PROTOCOL TITLE:

Stay Active

PRINCIPAL INVESTIGATOR:

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Weight Management

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VERSION NUMBER/DATE:

V4 / 9.17.2020

REVISION HISTORY

This Revision History table is provided for the benefit of study team version control. If this table will not be useful to your team, you do not need to include it.

Revision #	Version Date	Summary of Changes	Consent Change?
1	8.31.2020	Updated sample size information to include parents and teachers (Section 1.0) Updated to include weekly teacher survey information, post-study interview, and pre-study training options (Section 5.2) Updated for clarity on additional support resources being sent to families and family survey information (Section 5.3) Updated to match previous updates as well as information on opt-out detail, how the Garmin devices will be given to participants (Section 6.1) Updated to include who will receive weekly text messages and how data might be shared with PE teachers (Section 9.1) Updated to include corrected sample information (Section 13.2)	

		Updated to include study information letter (Section 14.2) Updated to include Garmin device value (Section15.2) Updated to include withdrawal information (Section15.4) Updated data management practices for participant surveys (Section 20.5) Updated to include P/A/C information for non-English speakers and teachers (Section 25.1) Updated to clarify who can provide consent to participate for children (Section 25.2)	
2	9.7.2020	Updated to include Stay Active Information Letter (Section 6.1 and 14.1) Updated Multi-Site Research to include KUMC and UMKC information (Section 29.0)	
3	9.17.2020	Update that all parents of students with a Garmin will receive text reminders regarding wear of device (Section 5.3) Clarification update for students who opt out of CBPA portion of the study (Section 6.1) Updated to clarify no recording of physical activity sessions will occur and video conferencing will be set up by the classroom teacher (Section 6.1) Updated to include recruitment of classrooms are determined by the school/district (Section 14.1)	

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1.0 Study Summary

Study Title	Stay Active
Study Design	Experimental Intervention
Primary Objective	To compare the impact of two physical activity interventions on student's physical activity.
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	Two arms: Arm 1: classroom based physical activity Arm 2: classroom based physical activity plus family support for physical activity.
IND/IDE #	
Study Population	Up to 15 classrooms from Kansas City area elementary schools.
Sample Size	Up to 250 Students, 250 parent(s)/guardian(s), and 15 teachers
Study Duration for Individual Participants	1 semester (for about 4 months)
Study Specific Abbreviations/ Definitions	CBPA: classroom based physical activity

2.0 Objectives

2.1 The pilot study will create, implement, and evaluate a physical activity program in both the school and home setting during the COVID-19 pandemic.

3.0 Background

3.1 COVID-19 has created numerous challenges to children's ability to engage in healthy lifestyles. The need for physical distancing creates barriers to many types of physical activity children typically engage in. The school setting is an essential source of children's physical activity and the recent move of school education from in-person to online eliminated over half of children's daily physical activity. Since the COVID-19 pandemic is accelerating socioeconomic disparities, which have major implications for long term health, it is more important than ever to provide safe opportunities for children from low-income families to engage in active lifestyles.

The 2020-2021 school year in the Kansas City area will create numerous challenges to teachers and other school personnel. Whether classes will be conducted online, in-person, or using a mix of the two approaches is still unknown, but all approaches will substantially limit opportunities for children to engage in healthy lifestyles. Schools will be forced to constantly adapt to new procedures that prevent the spread of infection. These challenges will make it even more difficult for elementary schools to support children's health and physical activity.

In addition to supporting health, the activities reenergize students and improve attention, learning, and positive behavior in the classroom. Teachers are trained and supported to deliver additional activities throughout the week, but our physical activity leaders minimize burden on the teachers as we acknowledge that teachers are in a particularly challenging situation due to the pandemic.

4.0 Study Endpoints

4.1 The primary endpoints are daily step counts and daily physical activity minutes.

4.2 The secondary endpoints are parent and teacher perceptions.

5.0 Study Intervention/Investigational Agent

5.1 This study will be conducted in in-school and out-of-school settings.

5.2 Arm 1 (CBPA):

- CBPA: Physical activity support is provided by integrating daily structured activities in the classroom delivered by physical activity leaders through a video conferencing platform in partnership with the classroom teacher. Activities last about 10 minutes or less and have the flexibility of being integrated with academic lessons or serving as a break from academics.

  The activities are simple and get kids moving in place. The activities will be delivered by a research staff member via video conferencing (using the schools preferred platform). A combination of live activities led by the research team and pre-recorded videos will be used (see example below). If live videos do not work for the teacher, they will have the option to only use the pre-recorded videos or receive a list of resources to promote CBPA in their classrooms.

  Teachers will be asked to complete weekly a weekly REDCap survey to track the amount of CBPA they offered to their class outside of the time study staff provided physical activity support. Teachers will also be asked to complete one post-study survey and interview to provide their perceptions of the Stay Active program.

  Study staff will provide an optional training session for teacher to walk through the importance of CBPA, as well as accessing the resources that will be provided to them. This training will be accessible through live videoconference or a PowerPoint presentation sent via email.

5.3 Arm 2 (CBPA plus family):

- CBPA component will be identical to above.
- Family Component: A newsletter, with supporting handouts and resources for the family to use, will be sent to parents or guardians once every two weeks over the semester and posted on the study website. The newsletters include physical activity information related to safety/protection, skills building, motivation, overcoming barriers, and goal setting and monitoring. The handouts include optional worksheets and physical activity tracking sheets to support families. As part of the program, children also receive a Garmin wearable physical activity monitor. Parents or guardians will receive text messages with behavior change messages based on the Garmin data. Text messages also contain links to website materials. Parents/Guardians of students who receive a Garmin will receive text reminders about wearing the device if no steps or minutes of physical activity are being detected.

  Texts will be sent out using the Twilio platform.

  Participants (both parent and child) will be asked to complete two surveys during the study. Surveys ask questions related to general demographics, household physical activity habits, and COVID-19 related questions. The first survey has been submitted in the SmartForm (Baseline Survey_Version_0.02), the second survey will be submitted later as an amendment, as it is still being developed.

6.0 Procedures Involved

6.1 Data Collection Procedures

- Describe the method for identifying candidates for the study
  - School Recruitment: We will work with district contacts to identify schools and classrooms to participate. School staff will be provided an informational letter about the study.
  - Participant Recruitment: A recruitment flyer will be sent to families via their classroom teacher.
- Describe the procedure for obtaining data
  - Teachers will receive weekly emails containing a brief REDCap survey to complete.
  - Teachers will complete a post intervention survey (we will submit this later as an IRB amendment, as it is still being developed).

- Teachers will complete a post intervention interview (we will submit this later as an IRB amendment, as it is still being developed).

- If the teacher withdraws from the study, their class will no longer be able to participate in the Arm #1 of the study.

- Parents or guardians will complete a pre- and- post intervention survey, with the options of on paper or over RedCap. The post intervention survey will be submitted later as an IRB amendment, as it is still being developed.

- Students in both arms will be asked to wear Garmin physical activity devices to provide physical activity information throughout the intervention. The Garmin is worn like a wristwatch. The device is small and non-intrusive. The Garmin device is a consumer wearable that will automatically detect and track activity such as walking, running, and cycling.

- Study staff will set up the Garmin account with an email address provided by the parent and a generic password. This information will be shared in the Participant Garmin Instructions sent in the mail along with the Garmin device. Study staff will not input any personal information, aside from the provided email address, while creating the Garmin account.

- Students can participate in the CBPA portion of the study without opting in to wearing the Garmin device. This participant will not be consented or assented but will still receive the classroom physical activity lessons via their classroom.

- Students who neither opt out or opt in to the study will be allowed to participate in the CBPA portion of the study. No personal information or data will be collected from these students.

- Any potential participant that opts out of the CBPA portion of the study will be told that they can watch, engage in a separate activity, or leave the session temporarily.

- No data aside from that which is already being collected via the Garmin devices will be collected from the physical activity sessions.

- Two-way video conferencing will be used to deliver physical activity study, but sessions will not be recorded by study staff. Study staff is will be joining an existing video meeting set up by the school (meetings that are already being used by the school). Staff will not set up the meeting platforms for the physical activity sessions.

- No personal information will be recorded in the recruitment phase prior to a participant enrolling in the study.

- Garmin devices, device set up and participant information, along with a hardcopy of surveys if requested by the participant will be sent to the provided mailing address of the participant. Mailing address is collected during the consent process and will be stored securely in REDCap.

7.0 Data and Specimen Banking

7.1 N/A.

8.0 Genetic Analysis Information

8.1 N/A

9.0 Sharing of Results with Subjects

9.1 Parents or Guardians of students in Arm #2 will receive weekly text messages with updates on the students overall physical activity and previous weeks step count. Step and minutes of physical activity information from the Garmin data may also be shared with the PE teachers. Information will be aggregate and will not contain any identifiers.

10.0 Study Timelines

	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2020	Feb 2020	Mar 2020
Recruit participants								
Collect data								
Conduct intervention								
Analyses								
Publication and presentation								

11.0 Inclusion and Exclusion Criteria

11.1

Inclusion Criteria

- *Classrooms*

  - Teacher of a 4th or 5th grade class in the Kansas City area.
  - English speaking only

- *Students*

- Any student in the selected classrooms
- A parent or guardian of the student that has a smartphone
- English speaking only

Exclusion Criteria

- Does not meet the required criteria above.

11.2 Indicate specifically whether you will include or exclude each of the following special populations:

- Adults unable to consent- EXCLUDE
- Individuals who are not yet adults (infants, children, teenagers) - INCLUDE
- Pregnant women – we will not be screening for pregnancy so there is potential that pregnant women will be participating.
- Prisoners – EXCLUDE
- Wards of the state - EXCLUDE

12.0 Vulnerable Populations

12.1 **Children:** P/A will be obtained from participants under the age of 18 and their parent/LAR. Research staff involved in the P/A process will review the HRP-416 CHECKLIST – Children to ensure sufficient information is provided during the P/A appointment with the child and their parent/LAR.

13.0 Local Number of Subjects

13.1 Up to 15 Kansas City school teachers and classrooms.

13.2 Up to 250 students (4^{th} and 5^{th} graders), 250 parent(s)/guardian(s), and 15 teachers

14.0 Screening and Recruitment Methods

14.1 Classrooms

- We will work with district contacts to identify schools and classrooms to participate.
- A study information letter will be sent out via multiple modes of communication to schools and teachers.
- Study staff will communicate with the leader in the district who has authority to approve the project. The leader then identifies the classrooms and relays what classrooms have been selected to study staff.

14.2 Participants

- A recruitment flyer will be sent out via multiple modes of communication to all families of 4^{th} and 5^{th} grade students in

classrooms of selected teachers that are participating. The recruitment flyer will be sent by the teacher.

- The recruitment flyer will describe the CBPA as all students in the classroom (even those who do not wear the Garmin device) will be able to participate in the CBPA if desired. The recruitment flyer will explain that such students/families can opt out of receiving the CBPA by contacting the study team or their teacher. These students will not complete any study assessments.
- The recruitment flyer will also describe the Garmin assessment portion of the study and the potential family content that half of the classrooms will be randomized. To enroll in the Garmin portion of the study participants will need to opt in by contacting the study team. Thus, these are the study participants who will be consented/assented and measured/assessed.
- Research staff will respond via email or telephone to inquiries generated by the recruitment email and flyer. The research team will go over the details of the study with potential participants over the phone or email. If a potential participant says they want to enroll in the study after receiving the study information, having any questions answered by the research team member, and being confirmed as eligible, the parent and child will be consented and assented over the phone. E-consent will then officially take place over the phone and REDCap. The participant will receive a copy of the P/A/C form and participant instructions by e-mail or in the mail.

14.3 We will have access to parent names, email addresses, and phone numbers prior to obtaining permission/assent. We are requesting a waiver of HIPAA authorization for recruitment purposes only. We will not retain any data from potential participants who do not enroll in the study.

15.0 Reimbursement, Payment and Tangible Property provided to subjects

15.1 Classroom teachers who complete the post intervention assessments will receive a Greenphire ClinCard in the amount of $50.

15.2 Participants will receive up to $50 for participating. The cash card will be issued at the end of the fall semester. $25 will be given to participants who wear the Garmin device the first week of the study. Another $25 will be given to participants who wear the device the last week of the study and complete the final survey, which is completed by the parent and child. In addition to the cash card, the participant will be able to keep the Garmin device at the end of the program, which is valued at $80.

15.3 The research team will collect the required information (e.g. address and date of birth) for issuing compensation after P/A/C has been obtained during the P/A/C appointment. This information will be immediately entered into Greenphire by the research team and then shredded to protect confidentiality. Payment will be issued to the participant when they complete the study and complete the final survey.

15.4 If the participant chooses to withdraw at any point during the study, they will not be asked to return the Garmin device. They will be compensated for each portion of the study they complete.

16.0 Withdrawal of Subjects

16.1 Participants will be informed that they may withdraw from the study at any time by contacting a member of the research team.

16.2 Data collected from subjects prior to withdrawal will be retained for analysis. At the time subjects withdraw, no additional data will be collected from the subject.

17.0 Risks to Subjects

17.1 Classroom:

- The primary risk, albeit minimal, is the risk of loss of confidentiality. The use of video conferencing could result in a potential loss of privacy, but study staff will be using the schools video conferencing system to minimize this risk.

17.2 Participants:

- The risk to the child's comfort, albeit minimal, is the wearing of the device daily on their wrists.
- There is a risk to the participant of loss of privacy due to the Garmin being a consumer device that uploads data to Garmin servers.
- There is a slight risk of loss of privacy due to the use of Twilio as the text messaging platform.
- There is a slight risk of burden to the parents or guardians due to the text messaging frequency.

18.0 Potential Benefits to Subjects

18.1 Participants will benefit from resources and opportunities provided on how to be physically active during the COVID-19 pandemic.

18.2 Participants may experience health and developmental benefits from increasing their physical activity.

19.0 Investigator Assessment of Risk/Benefits Ratio: (IRB makes the final determination) *Based upon your response in Sections 17.0 and 18.0, please provide your assessment of risk and benefits in below table.*

Select as applicable:	**Pediatric Risk Category:**	
X	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (45 CFR §46.405 and 21 CFR §50.52)
	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
X	Not Greater than Minimal Risk	
	Greater than Minimal Risk	

20.0 Data Management and Confidentiality

20.1 Measures

- *Primary measure(s):* Daily minutes of physical activity and step count
- *Secondary measure(s):* parent and teacher perceptions

20.2 General Design Issues

- Pre-post between group comparison

20.3 Sample size determination

- Based on availability of resources

20.4 Data Analyses

- Mixed effects models will account for nesting of time within participants and participants within classrooms. Changes in PA from pre to post will be compared between the intervention groups.

20.5 Secure Storage of Data

- Garmin data will be obtained through the Garmin API. It will show each student's daily minutes of physical activity and step counts when participants were wearing the device. Participant also have access to this information through their Garmin Connect account. As part of the consent/assent process study staff will describe that information from the devices will be

collected through the Garmin API and that Garmin will have access to this information.

Garmin data are stored on Garmin servers and will be accessed by the research team via the Garmin web apps on CMH secure computers. Study staff will not provide Garmin access to participant names or any other PHI that would make a participant readily identifiable. Reports will be aggregated across the participants so no participant will be identifiable, and no identifiable data will be published or presented.

Online surveys will be managed in REDCap.

To protect the security of responses on hardcopy surveys, participants will complete a confidential survey that includes a participant identification number on the form. The participant ID#, rather than name, will be recorded on hardcopy surveys. A master list containing the names and associated IDs will be kept securely in REDCap. No one except the study team members will have access to this master list. Names and descriptions of participants will not be published or reported. All data will be stored without identifiers, and only participant number. Survey data are entered on Children's Mercy computers and will be stored in REDCap. Research team members are trained to not divulge participants' information in anyway.

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

21.1 Describe:

- N/A – the study is minimal risk.

22.0 Provisions to Protect the Privacy Interests of Subjects

22.1 Secure Storage of Data (repeated)

Garmin data will be obtained through the Garmin API. It will show each student's daily minutes of physical activity and step counts when participants were wearing the device. Participant also have access to this information through their Garmin Connect account. As part of the consent/assent process study staff will describe that information from the devices will be collected through the Garmin API and that Garmin will have access to this information.

Garmin data are stored on Garmin servers and will be accessed by the research team via the Garmin web apps on CMH secure computers. Study staff will not provide Garmin access to participant names or any other PHI that would make a participant readily identifiable. Reports will be aggregated across the participants so no participant will be identifiable, and no identifiable data will be published or presented.

23.0 Compensation for Research-Related Injury

23.1 N/A

24.0 Economic Burden to Subjects

24.1 Time.

25.0 Permission/Assent/Consent Process

25.1 Arm 1: The recruitment flier allows parents/students to opt out of the CBPA portion of the study and to opt in to the Garmin assessments and potentially receiving the family component of the intervention (if randomized to the second study arm). P/A/C for the family component would then follow the process for Arm 2.

Non-English speakers will be able to call the study line to have the recruitment flyer read to them by an interpreter. A list of those who opt out of the CBPA portion of the study will be kept on secure CM servers for the duration of the study and will then be deleted.

We will obtain permission/assent/consent for teachers but will not document permission/assent/consent in writing, and have developed a permission, assent and or consent scripts (e.g., Study Information Sheet) as applicable and uploaded them in myIRB in lieu of full permission/assent/consent forms. We have reviewed HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that we have provided sufficient information.

25.2 Arm 2: The study team will obtain permission/assent/consent via eConsent Lite on the potential participants smart device over the phone:

- The p/a/c process will take place via telephone and will follow CM research policy (10.05 Telephone Process).
- The potential participant will have a chance to ask questions and decide if they'd like to participate.
- The Study team will be following CM research policies on informed permission/assent/consent.
- Dr. Jordan Carlson's research team, as well as the study coordinator or other research staff listed on the IRB may complete consent
- Time devoted to consent will be will only consist of an eConsent conversation over the phone.
- Participants and their families will be given plenty of time to consider participation (they can decline to participate during the consent phone call and request follow up) as well as ask any questions they have.
- Study staff will explain each main section of the p/a/c form as well as provide a summary. Checking for understanding while going through the form and after.

Subjects who are not yet adults (infants, children, teenagers)

- The study team will consider participants in the sample of 4th and 5th graders not yet adults.
- One parent will provide permission, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
- Permission will only be obtained from individuals that are parents or legal guardians.

Consent at 18 years of age, when minor subjects become adults

N/A

Non-English Speaking Subjects

N/A

Cognitively Impaired Adults

N/A

Adults Unable to Consent

N/A

26.0 Process to Document Permission/Assent/Consent

26.1 The study team will be following CM Research Policy 10.04 Obtaining Permission/Assent/Consent.

27.0 Setting

27.1 Research staff will receive a letter of support from schools or districts prior to enrolling classrooms. This letter will be provided to the IRB via modification and no study related activities will take place until the modification has been reviewed and approved.

27.2 Research will occur in both the school classroom setting as well as outside of the classroom.

28.0 Resources Available

28.1 Our research team has the research training and equipment needed to conduct this study according to protocol. We anticipate being able to recruit participants through our existing partner networks and

organization. All research team members will review the protocol and be given instructions, as appropriate, for conducting the study.

29.0 Multi-Site Research

29.1 Study-Wide Number of Subjects = up to 250 students, 250 parents/guardians, and 15 classroom teachers.

29.2 Investigators in the form of graduate and undergraduate research assistants from University of Kansas Medical Center (KUMC) and the University of Missouri- Kansas City (UMKC) will be involved in the study. These assistants will help gather and analyze data.

30.0 International Research

30.1. *N/A*