Informed Consent Form
6-week Text Message
Study

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Funding Agency: National Institutes of Health

Study Title: Digital Health for Medication Adherence Among African Americans with Hypertension

Summary: The main purpose of this 6-week pilot study is to evaluate the effectiveness of a text message system called Memento, for improving medication adherence in African Americans with hypertension.

If you agree to participate, you will fill out health questionnaires including your blood pressure medication details and demographic data. You will also be asked to use a blood pressure cuff (which will be given to you for free) to check and record your blood pressure once at the beginning and once at the ending of the 6-week study. You will be asked to send us your blood pressure reading numbers either by text or by an emailed photo. During the 6-week study period, you will receive daily text messages with pill reminders and encouragement. A pharmacist on the study team will also be available to answer texted medication questions and may check in with you by text to offer medication support if you start to miss doses of your pills. Any information provided by the team pharmacist should *not* be a substitute for your own healthcare provider's medical advice. A study staff member also may call you about once a week to provide assistance and answer any questions. At the end of the study, you will again be asked to fill out questionnaires and participate in a zoom focus group or an individual interview (by phone or zoom) to tell us what you liked or did not like about the text message system. If, for some reason, you cannot participate in the end-of-study interview or focus group, we will email additional written questions to you, which you can email back to us.

There is a risk that someone may see your text messages and realize that you take blood pressure medication. You should delete any texts that you do not wish others to see. While state-of-the-art, HIPAA-compliant security protections will be in place for any data in transit from the platform to your phone, there is still a risk to data in transit or privacy loss due to someone reading your text messages or a breach of confidentiality due to any of the data in transit or data storage. If you are uncomfortable with these risks, you should not participate in the study.

There is also the possibility that daily texts may malfunction, so you should continue

Participant's Initials: _____
Date: _____

using your normal methods to remember to take your pills during the study. The blood pressure cuff you receive might also malfunction, so you should not rely on it to monitor your blood pressure. Any information provided to you as a part of the study should not replace your own healthcare provider's advice.

You may also experience some discomfort as part of talking about your use of the text

Participant's Initials: _____

Date: _____

messaging system as part of end-of-study focus group. If you are uncomfortable with this, we can ask you the focus group questions in an individual phone interview or through a written form.

In order to receive the free blood pressure cuff, we will need to share your home address with a third-party supplier of the cuff, such as Amazon, who will send the cuff directly to you. We will not share any other information about you with the supplier. If you have concerns about this, you should not participate in the study.

This study may help you understand more about the importance of taking your daily blood pressure medication.

Participant's Initials: _____
Date: _____

Alternatives: Your alternative is not to participate.

Confidentiality and Authorization to Use and Disclose Personal Health Information: All information collected in this study will be kept strictly confidential, and no identifying information will be collected from you. Your participation is voluntary and will not in any way affect employment or access to any services received from any provider or agency or clinic.

A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA) describes how your personal healthy information may be used, disclosed and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This study can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records: the sponsor (NIH) personnel associated with this study, regulatory agencies, such as the Food and Drug Administration (FDA), and the Pearl Institutional Review Board (IRB), a committee that has reviewed this study to help ensure that your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner. Because of the number of individuals who may want to see your records, absolute confidentiality cannot be guaranteed. If any of your health information is likely compromised, the sponsor or other organization must notify government authorities. The Food and Drug Administration/IRB may inspect the records.

Personal information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other records, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, your records may not be available until the study has been completed. Finally, your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

You may, by written notice to the study doctor, cancel your authorization to use or

Participant's Initials: _____
Date: _____

disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization has no expiration date.

Any significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

Online data collected for this study will be removed from the Qualtrics platform, which is HIPAA compliant, stored in our HIPPA compliant EHG Google Drive, and backed up on encrypted folders on an EHG MacBook Pro. Passwords to access the folders will be stored in LastPass, which uses strong encryption algorithms and provides extra security. LastPass is considered highly secure by industry standards.

Termination of Participation: You may choose to withdraw from this study at any time and for any reason. You will simply need to contact the investigator.

Compensation: You will receive a $20 Amazon gift card for completing the questionnaires at the beginning of the study. Then, after finishing the 6-week study and retaking the questionnaires and completing the end-of-study focus group or interview, you will receive a $130 Amazon gift card. In total, you will receive $150 in Amazon gift cards.

Costs: There will be no costs to you.

Reasons for Withdrawal or Termination: The Investigator may terminate your participation in the study if any clinical adverse event or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of you**.** You meet an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation**.**

Questions: All of my questions have been answered to my satisfaction and if you have further questions about this study, you may call Dr. Patricia Weitzman, Investigator, at telephone number 617-455-5976.

If you have any questions concerning your rights as a research subject, or any related concerns or complaints, you may contact Pearl IRB at 29 East McCarty Street, Suite 100 Indianapolis, IN 46225 or via phone at (317)-899-9341. An Institutional Review Board is a committee that has reviewed this study to help ensure that your rights and welfare as a research participant are protected and that the study is carried out in an ethical manner.

Participant's Initials: _____

Date: _____

<u>Voluntary Consent</u>: I am free to withdraw or refuse consent, or to discontinue my participation in this study at any time without penalty or consequence. I voluntarily give my consent to participate in this research study. I will be given a signed copy.

Participant's Initials: _____

Date: _____

Signatures:

_____

Participant's Name Date

_____

Participant's Signature Date

_____

Investigator's Name Date

_____

Investigator's Signature Date