Consent

Please read the following information and consent below.

Thank you!

Testing Effects of Swim Instruction on Autistic Children's Swimming and Water Safety Skills

Dr. Mische Lawson is doing the study at the University of Kansas Medical Center (KUMC). About 50 people will be in the study.

Why is this study being done?

Children with autism are at high risk for drowning, up to 160 times higher than other children. Swimming lessons may be helpful for preventing drowning. However, swim lessons can be challenging for children with autism due difficulties with social interaction and communication, sensory processing and motor challenges, and restricted or repetitive behaviors. These characteristics of autism can limit both a child's ability to participate in swimming lessons and a program's ability to support them. Sensory Enhanced Aquatics was developed to make learning swimming and water-safety easier for children with autism and a small study showed it to be feasible and beneficial. We are doing the study to compare Sensory Enhanced Aquatics to standard swimming lessons to know what instructional methods work best for children with autism.

What is being tested in this study?

We comparing standard swim lessons to Sensory Enhanced Aquatics for teaching swimming and water-safety skills to children with Autism. We are also exploring what teaching methods work best for children with different challenges related to their autism to see who best benefits from lessons.

How long will I be in this study?

The study will last 3 months and involve 18 visits to a community swimming pool or recreation center.

What will I be asked to do?

This study involves 18 in person visits at community recreation centers. Children should wear a swimsuit and bring a towel to each session. Parents will not be in the water with their child at any time. Your participation in the study will have three parts:

Screening & Testing

Intervention

Testing & Interview

Parents complete demographic form and autism questionnaire (20-30 minutes)

Children complete motor test and swim test (1 hour)

16, 30-minute swim lessons (Sensory Enhanced Aquatics or standard lessons)

Children complete swim test (30 minutes)

Parents and children complete interview (30 minutes)

Part 1: Screening & Testing

Parents will complete a demographic form questionnaire about their child's autism symptoms to determine if children are eligible for the study. Completing the forms will take 20-30 minutes.

Children will complete a motor test and swim test at a community recreation center. Children will have support from a swim instructor and research team member to complete the testing. For the motor test your child to complete activities like walking, balancing, and stretching. For the swim test your will be asked to child enter the pool, come to the surface, tread water and swim to the side if able. Your child can try the swimming activities with support or choose not to do them. This session will take about an hour.

If eligible, children will be randomized to Sensory Enhanced Aquatics Swim Lessons or standard swim lessons.

Children have a 1 in 2 chance of being assigned to either group. Group assignments are random, like flipping a coin or rolling the dice

Part 2: Intervention

Children will complete 16, 30-minute swimming lessons.

Sensory Enhanced Aquatics is a specialized swimming and water safety program for autistic children that uses a sensory assessment to plan lessons. It uses evidence-based teaching approaches, like 1) visual supports such as social stories, 2) sensory supports such as thermal suits, 3) communication strategies such as "first/then" language, 4) behavioral strategies such as token systems, and 5) modeling/demonstration to maximize skill acquisition. Lessons are 1:1 with social opportunities at the beginning and end of each lesson. Swimming skills are taught in progression from water orientation to advanced swimming.

Standard swim lessons which are provided to the general public will be used as the comparison group. Standard swim lessons will adhere to USA Swimming Foundation Swim Network Provider requirements ensuring lessons meet or exceed industry best practices. Lessons have up to a 1:5 instructor to child ratio and will focus on stroke development and water-safety with skills advancing from water-orientation to stroke technique and endurance. Children will be registered based on age and evaluated at the beginning of each session to be placed in the appropriate class level.

Part 3: Testing and Interview

Children will complete the same swim test again with the support of a swim instructor. Parents and children will be invited to complete an interview about their experience with swim lessons. This session will take about one hour.

What are the risks of being in the study?

With all swimming activities there is a risk of drowning. We minimize this risk with instructors within reach of the child and lifeguards at all lessons. There is small risk of physical discomforts like ear infection, skin irritation or diarrhea. Pools are routinely tested to ensure water is safe for swimming and we will share educational materials to

IRB STUDY00150354 | Approved 7/22/2024 - 7/21/2025 | HSC#00034

Are there benefits to being in this study?

A potential benefit is children will learn swimming and water-safety skills and be safer around water. The study will also benefit the autism population by informing how swimming and water-safety skills can best be taught to children with autism.

Will it cost anything to be in the study?

No, it will not cost you or your child anything to be in the study.

Will I get paid for participation?

You will receive $25 after completing screening and testing, $25 after completing the intervention, and $25 for completing final swim test and interview for a total of $75. You will be given a ClinCard, which works like a debit card. Payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf. Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What are the financial arrangements for this study?

The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, National Institute of Health, for conducting this study. Payments will be used for research purposes only.

What happens if I get hurt or sick during the study?

If you have a serious side effect or other problem during this study, you should contact Lisa Mische Lawson at 913-945-7339. If you have a physical injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party. You will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

What other choices do I have if I don't want to be in the study?

You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my information be protected?

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

KU IRB#STUDY00150634 | Approved Across Groups | 5/21/2026 | Version 1.1

matches your name to the research ID number. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and a physician release to participate in the study. The team may use any of your information needed for the study. Your research records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

Federal agencies that oversee human research (if a study audit is performed) National Institute of Health Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue Other groups that help manage or provide services to support the study Ethics committees that review the study for other locations

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Lisa Mische Lawson. The mailing address is Lisa Mische Lawson, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of intervention. They are permitted to use and share information that was gathered before they received your cancellation.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.

One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.

Will I be told about research results?

At the end of the study, we will send you a letter with a summary of the results.

In the future, researchers at KUMC and at other locations might re-use the information from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

This project is being funded by the NIH. Research studies that receive funding by the NIH are required to share de-identified data so that it is possible to learn more about health and diseases. The NIH will make your data available for other research studies that may be done in the future. Only de-identified information data will be shared.

Your data will be combined with others who participate in this study and uploaded into a controlled database. Once uploaded, it may not be possible to remove your information.

The place where your data will be stored may not be controlled by or owned by KUMC or by the Principal Investigator for this study. The decision on how and with whom your data is shared is made by individuals who own the database.

Can I stop being in the study?

You may stop being in the study at any time. Stopping will not prevent you from getting treatment or services at KUMC.

Could my participation be stopped early?

This study might be stopped, without your consent, by the investigator or the sponsor. Your participation also might be stopped by the investigator or by the sponsor if it is in no longer safe for you or if you do not follow the study requirements. The University of Kansas Medical Center, the sponsor, and the investigator are not obligated to provide you with any intervention if the study is stopped early.

Who can I talk to about the study?

Dr. Mische Lawson or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

CONSENT

Dr. Mische Lawson or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.

You will be given a signed copy of the consent form to keep for your records.

Print Child Participant's First Name :

Print Child Participant's Last Name

_____

KUMC Parental/ Guardian Permission

You are a parent or legal guardian of a child on with autism. You are being asked to provide permission for your child to participate in the research study described in this consent form.

By signing this form, you agree that Dr. Mische Lawson or the study team have given you the information you need to make your decision. The study team has explained what will happen in the research with your child. They explained any inconvenience, discomfort or risks that your child may experience.

By signing this form, you are granting permission for your child to participate in this research study. You have read the information and had your questions answered

You will be given a copy of the Consent Form and this signed Parental Permission to keep for your records.

Date:

_____

Child's Age

_____

Print Parent/Guardian First Name

_____

Print Parent/Guardian Last Name

_____

Parent/Guardian Signature

_____

In the future, the researchers may conduct additional studies about swimming and water-safety. If you agree, the researchers will contact you to see if you want to join future studies. You would receive a separate consent form describing the future studies.

◯ Yes, I would like to be contacted if I qualify for future studies.
◯ No, Please do not contact me about future studies.

Is your child capable to provide Assent?

◯ Yes
◯ No

CHILD ASSENT

You are being asked to take part in research to see if swim lessons can help you learn swimming and water-safety skills. If you want to be in the research, you will take swim test and motor test, complete 16 swim lessons, take the swim test again, and complete an interview. If you don't want to take the test or swim lessons, you can stop. Your parents will fill out some forms about your autism and complete an interview.

Your parents have said that it is okay for you to be in this research. Being in this research is up to you. If you say "yes I want to be in the research" or sign on the line, it means you want to be in the research. If you don't want to be in the research, say no and don't sign your name. You can stop being in the research any time, even if you agree today. No one will be upset if you say no or change your mind later. If you want to stop later on, you need to tell mom or dad.

Your Signature

_____

Date:

_____

Child's Age

_____

Witness Information

Print First Name of Person Obtaining Consent

_____

Print Last Name of Person Obtaining Consent

_____

Signature of Person Obtaining Consent Date

_____

Date:

_____