Participant Name: _____ Date:_____

Title of Study: Improving Depression Management in Primary Care

Principal Investigator: Lucinda Leung, MD, PhD VA Facility: VA Greater Los Angeles_

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are invited to take part in a research study that is funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any possible risks to you, as well as any possible benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By conducting this study, we hope to improve depression care by looking at new ways to treat Veterans with depression. You will be enrolled in this study for 3 months. During that time, you will get either 1) usual depression care at the VA or 2) usual care at the VA + online therapy through our study. You will also be asked to complete two 45-minute telephone surveys (90 minutes of time total).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might benefit from online therapy if you choose to be part of this study.

You may choose to volunteer if you want to be part of research that might help improve how Veterans get depression care at VA Greater Los Angeles (GLA).

For a complete description of benefits, look at the Detailed Information section of this informed consent form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

It is possible doing parts of this study may make you uncomfortable.

It is possible that sensitive or personal information may be accidentally shared. To prevent this, researchers will follow strict data security procedures (see below “How will my private information be protected”).

This is a minimal risk study.

For a complete description of risks, refer to the Detailed Information section below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

No, you do not have to take part in this study. If you decide to take part in this study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Lucinda Leung, MD, PhD at the VA Greater Los Angeles Healthcare System. If you have questions, suggestions, or concerns about this study or you want to stop being part of the study her contact information is: Lucinda.Leung@va.gov.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

Depression is disabling and affects 1 in 5 Veterans. Veterans prefer therapy treatment for depression, but it is not easy to get (there are long wait lists and patients often must travel to get to a clinic). By doing this research project, we hope to improve therapy access for Veterans by delivering therapy for depression online.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2 years. You will be enrolled in the study for 3 months. During that time, you will get either usual depression care at the VA or usual depression care at the VA + online therapy through our study. You will be asked to complete two 45-minute telephone surveys (90 minutes of time in total). If you end up in the usual depression care + online therapy group, you will also spend 6-10 hours doing the therapy program. This will be spread out over 3 months.

After the study, we will ask permission to contact you about participating in future research studies. If you do not wish to be contacted, please let us know. You can choose to be contacted for a future study and later choose not to participate.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

- You will be contacted by the Project Coordinator. She will give you details about participating in the study. She will go through an eligibility checklist to make sure you are eligible, in other words a good fit, for the study. If you are eligible, she will schedule you for a baseline and follow-up surveys.
- The Project Coordinator will also assign you to one of two groups: 1) usual depression care study group or 2) usual care + online therapy study group. You will be assigned randomly or by chance, like the flip of a coin.
- At a scheduled time, you will be contacted by a Research Assistant who will go through the baseline survey with you over the telephone. It will take about 45 minutes to

complete. You are free to skip any questions you do not want to answer. After doing the baseline survey, you will be paid for your time with a $30 VCS gift voucher.

- If you are assigned to the usual care group, you will keep getting care at the VA as you normally do.
- If you are assigned to the usual care + online therapy group, you will be contacted by the study Care Manager who will help you set up an account for the online therapy. You will then follow the online therapy as the program says to using your own computer or tablet. The online therapy has 5 lessons and each lesson takes about 1 hour to complete. You will also check-in with the Care Manager after each lesson. She will talk with you about the lessons you did and about your depression symptoms.
- After 3 months, you will be contacted by a Research Assistant who will go through the follow-up survey over the telephone. It will take about 45 minutes to complete. You are free to skip any questions you do not want to answer. After completing the follow-up survey, you will be paid for your time with a $45 VCS gift voucher.

During the eligibility checklist, baseline, and 3-month surveys you will be asked questions about your intention to harm yourself. If you indicate that you have any intention to harm yourself, study team members are obligated to report it.

If you have thoughts about harming yourself, call the Veterans Crises Line at 1-800-273-8255 (and press 1). This line is available 24 hours a day, 7 days a week.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

You are expected to…

- Keep your study appointments. If you miss an appointment, please contact the Project Coordinator or Care Manager to reschedule as soon as you know you will miss the appointment.
- If you are in the usual care + online therapy study group, complete the online therapy as the program says.
- Schedule and complete the baseline and follow-up telephone surveys.
- Ask questions as you think of them.

While doing this research study, please let the study team know if you choose to take part in any other research. This is to protect you from possible injury. Taking part in other research studies without first talking to the study teams may also affect the results of this and other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study has possible risks and discomforts. You may become uncomfortable when asked about your depression history, while completing health surveys, or while doing the online therapy. You do not need to share anything that makes you uncomfortable. You may skip any part of the survey or online therapy lesson at any time. You may also choose to stop participating in the study at any time.

This study may also have some risks to your privacy. It is possible that sensitive or personal information may be accidentally shared. To prevent this, researchers will follow strict data security procedures (see below "How will my private information be protected").

Risks of the usual care you receive are not risks of this study. Those risks are not included in this research consent document. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this study. However, if you end up in the usual depression care + online therapy study group, you may benefit from the online therapy.

If you end up in the usual depression care group, you will not personally benefit from the study. However, we expect this research will be used to help improve the quality of healthcare. It may also improve how Veterans get healthcare at VA Greater Los Angeles (GLA).

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you do not want to join this study, you are free to start or continue care as usual at the VA. You do not have to be part of this study to receive depression care at the VA. Talk to your health care provider if you want or need depression care.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

If you take part in this study, you will be asked for private information about your physical and mental health. This information will be protected in the following ways:

- All information will be stored in restricted-access project folders on the GLA HSR&D computer server. Only study team members with permission to use the VA computer

network and added permission to open the project folder will be able to see your information.

- Your private information (name, address, and phone number, last 4 of your social security number, and date of birth) will be kept in separate electronic files from your physical and mental health information. A study ID, unique to you, will be used to link your name to your health information.
- Final reports, publications, or presentations on this study will not contain information that will identify you.

Please note, we will add information about your participation in this study to your medical record.

After this study is finished, we will remove personal identifiers (such as name, date of birth, address, or telephone number) from the information you have given us and use it for future research. We will use or share this "de-identified" information without a separate informed consent from you.

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

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study (in other words, usual care).

You will need to use your own tablet or computer (with internet) and your telephone. You will not be reimbursed for this or other unforeseeable costs.

HOW WILL I BE COMPENSATED FOR TAKING PART IN THIS STUDY?

You will be compensated for your time with a $30 VCS gift voucher after your complete the baseline survey and with a $45 VCS gift voucher after you complete the 3-month follow-up survey, $75 total. The Project Coordinator will mail you the vouchers after you complete each survey. The vouchers can be exchanged, in-person, for goods and food at VCS Patriot Stores and Cafes.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to a participant not complying with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

No compensation beyond necessary medical care is available if you are injured as a result of taking part in this study. You, as a participant, do not give up any legal rights or release the VA from any liability if you choose to consent to participate in this study.

If you have medical concerns or get hurt or sick as a result of taking part in this study, call:

VA Greater Los Angeles Healthcare System (VISN 22)
Sepulveda Research Office:
16111 Plummer Street, Building 1 Sepulveda, CA 91343, (818) 895-9416

or

West Los Angeles Research Office:
11301 Wilshire Blvd., Building 114 Los Angeles, CA 90073, (310) 268-4437

DO I HAVE TO TAKE PART IN THE STUDY?

Participating in this study is voluntary. Participating, or not, won't affect your treatment or benefits at VA Greater Los Angeles. You can choose to withdraw or leave the study as any time without penalty or loss of benefits. If you withdraw from the study, you will still receive usual depression care.

If you choose to withdraw, the research team may continue to use any information or data collected before you withdrew but will not collect any new information or data.

If you want to withdraw from the study please contact the Study Lead, Lucinda Leung MD, PhD at[redacted]

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The Study Lead may choose to remove you from the study if you become too sick or mentally unable to participate safely. Should this happen, the Study Lead will let you know and refer you to any necessary health care.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

The person in charge of this study is Lucinda Leung, MD, PhD (Study Lead, Principal Investigator at VA GLA). Her contact information is[redacted]. Please let her know if you have questions suggestions, or concerns.

FOR IRB USE ONLY

PI/SC Approval Date:

VA GLA IRB
Effective Date: August 18, 2021

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the GLA Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Sepulveda Research Office [(818) 895-9416] or the West Los Angeles Research Office [(310) 268-4437] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Any private information or data kept after the study for use in future research, will be kept on a restricted-access, secure VA server. Only the research team will have access to your private information.

We will ask your permission to contact you about participating in future research studies. If you do not wish to be contacted, please let us know. You can choose to be contacted for a future study and later choose not to participate.

Participant Name: _____ Date:_____

Title of Study: Improving Depression Management in Primary Care

Principal Investigator: Lucinda Leung, MD, PhD VA Facility: VA Greater Los Angeles

California Bill of Rights of RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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PI/SC Approval Date:

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Effective Date: August 18, 2021