

Meet Me on the Pitch: Developing and Testing a Community-Based Sports and Behavioral Health Intervention for Youth

NCT07339228

Informed Consent Form (ICF)

Approved by the Institutional Review Board of the University of California, San Francisco

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT/ASSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title	Meet Me on the Pitch: Developing and testing a community-based sports and behavioral health intervention for newcomer youth
Principal Investigator (Person in charge of this study)	Mara Decker, DrPH, Associate Professor Philip R. Lee Institute for Health Policy Studies, UCSF mara.decker@ucsf.edu
Study Coordinator	Natasha Borgen, MPH Philip R. Lee Institute for Health Policy Studies, UCSF Natasha.borgen@ucsf.edu
Study Contact Information	soccer@ucsf.edu
Clinicaltrials.gov National Clinical Trial (NCT) Number	<i>Not yet assigned.</i>

1. Why have I been given this document?

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

2. Do I need to take part in this research study?

No. Taking part in research is voluntary. If you don't want to take part, there will be no penalty and you can continue with your team. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your coach, your family, and friends before deciding.

3. This section describes key information to consider about this study

3.1 Why is this study being done?

This study is being done to learn whether a new soccer-based program called *Meet Me on the Pitch* can improve mental health, school engagement, and social connection for newcomer youth. The program trains trusted soccer coaches to provide support and connect youth with needed services.

3.2 How long would I be in this study? How many study visits are there?

You would be in the study for about eight months. This study has two different groups.

- If you are assigned to group 1, you will participate in six 1-hour *Meet Me on the Pitch* sessions in addition to regular Soccer Without Borders activities. Before the first session, you will also be asked to complete a 20-30-minute survey, and at the end of the last session you will complete a short 5-10 minute survey. You will also be contacted to complete two more surveys (10–15 minutes each) at 3 and 6 months after the last session.
- If you are assigned to group 2, you will continue to participate in regular Soccer Without Borders activities without the additional *Meet Me on the Pitch* sessions. You will still be asked to complete the same set of surveys at baseline, and again 3 and 6 months later.

We will tell you more group assignments later in this form.

3.3 What are the procedures with the most risk in this study?

The procedures with the most risk in this study are:

- Program materials or survey questions that may ask you to reflect on your feelings, stress, or challenges. Talking about these topics could feel uncomfortable for some youth.
- Potential loss of privacy by others in the group sharing what is said.

3.4 What risks and discomforts are most severe? What risks and discomforts are most common?

Rare but possible risks and discomforts of this study:

- Feeling uncomfortable or upset about program materials, program activities, or survey questions about sensitive topics.

- Loss of privacy by others in the group sharing what is said.

We will tell you more about risks and discomforts later in this form.

3.5 Are there benefits to taking part in this study?

You may or may not benefit from participating in the study. The information learned from this study may help others in the future.

3.6 What are my other options if I don't want to take part in this study?

You may be able to take part in another study if one is available.

4. How many people will take part in this study?

About 480 youth will take part in this study at Soccer Without Border sites.

5. Who is paying for this study?

This study is being paid for by the National Institute for Health [grant number A144370].

6. Do any UCSF researchers of this study have financial interests that I should know about?

No.

7. What are the research procedures of this study?

- The first session will be focused on the study. You will be asked to complete a 20-30-minute online survey that includes topics such as your background, community, school, goals, and mental health.
- You will be asked for your contact information so the study team can reach you for follow-up surveys.
- You will then be randomized to receive or not receive the *Meet Me on the Pitch* program.

Randomization: This study has two different groups. You will be put into a group by chance, like flipping a coin or rolling dice.

- *If you are in group 1* you will receive the *Meet Me on the Pitch* program in addition to your regular Soccer Without Borders activities. The program consists of six 1-hour sessions that focus on building skills to manage stress, setting personal and academic goals, and strengthen relationships. During the last session, you will complete a 5-10 minute survey about your opinions of the program and what you learned. SWB coaches will complete attendance logs for each session, and members of the UCSF research team may observe some sessions to see how activities are being delivered. These observations are not evaluations of you or your team. They are only to understand how the program works in real life.
- *If you are in group 2* you will continue to participate in regular Soccer Without Borders Activities without the additional *Meet Me on the Pitch* sessions. You may be eligible to receive the *Meet Me on the Pitch* after the study is complete.

Follow-up surveys for both groups:

- You will be contacted to complete brief online surveys at 3 and 6 months after the last session. These will take 10-15-minutes to complete.
- You can complete them at a time and place that is convenient and private.
- Surveys will ask your knowledge, attitudes, and behaviors on health topics.

7.1 Where do the procedures happen?

Meet Me on the Pitch sessions will be held at your Soccer Without Borders school site.

8. What are the risks of this study?

Rare, but possible, risks related to this study include:

- Program materials, program activities, or survey questions about sensitive topics that may make you feel uncomfortable or upset.

- Loss of privacy by being identified as a participant or by others in the group sharing what is said. The group will be asked to use first names and not share what is said in the group outside the group.
- If you share information with coaches that makes them believe that you or someone else is being hurt, might hurt themselves, or might hurt someone else, as mandated reporters, they are legally required to report that information to the appropriate authorities to help keep you or others safe.

9. Will I be paid if I take part in this study?

You can earn up to \$100 in gift cards for participating in the study.

Gift cards for participating in the surveys include:

- \$20 after the baseline survey
- \$5 after the immediate post program survey (group 1 only)
- \$25 after the 3-month survey
- \$50 after the 6-month survey

Gift cards will be sent immediately upon survey completion.

10. Will I be reimbursed for expenses if I take part in this study?

This study does not involve any expenses to research participants.

11. How will my information be used?

We will use your information to conduct this study. Information gathered during this research study will only be used for this study. They will not be shared with other researchers.

12. How will information about me be kept confidential?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But we cannot guarantee total privacy. Your personal information may be given out if required

by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

12.1 Who may review my research information?

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Office of Human Research Protections (OHRP)
- Representatives of the National Institute of Health (NIH)

12.2 Certificate of Confidentiality

This study has something called a Certificate of Confidentiality. This helps keep your information private. Researchers can't be forced to share your information with others like courts or law enforcement.

There are some things that the certificate does not stop:

- Reporting abuse of children or elders, or if you or someone else is in danger.
- Reporting of certain diseases.
- Groups (like those listed in 12.1) from checking the research records to make sure the study is going okay.
- Agencies from getting information if they need it for safety reasons.
- Your information from being used in other research if it follows the rules.

The certificate doesn't stop you from:

- Talking about being in this research study.
- Looking at your own medical records.

13. Does this study involve testing of diseases and conditions that must be reported to the public health department?

No, this study does not involve testing for reportable diseases and conditions.

14. What happens if I am injured or feel harmed because I took part in this study?

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

15. Are there any costs to me for taking part in this study?

There will be no costs to you for being in this study.

16. Can I stop being in the study if I want to?

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team, so they can discuss any risks of stopping with you. If you stop being in the study, any data we have already collected will remain part of the study records.

17. Can I be removed from the study by the Principal Investigator?

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

18. What are my rights if I take part in this study?

You may choose to take part or not to take part in this study. It's your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

19. Who can answer my questions about this study?

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

19.1 Where can I get more information about this study?

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

20. Consent/Assent

You will be given a copy of this form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say "No" to this study now or at any point without penalty.

Please click if you agree to be in the study or if you do not agree to be in the study by answering the following question:

Do you agree to participate in this study?

- ☐ Yes, I agree to participate in the study
- ☐ No, I do not want to participate in the study

If you agree to participate in the study, please sign your name below:

X _____