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RESEARCH PROTOCOL TEMPLATE
INVESTIGATOR INITIATED TREATMENT TRIALS

Instructions: Protocols should be formatted according to the following outline and include all of the elements indicated.

Title of Project: Testing Design Thinking Methodology to Engage Hispanic and Latino Families of Autistic Children in Research

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Co-Investigators: Lady Rios-Vega, OTD, OTR/L; Department of Occupational Therapy

Abstract

Persons from racial and ethnic minorities who have autistic children often experience delays in access to and quality of, intervention services that can result in increased parental and financial stress and poorer outcomes. Many autism interventions were developed and tested on White participants, assuming they could be transferable to minority populations. However, research shows that this is not the case and that interventions that are not adapted to an individual's culture and ethnicity do not work as well and are not used as frequently. Thus, autism interventions require input from stakeholders to assure that cultural adaptation of interventions is responsive and appropriate to target populations. In this project, we compare two methods of stakeholder engagement, Design Thinking (DT) and Focus Groups (FG), to evaluate their effectiveness in obtaining input from Hispanic and Latino families of autistic children about occupational therapy service access and delivery. We focus on Hispanic and Latino families, as this is the largest minority group in the US, with one of the fastest-growing groups of autistic children. Occupational therapy using Ayres Sensory Integration (OT-ASI) is the only evidence-based intervention that addresses the sensory symptoms in autism and their impact on participation in daily life activities. We will use data from these engagement sessions to adapt two versions of the existing OT-ASI manual: one using DT data and the other using FG data, and compare their acceptability and feasibility. The planned outputs of the study are data on minority stakeholder engagement methods and a culturally adapted OT/ASI manual for Hispanic and Latino autistic children.

Research question: Does the Design Thinking (DT) or Focus Groups (FG) process result in higher stakeholder engagement and satisfaction in the research process for Hispanic and Latino families of autistic children as measured by stakeholder engagement scales? Secondary question: do cultural adaption using DT or FG data yield higher scores of acceptability and implementation feasibility as measured by acceptability and feasibility scales?

Note: The Research Plan, A through E, should not exceed 4 pages.

A. Specific Aims

State the hypothesis and specific aims. List the long-term objectives and what the proposed research will accomplish. (Suggested length: a paragraph or two)

This research aims to improve the health and well-being of Hispanic/Latino autistic children and their families by improving access to and utilization of, an evidence-based therapeutic autism intervention, namely occupational therapy, using Ayres Sensory Integration (OT-ASI; Steinbrenner, et al., 2020). To achieve this objective, we will obtain participant input on barriers and facilitators in accessing and

utilizing therapeutic services and the intervention. In obtaining this input, we will test engagement methods to determine which is more effective in gaining information. We will be guided by participants and stakeholders at each phase of the research, from conceptualization to dissemination, as described in the stakeholder engagement plan below (table 1).

- *Aim 1:* Compare Design Thinking (DT) and Focus Group (FG) methods on measures of stakeholder engagement (measured by the Stakeholder-Centric Engagement Evaluation (Martínez et al., 2021)
  - H1: DT protocol will yield greater participant engagement per the PCORI engagement principles.
  - H2: Participants will indicate higher satisfaction in engagement with DT in comparison to FG

- *Aim 2: Compare the acceptability, appropriateness, and feasibility of the adapted intervention manuals (one based on FG and another on DT data)*.
  - H1: Blinded stakeholders (clinicians, selected caregivers, autistic persons, and cultural experts) will rate the acceptability, feasibility, and cultural appropriateness of the protocol based on DT data higher than the protocol based on FG data.
    - The Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM) (Weiner et al., 2017)

B. Background and Significance

Briefly provide the background information leading to this study, evaluate existing knowledge, and identify gaps which this study will fill. State the importance of the research by relating the specific aims to the long-term objectives. (suggested length: ½ page)

Minority families with an autistic child experience significant delays in access to and initiation of autism intervention compared to White children, and these disparities contribute to delays in development, decreased quality of life, increased caregiver stress, and economic burden (Smith et al., 2020). Minority families of autistic children are also sorely under-represented in autism intervention research and experience challenges finding evidence-based interventions that are culturally sensitive to their unique needs (Dallman et al., 2020). Evidence shows that interventions that are not culturally adapted and do not consider stakeholders' culture and needs are less effective (Davenport et al., 2018). Thus, in order to conduct rigorous comparative effectiveness studies of autism interventions that include minority families and best serve minority autistic children in a culturally- sensitive way, stakeholder input is needed (Kumpfer et al., 2016).

Stakeholder engagement in the research process can improve utilization and acceptability, increase adherence, improve outcomes, and empower parents toward greater participation in research and the use of evidence-based interventions (Kim et al., 2018). To our knowledge, no studies have compared strategies for caregiver stakeholder participation in autism research. We build on our experiences testing autism interventions and expand it to include evaluation of engagement to inform the research process. We focus on Hispanic/Latino families of autistic children who present with a high need for evidence-based diagnostic and therapeutic services (Dallman et al., 2020; Davenport et al., 2018). These families will become partners with researchers to provide input on cultural adaptations needed for autism intervention.

PCORI Evaluation Criterion 1: How the project identifies critical methodological gaps in the science of engagement:

Minority families are not only sorely underrepresented in research, but their voices are also often not included or heard. In traditional methods of stakeholder engagement such as focus groups, a qualitative research methodology based on grounded theory and used to gain an in-depth

understanding of complex social issues, “minority voices may feel unwelcomed” or unintentionally devalued (Franz, 2011)Thus, additional methods of stakeholder engagement may be beneficial.

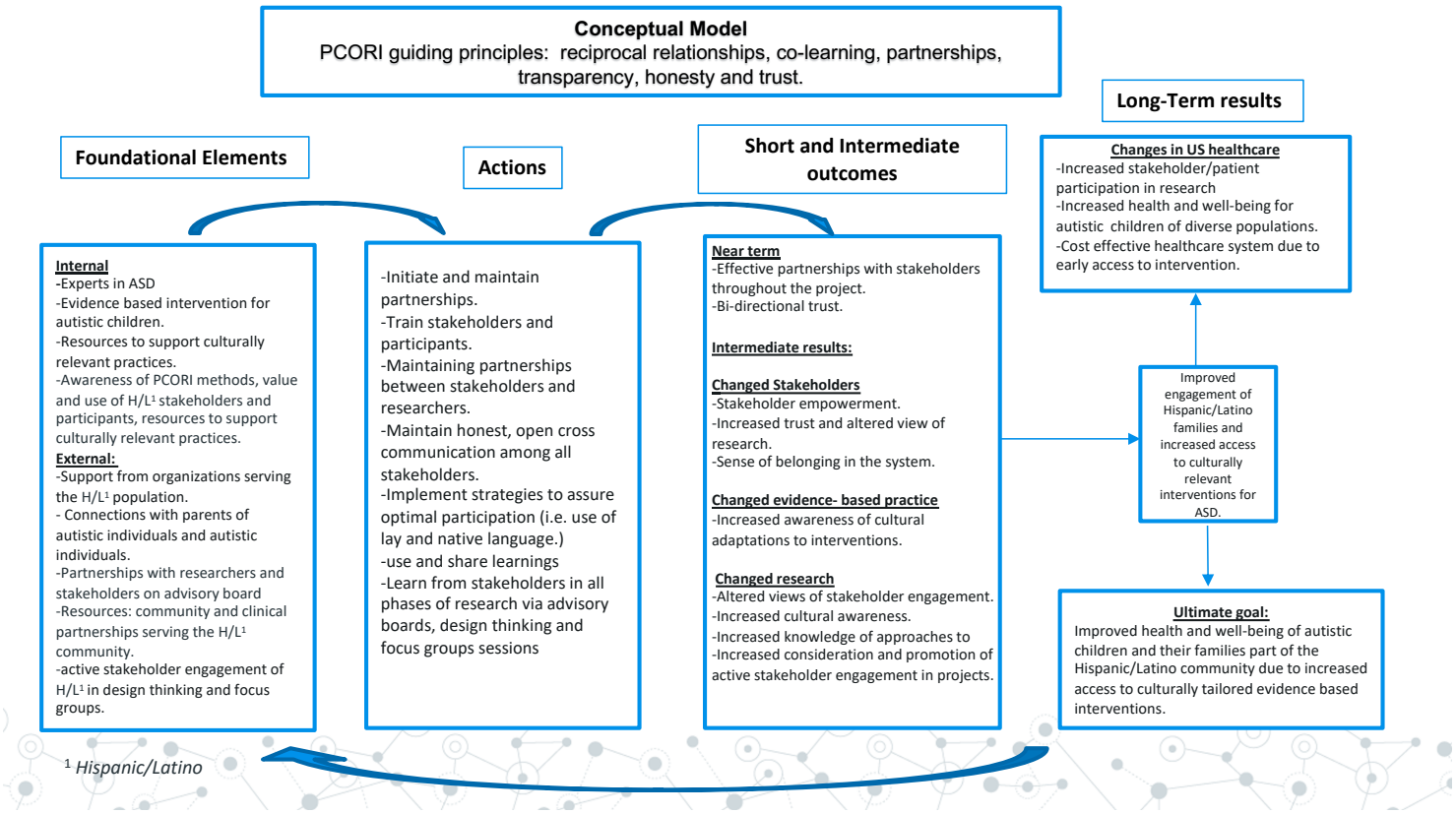
PCORI Evaluation Criterion 2: How this project will generate evidence on effective engagement strategies and whether they are effective for engaging minority participant stakeholders and informing future projects). Measurement of stakeholder engagement will be accomplished in two ways. First, we will randomly assign participants to either DT or FG sessions where they will identify/discuss facilitators and barriers in access to and utilization of, an evidence-based occupational therapy intervention. Data from these sessions will be used to culturally adapt the existing, evidence-based intervention manual (described below) to improve its cultural sensitivity, usability, and acceptability by Hispanic and Latino families of autistic children (i.e.: one manual based on DT data, and another based on FG data). Next, each adapted intervention manual will be evaluated for acceptability and feasibility by the stakeholders, who will be blinded as to the source of data for manual adaption (DT or FG). This provides a second way to evaluate stakeholder methods of engagement.

PCORI Evaluation Criterion 3: Engagement methods are based on existing supportive evidence and conceptual model: Recently, Design Thinking (DT) emerged as an engagement strategy to enhance problem-solving in healthcare through human-centered approaches, multidisciplinary collaboration, and participatory design (Milroy et al., 2021). DT engages multiple stakeholders simultaneously in an interactive, dynamic process aimed at generating solutions and has been found to be an effective approach to addressing health disparities, particularly for underserved minorities, including the Hispanic and Latino communities (Ramos et al., 2016). Further, the use of this approach inherently increases trust and builds rapport with diverse communities, generating co-construction of knowledge and improved outcomes (van der Westhuizen et al., 2020). Engagement activities include brainstorming, working in small groups to design solutions, and collaboratively choosing the best solution to help define the process. DT can also present some limitations that include the requirement for heavy involvement of participants, perception of high costs and benefits of being involved, issues around empowerment and inclusion, and differing value systems between researchers and participants. Unfortunately, the application of DT in autism has received little study (Fabri et al., 2016). Using the Conceptual Model shown below (Figure 1) to guide the project, the inputs used to support the project; outputs, outcomes, and impact are displayed. Stakeholders are included in the entire process to guide the study, evaluate and interpret data, and guide dissemination activities.

Conceptual Model Guiding Stakeholder Engagement: The conceptual model used for this project is based on the foundations of patient engagement in research and the Patient-Centered Outcomes Research Institute (PCORI) engagement principles (Advisory Panel on Patient Engagement, 2021). This model guides the research process and is organized around three concepts. The first is the foundational elements (i.e.: internal elements guiding the research process such as evidence, resources to support culturally relevant practices and engagement, and awareness of the PCORI engagement principles) and external elements such as organizations and partnerships that support and facilitate the project to ensure appropriate involvement of the Hispanic and Latino community and appropriate conduct of research. The second concept represents the actions to be implemented in the project for successful engagement of the stakeholders following the principles of stakeholder engagement, and lastly, the short, intermediate, and long-term outcomes resulting from the relationship between the foundational elements and the actions. As shown in Figure 1, the short-term and intermediate outcomes include effective partnerships that result in changed researchers and stakeholders resulting in shared partnership, as well as improved awareness of evidence-based practices and the need for cultural adaptations to apply evidence to minority groups. Long-term outcomes include several changes in healthcare resulting from the engagement of Hispanic/Latino families and autistic persons. Finally, the ultimate long-term goal of improved outcomes for

Hispanic/Latino autistic children and families resulting in improved health and well-being occurs due to the interaction of all factors in the model.

Figure 1: Conceptual Model



C. Preliminary Studies/Progress Report

Provide an account of preliminary studies and/or information that establishes the experience and competence of the investigator to pursue the protocol. (suggested length less than ½ page)

Our team is dedicated to improving access for minority families to needed therapeutic interventions that will improve short and long-term outcomes and quality of life. The research leadership team has the experience needed to ensure the success of the project. The team has worked together successfully on projects using DT and FG in prior studies. One study used FG to improve access to intervention for Black and African American autistic children, and another used DT methods to obtain stakeholder input on the design of a sensory adaptive environment to improve access to healthcare for autistic children. These projects involved joint IRB approvals and data-sharing agreements. Thus, we have the experience and competence to conduct this study.

The PI of the project, Dr. Roseann C. Schaaf, PhD, OTR/L, is the Director, of the Jefferson Autism Center of Excellence, Faculty of Farber Institute for Neuroscience, and Professor at the College of Rehabilitation Sciences. She manualized and tested the intervention that will be culturally adapted and tested (Schaaf, et al., 2014); is currently Co-PI of a large NIH-funded comparative effectiveness trial of the intervention, Co-PI of a current cultural adaptation study for Black/African American families, and served as PI of a large multi-site program project grant funded by the Lurie Autism Foundation. She brings expertise in autism and intervention research.

The study Co-I, Dr. Lady Rios-Vega, OTD, completed her post-doctoral fellowship at the Jefferson Autism Center of Excellence with a project to adapt the evidence-based Ayres Sensory Integration intervention for Black and African American Families. As a member of the Hispanic/Latino community, Dr. Rios-Vega brings her expertise in working with diverse communities from underserved areas and her knowledge and expertise in autism, focus groups, and design thinking.

The team also includes a design thinking expert, J. Matthew Fields, MD (Co-I, Associate Professor and immediate past Associate Director for the Health Design Lab at Thomas Jefferson University); and a focus group/qualitative research expert, Kristin Rising, MD (Co-I) who a physician-scientist with substantial experience conducting patient-centered and qualitative research and with prior experience running a PCORI-funded study comparing different methods of engaging patients.

D. Research Design and Methods

Describe the research design and procedures to be used (what, when, how) Include the duration of participation and early termination criteria. Provide a flow diagram or timetable. Procedures, situations, or materials that may be hazardous to personnel and the relevant precautions, should be outlined here. (Suggested length not more than 2 pages) (FG and DT diagram)

Study Design and Approach:

A randomized mixed methods design is used to evaluate stakeholder engagement methods. Phase one will compare two stakeholder engagement methods (Design Thinking –DT, and Focus Group - FG) and evaluate stakeholder engagement using the Stakeholder-Centric Engagement Evaluation. In addition, data from the DT and FG will be transcribed and analyzed using qualitative methods. Phase two utilizes data from phase one to culturally adapt the intervention (two separate intervention protocols will be adapted – one based on FG data and another based on DT data) and obtain stakeholder input on acceptability and feasibility for the Hispanic/Latino autistic population via survey methods. This provides a second way to measure the effectiveness of each stakeholder engagement method.

Stakeholder Engagement Approach

This project has been uniquely designed to actively engage a variety of stakeholders and participants at a high level of engagement, along the full continuum of PCORI's engagement practices from conceptualization through dissemination. We utilize an iterative process during stakeholder engagement, actively soliciting the knowledge, experience, and values of individuals to create shared understanding, and, in the case of DT, to identify relevant, transparent solutions. We include a **Stakeholder Research Steering Committee (SRSC)** consisting of a caregiver of autistic children, autistic person, cultural expert, teacher, and/or clinician who participates in planning and directing the project; a **Stakeholder Advisory Board (SAB)** who will provide input on the project design and implementation throughout its duration, **an Evaluation/Dissemination Stakeholder Advisory Board (EDSAB)** who will guide dissemination and implementation; and participants who will participate in the Focus Group and Design Thinking sessions. All stakeholder groups are Hispanic and Latino persons (or, in the case of clinicians, serving Hispanic/Latino autistic children). Table 1 depicts the stakeholder advisory groups and their interaction with the research team; as well as the partners or participants in the study. All stakeholders and participants will be compensated for their participation in keeping with the PCORI compensation of stakeholders guidelines.

The persons involved in the stakeholder groups will not be collecting any participant data or have access to identifiable information. The stakeholder groups are developed with the purpose of guiding the project at different stages to ensure the highest standards. Any data presented to the stakeholder groups will be de-identified to protect the participant's privacy.

Table 1: Stakeholders and Partners

Stakeholder Partners	Inclusion Criteria	Justification/Strategies for Participation	Goals
Stakeholders in Leadership Roles			
Stakeholder Research Steering Committee (SRSC) • PI, Co-I • Autism expert • Hispanic/Latino service provider • parent partner • Diversity and inclusion expert • Teacher of autistic individuals • Autistic individual	-A leader in the Hispanic/Latino community, a parent/caregiver of an autistic child, and autistic individual who received OT services, a researcher or clinician with experience with the Hispanic/Latino community. -Willingness to serve on committee and devote 5-7 hours monthly.	-Provide input and direction on planning and implementation of the project.	-Provide input and direction to assure cultural relevance and inclusivity, research rigor, and relevance for H/L autistic populations.
Stakeholder Advisory Board (SAB) • PI,Co-I • Hispanic/Latino service provider • Parent partner • Autism expert • Teacher of autistic individuals • Autistic individual	-Hispanic/Latino researcher or clinician with experience with Hispanic/Latino children. A caregiver of an autistic child and an autistic person who received OT services. -Willingness to serve on committee and devote 5-7hours monthly.	-Actively assist researchers with design, plan, implementation, evaluation and dissemination.	-To inform, consult, and collaborate on design, processes, data collection and analyses throughout the project.
Evaluation/Dissemination/ Stakeholder Advisory Board (EDSAB) • PI, Co-I • Hispanic/Latino	-Hispanic/Latino researcher or clinician with experience with Hispanic/Latino children. A caregiver	-This expertise and experience are needed to assist with the development and implementation of a comprehensive,	-Inform, advise, evaluate and disseminate. develop a plan to

service provider • parent partner • Expert in the Autism community • Diversity and inclusion expert • Teacher of autistic individuals • Autistic individual	of an autistic child - autistic person who received OT services. -Willingness to serve on committee and devote 5-7 hours monthly.	culturally relevant, and inclusive evaluation and dissemination plan.	disseminate findings.
Participant Stakeholders			
Caregiver partners (n=158)	-H/L caregivers of autistic child who receives therapeutic services.	-The input of this stakeholder group is needed to identify the facilitators and barriers to service access and use.	-Provide input via FG or DT participation.
Patient partners (n=12)	-Autistic persons who received OT as a child or teachers of autistic individuals.	-The input of this stakeholder group is needed to identify the facilitators and barriers to service access and use.	-Share experiences during DT and FG sessions.
OT Clinician Stakeholder Partners (n = 12)	-OT clinicians providing services to autistic children ages 3-12.	-The input of this stakeholder group is needed to share experiences re providing OT to H/L autistic children.	-Share experiences and brainstorm solutions.
Teacher Partners (n = 4)	-Teachers who educate autistic individuals.	-The input of this stakeholder group is needed to share experiences teaching H/L autistic children.	-Share experiences and brainstorm solutions

CSH – Children's Specialized Hospital, JeffACE = Jefferson Autism Center of Excellence, H/L = Hispanic/ Latino, OTD = Occupational Therapy Doctorate

Procedures:

As shown in Figure 2, the project includes multiple stakeholder groups who serve to advise and direct the project activities. Initially, we will receive input from the Stakeholder Research Steering Committee (SRSC) on study design, procedures, and DT/FG questions; and input from other stakeholder advisory groups on specific aspects of the study. Participants (described below) will be recruited regionally, and when we have enough for two groups in a given geographic region, we will send information to the statistician for randomization. DT and FG sessions are designed to engage stakeholders to provide input about the facilitators and barriers of access to, and utilization of, therapeutic services using two conceptually different methods. DT sessions (often called "sprints") utilize guided exercises that encourage participants to interact with each other in a stepwise process focused on problem identification and solution generation. FGs are a more linear process of obtaining input whereby data is gathered from conversations and themes extracted by researchers. We will hold 8 DT and 8 FG sessions, and each will consist of 8-10 participants (Halcomb et al., 2007). We aim for each DT and FG session to be made up of approximately 6 caregivers, 1 or 2 autistic persons, 1 clinician, and 1 teacher. Each session protocol will be reviewed by the advisory board stakeholders to assure it is in keeping with its respective conceptual framework and procedures, culturally sensitive, and in the native language of those who do not speak English as their first language. The protocols won't contain any personal or identifiable participant information. Accommodations will be available for all sessions as needed. The sessions will be held in locations (i.e., community sites) and formats that allow caregivers and autistic persons participants to easily attend. Transportation vouchers will be provided, as well as stipends for participation.

The participants must complete some steps before they are eligible. Interested individuals must first reach out via email, phone, or text message to the study team if interested. The team will then schedule a phone call to review study information and complete a phone screening to determine eligibility. If eligible, the participants will be verbally consented following the phone screen or will schedule a follow-up call to complete the verbal consent. On the day of the FG/DT session, the participants will review and sign a second consent form prior to the session with a study member who will also answer any questions for the participants.

DT and FG sessions will be audio-recorded. The recording will only start after the participants have introduced themselves and have shared their roles to minimize the collection of identifiable information. To assure that no identifiable information is on the FG and DT audio recordings, the research team will complete quality checks on the audio recordings and will remove any identifiable information for privacy protection before the transcriptions. FG/DT sessions will be rated for fidelity by an independent evaluator using fidelity measures designed for each. A fidelity rating will assure that each session is in keeping with the standard protocol for implementation. Outcomes data (described below) are collected immediately following each engagement.

Upon completion of all FG/DT sessions and analysis of the data, the cultural adaptation of the Ayres Sensory Integration intervention will take place. One manual will be adapted based on FG data, and one based on DT data. All session participants will be asked to complete an online survey to rate the acceptability, feasibility, and cultural appropriateness of the adapted intervention. The participants will be blinded to which data (FG or DT) was used for the cultural adaptation of the manual.

Figure 2. Engagement Approach

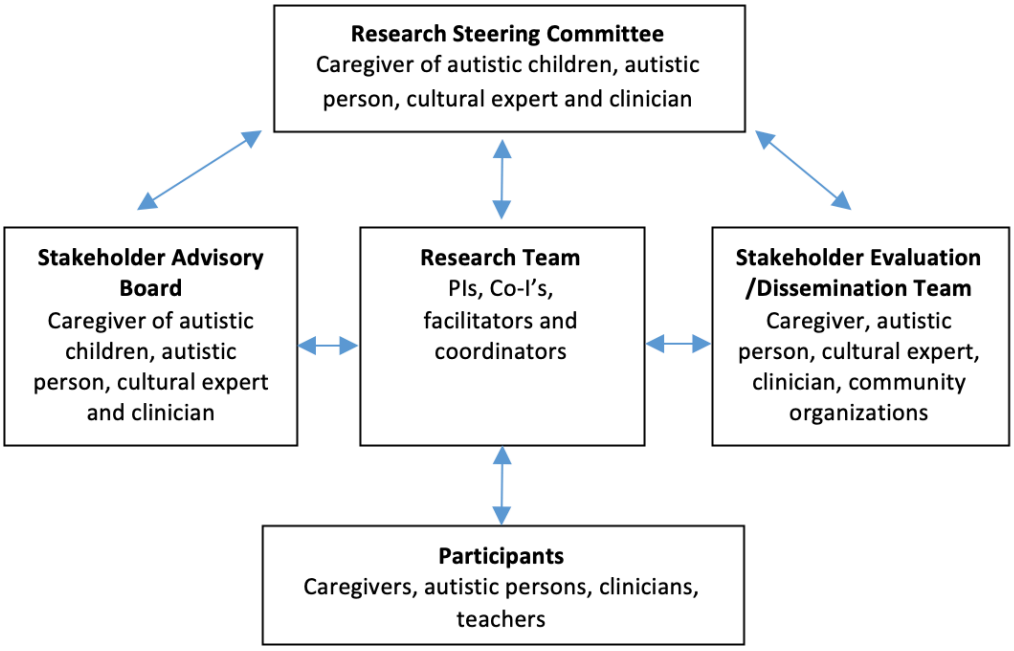
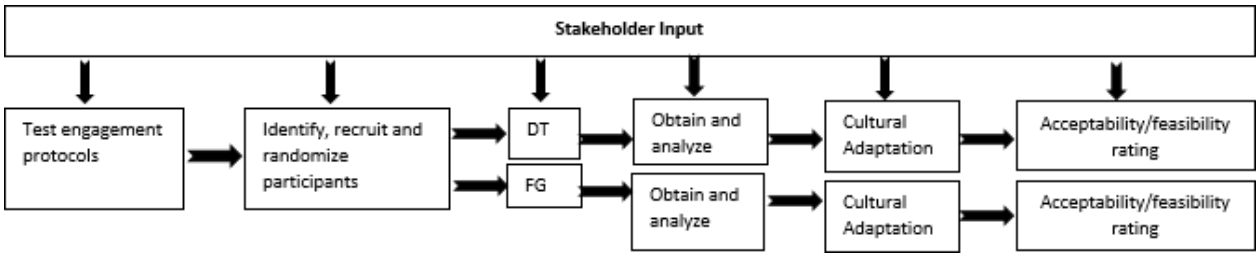


Figure 3: Design and Flow through the Study

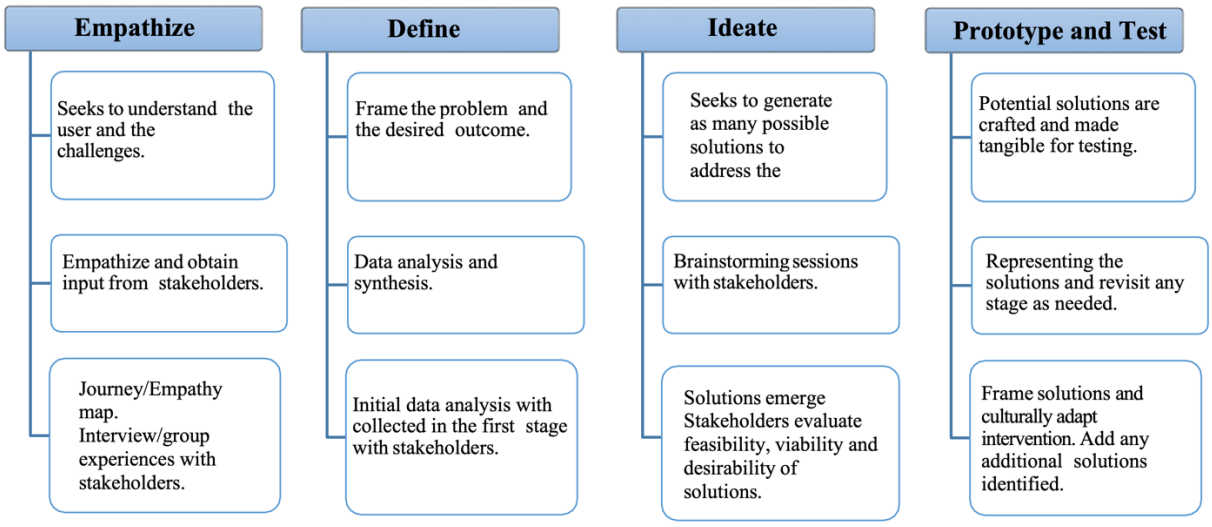


Design Thinking Sessions (DT)

As shown in Figure 4 below, DT encourages active engagement from all stakeholders (parent/caregiver participants, autistic persons, and clinicians) in each of its five stages: empathize, define, ideate, prototype, and test. During the empathize stage, the researchers learn about the problems (in this case, those associated with access to and utilization of therapeutic interventions) and use empathetic approaches to set aside any assumptions and understand the user's (caregivers) perspective and challenges. This includes creative approaches such as open-ended individual interviews, observation, or the creation of a journey map, which is a visual map documenting a user's step-by-step experience with a product or service (Pomeroy-Stevens et al., 2020). After gaining insight into each user's perspective and experience, the group will work together to identify problem areas or unmet needs. While many problem areas may be identified, the team works together to come to a consensus around a single problem or unmet need, which is then framed, and the desired outcome identified in the define stage. During the ideate stage, the team brainstorms solutions to the problem through guided exercises. The goal is to generate as many solutions as possible. The group will reflect on the solutions generated and then work collaboratively to choose the most feasible solutions to move forward. The final stage is the prototype and test stage in which the team will represent a solution through visual representation, which can include techniques such as

storyboarding, brainstorming ("acting out"), or creating a prototype solution. The feedback received through testing allows the team to gain immediate feedback and potentially further refine the solutions. At any point in the process, teams may revisit previous stages as new insights may be developed. Identified solutions will be used to adapt the manual to improve accessibility and feasibility of use by the Hispanic/Latino population.

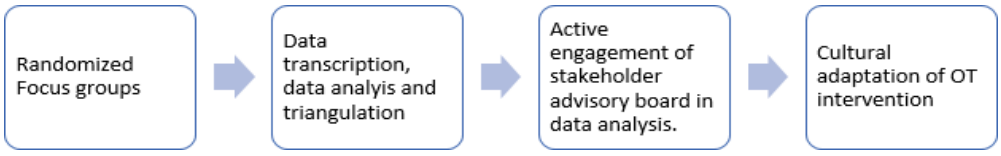
Figure 4: Design Thinking Format



Focus Group Sessions (FG):

As shown in Figure 5 below, FG follows a more linear process than DT. Each FG will have dual monitors who will follow a specific set of semi-structured questions previously crafted in collaboration with the Research Steering Committee to facilitate discussion on the barriers and facilitators in access to and utilization of therapeutic interventions for Hispanics and Latinos. Visual aids such as PowerPoint slides with the questions will be presented with the information in English and Spanish. Each FG will be recorded, and the data will be transcribed and analyzed using specialized multi-lingual computer software. The data will then be analyzed utilizing coding software, and a thematic analysis approach. Data is then subject to triangulation and member checking for increased credibility. The stakeholder advisory board will be actively engaged in the delivery and analysis of the FG. The identified themes will be identified and reviewed via consensus and operationalized into adaptations for the intervention manual.

Figure 5: Focus Group Format



Strategies to assure Cultural Sensitivity for DT and FG sessions

Cultural sensitivity and responsiveness to cultural differences will be guided by best-practice principles in cultural sensitivity (Galanti, 2012). We are guided in this process by the Stakeholder Research Steering Committee. Beginning with the conceptualization of the project, steps have been taken to

ensure that the project promotes and cultivates an inclusive environment where everyone feels valued, an important team member, and supported. Some strategies identified to implement throughout the project, particularly during the FG and DT sessions, include ensuring that the moderators will avoid stereotyping and generalization of participants as each participant's individual cultural norms and values will be acknowledged and valued. Stereotyping will be reduced by creating a culture of individualization where the moderators learn about everyone's culture, beliefs, and ideas. Generalization will be reduced by cultivating the value of uniqueness, emphasizing that all persons of a cultural group do not necessarily share beliefs, behaviors, and customs (Galanti, 2012). Moderators will use the 4 C's of culture (A Mnemonic for Health Care Professionals) when facilitating sessions: Condition or the individual's perception of the experience, Call, their belief of the cause (Cause), what has been done to "treat" the condition (Cope), and the concerns the individual has about the condition and/or treatment (Galanti, 2012).

Assurance of a non-bias approach: Focus groups and design thinking have unique theoretical perspective that drive their methods and outcomes. Our study will be a novel comparison of these two approaches to determine which may yield greater engagement and richer data related to our research questions. We are cognizant of the inherent similarities and differences in the DT and FG approaches. They are both human-centered approaches, both engage stakeholders to provide input in an active and somewhat dynamic way, and have similar time periods for interaction (see table 2). Below clarify the inherent differences in these approaches such as that design thinking is process-oriented, relatively non-linear, and iterative with the goal of developing a prototype; whereas focus groups utilize collaboration, discussion, and reflection with the goal of unpacking participants' lived experiences and opinions to understand the problem and create solutions from the themes identified in the data. Further, we assure that the time for each approach is similar (see Table 2).

Table 2 Comparison of use of Design Thinking and Focus Groups in stakeholder engagement

Design Thinking Process and Timetable	**Focus Group Process and Timetable**
Welcome (10 minutes) • Setting Goals and Expectations – 5 minutes • Icebreaker Exercise – 5 minutes	**Welcome (10 minutes)** • Introductions – share lived experience • Overview of project • Review project goals and why participants were selected.
Stage 1: Empathize (35 minutes) Interview • Small group or pairs interview a stakeholder about experiences, ask about problems, pain points) – 20 minutes • Share out with group – 5 minutes • Create Empathy Map – 10 minutes	**Stage 1: Introduction to the process (10 minutes)** Format and ground rules • Responding to questions • There are no right or wrong answers, only differing points of view • Respectful listening • Role of moderator and note taker • English translations if there are participants who prefer English • Recording of sessions
Stage 2: Define (20 minutes) • Dot Voting (Teams come to consensus on one problem area to tackle) – 5 minutes	**Stage 2: Discussion (90 minutes)** • Questions, probes, elaboration and/or clarification of responses (approximately 15 minutes per

• Teams create a "How Might We Statement (HWM)" – 10 minutes • Share out HWM Statements – 5 minutes	question X 6 questions = 90 minutes). • Facilitator has opportunity to follow up with comments or questions.
Stage 3: Ideate (35 minutes) • Group Brainstorming of solutions – 20 minutes • Solutions Categorized – 5 minutes • Team evaluates feasibility, viability and desirability of solutions and dot voting on solutions – 10 minutes	**Stage 3: Wrap up (20 minutes)** • Final question and summary • Review of purpose of study, "have we missed anything?" • Bringing the session to a close
Stage 4: Prototype and Test (20 minutes) • Group determine method to visually represent solution ("prototype") – 10 minutes • Record Feedback • Revisit any stage above as needed to improve solution – 10 minutes	
Total Time: 130 minutes (additional 10 minutes for break if needed)	**Total time: 130 minutes** (additional 10 minutes for break if needed)

Additional strategies to strengthen external validity: Other ways that we control for external validity are to assure data analysts are blind to the study arm so that their interpretation and analysis of the data are unbiased. Further, in Aim 2, the two adapted intervention protocols will be created, each based on data from either the design thinking or focus group sessions. These protocols will then be rated for acceptability, feasibility, and cultural appropriateness using standardized measures and stakeholder input. This rating will be performed by stakeholders who are blinded to the study arm that was used for the adaptation of each protocol. Thus, we include a second method of control for bias and improve external validity. Lastly, we address external validity by including a large sample (n = 158) that is representative of the population of interest, and large enough to obtain divergent views.

Cultural competency

In order to ensure cultural competency, researchers and stakeholders in all advisory board roles will complete a cultural competence assessment to determine their level of competence and any training or education needed to improve it. The Inventory for Assessing the Process of Cultural Competence Among Healthcare Professionals- Revised (IAPCC-R ©) (Campinha-Bacote, 2002) will be used. This tool has been widely used to assess the cultural competency of healthcare professionals, graduate students, and allied health professionals (Davis-Cheshire & Crabtree, 2019; Hayward & Li, 2014). The IAPCC-R © measures the level of cultural competence of an individual across 25 items that measure five separate areas of desire, awareness, knowledge, skill, and encounters. Items are rated on a 4-point Likert scale to reflect agreement, awareness, knowledgeability, comfort, or involvement (Campinha-Bacote, 2002). This measure is available in several other languages than English, including Spanish. If cultural competence is lacking, stakeholders will be trained in cultural competency prior to participation.

Finally, all sessions will be held in Spanish and/or English based on the groups' preferences. Since our intent is to hear the voices of Hispanic/Latino stakeholders, it seems valuable to hold focus

groups in Spanish when the participants are Spanish as first language speakers (hereafter referred to as Spanish-first) with audio recordings and later transcription into English for analysis. To accommodate those who prefer English, we will make every effort to group these participants together. When, and if, the Spanish-first groups include participants who prefer English, we will have a Spanish-to-English translator available. In other words, we will be respectful of each participant's language to optimize their comfort in the engagement sessions. We are fortunate that the co-I of this study is a Hispanic/Latino researcher who is fluent in Spanish and English, knowledgeable of the content area, sensitive to the cultural norms of our population of interest, and skilled in focus group facilitation. We feel certain that she will create the positive synergy needed to foster comfort, assure all voices are heard, and facilitate the rich discussion needed to obtain data reflective of the participant's experience.

E. Statistical Methods

If not a pilot study, provide biostatistical design, power calculations determining the number of participants, and the proposed analysis. (Suggested length: ½ page)

Data Collection, Organization, and Handling: For Aim 1, data on stakeholder engagement will be collected after each DT and FG session using the Stakeholder-Centric Engagement Evaluation (described below). These data will be organized and stored using the secure Research Electronic Data Capture (RedCap) data management system and handled by the PI, Co-I's, and Research Coordinator. No identifying information will be stored in RedCap or other comparable data management system. All sessions will be video recorded and uploaded to a secure server and, in addition to the research team, the fidelity raters will have access to these data. Data reliability checks will be completed by the research team. For Aim 2, the EDSAB will use the Acceptability of Intervention Measure (AIM), the Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM; Weiner et al., 2017), described below, to review and rate the adapted intervention manuals. Manuals will be housed on a secure server.

FG data will be recorded, transcribed, and coded using the NVivo Qualitative Data Analysis Software. Key themes will be identified via thematic analysis. Steps will be taken to increase trustworthiness and internal validity (Johnson et al., 2020) in the following ways: Credibility will be increased through the triangulation of data using multiple investigators to develop a comprehensive understanding of the facilitators and barriers of access to evidence-based interventions for our target group and member checking to verify transcripts with participants. Transferability will be addressed via thorough reporting of the sample and setting. Dependability will be improved through the completion of an audit trail to document key decisions made throughout the analysis process. A peer review of the audit trail will be completed to further check potential researcher bias. Once consensus is reached on themes, these data will be compiled into a table that details the recommended adaptations for each manual. These adaptations will be added to the manual by the research team and subject to member checking by the advisory board.

DT: solutions generated will be organized by the DT facilitators and then ranked by the stakeholders Evaluation and Dissemination team. Adaptations based on these solutions will be compiled into a table that details recommended manual adaptations.

Measures

Stakeholder-Centric Engagement Evaluation (Martínez et al., 2021): The instrument was developed to evaluate stakeholder engagement via the PCORI engagement principles. It can be customized for given stakeholder groups and projects. As shown in Table 3, we adapted the tool for this project to evaluate stakeholder engagement in the 5 PCORI engagement areas. DT and FG participants use this instrument to rate engagement in throughout the research process using a Likert scale with 1= never and 5 = always. Face validity and acceptability are high (M = 4.50/5.0, SD = 86), clarity (M = 4.56/5.0, SD = .78), and relevance (M = 4.67/5.0, SC =.49).

Table 3: Adapted Stakeholder-Centric Engagement Evaluation

Engagement areas	PCORI principles
1. Respect and value of stakeholder's perspectives	Honesty, Trust
2. Seek stakeholder's input	Co-learning, reciprocity
3. Act on stakeholder's input	Partnerships, Co-learning
4. Communicate with stakeholders using effective methods	Reciprocity, Partnerships
5. Transparency	Transparency, Honesty, Trust

Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM) and the Feasibility of Intervention Measure (FIM) (Weiner et al., 2017): are outcome measures that evaluate implementation success via the extent to which stakeholders believe the intervention is acceptable, appropriate, and feasible. Each measure uses a Likert response scale where 1 = completely disagree and 5 = completely agree. All items demonstrate substantive and discriminant content validity; acceptability (Cronbach alphas = 0.85), .91 for appropriateness (.91), and feasibility (.89). A three-factor CFA exhibited acceptable fit (CFI = 0.96, RMSEA = 0.08) and high factor loadings (0.75 to 0.89), indicating structural validity. Test-retest reliability ranged from 0.73 to 0.88, being a valid and effective outcome measure.

Data Analysis:

Demographic characteristics of all randomized participants who attend the DT or FG sessions will be summarized by session type. For the primary analysis of Aim 1, we will jointly analyze the Stakeholder-Centric Engagement Evaluation engagement scores ("How Often" and "How Well") for each of the 5 engagement areas shown in Table 3 using a multivariate analysis of variance analysis implemented within a mixed-effects model. The mixed effects approach allows for randomly missing items without throwing out the vector of measurements for a subject. It will also allow us to account for correlation among the multiple engagement scores measured on the same subject and among subjects who participated in the same specific group. We will assume outcome-specific means for the 5 engagement scores for each session type (DT vs FG) and that the residuals of the vector of engagement scores have an unstructured variance- covariance matrix. We will further assume independent random intercepts for each outcome-group combination to account for clustering within groups. Within the mixed effects model, we will estimate the mean score for each arm and perform tests of the null hypothesis that the means are equal at the 0.005 level. Comparisons of the session types with respect to the number of times stakeholders participate will be performed using GEE Poisson regression accounting for clustering with group. The number of solutions developed will be counted for each group, and the session types will be compared using a Wilcoxon rank sum test. We anticipate that missing data post-randomization will result from not attending the sessions. We expect that attendees will have very little missing data on the Stakeholder-Centric Engagement Evaluation engagement scores. We do not expect probability of attendance to vary by randomization assignment. We will evaluate this assumption and evaluate whether other baseline characteristics are related to non-attendance. We will perform a sensitivity analysis adjusting our primary analysis model for any identified predictors of non-attendance. Although we do not anticipate that any subjects would attend a session type different from the one, they are randomized to, if this happens, we will analyze subject responses based on the session type attended, not randomized. A 'per-protocol' sensitivity analysis will be performed only, including subjects who attended the session to which they were randomized.

For Aim 2, each of the EDSAB will be asked to evaluate the protocol developed under DT and the protocol developed under FG. Ratings will be summarized by protocol type (DT and FG).

We will use paired t-tests (or signed rank tests) to compare the evaluations of the two protocols. We will explore whether relative ratings of the two interventions differ by stakeholder characteristics including age of the caregiver and age of the autistic child.

We will code for level of engagement by viewing and coding the video recordings of each session. After achieving adequate reliability and validity on coding, coders will view the session video and code for stakeholder engagement. Given that we are interested in the level of engagement, coding will be relatively straightforward and guided by our qualitative expert with coding for each occurrence of engagement by participants and the type of engagement. We will compare and contrast these between these groups.

F. Gender/Minority/Pediatric Inclusion for Research

All protocols must include documentation of the inclusion of women and minorities in the research protocol. If women and minorities are not to be included, provide rationale for exclusion.

Rationale for selection of sex/gender and race/ethnical groups:

The primary aim of this study is to improve the utilization of occupational therapy services of Hispanic and Latino families of autistic children; recruitment of caregivers will exclude other racial groups outside of Hispanic and Latino for the caregiver participant partners and the autistic/patient partners. Recruitment of occupational therapy clinicians may include all races and ethnic groups. Participants will include all sexes and genders.

Rationale for proposed outreach program for racial/ethnic groups:

As this study is focused on recruiting Hispanic and Latino families of autistic children as key stakeholders for the focus group and surveys, it is crucial for the outreach efforts to be focused on evidence-based strategies. Hispanic and Latino community members have indicated barriers to participating in autism research, including fear of legal uncertainties, literary barriers, and distrust of healthcare systems (Burkett et al., 2022). Literature also indicates that important to have trust and collaboration in the recruitment of minority populations (Ibrahim & Sidani, 2014). Additional barriers to recruitment include lack of knowledge of research, lack of access to transportation, and personal characteristics, including health status, religion, and beliefs (Ibrahim & Sidani, 2014). Therefore, it is crucial to actively address recruitment barriers and concerns through evidence-based strategies.

This study does not involve children as human subject.

Planned Enrollment Report

Table 4: Estimated Final Racial/Ethnic and Gender Enrollment Table for 110 Caregiver Participant Partners

Race	Male (N)	Female (N)	Other * (N)	Total (N)
American Indian/Alaska Native	2	10	0	12
Asian	0	0	0	0
Black/African American	5	8	0	13
Hawaiian/Pacific Islander	0	0	0	0
White	13	31	0	44
Multirace	10	31	0	41
Ethnicity	**Male (N)**	**Female (N)**	**Other * (N)**	**Total (N)**
Hispanic (Latino/Latina)	31	79	0	110
Non-Hispanic	0	0	0	0

Table 5: Estimated Final Racial/Ethnic and Gender Enrollment Table for 10 Patient Partners

Race	Male (N)	Female (N)	Other * (N)	Total (N)
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Black/African American	0	2	0	2
Hawaiian/Pacific Islander	0	0	0	0
White	1	3	0	4
Multirace	1	3	0	4
Ethnicity	**Male (N)**	**Female (N)**	**Other * (N)**	**Total (N)**
Hispanic (Latino/Latina)	3	7	0	10
Non-Hispanic	0	0	0	0

Table 6: Estimated Final Racial/Ethnic and Gender Enrollment Table for 10 OT Clinician Stakeholder Partners

Race	Male (N)	Female (N)	Other * (N)	Total (N)
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Black/African American	0	2	0	2
Hawaiian/Pacific Islander	0	0	0	0
White	1	4	0	5
Multirace	0	3	0	3
Ethnicity	**Male (N)**	**Female (N)**	**Other * (N)**	**Total (N)**
Hispanic (Latino/Latina)	1	5	0	6
Non-Hispanic	0	4	0	4

G. Human Subjects

1. Provide number, age range, and health status of the subject population. List criteria for inclusion or exclusion.

The proposed involvement of human subjects is described below:

158 Hispanic and Latino parents/caregivers of autistic children: Including individuals of all health conditions if the subjects have no cognitive or communication conditions impacting their ability to participate in DT or FG sessions and respond to questions to provide input about the facilitators and barriers related to utilization of OT intervention. Hispanic and Latino parents/caregivers over 18 years old will be able to share their wisdom and experiences so that the OT intervention can be adapted to allow better access and utilization. This will assist in informing changes to the existing intervention protocol to address the identified logistical and sociocultural factors impacting service access.
14 Patient Partners/Autistic Person Partners: Autistic persons over 18 years old who have received therapeutic interventions as a child who will participate in the Focus Group or Design Thinking sessions to share their personal experiences and provide input and feedback about access to and utilization of therapeutic interventions.
14 Clinician Stakeholders: These OT clinicians can provide clinical expertise in identifying barriers and facilitators to care for Hispanic and Latino families of autistic children and have a professional lens in reviewing the adapted occupational protocol to identify if it is feasible and appropriate for supporting families and OT clinicians in implementing this protocol.

Inclusion/exclusion criteria

Inclusion criteria for autistic person: 1) confirmed diagnosis of autism spectrum disorder; 2) Hispanic/Latino; 3) received therapeutic services as a child; and 4) willing and able (with i.e.: language and cognitive skills) to participate in the design thinking or focus group session designed to learn about the facilitator and barriers to receipt of therapeutic services.
Inclusion criteria for caregiver partners: 1) Hispanic/Latino caregiver of an autistic child who receives or received therapeutic services such as occupational, physical, speech and language therapy; 2) willing to participate in the design thinking or focus group session designed to learn about the facilitators and barriers to receipt of therapeutic services. Participants can be English or Spanish speakers.
Inclusion criteria for clinician stakeholders: 1) currently provide or provided therapy services to participants and their families part of the Hispanic and Latino community for at least a year; 2) willing to participate in the design thinking or focus group session designed to learn about the facilitators and barriers to the receipt of therapeutic services.

Exclusion criteria

Exclusion criteria for caregiver partners: 1) not being part of the Hispanic/Latino community.
Exclusion criteria for autistic individuals: 1) being under the age of 18. 2) not having a formal autism diagnosis.

2. Identify sources of research material in the form of specimens, records, or data.

The records part of this research includes qualitative data from the DT and FG, quantitative data collected from the stakeholder-centric Engagement Evaluation Instrument (Martínez et al., 2021); and the surveys administered after the cultural adaptation of the manuals.

3. Describe plans for recruitment and consent procedures to be followed.

Recruitment:

Recruitment plans include online posts on social media, printed and electronic flyers, TV spots, and e-mails through community organizations. Participants will be reaching out to the study team via the e-mail address, text messaging or phone call listed on the recruitment materials.

To facilitate recruitment, we use the rich resources and database of the Health System and build on our experiences recruiting minority participants for current trials. In addition, we will establish relationships with our Hispanic and Latino community partners and be respectful of religious and cultural beliefs when scheduling sessions. The Jefferson Clinical Research Institute fosters and promotes excellence in all clinical research activities including those throughout the health system as well as with external. We will engage our many partners including the Swank Autism Center of Nemours Children's Health (Wilmington, Delaware) and the Children Specialized Hospital (CSH, New Jersey) for recruitment. Both centers with active programs for autistic children that serve large numbers of minority families, and with whom we have a successful working relationship in prior and current studies. We will also engage our Hispanic and Latino community partners, who include several organizations across Philadelphia and New Jersey. In addition to recruitment, the Nemours Swank Autism Center, will also serve as a site to implement the engagement sessions (design thinking and focus groups). We also built collaborations with Hispanic/Latino community organizations including Casa del Carmen, Hispanos Unidos Para Niños Excepcionales (HUNE), and Catholic Community Services in Philadelphia. In total, our recruitment pool is over 700 Hispanic/Latino families of children with autism.

Vulnerable population recruitment and retention strategies: Active engagement of autistic adults (vulnerable population) from the Hispanic/Latino communities are included. We will use our vast community outreach networks to assist with recruitment as described above. Retention will be facilitated by building trust, appropriate compensation, accommodation of schedules, and provision of activities within Hispanic/Latino communities and in native language. Some proposed programs for equitable recruitment include:

- All outreach materials and community events will be held in Spanish and English.
- Work with the Office of Diversity, Equity and Inclusion at Thomas Jefferson University to assure all recruitment materials are culturally appropriate.
- Collaborate with the Jefferson Recruitment Enhancement Service (RES) who aid in creating comprehensive, strategic recruitment plans throughout the Jefferson Health system to maximize recruitment efforts.

- Collaborate with recruitment sites for dissemination of information about the study.
- Attend autism events in the community (Ibrahim & Sidani, 2014; Ratto et al., 2017)
- Distribute flyers with a focus of more visuals and less text; use of brochures; or use of posters (Ibrahim & Sidani, 2014; Ratto et al., 2017).
- Ensuring recruitment materials are available in Spanish and English (Aguirre et al., 2018; Kao et al., 2011)
- Provide outreach and information at local parent support groups, churches, schools, etc. in the area (Ibrahim & Sidani, 2014).
- Collaborate with bicultural community liaisons and community leaders to provide insight into the recruitment process (Aguirre et al., 2018; Ibrahim & Sidani, 2014; Zamora et al., 2016).
- Digital links and mobile survey outreach for Hispanic and Latino families of autistic children (Bhakta et al., 2022)

Consent procedures:

Individuals interested in the study will reach out to the team via email, phone, or text messaging. The team will then schedule a phone call to review the study information and, if interested, will complete a screening to determine eligibility. Participants will be verbally consented if they are found eligible. The participants will also review and sign an informed consent with a study member who will answer any questions the participants may have before the FG/DT session. The participants will also complete a W-9 form for payment.

Each participant will be assigned a code/number. The code/number will be a unique three-digit number (between 100 and 500) generated by the research team. Only the research team will have access to the assigned codes.

The completed phone screens signed consent forms, and the W-9 / forms for participant payment will be retained in the participant partner's research file and will be stored in a locked file cabinet in the Thomas Jefferson University (TJU) research offices.

4. Describe risks and assess likelihood and seriousness.

The study is not expected to pose any major risks to the participants. Minor risks are detailed below.

Risks during DT/FG sessions:

The human subjects' responses involve identifying/discussing facilitators and barriers in access to and utilization of an evidence-based occupational therapy intervention and evaluating the acceptability, appropriateness, and feasibility of the adapted intervention. There is a possibility that participants may feel discomfort as some questions will involve identifying barriers to accessing OT services. If this is the case, they don't have to answer the questions. However, this information and the participants' responses would not reasonably place any participant in any negative legal, criminal, educational, or reputational risk outside of the research setting.

5. Describe procedures for protecting against or minimizing potential risks.

The research team has had success in protecting against such risks in their previous studies and research trials. The following details the protections against potential risks:

Risks during DT/FG sessions: During the phone screen consent and at the start of each FG/DT session, all the participants will be reminded that they do not have to speak about anything that causes discomfort and can take breaks/stop at any time.

Confidentiality: The audio recording of the sessions will only start after the participant introductions to minimize the risk of collecting identifiable information. The team will complete quality checks on the recordings and any potentially identifiable information will be immediately removed before being transcribed to protect the participant's privacy. Both recordings and transcriptions will be password-protected. Only de-identified information will be available in the transcriptions and entered in NVivo and RedCap for data analysis purposes, which will also be password protected. Participants will only be identified by the randomly assigned participant study ID number. The surveys will be completed via Qualtrics and will be collecting the participants' names for Clincard purposes. The names will be replaced by the participant's IDs. The surveys will be de-identified before the review/analysis.

The identified documents for consent and phone screen are stored separately in a locked file cabinet in the TJU research office. Further, the use of a randomized participant ID for each participant for their de-identified data keeps the identity of the human subjects from being directly linked or accessed. The coding sheet that links the participant IDs and participant names will be password protected. The de-identified data will be stored in Box through the Jefferson domain.

Handling Incidental Findings: This study does not involve any image testing or paternity testing. If any new information may come out during this study, the participants and parents/caregivers will be given any new information that could change their decision to take part in the research.

6. Describe potential benefits and importance to the subjects and others.

This project could improve the accessibility of therapy services and evidence-based interventions to the Hispanic and Latino autistic population. The findings could improve the quality of the delivery of services to this population due to the availability of resources to deliver culturally competent practices.

7. Discuss why risks are reasonable in relation to benefits.

Participants' responses involve identifying/discussing facilitators and barriers in access to and utilization of an evidence-based occupational therapy intervention and evaluating the adapted intervention's acceptability, appropriateness, and feasibility. This information and the participants' responses would not reasonably place any participant in any negative legal, criminal, educational, or reputational situations outside of the research setting. The potential benefits of this research include an increase in access to autism services for the Hispanic/Latino population and a culturally tailored evidence-based intervention for improved health and well-being.

H. Data and Safety Monitoring Plan

This study will compare two methods of stakeholder engagement in research with a focus on Hispanic and Latino parents of autistic children. The stakeholder engagement methods are Design Thinking and Focus Groups. Both types of engagement involve 8-10 partners (aka research participants) who will meet for 130 minutes to engage in discussion (during Focus Groups) or interactive problem-solving (during Design Thinking Groups). As such, this study constitutes minimal risk; however, research compliance, data security, and safety of the research protocol will be monitored by the Principal Investigator (Schaaf), Co-Investigator (Rios-Vega), and the Stakeholder Research Steering Committee (mandated by the project).

PI and Co-I Monitoring: PI Schaaf and Co-I Rios-Vega will monitor recruitment and enrollment data, protocol compliance, and Focus Group and Design Thinking activities by completing monthly reviews of:

- Recruitment/accrual/retention for the partners/participants by reviewing partner/participant log and project timeline/milestones
- Protocol compliance – review current protocols/group performance compared to IRB approved procedures to ensure adherence
- Participant confidentiality – review current status of informed consent process, data storage, and ensuring no identifiers are present in electronic database
- Safety monitor – review any potential conflicts of interest involved or occurring with the study

PI will also oversee any adverse event reporting according to IRB procedures as described below (see "Reporting of Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Problems (UPs)").

Frequency of Monitoring: PI and Co-I will review all the data listed above monthly to ensure that safe protocols are followed.

In addition, the Stakeholder Research Steering Committee (mandated by the project) will serve as the Research Data and Safety Monitoring Committee. This committee consists of an expert in research, a Hispanic/Latino educational expert, a Hispanic/Latino cultural expert, a parent of an autistic child and a teacher of autistic persons. The committee will review the study protocol and the data described below to assure that the study is being carried out in a timely and ethically sound way.

Framework and Frequency of Monitoring: The research data and safety monitoring committee will monitor data according to the table below:

Table 7: Data Safety and Monitoring Plan

Type of Data	Frequency	Tasks
Regulatory Adherence	• Prior to initiation of the first Focus Group or Design Thinking Session • Following completion of the first Focus Group and Design Thinking sessions • Following the completion of 8 sessions • At final report	Review study progress, enrollment procedures, Focus Group and Design Thinking Procedures, IRB approvals, confidential data storage, and plans for data analysis.
Group Activities	• Prior to initiation of the first Focus Group or Design Thinking Session • Following completion of the first Focus Group and Design Thinking sessions • Following the completion of 8 sessions • At final report	Will review current recruitment strategies and participant accrual and retention (i.e., age, gender, race/ethnicity)
Protocol Adherence	• Prior to initiation of the first Focus Group or Design Thinking Session • Following completion of the first Focus Group and Design Thinking sessions • Following the completion of 8 sessions • At final report	Will review IRB-approved study protocol and compare to actual activities
Participant Risk vs Benefit	• Prior to initiation of the first Focus Group or Design Thinking Session • Following completion of the first Focus Group and Design Thinking sessions • Following the completion of 8 sessions • At final report	Will review current status of enrolled/completed partners/participants, review any current risks and how to minimize or stop any potential risks
Quality checks on timeliness and the quality of the data	• Prior to initiation of the first Focus Group or Design Thinking Session	Will review documentation to make sure that all data is secure, confirm all the data is entered and is accurate

	the procedures for quality checks will be reviewed. • Following completion of the first Focus Group and Design Thinking sessions • Following the completion of 8 sessions • At final report	

The Research Data and Safety Monitoring Committee, PI Schaaf, Co-I Rios-Vega or study sponsor may initiate an ad hoc data and safety monitoring meeting if there is a significant safety concern or significant participant safety issue. Some examples of significant safety concerns include:

- Participant death or a life-threatening condition
- Any unanticipated issues in the study protocol that cause unnecessary risk to the participants
- If an investigator or sponsor identified any other participant safety issues

Reporting of Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated problems (UPs):

The research team will adhere to all Thomas Jefferson University IRB policies for reporting AEs, SAEs and UPs. This includes documenting and reporting any AEs, including SAEs, and UPsand reporting these to the funder (PCORI) and to the IRB immediately through the Electronic Serious Adverse Event Reporting (eSAEy) system. Any UPs must be reported within 10 business days using the Electronic Unanticipated Problem Reporting (eazUP) system and reported to the DSMB.

Individuals/Group Responsible for Monitoring:

The PI, Co-I (Rios-Vega) and the Research Data and Safety Monitoring Committee will be responsible for monitoring all aspects of the study.

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