

**Title: An Empowering Parent Training Intervention to Increase Physical Activity in
Preschool Aged Children With Autism: A Randomized Control Trial**

NCT: not yet assigned

Date: 01-28-26

**Document contents: Informed Consent, Statistical Analyses Plan
and Study Protocol**

Informed Consent Form: Study 2

Start of Block: Default Question Block

Please find the study details discussed in this meeting below. If you wish to enroll in the study, please complete the informed consent by signing the electronic signature box with your name and date.

We are inviting parents of children with autism between the ages of 3 to 5 years old to participate in a dissertation research study. Participating is voluntary; you do not have to participate if you do not want to. You can withdraw from the study at any time. The purpose of this study is to evaluate an online training program **to help parents support physical activity for their young children with autism**. All study activities will take place **online**.

Northeastern University, Department of Applied Psychology

Name of Investigator(s): Jessica Hoffman, Ph.D., Haley Medeiros, M.S.

Title of Project: Wellness Enhancing Physical Activity for Young Children

Funded by: Society for Pediatric Psychology (Division 54 of the American Psychological Association)

Version date: January 14, 2026 #IRB 12-22-25

Informed Consent to Participate in a Research Study

Key Information: We are inviting you to take part in a research study. You may ask us any questions that you have. When you are ready to decide, please sign and date below if you want to participate. **Participating is voluntary; you do not have to participate if you do not want to.** The researcher will email you an electronic copy of this document to keep after you electronically sign. We will ask you to complete an online training about promoting children's physical activity and three surveys that will each take about 10

minutes. We expect that your total participation in this study will take about 2 hours. The risks to you include fatigue and potential risks to confidentiality.

Why are we doing this study? The purpose of this research is to understand ways to help children with autism be more physically active by supporting their parents and caregivers with tools to do so.

What will you be asked to do? This study is being conducted to evaluate an experimental online parent training designed to help parents promote active play in their 3- to 5-year-old children with autism.

What to Expect: If you choose to participate in this study, you will be asked to:

- Review and sign this online informed consent form.
- Complete a set of questionnaires at three timepoints: pre-training, post-training, and 3-month follow-up that will ask you about your knowledge and confidence to help your child be physically active. They also will ask your perspectives about the training and any physical activity promotion strategies you use/used with your child. These will each take between 10-15 minutes.
- Participants will be randomly assigned to take the training over the next two weeks or be offered the training after 3 months. The online training takes about 90 minutes.
 - It includes watching informational videos, viewing video clips of adults helping children be active, reading handouts on behavior management tips and social stories, participating in an anonymous discussion board with other parents and completing a self assessment.
- All study activities will be completed online. Once questionnaires are complete, you will receive a \$40 gift card.

Where will this take place? How much time will it take? This study will take place entirely online. The first part of the study is a 90-minute training and review of materials. The other part of the study involves answering survey questions online. These surveys will

be emailed to you, and each take approximately 10-15 minutes to complete for a total of 30-40 minutes.

- The pre-training survey will be completed in this meeting immediately after the consent is signed.
- The post-training survey will be sent you to approximately 2 weeks after beginning the study.
- The 3 month follow up survey will be emailed to you approximately 3 months after the study begins.

Will being in this research help you? You may find the information and strategies in the training helpful with your own children. The information we learn from this study may help you use better parenting strategies, which can help you with your own child and it may help other parents of children with autism in the future.

Will there be any risk or discomfort to you? For parents, there is minimal risk involved in participating. However, participating in activities that are new may be stressful for parents. The online training is self-paced and can be paused and returned to at any point that is convenient over a two-week period. Another possible unlikely risk is that your confidentiality could be lost: that is, people outside the study might access information about you. We will do everything we can to minimize this risk, as described below.

Who will see the information about you? For the most part, only the research team will see the information about you. We won't use any identifiable information in reports or publications. Sometimes, authorized people may ask to see research information about you and other people in this study. They would only look at the information to make sure that the research is done properly. We would only permit people to see this information if they are authorized by the Northeastern University Institutional Review Board. We will keep identifying information separate from our research data, to make it harder for anybody to tell who you are. Any information that links the participant's ID with their name will be in a password-protected file of which only the research investigators will have access. There is a minimal risk that outside parties could access confidential parent or child information

outside of the research team. We will store your information on secure servers at Northeastern University. We plan to keep the identifiable information for about 4 months.

Future Use of Data: After we remove identifying details, we might re-use information about you for future research studies or share it with other researchers without additional informed consent from you.

Can you stop your participation in this study? Yes, you can quit the study at any time. You can also refuse to answer any questions you don't want to answer. If you do not participate or if you decide to quit, there will be no penalty, and you will not lose any rights, benefits, or services that you would otherwise have. Compensation will be provided to participants who complete all parts of the research study. If you leave the study or the researcher removes you from the study, then any information already collected from you will not be used for the study.

Will you be paid for your participation? You will be given \$40 in a gift card as a thank you for completing the surveys. Please provide the best email to send this gift card in the space below.

Who can you contact if you have questions or problems? If you have any questions about this study, please contact Haley Medeiros, Medeiros.ha@northeastern.edu, the person mainly responsible for the research. You can also contact Jessica Hoffman, j.hoffman@northeastern.edu, the Principal Investigator.

Who can you contact about your rights as a participant? If you have any questions about your rights in this research, you can contact the Northeastern University Department of Human Research at Tel: (773) 396-2327, or Email: IRBReview@northeastern.edu . You may call anonymously if you want.

*****This study has been reviewed and approved by the Northeastern University Institutional Review Board.*****

Q1 If you wish to participate in the study, please provide your electronic signature below.

Consent to Participate: I agree to take part in this research and provide my signature below. **Decline to Participate:** If you do not wish to participate in the study, please exit the survey.

Q2 Thank you for your interest in the WE PLAY study! Please provide your preferred name and the best phone number and email address to contact you throughout the study.

End of Block: Default Question Block

Statistical Analyses Plan

Descriptive statistics will be calculated to report participant demographics. Full information maximum likelihood estimation will be utilized to account for missing data across all variables (Enders, 2010).

To test hypothesis 1 (i.e., Parents/caregivers in the WE PLAY group will report higher levels of PA promotion knowledge, self-efficacy, behavioral intentions, and perceived behavioral control from pretest to posttest and when compared to parents/caregivers in a control group), a 2 (time) X 2 (group) repeated measures analysis of variance (ANOVA) will be used with time (pre v. post) as the within subjects factor and group (experimental v. control) as the between subjects factor to assess if change over time differs between the two groups. Effect sizes will be calculated where $d = 0.2$ is considered a small effect, $d = 0.5$ is considered a medium effect and $d = 0.8$ is considered a large effect (Cohen, 1988).

To test hypothesis 2 (i.e., Parental/caregiving variables at post-test, including self-efficacy, behavioral intention and perceived behavioral control, will significantly predict the extent to which changes in PA promotion practices (i.e., parent behaviors) are reported at 3-month follow up), two multiple linear regression models will be used to examine the extent to which post-test parental (a) perceived behavioral control (average of perceived behavior control items) (b) behavioral intentions (average of behavior intention items), and (c) self-efficacy (summative score of the PPCQ) predicted the number of PA promotion practice changes that were reported at follow up using the PAPP and the researcher developed PA promotion changes questions while controlling for child age, child gender, and race.

Lastly, hypothesis 3 (i.e., Following the training at post-test, participants will rate the adapted WE PLAY training as acceptable, feasible, and understandable) will be explored by

calculating means and standard deviations for the three URP-IR subscales (i.e., acceptability, understanding and feasibility).

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PROTOCOL NON-EXEMPT APPLICATION FORM

Protocol Version Date¹: 01.23.2026

Before completing this application, please familiarize yourself with the *[Policies and Procedures for Human Research Protections](#)* to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. **It is the policy of Northeastern University [NU] that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB).**

Application materials need to be submitted to IRBReview@northeastern.edu. The Principal Investigator (PI) is ultimately responsible for the entire research project, including the submission of the application for IRB review. While research team members may assist in preparing the application, only the PI is authorized to submit the final version.

Only complete applications will proceed for review. A complete application includes:

- A signed [PI Assurance Form](#) [Note: this is a separate form and can be found on the Forms page of the IRB website.]
- Informed consent materials (refer to [consent form templates](#))
- All data collection instruments (including survey questions, interview guides, and/or other data collection sheets), recruitment materials, and any other participant facing materials used in the conduct of the study.
- CITI training completion dates for study team members. Information about how to access and complete required training can be found on our [website](#).

PROTOCOL INFORMATION

Principal Investigator: Jessica Hoffman, Ph.D.

Student Investigator [if applicable]: Haley Medeiros, M.S., CAGS

Protocol Title: An Empowering Parent Training Intervention to Increase Physical Activity in Preschool Aged Children with Autism: A Randomized Control Trial

FUNDING INFORMATION

Funding agency/source [NU if no external funding source]: Society for Pediatric Psychology

Grant Title: Marion and Donald Routh Student Research Grant

Grant ID: A copy of IRB approval is required for distribution of grant funds, so NA for now

REVISION HISTORY (for changes submitted to the IRB *after* approval via the modification process):

Revision number	Submission Date	Reason for change
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1

2

3

4

(Add additional lines as needed)

¹ This date is to be updated whenever modifications are made to an approved IRB protocol application

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1. INVESTIGATOR INFORMATION

Principal Investigator (PI cannot be a student): Jessica Hoffman, Ph.D.

CITI Human Subjects Research course completion date: 6/27/2023

PI Eligibility (see the [Investigator Manual](#) for specific requirements):

- Professor or Research Professor
- Associate Professor or Associate Research Professor
- Assistant Professor or Assistant Research Professor
- Other: Click or tap here to enter text.

College or Department: Department of Applied Psychology, Bouvé College

NU Email: j.hoffman@northeastern.edu

Dual Appointments: does the PI also have any non-NU appointments at any other universities, hospitals, or other institutions that conduct research or may be related to this project?

- No other appointments or positions
- Has one or more other appointment(s) or position(s). Please explain the position and how the position might or might not relate to this research project: Click or tap here to enter text.

Is this student/postdoc/trainee research? Yes No

If yes, please provide the following information:

Student/Postdoc/Trainee Name: Haley Medeiros, M.S., CAGS

CITI Human Subjects Research course completion date: 12/20/2024

NU Email: Medeiros.ha@northeastern.edu

Dual Appointments: does the student/postdoc/trainee also have any non-NU appointments at any other universities, hospitals, or other institutions that conduct research or may be related to this project?

- No other appointments or positions
- Has one or more other appointment(s) or position(s). Please explain the position and how the position might or might not relate to this research project: Click or tap here to enter text.

Oversight Plan: How will communication occur between the PI and student/postdoc/trainee researcher to ensure appropriate oversight of study conduct, unexpected problems, project modifications, and interim results? Address any particular needs for oversight related to the study's risks.

PI oversight will occur in weekly in person research supervision. Additionally, the student researcher will contact the PI with any immediate concerns or questions via email or phone.

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Other NU Investigators

Are there other NU-affiliated investigators working on the project?

- No. Only the PI and student (if listed) will be working on the project.
 Yes. Submit a [Research Team Form](#).

Multisite or Collaborative Research

Will the study involve any collaborators outside Northeastern and/or team members with appointments at other institutions?

- No. Only the PI, student (if listed) and other named NU personnel will be working on the project.
 Yes. Submit a [Reliance Plan or Multi-Site Review Plan Form](#).

Is this a **federally-funded** study where NU is *not* the direct recipient of the grant?

- No. NU is the direct grant recipient, or there is no federal grant.
 Yes. Submit a [Reliance Plan or Multi-Site Review Plan Form](#). (*The direct grant recipient always needs IRB oversight, even if they aren't doing any work for the project.*)
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2. CONFLICTS OF INTEREST

Does the PI or student investigator (or any of their immediate family members) have a financial interest or fiduciary relationship with the research sponsor?

Yes No

Click or tap here to enter text.

Does the PI or student investigator (or any of their immediate family members) have a financial interest or fiduciary relationship that is related to the research?

Yes No

Click or tap here to enter text.

3. RESEARCH LOCATIONS

A **research location** is a location or place where the NU researchers will conduct the research procedures. Examples: lab space, schools, community centers, public venues

Where will study activities occur? Outline each location, describe what activities will occur at each.

Research activities will occur online. Participants will access the WE PLAY intervention on Canvas, complete the consent and survey review feedback electronically in Qualtrics, and engage with researchers in any necessary additional individual meetings over Zoom (e.g., for technological support or for specific questions regarding study participation).

Research teams are responsible for obtaining letters of approval, permission, or support from each research location before any research activities begin. Please keep in mind that if you plan to do research in K-12 schools, some school systems require an additional research review process.

Will any study activities (data collection, recruitment, or other) occur internationally, or is it likely that participants and/or their data will be subject to GDPR, PIPL, or another international privacy law?

Yes No

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If yes, complete the [International Research Form](#). As you complete this form ensure that relevant laws, policies, and regulations are being applied such as: GDPR, PIPL, country specific regulations, and other relevant policies. Please see globalsafety.northeastern.edu and security.its.northeastern.edu for support.

4. RESEARCH SUMMARY

In lay language, summarize the objective and significance of the research.

Children on the autism spectrum are often less engaged in physically active play and caregivers face challenges to support their child in physical activity. WE PLAY (Wellness Enhancing Physical Activity for Young Children) was originally developed by our research team as an online professional development training to help preschool teachers promote their student's physical activity and better include students on the autism spectrum in physically active play with peers. We recently adapted WE PLAY for parents of children with autism to support active play promotion in other contexts (e.g., home and community) using the prior validated WE PLAY intervention. In this study, the newly adapted online intervention will be tested in a two-group randomized controlled trial with parents of preschoolers with autism (N=114) to evaluate effects on the intervention on parent knowledge, self-efficacy, behavioral intentions, perceived behavioral control, and implementation of physical activity strategies. The goal of this study is to test an adapted intervention with parents thereby bridging evidence-based practices from school to home to support children's development across contexts.

Background and Lit Review. Describe the study's background via a short summary. Outline what is currently known from the existing literature/scholarship and explain the gap in the literature that this research aims to address. Where relevant, include citations. The IRB needs to understand the scholarly context of the research in order to determine that risks are reasonable in relation to scientific benefits. Use lay language whenever possible. Length should be commensurate with risk. Low risk research can be ~1-2 paragraphs.

Physical activity (PA) is linked to improved physical health, self-regulation, attention, and learning, thus promoting overall quality of life in children (Carson et al., 2014; Healy et al., 2019). Although estimates vary, most preschoolers fail to meet PA recommendations, requiring support to engage in sufficient PA (Hyman et al., 2020). PA concerns are heightened for children with autism, who participate in fewer activities, experience motor skill delays, and face barriers including behavior challenges, social communication difficulties, and adults' uncertainty about adapting activities (Must et al., 2014; Barry et al., 2024). These disparities emerge in toddlerhood and increase through adolescence, underscoring the importance of early interventions to support active play for preschoolers with autism.

The Wellness Enhancing Physical Activity in Young Children (WE PLAY) teacher training was developed to help early childhood educators promote the PA of their students and include children on the autism spectrum in active play with their peers (Hoffman et al., 2019; Hoffman et al., 2020; Schmidt et al., 2021; Schmidt et al., 2023). WE PLAY includes online training that focuses on the importance of PA for children and effective strategies for PA promotion and supplemental resources (e.g., video library of structured games, game instruction sheets, teacher self-assessment). The WE PLAY teacher training course has been completed by nearly 22,000 early childhood educators between April 2022 and November 2025. Between 2022-2023, 546 WE PLAY users completed pre/post surveys about WE PLAY as part of a program evaluation. These data showed that the WE PLAY training improved early childhood educators' knowledge and attitudes about PA promotion with autistic children, led to positive changes in their teaching practices, and was understandable, feasible, and acceptable (Medeiros et al., in preparation). Prior WE PLAY research has focused on early childhood educators as agents of child behavior change. Extending WE PLAY to parents is important because they also play a critical role in shaping young children's daily routines and environments, including opportunities for PA outside of school. By equipping families

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with the same knowledge and strategies as educators, this intervention has the potential to support more consistent and inclusive PA experiences across home and school settings, particularly for children with disabilities who may face additional barriers to active play. In fall 2025, WE PLAY was adapted for parents using a mixed methods approach with parents of children with autism. WE PLAY's acceptability and usability were measured.

In the current study, we will use an experimental design to examine the effect of the adapted WE PLAY for parents on parental self-efficacy, knowledge, behavioral intention/control and implementation of physical activity strategies. Participants will be parents of autistic preschool-age children and they will be randomized to one of two conditions (WE PLAY vs. Waitlist Control). Data will be collected online at pre-test, post-test, and 3-month follow up using online surveys.

We hypothesize that:

1. Following intervention, parents/caregivers in the WE PLAY group will report higher levels of PA promotion knowledge, self-efficacy, behavioral intentions, and perceived behavioral control from pretest to posttest and when compared to parents/caregivers in a waitlist control group.
2. Parental/caregiving variables at post-test, including self-efficacy, behavioral intention and perceived behavioral control, will significantly predict the extent to which changes in PA promotion practices (i.e., parent behaviors) are reported at 3-month follow up.
3. ***Following the training at post-test, participants in the WE PLAY group will rate the intervention as acceptable, feasible, and understandable.***

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5. PARTICIPANT INFORMATION

List the estimated total number of participants (a range can be listed) and how the sample size was decided. If you are targeting multiple different cohorts of participants, provide estimates for each cohort.

*We aim to enroll 114 participants (57/group). A power calculation was conducted to estimate the required sample size based on the research questions with a 20% drop-out rate estimated from baseline to the 3-month follow-up period. Calculations were conducted using G*Power 3.1.9.4, with an alpha level set to 0.05 and power to 0.8 and prior pilot study data from WE PLAY. Participants will be randomized using block randomization using race as a variable in an effort to create a diverse sample across groups. Race will be dichotomized to people of color and White people.*

Describe all inclusion and exclusion criteria/the population being recruited (in narrative):

Parents or caregivers of children with a prior diagnosis of autism from a school or medical setting that are currently between 3 to 5 years of age and can read and write in English will be eligible for participation in this study. There will be no other identity-based eligibility criteria.

Select all participant populations that will be recruited, either intentionally or are likely to be included:

Age & Enrollment goal

- Adults (18+ years old), specify age range: 18 years or older
- Minors (≤ 17 years old), specify age range: Click or tap here to enter text.

Other special populations targeted or discernable:

- Individuals with low literacy levels
- Individuals who are cognitively impaired or legally unable to consent.
- Parolees or incarcerated individuals
- Members of a recognized American Indian or Alaskan Native tribe (provide details related to tribal approval if so)
- Wards of the state or Emancipated Minors
- Pregnant women or fetuses
- Undocumented individuals

If the study will enroll limited or non-English fluent individuals or use translated materials, describe any information related to enrolling and translating for these participants. For translated materials, be sure to submit a completed [Certificate of Translation form](#) and translated materials (may be submitted at a later date after initial approval). See our [Investigator Manual](#) for more information.

N/A

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6. RECRUITMENT PROCEDURES

Select all recruitment procedures that will be used.

- Pre-existing student subject pool e.g., NU's PsyLink Psychology Participant Pool. *Please specify:* Click or tap here to enter text.
- Social Media. *Please specify all platforms and social media accounts to be used:* Facebook, Special Education Advisory Parent Council accounts, Autism Parenting groups
- Email distribution to a listserv or other existing group. *Specify the listserv, mailing list, etc. to be used, describe what it is/who maintains it, and estimate the number of users:* Click or tap here to enter text.
- MTurk, Qualtrics Panel, Prolific, or similar. *Specify:* Click or tap here to enter text.
- US Mail
- Flyers: to be distributed via facebook in electronic format.
- Website ad and/or online announcement, internal or external to NU
- Other. *Specify:* Snowballing sampling: (encouraging participating parents to share information about the study with other parents in their networks)
- Not applicable (secondary data use only)

Attach all recruitment material with your application.

For each group of participants, describe the details of the recruitment process. Include how potential participants will be identified, who will recruit participants, what type of recruitment material will be used, and how the materials will be disseminated. *(The consent process will be described in a later section)*

The student investigator (Haley Medeiros--HM) will recruit participants. Participants will be recruited through Facebook parent/caregiver Special Education Parental Advisory Committee (SEPAC) and autism parent support groups using written posts with an electronic flyer. Further, the student investigator email is provided in the recruitment materials if parents are reaching out to find out more information. Parents may email HM expressing their interest. HM will respond to inquiries using the email template in this IRB application to (1) provide potential participants with more information about the study and (2) provide the Qualtrics link to enroll if parents choose to do so.

Participants will be screened through a short demographic questionnaire that will identify eligibility factors. Participants will be parents of a child with a prior diagnosis of autism between the ages of 3 and 5 who can speak and read/write in English. The eligibility screener is embedded in Qualtrics in the recruitment materials attached to this submission (email link/Facebook post QR code/flyer QR code) attached as an additional document with Qualtrics link. The eligibility screener is imbedded in the document titled "Family Information Form 01.14.26"

Explain whether the recruitment process poses any potential for (real or perceived) coercion or undue influence due to existing relationships (student/professor, employee/employer, etc.). If so, explain how you will mitigate this potential. *(See our [guidance](#) on Research involving employees, colleagues, and/or subordinates or Enrolling your students)*

There is no perceived potential for coercion or existing relationships with parent participants.

Select all that apply.

- Eligibility is assumed due to the population being recruited or by virtue of responding to recruitment materials.
- Eligibility is confirmed via a screening tool or process (screening questions, survey, interview, etc.).
- Eligibility will be confirmed via existing data (chart review, student records, etc.).

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Narratively describe any screening processes selected above. Be sure to also submit any questions/materials you might use to screen.

Only parents of children with an existing diagnosis of autism spectrum disorder ages 3-5 are eligible for participation in the study. We will ask parents to indicate that their child has a diagnosis of autism, at which age they were given the diagnosis, and by which medical/psychological provider.

7. STUDY PROCEDURES

Select all research methods and/or data sources.

- Interviews
- Surveys, questionnaires, writing prompts, cognitive/aptitude testing
- Focus groups
- Observations of private or public behavior
- Audio/video recording and/or taking photographs

- Computer based assessments (such as n-back, NIH Toolbox, video-game like activities, etc.)
- Artificial Intelligence platforms or tools (please complete the [AI Form](#))
- Mobile applications (phone, tablet, or other similar apps)
- Custom software developed by the study team

- Intervention (behavioral or biomedical): **WE PLAY Parent Training (hosted online in Canvas)**

- Physiological measurement *routinely used* in clinical practice (EEG, 3T MRI, Eye Tracking, Pulse ox, etc.)
- Physiological measurement *not routinely used* in clinical practice (9T MRI, GSR, MP-NMES, etc)
- Commercial consumer-grade devices used as marketed (fitness bands, VR headsets, etc.)
- Custom devices, non-consumer-grade devices, or existing devices used for a new purpose.
- Other not described above, *please specify*: Click or tap here to enter text.

Describe each research procedure checked above (in narrative), the order in which they will be conducted, the duration of each, and the total duration of participating in the study. For studies involving multiple visits, or sessions, describe the timing between sessions.

Data will be collected over a 4-month period with rolling enrollment. The study will be implemented in the following order:

- 1. After providing electronic informed consent, participants will be randomized into the experimental or waitlist control group using an online block randomization tool with race as the determining variable. Race will be dichotomized to people of color and White people.**
- 2. All participants will take the pre-training survey (measures include Physical Activity Knowledge assessment, Preschool Parent Confidence Questionnaire (PPCQ), adapted Early Childhood Educator Movement Behavioral Intention and Perceived Control Questionnaire (ECE-MBIPC)) (expected to take 10-15 minutes)**
- 3. Participants in the WE PLAY group will be asked to complete the intervention (the WE PLAY online training and material review) in a two-week period. (The intervention takes approximately 1.5 hours to complete and can be done in multiple sessions)**
- 4. Participants in the WE PLAY group who do not complete the intervention after 10 days will be sent a reminder via email and text message to complete the training within the next 4 days.**
- 5. Participants in both groups will complete the post-test approximately 2 weeks after the pre-test. Measures include Physical Activity Knowledge, Preschool Parent Confidence Questionnaire (PPCQ), Early Childhood Educator Movement Behavioral Intention and Perceived Control Questionnaire**

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- (ECE-MBIPC). Participants in the WE PLAY group will also answer survey questions using the Usage Rating Profile-Intervention-Revised (URP-IR). (The post-test and URP-IR are expected to take 15 minutes in total).*
- 6. All participants will complete the 3-month follow-up survey approximately 3 months after completing the post-training survey (measures include the Preschooler Physical Activity Parenting Practices (PPAPP) and a researcher developed self-assessment). (expected to take 5-10 minutes)*
 - 7. Participants in both groups will be emailed a gift card to incentivize study participation in two installments (\$20 after completing the post-training survey and \$20 after completing the follow up survey).*
 - 8. Participants in the waitlist control group will be given access to the WE PLAY training along with the second gift card via email after all study measures are completed.*

List all research instruments, surveys, interview guides, data collection sheets, etc., that will be used in this research. Be sure to submit copies of each.

- Family Information Form. Participants will report information about themselves and their family (age, race/ethnicity, gender, number of children, child disability status, household composition, education, income, and employment). The form was designed to be completed within 5 minutes at pre-training.*
- Physical Activity Knowledge. Ten multiple-choice items, based on WE PLAY content, assess participants' knowledge of PA and its benefits at pre- and post-training. Scores range from 0–10. The form was designed to be completed within 5 minutes.*
- Self-Efficacy. The 17-item Preschool Parent Confidence Questionnaire (PPCQ) (Coleman, 2010) measures parental confidence in promoting PA in children with disabilities. The measure will be completed at pre- and post-training. Items are rated 0–10, yielding total (0–90) and three subscale scores. The PPCQ demonstrates strong reliability ($\alpha = 0.92–0.94$). This can be completed within 5 minutes.*
- Behavioral Intentions and Perceived Behavioral Control. Adapted from the validated Early Childhood Educator Movement Behavioral Intention and Perceived Control Questionnaire (ECE-MBIPC), this questionnaire assesses behavior intentions and perceived control over five PA-related behaviors. The measure will be completed by participants at pre-training and post-training (Brujins et al., 2023). The items are rated using a 7-point, Likert-type scale, and generates composite scores for behavioral intention and perceived control, with higher scores indicating greater likelihood of engagement. The ECE-MBIPC questionnaire shows high internal consistency (Cronbach's $\alpha > 0.85$ across subscales). This can be completed within 5 minutes.*
- Parent Physical Activity Promotion Behavior Change. At follow-up, parents in both groups will report on their PA promotion practices using the Engagement subscale of the Preschooler Physical Activity Parenting Practices (PPAPP). This measures parental encouragement of PA (15 items rated using a 5-point scale; scores range from 0–75, Cronbach's α values 0.87-0.92). Higher scores indicate more frequent PA-promoting practices (O'Connor et al., 2014). This can be completed within 5 minutes.*
- Acceptability, Understanding, and Feasibility. Parents in the WE PLAY group only will complete the Usage Rating Profile-Intervention Revised (URP-IR) to assess intervention acceptability (7 items), understanding (3 items), and feasibility (6 items). Items are rated using a 6-point scale (Briesch et al., 2013; $\alpha = 0.72–0.95$). Higher scores reflect greater likelihood of adoption and use. This can be completed within 5 minutes.*
- WE PLAY Online Training: The WE PLAY training can be completed over a 2-week period wherever participating parents have internet access and can attend to the training materials. The WE PLAY intervention includes: an asynchronous online training, viewing video clips of an adults promoting active play, reviewing handouts with behavior management tips and social stories, participating in*

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an anonymized discussion board with other parent participants and completing a self-assessment. Completing the training and reviewing associated materials is anticipated to require up to 2 hours (average 90 minutes) based on prior pilot study data with parents. The WE PLAY training can be accessed here: <https://canvas.instructure.com/courses/12165139> with activation code: 6WM96K

- ***WE PLAY Self-Assessment:** Is comprised of 8 questions that encourage the parent to reflect on the last time their child played actively with them. It can be completed in 5 minutes and will be embedded in the WE PLAY training.*

Who will conduct the research procedures; collect data; administer surveys, etc.

Haley Medeiros (HM), the primary student investigator, will conduct participant recruitment procedures, email the Qualtrics survey consent link to parents/guardians who demonstrate interest, conduct the consent meetings, and oversee all data collection, implementation fidelity, and technological management of the study including the WE PLAY intervention hosted on Canvas Free for Teachers. Trained research assistants who are master's degree students in Northeastern's School Psychology Program will send out survey links at post-test and follow up, and they will organize study data collected in Qualtrics. Dr. Jessica Hoffman will provide consultation and supervision of all study procedures.

If the study will audio or video record participants, describe who will be recorded, describe whether it is optional (and how/when participants will be able to opt in or out), and the analysis/dissemination plan for the recordings.

N/A

8. CONSENT AND PARENTAL PERMISSION

Approved consent documents will be converted to PDF and stamped with the approval date. These stamped versions must be provided to potential participants; in a format they can keep. *Studies with multiple consent forms or processes should explain each process clearly below.*

Describe *when* the consent materials will be presented to potential participants.

The consent form will be presented to participants after they indicate interest in the study (by interacting with recruitment materials and filling out the family information form). and during the Zoom meeting that the investigator has scheduled with the potential participant.

Describe *how* and *where* the consent materials will be distributed to participants.

The consent will be presented to participants in electronic format in Qualtrics when they meet with the primary investigator in the study via Zoom (e.g., by clicking on the QR code or emailing the primary investigator to request information/meeting). They will also be emailed a copy of their consent form following the meeting.

Will a 1:1 consent discussion occur between a study team member and each prospective participant?

- Yes, please outline what will be discussed: a 1:1 consent discussion will review all relevant information in the signed consent form (see attached document titled WE PLAY Study 2 Informed Consent 01.14.26). This document clearly outlines the study purpose, procedures including waitlist control groups, potential risks and benefits, and participants' rights, ensuring that individuals can make an informed decision about participation without the need for a separate discussion. Additionally, the primary investigator will show the participants how to access the online training for**

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those in the experimental group through sharing her computer screen and providing an access code. If there are additional technological difficulties with accessing the training or questions the parents prefer answered through a 1:1 discussion, the primary investigator HM may conduct a second meeting.

- No, please explain why a discussion is not practicable or feasible: Click or tap here to enter text.

How will consent be documented?

- Physical signature
- Digital signature, specify how signatures will be collected: **by providing initials in a Qualtrics response box with the date**
- Requesting a **waiver of documentation** of consent (for verbal consent, checkboxes, or any other consent process that doesn't include collection of a legally-valid signature), *please select the regulatory pathway:*
- The research procedures don't normally require a written signature outside of the research context, AND the research poses no more than minimal risk of harm to participants.
 - The only record linking the participant to the research would be the informed consent form, AND the main risk of the study is the harm that could result from a breach of confidentiality. Each participant must be asked whether or not they want documentation linking them with the research, and the subject's wishes will govern (i.e. they can choose) whether or not to sign the consent).
 - The participants are members of a distinct cultural group or community in which signing forms is not the norm, AND the research poses no more than minimal risk of harm to participants, AND there is an appropriate alternative mechanism for documenting that informed consent was obtained: Click or tap here to enter text.
- Requesting a **waiver of consent** or waiver of parental permission (meaning there will be no active and affirmative consent process). *Complete the **waiver of consent** criteria below.*

Will the study involve deception (providing inaccurate information to participants) and/or incomplete disclosure (leaving out information about the procedures, study purpose, or other key elements of informed consent)?

- Yes, study involves Deception or Incomplete Disclosure: Requesting an alteration of consent – *Complete the **waiver of consent** criteria below. Please also explain what parts of the consent process or content will be waived or not included:* Click or tap here to enter text.
- No, all key elements of consent will be included and accurate.

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Complete the following to request a waiver of consent OR an alteration of consent.

Please provide a detailed explanation of why, specifically, each of the criteria apply to your research study. See our [Guidance page for information about waivers.](#)

- i) The study is no more than minimal risk to the participants
Click or tap here to enter text.
- ii) You could not practicably (feasibly) carry out the research without the requested waiver or alteration:
Click or tap here to enter text.
- iii) If the research involves using identifiable private information or identifiable biospecimens, you could not practicably (feasibly) carry out the research without using such information or biospecimens in an identifiable format:
Click or tap here to enter text.
- iv) The waiver or alteration will not adversely affect the rights and welfare of the participants:
Click or tap here to enter text.
- v) Whether you will provide participants with additional pertinent information after participation (i.e., whether you will debrief participants). If providing information or debriefing, outline this process (when it will occur, how, and using what materials):
Click or tap here to enter text.

Additional Considerations for the Consent Process and Forms:

*If you plan to obtain approval to access identifiable student educational records protected by the FERPA law, FERPA requires that the consent to access FERPA-protected information be signed and dated by the student (or the student's parent, depending on what level of school the student is enrolled in).

9. ASSENT

Does the study include subjects who cannot legally consent for themselves? (minors or decisionally-impaired adults)

Yes No

If yes, please complete this section:

Please note that you must obtain parental permission *and* child assent for children's participation in research unless the IRB grants a waiver of parental permission. The IRB expects you to use and document the assent process with children ages 7 years to 17 years old, unless special circumstances justify a waiver of assent. You must tailor the assent process to the reading and comprehension levels of the children you plan to enroll in your study.

Describe the process(es) for explaining the study to the participants and seeking their assent to participate. State whether and how you will document the assent (participant's signature on an assent form, a checkbox on a parental permission form confirming verbal assent, etc.). (See our [guidance on research enrolling minors](#) and our [investigator manual](#) for information about the assent process and determining capacity for consent)

Click or tap here to enter text.

Describe the process for obtaining informed consent from any participant who turns 18 during the conduct of the study (or an adult who regains their decision-making ability). Note that the prior parental/guardian permission is no longer applicable, so the participant must give consent *before* the continuation of any research activities, including analysis of their identifiable data.

Click or tap here to enter text.

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10. SUBJECT COMPENSATION

Will subjects receive compensation, rewards, or gifts before, during, or after participation?

Yes No

If yes, provide a brief description of compensation or rewards, including amount, payment frequency/schedule (including pro-rating, approximate timing), and any odds of winning a raffle/etc. **Participants will receive \$40 compensation in the form of two gift cards for completing the study surveys. Information about the compensation timeline will be provided to the email they give during the consent process. Specifically, participants will be emailed their first gift card (\$20) after completing the post-test survey. They will receive the second gift card (\$20) after completing the follow up survey. We are still awaiting grant funding review to determine this funding mechanism.**

11. ACCESSING OR USING EXISTING DATA OR NON-RESEARCH DATA

Does the study include secondary analysis of data that was already collected or that will be collected for a different purpose?

Yes No

If yes, please complete this section:

What is the original source of data? (Check all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Survey/Questionnaire | <input type="checkbox"/> Department Data |
| <input type="checkbox"/> Medical Records/Charts | <input type="checkbox"/> Student Data |
| <input type="checkbox"/> Previous IRB-Approved Study | <input type="checkbox"/> Institutional Research & Assessment |
| <input type="checkbox"/> Interview transcripts | <input type="checkbox"/> Other, <i>please specify:</i> Click or tap here to enter text. |

Provide a comprehensive overview of all the data elements, characteristics, and variables of the dataset(s) or provide a code book containing only the data elements you will be analyzing:

Click or tap here to enter text.

What permission(s) do you have to access and analyze the dataset?

Describe the investigator, agency or institution granting access and permission for secondary analysis of the data for research purposes. *Note that having access to the data for non-research purposes is not equivalent to having permission to use it for research purposes.*

Click or tap here to enter text.

12. RISKS AND BENEFITS

Select all potential risks that may result from taking part in the study:

- Emotional (e.g. discussing sensitive topics, reliving troubling experiences)
- Physical discomfort (including temporary pain, soreness, or discomfort from being touched by research staff)
- Health or physical injury risks
- Privacy and Confidentiality Risks
- Social risks (e.g. stigma)
- Financial risks
- Professional or academic risks

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- Population-specific risks
- Risks to individuals who are not the research participant (e.g. family members, research staff, community)
- Other risks not covered

Narratively describe each potential risk including their magnitude and likelihood

There is a minimal risk that the information described below could be accessed by parties outside of the research team. Participants' names, contact information, and family information will be recorded during the study. Parents will otherwise engage in typical family practices as they implement the WE PLAY training, and no additional risks are anticipated because of their participation. Children will play active games that involve typical community and parenting practices. As such, no additional risks beyond potential privacy or confidentiality concerns are anticipated.

Describe what safeguards will be implemented to minimize each risk.

To address the privacy and confidentiality risk, all identifying and contact information and assessment results will be stored on a password protected computer in secured files. This information will only be available to the PI and lead student researcher (HM). Participants' contact and identifying information will be permanently deleted after completion of the study. Assessment information that may be needed after completion of the study to aid in data analysis or manuscript revisions will be stored on a password protected computer and secured file. This information will be de-identified using participant ID numbers for participating families.

Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Greater than minimal risk studies typically require a plan]

- No
- Yes (please also submit a copy of your plan as a document)

Describe any potential direct benefits to participants in this study. If there are no direct benefits, please explain. *Direct benefits are ways in which the research procedures themselves might benefit participants – not ways in which the results of the study might later benefit the entire population.*

Note: Payment is not considered a benefit for the purposes of IRB review.

Participating parents will receive training in promoting preschool children's physical activity, specifically tailored for their child who is on the autism spectrum. They may increase their skills and confidence because of participation in this study. Direct benefits to the children of these participating parents include increased physical activity opportunities and potential enjoyment of physically active games.

Explain why, in your opinion, the benefits of the study outweigh the possible risks.

Participation in this study will potentially help parents to better meet the physical and social wellbeing needs of their children. Additionally, this research will contribute to the development of knowledge about how to help preschoolers with autism be better involved in active play, promoting holistic development for this clinical population. These benefits outweigh the minimal potential risks that caregivers face due to participating in this study.

Describe any potential for direct community impacts/benefits in this study (beyond the scientific knowledge created).

Parents will have access to a discussion board within the intervention to anonymously interact with other parents with similar experiences. This is intended to allow parents to glean ideas for physically active play

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from their own peers and forge a sense of community in an area that may be daunting for parents. Parents in the waitlist control group will also receive access to this discussion board at the end of the study period.

13. CONFIDENTIALITY AND PRIVACY

Select all identifiers collected or used at any stages of the project (including recruitment, data collection, and transmission):

- Names
- Dates (date of birth or other dates)
- Emails, phone numbers, or usernames
- GPS, Street address, or other location data
- Audio recording
- Video recording or photographs
- Detailed demographic data
- Other identifiers, usernames, ID#s, etc.
- No identifiers used or collected

Describe the identifiers checked above (in narrative):

Participant names and emails will be collected for scheduling purposes. Participants will also report data includes their child's current age in years, their own race, ethnicity, gender, socio-economic status, employment status, home zip code, level of education, child disability type.

Will your data be coded or anonymized?

- Coded:** All identifying information is replaced with a code in your study data, but you keep a “key” listing which code goes with which identifiers.
- Anonymized:** Any identifiers are destroyed. You won't keep a “key” that can relink data. It'll be impossible for you to re-identify the subjects. “Anonymization” means a process that permanently and irreversibly removes the association between the identifying dataset and the individual such that the individual can no longer be directly or indirectly identified.
- Neither:** You will keep identifying information in your study data. Please explain why this is necessary: Click or tap here to enter text.
- N/A:** You will never collect or use any identifiers.

If you will code the data, explain the following aspects of the coding process:

- The process for how subject IDs will be generated/assigned (e.g. random, sequential)
- What identifiers will be replaced in each dataset/source of data and what data will remain.
- When (in the timeline of research activities) identifiers will be replaced in each dataset/source of data.

Participants will receive a unique and randomized study ID that is not linked to any demographic or identifying information. All data with identifiers will be anonymized by numerical code (e.g. race to 1,2,3,4,5) during data analysis. Identifiers will be anonymized to numerical code after participants are randomized to experimental or control groups.

If a key or code re-linking IDs to identifiers will be created, describe:

- The place where the key will be stored
- The role(s) of all individuals who will have access to the key

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- When the key will be destroyed

The study key linking the IDs with direct identifiers will be kept in Excel only on Northeastern's secure platform. The PI and student researcher (HM) will have access to the key. The key will be destroyed after completion of the dissertation (expected June 2027).

Select all methods used to safeguard research records during storage (select any that apply):

Data Management Practices

- Signed consent, assent, or parental permission forms are stored in a separate location from all data.
- Direct identifiers are removed from collected data as soon as possible
- Direct identifiers (including the key/master list) are destroyed as soon as possible
- Direct identifiers are removed and data is coded as soon as possible. The master list or key linking codes to identifiers is stored separately from the data, e.g. with separate passwords or in separate physical locations.

Physical Material or Data (paper consent forms/surveys/notes, physical documents, physical specimens, etc.)

- Yes: describe where physical materials will be collected, stored, and disposed of in a secure manner: Click or tap here to enter text.
- No physical materials will be collected or stored.

Digital Data (online data collection, online surveys, cloud storage, transferring data via online platforms, etc.)

- Yes: describe how digital data will be collected, stored, and disposed of in a secure manner:
Online or cloud digital data is collected and/or stored using NU-approved platforms (Qualtrics) using only NU-official account login credentials: De-identified data that is needed for data analysis will be stored on the NU OneDrive in a shared folder accessible only to the research team.
- No digital materials will be collected or stored.

Other methods to secure data not described above:

NA

How long will identifiable data be kept? For interview and group recordings, when will these be destroyed following transcription?

Participants' contact information will be retained until the study is ready for publication to share study findings with participants (anticipated latest June 2027).

Destruction of data (confirmation is required for all studies):

- All data will be retained and destroyed in accordance with the [Investigator Manual](#) and [Policy on Retention and Disposition of University Records](#).

Check provisions to protect the privacy interests of subjects.

In-person interactions or interventions:

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- All interactions or interventions will occur in a private setting where others cannot see or overhear activities.
- The study team will ask participants if they are comfortable answering questions in that location and setting
- Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- Other, *please specify*: No in person interactions will occur

Remote interactions or interventions (Zoom, Teams, phone, etc.):

- Conducting activities in a private location with only study staff present, closing doors, and wearing headphones.
- Asking participants if they feel their own setting is appropriate for the discussion or intervention and that others won't be able to overhear/oversee.
- Ensuring that non-participants/individuals who did not consent are not captured in any video or audio recordings.
- Offering a way to stop and resume later if privacy is compromised
- Other, *please specify*: **these remote interactions will only occur if necessary for specific participants* (e.g., questions about the intervention, technological support)**

Group interactions or interventions, in-person or remote (e.g. focus groups, group surveys, or family interactions):

- Discussing the importance of not talking outside the group about what other people say during the group activities.
- Encouraging participants to use a pseudonym or limit the use of names or other details during the group activity
- Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
- Collecting documents in a box, envelope, etc. to ensure others cannot see responses.
- Other, *please specify*: **Group interactions will occur using an anonymized discussion board in Canvas.**

Communicating with participants via phone, email, text, or mail (including for recruitment, scheduling, follow-up, etc.):

- Leaving/sending generic messages, emails, or letters that avoid using study and participant identifiers, such as names, clinics, study topics, etc.
- Obtaining permission prior to leaving voicemails or sending letters, emails, or text messages.
- Using generic return addresses, labels, or document headers that don't suggest a research topic, lab, or department.
- Removing participant identifiers and study topics from voicemails, letters, emails, or text messages.
- Other, *please specify*: Click or tap here to enter text.

Analyzing and disseminating data (Required for all studies)

- Only publishing or presenting aggregate data or results (i.e. no individual-level information published or shared outside the research team, even de-identified).
- Analyzing data in a private space with only study staff present, closing doors, and wearing headphones.

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- Permanently blurring, hiding, or redacting any identifiable features (faces, tattoos, birthmarks, etc.) before analyzing data.
- Removing any direct and indirect identifiers from any transcripts or open-ended responses before analyzing data.
- Other, *please specify*: Click or tap here to enter text.

14. DISSEMINATION AND FUTURE USES OF DATA

Will identifiable data be used for future research?

- Only fully-anonymized data will be used for future research, or shared with other researchers for their own studies. If not already explained above, explain how data will be anonymized including how any code/master list will be destroyed before any data is used or shared for future research: explained above.
- Coded or directly identifiable data might be used for future research and may be shared with other researchers for their own studies or added to a registry. If yes, submit a completed [Research Registry or Repository form](#): Click or tap here to enter text.
- N/A: Data will only ever be used for this research study and will **never** be reused or shared for any purpose (including sharing de-identified data privately with other researchers upon request, engaging in open-science practices, posting it to meet funders' or journals' requirements, etc.)

Will any identifiers (including audio or video recordings and photographs) be published, shared, or otherwise disseminated?

Yes No

If yes, describe what identifiers might be published or shared. Note that the consent form should provide the opportunity for the participant to opt-out of this, or explicitly inform participants that it is required in order to participate in the study.

Click or tap here to enter text.

Will the individual or aggregate results be returned to participants?

Yes No

If yes, explain the plan to return results. Please specify what information will be returned, how results will be contextualized, how participants might use the results, and how you will ensure participant privacy and confidentiality in any communication attempts.

Participants will be emailed a report summarizing general study findings in lay language.

15. DOCUMENTS

List all documents to be used in this research study and provide a version date for each. Documents may be added, modified, or removed any time after initial approval is granted. The version date should be updated to reflect this change. Add additional rows, as needed.

Documents that need to be listed might include: consent and assent documents; consent/assent scripts; online consents; participant information sheet; all data collection documents to include: interview instruments; survey instruments; focus group instruments; and any other standardized tools used to collect data; recruitment material (both written and text for online recruitment). Add additional lines, as needed.

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<u>Document Name</u>	<u>Description of document use</u>	<u>Version Date</u>
Family Information Form 01.14.26	Self-report completed by caregivers in Qualtrics to provide background and demographic information on caregivers and their child and determine eligibility for the study.	01/14/2026
WE PLAY Study 2 Informed Consent 01.14.26	Informed consent to be reviewed in consent meetings with parents and electronically signed in Qualtrics	01/14/2026
WE PLAY Parent Recruitment Flyer	Flyer and written language for social media post for caregiver recruitment	12/12/2025
PI-Assurance-Form-11.5.2025	Documentation of PI assurance	11/05/2025
Research Team Form -11.4.2025	Documents research assistants working on the study	11/04/2025
WE_PLAY_Caregiver_-_Pretest 12.10.25	Self-report measure in Qualtrics completed by caregivers that will contribute to measurement of dependent variables	12/10/2025
WE_PLAY_Caregiver_-_Post-test_-_V1_12.12.25	Self-report measure in Qualtrics completed by caregivers that will contribute to measurement of dependent variables	12/12/2025
WE_PLAY_Caregiver_-_Post-test_-_V2_-_URP-IR-12.12.25	Self-report measure in Qualtrics completed by caregivers that will contribute to measurement of dependent variables and program evaluation for the experimental group	12/12/2025
WE_PLAY_Caregiver_-_Follow-Up_Survey 12.12.25	Self-report measure in Qualtrics completed by caregivers that will contribute to measurement of independent variables.	12/12/2025
WE PLAY Caregiver Self-Assessment	Self-report measure in Qualtrics completed by caregivers documenting their physical activity promotion practices that is embedded into the online training	12/12/2025
citiCompletion certification HM	Documents Haley Medeiros' CITI training completion	12/20/2024
citiCompletion certification JH	Documents Jessica Hoffman's CITI training completion	06/23/2023
citiCompletion certification GB	Documents Grace Burch's CITI training completion	11/04/2025

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citiCompletion certification TG	Documents Tyler Griff's CITI training completion	11/04/2025
Emails to Participants 12.12.25	Email scripts to communicate with participants	12.12.25
Handouts combined.pdf	All physical activity promotion and behavior management tip handouts embedded within the online training	01.14.26
WE PLAY Training in ppt form.ppt	All content of the training created by researchers in PowerPoint form	01.14.26
Video and discussion post explanations 1.23.26.docx	Short explanations of videos and documentation of discussion posts embedded throughout training	01.23.26