CONSENT FORM: Ages 18 and up

Study Title: Lifestyle Enhancement for ADHD Program (LEAP) Study

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The Research Team:

Name/Degree	Phone Number	E-mail
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If you have questions about your rights as a research study participant, you can call the Institutional Review Board at (206) 987-7804.

24 hour Emergency Contact Number(s): 206-884-1130

1. Researchers' Statement:

You have the option to take part in a research study. The goals of this form are to give you information about what would happen in the study if you choose to take part and to help you decide if you want to be in the study.

Feel free to take notes, write questions or highlight any part of this form.

Potential Participants 18 years and older: This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care at Seattle Children's.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

3. What is the goal of this study?

The goal of any research study is to answer questions. We (the research team listed on the front of this form and our staff) are doing this research study to answer the question:

- Is a family-based ADHD intervention involving increased physical activity and behavior management training for parents feasible to provide, acceptable to families, and helpful for improving behavior?

4. Why do I have the option of joining the study?

You have the option to take part in this research study with your child because you have a child that is 5-10 years old that has been diagnosed with ADHD.

5. How many people will take part in the study?

We think that about 45 families will take part in this research study at Seattle Children's.

6. If I agree to join this study, what would I need to do?

If you join the study, first we would ask you to participate with your child in a screen to determine if you are eligible for this study. This screen would involve filling out several questionnaires and an interview, taking up to 1.5 hours total. If we determine you and your child qualify to join the study, you would be asked to complete some surveys and participate with your child in a program to help with managing ADHD. Parents will be asked to attend 8 weekly group program sessions lasting 1.5 hours each with other parents, and join a Facebook

group associated with the group. . We would also ask that you and your child to wear a wristband that monitors your physical activity. At the end of the procedures, you will be asked to participate in a focus group so that we can get your feedback about how the study went for you and your child.

Explanation of Research Procedures:
The procedures that would be part of this study include:

- Surveys: You will be asked to answer questions about you and your child's activity, health, and parenting. We will also ask your permission to send some forms to your child's teacher for them to fill out.
- We will ask you to wear an Activity Wristband (Garmin Vivofit3): A small, light, battery powered band, similar to a Fitbit or small watch that is worn on your wrist. It measures your activity using steps and minutes of activity. To use this device, we will ask you to put an app on your smart phone or iPod so the data from the device can be tracked for the study. If you do not have a smart phone or iPod, you can borrow one during the study.
- Participation in weekly intervention group: This parent group will meet weekly at Seattle Children's for approximately 8 weeks. The interventionists will cover topics such as ADHD, physical activity, sleep, and goal setting. You and your child will be asked to do "homework" between meetings to work on specific topics that were covered in the sessions.
- Participation in Facebook parent group: A private Facebook group to encourage physical activity and promote social support and positive parenting will be created for this study. You will be asked to follow this group and participate by liking, commenting, or posting to the extent that you feel comfortable We will also encourage you to share your Vivofit data on your personal Facebook page.
- We will be using a texting platform to text you during this time to send you reminders and goals.
- Participation in a focus group: we will ask you to participate in a one hour focus group at the end of the 8 week intervention sessions to give feedback on your experiences. This focus group will be audio recorded.

Procedures that would happen to your child are described in the accompanying parental permission form.

Research Study Visits:

Visit #	Procedures	Location	How much time the visit will take
#1 Screening Visit	• Surveys • Interview	Seattle Children's	**1.5 hours**
#2 -5	• Participate in weekly group intervention meetings • Wear activity wristband	Seattle Children's (wearing device at home)	**1.5 hours each week**
#6	• Surveys	Seattle Children's	**30 minutes**
#7-9	• Participate in weekly group intervention meetings • Wear activity wristband	Seattle Children's (wearing device at home)	**1.5 hours each week**
#10	• Follow-up assessment and Focus group	Seattle Children's	**1.5 hours**

7. How long would I be in the study?

If you choose to take part in all the study visits, you would be in the study for 10 weeks.

Results will be shared with participants once finalized and published.

If you join the study, you can decide to stop **at any time and for any reason**. If you decided to stop, please let the researchers know. We may ask about your decision to leave the study and ask some follow up questions about your experiences to improve studies in the future.

8. What are the potential harms or risks if I join this study?

- You many feel uncomfortable discussing personal experiences and opinions. Some of the questions in the surveys involve sensitive content about suicidal thoughts, illegal activities, etc. Research staff are trained to provide appropriate support and help participants should you feel any discomfort.
- You may feel uncomfortable having your and your child's physical activity monitored.
- The wrist activity tracker and hip activity meter are small, lightweight electronic devices that are designed to be worn over long periods of time by children and adults. Some people may feel slightly uncomfortable wearing the devices for long periods of time.

- Some people may feel that wearing an activity meter is an invasion of privacy.
- Some participants may feel embarrassed if their devices are seen or questioned by others.
- You may feel embarrassed about sharing your experiences and physical activity in a group setting or via discussions on social media.

9. What are the potential benefits if I join this study?

Potential Benefits for You:

Being in this study might benefit you in the following ways:

- You may experience changes in your physical activity.
- Your child may experience in physical activity, as well as a decrease in ADHD symptoms and associated behavioral difficulties through participation in the intervention program
- There may be no benefit to either you or your child.

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Potential Benefits for Others:

We hope to use information we get from this study to benefit other parents who have children with ADHD.

10. What other options do I have?

The alternative to participating in this study is to not take part. You can seek out other means to address your child's ADHD.

11. What about confidentiality and privacy?

If you join the study, we will keep your information confidential as provided by law.

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.
- If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research information may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

There is no time limit for the use or sharing of your information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If your information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about you, but information that has already been collected may still be used and shared with others.

The use or sharing of your information will follow privacy laws, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you would not be used.

Your permission is documented by signing this form below. If you decide that we cannot use or share your information, you cannot participate in this study.

Certificate of Confidentiality

We have a Certificate of Confidentiality from the federal government. It means we can't be forced to give out information about you if you take part in this study. This is true even if we are asked to by a court of law. It's not likely that someone would ask us to give out your personal information but this Certificate helps protect it. However, there are times when we would still need to share information about you.

Even with the Certificate, your information could still be given out under these situations:

- Federal agencies, like the FDA, may review study records
- Seattle Children's or the funding agency may look at study records to make sure the study is being done well
- You or a family member could share information about you or your part in this research study
- You give written permission to an insurer, employer or other person to receive information about you
- We must report child abuse or if you intend to hurt yourself or others

Note that as part of this study, you will also be asked to use the Garmin and Facebook applications/websites and will need to agree to their terms of service.

12. Would it cost me money to be in the study?

If you take part in this study, there would be no cost to you and no cost to your insurance company.

13. What if I were injured because I joined the study?

We do not anticipate that any study procedures will cause you or your child to be injured.

If you think you have been harmed from this study, please contact Pooja Tandon (phone 206-884-1130 or pooja.tandon@seattlechildrens.org).

14. Would I be paid if I join this study?

The study will reimburse you for out-of-pocket costs to you. This would include:

- Childcare or Transportation costs to the hospital or clinic for study tests and visits. Parent participants will be given $20 to cover childcare/transportation costs for each study assessment visit you attend (NOT each of the 8 group program sessions).

You will receive compensation for completing study assessments in the following amounts: (1) $15 for screening visit and completion of accelerometry screening; (2) $25 for completing the baseline visit (3) $25 for Week 5 assessment (4) $50 for week 9 assessment (5) $15 for participating in focus group. The amount will total $130 per family.

You would receive the payment on a Seattle Children's reloadable debit/gift card called a ClinCard. The study staff will provide you with additional information about how the ClinCard works. It is important that you do not lose the ClinCard. Costs for replacing a lost or stolen ClinCard will be your responsibility. The cost to replace the ClinCard is $7.

The IRS has certain rules about paying people who take part in research studies. If you took part in this study, we would ask you to provide your name, mailing address, and social security number so we could pay you.

You can be in this study even if you do not give us this information. If you decide not to give us this information, you would receive no payment.

The payments you would receive for being in this study might be taxable. Seattle Children's is required to report to the IRS study payments totaling $600 or more made to anyone in any year.

15. Who do I contact if I have problems, questions or want more information?

If I have questions or would like to know about …	You can call …	At …
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Pooja Tandon	Phone: 206-884-1130
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	Erin Schoenfelder Gonzalez	Phone: 206-987-2161

If I have questions or would like to know about …	**You can call …**	**At …**
• **Your rights as a research participant** • **Study questions, concerns or complaints.** • **Contacting someone outside of study team**	**Institutional Review Board This is a group of scientists and community members who make sure research meet legal and ethical standards**.	**Phone: (206) 987-7804**

16. If I join the study, can I stop?

Yes. Taking part in research is always a choice. If you decide to be in the study, you can change your mind at any time. We ask that you tell Pooja Tandon. You can contact this person by phone/email at (206)884-1130 or pooja.tandon@seattlechildrens.org

If you choose to leave the study, it will not affect your care at Seattle Children's. You will not lose any benefits or be penalized if you choose to leave the study.

If you decide to stop participation in the study, the data collected until the time you withdraw will remain part of the study database unless you request us to remove it. We would not be able to delete data collected within the Garmin smartphone application, but this would be retained consistent with the terms and conditions of the application.

17. What would my signature on this form mean?

Your signature on this form would mean:

- The research study was explained to you.
- You had a chance to ask all the questions you have at this time. All your questions have been answered in a way that is clear.
- You understand that the persons listed on this form will answer any other questions you may have about the study or your rights as a research study participant.
- **You have rights as a research participant. We will tell you about new information or changes to the study that may affect your health or your willingness to stay in the study.**
- By signing this consent form, you do not give up any of your legal rights. The researcher(s) or sponsor(s) are not relieved of any liability they may have.
  - You agree to take part in the research study.
  - You permit the creation, use, and sharing of your health information for the purposes of this research study as described in Section 11 above.

Please Note: If the person taking part in this research study is a foster child or a ward of the state, then please tell the researcher or their staff.

_____
Printed Name of Research Participant

_____
Signature of Research Participant

_____ _____
Date *Time*

_____
Printed Name of Parent or Legally Authorized Representative

_____
Signature of Parent or Legally Authorized Representative

_____ _____
Date *Time*

For study team use only:

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient.
- ❑ Second parent is deceased, unknown, incompetent or not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

For study team use only (fill out for any enrolled minors and any enrolled adult participants incapable of providing consent):

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

18. Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/ legally authorized representatives questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

_____

Printed Name of Researcher Obtaining Parental Permission or Consent

_____

Signature of Researcher Obtaining Parental Permission or Consent

_____ _____

Date *Time*

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Contact Information

We may text or e-mail you information about parent group or your weekly activity goals. Please provide your contact information below.

☐ Cell Phone: _____
(Check if preferred contact)

☐ E-mail: _____
(Check if preferred contact)

Original form to:
Research Team File

Copies to:
Participant