

PROVIDER INFORMATION

INSTRUCTIONS FOR USE (dated July 18th, 2024)

Woebot for Adults (Woebot Life 2.0)

Non-Prescription Digital Mental Health Software

Woebot Health

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Glossary

Term	Definition
<i>CBT</i>	<i>Cognitive Behavioral Therapy</i>
<i>DBT</i>	<i>Dialectical Behavioral Therapy</i>
<i>DMHI</i>	<i>Digital Mental Health Intervention</i>
<i>FDA</i>	<i>Food and Drug Administration</i>
<i>GAD</i>	<i>Generalized Anxiety Disorder</i>
<i>IPT</i>	<i>Interpersonal Psychotherapy</i>
<i>M</i>	<i>Mean (Arithmetic Average)</i>
<i>MDD</i>	<i>Major Depressive Disorder</i>
<i>NLP</i>	<i>Natural Language Processing</i>

Descriptive Information

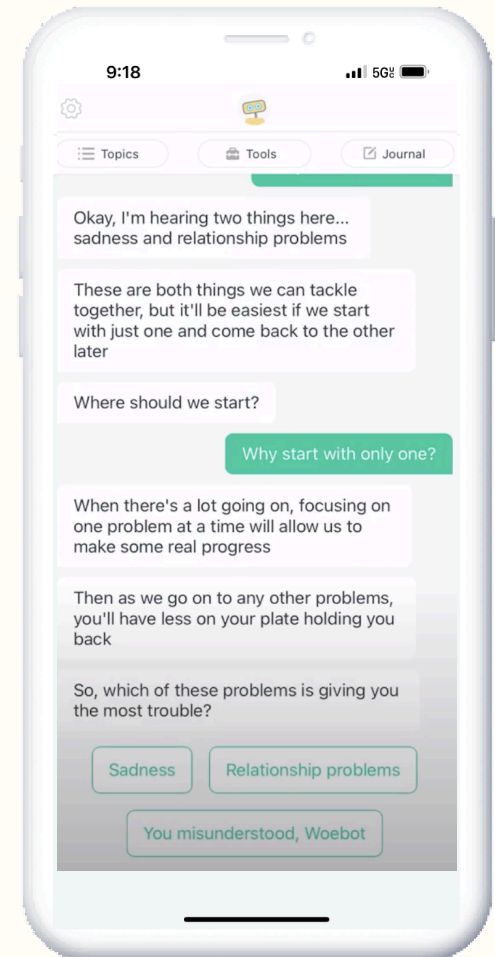
Intended Use / Indications for Use Statement

Woebot for Adults is intended for adults 18 years and older and is available either as a mental health general wellness or support tool. Woebot for Adults is intended to be used as an adjunct to clinical care; it does not replace the care of a medical provider or a patients' medication. Woebot for Adults has not been evaluated, cleared or approved by FDA.

What Is Woebot for Adults?

Woebot is a fully-automated mental health ally your patients can chat with through an app called Woebot for Adults, on their smartphone or tablet, anytime day or night. Woebot helps your patients work through challenging thoughts, feelings, and behaviors and fits right into their life.

Woebot for Adults invites your patients to monitor and manage their mood using tools such as mood tracking, progress reflection, gratitude journaling, and mindfulness practice. Woebot for Adults is intended to help your patients manage mood and anxiety symptoms and can be used as a mental health support tool to supplement treatments, therapies, or self-care practices.



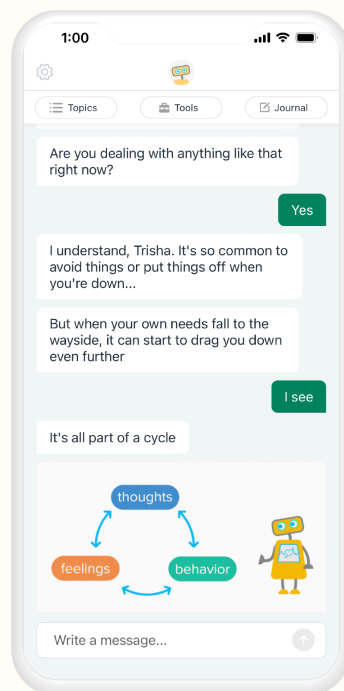
More about Woebot's Conversations...

Woebot is always available to work through a problem or feeling. If your patient is feeling stressed or overwhelmed, or wants support at 3 a.m., they can open Woebot for Adults and start a text-based chat.

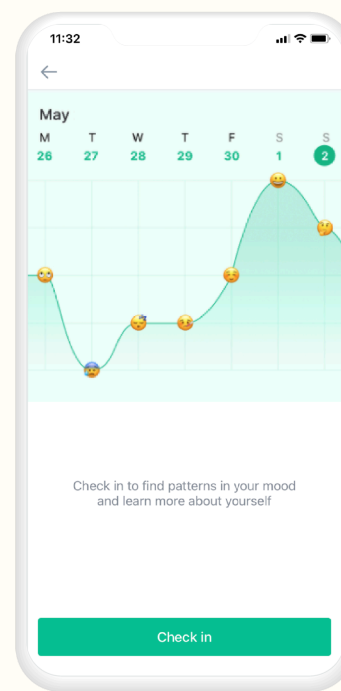
Woebot starts a conversation by asking your patients how they're feeling and, based on what they share, Woebot suggests tools and content to help them identify and manage their thoughts and emotions and offers techniques they can try to help them feel better.

Woebot's conversations are written by conversational writers using elements from evidence-based approaches like Cognitive Behavioral Therapy (CBT), Interpersonal Psychotherapy (IPT), and Dialectical Behavioral Therapy (DBT), along with collaboration from our Clinical experts.

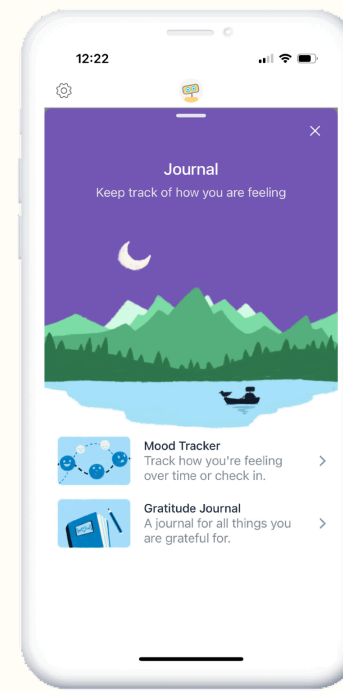
In some cases, Woebot for Adults can administer assessment questionnaires, including patient-reported outcomes (PROs) that may help you as their healthcare provider track their progress over time.



Guided self-help content



Mood tracker



Gratitude journal

Who Should Use Woebot for Adults? Eligibility & Contraindications

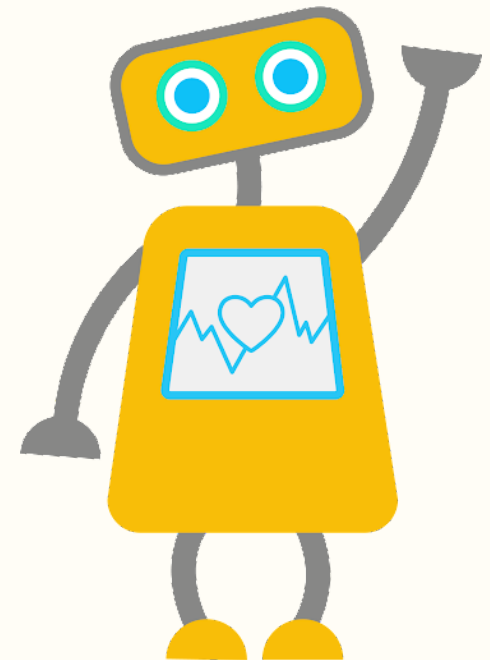
Woebot for Adults may be suitable for patients who:

- Are 18 years of age or older
- Are able to read and understand English
- Are experiencing difficulties with mood and anxiety
- Have regular access to a smartphone / internet-enabled mobile device
- Have consistent access to the internet

Woebot for Adults may not be suitable for individuals with certain mental health symptoms or conditions, such as:

- thoughts of suicide or violence toward others
- conditions or symptoms that compromise thinking and decision-making (e.g., dementia or other cognitive impairments).

Woebot for Adults has been tested in research settings among individuals who have presented with, and are primarily interested in, managing mood and anxiety symptoms for a period of up to 8 weeks. If your patient is experiencing distressing psychiatric or psychological symptoms outside of mood and anxiety, they should consult with a healthcare provider before using Woebot for Adults. The benefit of Woebot for Adults for individuals with comorbid psychiatric diagnoses has not yet been established.



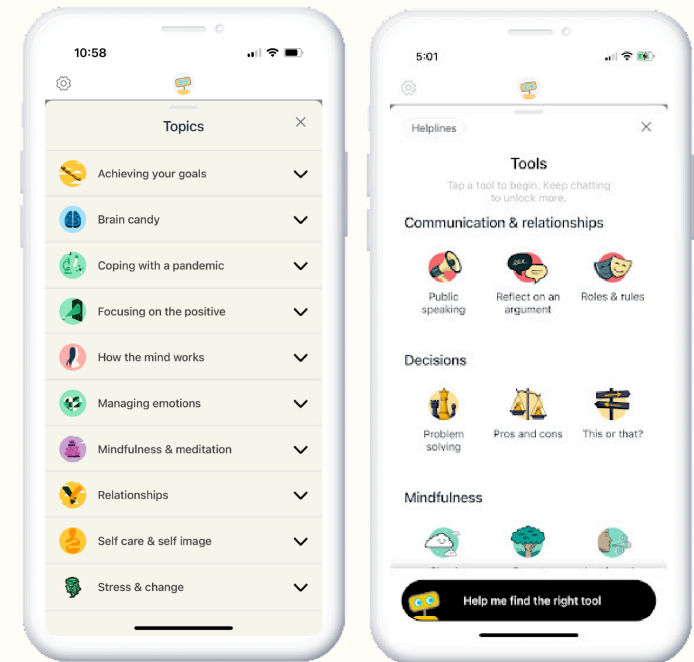
What Can Woebot for Adults Help With?

Woebot for Adults offers many topics and tools based on elements from evidence-based approaches such as CBT, DBT, and IPT. These tools can help you build skills related to:

- Thinking, concentrating, remembering
- Identifying emotions
- Managing and controlling emotions
- Coping
- Relationships
- Activities and energy levels
- Balancing needs and responsibilities
- Feeling capable
- Gratitude practice
- Connecting with others
- Communication skills
- Mindfulness

Woebot for Adults helps your patients use these skills to tackle various problems like:

- Anxious feelings and stress
- Loneliness
- Worry about finances
- Sleep problems
- Guilt and regret
- Sadness and low mood
- Grief about a loved one
- Coping with sickness, and physical or chronic pain
- Feelings and behaviors related to substance use
- Anger and irritability
- Relationships
- Procrastination



When to use Woebot for Adults

Your patients can chat with Woebot as often as they'd like - whether in specific moments of need and/or as a part of their daily self-care mental health practice. Woebot is available to your patients day or night, 24/7. They can open the Woebot for Adults app whenever they want and chat with Woebot.

Becoming familiar with Woebot for Adults can help your patients start applying what they're learning in their everyday life right away. Based on our experience to date, we recommend using Woebot for Adults at least once a day for the first three days, and then at least once a week afterwards. Each session can be as long as your patient likes, but at least 3-5 minutes is recommended. We continue to study different ways of using Woebot, and which may help most.

What happens when the program concludes?

If your patient joined Woebot for Adults through a partner program or research study, then their access may be tied to that program's duration. After membership ends, access to the app may change. Details below.

Approaching End of Access:

- **Notifications:**
 - Patients will receive in-app and/or email notifications well before their access expires, allowing them to plan ahead.
 - Patients can also see how much time is left in their membership by visiting details located in Settings
- **Grace Period:** A configurable grace period of no less than 7 days is provided to allow patients to:
 - Complete Activities: Wrap up any ongoing activities or exercises within the app.
 - Connect with You: Reach out for further support or guidance before access ends.
- **Customizations:**
 - We recommend beginning the grace period at least 14 days before their access to Woebot is scheduled to end. This gives patients ample time to address any questions or concerns they might have about renewing their membership or continuing their program.

- While 14 days is a good starting point, this notification time frame can be adjusted to fit your organization's specific needs. However, for optimal patient experience, we recommend giving them at least 7 days notice before their access ends so they have sufficient time to take action and avoid any disruption to their wellness journey.

After Access Ends:

- **Woebot Says Goodbye:** Woebot will acknowledge your patient's hard work and offer a supportive farewell message.
- **Features On Hold:** Core features like conversation chats, journaling prompts, and mood tracking will become unavailable.
- **Questions:** Patients can access an FAQ section to learn how to download or delete their conversations with Woebot. Or reach out to our customer support staff at support@woebothealth.com for any other questions.
- **Ongoing Support:** While individual paid subscriptions are not currently offered, Woebot will provide a list of resources for further mental health support.

When Access Resumes:

- **Regaining Membership:** Sometimes, a patient's membership status may change based on information we receive from their partner organization. If your patient regains their membership, they'll be notified through the app and/or by email.
- **Full Access Restored:** Once membership is restored, your patient will have full access to all their past chats and history with Woebot within the app.
- **Picking Up Where They Left Off:** When your patient returns to the app, Woebot welcomes them back with a greeting and they can seamlessly continue their program from where they left off.
- **Membership Status Updates:** Patients can always check their current membership status and find any related details by visiting the Settings section of the app.

Preparing Your Patients:

As their clinician, you can help your patients navigate the end of access by:

- **Discussing the Transition:** Anticipate the potential end of their access period and explore alternative support strategies.

- **Maximizing the Grace Period:** Encourage patients to utilize the grace period to complete activities and reach out for additional support if needed.
- **Exploring Ongoing Resources:** Help patients explore the provided resources for continued mental health support beyond Woebot.

Limitations of Use

Woebot for Adults does not provide medical or mental health care or immediate medical attention and/or crisis support. If your patient is experiencing a crisis or medical emergency, and/or someone is hurting them, they should immediately dial 911 and/or go to the nearest emergency room. If your patient is experiencing suicidal thoughts, they should immediately dial 988 and/or go to the nearest emergency room. Woebot does not provide crisis counseling. Woebot is not a suicide detection, prevention or crisis intervention service. Woebot is not a child or elder abuse detection, prevention, or intervention service.

Woebot for Adults is not a replacement for other medical or mental health care and should not be relied upon to treat psychiatric conditions.

Your patients should not disregard professional medical advice or delay seeking care because of information they encounter within Woebot for Adults.

We do not advise that your patients make any changes to their current treatment (e.g., changes to therapy or medication) before or while using Woebot for Adults without the consultation of their healthcare provider.

Patients should always seek advice from their healthcare provider before making any changes to their current treatments. We strongly recommend that they consult a healthcare provider if at any time they are concerned about their physical or mental health.

Woebot for Adults is not intended as a communication portal for healthcare providers and patients. Healthcare providers should clearly instruct patients not to use Woebot for Adults to communicate any urgent or emergent information to healthcare provider(s). Communications in Woebot for Adults are not monitored by a human in real time (though transcripts may be reviewed by Woebot Health staff at a later time).

Woebot for Adults is not a remote monitoring device and is not intended to manage a patient's care pathway or treatment protocol without involvement of a healthcare provider.

Patients should continue to take their medications as instructed by their healthcare provider.

Patients whose mood or anxiety symptoms worsen while using Woebot for Adults should tell their Healthcare Provider.

In general, if your patient feels like you need more support than Woebot for Adults can provide, have questions about your mental health, or have questions about Woebot for Adults' suitability for you, we recommend that you speak to your healthcare provider before using Woebot for Adults.

Security and Privacy

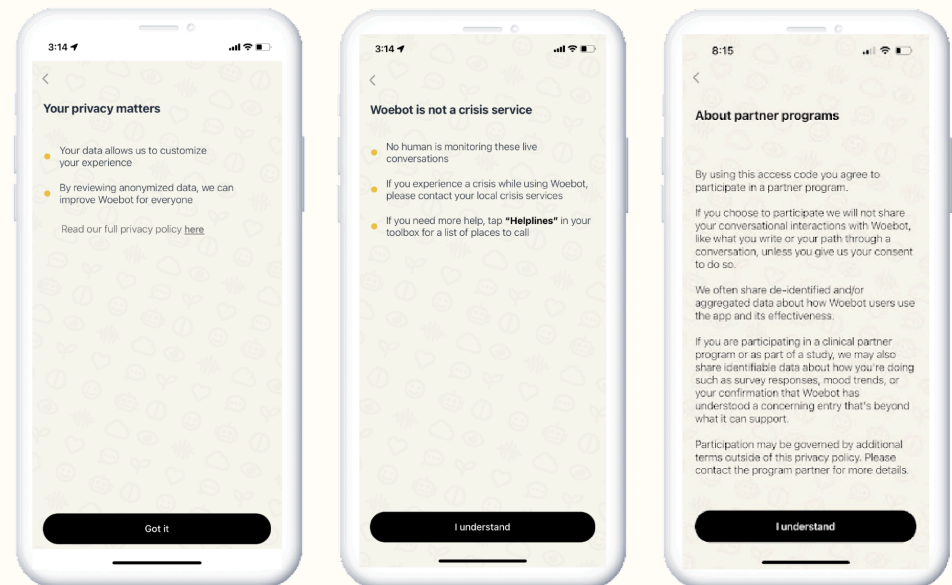
Woebot for Adults may contain and transmit protected health information and/or personally identifiable information. Information such as patient survey information, engagement data (e.g., number of mood check-ins), or content satisfaction ratings (e.g., “thumbs up” or “thumbs down” ratings of psychoeducational materials) may be transmitted to a clinician if the patient is receiving access to Woebot for Adults through a clinical partner program. For more information on patient data, please view our [Privacy Policy](#).

Although there are many protections in place to secure user data, there is the potential for a data breach (accidental sharing of information) that includes personal information. We adhere to high security standards and user data is always encrypted, both in transit and at rest. We also ensure that user data is stored in an anonymized and de-identified manner whenever possible.

Woebot for Adults requires users to enter an email and password prior to use. Please instruct your patients not to share their email and password with others.

To protect their privacy, patients should:

- Remain on WiFi networks they trust
- For your patient’s device:
 - Set a passcode. Protecting their device with a passcode will reduce the risk that someone else opens up your Woebot for Adults app.
 - Turn on the device's auto-lock. This will lock the screen when they stop using the device for a while, and keep others from using the app.
 - Keep the device software up to date
- For your patient’s Woebot for Adults app:
 - Use a password, pin or biometric lock to access the app
 - Keep the Woebot for Adults app up to date
 - Keep login information private

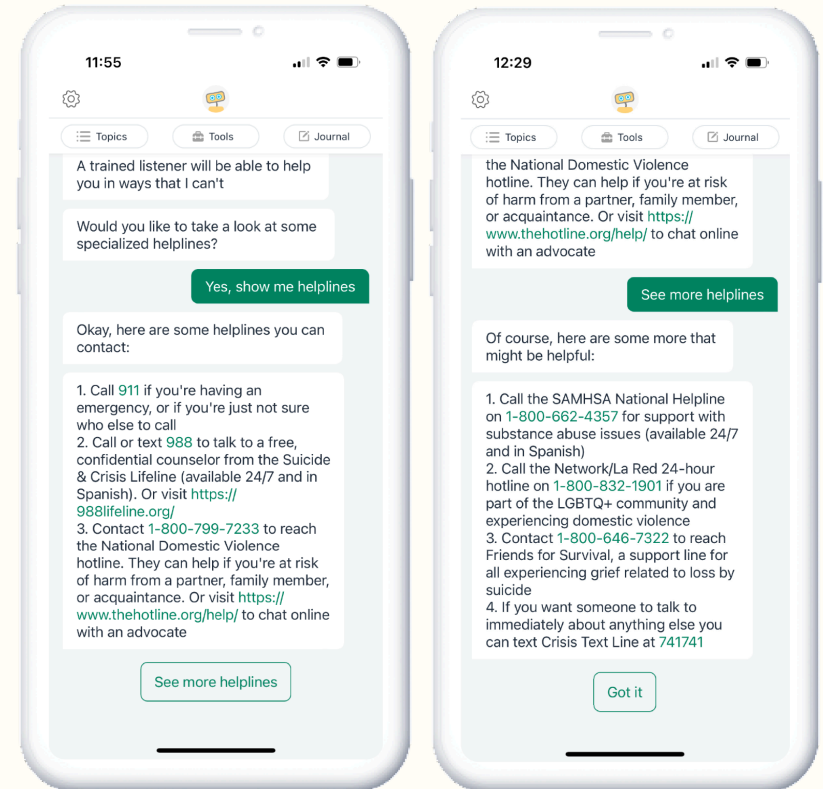


For more information about Security at Woebot Health, see <https://woebothealth.com/security/>

Concerning Language Recognition

Woebot for Adults is not a crisis service. It is equipped with a Natural Language Processing (NLP) algorithm that flags language that may be concerning in user free-text input. Upon recognition, Woebot for Adults will ask the user if they would like to be provided a list of resources that includes emergency contact phone numbers, and suicide crisis hotline contact information.

Woebot for Adults then offers tools to assist with addressing upsetting emotions and thoughts. The list of resources is also immediately available at any time from the “Tools” menu. Woebot for Adults is not monitored by a human in real time (though transcripts may be reviewed by Woebot Health staff at a later time).



General Warnings and Precautions

Woebot for Adults is not evaluated, cleared or approved by FDA. It may be considered as an adjunct to clinical care, it does not replace clinical care.

Woebot does not provide crisis counseling. Woebot is not a suicide detection, prevention or crisis intervention service. Woebot is not a child or elder abuse detection, prevention, or intervention service. Concerning language is not reviewed or assessed internally at Woebot Health in real-time for intervention and such data is not used for managing potential crises or any acute or non-acute patient safety issue. Discomfort may be experienced when answering sensitive questions. Temporary upset may occur as a result of discontinued access to Woebot for Adults.

Adverse Events

Woebot Health has not yet extensively tested Woebot for Adults for potential adverse events (safety issues). The clinical studies we have conducted to date on Woebot for Adults have not identified any adverse events related to the use of Woebot for Adults based on spontaneous user reports.

Operating Information

How to Start Using Woebot for Adults

Follow 3 simple steps to get your patients started with Woebot for Adults.

Step 1: Determine if your patient is a good fit for Woebot for Adults

Read the Indications for Use, Patient Eligibility, Limitations of Use, and the entirety of this Instructions for Use document. This will allow you to determine if Woebot for Adults is appropriate for your patient(s).

Step 2: Recommend Woebot for Adults and create a plan for how you will integrate the program into their care.

When should I recommend Woebot for Adults?

Woebot for Adults can be used as a complement for outpatient treatment, or as an immediate support for patients post-screening and pre-evaluation (i.e., waitlist).

How should it be offered as an adjunct to usual care?

Woebot for Adults is not designed to replace usual care. It is up to the provider's discretion to decide whether or at which stage of care Woebot for Adults may be most appropriate. Woebot for Adults may be initiated at any time in the course of usual medical care. This may include post-screening and pre-evaluation (e.g., while on a waitlist), during the course of treatment (e.g., psychotherapy or pharmacotherapy), or as part of a maintenance or follow-up plan.

How might I introduce Woebot for Adults to my patients?

Patients should read and understand the User Instructions for Use document before beginning use of Woebot for Adults.

Introduction of Woebot for Adults is entirely at the provider's discretion. For optional suggestions of how you might introduce Woebot for Adults to your patients, see below:

- “Woebot is a mental health ally who is available to you at any time, 24/7
- You can download it immediately
- Woebot Health recommends using the app at least once a day for the first 3 days of Week 1 to get to know what Woebot can do for you. Starting in Week 2, they recommend using Woebot at least once a week so you can begin to apply what you're learning in everyday life. Each session can be as long as needed, but at least 3–5 minutes is recommended. But – you can use Woebot as much or as little as you like. Just open the app and talk to Woebot when you need it most.
- We can check in on how you are doing at a follow-up visit

- If you feel as though your symptoms are worsening, please contact your healthcare provider
- If you are experiencing a crisis or medical emergency and/or someone is hurting you, immediately dial 911 and/or go to the nearest emergency room. If you are experiencing suicidal thoughts, you should immediately dial 988 or go to the nearest emergency room.
- Woebot for Adults is not a crisis service or replacement for medical care of any kind. You should read the limitations of use carefully and understand what Woebot for Adults can and cannot do.”

Step 3: Refer patients and provide instructions for access

You or your organization should be provided with access codes you can share with your patients. If you have questions about where to obtain access codes, please contact Woebot Health and/or your organization.

Patients should make sure they enter their correct, complete access code into the app. If their code doesn't work, they should double check to make sure they entered it correctly. If the code continues not to work, they can contact support@woebothealth.com for assistance. After entering their access code, patients will need to create an account using a valid email address and password.



Woebot: Your Mental Health Ally

If patients have an iPhone or iPad they should:

- Make sure they are logged into the Apple App Store
- Open up the Apple App Store and search “Woebot”
- Download the app and log in using their access code and email address

If patients have an Android device they should:

- Make sure they are logged into the Google Play Store
- Open up the Google Play Store and search “Woebot”
- Download the app and log in using their access code and email address

That's it! Once your patient creates an account, they will be able to begin using Woebot for Adults.

Direct Healthcare Provider Referral via Text Message

As part of select partnerships, you may be able to give your patients access to Woebot for Adults by a direct referral using a text-message generated by your EMR. Please contact Woebot Health, and/or your organization to learn more about direct referrals.

What Operating Systems Does Woebot for Adults Support?

Woebot for Adults is compatible with smartphone and tablet devices running:

- iOS version 15.0 or higher
- Android version 8.0 or higher

Please ensure your smartphone is running an Operating System (OS) version matching those above. If not, then please update your software version before downloading and using Woebot for Adults.

Troubleshooting and Support

Where do I get more information about Woebot for Adults?

Providers with additional questions or requests for medical information about Woebot for Adults can email: support@woebothealth.com

What if I have a problem or concern with the app?

To help us improve Woebot for Adults, you may also share any concerns, complaints, or feedback with Woebot Health using this form [here](#) or by emailing support@woebothealth.com.

How do I know Woebot for Adults is safe?

Woebot Health takes safety, privacy, and security very seriously. Please see <https://woebothealth.com/safety/> for up-to-date information on the safety of Woebot Health's products. In order to build and maintain proactive safety vigilance, Woebot Health has adopted rigorous safety reporting procedures for potential product safety events, including adverse events, adverse device effects, unanticipated adverse device effects, device deficiencies and product complaints. *The safety of Woebot for Adults has not been reviewed by the U.S. Food and Drug Administration.*

What if my patient's symptoms are worsening?

While using Woebot, we recommend that your patient maintains regular contact with their healthcare provider.

What if my patient is in a crisis or emergency?

If your patient is experiencing a crisis or medical emergency and/or someone is hurting them, we recommend they immediately dial 911 and/or go to the nearest emergency room. If your patient is experiencing suicidal thoughts, they should immediately dial 988 or go to the nearest emergency room.

How do I get access to my patient's data?

Patient survey information can be transmitted to a healthcare provider if made part of the software implementation for a specific customer. Engagement and patient survey metrics are available through the Woebot platform, where applicable.

What if my patient needs technical support?

Patients can visit <https://woebothealth.com/faq/> to view a list of frequently asked questions about the Woebot for Adults program. If patients need technical support, have additional questions, or want to leave feedback about the Woebot for Adults program, they can contact us via this [webpage](#) or email the Woebot Health team at support@woebothealth.com. Messages sent to this email/form are not reviewed immediately, and you may not receive a response.

Contact and Additional Information

More information about Woebot for Adults:

- Woebot for Adults Website: <https://woebothealth.com/adult-mental-health/>
- Privacy Policy <https://woebothealth.com/privacy-webview/>
- Terms of Service <https://woebothealth.com/terms-webview/>
- Security Overview <https://woebothealth.com/security/>
- Safety Information: <https://woebothealth.com/safety/>

Company Address and Contact Information

Woebot Health

535 Mission Street, 14th Floor

San Francisco, California, 94105, United States

(415) 273-9742

<https://woebothealth.com/>

To contact Woebot Health, please complete this [form](#) or email support@woebothealth.com

This Instructions for Use document is dated 07/18/2024 and is applicable for Woebot for Adults version 2.0.0 and subsequent minor versions.