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

Title of the study: Text messaging to increase physical activity

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This is a research study about a text messaging program to help patients be more active. The study researchers, Adrian Aguilera, PhD from the UCSF Division of Psychiatry and Courtney Lyles, PhD from the UCSF Division of General Internal Medicine at ZSFG, or a member of their research team, will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to participate in this study because you are a patient at Zuckerberg San Francisco General Hospital who meets the eligibility criteria for chronic illness diagnoses for a text messaging-based program to increase daily physical activity.

Why is this study being done?

The purpose of this study is to better understand the role that exercise plays in the daily life of patients at ZSFG, as well as which text messages will encourage individuals to exercise more regularly in daily life, which could also help improve blood sugar control and mood symptoms. This study also aims to use your smartphone’s GPS location data to better capture the distance and activity people are doing in order to better understand patient activity and the environments in which physically activity occurs. This information will be used to inform the development of a text-message based intervention to promote daily exercise.

This study is financially sponsored by the Agency for Healthcare Research and Quality.

How many people will take part in this study?

About 280 people will take part in the overall study. About 240 people will take part in this part of the study to help us learn more about using the texting program in everyday life.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

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We will enroll you in a 6 month program to increase your walking, which could also help improve blood sugar control and mood symptoms. You will participate in up to 2 interviews: one at the beginning of the program and a final one at the end of the 6 months of the program.

At 2 and 4 months you will receive a text with a link to complete the PHQ-8 depression scale survey online, this can take up to 10-15 minutes.

At the first interview, you will participate in an in-person interview at one of our study offices that will take about 60-90 minutes. We will ask you questions about yourself and your health status, and work with you to download an application on your phone that tells us how many steps you are taking each day. We will also ask for your cell phone number so that we can send you text messages from the program. We will ask you to reply to certain messages. A research staff member will provide you with instructions on how to reply to these messages during your initial enrollment study visit.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. An application will place you in one of the groups. Neither you nor study staff can choose the group you will be in. You will have an equal chance of being placed in any group.

- **If you are in group 1** you will receive 1 text message weekly inquiring about your mood.

- **If you are in group 2** you will receive 2 daily text messages about physical activity feedback and motivation + 1 weekly message inquiring about your mood.

- **If you are in group 3** you will receive 2 daily text messages, but these will be personalized to that individual to predict the best message to increase physical activity based on the participant’s characteristics such as recent step count history + 1 weekly message inquiring about your mood.

And in general, everyone gets a text message that reminds them to open their app if the system has not received data from them for 24 hours. If we receive your data, you will not get a reminder text message.

You will be asked to give permission to access your medical records for up to 15 months after the start of your participation. We will assess results from blood A1c tests.

We will also have the option to give permission to the DIAMANTE application to access your smartphone device’s global positioning system (GPS) location data. Research staff will know your precise location during the time you allow DIAMANTE access to your location data. You do not have to agree to the sharing of location data to be part of the study.

At the second interview, at the end of six months, we will ask you to complete a final in-person interview that will take about 30-60 minutes. Your interviews will be audio-recorded to allow for later analysis. At the end of the 6 month interview, you will be given the option to continue participating for an additional 10 weeks receiving text messages and tracking your steps. You will give verbal permission to study staff to keep you enrolled. It is voluntary to continue in the

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program; you may choose not to continue in the program if you do not enjoy the program or find it too long.

- **Study location:** All these activities will take place at Zuckerberg San Francisco General Hospital or the UCSF Center for Vulnerable Populations.

**How long will I be in the study?**

You will participate in the texting program for up to 6 months, with an optional 10 additional weeks. The first interview will take approximately 60-90 minutes. The approximate amount of time that you will spend responding to text messages will be about two minutes per message or less. The two and four month online surveys will take approximately 10-15 minutes. The second interview will take approximately 30-60 minutes.

**Can I stop being in the study?**

Yes. You can decide to stop at any time. Just tell the study researcher right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**What side effects or risks can I expect from being in the study?**

You may feel discomfort answering questions about your health status or beliefs or discussing your opinions of the text messages and application with a researcher and having this discussion audio recorded.

You may also experience discomfort or a sense of loss of privacy as a result of revealing your exact location, habits and behaviors while allowing the DIAMANTE application to access your GPS location data during the study period.

While there is a chance that the confidentiality of the information you share could be compromised, we will take steps to prevent this from happening.

To better protect your privacy, we will refer to you only by first name during the interview and will omit your last name. All information collected via the audio-recorded discussion will be kept confidential. Audiotapes of this discussion will be kept only as long as it takes to code responses from these tapes. As soon as coding is complete, the tapes will be destroyed, including any information that could link your responses to your identity. During the period before the tapes are destroyed, they will be stored in a locked filing cabinet in Dr. Aguilara’s laboratory, separate from any identifying information associated with this study.

You can refuse to answer any questions or stop the interviews at any times. The server receiving data from the DIAMANTE application is hosted behind the UCSF firewall in a secure location, subject to healthcare-grade security measures, including strict firewalls, intrusion detection, and active monitoring by study and University staff.

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Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

You may experience physical injury and/or discomfort as a result of being physically active. You should communicate with your regular doctor if you experience any injury and/or discomfort.

**Are there benefits to taking part in the study?**

There are no direct benefits to you from participating in this research. However, your participation will help us better understand how to use text messaging technology related to physical activity.

**What other choices do I have if I do not take part in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

**Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. Examples of times that we cannot guarantee privacy and confidentiality are if you report child/elder abuse or suicidal ideation. In these cases, we may have to report this information to the appropriate authorities in accordance with laws and professional ethics. All data collected from your interviews and your smartphone’s GPS will be kept confidential within the research team. You will not be personally identified in any reports or publications that may result from this study. Any personal information about you that is gathered during this study will remain confidential to every extent of the law. A special number (code) will be used to identify you in the study, and only the investigators will know your name. If you have any questions or concerns about confidentiality, do not sign this form until you have had a chance to discuss your questions with the researchers.

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 Agency for Healthcare Research and Quality

**What are the costs of taking part in this study?**

There are no costs to you to participate in this study.

**Will I be paid for taking part in this study?**

You will be paid up to $110 for participating in this study in the form of cash. You will receive
compensation in two parts. You will receive $40 for participating in the first interview at one of our study offices. You will receive $70 at the end of 6 months for completing the second interview at the end of the second week of being enrolled in the program.

**What happens if I am injured because I took part in this study?**

It is important that you tell your study doctor Adrian Aguilera, PhD or Courtney Lyles, PhD, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them at 628-206-6166 or 628-206-6483.

**Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. You may also choose not to answer any question in the interviews that you do not wish to answer and still receive full compensation for your participation. You may also choose to not allow the DIAMANTE application permission to access your location or stop sharing location data at any time after the start of the study by going into the application’s settings and removing permissions. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

**Who can answer my questions about the study?**

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the researcher, Dr. Aguilera at 628-206-6166.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](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.
CONSENT

You have been given a copy of this consent form to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date _______________ Participant's Signature for Consent

Date _______________ Person Obtaining Consent

CONSENT FOR SHARING LOCATION DATA

If you wish to have your device’s GPS location data, you should sign below. You have the right to decline and not sign this section of the form.

Date _______________ Participant's Signature for Consent

Date _______________ Person Obtaining Consent

CONSENT FOR FUTURE CONTACT

If you wish to be contacted about opportunities in future studies, you should sign below. When you are contacted, you will be asked to provide consent for that specific study if you are eligible. You have the right to decline and not sign this section of the form.

Date _______________ Participant's Signature for Consent

Date _______________ Person Obtaining Consent

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