NCT06216613

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

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Supported by:

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(R21HD111917)

Version 5
February 3, 2025

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I. Purpose, Background and Rationale

A. Aim and Hypotheses

1. Drowning is a leading cause of death among all children. However, autistic children are 160 times more likely to die from drowning than the general pediatric population. The American Academy of Pediatrics recommends children over age four participate in swimming lessons to acquire necessary swimming and water safety skills to reduce risk of drowning. However, swim lessons can be challenging for children with autism, a population who experiences 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. For example, children's hypersensitivity and hyperactivity contribute to inattention during swim lessons. Combined with impulsivity this may manifest as behaviors that swim instructors find difficult to manage. While there is a strong need to develop swim lessons adapted for autistic children, we are unaware of previous studies that have evaluated different strategies to increase the effectiveness of swim instruction for autistic children.

   We developed Sensory Enhanced Aquatics (SEA) to overcome many of the barriers to traditional swim lessons that autistic children experience. SEA uses standardized sensory assessment and evidence-based teaching methods to individualize swimming instruction for autistic children. Early program evaluation in 42 autistic children who participated in eight, 30-minute SEA lessons demonstrated that SEA is feasible, highly preferred by autistic children and their families, and improved children's swimming skills. Survey data indicated that 100% of parents felt their children were safer in and around water and 100% of swim instructors felt more competent teaching autistic children after receiving SEA training. Subsequent research by our team investigated SEA instructional methods (e.g., visual and sensory supports, etc.) and children's and families' swimming experiences to strengthen the fidelity of the intervention, created training materials to increase capacity of swim instructors serving autistic children, and investigated feasibility of research procedures (e.g., frequency and duration of intervention, randomization, etc.) and outcome measures (e.g., Children's Health Questionnaire, activity monitors). While SEA has demonstrated promise, the effectiveness of SEA compared to traditional swim lessons to improve swimming and water safety skills in autistic children is unknown.
   Thus, as requested by NOT-HD-21-048, we propose to leverage our expertise in autism and aquatics to be the first to compare specialized swimming lessons (SEA) to standard swimming lessons for improving swimming and water-safety skills of autistic children.

   We will enroll 50 children (25 intervention, 25 matched control) aged 5-9 years with an autism spectrum disorder diagnosis to a single blind, randomized controlled pilot trial comparing 16, 30-minute SEA swimming lessons to standard swimming lessons. Both the SEA and standard swim lessons will be delivered at local community pools by community swim instructors.

2. Aim 1. Compare the effects of a SEA to standard swimming lessons on swimming and water safety skills of autistic children. For our primary endpoints, we will compare the difference between groups in post-intervention swim skills (e.g., entering and exiting the water, submerging, floating, treading water, and swimming) and water safety skills (e.g., pool-side behavior, permission to enter water) using American Red Cross Guidelines. We hypothesize that children in the SEA group will demonstrate higher swim skill and water safety scores than children in standard lessons after adjusting for baseline scores.

Aim 2. Assess which participant characteristics (e.g., age, motor ability, autism severity) are associated with the highest post-intervention swim skills and water safety across both groups to inform who benefits most from swim instruction. We hypothesize that autism severity and motor ability will have the greatest associations with swim skill in both the SEA and standard swimming lesson groups.

Exploratory aim: We will employ post-intervention semi-structured interviews to explore child, parent, and instructor perspectives about instructional methods most effective for developing swimming and water-safety among autistic children.

B. Background and Significance

1. Study Significance: Effective programs for swimming and water-safety instruction for autistic children are not currently available and tremendous variability among types and techniques of swim instruction exists. This project will compare the effects of a specialized swimming and water-safety program for autistic children (Sensory Enhanced Aquatics-SEA) to standard swimming lessons, examine characteristics of instruction associated with skill attainment, and explore child, parent, and instructor perspectives about instructional methods most effective for developing swimming and water-safety among autistic children. If the project is successful, it will increase knowledge of best practice swim instruction for autistic children to potentially reduce the high risk of drowning in this population.
2. The proposed plan builds on the primary investigator's program development and program evaluation findings with autistic children. In 2012, Drs. Mische Lawson and Foster developed Sensory Enhanced Aquatics (SEA; formerly Sensory Supported Swimming) with funding from Autism Speaks to fill a critical need in the community. Funding requirements included a rigorous program evaluation plan to ensure SEA met goals to teach autistic children swim skills and water safety, increase capacity of swim instructors, and increase physical activity. 100% of parents whose children completed the program (n=40) during the first year of implementation felt safer with their children in and around water and 91.1% of parents indicated their children were more interested in swimming as a physical activity[17]. 100% of swim instructors felt more competent teaching autistic children. Children's swimming skills (based on American Red Cross Learn to Swim levels) were assessed at the first and last lesson. Of the 40 participants, 74% improved at least one skill level after eight lessons: 11 improved skills within their starting level, 25 advanced one swim level, and four improved two swimming levels. This means a child who started the program unable to submerge eyes and nose advanced to submerging the face and floating with support (1 level) or independently floating and moving through water (2 levels) after eight lessons. Children who improved within their starting skill level were fearful of the water and started at the water adjustment/exploration stage. While they were able to blow bubbles and submerge their nose and/or mouth, advancement to the next stage required full immersion of the child's face (including eyes), which did not occur within eight weeks for some children. Program evaluation revealed the American Red Cross Curriculum required modification to meet the needs of children with ASD (e.g., swim levels did not capture advancement), informing the development of Sensory Enhanced Aquatics.

   Our subsequent work focused on increasing fidelity of the Sensory Enhanced Aquatics intervention by better understanding autistic children and families' experiences with swimming and developing training protocols. We analyzed Sensory Profile scores and documentation of 83 autistic children's first 8 lessons of SEA.[18] Results showed similarities in the swim skills children attained regardless of sensory processing pattern, demonstrating mostly basic water orientation and emerging front and backstroke skills. Children with sensory seeking preferences (high threshold for sensory stimuli and active responding)

demonstrated fewer water safety skills (e.g., waiting for instructor) but more overall swim skills than children with other sensory patterns. Autistic children entering swim lessons with no or minimal swimming experience require more than 8 lessons to attain the skills necessary for water competence. Our qualitative study confirmed the need to reinforce water safety during swim lessons with parents sharing a need for constant vigilance around water and describing near drowning situations. Parents and children indicated swimming lessons should have a low instructor to swimmer ratio, use evidence-based strategies (e.g., visual aids), provide structure, push children just beyond their comfort level, and be fun. According to parents, swim instructors' knowledge of autism challenges (e.g., inattention, impulsiveness, sensory needs) and strategies to accommodate them (e.g., visual supports, behavioral and sensory strategies) were important to bond with the child and provide better instruction. Results of these studies informed development and testing of swim instructor training. After attending a 10-hour workshop with classroom and in-pool instruction, instructors reported greater knowledge of autism and teaching methods. They indicated preference for in-pool demonstration and learning from parents of autistic children. Additionally, we developed online training materials in which SEA instructors complete online training and shadow an experienced instructor for 8 lessons prior to independently teaching autistic swimmers.

Results of our pilot studies demonstrate the SEA intervention can improve swimming and water safety skills. Retention to the intervention was 95% and session attendance was 89-94%[17,19], with most absences attributed to vacation or illness. Families drove up to 49 miles one-way to attend the 30-minute lessons, indicating the intervention is highly desirable to families.19 Results indicated twice weekly swim lessons may be burdensome to parents' time, suggesting twice weekly is the maximum frequency families can adhere to the intervention.[20] Thus, we believe our SEA intervention delivered twice weekly to autistic children represents a feasible and potentially effective approach to improve swimming and water safety skills.

3. Literature Review:

Autism Spectrum Disorder (ASD). According to the American Psychiatric Association's Diagnostic and Statistical Manual, ASD is a developmental disorder that impacts 1 in 44 children and is characterized by, 1) persistent differences in communication, interpersonal relationships, and social interaction across different environments, and 2) restricted and repetitive behavior, patterns, activities and interests[1]. These complex disorders are usually of lifelong duration and affect multiple aspects of development, learning, and adaptation at home and in the community. Many children with ASD also have associated intellectual disability (~35%)[2], sensory processing differences (~95%)[3,4] and motor challenges (~80%)[5,6] that interfere with daily life. Individuals with ASD are 3 times more likely to die by unintentional injury than the general population, with children younger than 15 years at greatest risk. Drowning, suffocation and asphyxiation account for 79.4% of unintentional deaths[7].

Drowning. 2.5 million lives were lost worldwide to drowning in the last decade, with most of these deaths being preventable.[8] In response to this global heath burden, the United Nations adopted a Resolution on Drowning Prevention in 2021 which identified children and adolescents to be disproportionally affected. In the United States drowning is a leading cause of death among children,[9,10] and research indicates autistic children are 160 times more likely to die from drowning than the general pediatric population7. Nearly half of autistic children wander from safe places, and of those 32% have had a close call with drowning.[11] Wandering accounts for nearly 74% of fatal drowning incidents among autistic

children9, possibly because autistic children are reported to be drawn to water.[12] Though research has helped identify drowning risk factors, little is known about what intervention strategies are most likely to prevent drowning, particularly among populations with greater risk. Swim lessons are recommended for drowning prevention in the general pediatric population,[9,10] but have not been investigated as a drowning prevention strategy for autistic children.

Water Competence. Swim skills, which are often obtained through swim instruction, can decrease drowning risk; however tremendous variability among types and techniques of swim instruction exists. Similarly, there is no common definition for water competence, though it is generally defined as the ability to anticipate, avoid, and survive common drowning situations.[13] The American Red Cross describes a sequence of critical water safety skills necessary for water competence.[14] These skills include the ability to: 1) step or jump into water over your head; 2) return to the surface and float or tread water for one minute; 3) turn around in a full circle and find an exit; 4) Swim 25 yards to the exit; 5) exit from the water (in a pool, be able to exit without using the ladder). Only 26% of children are reported capable of swimming at least 25 yards[15], with no estimates of swimming ability specific to autistic children.

Swim Instruction and Autism. Parents report traditional swim lessons are inadequate for autistic children[12]. Community lessons are up to a 1:5 instructor to child ratio. Impulsivity and lack of judgement is common among autistic children who may jump into or leave the pool when the instructor is teaching other children. Hypersensitivity and hyperactivity can lead to inattention, thus autistic children often cannot focus during standard instruction. Even when lessons are 1:1, parents report instructors of typical lessons lack the knowledge of autism, patience and consistency autistic children require.[12] Research suggests autistic children benefit from adapted instruction specific to their needs, particularly instruction accommodating behavioral, communication and sensory needs[16]. However, the research is extremely limited with sample sizes <7 in over half the studies and no existing comparison studies of instructional methods.

C. Rationale

1. Literature shows drowning is a leading cause of death among children and autistic children are at heightened risk. Swimming lessons are recommended to reduce risk of drowning, but they have not been investigated with autistic children. There is great variability in swim instruction types and techniques for developing water competence. It is critical to evaluate evidence-based best practices of swim instruction, particularly among children with ASD who are at increased risk of drowning. Therefore, literature supports the proposed specific aims and hypotheses.
2. The information obtained from this study will improve our understanding of the best strategies for swim instruction for autistic children and support our long-term goal to make SEA scalable on the national level to prevent drowning of autistic children.
3. This study will advance knowledge in the file though these innovations: Most aquatic programs for autistic children are therapeutic and do not intentionally develop swimming competence and water-safety skills. We are unaware of previous evidence-based swimming and water-safety programs that meet the unique learning needs of children on the autism spectrum. The proposed study is conceptually innovative as it investigates our well-established swimming and water-safety program specifically for autistic children. The proposed trial may not be innovative in the context of behavioral interventions for autistic children; however, no randomized clinical trials have compared types and techniques of

swim instruction for autistic children. Finally, the intervention will be delivered in the community setting which will allow for dissemination into community programs across the nation. The proposed study is methodologically innovative as the first to compare adapted swimming lessons to standard swimming lessons for improving swimming and water-safety skills of autistic children. Also, this is the first study to investigate characteristics of swim instruction that best predict attainment of swimming skills among autistic children to develop metrics for identifying effective, quality swim instruction.

II. Research Plan and Design

A. Study Objectives: We propose to conduct a single blind, randomized controlled pilot trial to test the differential effects of an eight-week (16 lesson) SEA intervention and standard swim lessons on attainment of swimming and water-safety skills of autistic children. We will enroll 50 autistic children aged 5-9 years who will be randomized 1:1 to either the SEA intervention or standard swim lessons with adaptive randomization to minimize imbalanced group allocation by autism severity and baseline swim skill. **Aim 1** will compare the effects of SEA to standard swimming lessons on swimming and water safety skills of autistic children with a swim test based on Red Cross water-competency guidelines. **Aim 2** will assess which participant characteristics (e.g., age, motor ability, autism severity) are associated with the highest post-intervention swim skills and water safety across both groups to inform who benefits most from swim instruction. Child sex and co-occurring motor impairment will be considered as potential covariates. Data will be collected before swim lessons and after 8 weeks of SEA or standard lessons. We hypothesize children in both groups will demonstrate improvement in swimming and water safety skills with greater improvements in the SEA group; autism severity and motor ability will have the greatest associations with swim skill in both groups. Our **exploratory** aim will employ post-intervention semi-structured interviews to explore child, parent, and instructor perspectives about instructional methods most effective for developing swimming and water-safety among autistic children. The information obtained from this study will improve our understanding of the best strategies for swim instruction for autistic children and support **our long-term goal to make SEA scalable on the national level to prevent drowning of autistic children.**

B. Study Type and Design:

We will conduct a single blind, randomized controlled pilot trial to test the differential effects of an eight-week (16 lesson) SEA intervention and standard swim lessons on attainment of swimming and water-safety skills. We will enroll 50 participants who will be randomized 1:1 to either the SEA intervention or control condition with standard swim lessons. Based on our preliminary data, change in swim skills (e.g., entering and exiting the water, submerging, floating, treading water, and swimming) and water safety skills (e.g., pool-side behavior, permission to enter water) will be our primary outcomes. We will also explore characteristics (e.g., age, motor ability, autism severity) associated with the greatest improvement in swim skills and water safety to inform who benefits most from swim instruction. We will employ postintervention semi-structured interviews to explore child, parent, and instructor perspectives about instructional methods most effective for developing swimming and water-safety among autistic children.

C. Sample size, statistical methods, and power calculation

1. 50 participants will be randomized 1:1 to either the SEA intervention or control condition

2. The nature of our intervention precludes blinding of the interventionists and participants; however, investigators not involved in the intervention, data analysis and research assistants will be blinded to condition.
3. Statistical power for a sample size of N=48 children was estimated by simulating data based on our previous findings 1000 times, with mean baseline swim skill scores of 7.0 (SD=3.0), mean post-intervention scores of 9.2 (SD=4.2) and 17.1 (SD=6.3) for standard vs. SEA lessons, evenly stratified for autism severity, and varied mean scores by severity (pre: mild=10.8, moderate=7.2, severe=3.1; post: 2.5- vs. 1.25-fold score increases after SEA vs. standard lessons). ANCOVA models testing the effect of swim lesson group for each simulation, adjusted for baseline skill scores and autism severity, revealed >95% power to detect our expected post-intervention group difference at α=0.05 (Aim 1). Using ANCOVA models estimating the association between autism severity and post-intervention swim scores for all data simulations, adjusted for group and baseline skill scores, we observed 94% power to detect a model-generated effect size of 2.3 (Aim 2). Given the strong expected difference in skill scores by swim lesson groups, our estimated power remains >90% if other covariates requiring 6 additional degrees of freedom are included for adjustment in multivariable models. We propose a sample size increase of N=2 to account for small, expected risk of attrition (total N=50).

D. Subject Criteria (See Vulnerable Populations appendix, if applicable):

1. Inclusion criteria: 1) Age 5-9 yrs. who have received a clinical diagnosis for ASD based on DSM-5 criteria (see Inclusion of Individuals Across the Lifespan for age justification). 2) A Social Responsiveness Scale-2 (SRS-2) T-score of ≥ 60. A cut-off score of 60 on the SRS-2 identifies 96.8% of children with ASD, thus this criterium is necessary to confirm ASD diagnosis[21]. 3) Sufficient functional ability to understand directions and communicate preferences (verbally or non-verbally). 4) Baseline swim test score ≤22. 5) No plans to relocate outside the study area during the intervention period. 6) Physician consent. 7) willingness to be randomized to either the SEA or standard lessons.
2. Exclusion criteria: 1) Uncontrolled epilepsy, as seizures increase risk of drowning. 2) Baseline swim test score ≥23. 3) Aggressive behaviors that would put instructor safety at risk.
3. Withdrawal/Termination criteria: Participation will be terminated if subjects develop any of the conditions (e.g., uncontrolled epilepsy, aggressive behaviors) listed in the exclusion criteria during the study. Subjects may withdraw at any time with no safety precautions necessary.
4. Subjects may participate in another research study while participating in this research study as long as the research is unrelated to swimming instruction and drowning prevention.

E. Specific methods and techniques used throughout the study

1. Laboratory tests: N/A
2. Study Procedures:
   We will conduct a single blind, randomized controlled pilot trial to test the differential effects of an eight-week (16 lesson) SEA intervention and standard swim lessons on attainment of swimming and water-safety skills. We will enroll 50 participants who will be randomized 1:1 to either the SEA intervention or control condition with standard swim lessons. Based on our preliminary data, change in swim skills (e.g., entering and exiting the water, submerging, floating, treading water, and swimming) and water safety skills (e.g., pool-side behavior, permission to enter water) will be our primary outcomes. We will explore also characteristics (e.g., age, motor ability, autism severity) associated with the greatest improvement in swim skills and water safety to inform who benefits most from swim instruction. We will employ

post-intervention semi-structured interviews to explore child, parent, and instructor perspectives about instructional methods most effective for developing swimming and water-safety among autistic children.

Screening Measures.

Demographic Form (unpublished questionnaire). The demographic form will provide information about child sex and family characteristics, such as race/ethnicity, socioeconomic status, and number of children in the household. The form includes services and medications related to the child's ASD.

Social Responsiveness Scale- 2nd Edition (SRS-2;)[22]. The SRS-2 is a 64-item, respondent-based measure of the severity of social deficits and symptoms related to ASD. The SRS-2 provides a total T-Score. T-scores indicate: <59= low/no symptomology, 60-65 =mild to moderate deficits, 66-75=moderate deficits, >76=severe deficits. The SRS-2 has convergent validity with the Autism Diagnostic Interview-Revised[22,23]. The SRS-2 will be used to confirm autism diagnosis and stratify by severity of symptoms in our groups.

The Bruininks-Oseretsky Test of Motor Proficiency-2nd Edition (BOT™-2; Short Form)[24]. The BOT-2 Short Form is a 46-item standardized, norm-referenced, individually administered measure of fine and gross motor skills of youth 4 through 21 years of age. We will use the short form subtests: Fine Motor Precision, Fine Motor Integration, Manual Dexterity, Balance, Running Speed and Agility, Upper-Limb Coordination and Strength. Psychometric assessment of the BOT-2 indicates its subscales have high internal consistency and test–retest reliability, very consistent inter-rater reliability, and established validity.[24,25] BOT-2 data will inform analysis.

Child Sensory Profile-2 (CSP2).[26] The CSP2 is a caregiver reported questionnaire with 86 questions related to sensory preferences in children ages 3-14 years. The assessment provides scores for four sensory processing quadrants (registration, seeking, sensitivity, and avoiding), six sensory sections (auditory, visual, touch, movement, body position, and oral), and three behavioral sections (conduct, social-emotional, and attentional). The CSP2 demonstrates good validity, reliability, and goodness of fit for the four sensory processing quadrants.[27] The CSP2 will inform the SEA intervention.

Child Swim Test. We will use American Red Cross Water Competency Guidelines to assess children's swim skills at baseline and for our primary outcome. Each skill will be scored on a 4-point scale (0=unable to complete, 1=completed with physical assistance, 2=completed with equipment; 3=completed independently). After a brief acclimation, the tester will demonstrate each preparatory skill and invite the child to perform the skill. After inviting the child to perform the skill twice, if the child is unable or refuses to perform the skill it will be scored as 0. A child able to perform all preparatory skills will be invited to complete the Red Cross Water Competency skills following the same procedures. A RA will observe and score the test from the pool deck. The RA will observe water-safety from the time the child enters the pool area and will score two water-safety skills on a similar 4-point scale. Total scores can range from 0-38.

3. Both the SEA intervention and standard lessons routinely collect demographic information. The SEA intervention uses the Child Sensory Profile to inform swim lessons. All other measures are specific to this study.
4. No body components will be collected for this study.
5. Timeline:

Table 1. Sensory Enhanced Aquatics Study Timeline								
	Year 1				Year 2			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Personnel Training	X							
Finalize Study Materials	X							
IRB Approval	X							
Swim Instructor Training		X						
Recruit & Enroll (n=40)		X	X	X	X	X	X	
Data Analysis							X	X
Prepare/Submit manuscript								X
*The study timeline allows for 5 sessions of swim lessons (8 weeks each) aligned with naturally occurring breaks of standard lessons								

Schedule of Events													
				Phase 1									Phase 2
Study Activity	1st Screen	2nd Screen	Pre-Intervention	W1	W2	W3	W4	W5	W6	W7	W8	Post-testing	
Consent form	X												
CRC checklist	X												
Physician Consent	X												
Demographics	X												
SRS2	X												
CSP2		X											
Swim Test		X										X	
BOT2		X											
Randomization			X										
Enrollment			X										
Intervention				X	X	X	X	X	X	X	X		
Program Records				X	X	X	X	X	X	X	X		
Interviews													X
Children													X
Parents													X
Instructors													X

*Screening to occur April/May 2024, August 2024; Intervention to occur June-July 2024, Sept-Dec 2024, Jan-April2025

F. Risk/benefit assessment: Risks to participation in this study are minimal. There have been no serious adverse events in the Sensory Enhanced Aquatics programs in the eleven years it has been offered. There are no serious risks associated with participating in interviews.

1. Physical risk: minor issues such as skin irritation, diarrhea, or ear infections
2. Psychological risk: possible fear of water. Discomfort answering interview questions.
3. Social risk: no known risks
4. Economic risk: no known risks
5. Potential benefit of participating in the study
    a. Children will learn swim skills and parents may feel safer to engage in family aquatic activities
    b. The Population will have a better understanding of characteristics of swim instruction necessary to teach swimming and water-safety to children with ASD.
    c. Better understanding the effects of swim instruction on developing swimming and water-safety skills may benefit society by preventing drowning.

G. Location where study will be performed: Recruitment, consent interviews and swim lessons (intervention and control) will take place at Fairway Pool, Merriam Community Center, and Lenexa Community Center. Consent interviews can take place virtually or in the PI's lab if subjects prefer. Research subjects' records will be kept in the PI's locked office in a locked file cabinet and on the PI's Teams Channel and protected drive.

H. Collaboration (with another institution, if applicable): N/A

I. Single IRB Review for a Multi-site study (if applicable): N/A

J. Community-Based Participatory Research (if applicable) This study is a randomized controlled pilot trial. Though it is not Community-Based Participatory Research, community organizations will collaborate to deliver the control intervention, so CBPR principals influence the work.

1. Participants and the nature of their involvement: Children with ASD and their families are the community of interest for our primary aims. The organization Autism Grows will support recruitment of children underrepresented in autism research (e.g., females and children with severe challenges related ot their autism). Swim instructors and managers/directors are subjects of our exploratory aims. Parks & Recreation and Aquatics Directors for the Cities of Fairway, Merriam and Lenexa have shared challenges in recruiting, training and retaining swim instructors. Their experiences influenced the semi-structured interview questions for our exploratory aims.

2. Cultural issues: Black and Latino children are less likely to learn to swim than Caucasian children, partially due to their parents fear of water or lack of swim lessons. Approximately 40% of Sensory Enhanced Aquatics program participants are non-Caucasian. We will use methods and materials that have been successful reaching minority populations for SEA programming to recruit for research.

3. Origin of the research question: The research question was defined by the researcher after years of collaboration with community recreation agencies providing aquatic programs. This shared clinical/program work provided incidental opportunities to discuss challenges from the recreation provider perspective. The aquatic and recreation directors collaborating to provide the control condition enthusiastically support the work and 2/3 have presented the potential research to their Parks & Recreation boards.

4. Risks and Benefits: Because the SEA intervention serves autistic children, there is possibility of being identified as autistic through participation in the program. There is a risk that community organizations offering autism specific services may deter people unfamiliar with autism from engaging in services. However, our community collaborators indicate the benefits far outweigh the risk. Benefits include: 1) serving a marginalized population, 2) positive exposure as an inclusive/welcoming community, 3) increased programming. SEA has provided education/training to lifeguards and staff, supported transition to existing community programs, problem-solved challenges during our 10+ years of collaboration to minimize risks.

5. Study Description and Process: Our three community collaborators (Cities of Fairway, Lenexa and Merriam) and Autism Grows (foundation for families with ASD) provided insight on the need for the study and recruitment. All will assist with recruitment and Cities of

Fairway, Lenexa and Merriam will provide the comparison group swim lessons. Prior to recruitment the PI will meet with aquatics directors at the 3 sites to share recruitment materials and provide training on the recruitment process. The PI will be onsite 20% of the intervention to conduct fidelity checks. During these onsite visits she will be available to reinforce training and answer questions.

6. Return of results: Results will be shared with Recreation Directors, Aquatic Directors, and Park and Recreation Boards of our three collaborators (Cities of Fairway, Lenexa and Merriam)

7. Sustainability: We are investigating a program, Sensory Enhanced Aquatics, that has been operated for 10+ years through community partnerships, program grants, and fees for service. Our research of Sensory Enhanced Aquatics has been sustained through foundation grants, which we will continue to pursue along with federal funding for research.

K. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s): PI, Co-I, Clinical research Coordinator, Program manager, GRA
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: PI, Clinical Research Coordinator
    b. Obtaining informed consent: PI, Clinical Research Coordinator, GRA
    c. Providing on-going information to the study sponsor and the IRB: PI
    d. Maintaining participant's research records: PI & Clinical Research Coordinator
    e. Completing physical examination: N/A
    f. Taking vital signs, height, weight: N/A
    g. Drawing / collecting laboratory specimens: N/A
    h. Performing / conducting tests, procedures, interventions, questionnaires: PI, Co-I, GRA
    i. Completing study data forms: PI, Co-I, GRA
    j. Managing study database: PI, Biostatistician

L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan (this section was inserted into protocol version 5 from the DSMP document for upload to clinical trials.gov)

1.0 Participant Safety

This section outlines the potential risks and benefits of the research for the study participants.

1.1 Potential Risks and Benefits for Participants

1.1.1 Risk of Swim Instruction

Risk of swim instruction for autistic children is minimal. We have used the SEA with autistic children in previous trials with no serious adverse events.

1.1.2. Risk of Swimming

Swimming may be associated with minor physical risks such as skin irritation, diarrhea, and ear infections. Additionally, all water activities include risk of drowning.

1.1.3 Risk of interviews

Risk of interviews are minimal as swim instruction is not a sensitive topic; interview questions may be associated with distress for some participants.

1.1.6. Potential Benefits

The benefits to participants are the known and potential benefits of swim instruction to improve swimming and water-safety skills to reduce risk of drowning. Participants and their parents may benefit from an increased understanding of the importance of water-safety. The information obtained from this study will improve our understanding of the best strategies for swim instruction for autistic children. This study presents minimal risk to participants; however, the benefits to both participants and other autistic children are potentially large.

1.2 Adverse Event and Serious Adverse Event Collection and Reporting

Staff involved in performance of the protocol will continually monitor participants for adverse events throughout all outcome assessments and individual behavioral sessions. Mild discomforts or illness consistent with a participant's prior medical history or regular water exposure (e.g., skin irritation, diarrhea, ear infection) will not be considered an adverse event (AE).

1.2.1 Adverse Event Grading

This study uses the definition of AEs from the "NIH Adverse Event and Serious Adverse Event Guidelines, Version 3 December 2013". An AE is defined as any untoward or unfavorable medical occurrence in a human subject participant, including any abnormal sign, symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

The PI and Co-Is will determine the severity and relatedness of the AE to the intervention and will be responsible for reporting to the NIH in the appropriate time frames. Seriousness of the adverse event will be determined using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) v3.0.

1.2.2 Serious Adverse Events

A serious adverse event is defined as any adverse event that results in:

- Death.

- Life threatening event, a condition that places the study participant at immediate risk of death if they do not seek medical treatment.

- Inpatient hospitalization.

- Permanent disability, defined as the interruption of a study participant's ability to conduct normal life functions.

1.2.3 Unexpected Events

Expectedness refers to whether the AE is expected to occur or is not anticipated based on current knowledge found in the risks section of the informed consent. These events are reported on the Adverse Event form. The vast majority of AEs are not unexpected problems. Few if any AE are anticipated to be unexpected problems in the study, given the well-recognized safety of the study procedures. According to NIH Guidelines, these are any incidents, experiences, or outcomes that meet all of the following criteria:

- Unexpected – in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study population.

- Related or possibly related to participation in the research (possibly related means there is reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

1.2.4 AE Relationship Definitions

All AEs will be assessed as to their relationship to the study. The AE is categorized as:

- *Definitely Related:* The AE is clearly related to the investigational agent/procedure – i.e., an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.

- *Possibly Related:* An AE that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors.

- *Unknown:* Relationship for which no evaluation can be made.

- *Not Related:* The AE is clearly not related to the investigational agent/procedure - i.e., another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible.

1.2.5 Adverse Event Reporting

The PI and Co-Is will review and evaluate AEs within 72 hours. AEs are reported to the Safety Officer bi-annually for review, and immediately if unexpected. A summary of these reports is provided to the IRB on an annual basis. Deaths and serious adverse events (SAEs) are handled in an expedited fashion as follows:

- *Deaths:* All deaths will be reported within 24 hours to the NIH Program Officer, Safety Officer, and the IRB.

- *Unanticipated SAEs:* When SAEs occur that are unanticipated and related to the intervention, they will be reported to the NIH Program Officer, Safety Officer, and the IRB within 48 hours of study team's knowledge of the SAE.

- *Other SAEs:* The summary of all other SAEs will be reported to the NIH Program Officer and Safety Officer semi-annually.

All potential AEs will be collected on an Adverse Event Form. If study staff, tester, participant, or other individual interacting with the participant during the testing visits or swim lessons reports AEs or complaints, relevant information will be collected and documented using REDCap.

1.3 Protection Against Study Risks

All research data are maintained confidentially by numerical code in password-protected REDCap databases. All paper copies are filed by number in accordance with professional standards of privileged information. Confidentiality is strictly safeguarded by HIPAA-compliant standards.

Additionally, the following policies will be adopted to assure the safety of the participants in this study:

1. Strict adherence to institutional regulations for conducting clinical research.

2. The involved support staff will be adequately trained to conduct human research and will have completed the necessary institutional web-based training prior to the study.

3. We will comply with HIPPA regulation and commit to maintaining the patient confidentiality.

4. Any research presentations or publications from the proposed studies will not disclose any

personal identity information.

1.3.1 Protection Against Swim Instruction

All participants will need PCP clearance to enroll in the study.

1.3.2. Swimming

Risks associated with swimming (e.g., skin irritation, ear infection, drowning) will be minimized by providing instruction to child participants and parents prior to beginning swim lessons. Lifeguards and aquatics staff will supervise swim lessons and children will always be within arms-reach of instructors to mitigate drowning risk. We have appropriate inclusion/exclusion criteria, and physician consent for participation to minimize these risks.

1.3.2 Interviews

Empathetic staff minimizes risk of distress. Additionally, participants may choose not to answer questions that make them feel uncomfortable.

2.0 Interim Analysis

2.1 Interim Analysis of Outcomes

No interim analysis of outcomes are planned.

2.2 Stopping Rules

We believe this trial conveys minimal risk. Swimming and water-safety instruction is desirable and may lead to health benefits. The most likely scenario indicating the need to stop the investigation would be a failure to recruit or deliver the intervention as planned. Another issue relating to stopping rules for this trial could include new information that might become available that would warrant stopping the trial, although this is a remote possibility.

3.0 Data and Safety Monitoring

3.1 Responsibilities of the PI and Co-Investigators

The Principal Investigator and co-investigators will be responsible for ensuring study staff are appropriately trained in good clinical research practice and human subjects protections to minimize risk and maximize the value of the participants' contributions. The PI and co-investigators will be responsible for ensuring the collection of all the information necessary for the Safety Officer to evaluate the quality and safety of the study. The PI will

be responsive to the questions, inquiries, and concerns of the Safety Officer, IRB, and NIH regarding these data and procedures.

3.2 Frequency of Data and Safety Monitoring

The frequency of data review for this study differs according to the type of data, the availability of data collected, and the perceived level of risk. Safety reports are sent to the SO at least twice a year and will include a detailed analysis of study progress, data and safety issues.

Data type	Frequency of review
Subject accrual (adherence to protocol regarding demographics, inclusion/exclusion)	Quarterly
Adverse events (injuries/illness)	As they occur
Compliance to treatment	Quarterly
Stopping rules report regarding statistical power implications of drop outs and missing data	Semi-annually

3.3 Data Analysis and Coordination

Data will be checked for outliers and normalcy at logical time points but at least at 4-month intervals. Questionable data (e.g., >3 SD from the mean) will be re-checked and re-entered, if necessary.

3.3.1 Measurement and Reporting of Subject Accrual, Adherence to Inclusion/Exclusion Criteria.

The study statistician Dr. Chollet Hinton will review the rate of subject accrual and adherence to inclusion/exclusion criteria quarterly to assure that participants meet eligibility criteria and ethnic diversity goals outlined in the grant proposal.

3.3.2 Measurement and Reporting of Participant Compliance to the Treatment Protocol.

Compliance to the intervention will be reported monthly by Ms. Hamner. To monitor compliance, Ms. Hamner will report the mean attendance to the swim lessons and any reasons for missing . Compliance to the intervention protocol will be reviewed monthly by the PI and Co-Is Dr. Ptomey & Dr. Foster.

3.4 Content of the Data and Safety Monitoring Reports

The reports to the Safety Officer and NIH will contain information as outlined by the NIH and IRB, including but not limited to:

- Protocol Synopsis and Changes
- Summary of Past Reports and Status
- Progress of the Trial and Recruitment

- Summary of Protocol Changes
- Data Quality

- Incidence of Adverse Events
- Severity of Adverse Events
- Deaths

3.5 Safety Officer

A safety officer (TBD) not associated with the study team will be assigned to monitor the trial. The safety officer will have experience with safety monitoring of clinical trials with individuals with autism and/or intellectual disabilities.

3.6 Conflicts of Interest

The safety officer will have no direct involvement with the study investigators or intervention. The safety officer will sign a Conflict of Interest Statement which includes current affiliations that could be perceived as a conflict of interest related to the study and/or associated with commercial or non-commercial interests pertinent to study objectives.

3.7 Protection of Confidentiality

Study Report tables will be generated only from aggregate (not by group assignment) baseline and aggregate safety data for the study population. A separate Closed Safety Report, with masked group baseline and safety data, will be generated for the Safety Officer by a designated unmasked member of the team but will not be reviewed by the study team. The Closed Session reports will be destroyed at the conclusion after the SO completes the review. Participants names and PHI will not be included in the closed reports.

3.8 SO Responsibilities

The safety officer will review the reports sent by the study coordinator semi-annually and adverse events as they occur and will use the checklists attached to this document to determine whether there is any action, such as an ad hoc review or stopping rule violation that should be communicated to the study investigators, The University of Kansas Medical Center Human Subjects Committee, or NIH.

Checklist for safety officer to complete after reviewing the safety report:

Please reply in the right column

1. Minority recruitment rate achieved? At what percentage?	
2. Were participants accrued according to the recruitment schedule? How many subjects were recruited?	
3. Do all recruited subjects meet eligibility criteria?	
4. Are the dropouts above 30%?	
5. Is the overall injury rate for this quarter different between groups?	
6. Is the severe injury rate for this quarter significant and does it merit review by the statistician and MPI's?	

7. What is the % compliance (out of total possible) for this quarter?	
8. Based on any of the replies above, is there any need to communicate with the KUMC HSC and/or the NIH regarding data monitoring or safety of participants?	
9. Based on your review of the safety report, is there need for discussion between study investigators regarding data monitoring and/or participant safety?	

III. Subject Participation

A. Recruitment:

1. Individuals recruited for this study will have an autism spectrum disorder and will live with a parent/guardian. Potential participants will be recruited through the Occupational Therapy Education Department research registry, and with print and web advertisements in our target area, a recruitment strategy that we successfully employed in previous studies. Questions from interested parents will be addressed and initial eligibility screening will be completed via phone or email. If the parent remains interested, in-person visits will be scheduled with parent and potential participant to explain the project, answer questions, and obtain parental consent and child assent. Parent and instructor participants will be invited to participate in a semi-structured interview at the conclusion of swim lessons. Those agreeing to participate will complete informed consent.
2. The PI and Clinical Research Coordinator will conduct the recruitment. For previous studies we were able to recruit all participants from an autism research registry managed by the Occupational Therapy Education Department at KU Medical Center, where Dr. Mische Lawson is a professor. If additional efforts are needed, we will recruit potential participants through the Center for Child Health and Development (CCHD) Research Database and Registry within KU Medical Center. This CCHD Database and Registry includes diagnostic and assessment data from interdisciplinary evaluations and clinic visits from 4,500 individuals with autism or other neurodevelopmental disabilities. CCHD has IRB approval for families to be contacted for research purposes. Autism Grows, a non-profit parent group advocating for autistic individuals with severe challenges, will assist with recruitment and retention of females to this pilot trial
3. The attached flyers will be placed on community boards at pools and recreation centers in Fairway, Lenexa and Merriam. They will also be distributed to an autism research registry in the Occupational Therapy Education Department.
4. The flyer will be placed on the Accessible Leisure Lab webpage with the attached website information. It will also be distributed by email to research distribution list with the attached introductory statement.

B. Screening Interview/questionnaire: Participants will complete the demographic form and Social Responsiveness Scale-2 to determine eligibility (see attached).

C. Informed consent process and timing of obtaining of consent

1 Lisa Mische Lawson, Lauren Foster or a GTA TBD will give subjects detailed and comprehensive information about the study and obtain their written consent.

2 Informed consent will be provided by email ahead of consent meetings for potential participants to review and ask questions. See Appendix I for details

3 Parents or legal guardians will provide consent for all child participants.

D. Alternatives to Participation: Children with autism may participate in Sensory Enhanced Aquatics or swim lessons with our community partners without enrolling in research.

E. Costs to Subjects: N/A

F. How new information will be conveyed to the study subject and how it will be documented: We will provide intervention news and updates via monthly emails to be documented by any emails that come back undeliverable.

G. Payment, including a prorated plan for payment:

Subjects will receive $75 at the completion of all study activities. Travel costs will not be reimbursed.

H. Payment for a research-related injury: N/A

IV. Data Collection and Protection

A. Data Management and Security:

1. The PI and Clinical Research Coordinator and GRA will have access to identifying data. Other study team members (Co-Is, program manager, clinical information specialist) will have access to deidentified data
2. Subject confidentiality will be maintained by performing consent interviews virtually and testing in private areas of the community sites. Identifying information will be stored on a KUMC private Microsoft TEAMS channel and protected drive and records will be retained per university policy.
3. Human subjects will be identified through coded information.
4. The PI and the Clinical Research Coordinator and gRA will have access to the key to the code on a protected drive
5. Data will be linked to subjects during the study with an assigned identification number
6. Data collected at the community sites will be stored in lock boxes and transported to the PIs locked office to be stored in a locked file cabinet. Electronic data will be stored on a KUMC private Microsoft TEAMS channel and protected drive.
7. No mobile devices will be used for data collection and storage. Data collected at community sites will be stored on a KUMC computer or in a lock box for transport to the PIs office.
8. Identifying data will not be sent outside KUMC.

B. Sample / Specimen Collection: N/A

C. Tissue Banking Considerations: N/A

D. Procedures to protect subject confidentiality: Confidentiality could be at risk during the consent interview and swim testing at community sites. These activities will occur at low volume times at the facility in provide spaces to protect subjects

E. Quality Assurance / Monitoring

1. A biostatistician will provide biostatistical oversight for the creation of the study database as well as validate the electronic case report forms within the database prior to their activation. The Biostatistician will perform final statistical analyses for the study aims listed in the protocol. A Clinical Information Specialist will build the study database into the REDCap system and train study personnel on entering data into this system. The PI will be responsible for conduct and integrity of this trial, including overseeing onsite data collection to ensure it is accurate, complete and reliable. The PI will also complete fidelity monitoring of 30% of intervention to ensure consistency and reliability.
2. Third party monitoring for safety is described in section L. QA monitoring will be conducted by the study team. Dr. Ptomey is a Co-Investigator with extensive clinical trial expertise with individuals with intellectual disability. She will provide expertise and guidance in conducting clinical trials in individuals with autism, including strategies for recruitment/retention, ensuring the scientific rigor of the study, database management, and clinical trials reporting.

V. Data Analysis and Reporting

A. Statistical and Data Analysis:

Descriptive statistics will be used to summarize all variables and evaluate statistical model assumptions.

Aim 1. The primary analysis for Aim 1 will test whether post-intervention swimming and water safety test scores differ between the 8-week (16 lesson) SEA program and standard lesson control group using an analysis of covariance (ANCOVA) model with autism severity (continuous SRS-2 score) and baseline swim skill (continuous Child Swim Test score) included as covariates to adjust for group allocation by minimization for these factors. Other screening measures (e.g., demographic factors, BOT-2 motor impairment, CSP2 subscales) will be considered as potential covariates.

Aim 2. Analysis for Aim 2 will examine associations between participant characteristics assessed at baseline and post-intervention swim skill scores using linear regression models adjusted for both stratification factors. Subgroup analyses with ANCOVAs and contrast estimation will assess differences in post-intervention swim skills by swim group within levels of autism severity and baseline swim skills. Minimal missing data are expected given very low previous attrition; if present, the missing at random assumption will be tested and mitigated by complete-case or imputation methods as needed

Exploratory aim: We will employ post-intervention semi-structured interviews to explore child, parent, and instructor perspectives about instructional methods most effective for developing swimming and water-safety among autistic children. A content analysis of data from the interviews will be conducted to systematically organize and analyze the data using an integrative analysis34. Initial themes will be categorized based on our previous findings from interviews with parents of autistic children (i.e., deductive approach)12,35 and emerging themes (inductive approach) that give insight to the characteristics of swim instruction that

facilitate or hinder autistic children's acquisition of swimming and water-safety skills. Subsequent procedures will include an iterative analytic coding process, wherein similar codes will be grouped together and appropriate subcodes with higher order themes will be identified36. Dr. Foster will discuss discrepancies with Drs. Mische Lawson and Ptomey until a consensus is reached to ensure triangulation and reduce researcher bias37,38. As interviews are complete and transcripts are finalized, they will be uploaded along with the coding scheme into a qualitative software. Drs. Foster, Mische Lawson & Ptomey will complete interrater reliability evaluation for interview coding until a high level of agreement is achieved ($r = .85$)[39]. As the transcripts are complete, they will be uploaded, coded, and analyzed with the finalized coding scheme; any ambiguity will be discussed in detail. The collaborative and rigorous qualitative procedures presented here will ensure reliability and accuracy in coding to allow for the specific assessment of characteristics of swim instruction most beneficial to autistic children[40]

B. Outcome: We expect all child subjects in both groups will have improved swimming and water-safety skills and that children in the SEA group will demonstrate higher swim skill and water safety scores than children in standard lessons after adjusting for baseline scores. We expect that autism severity and motor ability will have the greatest associations with swim skill in both the SEA and the standard swimming lessons groups. Recruitment of full sample and adherence to the SEA intervention are criteria for success. Failure to recruit our sample withing the first 15 months would indicate need to consider endpoint for the study.

C. Study results to participants: Study results will be shared with subjects at the conclusion of the study with a one-page summary in layman's terms to inform children with ASD and their parents if swim lessons are effective for teaching swimming and water-safety skills and what characteristics of effective lessons they should look for.

D. Publication Plan: The results will be published in an open access journal. Additionally, the study will be registered with ClinicalTrails.gov and results will be updated within 12 months.

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APPENDIX I: VULNERABLE POPULATIONS

I. All recruitment materials will include contact information for our study coordinator (toll-free phone, email, website). Potential participants will be asked to contact the study coordinator who will answer questions and administer an initial participant eligibility screener. A site visit will be scheduled with those remaining interested and potentially eligible. During the visit, we will obtain child assent for participation, as well as parental consent. Parents will complete screening measures during the site visit. The study coordinator will send a form (fax/email) to the potential participant's primary care provider which describes the eligibility criteria, study requirements, and request clearance for participation in the trial. Individuals determined to be ineligible will be provided with alternate resources for swimming lessons in our local area. The study coordinator will invite aquatics directors/managers and swim instructors of child participants to participate in an interview at the end of lessons and obtain informed consent of those interested in participation.

II. **Cognitively or decisionally impaired individuals**: All subjects are children with cognitive or decision challenges. Parents or legal guardians will provide consent for all child subjects.

III. **Children**: Parents or legal guardians will provide consent for child subjects participation. Children over the age of 12 with ability to provide assent will be invited to do so. Due to the age of subjects and short duration of the intervention no subjects will attain age 18 years while in the study.

IV. **Pregnant women: N/A**

V. **Prisoners: N/A**

VI. **Students and/or Employees**: Sensory Enhanced Aquatics instructors are students and/or employees. SEA instructors who teach child subjects will be invited to participate in an interview at the end of lessons regarding their perceptions of the instructional approaches most effective for teaching child participants. The clinical research coordinator, who is not a supervisor or director of SEA instructors, will invite optional participation in interviews to ensure there is no unintentional pressure to participate.