

Official Title of the study: Utilizing Digital Health Approaches to Promote Early Childhood Healthy Eating and Activity Behaviors

NCT number (if available): Pending

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eHEROs (Know How) Pilot Study Overview

The overall aim of the electronic HEalthy EnviRONments study (eHEROs) is to transform a tested, traditional, in-person parent intervention for families of young children to a digital platform promoting healthy eating and activity behaviors and environments, and ultimately healthy growth. The intervention program is called Know-How: Building Healthy Eaters and Movers (Know-How). The intervention will be 10 weeks. Week 0 will be an introduction to the overall study followed by 9 weeks of Know How programming. *Please note that the formal name of the study is e-HEROs, but participants will only see the term Know How program/study use.*

Intervention Design

The Know-How program provides parent education on the topics of mindful parenting, healthy eating, and physical literacy and will consist of 3 components: 1) a custom mobile application (app) ; 2) virtual group discussions and 3) child-centered support materials mailed to participating families.

1. Know-How app

The Know-How app will provide parent education using a variety of modalities The ‘know’ will provide parents with the core information on mindful parenting, healthy eating, physical literacy and the ‘how’ will give strategies to incorporate the information into daily routines and activities. To facilitate the transition from the ‘know’ to ‘how’, the app will have a ‘Kid Zone’ will content to engage in activities with the preschooler. Content will be based on the theoretical constructs of the Adult Learning Theory and Social Cognitive Theory. Content will be divided into five modules that include A) lessons (text, audio, video), B) activities, and C) assessments.

A. Lessons

Table 1. Know-How Topics by Content Area	
Content Area	Topics
Mindful Parenting	<ul style="list-style-type: none"> • Parenting Mindfully • Non-Judgmental Acceptance • Listening Mindfully • Emotionally Mindful • Parenting Compassionately • Self-Regulation
Healthy Eating	<ul style="list-style-type: none"> • Offering New Foods • Mealtime Conversations • Home Food Environment
Physical Literacy	<ul style="list-style-type: none"> • Movement Skills • Active Play • Activity Opportunities
Kid Zone	<ul style="list-style-type: none"> • Intro to the Sporks Family • Let’s Eat • Let’s Move • Let’s Go

B. Activities

To engage participants with the lesson content, activities will be interspersed within the lessons. Activities will include quizzes, goal setting and monitoring, and behavioral activities.

- *Quizzes* will inquire about participants:
 - Confidence in offering healthy foods, providing PA opportunities to child, engaging in positive interactions with child related to healthy eating, PA and modifying the home environment.
- Knowledge on feeding and practices and misconceptions; physical literacy; and other core content.
- *Goal Setting and monitoring* activities will embed mindful parenting strategies to enactment of the 3 healthy eating topics and 3 physical literacy topics. Participants will choose at least 2 of the mindfulness prompts (watch, listen, talk, try) and plan how to practice a new behavior, record if they accomplished the plan, and reflect on the experience.
- *Behavioral activities* and reflections will provide participants with experiences to move from the ‘know’ to the ‘how’. They will be asked to choose a new food to offering their child and reflect on how it went (child’s sensory behaviors, liking, their experience and observations). Secondly, they will be asked to upload photos of meals and snack offerings to reflect on meal composition (which food groups were provided, portion sizes), environmental factors (who did the child eat with, mealtime environment/distractions) and timing and frequency of snacks. Related to physical activity, participants will upload short videos (15-30 seconds) of their child participating in a Kid Zone activity or practicing a movement skill. Parents will reflect on their interactions with the child (e.g., modeling, verbal encouragement, instruction, etc.).

C. Assessments

Two assessments will be built into the app (to complement survey distributed via REDCap) and administered at baseline and post-intervention. These assessments – Food Photography and Child Movement Skills – will require photo and video upload. To reduce participant burden of learning a new system, we have built these 2 assessments into the app.

- *Food Photography*: To assess mealtime food quality and intake, parents will be asked to take 2 photos of their child’s meal (before the child eats (pre-meal) and post-meal) on 3 days (2 weekday and 1 weekend day) over a 7-10, day period. Along with pre-meal photo, participants will be asked to provide a text description of the meal components/ingredients. Parents will have the opportunity to provide any optional text about the meal with the post-meal photo (e.g., second servings, spilled items, an additional food item added mid meal). Photos will be downloaded and stored on
- *Child Movement Skills*: To assess movement skills, parents will be asked to record their child attempting 11 movement skills in 4 groups:
 - Locomotor 1 – run, gallop slide
 - Ball skills 1 – overhand throw, underhand roll, catch
 - Locomotor 2 – hop, leap, horizontal jump
 - Ball skills 2 – dribbling and kick

2. Group Discussions

During the 9-week intervention, participants will meet via Zoom for 6, 45-60 minute sessions to connect with a trained group facilitator (member of the research team) and a group of peers (6-8)

from their cohort. The discussions will consist of 2-3 topics (e.g., picky eating, motor development) that complement the materials from the app and allow participants to discuss their experiences, successes or challenges with the material or activities. The purpose is to build community and provide social support to the participants. Embedded within the discussions will be questions about quality of conversation (Discussions 2 & 4), acceptability of program (Discussion 3) and community belongingness (Discussion 5).

3. Support materials

Materials to support both assessment (e.g., balls) and programming (e.g., chef's hat and apron, activity dots, scarves, etc.) will be mailed to participants. We anticipate ~3 mailings spread out over the program. Materials are intended to support behavioral activities and to provide incentive to engage with the children's activities (KidZone) and to continue with/complete the Know How program.

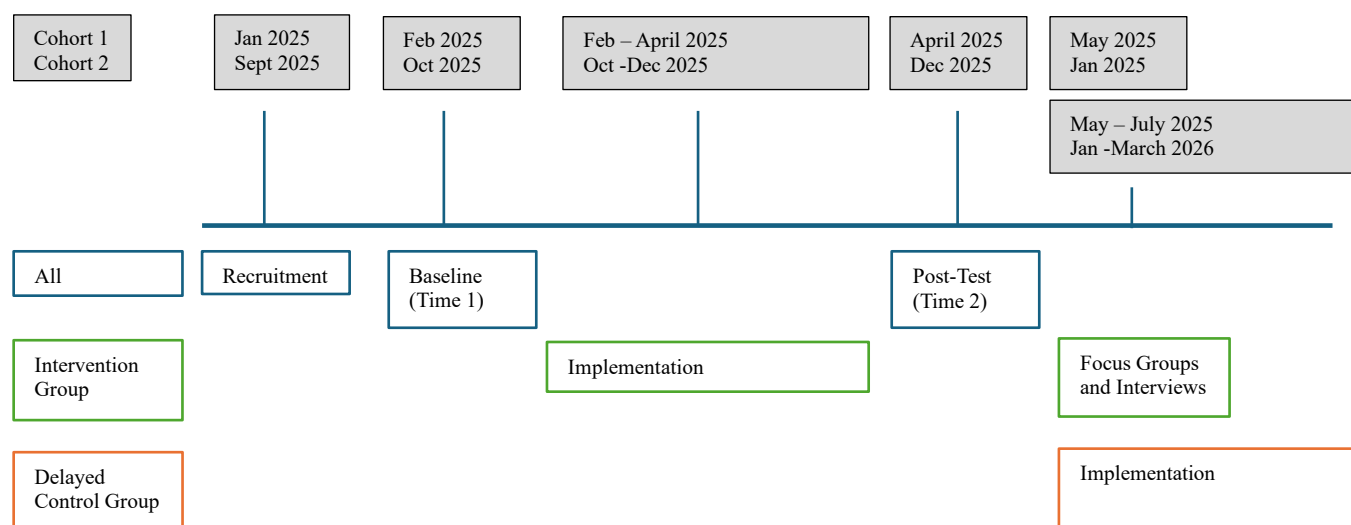
Table 2: Know How Intervention Design

Activity	Week									
	0	1	2	3	4	5	6	7	8	9
Know How App Modules	Study Overview	Introduction		Know Your Child		Know Your Self		Know Your Home		Summary
Group Discussion	1		2		3		4		5	6
Support Materials	X			X				X		

Study Design

This study is a feasibility study that will include 2 cohorts with a delayed control group (Figure2). Study assessments will be collected at Baseline (Time 1), pre-intervention and at Post-Test (Time 2), post-intervention at the same time for both groups. No additional assessments will be collected for the delayed control group at the conclusion of implementation.

Figure 1: Study Timeline by Cohort and Intervention Group



Measures

Table 2 outlines the measures that will be collected at either Baseline (Time 1) or Post-Intervention (Time 2). Measures will be either included in the mobile app or provided to participants via REDCap.

Table 2. Feasibility Pilot Study Measures						
Activity/Testing	Measures	Variables	Data Source	Time 1 2		IRB Submission
Screeners	Eligibility Criteria	<p>Inclusion: Participants must have a preschool-aged child (3-5 years) with no disabilities or conditions that impact typical eating and activity behaviors. Adult participants must have access to a smartphone, reliable internet at home, and can make video calls.</p> <p>Exclusion: Adults who do not have a child aged 3-5 or child has a disability/condition. Technology access is limited. Adults who read, write or speak a language other than English.</p>	0. Screener	Prior to enrollment		√
Participant Information	Demographics & Participant Characteristics	<p>Demographics: Age, Gender, Race, Ethnicity, Education, Income</p> <p>Participant Characteristics: Digital literacy, child food fussiness, physical activity ability</p>	1.Information Sheet	X		√
Feasibility <i>Primary Outcome</i>	Recruitment	Completed interest form, eligibility status, and enrollment	Study records	X		
	Retention	Proportion of intervention and app modules completers	Study records and App backend data		X	
	Usability	Ease of use, complexity, confidence in using, likelihood of use	2. Experience with Know How Program		X	√
	Acceptability	Ratings of information helpfulness, goal setting, liking, willingness to recommend, desire for additional information	2. Experience with Know How Program		X	√
Implementation Outcomes <i>Primary Outcomes</i>	Digital Engagement	Delivery, receipt, and dosage - amount of time engaged by topic, features, and temporal patterns; completion rates of modules and within-app activities.	App backend data		X	
	Enactment	Participation in target behaviors	Data from behavioral outcomes (below); A.Focus groups and		X	√

			B.Interviews			
	Intention to Sustain	Identify intervention strategies relating to target behaviors which were implemented or adopted	A.Focus groups and B.Interviews		X	√
	Peer Support	Gauge quality of conversations, sense of community as well as acceptability of programming.	3. Group Discussions	During Intervention		√
Behavioral Outcomes <i>Secondary Outcomes</i>	Mindful Parenting	Listening with full attention, emotional awareness of self and child, self-regulation, compassion of self and child, non-judgmental acceptance of self and child	4. Parenting	X	X	√
	Parenting Practices	Parent-Child Feeding Practices: Autonomy (encourages exploration of new foods, offers new foods, repeatedly presents new foods) and Structure (mealtime) Physical Activity Parenting Practices: Structure (nondirective support, supportive expectation, restriction of PA inside), Autonomy (support, guided choice) Snacking Parenting Practices: Snacks to manage behavior, snack planning, monitoring, and limit setting.	5. Child Feeding 6. Physical Activity and 7. Snacking	X	X	√
Behavioral Outcomes <i>Exploratory Outcomes</i>	Home Environment	Availability of Fruit, Convenience Foods, Beverages and Whole Grains; Physical activity equipment	8. Home Health Environment	X	X	√
	Mealtime Food Photography	Mealtime food quality & intake	9. Mealtime photos (downloaded from app)	X	X	√
	Child Movement Skills	Locomotor skills: run, gallop, hop, leap, horizontal jump, slide Ball skills: dribbling, catch, kick, overhand throw, underhand roll	10. Movement videos (downloaded from app)	X	X	√
	Child Dietary Intake	Frequency of child's consumption of a subset of foods – fruits, vegetables, protein, grains, beverages, dairy.	11. Child's Diet	X	X	√
	Child Physical Activity	Opportunities for structured and unstructured PA	12. Physical Activity Opportunities	X	X	√

Time 1= Baseline, Time 2= Post-Intervention