Official Title: Preventing Obesity Through Parent Empowerment and the Activation of Routines (PrO-PEAR)

ClinicalTrials.gov ID (NCT number): NCT05020366

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Informed Consent Form

Welcome to PrO-PEAR

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: PrO-PEAR Optimization and Feasibility: A Pilot RCT

PRINCIPAL INVESTIGATOR:

Angela Caldwell, PhD, OTR/L
University of Pittsburgh
Dept. of Occupational Therapy
100 Technology Drive, Suite 350
Pittsburgh, Pennsylvania 15209
Telephone: 412-323-7231
Email: ARL78@pitt.edu

CO-INVESTIGATORS:

Daniel Shaw, PhD
University of Pittsburgh
Department of Psychology
Email: casey@pitt.edu

Roxanna Bendixen, PhD
University of Pittsburgh
Department of Occupational Therapy
Email: bendixen@pitt.edu

Lauren Terhorst, PhD
University of Pittsburgh
Department of Occupational Therapy
Email: lat15@pitt.edu

RESEARCH ASSISTANTS:

Emily Haus
University of Pittsburgh
Department of Occupational Therapy
Email: eeh53@pitt.edu

Marissa Meissner
University of Pittsburgh
Department of Occupational Therapy
Email: mlm286@pitt.edu

Drew Nguyen
University of Pittsburgh
Department of Occupational Therapy
Email: den29@pitt.edu

Shannon O'Leary
University of Pittsburgh
Department of Occupational Therapy
Email: seo41@pitt.edu

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Key Information

You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

If you decide to take part:

- We will coach you to collect data in your home over a one-week period.
- Your child will wear a wristband and a thigh-worn device that counts activity.
- You may take part in intervention sessions in your home and via Zoom.

Risks include:

- Your child may not like wearing the wrist band or thigh-worn device
- It is possible that the devices may irritate your child's skin
- While it is not likely, unauthorized people may access your information

There is a potential benefit to learning how to support your child's development. We can also refer you to local clinics and early intervention programs to support your treatment needs.

What is the purpose of PrO-PEAR?

The goal of this study is to test and improve the Preventing Obesity through Parent Empowerment and the Activation of Routines (PrO-PEAR) intervention for young children with Down syndrome. Children with Down syndrome have a high risk of obesity. We want to help families overcome common and unique barriers to healthy routines. If you take part, your family will be assigned to receive either the PrO-PEAR intervention or Enhanced Usual Care (EUC) as a control group. If you are assigned to receive EUC, you will receive information about your child's performance and behavior in the areas of healthy eating, level of activity, and sleep in addition to the services you already receive.

Who is being asked to take part in this research study?

You and your child are being asked to take part in this research because you have a young child (aged 12-36 months) with Down syndrome. We focus on young children because habits formed early in life are likely to continue.

What is involved in participating in PrO-PEAR?

Physical Activity Monitoring: We will assist you to place a Phillips Actiwatch on the wrist of your child and/or an activPAL on the thigh of your child and ask that they wear the device(s) for 1 week to measure activity and sleep patterns. A team member will check in 3-4 times per week to discuss any issues. We will ask you to return this wristband and thigh-worn device

after wearing it for one week. This will occur when you first enter the study, after you receive the intervention (~12 weeks), and at a 6-month follow-up (~24 weeks).

Healthy Habit Measures: We will also help you to answer questions about your child's feeding, activity, and sleep when you first enter the study, after you receive intervention (~12 weeks), and at a 6-month follow-up (~24 weeks). These questions will take about 60 minutes. During your first appointment to complete these measures, we will collect data on your child's sensory processing and general development using a standardized tool. Because of these additional measures, your first appointment may last up to 2 hours.

PrO-PEAR Intervention: If you are assigned to receive the PrO-PEAR intervention, you will receive 12 weekly sessions in your home. These sessions may be in-person or delivered remotely via Zoom and last 30-60 minutes. In each session, you will learn ways to promote health daily by making small changes to your daily routines. Topics will include eating, sleeping, activity, and screen time. Each session will be delivered by an occupational therapy clinician and tailored to meet the needs of your child and family.

Enhanced Usual Care: If you are assigned to receive EUC, you will receive a print-out of your child's performance and behavior in healthy eating, level of activity, and sleep after each assessment time point.

Assessment of Usual Care: We want to learn more about how much information and intervention you already receive related to healthy routines. Therefore, we will ask you questions about what services you receive and estimate how much healthy eating, physical activity, and sleep are addressed during these services. We will also ask you a few questions using an interview format to gain additional information about the treatment you already receive related to health promotion.

Chart Review: We also request your authorization or permission to review your medical records to determine whether you meet the conditions for participation in this study and to place this information in the research registry. We will obtain the following information: medical outcomes, such as growth, service utilization, and history of procedures already done as part of your standard care at UPMC Children's Hospital of Pittsburgh and the Down Syndrome Center of Western Pennsylvania. This identifiable medical record information will be made available to members of the research team for an indefinite period. Your medical information may be shared with other groups as described above, possibly including authorized officials from the National Institutes of Health, and the University of Pittsburgh Research Conduct and Compliance Office, to monitor the study. Authorized representatives of UPMC or affiliated healthcare providers may also have access to this information to provide services and address billing and operational issues.

We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but we cannot guarantee the confidentiality of your research

records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

Will I feel comfortable during the study participation?

Our procedures are designed for comfort. You do not have to answer any question that you do not want to. You do not have to give any reason for not wishing to respond to the question. You can feel free to ask questions now or later. All research activities will take place in your home, and you will play an active role in building new routines to try in your daily life. We will provide all supplies you need to collect data in your home. You will not be asked to share information that you do not want to share. Neither you nor your insurance provider will be charged for the cost of the procedures performed only for the purposes of this research study.

Are there risks?

Likely, some children may not like wearing the devices – as they are new and may cause minor discomfort. We will adjust them to fit your child. We will also ask you to look at your child's skin often to ensure it is healthy. There is a less likely risk that the devices will hurt your child's skin. If so, you should remove it and contact us. There is also an unlikely risk that the personal information you provide to us will be seen by someone other than the research team. We take many steps to protect your information and to decrease this risk.

Are there benefits?

We cannot guarantee any benefits from being in this research study. There is a chance you and your child may benefit from the intervention you receive. If you are assigned to receive PrO-PEAR, you will learn how to promote health and growth for your child in important areas (e.g., nutrition and movement). If you are assigned to EUC, you will receive valuable insights into your child's performance in the areas of healthy eating, activity, and sleep. We can refer you to local programs, such as Down syndrome clinics, parent organizations, and local Early Intervention agencies to meet other needs that you have. Reach out to your local agencies or contact our team to help you learn more about these programs.

Can my or my child's data be used for medical purposes?

No. Data are collected for research purposes only. This data will not be used clinically.

Will I be paid to participate in this research study?

Yes. You will receive:

- $75 for completion of each assessment appointment (including wearing devices for one week).

If you would like to withdraw from the study, you will be paid for each assessment time point you have already completed. You may receive up to $225 for completing all study tasks.

Who will know that I am taking part in this research study?

We will not tell anyone about you or your child being in this study. We will use numbers instead of names on your files. The code that links these numbers to you is stored in a secure web-based server in a different location than other data. Only our team will have access to the data. It is possible that we will share de-identified data with research colleagues here or at other universities. You will never be mentioned by name in any publication of the results.

Your information may be shared with other groups, possibly including authorized officials from the Food and Drug Administration and the University of Pittsburgh Office of Research Protections, to monitor the study. You are allowed to withdraw from this study at any time. Any data obtained up to that point will continue to be used by the research team.

All research records must be maintained, per University of Pittsburgh policy, for 7 years after study participation ends. In unusual cases, your research records may be released in response to an order from a court of law. Also, if the investigators learn that you, your child, or someone with whom you/your child are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Because we will meet with you more than once, we will ask you for your email address and a phone number for contact. By signing this form, you will be stating that you allow us to contact you for the follow-up to complete assessments and to collect the study supplies after you are done being in the study.

If I agree to participate, can I later decide that I don't want to participate?

Being part of this study is completely voluntary. You can, at any time, withdraw from this research study. This means that you and your child will also be withdrawn from any other research tasks for this study. We will use the data that we gathered before the date you withdrew from the study for research purposes.

To withdraw from this research study, you should provide a written and dated notice stating such to the principal investigator at the address listed on the first page of this form. Your choice to withdraw from this study will not affect your or your child's current or future relationship with the University of Pittsburgh.

Your choice to withdraw your consent to be part of this research study will have no effect on:

a) your or your child's current or future medical care at a UPMC hospital or affiliated health care provider
b) your current or future relationship with a health care insurance provider.

Can I be removed from the study?

If you cannot complete research tasks, we may dismiss you from this study. Any data collected up to that point may continue to be used.

Disclosures

None of the researchers in this study have anything to disclose, and no researcher in this study will benefit or profit from your participation in this study.

Please feel free to contact us at any time:

Dr. Angela Caldwell (Principal Investigator), phone: 412-383-7231, email: arl78@pitt.edu

Voluntary Consent for Parent and Child Participation

All of the above has been explained to us and all of our current questions have been answered. We understand that we are encouraged to ask questions about any aspect of this research at any time. Any questions we have about my/my child's rights, as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study, which includes data collection over one week in my home. I understand that, as a minor (less than 18 years), the below named child is not permitted to participate in this research study without my consent. By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____
Child's name (print)

_____ _____
Parent's name (print or type) Relationship to child

_____ _____
Parent's signature Date

OPTIONAL CONSENT:

- ☐ I provide my permission for the identifiable video-recordings of sessions to be used for educational (in addition to research) purposes.

- ☐ I would like to be contacted about future research related to building healthy routines.

_____ _____
Name (Print) Date

_____
Signature

_____

Person Obtaining Consent

CERTIFICATION of INFORMED CONSENT:
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____	_____
Name of Person Obtaining Consent (Print)	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date