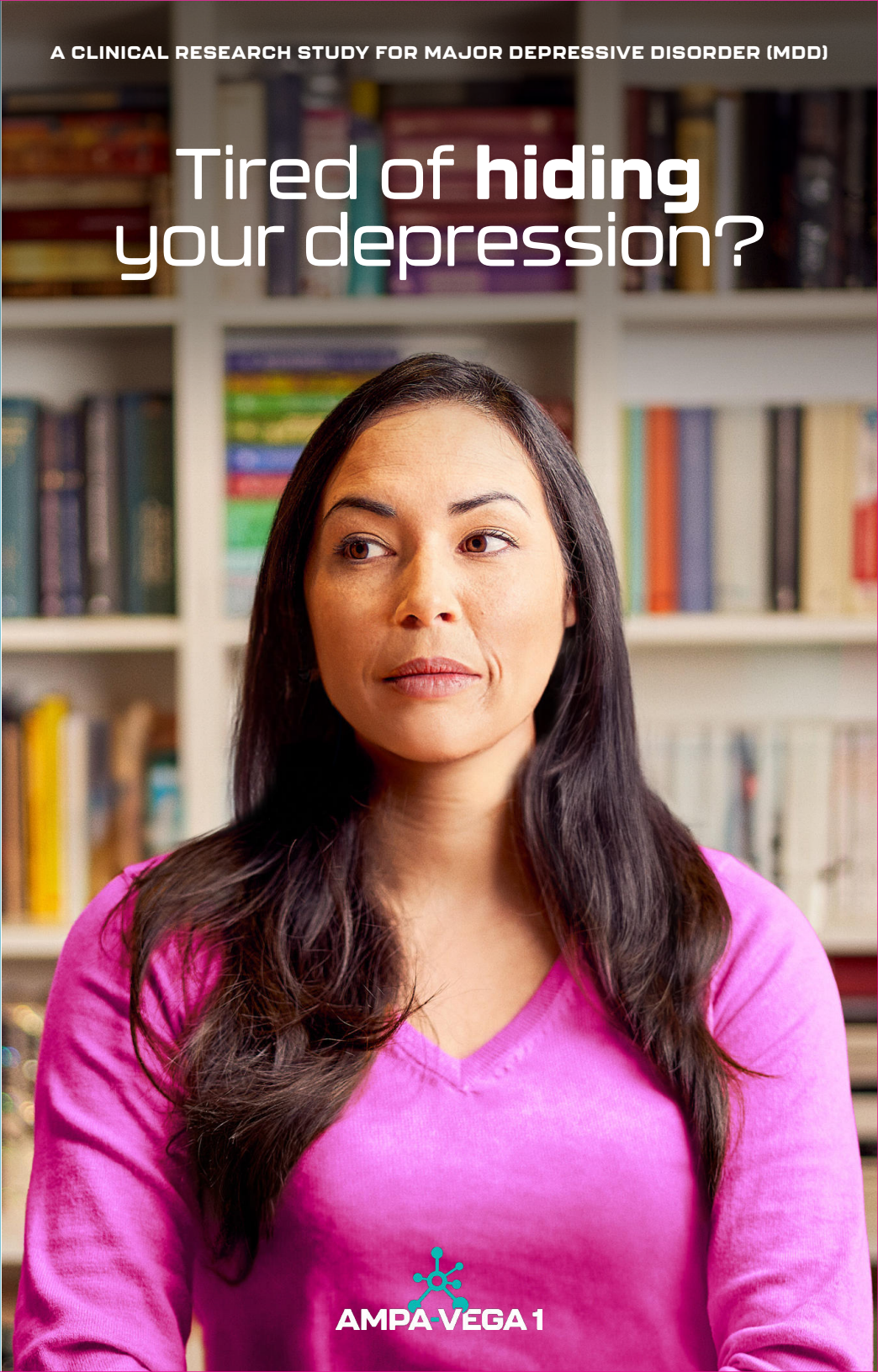
A CLINICAL RESEARCH STUDY FOR MAJOR DEPRESSIVE DISORDER (MDD)

Tired of **hiding** your depression?



AMPA-VEGA 1

ABOUT THE **STUDY**

The **AMPA-VEGA 1 STUDY** is part of the **AMPA PROGRAM,** and is researching an investigational medication to see if it may delay relapse of MDD symptoms when taken alongside current antidepressant medications.

STUDY SCHEDULE

Participation in this study is variable in length. It is expected to last at least 5 months and may exceed 24 months. Participants can anticipate monthly visits, with a few weekly visits. The number of visits is related to the length of time you are in the study.

Screening

28 days
(1 visit)

Treatment

16 weeks
(10 visits)

Maintenance

Varies based on the length of time you are in the study

Follow-up

2 weeks
(1 visit)

Open-label study

Up to 3 years
(42 visits)

Screening period – A study doctor will evaluate you to see if this study is a good match. You will first need to give your consent, or permission, to join this clinical research study by reading and signing the Participant information sheet and consent form.

Open-label treatment period – You will continue to take your current antidepressant medication(s) and begin taking the investigational medication. The study team will monitor your health at regular visits. Some of these visits may be done virtually.

Double-blind maintenance period – Neither the patients nor the doctors know who is getting the real treatment and who is getting a placebo (a 'dummy' treatment). You will have a 50/50 chance to either continue taking the investigational medication or switch to a placebo. Regardless of what study treatment you are assigned, you will continue to attend visits and be monitored by the study team. Some of these visits may be done virtually.

- A placebo is a substance that looks like the investigational medication but contains no medicine.
- You will be in the double-blind maintenance period until a relapse of your MDD symptoms occurs, the study ends or you voluntarily withdraw.

Follow-up period – The purpose of this period is to check on your health after stopping the assigned study treatment. If you join the long-term open-label study, this follow-up period is not required.

Optional long-term open-label study – You may have the option to join a 3-year open-label study, during which you will continue to take your current antidepressant medication(s) and receive the investigational medication for an extended period of time. If you were assigned to the placebo previously, you will be switched over to the investigational medication.

Regardless of whether you are assigned to receive the investigational medication or placebo, you will continue to take your current antidepressant medication(s) throughout study participation.

ABOUT THE INVESTIGATIONAL MEDICATION

The investigational medication being evaluated in this study is an oral tablet that will be taken once daily.

A placebo will be used to provide researchers with a baseline that they can compare the investigational medication to. To keep the research results as accurate as possible, participants, study doctors and the study research teams will not know if you are receiving the investigational medication or placebo. Participants who receive the placebo will get the same care as participants who receive the investigational medication.

WHO CAN PARTICIPATE?

TO PARTICIPATE IN THIS STUDY, YOU MUST:

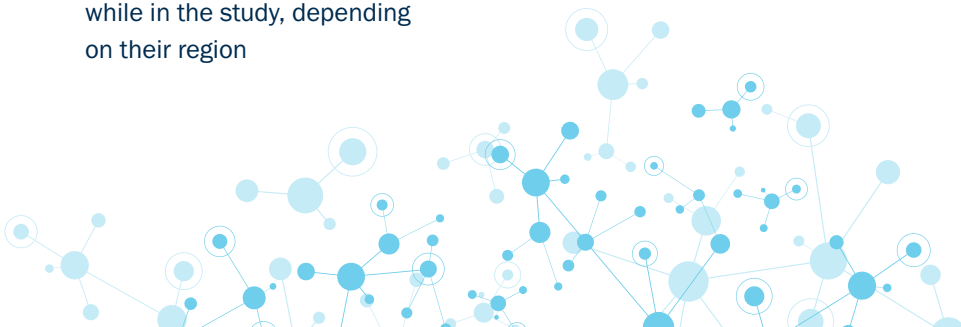
- be at least 18 years old
- have a primary diagnosis of MDD
- currently be receiving at least 1 antidepressant medication
- have had inadequate response to up to 5 oral antidepressant medications
- not be pregnant, breastfeeding or planning to become pregnant during the study

There are additional eligibility criteria and study requirements, which the study team will discuss with you.

WHAT TO EXPECT

PARTICIPANTS IN THIS STUDY WILL:

- receive the investigational medication for 16 weeks
- be assigned at random to either continue receiving the investigational medication or begin receiving the placebo (the assigned study treatment)
- receive the assigned study treatment and study-related procedures at no cost
- be reimbursed for applicable travel costs and inconveniences while in the study, depending on their region
- continue taking their current antidepressant while also taking the assigned study treatment daily
- receive support from their study doctor and site staff, who will check on their health while they are in the study
- have the option to be enrolled in other studies once they have completed this study



For more information, contact us:
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www.thermh.org.au/research/clinical-trials-research-studies/the-ampa-vega-1-study