



CHAMP: A cluster randomized-control trial to prevent obesity in child care centers



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ABSTRACT

Foundational elements of lifelong health are formed during the preschool years. Child care attendance has nearly doubled in the past 5 years making child care centers an ideal setting to establish healthy habits that prevent pediatric obesity. Despite the promising evidence of efficacy of child care-based obesity prevention interventions, limited attention has been directed to criteria needed for implementation at scale. There is potential to improve children's dietary and physical activity behaviors in diverse communities through theory-based, culturally appropriate, manualized interventions, delivered by child care staff. CHAMP (Creating Healthy Habits Among Maryland Preschoolers) is a 3-arm cluster randomized controlled childhood obesity prevention trial, aiming to improve motor skills, physical activity and willingness to try new foods among 864 preschoolers (age 3–5 years) enrolled in 54 child care centers in 10 Maryland counties. CHAMP is informed by social-cognitive and bioecological theories and based on an evidence-based program, The Food Friends®. The two intervention arms include: 1) child care-center based lessons (18-week gross motor and 12-week nutrition) administered by trained child care staff, and 2) a web-based intervention for caregivers in addition to center-based lessons. Evaluations are conducted among children, caregivers, and child care staff at fall enrollment, midline, and spring, following intervention completion. Analyses include linear mixed-models, accounting for clustering and repeated measures, incorporating center-arms as moderators. CHAMP will provide evidence-based information to inform wellness guidelines and policies that can be disseminated broadly, to ensure that child care centers provide opportunities for children to develop healthy eating, and physical activity habits.

Trial Registration: [NCT03111264](https://clinicaltrials.gov/ct2/show/NCT03111264); <https://clinicaltrials.gov/ct2/show/NCT03111264>

1. Introduction

Pediatric obesity is a major public health problem that often begins early in life and increases the risk for chronic health conditions and health disparities. Excess weight gain by age five is often maintained into adulthood [1,2], increasing the risk of obesity-related co-morbidities later in life. To prevent obesity-related health disparities, interventions must start early in life, before poor dietary and physical activity patterns have been established and excess weight gain has occurred [3,4].

A growing number of young children in the United States do not meet dietary guidelines [5–8]. One possible explanation is that children are not exposed to healthy choices during early childhood. Children's food preferences, formed during preschool years, tend to persist into adulthood [9]. Children who are willing to try new foods have higher quality diets, compared to children who resist new foods. Food neophobia is a normal developmental phase where children reject unfamiliar foods [10,11]. Repeated food exposures (8–12 interactions) are recommended to progress past food neophobia and promote children's healthier food preferences [12–15]. However, repeated exposures may

Abbreviations: BMI, Body Mass Index; BMIZ, Body Mass Index Z-score; CACFP, Child and Adult Care Food Program; CEBQ, The Child Eating Behavior Questionnaire; CHAMP, Creating Healthy Habits Among Maryland Preschoolers; EPAO, The Environment and Policy Assessment and Observation; GLMM, Generalized linear mixed models; LMM, Linear Mixed Models; MVPA, Moderate-vigorous physical activity; NAP-SACC, Nutrition and Physical Activity Self-Assessment for Child Care; PA, Physical Activity; PALS, Play and Learning Strategies; PCIT, Parent Child Interaction Therapy; SES, Socioeconomic Status; SMS, Short Message Service

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not be feasible for low-income families who are balancing mealtime efficiency (e.g., not waste time, food, or money) and the desire for their child to develop a preference for fruits and vegetables [16]. Although promotion of fruit and vegetable consumption is an effective strategy to prevent obesity and chronic diseases [17,18] there is limited evidence on strategies to improve fruit and vegetable intake among preschoolers [19].

During the early years, physical activity and motor skills are interconnected [20], with both linked to obesity as well as current and future health indicators [21–23]. Motor skill deficits may underlie preschoolers' failure to meet physical activity guidelines, particularly in underserved low-income areas that have few safe places to be active and develop age appropriate gross motor skills [24]. Thus, obesity prevention efforts aimed at altering developmental pathways by targeting food neophobia and gross motor development may improve healthy eating and increase children's likelihood of being physically active throughout life, ultimately reducing obesity risk.

Child care centers are an ideal setting to prevent pediatric obesity [25]. An estimated 5.9 million children (age 3–5) often spend a majority of waking time in child care [26]. Wellness guidelines for child care centers are emerging through federal legislation including The Healthy Hunger Free Kids Act of 2010, and the United States Department of Agriculture (USDA) Child and Adult Care Food Program (CACFP), ensuring that children are exposed to healthy food options. Similarly, Healthy People 2020 calls for state regulations ensuring children in child care centers have opportunities to be physically active, along with the World Health Organization's recently released guidelines for physical activity among children under age 5 years [27]. Young children are also uniquely influenced by adults at home [28]. Extending intervention strategies from child care centers to the home environment can simultaneously intervene across the different levels of the bioecological model that shape child behavior.

Building on existing studies promoting health in child care settings [29–31], CHAMP (Creating Healthy Habits among Maryland Preschoolers) is a multi-component child care-based intervention designed to improve both physical activity and healthy eating behaviors among preschoolers. CHAMP is comprised of interactive lessons delivered by child care staff and evaluates the impact of incorporating web-based strategies designed for caregivers. Ultimately, through improvements in nutrition and physical activity, CHAMP aims to prevent obesity among preschool children (age 3–5 years) in urban and semi-urban settings.

2. Methods/design

2.1. Study design

CHAMP is planned with the collaboration of four partners: the state Department of Health, the state Department of Education (including the Office of Child Care), a statewide network to provide training and support to child care centers, and the state School of Medicine, following a preliminary study conducted among child care centers in three counties [32]. The aim of CHAMP is to evaluate strategies to prevent health disparities by building wellness-related habits of diet and physical activity into daily child care activities and extending the habits introduced in child care centers to caregivers. The impact of CHAMP is evaluated by recruiting 54 child care centers throughout Maryland and randomizing them through a 3-arm cluster randomized controlled trial. Centers randomized to the CHAMP group receive a wellness-related habits intervention delivered by child care staff; the centers in the CHAMP+ group receive the CHAMP intervention, plus a caregiver intervention delivered to primary caregivers through a website. Control centers receive intervention materials the following year, with no intervention during the study evaluation period. The hypothesis is that children in child care centers randomized to the CHAMP+ intervention group demonstrate more improvement across domains including gross motor competency, physical activity, food neophobia and maintenance

of a healthy body weight from baseline to end line, compared to control centers, with the CHAMP group in an intermediate position (CHAMP + > CHAMP > control).

2.2. Intervention

The CHAMP intervention is based on The Food Friends®, an evidence-based preschool program developed at Colorado State University in partnership with Head Start. The Food Friends curricula is delivered by child care staff and is designed to prevent childhood obesity by establishing healthful eating and physical activity habits early in life [33]. The program curriculum is composed of two models: physical activity and eating behaviors. The physical activity component, Get Movin' with Mighty Moves®, is an 18-week program that promotes gross motor skills implemented 4 days/week for 15–20 min per day (72 lessons) during the fall and winter months [34,35]. The healthful eating component, Fun with New Foods®, is a 12-week program that provides 15–20 min twice-weekly nutrition activities (story books, arts and crafts, and sensory activities) and twice-weekly opportunities to try new foods that takes place in the spring. The curricula are based on social cognitive theory and the bioecological model [36–38], utilize social marketing strategies [33,39], incorporate a superhero theme (Super Taster and Mighty Mover) to engage children, and include detailed implementation manuals on lesson plans and classroom activities [40,41]. The CHAMP intervention modified Food Friends to make it culturally sensitive and appealing to a mid-Atlantic urban and semi-urban population by altering the vocabulary (i.e. replacing the term “junkie” with “enthusiast” and “sassy” with “friendly”), foods promoted (i.e., replacing, water chestnut for daikon radish, lychee for tangelo, hominy for tempeh) and replacing a puzzle activity with a Montessori based sensory activity (i.e. smelling jars). Alterations to the intervention were piloted in a local child care center the summer before the first cohort. CHAMP staff observed pilot lessons and gathered feedback from child care staff on clarity and acceptability of the lessons and associated materials. Alterations to the intervention were guided by feedback from focus groups and interviews with child care directors.

The CHAMP+ intervention arm extends the child care intervention to caregivers through a caregiver education website, hosted by the university. Each week caregivers in the CHAMP+ arm of the intervention are provided content on physical activity, nutrition, and wellness topics relevant to caregivers of preschoolers and coordinated with the activities conducted in the classrooms. For example, nutrition topics include appropriate serving sizes, strategies to support preschoolers trying new foods, and how to handle picky eating. Physical activity topics include ideas for games and activities for the family. General wellness topics include information on behavior management parenting strategies, toddler sleep, and stress management. Content is created by the interdisciplinary CHAMP research team, which includes registered dietitians, pediatric psychologists, public health professionals, exercise scientists and early childhood education specialists. Evidence-based content is used to create infographics and short videos (i.e. playing and learning strategies [PALS] [42], Parent Child Interaction Therapy [PCIT] [43]). Caregiver intervention content and website usability were piloted in focus groups with caregivers from a local child care center the summer prior to the start of the first cohort. Photos of children participating in the CHAMP+ arm of the intervention are included weekly on the website to increase caregiver engagement. Additionally, quizzes and monthly challenges are available to increase caregiver interaction with the online content. Caregivers in the CHAMP+ arm are notified weekly (by email or text message) when new content is available on the website. Simple Texting is the short message service (SMS) platform used to communicate with caregivers. The platform provides analytics to track the number of users who click on the website link provided in the text message each week.

The CHAMP research team provides a tablet to each of the 54 child care centers. The child care staff use the tablet to take photos of

children during the day. Photos are automatically uploaded to a center specific Google cloud. In the CHAMP+ arm, pictures are screened by the CHAMP research team and then uploaded to the CHAMP+ website along with new weekly content. Photos on the website are accessible only to caregivers in the CHAMP+ arm with a password unique to their child care center. For control and CHAMP arms, photos are compiled and returned in electronic form to the centers.

2.3. Timing, recruitment and randomization of child care centers and training

2.3.1. Timing

The CHAMP intervention and evaluation are designed to be implemented in one academic year (from August to June). Child care centers and staff are recruited in the summer before the academic year (June/July). Caregivers and children are recruited in August, followed by the baseline evaluation. Child care staff training to administer the physical activity curriculum Get Movin' with Mighty Moves is conducted in August, and the 18-week Mighty Moves intervention begins following the baseline evaluation and extends through the fall and into the early winter. Staff training for Fun with New Foods (12-week intervention) is conducted at the conclusion of Mighty Moves, and prior to the start of the Fun with New Foods intervention. The Fun with New Foods portion of the intervention extends through the spring. The midline evaluation occurs following the Mighty Moves intervention and the end line evaluation occurs in the spring following the Fun with New Foods intervention (Fig. 1).

The CHAMP intervention includes 54 child care centers and is implemented over two to three years across two to three different cohorts. Fig. 1 describes the planned recruitment, enrollment and participant flow of the study.

2.3.2. Recruitment of centers

A list of licensed centers is provided by the state Office of Child Care. Eligibility for centers includes: licensed, children age 3–5 years enrolled, and serving low-income communities. Low-income is defined by CACFP participation, acceptance of child care vouchers or a cost of less than \$300/week for child care. Head Start centers are excluded due to existing infrastructure to support wellness policies [44]. The remaining list of centers is filtered to include those that are within 50 miles of the university and have > 20 total children enrolled. The remaining eligible centers are contacted by phone by a CHAMP team member who describes the program, assesses initial eligibility and, in response to interest, sets up an appointment to visit the center and meet the director. Centers with at least 20 children enrolled between the ages of 3–5 are prioritized to allow for adequate sample size. Directors are shown an informational video about CHAMP. They are given information about the intervention, randomization, and evaluation processes. All eligible centers that express interest and complete the initial recruitment visit within the recruitment timeframe are invited to participate.

Randomization. Following recruitment of all centers within a cohort, centers are randomized using a stratified cluster randomization procedure. CHAMP staff match centers into stratified groups of three based on similarity of center size, location (urban/semi-urban), and racial/ethnic mix. Centers within the stratified group of three are then randomized (using a computer-generated random number with equal randomization allocation ratio) to one of the three intervention conditions (CHAMP, CHAMP+, and control), to maintain demographic balance across the three conditions. Randomization is conducted by a member of the research team not involved in data collection or intervention implementation.

2.3.3. Child care training

Trainings are conducted by the CHAMP research team in each child care facility. Child care staff receive two training sessions during the

year which last approximately 1–2 h each. During the trainings, child care staff are provided with general psychoeducation regarding childhood obesity, food neophobia and gross motor development. Child care staff are introduced to the intervention materials (including the provided materials and manualized lessons) and hands-on participatory activities are demonstrated and practiced. Child care staff are encouraged to discuss potential barriers and strategies to fit lessons into the existing curriculum at each center. Child care staff and directors receive a printed manual and have access to a staff website where they can access weekly lessons plans, handouts, additional resources and program content including music to accompany lessons. Each week, lesson plans are emailed or texted to child care staff. Child care staff in the CHAMP+ arm receive additional information about the caregiver website.

2.4. Liaisons, eligibility and recruitment of children and caregivers

A multi-step approach is used to recruit child care center directors, child care staff, and children and caregivers within centers. The center 'liaison' is a child care staff member whose job is to communicate with CHAMP research staff throughout the project. The eligibility and recruitment process for each role are described below.

2.4.1. Child care director

As described above, child care directors are initially contacted. They are given information about the intervention, randomization, and evaluation processes, and shown an informational video about CHAMP. After an initial in-person meeting with CHAMP research staff to verify center eligibility and answer any questions, child care directors can either agree or decline for their center to participate in the project.

2.4.2. Liaison

After participating centers are recruited, center directors identify a 'liaison' who serves as the contact person responsible for communication between CHAMP and the child care center. Eligible liaisons must be employed at the child care center, and be willing to communicate with the CHAMP staff on a regular basis and complete several center level questionnaires (listed below). Liaisons can include directors or child care staff.

2.4.3. Child care staff

Child care directors in participating centers identify potentially eligible staff members who are then contacted by the CHAMP research team. Classroom staff are eligible if they have direct contact with students (age 3–5) in their classroom, are willing to fill out questionnaire measures and if they agree to receive training and deliver the intervention.

2.4.4. Eligibility of children and caregivers

The intervention is delivered to all children in a classroom at participating centers. Children attending participating child care centers (at least 3 days per week) are eligible to be enrolled in the evaluation portion of the study if they are: between the ages of 3–5, are English speaking, their caregiver intends that the child will be enrolled in the center through the spring, and their caregiver signs the informed consent. Children with developmental delays that prevent assessment of key study outcomes (i.e. severe autism, Down syndrome) are excluded from participating in the evaluation. Children with physical disabilities that prevent them from participating in physical activities may be enrolled in the evaluation, though not assessed for gross motor skills. Siblings in the same center are eligible to participate in the evaluation. Siblings are flagged for sensitivity analyses during data analysis. Caregiver eligibility criteria include: being the child's primary caregiver (living with the child for > 3 days each week) and basic English literacy (per caregiver self-report).

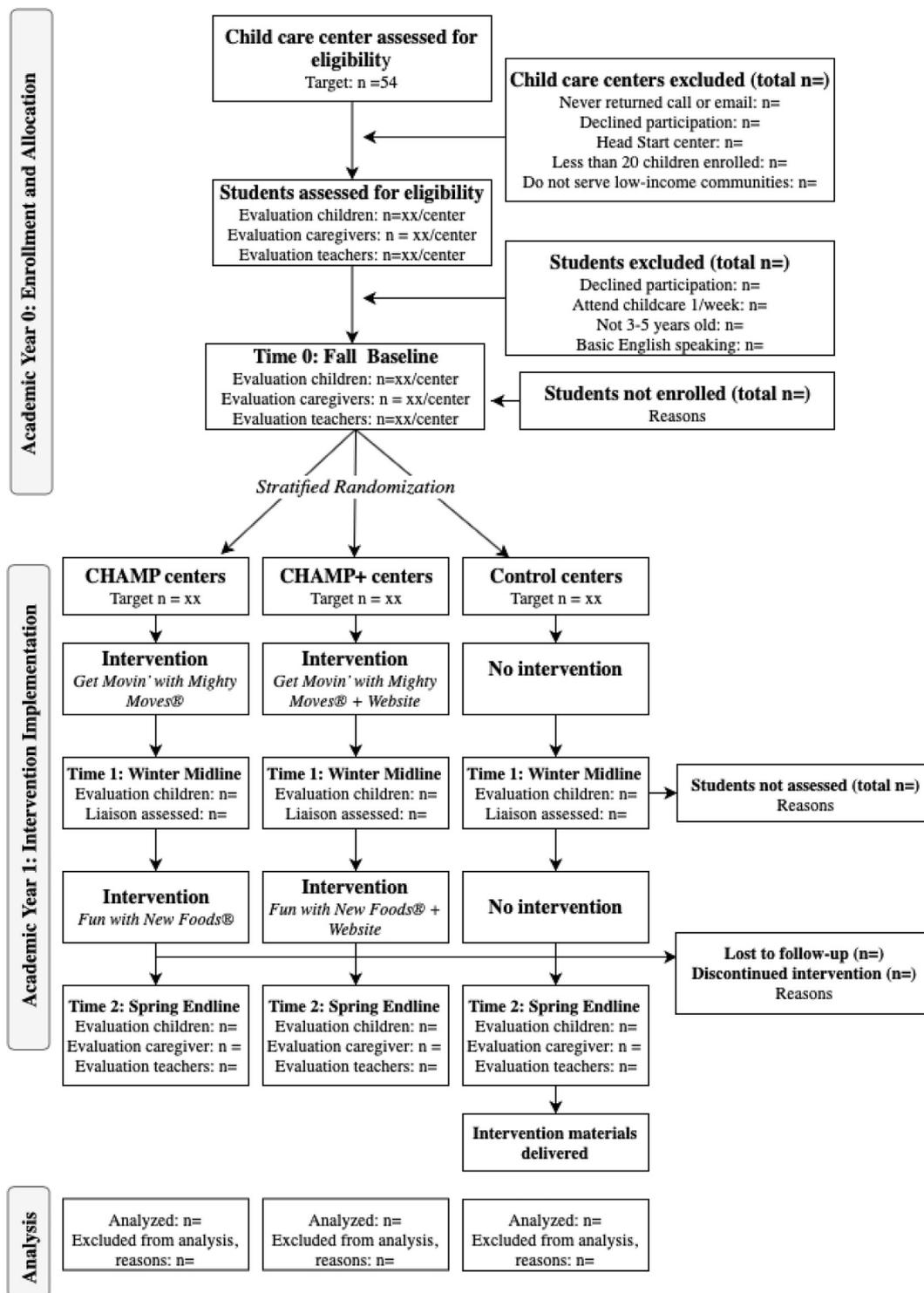


Fig. 1. Study design and participation flow of CHAMP 3-arm intervention trial.

2.4.5. Recruitment of children and caregivers

Liaisons assist with recruitment of children and caregivers in each center. CHAMP staff and center liaisons develop a child/caregiver recruitment plan for each center. Plans include flyers sent to caregivers, posters displayed in the center, and a short CHAMP video that outlines the program, presentations at back-to-school nights, and CHAMP staff attendance at drop-off/ pick-up times to talk directly with caregivers. Liaisons inform families about the program, collect consent forms and relay information between child care staff and the CHAMP research team. Liaisons are incentivized to recruit eligible participants (up to 20

children per center) with a gift card (maximum \$50).

2.5. Ethical approval

The protocol is approved by the ethics committee of the university conducting the investigation. Caregivers provide written consent for their child to participate in the study, including consent to have child care center staff take photos of their child that are returned to the centers. Caregivers in the CHAMP+ centers provide additional consent to have their child's picture uploaded to a secure website hosted by the

university. Caregivers and child care staff provide consent for themselves through online explanations and consent forms. Child care staff are invited to participate in a direct assessment of physical activity by wearing an Actical accelerometer; written consent is provided separately for this portion of the study. Verbal child assent is obtained by research staff during data collection.

2.6. Sample size estimation

The proposed study design is a cluster-randomized trial, with individual preschoolers nested in child care centers (clusters). We anticipate enrolling 864 children across 54 centers (an average of 16 children per center). Power and sample size estimates are calculated with the GLIMMPSE 2.0 online tool designed for multilevel data [45]. Based on previous literature, we assume an average ICC of 0.03. This is an average intraclass correlation coefficient (ICC) estimate across outcomes based on previous studies reporting ICCs of 0.06 for child body mass index (BMI) [46], 0.08 for child moderate-vigorous physical activity (MVPA) [47], 0.001 for willingness to try new foods [48], and 0.001 for fruit and vegetable consumption [49]. We assume a correlation of ($r = 0.5$) between repeated measures of the same individual.

After accounting for a loss-to-follow-up rate of 20% (higher than anticipated) our proposed sample size will provide adequate power (> 0.8) to detect an effect as small as 0.27 standard deviations (SD) across outcomes (Cohen's $d = 0.27$). An effect of this size is roughly equivalent to about a 10-minute difference in MVPA, a 7% greater probability that a child will try a novel food (based on pilot data), a 6-point increase in gross motor skill percentile score [50], or a 0.3 difference in BMI z-score [51]. An effect of this magnitude is plausible given results of our previous interventions where we detected an intervention effect size of 0.27 on toddler's total fruit consumption, as part of a randomized trial of obesity prevention among toddlers [52].

3. Measures

Assessments for CHAMP range across multiple levels of the bioecological model from the individual child to the interpersonal- and organizational-levels (caregivers and child care staff) and community-level (child care environment) with combined key constructs from the social cognitive theory (Fig. 2). The individual level shows interactions between child characteristics in relation to eating and physical activity behaviors that ultimately influence healthy growth and development. The interpersonal level is characterized by the home food and physical activity environment that can concomitantly be shaped by and

influence children's behavior. At the organizational and community levels, CHAMP strengthens and expands collaborations with key players and policies governing state health and education systems that influence preschool eating and physical activity behaviors.

3.1. Observational child measures

Child-related measures are described below and summarized in Table 1. The following measures are collected by trained CHAMP data collectors at the child care centers. CHAMP data collectors are unaware of the center's randomization group. Data collectors receive at least two hours of initial training and one hour of booster training on each of the assessment measures below.

3.1.1. Anthropometry (Primary outcome)

Height, weight, and waist circumference are measured at baseline, midline, and end line, after removing children's jackets, sweaters, and shoes. Height is measured with a portable stadiometer (Shorr Productions, Olney, Maryland) to the nearest 1 cm. Waist circumference is measured at the navel to the nearest 0.1 cm. Height and waist circumference measures are performed three times. Measures are repeated until difference between them is < 2.0 cm. Weight is measured with TANITA BWB-800 (TANITA, Tokyo, Japan) digital scales to the nearest 0.1 kg. Weight measurement is performed twice and a third time if the two initial measures are not identical. BMI is calculated as weight in kg divided by height in meters squared; BMI-for-age z-scores (BMIZ) are calculated based on the age- and sex-specific 2000 CDC Growth Charts [54].

3.1.2. Gross motor skill

The Test of Gross Motor Development-2 (TGMD-2) [55] is a norm-referenced instrument designed to assess gross motor development among children aged between three and 10 years and encompasses two sub-tests that evaluate locomotor and object control mastery. Skills such as throwing and catching a ball, running, hopping, and jumping are observed and rated as "1" (accurate completion) or "0" (non-completion). The TGMD-2 has been widely used in evaluating fundamental movement skills among typically developing children and shown to be a reliable and valid measure of gross motor development [56,57]. Children are tested individually by two trained CHAMP data collectors. One data collector is responsible for demonstrating the 12 skills to the child while the second data collector records the scores on a tablet using the open source data collection software Epicollect (www.five.epicollect.net). Data collectors complete over 5 h of training using a combination of videos and in-vivo assessments of preschoolers engaging in the 12 skills. Training includes group discussion, scoring consensus, and role-playing scenarios. Data collectors must achieve reliability above Kappa = 0.75 to score the TGMD-2 [58]. Follow-up training is conducted halfway through baseline data collection to prevent drift and preserve inter-rater reliability.

3.1.3. Objective physical activity

Actical accelerometers (Philips Respironics, Minimeter, Bend, OR) are secured on hospital bands and attached to the lateral malleolus of the non-dominant ankle of the children and worn continually for at least 7 days. The Actical is a small, light-weight, and waterproof device that can be worn throughout all activities—sleeping, swimming, and running [59]. Actical protocols and data cleaning are based on previous studies which have used this device to measure physical activity and sleep among young children from low income families [59,60]. Accelerometers are configured using Actical software (version 3.11) and data are collected in 15-s intervals. At the child care centers, trained research assistants remove children's accelerometers after seven consecutive days. Days with < 20 activity counts per 15 s and 80 activity counts per minute are considered incomplete and are not included in analyses. Additionally, only data collected over a 24-hour period are

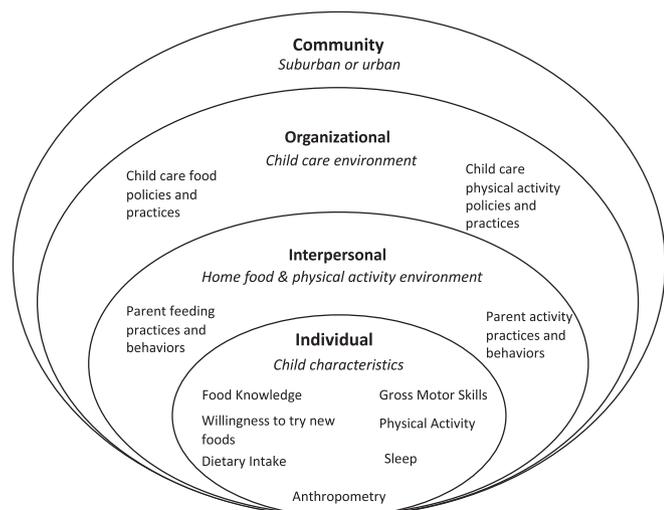


Fig. 2. Conceptual model for CHAMP intervention based on Bellows et al. [53].

Table 1
Child-related anthropometry and behavioral measures and timing of data collection.

Child measures	Method	Baseline	Midline	End line
Anthropometry				
Weight, height, waist circumference	Direct	X	X	X
Gross Motor Skills				
Test of gross motor development 2- Object control	Direct	X	X	X
Test of gross motor development 2- Locomotor	Direct	X		X
Physical activity/sedentary behavior/sleep				
Actical accelerometer	Direct	X		X
Eating/nutrition/ dietary habits				
Willingness to try new foods	Direct	X		X
Fruit & Vegetable Knowledge	Direct	X		X
Food Neophobia Scale – Child version	Caregiver-proxy report	X		X
Child dietary habits (Food Frequency Questionnaire)	Caregiver-proxy report	X		X
Child Eating Behavior Questionnaire (CEBQ)	Caregiver-proxy report	X		X
Child Behavior				
Child screen time assessment	Caregiver-proxy report	X		X
Child Strengths & Difficulties Questionnaire ^a	Caregiver-proxy report	X		
Child Sleep Habits Questionnaire ^a	Caregiver-proxy report	X		
Behavior Rating Inventory of Executive Function (BRIEF) – Inhibitory & Emotional Control Subscales*	Caregiver-proxy report	X		

^a Measures with asterisks are considered auxiliary outcomes

included in analyses, meaning the first and last partial days are removed. If children wear the Actical longer than a week, the excess days are truncated [59]. Age specific thresholds are applied to categorize MVPA, light and sedentary activity [59]. Sleep is parsed from accelerometer data using the Sadeh sleep algorithm [61,62].

3.1.4. Willingness to try new foods

To assess children's willingness to try novel foods, children are presented with a flight of 9 foods; 6 novel and 3 familiar, following published methods [14,53]. Such protocols have been shown to be sensitive to changes in children's willingness to try new food and associated with parental reports of food neophobia [53]. Novel foods are defined using pilot data indicating that the food is unknown to at least 75% of preschool children. The foods range from sweet to savory and include edamame (6 g), papaya (6 g), chick peas (6 g), water chestnut (6 g), olive (6 g), kidney bean (6 g), whole wheat cracker (4 g), grapes (9 g), and cheese (13 g). Children are presented one food at a time and asked whether they know the food, what the name of food is, if they have eaten the food, and to rate the food as “Yummy”, “Yucky” or “Just Ok.” Children respond verbally or by pointing to visuals displaying faces that correspond to the descriptions. After answering the prompts, children are given 10 min to try the foods if they choose. A CHAMP data collector records the order and whether each food is tried or refused. Data collectors also note if a child discusses, smells, touches, or spits out each food. After 10 min, children are asked to rate each food a second time. Each food is weighed on a portable digital scale (Taylor 1020NFS) and subtracted from the initial food weight to determine consumption. All food assessments are conducted in the mornings prior to children's lunchtime. Time of assessment is recorded and can be controlled for in analysis if needed.

Table 1. List of Child Measures.

3.1.5. Fruit & Vegetable Knowledge

The Fruit & Vegetable Knowledge assessment captures children's knowledge of fruits and vegetables [63]. Following two sample items to ensure children's understanding of the task, each child is shown photographs of 9 fruits, 10 vegetables, and 1 common food (French fries). After each picture, a CHAMP data collector asks 3 questions: “What is this food?” “Have you eaten this food?” “Do you think it is “Yummy”, “Yucky”, or “Just OK”? CHAMP data collectors are trained to remain neutral. This measure has good internal consistency ($\alpha = 0.87$), test-retest reliability ($r = 0.73$) and has been shown to be predictive of food consumption [63].

3.2. Child-related caregiver report measures

The following measures are completed by the child's primary caregiver using the web-based questionnaire system Qualtrics. Caregivers are reimbursed with a gift card (between \$20–40) for the completion of the questionnaires. All caregivers are asked to complete the primary measures. Secondary measures are offered to caregivers for an additional gift card incentive.

3.2.1. Child food neophobia

Caregivers complete the Food Neophobia Scale (child version) that assesses a child's willingness to try new foods. The 10-item questionnaire uses a 7-point Likert scale ranging from “Strongly Agree” to “Strongly Disagree.” This measure has been shown to be reliable ($\alpha = 0.88$) [64] and has been validated against behavioral observations of willingness to try new foods, and caregiver predictions of child's willingness to try new foods [53].

3.2.2. Child dietary habits (Food Frequency Questionnaire)

A 17-item short Food Frequency Questionnaire (sFFQ) [65] is used to assess children's dietary habits. The caregiver report questionnaire is designed to assess preschoolers' usual eating habits for: daily servings of fruit, daily servings of vegetables, daily cups of beverages (e.g., milk, soft drinks, fruit juice, and water), and frequency of eating red meats, processed meats, take-out foods, snack foods, and desserts. The questionnaire also assesses behavioral habits including the regularity of consuming breakfast and eating in front of the television. The measure has been shown to be reliable [66] and moderately valid to quickly assess dietary habits of 2–5 year-old children [65] and has been used in similar obesity prevention cluster randomized trials [67].

3.2.3. Child eating behavior

The Child Eating Behavior Questionnaire (CEBQ) [68] is a caregiver-report measure designed to assess dimensions of a child's eating style. It is comprised of 8 scales: Food Responsiveness ($\alpha = 0.80$), Emotional Over-Eating ($\alpha = 0.79$), Enjoyment of Food ($\alpha = 0.91$), Desire to Drink ($\alpha = 0.89$), Satiety Responsiveness ($\alpha = 0.74$), Slowness in Eating ($\alpha = 0.74$), Emotional Under-Eating ($\alpha = 0.74$), and Food Fussiness ($\alpha = 0.91$). The CEBQ is comprised of 35 items, each scored on a five-point Likert scale that ranges from 1 = Never to 5 = Always. It has been shown to have good internal consistency and test-retest reliability [68].

3.2.4. Child screen time

Caregivers report on children's screen time (smart phone, tablet, television, video game, and computer) during weekdays and weekends by responding to the prompt "How much screen time does your child have on an average weekend/weekday." Similar single items measures have been used as part of the national Health and Nutrition Examination Survey (NHANES) to assess screen time among preschoolers and shown to be associated with obesity [69] and active play [70].

3.3. Auxiliary child-related caregiver report measures

To minimize participant burden, caregiver questionnaire measures are prioritized between primary and secondary. Caregivers are invited to complete the secondary questionnaires for additional compensation following the completion of the primary measures. Sensitivity analyses are conducted to examine predictors of those caregivers willing to complete the secondary measures. Measures selected as secondary focus on proposed mechanisms or moderators of treatment effectiveness. Exploration of potential moderators and mediators will inform future studies.

3.3.1. Child Strengths & Difficulties

The 25-item Child Strengths and Difficulties Questionnaire (SDQ) assesses child attributes (10 strengths, 14 difficulties, and 1 neutral) divided between 5 scales of 5 items each: Hyperactivity, Emotional Symptoms, Conduct Problems, Peer Problems, and Prosocial [71]. The questionnaire uses a 3-point Likert scale ranging from "Not true", "Somewhat true", to "Definitely true". The SDQ has shown to be reliable and has been validated against the well-established Rutter Child Behaviour Questionnaire which measures emotional and behavioral problems in young children [71].

3.3.2. Child sleep habits

Caregivers report on children's usual sleep quantity, and the previous week perceived quality and adequacy of children's sleep using an abbreviated 18-item version of the Children's Sleep Questionnaire [72]. For each item, caregivers report the frequency of a sleep problem in the previous week on a scale from "rarely" (0–1 night/week), "sometimes" (2–4 nights/week), to "usually" (5–7 nights/week). This measure has shown adequate internal consistency ($\alpha = 0.68$) and satisfactory test-retest reliability ($\alpha = 0.62$ – 0.79) [73] and shown to be associated with children's sleep measured via actigraphy and distinguish between children with and without clinical sleep difficulties [74].

3.3.3. Child inhibitory and emotional control

Children's ability to modulate actions, responses, emotions, and behaviors is measured via the brief version of the caregiver-administered Inhibitory Self-Control Index on the Behavior Rating Inventory of Executive Function (BRIEF) [75]. The index is composed of the Inhibit and Emotional Control subscales. The BRIEF is normed among preschoolers in the United States, and has shown good internal consistency ($\alpha > 0.80$), test-retest reliability and has been validated for use among preschool samples [76].

3.4. Caregiver and household measures (caregiver report)

3.4.1. Demographics

Primary caregivers report on demographics including age, race/ethnicity, gender for themselves and the participating child. Additionally, caregivers report on the number of children and adults in the home, annual income, marital status, caregiver level of education and employment status. Caregiver weight and height are self-reported. A summary of caregiver and household measures, method of assessment, and timing of data collection is presented in Table 2.

Table 2

Caregiver demographic, behavioral and household environment measures.

	Method	Baseline	Endline
Anthropometry/demographics			
Caregiver Weight & Height	Self-Report	X	X
Demographics	Self-Report	X	
Caregiver health behaviors			
Food Behavior Checklist	Self-Report	X	X
International Physical Activity Questionnaire (IPAQ)	Self-Report	X	X
Caregiver feeding/nutrition environment			
Comprehensive Feeding Practices Questionnaire	Self-Report	X	X
Screening Questionnaire for Food Insecurity (2 items)	Self-Report	X	X
Home Assessment for Physical Activity & Healthy Eating Environment	Self-Report	X	X
Caregiver psychological factors			
Parenting Sense of Competence (PSOC) ^a	Self-Report	X	
Weight Related Eating Questionnaire (WREQ) ^a	Self-Report	X	
Contour Drawing Rating Scale ^a	Self-Report	X	
Preschooler Silhouettes [Perceived Child Body Size] ^a	Self-Report	X	
Spielberger State-Trait Anxiety Inventory (STAI) ^a	Self-Report	X	
Perceived Stress Scale (PSS) ^a	Self-Report	X	
Center for Epidemiologic Studies Depression Scale (CESD-R 10) ^a	Self-Report	X	

^a Measures with asterisks are considered auxiliary outcomes.

3.4.2. Caregiver dietary intake

The Food Behavior Checklist questionnaire [77] (16 items) is designed to be easy to administer and includes representative visuals to improve accuracy of the self-reported information. Items are separated into 5 topics to assess usual food-related behaviors: usual daily fruit and vegetable intake ($\alpha = 0.79$), consumption of dairy items ($\alpha = 0.67$), fat and cholesterol ($\alpha = 0.28$), perceived diet quality ($\alpha = 0.61$), and food security ($\alpha = 0.85$) [78]. An additional question also assesses nutrition label understanding. Items have been shown to be correlated with biomarkers for food intake and 24-hour recall measurements [79]. This measure has been used with caregivers in similar preschool obesity prevention studies [80].

3.4.3. Self-reported physical activity

The International Physical Activity Questionnaire (IPAQ) is a 27-item seven-day recall of activity classified as either "vigorous" or "moderate". This self-reported activity measure has been validated and demonstrated good reliability [81]. The IPAQ consists of four different subscales: Job-Related Physical Activity, Transportation Physical Activity, Housework and Caring for Family, Sedentary Activities, and Recreation and Leisure-Time Physical Activity.

3.4.4. Caregiver feeding practices

The Comprehensive Feeding Practices Questionnaire (CFPQ) [82] is a self-report measure to assess the feeding practices of caregivers of young children. It is comprised of 12 factors: Monitoring, Emotion Regulation, Food as a Reward, Child Control, Modeling, Restriction for Weight, Restriction for Health, Teaching Nutrition, Encourage Balance and Variety, Pressure, Healthy Environment, and Involvement. Internal consistency has been shown to be adequate to good ($\alpha = 0.58$ – 0.81) [82]. The CFPQ has also demonstrated convergent validity with caregiver attitudes regarding child weight and responsibility for feeding [82].

3.4.5. Household food security

A two item food insecurity screening questionnaire identifies families at risk for food insecurity. It contains 2 questions rated as 'Often

True' to 'Sometimes True' to 'Never True'. The 2-item measure has been found to demonstrate sensitivity (97%), specificity (83%), and convergent validity with the USDA Household Food Security Survey Module measure of food insecurity [83].

3.4.6. Home assessment for physical activity & healthy eating environment

The Home Environment Inventory is used to assess accessibility/availability of foods and parenting behaviors. The inventory is comprised of the Fruit and Vegetable Availability subscale, Fats and Sweets Availability subscale, Physical Activity subscales for Parental Modeling and Policies [84] and the Beverage Availability subscale [85]. Responses are rated on a 5-point scale: Never, Rarely, Sometimes, Frequently, Always [84]. The Fruit and Vegetable Availability subscale has been shown to have high internal and test-retest reliability ($\alpha = 0.84-0.82$ respectively) and is associated with caregiver healthy role modeling and child nutrition [84]. The Parental Modeling and Policies subscales have been shown to be moderately reliable ($\alpha = 0.68-0.79$) and associated with objective child physical activity and caregiver physical activity [84].

3.5. Auxiliary caregiver and household measures (caregiver report)

3.5.1. Parenting sense of competence

The Parenting Sense of Competence (PSOC) scale is used to measure parenting self-esteem [86]. This questionnaire is comprised of 17 items measured on a 6-point scale ranging from "strongly agree" to "strongly disagree." The questionnaire consists of two subscales; Satisfaction ($\alpha = 0.76$) which measures liking the parenting role, and Efficacy ($\alpha = 0.88$) defined as a caregivers' perceived competence in the parenting role. The questionnaire has been validated for use among caregivers of infants up to elementary school-aged children [87,88].

3.5.2. Weight related eating

Weight Related Eating Questionnaire (WREQ) is a 16-item, four-factor questionnaire which measures two constructs of dietary restraint (Routine and Compensatory Restraint), susceptibility to external cues (External Eating), and Emotional Eating. The questionnaire has shown to have good reliability ($\alpha = 0.76-0.90$) and has been validated against similar disordered eating inventories [89].

3.5.3. Caregiver body size perception/dissatisfaction

The Contour Drawing Rating Scale consists of 9 gender specific contour drawings that are graduated in sizes. Participants are asked to select a body silhouette that most resembles their own body size. They are then asked to select the size they would like to be. The difference between current and ideal size is used to calculate body dissatisfaction. There is evidence to support strong test-retest reliability and validity to measure body size-perception and body size dissatisfaction [90].

3.5.4. Perceived child body size/dissatisfaction

Caregivers' perception of their child's body size is assessed by figure silhouettes of 4-year-old children [91]. These rating scales consist of line drawings of children's bodies designed to be age and race appropriate. Caregivers are shown images containing seven figures which correspond to the gender and race of their child. They are prompted to view the images and indicate which of the seven figures most closely resembles the current size of their child and the ideal size or which child figure they would desire for their child. The difference between ideal and current size is used to define body size dissatisfaction. BMI for each child figure is determined by applying the volume to the CDC age- and gender-specific growth charts for 4 and 5 year-old children, and has been validated among mothers of preschool children [91] and found to be reliable among parents of young children [92]. Accuracy of child body size is determined by the response to the question, "Which picture looks most like your child?" with an allowance of 1 silhouette on either side of the child's measured BMI.

3.5.5. Caregiver anxiety

The 6-item short form of the State-Trait Anxiety Inventory (STAI) is one of the most frequently used measures of anxiety in applied research and has been shown to be a reliable ($\alpha = 0.82$) and sensitive measure of anxiety [93]. The six-item short-form of the STAI produces scores similar to those obtained using the full 20-item STAI across subject groups manifesting normal and raised levels of anxiety [94].

Caregiver Perceived Stress. The 4-item Perceived Stress Scale (PSS) [95,96] measures the degree to which situations in the previous month are appraised as stressful. The assessed items are general in nature rather than focused on specific events or experiences. Answers are rated on a 5-point scale. The PSS is designed for use in community samples and has been used to assess parenting stress. The measure has been shown to have acceptable psychometric properties [97].

Caregiver Depressive Symptoms. The CESD-R (Center for Epidemiologic Studies – Depression Scale (Short Form)) is designed to measure depressive symptomatology in the general population. The scale is one of the most widely used instruments in the field of psychiatric epidemiology and has been shown to have good validity and reliability [98].

3.6. Child care staff measures

The following measures are assessed using the web-based questionnaire system Qualtrics. Child care staff are compensated with a gift card for the completion of all questionnaires. Table 3 provides an overview of the child care staff measures. Weight and height, and demographics are self-reported by child care staff.

3.6.1. Child care staff demographics

Child care Staff report information including age, race/ethnicity, gender. Additionally, staff report on the number of children and adults in the home, annual income, marital status, level of education and employment status. Staff weight and height are self-reported. A summary of child care staff measures, method of assessment, and timing of data collection is presented in Table 3. Part of the survey given to caregivers is also applied to child care staff and teachers. Similar questionnaires include: Dietary Intake [77], Objective and Self-Reported Physical Activity [81], Body Size Perception/Dissatisfaction

Table 3
Child care staff demographic and behavioral measures.

Child care staff measures	Method	Baseline	End line
Anthropometry/demographics			
Child Care Staff Height & Weight	Self-Report	X	X
Demographics	Self-Report	X	
Child care staff health behaviors			
Actical Accelerometer	Direct	X	X
International Physical Activity Questionnaire (IPAQ)	Self-Report	X	X
Food Behavior Checklist	Self-Report	X	X
The Pittsburg Sleep Quality Index (PSQI)	Self-Report	X	X
Child care staff feeding/nutrition environment			
Child Care Staff Feeding Attitudes	Self-Report	X	X
Child Care Staff Child Feeding Knowledge	Self-Report	X	X
The Child Care Food and Activity Practices Questionnaire (CFAPQ)	Self-Report	X	X
Child care staff psychological factors			
Spielberger State-Trait Anxiety Inventory (STAI)	Self-Report	X	X
Perceived Stress Scale (PSS)	Self-Report	X	X
Weight Related Eating Questionnaire (WREQ)	Self-Report	X	X
Screening Questionnaire for Food Insecurity (2 items)	Self-Report	X	X
Center for Epidemiologic Studies Depression Scale (CESD-R 10)	Self-Report	X	X
Contour Drawing Rating Scale	Self-Report	X	X

[90], Food Security [83], Anxiety [93], Stress [95,96], Depressive Symptoms [98], and Weight Related Eating [89].

3.6.2. Child care staff sleep quality

The Pittsburgh Sleep Quality Index (PSQI) is used to assess child care staff sleep. The PSQI self-report measure of sleep quality, quantity and disturbance retrospectively over a 1-month period. The PSQI has been shown to distinguish between “good” and “poor” sleepers in clinical populations and shown to have acceptable internal consistency ($\alpha = 0.83$) [99].

3.6.3. Child care staff feeding attitudes

The Child Care Provider Healthy Eating & Activity Survey (CCPHEA) is a 14-item questionnaire to assess child care providers' beliefs and practices, regarding their role in child eating behaviors. Items are scored on a four point Likert scale from “strongly disagree” to “strongly agree” and “low priority” to “high priority.” The subscales of Efficacy, Misconceptions, Feeding Knowledge, and Priority have shown good internal consistency ($\alpha = 0.75, 0.70, 0.71,$ and 0.64 respectively) [100] and demonstrated initial validity [4,101].

3.6.4. Child care staff food and activity practices

The Child Care Food and Activity Practices Questionnaire (CFAPQ) is comprised of items from the CFPQ (described above) and select items from the Preschooler Physical Activity Parting Practices (PPAPP) questionnaire. The questionnaire is adapted for child care settings show sufficient internal consistency ($\alpha = 0.53$ to 0.96) [102].

3.6.5. Child care staff child feeding knowledge

Child care staff feeding knowledge is assessed using a self-report measure consisting of 13 true or false questions, and been shown to have both face and construct validity [103].

3.7. Child care center measures

Center-level measures are collected via staff-report or via observation by a trained CHAMP data collector (Table 4).

3.7.1. Nutrition and physical activity self-assessment for child care

NAP- SACC self-assessment instrument details the physical activity and nutrition policies and practices in child care settings, from the perspective of the director and staff [104]. Previous studies indicate that this self-assessment is a stable and reasonably accurate instrument [104]. The NAP- SACC self-assessment instrument is completed by all center liaisons prior to the intervention.

3.7.2. Environmental policy assessment and observation

The EPAO measure is a comprehensive instrument that assesses the nutrition and physical environment of child care facilities. The EPAO has demonstrated good interobserver agreement (~80%) [105] and has been shown to be associated with children's physical activity [106]. The measurement includes a one-day observation of a classroom for children age 3–5 years and review of center documents (food menus, guidelines, and policies) per child care center. CHAMP data collectors receive 4–5 h of training on the EPAO to ensure reliability of information gathered. Data collection training and certification consists of video and in-person mock assessment compared to an experienced observer (gold standard). Data collectors must reach a reliability of

Table 4
Child care center-level measures.

Child care center measures	Method	Baseline
EPAO	Direct Audit	X
NAP-SACC self-assessment instrument	Staff Report	X

Kappa > 0.7, prior to collecting data.

The EPAO and the NAP-SACC self-assessment instrument are similar measurements, however the EPAO is an observational non-biased collection of data from a researcher and the NAP-SACC self-assessment instrument is reported by a child care staff member (liaison) [107]. The NAP-SACC is conducted prior to randomization, and the EPAO is collected during the course of the intervention.

3.8. Process evaluation

Monitoring of intervention implementation is assessed weekly by the CHAMP research team. Implementation indicators for Reach, Fidelity and Participant Responsiveness are based on existing literature [108–110]. Process indicators are measured at the child and caregiver levels and differ conceptually to better capture the distinct nature of the intervention implemented at each level. For instance, process evaluation indicators for caregivers are based on the website intervention and include only caregivers in the evaluation sample assigned to CHAMP + arm. Website process evaluation data are derived from Google analytics weekly reports generated online by two trained data collectors.

Process evaluation for children reflects the implementation of the child care-based CHAMP curriculum as delivered by child care staff. Trained data collectors conduct weekly phone calls with child care staff/center liaisons to gather information on implementation indicators. Each week child care staff report child care attendance, number of lessons implemented, and any challenges with implementing the CHAMP curricula. In addition, trained data collectors conduct in-person visits to the center to observe at least two lessons throughout the intervention. The in-person data collection informs data reported by child care staff over the phone using a paper instrument modified from previous childhood interventions [111–113]. Only centers assigned to CHAMP and CHAMP + arms are assessed for process evaluation and information gathered reflects the entire classroom, extending beyond the child evaluation sample.

Reach is defined for caregivers as the total number of individuals using the website per week (i.e. unique IP addresses). Reach for children is defined as the number of children (age 3–5 years) receiving CHAMP lessons in child care.

Fidelity measures the extent to which the intervention was delivered as planned [108]. For children, fidelity is defined as the quality and integrity of intervention lessons delivered as described in the implementation protocol (e.g., lesson objectives met (assessed via direct observation by the CHAMP research team)). For caregivers, this is defined as the extent to which teachers upload photos of the lessons to the website, number of weekly content uploads to the website (e.g., number of recipes, infographics, videos, and challenges), and number of text messages and email reminders sent. Caregivers are sent one text message per week ($n = 28$) through the Simple Texting SMS marketing service. They also receive weekly text messages containing the website link when content is uploaded to the website.

Participant Responsiveness measures the extent to which the target audience view, receive, or actively engage with CHAMP materials [108]. For children, responsiveness is defined as the number of food sampling opportunities staff provided each week. For caregivers, this is defined as average amount of time per week caregivers spend on the CHAMP website, number of unique IP address log-ins to the website, and participation in CHAMP website quizzes and monthly challenges. This is calculated as the Website Engagement Index (see Table 5). An engagement index (EI) [114] is used to characterize and quantify participant interaction with the CHAMP + website and it is one of the domains of Dose Received. The Engagement Index includes five sub-indices (Table 5). Metrics needed to calculate the sub-indices are identified a priori and extracted from Google analytics. The Engagement Index formula is combined to assign an overall score as well as individual index scores. Data are collected at the unit of unique IP address.

Table 5
Engagement index (EI) indices and metrics.

Indices	Definition	Analytic Equivalent
Click Depth Index (Ci)	The number of pages viewed in one session (session = 30 min) by a single internet connected device	pages/session
Loyalty Index (Li)	How many sessions per user	# of sessions per user
Interaction Index (Ii)	# of links clicked, # of interactive text, email message sent	links clicked from text/email messages
Recency Index (Ri)	How many days since last visit to the website	# of days since last session
Feedback Index (Fi)	Short website survey given at the final time point	

Sustainability. Following the intervention period, child care staff are asked about potential sustainability in exit interviews (see supplemental file 1). For centers in the intervention conditions (CHAMP and CHAMP+) child care staff are contacted following the intervention year and invited for in-depth interviews to assess barriers and facilitating factors for continuing to deliver the intervention with reduced CHAMP team technical support. The CHAMP team continues to monitor the CHAMP+ website engagement which remains available for the CHAMP+ centers. Child care staff are encouraged to send reminders to caregivers about the website.

3.9. Data management and analysis

Direct data entry systems (i.e. Qualtrics, EpiCollect) are used when possible to minimize data entry errors. Manually entered data are double entered by independent research assistants. Range and plausible value checks are conducted prior to any formal data analysis. Data are de-identified and stored on a password protected server. A Data and Safety Monitoring Board (DSMB) is assembled and meetings are held annually to review study progress and monitor for adverse events.

Intent-to-treat analyses are conducted for the primary outcomes. Initially descriptive analyses are conducted, including frequencies, means and standard deviations. Initial bivariate relationships between the sociodemographic variables and the outcome variables are examined to determine potential covariates. Analyses are adjusted for any significant relationships (covariates) in hypotheses testing. The initial hypothesized covariates are child age, race/ethnicity, sex, and family socioeconomic status (SES). Other candidate variables include household food security and caregiver age, sex, and education.

The primary outcomes are gross motor competence, physical activity, avoidance of food (neophobia), and maintenance of a healthy body weight. To assess the intervention effects, linear mixed models (LMM) are conducted for continuous outcomes variables (e.g., gross motor competence, physical activity, neophobia), and generalized linear mixed models (GLMM) are conducted for categorical outcome variables (e.g. child overweight or obesity). Models account for (1) repeated measures within each individual (e.g. child, caregiver, or staff), and (2) clustering of the individuals within each child care center. All analyses are conducted adjusting for location of child care centers (urban versus semi-urban) and other possible confounders (e.g. child's age, race/ethnicity, sex and SES for caregiver or children's outcomes). Nested model fit indices (AIC, BIC and -2LL) are used to determine if inclusion in the model improves model specification. Intervention is a three-category variable (control, CHAMP, CHAMP+). Two dummy variables are created (CHAMP, CHAMP+) with the control as a reference group. Time is also a three-categorical variables (baseline, midline and end line) and two dummy variables are created (midline and end line) with baseline as a reference group.

4. Discussion

Increases in child care enrollment make the child care setting ideal for childhood obesity prevention efforts. As enrollment in child care centers increases throughout the United States [26], CHAMP represents a timely investigation with the potential to inform policies and programs to advance children's health and well-being. Not only do the

majority of preschool-age children with working mothers attend a child care center for an average of 30 h per week [115,116], but they often eat two meals and at least one snack and engage in both indoor and outdoor physical activities. During the preschool years, children are building daily habits that can last throughout childhood. Daily preschool activities provide opportunities to ensure that children's habits are comprised of healthy dietary and physical activity patterns.

A growing number of child care-based interventions to prevent childhood obesity have reported positive impacts on healthy eating, physical activity, and weight gain [30,117,118]. CHAMP adds to the current body of literature in five important ways: 1) tests the effect of a multi-component intervention to prevent obesity in child care; 2) tests the additive effect of a web-based caregiver intervention to augment the child care intervention; 3) builds capacity of child care staff to deliver intervention curricula; 4) adds to the science of scaled evidence-based interventions to promote nutrition and physical activity [33] implemented in low-income urban and semi-urban settings; 5) evaluates the impact of the intervention on children, caregivers, and center-levels. CHAMP will provide evidence-based information to be included and reinforced in wellness guidelines and policies for child care centers, ensuring that children are exposed to healthy eating practices and opportunities for motor development and physical activity. Most of the CHAMP manualized intervention materials are available electronically, enabling the CHAMP intervention to be scaled and modified as needed to cultural-specific settings.

Key strengths of the current study protocol include cultural modifications, implementation, and expansion of an evidence-based intervention developed using social cognitive and bioecological theories, which span across multiple levels of the bioecological model (child, caregivers, child care staff, and center). Studies that are implemented and evaluated at multiple levels of the bioecological model and informed by theory have been shown to be most effective [117]. Furthermore, CHAMP extends the evidence-based intervention developed by Bellows [33] by testing the effectiveness across bioecological contexts.

CHAMP also examines the impact of a web-based intervention augmentation to increase caregiver engagement in the child care based intervention and promote behavior and environmental changes at the family-level. Web-based interventions offer a potential low-cost method to target families who may have limited time and resources to otherwise engage in an in-vivo intervention format. Novel caregiver communication strategies outside distribution of newsletters have been associated with greater intervention effects in school-based physical activity intervention [119]. Website usage analytics provide direct assessment of caregiver engagement with the website and are used to test utilization of the intervention. Research that utilizes direct and engaging strategies is needed to establish the potential value of caregivers in maximizing the effectiveness of dietary and physical activity interventions in child care settings [120].

The longitudinal design of the current protocol allows for examination of bi-directional interactions among caregivers, child care staff and children over the course of a school year, supporting a bi-directional view of caregiver-child interaction over time. Furthermore, the current study extends research by Bellows [53] by examining the food and physical activity environments in urban and suburban child care centers in another state, both with validated subjective measures

and objective audits.

Several limitations of the current study design should be acknowledged. The current study relies on child care staff and caregivers for self-reported measures of their attitudes and behavior, including height and weight. However, self-reported adult height and weight have been shown to be strongly related to objectively measured BMI [121]. Although the current study utilizes novel website analytics methods to measure caregiver engagement, data are collected using device specific IP addresses, and therefore cannot be linked to specific caregiver data and may misattribute engagement data for caregivers who utilize multiple devices. Additionally, only a subset of child care staff are invited to wear the Actical accelerometer to measure objective physical activity due to limited device availability. Nevertheless, child care staff physical activity has been understudied and information from this study will provide valuable information on how child care staff physical activity relates to children's physical activity. Furthermore, there is significant variability of preschool attendance over the course of a year, and the current study timeline is limited due to the transition of children in and out of child care centers. Unlike school attendance, which is mandatory, preschool attendance is influenced by factors, such as caregivers' work schedules or the availability of alternative child care arrangements. Lastly, there is significant variability in competing activities in child care centers. Many have existing wellness policies and practices in place. However, using systematic interviews at recruitment, as well as center-level questionnaires and direct observations, we are able to measure existing wellness policies and practices and examine their potential impact on intervention outcomes.

5. Conclusion

Child care centers have the potential to be an effective point of intervention to help young children develop healthy dietary, motor, and physical activity habits that prevent childhood obesity and can be sustained throughout childhood. The current study allows for the longitudinal evaluation of an evidenced-based obesity prevention program implemented in urban and semi-urban areas throughout Maryland. The inclusion of the caregiver intervention through a web-based platform is innovative and may increase the impact and sustainability of the intervention. The long-term effects of early childhood wellness interventions are to reduce health disparities throughout life. The current study can inform wellness guidelines and policies that can be disseminated and implemented broadly, to ensure that child care centers provide opportunities for children to develop healthy eating, motor, and physical activity habits. Thus, CHAMP provides an important contribution to public health research and practice.

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Appendix A. Supplementary data

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