Title: Enhancing Child Digital Dietary Self-monitoring: Proof-of-concept Trial

NCT Number: NCT06193967

Document Date: 11/07/2024

For this proof of concept trial, a mobile-optimized, web-based dDSM log will be developed to test the two positive reinforcement strategies: caregiver praise and gamification. The dDSM log will be developed as a mobile-optimized website, rather than an app, so that phone operating system will not be a limitation of use. Families will therefore be able to access the dDSM log from a computer, smartphone, or other internet-enabled device. All dDSM logs will include three basic features: 1) ability to log targeted food groups with amounts and serving consumed, 2) ability to indicate logging is complete for the day, and 3) access to a help feature that provides guidance on tracking and serving sizes. Children will be instructed to self-monitor their daily intake of the following food groups: fruits, vegetables, sweet and salty snack foods, and sugar-sweetened beverages (SSBs). DSM will focus on these four food groups because they have an established influence on health. Fruit and vegetable consumption is associated with decreased risk of chronic disease, and reduced consumption of energy-dense foods like sweet and salty snacks and SSBs is recommended for weight loss in children. Additionally, these food groups are frequently targeted in childhood obesity treatment and are easily understood by young children.

Using a 2x2 factorial design, each child-caregiver dyad will be randomly assigned to 1 of 4 conditions: BASIC, PRAISE, GAME, or PRAISE+GAME. Each child will be provided a unique URL to access a personal dDSM log with the appropriate, randomly assigned features (praise and/or gamification). Caregivers will be provided a separate unique URL to review their child's log and access the caregiver check-in feature, which will not be available in the child link. For PRAISE and PRAISE+GAME conditions, caregivers will be instructed to provide daily process praise to their child related to DSM behaviors (see additional description in the Family dDSM Training section below). While DSM is frequently implemented within treatment, children in the proposed study will engage in DSM without a concurrent intervention to tightly control the influence of the independent variables on DSM behaviors only (as compared to having all adult caregivers learning how to praise or having caregivers focus their praise on achieving dietary goals, which are both standard components of family-based, childhood obesity interventions). Thus, only caregivers randomized to PRAISE or PRAISE+GAME will be instructed on praise and, in the absence of dietary goals for intervention, caregivers will only have one behavior (DSM) to praise. For GAME and PRAISE+GAME conditions, logs will integrate three game mechanics: points, levels, and a virtual pet. Points will be accumulated for engaging in DSM behaviors, and accrual of points will evolve a virtual pet over time, acting as digital token economy. The number of points to level up will increase with each level, so that each consecutive level is harder to attain than the previous one. At the end of the 4-week DSM period, families who complete follow-up assessments will receive two $25 gift cards (one for caregiver, one for child) and will be provided access to a short online behavioral nutrition education program.

The primary DSM outcomes will be frequency (i.e., number of days any food/beverage item is tracked or logging is marked complete) and timing (i.e., how many sessions of recording are completed each day and whether foods/beverages were logged on the day of intake). On days in which no targeted food group is consumed, children will have the ability to mark logging as complete for the day (Figure 1a). Indicating logging is complete in the absence of any tracked foods will be considered a “tracked” day. Pre-post changes in intrinsic motivation will also be examined.

Study Population and Recruitment

For the proof-of-concept trial, children ages 8-12 years at or above a healthy weight [defined as body mass index (BMI)-for-age ≥ 5th percentile] who report eating foods/beverages (any serving size) from ≥2 targeted food groups (fruits, vegetables, sweet and salty snack foods, and SSBs) on ≥3 days/week each and who have an adult caregiver ≥18 years of age willing to participate will be eligible for enrollment. Families will be excluded if the child is already self-monitoring his or her diet or has major psychiatric diseases or organic brain syndromes, or if the family does not live in the greater Knoxville area or does not speak English. Additionally, families must have reliable access to the internet via phone, computer, or another device that the child is able and permitted to operate.

Potential participants will be identified via several strategies. First, researchers will utilize the ongoing recruitment efforts for the Families Becoming Healthy Together (FBHT) trial (NIH 1R01DK121360; PI: Hollie Raynor, PhD) being conducted at the Healthy Eating and Activity Laboratory at the University of Tennessee. FBHT is an intensive 18-month childhood overweight and obesity treatment program enrolling a similar population (i.e., children 8-12 years). Given the length and intensity of the FBHT intervention, it is not a good fit for all families, and/or families might not meet the stringent inclusion and exclusion criteria. Families who screen ineligible for FBHT will be asked whether they would like to receive information about the proposed study. If yes, families will be referred to research staff of the proposed study who will provide a description of the study and complete eligibility screening by phone. Other recruitment strategies include recruitment flyers that will be distributed to UT departments via campus mail, provided to the daycare centers and other businesses/organizations (e.g., YMCA) for distribution to parents, distributed at community events (e.g., farmers markets), and posted in public spaces in the Knoxville area, and online advertisements will be posted on social media (e.g., Facebook) that provide a link to a Qualtrics form that collects contact information and obtains permission to contact. Additionally, researchers will set up a booth at the Cherokee Mills office campus where the University of Tennessee operates an office space. This campus is also occupied by a Cherokee Health Systems clinic that serves both adults and children who may be eligible for the proposed study. Finally, ResearchMatch will be used to contact a de-identified group of potential volunteers that might be interested.

Study Flow

After an initial phone screening to determine eligibility, interested families will be invited to attend an orientation at the Healthy Eating and Activity Laboratory (HEAL) at the University of Tennessee Knoxville. For families who agree to participate, caregivers will complete informed consent forms and children will provide assent. After consent/assent, families will complete baseline assessment measures (see Measures). Immediately after baseline measures are completed, families will be told their assigned condition (randomized using a random numbers table). All families will be provided information on the benefits of DSM and the relationships of the four targeted food groups with child health. Families will be informed that the child's DSM records over the next 4 weeks will be used to provide individualized feedback on their child's nutrition status at their follow-up visit, at which time they will receive access to a short online behavioral nutrition education program (described below).

Each family will be provided a access to a dDSM log that matches group assignment. Caregivers will be instructed to review their child's DSM each day and complete a caregiver check in. Additionally, to get children started, all caregivers will be instructed to sit with their child each day for the first 3 days of the DSM period to help their child log any foods consumed

from targeted food groups. If no logging is completed within the first 4 days of a family's DSM period, a research assistant will reach out to the caregiver to problem solve and provide support.

At the end of the 4-week DSM period, families will schedule a virtual appointment to complete follow-up assessment measures. To provide feedback to families, days for which tracking was marked as completed in the dDSM log will be entered into the Nutrition Data System for Research (NDSR) software to determine servings of fruits and vegetables consumed, as well as intake of added sugars and saturated fats from sugar-sweetened beverages and sweet and salty snack foods. These values will be entered into a feedback template that compares the child's intake to the recommendations in the Dietary Guidelines for Americans (DGA) 2020-2025. Families will also be provided access to a short online behavioral nutrition education program that will consist of four modules: 1) DGA recommendations and basic nutrition information, 2) establishing a healthy home environment, 3) positive reinforcement of healthy behaviors, and 4) pre-planning and problem solving.

Family dDSM Training. After baseline measures, families will complete a DSM practice session using their dDSM log under the observation of research staff. The family's personal dDSM will be used; therefore, GAME/PRAISE features related to the family's assigned condition will be included. The family will practice logging foods and beverages from a standard list and will then be instructed to mark logging as complete for the day. Research staff will answer any questions the family has and will explain how to use the "Help Me Log" feature. Caregivers will also be shown how to complete the caregiver check in feature.

For families randomized to the PRAISE conditions (PRAISE and PRAISE+GAME), caregivers will also provide praise to their child during the DSM practice session so that research staff can observe and provide feedback. During training session, caregivers will be provided a brief training on providing process praise. A description of process praise will be provided, including a list of examples, and caregivers will complete a brief "quiz" in which they attempt to correctly identify process praise statements. Caregivers will also be encouraged to avoid negative reinforcement (e.g., nagging). If the caregiver notices the child is not using the dDSM log, he or she will be encouraged to engage in problem solving/preplanning (rather than nagging) to encourage the child to self-monitor. If the caregiver notices the child is engaging in undesirable behaviors (e.g., recording unhealthy foods), this should be ignored rather than criticized. Additionally, caregivers will be encouraged to provide the praise as close to the occurrence of the behavior as possible to increase its effectiveness. For PRAISE conditions, completion of the caregiver check-in will prompt the caregiver to also complete a praise check-in ("Would you also like to complete a praise check in?"). If no praise check-ins are completed within the first 4 days of the DSM period, a research assistant will reach out to the caregiver to problem solve and provide support.

For families randomized to GAME conditions (GAME and PRAISE+GAME), children and caregivers will observe how points are accrued during the DSM practice session. Prior to the practice session, research staff will explain how points are earned and how points help to "level up" the virtual pet. Points will be accrued and represented in the dDSM log in real time so that children will immediately be rewarded for engaging is DSM behaviors.

At the conclusion of the study, results will be disseminated to former participants via email.

Sample Size

Targeted enrollment will be 40 families (10 families per group) for the proof-of-concept trial.

Measures

Sample characteristics

Demographics. Demographic information will be used to describe the study sample. Information collected will include child and caregiver age, race and ethnicity, and gender and caregiver marital status, education level, employment status, and household income.

Child height and weight. Child height and weight will be collected to confirm study eligibility, and BMI z-score will be calculated based on sex and age.

Parenting style. Previous research has associated parenting style with intrinsic motivation in children. To determine parenting style, caregivers will complete Parenting Styles and Dimensions Questionnaire (PSDQ)-Short Version. The PDSQ-Short Version is a 32-item questionnaire that uses a 5-point Likert scale (never to always) to provide scores for three parenting style factors: authoritativeness, authoritarianism, and permissiveness.

Primary measures: DSM behaviors

Foods, beverages, and serving sizes entered in the dDSM logs by participants will automatically populate a web-based spreadsheet that will collect participant ID number, date and time of entry, food/beverage name, and serving size. This spreadsheet will be exported to Microsoft Excel, and data management and analysis will be conducted in SAS Enterprise Guide 8.3.

Frequency. I.e., number of days with any logging. DSM frequency has been shown to predict success in family-based based childhood overweight and obesity programs. A day will be counted as “tracked” if any food or beverage is logged on that day or, if no food or beverage is logged, the “Logging Complete” button is clicked.

Timing. I.e., proportion of days on which food/beverage items were tracked on the day of intake, as well as the average number of logging sessions per day. Sessions will be considered as distinct tracking events if they occur >15 minutes apart.

Secondary measures

Child intrinsic motivation. Gamification and caregiver praise may differentially affect child motivation to engage in DSM. The Task Evaluation Questionnaire of the Intrinsic Motivation Inventory (IMI) will be used to determine whether are differences in pre-post changes in child intrinsic motivation. This questionnaire consists of 22 items and utilizes a 5-point Likert scale (not at all true to very true) to assess interest/enjoyment, perceived choice, perceived competence, and pressure/tension. At baseline, the measure will be administered after the child has practiced using dDSM with the research assistant so that he or she has some familiarity with the behavior before completing the measure.

Child motivation to change eating behaviors. Child’s motivation to change eating habits will be measured, as this may influence engagement in DSM. Children will be asked to complete the

8-item diet subscale of the Motivation to Exercise and Diet Questionnaire—Adapted for Children (MED-C), which is based on self-determination theory. The MED-C diet subscale utilizes a 5-point Likert scale (never to always) and includes 5 items related to motivation and 3 items related to self-determination theory needs (autonomy, competence, relatedness). This validity of the questionnaire has been tested in children aged 7 to 11 years.

Child dietary intake. The act of self-monitoring a behavior may result in reactivity, or improvements in the monitored behavior in the absence of other intervention. Thus, child dietary intake will also be assessed at baseline and follow-up using the Block Food Screener for Ages 2-17 2007. The instrument asks about intake in the "last week" and focuses on take of fruit, fruit juices, vegetables, potatoes (including French fries), whole grains, animal-based proteins, dairy, legumes, saturated fat, added sugars (in sweetened cereals, SSBs), glycemic load and glycemic index. It takes approximately 10-12 minutes to complete.

Usability and acceptability

Child/Caregiver usability and acceptability survey. A survey will be developed (adapted from Marsac et al.108) to capture family's experiences with the dDSM log, as well as the caregiver praise (PRAISE and PRAISE+GAME only) and gamification (GAME and PRAISE+GAME only) features. The survey will address both usability and acceptability.

Adherence and dose

Caregiver praise. To examine whether the caregiver praise manipulation was successfully implemented, the number of completed caregiver check-ins in which the caregiver marked 'yes' for praise provided will be calculated.

Caregiver reminder questionnaires. To examine whether caregivers avoided the use of negative reinforcement (e.g., nagging), items related to caregiver reminders will be administered to the child and parent at follow up.

Gamification. To examine whether the gamification manipulation was successfully implemented, the average number of points received/levels achieved will be calculated. Higher point totals and maximum levels will indicate receipt of a higher dose of the gamification manipulation.

Statistical Analysis

Summary statistics will be used to describe sample characteristics (demographics, child weight status, parenting style). Intent-to-treat analysis will be performed, and missing data will be addressed using a multiple imputation approach. Absence/presence of DSM will be coded as '0' or '1' for each day, with '0' representing no food or beverage tracked AND tracking not marked as complete for the day and '1' representing ≥1 food or beverage tracked AND/OR tracking marked as complete for the day. Therefore, the possible range for overall DSM frequency for the 4-week period will range from 0 (no DSM any day) to 28 (DSM on all days). The possible range for DSM by week will range from 0 to 7. DSM timing will be calculated two ways: 1) the mean number of DSM sessions per day (must be >15 minutes apart to be considered distinct sessions) and 2) the percent of food or beverage items tracked on the day of intake (i.e., the number of food or beverage items tracked on the day of intake divided by the total number of food or beverage items tracked). To assess dose of positive reinforcement

received, the mean number of points accumulated by children in the GAME groups will be calculated, as well as the total number of days in which praise check-ins were completed for children in the PRAISE groups.

To determine the main effects of positive reinforcement on DSM behavior, a 2x2 factorial ANOVA will be conducted with gamification and caregiver praise status as the independent variables and a dependent variable of DSM behavior (frequency or timing). A gamification*caregiver praise interaction term will also be included in the model to test for interactive effects.

To examine how DSM changes over time, linear mixed-factor ANOVA will be used with a between-subject factor of group, a within-subject factor of time (week), and a dependent variable of DSM behavior (frequency or timing). Additionally, graphical representations of daily DSM frequency and timing by group will be plotted to help visualize trends over time.

To explore how positive reinforcement influences motivation, a 2x2 factorial ANCOVA will be conducted with gamification and caregiver praise status as the independent variables, a dependent variable of intrinsic motivation at follow-up, and a covariate of intrinsic motivation at baseline. A gamification*caregiver praise interaction term will also be included in the model to test for interactive effects. This statistical procedure will be repeated with the other secondary measures of child motivation to change eating behaviors and child dietary intake, with follow-up measures as the dependent variable and baseline measures as covariate.

To examine how changes in secondary measures over time, linear mixed-factor ANOVA will be used with a between-subject factor of group, a within-subject factor of time (baseline and follow-up), and a dependent variable of intrinsic motivation, child motivation to change eating behaviors, or child dietary intake, respectively.