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COMPOUND AUTHORIZATION AND PARENTAL PERMISSION FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: ***Randomized Study Of Novel Enuresis Alarm (GoGoband®) Vs Standard Bedwetting Alarm***

Principal Investigator (the person who is responsible for this research):
Adam Hittelman, MD, Ph.D
789 Howard Ave
New Haven, CT 06520
Phone Number: **203** 645-9662
24-Hour Phone Number: **203 785 7671**

Research Study Summary:

- We are asking your child to join a research study.
- The purpose of this research study is to evaluate the effectiveness of standard bedwetting alarm and GoGoband®
- Study procedures will include: your child will be asked to use and/or wear a bed wetting device at night for 3 months and have 4 check in visits.
- Your child will be randomly assigned one of 2 alarms, either a GoGoband® or a standard bedwetting alarm.
- You will then keep track of nightly accidents and whether the alarm was used that night and did your child wake up with the alarm.
- 4 visits are required.
  These visits will take 2 hours total.
  There are some risks from participating in this study in that alarms may wake up other family members, the alarms may startle some children, or your child may not become dry with use of the alarm.
- The study may have potential benefits to your child by helping to stop their bedwetting problems during the study. We may find out which alarm works better for other people with similar bedwetting issues.
- There are other choices available to your child outside of this research. You can decide to not participate in this study and undergo no treatment, treatment with either medications or alarm therapy of your choice.
- Giving permission for your child to take part in this study is your choice. You can choose to give permission, or you can choose not to. You can also change your mind at any time. Whatever choice you make, your child will not lose access to his or her medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to give permission for your child to participate; if so, you will have to sign this form.

Why is this study being offered to my child?

We are asking your child to take part in a research study because your child has bedwetting that we describe as monosymptomatic nocturnal enuresis in plain language simple bedwetting. We are looking for 100 children to be part of this research study.

APPROVED BY THE YALE UNIVERSITY IRB 3/7/2024

Who is paying for the study?
GoGoband® is providing the alarms for the study from a research award that they received from the Southwest Device consortium and American Academy Pediatrics Section of Urology Pediatric Urology Device Prize

Who is providing other support for the study?
The department of urology at Yale School of Medicine

What is the study about?
The purpose of this study is to compare standard bed wetting alarms with the GoGoband® bed wetting alarm. Standard bed wetting alarms have had a success rate of less than 50% success. Data from patients who have used GoGoband® bed wetting alarms have shown to have a much higher success rate at staying dry at night. This study will compare the results of the 2 systems to see which one is better at preventing bed wetting.

What are you asking my child to do and how long will it take?
Since you have decided to use a bed wetting alarm system for your child, as part of this research your child will be randomly assigned (like flipping a coin) to use either a typical bed wetting alarm system or a new alarm system called the GoGoband alarm system.

We ask that you and your child maintain a log nightly and record whether they have device and also whether they have had an accident or remained dry.
We ask that you and/or your child forward to us the log sheets every two weeks or bring them in at each monthly visit which can be a video or in person visit for 3 months.
You will need to have a visit at 1, 2, 3 months which should last each about 15 minutes.

Standard bedwetting alarm patients:

- The alarm comes in 2 parts and the sensor will be attached to the underwear to detect moisture. The alarm unit will be attached to the night clothes. The nightclothes should be worn over the wire to prevent the child from entangling themselves in the wire and pulling off the sensor. The alarm will ring and also can vibrate if it is set to vibrate. The parents are expected to wake up and make sure the child has woken up with the alarm. A bed pad can be used to keep the bed dry or pull ups if this is the regular routine. If the child uses pull ups they should wear underwear and attach the wetting sensor to the underwear then put on the pull up, otherwise the sensor will not record moisture through the pull up.

GoGoband® alarm patients:

- There are 4 parts to the alarm; a tablet, a bracelet that measures heart rate, a wetting sensor and a parent app. The tablet will be set up at the bedside and needs a good wifi signal to function properly. Loss of the signal during the night can render the alarm nonfunctional and will not help prevent wetting. The bracelet will be placed on the calf or upper arm depending on preference to the child. The Wetting sensor will be attached to the underwear and if the patient or parent wishes they can place a pull up over the underwear to prevent soiling the bed or use a bed pad. The parent app should be installed on the parent's cell phone since this will alert the parent that the child needs to wake up if they don't hear the bedside alarm. When a wetting incident is about to occur, the alarm will sound to wake the patient and it will also sound if the patient has a true accident. The first 7-14 days the system may only function like a regular bedwetting alarm meaning that it will alarm only when the patient wets themselves. This is normal

and part of the learning process for the system to recognize when the patient is going to have an accident. The less accidents the child has during the learning phase the longer it will take for the system to go into prediction mode. Once in prediction mode the alarm will sound as previously mentioned. After 4 consecutive weeks of dry nights the system will revert to weaning mode which will begin to not alarm every night to see if the patient is capable of remaining dry by themselves. If the patient has too many accidents during this phase it automatically goes back to prediction mode. These cycles continue until the patient ceases having accident.

What are the risks and discomforts of participating?

There minimal risk with using either alarm except that alarms are loud and may wake up other family members and startle some children.

- The child may become disoriented by the sound of the alarm. To mitigate this a soft rug or padding at the bedside will help prevent injury should your child roll out of bed upon awakening. Minimizing the elevation of the bed above the floor is advisable.
- The GoGoband® needs a good WiFi signal to function properly. Loss of the signal during the night can render the alarm nonfunctional and will not help prevent wetting and could lead to a wetting accident.
- There is a remote risk of electric shock since the both systems are battery operated low voltage system,
- In the standard alarm, there is a potential risk of becoming entangled in the cord during installation and during usage, however, wearing a shirt over the cord helps to minimize this risk.
- If you choose to attach the alarm unit using a safety pin, use of a secure pin that does not come loose easily can also help minimize this risk.
- Choking can be a hazard if any of the associated components are placed in the mouth. Since your child is 6 years or older, this is not expected to be regular behavior in children of this age. If you know that this is a behavior that your child exhibits, please let us know as your child may not be a candidate for this study.
- There may be no benefit from either alarm therapy

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about your child taking part in this study.

Investigator Interest:

A Co-investigator in this study is the Chief Science Officer at GoGoBand. He has not received financial compensation from the manufacturer of the device at this time but may in the future. You may request to speak with Dr. Franco about this interest.

How can the study possibly benefit my child?

Participation in this study may benefit your child by treating their nocturnal enuresis (bedwetting) using either bedwetting alarm. However, there is a possibility that neither alarm will help. Standard alarm therapy has success rates ranging from 30%to 50%. Participation in this study allows us to compare Regular alarms to a newer more technologically advanced alarm that in preliminary data has success rates that are higher than those of the prior mentioned method. In a side by side test in a well selected population we can see if the preliminary data is correct and this new treatment (GoGoband®) is better and more cost effective. In so doing if your child

fails to become dry after participating in this study, they could possibly benefit from the more advanced treatment of the GoGoband®.

How can the study possibly benefit other people?

Your child's participation may help us understand better ways to help other people with nocturnal enuresis.

Are there any costs to participation?

If your child takes part in this study, you will not have to pay for either of the bedwetting alarms or the service that monitors the GoGoband®. Since normal follow up includes monthly visits for the management of our bedwetting patient services, Your or your child's health insurance must pay for services, supplies, procedures, and care that are part of their routine medical care. You will be responsible for any co-payments required by your child's insurance.
There may be additional costs which can include costs of transportation and time to come to the study visits.
The GoGoband® monitoring service will be provided free for 6 months. After 6 months if you wish to continue to use the GoGoband® there is a charge to use the internet monitoring.

Will my child be paid for participation?

Your child will not be paid for taking part in this study. If you choose Alarm therapy, you will be provided with an alarm free of charge for the duration of the study and to keep. If the alarm you are given is the GoGoband® you will be provided with free internet monitoring for 6 months.

What are our choices if I decide not to give permission for my child to take part in this study?
Instead of participating in this study, you have some other choices.
Your child could:

- Get treatment without being in a study.
- You can decide to not participate in this study and undergo standard treatment with either desmopressin or alarm therapy of your choice.

How will you keep my child's data safe and private?

We will keep information we collect about your child confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that someone is hurting a child or an older person.
We understand that information about you obtained in connection with your child's health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and contact information and date of birth. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator (PI) will keep a link that identifies you to your coded information, and this link will be kept secure and apart from the data we collect, and available only to the PI and selected members of the research team. Your biweekly logs will be placed in your electronic medical record will be available to those that have access to your medical record. Any information that can identify you will remain confidential. All collected data will be stored in filing cabinets that are locked except when in use and in

password protected computers. The research team will only give this coded information to others to carry out this research study. The link to you and your personal information as well as your de-identified data, including the questionnaires, voiding diary, will be kept indefinitely.

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider).

When we publish the results of the research or talk about it in conferences, we will not use your child's name. If we want to use their name, we would ask you both for your permission.

We may also share information about your child with other researchers for future research but we will not use his or her name or other identifiers. We will not ask you for any additional permission.
Identifiers will be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

What information will you collect about my child in this study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your child's health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.
The specific information about your child and their health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your child's study visits
- Information obtained during this research regarding
    - Physical exams
    - Laboratory, x-ray, and other test results
    - Diaries and questionnaires
    - The diagnosis and treatment of a mental health condition
    - Records about any study drug your child received
    - Records about the study device

How will you use and share my child's information?
We will use your child's information to conduct the study described in this consent form.
We may share your child's information with:

- The U.S. Department of Health and Human Services (DHHS) agencies

- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about the ***bedwetting devices*** involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor or manufacturer of study drug/device
- Health care providers who provide services to your child in connection with this study.
- Laboratories and other individuals and organizations that analyze your child's health information in connection with this study, according to the study plan.
- The study's Principal Investigator
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your child's information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your child's information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your child's health information, agreements are in place with these individuals and/or companies that require that they keep your child's information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your child's information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your child's health information in their medical record.

What if I change my mind?

The authorization to use and disclose your child's health information collected during their participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to ***Israel Franco, MD 789 Howard Ave FMP308,*** at the Yale University, New Haven, CT 06520.

If you withdraw your permission, your child will not be able to stay in this study but the care they get from their doctor outside this study will not change. No new health information identifying your child will be gathered after the date you withdraw your permission. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

What if I want to refuse or end my child's participation before the study is over?

Allowing your child to take part in this study is your choice. You can choose to give permission, or you can choose not to give permission. You also can change your mind at any time. Whatever choice you make, your child will not lose access to his or her medical care or give up any legal rights or benefits.

Your child will be asked to give their assent to be in the study. If they decide they do not want to be in the study, they will not be enrolled in the study even if you have given permission. You will not be told the reason why your child didn't want to participate.

We would still treat your child with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your child's relationship with their own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want your child to take part.

The researchers may withdraw your child from participating in the research if necessary.

For the following reasons:
Non-compliant patients will be removed from the study. Alarms will not be requested back from the your child.
Reasons for noncompliance will be for the following reasons:
Not using device
Not filling in and submitting biweekly logs.

What will happen with my child's data if they stop participating?

When you withdraw your permission or if your child is withdrawn from the study, no new health information identifying your child will be collected after that date. Any information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **2037857671**

If you have questions about your child's rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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

Authorization and Permission

Your signature below indicates that you have read this consent document and that you give permission for your child to be in this study.

We will give you a copy of this form.

Your child's Printed Name		
Parent Signature	Relationship to your child	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date