

Title: A health-literacy module for overweight adolescents and their parents on canine physical activity, nutrition and behavior: Enhancing DHHS' BodyWorks program at a Federally Qualified Health Center

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A health-literacy module for overweight adolescents and their parents on canine physical activity, nutrition and behavior:
Enhancing DHHS' BodyWorks program
A randomized, double-masked, 208-subject clinical trial of dog-owning families in the treatment of childhood overweight/obesity.

Study Chairman or Principal Investigator:

(Larry Yin, MD, MSPH, Division Chief of General Pediatrics, Director of USC UCEDD at Children's Hospital Los Angeles)

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PRÉCIS

1 A HEALTH-LITERACY MODULE FOR OVERWEIGHT ADOLESCENTS AND THEIR PARENTS ON CANINE PHYSICAL ACTIVITY, NUTRITION AND BEHAVIOR: ENHANCING DHHS' BODYWORKS PROGRAM (DOG OWNERSHIP AND PHYSICAL ACTIVITY AMONG OVERWEIGHT/OBESE AND PHYSICAL ACTIVITY AMONG OVERWEIGHT/OBESE ADOLESCENTS ENROLLED IN BODYWORKS

Objectives

Primary objective: Test the feasibility and acceptability of a concurrent approach using physical activity trackers and Ecological Momentary Assessment. (a): Test the feasibility and acceptability of objective measurement of physical activity using wireless fitness trackers for adolescents (FitBit Ace), their parents (FitBit Flex2), and their dogs (FitBark); (b): Test the feasibility and acceptability of using mobile phones for Ecological Momentary Assessment of types and contexts of adolescent's physical activity with dogs.

Secondary Objective: To establish the size of the effect, and the variability associated with the 7 week-long BW + CHL module, as compared with the control group who received the standard BW program in (a) adolescents' positive affect during or after physical activity with the dog, as measured by the Ecological Momentary Assessment using prompts on mobile phones; and (b) levels of overall physical activity for the adolescents, their parents, and the dogs as measured by the FitBit Ace (adolescents), FitBit Flex2 (parents) and FitBark (dogs). The project will establish feasibility, acceptability, attrition, and protocol compliance, and will collect pilot data needed for power calculations in preparation for an R01 Randomized Controlled Trial as a next step to test the effectiveness of our enhanced BW+CHL program. This project represents a significant methodological and theoretical advancement in the field of Human-Animal Interaction (HAI) and in research on overweight and obesity.

Design and Outcomes

This is a double-blind, controlled clinical trial to test the feasibility and acceptability and to establish the effect size of an intervention, Bodyworks in a form adapted for dog-owning families on physical activity in adolescents ages 9-17 years of age.

This R21 proposes a feasibility, acceptability, and pilot study that leverages the psychosocial benefits of informed and attached dog ownership among treatment-naïve overweight or obese adolescents. We draw upon a socio-ecological model of health behavior that pursues multiple levels of influence (Richard et al., 2011), including those extending across species lines such as physical activity. We utilize BodyWorks (BW), a Comprehensive Behavioral Family Lifestyle Interventions (CBFLI), a national, empirically validated, curriculum-based 7-week program (Borden et al., 2012; DHHS, 2013) offered at Children's Hospital Los Angeles AltaMed Division of General Pediatrics. AltaMed General pediatrics is part of AltaMed, a Federally Qualified Healthcare Center that serves over 300,000 families at more than 50 clinics in Los Angeles and Orange Counties.

There is a pretest, posttest, ecological momentary (EMA) assessments at weeks, 1,4, 7, and a 3-month follow-up.

Interventions and Duration

Control: Standard BodyWorks Program; 7 weeks + 3-month follow-up

Intervention: Adapted Canine Health Literacy Module +BodyWorks; 7 weeks + 3-month follow-up

Sample Size and Population

We will recruit intervention-naïve adolescents ages 9-17 and their parents who were referred to BodyWorks and who have a dog in the home. Based upon our surveys, we estimate that over 54% of families participating in BW have a companion dog, thus we will have a sufficient number of dog-owning families to recruit for eight 7-week group cycles, 10 families per group. With 30% attrition (Espinoza et al., 2017), we will need to recruit at least 104 parent-adolescent dyads, or 208 subjects, who will have a minimum of 104 dogs. We will randomly assign half of the recruited adolescent-parent dyads to either the intervention group (BW+CHL) or to a control group (BW).

Stratification

- Language (English and Spanish)

STUDY TEAM ROSTER

Principal Investigator: Larry Yin, MD, MS

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Main responsibilities/Key roles: As PI, Dr. Yin will oversee all components of the study and will guide the team on all aspects of the recruitment / retention strategies, data collection protocols, and data analysis and dissemination for both qualitative and quantitative aspects of the research.

Co-Investigators: Olga Solomon, PhD

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Main responsibilities/Key roles: Dr. Solomon will participate in all aspects of data collection, analysis and dissemination related to the design the add-on module on canine health and behavior in collaboration with the Tufts Co-Investigator, Dr. Deborah Linder, DVM. Dr. Solomon will participate in all aspects of dissemination of qualitative study results in journal publications and conference presentations.

Co-Investigators: Alexis Deavenport-Saman, DrPH, MPH

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Main responsibilities/Key roles: Dr. Deavenport-Saman will oversee and supervise the BodyWorks Project Coordinator's activities, and the recruitment and retention of the study participants.

Co-Investigators: Juan Espinoza, MD

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Children's Hospital Los Angeles

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Fax: 323-361-4429
jespinoza@chla.usc.edu

Main responsibilities/Key roles: Dr. Espinoza will manage data collection and analysis from Personal Activity Trackers for humans (Fitbit Ace and Fitbit Flex 2); and will carry out the management and analysis of the PAT data in coordination with the biostatistician, Dr. Melissa Wilson.

Co-Investigators: Deborah Linder, DVM

Cummings School of Veterinary Medicine Tufts University
200 Westboro Rd, North Grafton, MA 01536
508-839-5395
Deborah.Linder@tufts.edu

Main responsibilities/Key roles: Dr. Deborah will support the Primary Investigator and work as an inter-disciplinary team member to conduct the research described in this proposal. This includes conception of the study, development of the canine health module, interpretation of the data, and publication of the final results.

Co-Investigators: Tyler Mason, PhD

Department of Population and Public Health Sciences
University of Southern California
2001 N. Soto Street Los Angeles, CA
(323) 442-8203
Fax
tylermas@usc.edu

Main responsibilities/Key roles: Dr. Mason will work directly with Dr. Yin and the other team members to develop and oversee the procedures related to Ecological Momentary Assessment (EMA) involved in the study; he will be involved in all aspects of EMA data collection, data management protocols and procedures; and data analysis and dissemination.

Co-Investigators: Melissa Wilson, PhD

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Main responsibilities/Key roles: Dr. Wilson will oversee the design, conduct and analysis of elements of the study related to statistical analysis and integration of three streams of Physical Activity FitBit data with the data collected for the Ecological Momentary Assessment. Dr. Wilson will ensure the most efficient and up-to-date

techniques are used in the analysis of the data in this proposed project. Dr. Wilson will leverage the resources of the SCRC for data management and statistical analyses required by the aims of the proposed project, including computing resources and expert consultations. Dr. Wilson will be involved in all aspects of Physical Activity measurement involving Personal Activity Trackers (FitBit and FitBark) and EMA data collection, data management protocols and procedures; and in all aspects of statistical data management, analysis and dissemination.

Project Coordinator: Andrea Salcedo, MPH

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Main responsibilities/Key roles: As a project co-coordinator, Ms. Salcedo will carry-out outreach, screening, consenting, and study enrollment, including preparing study devices for each families participation. She will co-teach the BodyWorks classes together with Ms. Chirino in English and Spanish.

Project Coordinator: Claudia Chirino, MPH, MSW

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Main responsibilities/Key roles: As a project co-coordinator, Ms. Chirino will carry-out outreach, screening, consenting, and study enrollment, including preparing study devices for each families participation. She will co-teach the BodyWorks classes together with Ms. Salcedo in English and Spanish.

PARTICIPATING STUDY SITES

Medical Director, General Pediatrics at CHLA: Larry Yin, MD

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Main responsibilities/Key roles: Dr. Yin will oversee
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Medical Director, AltaMed General Pediatrics at CHLA: Yvonne Gutierrez, MD

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Main responsibilities/Key roles: Dr. Gutierrez will oversee
recruitment at AltaMed CHLA.

Medical Director, AltaMed Westlake Clinic (3rd and Alvarado): Jimmy Kakkanad, MD

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Children's Hospital Los Angeles
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jkakkanad@chla.usc.edu
Main responsibilities/Key roles: Dr. Kakkanad will oversee
recruitment at AltaMed Westlake (3rd and Alvarado). He is also based at CHLA.

Clinic Administrator, AltaMed Boyle Heights: Adriana Howard

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Main responsibilities/Key roles: Ms. Howard will oversee
recruitment at AltaMed Boyle Heights.

Medical Director, AltaMed Commerce-Goodrich: Norma Perez, MD

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Commerce, CA 9022
Phone: 323-853-6110
nperez@altamed.org
Main responsibilities/Key roles: Dr. Perez will oversee
recruitment at AltaMed Boyle Heights.

Medical Director, AltaMed South Gate:Melissa See, MD

AltaMed Commerce-Goodrich
8627 Atlantic Ave, South Gate, CA 90280
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melsee@altamed.org

Main responsibilities/Key roles: Dr. See will oversee
recruitment at AltaMed South Gate.

Recruitment Sites

CHLA

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AltaMed General Pediatrics at CHLA

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AltaMed Westlake Clinic (3rd and Alvarado

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AltaMed Boyle Heights

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AltaMed Commerce-Goodrich

AltaMed Commerce-Goodrich
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Phone: 323-853-6110
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AltaMed South Gate

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Fatty Liver Clinic, Gastroenterology:

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Gastroenterology:

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Fax: (323) 361-1650
avidmar@chla.usc.edu

Pulmonology:

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Manager, Clinical Nutrition and Lactation Services: Shannon Goff, MS

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Main responsibilities/Key roles: Ms. Goff will oversee nutrition outpatient recruitment at CHLA.

CHLA Health Network- South Bay Specialty Center:

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310-303-3890
310-303-3893

CHLA Health Network- Glendale Pediatrics:

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CHLA Health Network- Santa Clarita Pediatrics

CHLA Health Network- Santa Clarita Pediatrics
23823 Valencia Boulevard Suite No. 120 Valencia, CA 91355
Phone: 661-253-4971
Fax: 661-253-4972

CHLA Health Network- Central Pediatrics:

CHLA Health Network- Central Pediatrics
Glendale, California Address:
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CHLA Health Network-

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CHLA Health Network-

CHLA Health Network-
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CHLA Health Network-

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CHLA Health Network- Discovery Pediatrics:

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CHLA Health Network- Valley Pediatric Medical Group:

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2 STUDY OBJECTIVES

2.1 Primary Objective

We propose to test a theory of change that links an increase in adolescents' health literacy about both human and canine physical activity and nutritional needs to more positive affect in the presence of the dogs during physical activity (Liao et al., 2017), which will reinforce increased physical activity levels that are anticipated to meet or approach physical activity guidelines (DHHS, 2018) known to be associated with a stabilization or reduction of BMIz overtime.

Studying these associations, our two primary hypotheses are that compared to the control group of dog-owning, intervention naïve adolescents who receive the standard BW program, the participants in the intervention group who receive BW plus our Canine Health Literacy module (BW+CHL) will have 1) higher levels of positive affect during or after physical activity in the company of their dogs (Liao et al., 2017), and 2) higher levels of weekly overall physical activity as measured by the physical activity trackers FitBit Ace.

2.2 Secondary Objectives: To establish the size of the effect, and the variability associated with the 7 week-long BW + CHL module, as compared with the control group who received the standard BW program in (a) adolescents' positive affect during or after physical activity with the dog, as measured by the Ecological Momentary Assessment using prompts on mobile phones; and (b) levels of overall physical activity for the adolescents, their parents, and the dogs as measured by the FitBit Ace (adolescents), FitBit Flex2 (parents) and FitBark (dogs).

BACKGROUND AND RATIONALE

2.3 Background on Condition, Disease, or Other Primary Study Focus

Helping dog-owning, overweight or obese adolescents to meet physical activity guidelines Compared to other companion animals, dogs occupy a unique place in the social networks of children and adolescents (McNicholas & Collis, 2001; Muldoon et al., 2019). Attachment to dogs is strongly linked to well-being that is attained via emotional reciprocity and shared play (Melson, 2011). It is even more central for overweight or obese children and adolescents who have greater mean dog attachment score compared with healthy weight peers (Linder et al., 2017, 2018).

Currently, over 60.2 million (48%) of U.S. households have at least one dog, and this percentage is reported to be higher in households with children (American Pet Products Association, 2018;

Serpell, 2017). This makes dog ownership a vehicle for large-scale multi-level public health interventions, especially for pediatric overweight and obesity (Salmon & Timperio, 2011).

Dog ownership alone, however, is not sufficient to motivate the majority of dog-owning population to be more physically active with their companion dogs (Richards, 2016; Westgarth et al., 2016).

2.2 Study Rationale

It's increasingly important to develop strategies that harness the benefits of dog ownership to increase physical activity for all age groups, but especially for children and adolescents. This is because their habits related to physical activity are to a large extent shaped by their family, making them vulnerable to overweight and obesity not only because of their own habitual inactivity, but also because of the inactivity of their families (Merrick & Kendell, 2003).

3 STUDY DESIGN

- Design of trial: randomized-controlled, double-mask, trial
- Primary and secondary outcomes: Primary objective: Test the feasibility and acceptability of a concurrent approach using physical activity trackers and Ecological Momentary Assessment. (a): Test the feasibility and acceptability of objective measurement of physical activity using wireless fitness trackers for adolescents (FitBit Ace), their parents (FitBit Flex2), and their dogs (FitBark); (b): Test the feasibility and acceptability of using mobile phones for Ecological Momentary Assessment of types and contexts of adolescent's physical activity with dogs.
- Secondary Objective: To establish the size of the effect, and the variability associated with the 7 week-long BW + CHL module, as compared with the control group who received the standard BW program in (a) adolescents' positive affect during or after physical activity with the dog, as measured by the Ecological Momentary Assessment using prompts on mobile phones; and (b) levels of overall physical activity for the adolescents, their parents, and the dogs as measured by the FitBit Ace (adolescents), FitBit Flex2 (parents) and FitBark (dogs). The project will establish feasibility, acceptability, attrition, and protocol compliance, and will collect pilot data needed for power calculations in preparation for an R01 Randomized Controlled Trial as a next step to test the effectiveness of our enhanced BW+CHL program. This project represents a significant methodological and theoretical advancement in the field of Human-Animal Interaction (HAI) and in research on overweight and obesity.
- Study population and groups/arms including sample size: Adolescents ages 9-17 years; 104 families: Parent-child dyads (208 individuals)
- Study location: out-patient clinics

- Approximate duration of enrollment period and follow-up: 7 weeks intervention +3 months follow-up; Total study duration: 3 years
- Intervention and administration: BodyWorks' theoretical framework: Social Cognitive Theory (Bandura, 1986), Stages of Change Theory (Prochaska et al., 2001), and Motivational Interviewing (Miller & Rollnik, 2012) form a theoretical framework for BW (DHHS, 2009, 2013). This framework will be amenable for integrating the Canine Health - Literacy module into BW curriculum that will encourage the adolescents and their parents to learn about their dogs' physical and nutritional needs, and utilize this knowledge to make a health promoting behavior change.
- Randomization: BodyWorks' theoretical framework: Social Cognitive Theory (Bandura, 1986), Stages of Change Theory (Prochaska et al., 2001), and Motivational Interviewing (Miller & Rollnik, 2012) form a theoretical framework for BW (DHHS, 2009, 2013). This framework will be amenable for integrating the Canine Health -Literacy module into BW curriculum that will encourage the adolescents and their parents to learn about their dogs' physical and nutritional needs, and utilize this knowledge to make a health promoting behavior change. Families will be randomly assigned to either the intervention (BW + Canine health literacy module) or to the control group (BW only).
 - Stratification is by language (English or Spanish)
- Other protocol specific details, such as centralization of evaluations: Pretest, posttest, and 3-month follow-up

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

- All participants in both the control and the intervention group are dog-owning families, independently of which pathway they were recruited from (AltaMed or CHLA).

Inclusion criteria:

- 1) This study focuses on pediatric overweight and obesity among ambulatory adolescents ages 9 -17, therefore this age group will be recruited for the study.
- 2) Dog-owning pediatric patients referred to BW because of overweight or obesity concerns will be eligible to participate.
- 3) To establish eligibility related to dog safety, we will administer a dog safety screener to ensure dogs are physically and behaviorally appropriate to participate.
- 4) To establish eligibility related to a strong attachment to the dog, we will administer *Pet Attachment - Parent Report* survey to the parents.

- 5) To establish eligibility related to dog physical and behavioral health *the* participating parent will fill out and sign a Family Agreement of Behavioral Health and Safety of the Family Dog.
- 6) The team will confirm that the adolescent's physician does not see any contraindications to their participation in the study.
- 7) Parents confirm that they will be available to attend a program orientation and the 7 weekly sessions with the child of the program which is administered remotely.

4.2 Exclusion Criteria

- 1) Younger children are excluded (children who are 0-8), because according to our preliminary data, they are unable to retain health literacy information.
- 2) Older children who are over 17 years of age will be excluded while older adolescents may have other developmental needs related to attachment than the younger 9-17 years old group.
- 3) Non-ambulatory children are excluded as the physical activity trackers measure active paces.
- 4) Children with severe intellectual disability will be excluded, as they may not be able to understand the curriculum.
- 5) Both experimental and control groups **need to be dog-owning**, so if they do not have a dog, they are not eligible to participate in the study.
- 6) Prior participation in the BodyWorks Program anywhere is an exclusion criterion.

4.3 Study Enrollment Procedures

- **Recruitment Pathway 1:** AltaMed recruitment and enrollment procedures: The clinic liaison or medical director will provide a list of patients who meet the inclusion criteria for age, overweight/obesity status, and ambulatory status. Some families may choose to do a pre-screen with via a QR code from the study flyer. The team will then reach out to these families, screen them to identify those with family dogs, and then provide information about the project and an invitation to discuss their participation further with the team if interested.
- **Recruitment Pathway 2:** CHLA clinics and CHLA Health Network clinics recruitment and enrollment procedures: The clinic liaison or medical director will provide a list of patients who meet the inclusion criteria for age, overweight/obesity status, and ambulatory status. Some families may choose to do a pre-screen with via a QR code from the study flyer. The team will then reach out to these families, screen them to identify those with family dogs, and then provide information about

the project and an invitation to discuss their participation further with the team if interested.

- Screening Process: A Parent Phone Screener: Dog safety, a Parent Phone Screener: Dog Attachment, and a Family Agreement of Behavioral Health and Safety of the Family Dog.
- Consent procedures: Typically developing children and children with mild-to-moderate intellectual disability with or without a developmental disorder are eligible to participate in the study based upon the need to comprehend the health literacy curriculum. If there is a question regarding developmental disability, we will request that the clinic liaison reviews the medical chart to confirm absence of intellectual disability or a non-ambulatory status.
- Randomization procedure: After the adolescents and the dogs meet all of the eligibility criteria, they will be randomized by a random number generator to an intervention or a control group in RedCap.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Control: Standard BodyWorks Program; 7 weeks + 3-month follow-up

Intervention: Adapted Canine Health Literacy Module +BodyWorks; 7 weeks + 3-month follow-up

The intervention and control groups will be administered virtually and separately from each other. Families from any AltaMed clinic, CHLA clinic site or CHLA Health Network site can participate in the study.

The U.S. Department of Health and Human Services, Office of Women's Health administered and tested BodyWorks. Characteristics of the BodyWorks Program evaluation and outcomes. The Office of Women's Health from the Department of Health and Human Services reported that after participating in BW, 85% of adolescent girls planned to make healthy choices in the next few months, 78% strongly agreed/agreed that they planned to exercise more often, 67% planned to exercise more vigorously, 78% planned to set nutrition goals, and 80% planned to set physical activity goals. Upon follow-up, 64% of adolescents developed both nutrition and physical activity goals within the past month at the time they were surveyed. Parents were significantly more likely to be physically active ($P < 0.03$), and to help their adolescent to be more physically active ($P < 0.011$), and did more active things with their adolescent active ($P < 0.01$). These findings were statistically significant after controlling for parent and adolescent BMIs.

5.2 Handling of Study Interventions

The BW curriculum is standard of care at AltaMed. Patients from all the participating sites (AltaMed, CHLA, and CHLA Health Network) will be randomized to one of the following groups:

- Control group: BW + Fitbits +Fitbark +EMA
- Intervention: BW + **CHL module**, + Fitbits +Fitbark +EMA

The only difference between the intervention and the control groups is that the intervention group receives the CHL module in addition to the BodyWorks curriculum.

Two distinct recruitment and intervention pathways:

Recruitment Pathway 1: BodyWorks is a standard of care intervention for AltaMed Participants: BodyWorks courses are available inside of AltaMed.

Recruitment Pathway 2: BodyWorks is a research intervention for subjects recruited from CHLA clinics: We will conduct the BodyWorks program outside of AltaMed because subjects from the CHLA Clinics don't have it available to them via AltaMed.

AltaMed Recruitment Procedures

Most procedures related to the BW curriculum and program activities are the current standard of care at AltaMed. However, due to COVID, the BodyWorks program will no longer be delivered in-person, but will instead be delivered via Zoom. The NICHD has approved this change. As a result, receiving Fitbits is no longer standard of care, and Fitbits (aside from the FitBark) will be given to subjects as part of this research project.

CHLA Specialty Clinics Recruitment Procedures

Each clinic will receive recruitment flyers and will provide outreach to their patient population. The flyers will be posted in the space of the clinics and handed out to interested families. A digital copy of the flyer will be provided for dissemination via email. These clinics will either give us a list of patients or we will go into KIDs or ATS (CHLA and UCEDD EMRs) to obtain a list of patients who meet the eligibility criteria for age and weight status.

All AltaMed and CHLA Clinics Intervention Procedures

During each 7-session BW cycle, each parent and child enrolled will receive personalized, weekly feedback based on the physical activity data from their PAT. Participants will be weighed pre and post-intervention due to COVID. We will also analyze activity level patterns within the parent-child dyad to explore the effect of the child's and the parent's activity level on each other as well as on total weight loss.

AltaMed and CHLA Administration of Program.

The two recruitment pathways will converge at the group level because each group, either control or intervention, will have people coming from the AltaMed Pathway and the CHLA clinic pathway. Once, randomized, it will not matter which pathway the family took to enter the study. Their research participation experience will be identical. The BodyWorks program will be

administered by the R21 research coordinators whether the families are from AltaMed or CHLA sites. BodyWorks is free to participants whether the families are from AltaMed or CHLA sites.

For lifestyle/behavioral interventions, describe the intervention and general approach for delivering the intervention (e.g., manual describing procedures).

The BW curriculum is standard of care at AltaMed. Patients from all the participating sites (AltaMed, CHLA, and CHLA Health Network) will be randomized to one of the following groups:

- Control group: BW + Fitbits +Fitbark +EMA
- Intervention: BW + **CHL module**, + Fitbits +Fitbark +EMA

The only difference between the intervention and the control groups is that the intervention group receives the CHL module in addition to the BodyWorks curriculum.

Intervention group: BW +CHL

Session 1: Introducing BodyWorks to Your Family, Stages of Change, Setting Goals, Parenting skills; **Canine Component:** Introduction of ideal body condition for dogs and goal setting

Session 2: Portion size, Dietary Guidelines Resource List, tips to eat well and move more, We Can! Go, Slow, and Whoa Foods; MyPlate nutrition education: how to build a healthy meal; **Canine Component:** Calculating calorie needs for dogs, portion control and meal planning

Session 3: Your physical activity: the role of families; screen time, tips to reduce screen time and get active; **Canine Component:** Determining physical activity needs of dogs and strategies for active play

Session 4: Estimated calorie needs, how to talk to children about nutrition; what's in your lunch bag; quick and easy snacks; making healthy lunches; **Canine Component:** Healthy snacking for dogs, a treat allowance, avoiding toxic foods

Session 5: Cooking with children, using weekly planner, talking to your children about fast-food restaurants, rethink your drink: avoiding sugary sodas (liquid calories); **Canine Component:** Similarities between children's and dogs' need for water

Session 6: Food facts: reading labels, smart shopping for fruits and vegetables, fats and oils to choose from, say 'yes' to family meal, important reasons for family mealtimes; **Canine Component:** How to read pet food labels and recognize marketing tactics in pet food

Session 7: Physical Activity – Aerobic, Muscle- and Bone-strengthening; **Canine Component:** Creating an activity plan for your dog
Control group: BW

Session 1: Introducing BodyWorks to Your Family, Stages of Change, Setting Goals, Parenting skills

Session 2: Portion size, Dietary Guidelines Resource List, tips to eat well and move more, We Can! Go, Slow, and Whoa Foods; MyPlate nutrition education: how to build a healthy meal

Session 3: Your physical activity: the role of families; screen time, tips to reduce screen time and get active

Session 4: Estimated calorie needs, how to talk to children about nutrition; what's in your lunch bag; quick and easy snacks; making healthy lunches

Session 5: Cooking with children, using weekly planner, talking to your children about fast-food restaurants, rethink your drink: avoiding sugary sodas (liquid calories)

Session 6: Food facts: reading labels, smart shopping for fruits and vegetables, fats and oils to choose from, say 'yes' to family meal, important reasons for family mealtimes

Session 7: Physical Activity – Aerobic, Muscle- and Bone-strengthening

5.3 Concomitant Interventions

This section should be consistent with the medications and interventions restrictions in the inclusion/exclusion criteria.

Two distinct recruitment and intervention pathways:

Recruitment Pathway 1: BodyWorks is a standard of care intervention for AltaMed Participants. We are getting a list of subjects referred to BodyWorks by AltaMed physicians. Some of these patients do not meet eligibility criteria of having a dog. The ones who do qualify for our study go through the eligibility and consenting process and if they are qualified and interested, they are recruited into our study. If not, they are referred by our study staff to the AltaMed main BodyWorks program.

Recruitment Pathway 2: BodyWorks is a research intervention for subjects recruited from CHLA clinics. We are getting a list of subjects referred to the study from CHLA and CHLA Health Network Physicians. If after going through the eligibility and consenting process, the families do not get recruited into the study, we offer to provide the BodyWorks materials by email if they are interested.

5.3.1 Required Interventions

BodyWorks is the only required intervention.

5.3.2 Prohibited Interventions

Being part of BodyWorks previously is an exclusion criteria because only intervention- naive subjects are intended to participate.

5.4 Adherence Assessment

Feasibility will be determined by data completeness and include the number of days and hours of data that can be obtained through 80% of physical activity tracking. Feasibility will be determined by 70% of data completeness for the ecological momentary assessment, i.e. the proportion of questions answered and the time it took to answer the items during a prompt.

6 STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessment	Screening: Visit-1 (Day- 14 to Day -1)	Baseline, Enrollment, Randomization : Visit 1 (W0)	Treatment Visit 2 (W1)	Treatment Visit 3, 4 (W2, W3)	Treatment Visit 5 (W4)	Treatment Visit 6 (W5)	Treatment Visit 7 (W6)	Treatment Visit 8 (W7)	3-Month Follow-up Visit 9 (W19)
<u>Inclusion/Exclusion Criteria</u>	X	X							
<u>Informed Consent Form</u>		X							
<u>Enrollment/ Randomization</u>		X							
<u>Anthropometrics</u>		X							
<u>Medical History: Diagnoses</u>		X							
<u>Screenings: Depression, Food insecurity</u>		X							
<u>Vital signs</u>		X							
<u>Parent/Family Demographics Survey</u>		X							
<u>Adolescent Dog Health Pretest/Posttest</u>		X						X	
<u>Adolescent BodyWorks- Abbreviated Pretest/Posttest</u>		X						X	
<u>Parent BodyWorks- Abbreviated Pretest/Posttest</u>		X						X	

<u>Ecological momentary assessments</u>			X		X			X	
<u>Adolescent Post-study Feedback</u>								X	
<u>Adolescent Fitbit Exit Interview Survey</u>								X	
<u>Adolescent Fitbark Exit Interview Survey</u>								X	
<u>Parent Fitbit Exit Interview Survey</u>								X	
<u>Adolescent Exit Survey</u>								X	
<u>Adolescent Post Study 3 months Follow-up</u>									X
<u>Adverse/Reportable Events</u>		X	X	X	X	X	X	X	

6.2 Description of Evaluations

6.2.1 Screening Evaluation

These evaluations occur to determine if the candidate is eligible for the study.

Consenting Procedure

There is a single informed consent form that describes study procedures.

Research Coordinators: Andrea Salcedo, MPH and Claudia Chirino, MPH, MSW will conduct the consent process.

Both coordinators have the human subjects research training, and HIPAA Certification. The PI and Co-Is will review any needed and necessary changes in the consent forms with the research coordinators after approval of a study amendment. Hard copies of the consent forms will be securely stored under lock and key in the study office.

Screening

- At least one week before enrollment, to establish eligibility related to dog safety, we will administer a dog safety screener to ensure dogs are physically and behaviorally appropriate to participate.
- At least one week before enrollment, to establish eligibility related to a strong attachment to the dog, we will administer Pet Attachment - Parent Report survey to the parents.
- At least one week before enrollment, to establish eligibility related to dog physical and behavioral health the family will complete a Family Agreement of Behavioral Health and Safety of the Family Dog .
- The latest that a participant can join the program is in week 3.

6.3 Enrollment, Baseline, and/or Randomization

Enrollment

- We are obtaining a list of potentially eligible participants. We are the ones enrolling them into the present study. If they don't qualify or are un-interested, they go into the general BodyWorks program outside of the study.
- Recruitment Pathway 1: BodyWorks is a standard of care intervention for AltaMed Participants: We are getting a list of subjects referred to BodyWorks by AltaMed physicians. Some of these patients do not meet eligibility criteria of having a dog. The ones who do qualify for our study go through the eligibility and consenting process and if they are qualified and interested, they are recruited into our study. If not, they are referred by our study staff to the AltaMed main BodyWorks program.
- Recruitment Pathway 2: BodyWorks is a research intervention for subjects recruited from CHLA clinics. We are getting a list of subjects referred to the study from CHLA and CHLA Health Network Physicians. If after going through the eligibility and consenting process, the

families do not get recruited into the study, we offer to provide the BodyWorks materials by email if they are interested.

To be eligible to participate in the current cycle, the participants must meet the inclusion criteria at least 7 days prior to week 0.

Enrollment is defined as the randomization date or as the date all of the screening criteria are met and the family agrees to participate.

The enrollment date is recorded in RedCap on the date they are randomized.

Baseline Assessments

- Anthropometrics: weight, height, BMI z-scores
- Medical History: Diagnoses
- Screenings: Depression, Food insecurity
- Vital signs: Blood pressure
- Parent/Family Demographics Survey: Family characteristics (age, sex, race, ethnicity, etc.)
- Adolescent Dog Health Pretest: adolescent self-efficacy about taking care of their dog's health
- Adolescent BodyWorks- Abbreviated Pretest: Adolescent demographics, how much adolescents want to change their eating and exercise habits
- Parent BodyWorks- Abbreviated Pretest: How much parents want to change their eating and exercise habits

Randomization

(a) The randomization date is the date all of the screening criteria are met and the family agrees to participate

(b) Initiation of study intervention relative to randomization will take place on predetermined dates to start the cycle of classes.

6.4 Follow-up Visits

Visits 2, 5, 8 (Week 2, 1, 4, 7): ± 6 days

Ecological momentary assessments: Weeks 1, 4, 7: Ecological Momentary Assessment (EMA) of physical activity using mobile phones for 7 weeks of the BW program, prospectively collecting data on 4 days per week to have a better understanding of the potentially predictive linkages between adolescents' in the moment affective states and their physical activity with, or in the presence of, their dogs (Liao et al., 2017), and their overall objectively measured weekly physical activity with and without the dogs.

6.5 Completion/Final Evaluation

Visit 8 (Week 7): ± 6 days: To discontinue intervention

- Adolescent Dog Health Posttest: adolescent self-efficacy about taking care of their dog's health
- Adolescent BodyWorks- Abbreviated Posttest: Adolescent demographics, how much adolescents want to change their eating and exercise habits
- Parent BodyWorks- Abbreviated Posttest: How much parents want to change their eating and exercise habits
- Adolescent Fitbit Exit Interview Survey: Experience using the Fitbit (personal activity tracker)
- Adolescent Fitbark Exit Interview Survey: Experience using the FitBark (personal activity tracker for dog)
- Parent Fitbit Exit Interview Survey: Experience using the Fitbit (personal activity tracker)
- Adolescent Exit Survey: Experience responding to the EMA prompts

Follow-up

Visit 9 (Week 19): ± 6 days

- Adolescent Post Study 3 months Follow-up: What did adolescents like/dislike about the program.

7 SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

The risk of participating in the study is no greater than minimal risk of ordinary everyday activities.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

Risks associated with this research include potential loss of privacy, and discomfort experienced by overweight or obese adolescents in the study reflecting on their weight status and the health conditions that they may face. It may provoke adolescents and their parents to experience difficult or emotional reflection on their current situation and past experiences of stigma, bullying or discrimination. Additional discomfort may stem from discussing their dogs' health and physical activity, especially if these are linked to past loss of a companion dog, or another uncomfortable or emotionally difficult situation linked to dog ownership.

We implemented the following methods to maximize safety of participation in regard to Internet safety.

Adolescents may use their personal phones for study participation if they want.

We have a Device Agreement form: to provide information for families that the phones are for study use only; to encourage parent monitoring of the study devices; to provide date when the form was signed;

We created a Study Task Form: This form will be used as a reminder of the specific study tasks for which the families have agreed to use the phones and a requirement not to use the phones outside of the study tasks.

We created a handout on Internet Safety Guidelines for Parents, adapted from an article by an MD. We will provide both forms during study enrollment when the parents receive study devices.

Specifically, the following precautions have been designed in collaboration with the Department of Information Security:

Removal of the ability to:

- 1) Text
- 2) Email
- 3) Use an Internet Browser
- 4) Download applications
- 5) Take and store pictures in the gallery and locate them

Information Security tested the study phones per the Interim CSIO, on all of the parameters of #1-5 above and that the safety barriers withheld Information Security's deliberate attempts to jailbreak the phones.

We are using the CANVAS learning platform on the study phones or on the study participants' personal devices. We have approval from information security and the MediTract approval has been secured.

An informational video on Canvas can be found here:
https://canvas.instructure.com/register_from_website

CANVAS is needed to safely communicate with parents and adolescents to remind them of study activities and to provide the intervention curriculum in a single, easily accessible and secure place.

7.3 Adverse Events and Serious Adverse Events

An **adverse event (AE)** is defined as any unfavorable and unintended diagnosis, symptom, sign, syndrome or disease which either occurs during the study, having been absent at baseline, or if

present at baseline, appears to worsen. Adverse events are to be recorded regardless of their relationship to the study intervention. (e.g. a dog bite by the family dog during physical activity).

A **serious adverse event (SAE)** is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly. (e.g. getting by a car during physical activity)

Describe which AEs will be collected as solicited events. Describe how unsolicited events will be captured. Assure that the reporting and data collection systems avoid double capture.

There are no solicited AEs.

Unsolicited AEs will be reported to the IRB within 48 hours.

7.4 Reporting Procedures

All clinical trials must have a safety reporting system in place. Include details of the reporting procedures and time lines, including the individual responsible for each step (e.g., the Investigator, the Medical Monitor, etc.), how decisions will be made regarding determining relatedness and severity, which forms should be completed, (specific information on where to send this form is included), how reports will be distributed and what follow-up is required.

The PI will be responsible for reporting unsolicited AEs to the IRB within 48 hours in iStar. The PI will follow-up with responding to questions as needed in iStar.

7.5 Follow-up for Adverse Events

Any AE will be analyzed for general risk to the entire cohort. In the event that an AE is generalizable to the entire cohort, all current study participants will be informed and additional precautions will be developed and implemented. The PI will follow-up with the IRB responding to questions as needed to ensure the safety of participants until the issue is resolved or considered stable.

Safety Monitoring

A DSMB will be established for this R21 study, composed of 1 Chair and 3 clinical/clinical research faculty who are not involved in the study protocol/project and who have relevant experience and expertise. The DSMB will be formally convened once funding has been granted. However, we will aim to have representatives with the following four areas of expertise: (1) clinical individual and group treatment for overweight and obesity through bio-psychosocial approaches, including expertise in social determinants of health; (2) child and adolescent moderate-to-vigorous physical activity and multi-level community based strategies for meeting the DHHS 2018 guidelines; (3) canine physical activity, health, and nutrition; and canine cognition and social behavior and (4) human-animal interaction and bond.

The DSMB will meet at regular intervals, not less than twice per year, and more frequently if deemed necessary. The DSMB for this study will: 1) review twice yearly summary reports filed by the PI (Dr. Larry Yin) to the DSMB regarding the conduct of this study; and 2) review the

nature of any serious adverse event that occurs during the study; serious adverse events will be reported to the DSMB within 5 business days from the time that the research team becomes informed of the event. The DSMB will monitor recruitment, protocol deviations, adverse events, unanticipated problems, serious adverse events, and descriptive characteristics of the enrolled participants. DSMB members will summarize action steps, if any, and sign meeting minutes at scheduled and ad hoc meetings.

DATA SAFETY AND MONITORING PLAN will have **four components**:

First, all Children's Hospital Los Angeles Human Subject Protection Program (HSPP) and USC Health Sciences IRB (HSIRB) policies and continuous reporting requirements will be followed in conducting the proposed study. Any actions taken by the HSPP and / or HSIRB as part of its continuing review will be reported to the NICHD.

Second, USC Institutional Animal Care and Use Committee will review and approve the IACUC study protocol to assure data and safety of the canine-related component of the study. Dr. Linder, DVM, DACVN, who is a licensed veterinarian and Co-Director of the Tufts Institute for Human-Animal Interaction will participate in by-weekly meetings with Dr. Yin and the research team by conference call where the data safety and monitoring related to the canine participation component of the study will be discussed and addressed. In case of an adverse event, Dr. Linder will be contacted immediately by telephone and e-mail. Adverse events will be reported to the USC HSC IRB Institutional Animal Care and Use Committee overseeing protocol compliance.

Third, an internal committee including the PI (Yin), and the Co-Is responsible for the conduct of the study at CHLA (Deavenport-Saman, Espinoza, and Solomon), and the USC sub-contract researchers (Wilson and Mason) and all the study personnel interacting with the families and collecting, transcribing, and analyzing data will meet quarterly to assess: participant recruitment, accrual, and retention; data quality and timeliness; participant risk versus benefit; and the assessment of external conditions that could potentially affect the study. Significant problems or adverse events will be reported immediately to the CHLA HSPP IRB, the USC HSC IRB, and the NICHD.

Fourth, as part of their training for the study, all personnel who will interact with subjects will receive instruction in identifying and reporting potential adverse reactions, including promptly reporting it to the PI (Dr. Larry Yin) and the research coordinator.

8 INTERVENTION DISCONTINUATION

Subjects may withdraw voluntarily from participation in the study at any time and for any reason. Participants should continue to be followed, with their permission, even if the study intervention is discontinued.

If the family's dog-ownership status changes or if the dog becomes unable to participate in PA, we will use an 'intent to treat' approach and keep the adolescents and their parents in the original cycle. If the family's dog-ownership status changes or if the dog becomes unable to participate in PA, we will use an 'intend to treat' approach and keep the adolescents and their parents in the

original cycle if the change occurs after week 4, and move to another BW cycle if the change takes place at week 3 or earlier.

If a participant is discontinued from study intervention, they will continue to be followed for weight outcomes

If participants discontinue within the first 2 weeks, and maximum class capacity has been reached, then we will replace that subject with a new participant.

We will continue to collect safety data on any subject discontinued due to an AE or SAE. Every effort will be made to undertake protocol-specified safety follow-up procedures. If voluntary withdrawal occurs, the subject will be asked to continue scheduled evaluations in their regular care.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

Theory of change: We propose to test a theory of change that links (A) an increase in overweight or obese adolescents' health literacy about both human and canine physical activity to (B) more positive affect in the presence of their dogs during physical activity (Liao, Solomon & Dunton, 2017), which will reinforce (C) increased MVPA levels that meet or at least approach the current physical activity guidelines (DHHS, 2018), which are known to be associated with (D) a stabilization or a reduction of BMIz overtime.

Studying the associations only between A, B, and C in this proposal, our two primary hypotheses are that compared to the control group of dog-owning, intervention-naïve adolescents who receive the standard BW program, the participants in the intervention group who receive BW plus our Canine Health Literacy module (BW+CHL) will have 1) higher levels of positive affect during or after physical activity in the company of their dogs (Liao et al., 2017), and 2) higher levels of weekly overall physical activity as measured by the physical activity trackers FitBit Ace. Our secondary hypothesis is that the dogs of the adolescents in the intervention group will have higher levels of overall weekly physical activity as measured by FitBark trackers compared to the dogs of the adolescents in the control group.

Secondary hypotheses and the primary and secondary outcome measures as well as their validity and reliability. To establish the size of the effect, and the variability associated with the 7 week-long BW+CHL module, as compared with the control group who received the standard BW program in 3(a) adolescents' positive affect during or after physical activity with the dog, as measured by the Ecological Momentary Assessment using prompts on mobile phones; and 3(b) levels of overall physical activity for the adolescents, their parents, and the dogs as measured by the FitBit Ace (adolescents), FitBit Flex2 (parents), and FitBark (dogs).

Acceptability will be measured by qualitative, open-ended pen and paper surveys distributed to participants. Descriptive data for acceptability will be prevalence of responses to be computed to

get estimates of central tendency and variability for planning of a future trial.

Primary Feasibility of using physical activity trackers Weekly for 7 weeks. At each weekly meeting, FitBit data will be downloaded to a CHLA computer. FitBark data will be shared by the adolescents on their phones during weekly meetings, or accessed by the team via a computer log in. Feasibility will be determined by data completeness and include the number of days and hours of data that can be obtained through the objective activity trackers. Descriptive data for feasibility will be prevalence of responses computed to get estimates of central tendency and variability for planning of a future trial.

Primary Acceptability of using physical activity trackers. Final three weeks of the data collection cycle: weeks 5, 6, & 7.

Acceptability will be measured by qualitative, open-ended pen and paper surveys distributed to participants. Descriptive data for acceptability will be prevalence of responses to be computed to get estimates of central tendency and variability for planning of a future trial.

Primary Feasibility of Ecological Momentary Assessment A total of 3 waves of data will be collected, at baseline (after recruitment during week 1), at week 4, and, at week 7. Feasibility of EMA will be determined by data completeness, i.e. the proportion of questions answered and the time it took to answer the items during a prompt. This will include the number of days and hours of data that can be obtained through EMA.

Primary Variability associated with the BW+CHL intervention 7 weeks of the intervention Determining the mean difference between the groups' variability in the PA and EMA outcomes.

Secondary Correlate dog PA with adolescents' change in health literacy Week 7 of the intervention Correlate the changes in dogs objectively measured PA with the changes in the adolescents health literacy total score.

Secondary Correlate dog PA with adolescent change in positive

Affect Week 7 of the intervention Correlate the changes in dogs objectively measured PA with the changes in the adolescents positive affect measured by EMA.

9.2 Sample Size and Randomization

Analyses will be performed using SPSS (V.25). Each child's positive affect ratings following reported activity with their dogs will be averaged to create a total positive affect response after PA with dog variable. An ANCOVA model will be run comparing the experimental group and control group on this variable. For EMA and PA measures, we will use longitudinal generalized estimating equations to determine the difference between group, adjusting for repeated measurements within participants, time, and the clustering of the treatment by cycle. This method allows us to adjust for different types of outcomes, including continuous and count data (number of steps, amount of activity) and ordinal responses (reported current emotional state). Diagonal covariance matrices will be used within repeated measurements of the participants, as we assume strong intrachild association that will be independent of other children. These models

will be expanded to examine the association of child activity with that of dog activity as well as parent activity. As the aim is to estimate the size of the effect, the focus will be on determining the mean difference between groups in the outcomes as well as the variability. Along with SA2 analysis, this will help determine sample size for a fully powered trial. We expect to have 80 parent-adolescent dyads go through and complete the BW program, with an estimated 30% attrition; therefore we will need at least 104 dyads, or 208 participants.

9.3 Treatment Assignment Procedures

After the adolescents and the dogs meet all of the eligibility criteria, they will be randomized by a random number generator to an intervention or a control group in RedCap. We will stratify by language (English and Spanish). The research coordinators will be responsible for maintenance of trial randomization codes and maintaining appropriate masking for the study, including the timing and procedures for planned and unplanned breaking of randomization codes.

At the conclusion of the study, the participants and the control group will receive all of the intervention materials that the control group will receive. At this point they will be unmasked to their group. The study team members will be unmasked after the data analysis is completed.

9.4 Interim analyses and Stopping Rules

No interim analysis is planned. If by midpoint of the funded period 2022-2023, we have less than 15 families recruited, the slow accrual will result in stopping the study.

Since this is a minimal risk study, we don't anticipate any safety findings or statistical rules that would temporarily suspend enrollment and/or study intervention. However, if there are any adverse events, we will follow IRB protocol until a safety review is convened (either routine or ad hoc) to determine whether the study should continue per protocol, proceed with caution, be further investigated, be discontinued, or be modified and then proceed.

9.5 Outcomes

Primary outcome: Secondary hypotheses and the primary and secondary outcome measures as well as their validity and reliability. To establish the size of the effect, and the variability associated with the 7 week-long BW+CHL module, as compared with the control group who received the standard BW program in 3(a) adolescents' positive affect during or after physical activity with the dog, as measured by the Ecological Momentary Assessment using prompts on mobile phones; and 3(b) levels of overall physical activity for the adolescents, their parents, and the dogs as measured by the FitBit Ace (adolescents), FitBit Flex2 (parents), and FitBark (dogs).

Our secondary hypothesis is that the dogs of the adolescents in the intervention group will have higher levels of overall weekly physical activity as measured by FitBark trackers compared to the dogs of the adolescents in the control group.

9.6 Data Analyses

Analyses will be performed using SPSS (V.25). Each child's positive affect ratings following reported activity with their dogs will be averaged to create a total positive affect response after

PA with dog variable. An ANCOVA model will be run comparing the experimental group and control group on this variable. For EMA and PA measures, we will use longitudinal generalized estimating equations to determine the difference between group, adjusting for repeated measurements within participants, time, and the clustering of the treatment by cycle. This method allows us to adjust for different types of outcomes, including continuous and count data (number of steps, amount of activity) and ordinal responses (reported current emotional state). Diagonal covariance matrices will be used within repeated measurements of the participants, as we assume strong intrachild association that will be independent of other children. These models will be expanded to examine the association of child activity with that of dog activity as well as parent activity. As the aim is to estimate the size of the effect, the focus will be on determining the mean difference between groups in the outcomes as well as the variability. Along with SA2 analysis, this will help determine sample size for a fully powered trial. We will adjust for sociodemographic characteristics. We expect to have 80 parent-adolescent dyads go through and complete the BW program, with an estimated 30% attrition; therefore we will need at least 104 dyads, or 208 participants

In accordance with NIH policy, we will conduct a valid analysis of the intervention effect for the following subgroups: Race/ethnicity (White vs. Hispanic/Latinx).

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Anthropometrics, pretest, posttest, and 3-month follow-up data will be collected through a link in Redcap. Other baseline measurements are already entered in the medical record as part of a clinical visit. Because of technological limitations, the research coordinators interview the participants and enter their replies in RedCap. RedCap is a HIPAA compliant platform that's secure and password protected. Ecological momentary assessments are collected in LifeData, an application to collect ecological momentary assessment survey data. We will also collect data in FitBit and FitBark applications. A unified family ID will be used to link all data types.

10.2 Data Management

Data will be collected and managed by research coordinators. The study uses two data collection platforms: 1) RedCap, a HIPAA compliant platform that's secure and password protected; 2) LifeData, an application to collect ecological momentary assessment survey data. 3) FitBit: an application to track human physical activity; 4) FitBark: an application to track canine physical activity. Additionally, an excel file contains information the family names and study ID numbers. Another excel file contains attendance and attrition for each participating family. Both files are located on a secure password protected CHLA server.

The CHLA research site will serve as the Data Coordinating Center and has all the responsibilities in data collection and management.

Data collection forms are as follows:

Baseline Assessments

- Anthropometrics: weight, height, BMI z-scores: entered in

- Medical History: Diagnoses
- Screenings: Depression, Food insecurity
- Vital signs: Blood pressure
- Parent/Family Demographics Survey: Family characteristics (age, sex, race, ethnicity, etc.)
- Adolescent Dog Health Pretest: adolescent self-efficacy about taking care of their dog's health
- Adolescent BodyWorks- Abbreviated Pretest: Adolescent demographics, how much adolescents want to change their eating and exercise habits
- Parent BodyWorks- Abbreviated Pretest: How much parents want to change their eating and exercise habits

Visits 2, 5, 8 (Week 2, 1, 4, 7): ± 6 days

Ecological momentary assessments: Weeks 1, 4, 7: Ecological Momentary Assessment (EMA) of physical activity using mobile phones for 7 weeks of the BW program, prospectively collecting data on 4 days per week to have a better understanding of the potentially predictive linkages between adolescents' in the moment affective states and their physical activity with, or in the presence of, their dogs (Liao et al., 2017), and their overall objectively measured weekly physical activity with and without the dogs.

Visit 8 (Week 7): ± 6 days: To discontinue intervention

- Adolescent Dog Health Posttest: adolescent self-efficacy about taking care of their dog's health
- Adolescent BodyWorks- Abbreviated Posttest: Adolescent demographics, how much adolescents want to change their eating and exercise habits
- Parent BodyWorks- Abbreviated Posttest: How much parents want to change their eating and exercise habits
- Adolescent Fitbit Exit Interview Survey: Experience using the Fitbit (personal activity tracker)
- Adolescent FitBark Exit Interview Survey: Experience using the FitBark (personal activity tracker for dog)
- Parent Fitbit Exit Interview Survey: Experience using the Fitbit (personal activity tracker)
- Adolescent Exit Survey: Experience responding to the EMA prompts

Follow-up

Visit 9 (Week 19): ± 6 days

- Adolescent Post Study 3 months Follow-up: What did adolescents like/dislike about the program.

10.3 Quality Assurance

10.3.1 Training

All study staff go through CITI and HIPAA certifications. All senior members of the research team have good clinical practices (GCP) training. The research coordinators receive training on program content and study procedures at the start of the project.

10.3.2 Quality Control Committee

The individuals below will review the NIH DSMB report template from the NIH.

Name	Title
Seana Dowling-Guyer, MS	Associate Director, Center for Shelter Dogs Faculty, Center for Animals and Public Policy Cummings School of Veterinary Medicine at Tufts University
Liao Yue, MPH, PhD, CPH	Instructor, Department of Behavioral Science The University of Texas MD Anderson Center
Jimi Huh, PhD	Associate Professor of Research Preventive Medicine
Eldin Dzubur, PhD	Research Assistant Professor of Social Work
Christine Mirzaian, MD, MPH, CLC	Director, Clinical Services at UCEDD Assistant Professor of Clinical Pediatrics at Keck School of Medicine of USC

10.3.3 Metrics

Quality control metrics for outcome measures include: EMA response compliance checks in LifeData, and FitBit and FitBark compliance checks in the FitBit and FitBark applications.

10.3.4 Protocol Deviations

Describe how protocol deviations will be captured, documented, and reviewed.

10.3.5 Monitoring

Every quarter the Co-Is: Dr. Solomon and Dr. Deavenport-Saman and the research coordinators will hold internal “data audits” to examine collected data for completeness and accuracy and to establish protocol compliance, data quality at the clinical sites, including review of records, and completion of consent forms. A summary of the “data audit” will be reported to the PI, Dr. Yin.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent and assent document and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study. The consent form is separate from the protocol document.

11.2 Informed Consent Forms

There will be a separate informed consent and assent for AltaMed clinics and a separate consent and assent for CHLA clinics and the CHLA Health Network clinics.

A signed consent form will be obtained from each parent and will be available in both English and Spanish. A signed assent form will be obtained from each adolescent and will be available in both English and Spanish. The hard copies of these consent forms will be stored under lock and key in a secure CHLA office. Because our inclusion criteria include only mild-to-moderate intellectual disability, there are no participants who are anticipated to be unable to consent for themselves. However, in the event that participants cannot consent for themselves, such as those with a legal guardian (e.g. person with power of attorney), these individuals must sign the consent form. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant or legal guardian and this fact will be documented in the participant's record.

11.3 Participant Confidentiality

All adult participants will sign a HIPAA form. There will be a separate HIPAA form for AltaMed clinics and a separate HIPAA form for CHLA clinics and the CHLA Health Network clinics.

Anthropometrics, pretest, posttest, and 3-month follow-up data will be collected through a link in Redcap. Other baseline measurements are already entered in the medical record as part of a clinical visit. Because of technological limitations, the research coordinators interview the participants and enter their replies in RedCap. RedCap is a HIPAA compliant platform that's secure and password protected. Ecological momentary assessments are collected in LifeData, an application to collect ecological momentary assessment survey data. We will also collect data in FitBit and FitBark applications. A unified family ID will be used to link all data types.

Data will be collected and managed by research coordinators. The study uses four data collection platforms: 1) RedCap, a HIPAA compliant platform that's secure and password protected; 2) LifeData, an application to collect ecological momentary assessment survey data. 3) FitBit: an application to track human physical activity; 4) FitBark: an application to track canine physical activity. Additionally, an excel file contains information the family names and study ID numbers. Another excel file contains attendance and attrition for each participating family. Both files are located on a secure password protected CHLA server.

Any data, forms, reports, and other records that leave the site will be identified only by a participant identification number (Family ID) to maintain confidentiality. All records will be

kept in a locked file cabinet. All computer entry and networking programs will be done using FIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the NICHD, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NICHD, the OHRP, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

Our ethical guidelines are derived from the Department of Health and Human Services (DHHS) final revision to the human subjects regulations known as the “Common Rule”. These DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. The revised regulations become effective on January 21, 2019, “The Revised Common Rule Compliance Dates and Transition Provision (45 CFR 46.101(l))”. We will also follow the guiding ethical principles from the Declaration of Helsinki, CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), or whichever provides the most protection to human subjects. We will also follow HIPAA (45 PARTS 160 AND 164). The HIPAA Privacy Rule is under the jurisdiction of the Office of Civil Rights which is responsible for interpreting, establishing guidelines, and any subsequent modifications of the rule. Information regarding the most recent version of the Privacy Rule – Health Information Technology for Economic and Clinical Health (HITECH Act).

13 COMMITTEES

Publication Committee: consists of PI and Co-Is who determine potential papers to publish.

14 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures developed by the Publication Committee.

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Children's Hospital Los Angeles
CONSENT/PERMISSION/ASSENT¹ TO PARTICIPATE IN A RESEARCH STUDY

Dog Ownership and Physical Activity among Adolescents Enrolled in a Comprehensive
 Behavioral Family Lifestyle Intervention (CBFLI) Program
 (CHLA)

Name: _____

Medical Record #: _____

Birth Date: _____

KEY INFORMATION

- (1) The information in this form is being used to seek your consent for a research study. Being in the study is up to you. This research is being done to find out if increased health literacy about both humans and dogs would help adolescents ages 9-17 to be more physically active. Information about the study and the study results are publically available at ClinicalTrials.gov under the identifier: NCT04516252.
- (2) Participation will last up to 8 weeks. Study procedures for this research are:
 - Enroll in the BodyWorks program
 - Complete pre-and posttest surveys about the BodyWorks Program.
 - Your child will complete child ecological momentary assessments (surveys on a cell phone delivered through a mobile phone app).
 - Wear a personal activity tracker/wristband to measure your physical activity.
 - Have your child also wear a personal activity tracker/wristband to measure his/her physical activity.
 - Have your dog wear a personal activity tracker: FitBark.
- (3) The most likely risks to you of the research are:
 - There is a small risk that people who are not connected with this study will learn your identity or their personal information, but we will do the best to keep information as confidential as possible. You do not need to answer any information that will make you uncomfortable. We will code data, and only the research team will have the link to any personal information.

➤ Please see the **POTENTIAL RISKS AND DISCOMFORTS** section for a complete list of expected risks.
- (4) You should not expect benefits as a result of being in this research study. Other parents and their adolescents may benefit from what the doctors will learn because of your participation.
- (5) If you decide to not be in the research, your choices are:
 - To receive the BodyWorks curriculum materials in digital form via email
 - The alternative is to not participate.

¹ This form will also serve as the "Consent/Permission for Child to Participate in Research" form for the parents to read and sign. In this case, "You" refers to "your child"

INTRODUCTION

You are being asked to participate in a research study conducted by a team of medical doctors from the General Pediatrics Department at Children's Hospital Los Angeles, Larry Yin, MD, MSPH and Juan Espinoza, MD, social scientists Alexis Deavenport-Saman, DrPH and Olga Solomon, PhD, also from the General Pediatrics Department at Children's Hospital Los Angeles, and preventive medicine researchers Tyler Mason, PhD and Melissa Wilson, PhD from the Department of Preventive Medicine at the University of Southern California.

This research is supported by a grant awarded to Children's Hospital Los Angeles from the National Institute of Child Health and Human Development (NICHD R21HD097761). Up to 208 (104 parents and 104 kids) people will be invited to join the study at CHLA. Participation in this study is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

PURPOSE OF THE STUDY

The purpose of the study is to find out if increased health literacy will increase from participating in BodyWorks (a comprehensive behavioral family lifestyle intervention (CBFLI)) helps to increase physical activity.

We will study the adolescents' and their parents' physical activity levels, and how the adolescents feel during physical activity depending on who is with them. The data from this research will be used to determine whether or not the use of physical activity trackers in dog-owning families increases adolescents' physical activity.

PROCEDURES

If you participate in this study, we would ask you to do the following things:

- Enroll yourself and you adolescent in the study's BodyWorks program, a comprehensive behavioral family lifestyle intervention (CBFLI), designed to increase physical activity.
- Allow us to use your and your child's information collected as part of the BodyWorks program for research purposes. This includes your child's height and weight.
- Allow us to collect your and your child's information from the personal activity tracker (FitBit) issued to you as part of the study. You and your adolescent are expected to refresh the Fitbit application once a week on your phones. Your adolescent will have either a study phone or can use their own phone. Agree to be randomized to either a group that uses physical activity trackers and cell phones, or to a group that uses physical activity trackers and cell phones, and also has an educational component that will be added to the Body Works program. A computer program will determine which group you are put in. You have a 50/50 chance of being assigned to either group, like with a flip of a coin. You do not get to decide which group you are put in.
- Agree to use a physical activity tracker FitBark for the family dog. This will involve attaching the FitBark to your dog's collar and having your dog wear the collar at all times for the duration of the study. You will need to refresh the FitBark application at least once a week on their phone, either the study phone or their own phone.
- Fill out questionnaires about your family demographics and the BodyWorks program.
- Agree to have your adolescent use the cell phone, either their own or the one we provide, and respond to prompts / texts asking where they are, who else is there, and how they feel. This

will be done in the first week of the Body Works program, and then in Week 4, and the last week of BodyWorks, week 7. During each of these three weeks, your adolescent will be asked to reply to texts from Thursday to Sunday, inclusive. On Thursdays and Fridays, the texts will be delivered 3 times outside of school hours; and on the weekend, there will be 8 texts per day. When your adolescents are not using the phone for surveys, online weekly class, or updating their Fitbit or FitBark data, please take the phone from your adolescent. The phone should be in your possession during the evenings of weeks, 1,4,7 and for the entire weeks of 2, 3,5,6. Please keep the phone in a location where to keep the phone stored away in a safe area, where no one will have access to the phone except for you.

- You and your adolescent agree to not use the phone for anything other than the study.
- Due to past incidents involving study phones, most of the typical smartphone functions including making or receiving calls and texts, web browsing, the photo app/gallery, and access to app store are disabled on the phone your adolescent will receive.
- To maximize the safe use of study phones, you and your adolescent should understand that the history of use of the study phone can be traced by the Children's Hospital Los Angeles Information Security Department.
- If your adolescent uses his/her own phone, we will download 5 applications to the phone. These applications are Lifedata, FitBit, FitBark, Canvas, and WebEx. Other than these downloads, nothing else will change on your adolescent's phone.
- If your adolescent is not using a study phone, please continue to monitor their safe use of the phone as you typically do. To assist you, we will provide Internet Safety Guidelines for our information.

INFORMATION ABOUT DATA

The data collected as part of this study will be "de-identified." "De-identified" means that the data may still have your study ID recorded with them, but the link connecting the study ID to your name will be destroyed.

Once your data have been de-identified, they may be used by the researcher conducting this study or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. This future research may be done without consulting you or obtaining consent (permission) for this additional use.

POTENTIAL RISKS AND DISCOMFORTS

There is a small risk that people who are not connected with this study will learn your identity or their personal information, but we will do the best to keep information as confidential as possible.

When you receive a personal activity tracker, it may be irritating to wear on your wrist. Answering prompts may be distracting for your adolescent in what they are doing.

There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

ANTICIPATED BENEFITS TO SUBJECTS

You should not expect benefits as a result of being in this research study.

ANTICIPATED BENEFITS TO SOCIETY

Potential benefits to society/science may include increasing the families' awareness about use of devices to track activity and benefits of this use. Other parents and their adolescents may benefit from what the doctors will learn because of your participation.

ALTERNATIVES TO PARTICIPATION

The alternative to being in this research study is to obtain the BodyWorks curriculum in a digital form via email.

PAYMENT FOR PARTICIPATION

You will receive a \$25 gift card to Amazon when you complete 5 out of 7 online BodyWorks classes. Adolescents will receive a \$25 giftcard with the completion of 80% of phone surveys and 80% completion physical activity as measurement on Fitbit/Fitbark devices.

FINANCIAL OBLIGATION

All study procedures are provided at no cost to you.

PRIVACY AND CONFIDENTIALITY

The data collected as part of this study will be "coded". Coded means that the data will have your study ID recorded with them, and the link connecting the study ID to your name will be kept separately in a secure location by a member of the research team. Only the members of the study team will be able to see the link or the information that can identify you

People on the research team and your adolescent's doctors, nurses, or other clinical staff may know that your family is in this research study if you were referred by them. All results will be kept confidential. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law (i.e., child or elder abuse, harm to self or others, reports of certain infectious diseases)

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. All measurements taken during the study will be done privately and surveys will also be administered online or in a private setting. The study protocol follows all hospital and ethical guidelines for conducting research during the COVID-19 pandemic.

Authorized representatives of the Department of Health and Human Services, and the CHLA Institutional Review Board (IRB) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others. Data will be stored on the principal investigator's password protected computer in a locked office and only the principal and co-investigators will have access to the data.

PARTICIPATION AND WITHDRAWAL

Date of Preparation: 7/13/22
IRB#: CHLA-CG-19-00001

Your participation in this research is VOLUNTARY. You do not have to participate in this research. You can stop your participation at any time. You do not have to answer any questions you do not want to answer. Your choice about whether or not to participate will have no effect on your care, services or benefits at Children's Hospital Los Angeles, the Children's Hospital Los Angeles Health Network, or the BodyWorks program. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at Children's Hospital Los Angeles, the Children's Hospital Los Angeles Health Network, or the BodyWorks program. Please contact the Principal Investigator, Dr. Yin if you wish to leave the study at (323) 361-3855.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigator may withdraw you from participation in this research if necessary to protect your health or if other situations arise that make it necessary to do so. If you become ill during the research, you may have to drop out even if you would like to continue. Dr. Yin will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

HOW TO OBTAIN INFORMATION

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. Yin at (323) 361-3855.

FINANCIAL INTEREST OF THE INVESTIGATOR

Funding for this research study is provided by The National Institutes of Health. The amount of funding is not based upon the number of research subjects enrolled. If your doctor is an investigator for this study, he is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your physician.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator Dr. Yin at (323) 361- 3855; or just want to talk to someone other than the Investigator, you may call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

FUTURE CONTACT

The researchers may have opportunities for your family to participate in future research. If you would be willing to allow the researchers to contact you within the next 5 years to invite you to participate in additional research, please check the box below. At that time, the future research will be explained to you and your consent will be obtained before that research begins. You have the right to opt-out of future contact at any time and you have the right to decide not to participate in any future research project.

_____ Yes _____ No [for subject to complete, if the subject is 14 years or older]

_____ Yes _____ No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

Print Name of Subject

Signature of Subject

Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

Print Name(s) of Parent(s)/Legal Guardian(s)

Signature of Parent/Legal Guardian

Date

Signature of Parent/Legal Guardian

Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give assent/consent/permission to participate.

Print Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent

Date

SIGNATURE OF WITNESS (if applicable)

My signature as Witness indicates that the subject and/or the subject's parent(s)/guardian(s) voluntarily signed this assent/consent/permission form in my presence.

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

Print Name of Witness

Signature of Witness

Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

Please check appropriate box and sign below.

☐ The undersigned, _____, hereby certifies that verbal assent was obtained from the subject.

☐ Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information; etc.)

Date: _____

Time: _____ Signature _____

Routing of signed copies of the form:

- 1) Give to the subject if at least 14 years old (copy)
- 2) Give to the parent/legal guardian if subject is a minor (copy)
- 3) Place in the Principal Investigator's research file (original)

Children's Hospital Los Angeles
CONSENT/PERMISSION/ASSENT¹ TO PARTICIPATE IN A RESEARCH STUDY

Dog Ownership and Physical Activity among Adolescents Enrolled in a Comprehensive
 Behavioral Family Lifestyle Intervention (CBFLI) Program
 (AltaMed)

Name: _____

Medical Record #: _____

Birth Date: _____

KEY INFORMATION

- (1) The information in this form is being used to seek your consent for a research study. Being in the study is up to you. This research is being done to find out if increased health literacy about both humans and dogs would help adolescents ages 9-17 to be more physically active. Information about the study and the study results are publicly available at ClinicalTrials.gov under the identifier: NCT04516252.
- (2) Participation will last up to 8 weeks. Study procedures for this research are:
 - Complete the additional program content we're adding to the standard Body Works program.
 - Complete pre-and posttest surveys about the BodyWorks Program.
 - Your child will complete child ecological momentary assessments (surveys on a cell phone delivered through a mobile phone app).
 - Wear a personal activity tracker/wristband to measure your physical activity.
 - Have your child also wear a personal activity tracker/wristband to measure his/her physical activity.
 - Have your dog wear a personal activity tracker: FitBark.
- (3) The most likely risks to you of the research are:
 - There is a small risk that people who are not connected with this study will learn your identity or their personal information, but we will do the best to keep information as confidential as possible. You do not need to answer any information that will make you uncomfortable. We will code data, and only the research team will have the link to any personal information.

➤ Please see the **POTENTIAL RISKS AND DISCOMFORTS** section for a complete list of expected risks.
- (4) You should not expect benefits as a result of being in this research study. Other parents and their adolescents may benefit from what the doctors will learn because of your participation.
- (5) If you decide to not be in the research, your choices are:
 - Continue the regular participation in BodyWorks
 - The alternative is to not participate.

¹ This form will also serve as the "Consent/Permission for Child to Participate in Research" form for the parents to read and sign. In this case, "You" refers to "your child"

INTRODUCTION

You are being asked to participate in a research study conducted by a team of medical doctors from the General Pediatrics Department at Children's Hospital Los Angeles, Larry Yin, MD, MSPH and Juan Espinoza, MD, social scientists Alexis Deavenport-Saman, DrPH and Olga Solomon, PhD, also from the General Pediatrics Department at Children's Hospital Los Angeles, and preventive medicine researchers Tyler Mason, PhD and Melissa Wilson, PhD from the Department of Preventive Medicine at the University of Southern California.

You are invited to join this study because your family is participating in the Bodyworks program and you have a dog at home. Up to 208 (104 parents and 104 kids) people will be invited to join the study at CHLA. This research is supported by a grant from the National Institute of Child Health and Human Development (NICHD R21HD097761). Participation in this study is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

PURPOSE OF THE STUDY

The purpose of the study is to find out if increased health literacy from participating in BodyWorks (a comprehensive behavioral family lifestyle intervention (CBFLI) helps to increase physical activity.

We will study the adolescents' and their parents' physical activity levels, and how the adolescents feel during physical activity depending on who is with them. The data from this research will be used to determine whether or not the use of physical activity trackers in dog-owning families increases adolescents' physical activity.

PROCEDURES

If you participate in this study, we would ask you to do the following things:

- Allow us to use your and your child's information collected as part of the BodyWorks program for research purposes. This includes your child's height and weight. We will also collect your and your child's information from the personal activity tractor (FitBit) issued to you as a part of the BodyWorks program. You and your adolescent are expected to refresh the Fitbit application once a week on your phones. Your adolescent will have either a study phone or can use their own phone.
- Agree to be randomized to either a group that uses physical activity trackers and cell phones, or to a group that uses physical activity trackers and cell phones, and also has an educational component that will be added to the Body Works program. A computer program will determine which group you are put in. You have a 50/50 chance of being assigned to either group, like with a flip of a coin. Your doctor does NOT get to decide which group you are put in.
- Agree to use a physical activity tracker FitBark for the family dog. This will involve attaching the FitBark to your dog's collar and having your dog wear the collar at all times for the duration of the study. Your adolescent will need to refresh the FitBark application at least once a week on their phone, either the study phone or their own phone.
- Fill out questionnaires about your family demographics and the BodyWorks program.
- Agree to have your adolescent use the cell phone, either their own or the one we provide, and respond to prompts / texts asking where they are, who else is there, and how they feel. This

will be done in the first week of the Body Works program, and then in Week 4, and the last week of BodyWorks, week 7. During each of these three weeks, your adolescent will be asked to reply to texts from Thursday to Sunday, inclusive. On Thursdays and Fridays, the texts will be delivered 3 times outside of school hours; and on the weekend, there will be 8 texts per day. When your adolescents are not using the phone for surveys, online weekly class, or updating their Fitbit or FitBark data, please take the phone from your adolescent. The phone should be in your possession during the evenings of weeks, 1,4,7 and for the entire weeks of 2, 3,5,6. Please keep the phone in a location where to keep the phone stored away in a safe area, where no one will have access to the phone except for you.

- You and your adolescent agree to not use the study phone for anything other than the study.
- Due to past incidents involving study phones, most of the typical smartphone functions including making or receiving calls and texts, web browsing, the photo app/gallery, and access to app store are disabled on the phone your adolescent will receive.
- To maximize the safe use of study phones, you and your adolescent understand that the history of use of the study phone can be traced by the Children's Hospital Los Angeles Information Security Department.
- If your adolescent uses his/her own phone, we will download 5 applications to the phone. These applications are Lifedata, FitBit, FitBark, Canvas, and WebEx. Other than these downloads, nothing else will change on your adolescent's phone.
- If your adolescent is not using a study phone, please continue to monitor their safe use of the phone as you typically do. To assist you, we will provide Internet Safety Guidelines for our information.

INFORMATION ABOUT DATA

The data collected as part of this study will be "de-identified." "De-identified" means that the data may still have your study ID recorded with them, but the link connecting the study ID to your name will be destroyed.

Once your data have been de-identified, they may be used by the researcher conducting this study or other researchers (at CHLA or elsewhere) for future research projects that are unrelated to the purpose of this study. This future research may be done without consulting you or obtaining consent (permission) for this additional use.

POTENTIAL RISKS AND DISCOMFORTS

There is a small risk that people who are not connected with this study will learn your identity or their personal information, but we will do the best to keep information as confidential as possible.

When you receive a personal activity tracker, it may be irritating to wear on your wrist. Answering prompts may be distracting for your adolescent in what they are doing.

There may be additional risks to participation in this study that we do not know about and therefore cannot describe.

ANTICIPATED BENEFITS TO SUBJECTS

You should not expect benefits as a result of being in this research study.

ANTICIPATED BENEFITS TO SOCIETY

Potential benefits to society/science may include increasing the families' awareness about use of devices to track activity and benefits of this use. Other parents and their adolescents may benefit from what the doctors will learn because of your participation.

ALTERNATIVES TO PARTICIPATION

The alternative to being in this research study is to get the standard treatment for your condition. You child can still participate in BodyWorks without being in the study.

PAYMENT FOR PARTICIPATION

You will receive a \$25 gift card to Amazon when you complete 5 out of 7 online BodyWorks classes . Adolescents will receive a \$25 giftcard with the completion of 80% of phone surveys & 80% completion physical activity measurement on Fitbit/Fitbark devices.

FINANCIAL OBLIGATION

All study procedures are provided at no cost to you. You must be in the BodyWorks program to participate in this research. The BodyWorks program is standard treatment. The cost of procedures related to the BodyWorks program may be billed to your insurance company or other third-party payer. You may be responsible for any co-pays or deductibles related to Bodyworks.

PRIVACY AND CONFIDENTIALITY

The data collected as part of this study will be "coded". Coded means that the data will have your study ID recorded with them, and the link connecting the study ID to your name will be kept separately in a secure location by a member of the research team. Only the members of the study team will be able to see the link or the information that can identify you

People on the research team and your adolescent's doctors, nurses, or other clinical staff may know that your family is in this research study if you were referred by them. All results will be kept confidential. No information about you, or provided by you during the research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law (i.e., child or elder abuse, harm to self or others, reports of certain infectious diseases)

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. All measurements taken during the study will be done privately and surveys will also be administered online or in a private setting. The study protocol follows all hospital and ethical guidelines for conducting research during the COVID-19 pandemic.

Authorized representatives of the Department of Health and Human Services, and the CHLA Institutional Review Board (IRB) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others. Data will be stored on the principal investigator's password protected computer in a locked office and only the principal and co-investigators will have access to the data.

PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. You do not have to participate in this research. You can stop your participation at any time. You do not have to answer any questions you do not want to answer. Your choice about whether or not to participate will have no effect on your care, services or benefits at Children's Hospital Los Angeles or the BodyWorks program. If you agree to participate, but later decide to withdraw from this study, you may do so without affecting your rights to health care, services or other benefits at Children's Hospital Los Angeles or the BodyWorks program. Please contact the Principal Investigator if you wish to leave the study.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigator may withdraw you from participation in this research if necessary to protect your health or if other situations arise that make it necessary to do so. If you become ill during the research, you may have to drop out even if you would like to continue. Dr. Yin will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

HOW TO OBTAIN INFORMATION

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. Yin at (323) 361- 3855.

FINANCIAL INTEREST OF THE INVESTIGATOR

Funding for this research study is provided by The National Institutes of Health. The amount of funding is not based upon the number of research subjects enrolled. If your doctor is an investigator for this study, he is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your physician.

RIGHTS OF RESEARCH SUBJECTS

You may withdraw from this study at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding the rights of research subjects or if you have complaints or concerns about the research and cannot reach the Principal Investigator Dr. Yin at (323) 361- 3855; or just want to talk to someone other than the Investigator, you may call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265.

FUTURE CONTACT

The researchers may have opportunities for your family to participate in future research. If you would be willing to allow the researchers to contact you within the next 5 years to invite you to participate in additional research, please check the box below. At that time, the future research will be explained to you and your consent will be obtained before that research begins. You have the right to opt-out of future contact at any time and you have the right to decide not to participate in any future research project.

_____ Yes _____ No [for subject to complete, if the subject is 14 years or older]

_____ Yes _____ No [for parent to complete, if subject is a minor]

SIGNATURE OF RESEARCH SUBJECT (If the subject is 14 years or older)

Your signature below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

Print Name of Subject

Signature of Subject

Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S) (If the subject is a minor)

Your signature(s) below indicates

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

Print Name(s) of Parent(s)/Legal Guardian(s)

Signature of Parent/Legal Guardian

Date

Signature of Parent/Legal Guardian

Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give assent/consent/permission to participate.

Print Name of Individual Obtaining Consent

 Signature of Individual Obtaining Consent

 Date

SIGNATURE OF WITNESS (if applicable)

My signature as Witness indicates that the subject and/or the subject's parent(s)/guardian(s) voluntarily signed this assent/consent/permission form in my presence.

- I was present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian(s);
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in my presence.

 Print Name of Witness

 Signature of Witness

 Date

Study Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the subject or assent was not obtained from the subject.

Please check appropriate box and sign below.

☐ The undersigned, _____, hereby certifies that verbal assent was obtained from the subject.

☐ Assent was not obtained from the subject. (Please state the reason. Examples include: subject is an infant; subject is comatose; subject lacks cognitive abilities to understand the information; etc.)

Date: _____

Time: _____ Signature _____

Routing of signed copies of the form:

- 1) Give to the subject if at least 14 years old (copy)
- 2) Give to the parent/legal guardian if subject is a minor (copy)
- 3) Place in the Principal Investigator's research file (original)

Date of Preparation: 7/13/22

IRB#: CHLA-CG-19-00001