
# Feasibility Trial of the iAMHealthy Intervention for Healthy Weight in Rural Children Recruited From Primary Care Clinics

NCT04142034

Informed Consent Document (May 28, 2020)

Study Title: Feasibility Trial of the iAmHealthy Intervention for Healthy Weight in Rural Children Recruited from Primary Care Clinics
PI (researcher): [insert local context here]
Institution: [insert local context here]
Sponsor: ISPCTN DCOC
Support: National Institutes of Health (NIH)

KEY INFORMATION FOR

# Feasibility Trial of the iAmHealthy Intervention for Healthy Weight in Rural Children Recruited from Primary Care Clinics

We are asking you to choose whether or not to volunteer you and your child for a research study about children who weigh more than is generally considered healthy. Researchers want to find out how to ask people to be part of the study and how to keep people in the study after they volunteer. The researchers will also determine how well 2 different educational methods work to help improve your child's health.

This page and the next page give you key information to help you decide whether to participate. We have included detailed information after these pages. Ask the research team questions. If you or your child have questions later, the contact information for the research investigator in charge of the study at your site is provided near the end of this form.

## WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

- We are doing this study to find out which of 2 ways works best to get rural participants interested in a research study about children whose weight is above the healthy range.
- We also want to find out which of 2 ways work best for keeping participants in the study once they have decided to be in the study.
- We want to find out how well participants follow the study instructions.
- We want to find out if one of 2 methods is better than the other for helping improve the health of children who weigh more than is recommended for children of their age and sex. The 2 methods are newsletters only and newsletter plus behavioral intervention (also called electronic tablet group). We want to know if one of the 2 methods is better than the other for lowering a child's weight, increasing his/her physical activity, and increasing the amount of fruits and vegetables a child eats.
- We also want to find out if the tablet method works equally well in different parts of the country and with different groups of people.
- You/your child's participation in this research will last about 28 weeks. If you join, you/your child will be assigned the newsletter only group or the electronic tablet group. The chance of being in either group is like the chances of getting either heads or tails when you flip a coin.

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## WHY MIGHT I CHOOSE TO VOLUNTEER FOR THIS STUDY?

You and your child may not benefit directly from being in this study. Benefits could include improvements in you/your child's weight management skills and overall health.

- For a complete description of benefits, refer to the Full Consent.

## WHY MIGHT I CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

- Someone could find out that you/your child are in the study and learn something about you/your child that you did not want others to know.
- You/your child may feel like being in the study is too much work.
- For a complete description of risks and alternative treatments, refer to the Full Consent and/or ask your doctor.

## DO I HAVE TO TAKE PART IN THE STUDY?

No. It is okay to say no. If you/your child decide to take part in the study, it should be because you really want to volunteer. You/your child will not lose any services, benefits, or rights you would normally have if you/your child choose not to volunteer.

If you want to know more about the research, let the study team know so they can give you more information.

Also, tell the study team if you have decided you don't want to be in the study. It is perfectly okay to say no.

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# <insert local institution name>

## Informed Consent Form

- **We are asking you and your child to be in a research study. You do not have to join the study.**
- **You/your child can still get your medical care from [insert local context] even if you are not in the study.**
- **Please take as much time as you need to read this form and decide what is right for you and your child.**

### Why am I being asked to be in this research study?

- We want to learn which of 2 ways will work best to get parents/guardians and children interested in being part of a research study about children who weigh more than is generally considered to be healthy.
- We want to learn which of 2 ways will work best to help parents/guardians and children keep participating in a research study they have already agreed to be in.
- We are asking children who are considered to be in the unhealthy weight range, plus 1 of the child's parent(s) or legal guardian(s), to be a part of this study.
- Children between 6 and 11 years old at the time the consent form is signed will be part of this study.
- Up to 224 children, as well as one of each child's parents/guardians, will be consented for this study. There will be up to 32 child + parent/guardian pairs randomized into the study in <insert state/location name here>.

### What if I don't understand something?

- This form may have words you don't understand. If you'd like, research staff will read it with you.
- You/your child are free to ask questions at any time – before, during, or after you and your child are in the study.

- Please ask as many questions as you like before you decide whether you want you and your child to be in this study.

**What will happen if I say yes, I want to be in this study?**

We first will see if your child qualifies to be in the study. We will:

- Check your child's height and weight and then determine body mass index (BMI). BMI is calculated from height and weight measurements. Your child's BMI will be compared to the BMI of other children who are the same age and same sex.

  You and your child can be a part of the study if he/she has a BMI that is higher than 85% of children who are the same age and sex.

- Make sure your child is between 6 and 11 years old (up to the day before his/her 12th birthday) at the time of consent.
- Make sure your child lives a rural area.
- Make sure you and your child speak English.
- Make sure your family can make the meeting times if assigned to the electronic tablet group.

**You and your child CANNOT be part of the study if**:

- Your child does not receive both well-child care and sick care from the clinic or practice from **[insert name of clinic]**. (If you change clinics after you sign this form, you can still be in this study.)
- Your child has a physical problem that keeps him/her from doing the physical activity part of the study.
- Your child has a major medical issue (such as cancer).
- Your child has a major developmental delay or a condition that prevents him/her from understanding the material that will be given to him/her.
- Neither parent/guardian is able to understand the material that will be provided.
- Your child has a brother or sister who is already signed up to be in this study.

**If your child qualifies and if you agree to participate, we will do these things:**

- Both you (1 parent/guardian) and your child will be involved in this study. You will be asked to provide information about you/your child's health and behavior.
- At various times in the study we will ask you/your child questions. You/your child can skip any questions that either you/your child do not want to answer. We will help you answer questions if you want us to help.

**The following information will be collected:**

- Height and weight of you and your child
    - Your child's height and weight will be measured or you will be asked to measure your child's height and weight. This will be done 3 times. The times are:
        - after the consent form is signed,
        - during baseline measures,
        - after the intervention occurs, around 28 weeks.
    - Your height and weight will be measured or another adult will be asked to measure your height, and you will be asked to measure your weight. This will also be done 3 times. The times are:
        - after the consent form is signed,
        - during baseline measures,
        - after the intervention occurs, around 28 weeks.
    - Your body mass index (BMI) and your child's BMI percentile score will be figured out from these height and weight measurements.

- Physical Activity of Child
    - Physical activity will be measured by your child wearing the ActiGraph Physical Activity Monitor over his/her hip. It will be on a belt. You will receive detailed instructions on wearing and caring for the monitor. You will be asked to write down what times your child wears the monitor. The monitor will be worn for a maximum of 7 consecutive days and a minimum of 4 consecutive days at 2 different times during the study. The times your child will wear the monitor are:
        - After you sign this document,

        - After the intervention (between weeks 25 and 28).

- What Foods Your Child Has Eaten
    - You/your child will be asked about what your child has eaten over the last day. You will receive information to help you with this task.
        - At the beginning of the study, there will be a series of 3 phone calls to talk about what your child ate. All calls will take place within 1 week.
        - There will be a final series of phone calls after the intervention (between 25 and 28 weeks).
    - Each call will last for 15-30 minutes. Calls will be with the team of people who are conducting the research study.

- General information about your family and your family's health and daily activity, including:
    - The following questions will be asked only at the beginning of the study:
        - You will be asked questions about you/your child's date of birth, race, ethnicity, education, and income.
        - You will be asked about you/your family's physical activity, eating habits, and ability to buy food.
- Post-Trial Questionnaire
    - You will be asked to complete a 2-part post-trial questionnaire at the end of the study. This questionnaire has about 100 questions and includes questions about how much time you spent doing the study, your feelings about a number of issues, your satisfaction with the study, and more. You will not be asked to answer any questions that you do not want to answer or that make you uncomfortable.
- Throughout the study, you/your child will be contacted periodically to encourage you/your child to remain in the study. These contacts may include thank you cards, texts, or emails.

After participants have consented to be in this research study, each family (child + parent/guardian) will be told they are in one of two groups. The two groups are the newsletter-only group or the electronic tablet group. Participants in both the newsletter-only group and electronic tablet group will provide the same information to the

researchers. All participants in both groups will have the same measurements taken.

- Group 1 (Newsletter-only Group)
  - Group 1 participants will get their information from a newsletter. Each newsletter will have nutritional, exercise, and behavioral suggestions to improve your child's health.
  - Group 1 will be considered the control group.
  - If you are in Group 1, you will receive your newsletter once a month for 6 months. You will get the newsletter by regular mail.
- Group 2 (Electronic Tablet Group)
  - Group 2 participants will get most of their information through an electronic tablet. Group 2 participants will also get the same hard-copy newsletter that the newsletter-only group gets. The newsletter will be delivered by regular mail.
  - The researchers will loan the electronic tablet to the family.
  - The electronic tablet will have a mobile meeting app like Zoom or GoToMeeting™. Researchers will teach participants how to use the mobile meeting app.
  - Group 2 families (1 parent + 1 child) will use the mobile meeting app to have group meetings for about 1 hour each week. Weekly group meetings will occur once a week for 12 weeks. You and your child must be present for the whole hour of each weekly meeting. Other members of your family like your child's brothers and sisters or the other parent can join the meeting too, but they will not have any measurements taken or be asked to answer any questions.
  - After the first 12 weeks, families will have group meetings for 1 hour, once a month, for 3 months.
  - The group meetings will include you and your child plus up to 27 other families from the same clinic your child goes to.
  - Families will call into the group meetings from their homes. Meetings will usually take place in the evenings or during the weekend.
  - Group meetings will include information about healthy eating, exercise, and behavior. This information is meant for you and your child to use to

help improve your child's health. You and your child need to participate in all group meetings.

- Between group meetings, you and your child will use the electronic tablet to meet with a health coach. You and your child will have homework. Your coach may help you complete the homework. There will be 11 hours of homework total.

- Group 1 and Group 2 – Return of Equipment
  - The study team will mail you a scale and tools to measure your height. If you do not qualify for the study, you will mail those back to the study team using the box provided. If you do qualify for the study, you can keep the scale and measurement tools.
  - You will be asked to return the ActiGraph physical activity monitor and, if applicable, electronic tablet at the end of the trial.
  - You may mail the Actigraph directly to the study staff at

    [insert local context here].

    If you are in the electronic tablet group, you will be asked to return the tablet using a pre-addressed box. You will be given additional instructions for returning the tablet when it is time to return it.

    If you do not return these devices, final study payment may be withheld until the devices are returned.

**How long will this study take?**

The study will take about 28 weeks (7 months) to complete:

- Participants in Group 1 (newsletter-only) will get a newsletter once a month for 6 months. After month 6, participants will be asked to provide additional information and may be asked to go to the clinic office.
- Participants in Group 2 (tablet) will meet (by internet) once a week for months 1-3, then once a month for months 4-6. After month 6, participants will be asked to provide additional information and may be asked to go to the clinic office.

**What if I say no, I do not want to be in this study**?

- Nothing bad will happen.

- You can still get medical care at [insert local context / clinical name].

**What happens if I say yes, but change my mind later?**

- You and your child can stop being in the study at any time.
- Nothing bad will happen.
- You/your child can still get medical care at [insert local context / clinical name].
- If you/your child decide to stop being in the study, call [insert head researcher name here/local context] at [insert local context telephone contact number of head researcher].

**Will it cost me anything to be in the study**?

The study will not cost you or your child anything. You or your child's insurance company will be responsible for your child's regular medical care, as usual.

**Will I be paid for being in the study?**

Yes. We will give you $20.00 when you sign and return the consent form. Then, you will receive $20.00 for each month you remain in the study, during the 6-month intervention period. This will be given to you each month as you go through the study. At the end of the study, when you have completed all of the measurements, phone calls about what your child ate, activity monitoring, and returned any study equipment, you will receive $100. If you are in the study for all 6 months, you will receive $240.00. This is to thank you for your time. We will give it to you [insert local context method of payment].

If you change your mind and decide not to be in the study, you will only be paid for the parts of the study that you/your child have completed.

If you receive more than $600 in one year (January-December) from *(insert local context/institution)*, we may send you a tax form if required by law.

**Will being in this study help me/my child in any way**?

Being in the study may or may not help you or your child, but may help people are who are in the unhealthy weight range (BMI is too high) in the future. What we learn may help you/your child in the following ways:

- You and your child will have the chance to learn about nutrition, exercise, and behaviors that may improve your and your child's:
  - weight and/or weight management skills,
  - overall health,
  - family's social interactions.

**What are the risks of being in this study?**

The risks are:

The risks for this study are no more than what happens in everyday life.

- Someone could find out that you/your child are in the study and learn something about you/your child that you did not want others to know. We will do our best to protect your/your child's privacy.
- You or your child may engage in weight loss habits that are not good for you.
- You or your child may feel like it's a lot of work being in the study.
- You or your child may feel like being in the study causes interactions with family to be more difficult.
- Your child could get minor sprains or strains in his or her body because of the physical activity required in the study.

**What if I get sick or hurt while I'm in this study?**

*LOCAL CONTEXT*

- If you get hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and/or follow-up care.
- If you are not here and get hurt or sick, and think it is because of the study, do these things:
  - ✓ call your doctor or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study *(insert name of study)*
    - the name of the head researcher for this study *(insert researcher name)*

- a copy of this form if you have it

✓ call the head of the study *(insert researcher name and 24 hour phone #)*

*Choose from these options:*

- This treatment may be billed to you or your insurance company in the normal manner. No other form of payment is available.

**What are the alternatives to being in this study?**

You and your child do not have to be in this study. If you do not want you and your child to be in this study, the options are to get individual treatment or enter a program for controlling weight.

**Can I/my child be taken out of the study even if I/my child want(s) to continue?**

Yes, the study doctor (or head researcher) can take you and your child out of the study if:

- You or your child do not follow study instructions.
- It is not in you or your child's best interest to continue.
- The study is stopped for any reason.

**What information will be collected about me and my child in the study?**

During the study, we will need to learn private things about you and your child, including:

- Name
- Date of birth
- General contact information about you and your child, such as address, telephone number, and email address
- Medical information, such as medical history, including current height and weight
- Demographic information, such as race, ethnicity, education, family income, and other information about your family

- For those in the tablet group, video & voice recordings will be made of the online sessions.

**Who will see this information? How will you keep it private?**

- The study team will know your and your child's name and have access to your/your child's information.
- We will do our best to make sure no one outside the study knows you or your child are part of the study.
- You/your child's information will be sent to the lead study team for the IDeA States Pediatric Clinical Trials Network at the University of Aransas for Medical Science. This information may include protected health information, such as date of birth, but will not include you or your child's name. You will be asked to sign a separate HIPAA authorization that will allow us to use protected health information that we need to do this study.
- We will take you and your child's name off information that we collect from you during the study. You/your child's names will be replaced with a code. Only the study team will be able to link your identity to the code.
- When we share the results of the study, we will not include you or your child's name or anything else that identifies you or your child.
- There are people who make sure the study is run the right way. These people may see information from the study about you or your child. This information may include information that identifies you or your child. The people that may see this information are:
    - National Institutes of Health (NIH)
    - IDeA State Pediatric Clinical Trials Network (ISPCTN) Data Coordinating and Operations Center (DCOC)
    - OHRP (Office for Human Research Protections), a federal agency
    - Members of the UAMS IRB and other institutional oversight offices
    - Study monitor
    - Members of the local context: local name IRB
    - Overall-study Principal Investigator (PI)
    - site Investigator name

- [Add local context site

- Additional LOCAL CONTEXT re: state laws: Example 1: State law requires that we report to the Arkansas Department of Health cases of certain diseases that a sick person could give to someone else. If we learn you have such a disease, we will share your name and contact information with the health department. *(Include only if applicable,*
- Example 2: State law requires we tell the authorities if we learn
  - about possible child or adult abuse
  - that you might hurt yourself or someone else

**Where and how long will my information be kept?**

- We will code your and your child's information and limit access to the code. Only people who must have access will be allowed to see the information.
- Only the study team and ISPCTN DCOC (the study sponsor) will be able to link your information to you and your child.
- LOCAL CONTEXT (change if needed) We will put a copy of this form in you/your child's medical record.
- You/your child's information will be kept for insert length of time and other pertinent local context.

**If my child and I stop being in the study, what will happen to any information collected from me and my child in the study?**

- We will not be able to take you or your child's information out of the study after it has started.

**Will my and my child's information from the study be used for anything else, including future research?**

This study is funded by NIH, which means all of the de-identified study data must be made available to the public, per NIH policies. This means the data can be used for future research and can used by other researchers.

The data will be de-identified, which means no one will be able to tell that the information came from you or your child. Since the data will be de-identified, other researchers will be able to use these data without getting additional consent from you.

**Will you tell me the results of the study?**

- No. We will not notify people in the study about what we find. We will, however, publish the results in an academic journal. (What we publish will not include anything that can identify you though.)

**Will you tell me anything you learn that may impact my health or my child's health?**

- Yes. We will send out letters that include your child's key results from the study.
- If we learn anything, in addition to the key results, about you or your child that might be important for your or your child's health, we will tell you.

**What if new information comes up about the study?**

- We want you and your child to know about anything that may change your mind about being in the study.
- The study team will let you know by one or more of the following:
  - calling you
  - sending you a letter
  - telling you at a follow up visit

**Where can I find more information about this clinical trial?**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

**What if I have questions**?

- Please call the *<insert title (Principal Investigator, site investigator and/or other title)>* of the study *<insert researcher name and phone #>,* if you:

  - have any questions about this study
  - have questions about you/your child's rights
  - feel you/your child have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you can't reach the study team or want to speak to someone not directly involved with this study. To do so call the UAMS Institutional Review Board at 501-686-5667.

**By signing the document, I am saying:**

- I understand that joining this study is voluntary.
- I agree to be in the study and for my child to be in the study.
- Someone talked with me and my child about the information in this document and answered all of my questions.
- I have been asked if I wish to talk directly to the study doctor.

**I know that**:

- I can stop any and all parts of the study at any time and nothing bad will happen to me/my child.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my or my child's rights.
- [Insert additional local context if appropriate/required]
- I do not give up any of my/my child's rights by signing this form.
- My decision will not change my/my child's medical care at [Insert local context institution name here].

**I agree to be part of this study and to allow my child to be part of this study:**

_____
Printed Name of Parent or Legal Guardian

_____ _____
Signature of Parent or Legal Guardian Date (mm/dd/yyyy)

**Child's Name:** _____

**Person Obtaining Consent:**

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date (mm/dd/yyyy)