ClinicalTrials.gov Cover page

Official Title of the study

FUEL: Food, fUn, frEsh, famiLy program. Promoting children's diet through afterschool program and family support.

NCT number

To be assigned

Date of the document

July 21, 2023

Unique Protocol ID:

STUDY00004545

INSTRUCTIONS

- **This form is only for studies that are considered greater than minimal risk (full board) or qualify for expedited review (fits in one or more expedited review categories)**. See section 5.3 of the UT IRB Policies and Procedures Manual for details regarding expedited research.
- **Do NOT submit this form if the study will qualify for exempt review**. If your study is exempt, submit HRP-UT902 Template IRB Proposal Exempt Submission. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- **If you are only using secondary data that will not be initially collected solely for this research project, do not complete this form**. Instead, use HRP-UT903 Template IRB Proposal Secondary Use form instead. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- For studies following a sponsor protocol, please use this guidance to assist in your completion of this form.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, click on the check box (or double click and type an "X" if using Google Docs). Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.
- To fill in a text box, make sure your cursor is within the grey text box before typing or pasting text.
- **Do not convert this Word document to PDF.** The ability for UTRMS-IRB to implement "tracked changes" is required to facilitate efficient review.

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GENERAL STUDY INFORMATION

Study Title

Include the study title below.

FUEL: Food, fUn, frEsh, famiLy program. Promoting children's diet through afterschool program and family support.

1 Review Type (Choose one)

Please choose which level of review best fits your research. This is an investigator's assessment of review and does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination of review conflict, the IRB's determination will be considered the official determination.

***Note**: Expedited review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by OHRP. If you would like help determining which type of review best fits your research study, please contact the IRB staff in the Office of Research Support & Compliance: https://research.utexas.edu/ors/human-subjects/get-help/*

a ☐ **Full Board Review – Greater than Minimal Risk Research**

b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypotheses

Please describe the research aims and hypotheses in the box below. To input text, click in the box below and start typing.
Note: Procedures will be explained in a separate section below.

Our primary hypothesis is that the effect of an after-school curriculum on nutrition and physical activity for elementary aged children improves overall child diet better when resources to encourage healthier eating are provided to caregivers at the same time than if they are not provided.

3 Study Background

Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

One approach to improving child health trajectories including diet has focused on after-school programming. A prominent example, the "Coordinated Approach to Child Health" (CATCH) program, provides curriculum on nutrition and physical activity. CATCH has, over almost two decades of implementation and assessment, shown positive impacts on reducing the incidence of obesity and improving child diet (Hoelscher et al, 2010). It is regularly used by organizations such as the Boys and

Girls Clubs as part of after-school programming. In addition to the core program for children, parental and community involvement and family support have been shown to improve outcomes when added to such after-school programming (Brown et al, 2019). However, family support is not a standard part of such programs today.

Although family support is not simple to implement, there are a variety of approaches of providing family support that can layer onto after-school programming and might enhance results for the child. For example, fruit and Vegetable (VF) vouchers provided to parents and caregivers as "prescriptions" during clinic visits have resulted in modest improvements in child diet (Ridberg et al, 2019, Saxe-Custack, et al 2021). In 2021 our laboratory implemented and tested a brief program to provide resources to caregivers to see if that might help them support their children in improving diet. In partnership with the Boys and Girls Clubs of the Austin Area (BGCAA), we piloted a 4-week intervention for improving Elementary school age child diet by providing weekly a 10-lbs FV box and a $10 grocery store gift card to the BGCAA's pandemic protocol of curbside distribution of resources (Kahlon et al., 2022). The weekly FV boxes included customized recipes and cooking tips. An incentive was added for 3 weeks, where caregiver completion of a brief goals sheet provided an additional $10 gift card weekly. Child and caregiver diet were assessed at 4 weeks at the end of the program and after another 4 weeks, as follow-up. A randomized trial provided families with the program as described above (intervention) or at the end of 8 weeks with grocery store cards of equivalent value (control). Child diet was assessed by the validated Texas School Physical Activity and Nutrition, SPAN, and children in the intervention arm relative to those in the control arm showed statistically significant dose-dependent improvements in overall diet and in fruit and vegetable intake at 4 weeks, and sustained at 8 weeks.

Here we assess:

(1) Can we improve the effects of an evidence-based after-school program that focuses on nutritional education and physical activity by adding family support in the format we showed previously to be beneficial by itself. We will assess the incremental benefit of adding family support to allow caregivers some financial flexibility to help their children try healthier foods such as fruits and vegetables. We will compare the addition of family support with a randomized control group that does not receive the family support but is still in the same after-school program.

To aid our research, we have built a partnership for implementation with the Boys and Girls Club of the Austin Area (BGCAA). In addition, one of the original designers and frequent assessor of the evidence-based after-school program from the UT School of Public Health at Austin is our collaborator.

References

Brown T, Moore THM, Hooper L, Gao Y, Zayegh A, Ijaz S, Elwenspoek M, Foxen SC, Magee L, O'Malley C, Waters E, Summerbell CD. Interventions for preventing obesity in children. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD001871. DOI: 10.1002/14651858.CD001871.pub4. Accessed 11 May 2023.

Kahlon MK, Aksan NS, Aubrey R, et al. Effect of Brief Produce Exposure and Unconstrained Grocery Gift Cards on Caregiver Influence on Diet of Elementary Age Children: A Randomized Clinical Trial. *JAMA Netw Open.* 2022;5(5):e2212973. doi:10.1001/jamanetworkopen.2022.12973.

Hoelscher DM, Springer AE, Ranjit N, et al. Reductions in child obesity among disadvantaged school children with community involvement: the Travis County CATCH Trial. Obesity. 2010;18(S1):S36-44.

Olsho L EW, Klerman J A, Wilde P E, Bartlett S. Financial incentives increase fruit and vegetable intake among Supplemental Nutrition Assistance Program participants: a randomized controlled trial of the USDA healthy incentives pilot. Am J Clin Nutr. 2016;104(2):423-35. doi:10.3945/ajcn.115.129320.

Ridberg R A, Bell J F, Merritt K E, Harris D M, Young H M, Tancredi D J. Effect of a fruit and vegetable prescription program on children's fruit and vegetable consumption. Prev Chronic Dis. 2019;16(73):180555. doi:10.5888/pcd16.180555.
Saxe-Custack A, Lachance J, Jess J, Hanna-Attisha M. Influence of a pediatric fruit and vegetable prescription program on child dietary patterns and food security. Nutrients. 2021;13(8). doi:10.3390/nu13082619

4 Design and Methodology

Provide a brief description of the study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

Design: A two-arm randomized trial.

Randomization:

- Eligible households with at least one child (reference child) in the BGCAA after-school program whose caregiver/parent (guardian) (reference caregiver) consents to participate in the study will be randomized to either the active intervention or the control (1:1 ratio). Randomization will be stratified by the family's SNAP beneficiary status as SNAP could affect uptake of treatment elements offered in the family support arm.

Blinding: Outcome assessors, principal investigator, and biostatistician are blinded to participant allocation. Participant and other staff are unblinded.

Study arms (19 weeks) (Figure 1):

Randomized arms
Children in both intervention and control arms participate in the BGCAA's after-school program with CATCH curriculum.

1. Across participating school sites, the whole BGCAA's after-school program runs for 3h, Mon-Fri for the school year. Children enrolled are expected to attend a minimum of 2x/week.
2. CATCH curriculum will be delivered as a component of the after-school program in blocks of 45-60 min, twice a week.
3. Children also participate in active recreational time (approx. 60 min, offered 1x/week at a minimum) which consists of a mixture of free play, structured physical activity games, and/or sports activities (including soccer, football, and basketball).

Intervention arm: BGCAA after-school program + Family support

1. Children participate in the BGCAA's after-school program with CATCH curriculum as described above.
2. The child's caregiver will receive the following:
    - Weeks 1-4 (4 weeks):
        i. Weekly: 1 box of produce
        ii. Recipes accompanying each box (sample recipe card attached to submission)
        iii. Bi-Weekly: Grocery store gift cards (2x $20, to a total of $40)
    - Weeks 5-19 (total of 10 weeks over the 19-week study timeline):

i. For five weeks, an optional online form (or "*goal sheet*") will be sent to the parent/caregiver (5 sheets in total) with questions about trying new FV items to be completed within the next 7 days. As an incentive, a $10 gift card will be sent the following week to those who complete it (a potential total of $50).
ii. Week 11: $20 Grocery store gift card. Based on disruptions due to the school year breaks, we will provide an extra $20 gift card to re-engage the week after a school holiday.

Control arm: BGCAA after-school program only

1. Children participate in the BGCAA's after-school program with CATCH curriculum as described above.
2. At the end of the study, they will receive $120 as grocery store gift cards.

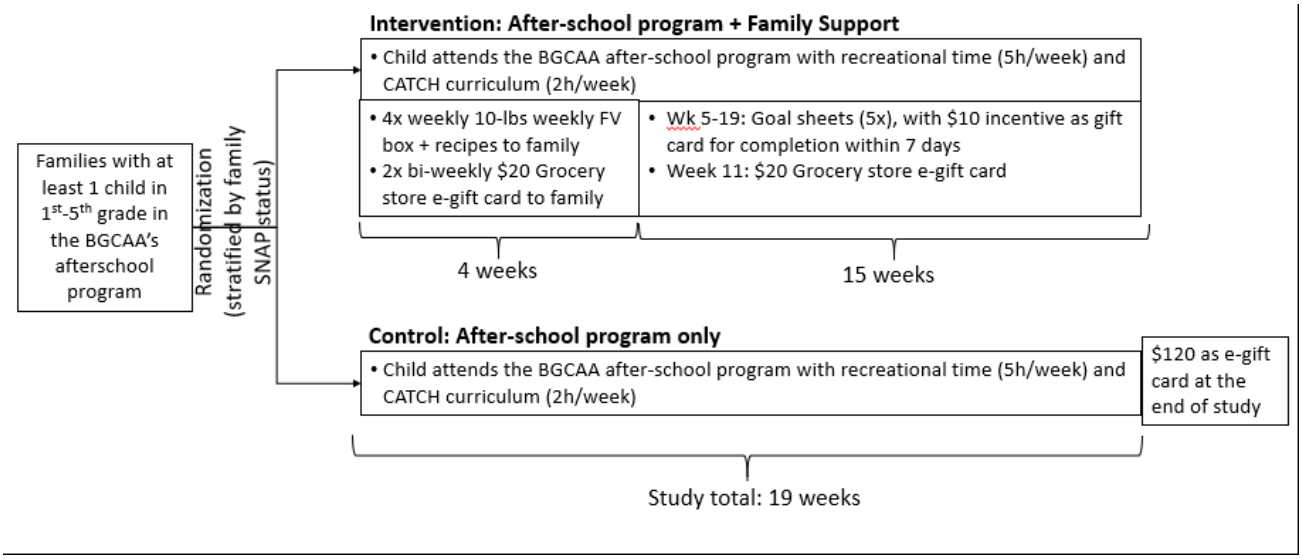

Figure 1. Study design: 2 randomized arms

Outcomes:

- Primary:
  - Child's diet quality: measured by Healthy Eating Index, HEI, scores calculated from the Texas School Physical Activity and Nutrition (SPAN), 2nd Grade.
  - Child's fruits and vegetable consumption, measured by SPAN, 2nd Grade.

- Secondary outcomes:
  - Caregiver/parent diet quality, measured by HEI scores calculated from the SPAN, 8th Grade.
  - Child's physical activity levels
  - Child's body mass index, as percentile of BMI-for-age

Study measurements:

Timepoint measurements for all study participants (child-parent dyads) include:

- baseline (approximately up to 4 weeks prior to the first produce bag and grocery store gift card being distributed). Height and weight will be taken during the first 1-2 weeks of the research program start date during a BGCAA field day.

- mid-point (planned for approximately weeks 5-8)
- end-point (approximately between weeks 16 and 21). Height and weight will be taken during the 19th week of the program at the BGCAA's field day.

Outcomes	Tool	Time points	Administration
Child's Diet (primary)	TX SPAN 2nd grade 2019-2020 – Dietary questions	Baseline, Mid-point, End point	Child, Guardian-report Structured interview over the phone by RA
	SPAN Healthy Eating Index scores	Baseline, Mid-point, End point	Child, calculated from SPAN
	SPAN F&V score; unhealthy foods score	Baseline, Mid-point, End point	Child, calculated from SPAN
Physical Activity	TX SPAN 2nd grade 2019-2020 – Physical activity questions	Baseline, Mid-point, End point	Child, guardian-report Structured interview over the phone by RA
	Physical Activity Questionnaire – Children		
Sedentary Behavior	TX SPAN 2nd grade 2019-2020 – Sedentary behavior questions	Baseline, Mid-point, End point	Child, guardian-report Structured interview over the phone by RA
BMI-to-age			
Weight	Weight scale	Baseline, End point	Intervention and control arms only: Measured by study staff
Height	Stadiometer	Baseline, End point	Intervention and control arms only: Measured, by study staff
Parent/Guardian's diet	TX SPAN 8th - 11th grade 2019-2020 – Dietary questions	Baseline, Mid-point, End point	Parent, self-report Structured interview over the phone by RA
	NHANES 2009-2010 Dietary Screening Questionnaire		
Parent/guardian's quality of life (physical/ mental)	Short Form 12 (SF-12)	Baseline, End point	Parent, self-report Structured interview over the phone by RA

Pop descriptors (Baseline only)	Tool	Administration
Demographics & social needs (PRAPARE)	Customized. Related to: 1. **parent/caregiver** (age, gender, ethnicity, health insurance, work status, transportation and housing) 2. **household** (income, housing, program participation like SNAP, shopping and food prep) 3. **child** (sex, DOB, health insurance, program participation like SLP or SBP, previous BGCAA programs)	Parent, Self-report Structured interview over the phone by RA

Food security	USDA 6-items	Parent, Self-report Structured interview over the phone by RA

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

Because both the primary and secondary outcome measures are continuous, normally distributed measures, we anticipate having to rely on normal theory analytic methods. Specifically, mixed linear regressions on the primary (HEI) and secondary outcome measures (such as Fruits & Vegetable subscores, BMI and parent HEI) will be fitted to test differential trajectories for two groups from baseline to midpoint and end point assessment of the program, time expressed as days elapsed from baseline. These models readily accommodate differential dropout in the arms with maximum likelihood estimation, random intercepts, and also adjust for any clustering effect of the BGCAA sites. Because randomization will be stratified by whether the family are SNAP recipients or not, the main effect of family's SNAP beneficiary status will be included in all models in addition to the main target terms of interest: two-way interactions of time X treatment, time X SNAP, and their three-way interaction. Overall alpha will be set at 0.05 for each child outcome on these target terms.

In addition to these intention-to-treat (ITT) analyses we will also conduct as-treated (AT) analyses incorporating the 'dose' variable that will be formed based on implementation database elements that permits the tracking of program elements consumed/ picked up/ attended by the target child and his/her parent/guardian in the two active arms. In AT models, total dose taken-up by the end of the program will enter into product terms with time. As is typical, we expect the AT models to have greater sensitivity/ precision in estimating the added value of the family support beyond the elements of the after-school program with CATCH for change in HEI and secondary outcomes. In addition the dose variable sheds light on the effects of Boys and Girls Club programming, including CATCH, regardless of other incentives. Statistical controls for family demographic characteristics, food insecurity, child age, sex, and SNAP beneficiary status will be included in the AT framework as 'dose' is not completely controlled by the randomization and hence would be expected to be correlated with these characteristics (e.g. economically disadvantaged families may be more likely to uptake more of the program elements).

The greatest opportunity lies in exploratory analyses of the two randomized arm participants that permit the estimation of dose-response based on family characteristics. Both the "after-school program with CATCH" and the "after-school program with CATCH + family support" intervention arms are expected to show variation in dose. In the case of dose for "after-school program only" participants, we expect dose variation to be predicted by structural characteristics of family routines (e.g. number of days the target child attends BCG after-school program is predicted by whether both parents are employed, family income, number of siblings and caretakers in the family as alternatives to BCG attendance). In contrast, dose for "after-school program with CATCH + family support" participants is more complex and includes distinct elements that require greater motivation on the part of the parent/ guardian to engage with (e.g. completing goal sheets and receiving incentives

versus not completing incentivized elements of the program). We will model the associations of separate aspects of 'dose' with response (HEI, physical activity) and predict separate aspects of 'dose' from family characteristics at baseline. These exploratory analyses will provide clues on how to structure future programs, incentivize participation, as well as inform who is likely to benefit the most. In the exploratory analytic framework, we will engage in omnibus correction for inflations in type-I error rate and will not interpret any significant single result unless at least 10% of all examined associations are significant.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Check each research procedure included in your study.
A full description of all study procedures should be provided in the Procedures (Details) section below.
Procedures denoted with "" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☐	Bio-specimens*	☒	Biometrics	☐	Registry or Repository*
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International Research*	☒	Interview/Survey	☐	MRI
☐	Protected Health Information*	☐	Observation	☐	Radioactive Material/PET/Nuc. Med
☐	Record Review	☐	Sensors (Externally Placed)	☐	Sensors (Inserted)
☐	Audio (only) Recording	☐	Video Recording	☐	X-Ray/CT/DEXA

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.
A full description of all study interventions should be provided in the Procedures (Details) section below.
** Interventions denoted with "*" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☒	Behavioral	☐	Device*	☐	Drug/Biologic*

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Check the box(es) below if you are implementing research procedures that require oversight from additional UT committees.

☐ **Energy introduced to the subject (electrical, magnetic, light)**

☐ **Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos**

☐ **Radiation exposure without direct clinical benefit**

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus UT IBC approval is needed.

a ☐ **UT IBC has (or will have) oversight.**

Provide UT IBC Number:

b ☐ **Biological samples collected will not be stored at UT Austin and another agency has responsibility for biospecimen safety.**

10 Alternatives to Participation in This Study

Provide a description of alternatives to participation in this study, as applicable.

Families who choose not to participate in the study will continue to benefit from their participation in the BGCAA after-school program, however, only families that choose to participate will receive the

family support component. Those on waitlist control that do not choose to participate, will remain on the waitlist until they are accepted into the BGCAA after-school program.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- *Description of all research procedures being performed and when they are performed, in sequential order.*
- *Describe/list all research measures/tests that will be used [**NOTE: upload copies of all measures, surveys, scripts, data collection forms, etc., in "Other Attachments" in UTRMS-IRB**].*
- *Secondary data or specimens that will be obtained, how they are collected, how are they used.*
- *Where research activities will take place and duration (include expected time commitment of participants).*
- *Study elements checked in #6 above should be described here.*

Note: if this is a multi-site or collaborative study include the following:

- *This is a "Multi-site Study that involves more than one site performing ALL aspects of the research procedures as outlined above." OR "This is a collaborative study that involves UT Austin researchers working with external researchers who are engaged in performing the following study activities (list activities)."*
- *For assistance with multi-site/collaborative research, download HRP-UT932 Request to Rely Assessment Form from the UTRMS-IRB Library and email irbreliance@austin.utexas.edu.*

Recruitment and arm allocation

1. Interest list
    a. BGCAA staff and Factor Health research staff (research associates, RAs) will use various methods (described in section 16) to identify interested participants. The name and contact of these potential participants will be put on a shared spreadsheet in UT Box and this will serve as the interest list that study members will use to recruit people into the program. The spreadsheet will only be shared between study staff.
    b. From tabling activities, we will collect people's names and phone numbers and will add to the interest list. These tabling events will occur at BGCAA sites.
2. Consent (caregiver/parent) + Assent (child)
    a. Interested participants will be called by study staff to screen and share consent and assent information, which is expected to last approximately 15 minutes. Consent and assent will be collected verbally in order to reduce burden on participating families.
    b. After RA obtains consent and assent, if time allows, will also gather baseline data over the phone on the same phone call. If time constraints exist, staff will schedule another time and date for baseline phone measurements (more below).
3. Participating families (parent-child dyads) will then be allocated to study arms as follows:

a. Dyads with one reference caregiver and one reference child in the BGCAA after-school program will be randomized to one of the two active arms (family support + after-school program, or after-school program only)

Measurements and data collection procedures:

There will be 3 data collection measurements over the course of 19 weeks. These are the baseline, mid-, and end-point measurements. The initial baseline phone call will take approximately 45 minutes (counting consent/assent), while the mid- and end-point measurements will take approximately 30 minutes. The height and weight measurements will take an additional 5 minutes. In total, participants can expect to spend approximately 3 hours of their time on study-related measurements and data collection.

Data will be collected by members of study staff listed as study team members in UT-RMS. Data collection will only happen with the families that are actively participating and have consented in to the research, not the families participating in BGCAA's regular program and not participating in our research study.

Questionnaire data:

At each measurement, the research associate (RA), blinded to the active study arm of the participants, will gather parent-reported data and child-reported data with parental guidance over the phone as structured interviews. The structured interviews will be done as follows:

1. The RA places the phone call to the reference parent/caregiver.
2. After introducing themselves and the purpose of the call, they will proceed with the questionnaires as shown in Section #4 (e.g., diet, physical activity, demographics). Questionnaires for children will be asked to the parent (guardian-reported) who can confirm answers with the child if they are present and as needed. At the parent's discretion, the child may answer the questions themselves.
3. After the children-geared survey answers are obtained, parent/caregiver will answer questions related to themselves and their diet.
4. Answers will be recorded in real time in REDCap by the RA.

Measured data (height and weight):

Collected in the first week of the program (baseline) and in the last possible week of the program (end-point) in person for approximately 5 minutes, as follows:

1. Children in the two randomized intervention and control arms:
    a. BGCAA staff and/or research study staff (blinded to the study arm allocation) at participating sites will embed weight and height measurements as part of their regular after-school activities during a field day.
    b. As part of the field day, all children will participate in an interactive activity that measures their weight, height and how high they can jump. Having all children participate in the activity will ensure participant and non-participant privacy. Height will be measured using a stadiometer against the wall before the activity. The activity will utilize athletic tape and/or post it notes that the children will write their name on and stick to a wall by jumping up. Prior to jumping, the child will stand on a mat with

an integrated scale that will measure their weight. Both height and weight measures will be calculated for all children as part of Boys and Girls Club's field day (non-study data), however, only the height and weight from the research participants will be collected and stored by Factor Health research staff (study data).

c. The values of height and weight for the children participating in the study will then be scanned or typed in a secure and HIPAA-compliant database, such as UT Box.
d. RAs involved in the study will then register them in REDCap for each child, both the original data and the transformed units (feet/inches for height and pounds for weight).

This integration of height/weight measurements with the after-school day has been agreed to between study and BGCAA staff. Together we wish to minimize the direct and open measurement of weight since it is a sensitive activity for some children. In the experience of BGCAA staff contextualizing it in a more fun and instructional activity (as the above) would reduce the likelihood of causing them unnecessary psychological discomfort while still providing height and weight measurements. During consenting into the study, parents/caregivers will be fully and dully informed about this activity in which their child's weight and height will be obtained.

Interventions

Arm #1 – Intervention arm: BGCAA after-school program + Family support

- Children participate in the BGCAA's after-school program with CATCH curriculum as well as other activities (such as active recreational time that could include sport activities such as soccer, basketball, etc, homework/power hour, and snack time) as they usually do.
    - Across school sites, the whole BGCAA's after-school program runs for 2-3h, Mon-Fri. The after-school program happens immediately after school and BGCAA provides transportation from the school to offsite locations if the program is not held at child's school.
    - CATCH (https://catch.org/) is a school-based program for health education and Whole Child wellness that BGCAA incorporates into their regular activities. BGCAA staff receives training (irrespective of the research) to focus on its healthy eating and healthy movement components. Each site's BGCAA staff will deliver these components over the course of the school semester on the days of the week of their choice, with a minimum frequency of 45-60 min, twice a week.
    - Children participate in daily (M-F) recreational time (45-60 min) which consists of a mixture of free play, structured physical activity games, and/or sports activities (including soccer, football, and basketball as examples).

4. The child's parent will receive the following as part of a family support:
    - Weeks 1-4 (4 weeks):
        i. Weekly: 1 box of produce to be delivered centrally to each of the participating after-school sites and will be distributed by BGCAA to the participating parents/caregivers during child pickup. At the BGCAA housing sites, some children may walk home with the produce bag and a BGCAA staff member will assist if needed (which is normal protocol for BGCAA). Participants cannot pick the groceries that are provided, and therefore will not have control over

potential allergens in the box. As such, participants with known food allergens related to produce items will be excluded from the study.

ii. Recipes accompanying each box (sample recipe card attached to submission). Recipes will be the same for all participants and will be sent via a text message link. The program team will also provide physical copies of the recipes in the event they cannot access the text link.

iii. Bi-Weekly: HEB Grocery store gift cards (total of $40)

- Weeks 5-16 (total of 10 weeks over the 19-week study timeline):
  i. At the start of weeks 5, 7, 9, 12, and 14: An optional online form (or "*goal sheet*") will be sent to the parent/caregiver (5 sheets in total) with questions about the produce items (including but not limited to: bananas, carrots, zucchini, squash, etc.) they received to be completed within the next 7 days. As an incentive, a $10 HEB gift card will be sent the following week to those who complete it (a potential total of $50).
  ii. Week 11: $20 HEB Grocery store gift card

Since the goal sheet will contain identifiers (such as names), this form will be built in a HIPAA compliant database, such as REDCap, Qualtrics, or other secure database where the information collected will be securely stored and then checked by unblinded Factor health staff for appropriate incentive distribution.

Arm #2 – Control arm: BGCAA after-school program only

- Children participate in the BGCAA's after-school program with CATCH curriculum as well as other activities (such as active recreational time, homework/power hour, and snack time)—as described for Arm #1.
- Children participate in daily (M-F) recreational time (45-60 min) which consists of a mixture of free play, structured physical activity games, and/or sports activities (including soccer, football, and basketball).
- They will be attending the same sites as the intervention arm (Arm #1). Hence, they will be exposed to the same after-school content at each participating site.
- The after-school program happens immediately after school and BGCAA provides transportation from the school to offsite locations if the program is not held at child's school.
- At the end of the study, the reference parent will receive $120 as HEB grocery store gift cards, independently of their end-point measurement being obtained.

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12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐ Active Military Personnel	☒ Children/Minors	☐ Decisionally Impaired Adults
☐ Emancipated Minors	☐ Fetuses	☒ Individuals with Limited English Proficiency
☐ Neonates (Uncertain Viability)	☐ Neonates (Non-Viable)	☐ Prisoners
☐ Pregnant Women	☐ UT Staff/Employees	☐ UT Students

13 Research Participant Information

Describe the general characteristics of the subject populations or groups including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

A household will be the subject of randomization, one index parent/caregiver and one index child (parent-child dyads) who meet inclusion criteria will be invited to participate in the research activities (data collection).
Participation in the BGCAA after-school program is governed by that organization according to their mandate.

b Minimum Age

Include the minimum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state the minimum age for each group.***

Children in 1st grade (approx. 6 yrs old); 18 for adult participants (parents)

c Maximum Age

Include the maximum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state maximum age for each group.***

Children in 5th grade (approx. 11 yrs old); No maximum age for adult participants (parents)

d Inclusion Criteria

Describe the specific criteria that will be used to decide who will be INCLUDED in the research from interested or potential subjects. Define technical terms in lay language, as applicable.

Parent must be 18 years or older. Child must be enrolled in grade 1 to 5 (aged approx. 6-11 y-o) for the 2023-2024 school year at one of the 11 sites where BGCAA offers after-school program to elementary-aged children, AND:

- For intervention and control arms: Participating in the BGCAA after-school program at the beginning of the 2023-24 fall semester. Families participating in the BGCAA after-school program will be known at the start of the 2023-2024 school year.

Participating families must be English and/or Spanish speaking.

Locations where BGCAA offers after-school programming include:

- Elementary schools:
  - NYOS (Not Your Ordinary School)
  - Woolridge Elementary
  - Overton Elementary
  - Walnut Creek Elementary
  - IDEA – Rundberg
  - McBee Elementary
- Off-site locations
  - Home Club (BGCAA's headquarters)
  - Meadowbrook Apartments (Housing Authority)
  - Booker T. Washington Court (Housing Authority)
  - Chalmers Court (Housing Authority)

e Exclusion Criteria

Describe the specific criteria that will be used to decide who will be EXCLUDED from the research. Define technical terms in lay language, as applicable.

Already having a sibling enrolled in the study, having any food allergy or dietary restriction associated with produce products, and not meeting the minimum age or exceeding the maximum age as stated above

14 Total Sample Size

Enter the total target sample size below.

We will invite all families across all 11 participating sites. Given numbers from the current year, we expect total number that could be invited (meeting inclusion/ exclusion criteria) to be 350 total index parent and child pairings. Below we discuss various realistic recruitment and retention scenarios given

the capacity of our partner, BGCAA. Our aim will be to maximize recruitment but are prepared for various recruitment scenarios.

15 Sample size rationale

Describe your sample size rational below.

We are conducting both as-treated (AT) and intention-to-treat (ITT) analyses.

To inform our sample size calculations and power for the ITT and AT analyses, we relied on information from the pilot trial conducted at BGCAA sites in the spring of 2021. The pilot also used the SPAN tool to measure diet for child and caregiver (Kahlon et al., 2022).

For the AT analysis, we use the results of the pilot from Spring of 2021 showing a dose response correlation, which was r = 0.31. We have 80% power to detect this association with total N = 79. Even if the enrollment and retention is as low as n= 64 for each active arm, we would be able to detect a dose-response correlation as low as 0.24 in the AT framework.

From the 2021 study, the effect size for the overall child's HEI (Healthy Eating Index) at the end of the study was .47 with an ICC of .20 for person x site clusters. For the present study, to be able to detect an identical difference between the two randomized arms (Program+Family Support and After-school program only) with 80% power at alpha = .05, we would need to retain 120 children in each arm. Considering a 15% attrition rate, a target recruitment of approx. 140 children into each active arm would permit sufficient power to observe the targeted moderate group difference.

Given the recruitment pool for our sample is limited by the BGCAA program capacity, we estimated the changes in effect sizes (i.e., our ability to detect differences) in two scenarios, maintaining 80% power at alpha = .05.

Assuming that all eligible households will be invited to participate and that a conservative potential pool of approx. **300 households** will be maintained in the fall (in the current school semester, Boys and Girls Club has approximately 313 households attending their after-school program with at least one child), we can expect the following:

- If we successfully enroll 75% in the study, N=226
  - With n=113 households in each active arm, we can detect a moderate effect size d= .45.
  - Considering 15% attrition in each arm, we would end the study with n=96 in each active arm and able to detect an effect size of d= .49.
- If we successfully enroll 50%, N=150
  - With n=75 in each active arm, we can detect a difference of moderate effect size d=.55
  - Considering 15% attrition, n=64 in each arm enable us to detect an effect size of d= .60.

Therefore, we will invite to participate in the study all households with at least one eligible child to maximize our ability to detect meaningful mean differences in children's HEI between the two active arms.

16 Identification and Screening

*Check the box below if this study involves a screening process **prior** to the informed consent process.*

☒ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**
1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 Identification and/or Screening Procedures

Describe the identification and/or screening procedures below.

The Identification of interested families will be done both by the BGCAA staff and our study staff through the various places where BGCAA can be reached, as follows:

- Distribution of flyers containing a QR code that links to an interest form to request more information later – at BGCAA sites & digitally via Class Dojo app that BGCAA staff use to communicate with families. In this form, if collecting interest information, we will collect the parent/guardian name, child name, school and/or afterschool site they attend, contact phone number, grade child will be in the fall, and preferred language. The path the QR code takes them will be to a secure and HIPAA-compliant database (UT Box, REDCap, and/or UT Qualtrics) that will securely house the information to be filled out by the parent/guardian.
- Tabling at participating BGCAA sites during parent pick-up (after the after-school program) and/or events by our study staff. If a parent wants to sign up to be contacted to learn more, the same fields listed above in bullet 1 will be captured by study staff to contact them at a later time. This data will be collected in the same way as mentioned in bullet 1 and also stored in the same way. BGCAA staff will not actively recruit participants on their own and will refer all questions about the study to the research study staff members.
- Posting about the research study on ClassDojo, a virtual platform BGCAA uses to communicate with their members. We also plan to use a QR code for the parents to learn more about the program (link to recruitment flyer) through BGCAA normal practices of communicating information to their members.
- BGCAA will share the families participating in the after-school program at the beginning of the 2023-2024 school year, so Factor Health research staff will know which families to reach out in regards to the program. Similarly, BGCAA will let Factor Health research staff know the families that are on the waitlist as of the beginning of the 2023-2024 school year.
- Tabling at participating BGCAA sites during parent pick-up (after the after-school program) and/or events both by our study staff and/or BGCAA site staff.

- Building upon BGCAA's regular process of notifying caregivers' child of enrollment into the after-school programming.
- Interested families will be further screened at BCGAA sites or via phone call by having the "Intro Script" (uploaded as part of the local site documents) read to them.

The families that express interest in joining the study or learning more about it will have their contact information (as above) added to a spreadsheet (i.e. interest list) kept securely in UT Box. Research staff from Dell Medical School involved in the study will further screen for interest and eligibility via a phone call and/or text message. During this phone call, research staff will explain the study in more detail, including exclusion/inclusion criteria information. As part of the screening, the research staff member will ask if there are any food allergies or sensitivities to be aware of. If so, they will not be able to participate in the study.

18 Recruitment Overview

Check box indicating all recruitment methods utilized for this research.

☐	E-mail	☒	Flyer
☒	In-Person	☐	Letter
☐	Social Media	☐	Research Pool
☒	Telephone/Text	☐	Snowball Sampling
☐	Web-post	☒	Word of Mouth

19 Describe the recruitment process, including where recruitment will take place.

Describe recruitment procedures in the box below. Describe all elements checked above to provide a complete understanding of the recruitment strategies/methods.
NOTE: Upload copies of all recruitment materials to UTRMS-IRB in the "Recruitment Materials" section.

Recruitment:

- Interest list
  - BGCAA staff and Factor Health research staff (research associates, RAs) will use various methods (described in section 17) to identify interested participants. The name and contact of these potential participants will be put on a spreadsheet in UT Box and this will serve as the interest list that study members will use to recruit people into the program. The spreadsheet will only be shared between BGCAA staff and Factor Health research staff.
  - RAs will outreach to the individuals on the interest list and explain the study in more detail before following consent/assent procedures.
- Tabling activities:
  - Research Staff will table at BGCAA sites when parents are expected to be there (i.e. pick-up/drop-off after school, etc.). From these tabling activities, staff can hand out

flyers and inform potential participating families about the study. RAs will collect contact names and phone numbers (specific fields indicated in Section 17) and will add to the interest list.

OBTAINING INFORMED CONSENT

20 Consent Overview

Check the box(es) for consenting procedures that will be used.

☐	**Obtaining Written Informed Consent/Parental Permission**	☒	**Requesting a Waiver of Documentation of Informed Consent**
☐	**Requesting a Waiver of Informed Consent**	☐	**Requesting an Alteration of the Required Elements of Informed Consent**
☒	**Obtaining Child Assent**	☐	**Obtain Consent Using a Short Form with a Witness**

21 Consent and Assent Processes

Provide a detailed description of consent/assent procedures in the box below. Include: who will obtain consent, where will consent be obtained, how is consent obtained, how consent/assent is documented, and when the consent process will occur in such a manner that participants will have sufficient time for adequate consideration.

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.

1. Research team members will contact by phone and/or text the individuals who indicated interest in the study via recruitment strategies and will further explain the study to confirm interest and screen participants.
2. When interest is confirmed, the research team member will ask individual for their e-mail and e-mail copies of the consent and assent forms. Then the research staff will proceed to read through the consent and assent forms over the phone (if the potential participant is willing to provide us an email address to do so). They will allow as much time as the person needs to ask any questions they may have.
3. Research staff will also explain that the research is voluntary and they are not required to participate and may withdraw at any time for any reason. If the potential participant agrees to participate, they will be asked for their verbal consent and parental permission. Attainment of

verbal consent and parental permission will be documented in Redcap. Verbal consent and parental permission will be obtained to reduce burden on participating families.

4. After parent/guardian has given their consent, researcher will talk with child and read through the assent form over the phone. Similarly, they will allow time to answer questions and explain that the research is voluntary. Once the child agrees to participate, the verbal assent will be documented in Redcap.

E-mail addresses will only be used to send consent and assent forms. No other correspondence will take place via e-mail.

When more than one child could be eligible for the study, the parent will be asked to select the child to be enrolled and assented into the study.

Copies of blank consent forms can be provided to families at BGCAA events, if potential participants wish to have a copy prior to expressing full interest.

For Spanish speaking families, consent will be provided in Spanish. The Spanish-translated consent forms will be uploaded to UTRMS via modification prior to administration.

22 Electronic Consent

Check the box below if this study involves obtaining consent with an electronic signature. Be sure the section above is consistent.
NOTE: This box should NOT be checked participants are responding "yes" or clicking "I Agree" on a consent form. ***This section should only be completed if an electronic signature is being obtained.***

☐ **This study involves documenting informed consent/parental permission using an electronic signature.**

If true, specify method for obtaining e-consent below (e.g., DocuSign):

23 Consent and Translation

Check the box below to indicate that consent documents/scripts will be translated to a language other than English.

☒ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

If above is checked, complete the below information describing the translation process. Either A or B must be checked.

A ☐ **The consent documents will be translated by a certified translator.**

B ☒ **A non-certified translator will translate the consent documents.**

If selected, complete the next two items below. Section describing qualifications must be completed and backtranslation (ii) must be true.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

Multiple English fluent and native Spanish speakers within research personnel. One will translate and the other will confirm translation.

ii ☒ **Another individual will confirm that the translation is accurate and appropriate**

26 Waiver of Documentation of Informed Consent

Only complete this section if a waiver of documentation of consent is requested (checked above in #21). To approve a waiver of documentation of consent, one of the following options must be appropriate and justified by the researcher.
*Please choose **one** waiver option and provide additional information as prompted.* ***Waiver option 2 is most common.***

A Waiver Option 1

Check the box below for each item (all required – #1-4) and provide protocol-specific information as to how the criteria below are met.
NOTE: This is the only applicable waiver of documentation option for greater than minimal risk research. If your study is greater than minimal risk and does not meet Option 1 criteria, you will need to obtain written consent.

1 ☐ **The only record linking the subject and the research would be the consent document.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

2 ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

4 ☐ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants.

B Waiver Option 2

Check the box below for each item (all required – 1-3) and provide protocol-specific information as to how the criteria below are met.

1 ☒ **The study is minimal risk.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

Surveys can be collected over the phone and minimize burden on participants. Though we will collect in-person height and weight measurements on the child, these will be done at events that parents don't typically attend. In addition, we aim to collect survey measurements before the in-person measurements, due to the program schedule.

2 ☒ **Written consent would not be required outside the research context.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

Families already participate in BGCAA programs outside the research context, which does not require written consent.

3 ☒ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants. To input text, click in the light grey area below.

i Informed consent and assent will be tracked in REDCap along with the enrollment/baseline measurement data.

C Waiver Option 3

Check the box below for each item (all required – 1-4) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

i **Describe the cultural group or community.**

2 ☐ **The research presents no more than minimal risk of harm to subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

4 **Describe mechanism for documenting that informed consent was obtained**

To input text, click in the light grey area below

27 Waiver or Alteration of Informed Consent

Only complete this section if a waiver or alteration of consent is requested. *To approve a waiver or alteration of consent, all of the following criteria must be appropriate and justified by the researcher.* ***All boxes must be checked.***

SKIP THIS SECTION IF NOT REQUESTING A WAIVER/ALTERATION OF CONSENT

A ☐ **The research involves no more than minimal risk to the subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

B ☐ **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

C ☐ **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining consent is required and not just impracticable to obtain consent).**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

D ☐ **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

28 Deception/Incomplete Disclosure and Debriefing

Only complete the sections below if requesting an alteration of informed consent for research that involves deception/incomplete disclosure.
Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.
Incomplete disclosure means that the principal investigator withholds some information about the real purpose of the study or the nature of the research procedures.
See IRB Policies and Procedures Section 15 for a description of deception.
If this study does not involve deception/incomplete disclosure, skip this section.

A ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive the subject to the nature of the study).**

B ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

C **Describe the nature of deception/incomplete disclosure and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

D **Describe debriefing procedures.**

To input text, click in the light grey area below. ***NOTE: Upload the debriefing form to UTRMS-IRB in the "Consent Forms" section.***

BENEFITS

29 Benefits to Society

Describe the scientific and societal benefit(s) below.

Addressing nutrition through delivery of produce boxes and grocery store gift cards could potentially result in families with elementary school aged children not only obtaining the opportunity to try more fruits and vegetables, but improve their overall diet.

30 Potential Direct Benefits to Participants

Click on the applicable check box. A or B must be checked.

A ☐ **There is no anticipated direct benefit to participants.**

B ☒ **There are anticipated benefits to participants.**

i **If applicable, describe the potential direct benefits to participants.**

Describe potential direct benefits to participants below.

Participating families may or may not benefit from this study. Families participating in this study may see the anticipated direct benefit of improved diet and access to healthy foods.

RISKS

31 Describe the risks associated with each activity in this research

To input text, click in the light grey area below. Note: Risks should also be outlined in the consent form(s).

- Accidental loss of confidentiality
- Although the study team and our BGCAA partners are taking every effort to minimize the possibility, psychological distress related to in-person weight measurement could occur.
- Potential discomfort answering the research questions about diet and exercise habits, and other personal details about their lives and health.
- May discover new food allergies or sensitivities from trying new foods (intervention arm ONLY, control does NOT get food of any kind from us as part of the study).

32 Describe how each risk is mitigated/minimized.

To input text, click in the light grey area below. Note: Risks mitigation should be outlined in the consent form(s), as applicable.

- Participant study numbers within REDCap will be used to protect patient confidentiality. All data will be stored in either Box or REDCap.
- The height and weight measurements will be integrated within an activity at the health fair to minimize psychological distress related to these.
- The research staff does not have control of the contents in the produce boxes, and we will not be able to accommodate special diets or prevent potential allergens from being in a produce box. As such, having a food allergy related to any produce product will result in exclusion from the program.
- Resources will be provided to help families identify the signs of a food allergy or sensitivity (Intervention only). These resources will provide guidance on symptoms and what to do if symptoms appear, and will be given to intervention participants along with the recipes they receive with their produce boxes.

33 Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.
One of the following must be checked (A, B, or C).

A ☒ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

B ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan to monitor for safety (Data Safety Monitoring Plan (DSMP)).**

Complete Data Safety Monitoring Details

C ☐ **This study has a Data Safety Monitoring Board (DSMB).**

*Complete Data Safety Monitoring Details section below **or** upload this study's Data Safety Monitoring Board's charter that contains the information below.*

34 Data Safety Monitoring (Details)

*Complete this section if the study has a Data Safety Monitoring Plan. **SKIP this section there is not a DSMP/DSMB.***
If the study has a DSMB, ensure all items below are addressed in the charter (and charted uploaded to UTRMS-IRB) or provide additional information below, as needed.

A **How is safety information collected?**

To input text, click in the light grey area below.

B **When will safety data collection start (for each participant or for the whole study, as applicable)?**

To input text, click in the light *grey area below.*

C **How frequently will safety data be collected?**

To input text, click in the light grey area below.

D **Who will review the data for safety?**

To input text, click in the light grey area below.

E **How frequently will data be monitored for safety concerns?**

To input text, click in the light grey area below.

F **What data will be reviewed?**

To input text, click in the light grey area below.

G **State the frequency or periodicity of the review of cumulative data.**

To input text, click in the light grey area below.

H **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

35 Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to next section. Include this information in your consent form.*

A **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

Participants may be withdrawn if it is determined it is unsafe for them to continue with the program. They may also be removed if a child leaves the BGCAA program and is in one of the randomized arms.

B **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

There are no procedures in place to ensure the safety of a participant that is withdrawn early. This is a minimal risk study and being withdrawn poses no risk to the participant.

36 Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.

To input text, click in the light grey area below.

None.

REQUIRED DISCLOSURES

37 Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form. Click on the check box (or double click and type an "X" if using Google Docs).

A ☒ **It is reasonable that researchers could discover or suspect child or elder abuse.**

Add appropriate disclosure in consent form(s).

B ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

Add appropriate disclosure in consent form(s). See Title IX and Research Guidance for information and download the Title IX Reporting Form on the Special Topics page.

C ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

Add appropriate language to consent form(s).

i **Articulate methods for addressing and reporting incidental findings, if applicable.**

Ensure appropriate information is in consent form(s), as applicable.

Given the population of interest involves children, it is reasonable that researchers could discover or suspect child abuse. If we learn during the study about child abuse or neglect, we will report the information to the appropriate authorities, including the police, Child Protective Services, and the Texas Department of Family and Protective Services.

PRIVACY AND CONFIDENTIALITY

38 **Privacy**

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants. Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.
To input text, click in the light grey area below.

Participant privacy will be maintained by conducting data collection over the phone. RAs will ensure no one who is not involved in the study is listening or around them. All phone calls will be conducted using a phone number provided by the participant. Privacy for the height and weight measurement will be ensured by masking the height and weight measurements during a field day at BGCAA which is a normal activity they typically have. Everyone, regardless of their participation in this study will participate in these field day activities that recreational activities such as soccer, football, and basketball. To ensure privacy of non-participants, both research participants and non-participants will have their height and weight taken at the field day, but only the data of the research participants will

be collected. All data to be collected by study staff will be done so discreetly on a secure file and in a secure database.

39 Confidentiality and Data Security Plan

Provide general information below regarding confidentiality and data security plan. Provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.
Include the following, as applicable:

- *If identifiers will be coded to protect confidentiality describe how and where identifiers are stored.*
- *Describe where and how data is stored and maintained.*
- *Include details regarding storage of consent forms, if applicable.*

To input text, click in the light grey area below.

All data will be stored in the Dell Medical School REDCap database and/or on UT Box. These secure, HIPAA compliant databases can only be accessed with password and dual authentication. REDCap will assign participants a unique study ID, protecting confidentiality.

Because verbal consent and assent will be obtained, no consent forms will need to be stored.

40 Research Data/Records Destruction Details

Confirm general research data/information (including consent forms, as applicable) destruction timeline. ***One of the following must be checked.***

☒ **Research Data/Records will be retained for 3 years after study completion per UT record retention policy.**

☐ **Research Data/Records will be retained for longer than 3 years and retention information is provided below.**

Describe data retention timeline below. To input text, click in the light grey area below.

41 Confirm identifiable data destruction details

One of the following must be checked.

☒ **Identifiable data will be destroyed.**

If checked, ensure the below section describes identifiable data destruction plan and timeline.

Identifiers will be destroyed 3 years after the completion of the study after all data has been analyzed. After the study ends, The University of Texas at Austin might contact participants to determine interest in media opportunities, which would be completely optional for them to partake in.

☐ **Identifiable data will not be destroyed.**

If checked, explain below the rationale for retaining identifiable data indefinitely.

42 Data Access

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.
If you plan on creating a repository, complete the repository form as well (download from Library in UTRMS-IRB).

☒ Study Team Members	☒ External Collaborators	☐ Data coordinating center
☐ Sponsor	☒ Future Sharing with other researchers	

☐ **Others**

Describe below. To input text, click in the light grey area below.

43 Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data.

To input text, click in the light grey area below. Ensure that data sharing and future use is addressed in the consent form(s).

Due to the nature of the study, identifiable data will be shared with BGCAA during the study. This is necessary to be able to conduct the research study as BGCAA needs to know which of their members are receiving the intervention. We will not record data of ineligible participants. Non-aggregated and de-identified study data may be shared with BGCAA after analysis for the purpose of improving programming within their organization. Aggregated and de-identified data will be shared with BGCAA and may be presented in public forums.

We may share data with other researchers for future research studies that may be similar to this study or may be different. The data shared with other researchers will not include information that can directly identify the participant.

44 Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.

If a Certificate of Confidentiality is not applicable for this study, skip this section.

A ☐ **NIH has issued a Certificate of Confidentiality for this study.**

Ensure CoC language is included in the consent form(s).

B ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

Ensure appropriate CoC language is included in consent form(s). Apply for a CoC for non-NIH funded research here: NIH Certificate of Confidentiality System. Once CoC is granted by NIH, you must update the consent form language and ensure a copy of the CoC approval (only for non-NIH funded research) is uploaded to UTRMS-IRB.

COMPENSATION AND COSTS

45 **Compensation**

Click on the check box (or double click and type an "X" if using Google Docs). A or B must be checked.

A ☒ **Subjects receive compensation.**

i ☒ **Confirm: Amount of compensation and its form is reasonable for this population for the activities requested of them.**

ii **Total Amount of Compensation**

Include the total amount of compensation below.

All participating families, whether in the intervention or control arm will be paid $30 for each measurement (baseline, mid-point and follow-up), for a total of up to $90.

iii **Type of Compensation**

☐ **Cash** ☐ **Check** ☒ **Gift Card**

☐ **Course Credit** ☐ **ClinCard** ☒ **Tango Card**

☐ **Other**

Describe other form of compensation below.

iv **Proration Schedule**

Describe the proration schedule for multi-visit/session studies. Skip if not applicable.

Participating families will be paid $30 for each measurement (baseline, mid-point, and follow-up) for a maximum of $90 over the duration of the study. Gift cards will be distributed to the participants via text message at the end of each measurement.

B ☐ **Subjects will not receive compensation.**

46 Costs

A or B must be checked.

A ☒ **Participants will have no costs associated with this study**

B ☐ **Participants will have the following costs associated with this study.**

- ☐ **Standard of care procedures contributing to study data**
- ☐ **Research procedures not associated with standard of care**
- ☐ **Administration of drugs / devices**
- ☐ **Study drugs or devices**
- ☐ **Transportation and parking**

i **Describe all costs below.**

To input text, click in the light grey area below.

CONFLICTS OF INTEREST

*This section is **required** for all studies. Please confirm that all research personnel who meet the definition of "covered individuals" are designated as such in the* Local Study Team Members *section of the SmartForm application in UTRMS-IRB.*

47 Financial Conflicts of Interest

Financial interest includes utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project. Additional guidance on financial conflicts of interest is available on the COI website

A or B must be checked.

A ☐ **The PI and/or other covered individual(s) has/have a financial interest related to this study**

i **If A is checked above, please provide the name(s) of the covered individuals involved, and briefly describe the interest:**

To input text, click in the light grey area below.

B ☒ **To the best of your knowledge, no one on the study team has financial interest related to this study**

48 Non-financial Conflicts of Interest

Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity,
- equity or business ownership in a company that has yet to make a profit and is related to this project,
- conflict of time/effort,
- personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study

A or B must be checked.

A ☐ **The PI and/or other covered individual(s) has/have a non-financial interest related to this study**

i **If A is checked above, please provide the name(s) of the covered individuals involved, and briefly describe the interest:**

To input text, click in the light grey area below.

B ☒ **To the best of your knowledge, no one on the study team has non-financial interest related to this study**