Study Protocol

Official Title: Promoting Health through Parent Empowerment and the Activation of Routines (Pro-PEAR)

ClinicalTrials.gov ID (NCT number): NCT05020366

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Scientific Background

Obesity disproportionately impacts children with Down syndrome. Despite serious comorbidities such as higher rates of type 2 diabetes and obstructive sleep apnea syndrome, obesity prevention efforts have been largely neglected within this population. As guided by the 6-SQuID framework, we: 1) defined the problem; 2) clarified causal/contextual factors; 3) identified mechanisms underlying change; and 4) identified how to most efficiently target the change mechanism. Our primary deliverable, a manualized intervention protocol for the PrO-PEAR intervention, will be optimized and tested for feasibility in this study.

Preliminary Data: The Facilitators and Barriers to Health in Young Children with Down syndrome (FaB Health Ds) survey data can help to inform intervention design and drive prioritization of intervention components. According to data collected during our pilot phase (N=33), nutrition and sleep are emerging as priority areas to target for the PrO-PEAR intervention. The World Health Organization (WHO) recommends toddlers consume 5 or more servings of fruits and vegetables per day, however, only 34% of our sample meet this recommendation per parent report. When asked how much quality sleep their child gets over a 24-hour period, less than half of all parents reported an estimate within the recommended range (11-14 hours). In contrast, most parents report that their children meet the recommendations for physical activity, in that they participate in at least 3 hours of activity each day. Most families reported meeting recommendations for sedentary behaviors, such as screen time and time spent restrained (e.g., in a device like a highchair) to 1 hour or less.

Preliminary data also suggest that parents may not be aware of their child's risk related to nutrition and sleep. Most parents are confident in their knowledge of nutrition recommendations (72%) and were "not at all concerned" with their child's consumption of fruits (67%) or vegetables (53%). Similarly, most parents were also confident in their knowledge of sleep recommendations (89%), yet only 22% considered their child's sleep to be problematic. These data signal a disconnect between parental confidence and/or knowledge of healthy behaviors and reports of their child's behavior. We plan to measure child behavior change in each Institute of Medicine obesity prevention priority over time and identify associations with parental knowledge, readiness for change, empowerment, and activation.

Study Objectives

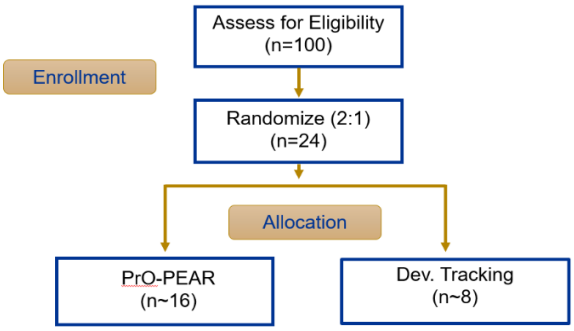
This proposed pilot RCT aims:

1) To determine the feasibility of the Pro-PEAR intervention in terms of recruitment, randomization, retention, adherence, and acceptability.
2) Estimate the effects of the Pro-PEAR intervention on parent reported child health behaviors in each IOM obesity prevention area (nutrition, physical activity, sedentary behavior, sleep) over time as compared to an enhanced usual care group**.**

Study Design & Methods

We will recruit 24 parent/child dyads from the Down Syndrome Center of Western PA to participate in a pilot RCT. Inclusion criteria for child participants are being between the ages of 12-36 months and having a diagnosis of Down syndrome; parent participants must be ≥18 years old and able to speak English fluently. We are recruiting children 12-36 months as most children are able to self-feed and sleep through the night at this time, yet it precedes the rapid weight gain observed among children with Down syndrome.[7] Sample size was determined based on prior recruitment efforts and data on number of children within this age range served at the clinic (~100). We will use a 2:1 randomization ratio for assignment to intervention versus control group status to gain more experience using the newly developed PrO-PEAR intervention (see Figure 3). Child health behavior in the areas of nutrition, physical activity, sedentary behavior, and sleep will be reported by parents, in addition to general health status and potential mechanisms of behavior change at baseline, 3-months (post-intervention) and 6-months (follow-up). We will track physical growth via chart review.

Figure 1. Randomization Plan



B.2.1.3. Treatment. We will test the feasibility of delivering the PrO-PEAR intervention and our ability to randomize to an enhanced usual care group. Participants randomized to enhanced usual care will receive feedback on health behaviors after baseline assessments and continue to receive usual care therapies outside of the study. The PrO-PEAR group will complete four in-person modules with an occupational therapist, each covering an IOM obesity prevention priority area: 1) Healthy Eating; 2) Sleep; 3) Sedentary Behavior; and 4) Physical Activity. Parents in the intervention group will also receive six telehealth visits of family-based coaching to help participants understand recommendations and adopt new, healthy routines.

B.2.1.4. Measures. A priori benchmarks for recruitment, retention, adherence, data collection and acceptability have been established to test the feasibility of the PrO-PEAR intervention. Potential issues in each of these areas have been identified with possible solutions for each barrier (see Table 1). Protocol adherence will be evaluated via review of sessions using clinician documentation. Intervention acceptability will be rated using the Treatment Acceptability Questionnaire (TAQ),[7] a valid and reliable assessment of parental intervention acceptance. Intervention completers are designated as those completing 80% of sessions (≤ 8 of 10).

Table 1. Indicators of Feasibility and Acceptability

Topic	Benchmark	Plan if Benchmark is Not Met
Recruitment	>3 parent/child dyads per month	Partner with other Ds clinics
Retention	≥80% of consented dyads will complete ≥ 8 sessions	Parent focus group to identify issues
Adherence	≥80% clinician protocol adherence during 100% of sampled sessions	Update protocol and increase training
Data Collection	≥80% planned assessments collected among intervention completers	Evaluate burden and reduce as needed
Acceptability	≥90% of parent intervention completers rate intervention as acceptable (>28/48 on TAQ)	Parent focus group to optimize protocol

We willl assess parent-reported child health behaviors, parental mechanisms of behavior change, and child anthropometrics and demographics over time (see Table 2). The knowledge test will be created using the World Health Organization's early childhood recommendations for obesity prevention. All other tools have been validated for use with parents of young children. For this study, we are specifically interested in parent factors that may influence behavior

change, as parents provide the opportunities, environment, structure and feedback that will determine a child's formation of healthy (or unhealthy) behaviors early in life. Data collected during this trial will inform intervention optimization to emphasize those mechanisms related to prioritized child behaviors.

Table 2. Intervention Measures

Assessment	Brief Description	Outcome
Facilitators & Barriers to Health: Down syndrome (FaB Health Ds)[8]	100-item parent survey designed to describe habits and facilitators/barriers to health in young children with Down syndrome (α=.91).	Parent-reported child nutrition, physical activity, sedentary behavior and sleep behaviors
Knowledge of Recommendations to Prevent Obesity in Young Children	10-item test to determine knowledge of recommendations for nutrition, activity, sedentary behavior and sleep	Parental knowledge of healthy behavior recommendations
Readiness, Efficacy, Attributions, Defensiveness, & Importance Scale – Short Form (READI-SF)[9]	15-item Likert-scale survey in which higher scores indicate greater parental readiness to engage in treatment and readiness for change (α=.94).	Parental readiness for change
Parent Empowerment and Efficacy Measure (PEEM)[10]	20-item Brief Likert-scale and strength-based assessment of parental empowerment and efficacy (α=.92).	Parental empowerment
Child Anthropometrics	Height, weight, body circumferences (waist, hip, arm, thigh)	Health status (growth)
Child Demographics	Age, medical diagnoses, service utilization, surgical history, race, ethnicity, household income	Health and socioeconomic status

B.2.1.4. Data Analysis. Feasibility data will be assessed using descriptive statistics (e.g., frequencies, means, percentages) and compared to a priori benchmarks. We will calculate bivariate correlations between demographics, intervention adherence, and outcomes to identify potential confounders or factors that may influence response to treatment. We will estimate effect sizes (Cohen's *d*) of child health behaviors and parental factors (knowledge, readiness, empowerment, activation) over time and between groups. Finally we will explore associations (bivariate correlations) between potential mechanisms of change (parental factors) and child behavior change scores. Parental factors significantly associated with child behavior change will be analyzed using multiple linear regression to identify significant predictors of child health behavior.

Eligibility Criteria

Inclusion criteria for child participants are being between the ages of 12-36 months and having a diagnosis of Down syndrome; parent participants must be ≥18 years old and able to speak English fluently. We are recruiting children 12-36 months as most children are able to self-feed and sleep through the night at this time, yet it precedes the rapid weight gain observed among children with Down syndrome.

Statistical Considerations

Feasibility data will be assessed using descriptive statistics (e.g., frequencies, means, percentages) and compared to a priori benchmarks. We will calculate bivariate correlations between demographics, intervention adherence, and outcomes to identify potential confounders or factors that may influence response to treatment. We will estimate effect sizes (Cohen's *d*) of child health behaviors and parental factors (knowledge, readiness, empowerment) over time

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