A cluster randomized controlled trial of an after-school playground curriculum intervention to improve children's physical, social, and emotional health: Study protocol for the PLAYground project

NCT ID not yet assigned

Date: June 20, 2022

INSTRUCTIONS

Complete each section of the application. Based on the nature of the research being proposed some sections may not apply. Those sections can be marked as N/A. Remember that the IRB is concerned with risks and benefits to the research participant and your responses should clearly reflect these issues. You (the PI) need to retain the most recent protocol document for future revisions. Questions can be addressed to XXX. **PIs are strongly encouraged to complete this application with words and terms used to describe the protocol is geared towards someone not specialized in the PI's area of expertise.**

IRB: 1. Protocol Title: FP00031876 Learning after hours: Taking social and emotional learning beyond the classroom with physical activity.

IRB: 2. Background and Objectives

2.1 List the specific aims or research questions in 300 words or less.
2.2 Refer to findings relevant to the risks and benefits to participants in the proposed research.
2.3 Identify any past studies by ID number that are related to this study. If the work was done elsewhere, indicate the location.

TIPS for streamlining the review time:

✔ Two paragraphs or less is recommended.
✔ Do not submit sections of funded grants or similar. The IRB will request additional information, if needed.

Response:

2. This project uses the **evidence-based Play On! program to promote social, emotional, and physical health of children** through active and inclusive play. The Play On! program will be **implemented during the after-school enrichment programs** at 14 elementary schools in the XXX School District using a tiered approach that begins with a playground design assessment and a training for after-school coordinators and healthy school staff (recess aides, physical education teachers, and healthy school managers), and extends to include trainings for students to become peer leaders to facilitate active and inclusive play during recess. This 'train the trainer' model allows for great reach as the students attending the 14 after-school programs will spread their knowledge and skills to all students attending the schools during recess.

IRB: 3. Data Use - What are the intended uses of the data generated from this project?

Examples include: Dissertation, thesis, undergraduate project**,** publication/journal article, conferences/presentations**,** results released to agency, organization**,** employer, or school**.** If other, then describe.

Response:

Data obtained from this project may be used in presentations/publication/journal articles and will be used as evidence to support future grant applications.

IRB: 4. Inclusion and Exclusion Criteria

4.1 List criteria that define who will be included or excluded in your final sample.
Indicate if each of the following special (vulnerable/protected) populations is included or excluded:

- Minors (under 18)
- Adults who are unable to consent (impaired decision-making capacity)
- Prisoners
- Economically or educationally disadvantaged individuals

4.2 If not obvious, what is the rationale for the exclusion of special populations?
4.3 What procedures will be used to determine inclusion/exclusion of special populations?

TIPS for streamlining the review time.

✔ Research involving only data analyses should only describe variables included in the dataset that will be used.
✔ For any research which includes or may likely include children/minors or adults unable to consent, review content [here]
✔ For research targeting Native Americans or populations with a high Native American demographic, or on or near tribal lands, review content [here]
For research involving minors on campus, review content [here]

Response:

Inclusion criteria:

Children:

- Children in after school programs in xxx Schools (N=294 students at 14 schools)
- **Children range in age from 5-13 (grades Kindergarten to 6th grade)**
- We will not include any other special population (adults who are unable to consent, prisoners, or economically/educationally disadvantaged individuals)

Adults (Healthy School Leaders):

- after-school program leaders in xxxc Schools
- Recess Aides in schools with after school programs in xxx Schools
- Active, Healthy & Safe team members in schools with after school programs in xxx
- Healthy School Managers in schools with after school programs in xxx Schools
- Physical Education teachers in schools with after school programs in xxx Schools:
- Principals in schools with after school programs in xxx Schools

Exclusion criteria:

- Any child without parental permission or assent
- Any adult from the aforementioned categories without a signed informed consent form

Inclusion/exclusion criteria have been previously determined to be appropriate for minors – in this case, school children.

IRB: 5. Number of Participants

Indicate the total number of individuals you expect to recruit and enroll. For secondary data analyses, the response should reflect the number of cases in the dataset.

Response:

We expect to recruit 294 children in grade three to six from 14 schools in xxx School District (about 21 students per school). We expect to recruit about 150 adults (~10 adults per school).

IRB: 6. Recruitment Methods

6.1 Identify who will be doing the recruitment and consenting of participants.
6.2 Identify when, where, and how potential participants will be identified, recruited, and consented.
6.3 Name materials that will be used (e.g., recruitment materials such as emails, flyers, advertisements, etc.) Please upload each recruitment material as a separate document, Name the document: recruitment_methods_email/flyer/advertisement_dd-mm-yyyy
6.4 Describe the procedures relevant to using materials (e.g., consent form).
✔

Response:

We will recruit all 14 of the after school program schools in xxx Schools to participate in the research. Seven of the schools will receive an intervention in year one and the other seven schools will receive in year two. All schools will participate in assessments during both the fall and spring each year.

We will work with the xxx Schools after school program coordinator to send a recruitment email (staff_email_05.15.22) to the program leaders at the 14 schools. Once the leader agrees to participate, they will send informed consents/assents to parents/guardians of the students in the after school program.

IRB: **7. Study Procedures**

7.1 List research procedure step by step (e.g., interventions, surveys, focus groups, observations, lab procedures, secondary data collection, accessing student or other records for research purposes, and follow-ups). Upload one attachment, dated, with all the materials relevant to this section. Name the document: supporting documents dd-mm-yyyy

7.2 For each procedure listed, describe **who** will be conducting it, **where** it will be performed, **how long** is participation in each procedure, and **how/what data** will be collected in each procedure.

7.3 Report the total period and span of time for the procedures (if applicable the timeline for follow ups).

7.4 For secondary data analyses, identify if it is a public dataset (please include a weblink where the data will be accessed from, if applicable). If not, describe the contents of the dataset, how it will be accessed, and attach data use agreement(s) if relevant.

TIPS for streamlining the review time.

- ✔ Ensure that research materials and procedures are explicitly connected to the articulated aims or research questions (from section 2 above).
- ✔ In some cases, a table enumerating the name of the measures, corresponding citation (if any), number of items, sources of data, time/wave if a repeated measures design can help the IRB streamline the review time.

Response:

We are using a crossover pre/post study design where seven after-school programs would receive the intervention in years 1 and 2 and seven schools would serve as matched comparison sites. During year two, the next seven schools would receive the intervention. This tiered approach begins with an initial assessment of the playgrounds to ensure that designs include the research-based elements of balancing, brachiating, climbing, spinning, sliding, and swinging. During years 1 & 2, Healthy School Staff will be trained with the xxx curriculum and the children will be trained as Peer Leaders (Fall Semesters 2022 and 2023) who are enrolled in the after-school program who then become peer leaders for all children during recess at their school.

Assessments include Physical, Social and Emotional Health Assessments administered fall and spring semesters of both years to track student behaviors. Assessments of the after-school setting will be conducted by Xplore program leaders on paper and include observations of all students attending Xplore programs. Assessments during recess would be conducted by recess aides/healthy school staff and would include a random sample of 25 students at recess. No identifying information will be recorded. Assessments will take approximately 5-10 minutes to complete. A copy of the assessment is included (K-6 Assessment).

We will ask the Healthy School Staff to complete a survey each fall and spring semester to learn about their perceptions of the training and playground activities. The survey will take approximately 5-10 minutes to complete. A copy of the staff assessment is included (Healthy School Staff Survey). Healthy School Staff may also be asked to participate in a 30-minute interview each spring semester.

We will ask students to complete a short survey about their physical, social, and emotional health and perceptions of the play activities in the program twice a year. The survey will take approximately 5-10 minutes to complete. A copy of the student assessment is included (Student Survey).

We will also track student participants' physical activity patterns each semester via accelerometry (total of 4 times) for the 7 intervention schools student participants (n=147), and at the other 7 program schools during their control condition year (n=147). Students will wear ActiGraph GT3X+ accelerometer devices for 24 hours over a period of seven days twice a year. Three members of our research team will visit the after school program to set up the students with devices, and on the following week to collect the devices. Students will initially be shown how to secure the devices using the easy velcro wristband upon arrival at the program in the afternoon by the research team. Participants will wear accelerometers on their wrist to promote greater wear compliance compared to the hip among children. The match-box sized accelerometers are the most commonly used accelerometers in PA research and have been utilized by our research team in studies involving elementary schoolchildren. If a participant loses the accelerometer, they will be asked to immediately inform the front office staff who will inform our research team via email. Each child participant will be assigned a unique unidentifiable number (study ID) which will be linked to a person and used throughout the study.

Students may also be asked to participate in a small group interview for 15 minutes about the changes in their afterschool program at the end of each semester.

The research team will collect attendance, behavioral referral information at the school level without names. As well as demographic information for student participants only (gender, age, race/ethnicity) at all schools from the front office staff at the end of each semester to look for significant relationships between participation in the project and reduced behavior referrals as well as increase attendance. The school district personnel have agreed to the study design and measures. This data will only be collected for participants in this project.

IRB: 8. Compensation

8.1 Report the amount and timing of any compensation or credit to participants.

8.2 Identify the source of the funds to compensate participants.

8.3 Justify that the compensation to participants to indicate it is reasonable and/or how the compensation amount was determined.

8.4 Describe the procedures for distributing the compensation or assigning the credit to participants.

TIPS for streamlining the review time.

✔ **If partial compensation or credit will be given or if completion of all elements is required, explain the rationale or a plan to avoid coercion**

✔ **For extra or course credit guidance, see "Research on educational programs or in classrooms" on the following page: https://researchintegrity.asu.edu/human-subjects/special-considerations.**

✔ **For compensation over $100.00 and other institutional financial policies, review "Research Subject Compensation" at: https://researchintegrity.asu.edu/human-subjects/special-considerations for more information.**

Response:

We have incentives for principals, teachers and students.

Incentives: Students: $10 per student per semester x 25 per school x 14 schools

Incentives: Program Leaders: $50 gift card per leader per semester x 5 per school x 14 schools

Incentives: Healthy School Leaders: $50 gift card per leader per semester x 5 per school x 14 schools

Note that all participants are participating in both year 1 and 2 either as a comparison or program participant.

IRB: 9. Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research.

TIPS for streamlining the review time.

✔ Consider the broad definition of "minimal risk" as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

✔ Consider physical, psychological, social, legal, and economic risks.

✔ If there are risks, clearly describe the plan for mitigating the identified risks.

Response:

There are no risks beyond regular physical activity participation. The after school program has had physical activity included in it so there are no additional risks with this program.

IRB: 10. Potential Direct Benefits to Participants

List the potential direct benefits to research participants. If there are risks noted in 9 (above), articulated benefits should outweigh such risks. These benefits are not to society or others not considered participants in the proposed research. Indicate if there is no direct benefit. A direct benefit comes as a direct result of the subject's participation in the research. An indirect benefit may be incidental to the subject's participation. Do not include compensation as a benefit.

Response:
Direct benefits include environmental upgrades to the playground facilities. Healthy school personnel and students will receive training in promoting social emotional learning through physical activity. Students will participate in the XXX curriculum with opportunities to develop their own social and emotional learning. Findings from this project will also be presented and published increasing the body of knowledge on our understanding of promoting social and emotional learning through physical activity.

IRB: **11. Privacy and Confidentiality**

Indicate the steps that will be taken to protect the participant's privacy.

11.1 Identify who will have **access to the data**.
11.2 Identify where, how, and how long data will be **stored** (e.g. ASU secure server, ASU cloud storage, filing cabinets).
11.3 Describe the procedures for **sharing, managing and destroying data**.
11.4 Describe any special measures to **protect** any extremely sensitive data (e.g. password protection, encryption, certificates of confidentiality, separation of identifiers and data, secured storage, etc.).
11.5 Describe how any **audio or video recordings** will be managed, secured, and/or de-identified. Only participants with picture/video permission will be photographed or digitally video recorded.
11.6 Describe how will any signed consent, assent, and/or parental permission forms be secured and how long they will be maintained. These forms should separate from the rest of the study data.
11.7 Describe how any data will be **de-identified**, linked or tracked (e.g. master-list, contact list, reproducible participant ID, randomized ID, etc.). Outline the specific procedures and processes that will be followed.
11.8 Describe any and all identifying or contact information that will be collected for any reason during the course of the study and how it will be secured or protected. This includes contact information collected for follow-up, compensation, linking data, or recruitment.
11.9 For studies accessing existing data sets, clearly describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes.
11.10 For any data that may be covered under FERPA (student grades, etc.) additional information and requirements is available at https://researchintegrity.asu.edu/human-subjects/special-considerations.

Response:
11.1 Data will be accessible only to members of the research team. All data will be de-identified prior to storage. Only unique student IDs will be accessible. School level data will be saved using students' ID as well (i.e., attendance, behavioral referrals, demographics).
11.2 Data will be stored in a locked file cabinet in the PI's locked office. Data from accelerometry will be stored on a password protected computer accessible only to the research team.
11.3 Data will be shared using only password protected files and will be destroyed five years after collection.
11.4 No identifying information will be stored, so extra protection for highly sensitive material is not warranted.
11.5 We will not obtain any audio or video recordings.
11.6 Consent and assent forms will be secured in a manilla envelope in a locked file cabinet in a locked room. They will be kept for 5 years. These forms will be kept separate from the rest of the data from the study.
11.7 We will use a master list of student IDs that will not be tied to any identifiable information. Any identifiable information included in this master list will be destroyed (deleted or shredded) as soon as the data are linked. These IDs will be used to link accelerometer devices to individual demographics such as sex and school.
11.8 No identifying information will be included in the research.
11.9 No secondary data will be utilized in this research.
11.10 We will not include any data covered under FERPA.

IRB: 12. Consent
Describe the procedures that will be used to obtain consent or assent (and/or parental permission).

12.1 Who will be responsible for consenting participants?
12.2 Where will the consent process take place?
12.3 How will the consent be obtained (e.g., verbal, digital signature)?

TIPS for streamlining the review time.

- ✔ If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in their preferred language. Indicate the language that will be used by those obtaining consent. For translation requirements, see Translating documents and materials under https://researchintegrity.asu.edu/human-subjects/protocol-submission
- ✔ Translated consent forms should be submitted after the English is version of all relevant materials are approved. Alternatively, submit translation certification letter.
- ✔ **If a waiver for the informed consent process is requested, justify the waiver in terms of each of the following: (a) The research involves no more than minimal risk to the subjects; (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) The research could not practicably be carried out without the waiver or alteration; and (d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.** Studies involving confidential, one time, or anonymous data need not justify a waiver. A verbal consent or implied consent after reading a cover letter is sufficient.
- ✔ ASU consent templates are [here].
- ✔ Consents and related materials need to be congruent with the content of the application.

Response:

12.1 Members of the research team will be responsible for consent.

12.2 Consenting will take place in person at the school site and through electronic communication. Initially, we will ask principals at 14 participating schools to provide informed consent, share their school bell schedule, and assist with recruiting all healthy school personnel in their school to participate. After-school program leaders will be asked to send this information to all parents/guardians. Those interested in enrolling their child will return the signed consent/e-consent (ESSER parent permission_06.29.22). Child assent will be obtained for students in grades 3-6.

12.3 Written documentation of consent will be obtained for adults, and written assent will be collected for children and marked as obtained by researchers.

IRB: 13. Site(s) or locations where research will be conducted.

List the sites or locations where interactions with participants will occur-

- Identify where research procedures will be performed.
- For research conducted outside of the ASU describe:
  - Site-specific regulations or customs affecting the research.
  - Local scientific and ethical review structures in place.
- For research conducted outside of the United States/United States Territories describe:
  - Safeguards to ensure participants are protected.
- For information on international research, review the content xxx

For research conducted with secondary data (archived data):

- List what data will be collected and from where.
- Describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes.
- For any data that may be covered under FERPA (student grades, etc.) additional information and requirements is available xxx
- For any data that may be covered under FERPA (student grades, homework assignments, student ID numbers etc.), additional information and requirements is available xxx

Response:

Research will be conducted at 14 xxx Schools that have after-school programs. Data will be collected during the after school program and during recess. Accelerometers will be worn for 24 hours across seven days.

IRB: **14. Human Subjects Certification from Training.**

Provide the names of the members of the research team.

ASU affiliated individuals do not need attach Certificates. Non-xxx investigators and research team members anticipated to manage data and/or interact
with participants, need to provide the most recent CITI training for human participants available at www.citiprogram.org. Certificates are valid for 4 years.

TIPS for streamlining the review time.

- ✔ If any of the study team members have not completed training through xxx CITI training (i.e. they completed training at another university), copies of their completion reports will need to be uploaded when you submit.
- ✔ For any team members who are affiliated with another institution, please see “Collaborating with other institutions”xxx
- ✔ The IRB will verify that team members have completed IRB training. Details on how to complete IRB CITI training through xxx

Response:

xxx

PROCEDURES FOR THE REVIEW OF HUMAN SUBJECTS RESEARCH

General Tips:

- Have all members of the research team complete IRB training before submitting.
- Ensure that all your instruments, recruitment materials, study instruments, and consent forms are submitted via ERA when you submit your protocol document. Templates are xxx
- Submit a complete protocol. Don't ask questions in the protocol – submit with your best option and, if not appropriate, revisions will be requested.
- If your study has undeveloped phases, clearly indicate in the protocol document that the details and materials for those phases will be submitted via a modification when ready.
- Review all materials for consistency. Ensure that the procedures, lengths of participation, dates, etc., are consistent across all the materials you submit for review.
- Only xxx faculty, full time staff may serve as the PI. Students may prepare the submission by listing the faculty member as the PI. The submit button will only be visible to the PI.
- Information on how and what to submit with your study in ERA is xxx. Note that if you are a student, you will need to have your Principal Investigator submit.
- For details on how to submit this document as part of a study for review and approval by the xxx IRB, visit xxx