



Instructions for use coobi care

These instructions are intended for the correct use of coobi care. Please read the information and follow the instructions contained therein. Please reach out to our support team (support@coobi.health) for additional help.

1. Intended Use

The coobi care app is a digital, software-based support tool designed as a supplementary medical resource for aiding in recovery, aftercare, and providing informational and behavioral guidance for patients with addiction disorders. The app aims to promote sustainable recovery success as a smartphone-based intervention, supported by data from a wearable device, to help prevent relapses and strengthen users in crisis situations. The coobi care app particularly encourages healthy self-initiative among affected individuals, fosters their social connections, supports the recognition and reflection of changes in behavior and condition, and provides interventions tailored to the specific situation. Communication with healthcare providers is enabled and facilitated through the app and its dashboard.

The coobi care app is intended to proactively support self-motivated medical self-help to prevent relapses in

general but does not replace medical advice or therapy. Instead, it can complement such treatments in everyday life. The app does not provide information that can be used for diagnostic or therapeutic decision-making purposes.

2. Indications of Use

The coobi care app is intended for use by patients with:

- Alcohol or substance use disorders (F10.2-F19.2)
- Harmful alcohol or substance use (F10.1-F19.1)

as a supplementary tool to aid in recovery and aftercare. The app should not be used for acute detoxification without prior assessment by a healthcare professional, as hospitalisation may be necessary.

3. Functionality

Courses & Tools:

The app includes a cognitive behavioral therapy (CBT) course that combines interactive exercises and psychoeducation content. The course helps people understand the connection between their thoughts, feelings, and actions. Through these exercises, users learn to identify negative patterns and replace them with healthier habits. The

content is designed to be easy to understand and apply in everyday life, offering practical techniques to manage the ups and downs of recovery.

Reflect & track:

Each evening, users engage in a structured self-assessment where they reflect on their sleep quality, mood, stress levels, cravings, and progress toward personal goals. By syncing with wearable devices, the app also allows to integrate wearable data on sleep, physical activity, and stress. By regularly observing how the day went, users can identify patterns in their behavior. This enhanced self-awareness is important to foster positive behavior change, as it helps to stay motivated and understand the impact of daily choices on recovery.

Craving Support:

Specialized tools are available to help users deal with cravings and sudden stress. These might include guided exercises, mindfulness practices, or quick tips to distract from or reduce the craving. The craving area gives users immediate, practical strategies that can be used whenever they feel vulnerable.

Stay Motivated:

Features like streaks and challenges encourage users to keep up with their daily practices. By celebrating small victories - whether it's a day without cravings or completing an exercise - these elements reinforce positive behavior. Regular success builds

confidence, making it easier for users to stick with their recovery plan.

Chat Group:

An anonymous chat group connects users with their aftercare group or self-help group who understand the journey of recovery. Sharing experiences in a safe, supportive space can be comforting and provide practical tips and encouragement, reinforcing that no one is alone in this process.

Share Data:

With the user's permission, all collected data can be shared with healthcare providers via the coobi clinic dashboard.

4. Device Compatibility Requirements

For the operation of the coobi care app, a smartphone with iOS (version 15.1 or higher) or Android OS (version 7.1 or higher) is required. The device should have a dual-core processor of 2 GHz or higher, RAM of 2 GB or more, and at least 1 GB of free disk space. Bluetooth 4.0 or higher is necessary for connectivity with wearable devices. An internet connection with a minimum speed of 5 Mbps is required for data synchronization. A compatible Garmin wearable device is also required for data collection.

For the operation of the coobi clinic dashboard, an internet-enabled computer with support for JavaScript

and cookies enabled in the browser is required.

5. Intended Users

The primary users of the coobi care device are individuals over 18 years of age with alcohol or substance use disorders or harmful alcohol or substance use who use the coobi care app for self-help and recovery support. Secondary users are healthcare professionals who use the coobi clinic dashboard to communicate with patients.

6. Contraindications

The app should not be used as the sole method of treatment for addiction disorders, but rather as a supplement to professional medical advice and therapy. coobi care is contraindicated for individuals with one of the following contraindications:

- Acute suicidality
- F10.3/4-F19.3/4 Unsuccessful withdrawal (acute withdrawal syndrome)
- F20-F29 schizophrenia, schizotypal or delusional disorder

7. Accessories

To use all the features of coobi care, a commercially available Garmin wearable is required. However, the device can also operate without this accessory.

Safety Information and Side Effects

8. Warnings and Precautions



1. The coobi care app does not replace medical advice or therapy. It is designed to complement such treatments in everyday life.
2. Users should not make changes to any existing treatments or medications based on the data or suggestions provided by the app without consulting a healthcare professional. If you are unsure about any data or information, consult with a healthcare professional.
3. Users should be aware that the data provided by the app is not scientifically medical and should not be used for any medical decision-making purposes. Users should not interpret the data provided by the app as medical advice or diagnosis.
4. If the user's condition worsens or does not improve over an extended period, they should contact their healthcare provider immediately.
5. The coobi care app and the coobi clinic dashboard handle sensitive patient data. Ensure that you are using secure and private internet connections to prevent unauthorized access and data breaches.

6. In case of software malfunction or data corruption, contact the support team immediately.

7. Users should ensure the security of their personal data by using usernames that don't identify the user, using strong, unique passwords and not sharing their login information.

8. Inaccurate data from user-input or the wearable can lead to inappropriate interventions. Always verify the data source of any interventions or recommendations received through the app.

9. The coobi care app and the coobi clinic dashboard are not intended to diagnose or treat any disease or condition. Always consult with a healthcare professional for medical advice.

9. Adverse Events

No serious adverse events have been reported in relation to the use of coobi care.

As a software-based application, coobi care does not have any known or anticipated physical side effects. However, it's important to note that the effectiveness of the app can vary depending on the individual's engagement with the program and their unique recovery journey. Users may experience emotional discomfort or distress when reflecting on their behaviors and conditions, which is an inherent part of the recovery process. If such discomfort persists or worsens,

users should consult with their doctor, psychologist or after-care coach.

The app should not be used as a substitute for professional medical advice or therapy. Always consult with a healthcare professional for any concerns or issues related to addiction disorders.

Security and Setup

10. Installation

The coobi care application is a software-only product that does not require any additional setup outside of accessing the application. The application can be downloaded and installed on a smartphone that meets the minimum hardware and software requirements. The coobi care app is compatible with iOS (15.1) and Android (7.1) operating systems.

The coobi clinic dashboard is a web-based application that can be accessed via Chromium-based browsers, Mozilla Firefox, or Safari with JavaScript and cookies enabled.

In addition to the app installation, users need to connect their compatible Garmin wearable device to the Garmin connect application via Bluetooth 4.0 or higher and allow the data connection with coobi care. This allows for the collection and synchronization of data between the wearable device and the coobi care app.

Please note that an internet connection with a minimum speed of 5 Mbps is

required for data synchronization between the app and the coobi clinic dashboard.

11. Training Required

No training is required to use the device. Additional information can be found on the website or in the help section of the app or dashboard.

12. Security

The coobi care device employs a comprehensive set of security measures to ensure the safety and privacy of user data.

1. Data Encryption: All data transmitted between the various components of the software architecture is encrypted using industry-standard protocols such as TLS (Transport Layer Security). Additionally, the database is encrypted at rest to further secure stored data.

2. Access Control: Access to the Database is strictly controlled through robust mechanisms that restrict unauthorized access. Role-based access control is implemented on the database, ensuring users can only access data and operations relevant to their role.

3. Secure Coding Practices: The development team adheres to secure coding practices to prevent common vulnerabilities. Regular code reviews and automated security scanning tools are used to identify and remediate potential security issues.

4. Network Security: Network security groups and firewalls are configured to limit access to the servers based on predefined security rules.

5. Regular Security Audits: The device undergoes regular security audits and penetration testing to identify and address security weaknesses within the software architecture.

6. Patch Management: All software components are kept up-to-date with the latest security patches to ensure the highest level of security.

These measures collectively ensure the secure operation of the coobi care device, protecting user data and maintaining the integrity of the system.

Instructions

1. Download and install: Download and install the coobi care app from your smartphone's app store.

2. Registration: Open the app, press "registration" and enter the access code you have received. Then follow the instructions to create an account. Be sure to provide accurate information for effective use of the app.

3. Connect your wearable: Follow the instructions to connect your portable device (Garmin) to your phone and the Garmin Connect app. Then follow the instructions to enable data transfer to coobi care.

4. Explore the app: Explore the home screen and daily tools, craving area, trends, modules and toolkit.

5. Join your chat group: If you are part of a group that uses coobi care, you can join the secure chat group. To do this, press the messenger icon on the home screen and enter the code you received from your group.

6. Sharing data with your therapist: With your permission, you can securely share your data with your therapist. Go to Settings and select "Share data with your therapist". Then follow the instructions to give your therapist the code and choose what information you want to share.

Technical Assistance

Write us an email at:

support@coobi.health

Contact us with the Chatbot on:

www.coobi.health

Use the contact form on:

www.coobi.health/kontakt

Emergency Information

In case of an emergency (e.g. crisis, suicidality) contact your medical doctor or psychotherapist immediately or call one of these emergency hotlines (for Germany):

- Ambulance: 112
- Police: 110
- Counselling: 0800 111 0 111 or 0800 111 0 222

In case no one answers please check if the numbers are up to date.

In the case of any serious incident that has occurred in relation to the use of coobi care, report it immediately via support@coobi.health

Release Date

2025-02-14

Manufacturer



Stigma Health GmbH
Barmbeker Str. 33, 22303
Hamburg
Deutschland



(01)4170000217251(10)100000(11)250214



This product is a Class I medical device according to EU MDR 2017/745.



Software version 10.00.00



coobi care