons (criteria intended to provide a more stable sample, to reduce loss to follow-up) |
| Exclusion criteria:  Exclusion criteria for consumers:   * Anticipate moving out of Baltimore City in the next 12 months * Pregnant (due to changes in diet, weight and body composition) |
| Study type | Interventional |
| Allocation: Randomized  Masking: N/A  Assignment: Parallel |
| Primary purpose: Testing feasibility of a web-based application on stocking and availability of healthy foods in urban corner stores. |
| Date of first enrollment | Expected: 3/15/2021 |
| Target sample size | Planned: 290 |
| Recruitment status | Pending |
| Primary outcome(s) | Outcome Name: Feasibility Metrics: Acceptability, operability, perceived sustainability and user satisfaction with the BUD app  Metric/method of measurement: Survey via BUD application  Timepoint: Multiple times during intervention delivery, post intervention  Outcome Name: Stocking of healthy and unhealthy foods  Metric/method of measurement: Store environmental checklist with structured observation  Timepoint: Baseline, During intervention treatment, Post-treatment  Outcome Name: Process Metrics: Reach, dose delivered, fidelity  Metric/method of measurement: In-person survey or via BUD application  Timepoint: During intervention treatment  Outcome Name: Sales of healthy and unhealthy foods  Metric/method of measurement: Point of Sale System on a tablet collected by the corner store worker/owner.  Timepoint: Baseline, 5 times during intervention for 7 days at a time, post-treatment. |
| Key secondary outcomes | Outcome Name: Purchasing of healthy foods by consumers  Metric/method of measurement: Adult Impact Questionnaire  Timepoint: Baseline, Post-treatment  Outcome Name: Consumption of healthy foods by consumers  Metric/method of measurement: Block Food Frequency Questionnaire  Timepoint: Baseline, Post-treatment  Outcome Name: Financial costs and benefits from perspective of suppliers  Metric/method of measurement: Producer, wholesaler, and store impact questionnaire  Timepoint: Post-treatment  Outcome Name: Prices of healthy foods  Metric/method of measurement: Store impact questionnaire, process evaluation survey/BUD app  Timepoint: Baseline, During intervention treatment 5 times, Post-treatment |
| Ethics review | Status: Not Approved  Date of approval: pending  Name and contact details of Ethics committee: Johns Hopkins Bloomberg School of Public Health Institutional Review Board, Joan Pettit, 410-502-1999, jpettit@jhu.edu |

5b. Name and contact information for the trial sponsor

**Trial Sponsor**: National Institutes of Health- National Heart, Lung, and Blood Institute  
**Sponsor’s Reference**: R34HL145368  
**Contact name**: Charlotte Pratt, Ph.D., M.S., R.D, FAHA**Address**: 10 Center Dr, Bethesda, MD 20814  
**Telephone**: 301-435-0382  
**Email**: [charlotte.pratt@nih.gov](mailto:charlotte.pratt@nih.gov)

5d. Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

The PI, Dr. Joel Gittelsohn, and the data manager/analyst, Lisa Poirier, will ensure data safety and security. The study biostatistician, to be determined at this time, will also meet with the PI and data manager/analyst regularly to ensure compliance and deal with new situations. JHSPH already has security software and locking file cabinets needed to securely store, password protect and encrypt any collected data, both electronic documents and hard copies. In the event that key personnel leave the project, the data manager will carefully document the names, locations, data types, etc. of all data collected, and regularly update the PI and relevant co-investigators. Passwords will be changed following the departure of key staff to ensure security.

11b. Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

We foresee that the only reason for discontinuing the intervention with a particular participant would be upon their request. We would allow for their discontinuation after a detailed discussion of their concerns and have determined that there is not a reasonable way to assuage theit concerns without affecting the study.

11d. Relevant concomitant care and interventions that are permitted or prohibited during the trial.

We are not prohibiting the participants from participating in other interventions or forms of care during our trial.

21a. Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

A data monitoring committee is not needed because we are not actively working with individuals participants in regards to a particular health outcome for this trial. The trial seeks to improve healthy food access, and is very low risk.

22. Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

In the case that an adverse event (AE), serious adverse event, or unanticipated problem occurs the study team will respond accordingly. As soon as the event occurs, study team members will notify Dr. Joel Gittelsohn, Dr. Gittelsohn will then work with the project coordinator to notify the Johns Hopkins Bloomberg School of Public Health Institutional Review Board and the NIH Office of Biotechnology, and immediately follow all instructions provided by both organizations.

24. Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

We have currently received an exempt status for our formative work from the Johns Hopkins Bloomberg School of Public Health Institutional Review Board. The team is currently in the process of seeking approval the for the rest of the study by drafting the research plan and completing all study documents including consent forms and data collection instruments, as required by the IRB.

25. Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)

The Johns Hopkins Bloomberg School of Public Health IRB has a system in place for submitting amendments for any modifications to an approved study. We will adhere by these rules and seek approval for any modifications. We will communicate any changes to study protocol at team meetings and update trial registries or participants if necessary.

27. How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial/ 19. Data management - Plans for data entry, coding, security, and storage

Every effort will be made to assure the confidentiality of respondents, and to securely store the data for long-term preservation. Data will initially be collected in both electronic and paper formats, depending on data type. All hard copies of the interviews, consent forms, surveys, and any forms with identifying information will be kept in a locked file cabinet in locked project offices, under the supervision of Dr. Joel Gittelsohn, Principal Investigator, and the Data Manager/Analyst. The data manager/analyst will be in charge of checking the forms for completeness and correction of errors, assigning IDs, photocopying and keeping track of all the forms. 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).

Completed data collection forms will be de-identified and password protected for data entry purposes. Only trained project staff will have access to these data, including the to be determined study biostatistician, and Dr. Antonio Trujillo, for economic data. For hard copy survey forms, data will be checked on-site for completeness and potential errors before entry. Identifiable data transferred or stored via portable electronic devices (e.g., laptops, flash drives) will be encrypted. The devices on which this information is stored will be accessible only to individuals who need access to these data such as the data manager/analyst, project coordinator, and project directors. NutritionQuest will supply a secure server where FFQs are automatically uploaded into their system after completion.

Once entered, the data will be de-identified, stored on password-protected servers and backed up on multiple hard drives, stored in different secured locations. The electronic databases will be managed by the data manager who will track and log issuance of analytic datasets, and return/removal when approved use ends. Access to analytic datasets will be subject to conditions established by the PI. Electronic analytic datasets will be provided to authorized study personnel, or approved investigators outside the study, with the same data protection requirements established for the study database.

All qualitative data collected with voice recording equipment will be done using a digital audio recorder. The voice recorders and media containing audio files will be kept in a locked filing cabinet separate from all identifying information, until they are transcribed onto a password protected computer. After transcription and checking for accuracy, the audio files will be deleted from the recorders and the computer. The transcribed interviews will not contain any identifying information. The study data manager/analyst will manage data entry and storage procedures.

Process data collected via REDCap will be completed on electronic tablets and then transferred to the online protected server owned and operated by Johns Hopkins University. Throughout the entirety of the project, electronic data collection will be encrypted using Secure Sockets Layer (SSL) encryption using REDCap and will be uploaded to a server at Johns Hopkins Bloomberg School of Public Health. All data collectors will receive unique user PINs that are ciphered using Secure Hash Algorithm (SHA) cryptography, and all stored REDCap data and REDCap application logs are encrypted using advanced encryption standards on tablet PC until the data are uploaded.

Data collected via the BUD app itself will include identifying information of the small store owners, wholesalers and producers, including names, addresses, purchases/offerings, prices, purchase amounts, completed orders, etc. The web-based BUD app will be hosted by the commercial provider Network Solutions, LLC with the following security features: an SSL (Secure Sockets Layer) Certificate that will be used to encrypt all customer data, automated scanning and removal of malware, and measures to protect against SQLi (SQL injection), XSS (cross-site scripting) and other hacking attacks. Furthermore, we will use the Square Payment Form and Transactions API (Application Programming Interface) of the mobile payment services company Square, Inc. for secure and PCI DSS (Payment Card Industry Data Security Standard) compliant payments. The payment process will be integrated into our app through this API, with security provided through secure single use tokens (nonce) that are uniquely generated for each credit card transaction.

29. Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

Key study team members will have access to the final trial dataset, as long as they have reminded in their current capacity on the team. If a key study team member leaves the team, they will have to request data access as anyone who is not part of the team will have to do. There are currently no contractual agreements that limit access for any of our investigators.

30. Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation.

We do not have any provisions for this occurrence. We consider this to be a low risk trial and do not foresee any issues that will require compensation for trial participation.

31a. Dissemination policy – Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

The clinical trial will be registered on the ClinicalTrials.gov website, not later than 21 days after the recruitment of our first participant.  Registration information will be updating annually, or if there is a change in recruitment status or if the trial is completed. The team understands that the results of this work ultimately belong to the public as a piece of the general body of scientific knowledge and will follow the timeline for results dissemination listed in the NIH policy. Per this timeline, we will submit the required data and the results to NIH and ClinicalTrials.gov in the 12 month timeframe following the primary completion date. Each informed consent document that study participants sign will disclose that the study is registered with the NIH and information on clinical trial is available at ClinicalTrials.gov, and that ultimately the results will be made public. Any consent forms will also provide the assurance that no identifiable individual or store-level data will be shared.

31c. Dissemination policy – Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

People may request data for research purposes, after data have been collected, cleaned, analyzed and the primary study outcome papers have been published. External parties would be required to complete an online request form, describing the specific datasets required, intended use/analyses, commitment to confidentiality, etc. Requests would be reviewed by the project steering committee (composed of study investigators and the appropriate NIH project officer). They will receive de-identified data spreadsheets with codebooks that explain the meaning of each variable and the corresponding codes for each variable. In addition, they will receive a detailed description of the study design.