Type of paper: Original paper

Title: Testing a web-based interactive comic tool to decrease obesity risk among minority preadolescents: A pilot RCT protocol

Authors and affiliations:
May May Leung, PhD, RDN¹, Katrina F. Mateo, MPH¹², Sandra Verdaguer, MS, MPH¹²;
Katarzyna Wyka, PhD²

¹School of Urban Public Health, Hunter College, City University of New York, New York, NY 10035; ²Graduate School of Public Health and Health Policy, City University of New York, New York, NY 10027

Corresponding Author:
May May Leung, PhD, RDN
Associate Professor of Nutrition
Hunter College School of Urban Public Health
2180 Third Ave
New York, NY 10035

maymay.leung@hunter.cuny.edu

Ph: 212.396.7774
Testing a web-based interactive comic tool to decrease obesity risk among minority preadolescents: A pilot RCT protocol

Abstract

**Background:** Childhood obesity is a public health crisis, particularly in low-income, minority populations in the United States. Innovative and technology-enhanced interventions may be an engaging approach to reach at-risk youth and their parents to improve dietary behaviors and feeding practices. However, such tools are limited, especially ones that are theory-based, co-developed with user-centered approaches, tailored to low-income, minority preadolescents, and include parent-focused content.

**Objective:** The objectives of the study include assessing the feasibility and acceptability, and exploring the potential impact, of the *Intervention INC* (Interactive Nutrition Comics for Urban, Minority Preadolescents) web-based tool, which is focused on decreasing childhood obesity risk in Black/African-American and Latino children ages 9 to 12 years.

**Methods:** *Intervention INC* is underpinned by the Narrative Transportation Theory, Social Cognitive Theory and Health Belief Model, and was co-developed by children and parents from the intended population. The child component consists of a 6-chapter interactive nutrition comic optimized for use on tablet devices, a goal setting and self-assessment feature, and weekly text/email messages and reminders. The parental component consists of six online newsletters, access to the child comic, and weekly text/email messages and reminders. The tool was evaluated using a pilot single-blind two-group randomized controlled study design. Child-parent dyads were randomized to either the experimental or comparison group, and assigned to a targeted behavior (increase fruit/vegetable or water intake) based on initial screening questions. Data were collected at four time points: baseline (T1), intervention midpoint (T2), intervention endpoint (T3), and 3 months post-intervention (T4). Primary measures comprise usage, usability, and feasibility of the web-based tool. Secondary measures comprise dietary knowledge, preferences, and intake and anthropometric measures (for child), and feeding practices and home food environment (for parent).

**Results:** Study enrollment was completed in November 2017. Eighty-nine child-parent dyads were randomized to either the experimental (n=44) or comparison (n=45) group. Data analysis is currently being conducted.

**Conclusions:** This study aims to implement and assess an innovative approach to delivering health messages and resources to at-risk minority preadolescents and their parents. If found to be acceptable, engaging, feasible, and potentially an approach to improving dietary behaviors, a full-fledged randomized controlled trial will be conducted to assess its efficacy and potential impact.

**Trial Registration:** NCT03165474
Introduction
Childhood obesity continues to be a serious clinical and public health issue in the United States (US). Over the last three decades, the rate of childhood obesity has tripled, with 17.0% of 2 to 19 year old children now considered obese [1]. While the US childhood obesity rate has leveled off in recent years, the challenge remains pronounced among certain populations, particularly in low-income, minority groups. Latino and Black/African-American (AA) children have the highest rates at 21.9% and 19.5% respectively [1]. This epidemic has profound short- and long-term consequences as it not only leads to negative health outcomes, such as type 2 diabetes and cardiovascular disease, and can compromise a child’s quality of life, but it also increases the risk of adult morbidity and mortality [2, 3, 4, 5, 6].

Effective, yet innovative interventions are needed to capture the attention of children living in a multimedia environment. Visual narratives, such as comics, may engage today’s youth population around health topics and promote positive psychosocial and behavioral outcomes [7, 8, 9]. Furthermore, the pervasiveness of technology and new media use in children, particularly within Black and Latino populations highlights opportunities and new avenues to engage with this priority population [10, 11]. A recent systematic review indicated that web-based programs, as part of a multi-component intervention, could reduce overweight and obesity in school-aged children [12]. Web-based and technology-enhanced interventions, particularly if developed with user-centered approaches and informed by theory [13], also have the potential to increase access, improve convenience, decrease cost, and increase participant engagement with dietary behavior change strategies, especially among culturally diverse and hard-to-reach communities [14, 15, 16, 17].

However, such interventions tailored to minority youth are limited, especially those which have been co-designed by and developed for this population [18, 19]. This is particularly apparent within the preadolescent population, which is an understudied, yet critical stage of development. Not only does obesity prevalence increase when children transition into adolescence [20], but food preferences and behaviors established during this developmental period often continue into adulthood [21, 21, 23, 24]. In addition, knowledge gaps and challenges related to the implementation and adoption of technology-enhanced interventions exist (e.g. identification and recruitment of at-risk, low-income minorities with internet access), which limit their potential effectiveness.

The purpose of this paper is to describe the protocol for the implementation and assessment of the Intervention INC (Interactive Nutrition Comics for Urban, Minority Preadolescents) web-based tool, which is focused on decreasing childhood obesity risk in Black/AA and Latino children ages 9 to 12 years. The objectives of the study include assessing the feasibility and acceptability, and exploring the potential impact of the intervention on dietary behaviors using a pilot single-blind two-group randomized study design.
Methods

Study Design
The Intervention INC study is a pilot single-blind two-group randomized controlled trial that evaluated a 6-week intervention, with a 3-month follow-up period (see Figure 1). Child-parent dyads were enrolled into the study on a rolling basis between August and November 2017. Dyads were randomized to either the experimental group, in which the child received a web-based comic with health messages promoting fruit/vegetable (F/V) and water consumption, or the comparison group, in which the child received online newsletters with information promoting F/V and water consumption. Parents of both groups received online health newsletters, however, parents in the experimental group were also given access to the child comic. Dyads were blinded to group assignment. Data were collected at four different time points: baseline (T1), intervention midpoint or 3 weeks post-baseline (T2), intervention endpoint or 6 weeks post-baseline (T3), and 3-month follow-up post-intervention (T4). The study was approved by the xx Institutional Review Board and is registered with the Clinical Trials Registry (xxx). Adult consent, parental permission, and child assent were obtained at baseline prior to the commencement of any study procedures.

![Figure 1: Study design of Intervention INC](image)

Study population
Children and their parent/guardian, residing in New York City (NYC), were recruited based on the following inclusion/exclusion criteria:

Child
Self-identifies as Black/AA and/or Latino; between the ages of 9 and 12 years (preadolescents) at the time of scheduled baseline visit; reads and speaks in English; has a Body Mass Index (BMI) percentile at or above 5% at baseline (categorized as healthy/overweight/obese); has regular internet access via a tablet device, smartphone, or computer/laptop; has regular access to a phone with texting capability; is comfortable reading/viewing material on electronic devices; is
comfortable speaking with study staff about thoughts/experiences while participating in the study; has no allergies, food aversions, food disorders, or medications with side-effects that may impact participation in the study; does not have a pacemaker or heart condition; has a legal parent/guardian willing to participate in the study. It should be noted that original criteria included a BMI percentile at or above 85% (categorized as overweight/obese). Due to recruitment challenges and evidence highlighting that most youth, regardless of BMI status (healthy, overweight, or obese), do not consume the daily recommended amount of fruits/vegetables and water [25, 26, 27], criterion was changed to expand the BMI percentile range to include healthy weight children (BMI percentile at or above 5%). Additionally, the criterion regarding comfort-level of child speaking with study staff was added after recruitment began due to observations at initial baseline visits of some children who were unable/unwilling to verbalize their thoughts/experiences.

**Parent/Guardian**
Legal parent/guardian of child willing to participate in the study; reads and speaks in English or Spanish; primarily responsible for preparing/purchasing food for child; has regular internet access via a tablet device, smartphone, or computer/laptop; has regular access to a phone with texting capability; comfortable reading/viewing material on electronic devices; able to attend in-person study visits and complete online questionnaires with their child over the full duration of the study.

**Recruitment**
Several recruitment approaches (with bilingual materials) were utilized to enroll child-parent dyads. Recruitment letters were sent to the parent/guardian of eligible child patients (based on age, race/ethnicity, and BMI percentile criteria) who had received care at a community-based clinic (partnering organization) in Upper Manhattan, NYC within the last two years. We also intended to send recruitment letters to similar child patients of a government-insured medical clinic based in Upper Manhattan, NYC. However, barriers related to accessing patient data were encountered, thus preventing use of this approach. Once the BMI percentile criteria was changed (see Study Population section above), recruitment approaches were expanded to include local community flyering in East Harlem/Upper Manhattan, posting inside/near local businesses, housing complexes, community centers, schools, and churches. Through several partnerships with local schools and community initiatives, recruitment efforts also occurred via tabling at community and school events.

Interested parents/guardians had the option to call, text, or email study staff to receive more information about the study. Those receiving recruitment letters also received a recruitment call to assess interest in the study and receive additional information. Interested parents/guardians completed a screening form via phone/email to determine study eligibility. Eligible participants were scheduled to attend a baseline (T1) visit where the child’s height and weight were measured to determine if their BMI percentile was at or above 5%.

To minimize attrition, child participants were compensated up to $70 in gift cards and parent/guardian participants up to $65 for completing data collection. Compensation was distributed in increasing amounts at each time point (T1: Child $10, Parent/Guardian $15, T2: Child $15; T3: Child $20, Parent/Guardian $20; T4: Child $25, Parent/Guardian $30). Each
participant had the option to select a gift card from either Whole Foods Market®, Aldi, Modell’s, or Target®. Participants also received a round-trip MetroCard for any in-person study visits. If a dyad completed data collection at all four time points, they were entered into a raffle for a $100 gift card.

**Sample Size**
The sample size for this study was determined to reliably assess feasibility, acceptability and preliminary efficacy of the intervention. We aimed to enroll a total sample size of 82 dyads (41 per group) [28, 29], which allows for assessment of: 1) intervention usage, usability and feasibility/acceptability of study implementation, and 2) both the within and between group effect sizes, as well as preliminary intervention efficacy based on mixed models methodology (d=.5, power=.80, alpha=.05, ICC=.6, 4 repeated measures), after taking into consideration estimated attrition of 20%. This sample size also allows to characterize potential socio-demographic moderators of the intervention, as well as guide power calculations for a subsequent full-fledged randomized controlled trial (RCT).

**Randomization**
At baseline (after height and weight data were collected), eligible participants were randomized to either the experimental group or comparison group using a minimization allocation strategy (performed using the QMinim web-based application). Randomization was performed at the dyad level and was balanced on child ethnicity (Hispanic or Non-Hispanic) and BMI category (normal, overweight or obese). Randomization was revealed at T4.

**Experimental Group Description**
Interviews/focus groups, usability testing, and continual quality improvement feedback on multiple prototypes with children and parents/guardians from our priority populations were used to inform development of Intervention INC, a theory-guided, interactive web-based tool promoting healthy dietary behaviors (increased F/V and water intake), with the goal of reducing childhood obesity risk in Black/AA and Latino preadolescents. It comprises a 6-chapter comic with embedded goal-setting and messaging components. The tool is hosted on a password-protected website and optimized for use on tablet devices and touch-screen computer/laptop devices. All study participants received training on how to use the website at baseline.

**Theoretical Framework**
The Narrative Transportation Theory (NTT), Social Cognitive Theory (SCT), and Health Belief Model (HBM) provided the theoretical framework for the Intervention INC tool. Comics, in particular manga comics (also known as Japanese comic art), are a unique form of multimodal narrative media that stimulate a reader’s attention by combining detailed visual images and text to create more of a subjective or personal viewpoint of a story [31]. The NTT explains how narrative communication, such as manga comics, could contribute to changes in health-related beliefs and behaviors by transporting the reader into the narrative world [32]. According to the NTT, transportation into a narrative world is believed to lead to acceptance of persuasive messages within a story through multiple mechanisms [33, 34, 35]. This theory also suggests that
images are most impactful when they are embedded in a story rather than provided in isolation as it could enhance the narrative influence [36]. Therefore, visual images relevant to the story’s message, such as those incorporated in manga comics, may further impact attitudes and beliefs.

Social cognitive theory (SCT) is a frequently used framework in effective dietary behavior change interventions, and also lends explanation to ways in which a manga comic may influence health behavior in youth [7, 8]. Exposure to characters in the storylines may facilitate observational learning and influence health behaviors, particularly when readers relate to the characters in the comics and consider them role models [37]. The development of entertainment-education narratives draws greatly on SCT by using role models to perform new behaviors [38, 39, 40]. SCT also supports self-regulatory behavior change procedures such as goal setting, self-monitoring, and feedback [41]. The Health Belief Model construct of cues to action also guided tool development, as it is a strategy to activate readiness for change and stimulate behavior change [42]. Thus, an innovative web-based interactive tool which includes health messages delivered in a narrative comic format, tailored feedback, and cues to encourage behavior change, guided by the NTT, SCT, and HBM, may be an effective vehicle to promote healthy eating behaviors (see Figure 2).

**Figure 2: Conceptual Framework of Intervention INC**

**Child Components**

**Comic**

Children randomized to the experimental group were given access to a 6-chapter interactive nutrition comic titled “Game On” containing health messages focused on F/V and water consumption (see Figure 3). One chapter was made available at the beginning of each week. Comic content was tailored (to include more information related to either F/V or water) based upon responses to initial screening questions related to either F/V or water intake, child self-efficacy to increase F/V and water intake, and parent self-efficacy to support child in increasing F/V and water intake. The comic was housed on a home page, which comprised of other sections including character profiles (highlighting demographic information for each character and personal fun facts, such as favorite food and beverage), and trivia questions (combination of
story-related and health-promoting questions, released as one per chapter). If all six trivia questions were answered correctly, the child received a prize of a downloadable screensaver image. Interactive features were also embedded into the comic, such as tap/click icons that either opened pop-up windows (highlighting health facts, food-related fun facts, or character information) or prompted audio/visual effects. The comic was primarily in black and white (the style typically observed in manga comics), however, images related to F/V and water, were featured in color.

**Figure 3:** Website homepage (top) and snapshot of the comic (bottom), accessible only to children in the experimental group

![Website homepage](image1.png)

**Goal Setting and Assessment**

At the end of each comic chapter, one of the comic characters asked the child to select a goal to work on for the week (see Figure 4). The child was able to choose from eight goals. Goals included ones that were child-focused (e.g. “I will eat fruits I like (such as grapes or bananas) as a snack” or “I will drink a glass of water when I wake up each morning”) and ones that incorporated the parent (e.g. “I will ask my parent to prepare vegetables I like (such as zucchini and tomatoes) for dinner” or “I will ask my parent to drink water with me during meals”). Once selected, a tip was provided to assist the child in achieving the goal throughout the week. At the end of the week, the child was asked to assess how s/he did on the goal they chose (i.e. “How often did you do this in the last week?” - Never, Sometimes, Most of the Time, All the Time) and tailored feedback/encouragement was provided depending on the response chosen (i.e. “Congrats! Keep up the good work!” or “Things take time - don’t give up!”). If the child selected “Most of the Time” or “All of the Time” in response to the goal assessment question, the child
was rewarded with bonus comic content (e.g. backstory for a specific character). The child was then prompted to select another goal for the following week. A total of five goals could be selected (as a goal was not selected at the end of the last chapter) and worked on during the intervention period.

**Figure 4:** Link to goal-setting component at the end of each comic chapter, accessible only to children in the experimental group

---

**Text/email messages**

Four messages were delivered to experimental group children each week (total of 23 messages throughout intervention). Messages included announcing the release of a new chapter by a comic character (see Figure 5), a reminder to read the comic, and a reminder to select a goal for each week. Messages were delivered via text and/or email based upon participant preference identified during the baseline visit.

**Figure 5:** Example of text messages sent only to children in the experimental group
**Parent/Guardian Components**

**Newsletters**
Parents/guardians in the experimental group received six online newsletters with similar health messages as their child (see Figure 6). Newsletter content comprised healthy recipes, healthy feedings tips for the family, links to coupons to support healthy eating, and links to fun community events (e.g., Fall and Winter Festivals). In addition, they were given access to the “Game On” comic and character profiles.

**Figure 6:** Example of an online parent newsletter sent to parents in the experimental group (left) and the comparison group (right)

---

**Text/email messages**
Two messages were delivered to experimental parents/guardians (total of 11 messages throughout intervention) each week. Parents/guardians received messages announcing the release of a new newsletter. In addition, they received reminders to encourage their child to read the comic. Messages were delivered via text and/or email based upon participant preference identified during baseline.

**Comparison Group Description**
The comparison group had access to web-based tool similarly hosted on a password-protected website and optimized for use on tablet devices and touch-screen computer/laptop devices (see Figure 3). All study participants received training on how to use the website at baseline.
**Child Components**

**Newsletters**
Children randomized to the comparison group received six online newsletters with F/V or water information (see Figure 7). Similar to the comic, newsletter content was tailored based upon responses to initial screening questions related to child F/V and water intake, child self-efficacy to increase F/V and water intake, and parent self-efficacy to support child in increasing F/V and water intake. Newsletters were housed on a home page, and one was made available at the beginning of each week. Newsletter content comprised healthy eating tips, healthy recipes, dietary-related knowledge/facts, health-promoting online games, and selected weekly goals. Of note, comparison group participants will be provided access to the "Game On” comic upon completion of all data collection.

**Figure 7:** Example of online child newsletter with link to goal-setting component, accessible only to children in the comparison group

---

**Goal Setting and Assessment**
Similar to children in the experimental group, comparison group children also had a goal setting and goal assessment component, wherein each week, the child could select one out of eight goals to work on (five goals in total during the intervention period), receive a tip to provide assistance in achieving that goal throughout the week, and self-assess at the end of the week on how s/he did on the goal and receive feedback/encouragement. Unlike the experimental group, the format in which the goal setting was conducted in the comparison group was non-narrative (see Figure 7).
Text/email messages

Three messages were delivered to comparison group children each week (total of 17 messages throughout intervention). Messages included announcing the release of a new newsletter, a reminder to read the newsletter, and a reminder to select a goal for each week (see Figure 8). Messages were delivered via text and/or email based upon participant preference identified during the baseline visit.

**Figure 8:** Example of text messages sent only to children in the comparison group

---

Parent/Guardian Components

Newsletters

Parents/guardians of the comparison group received the same six online newsletters as that of the parents/guardians in the experimental group. However, parents/guardians in the comparison group were not given access to the “Game On” comic and character profiles (see Figure 6).

Text/email messages

One message was delivered to comparison group parents/guardians (6 messages throughout intervention) each week announcing the release of a new newsletter. Messages were delivered via text and/or email based upon participant preference identified during baseline.
Measures
The measures collected are described in Table 1.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Data Source</th>
<th>Time points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>T1</td>
</tr>
<tr>
<td>Feasibility/acceptability measures (primary measures)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usage of web-based tool</td>
<td>Tracking system [internally created]</td>
<td></td>
</tr>
<tr>
<td>Usability of web-based tool</td>
<td>Interview, Questionnaire Items [43, 44, 45]</td>
<td>C</td>
</tr>
<tr>
<td>Feasibility of study implementation</td>
<td>Process data (e.g. recruitment, attrition)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome measures (secondary measures)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dietary Knowledge &amp; Attitudes</td>
<td>Validated Questionnaire Items [48, 49]</td>
<td>C</td>
</tr>
<tr>
<td>Dietary Intake</td>
<td>Validated Questionnaire Items [50, 51]</td>
<td>C</td>
</tr>
<tr>
<td>Anthropometric Measures</td>
<td>Digital Stadiometer, Body Composition Monitor</td>
<td>C</td>
</tr>
<tr>
<td>Feeding Practices</td>
<td>Validated Questionnaire Items [54]</td>
<td>P</td>
</tr>
<tr>
<td>Home Food Environment</td>
<td>Validated Questionnaire Items [55]</td>
<td>P</td>
</tr>
</tbody>
</table>

Time points indicated by T1=Baseline, T2=Midpoint (3 weeks post-baseline), T3=Endpoint (6 weeks post-baseline), T4=Follow-up (3 months post-intervention), O=Ongoing throughout intervention period. Data collected either from C=child, P=parent/guardian, S=study staff (internal). All non-validated questionnaire items were directly informed by validated questionnaires.

Feasibility/acceptability measures (primary measures)

Usage of web-based tool
A custom-built platform was created to automatically log child and parent user details (created at baseline) and usage details (over 6 weeks of the intervention). User details included username, user type (parent or child), study group (experimental or comparison), type of tailored content (F/V or water), user language (English or Spanish), user email address, user mobile phone number, and start date/time (when username was created at baseline). Usage details included week number of intervention, link clicked, click time, platform used (e.g., Mac OS, iPhone OS, Windows 7), browser used and version (e.g., Chrome 38.0, Safari 11.0). For child participants, additional usage data related to goal-setting included weekly goal selected, date/time goal was selected, evaluation at the end of the week (i.e. “How often did you do this in the last week?” - Never, Sometimes, Most of the Time, All the Time), and date/time goal was evaluated.
Usability of web-based tool

Questionnaires were administered to the child and parent at several time points throughout the study. Usability was assessed with an adapted version of the System Usability Scale (SUS) [43], Usefulness, Satisfaction, and Ease of Use questionnaire (USE) [44], and a 26-item acceptability/usability measure by Ben-Zeev et al [45], in order to assess five usability domains: usability, usefulness, ease of use, ease of learning, and satisfaction. The child’s questionnaire comprised 30 usability questions - 10 questions from SUS [43], 15 from USE [44] and 5 from the acceptability/usability measure [45]. Based on pilot testing, modifications were made to tailor the questionnaire according to literacy levels of our intended population. For example, the item “I found the system very cumbersome to use” was replaced with “I found it awkward to use” and “I would imagine most people would learn to use this system very quickly” was changed to “I think most people my age would learn to use it very quickly.” The parent questionnaire comprised nine usability questions - two questions from SUS [43], three questions from USE [44] and four questions from the acceptability/usability measure [45]. Based on pilot testing, one item was modified. Similar to the child questionnaire, the item “I found the system very cumbersome to use” was replaced with “I found it awkward to use.” As the content of the parent component was presented in a more didactic format compared to the child component, fewer usability questions were relevant to include in the parent questionnaire. In addition, usability data in the form of qualitative interviews with child participants (at T2, T3, and T4) and parent participants (at T3 and T4) were collected to supplement quantitative usage and usability questionnaire data.

Feasibility of study implementation

Process data collected throughout the study assessed the feasibility of implementing the study [46, 47]. These data included quantitative/qualitative measures of recruitment (i.e. enrollment rate, restrictiveness of eligibility criteria, attrition rate), assessment of resource capacity (i.e. recruitment man-hours, participant communication approaches), data collection (i.e. length of time to complete online questionnaires) and data reliability (i.e. study staff adherence to protocol). Satisfaction with study participation was assessed through questionnaire items and qualitative interviews with parent participants at T4 (i.e. frequency and format of communication and study visit scheduling with study staff), as well as qualitative observations of child participants at T1 and T4 while completing questionnaires (i.e. verbal and nonverbal expressions indicating frustration, boredom, and confusion).

Outcome measures (secondary measures)

Child Dietary Knowledge and Attitudes

Child participants completed a questionnaire related to knowledge, outcome expectations, self-efficacy, behavioral intention, attitudes and preferences regarding behaviors associated with F/V, water, junk food and sugary drinks. Six questions addressed knowledge (i.e. I should eat 1 cup of fruit each day for good health), 20 questions addressed outcome expectancies (i.e. Eating vegetables every day will keep me from getting sick), nine questions addressed self-efficacy (i.e. If I decide to not eat junk food every day, I can do it), ten questions addressed intention (i.e. If my parent offers me water, I will drink it), 15 questions addressed attitudes (i.e. I think sugary drinks are cool), and 24 questions addressed preferences (i.e. Which of the following fruits do you like or dislike?). A total of 84 questions were informed by and modified from the validated
ProChildren Questionnaire [48] and the validated Reynolds questionnaire [49]. Modifications to wording were made to ensure questions were appropriate for this study and to adjust for literacy levels of our intended population.

Child Dietary Intake
Child participants completed a questionnaire which assessed frequency of consumption of F/V, water, junk food and sugary drinks during the past seven days. This 17-item questionnaire comprised six questions from the validated 2017 YRBS Questionnaire [50], eight were informed by items in both the YRBS Questionnaire and the validated Beverage and Snack Questionnaire (BSQ) [51], and three were internally created (related to assessing intake of different types of water).

Child Anthropometric Measures
Height and weight of child participants were measured using standardized methods [52]. Height was measured to the nearest 1/8 inch using a digital stadiometer (SECA 264), with the participant fully erect, without shoes, feet together, head in the Frankfort Plane and at the end of a deep inhalation. Weight and body composition were measured using a Body Composition Monitor (Tanita MC-780U) wearing lightweight clothes and without socks and shoes. Weight was measured to the nearest 0.2 pounds and rounded to highest tenth. Height and weight were measured in duplicate and recorded. A third measurement was taken if there was any uncertainty on the accuracy of height or weight measurements (e.g. If height measurements differed more than 0.5 inch). An average of the measurements were used for BMI calculations. The Centers for Disease Control and Prevention BMI Percentile Calculator was used to determine BMI percentage [53]. If needed, the average height was rounded down to the nearest eighth of an inch and the average weight was rounded down to the nearest quarter pound, to accommodate the Calculator’s units of measurement.

Parent Feeding Practices
Parent participants completed a questionnaire that asked about multiple parental feeding practices, specifically including six questions related to environment (i.e. I offer a second helping of vegetables to my child during meals at home), four related to involvement in purchasing/preparing food (i.e. I allow my child to help prepare fruit and vegetable dishes for family meals), seven related to encouragement (i.e. I encourage my child to drink water drinks (unsweetened) before sugary beverages), eight related to modeling (i.e. I model drinking water for my child even if it is not my favorite), and two related to teaching about healthy food practices (i.e. I discuss with my child why it’s important to eat fruits and vegetables.). The 27-item questionnaire was informed by the validated Comprehensive Feeding Practices Questionnaire [54].

Home Food Environment
Parent participants completed a questionnaire related to the availability of fruits, vegetables and water in their home and how often they store fruits, vegetables and water in a place easily seen by their child. The questionnaire comprised six questions and was informed by the validated Home Environment survey [55].
**Potential Confounders**
Demographic factors, including age, gender, race/ethnicity, and if US was country of birth, for both child and parent were collected. Additional child measures included grade, technology use, physical activity, sedentary behavior, and perceived health. Parental measures also included marital status, education level, household income, household profile, SNAP participation, child participation in school breakfast and lunch program, and perceived health. These measures were collected at T1.

**Data Management**
A manual of procedures, including protocols related to data collection and storage, was developed at the outset of the study and refined continuously with input from all study staff. Study staff involved in collecting data were trained in implementing all procedures. Data collection and management procedures were reviewed at study staff meetings throughout the intervention period to ensure that they were followed with fidelity, and to also address any issues or barriers to implementation.

Data collected in this study includes both quantitative data (auto-generated website usage data, online questionnaires, anthropometric measures) and qualitative data (interviews). To ensure generated data are reliable, valid, and usable, the study staff used validated questionnaire items (or questionnaire items informed by validated questionnaires) and best practices for questionnaire, interview, and anthropometric data collection. Quantitative data were downloaded in spreadsheet format at least twice weekly, and qualitative data were downloaded as audio files weekly. All data were uploaded to password-protected institutional servers. Data were checked regularly to ensure accuracy of data capture. A data dictionary that includes original items, answer choices, scoring/coding of answers, scoring of scales, and examples was created to ensure that all project data are accurately and readily usable, and to aid in data analysis.

**Data Analysis**

**Quantitative Data**
Usage and usability of the web-based tool, along with feasibility of study implementation, will be assessed using descriptive analyses. While such data are valuable in better understanding how participants may interact with the web-based tool itself, these data will also be used to stratify analysis to determine if there are any significant associations between individual demographic characteristics and health-related outcomes. These data will have high relevance for interpretation of outcome data and further inform refinement and enhancement of the intervention.

The changes in study outcomes within and between groups will be examined using mixed models methodology with repeated assessments (T1, T2, T3, and T4), condition (experimental/comparison) and time by condition interaction. Both within and between group effect sizes will be calculated for all study measures to assess the magnitude of intervention effects overall and by potential moderators, and inform subsequent larger randomized controlled trials. To control for multiple comparisons, p-values will be evaluated based on the False Discovery Rate [56]. All analyses will be conducted using an Intent-to-Treat (ITT) approach.
Qualitative Data
Audio files of interviews conducted with children parents/guardians at T2, T3, and T4 will be transcribed. Inductive and deductive processes will be used to analyze qualitative data collected from interviews with child participants (at T2, T3, and T4) and parent participants (at T3 and T4), as well as qualitative observations (detailed notes) during in-person study sessions at T1 and T4. Using a content analysis approach [57], transcribed audio files and field notes will be coded by at least two independent reviewers and reviewed to identify trends and recurring themes, especially related to barriers and facilitators to use and adoption of the Intervention INC web-based tool. Qualitative analysis software will be used to assist with organizing, coding, and analyzing transcripts and notes.

Results
A total of 89 child-parent dyads were enrolled into the study on a rolling basis between August and November 2017. The dyads were randomized to either the experimental (n=44) or comparison (n=45) group. The pilot RCT is still being concluded, with an anticipated completion date of April 2018. Data analysis is currently underway as of March 2018.

Discussion
The Intervention INC web-based interactive tool was developed to help engage low-income, minority children to change individual dietary behaviors and provide parents information and resources to improve feeding practices and promote a supportive home food environment, with the ultimate goal of reducing childhood obesity risk.

To the best of our knowledge, this is one of the first studies to explore the potential impact of an interactive web-based tool specifically designed by and for at-risk, minority preadolescents. There is a distinct lack of effective health promotion tools that have been culturally-tailored to meet the needs and preferences of populations with disproportionate rates of chronic disease [58], even fewer have been developed for children [14]. Our tool aims to address this as it has been specifically designed for Black/AA and Latino children, who are at greatest risk of childhood obesity. Furthermore, our intervention engages parents, who play a significant role in shaping the home food environment and influencing child dietary behaviors [59, 60]. It is well-documented that sustained engagement of both children and parents in long-term interventions is a major challenge, particularly within at-risk populations [61, 62].

Intervention INC is unique given its innovative narrative and interactive web-based approach to enhance adoption of the tool with hard to reach, at-risk populations. Embedded points of interactivity, such as the pop-up features and special effects, may further enhance engagement of the tool, thus potentially increasing the exposure of the intervention through additional opportunities to deliver meaningful health information. Assignment to a tailored track was based on initial screening at baseline to assess child F/V and water intake and child/parent self-efficacy related to F/V and water intake. Results of the screening process identified which at-risk behavior (F/V or water intake) was targeted during the intervention.

Notably, user-centered approaches were used throughout formative and development stages of this intervention, including co-development of the storyline and other content with children and
parents and the use of multiple usability sessions to inform refinement of the tool. While several studies have emphasized how usability testing can improve technology-enhanced tools [63, 64, 65], few have conducted usability testing methods for health promotion tools with youth users [66, 67, 68]. Usability testing is a crucial step in the development of online health tools to ensure that they are accessible, understandable, and useful to end users, and are delivered in an efficient, effective, satisfying, and culturally-competent manner [69].

Our study has numerous strengths, which include objective measures such as tool usage (process) and BMI (outcome). Importantly, the collection and analysis of detailed usage data allows for the potential to identify mechanisms of change - that is, which components of the Intervention INC tool may be contributing to any observed dietary-related changes. Our study has also incorporated multiple strategies to minimize attrition which includes partnering with community organizations, basing the study site within our priority community, recruiting bilingual research team members who come from similar communities as our participants, providing incentives comprising gift cards to local stores (dispersed in increasing amounts) throughout participation period, and sending emails with recipes during the 3-month follow-up period.

This study does have some limitations, which should be noted. Participants have been recruited on a rolling basis over the course of three months, therefore, seasonality may bias various health-related behaviors, and thus our findings. In addition to overweight/obese children, healthy weight children have been recruited, which may dilute any anthropometric changes. The comparison group received similar health information (in non-narrative form), which may result in differences not being observed between groups. In addition, the comparison group (both child and parent) received one less text/email weekly reminder, which may influence tool usage, though this is likely to be minimal. Self-reported data from both the children and parents have been collected, which poses a validity risk, due to intentional/unintentional misreporting. However, our study design allows for children and parents to complete surveys at home as opposed to the study site with staff, which may contribute to decreased social desirability bias.

Conclusion
This study aims to implement an innovative approach to delivering healthy dietary messages and resources to at-risk minority children and their parents. If found to be acceptable, engaging, and feasible, a larger randomized controlled trial with the Intervention INC web-based comic tool will be conducted to assess its efficacy related to improving child dietary behaviors, child health outcomes, parent feeding practices, and the home food environment.
Acknowledgements
This project was supported by grant number R21H5024117 from the Agency for Healthcare Research and Quality (AHRQ). The content is solely the responsibility of the authors and do not necessarily represent the official views of AHRQ. The authors want to acknowledge Kris Hoyt (lead developer of the intervention platform and interface), the research team, as well as our community partners, for their contribution to this study.

Authors’ Contributions
MML conceived the intervention concept and study design. All authors contributed to the writing of the manuscript and provided critical feedback.

Conflicts of Interest
None declared.

Abbreviations
AA: African-American
BMI: Body Mass Index
F/V: fruit and vegetable
INC: Interactive Nutrition Comics for Urban, Minority Preadolescents
RCT: randomized controlled trial
References


