



Patient Instructions for Use

Product Overview

Rejoyn is a smartphone app to be used by adults 22 years and older with major depressive disorder (MDD), commonly referred to as “depression.” It is intended to reduce MDD symptoms.

Rejoyn requires a prescription from a healthcare provider.

Indications for Use

Rejoyn is a prescription digital therapeutic for the treatment of Major Depressive Disorder (MDD) symptoms as an adjunct to clinician-managed outpatient care for adult patients with MDD age 22 years and older who are on antidepressant medication. It is intended to reduce MDD symptoms.

Contraindication

There are no contraindications to using Rejoyn.

Safety Information/Warnings/Precautions

Rejoyn is not intended to be used as a standalone treatment. Rejoyn does not replace your current medication, including medication for treatment of MDD. You should continue your current treatment as directed by your healthcare provider.

Rejoyn cannot send alerts or warnings to your healthcare provider. If you feel that your depression symptoms are worsening or if you have feelings or thoughts of harming yourself or others, please contact your healthcare provider, dial 911, or go to the nearest emergency room immediately.

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Rejoyn is made up of three parts: Therapeutic Lessons, Brain Exercises, and Personalized Reminders and Messaging (see Table 1).

Table 1: Rejoyn Features, Duration, and Frequency

Core Feature	Typical Duration*	Frequency
Therapeutic Lessons**	3 to 4 minutes	3 times per week for 6 weeks
Brain Exercises	11 to 26 minutes*	3 times per week for 6 weeks
Personalized Reminders and Messages	Less than 1 minute	Regularly throughout treatment

*In a clinical study of Rejoyn, a majority of Brain Exercises were completed in this time frame. Duration will vary by individual user.

**Once the 6-week treatment period is over, Therapeutic Lessons are available to be revisited for an additional 4 weeks.

Supported Operating Systems and Browsers

Operating Information

Refer to the app store to ensure compatibility with your specific smartphone and device Operating System (OS) with an available internet connection. Rejoyn operates with the following operating systems:

- iOS®
- Android™

Ensure your smartphone is running an OS version matching those required. If not, update your software version before downloading and using Rejoyn.

We recommend that you keep 100 MB of available storage on your device to use Rejoyn.

Rejoyn is not currently compatible for use with computers or tablets.

Please log into Rejoyn on one smartphone. This will make sure you do not miss any important reminders and will allow Rejoyn to remember where you are in your treatment.

Security

You are required to enter a username and password prior to use of Rejoyn. Please do not share your username or password with others.

Updates will be pushed to your smartphone automatically, if enabled, or application updates can be downloaded from the app store and installed on your smartphone.

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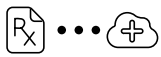
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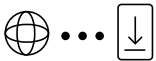
The purpose of this document is to provide instructions on how to use the Rejoyn digital therapeutic app administered via your smartphone.

Getting Started

Rejoyn is intended for people with MDD who are proficient with written and spoken English, who have access to a smartphone, and who are familiar with the use of mobile applications (apps).



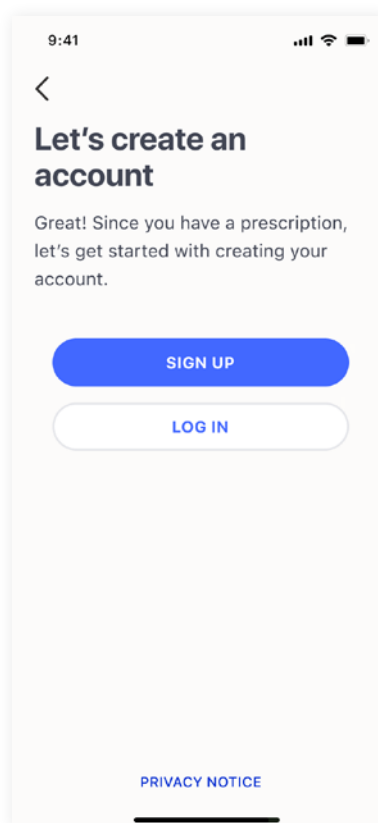
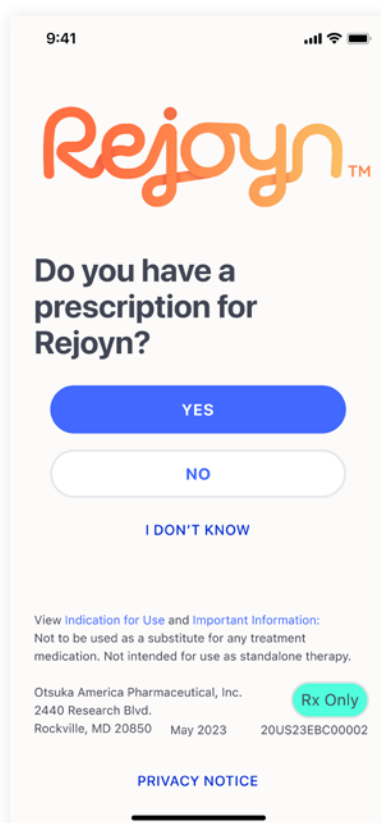
Your healthcare provider will prescribe Rejoyn and send your prescription to a pharmacy that dispenses Rejoyn access codes.



An internet connection is required to download Rejoyn on your smartphone. Rejoyn is available for download from the Apple App Store and Google Play Store. The app can be found by searching for Rejoyn.

SIGN UP

When you open the Rejoyn app for the first time, you will need to create a user account by selecting “Yes” to the question “Do you have a prescription for Rejoyn” on the landing page and then clicking on “Sign Up.”



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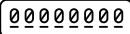
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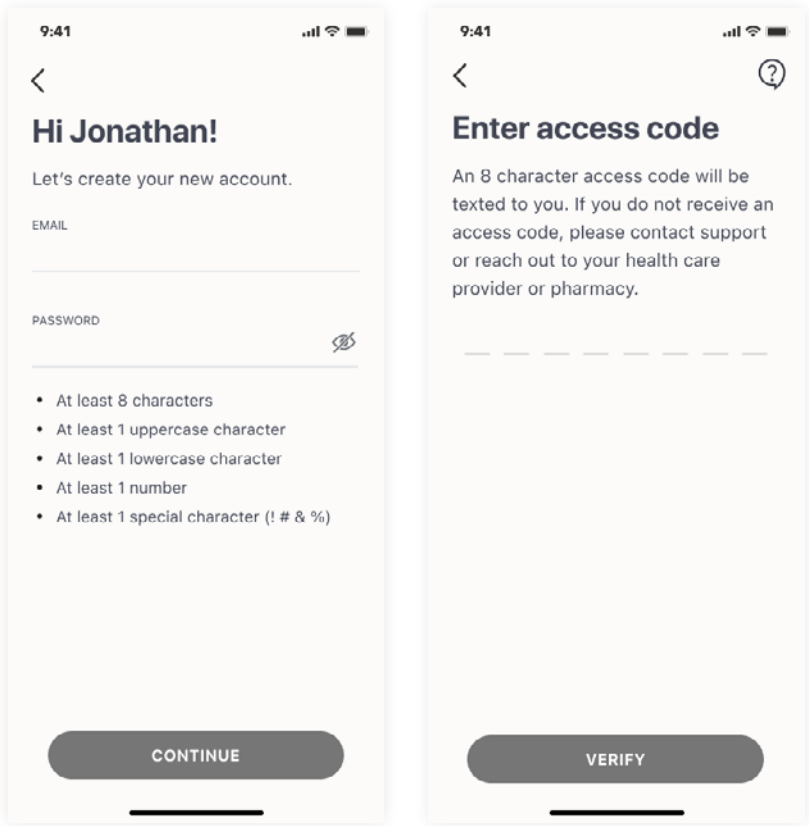
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After your account is created and your email address and mobile phone number are verified, an access code will be required to unlock treatment. The code will be provided by the dispensing pharmacy.

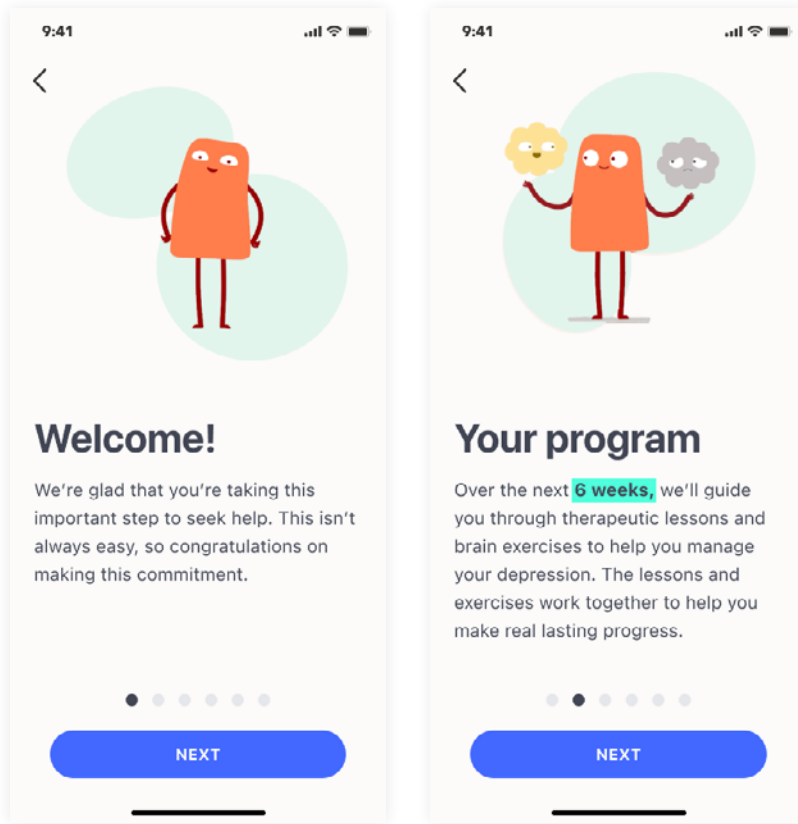


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Once the prescription access code is provided, you will then have access to your treatment program and can begin. Follow prompts in the app to complete your assigned activities.



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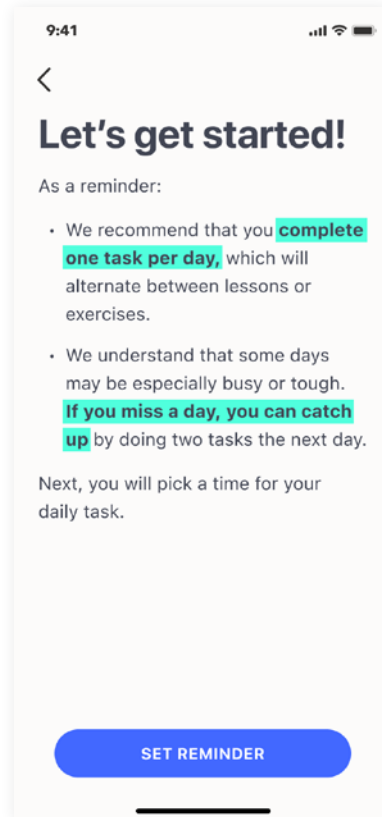
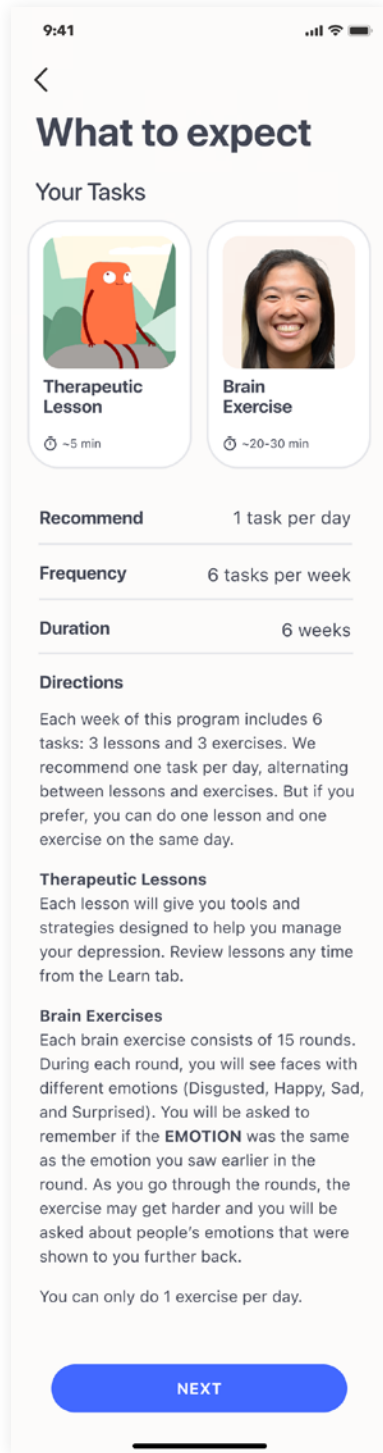
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Terms of Use and Privacy Notice

During account creation, you will be asked to agree to the “Terms of Use” and “Privacy Notice”. The “Terms of Use” and “Privacy Notice” are accessible by clicking on “Important Information” on the app landing page.

User Introduction

After you activate your prescription, you will be shown a set of screens that will guide you through your assigned activities and how to use the app. Tap the “NEXT” button at the bottom of each screen to navigate to the next screen. You can also tap the back arrow at the top to navigate to the previous screen.

There are six tasks per week, and it is recommended you do one task per day, which will alternate between Therapeutic Lessons and Brain Exercises.

For any reason if you miss a day, **do not worry. You can catch up** by doing two tasks the next day to stay on your weekly schedule. You cannot do more than two tasks per day. At the end of each week, any remaining Therapeutic Lessons are unlocked so you can view them later, but the previous week’s Brain Exercises will not be available.

An illustration of the recommended treatment schedule is shown in Table 2.

Table 2: Recommended Treatment Schedule

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1	Lesson 1	Exercise 1	Lesson 2	Exercise 2	Lesson 3	Exercise 3	Rest
Week 2	Lesson 4	Exercise 4	Lesson 5	Exercise 5	Lesson 6	Exercise 6	Rest
Week 3	Lesson 7	Exercise 7	Lesson 8	Exercise 8	Lesson 9	Exercise 9	Rest
Week 4	Lesson 10	Exercise 10	Lesson 11	Exercise 11	Lesson 12	Exercise 12	Rest
Week 5	Lesson 13	Exercise 13	Lesson 14	Exercise 14	Lesson 15	Exercise 15	Rest
Week 6	Lesson 16	Exercise 16	Lesson 17	Exercise 17	Lesson 18	Exercise 18	Rest
4 Weeks Continued Access	Option to revisit Lessons 1-18 at any time						

*Lesson refers to Therapeutic Lessons

**Exercise refers to Brain Exercises

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Table 3 shows an example of an alternate treatment schedule where you start treatment in the middle of the week and ‘double up’ on tasks some days.

Table 3: Alternate Treatment Schedule (Example)

	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday
Week 1	Lesson 1 Exercise 1			Lesson 2 Exercise 2	Lesson 3 Exercise 3		
Week 2		Lesson 4	Exercise 4	Lesson 5 Exercise 5	Lesson 6 Exercise 6		
Week 3		Lesson 7 Exercise 7		Lesson 8 Exercise 8		Lesson 9	Exercise 9
Week 4	Lesson 10	Exercise 10		Lesson 11		Exercise 11	Lesson 12 Exercise 12
Week 5				Lesson 13 Exercise 13	Lesson 14 Exercise 14	Lesson 15	Exercise 15
Week 6		Lesson 16 Exercise 16		Lesson 17 Exercise 17	Lesson 18 Exercise 18		
4 Weeks Continued Access	Option to revisit Lessons 1-18 at any time						

*Lesson refers to Therapeutic Lessons

**Exercise refers to Brain Exercises

Set a Reminder

You can choose to set a daily notification, which will remind you to do your daily task. The first time you use Rejoyn, you will be prompted to set up this notification. You can click on “Skip This” to continue without setting up these notifications.

You can add your reminder to your smartphone’s calendar to help you stay on track with your program. A prompt will display during the initial app set-up. You can click on “Add to Calendar” and follow the screen prompts. You can click “Skip This” to continue without setting up your calendar.

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Home Screen

Each time you re-open the app, you will be taken to the Home screen.

On the Home screen, you can:

- Monitor your weekly progress goal at the top of the screen in terms of percent completion.
- Start a Therapeutic Lesson by tapping on “Start” under “Lesson.”
- Start a Brain Exercise by tapping on “Start” under “Brain Exercise.”

Patient Profile

You can access your profile by tapping on the “Profile” icon at the top of the Home screen.

Support

Tapping “Support” under “Profile” will give you access to the number you can call to report side effects or quality complaints.

Edit Profile

Tapping “Edit Profile” under “Profile” will allow you to change the following information:

- Name
- Password
- Phone number

Reminder

Tapping “Reminder” under “Profile” will allow you to manage your daily notifications and make changes if desired.

Important Information

Tapping “Important information” under “Profile” will give you access to the following information:

- Unique Device Identifier (UDI)
- App Version
- Caution statements
- Indications for use
- Compatible devices
- Cybersecurity information
- Terms of use
- Privacy notice

Log Out

You can log out of the app by tapping on “Log out” at the bottom of “Profile” page.

Reset Password

Your Password can be reset by tapping on “Forgot Password” on the login page or by editing “Profile” on your “Profile” page.

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My Plan

Your plan progress or upcoming Therapeutic Lessons and Brain Exercises for the week can be accessed by tapping on “My Plan.”

Tasks

Each week the Rejoyn treatment includes six tasks: three Therapeutic Lessons and three Brain Exercises.

The Home screen will display your daily tasks. You will need to complete the Therapeutic Lesson before you can unlock the Brain Exercise.

Therapeutic Lessons

To begin your assigned Therapeutic Lesson, go to the Home screen in the app and tap “Start” which can be found in the Therapeutic Lessons box. Follow the instructions in the app to complete the Therapeutic Lesson.

When you complete the Therapeutic Lesson, tap “Done” and you will return to the Home screen to start your next task.

You can go back to finish Therapeutic Lessons any time from the “Learn” tab on the menu bar at the bottom of your screen.

Learn Library

There are a total of 18 Therapeutic Lessons. The Therapeutic Lessons are stored in the learn library and can be accessed by tapping “Learn.”

Toolkit

After the Therapeutic Lessons are completed, they will be added to the “Toolkit.” You can revisit and practice completed Therapeutic Lessons by tapping on “Toolkit.”

Brain Exercise

The Brain Exercises are designed to activate the parts of your brain that are responsible for emotion recognition and emotion regulation. Activating these two parts of the brain at the same time is believed to help strengthen the connection between them. This may help the brain better process emotions and improve symptoms of depression.

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The app will give you directions on how to complete the Brain Exercises. This may feel hard at times, but that is normal. You will have as much time as needed to complete the Brain Exercise once you begin; however, if you start a Brain Exercise and are then interrupted for 15 minutes or more, the app will restart your Brain Exercise session for the day. It's not about speed or accuracy. The point is to keep your brain challenged and engaged.

There are a total of 18 Brain Exercises. To begin your assigned Brain Exercise, go to the "Home" screen in the app and tap "Start" which can be found in the Brain Exercise box.

When you complete the Brain Exercise, tap "Done" and you will return to the "Home" screen.

Messages/Reminders

Rejoyn includes reminders to help keep you on schedule such as SMS text messages that reinforce the skills taught in the lessons and are meant to encourage completion of the program. Personalized SMSs are sent based on your behavior and reinforce concepts and skills acquired during the lessons.

Continued Access

The 6-week treatment course is followed by a 4-week lesson review period where you will have continued access to the Therapeutic Lessons only. Brain Exercises will no longer be available. After the 10-week time period (6-week treatment period plus 4-week lesson review period) has ended, you will no longer be able to access Rejoyn.

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Safety

Adverse events were directly assessed via phone or video based on the trial being conducted remotely. Adverse events were determined to be related or unrelated to Rejoyn by the investigator. No Treatment Emergent Adverse Event (TEAE) was assessed as related to Rejoyn during the trial. There were no discontinuations due to TEAEs. There was 1 discontinuation due to lack of efficacy in the Sham group. No serious TEAEs occurred during the treatment period. One serious TEAE of transient ischemic attack (assessed as not related to Rejoyn) was reported during the extension period.

The most common TEAEs during the treatment period (all nonserious and not related to Rejoyn) were upper respiratory tract infection (1.1% [n = 2] and 3.2% [n = 6] in Rejoyn and Sham, respectively), nasopharyngitis (1.1% [n = 2] and 2.7% [n = 5] in Rejoyn and Sham, respectively), and headache (2.1% [n = 4] and 1.6% [n = 3] in Rejoyn and Sham, respectively). Headache was the only TEAE that was experienced by at least 2% of subjects in the Rejoyn group at an incidence rate greater than Sham.

During the treatment period, one subject in the Rejoyn group experienced worsening depressive symptoms (based on predefined protocol criteria). In the Rejoyn group, 3.21% (n = 6) of subjects reported clinically important suicidality (based on predefined protocol criteria), compared to 4.84% (n = 9) of subjects in the Sham group. During the extension period, 0.53% (n = 1) of subjects in the Rejoyn group and 1.08% (n = 2) of subjects in the Sham group had clinically important suicidality.

Conclusions from the Mirai Trial

Effectiveness and safety data from the Mirai trial demonstrate that Rejoyn provides a benefit to patients with MDD when added to antidepressant pharmacotherapy. This data extends the findings from two earlier Emotional Faces Memory Task (EFMT) (Brain Exercises) studies where a reduction in depression symptoms was demonstrated in MDD patients. In the Mirai trial, the benefit of Rejoyn over Sham in reducing depressive symptoms was consistently rated by independent assessors via the MADRS, and by study investigators via the CGI-S.

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The effects of Rejoyn observed in the Mirai trial were larger and more durable over time for participants who had protocol-defined adherence (ie, completed 12 of 18 treatment sessions) and for participants with full adherence (ie, completed 18 of 18 treatment sessions) to the intervention. Rejoyn also showed benefit in depression symptoms in highly anxious participants with MDD, a subgroup who have been shown to have poorer outcomes.

These effectiveness data are particularly noteworthy in the context of Rejoyn's safety profile. Adverse events were directly assessed via phone or video based on the trial being conducted remotely. Adverse events were determined to be related or unrelated to Rejoyn by the investigator. Treatment-emergent adverse events were low in frequency, unrelated to Rejoyn, and not appreciably different across treatment groups. Rate of discontinuation from the study was also low. Overall, Rejoyn offers a positive therapeutic benefit-to-risk profile.

For additional details regarding the results of the clinical study, you can access the Rejoyn Clinician Brief Summary or the Rejoyn 510(k) summary at the following links:

- **Rejoyn Clinician Brief Summary:** <https://rejoynhcp.com/Clinician-Brief-Summary.pdf>, or
- **Rejoyn 510(k) summary:** https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231209.pdf

Support

For additional support with any aspect of the Rejoyn app, you can contact Rejoyn Support via phone at 1-833-973-5696.

Manufactured For

Otsuka Pharmaceutical Development & Commercialization, Inc.
508 Carnegie Center Dr, Princeton, NJ 08540

Rx Only

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