Overview

Motivista is a digital therapeutic smartphone app for patients with negative symptoms of schizophrenia. It is only intended to treat the negative symptoms of schizophrenia. Negative symptoms include low motivation, low enjoyment, and less interest in spending time with other people.

Motivista requires a prescription from a healthcare provider.

This document explains how to use the Motivista app on your smartphone.

Indications for Use

Motivista (CT-155) is a prescription digital therapeutic indicated for the treatment of negative symptoms of schizophrenia as an adjunct to clinician-managed outpatient care, including antipsychotic therapy, in patients 18 years of age and older with clinically stable positive symptoms.

Important Safety Information

Motivista is intended to be used as part of your treatment plan for schizophrenia. Your healthcare provider will decide if Motivista is an option for you.

Keep your regular visits with your healthcare provider while you use Motivista. Because Motivista cannot notify your healthcare provider if your symptoms change or if you stop using the app, it is important that you keep all scheduled appointments and reach out to your healthcare provider if anything changes. If you have a caregiver or family member involved in your care, consider asking them to help you stay in contact with your healthcare provider. Talk to your healthcare provider right away and consider stopping Motivista if you experience any of the following: worsening hallucinations, delusions, or disorganized thinking; stopping your antipsychotic medication; a new episode of depression or mania; worsening substance use; or thoughts of suicide or self-harm.

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If you are 18-21 years old, your healthcare provider may recommend monthly monitoring visits. It can also help to involve a caregiver, family member, or another member of your care team to support you along the way.

Warnings

- Motivista is not designed to treat patients who present a serious suicide risk such as patients with active suicidal ideation with method or intent within the last 3 months or patients with suicidal behavior within the last 6 months or presentation with suicide risk (based on opinion of the clinician).
- Motivista is not intended to be used as a standalone treatment.
- Motivista does not replace or substitute your medication, including medication for treatment of schizophrenia. You should continue your current treatment as directed by your healthcare provider.
- Motivista does not send alerts or warnings to your healthcare provider.
- If you feel that your schizophrenia symptoms are getting worse or if you think about harming yourself or others, stop using the app and get help right away:
    - Call your healthcare provider
    - Call 911
    - Go to the nearest emergency room
- During the clinical study, one participant had two episodes of a "psychotic disorder" that may have been related to Motivista. However, these episodes did not cause the participant to leave the study."

Precautions

- Motivista has not been studied in:
    - patients whose positive symptoms are not under control;
    - patients not taking antipsychotic medication;
    - patients who have serious memory or thinking problems;
    - patients who are not able to use the app by themselves;
    - patients who present a serious suicide risk, or;
    - patients less than 18 years of age.
- Tell your healthcare provider if your prescription or over-the-counter medications change while using Motivista.

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- Motivista is not for treating new or worsening symptoms of schizophrenia.
- Federal law restricts this device to sale by or on the order of a licensed prescriber.

Contraindications

- None known.

Product Overview

The Motivista app is a 16-week treatment you can use on your smartphone (running Apple or Android operating system). The app uses digital methods to deliver therapies shown by research to treat negative symptoms of schizophrenia. The specific types of therapy include behavioral activation, cognitive restructuring, social skills training, positive affect training, and distress tolerance skills. These methods are simple and flexible, so you can apply what you learn in your everyday life.

Motivista adjusts to fit your current needs, interests, and goals. Treatment has three parts: the Orientation Phase (21 days in length), the Goal Attainment Phase (84 days in length) and the Consolidation Phase (7 days in length). Treatment includes lessons, goals, activities, tools, daily check-ins, and personalized messaging.

- **Lessons** - Lessons teach about therapy topics and skills. They may show examples or have interactive parts to make learning more active. Each therapy section has its own lessons, with no more than one lesson per day.
- **Goals** - Goals are designed to encourage action and behavior related to the therapy. The goals and how hard they are get adjusted to fit you. Each goal is broken into four steps to help you make small steps so you can reach your goal.
- **Activities** - Activities appear in some lessons and goal steps. The app explains each activity, then guides you as you practice it. Sometimes it also helps you make a plan to complete the activity in your life.
- **Tools** - Tools are skills to help you manage stress and how you are feeling. You will first learn about tools in your lessons; after that, they will be available for you to use any time.
- **Daily Check-Ins** - The daily check-in asks about your mood. It may suggest something you can do for your mood, like practicing a tool. It may also ask if you did your last activity and how it went.
- **Personalized Messaging** - Text messages give you information about lesson topics. They remind you when there are lessons or goal steps to complete. They also encourage you to keep going with treatment.

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Typically, you will use the app for about 10 minutes each day. If you miss a day, the app will adjust your treatment journey.

Motivista is downloaded from the Google Play and Apple App Stores.

How to Start Using Motivista

Motivista is intended for people with negative symptoms of schizophrenia. To use it, you must read and speak English. You also need a smartphone that gets text messages. You must be able to use the phone on your own and be familiar with how to use apps.

Motivista is on the Apple App and Google Play Store, but you need a prescription from your healthcare provider to use it. During your visit, healthcare staff will explain how the app works and answer questions. After the pharmacy fills your Motivista prescription, you will get an access code from the pharmacy. This code activates your prescription in the app. Your prescription gives you access to Motivista for 16 weeks. Make sure you have a Wi-Fi or a data connection, then follow these steps:

1. Depending on what type of smartphone you have, open the Google Play or Apple App Store and search for Motivista.
2. Download the Motivista app on your smartphone.
    - It should be the phone you usually use so that you can receive text messages as a part of your treatment.
3. Once the app has been downloaded to your smartphone, open it.
4. When you open the Motivista app for the first time, you will need to create a user account by selecting “Sign up”. After selecting “Sign up”, the app will show some information about the program and then ask you to enter the access code you received from your pharmacy.

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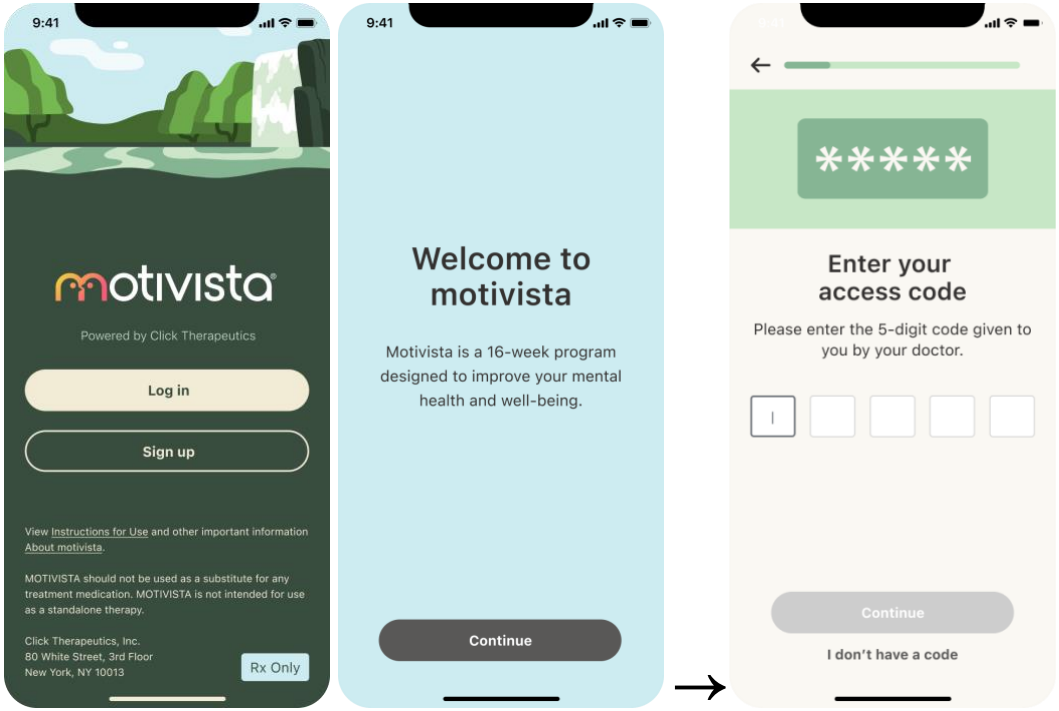

5. Next, confirm that you agree to the Terms & Conditions and Privacy Policy. Also confirm that you are at least 18 years old.
6. To continue creating your account, you will be asked to enter your name. Next, you will go to a screen titled “Create your account” where you will enter your email and create a password. A code will then be sent to your email address for you to verify.
    - You need to set a strong password with all of the following:
        - At least 8 characters
        - At least 1 uppercase character
        - At least 1 lowercase character

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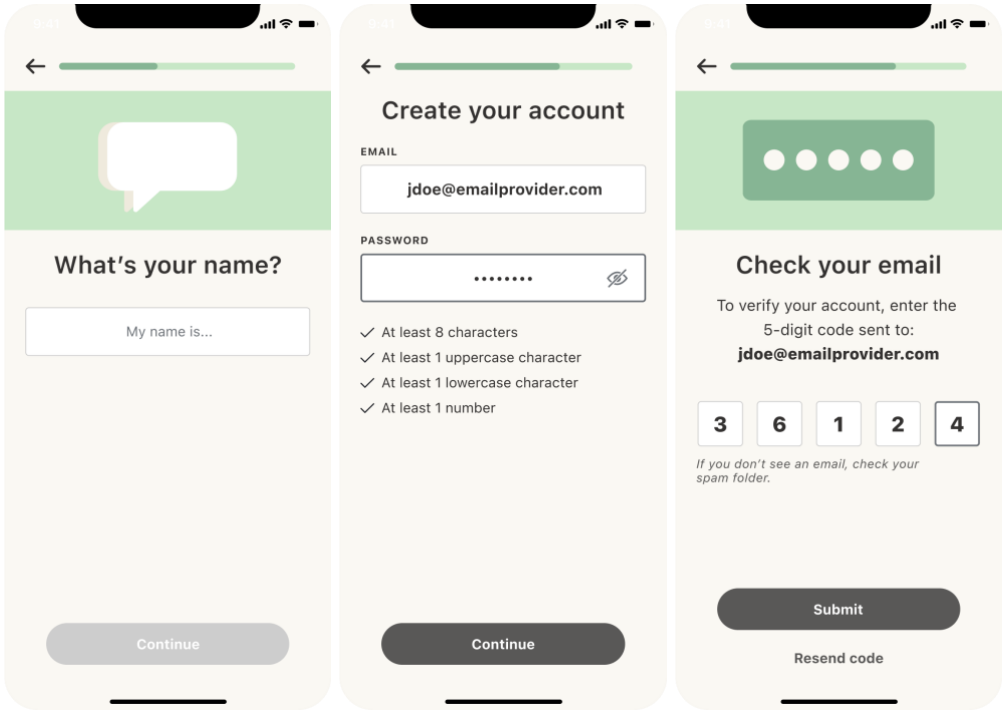
- At least 1 number



7. You will also be asked to enter your phone number to receive text messages as part of your treatment. A code will be sent by text to verify your phone number.

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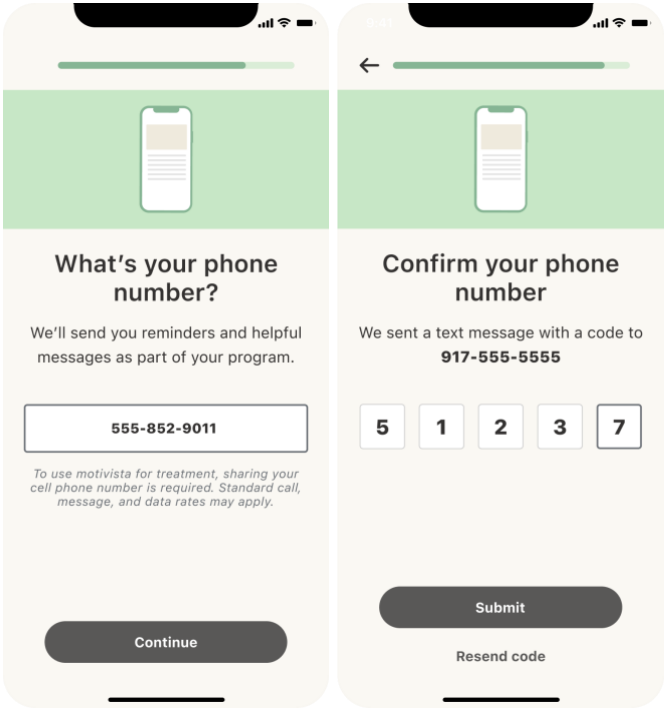

8. Once you verify your phone number, you can begin using the Motivista app.

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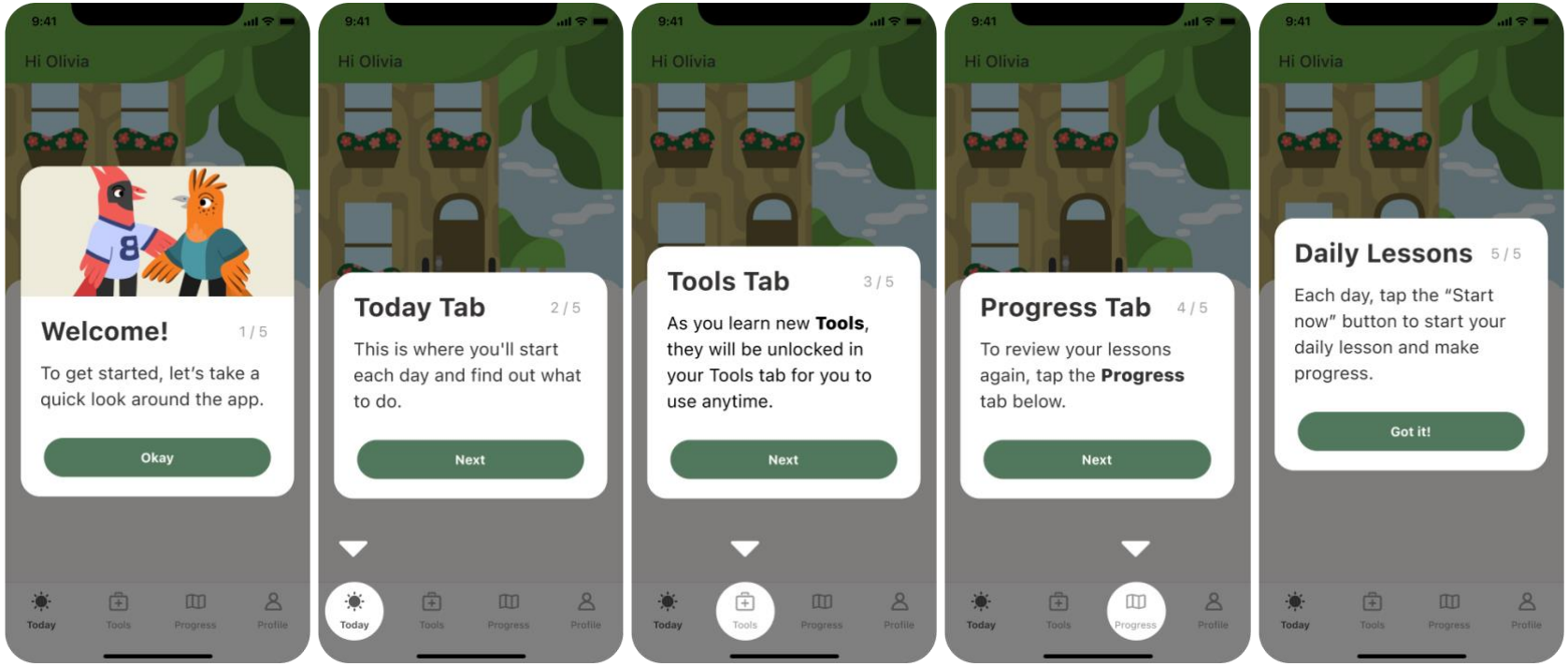
Motivista Features & Functionality

App Tour & Navigation

After you create your account, the app gives you a tour. The tour shows you the Today tab, where you can find your lesson or goal step for the day. It also points out the Tools tab, where you can use tools you have learned, and the Progress tab, where you can see lessons you finished. To see your profile, tap the Profile tab in the bottom right corner.



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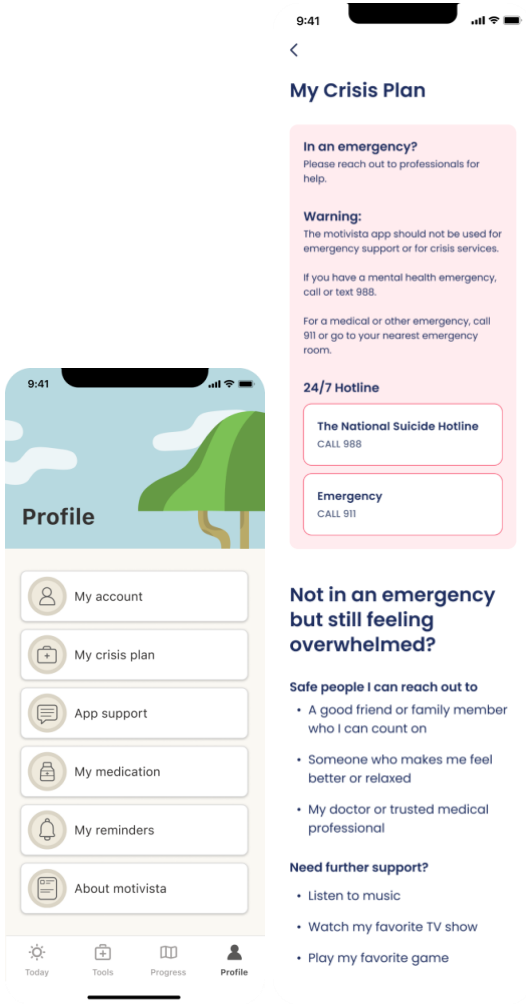
My Crisis Plan

During your first session, take a moment to find and review your “My Crisis Plan” under the Profile tab. This plan helps you figure out what you can do when you are having a hard time. During treatment, whenever you select “Not great” during your daily check-in, the app will provide a direct link back to your “My Crisis Plan.”



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Lessons

Lessons teach you about therapy topics and skills that can help you improve your health. The app groups related topics and skills together. Each day, tap the button on the Today tab to find your next lesson. You can also see some finished lessons in the Progress tab.

Some lessons include comics or short videos to show behaviors related to the topic. Lessons may also include activities, tools, or questions for you to answer.

Goals

During the Goal Attainment phase, the app sets goals to complete. Each goal is broken into four steps. One step can be completed per day in the Today tab. Each step contains activities designed to help you make progress towards your goals. The goal difficulty is based on your current ability. They get harder as you learn more skills.

A step is marked complete once you finish it from the Today tab, or confirm during a check-in that you tried or finished it. A goal is complete once all its goal steps are complete.

Activities

Activities are included in lessons and goal steps. The app explains the activity and guides you in planning or practicing the activity in daily life.

- **Activity Scheduling & Reminders** - When the app gives you an activity, you can choose to do it then, by tapping “I can do it now”, or later by tapping “Do it later”. If you choose later, you will be asked to pick a reminder time for later that day. At the time you chose, a notification will remind you to do the activity.
- **Activity Ratings** - Before some activities, the app asks you to rate how fun, hard, or rewarding you think they will be. After you finish, you will rate how the activity actually went. The app compares your answers to help you build balanced thinking patterns.
- **Activity Support** - When you have an activity scheduled, you can tap “I need help with my activity” on the Today tab. The app will ask what kind of help and give you ideas like practicing a tool or rescheduling your activity.

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Tools

Motivista helps you manage stress and how you are feeling with a set of tools. These tools are first presented in lessons. After you learn a tool in a lesson, like paced breathing or grounding, you can practice it from the Tools tab. The app will also recommend tools to try based on how you feel during your daily check-ins.

Daily Check-Ins

As you use Motivista, the app will begin to give you a check-in when you open the app for the first time each day. This check-in will ask about your mood and may suggest tools or actions based on your response. If you say you are feeling “Not great” during your check-in, the app provides a link to open “My Crisis Plan”. This plan helps you figure out what you can do when you are having a hard time. Additionally, if you have activities scheduled, the app may ask if you've finished them.

Personalized Messages

Motivista sends you text messages and notifications. These messages remind you to finish treatment activities and go over what you have learned. Each message is tailored to where you are in the treatment journey.

Progress Tab

From the Progress tab you can revisit lessons you have finished and view trophies you have earned on your treatment journey.

- **Revisit Lessons** - Some lessons become available in the Progress tab so you can repeat them after you finish. Lessons you did not finish also become available in the Progress tab over time.
- **Trophies** - You will earn trophies for successfully finishing lessons and goals. You can view all your trophies in the Progress tab by selecting "Go to my collection".

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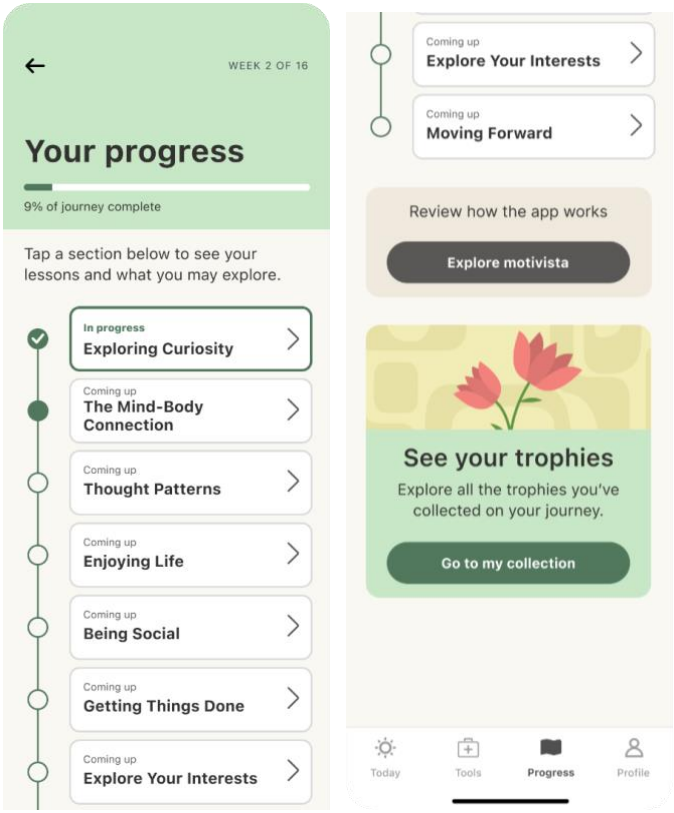

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Profile Tab

From the Profile tab you can go to:

- **Account Information** - Tap “My account” to see the name and email you used to set up your account, and the number of days left on your prescription. You can also sign out of the app on the “My account” page.
- **Emergency Support Information** - Tap “My crisis plan” to see emergency support information. The page instructs you to call 988 for mental health emergencies and 911 for all other medical emergencies. It also states that the app is not meant for emergency support. If you are in an emergency, please get professional help right away.
- **Technical Support Contact Information** - Tap “App support” to see a phone number and email address. Use them to get technical support or report quality complaints.
- **Medication Tracking** - Tap “My medication” to track whether you took your medication as prescribed. This works for both pills and long-acting injectable medication.
- **Daily Notification Reminder Time** - Tap “My reminders” to change the time of your daily reminder. You can also “Add a reminder” and “Reset my reminder”.
- **Important Information** - Tap “About motivista” to see information about Motivista:
    - Indications for Use
    - Restriction and caution statements
    - Unique Device Identifier (UDI)
    - Developer name
    - Manufacturer name and address
    - App version

  This tab also has links to the Instructions for Use, Terms of Use, Privacy Notice, and licenses.

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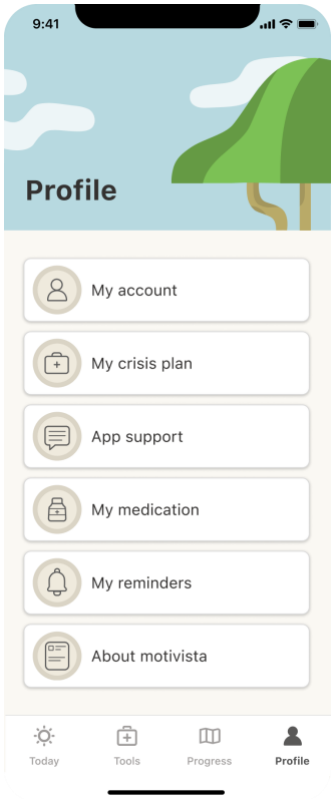

Continued Access

After your 16 weeks of treatment, you can still use parts of the app for four more weeks. You will still find your lessons and tools in the Progress and Tools tabs. Under the Profile tab, you can also access “My account”, “My crisis plan”, and “App support”. After those four weeks are up, the lessons and tools will no longer be available.

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Clinical Evidence

A pivotal clinical study supports using Motivista to treat negative symptoms of schizophrenia. Negative symptoms include low motivation, low enjoyment, and less interest in spending time with other people. The study found that Motivista benefited patients with negative symptoms of schizophrenia who were also taking antipsychotic medication. The study showed that Motivista reduced these negative symptoms more than a Digital Control. Experiential negative symptoms were measured with the Clinical Assessment Interview for Negative Symptoms, Motivation and Pleasure Scale (CAINS-MAP).

During the study, patients reported adverse events, and the study investigator reviewed them.

An adverse event is any bad or unexpected health problem that happens to someone while they are using a treatment, even if no one is sure the treatment actually caused it.

A serious adverse event is a health problem caused by a treatment that is dangerous or life-changing (like death, a life-threatening condition, a hospital stay, a lasting disability, or a birth defect). It can also include other medical problems that doctors believe could lead to one of these outcomes if not treated quickly.

Adverse events were similar between the Motivista and Digital Control groups. The study found no serious adverse events linked to Motivista. There was a very low incidence of suicidal ideation or behavior was observed in both arms. Although worsening psychotic symptoms that may have been related to Motivista were observed during the study, neither caused sufficient harm to cause participants to leave the study. The only study discontinuation due to suicidal ideation occurred in the Digital Control arm. Overall, Motivista patients tolerated Motivista well, and demonstrated a favorable safety profile.

During the study, about 8 out of 100 people using Motivista experienced an adverse event, compared to about 12 out of 100 people in the Digital Control arm. The most common type of adverse event was psychiatric in nature, such as worsening of psychotic symptoms. One participant using Motivista had two episodes of worsening psychotic symptoms that may have been related to Motivista, though neither episode caused sufficient harm to leave the study. No serious adverse events were linked to Motivista.

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Supported Smartphones and Systems

The Motivista app works on smartphones with Android or iPhone operating systems (OS). Motivista operates with the following systems:

- Apple iOS 16 and greater
- Android OS 13 and greater

If your smartphone's software is not running a compatible OS version, please update your OS version before you download and use Motivista.

Downloading Motivista requires at least 340MB of space available on your smartphone.

Motivista does not currently work on computers or tablets. To check if your smartphone works with Motivista, search for it on the Apple App Store or Google Play Store. If you cannot find Motivista, your smartphone may not work with the app.

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Security

Click Therapeutics uses industry best practices and security features to protect your data. Please do the following to keep your data secure:

- Use a strong passcode, pin code, Face ID or Touch ID to lock your smartphone.
- Set your smartphone to automatically lock when it's not in use.
- When creating your Motivista account, make sure to use a brand new password.
- Do not share your Motivista password or verification codes with others. Click Therapeutics will never ask for your password. If someone emails or calls asking for your login details, call +1 (855) 647-5187 or email Motivista@clicktx.com right away.
- Avoid connecting to unsecured Wi-Fi networks.
- Do not use a rooted or jailbroken smartphone.
- Keep your phone's operating system and the Motivista app updated to the latest versions.
- Turn on automatic app updates so you always have the latest version of Motivista. Software updates help to keep Motivista secure from security threats. If you are using an older version of Motivista, a message may pop up asking you to update it in the app store.
- When applicable, Click Therapeutics will share information about security vulnerabilities to affected users. Information may include details of the identified vulnerability and its potential impact, actions taken in response to the vulnerability, and guidance on any immediate actions you need to take to minimize the potential risk associated with the vulnerability.
- If Click Therapeutics stops supporting the Motivista app, including security patches and software updates, Click Therapeutics will communicate the potential security risks and disclose vulnerabilities that could be expected with continued use of the unsupported product.
- For information about the Software Bill of Materials, Architecture Diagrams, Motivista's Configuration, Backup and Software Update Processes, or any other security information for the Motivista product, please call +1 (855) 647-5187 or email motivista@clicktx.com

If you think there has been a security incident with Motivista, call +1 (855) 647-5187 or email motivista@clicktx.com.

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Support

Contact your healthcare provider if you think that you are having a side effect while using Motivista. To report possible side effects, or to get technical support with the app, call +1 (855) 647-5187.

If you have a problem with the Motivista app, this information may help:

- Confirm you are connected to Wi-Fi and / or cellular before downloading the app and creating your account.
- Stay connected to Wi-Fi and / or cellular data while using the app so your progress syncs and saves.
    - Motivista is designed to let you complete daily treatment offline, without a Wi-Fi or a cellular connection. However, if you stay offline for several days, the app may send text messages that do not match your treatment progress.
- To reset your password, tap “Forgot password” on the login page.
- You should use the same phone every time you use the Motivista app. Using a different phone means your progress may not sync and / or save.
- Note that once your Motivista treatment begins it cannot be paused.

If you try the steps above and still can't access Motivista for more than a few days in a row or need additional support, contact technical support at +1 (855) 647-5187 or motivista@clicktx.com.

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Manufacturer Address

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New York, NY 10013

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