Nia

Nia App User Guide

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Fields of use	1
Intended use	1
Who is the Nia App suitable for?	1
On which devices does the Nia App work?	1
User environment	1
Contraindications	1
Warning	1
Medical recommendation	1
Recommended updates	2
Essential functions	2
Summary	2
Essential functions	2
Getting started	2
Installation	2
Features	3
Start page	3
Analytics page	3
Plus button	3
Knowledge	4
More menu	4
Entries	4
Skin mood entry	4
Life quality index entry	5
Flare-up entry	5
Uninstallation	6
Uninstallation iOS	6
Uninstallation Android	7
Data security and data protection	7
Help	7
Troubleshooting	7
Support	7
Manufacturer information	7

1 Fields of use

1.1 Intended use

The product "Nia" collects individual data of patients with atopic dermatitis for calculation of dermatological scores for diagnosis and treatment support of the treating physician.

The users of the mobile application are self-affected patients or relatives of affected patients in the case of children under 18 years of age. The users are experienced in handling mobile devices and have previous knowledge about atopic dermatitis.

The application requires a smartphone supporting the operating system Android (from version 4.1) or iOS (from version 10.0) and is intended for home use.

1.2 Who is the Nia App suitable for?

The Nia App was developed for people:

- who are 18 years or older
- who have been diagnosed with atopic dermatitis or
- are the parents of a child suffering from atopic dermatitis
- who are under the supervision of a doctor or health care professional
- who are physically and mentally capable of independently taking care of their atopic dermatitis therapy
- who are capable of operating a smartphone

1.3 On which devices does the Nia App work?

The Nia App requires a device with iOS version 10.0 or higher or Android version 4.1 or higher.

Operation of the Nia App on rooted devices or with jailbreak installed is not supported. For data security reasons, it is not recommended to use the Nia App on such devices.

1.4 User environment

The Nia App can be used as a mobile app in any environment where the use of smartphones is allowed. For full use, a connection to the Internet must be available.

2 Contraindications

None known

3 Warning



3.1 Medical recommendation

The Nia App is a registered medical device and is used to support the treatment of atopic dermatitis, but cannot replace a visit to a doctor or an atopic dermatitis treatment team.

3.2 Recommended updates

To ensure the safe and optimal use of the Nia App, it is recommended to install software updates as soon as they are available.

4 Key features

4.1 Summary

Nia would like to make the daily management of atopic dermatitis easier and make your therapy as optimal as possible. This is only possible if you take an active role in your care, especially when it comes to tracking your skin condition. To motivate you, we have included some elements in the app. It is important that you enter as much information as possible and be honest with yourself. That's the only way you can learn from your values. False data will not help you or your doctor.

Nia main functions:

- Straightforward data entry
- Personalized evaluation overview (professional graphs)
- Practical photo documentation (several pictures per affected area possible)
- Knowledge Library
- Exciting challenges and motivating notifications
- Report (PDF)
- Practical documentation reminder

4.2 Essential functions

- Simple and fast recording (e.g. PO-SCORAD¹ and flare-ups)
- Convenient evaluation
- Useful and helpful photo documentation
- Motivational notifications
- High quality report
- Motivating feedback
- Social Sharing Function
- Course material

5 Getting started

5.1 Installation

iOS: After you find the Nia App in the <u>Apple App Store</u>, tap on it to open the details. Then press the "Load" button. After the App Store Authentication, the loading process will start and the app will be installed on your iPhone.

Android: After you find the Nia App in the <u>Google Play Store</u>, tap on it to open the details. Then press the "Install" button. You will have to accept the installation conditions to download the app. The download process will start and the app will be installed on your Android phone.

¹ The PO-SCORAD calculation is based on concepts of <u>clinically validated metrics</u>



To use the Nia App, you must first register with your name and email address. This is necessary to be able to export your data later (see Reports).

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6 Features

In the lower menu bar you will find the five functions, which you can quickly select with just one tap

6.1 Start page

You can access the overview page by tapping on the "Start" button (house symbol) on the far left of the lower menu bar.

Under the 'Regular checkups' title, you can find three dimensions; skin mood, life quality index and flare-ups. Tap on relevant dimensions to make an entry, or alternatively, select the center plus button in the lower menu bar (see 6.3).

Under the 'For The Doctor's Appointment' heading, you will find 'The PDF Report', where you can generate a report containing all the information from entries of a chosen time period. Alternatively, scroll to the bottom of the analytics page. Under the same heading you will also find 'Preparation for doctor's appointment', designed to help you get the most out of your next visit to your dermatologist. Under the final title 'Therapy support', you can select 'Reminder Notifications' to create prompts, for example to take medications or make entries in the app

6.2 Analytics page

You can access the analytics page by tapping on the analytics symbol (the three small vertical bars). The eight elements in the analytics display are the graphs for **PO-SCORAD**, for **Symptom Strength** (dryness, oozing/scabbing, redness, scratch wounds, swelling, skin thickening), for **Subjective Symptoms** (itching and sleep disturbance), for **flare-ups**, the list of your most common triggers, the **Life Quality Index graph**, **the body diagram** for the affected skin areas, as well as the **images** of affected skin areas sorted by date. You can also choose whether to view these results from the last 7 days, last month, or last 3 months. At the very bottom of the screen, you can quickly generate a report of the data from a specific time period.

6.3 Plus button

Via this button, which can be found in the lower center of the screen, you can make entries for skin mood, life quality index and flare-up.

6.3.1 Skin Mood

The menu item 'Skin Mood' (the standing person symbol) is a documentation tool used to determine the severity of the atopic dermatitis on a particular day and calculate your PO-SCORAD. This is collected by asking questions regarding your symptoms (supported by photo documentation), itchiness and sleep quality.

6.3.2 Life Quality Index

Using the Life Quality Index menu item (the seated person symbol), you can monitor the effect of your skin condition on your daily life including your physical and psychological well being. Your PO-SCORAD score will also be calculated in this case.

6.3.3 Flare-up

Using the Flare-Up Record menu item (the alarm symbol), you can record particular outbreaks of your atopic dermatitis. You can document your opinion on potential triggers using a list of common triggers or by creating custom triggers.

6.4 Knowledge

By tapping on the symbol of the small doctor's hat on the right side of the lower menu bar, you will reach the menu item Knowledge. Here you will find clinically validated atopic dermatitis contents in an extensive knowledge library in the categories of medical basics, psychology, care and nutrition. The contents are based on the curriculum of the AGNES e.V. (working group for atopic dermatitis training). You can access the contents at any time by tapping on the respective article. In the overview you can see the estimated reading time per article by the clock symbol. In addition, the play symbol tells you whether the article is additionally equipped with video material.

6.5 More Menu

Via the 'More' menu in the far right corner of the lower menu bar (symbol of the three horizontal small lines), you can access further functions:

User Settings

By selecting 'Account', you can manage your name, email, phone number and password information.

By selecting 'Authenticator', you will be taken to an information page with details on how to confirm your identity.

Introduction

Here you will find information about what the Nia app can achieve for you. By helping you to better understand your skin condition, preparing you for your doctor's appointments and providing you with relief through tips and knowledge, the Nia app can change your relationship with your atopic dermatitis.

Medical History

Here you make the app your own. Nia needs to know a few details about your health history to work. Bonus: With this you have all your atopic dermatitis information in one place!

Your Health Report

You can generate a report containing all the information you have inputted within a custom selected time period. Once the report has been created, you can export the data via the 'share' button.

About Nia

User Manual

Here you will find the document designed to assist your seamless use of the Nia App.

Medical disclaimer

Here the medical recommendation is referred to.

Data privacy

Here you will find our detailed privacy policy of the Nia App.

Terms & Conditions

Here you will find the rules and guidelines for using the Nia App.

Imprint

Here you will find information about the manufacturer, Nia Health GmbH.

Cooperation Partners

Here you can find information on our content and sponsoring partners.

Insurance Companies

Here you can find information about the health insurance companies we cooperate with. You can also activate the code provided by your insurance company to access the premium version of the app here. Other codes that can be inputted here might include those provided as a result of a challenge or study which unlock additional functions in the app.

Feedback

Here you can use your experience to influence the further development of the Nia App. You can suggest areas where you see potential for improvement or development. Praise is also always welcome.

Tell a friend

You can use this function to tell your friends and acquaintances about Nia. Do you know somebody who is also affected by atopic dermatitis?

Log out

With this menu item you can log out of your user profile with the Nia App. For security reasons, you will have to enter your password again the next time you log in.

7 Entries

7.3 Skin Mood Entry

You can select this function via the "Skin mood" menu item on the start page or via the plus button in the lower menu bar. Once selected, you can create the entry by following these steps:

- 1. Select the medication you are currently using.
- 2. Mark the areas affected by eczema.
- 3. Take a photo of the respective body region by double selection of the affected areas. Double selection will also allow you to deselect an incorrectly chosen area.
- 4. Select the current strength of the atopic dermatitis symptoms using sample images.
- 5. Retain sleep quality and itching
- 6. Add any important notes to the entry, such as the occurrence of particular events
- 7. Tap the "Save" button to complete the new entry

After entering all data, your results will appear in an easily readable format including a skin mood rating calculated by the app.

Well done! You will now find your new entry in "analytics" selected via the lower menu bar. Scroll to the bottom to view the results from a particular entry,

7.4 Dermatology Life Quality Index (DLQI) Entry

You can select this function via the "Dermatology Life Quality Index" menu item on the start page or via the plus button in the lower menu bar. Once selected, you can create the entry by following these steps:

- 1. Rate the soreness, painfulness and itchiness of the eczema over the past week from "very much" to "not at all"
- 2. Rate the self-consciousness caused by the eczema over the past week.
- 3. Rate the interference with daily activities such as going shopping or looking after your home.
- 4. Rate the eczemas influence over the clothes you have worn
- 5. Rate the effect on your social or leisure activities
- 6. Rate the effect on your ability to perform physical activities
- 7. State whether the condition has affected your ability to work or study
- 8. Rate the effect on relationships with your partner and other acquaintances
- 9. Rate the extent to which your skin has caused sexual difficulties
- 10. Rate how much of a problem the treatment for your skin has caused, for example by taking up time

After entering all data, your results will appear in an easily readable format including a life quality index rating calculated by the app.

Well done! You will now find your new entry in "analytics" selected via the lower menu bar. Scroll to the bottom to view the results from a particular entry.

7.5 Flare-Up Entry

You can select this function via the "Flare-up" menu item on the start page or via the plus button in the lower menu bar. Once selected, you can create the entry by following these steps:

- 1. Rate the flare-up on a scale of 1 (extremely low) to 10 (extremely strong)
- 2. Mark the areas affected by eczema.
- 3. Take a photo of the respective body region by double selection of the affected areas. Double selection will also allow you to deselect an incorrectly chosen area.
- 4. Select the possible triggers for the flare-up. You can either choose from a list of common triggers, or you can create a custom trigger.
- 5. Finally, make any additional notes that you consider to be relevant

After entering all data, your results will appear in an easily readable format including a flare-up rating calculated by the app.

Well done! You will now find your new entry in "analytics" selected via the lower menu bar. Scroll to the bottom to view the results from a particular entry,

8 Data Export

Select "Request report" at the bottom of the "Overview" menu item. You can now print out the PDF report or send it to your doctor by e-mail before your next appointment.

9 Deinstallation

9.3 Deinstalling iOS

Tap the Nia App icon and hold it until it starts shaking. Tap on the small "x" that appears in the upper corner. You will receive a message asking you to confirm (by tapping "Delete") or cancel (by tapping "Cancel") the uninstall.



8.2 Deinstalling Android

Search for apps in the settings of your Android smartphone and tap on the Nia app "Uninstall". Done!

10 Data security and data protection

Your data is safe with us. This is important to us. The strict requirements of the DSGVO are fulfilled by us. This means for you that Nia takes into account the highest security and reliability requirements. Your data will only be used for the purpose of score calculation and thrust trigger analysis and the results will only be made available to you. A transfer of data to third parties does not take place at any time. Nia Health GmbH operates dedicated servers in certified data centers in Germany to ensure that your data is protected from unauthorized access at all times. Due to the grey area of data protection law when using cloud providers for medical data, we have decided against using providers such as Google, Amazon or Microsoft, so we can offer you the optimum in data protection.

Your data is encrypted (TLS 1.2+) for transmission and access is secured by token-based authentication (openid) and authorization (oauth2).

Further information can be found in the privacy policy, as well as in our terms and conditions, which you can select directly from the "more" menu of the Nia app.

11 Help

11.3 Troubleshooting

We care about you! That's why we like to take care of your questions, worries and other concerns.

For quick troubleshooting please visit our FAQ Page

11.4 Support

If you have any questions about Nia, need help with the app or have found an error or problem, please contact us immediately at support@nia-health.de.

You can also reach us at the following phone number: +49 (0)30 83797797 (Germany)

In the event of serious incidents related to the use of this medical device, contact Nia Customer Service and the appropriate local authority.

12 Manufacturer information



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