¡Caminamos!: A Location-Based Smartphone App for Latina Women to Connect with Nearby Walking Partners

Phase II

NCT03854916

09/21/2021

CONSENT FORM: RANDOMIZED TRIAL

RESEARCH SUBJECT INFORMATION AND CONSENT FORM
Randomized Trial

TITLE:	*¡Caminamos!*: A Location-Based Smartphone App for Latina Women to Connect with Nearby Walking Partners - Phase II
PROTOCOL NO.:	R44 MD009652 IRB Protocol #20182102
SPONSOR:	National Institute on Minority Health and Health Disparities (NIH)
INVESTIGATOR:	David Buller, PhD 1667 Cole Blvd. Ste. 220 Golden, Colorado 80401 United States
SITE(S):	Klein Buendel, Inc. 1667 Cole Blvd. Ste. 220 Golden, Colorado 80401 United States
STUDY-RELATED PHONE NUMBER(S):	David Buller, PhD 303-565-4321

This consent form may contain words that you do not understand. Please ask the Principal Investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the Principal Investigator or staff explain the research study to you, and
- Asking questions about anything that is not clear.

You should not join this research study until all of your questions are answered. If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY
The overall goal of the study is to develop a smartphone application, *¡Caminemos Juntas!* that aims to improve physical activity among Latinas by providing opportunities to connect women face-to-face or remotely to promote walking, using user location and preferences through location-based services.

PROCEDURES
Your participation will involve attending a one-on-one orientation and baseline assessment session at Klein Buendel's office, located in Lakewood, CO. During this session we will explain the study and then we will ask that you complete six online surveys using a tablet computer. It should take about 45 minutes to complete the surveys. After you complete the surveys, you will be randomly assigned by chance (like a flip of a coin) to the experimental group that uses the *¡Caminemos Juntas!* app or the comparison group that uses the *World Walking* app. We will assist you with downloading the appropriate app to your smartphone and provide you with instructions on how to use the app. We ask that you use the app daily.

After approximately four weeks, we will contact you by email and ask that you complete a web-based survey.

After approximately eight weeks, you will attend a one-on-one post-test assessment where you will complete the online surveys and participate in a brief interview.

RISKS AND DISCOMFORTS
Some of the questions may make you feel uncomfortable. There is a slight risk that your confidentiality may be compromised.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study.

BENEFITS
There are no direct benefits to you for participating in this study. However, you may benefit from the knowledge that you have helped evaluate the effectiveness of a mobile software application, *¡Caminemos Juntas!*

COSTS
There are no costs associated with this study, except for your time.

PAYMENT FOR PARTICIPATION
You will receive a total of $100 for completing all three study assessments (baseline, 4-week, and 8-week). The following payment schedule will apply:

- $20 e-gift card for completion of the baseline assessment
- $40 e-gift card for completion of the 4-week assessment
- $40 e-gift card for completion of the 8-week assessment

ALTERNATIVE TREATMENT
This is not a treatment study. Your alternative is not to participate in this study.

CONFIDENTIALITY
Study information collected about you will be given to the sponsor. "Sponsor" means any persons or companies that are working for or with the sponsor or owned by the sponsor. This information may be shared with the Department of Health and Human Services and WCG IRB.
The consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- Department of Health and Human Services (DHHS) agencies,
- the sponsor;
- WCG IRB;

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

CERTIFICATE OF CONFIDENTIALITY
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the Principal Investigator or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

SOURCE OF FUNDING FOR THE STUDY

Funding for this research study is provided by National Institutes of Health; National Institute on Minority Health and Health Disparities.

CLINICALTRIALS.GOV

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.

QUESTIONS

Contact David Buller, PhD at 303-565-4321 for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-855-818-2289 or 360-252-2500
E-mail: researchquestions@wcgirb.com.

WCG IRB is a group of people who independently review research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

_____

Subject Name (printed)

CONSENT SIGNATURE:

_____ _____

Signature of Subject (18 years and older) Date

_____

Name of Person Obtaining Consent (printed)

CONSENT SIGNATURE:

_____ _____

Signature of Person Obtaining Consent Date