

Children's Healthcare of Atlanta Consent to be in a Research Study

Title: A Test of the Effectiveness of Buzzy the Boo Boo Bee for Pediatric Immunization Pain

Principal Investigator: Amy Baxter, MD

If this form is being read by the parent or legal guardian, the term "you" refers to "your child."

You are being asked to volunteer for participation in a research study because you are going to get shots (immunizations) today. In order to decide whether or not you want to be a part of this study, it is important that you read and understand this form. It is also important that you ask any questions that you may have and that you understand all the information in this form. This process is called "informed consent."

Why is this study being done?

Usually children get shots without any pain control. There are problems with all the types of pain control that exist now: they take time, or are expensive, or are messy. Some children become overly scared of needles because of shot pain, and avoid medical care when they are older. To prevent this, it would be good to stop needle pain in children.

A small device that vibrates and is cold decreases needle pain in adults who are getting IVs. This study will see if children who use the device have less pain than children who get shots the normal way. Sixty patients will be enrolled in this study at Sandy Springs Pediatrics and Adolescent Medicine.

What will happen to you in this study?

If you chose to participate in the study, after you sign the consent form:

- You will be asked to fill out a family information form.
- You will be asked about your feelings about shots. Your nervousness in the waiting room will be recorded on videotape to be measured later.
- Some, but not all, children will test the new device called "Buzzy". Whether you use "Buzzy" or not will be determined by chance, similar to the throw of a dice. You will open an envelope that tells if you are in the group having shots as usual or in the group that will use the device ("Buzzy"). The groups were decided randomly before the study started in a process like flipping a coin. Half of the envelopes say one group, and half the other.
- If you are in the "Buzzy" group, the vibrating cold device will be placed on your arm just above the spot where the immunizations will be given. It will be turned on and left on until you are finished getting your shots.
- You will have your reactions to the shots recorded on videotape to be measured later.
- After the shots, you will be asked up to 6 questions about your experience and the device.
- Your parents will be asked to answer one page of questions.

How long will you be in this study?

Your participation in this study is over after today's immunization shots.

What are the possible risks to being in this study?

There is a possibility that you will experience too much cold or may feel tickling when receiving the Buzzy device. Other risks are no different than with standard immunizations.

What are the possible benefits of being in this study?

A potential benefit to you being in this study is that you may hurt less with your immunization shots if you are in the device group. There may be no benefit to you, but the information may help other children have less pain with shots.

What are the alternatives to being in this study?

If you choose not to participate in this study, your treatment will not be affected. You will still receive immunization shots and receive your usual care.

What is the cost of being in this study?

There are no costs to being in this study.

What is the benefit of being in this study?

You will receive a \$10 Target gift card for participating in this study.

What if you have any questions or problems while in this study?

If you have any questions about this study call Dr. Amy Baxter, the Principal Investigator, at 404-785-4092. If you have any questions about your rights as a participant in this study, you can call the Children's Healthcare of Atlanta Institutional Review Board (IRB) at (404) 785-7477. The IRB is a committee of people that approves all research in this hospital and follows all the rules and regulations made by government agencies about how research is done.

Who will be able to see your records of study participation?

Your records of participation in this study are private and every effort will be made to maintain confidentiality. However, all records may be subject to subpoena by a court of law. Information that may be gained from this study will be used only for research and educational purposes. Information may be published in medical journals with permission of the Principal Investigator, Dr. Amy Baxter, but your identity will not be revealed or written in a way that you can be recognized. Additionally, identifying information will be available to people from the Children's Healthcare of Atlanta IRB.

What are your rights as a study participant?

Taking part in this study is voluntary. You may choose not to take part in this study. If you take part in this study, you may stop being in the study at any time. Your decision to not take part in the study or to stop being in the study will not in any way affect your current or future medical care at this hospital.

The study doctor may stop you from taking part in this study for any of the following reasons: (1) it would be dangerous for you to continue or (2) you do not follow study procedures.

Investigator Disclosure of Financial Interest

The Principle Investigator has a personal financial interest in MMJ Labs LLC, the company manufacturing Buzzy. Children's Healthcare of Atlanta Institutional Review Board has reviewed the nature of this financial interest and the design of the study and this committee has determined that the investigator's financial interest would not compromise the quality or reliability of the study. Furthermore, the Children's Healthcare of Atlanta Institutional Review Board has determined that the investigator's financial interest will not adversely affect the welfare of participating research subjects.

Your signature below indicates that you have read this informed consent form and understand its meaning, you have been given the chance to ask questions and have had those questions answered to your satisfaction, and you voluntarily agree to participate in this study and sign this informed consent form. You will be given a copy of the signed informed consent form.

Printed Name of Research Subject

Age

Date of Birth

Signature of Research Subject

Date

Time

(Required unless research subject is under the age of 18 years and assent was not obtained for reason provided below)

Signature of Research Subject's Parent/Legal Guardian
 (Required for research subjects under the age of 18 years)

Date

Time

Signature of Person Obtaining Assent/Consent/Permission

Date

Time

Signature of Witness

Date

Time

Signature of Interpreter

Date

Time

"In my opinion, the child is too young to assent to participate in this research study."

Signature of Person Obtaining Assent/Consent/Permission

Date

Time

Family Information Form - Questions about your Family

1. What is your Relation to Child: _1 Mother _2 Father _3 Grandparent _4 Other

If other, describe: _____

2. Your Gender: _0 Female _1 Male

3. Your Age: _____

4. Are you Latino? _0 No _1 Yes

5. Your Race: _1 White _2 Black _3 Asian/Pacific Islander _4 Indigenous _5 Mixed _6 Other

If other, describe: _____

6. How many years of school has the child's mother completed? _____

7. How many times have you personally brought your child to be vaccinated? _____

7a. How many times have you watched your child be vaccinated? _____

Questions about your child

1. Child's Gender: _0 Female _1 Male

2. Child's Age: _____ Child's Date of Birth _____

3. Is your child Latino? _0 No _1 Yes

4. Child's Race: _1 White _2 Black _3 Asian/Pacific Islander _4 Indigenous _5 Mixed _6 Other

If other, describe: _____

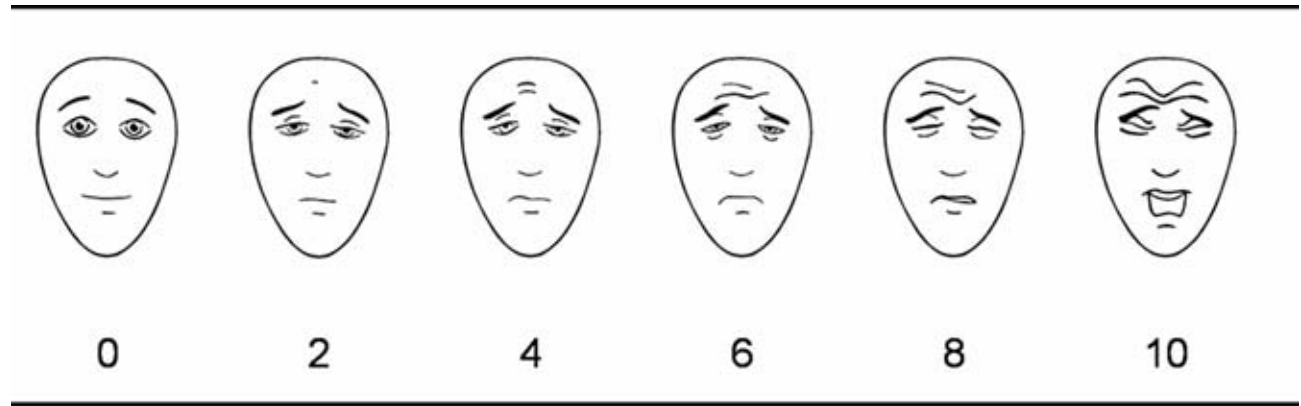
12. Has your child ever had an illness requiring > one shot per month? ? _0 No _1 Yes

Please Explain _____

13. Has your child had a bad experience with needles? ? _0 No _1 Yes

Please Explain. _____

Child Data Form AFTER PARENT/NURSE rate reaction to shots : Read script



If randomized to Buzzy:

1. What did you think of Buzzy?
2. What didn't you like?
3. What did you like?
4. What would you change?
5. Would you use it again if you had to get other shots?