Super Brains Client App Manual

Version	Date	Author	Approver	Change
1.0	2025-11-19	S. van Dam / M. Hille	D. den Hollander	- First release
2.0	2025-12-17	M. Hille	D. den Hollander	- Warning symbol added

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Beetsstraat 5
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The Netherlands
support@superbrains.nl
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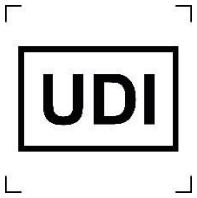
CE

CE 1234



UDI-PI: (01)8720892058201(11)yyyymmdd(10)X.X.xx

(Later te gebruiken als CE certificaat wordt uitgegeven door NOBO: CE+BSI nummer)

Super Brains is a class I medical device in accordance with 93/42/EEC (for MDD)

Super Brains strives to be a class IIa medical device in accordance with Regulation (EU) 2017/745 (for MDR) in the nearby future.

Explanation symbols

Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

This symbol indicates Consult instructions for use

This symbol indicates Consult electronic instructions for use

eIFU indicator

Indicates a website where a patient can obtain additional information on the medical product.

QR code link to manual app

Conformité Européenne

1234 Conformité Européenne This symbol indicates that a manufacturer declares that their product complies with European safety standards. The number refers to the Notified Body involved (not yet applicable)

This symbol indicates the item is a *medical device*

This symbol indicates the *manufacturer's catalogue number* so that the *medical device* can be identified

This symbol indicates a carrier that contains unique device identifier information

This symbol indicates the medical device manufacturer

Specific icons in the app are discussed in the part with introduction of the screens.

Product Description

Intended use:
Super Brains is a digital lifestyle training and progress monitoring platform designed to help users cultivate healthier lifestyle habits. The platform specifically aims to reduce negative behaviors associated with mental health conditions such as ADHD, ADD, Autism Spectrum Disorders, Substance abuse, Anxiety and Depression.

Clarification
Clients can benefit from personalized coaching provided by experience experts or receive peer support through community interaction. Superbrains leverages gamification techniques to effectively encourage users to achieve their individual goals.
Recognizing the challenges inherent in implementing lifestyle changes, Superbrains facilitates comprehensive support by enabling members within a client's personal circle — such as family or friends — to communicate, train and support one another through the app. When the app is used in this context—without practitioner oversight or involvement—it is classified strictly as a lifestyle management tool without medical claims.
The platform 'Superbrains' further expands its functionalities as a digital e-health platform, providing clients deeper insights into their treatment journey. Features include:

- Access to personalized treatment plans.
- Reporting functionality after appointments.
- Appointment scheduling in collaboration with practitioners.
- Real-time progress tracking accessible to both client and practitioner.
- Direct communication is possible between client and practitioner.
- Actively supporting clients in learning, implementing, and maintaining (healthy) routines and behavioral changes.

Additionally, the platform can be independently utilized for lifestyle training purposed without practitioner involvement.
The platform is for clients with one or more of the conditions mentioned above. Users must be able to read and write Dutch.

Characterization of Patient Population

Intended users:
SB is intended to be used by patients who suffer from ADHD, ADD, Autism Spectrum Disorder, substance abuse, anxiety, and/or depression in their home environment, as well as by the qualified medical practitioners (psychologists) and experts by experience who use the application to support patients who are on the waiting list to receive help from a mental health specialist.

Intended patient population:
To be used by patients who suffer from ADHD, ADD, Autism Spectrum Disorder, substance abuse, anxiety, and/or depression in their home environment and who are on the waiting list to be helped by a specialist within mental health care.

This app is meant for persons of the age of 16 and older.

Safety Information

Contraindications
There are no contraindications for the use of this app.

Warning and limitations
This app is meant for persons of the age of 16 and older.
Required to understand Dutch.

All results from the app, such as questionnaires, etc., must be checked thoroughly by a qualified physician to ensure that you do not make any incorrect assumptions or presumptions based on that information.

This app is not a substitute for professional care!

Circumstances in which the user should consult a healthcare professional

- When your condition or symptoms fall inside or outside the app's scope—for example, physical symptoms indicating serious illness or sudden deterioration requiring urgent or specialized care, consult a healthcare professional.

- If you urgently need help, contact your practitioner directly or call your family doctor.

- If you are feeling suicidal or having thoughts of self-harm, please know that you are not alone and help is available. It is important to seek immediate support from trusted individuals, healthcare providers, or crisis resources. If you are in immediate danger or at risk of harming yourself, please call emergency services right away (e.g., 112, 113, or your local emergency number).

- Reach out to a mental health professional or counselor as soon as possible for guidance and support.
- Use crisis helplines or chat services available in your area for confidential help

Reporting a Serious Incident

Please take note!
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!
If you want to report a serious incident which occurred with this medical device, then you can do so by contacting your national competent authority under the following contact information:
Inspectie Gezondheidszorg en Jeugd: IGJ.nl | Inspectie Gezondheidszorg en Jeugd

Information security incident

An information security incident is an event or series of events that compromise the confidentiality, integrity, or availability of information or information systems. This can include unauthorized access, personal data breaches, malware infections, or other activities that threaten the security of information.

A report of a security incident is necessary when an event or activity has the potential to compromise the confidentiality, integrity, or availability of information or information systems.

Specifically, reporting to SuperBrains BV is required when:

- Unauthorized access or attempts to access sensitive data occur.
- Personal data breaches or leakage of confidential information happen.
- Malware infections or ransomware attacks are detected.
- There is a disruption or degradation of Superbrains platform.
- Suspicious activities or anomalies that may indicate a security threat are observed.

Language

Super Brains App is available in Dutch only.
A manual in Dutch and English is available to the end user/client.
A manual in Dutch and English is available for practitioners.

Performance characteristics of the device

“The idea is that with just a few clicks, you have access to a wealth of information, exercises and professional guidance. These types of e-health platforms also make it possible to ask for help in a discreet manner. In addition, therapists and patients can communicate more easily, which can speed up treatment. In a sector where time and privacy are crucial, such a platform forms an indispensable link between healthcare providers and clients. Super Brains, for example, offers blended care and a balanced mix of tools and insights to support both healthcare providers and users.”

Characterization of User Profile

If the user can read Dutch and has basic knowledge regarding the use of an app, the user should be able to work with this without any problems.

Characterization of Use Environment Including Software / Hardware

The desktop runs on any web browser: Google Chrome, Safari, Microsoft Edge, and Firefox. The desktop is supported on Microsoft up to the latest supported version of Android and iOS.

The app runs on Android and Apple.
The app runs only when online!

Safety and Maintenance

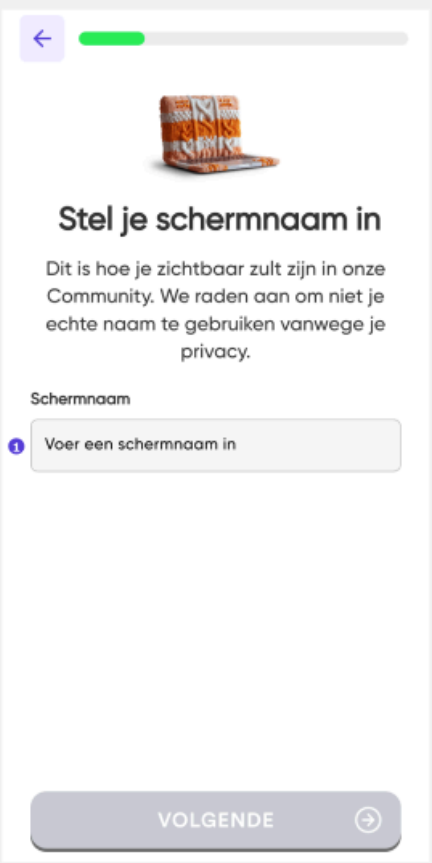
The software’s lifetime is conditional on receiving mandatory security and compatibility updates; once these cease, the Superbrains app is considered at end of life.

This is what is expected to be the maximum time until the implementation of a significant change, by which the manufacturer is able to react to the relevant changes to the software device environment, such as SOUP changes, cybersecurity innovations, or the evolving technological or medical state of the art.

Users can report malfunctions, lost passwords or a potential security breach via support@superbrains.nl

Walkthrough guide

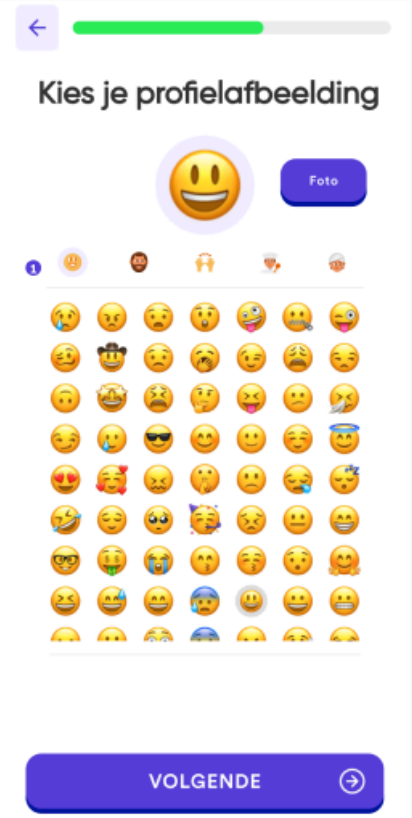
The following part of this manual is about using the software. It represents a walkthrough guide to explain functionalities including screenshots and links to helpful websites.



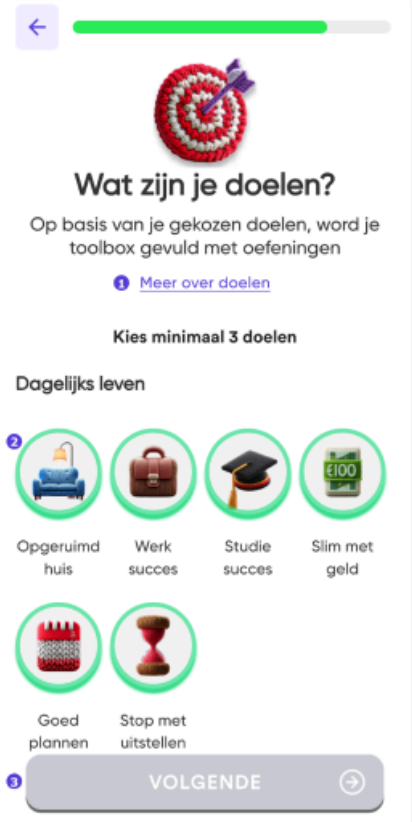
1 **Choose your screenname. This is the name others will see in the app.**

2 **Once you've entered your display name the 'VOLGENDE' button will turn purple and become clickable.**

1 **Choose your nickname. Your nickname is used for personal greetings and communications within the app.**



1 **Choose your profile picture. You can choose your own photo or an emoji.**

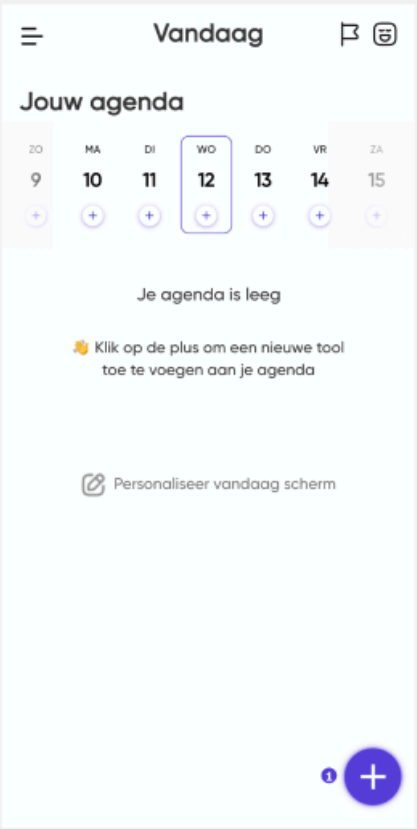


1 **Click here to learn more about goals.**

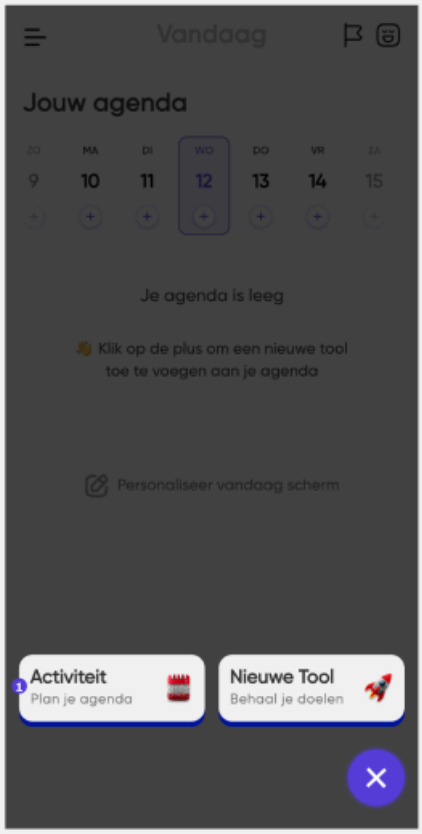
2 **Choose your goals. You can adjust your goals at any time.**

3 **Once you've chosen your goals the 'VOLGENDE' button will turn purple and become clickable.**

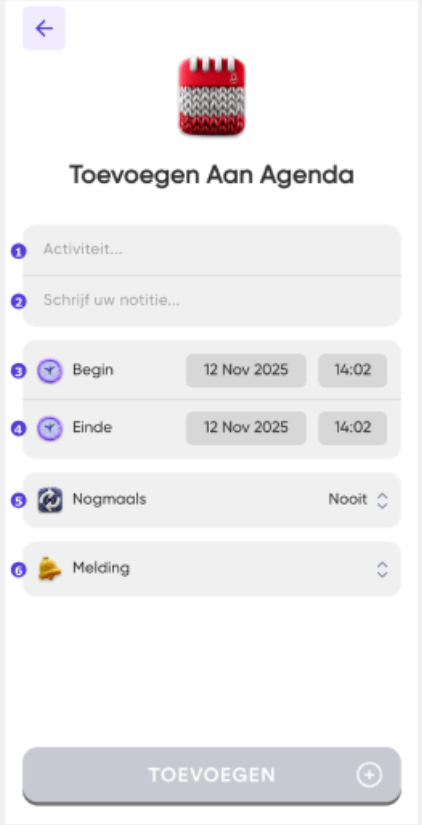
1 **Click here to earn your rewards.**



1 **Click here to add an activity or a tool.**



1 Click here to add an activity. An activity can be something like 'Do your laundry'.



1 What's the name of the activity?

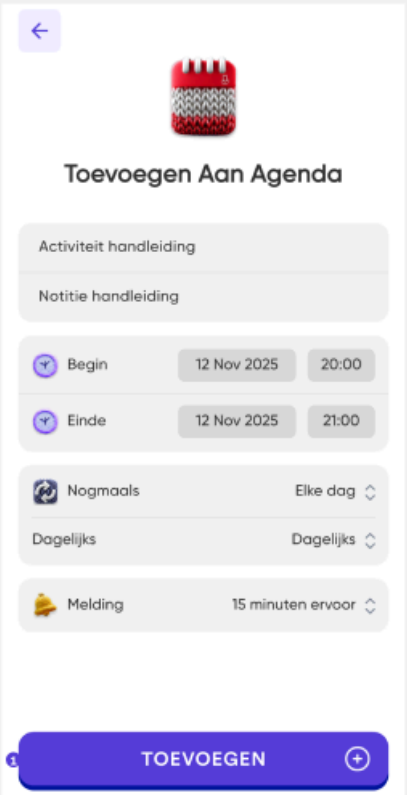
2 Write a notition for the activity

3 Choose a start date and time.

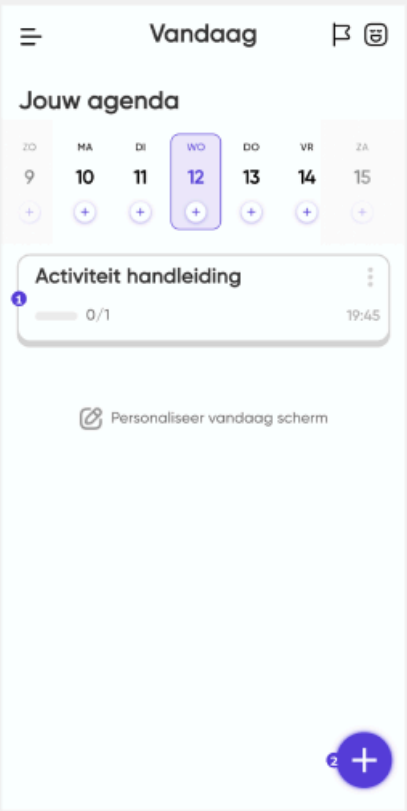
4 Choose an end date and time.

5 Choose if you want to repeat the activity.

6 Choose if you want to add a notification.

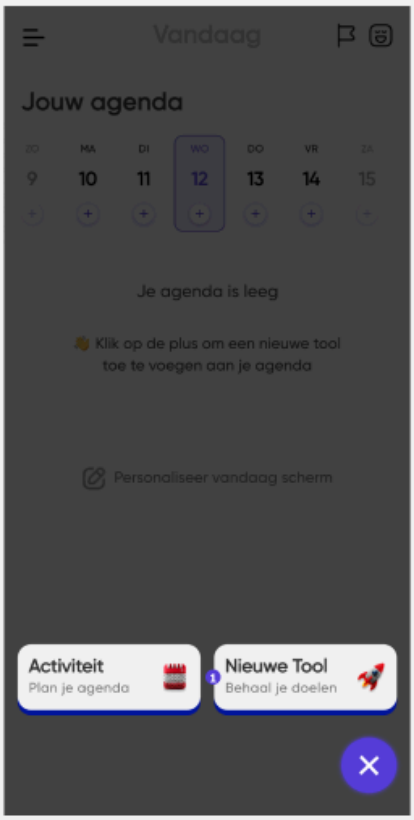


1 When you've filled in all required options the button 'TOEVOEGEN' will turn purple and become clickable.

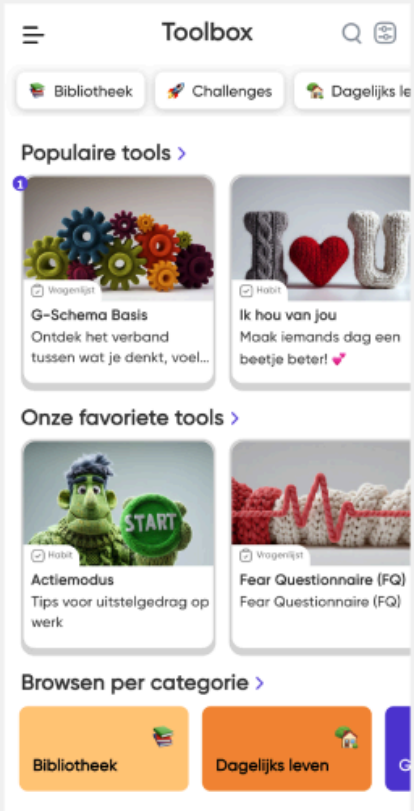


1 Click here to view the activity

2 Click here to add a tool.



1 **Click here to add a tool.**



1 **Select the tool you want to do**

Ik hou van jou

Habit · 1 min

Hou je van je familie en vrienden? Zeg het ze dan! ❤️

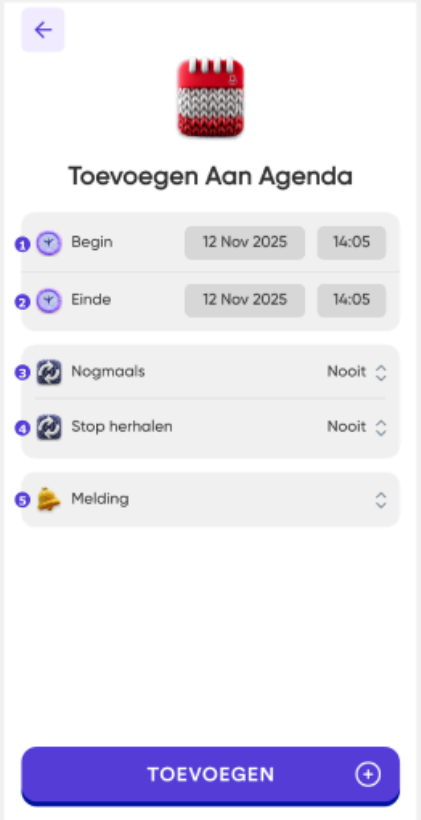
Woorden hebben kracht, niet alleen voor de ontvanger, maar ook voor degene die ze uitspreekt. Natuurlijk weten je familie en goede vrienden wel dat je van ze houdt, maar het is goed om het ook echt hardop zeggen. Zeg dus vrijuit: "Ik hou van jou"!

Als je dat niet gewend bent, kan het misschien even eng zijn en raar voelen, maar het is zo fijn om te horen. Ook zul je merken dat je het zelf heel fijn vindt om te zeggen tegen de mensen van wie je houdt. Dus verzamel je moed en vertel je naasten dat je van ze houdt! Wedden

1 HERHALEN | START

Een gewoonte begint met herhalen

1 **Choose whether you want to do the tool right now or schedule it for later.**



Toevoegen Aan Agenda

1 Begin 12 Nov 2025 14:05

2 Einde 12 Nov 2025 14:05

3 Nogmaals Nooit

4 Stop herhalen Nooit

5 Melding

TOEVOEGEN

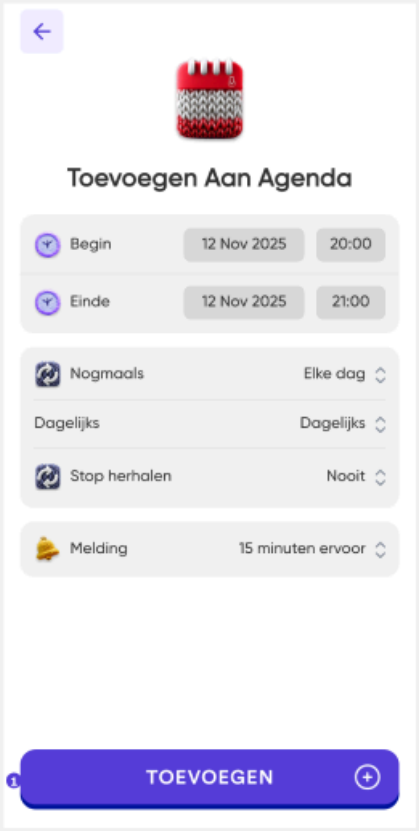
1 **Choose a start date and time.**

2 **Choose an end date and time.**

3 **Choose if you want to repeat the tool.**

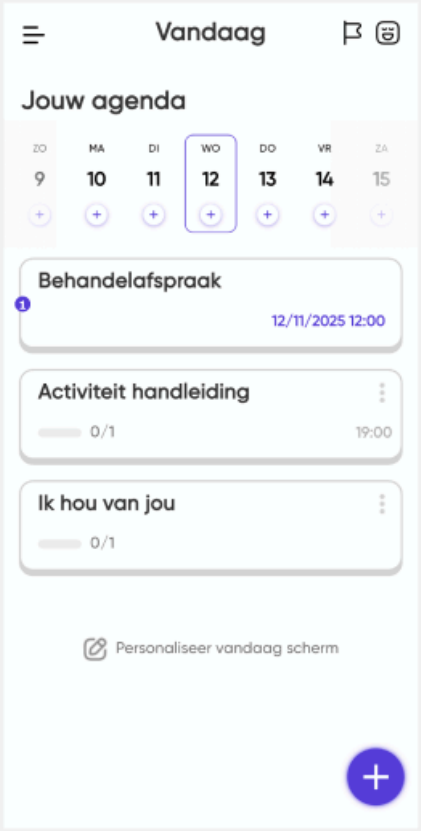
4 **Choose when you want to end the repeating tool.**

5 **Choose if you want to add a notification.**



1 **Click 'TOEVOEGEN' to add the tool to your agenda.**

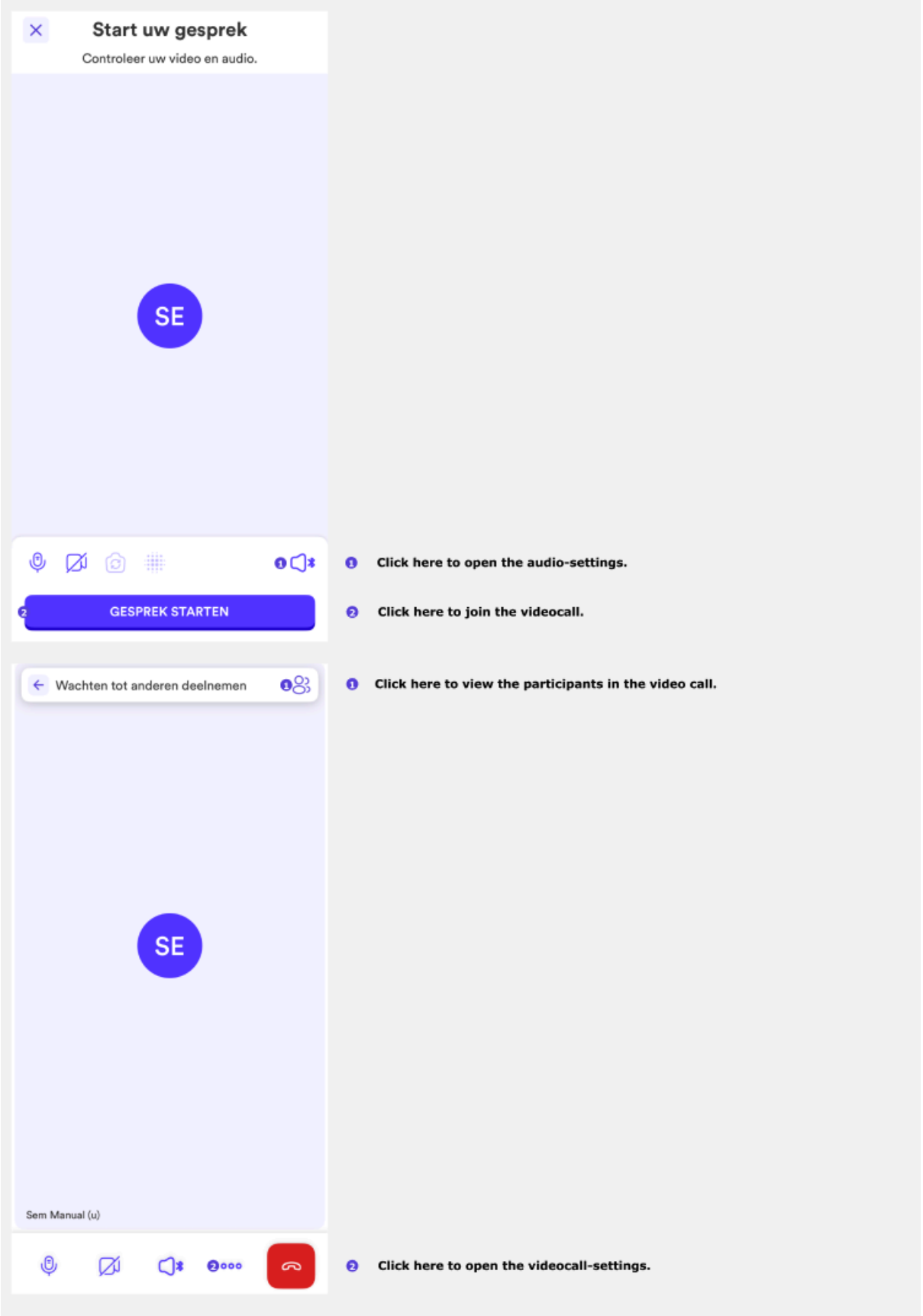
1 **Click here to open the side-menu.**

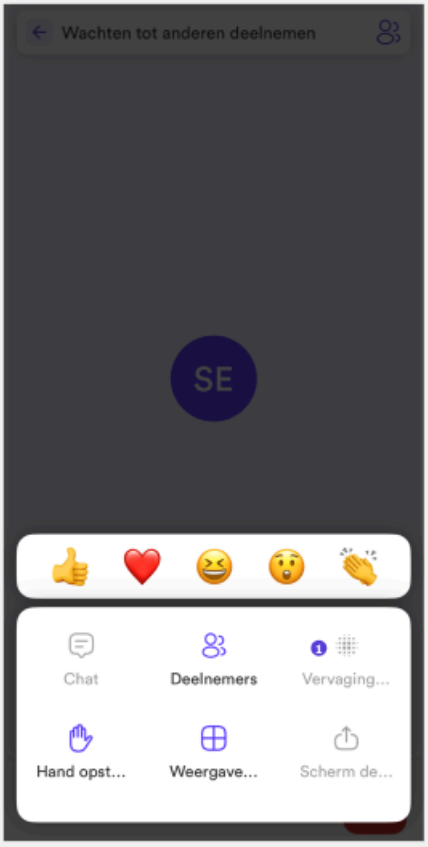


1 **Click here to view the appointment.**

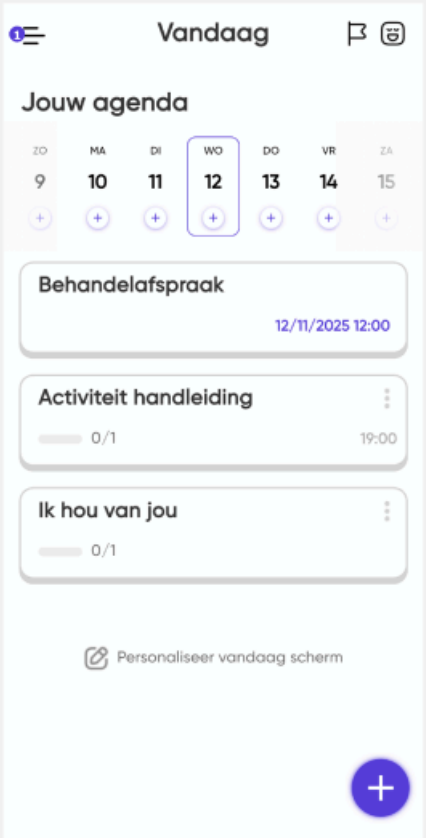
1 **Click here to join the videocall.**

2 **Click here when the appointment is finished.**

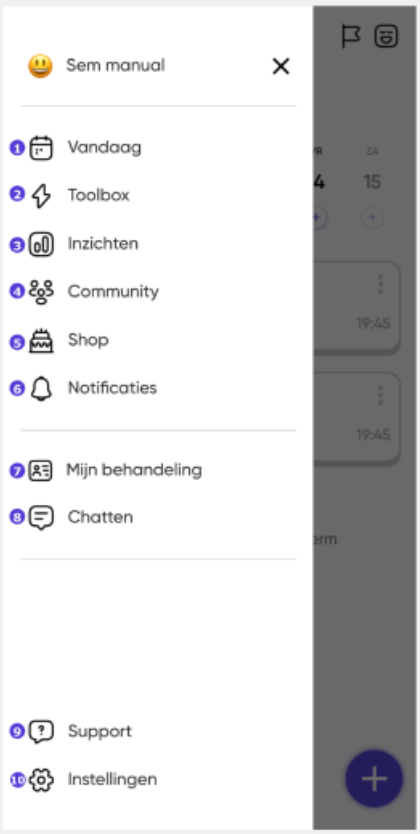

Start uw gesprek
Controleer uw video en audio.
SE
GESPREK STARTEN
Click here to open the audio-settings.
Click here to join the videocall.
Wachten tot anderen deelnemen
Click here to view the participants in the video call.
SE
Sem Manual (u)
Click here to open the videocall-settings.



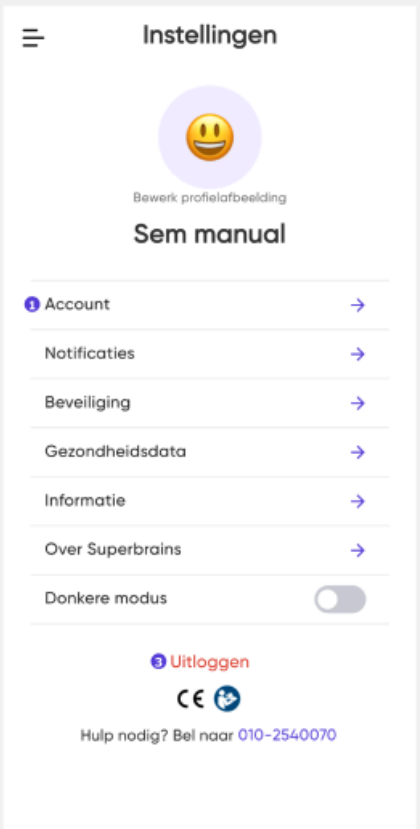
1 **Click here to open the audio-settings.**



1 **Click here to open the sidemenu.**



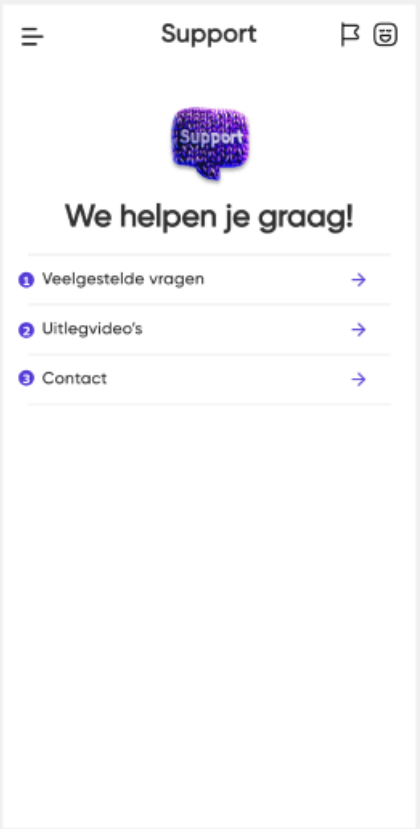
1. **Click here to open the agenda.**
2. **Click here to open the toolbox.**
3. **Click here to open insights.**
4. **Click here to open the community.**
5. **Click here to open the shop.**
6. **Click here to open your notifications.**
7. **Click here to open the treatment-section.**
8. **Click here to open the chat.**
9. **Click here to open the support-page.**
10. **Click here to open the settings.**



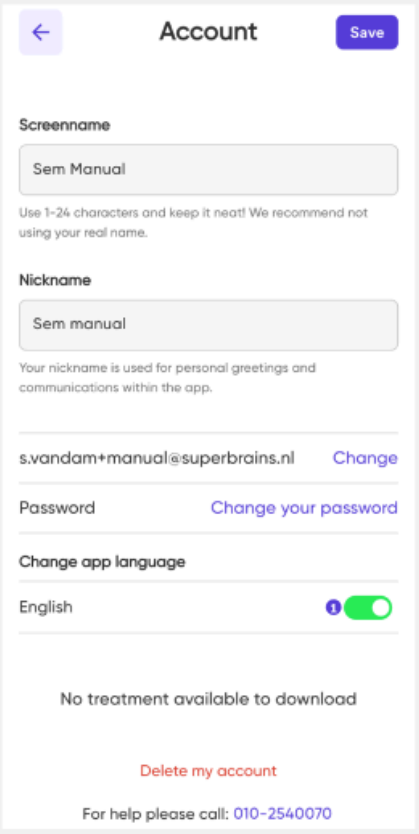
1. **Click here to open the account settings.**

3. **Click here to log out of Superbrains.**

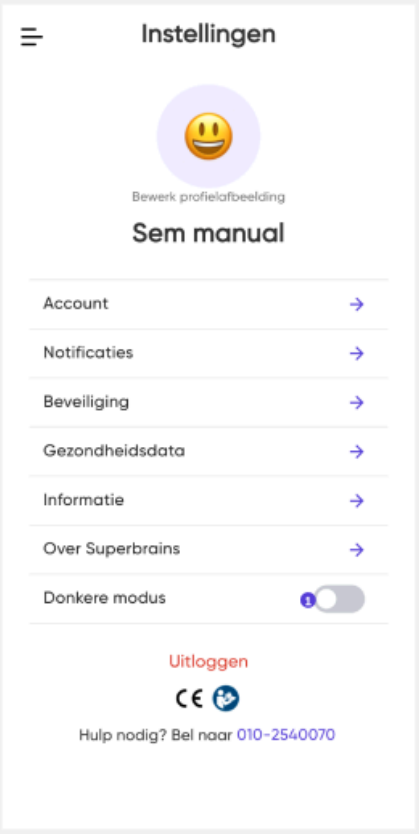
1. **Click here to change your email address.**
2. **Click here to change your password.**
3. **Click here to switch the app to English.**
4. **Click here to delete your account.**



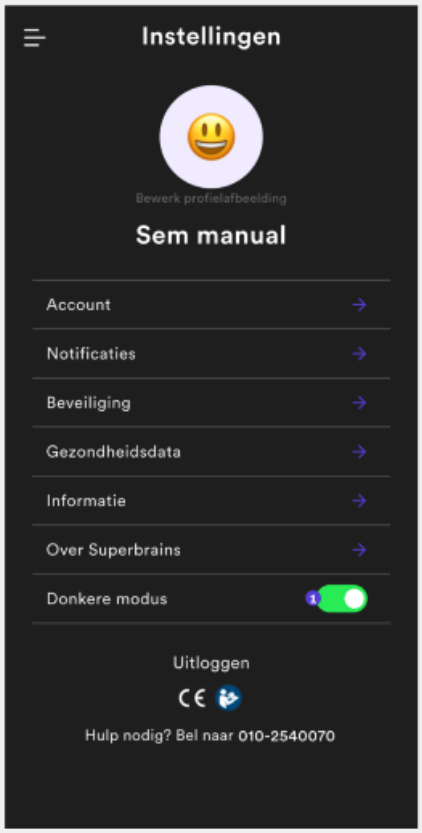
1. **Click here to open the Frequently Asked Questions.**
2. **Click here to view the support videos.**
3. **Click here to open the contact-support page.**



1 **Click here to switch the app to Dutch.**



1 **Click here to switch the app to Dark Mode.**



1 **Click here to switch the app back to Light Mode.**