

somnio

Instructions for use

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The product somnio

somnio is a software application (mobile or browser app) for the treatment of insomnia using cognitive behavioral therapy for insomnia (CBT-I) techniques. It is a medical device with CE marking and a Medsafe and WAND notified product. However, it is not registered as a Medical Device in Australia as the TGA has determined that the product is excluded from regulation by operation of section 7AA of the Act, Therapeutic Goods (Excluded Goods) Determination 2018 (Excluded Goods Determination).

With the help from the avatar "Albert", users define their individual sleep goals. These are monitored and evaluated over the course of the program. In order to achieve these goals, users complete training modules consisting of theoretical knowledge and practical application through exercises, questionnaires, and techniques based on cognitive-behavioral therapy. The content is illustrated by audiovisual elements, e.g. by graphic animations.

The digital sleep journal is an essential tool of the training to record and evaluate sleep data, such as information on sleeping and waking times and general well-being. Based on this sleep data and the individual situation of the client, the therapy is adjusted and personalized continuously.

Who is somnio suitable for?

somnio is designed for individuals who are at least 18 years old who experience **insomnia**



symptoms.

Essential for a successful sleep training with somnio is the willingness and motivation of users to work through the program content and to practically apply the new knowledge and suggestions for behavioral changes in their everyday lives.

Use criteria

You need a **personal e-mail address** and a **device with internet access (computer, laptop, smartphone, or tablet).**

An overview of supported web browsers and devices can be found below. Besides basic computer and internet skills, there are no specific requirements. The technical requirements are:

Desktop & Laptop

- 1.8 GHz CPU (dual core)
- 2 GB RAM
- PowerVR GT7600 GPU (or similar)
- 8GB memory
- Browser: Chrome (v. 83)
 Safari (v. 13)
 Firefox (v. 78)
 Edge (v. 83)

Mobile Devices

- iOS Safari (v. 13.5)
- Android Browser (v. 81) with Android 8.0 or higher
- Chrome for Android (v. 81) with Android 8.0 or later
- Chrome for iOS (v. 84)

Please note that technical requirements may change with newer versions of the software. For the latest requirements, visit https://somn.io/en-au/devices.

Type and duration of the program

somnio is accessible by registration on the website <u>https://au.somn.io</u>.

We recommend to fill in the sleep journal every morning and evening and to work on the 13 training modules 2-3 times a week, in a calm environment and a sitting position.

After completing a certain number of modules (e.g. after modules 1-3), the next module will be activated after you have completed 3 sleep journal entries. However, you should allow yourself enough time to work on the new content and to integrate the practical exercises into your daily life. We recommend a minimum treatment period of 8 weeks.

Exclusion criteria



The use of somnio is **not suitable** for individuals in an **acute mental health crisis**, especially if experiencing **suicidal thoughts** or intentions.

Epilepsy or bipolar disorder are the exclusion criteria for the method of bedtime restriction. At the beginning of the relevant introductory module, users must confirm that they do **not** suffer from epilepsy or bipolar disorder. Otherwise, this module and the bedtime restriction will be omitted.

The online sleep training of somnio does not replace treatment by a doctor or a psychologist. We therefore recommend that all users always consult a medical professional, so that individual backgrounds, which somnio as a digital application cannot capture, are sufficiently taken into account.

Side effects and important notices

The bedtime restriction, a clinically proven non-drug therapy method, is a central element of somnio sleep training. It reduces the time that users spend in bed each night, to help optimize sleep efficiency and quality. Afterwards, the bedtime can be gradually extended again.

This method can temporarily lead to drowsiness, and reduced performance or ability to focus. If this is the case for you, please refrain from activities during which the restrictions could become dangerous (e.g. driving), for the duration of the training.

somnio sleep training is a non-drug therapy. You should not make any changes to your medication and/or other treatments without consulting a qualified doctor.

Please contact your doctor/therapist if your insomnia symptoms do not decrease over a longer period of time or if they worsen.

Sign up for the program

- 1. Open the website (<u>https://au.somn.io/</u>).
- 2. Click on "Create new account".

3. Enter your e-mail address in the corresponding field.

4. Read our <u>Terms and Conditions</u> and <u>Privacy</u> <u>Policy</u>.

5. Check the box "I accept the **Terms and Conditions** and **Privacy Policy**".

6. Read the <u>Consent to the processing of</u> personal and health data.

7. Check the box "I consent to the processing of my personal and health data."

8. Read the Exclusion criteria.

9. Check the box "I have read the exclusion criteria"

10. Check the box "I want to receive the newsletter" (optional).

11. Click "Continue"

12. Enter your 16-digit license code included in the e-mail you have received.

13. Click on "Create account".

14. You will receive a **registration confirmation** by e-mail.

15. Click on the registration link in the e-mail.

16. Choose a password according to the criteria shown.

17. Click on "**Activate account**". You will then be taken directly to the program and a welcome message will be displayed to you.

18. Read the message and click on "ALL CLEAR!". Now you can see the training overview.

Log into the program

- 1. Open the website (<u>au.somn.io</u>).
- 2. Enter your user name and password.
- 3. Click on "Login".

Menu

Training

Select the training modules. Starting with the introduction, work through them one by one (see **Complete training modules**).

The following menu items are visible during the course of the training after completion of the corresponding modules:

• Sleep journal

Enter your daily sleep and waking times and receive overviews and analyses of your sleep efficiency and quality (see also **Complete the sleep journal**).



• Cycle of insomnia

Overview of your personal cycle of insomnia, as discussed in the module.

• Sleep window

Here, you can view and edit the time window you spend in bed, as determined by the digital sleep coach.

You can change your sleep window every 7 days, provided that you have completed at least three journal entries in the last 7 days. If your weekly average sleep efficiency is at least 85%, you can extend the sleep window by 15 minutes. If the efficiency is below 80% on the weekly average, we recommend shortening it by 15 minutes. The sleep window is always at least 6 hours and at most 9 hours long.

Change sleep window:

Move sleep window back (5 minutes per click)



Move sleep window forward (5 minutes per click)

+ 15 minutes: Extend sleep window by 15 minutes

- 15 minutes: Shorten sleep window by 15 minutes

Save sleep window.

Relaxation

Here, you can listen to and/or download the relaxation exercise.

• Sleep Rhythm

Here, you can see a graphic evaluation of your sleep rhythm of the last 3 to 12 weeks. By default you see the last 7 weeks, but you can adjust the evaluation for a period of your choice. Below you see the average fluctuation of the time when you went to bed.

Account

Under this section, you will find various tabs with more information about your account with somnio.

Profile

User account: Name, e-mail address, language, receive newsletter, and e-mail reminders.

You can change the program language here. After making changes, click on "Save profile".

Coach: Adjust speaking rate, show/hide subtitles. Click "Save" after making changes.

Goals: Customize personal training goals. Click "Save" after making changes.

Connection with trackers: Connect a sleep tracker to the training in order to automatically synchronize some relevant tracker data with the journal. In order to add or remove tracker connections, click on "Tracker connection management" and read the instructions of the pop-up window. You will be presented with a list of providers whose activity trackers can be connected to somnio. In the row of your tracker provider, select the data you want to have automatically synchronized by clicking the corresponding box below, followed by "Connect". You will be redirected to an external page. Follow the instructions there. After successful implementation, а confirmation message will appear in somnio and you can view and manage the tracker connection in your profile. You can find more information about sleep trackers here: https://somn.io/en-au/sleep-tracker/.

Create a new password: Enter your old password and the desired new password (including repetition) and click "Save".



Login without password: Click on "Setup". Scan your fingerprint according to the instructions that are displayed depending on the device you are using somnio on. Enter a self-selected name for the device and then click on "Save". You can disconnect this device connection at any time by clicking on "Disconnect device" or the trash can icon.

Export

Export user data: You can download all data stored about you in an interoperable format (JSON). To do this, click "Download".

Export sleep journal entries: You can download all journal entries as an Excel file. Click "Download" for this purpose.

Visual evaluation: You can view or download all journal entries as a PDF file. To do this, click on "View/ Download".

Data security: View and revoke your consent to the processing of personal data and delete your account. To view the consent, click on "Consent"; to view the privacy policy, click on "Privacy Policy"; to revoke the consent, click on "Revoke consent"; and to delete the account, click on "Delete account".

License

Information about the current license you have purchased.

Activate/renew license: By entering a new prescription or license code, the current license can be extended. Paste the code in the text field, read the T&C and PP (open in a popup window after click), check "I accept the T&C and PP" and click "Redeem code". Your new license is activated with immediate effect.

Medical report

View therapy data, create access code or

access link so that medical staff can access your data once or over a longer period of time (more on page 8).

Notifications

Information on software updates.

Support

A pop-up window opens. Click on "Content questions" if you have questions about the application itself. Click on "Technical questions" if you have questions or problems of a technical nature when using the program. You then have the option to send a message with your question to the support team. Alternatively, you can visit the <u>mementor support page</u> or contact us via the e-mail address <u>support-au@somn.io</u>.

Logout

Log out of somnio.

Privacy policy

Clicking on this menu item opens the application's privacy policy in a pop-up window.

Consent

Clicking on this menu item opens a pop-up window with the declaration of consent in short form for the processing of personal and health-related data when using the application.

Sources

Clicking on this menu item opens a popup window with the sources used to create somnio.

About somnio

Clicking on this menu item opens a popup window, with relevant data about the somnio application.

Participate in training modules

To start working on the training modules, please proceed as follows:

1. Open the website and login.

(au.somn.io).

2. In the menu on the left, click on "**My sleep training**" and select a sleep training module.

3. A welcome screen with a short module description will be displayed.

4. Click on the **arrow** to launch the session. If you have previously worked on this module, the module will continue at this stage. If you would like to start over, click on "**Restart**".

5. Listen to the steps introduced and follow the instructions from the digital sleep coach.

6. Reply to the questions by clicking on the corresponding tabs.

7. Navigation in the module:

- I rewind
- pause
- forward
- return to module selection
- show/hide menu

8. After completing a module, the next one will be unlocked. Some modules will be unlocked, after three new sleep journal entries have been created.

Complete the sleep journal

In order to create a sleep journal entry, proceed as follows:

1. Log in to the program.

2. Open the sleep journal in the menu on the left.

3. You will see an overview of your previous entries.

After getting up: Morning log

Make sure that the "Morning log" tab is selected in the upper left corner.

Click on the plus sign above the respective date.

• Fill in the fields:

"To bed from" (enter time).

"When did you get up" (enter time).

If applicable, click the tab "I didn't fall asleep".

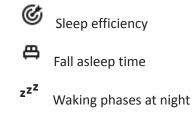
Otherwise, fill in the blanks:
"Awake time in sleep phase"
"Woke up"
"How was your sleep quality?" (select on

the slider)

- In any case, complete the field "In bed until".
- Click on "Save".

Evaluations

- Your daily sleep efficiency in % is displayed in the orange circle. You can find more information by clicking on the entries, the arrow keys, and the different icons.
- View your 7-day average:



 The arrow icons at the bottom indicate if you are getting closer to your personal goal(s) during the last 7 days. Through tapping/hovering over them, you can see your +/- tendency in percentages.

At the end of the day: Evening log

Select the "**Evening log**" tab in the upper right corner.

- Mood: Rate your mood, performance, and energy over the past day.
- Consumption: Select the amount of alcohol and caffeine consumed: "none", "little", "medium" or "high". Click "Save".
- You can now view the evaluations of your daily well-being and consumption. At the bottom, you can see your respective 7-day average on a scale of 10:



Performance

Energy

- If you would like to **edit** an entry, select it in the overview and click the "Edit" button.
- If you would like to **delete** an entry, select it and click on the trash can icon.
- At the top right, you may choose whether you would like to view the data as a weekly overview (Week), or over the course of the entire training (Overall).

Share data with medical personnel

- 1. Run the application and log in.
- 2. Use the program-internal function

"Medical report".

3. By clicking on "View medical report", you have the option to get an overview of your therapy data.

4. In order to make this data available to medical personnel, you have 2 options:

Access code: If you would like to share your data directly in the consultation, you can generate an 8-digit access code, which you then communicate verbally to your treating professional.

- Click on "Create access code".
- Medical staff opens the website <u>https://au.somn.io/doc</u> and enters the code you provided.
- You will receive a notice in your app that your practitioner would like to view the data. Click "Yes" to consent.
- The medical staff can view the therapy data within the next 24 hours. Afterwards, an automatic logout takes place.

Access link: If you would like to share your data with your treating specialist over a longer period of time and independently of the consultation hour, create an access link with which the specialist can access your therapy data at any time without manual confirmation.

- Click on "Create access link".
- Copy the link that now appears into the clipboard and send the link to your healthcare professional.
- Your specialist can now view your therapy data again and again for 3 months (or until your license expires).
- If you want to extend the access, click on "Extend". You will see directly below the link until when access is granted.

5. If you wish to delete the access code or access link, click "Delete access code" or "Delete access link".

Instructions for medical personnel/therapists

Use criteria

You need a **device with internet access** (computer, laptop, smartphone, or tablet). For an overview of supported **web browsers** and devices, please visit <u>https://somn.io/en-au/devices</u>



Apart from basic computer and internet skills, no training is required in order to be able to use the program.

Type and duration of application

You can check the report in the program which includes the development of therapy data. Your client can give you access to their data for either 24 hours or 3 months (or longer).

Access to therapy data with access code (24 hrs.)

1. Open the website https://au.somn.io/doc/

2. Enter your name or that of your institute, under which the client can recognize you, and the access code that you received from the client. Click on "Load evaluation".

3. The client must agree to the access. Once this has been done, you will receive an overview of:

- Program start, progress, connected devices, number of journal entries
- Overview of the various sleep data
- Current progress in the training modules

4. You do not need to log out yourself, after 24 hours it will be done automatically, or whenever you close the browser. With the access code, the client grants you access for 24 hours.

Access to therapy data with access link (3 months)

1. Open or click on the link that your client sent you.

2. You will receive an overview as described under 3. of the previous section "Access to therapy data with access code (24 hrs.)". With either method of access to therapy, you have the possibility to download the displayed overview as a PDF file by scrolling to the bottom of the page and clicking on "Download as PDF".

Support

If you have questions or problems concerning the use of the program, please visit the <u>mementor support page</u> or send an e-mail to <u>support-au@somn.io</u>.



somnio is a medical device in the EU and New Zealand. Note: Not a medical device in Australia. The TGA has determined that the product is excluded from regulation by operation of section 7AA of the Act, Therapeutic Goods (Excluded Goods) Determination 2018 (Excluded Goods Determination).

Created by



mementor DE GmbH Karl-Heine-Str. 15 04229 Leipzig, Germany www.mementor.de

Importer



Edensleep New Zealand Ltd, 131 Cobham Drive, Hamilton East, Hamilton, 3216, New Zealand

ResMed Asia Pacific Limited, 1 Elizabeth Macarthur Drive, Bella Vista, NSW 2153, Australia

Distributor



Edensleep New Zealand Ltd, 131 Cobham Drive, Hamilton East, Hamilton, 3216, New Zealand

ResMed Asia Pacific Limited, 1 Elizabeth Macarthur Drive, Bella Vista, NSW 2153, Australia

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