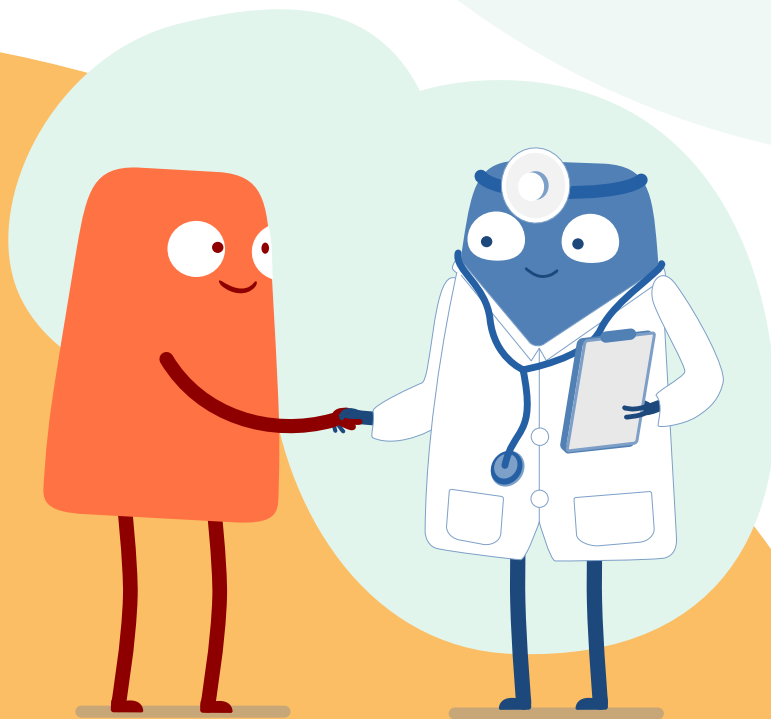


Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events or Product Quality Complaints/defects should also be reported to Otsuka by emailing medical.information@otsuka-europe.com or by calling 0203 375 8575.

CARE for MDD

An app-based treatment for major depressive disorder (MDD)

Patient user guide



Intended use: CARE for MDD is a digital therapeutic intended for the treatment of major depressive disorder (MDD) in adults. It is intended to be used alongside standard of care and supported by a Healthcare Professional.

Contents

Click to
navigate
to a section



Introducing CARE for MDD

Treatment with CARE for MDD

Part 1: Brain exercises

Part 2: Therapeutic lessons

Part 3: In-app notifications
and text messages

The CARE for MDD app

App navigation

Profile

Brain exercises

Therapeutic lessons

Treatment schedule

Technical support
and FAQs

Important
information



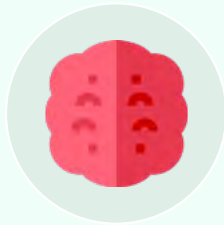
What is CARE for MDD?

CARE for MDD is a smartphone app (application) that has been developed to help manage your depressive disorder (also known as clinical depression or major depressive disorder).

This guide will provide you with an overview of CARE for MDD, what to expect from your treatment and instructions for using the app.

The CARE for MDD app is formed of three key parts:

1.



Brain exercises help to break the cycle of negative thinking that is part of this type of depression

2.

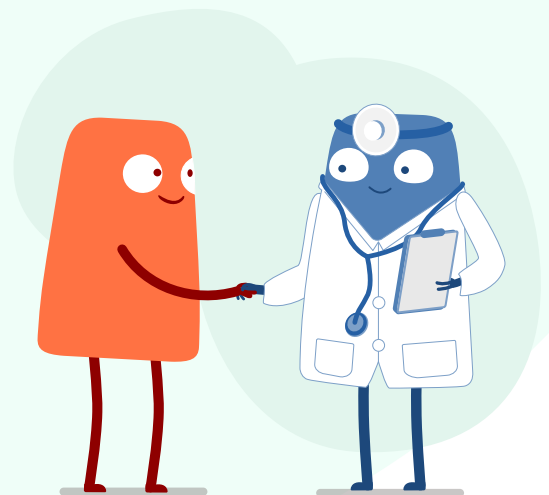


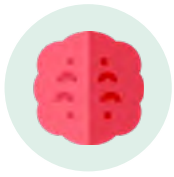
Therapeutic lessons teach skills related to positive thinking and emotional control

3.



Text messages and in-app notifications remind you of your treatment schedule

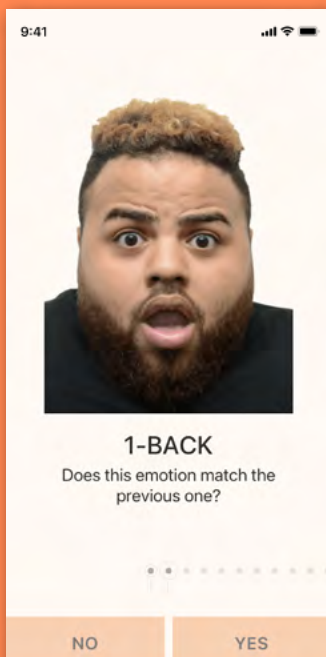
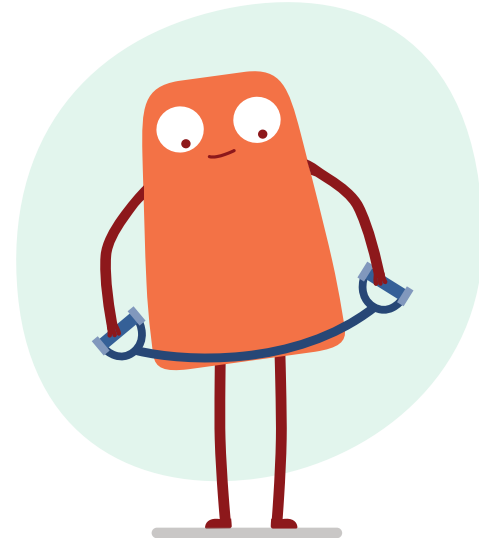




Part 1: Brain exercises

How do brain exercises help treat this type of depression?

- CARE for MDD features brain exercises that are designed to help you break the cycle of negative thinking that is a part of this type of depression
- With regular use, these exercises may strengthen the connections between the emotional and cognitive (or 'thinking') parts of your brain to help them work together better



How do I perform the brain exercises?

- You will practice identifying and remembering a sequence of emotions shown on screen
- During the exercise, you will identify and remember the emotions on a series of faces presented one at a time
- You will be asked to identify whether the current face is showing the same emotion as the previous face
- Exercises last 15–30 minutes and will be available on your app three times a week for 6 weeks

Brain exercises may be hard at first and take longer to complete, but don't worry, it's not about speed or accuracy. The exercises are to keep your brain challenged and engaged on a regular basis.

If you wish to learn more about brain exercises visit www.careformdd.co.uk.



Part 2: Therapeutic lessons

What are therapeutic lessons?

- Therapeutic lessons teach you skills related to positive thinking and emotional control
- The lessons are built on three principles:

1.

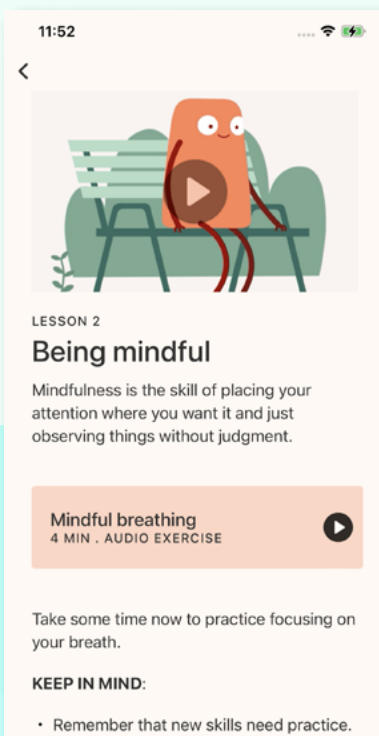
To provide skills to help with negative thinking and teach positive behaviours

2.

To develop real-life skills to build on the brain exercises

3.

To provide a regular routine of activities to maximise the potential benefits



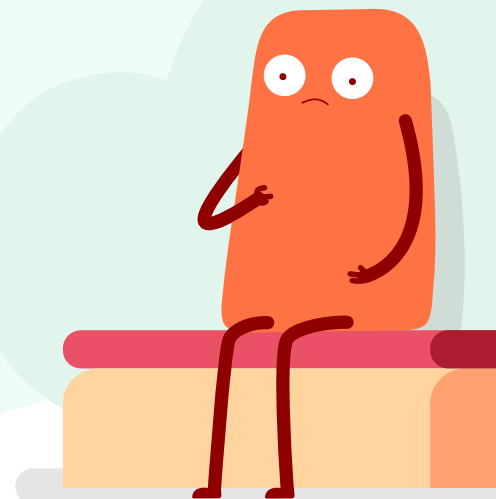
How do I complete the therapeutic lessons?

- Each 3-4 minute lesson contains a short, animated video followed by an exercise that corresponds to the video

When should I complete the therapeutic lessons?

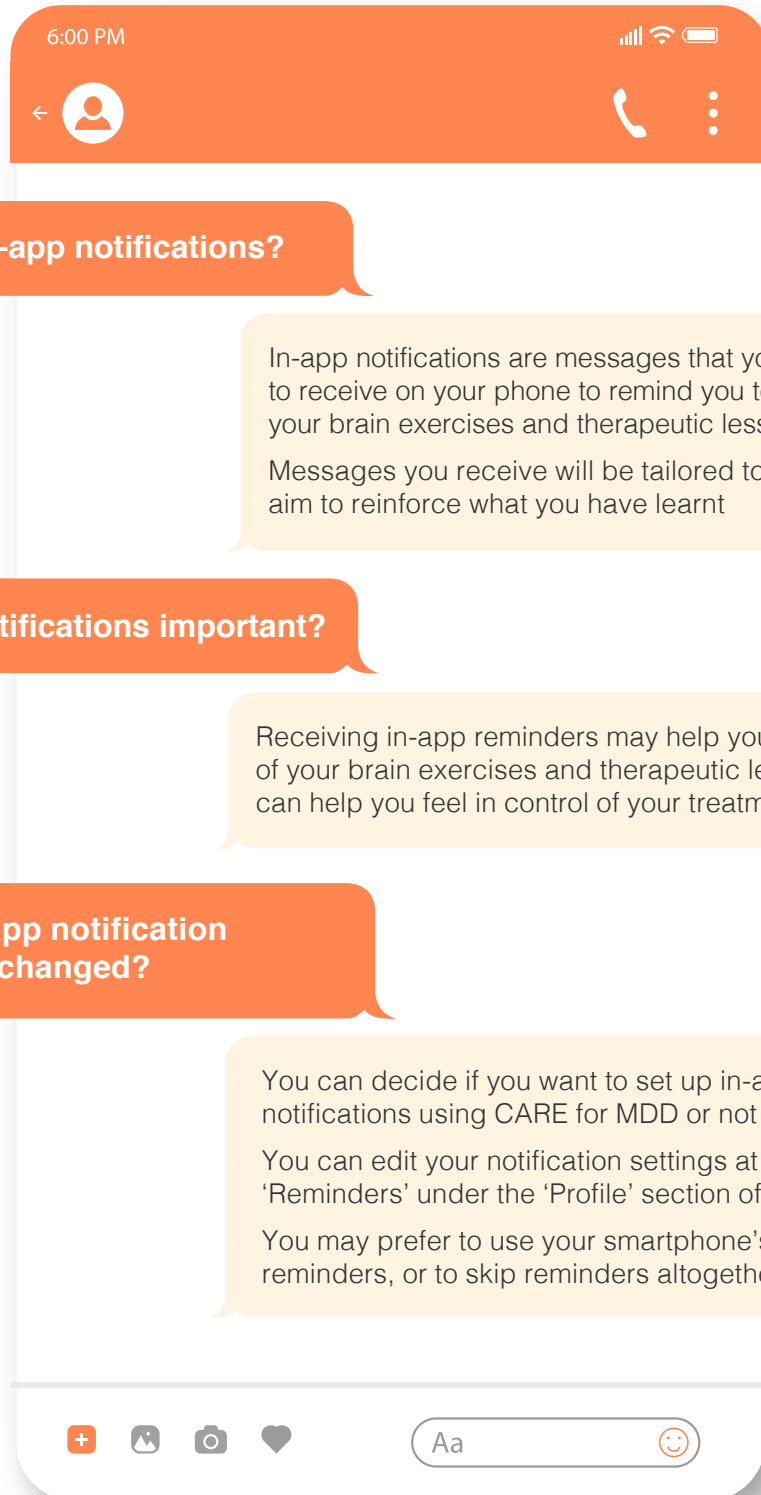
- Lessons will be unlocked on your app three times per week for 6 weeks
- Once completed, each lesson will be available on demand for a further 4 weeks after the initial 6-week period

If you wish to learn more about therapeutic lessons visit www.careformdd.co.uk





Part 3: In-app notifications and text messages



What are in-app notifications?

In-app notifications are messages that you can choose to receive on your phone to remind you to complete your brain exercises and therapeutic lessons
Messages you receive will be tailored to you and will aim to reinforce what you have learnt

Why are notifications important?

Receiving in-app reminders may help you to stay on top of your brain exercises and therapeutic lessons, which can help you feel in control of your treatment

Can the in-app notification settings be changed?

You can decide if you want to set up in-app reminder notifications using CARE for MDD or not
You can edit your notification settings at any time using 'Reminders' under the 'Profile' section of the app
You may prefer to use your smartphone's calendar reminders, or to skip reminders altogether



Getting started with the CARE for MDD app

Download the app

- You can download the CARE for MDD app from the Apple App Store or the Google Play Store by searching for '**CARE for MDD**'
- When you open the app for the first time, you will need to enter an access code

Request an access code

- You may receive your access code in a number of different ways. Your GP or therapist will provide you with information on how to request your access code, or they may request one for you with your permission.
- Your access code will be sent to you via email; if you cannot find your code in your inbox, please check the junk or spam folders

Set up your account

- Once you have entered your access code, you need to set a password
- Passwords must be at least eight characters long, including at least one uppercase letter, one lowercase letter and one number
- Next, you need to verify your email address (to allow you to register and reset your password if necessary) and mobile phone number (so you can receive text messages)
- CARE for MDD has been designed with privacy in mind and aligns with data protection and privacy standards. In order to use the CARE for MDD app, you will need to consent to the **Privacy Policy**

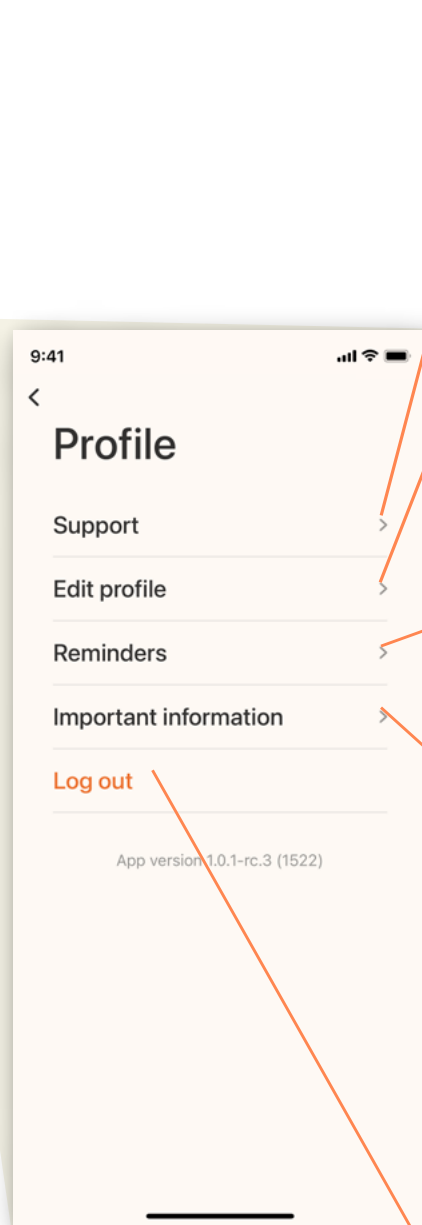
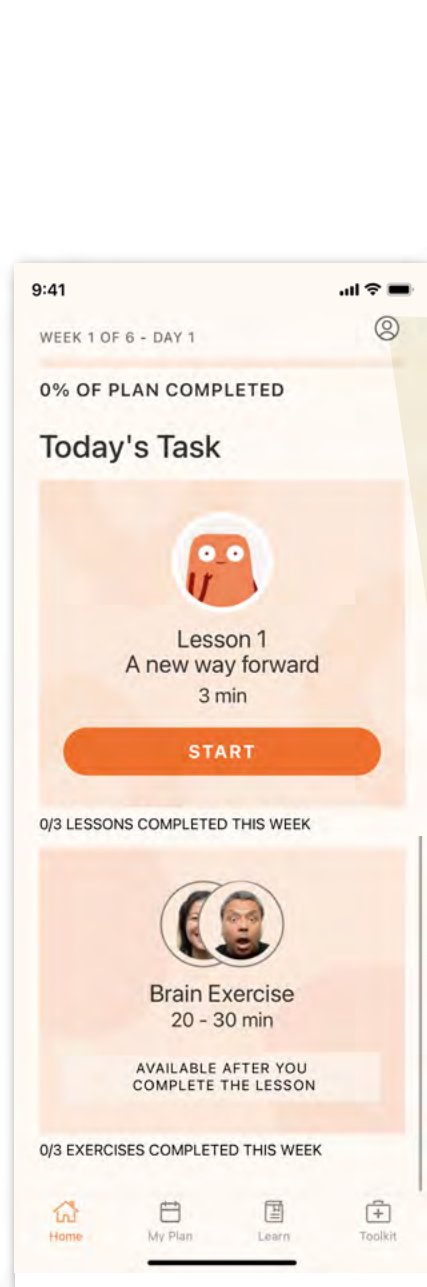
Your password can be reset by tapping on 'Forgot password' on the login page or by tapping 'Edit profile' under 'Profile' (see App navigation section).

If you are having any problems with downloading the CARE for MDD app or setting up your account, please visit the Frequently Asked Questions (FAQs) on the website (www.careformdd.com/faq) or call the CARE for MDD Support Centre on 0203 375 8575 (Monday to Friday, 09:00–17:00).



App navigation: Profile

You can view and edit your profile by tapping the profile icon in the top right of the home screen of the app.



Support

Tap 'Support' under 'Profile' to find the CARE for MDD Support Centre number

Edit Profile

Tap 'Edit profile' under 'Profile' to change your:

- Name
- Password
- Phone number

Reminders

Tap 'Reminders' under 'Profile' to manage your in-app notification settings

Important information

Tap 'Important information' under 'Profile' to access:

- Manufacturer information
- UK responsible person
- App version
- Intended purpose
- Instructions for use
- Terms and conditions
- Privacy policy
- Third-party licences

Log out

You can log out of the app by tapping on 'Log out' at the bottom of the 'Profile' page



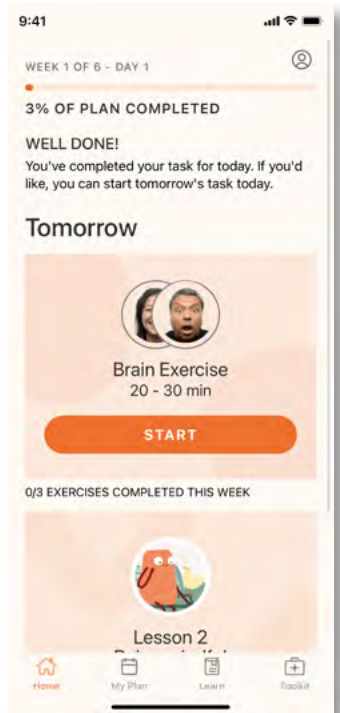
App navigation: Brain exercises

- There are 18 brain exercises in total
- To begin your brain exercise, go to the home screen and tap '**Start**' in the '**Brain Exercise**' box

- Select the level and tap '**Continue**', then '**Start**'

- Follow the on-screen instructions to complete your brain exercise
- You will have as much time as needed to complete the exercise once you begin
- If you start and are then interrupted for 15 minutes or more, the app will restart your session for the day

- When you complete your brain exercise for that day, you will see a '**Well Done**' message
- Tap '**Done**' to return to the home screen



Remember, it's not about speed or accuracy. The exercises are intended to keep your brain challenged and engaged.

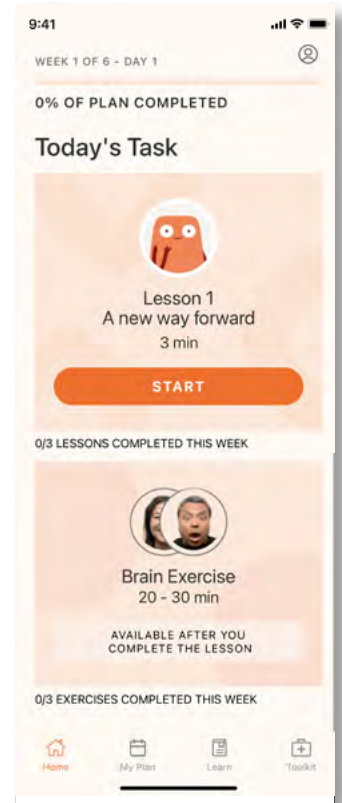


App navigation: Therapeutic lessons

- To begin your assigned therapeutic lesson, go to the home screen in the app and tap **'Start'** in the **'Therapeutic Lessons'** box

- Follow the on-screen instructions to complete the therapeutic lesson

- When you complete the therapeutic lesson, you will see a **'Well Done'** message
- Tap **'Done'** and you will return to the home screen



How to find previously completed lessons:

Learn library

There are a total of 18 therapeutic lessons. You can access the library by tapping **'Learn'** in the menu bar at the bottom of the screen

Toolkit

Each therapeutic lesson you complete will be added to the **'Toolkit'**, allowing you to revisit and practice them at any time



Treatment schedule

CARE for MDD is designed to fit into your daily schedule. The flexibility of a mobile app means you can decide when to do your activities.

Your treatment is expected to run for 6 weeks, including:

- Three brain exercises per week, each lasting 15–30 minutes
- Three therapeutic lessons per week, each lasting 3–4 minutes. Once completed, each lesson will be available on demand for a further 4 weeks after the initial 6-week period

Here's what a typical week of treatment with CARE for MDD looks like:

Sun	Mon	Tue	Wed	Thur	Fri	Sat
Lesson 1	Exercise 1	Lesson 2	Exercise 2	Lesson 3	Exercise 3	Rest

- If for any reason if you miss an exercise or lesson, do not worry. You can catch up by doing two tasks the next day to stay on track for the week. You cannot do more than two tasks per day
- At the end of each week, any remaining therapeutic lessons will be unlocked so that you can view them later
- Please note: Unlike therapeutic lessons, the previous week's brain exercises will not become available for later use

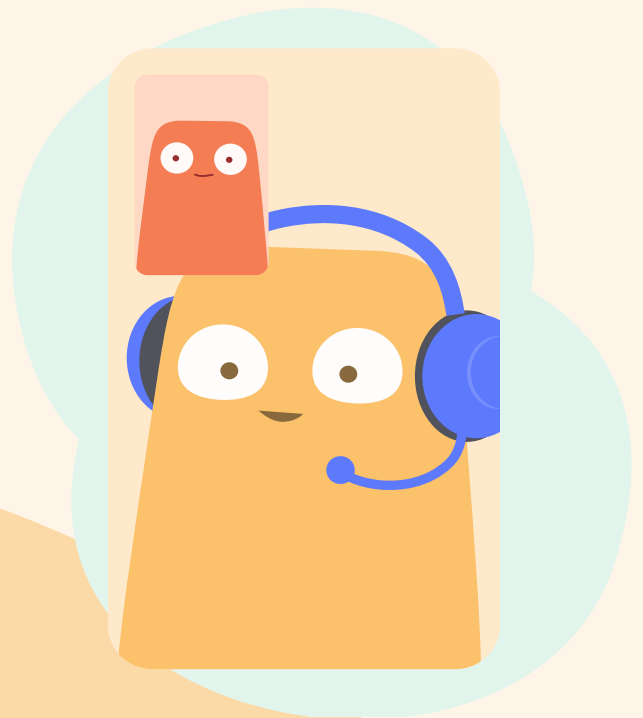




Technical support and FAQs

We hope you feel supported at every step of the journey. However, should you require technical assistance with the app or more information on CARE for MDD, there are options available to you:

- Visit the information and Frequently Asked Questions (FAQs) on the website www.careformdd.co.uk/faq
- Contact our dedicated CARE for MDD Support Centre on 0203 375 8575 available Monday–Friday (excluding national holidays) from 09:00–17:00 (calls charged at local rates)



If you feel that your depressive symptoms are worsening, or if you have feelings or thoughts of harming yourself or others, please contact your healthcare professional, dial 999 or go to the nearest Accident and Emergency department immediately.



Important information

Safety

- To access CARE for MDD you will require an access code. This will enable your participation in the treatment programme using the smartphone application (app)
- CARE for MDD is not a replacement or substitute for your current medical or mental health care treatments. You should continue with your treatment as directed by your Healthcare Professional
- CARE for MDD is intended to be used alongside your current treatment plan for MDD. Talk to your Healthcare Professional for additional information about MDD treatments that may be right for you
- CARE for MDD cannot send alerts or warnings to your Healthcare Professional
- If you feel that your depressive symptoms are worsening, or if you have feelings or thoughts of harming yourself or others, please contact your Healthcare Professional, dial 999 or go to the nearest Accident and Emergency Department immediately

Operating Information

- CARE for MDD is intended for people who have access to a smartphone and are familiar with using a smartphone app
- Refer to the Apple App Store or Google Play Store on your smartphone to ensure compatibility to your specific smartphone and Operating System (OS) with an available internet connection. CARE for MDD supports the two most recent versions of iOS and Android OS versions
- Ensure your smartphone is running an OS version matching those required. If not, update your smartphone software version before downloading and using CARE for MDD
- CARE for MDD is not currently compatible for use with computers or tablets
- Please log in to CARE for MDD on your smartphone. This will make sure you do not miss any important reminders and will allow CARE for MDD to remember where you are in your treatment

Security

- You are required to enter a username and password prior to using CARE for MDD. Please do not share your username or password with others
- Required updates will be installed on your smartphone automatically, if automatic updates are enabled. Otherwise, you will need to visit the app store to manually install the update on your smartphone before you can proceed with your treatment
- If automatic updates are enabled on your smartphone, the update will occur automatically. Otherwise, you can manually update from the app store at your convenience



Important information

Manufacturer

Otsuka America Pharmaceutical Inc. 2440 Research Blvd, Rockville, MD 200850

UK Responsible Person/Northern Ireland Authorised Representative

Otsuka Pharmaceutical Europe Ltd. 2 Windsor Dials, Arthur Road, Windsor, SL4 1RS,
United Kingdom

To get Care for MDD support or report CARE for MDD side effects or quality
complaints, contact:

Otsuka Pharmaceutical Europe Ltd. at +44 (0) 203 375 8575

Available: Monday–Friday (excluding national holidays)

Hours of operation: 9 AM to 5 PM

Website: www.careformdd.co.uk

SOFTWARE VERSION

Please refer to the 'Important Information' section in the Patient Profile section of CARE
for MDD for details of the current software version