

## USER INFORMATION

INSTRUCTIONS FOR USE (dated July 18th, 2024)

Woebot for Adolescents (Woebot Adolescent 1.0)

Non-Prescription Digital Mental Health Software

### Woebot Health

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# Glossary

<b>Term</b>	<b>Definition</b>
<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>EOT</i>	<i>End of Treatment</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>MDD</i>	<i>Major Depressive Disorder</i>
<i>NLP</i>	<i>Natural Language Processing</i>

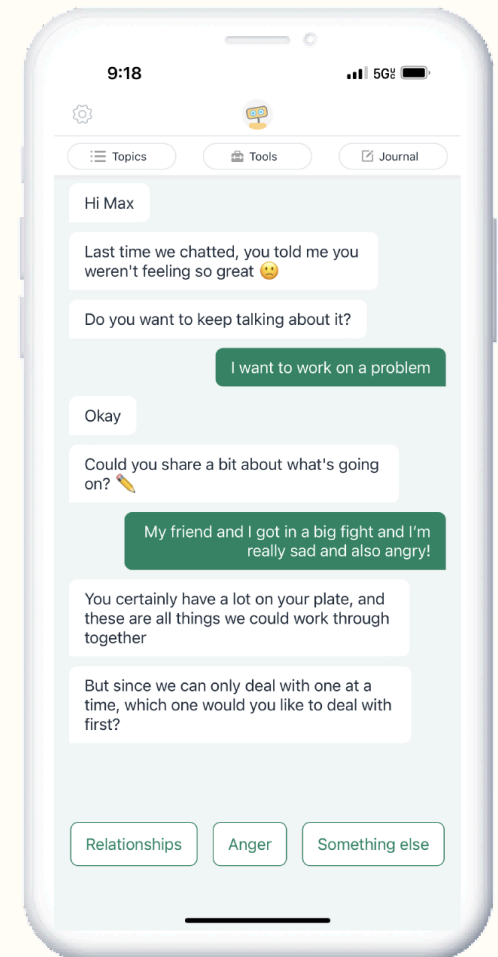
# Descriptive Information

## Intended Use / Indications for Use Statement

Woebot for Adolescents is intended for adolescents aged 13 to 17 years old and is available either as a mental health general wellness or support tool. Woebot for Adolescents 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 Adolescents has not been evaluated, cleared or approved by FDA.

## What Is Woebot for Adolescents?

*Woebot* is a fully-automated mental health ally you can chat with through an app called Woebot for Adolescents, on your smartphone or tablet, anytime day or night. Woebot for Adolescents invites you to monitor and manage your mood using tools such as mood tracking, progress reflection, gratitude journaling, and mindfulness practice. Woebot for Adolescents is intended to help you manage mood and anxiety symptoms and can be used as a mental health support tool to supplement treatments, therapies, or self-care practices.



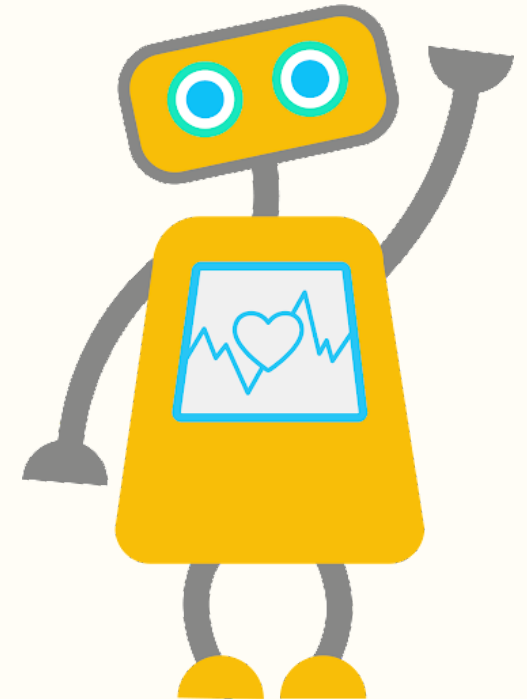
## More about Woebot's Conversations

Woebot is always ready to listen. If you're stressed about something at school or feeling down about a challenge you're facing, just open the Woebot app on your phone or tablet and start a text-based chat with Woebot.

Woebot starts a conversation by asking you how you're feeling and, based on what you share, Woebot suggests tools and content to help you identify and manage your thoughts and emotions and offers techniques you can try to help you 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 Adolescents may ask you surveys that may help you and your healthcare provider track your progress over time.



## Who Should Use Woebot for Adolescents? Eligibility & Contraindications

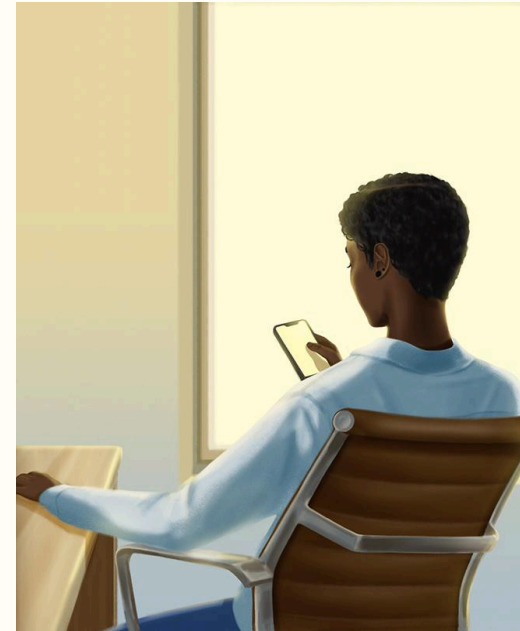
Woebot for Adolescents may be suitable for you if you:

- Are 13 to 17 years old
- 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 Adolescents 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 (like developmental disorders or cognitive impairments)

Woebot for Adolescents has been tested among adolescents who have mood and anxiety symptoms. If you experience distressing mental health symptoms outside of mood and anxiety, consult with a healthcare provider before using Woebot for Adolescents.



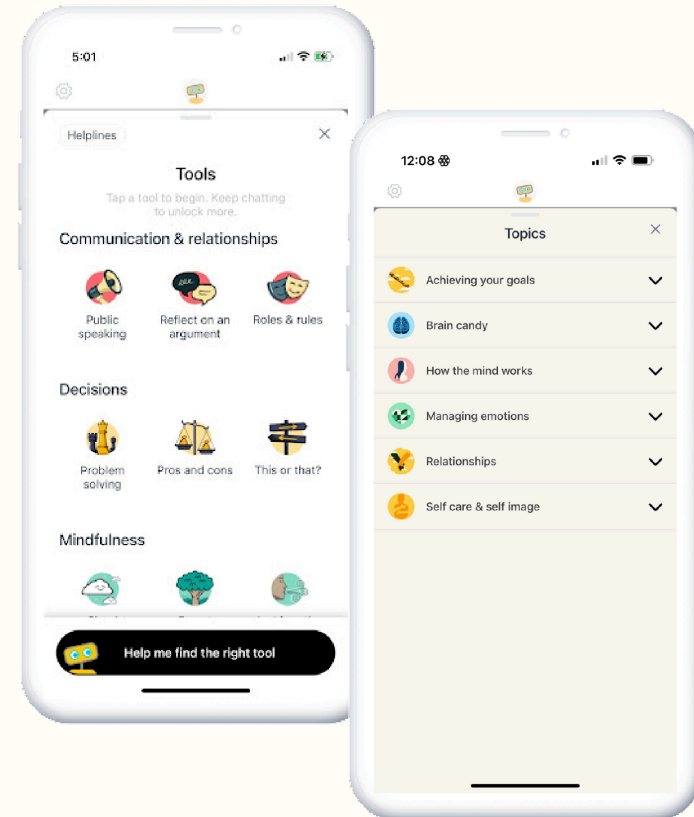
## What Woebot Can Help With?

Woebot for Adolescents offers many topics and tools created by experts trained in elements of evidence-based approaches such as CBT, DBT, and IPT. These tools can help you build skills related to:

- Achieving your goals
- Brain candy (psychoeducation)
- Coping with a pandemic
- How the mind works
- Managing emotions
- Relationships
- Self care & self image

Woebot for Adolescents helps you use these skills to tackle various problems like:

- Anxious mood and Stress
- Relationships
- Sadness and low mood
- Loneliness
- Anger and irritability
- Media literacy
- Communication problems
- Procrastination
- Sleep problems
- Guilt and regret
- Grief about a loved one



## When to use Woebot for Adolescents

You can chat with Woebot as often as you'd like - whether in specific moments and/or as a part of your daily self-care practice. Woebot is available day or night, 24/7. Just open Woebot for Adolescents app whenever you want to chat with Woebot.

Becoming familiar with Woebot for Adolescents can help you start applying what you're learning in your everyday life right away. Based on our experience to date, we recommend using Woebot for Adolescents at least once a day for your first three days and then at least once a week afterwards. Each session can be as long as you'd like, but at least 3-5 minutes is recommended.

## What happens when the program concludes?

You will have access to Woebot for Adolescents for a specific length of time depending on your partner program or research study. You may lose access to Woebot for Adolescents if you are no longer eligible through your partner program or research study.

After membership ends, your access to the app may change. Details below.

### What Happens When Your Membership Ends?

- **We'll Keep You Informed:**
  - You'll receive an in-app and/or email notification before your access ends, giving you time to plan
  - You can also see how much time you have left by visiting details located in Settings
- **Grace Period:** We provide a grace period for no less than 7 days to allow you to:
  - Complete your current activities in Woebot for Adults
  - Reach out to your clinician or program partner for further support or guidance

### After Access Ends:

- **Woebot Says Goodbye:** Woebot will acknowledge your hard work and offer a supportive farewell message
- **Features On Hold:** While your access is on hold, you won't be able to use Woebot's core features like conversations, journals, or mood log
- **Questions:** You can access our FAQ section to learn how to download or delete your conversations with Woebot for Adolescents. Or reach out to our customer support staff at [support@woebothealth.com](mailto:support@woebothealth.com) for any other questions

- **Ongoing Support:** While we don't currently offer individual paid subscriptions, Woebot will provide a list of resources for further mental health support for as long as Woebot is included with your partner organization's offerings

**When Access Resumes:**

- **Regaining Membership:** Your membership status may change based on information we receive from your partner organization. When your access is restored, you'll be notified through the app and/or by email
- **Full Access Restored:** Your restored membership will return you to full access to all your past chats and history with Woebot
- **Picking Up Where They Left Off:** When you return to the app, Woebot will welcome you back with a greeting and you can seamlessly continue from where you left off
- **Membership Status Updates:** You can always check your current membership status and find any related details by visiting the Settings section of the app

## Limitations of Use

Woebot for Adolescents does not provide immediate medical attention and/or crisis support. 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 having suicidal thoughts, 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 Adolescents is not a replacement for other medical or mental health care and should not be relied upon to treat psychiatric conditions.

Do not disregard professional medical advice or delay seeking care because of information you encounter within Woebot for Adolescents.

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

Always seek advice from your healthcare provider before making any changes to your current treatments. We strongly recommend that you consult a healthcare provider if at any time you are concerned about your physical or mental health.

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

Woebot for Adolescents is not a remote monitoring device and is not intended to manage your care pathway or treatment protocol without involvement of your healthcare provider.

You should continue to take your medications as instructed by your healthcare provider.

You should tell your healthcare provider if your mood or anxiety symptoms worsen while using Woebot for Adolescents.

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

# Security and Privacy

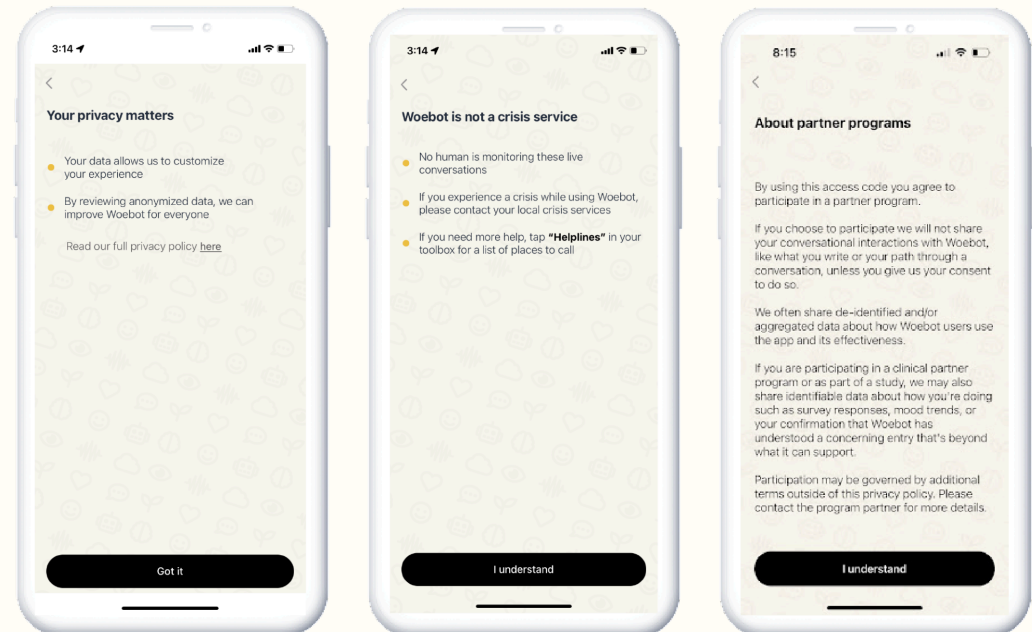
Woebot for Adolescents may contain and transmit protected health information and/or personally identifiable information. Information such as patient survey information, engagement data (e.g., number of mood check-ins), or content satisfaction ratings (e.g., “thumbs up” or “thumbs down” ratings of psychoeducational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

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

Woebot for Adolescents requires you to enter an email and password prior to use. Please do not share your email or password with others.

## Protect your privacy:

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



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

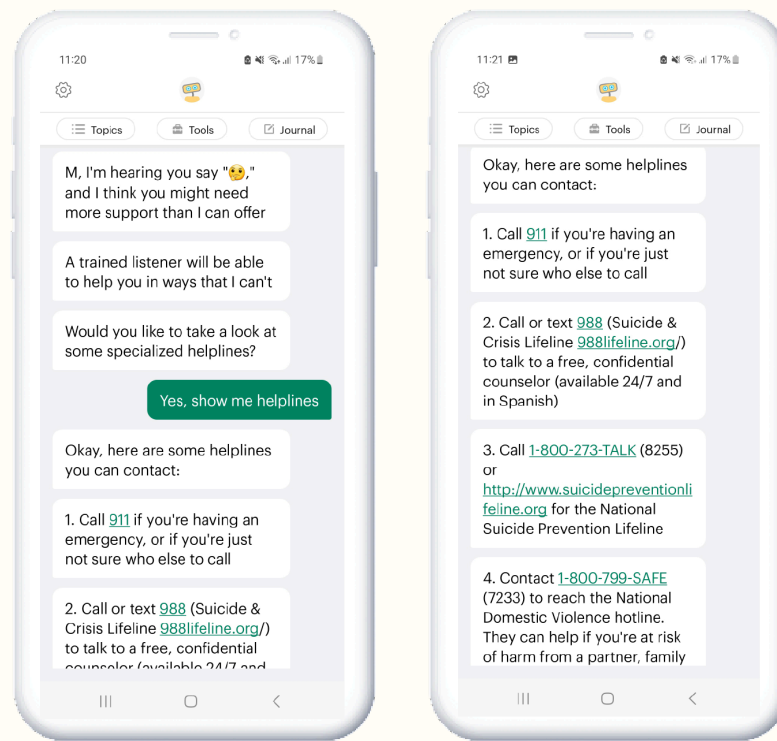
## Concerning Language Recognition

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

Woebot for Adolescents 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 Adolescents 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 Adolescents 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 Adolescents.

## Adverse Events

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

# Operating Information

## How to Start Using Woebot for Adolescents

### Access through Your Clinician

As a member of certain partner programs, you get immediate access to Woebot through your clinician.

1. You will receive a text when your clinician refers Woebot using their Electronic Medical Record System (EMR)
2. Click on the link provided in the text and sign into your partner account
3. You will be redirected to your smartphone's app store to download the Woebot Health app
4. Download the app and follow the prompts to create your account

### Access through an Access Code

Follow 3 simple steps to get access to Woebot for Adolescents using an access code provider by your partner program.



#### **Step 1: Download the Woebot App**

To download [Woebot on the iPhone or iPad](#):

- Tap the App Store icon on the home screen
- Tap the search icon and type “Woebot”
- Tap the “Get” button. You may need to enter your Apple ID and Password, or use Touch ID or Face ID to approve the download
- Tap the Woebot icon to open the app when download completes

To download [Woebot on an Android](#) phone or tablet:

- Tap on the Play Store app on the Android phone
- Tap on the search bar and type “Woebot”
- Tap “Install”
- When Woebot is downloaded, either tap “Open” in the Play Store or, go to the home screen and tap the Woebot icon

#### **Step 2: Enter Access Code (if asked)**

You may need an access code to use Woebot for Adolescents. You may have received this code from your partner program. Once you've downloaded and opened the app, enter a code if you have one.

### **Step 3: Create an Account and Password**

Next, you need to enter a valid email address and set a password. Your password must contain:

- At least 10 characters
- 1 uppercase character
- 1 lowercase character
- 1 number
- 1 special character (E.g. @ & \$ %)

Once your password is set, your account will be created and you can begin working and learning with Woebot.

## **Already Have Woebot installed on your Smartphone?**

1. Open the Woebot app
2. Log out of the app by clicking on Settings and selecting Sign out
3. Click the "I have an access code" button
4. Enter a different unique access code you get from your partner program
5. Select "Next"
6. Create a new account using an email address alias

For example, if the original email address is "jane@gmail.com", an alias could be created by adding a "+" and some text, like: "first name+last name@gmail.com" or "jane+doe@gmail.com". Emails sent to the alias will still deliver to your primary inbox.

### **Don't have an alias?**

If you've used Woebot before, please use a new email address this time.

## What Operating Systems Does Woebot for Adolescents Support?

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

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

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

# Troubleshooting and Support

## **Have another question?**

If you still have questions after reading through this Instructions for Use information, please contact us at [support@woebothealth.com](mailto:support@woebothealth.com).

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

To help us improve Woebot, you may also share any concerns, complaints, or feedback with Woebot Health using this form [here](#) or by emailing [support@woebothealth.com](mailto:support@woebothealth.com). Messages sent to this email/form are not reviewed immediately, and you may not receive a response.

## **How do I know Woebot for Adolescents 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. We have a rigorous process to track and document all incoming feedback on Woebot for Adolescents. This practice is consistent with the high standards commonly implemented for thorough and ongoing safety monitoring. *The safety of Woebot for Adolescents has not been reviewed by the U.S. Food and Drug Administration.*

## **What do I do if I feel like my symptoms are worsening?**

While using Woebot, please maintain regular contact with your healthcare provider. If you feel as though your symptoms are worsening, please contact your healthcare provider.

## **What do I do if I'm in a crisis or emergency?**

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 having suicidal thoughts, immediately dial 988 and/or go to the nearest emergency room.

## Contact and Additional Information

More information about Woebot for Adolescents:

- Woebot for Adolescents Website: <https://woebothealth.com/woebot-for-adolescents/>
- 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

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This Instructions for Use document is dated 07/18/2024 and is applicable for Woebot Adolescent version 1.0.0 and subsequent minor versions.