

Hackensack Meridian Health

Woebot for Adults Deployment Provider Training

Agenda

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1. Meet Woebot

 2. How Woebot works

 3. Woebot Health's Approach to Safety

 4. Demo

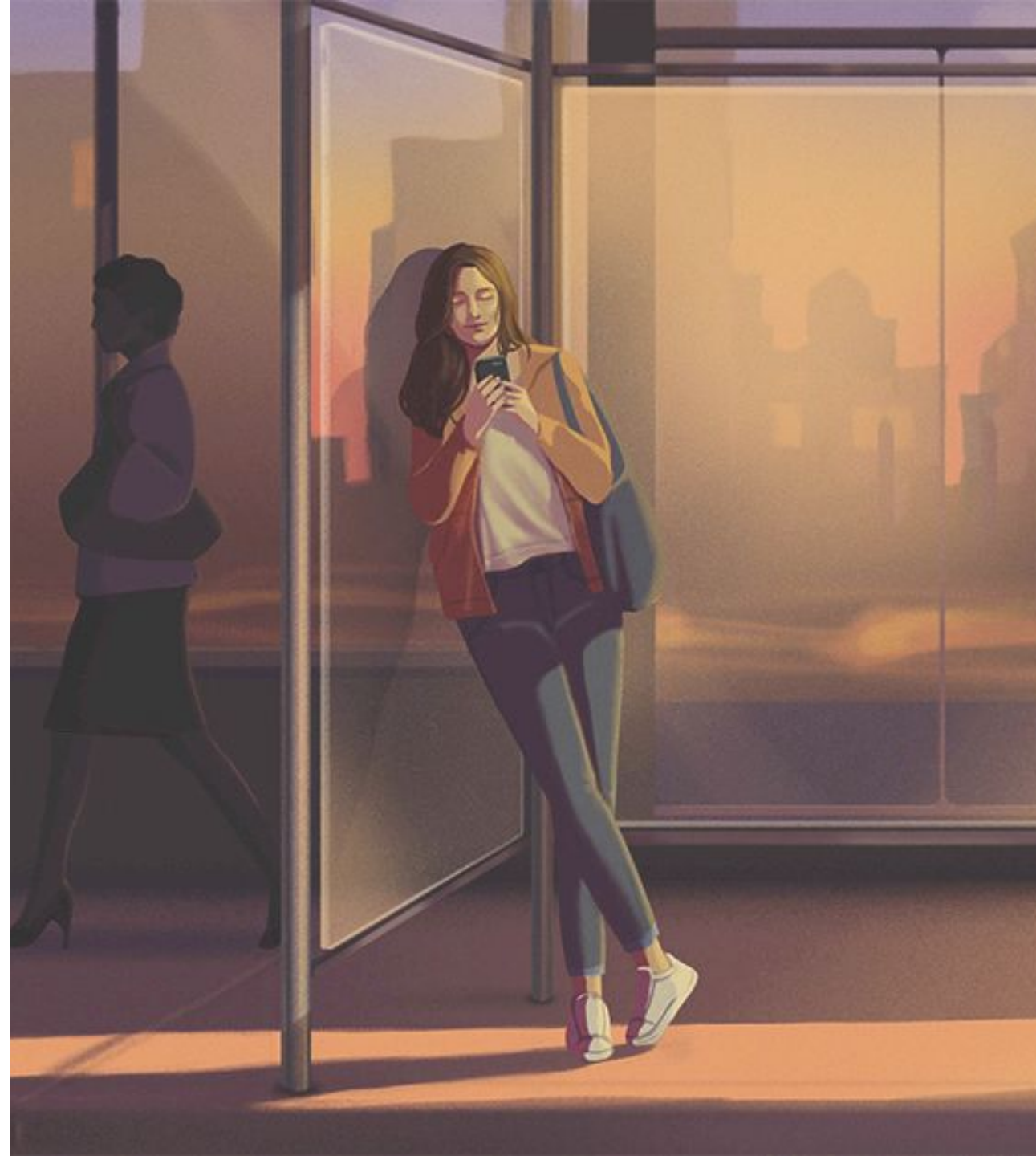
Mental health
needs have
multiplied.

Support hasn't.

We designed a mental health solution so your patients can have **24/7 in-the-moment access to mental health support** – acting as a support multiplier for clinicians.

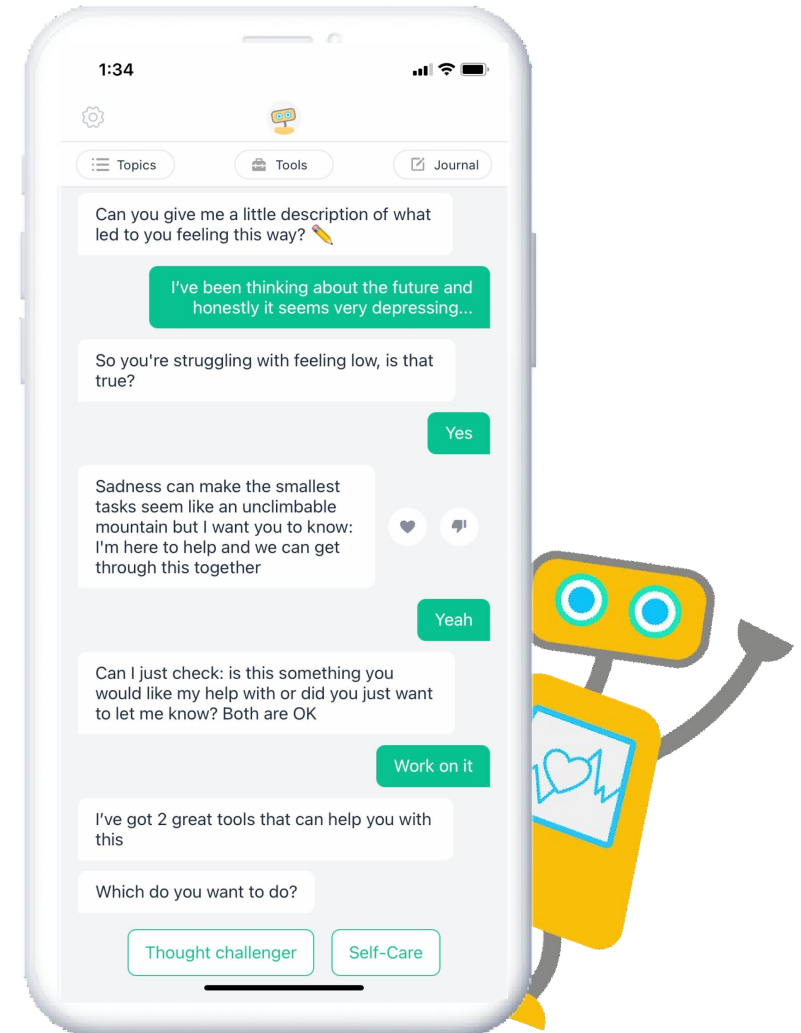
Woebot for Adults

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.



Meet Woebot

- Woebot is an app for smartphones or tablets
- Woebot is not just a chatbot, it's the first digital relational agent that can establish a human-level bond in 3-5 days with a user¹
- It's available any time, anywhere, in your patient's moment of need
 - 75%² of conversations happen outside business hours
- Can help patients develop skills to live better with symptoms of depression & anxiety, and allows your patients work through challenging thoughts, feelings, and behaviors
- Offers: mood tracking, gratitude journaling, and mindfulness practice
- Adjunctive to treatments, therapies, or self-care practices
- Unique access codes give patients access to Woebot for Adults
- Based on our experience, we recommend using Woebot for Adults at least once a day for the first 3 days after onboarding, and then at least once a week afterwards



Meet Woebot

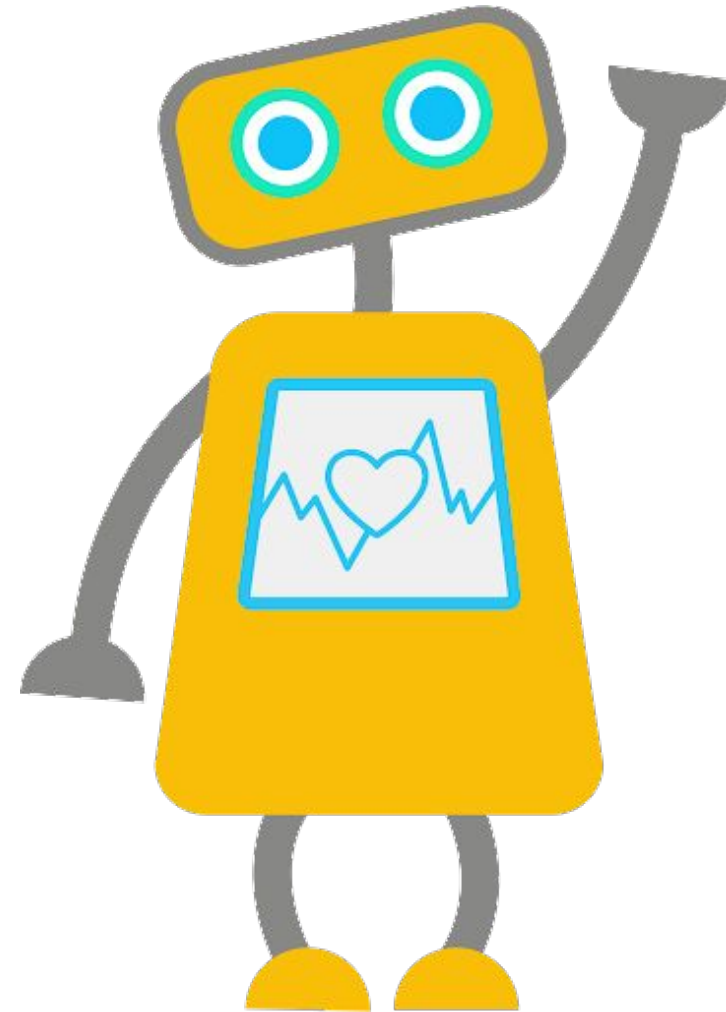
Woebot for Adults is suitable for patients who:

- 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:

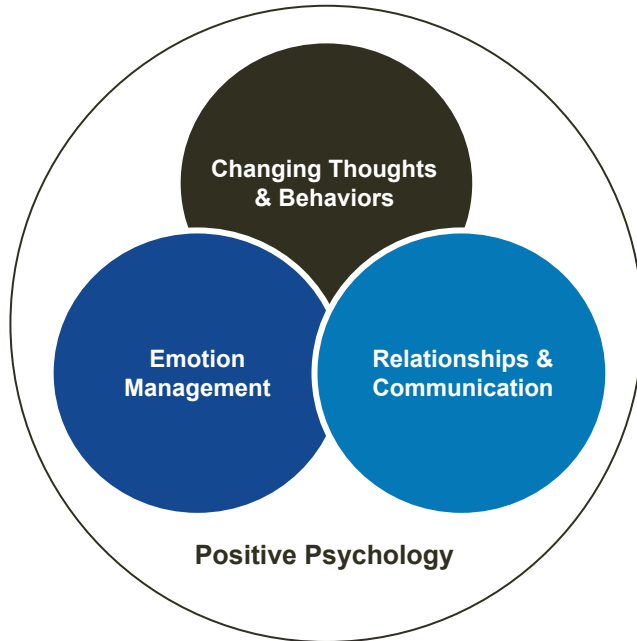
- Thoughts of suicide or violence towards others
- Conditions or symptoms that compromise thinking and decision-making (e.g., dementia or other cognitive impairments)

[Instructions for Use](#)



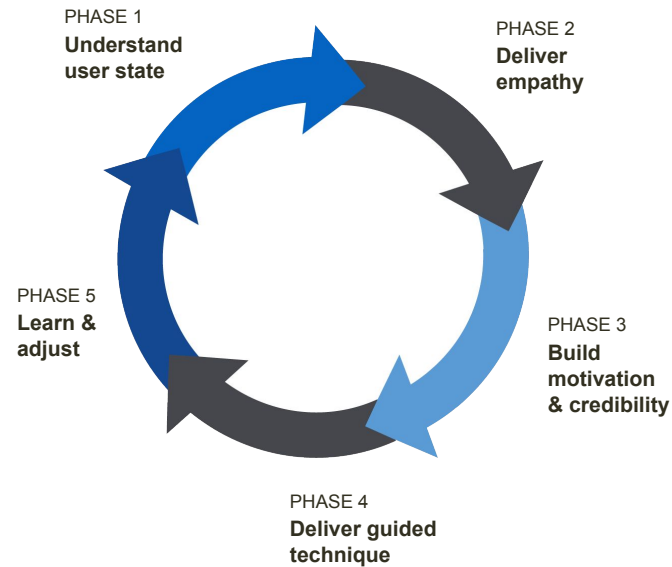
24/7 in-the-moment support patients can trust

Evidence Informed Content



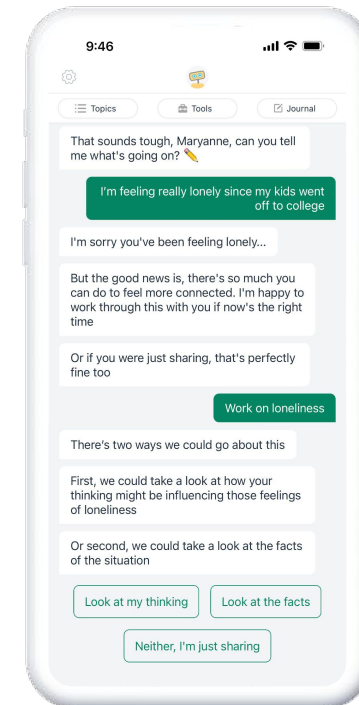
Evidence-based and built from concepts of **CBT**, with elements of **DBT** and **IPT** concepts. All content is written by conversational writers in collaboration with clinical experts

Conversational Flow



Re-envisioning the mental health support process by digitizing key elements

Responsible AI



Rule-based (non-generative) AI for understanding and **personalization** of user experience

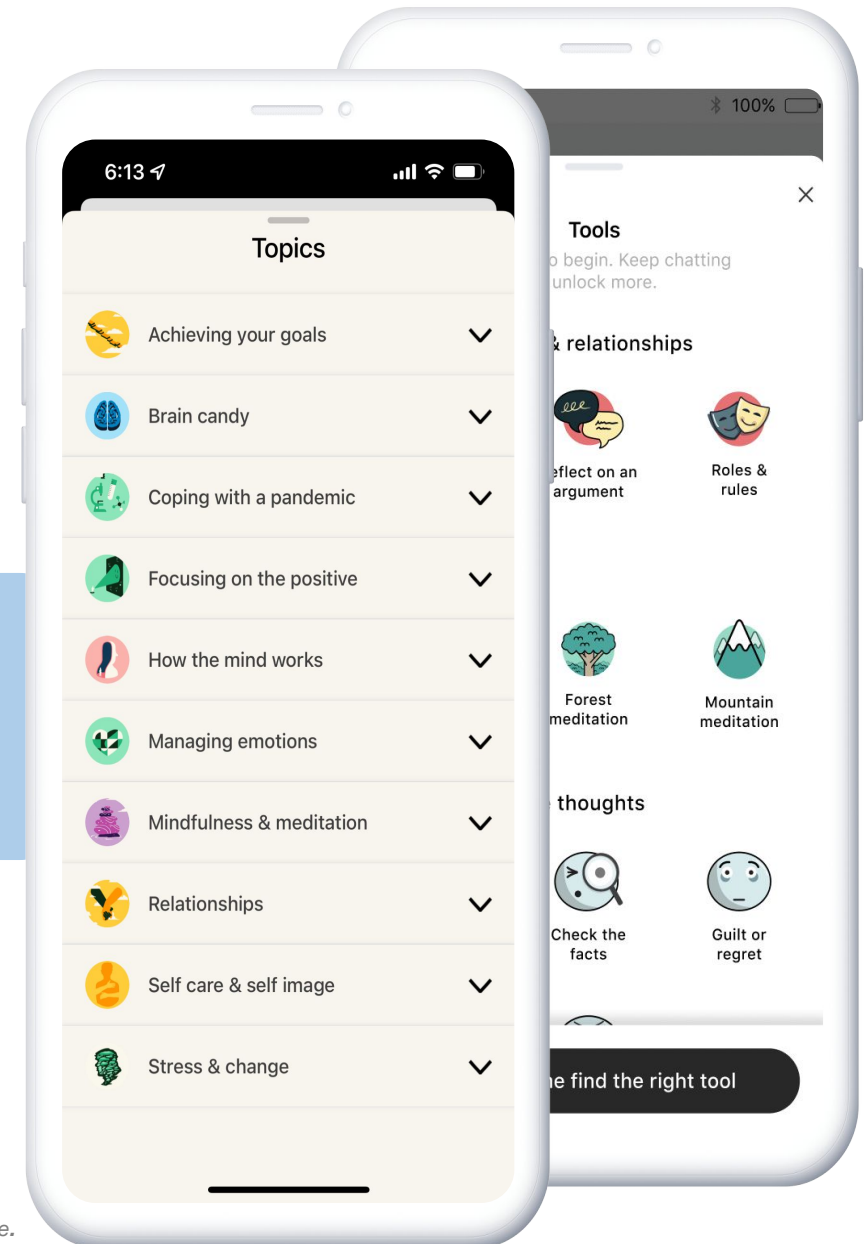
Psychoeducation and evidence-based tools

Supporting self-efficacy and self awareness building

Woebot has a library of psychoeducational topics and tools based on evidence based techniques such as CBT, DBT and IPT; Woebot uses these to help users address various issues 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
- Anger and irritability
- Relationships
- Procrastination
- Feelings and behaviors related to substance use

Woebot Psychoeducational topics are always available to the user within the app; If a tool is appropriate for repeated use, it appears in the user's personalized toolbox once they've tried it for the first time



Woebot Health's Approach to Safety

1

Informed Use

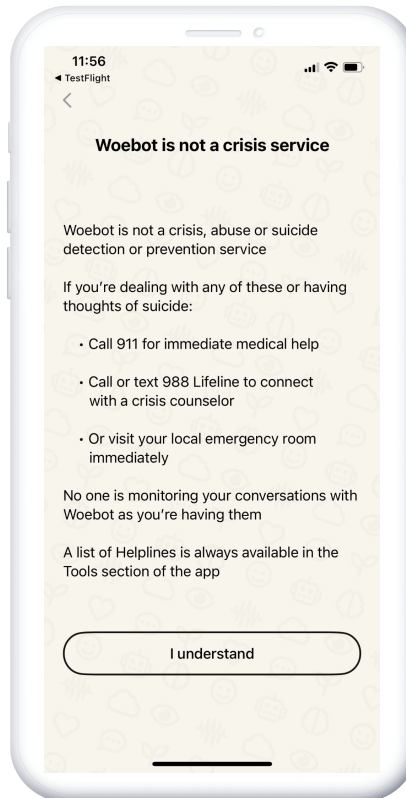
Immediately after download and registration, patients read the limitations of service

2

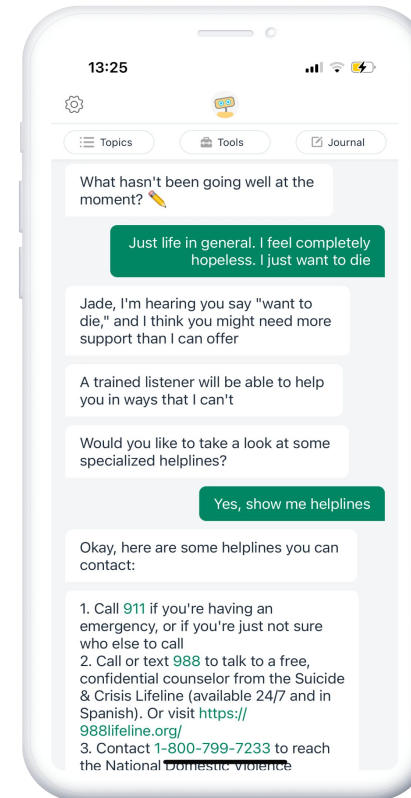
Potentially concerning language detection

Algorithms built to detect potentially concerning language; Conversational design reminds users of limits of services and offers resources if they wish

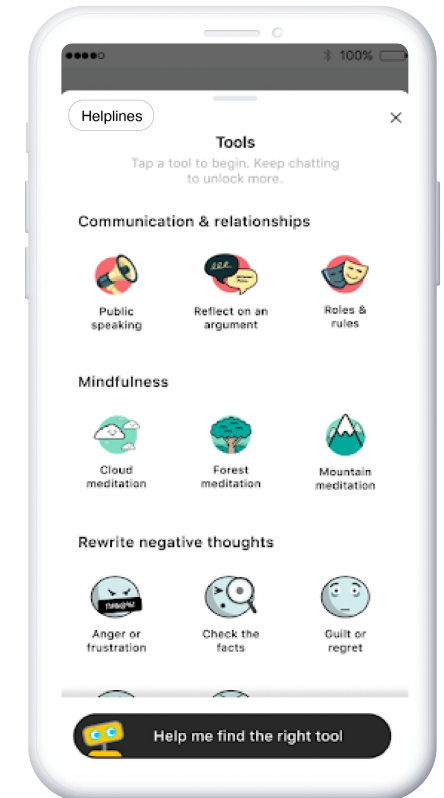
At Onboarding: Expectation Setting



During a Conversation: Routing to Helplines



From Tools Screen: Button to Helplines



Safety governance

Safety Assessment Committee



Robbert Zusterzeel
MD, PhD, MPH
VP, Regulatory
Science & Strategy



Athena Robinson,
PhD
Chief Clinical Officer



Gregory Fiore,
MD
External Physician
Chair, SSI

Education

- Device Vigilance & Safety Monitoring Training
- Standard Operating Procedures

Surveillance

- Commercial Deployments and Clinical Trials
- ePROs, Feedback, Complaints

Communication

- Cross-team Collaboration
- Recommendations

Safety monitoring overview

- Woebot Health **monitors all member feedback** & complaints asynchronously for any device safety issues including Adverse Events as defined by our **Quality Management System** and our Safety Assessment Committee
- All products are developed and maintained under the Quality Management System adherent to the ISO 13485:2016
- All potential safety & quality concerns are reported and monitored by our internal team, where safety concerns are flagged to our Safety Assessment Committee

Woebot Health's approach to monitoring

Monitoring

- We monitor our devices that are deployed in healthcare systems. We are required to track different types of events and feedback through various channels, including from providers.
- Tracking helps us build our safety profile and ensure users overall safety and app performance

Providers

- Please submit any of the following to Julianne Rizzotti or Dr. Weiner
- **Questions, suggestions, or feedback** from patients about Woebot for Adults
- Any **potential safety events, or product feedback or complaints** within 24 hours.
- Julianne or Dr. Weiner will then share with Woebot Health
- Safety events can also be submitted directly in this [form](#)

Examples of potential situations to report

Potential situations	How these can sound in the field
Use error / improper device use	<p><i>"I had my daughter use my app and she thought it was great"</i></p> <p><i>"I found a workaround that allows me to access the app quicker - I can bypass the normal app warnings to get started sooner!"</i></p>
Device provides ineffective support, leading to worsening condition or other device issue associated with other report of how patient feels	<p><i>"I am finding that the app is funny lately - it's not logically answering my prompts. I am getting laughs though - is that part of the regimen?"</i></p> <p><i>"I couldn't access the app and now I am feeling worse"</i></p>
Software failure or unavailability leads to delayed access	<p><i>"I am finding that the app is continuously lagging lately - its difficult to use and I don't feel supported like I used to"</i></p>

What to report

Adverse Event (AE):

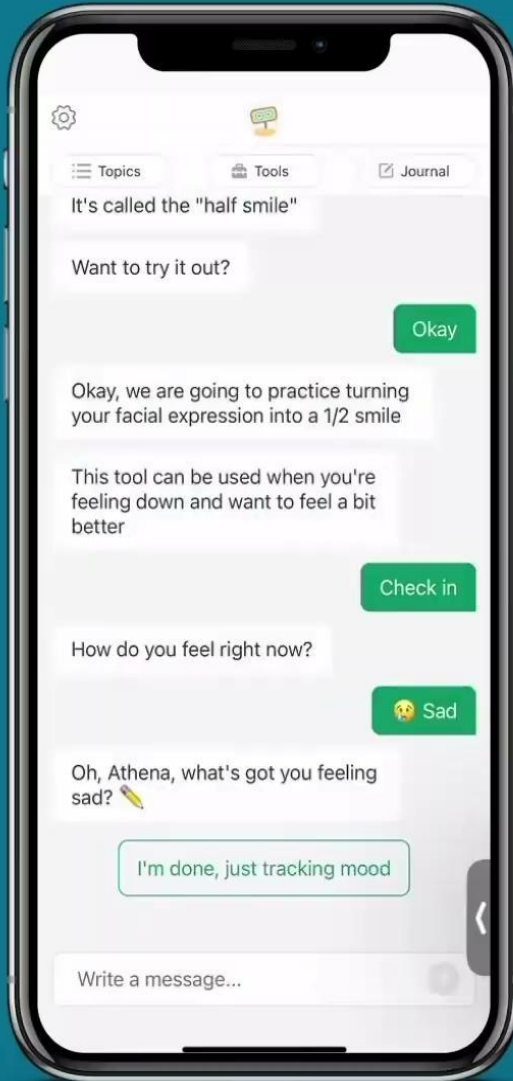
Any unfavorable and unintended sign, symptom, or disease temporally associated with the use of the product, **whether or not considered related to the product**. For that reason, an AE can be any unfavorable and unintended sign, symptom or disease associated with the use of an product. Worsening of a pre-existing medical condition in frequency or severity should also be considered an AE.

Serious Adverse Event (SAE):

Any adverse event that results in any of the following outcomes:

- death
- a life-threatening event (with immediate risk of death)
- inpatient hospitalization or a prolongation of an existing hospitalization
- persistent or significant disability/incapacity
- a congenital anomaly/birth defect
- important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above

Let's walk through an example



Quick talking points

- Woebot for Adults is always available and ready to listen - even if it's in the middle of the night
- If you're feeling stressed, worried, down, feeling blah, Woebot can help you identify how you're feeling and chat through ways to try to help you feel better
- What you write to Woebot is private - your conversations with Woebot are not shared with others (except to provide the services, improve the services, or to protect you & others)
- Woebot for Adults is an app on your phone or tablet to help support your mental health
- There are tools such as gratitude journaling, mood tracking, and mindfulness practices

