



# HORIZON 2020

The EU Framework Programme for Research and Innovation



# CAPABLE

**Cancer Patients Better Life Experience**

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## ***Deliverable No. 6.2*** **User Interfaces prototype 1**

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| Deliverable Type    |   |          |
|---------------------|---|----------|
| <b>R</b>            | Document, report  |          |
| <b>DEM</b>          | Demonstrator, pilot, prototype                                      | <b>X</b> |
| <b>DEC</b>          | Websites, patent fillings, videos etc.                              |          |
| <b>OTHER</b>        |   |          |
| Dissemination Level |   |          |
| <b>PU</b>           | Public  | <b>X</b> |
| <b>CO</b>           | Confidential (Consortium members including the Commission Services) |          |
| <b>CI</b>           | Classified Information (Commission Decision 2015/444/EC)            |          |

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## 1. Versions History

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| Version | Date       | Author              | Comments                          |
|---------|------------|---------------------|-----------------------------------|
| 1.0     | 27/06/2021 | Valentina Ganicheva | Initial draft                     |
| 2.0     | 02/07/2021 | Valentina Ganicheva | implemented comments after review |
| 3.0     | 5/07/2021  | Valentina Ganicheva | Final version                     |
|         |            |                     |                                   |

## 2. Executive Summary

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The aim of this deliverable is to illustrate the progress of the User-interface (UI) creation. This deliverable will provide an overview of the UI screenshots of both the mobile app for the Patients and web system for the Physicians.

UI mock-ups for the Physician's Web System and Patient's Mobile App are developed using Agile software development methods. According to the iterative approach, the figures with screenshots in Section 3 and Section 4 show the result of the second iteration of the UI development.

The UIs prototypes created cover current functional requirements which are described in detail in the Deliverable 2.1 "Requirements table and use case description" in Section 4.7 "Use case diagram" and in Section 5.9 "Use case diagram and functional requirements".

While producing the mock-ups, we considered that UIs should be user-friendly, simple, attractive, responsive and clear to engage users and not to create additional barriers.

All elements that are placed on a layout are there for a reason: we try to predict the user's expectations and place key elements exactly where needed for an optimal interaction.



### 3. Patient's Mobile App user-interface

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The Link to the prototype: [Link](#)

The Link to the UI Design: [Link](#)

The Patient's app will provide the following high-level functionalities:

- Tracking the health status: the CAPABLE application will provide a wide tracking of patient's health status through:
  - a system of symptoms reporting recorded by the patient
  - a follow-up of the symptoms reported
  - health questionnaires to be filled in by the patient
  - monitoring through the Activity Tracker device (the exact device will be specified during Year 2 of the project).
- Therapy Management: patients will be able to set up specific reminders related to the daily/weekly therapy.
- System recommendations: the application will provide different contents to the patient. These contents will be assigned to a patient helping to follow the therapy such as:
  - suggested actions to improve their wellbeing
  - feedbacks about the activities performed by the patient (questionnaires, info from the Activity Tracker device)
- Digital intervention through Goals and Capsules: it will be composed by educational content, specific exercises and physical activity to promote the wellbeing of the patients.
- Management of a patient's preferences: CAPABLE app will be customizable and configurable by the patient in terms of hobbies, activities to perform, type and timing of reminders
- CAPABLE will provide patients with a clear explanation of his rights in terms of privacy, and more in general GDPR.

The app is not only a method for reporting the symptoms to a physician, but it represents a real learning experience and something that will simplify patients' life.

The concept of the App is to support users during their cancer journey.

The main objective of this mobile application is to:

- empower patients to be aware of their health conditions and gaining control over decisions and actions affecting their health.
- to support patients to adopt a healthy lifestyle and positive attitude in their daily routine.
- Ease the communication of vital signs and side effects to the clinician, creating a sort of diary accessible to both sides.

The following figures with the screenshots show how that needed functionality is implemented into the App.

### 3.1 Health Status

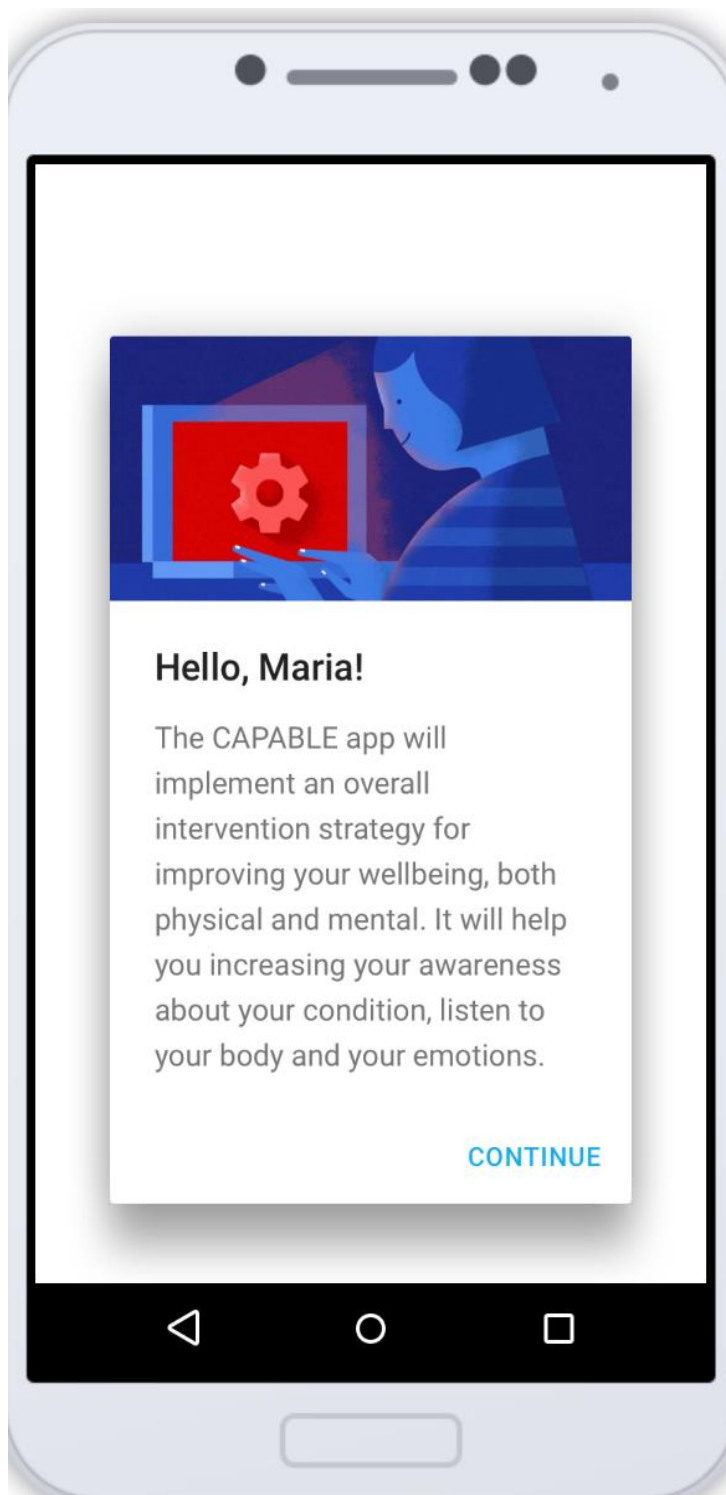


Figure 3.1.1 Onboarding - Introduction of a CAPABLE System to a Patient.

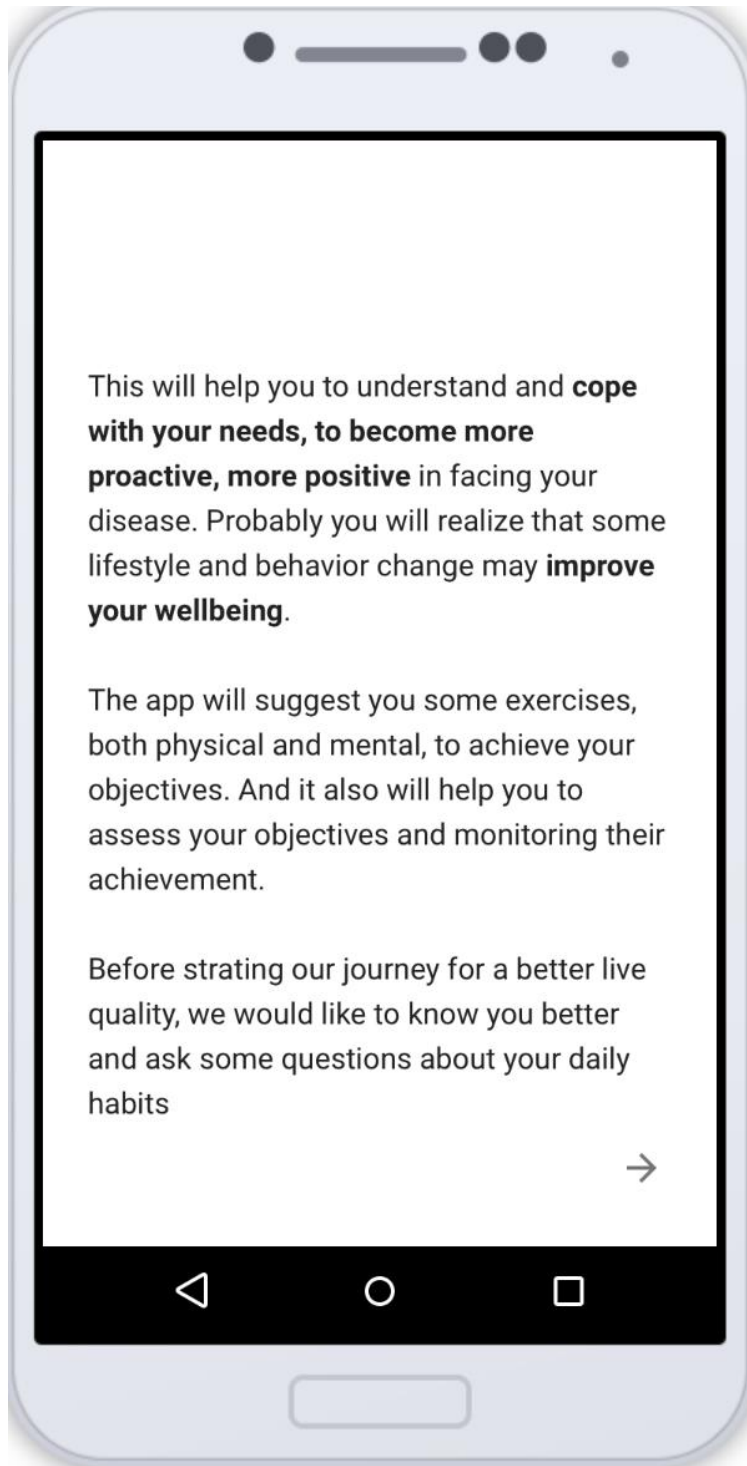


Figure 3.1.2 Onboarding - Introduction of a CAPABLE System to a Patient.

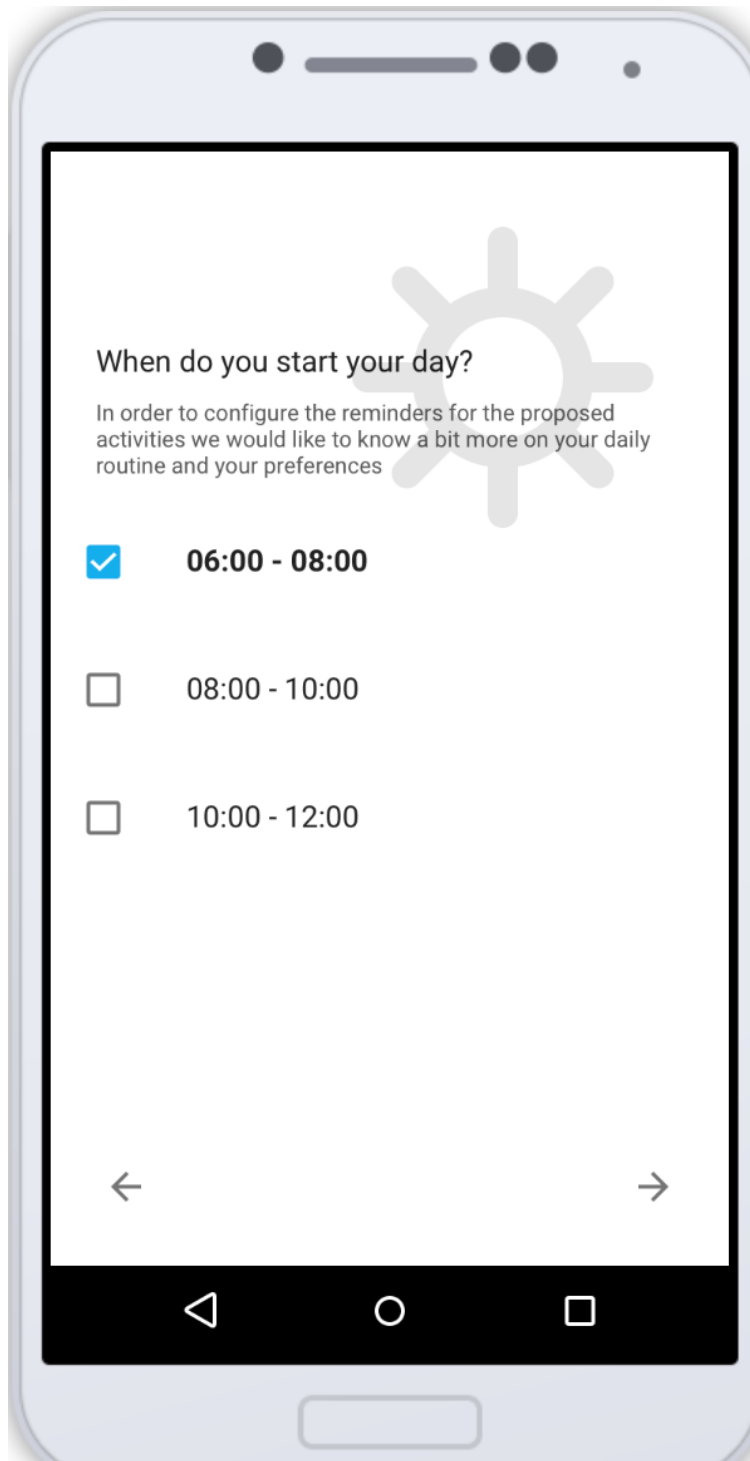


Figure 3.1.3 Onboarding - Patient's preferences about waking time.

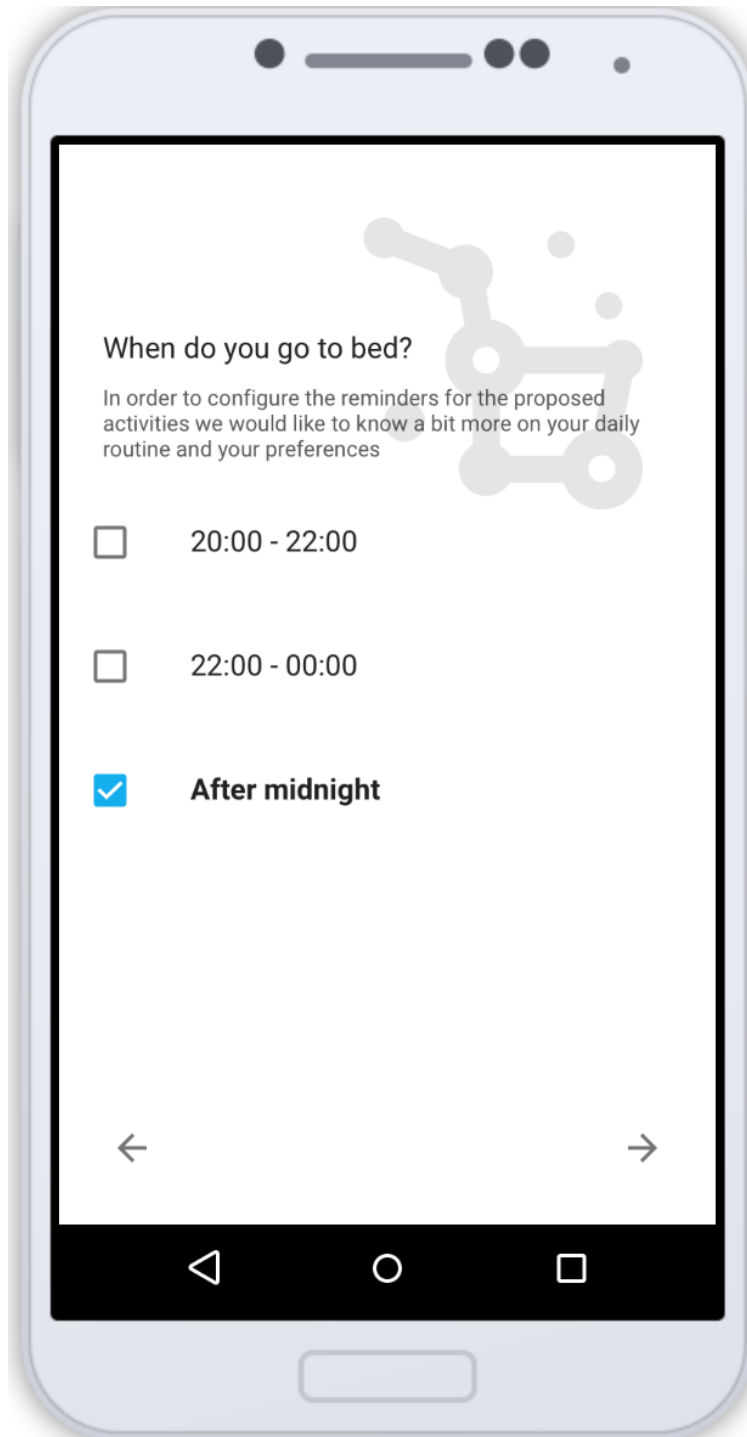
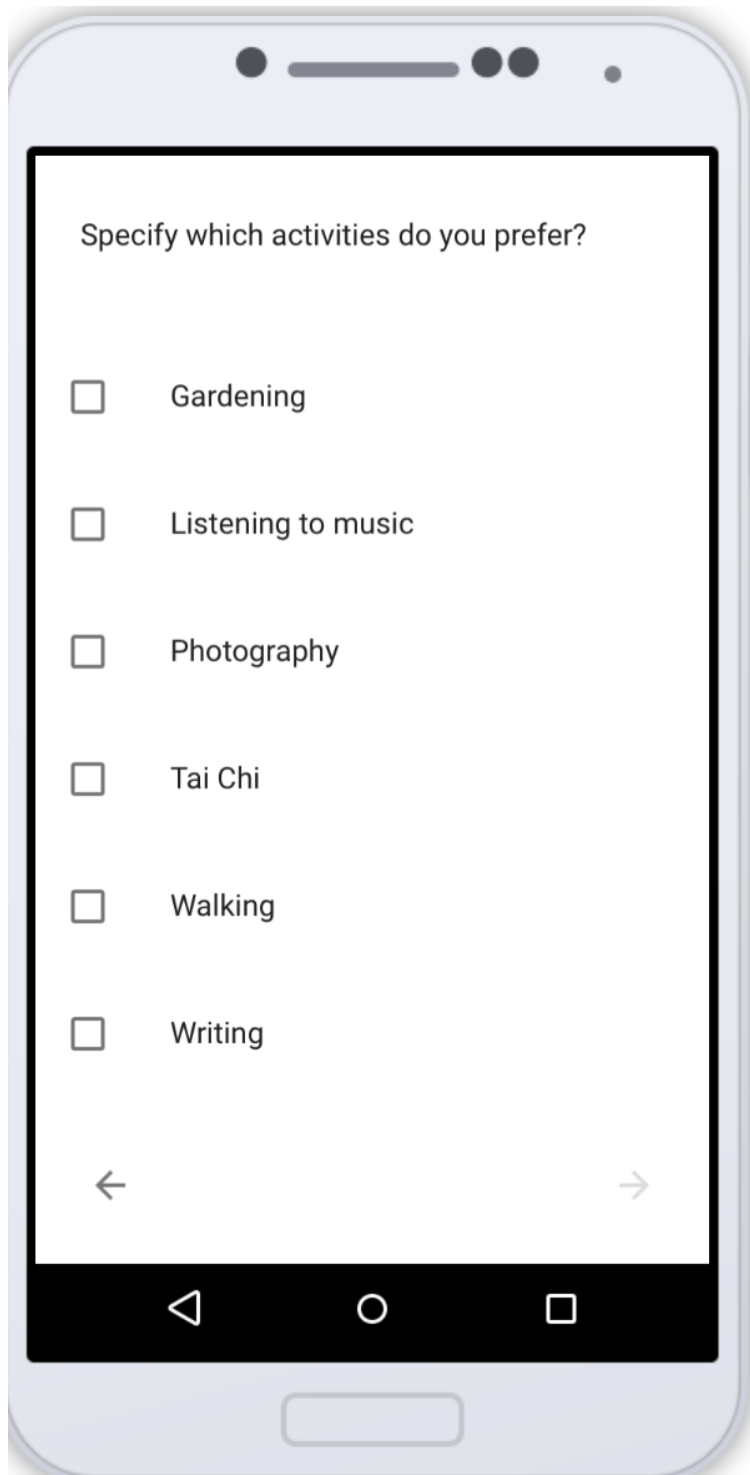


Figure 3.1.4 Onboarding - Patient's preferences about bed time.



Specify which activities do you prefer?

- ☐ Gardening
- ☐ Listening to music
- ☐ Photography
- ☐ Tai Chi
- ☐ Walking
- ☐ Writing

← →

Figure 3.1.5 Onboarding - Patient's preferences about hobbies.

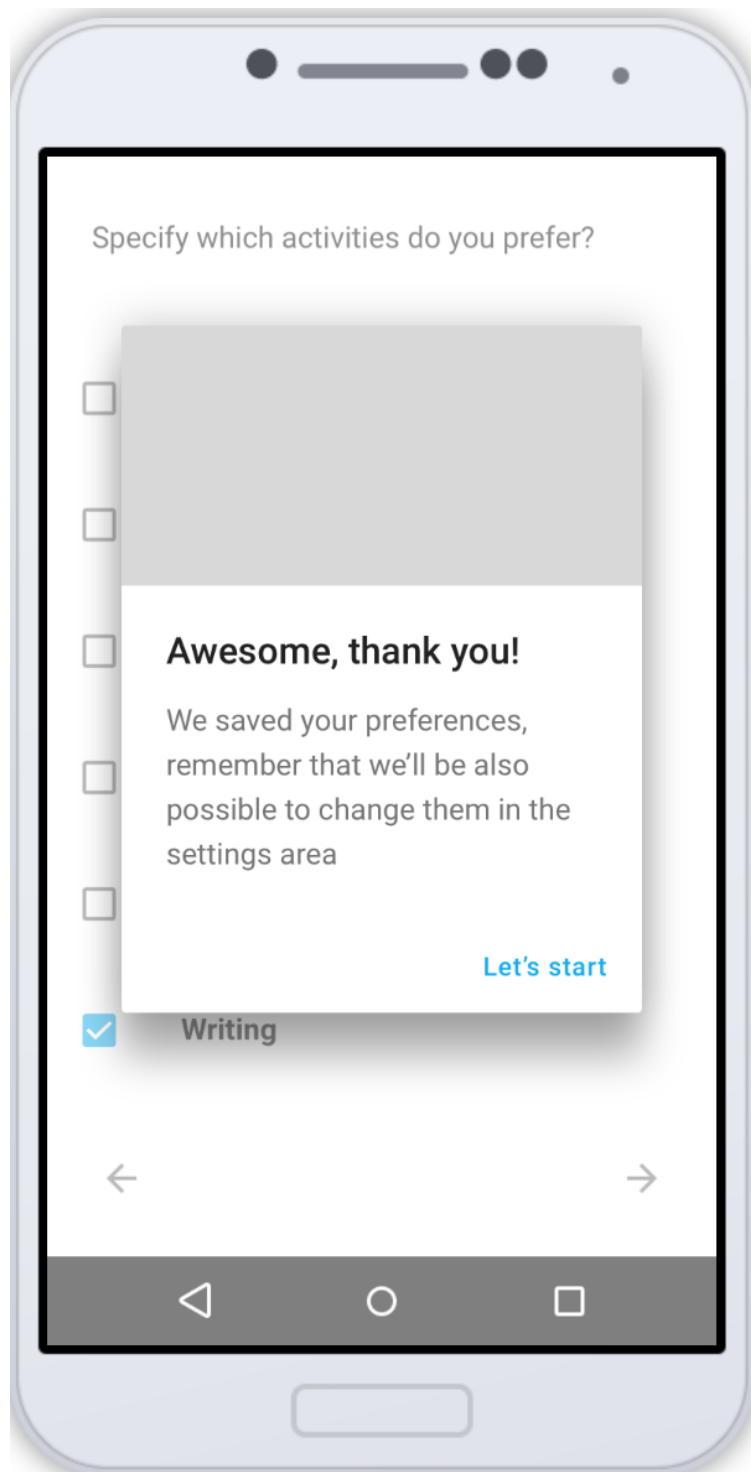


Figure 3.1.6 Onboarding - Patient's preferences and hobbies.

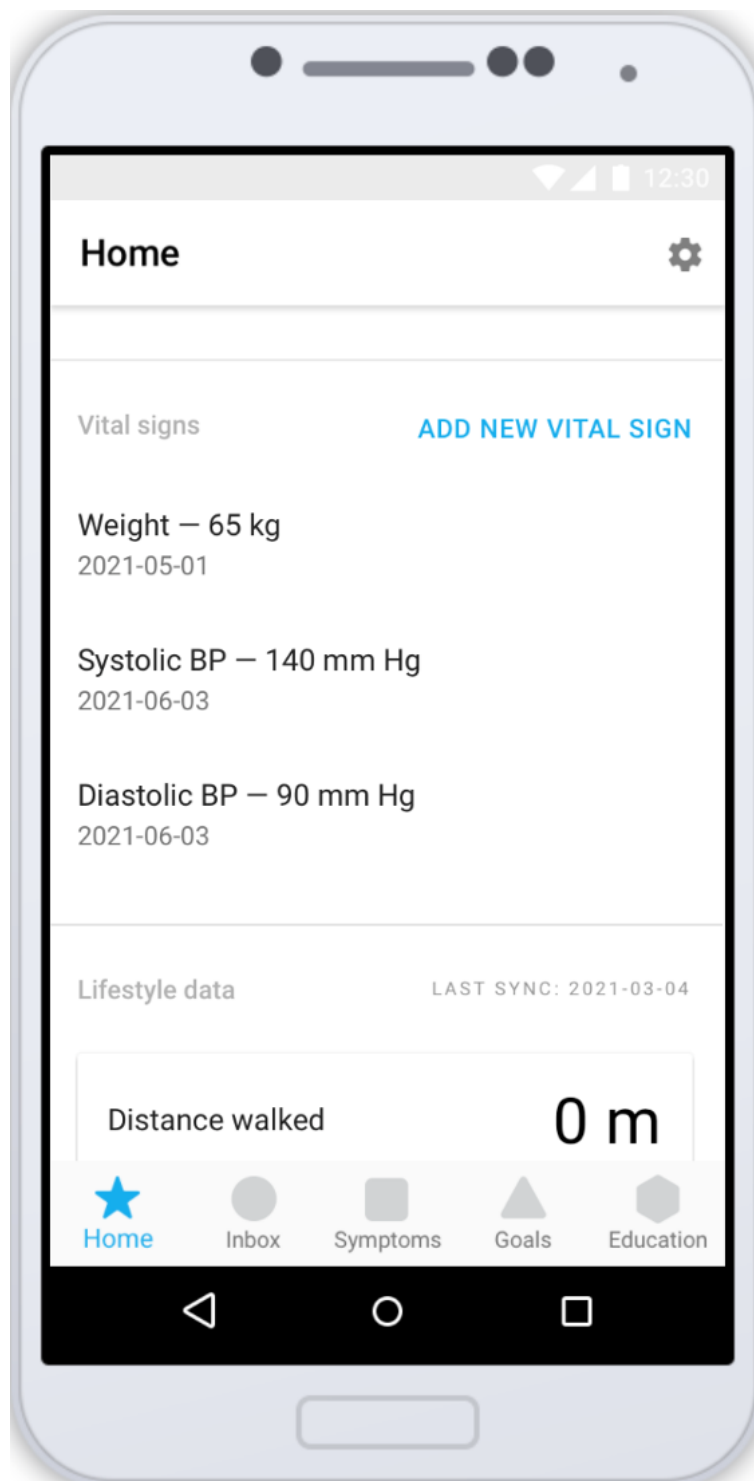


Figure 3.1.7 Home tab with the Vital signs – weight and blood pressure data entered manually by a Patient.



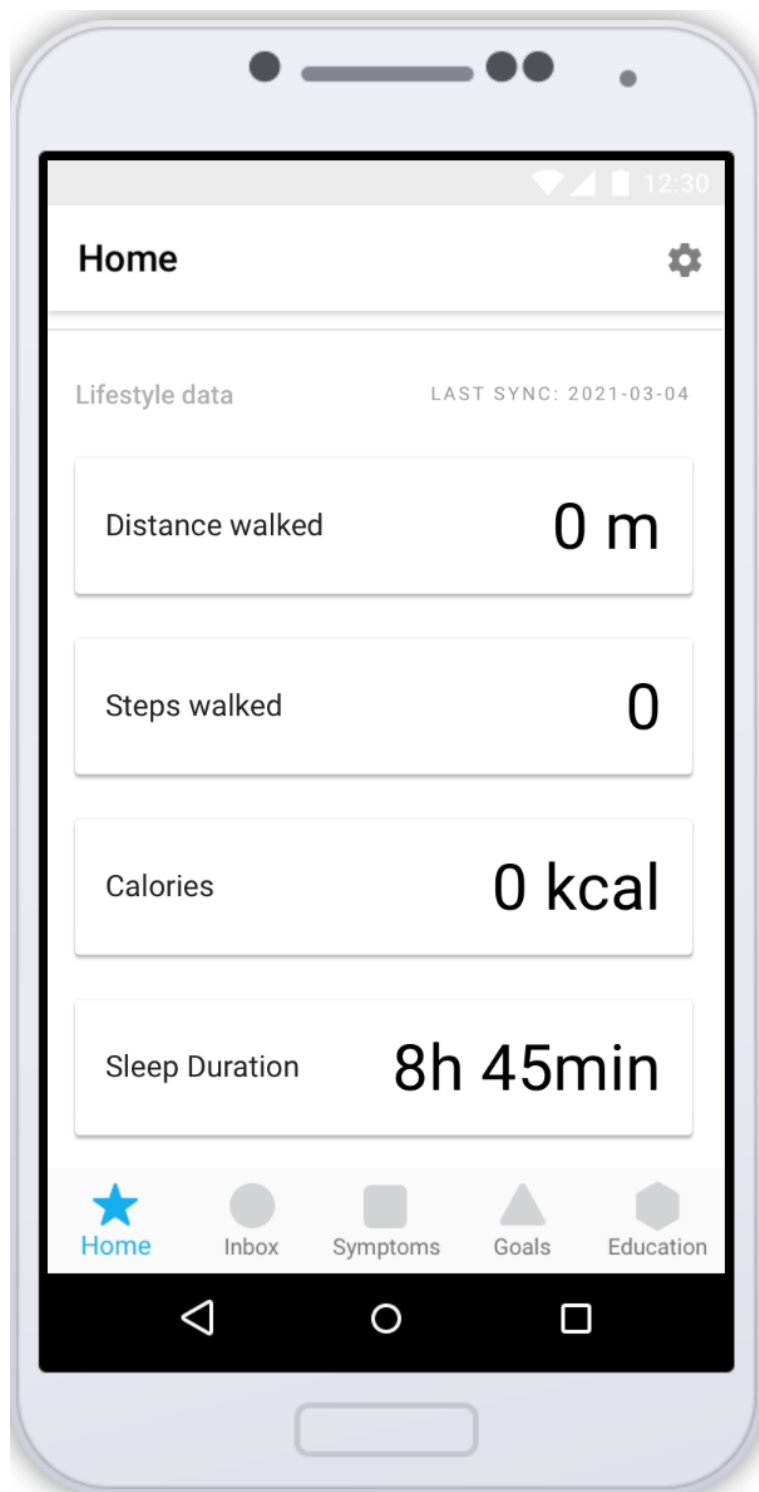


Figure 3.1.8 Home tab with the Data from connected Sensor and the last synchronisation date and time.

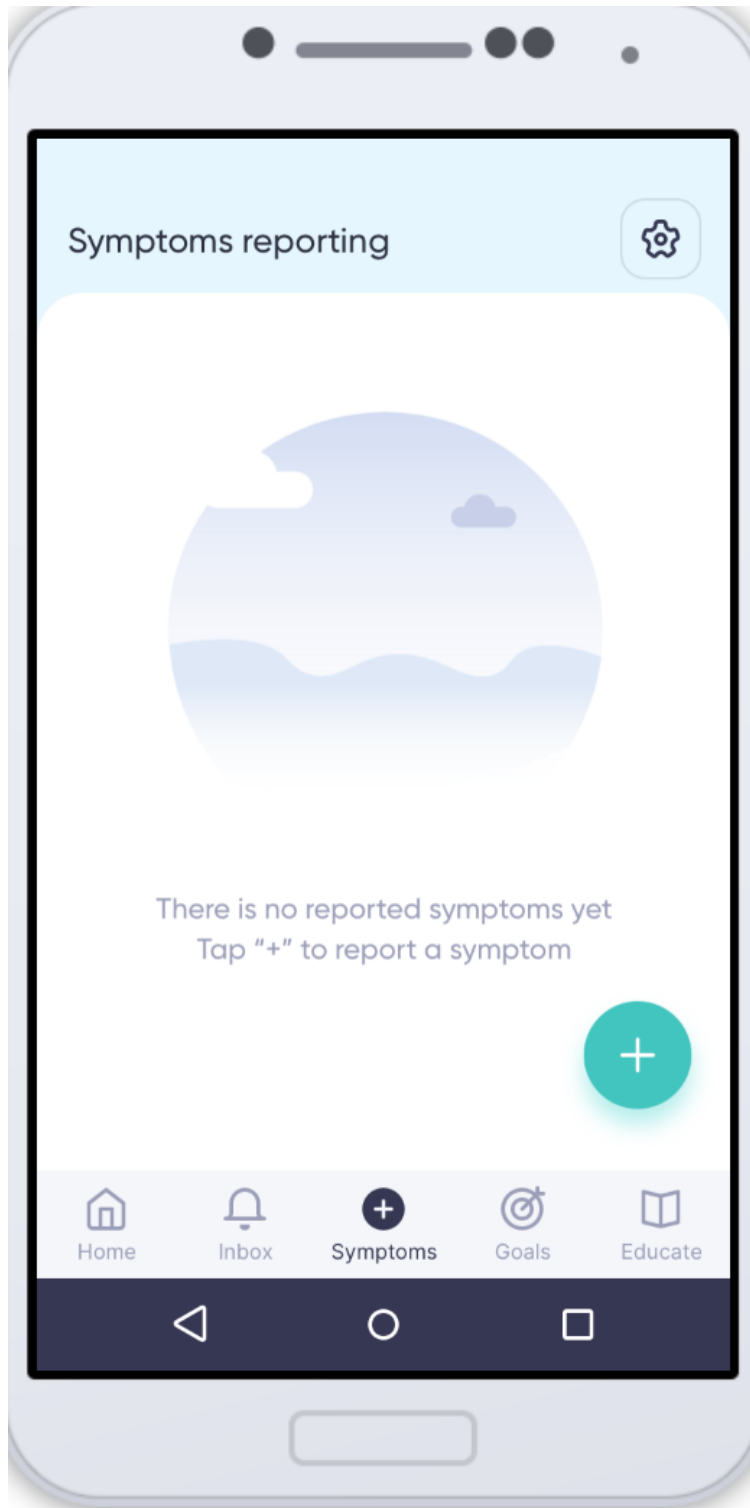


Figure 3.1.9 Symptoms tab - reporting on a new symptom - UI design.

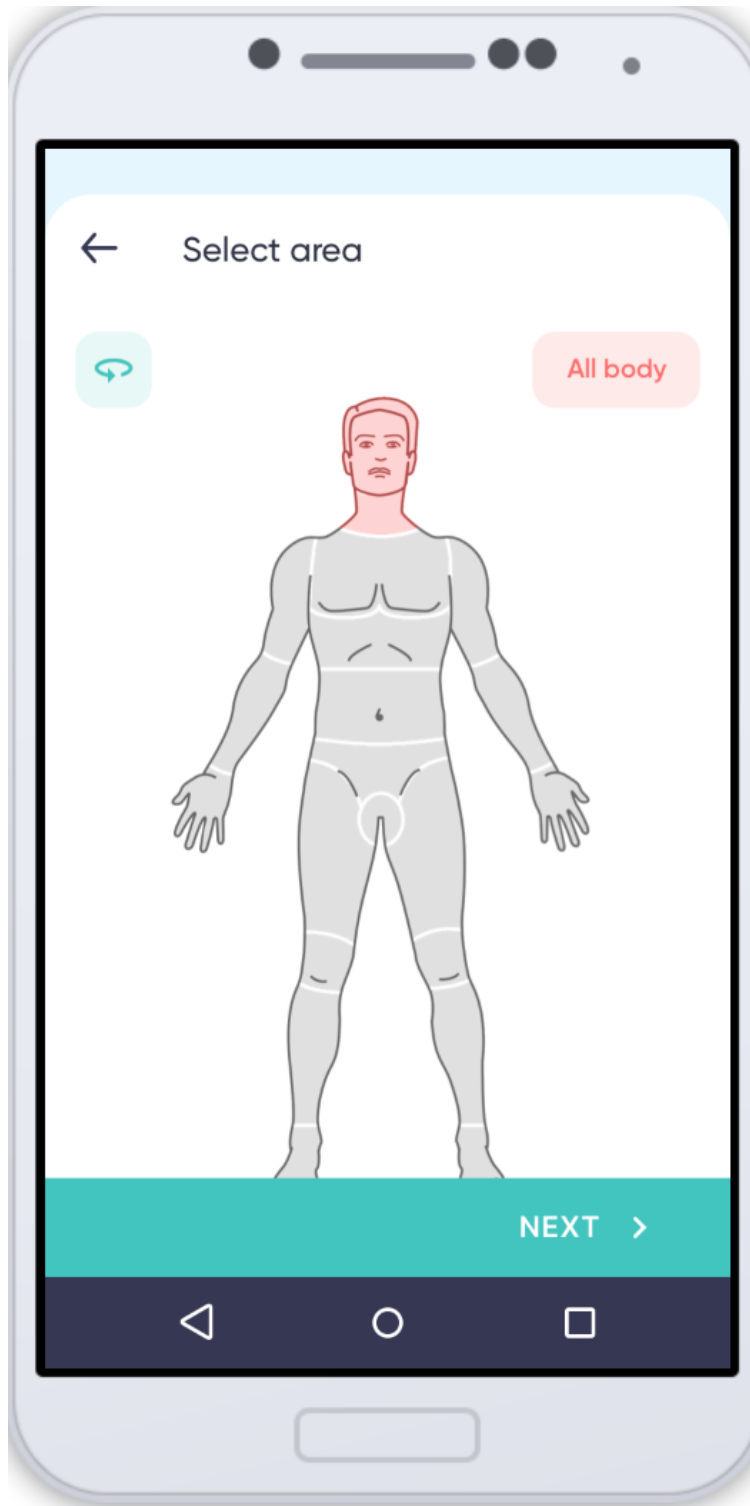


Figure 3.1.10 Symptoms tab - image of a human body; to indicate body part with a symptom, it's possible to turn it around, choose all the body and skip this step of a Symptom reporting flow - UI design.

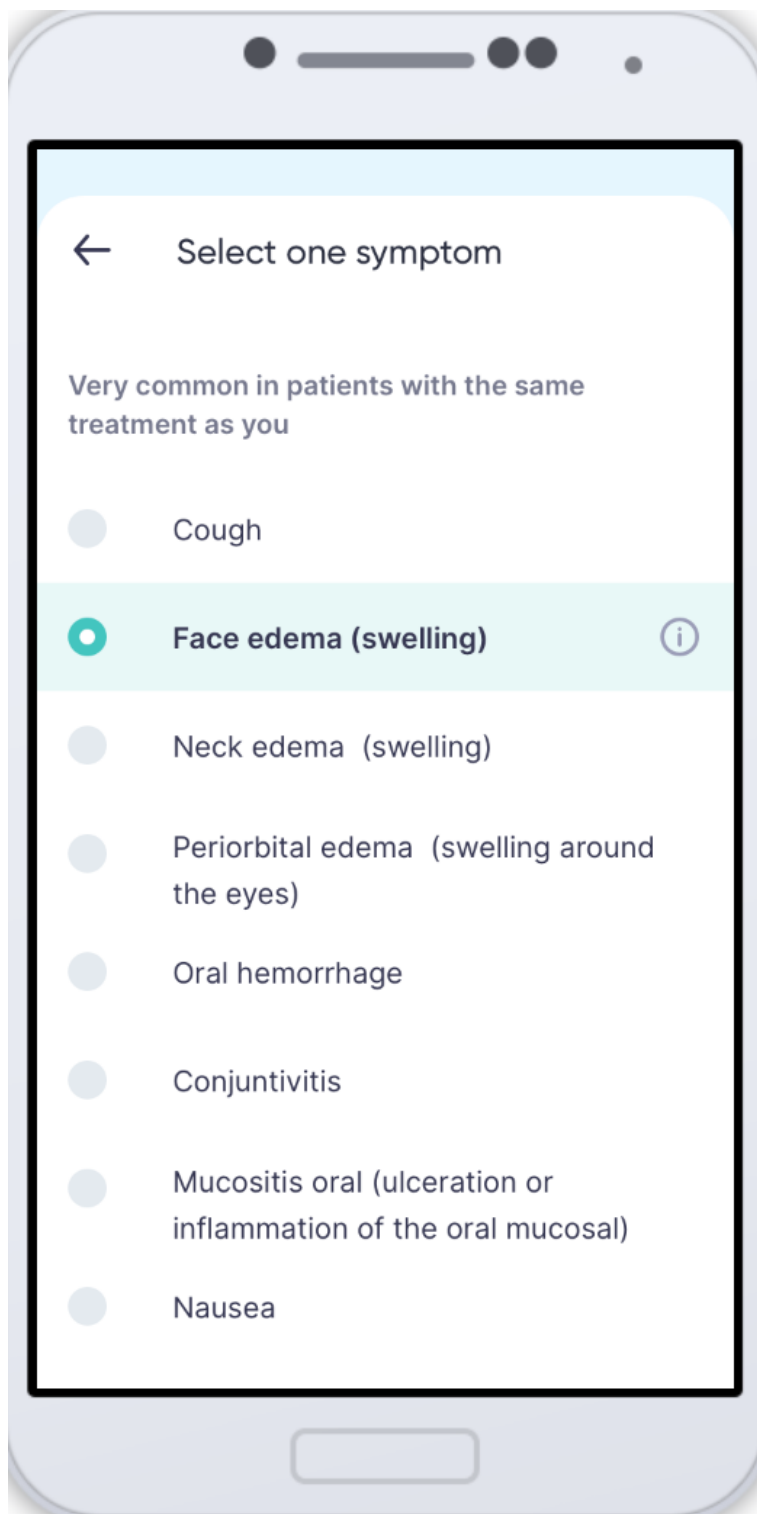


Figure 3.1.11 Symptoms tab - a list of Symptoms that can be reported by a Patient, divided into groups by frequency of occurrence in patients with the same cancer type - UI design.

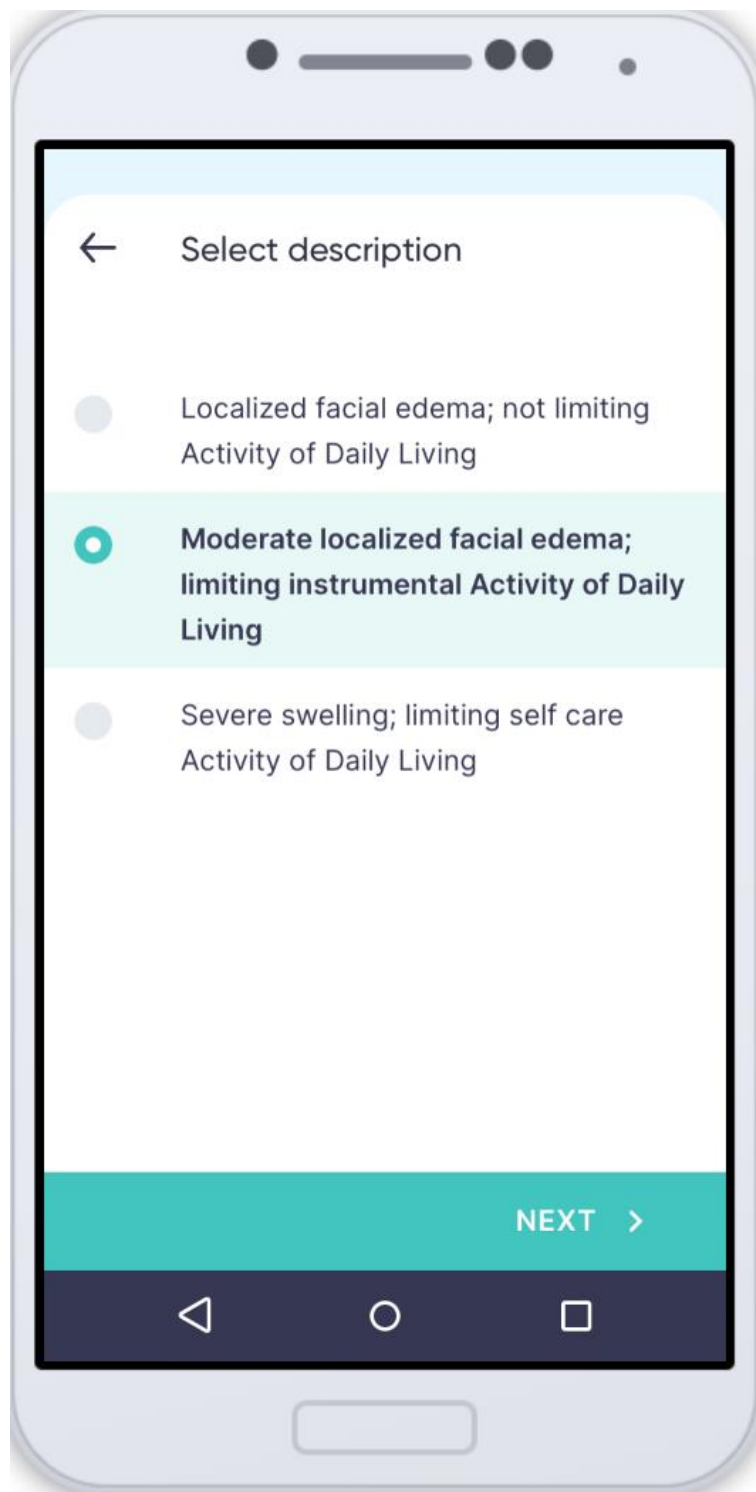


Figure 3.1.12 Symptoms tab - a list with the descriptions of grades of severity of a symptom, which a patient can select to better describe the symptom - UI design.

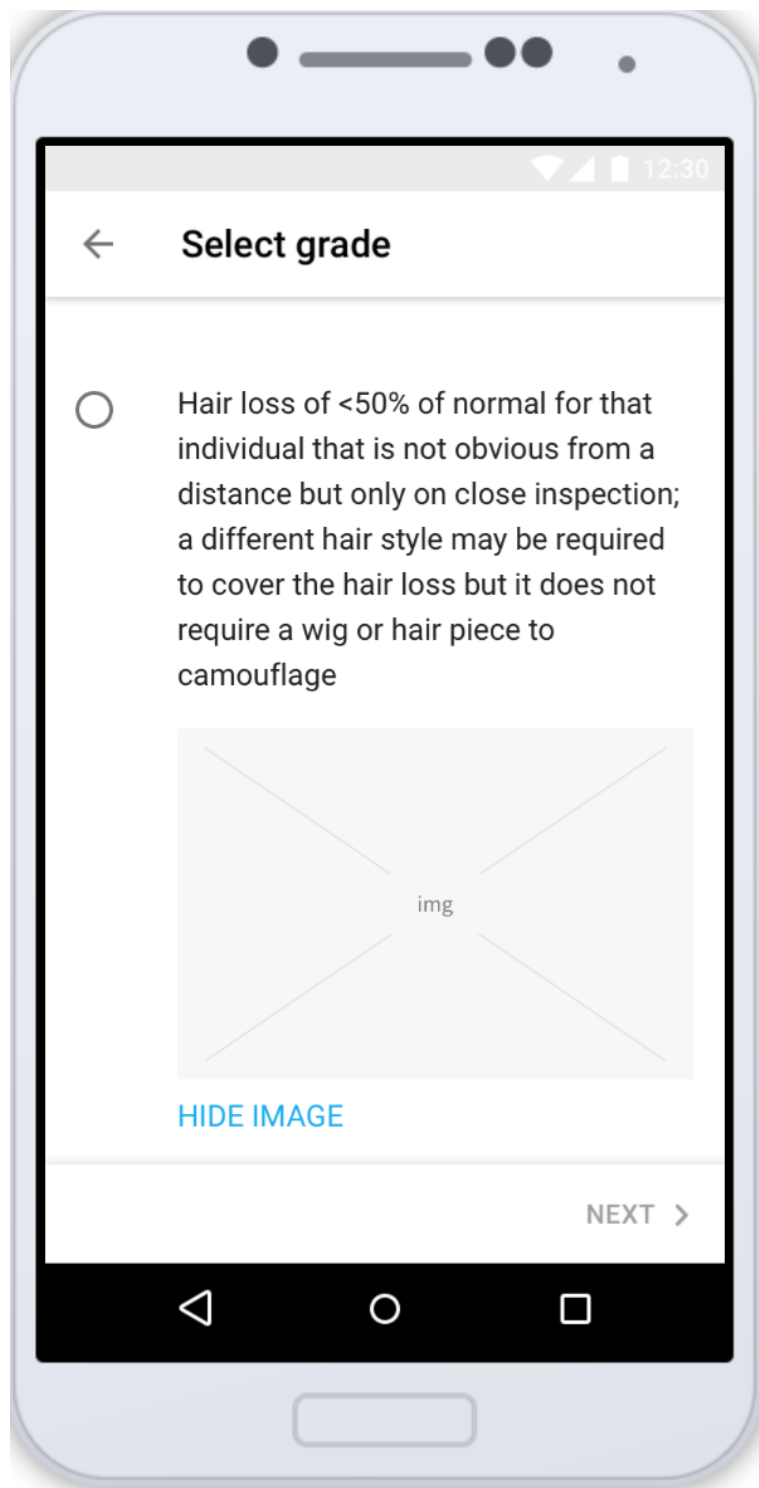
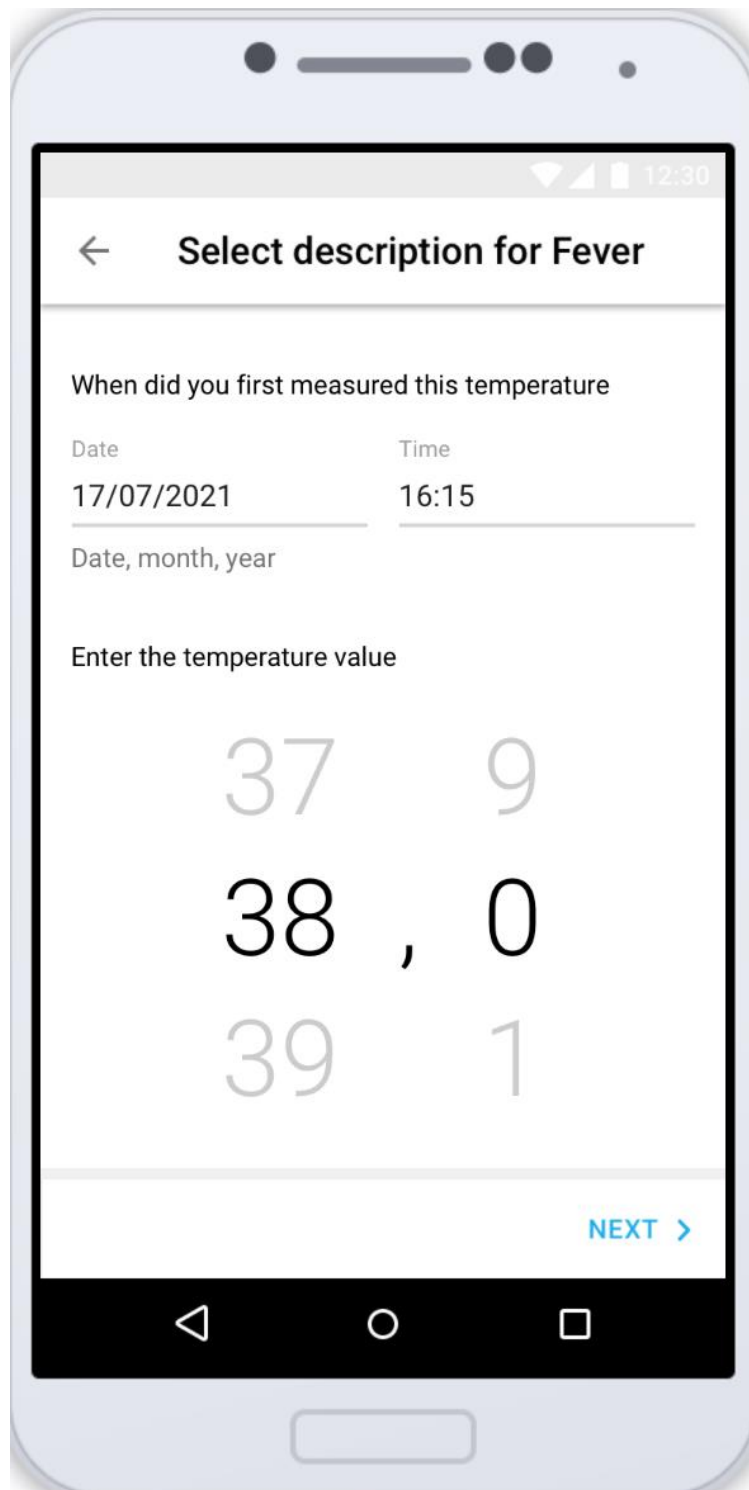


Figure 3.1.13 Symptoms tab - a list with the description of a specific Symptom with the explanatory images.



← **Select description for Fever**

When did you first measured this temperature

|                   |       |
|-------------------|-------|
| Date              | Time  |
| 17/07/2021        | 16:15 |
| Date, month, year |       |

Enter the temperature value

|    |     |
|----|-----|
| 37 | 9   |
| 38 | , 0 |
| 39 | 1   |

NEXT >

Figure 3.1.14 Symptoms tab - a list with the description of a Fever with the possibility to indicate precise temperature and fever onset time.

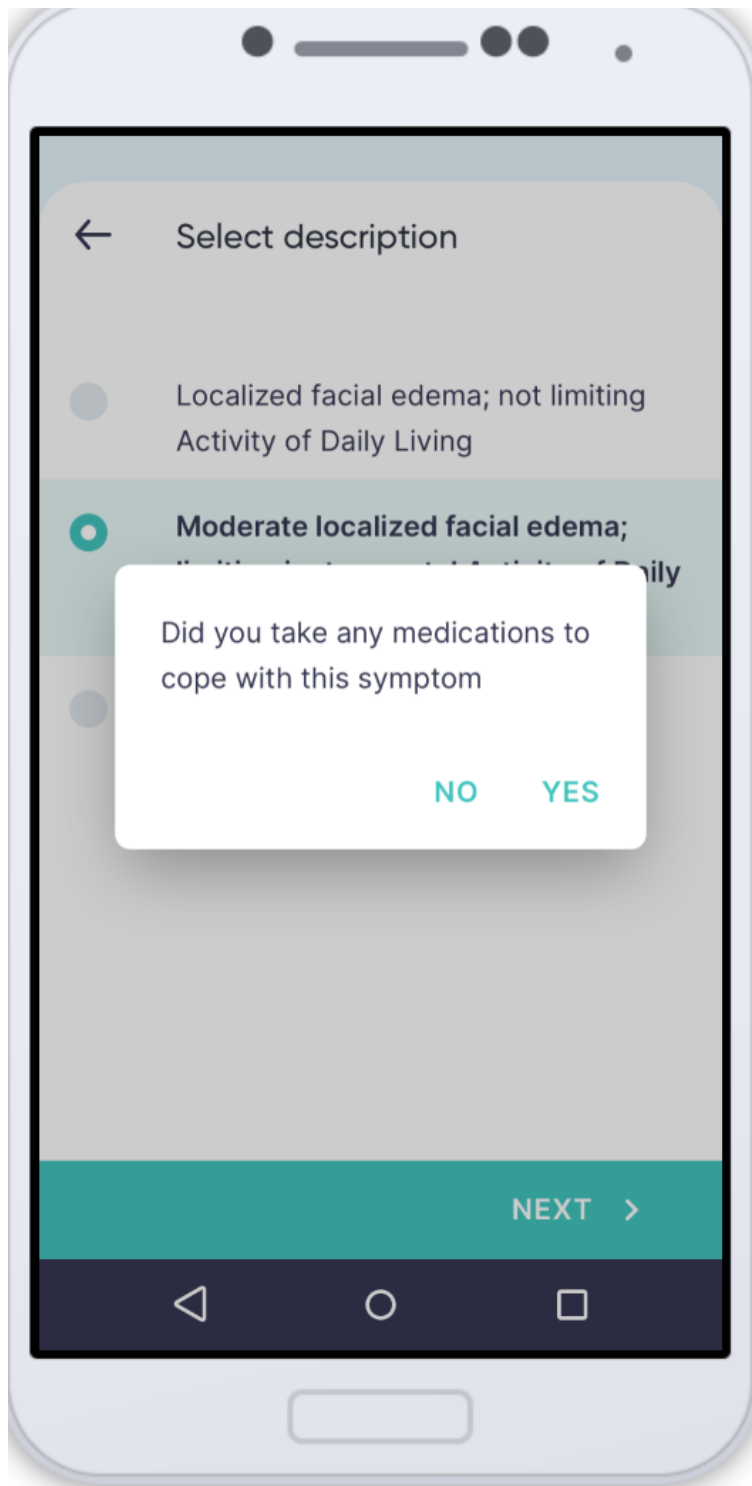


Figure 3.1.15 Symptoms tab - Medication intake due to a Symptom - UI Design.



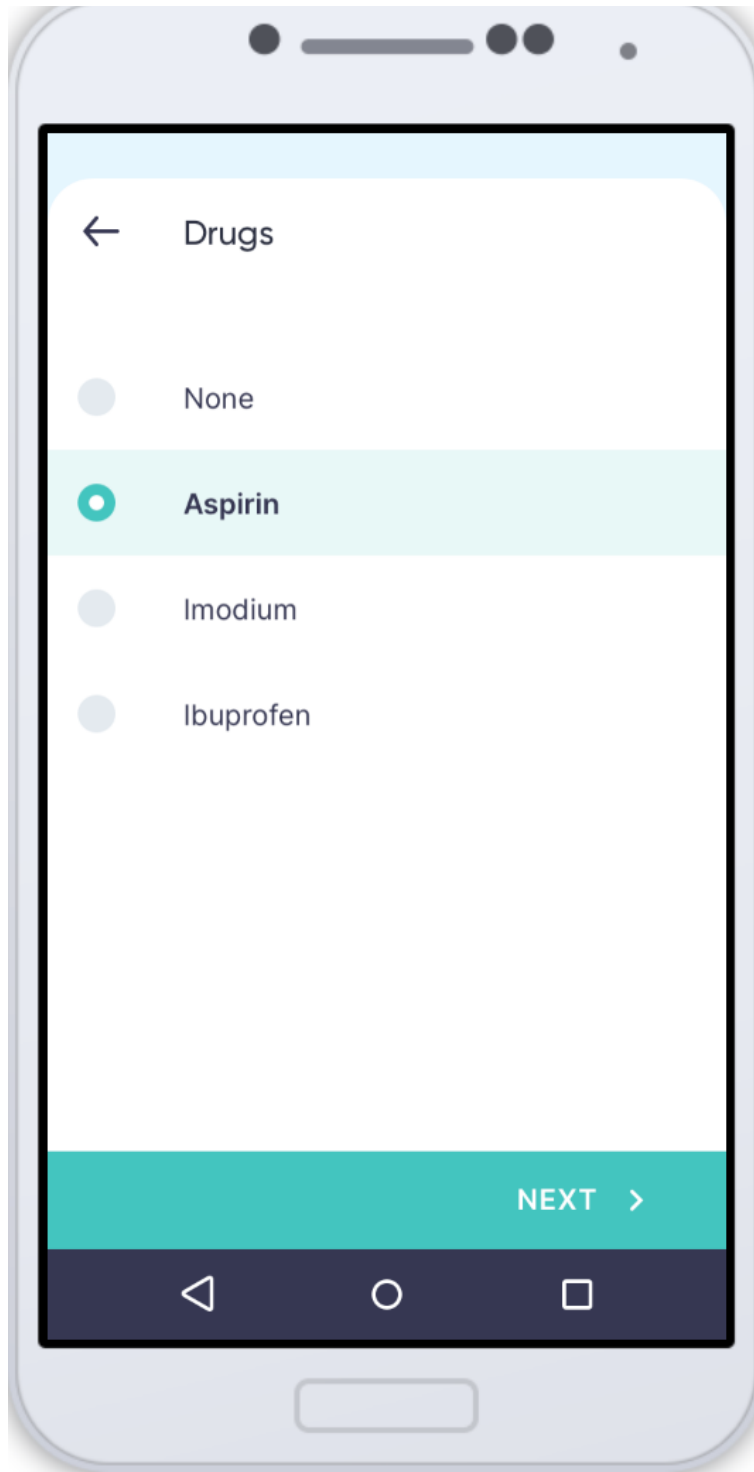
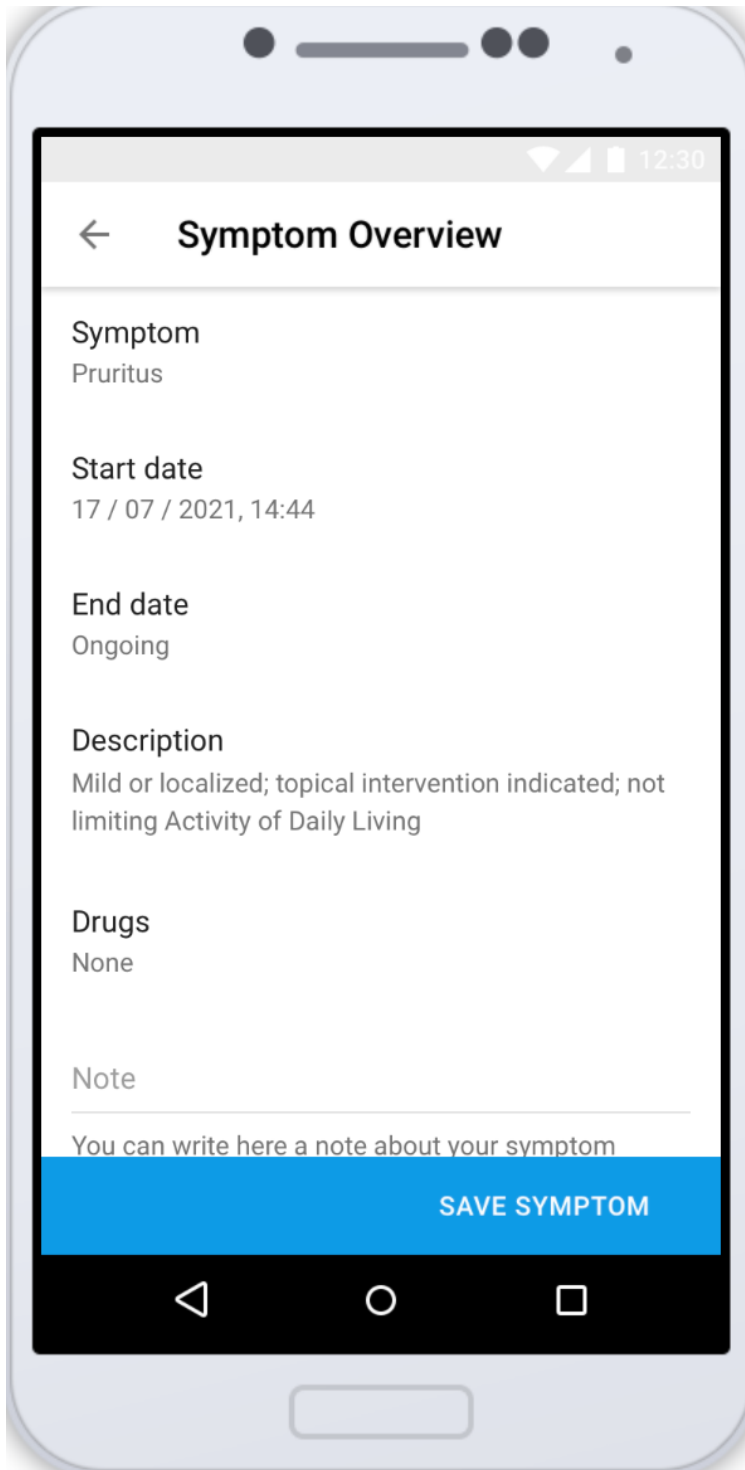


Figure 3.1.16 Symptoms tab - Medication intake due to a Symptom - UI Design.



The screenshot shows a mobile application interface for a 'Symptom Overview'. At the top, there is a status bar with signal, battery, and time (12:30) indicators. Below this is a header bar with a back arrow and the title 'Symptom Overview'. The main content area is divided into several sections: 'Symptom' with the value 'Pruritus', 'Start date' with '17 / 07 / 2021, 14:44', 'End date' with 'Ongoing', 'Description' with 'Mild or localized; topical intervention indicated; not limiting Activity of Daily Living', 'Drugs' with 'None', and a 'Note' section with a text input field containing the placeholder 'You can write here a note about your symptom'. At the bottom of the form is a blue button labeled 'SAVE SYMPTOM'. The entire form is displayed on a smartphone mockup with a home button at the bottom.

← Symptom Overview

Symptom  
Pruritus

Start date  
17 / 07 / 2021, 14:44

End date  
Ongoing

Description  
Mild or localized; topical intervention indicated; not limiting Activity of Daily Living

Drugs  
None

Note  
You can write here a note about your symptom

SAVE SYMPTOM

Figure 3.1.17 Symptoms tab - Symptom overview.

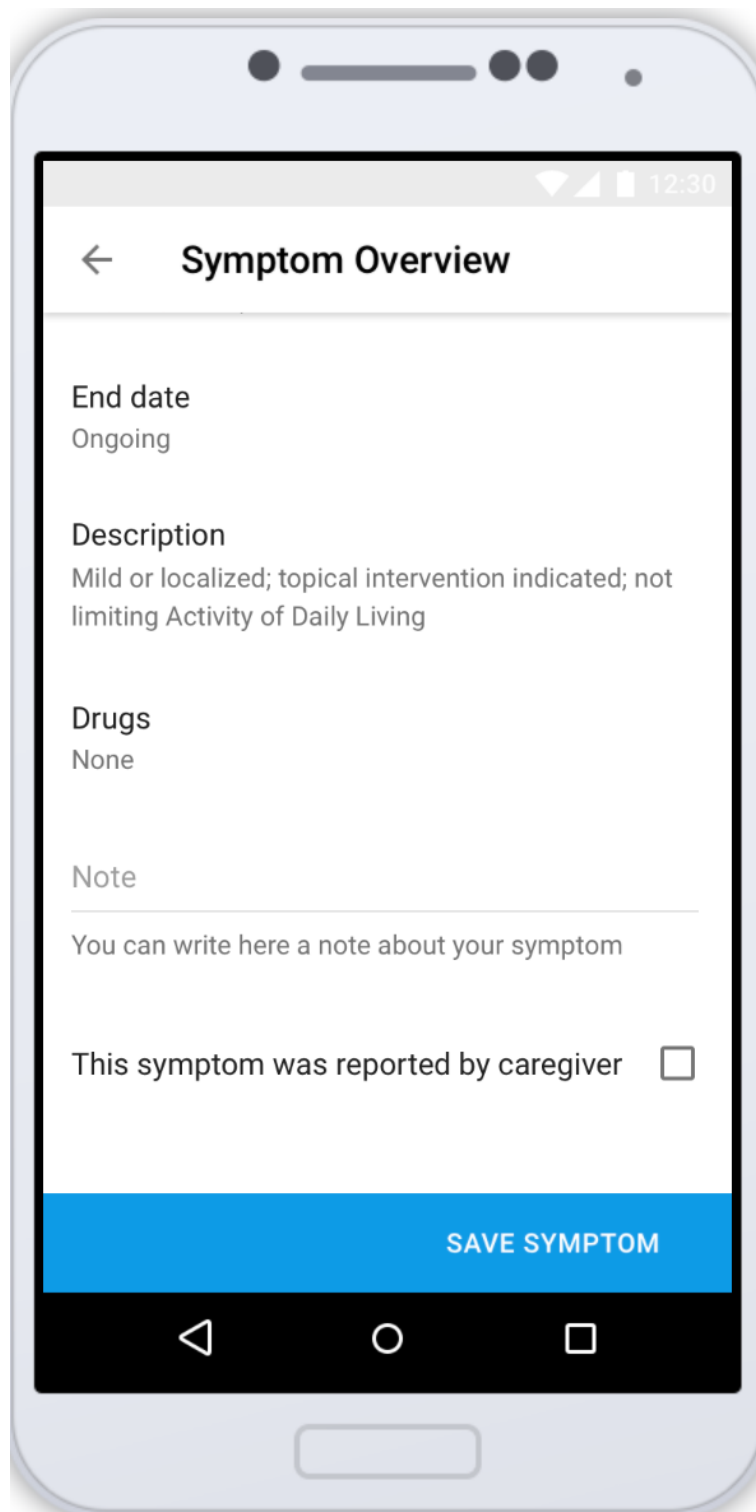
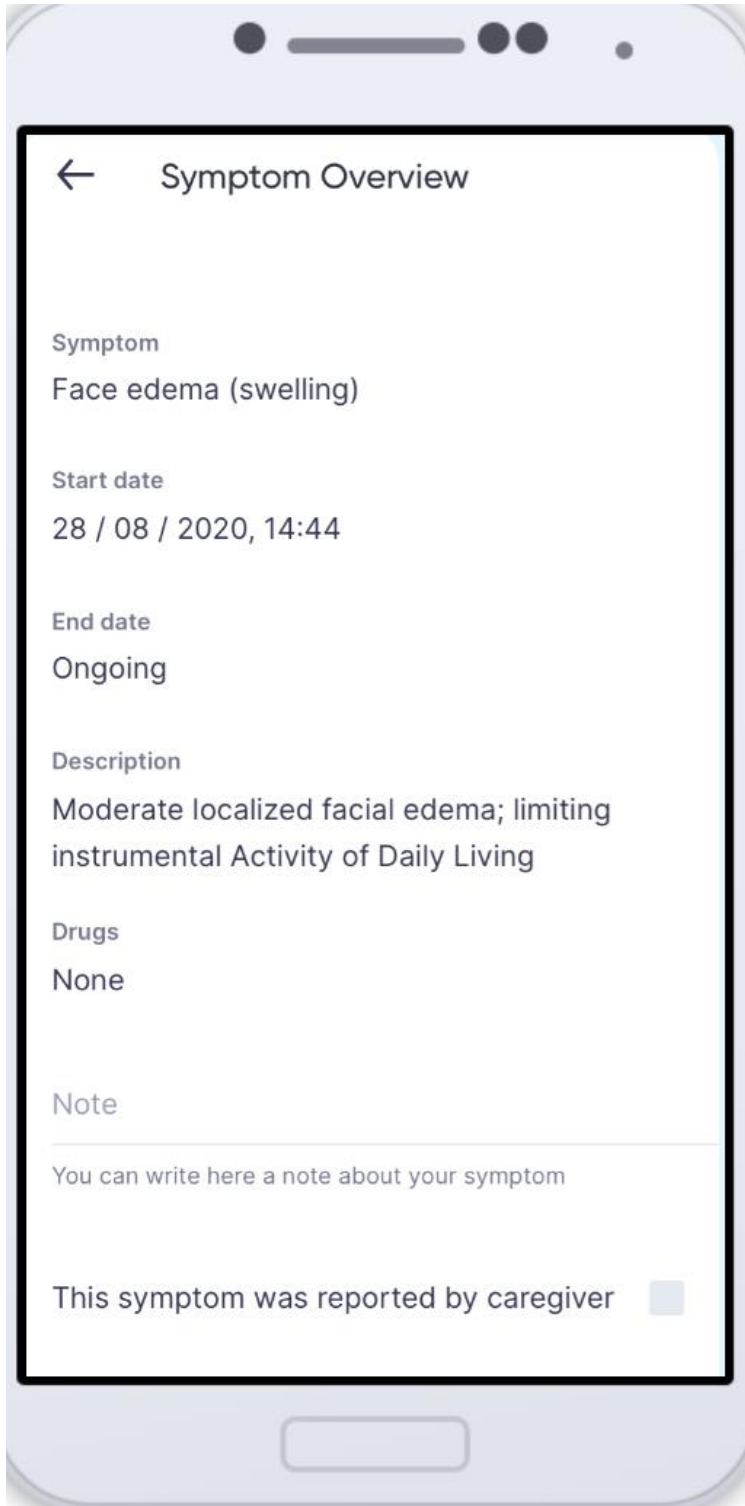


Figure 3.1.18 Symptoms tab - Symptom overview allows to put a note with a free text and a flag that shows a symptom is reported by a Caregiver.



← Symptom Overview

Symptom  
Face edema (swelling)

Start date  
28 / 08 / 2020, 14:44

End date  
Ongoing

Description  
Moderate localized facial edema; limiting instrumental Activity of Daily Living

Drugs  
None

Note  
You can write here a note about your symptom

This symptom was reported by caregiver ☐

Figure 3.1.19 Symptom overview allows to put a note with a free text and a flag that shows a symptom is reported by a Caregiver - UI Design.

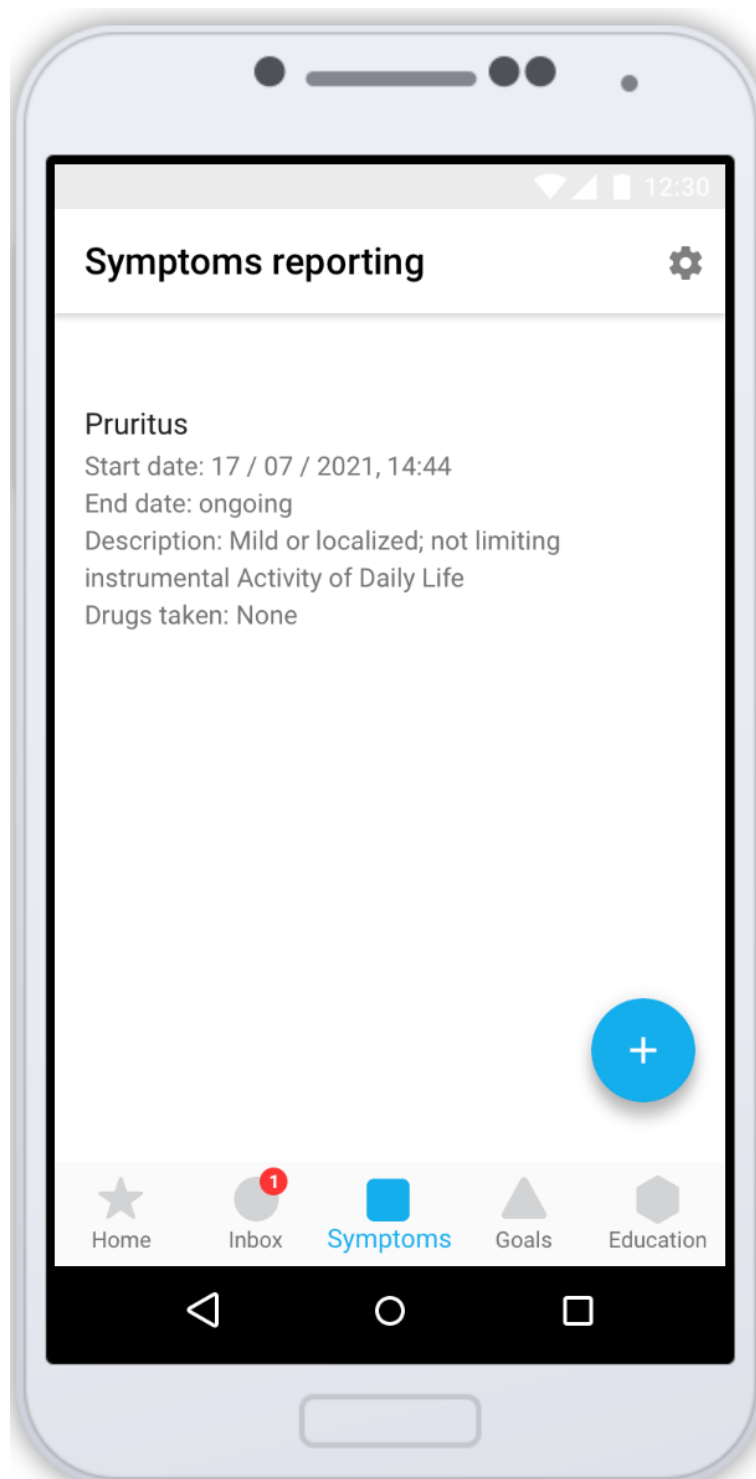


Figure 3.1.20 Symptoms tab - An example of a reported symptom.

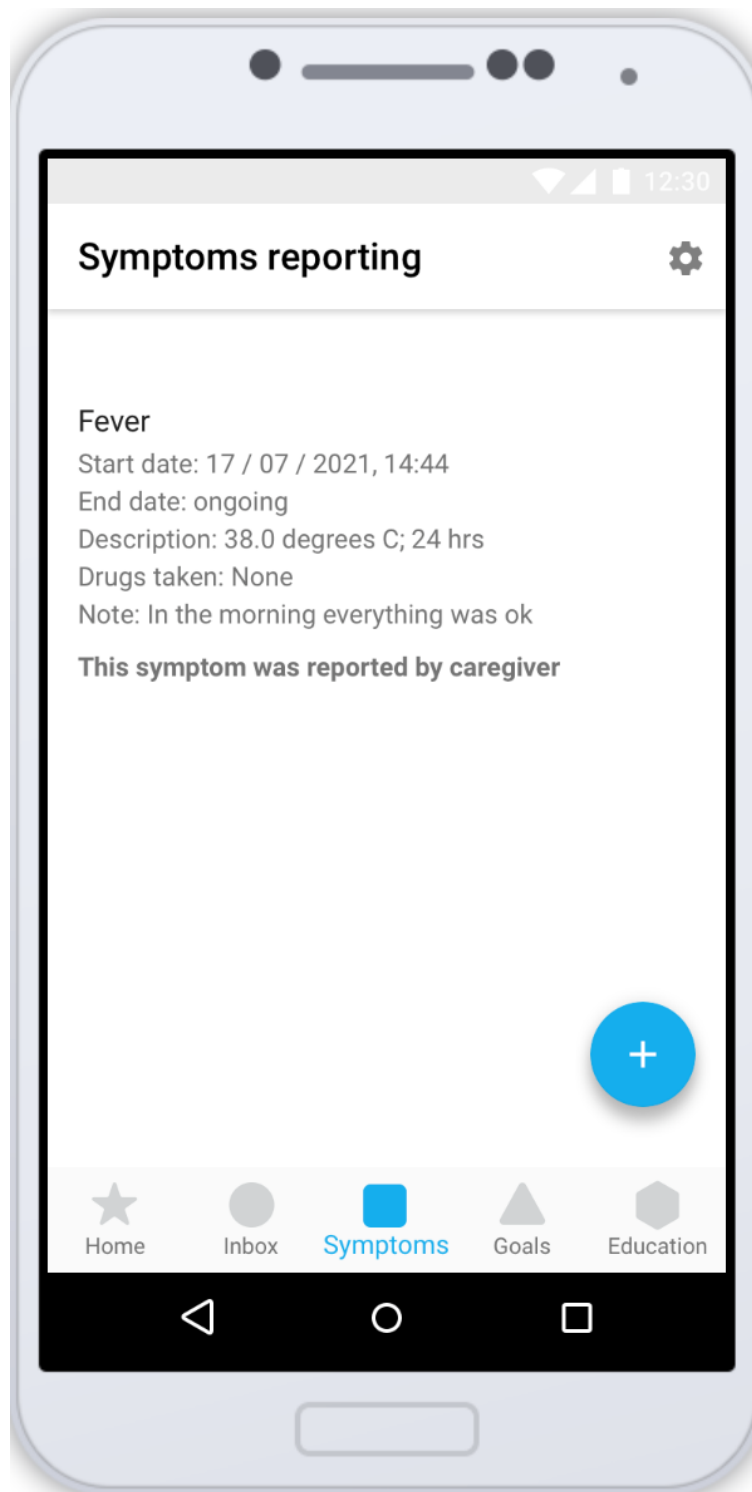


Figure 3.1.21 Symptoms tab - An example of a symptom reported by a caregiver.

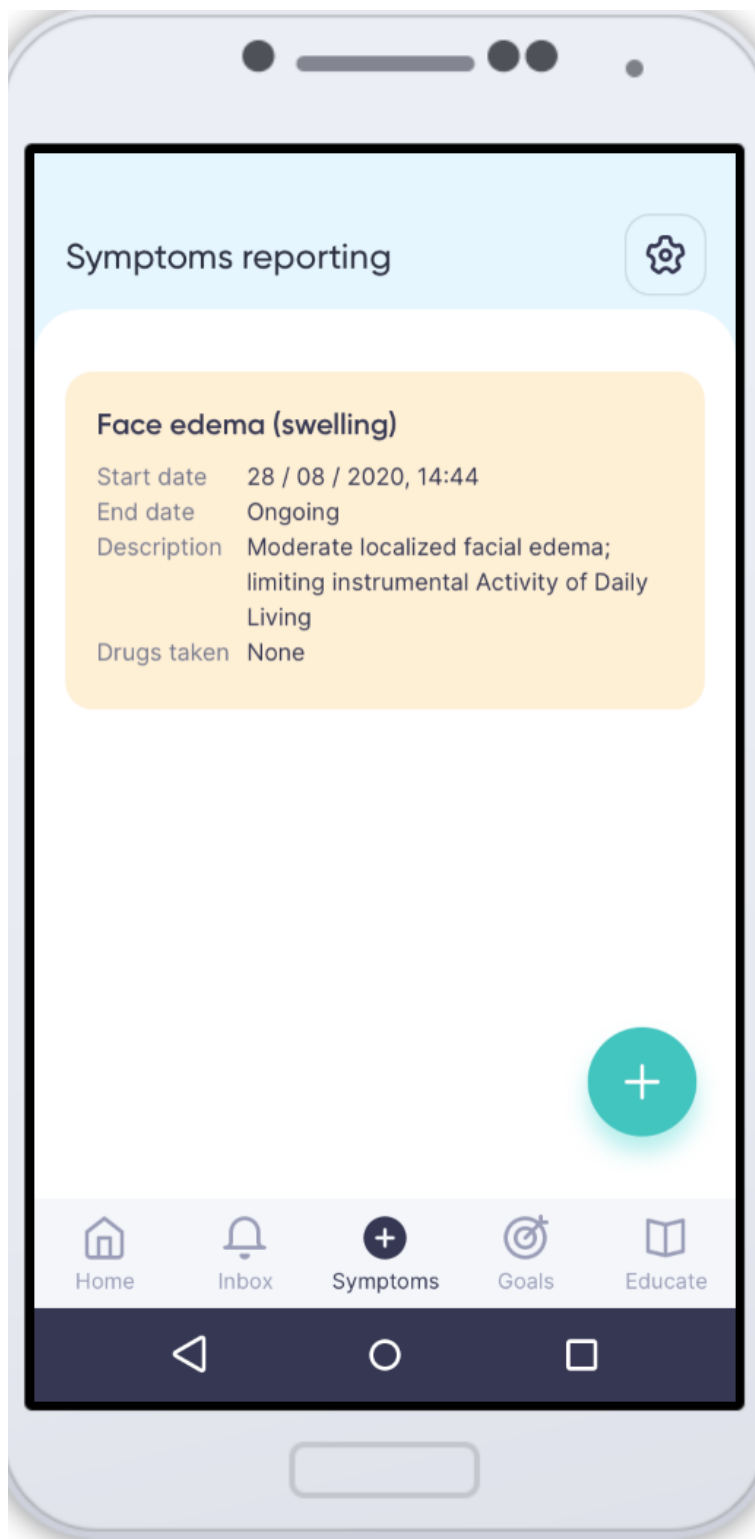


Figure 3.1.22 Symptoms tab - An example of a reported symptom - UI Design.

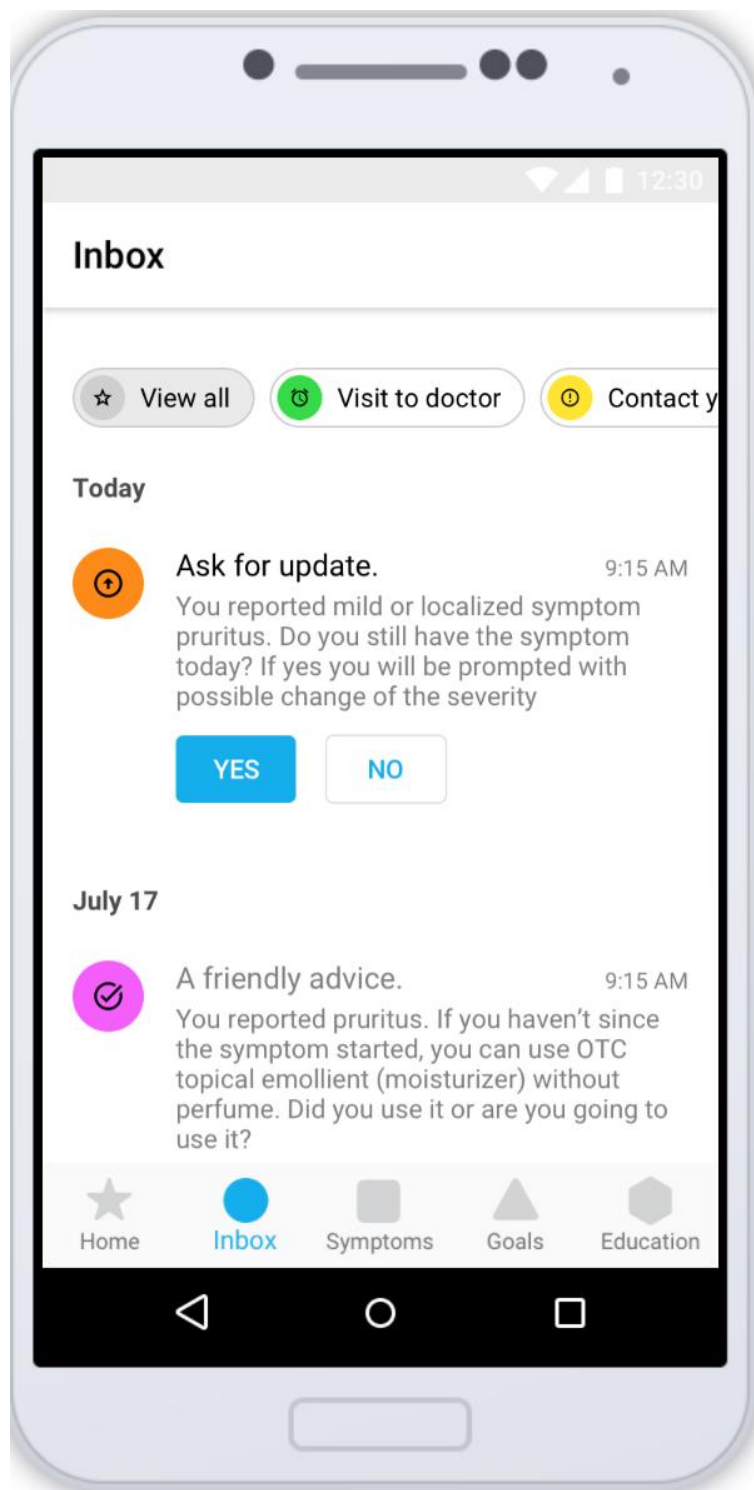


Figure 3.1.23 Inbox tab - Follow up on a Symptom. Top tabs allow to filter the messages according to the type



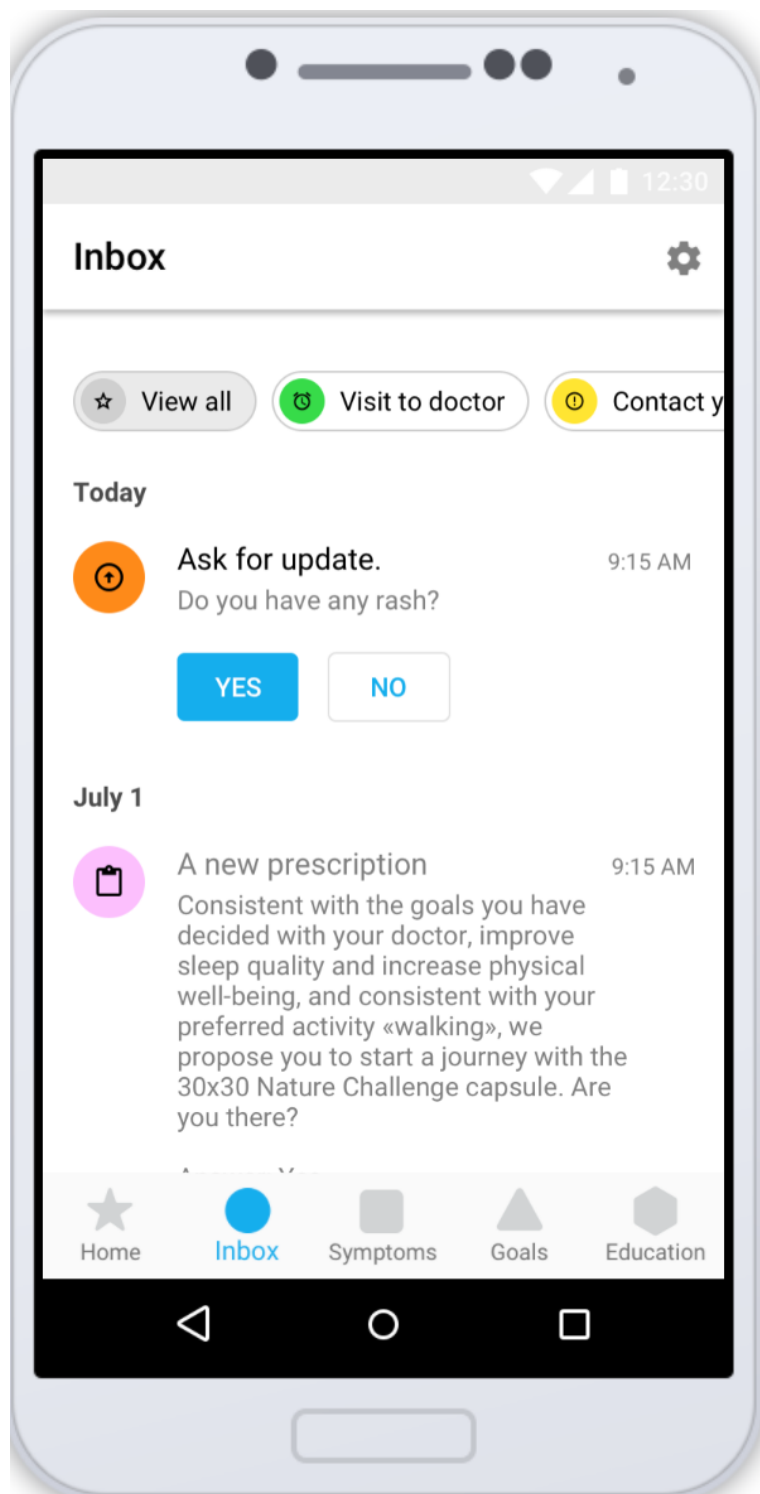


Figure 3.1.24 Inbox tab - Follow up on a Symptom.

### 3.2 Management of the therapy

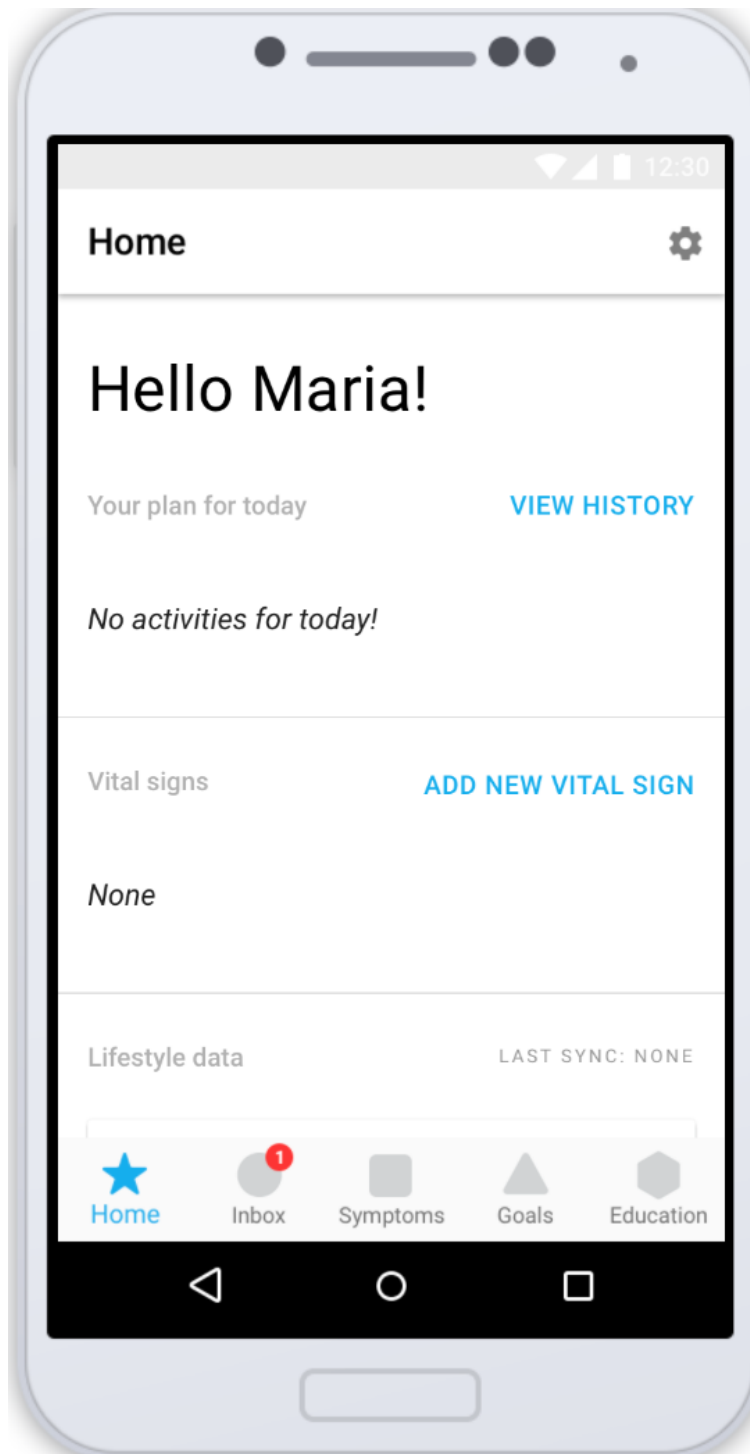


Figure 3.2.1 - Home tab with no activities in a Daily Plan.

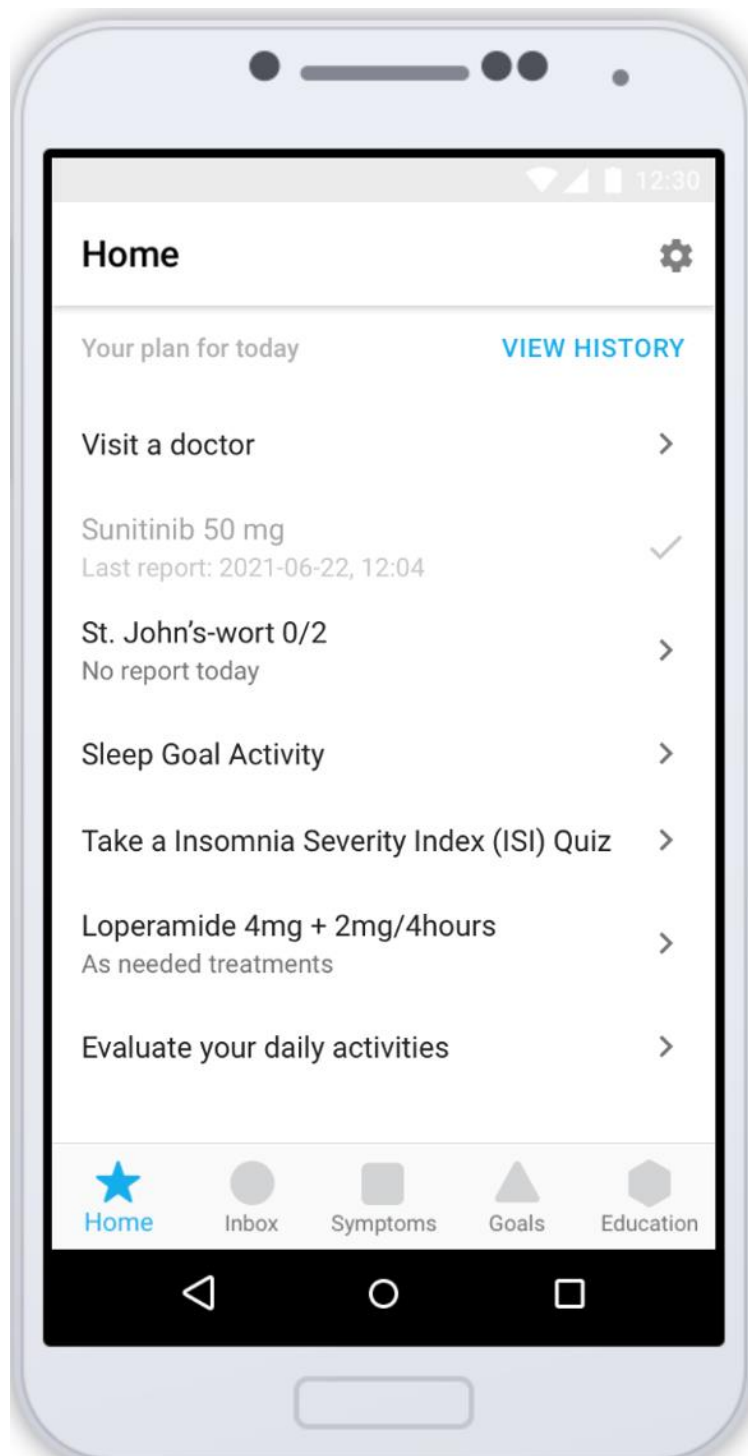


Figure 3.2.2 Home tab with a Daily Plan - a report of all the activities to do during the day - Treatments, Reminders, Goal activities, Questionnaires and Evaluation of Daily activities.

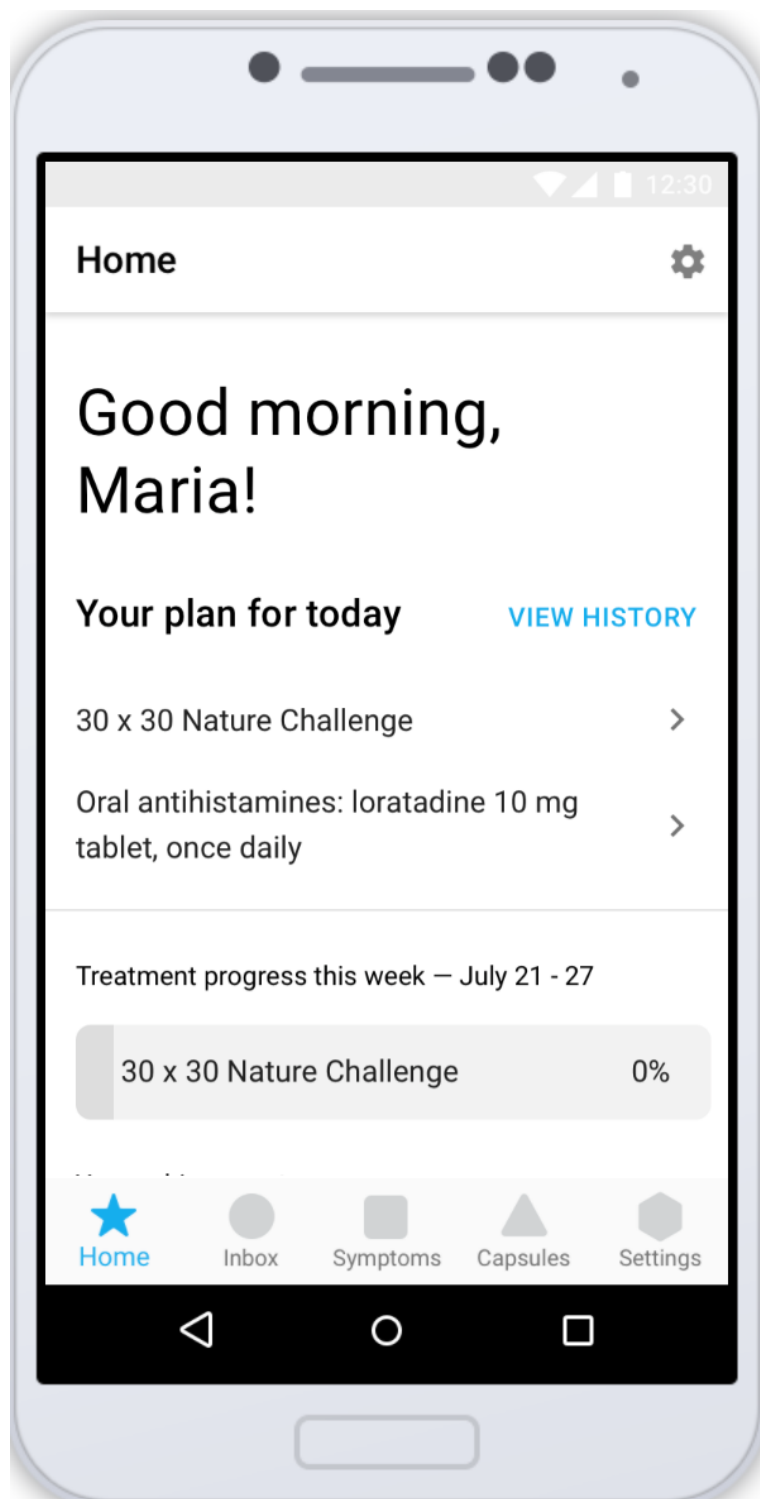


Figure 3.2.3 Home tab with a Daily Plan - reminder to take a drug.

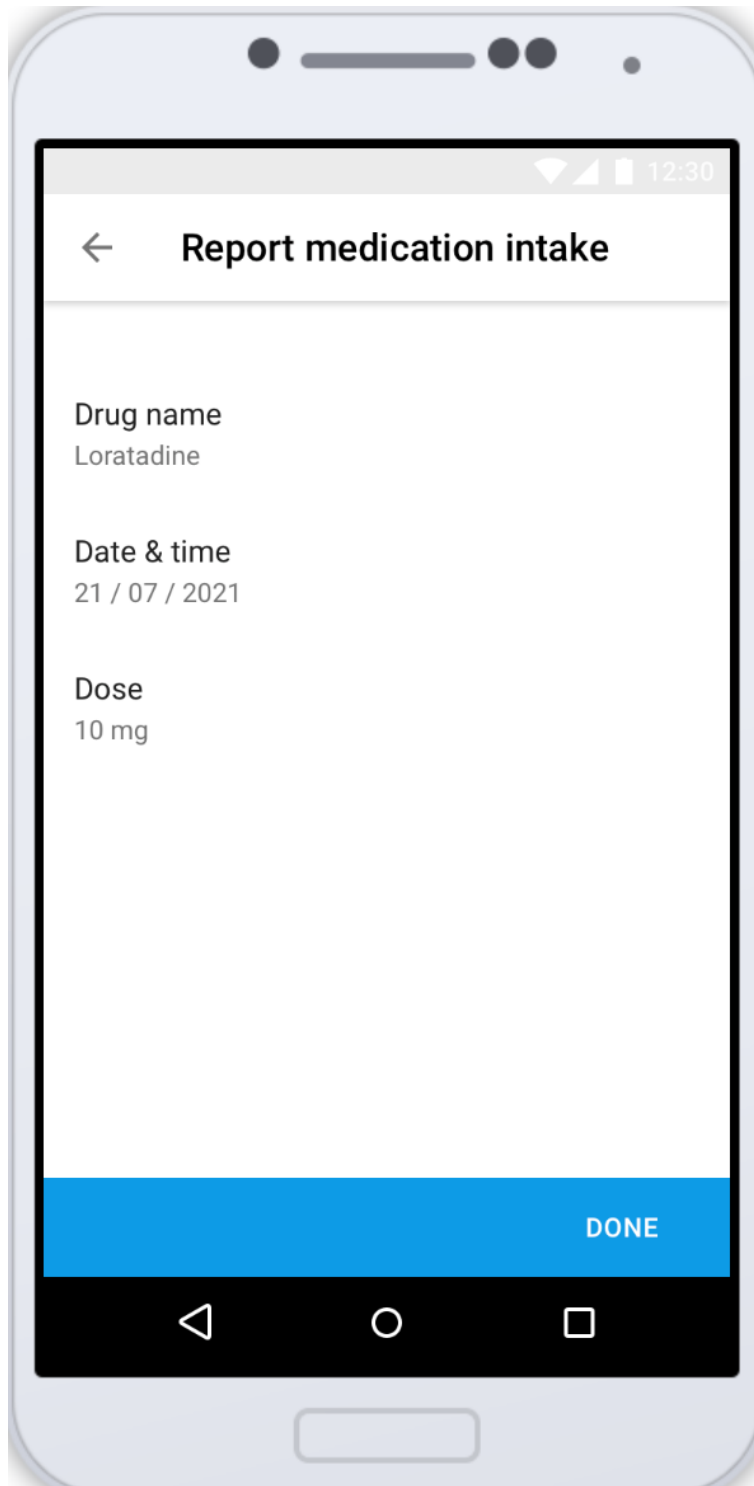


Figure 3.2.4 Home tab - report medication intake.

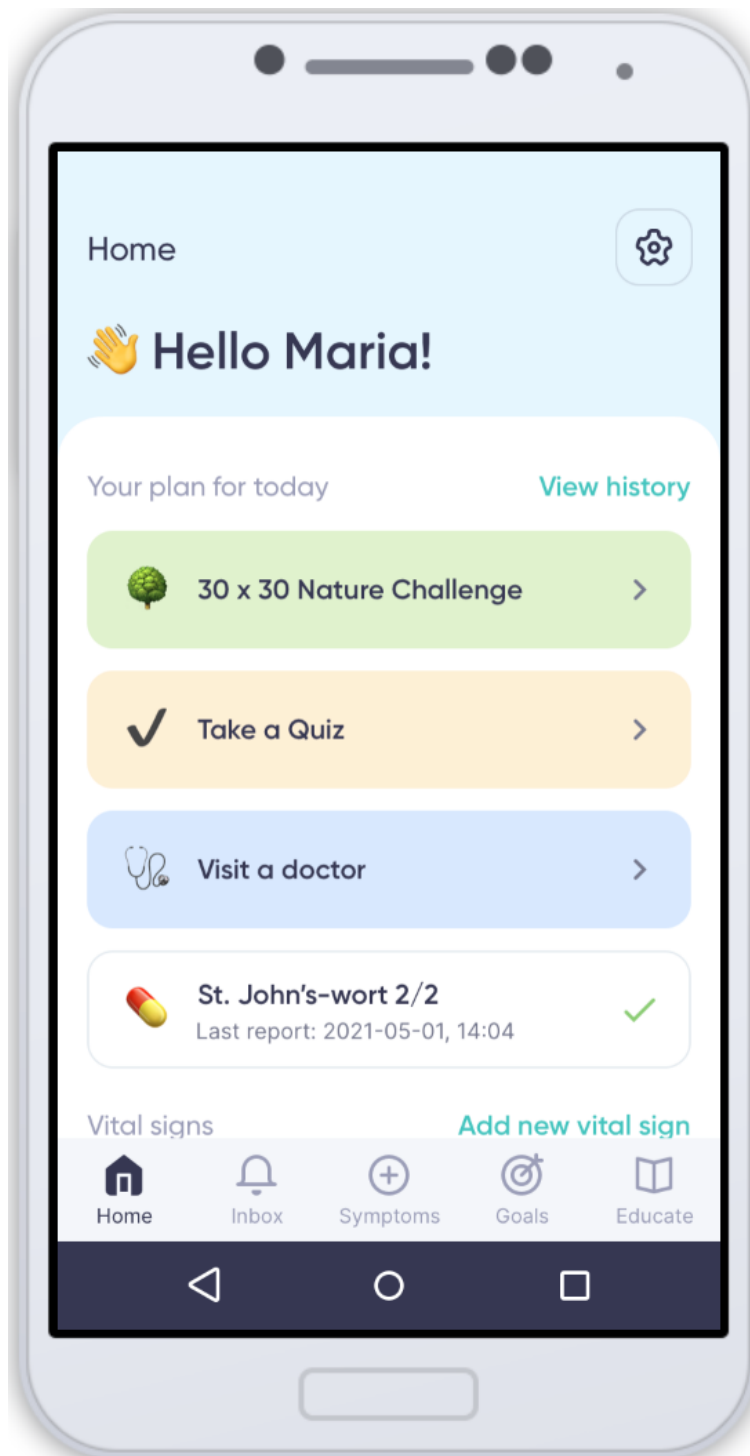
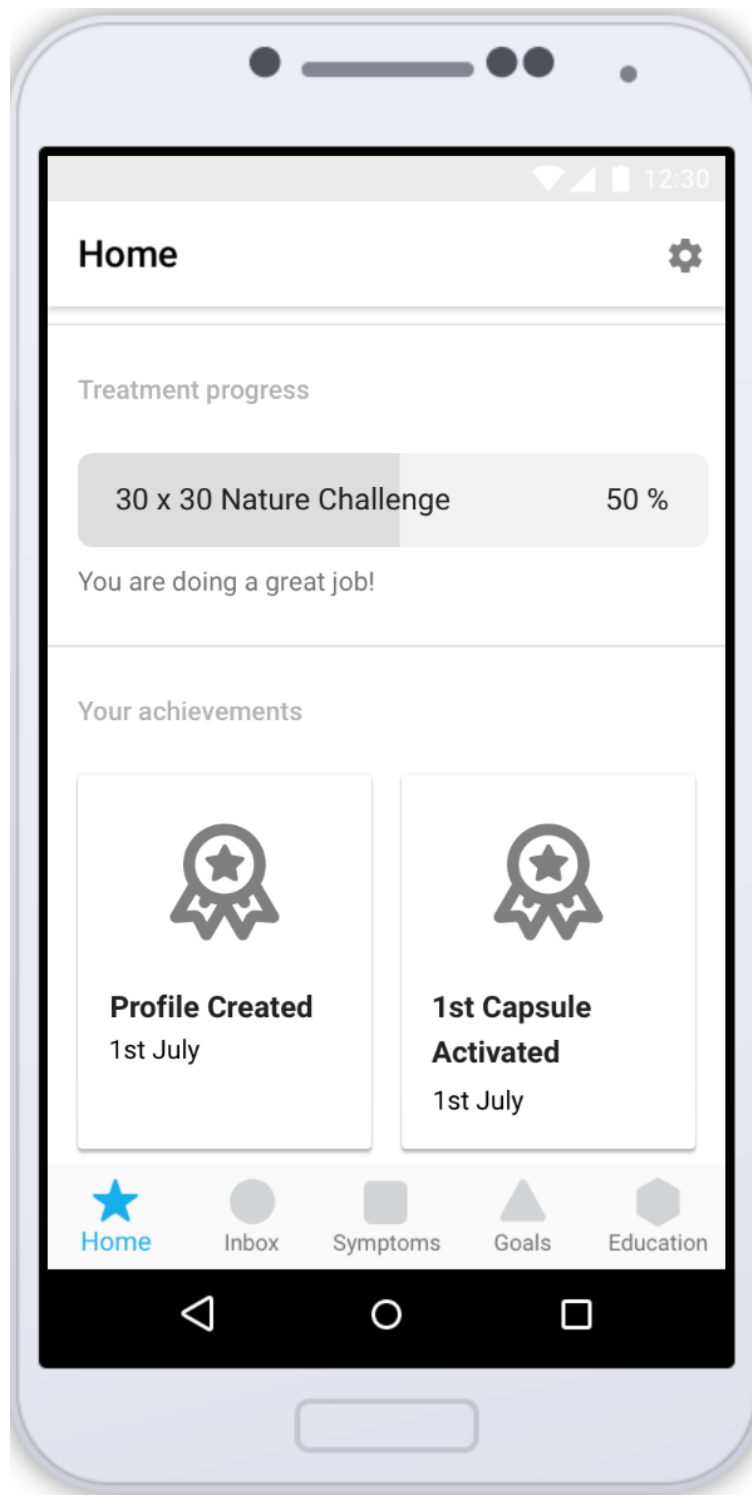


Figure 3.2.5 Home tab with a Daily plan, the screen with attached design - prettier display of the screens 3.2.1-3.2.3.

### 3.3 Recommendations and feedback



- Figure 3.3.1 Home tab with the Treatment Progress and Patient's achievements (Motivational feedback).

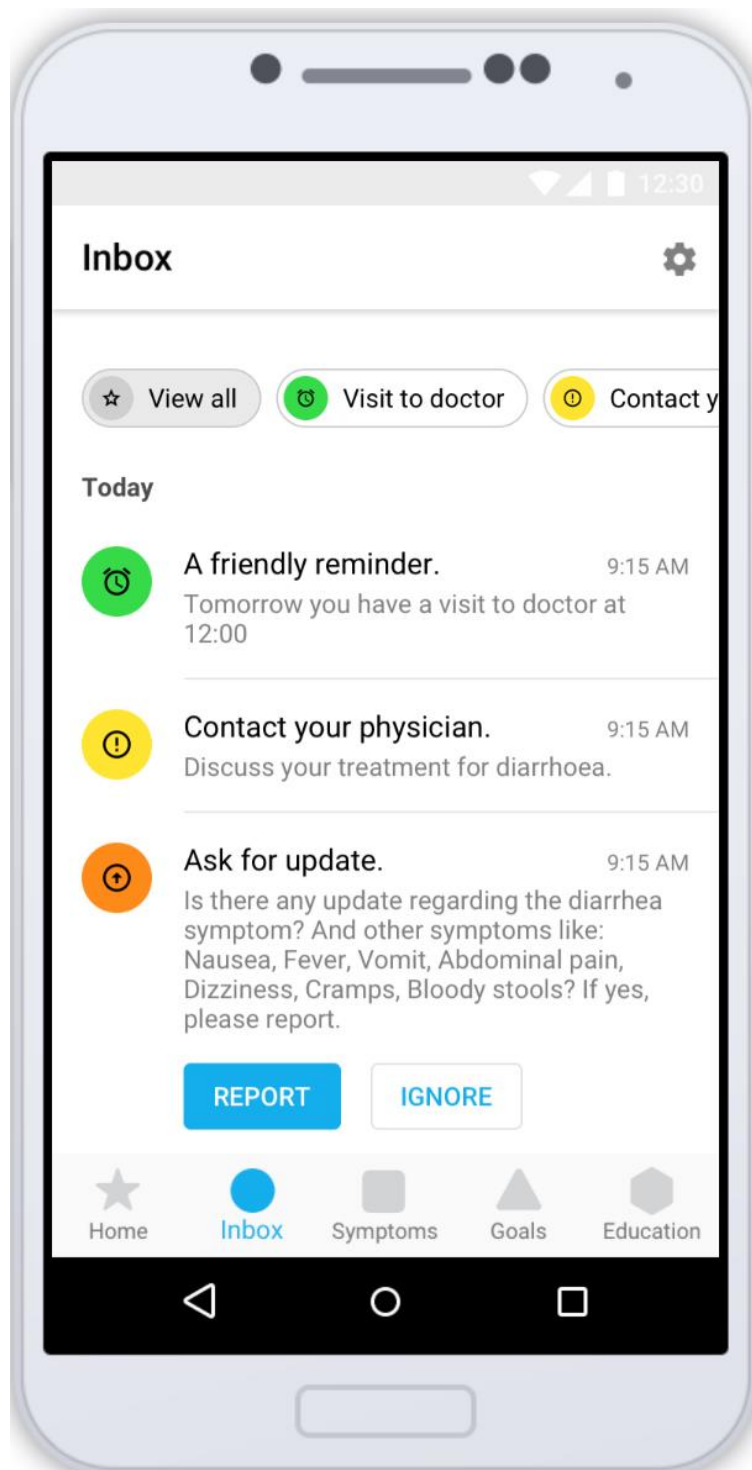


Figure 3.3.2 Inbox tab with different types of reminders and notifications.

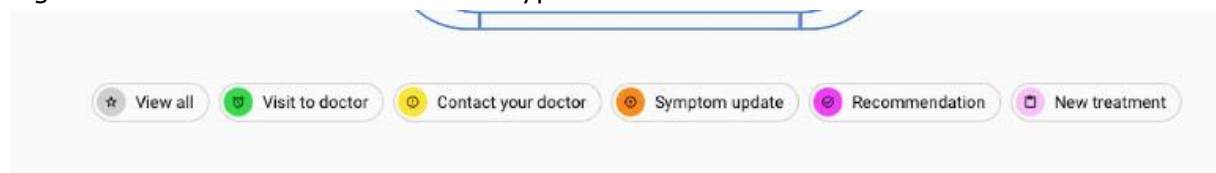


Figure 3.3.3 Types of reminders and notifications in an Inbox - Visit to doctor, contact your Doctor, Symptom update, Recommendation, New treatment, view all groups.



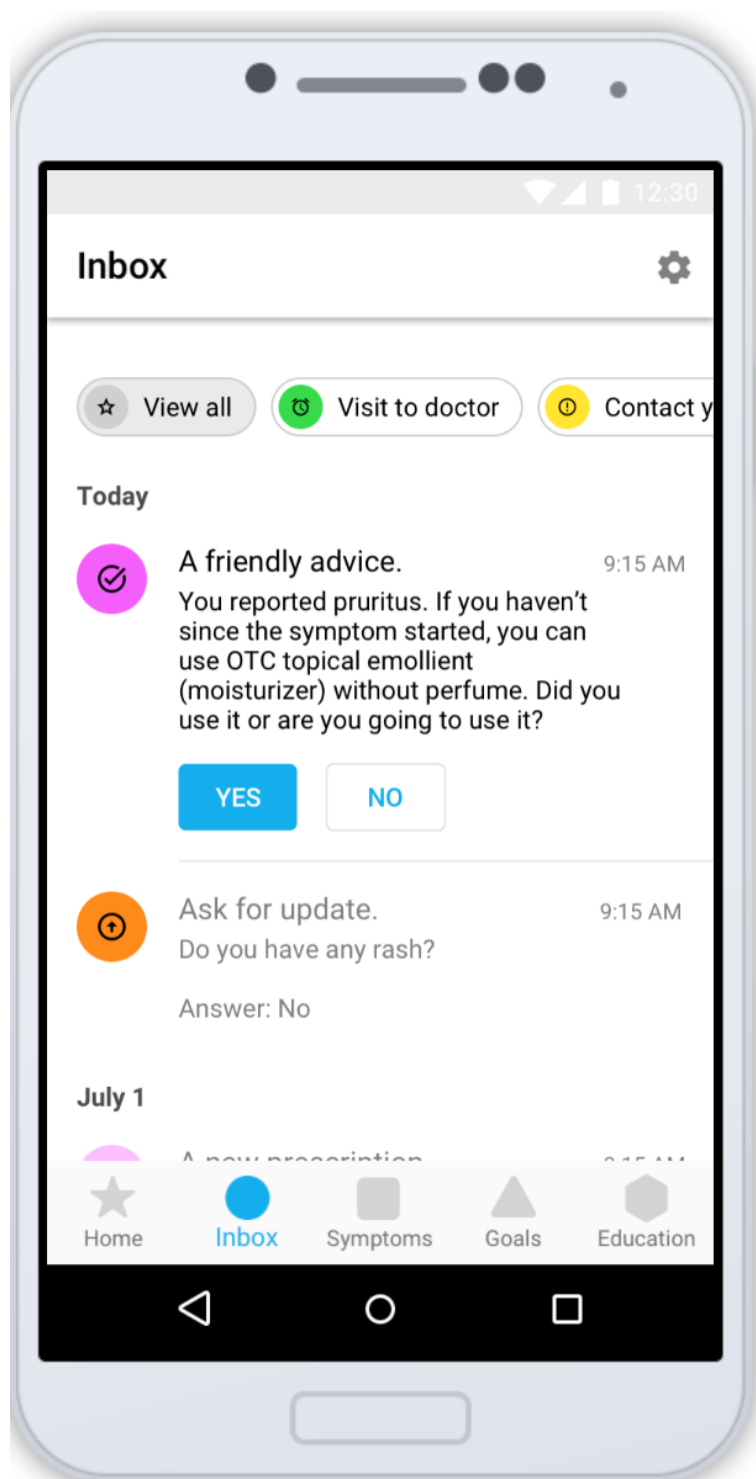


Figure 3.3.4 Types of reminders and notifications in an Inbox - example of a Recommendation.

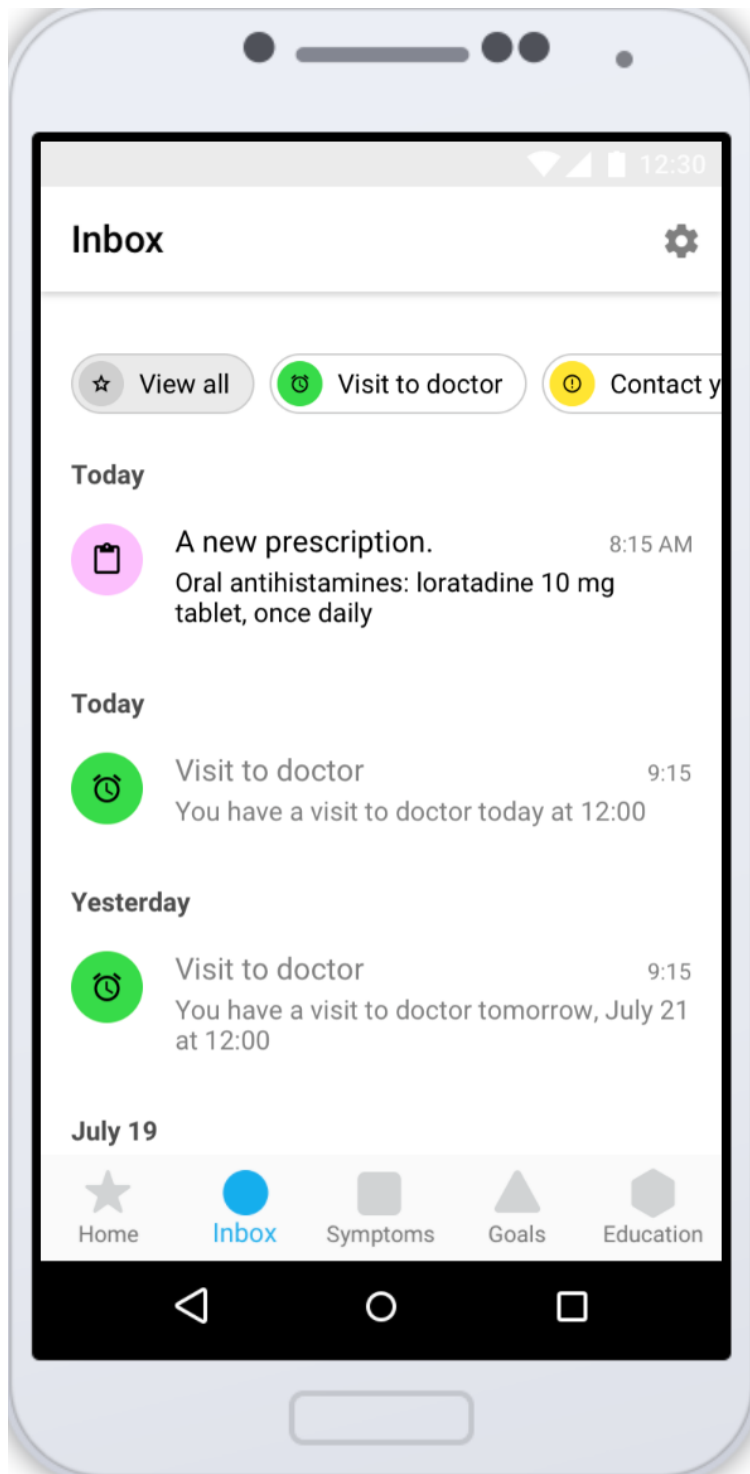


Figure 3.3.5 Types of reminders and notifications in an Inbox - example of a New treatment.

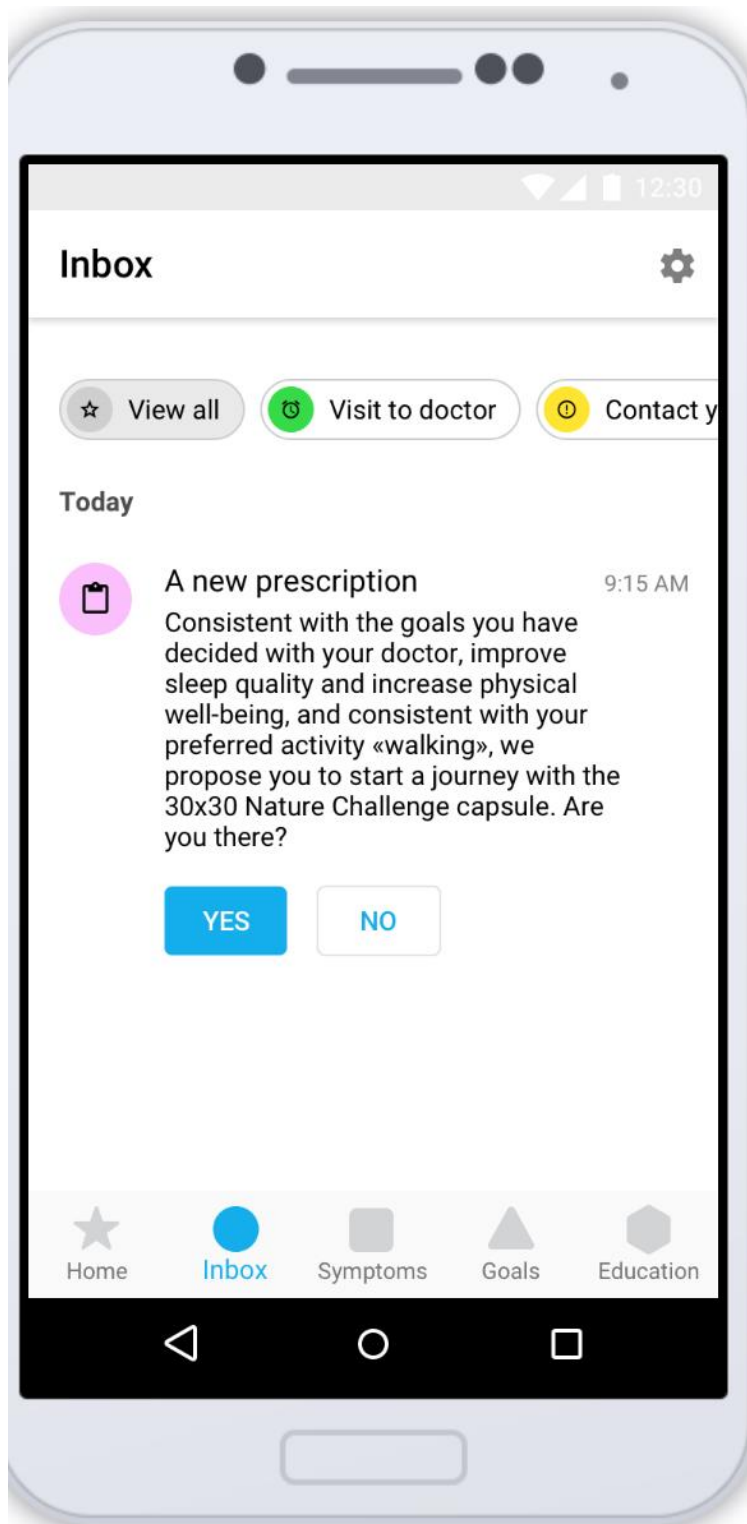


Figure 3.3.6 Types of reminders and notifications in an Inbox - example of a New treatment.

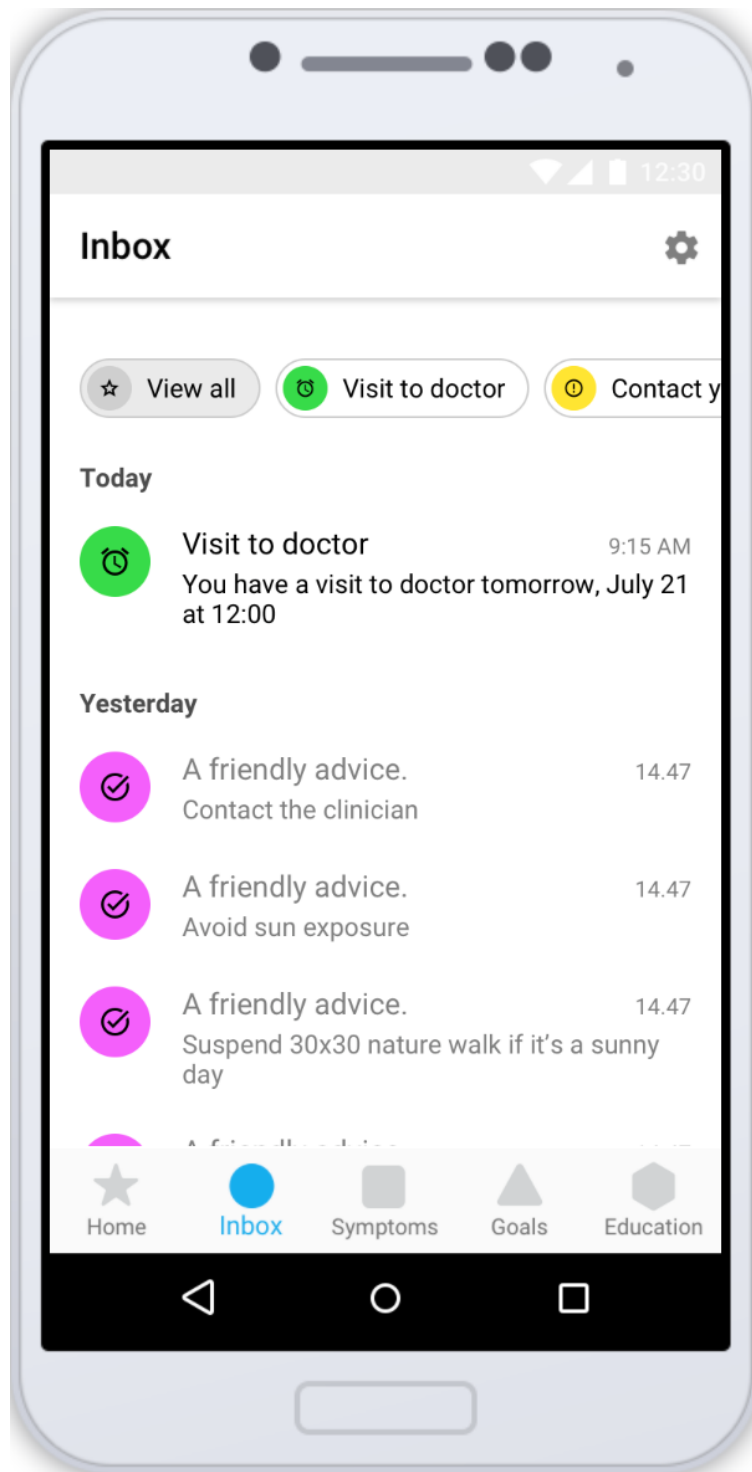


Figure 3.3.7 Types of reminders and notifications in an Inbox - example of a Visit to doctor notification the day before a visit.

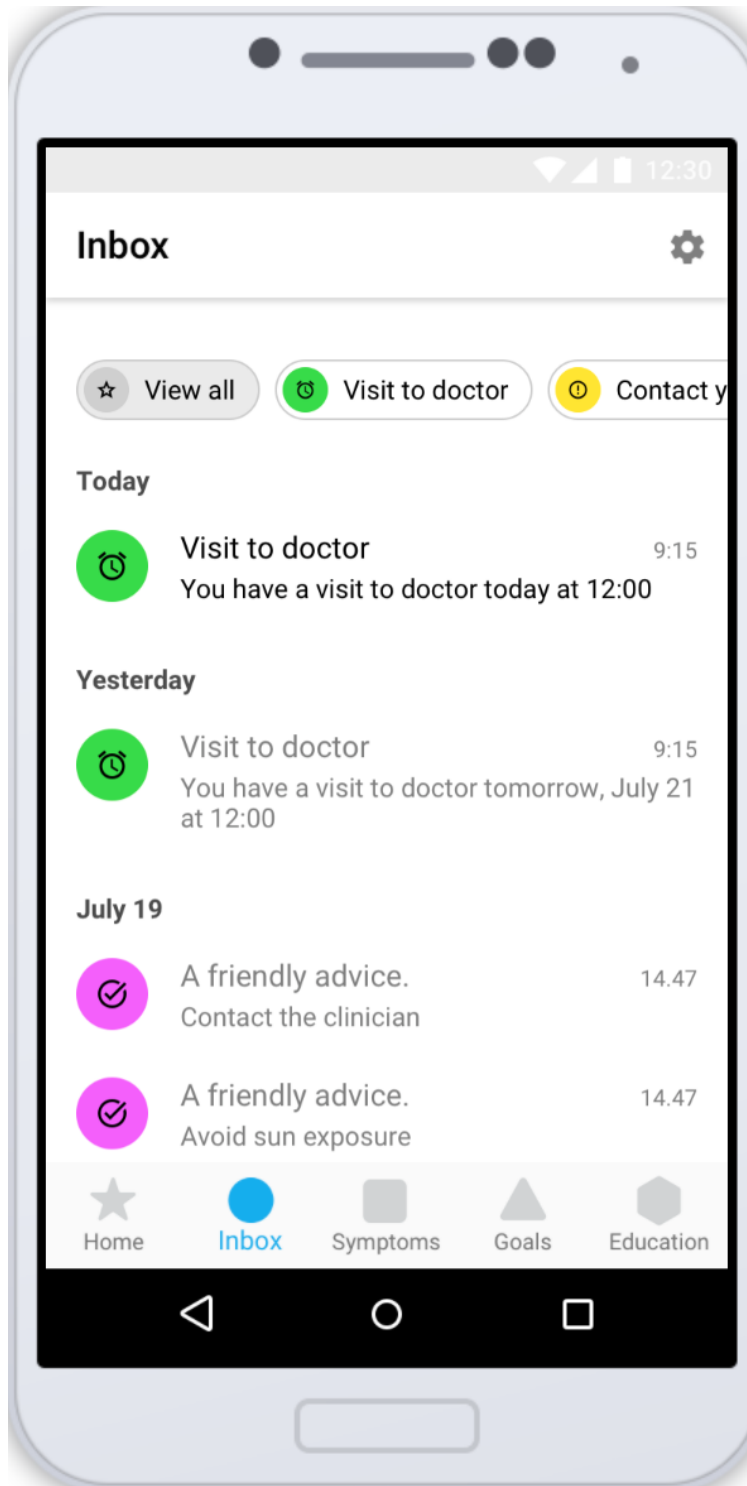


Figure 3.3.8 Types of reminders and notifications in an Inbox - example of a Visit to doctor notification on the visit day.

### 3.4 Capsules

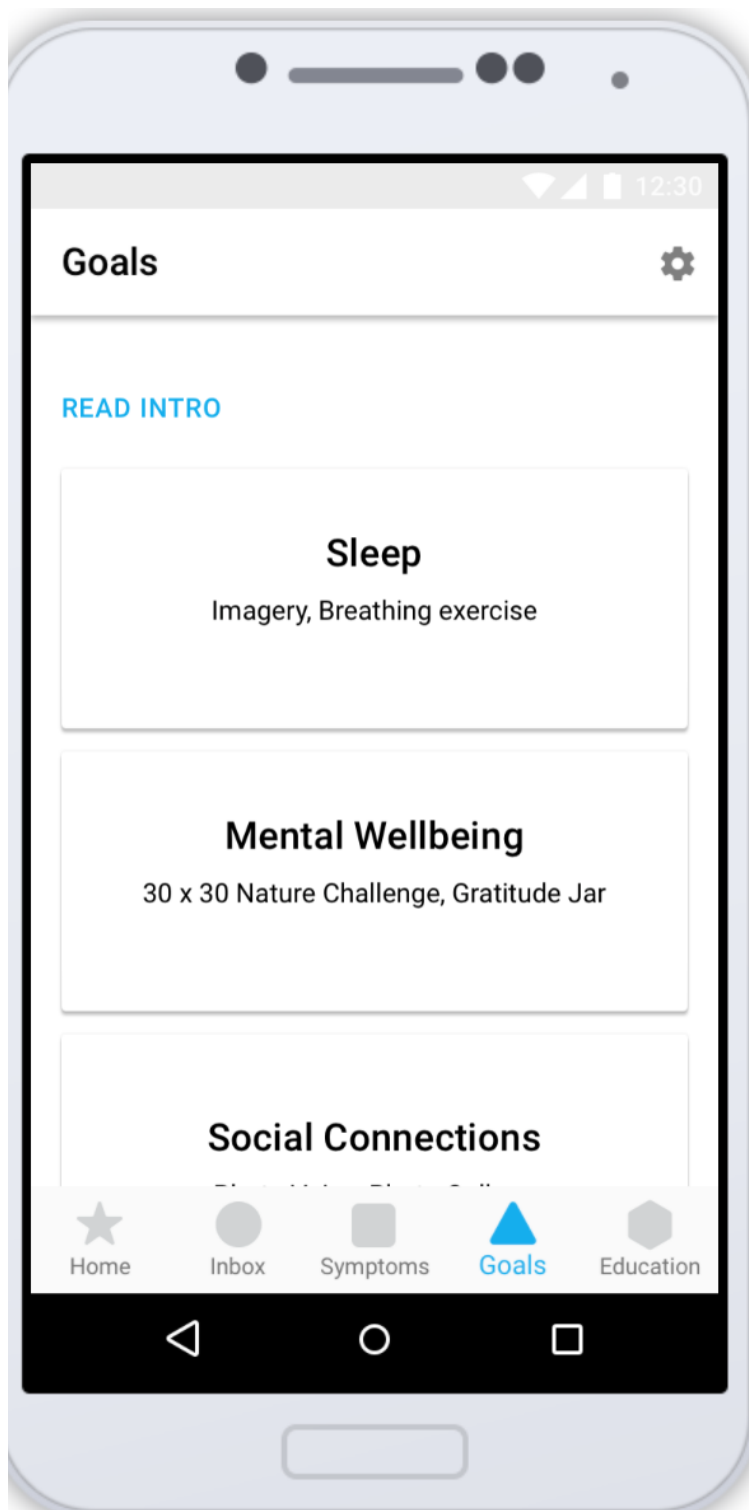


Figure 3.4.1 Goal tab - a Patient is shown the list of goals to achieve divided into groups and activities (that are called Virtual Capsules) that can be performed to achieve the Goal.

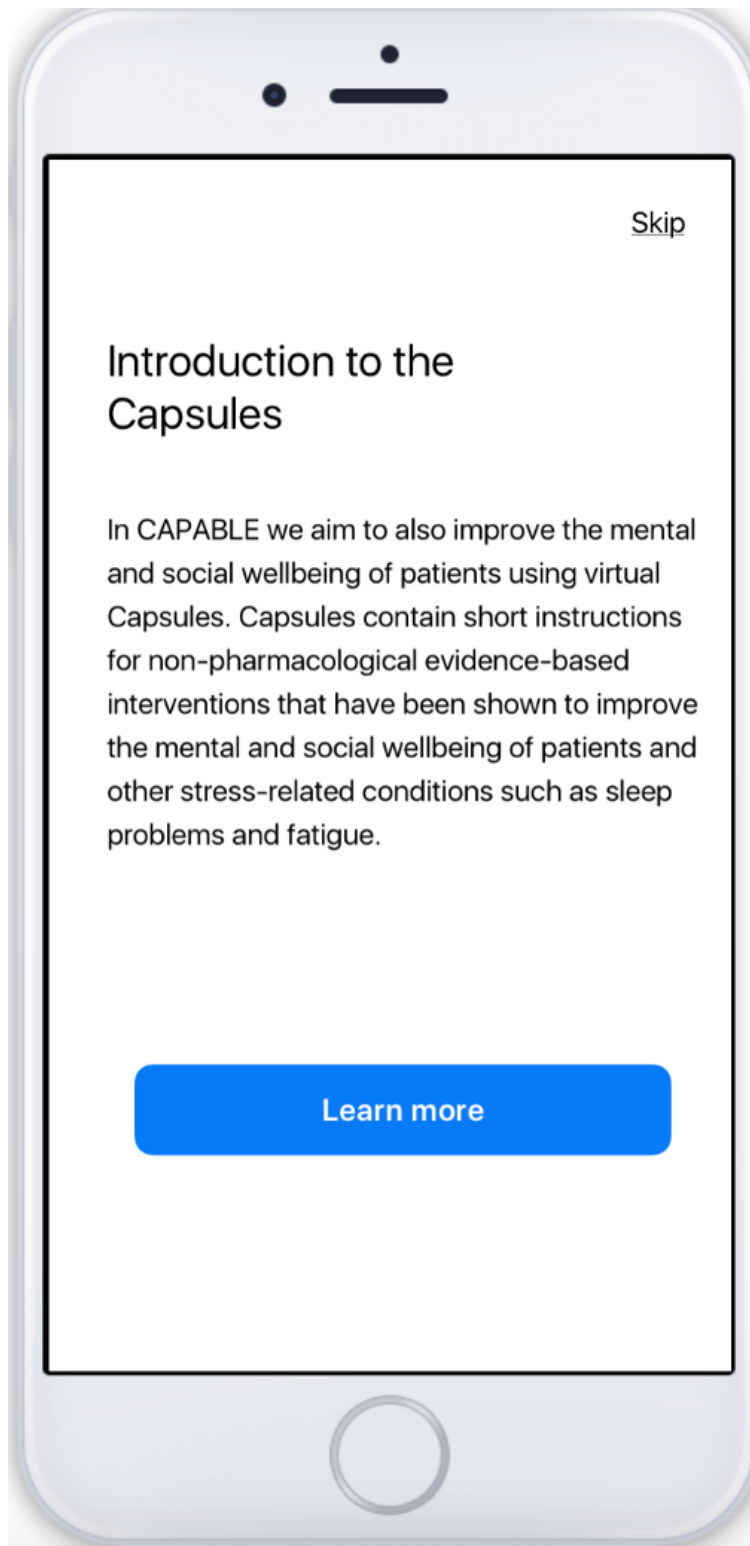


Figure 3.4.2 introduction to the Capsules.

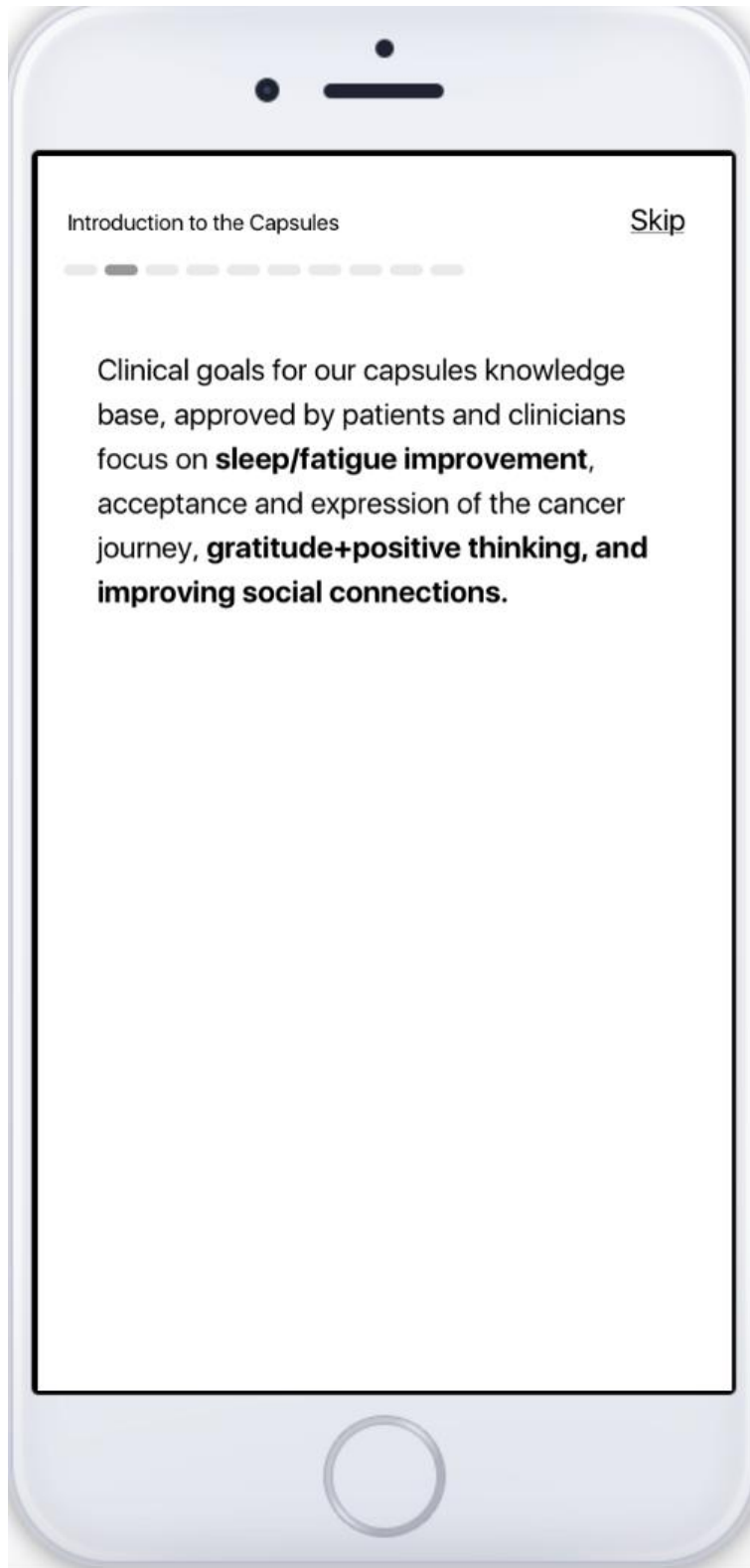


Figure 3.4.3 introduction to the Capsules - slides with information.



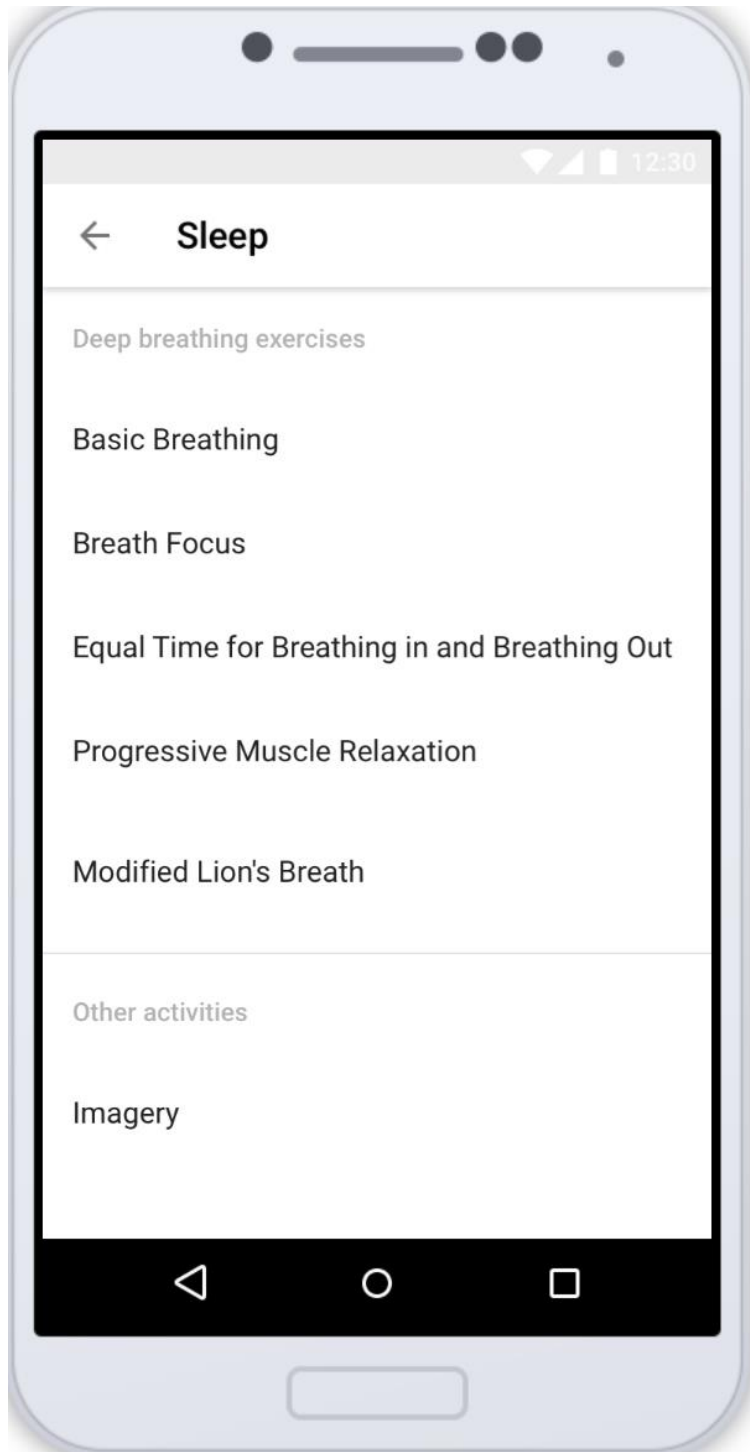


Figure 3.4.4 Goal tab - Available Capsules in the Sleep Goal folder.

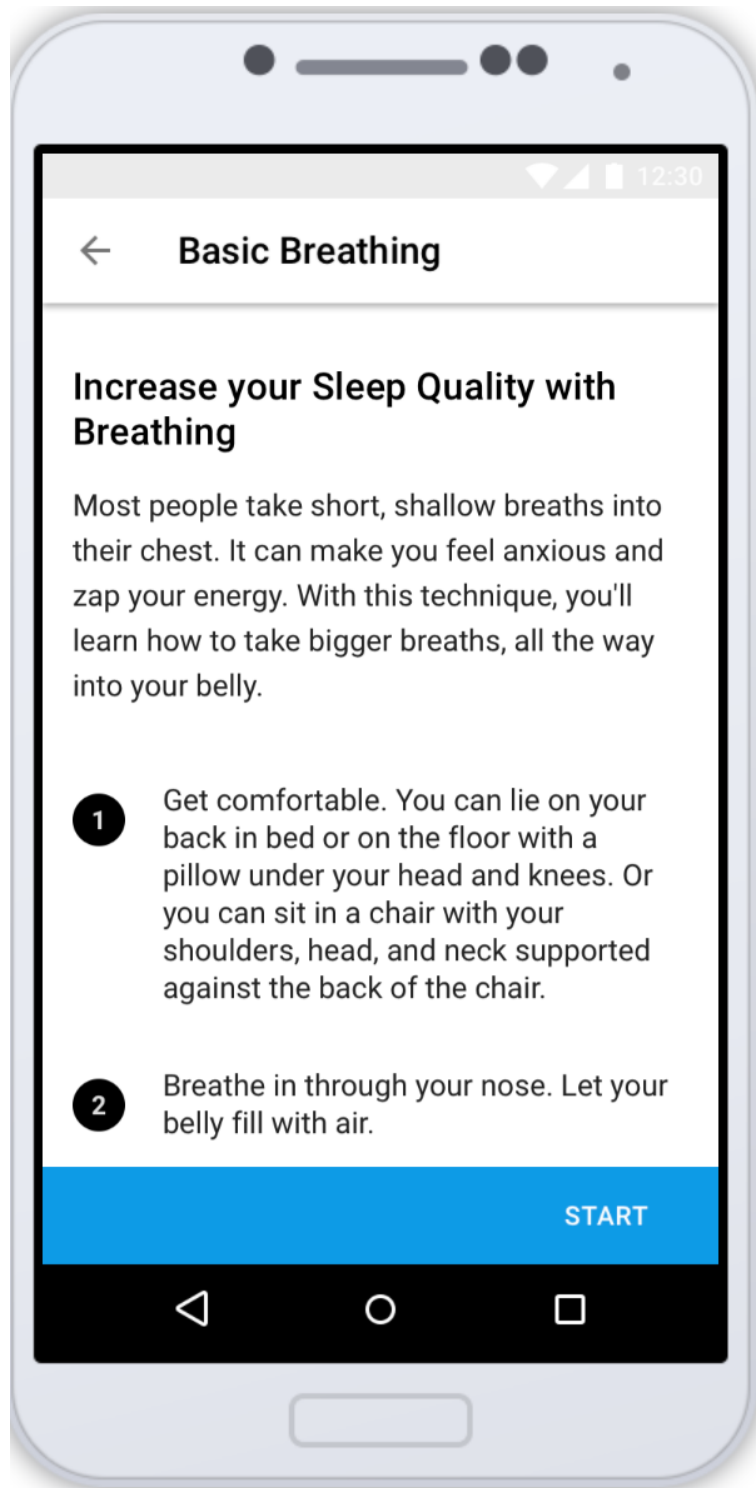


Figure 3.4.5 Introduction and instructions for the Deep Breathing Capsules - Each Capsule is based on the literature and starts with a description and a Source.

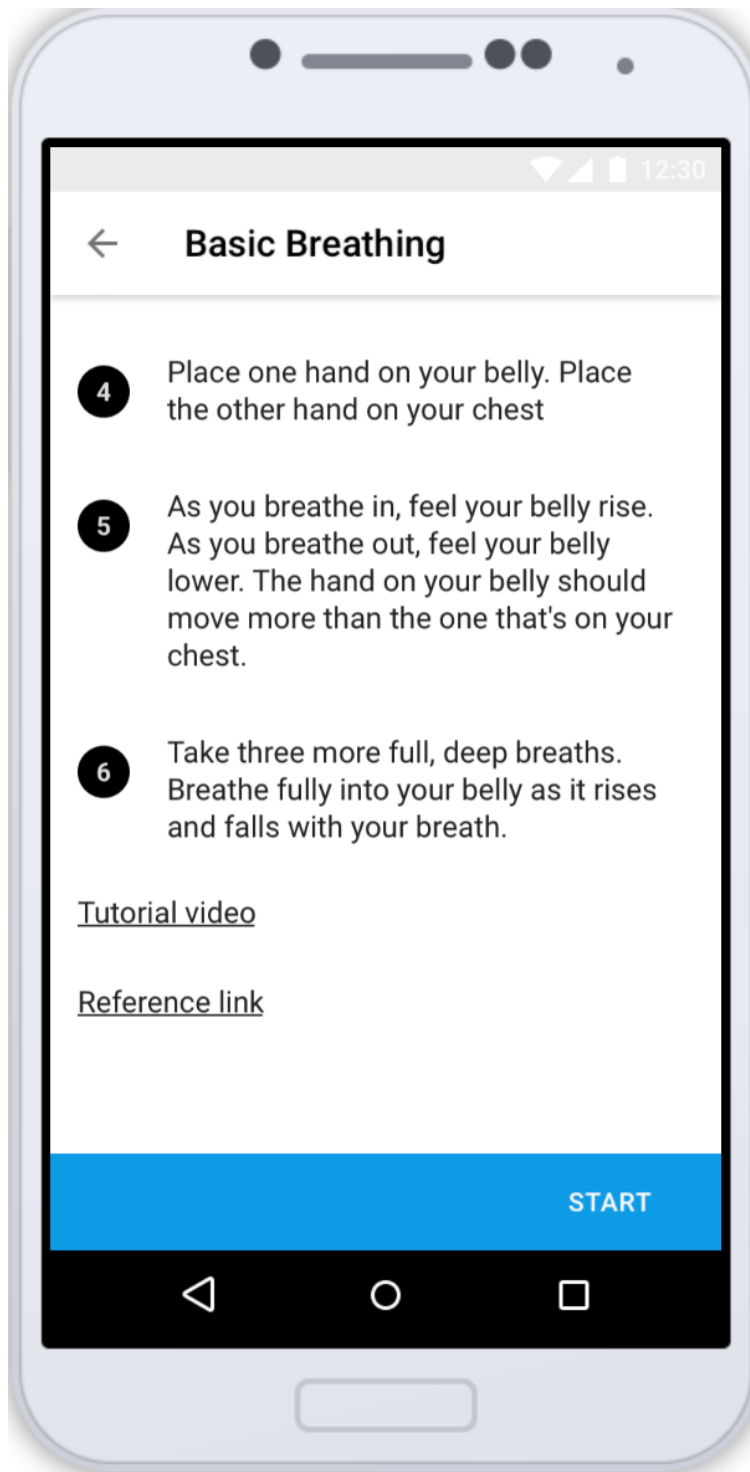


Figure 3.4.6 This screen presents what you see when you scroll down on the previous screen - Introduction and instructions for the Deep Breathing Capsules.

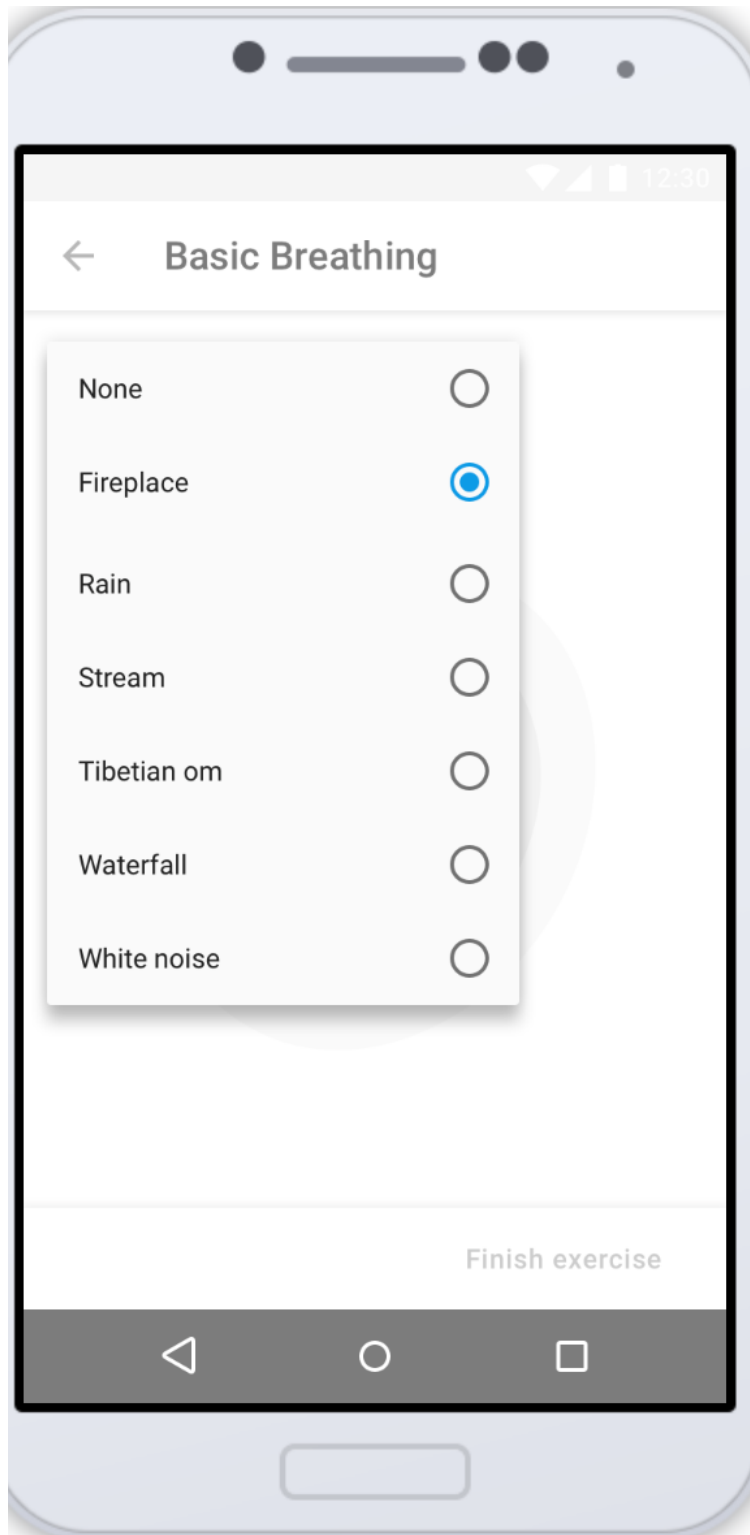


Figure 3.4.7 Basic Breathing Capsule - possibility to change audio.

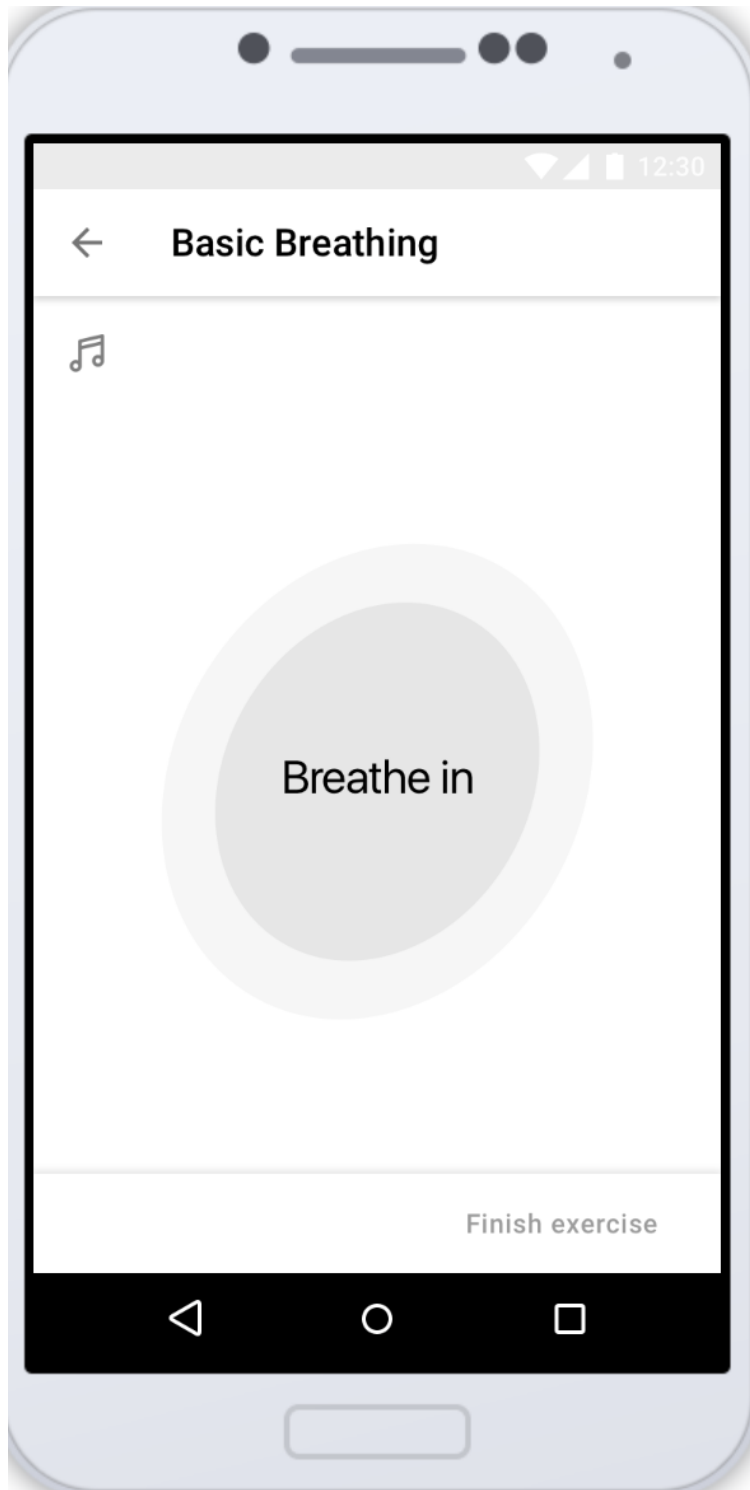


Figure 3.4.8 Basic Breathing Capsule - Breathe in.

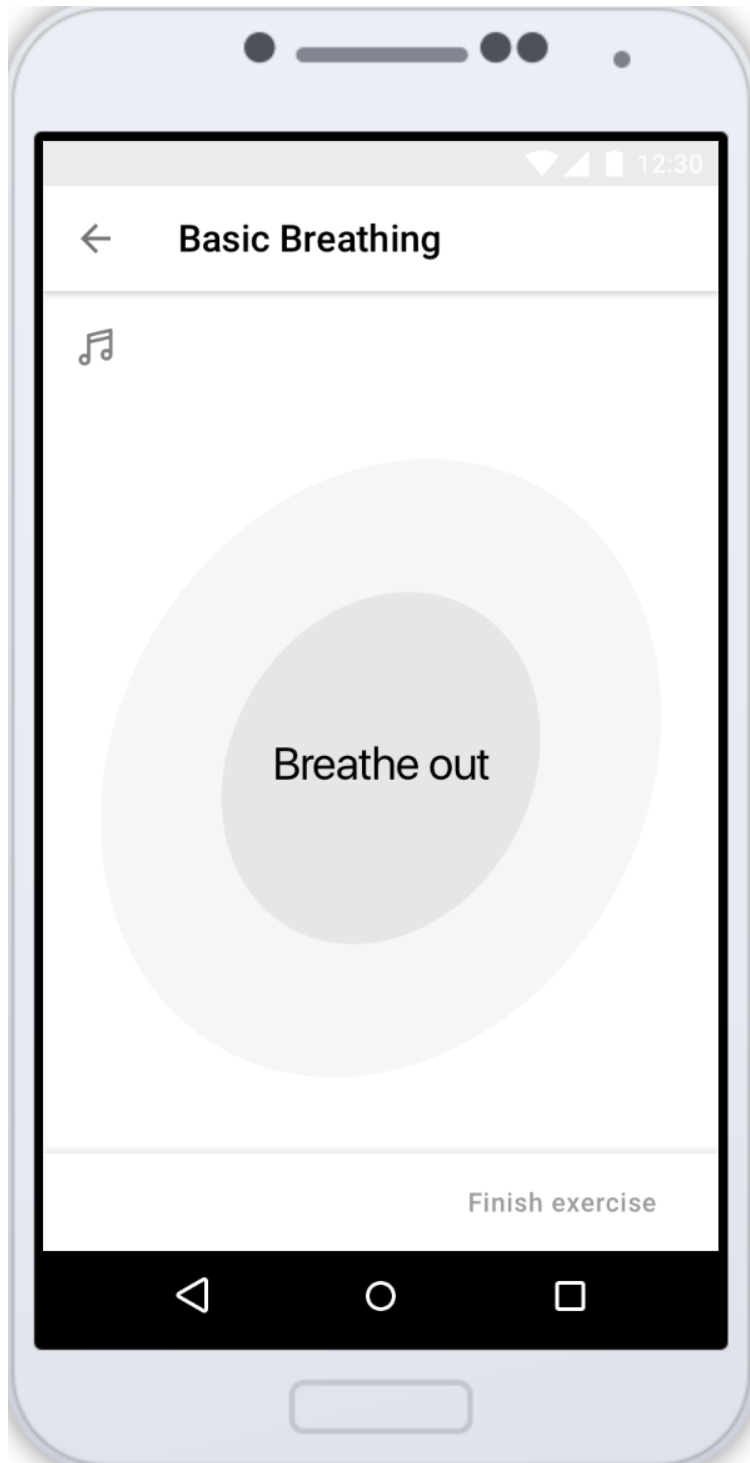


Figure 3.4.9 Basic Breathing Capsule - Breathe out.

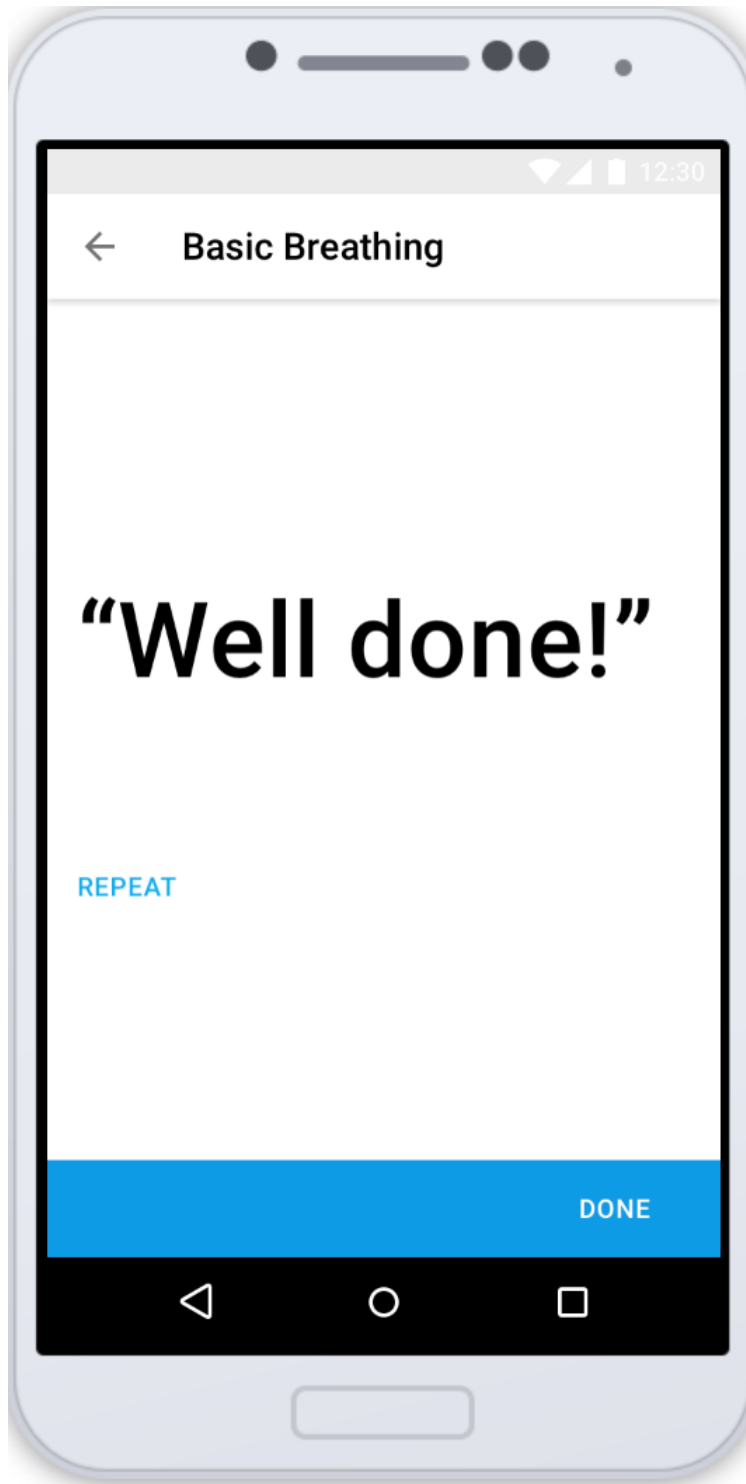


Figure 3.4.10 Basic Breathing Capsule - Motivation quote after performing a Capsule.

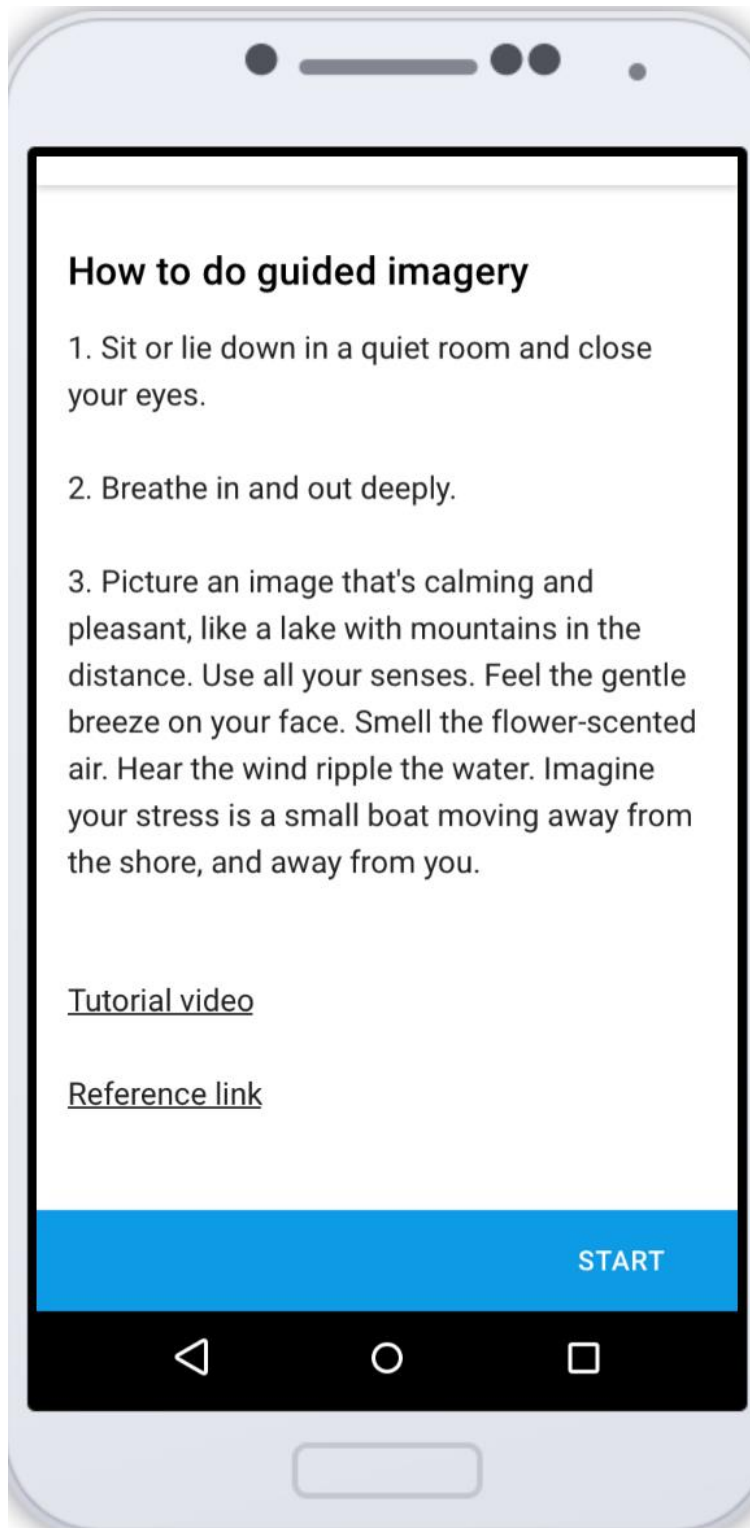


Figure 3.4.11 Introduction and instructions for the Guided Imagery Capsule - Each Capsule is based on the literature and starts with a description and a Reference information.



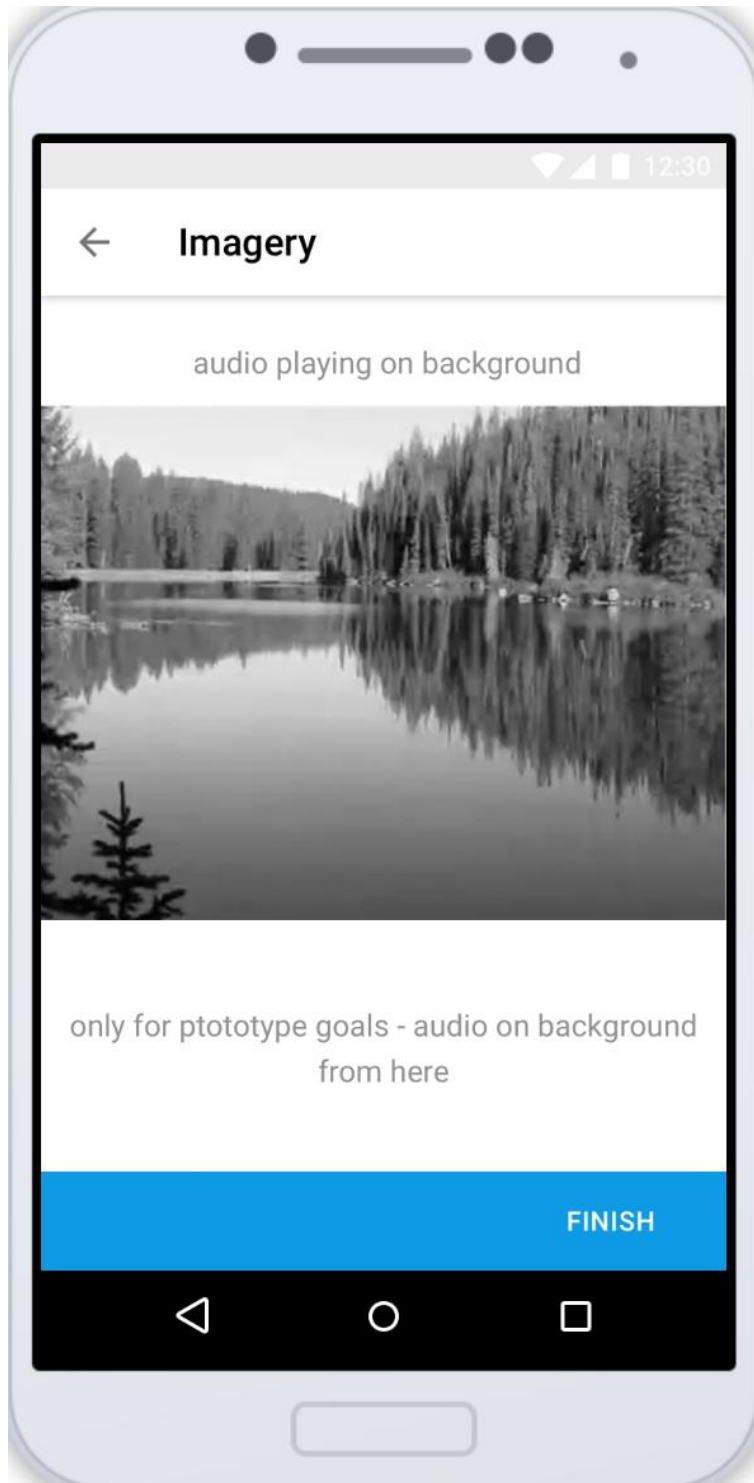


Figure 3.4.12 Guided Imagery - Example of the Capsule activities.

This capsule will be voiced on a later stage. Figure 3.4.12 is a mock-up and gives an idea how it will be organized.

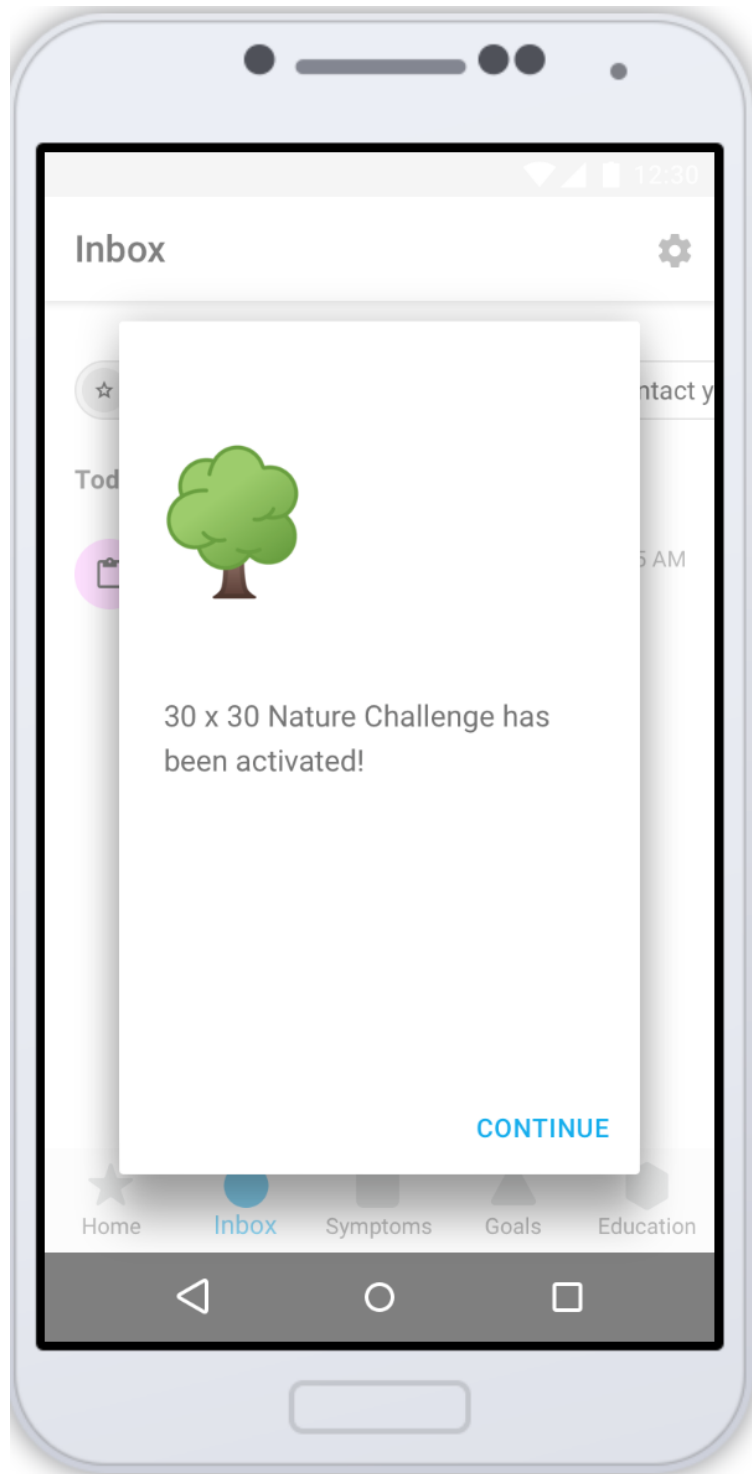


Figure 3.4.13 Inbox tab - Activation of a Capsule.

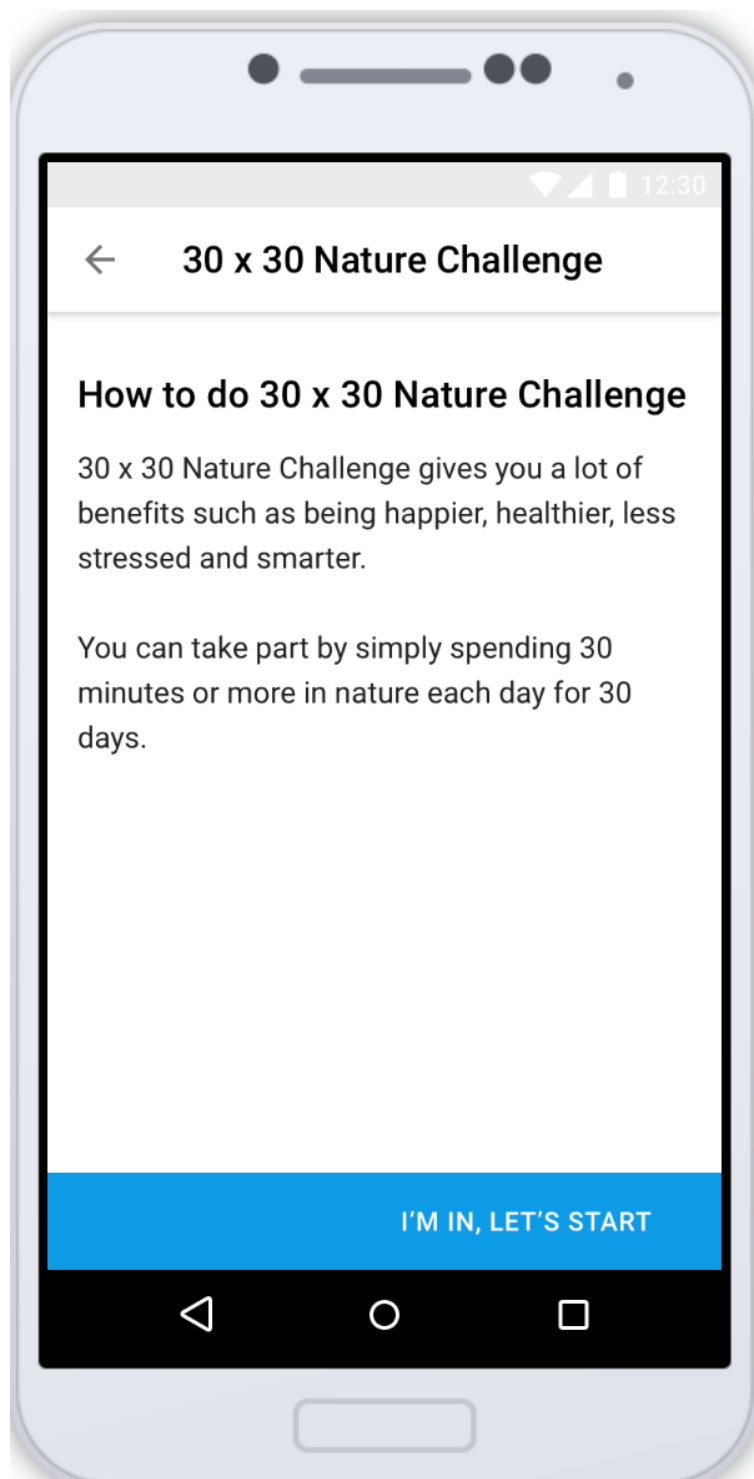


Figure 3.4.14 Introduction and instructions for the 30\*30 Nature Challenge Capsule. Each Capsule is based on the literature and starts with a description and a Reference information.

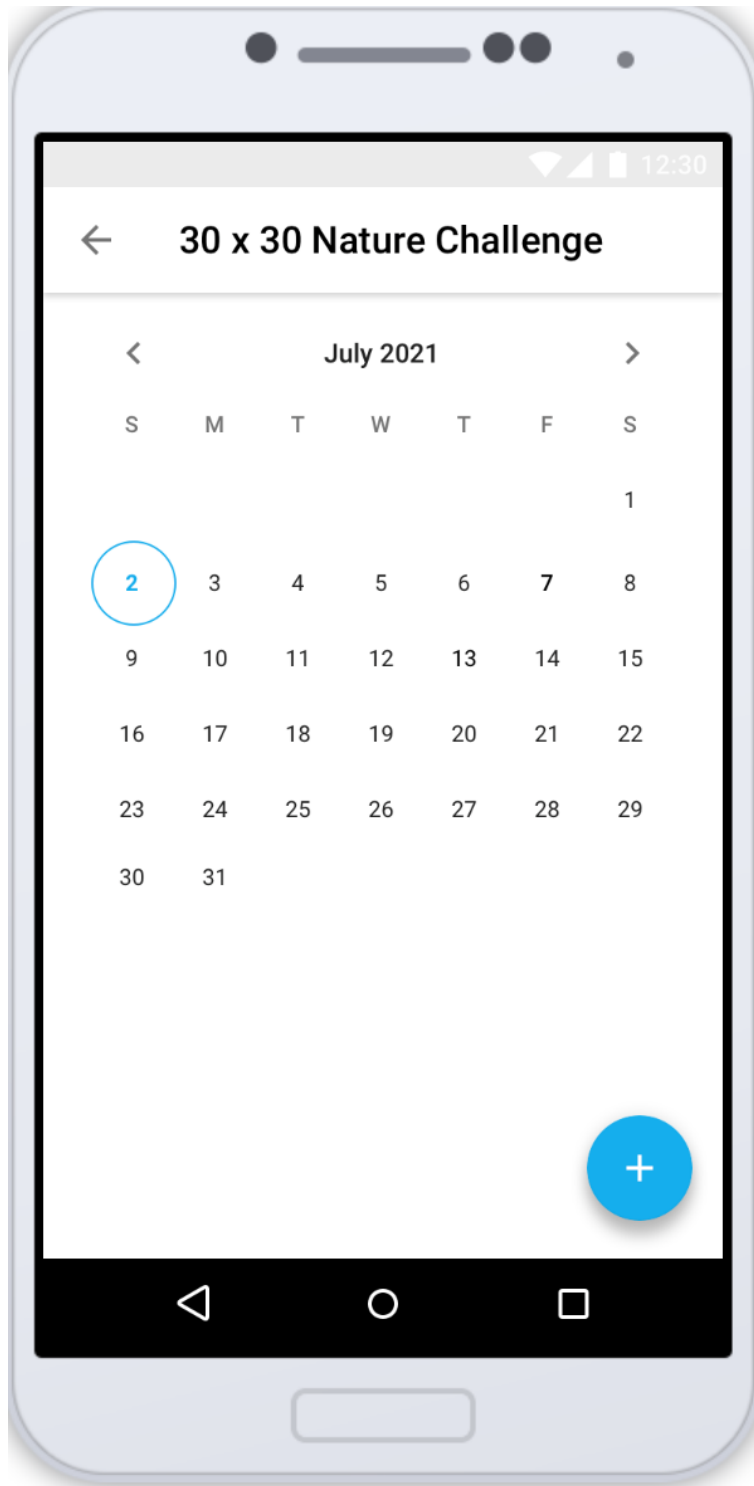


Figure 3.4.15 30\*30 Nature Challenge - Example of the Capsule activities - Calendar view - empty state when no activity is reported yet.

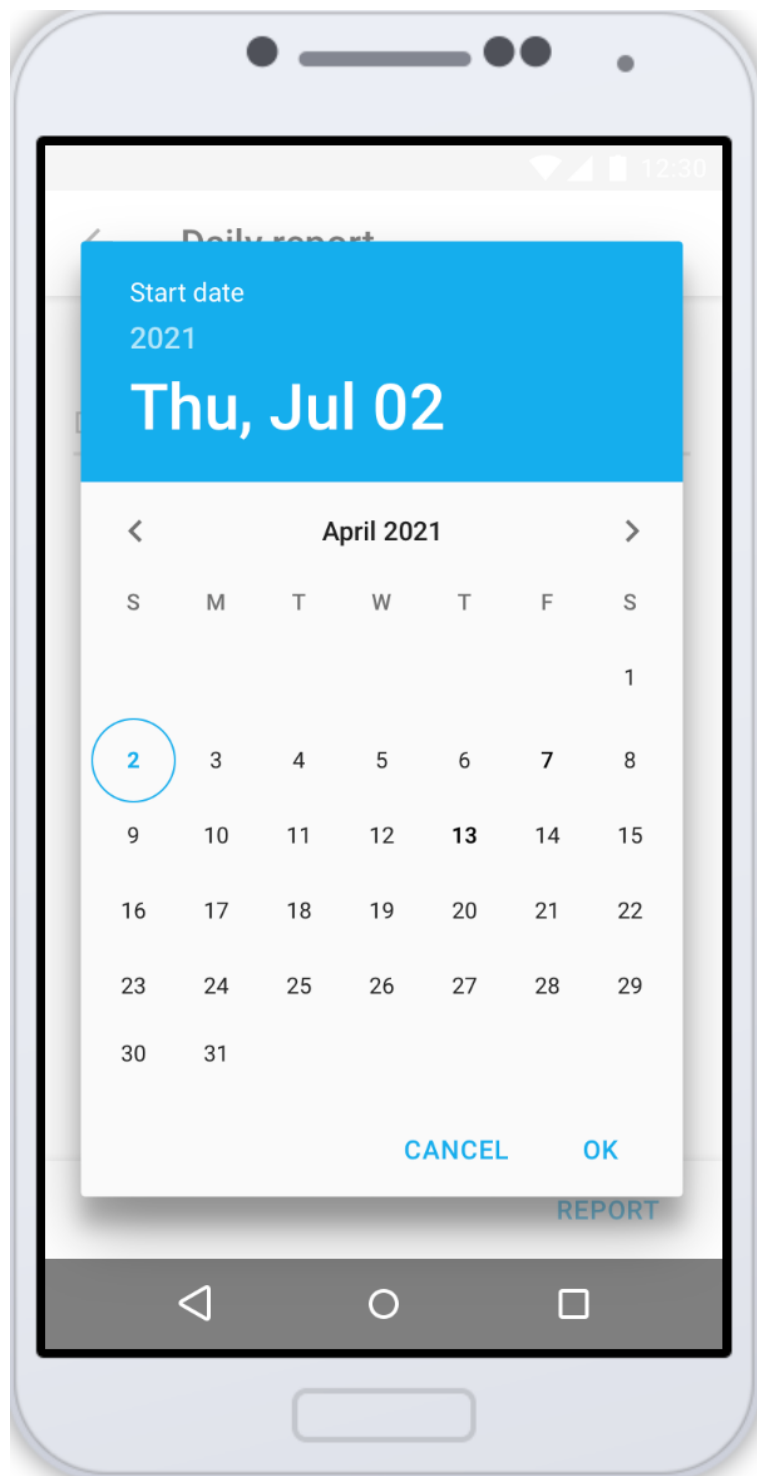
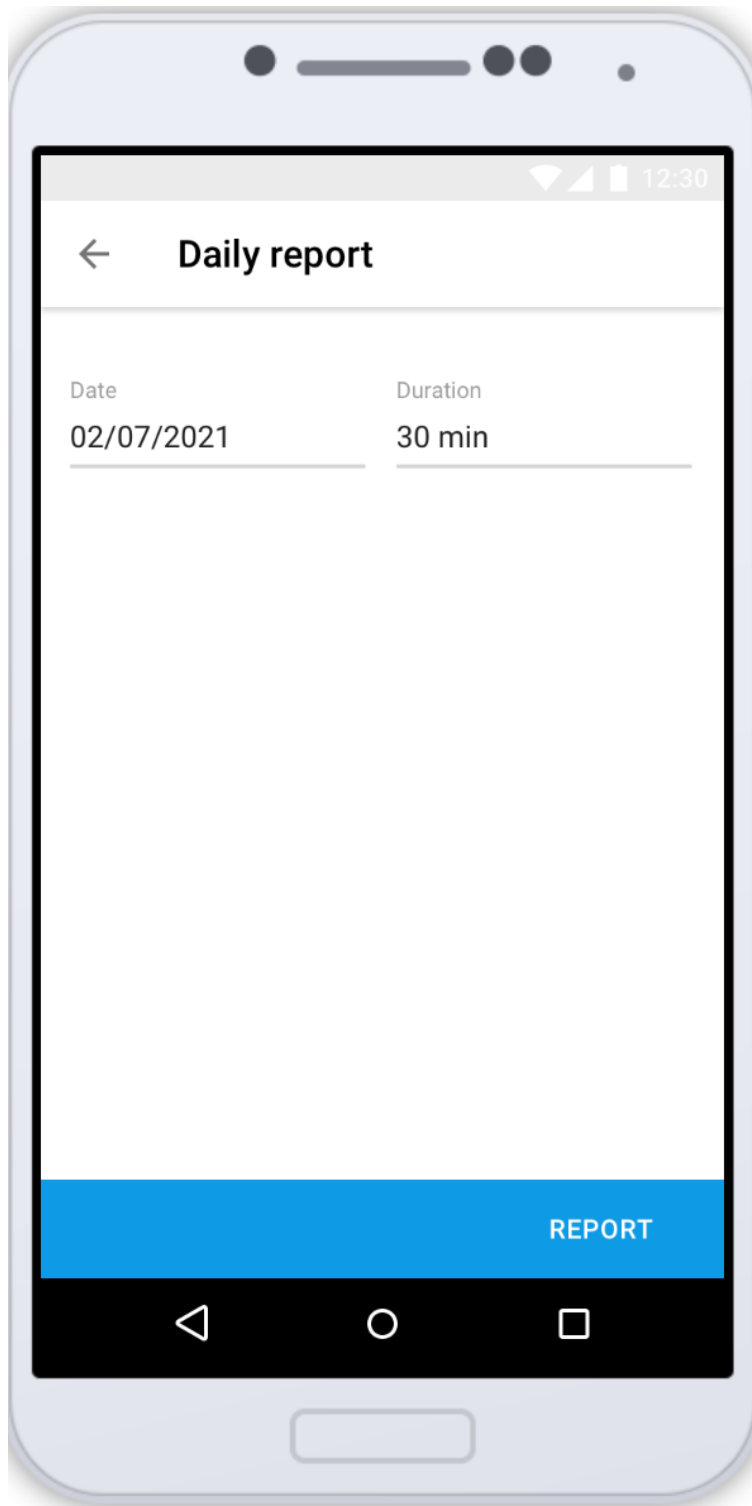


Figure 3.4.16 30\*30 Nature Challenge - Example of the Capsule activities - Date report - reporting of performing the capsule on that date.



The image shows a mobile application interface for a 'Daily report'. At the top, there is a status bar with signal, battery, and time (12:30) indicators. Below this is a header bar with a back arrow and the title 'Daily report'. The main content area contains two input fields: 'Date' with the value '02/07/2021' and 'Duration' with the value '30 min'. At the bottom of the form is a blue button labeled 'REPORT'. The entire interface is displayed on a smartphone screen with a home button at the bottom.

Figure 3.4.17 30\*30 Nature Challenge - Example of the Capsule activities - Date and Duration report.

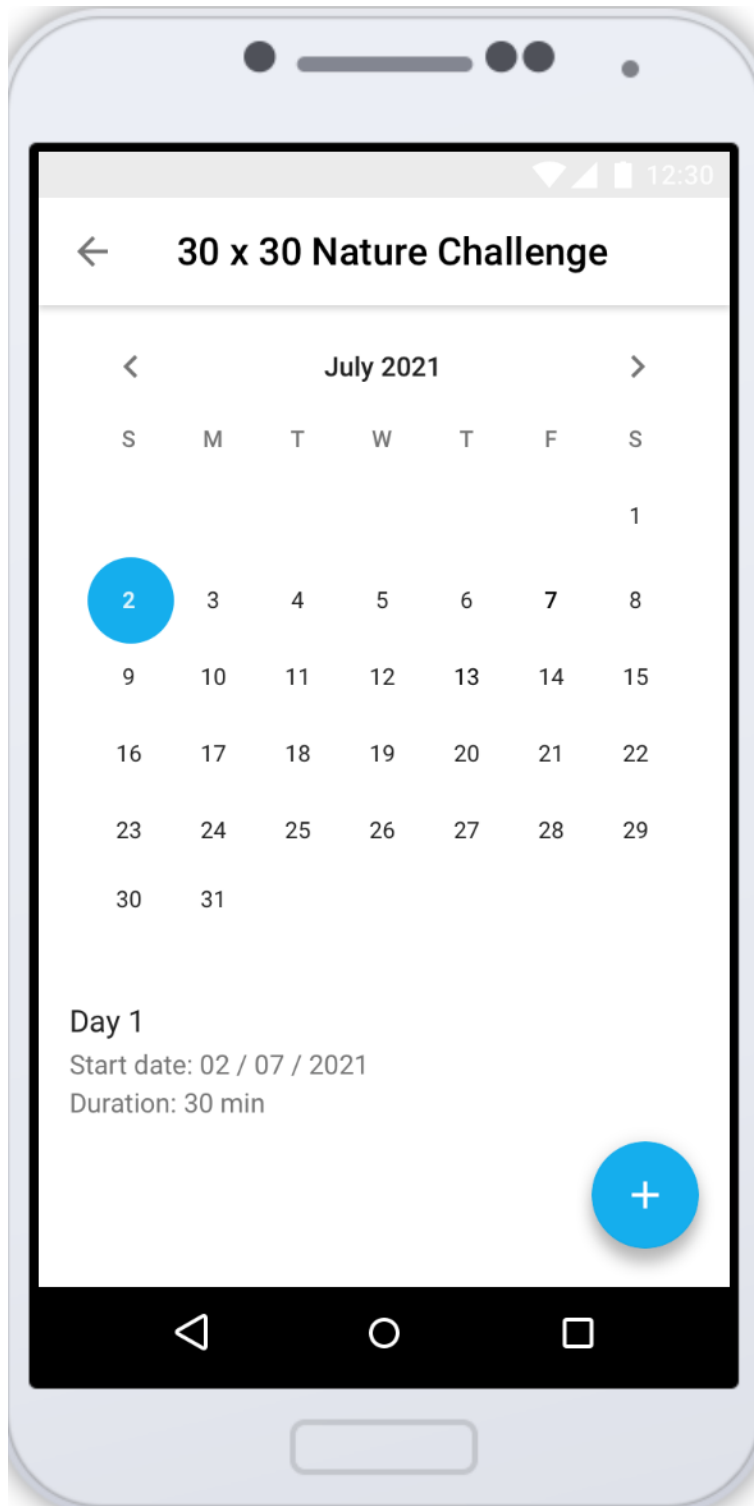


Figure 3.4.18 30\*30 Nature Challenge - Example of the Capsule activities - Calendar view with a report.



Figure 3.4.19 Introduction and instructions for the Garden Bowl Capsule - an activity for the goal of Accepting your Cancer Journey. Each Capsule is based on the literature and starts with a description and a Reference information.



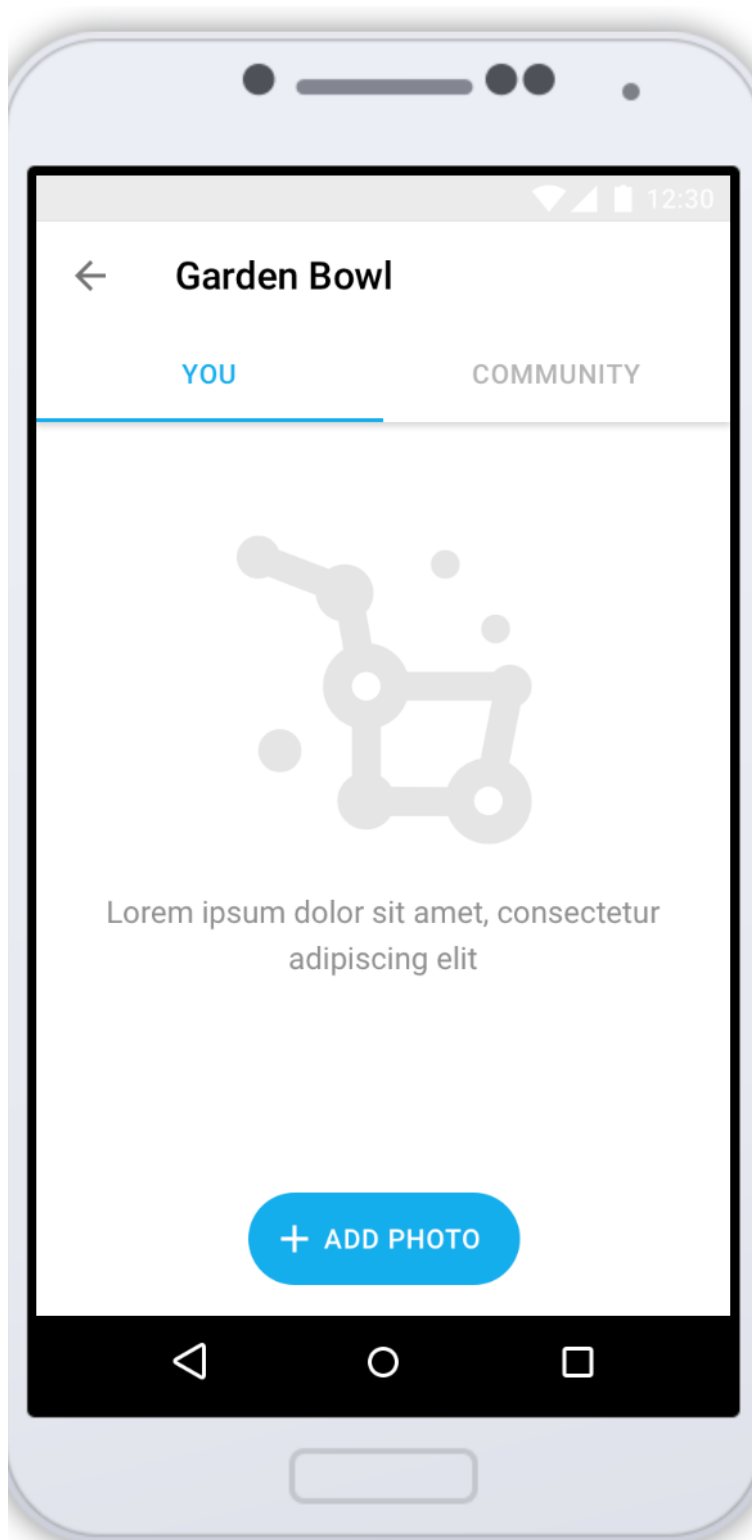


Figure 3.4.20 Garden Bowl - Example of the Capsule activity: uploading a photo of the garden bowl of the patient.



Figure 3.4.21 Garden Bowl - Example of the Capsule activities - Add photo with a possibility not to share with a community.

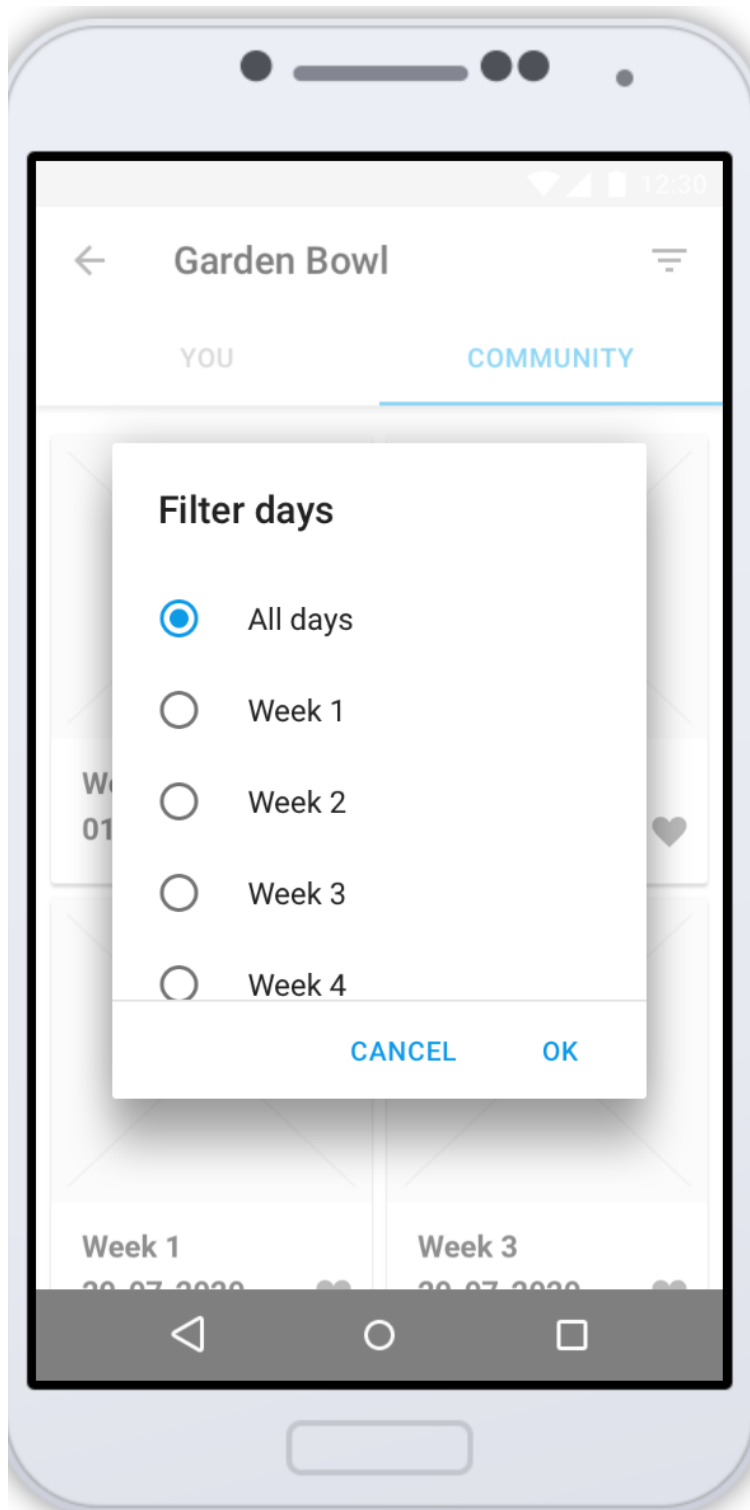


Figure 3.4.22 Garden Bowl - Example of the Capsule activities - Filter by weeks to show the photos from specific weeks since the start of this activity - to observe how the cancer journey is processing.

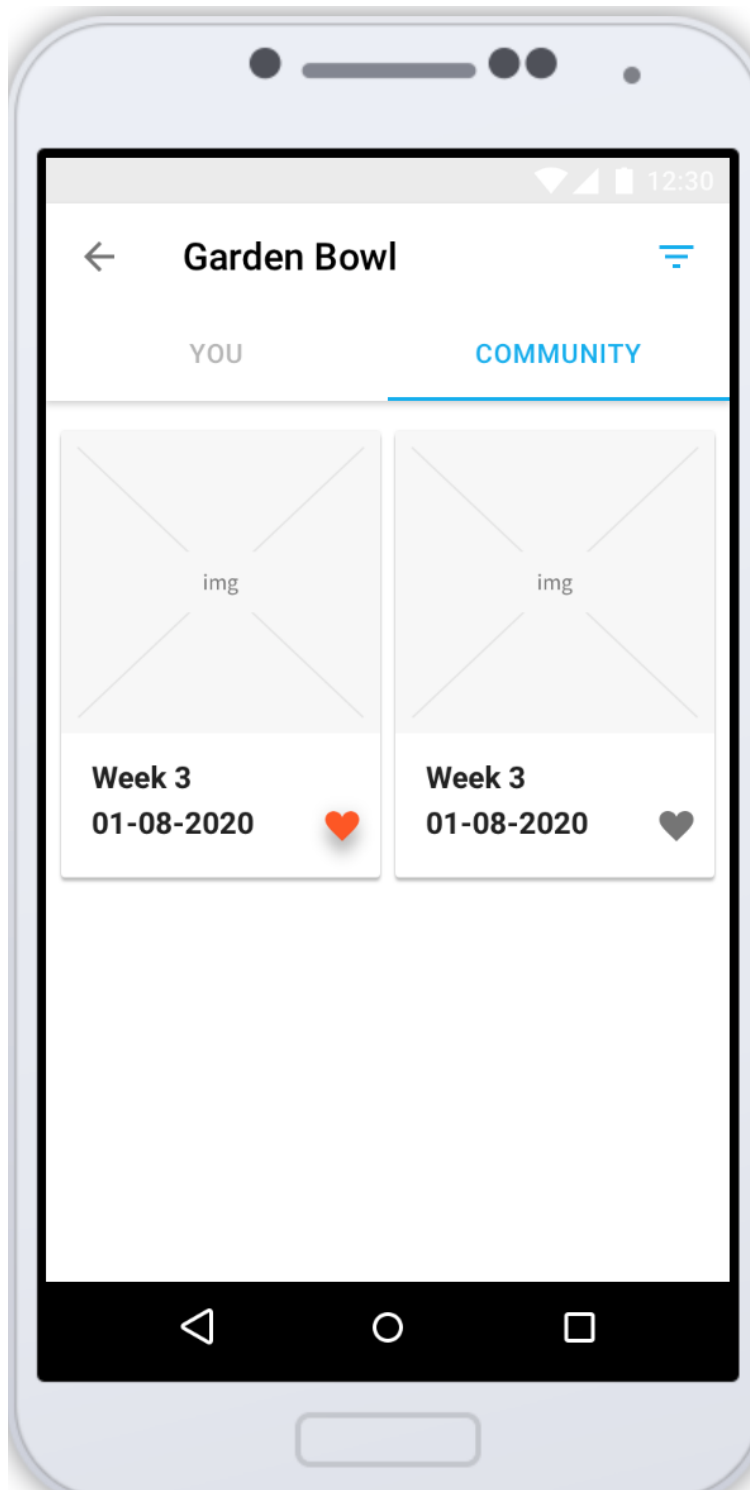


Figure 3.4.23 Garden Bowl - Example of the Capsule activities - Put "Like" functionality to like a photo uploaded by the member of the community.



Figure 3.4.24 Introduction and instructions for the Photo Collage Capsule. Each Capsule is based on the literature and starts with a description and a Reference information.

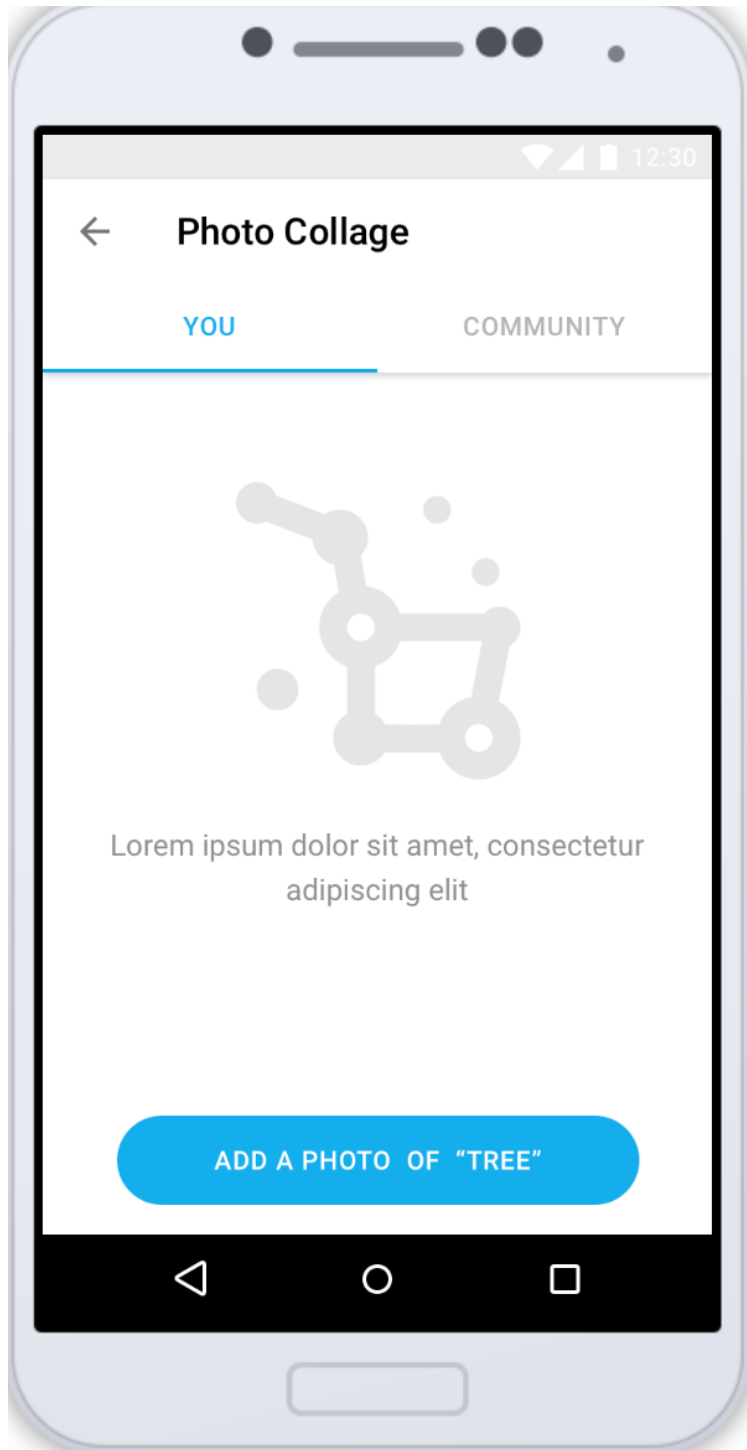


Figure 3.4.25 Photo Collage - Example of the Capsule activities.

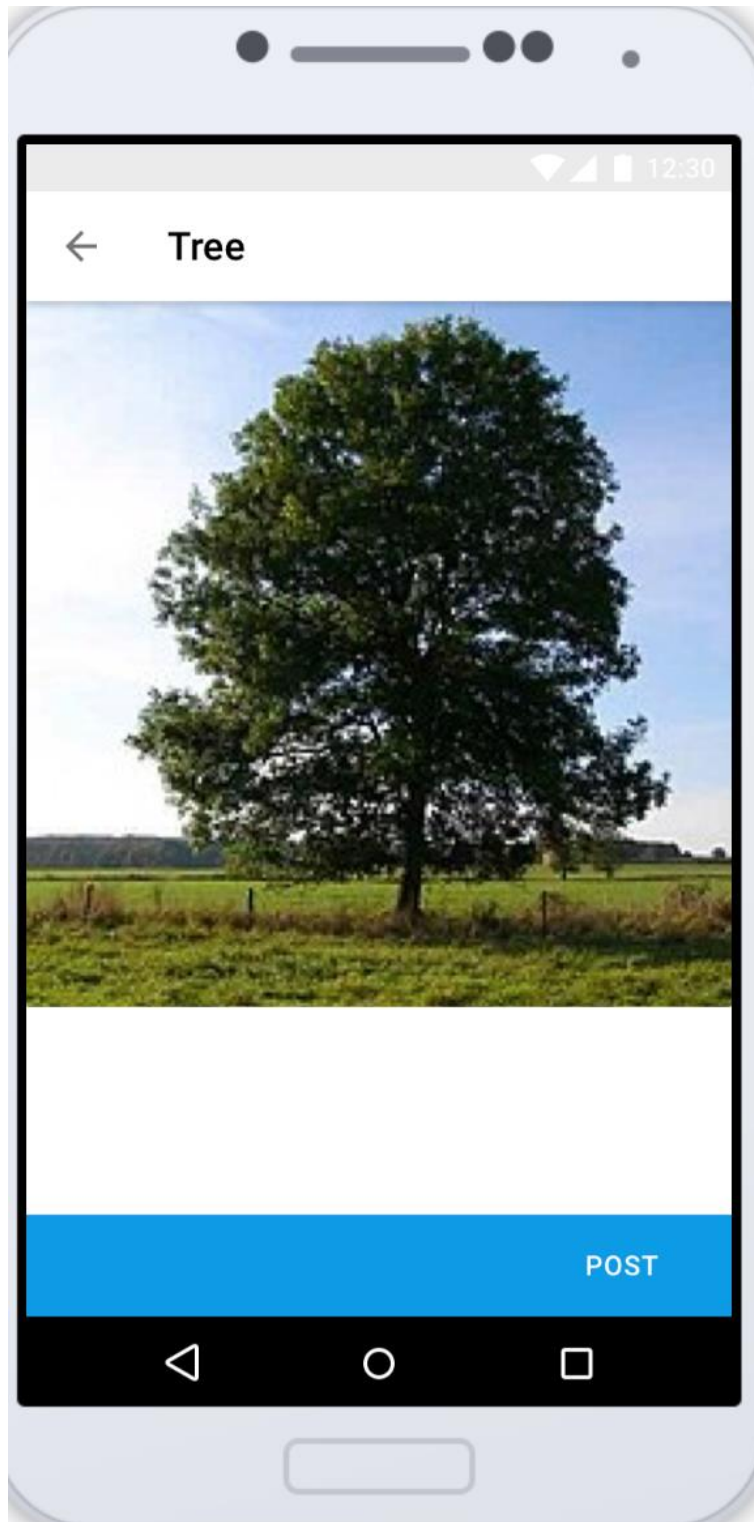


Figure 3.4.26 Photo Collage - Example of the Capsule activities - Add a photo.

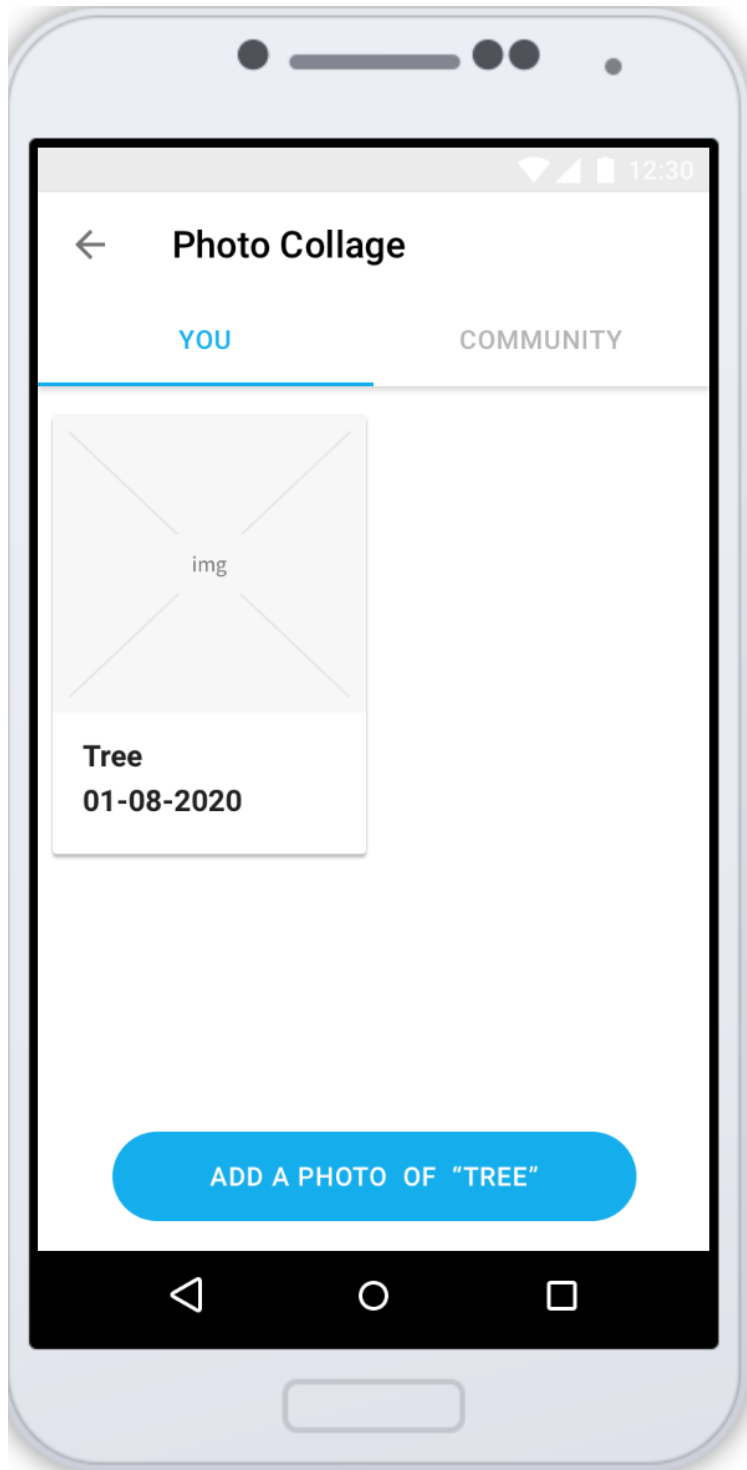


Figure 3.4.27 Photo Collage - Example of the Capsule activities.



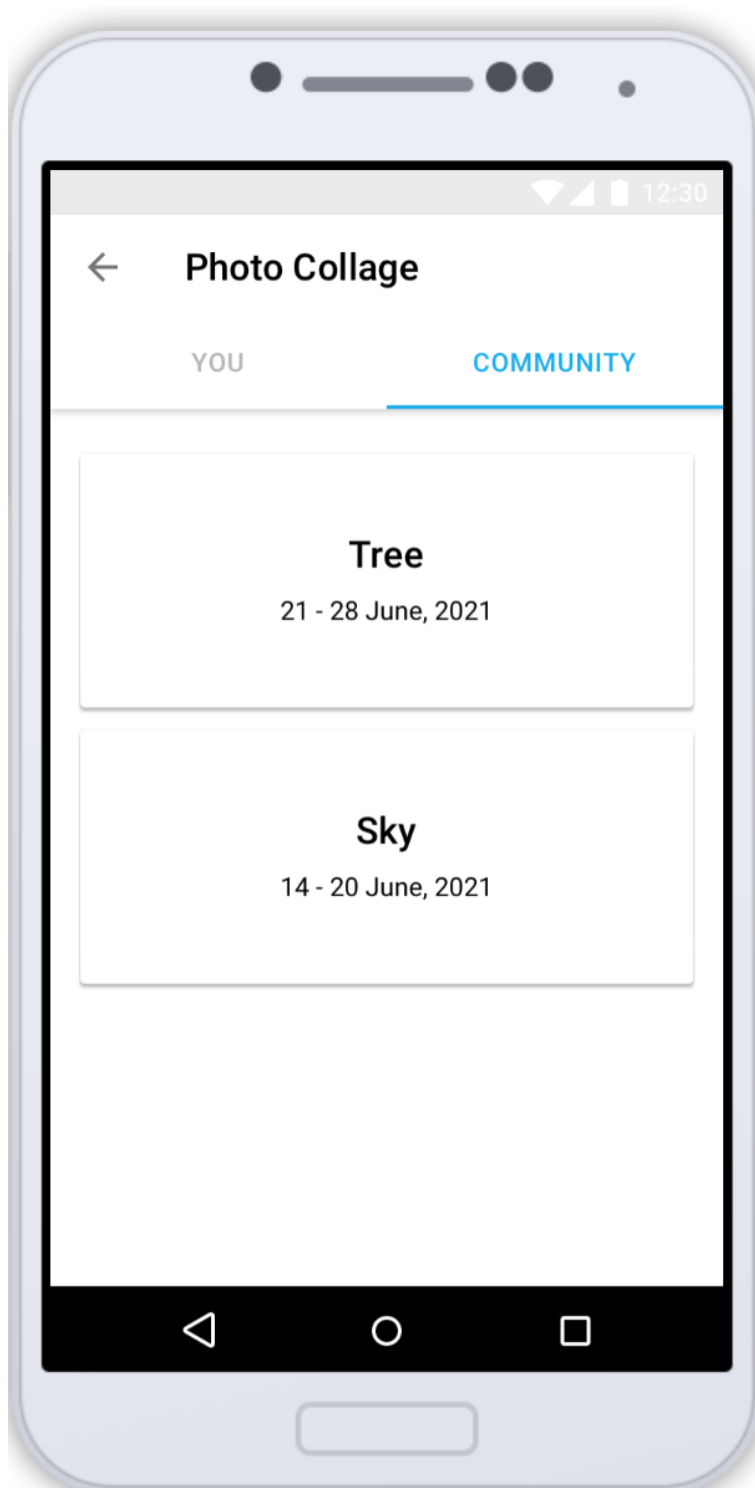


Figure 3.4.28 Photo Collage - Example of the Capsule activities - Filter photos taken by the community by Topics.

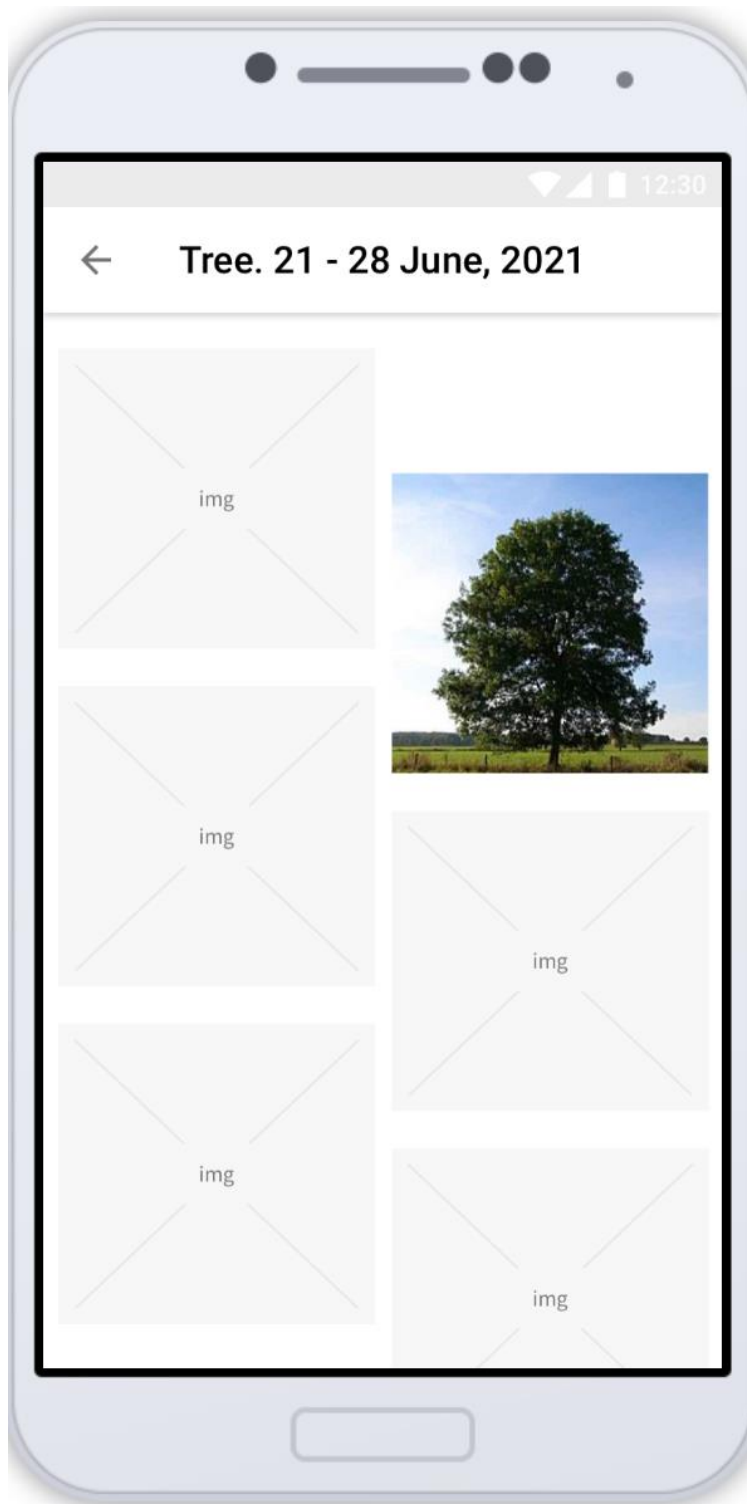


Figure 3.4.29 Photo Collage - Example of the Capsule activities - Photo Collage of the community photos.

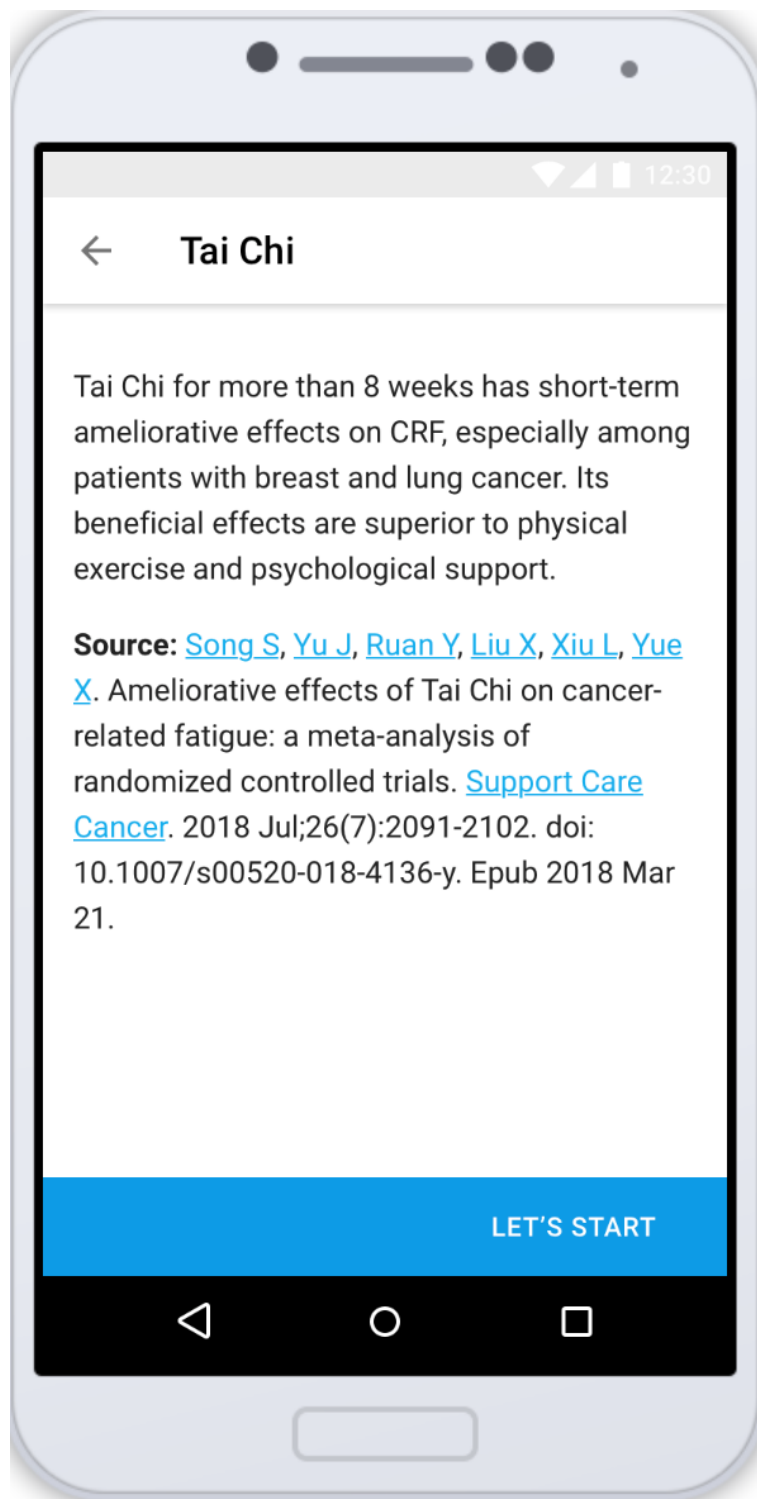


Figure 3.4.30 Introduction and instructions for the Tai Chi capsule for the goals of improving sleep and stress. Each Capsule is based on the literature and starts with a description and a Reference information.

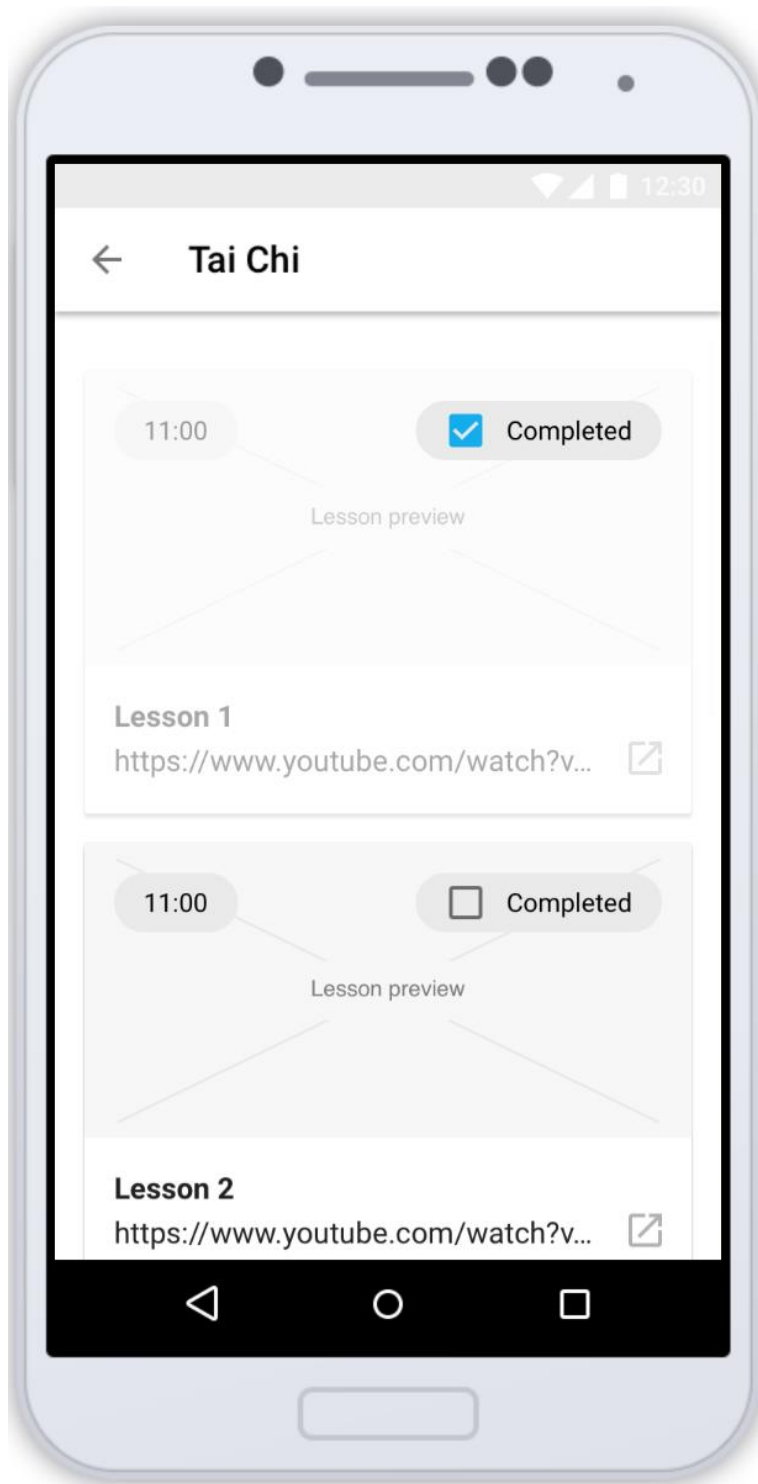


Figure 3.4.31 Tai Chi - Example of the Capsule activities. Provides Link to a video for performing 5 minutes of Tai Chi exercise. There is a selection from 7 recorded lessons

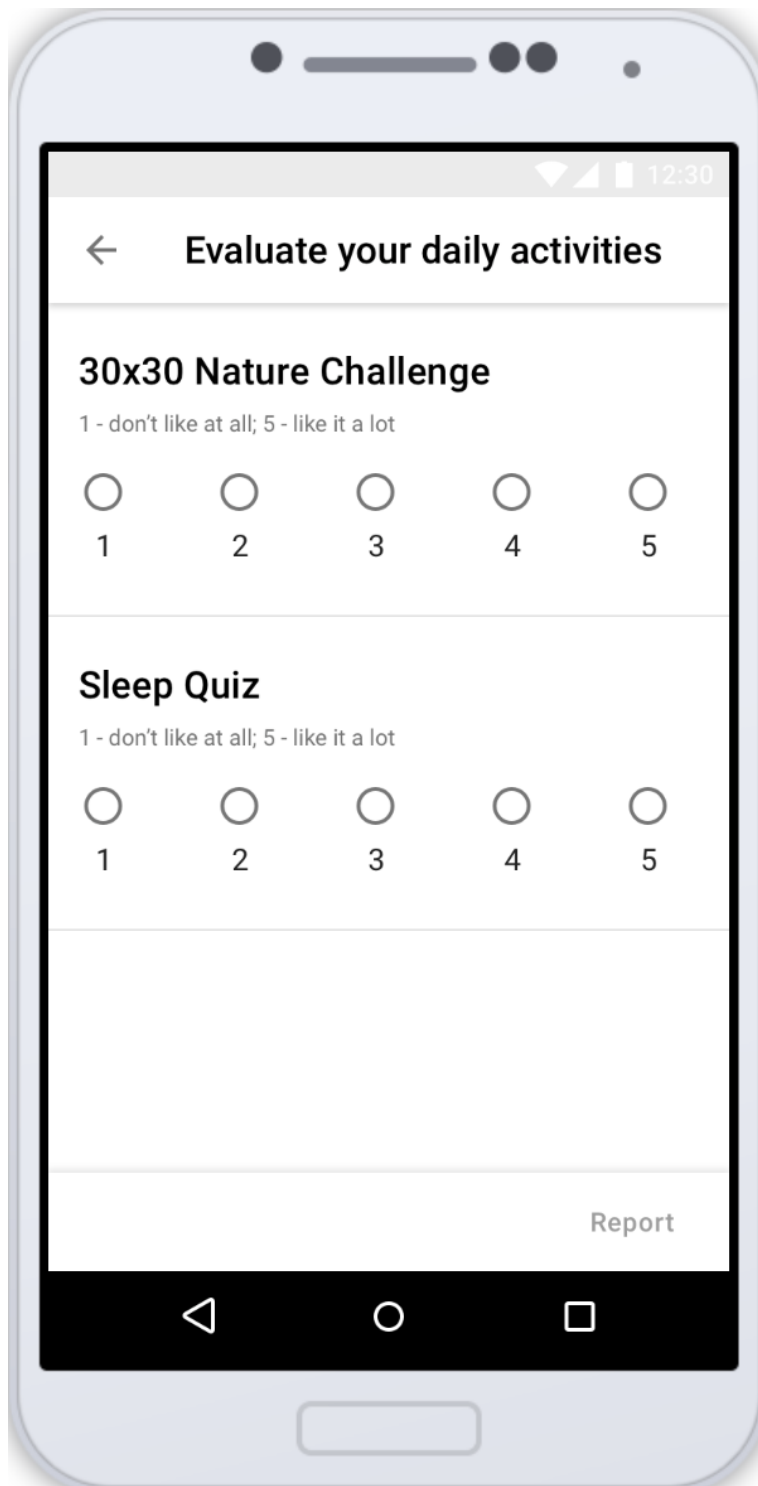


Figure 3.4.32 Home tab with the Evaluation of Daily activities.

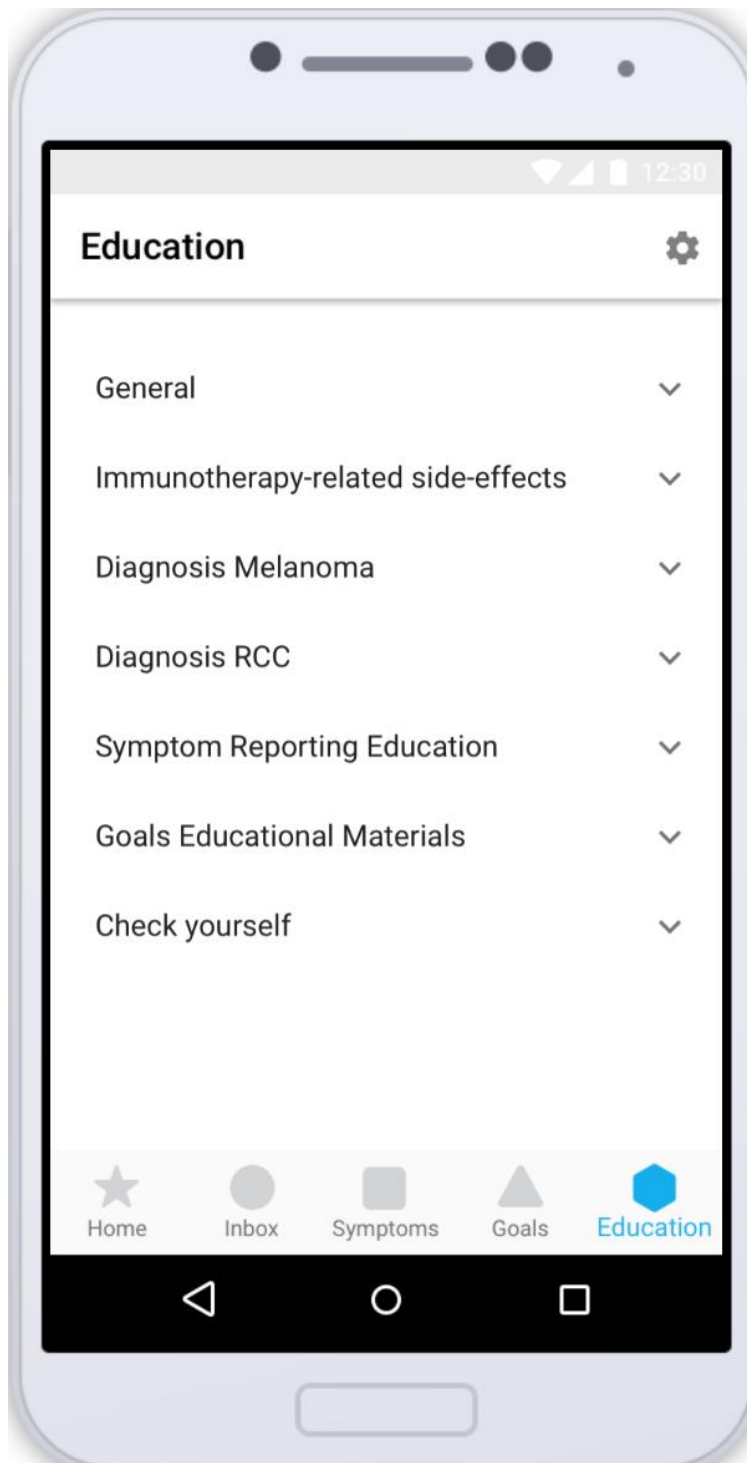


Figure 3.4.33 Education tab with all the educational content - information, facts, quizzes.

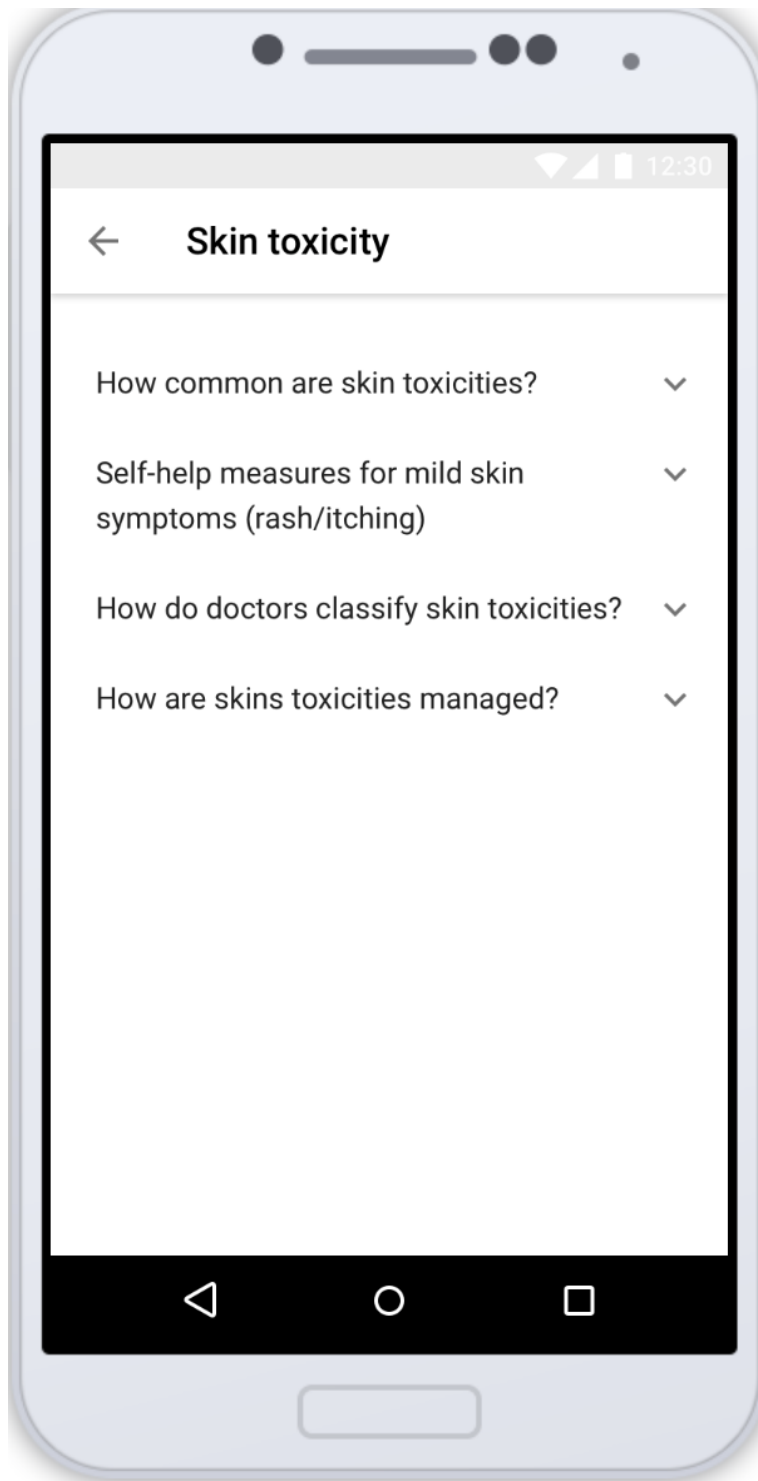


Figure 3.4.34 Education tab - example of subtabs.

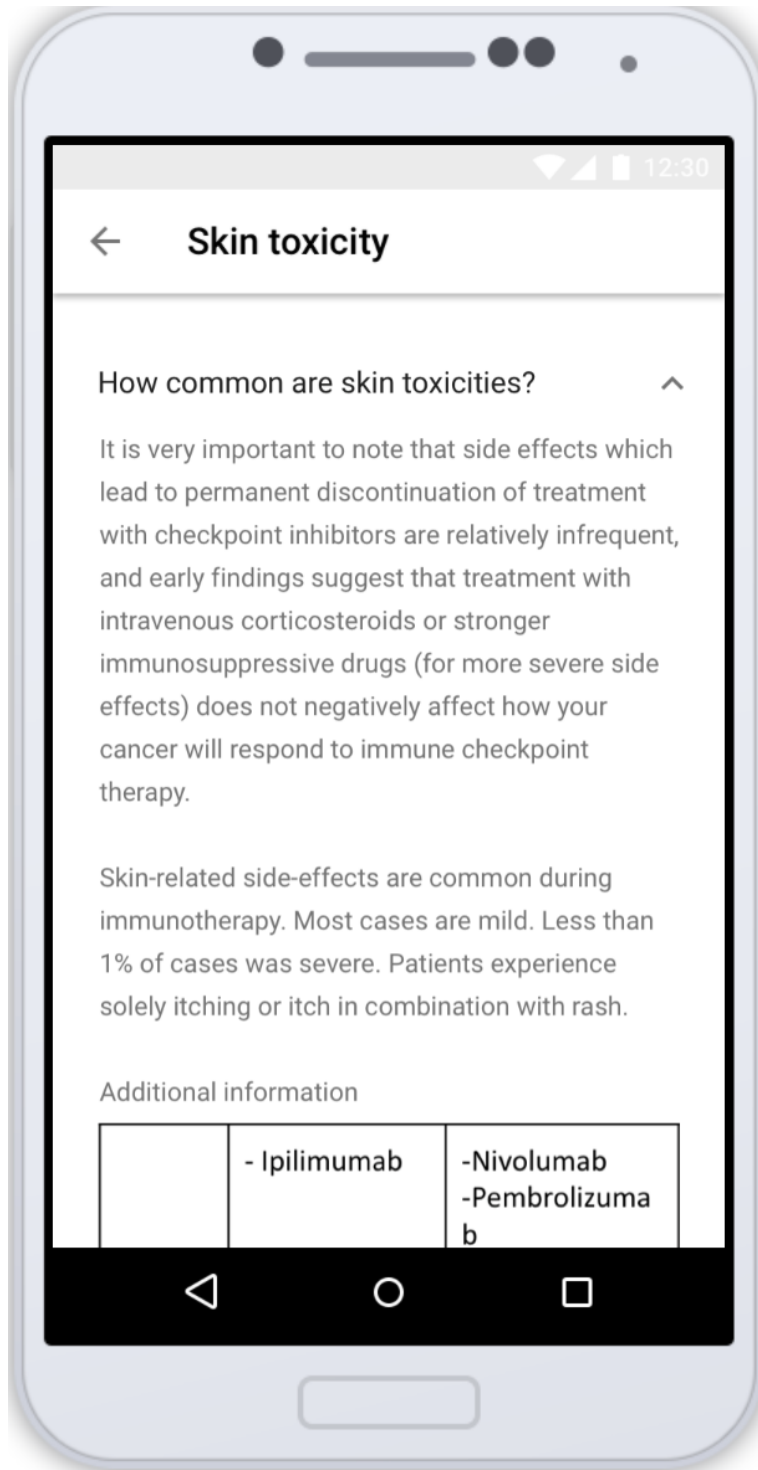


Figure 3.4.35 Education tab - example of an educational topic.



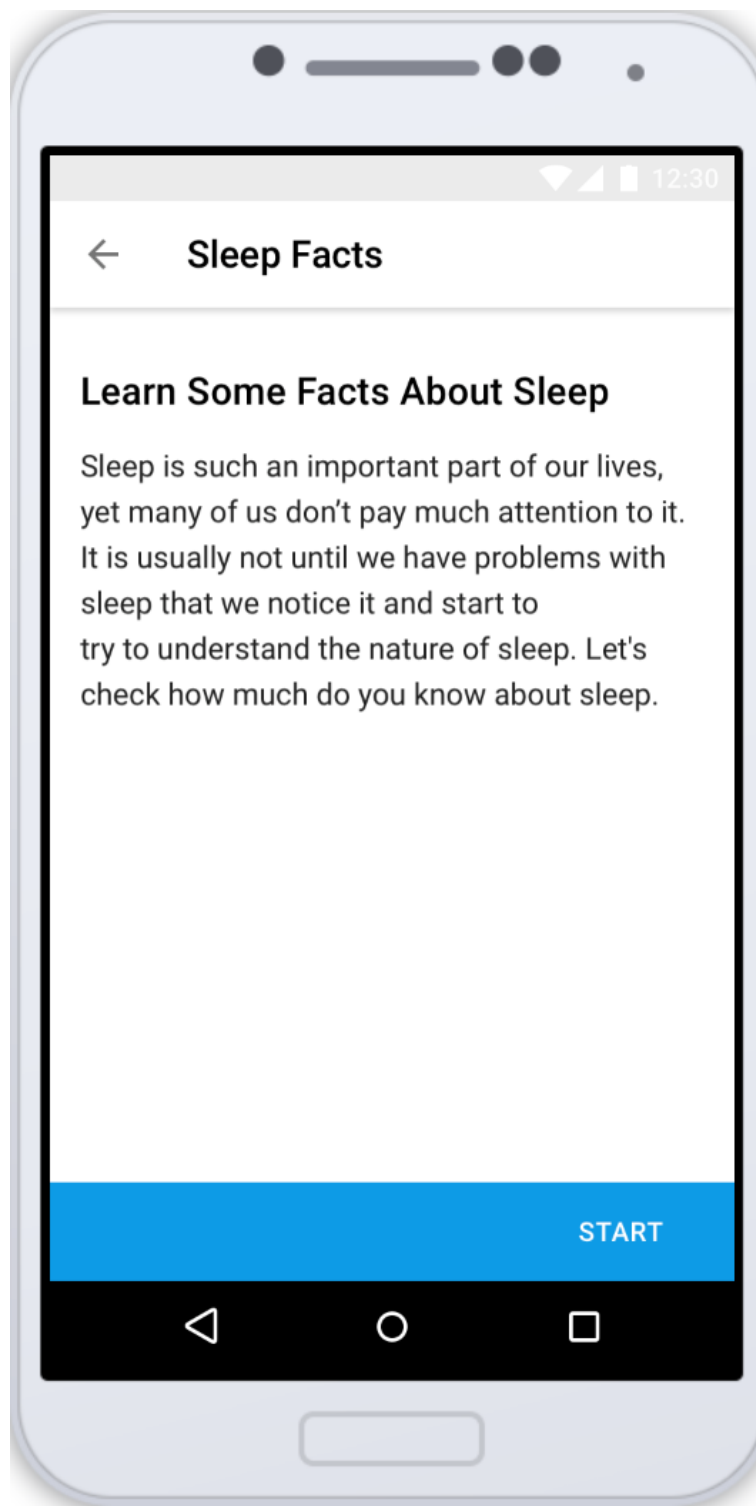


Figure 3.4.36 Education tab - example of educational facts.

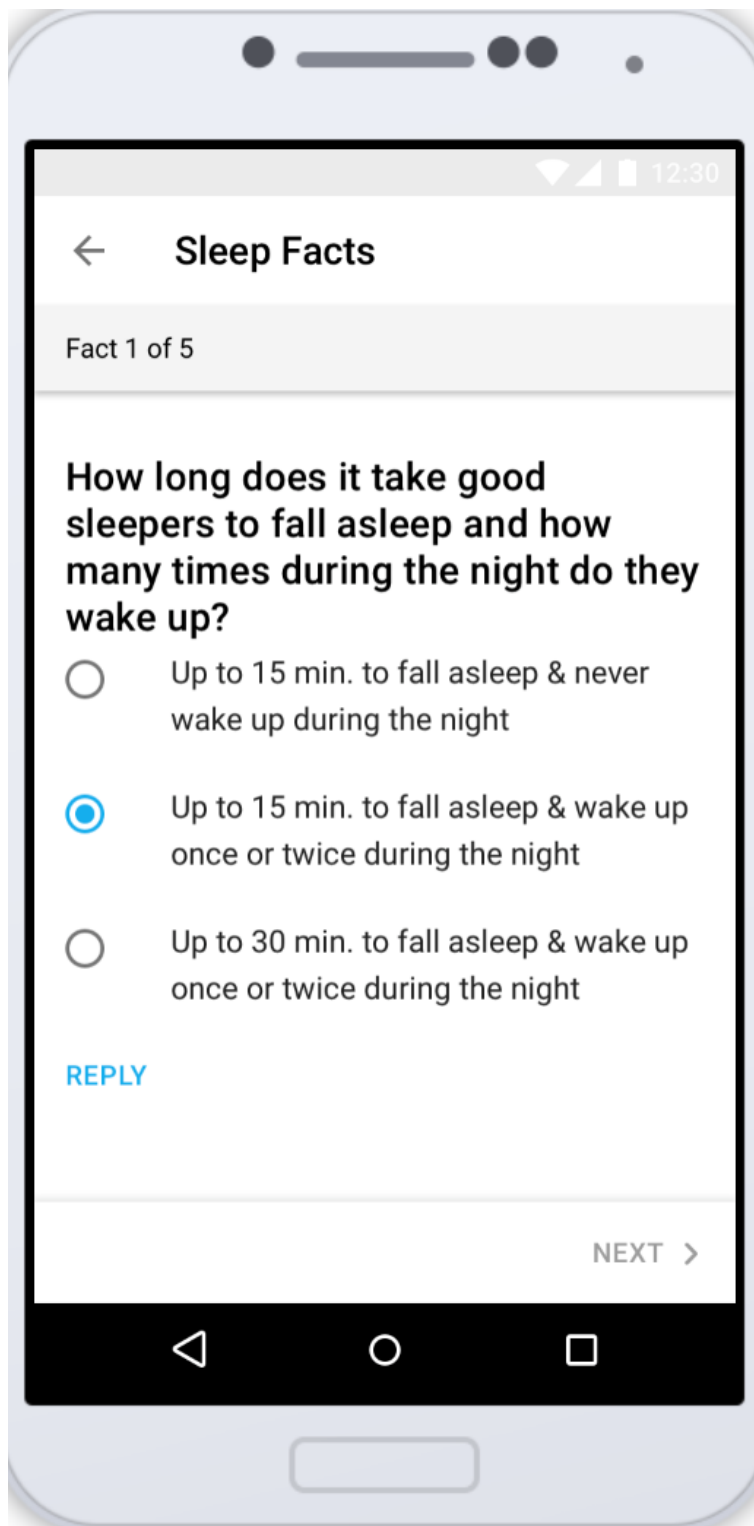


Figure 3.4.37 Education tab - Sleep Quiz as an example of Educational content

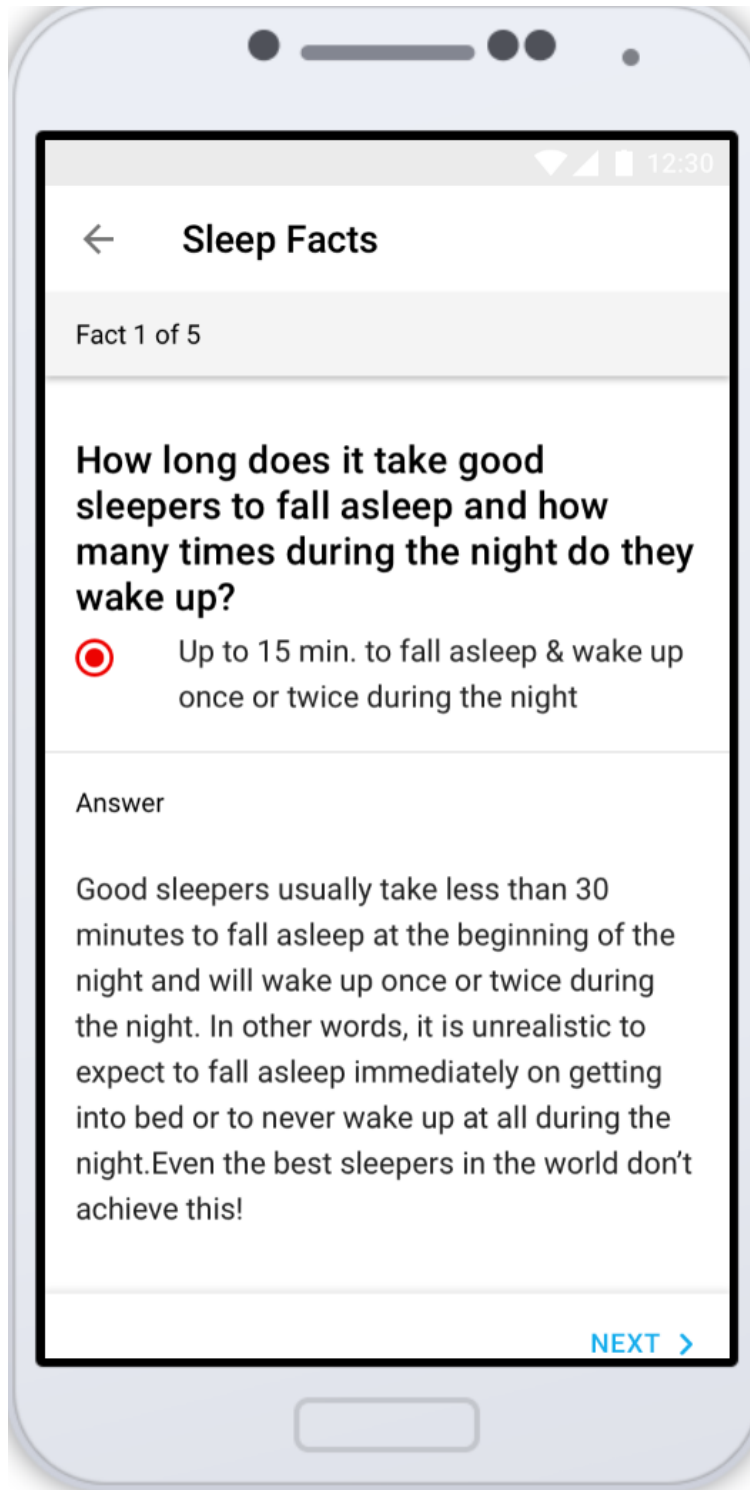


Figure 3.4.38 Education tab - Educational content example: the patient's answer to the Sleep quiz was wrong, the system feedback shows the correct answer.

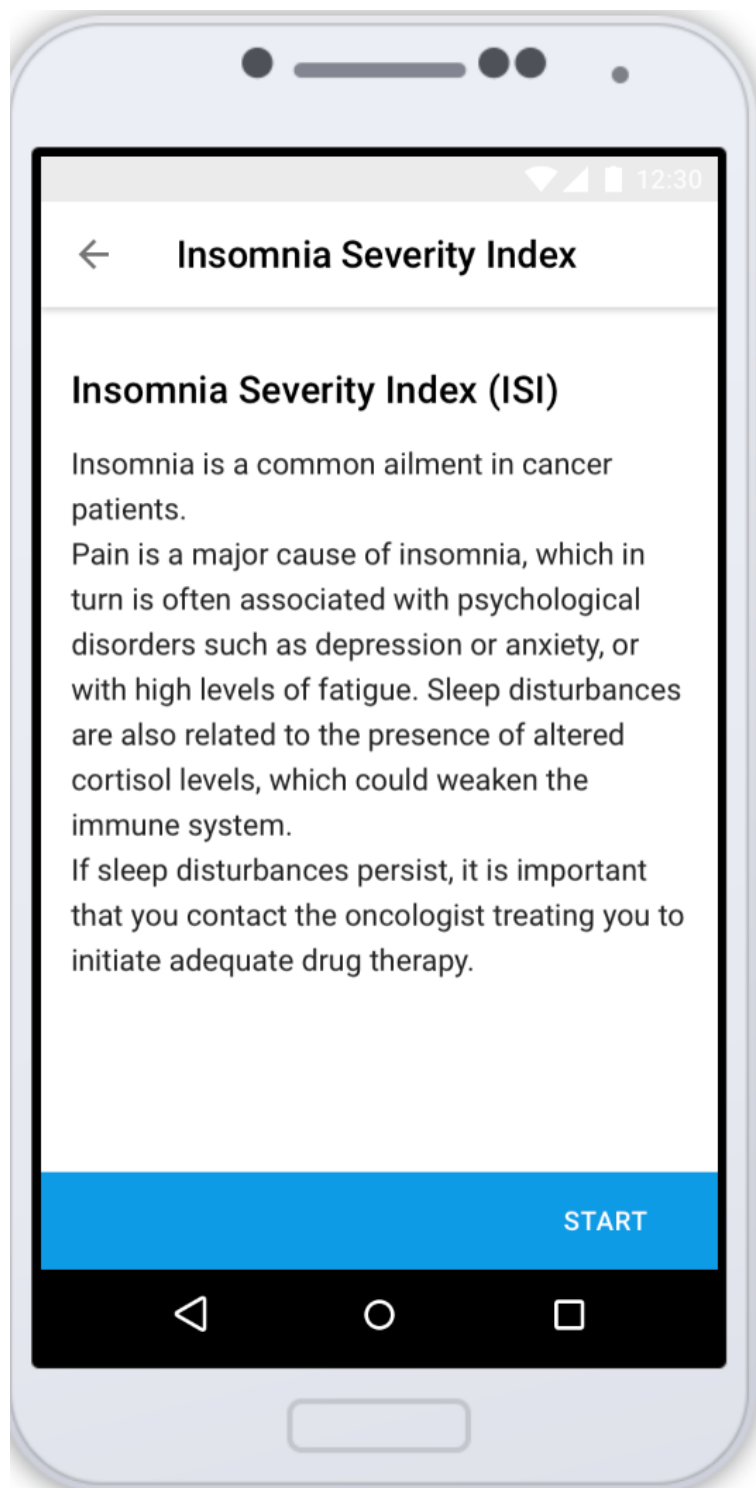
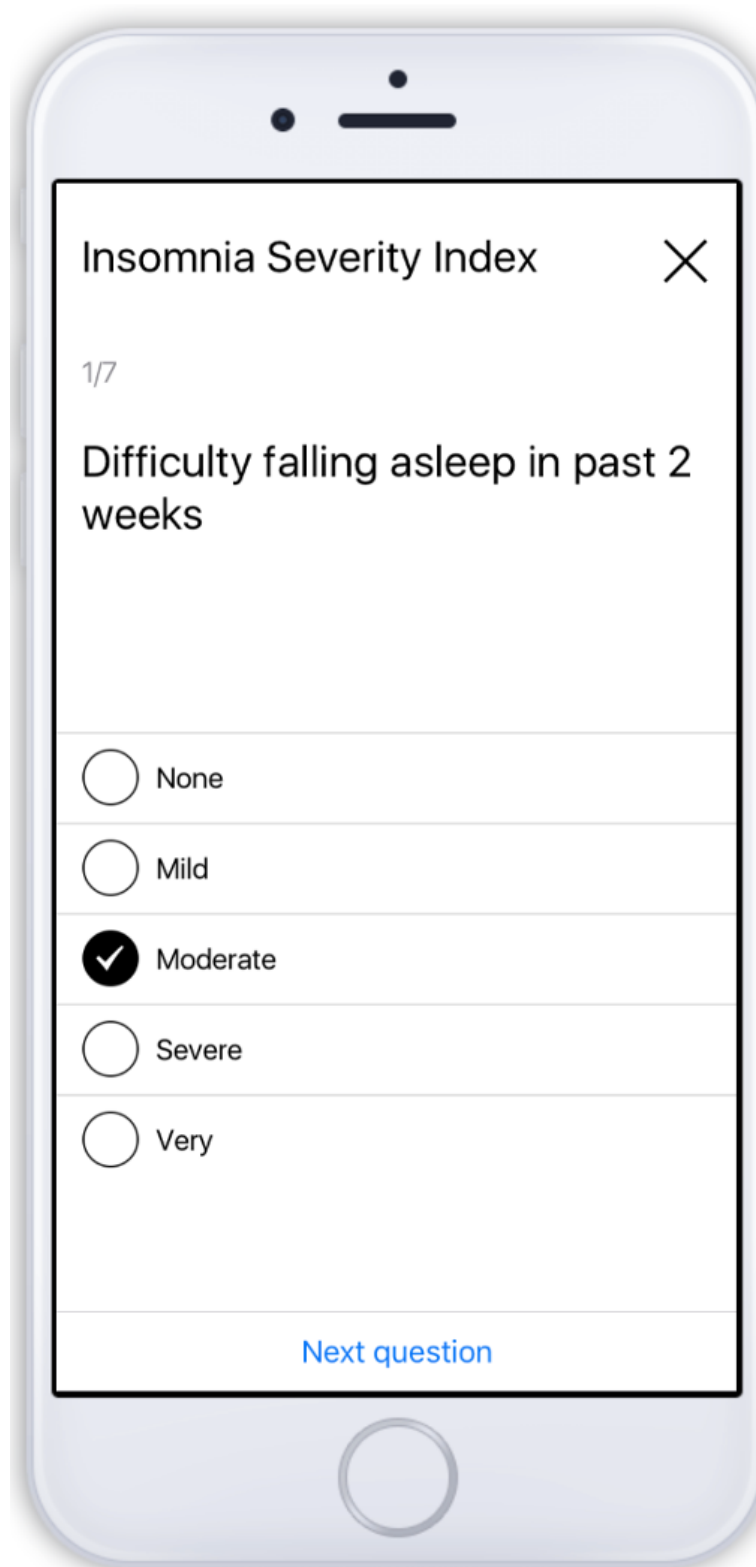


Figure 3.4.39 Questionnaire to assess the Insomnia Severity Index.



The image shows a smartphone screen displaying a questionnaire titled "Insomnia Severity Index". The screen has a white background with a black border. At the top, the title "Insomnia Severity Index" is followed by a close button (X). Below the title, the progress "1/7" is shown. The main question is "Difficulty falling asleep in past 2 weeks". There are five radio button options: "None", "Mild", "Moderate" (which is selected with a black dot and a checkmark), "Severe", and "Very". At the bottom, there is a blue link that says "Next question".

Insomnia Severity Index X

1/7

Difficulty falling asleep in past 2 weeks

☐ None

☐ Mild

☒ Moderate

☐ Severe

☐ Very

[Next question](#)

Figure 3.4.40 Questionnaire in progress.

### 3.5 Preferences & Info

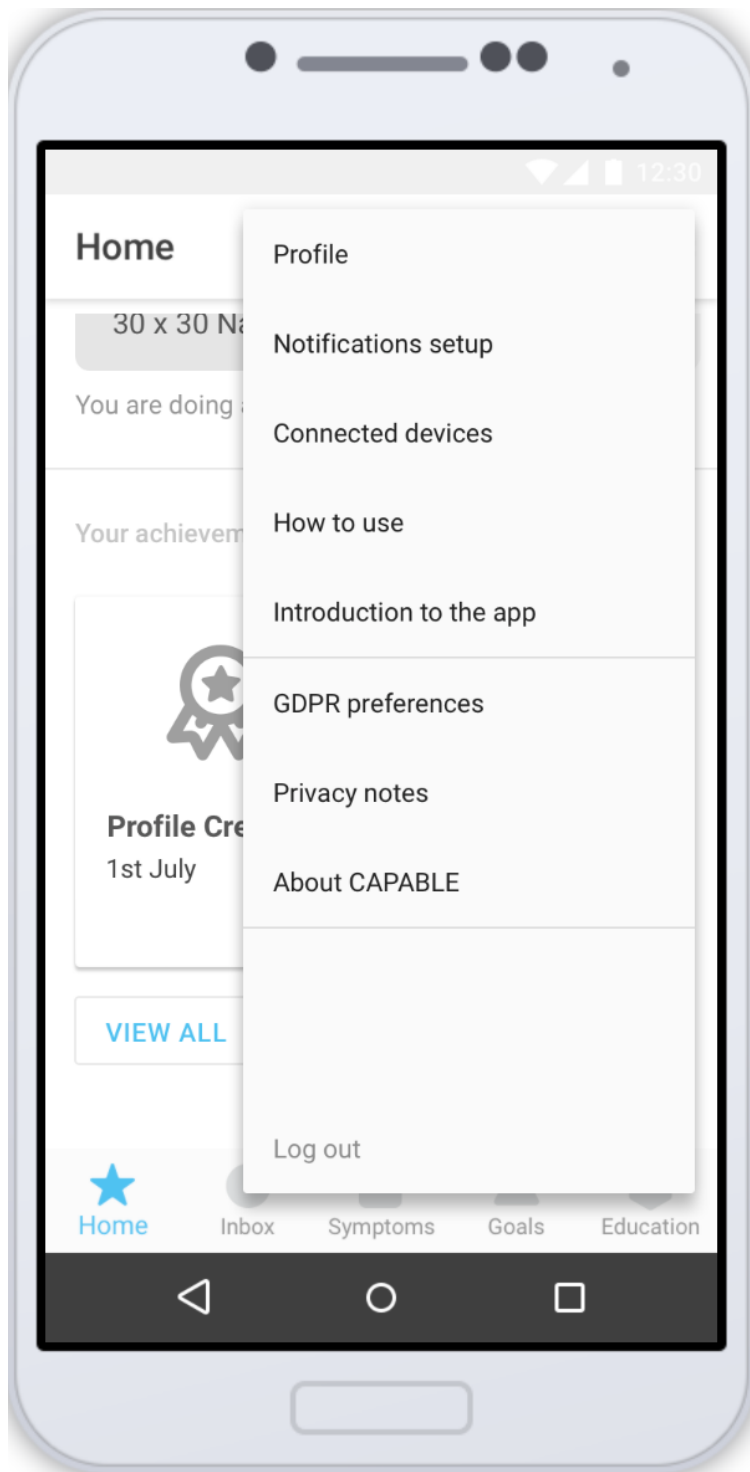


Figure 3.5.1 Home tab with Patient's settings that includes Profile, Notifications setup, Connected devices, How to use, Introduction to the app, GDPR preferences, Privacy Notes, About CAPABLE. GDPR preferences refer to the possibility for the patient to drop out of the study and to export a data summary to be shared with other stakeholders.

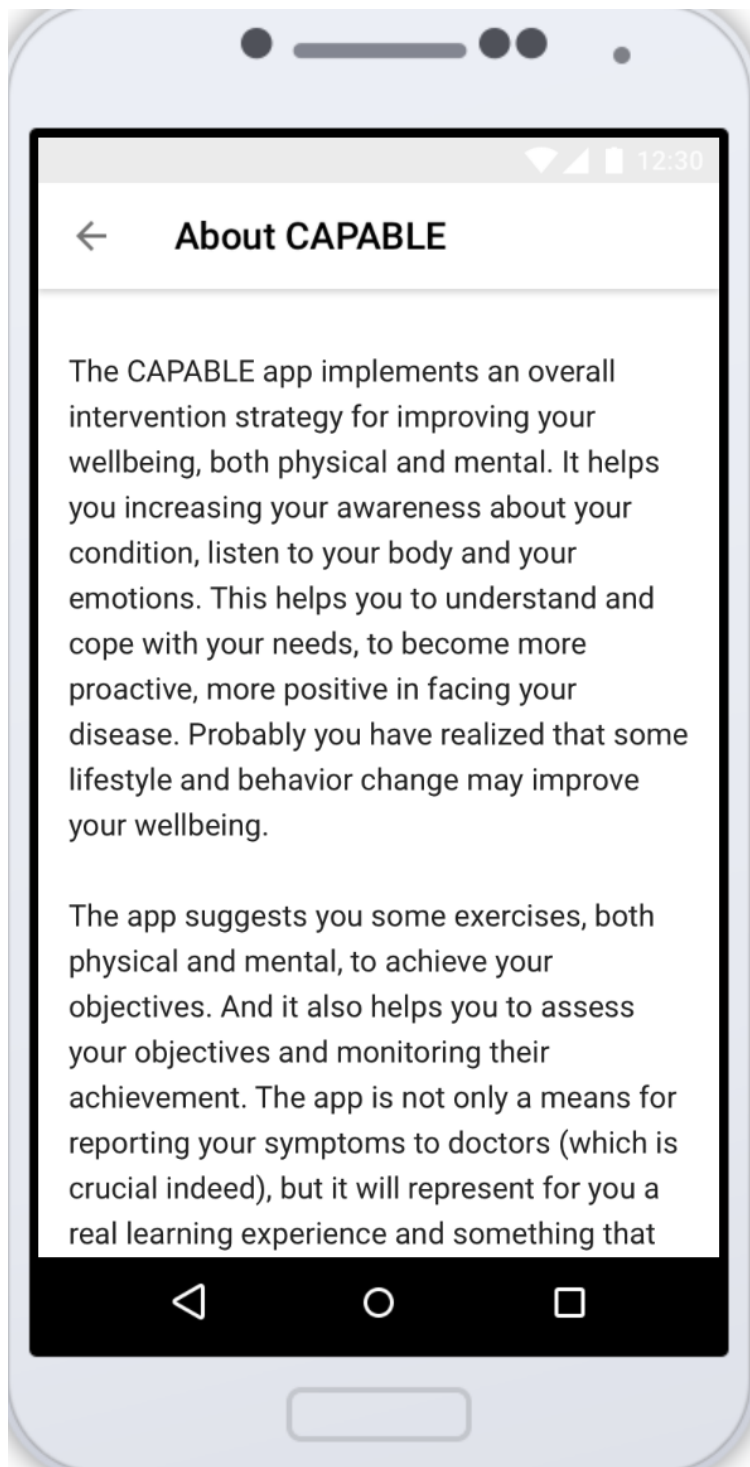


Figure 3.5.2 Home tab with Patient's settings - About CAPABLE.

## 4. Physician's Web System user-interface

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The Link to the prototype: [Link.](#)

The Link to the UI Design: [Link.](#)

The Physician's UI:

- visualize patients' data (integrated data from EHR + mobile app data + sensors)
- shows a summary of the personalized care plans (e.g. timeline, predicted risks, explanations, supporting evidence etc.)
- runs predictive models (to know a patient's risk stratification, to estimate the impact of different treatments)
- asks for decision support (i.e., running guidelines)
- shows the current state of the personalized patient's care plan, and decision options along with their supporting evidence patient data.

The UI allows an interactive engagement with the DSS and support for shared decision making. Built-in tools for query support will be also available to ease the process of accessing and analysis of the patient data.

Based on detailed analysis of all the requirements gathered from NKI and ICSM this section presents how the interface mock-up covers current functional requirements.



## 4.1 Enrollment



### Sign In

---

EMAIL  
john.fogg@email.com

PASSWORD  
\*\*\*\*\*




Remember me

[Forgot password](#)

SIGN IN

Figure 4.1.1 Login Page


**CAPABLE**
*for Doctors*

John Fogg

| ID     | NAME, SURNAME   | CANCER STATUS | TREATMENT       | ADVERSE EVENTS | STATUS         |
|--------|-----------------|---------------|-----------------|----------------|----------------|
| 890438 | Maria Floss     |               |                 | <side effects> | Action Needed! |
| 947474 | Felix Cruase    |               |                 | Skin rash      | <Status>       |
| 890438 | Susanna Gerra   |               |                 | Diarrhea       | <Status>       |
| 947474 | Arina Rotterman |               |                 | Diarrhea       | <Status>       |
| 890438 | Anna Boti       |               |                 | <side effects> | <Status>       |
| 947474 | Gustavo Rude    |               |                 | <side effects> | <Status>       |
| 890438 | Alex Ro         | stable        | Treatment title | <side effects> | Action Needed! |
| 947474 | Jamed Collins   | remission     | Treatment title | <side effects> | <Status>       |
| 890438 | Felicia Rose    | stable        | Treatment title | <side effects> | <Status>       |
| 999998 | Maria Rossi     | stable        | Treatment title | <side effects> | <Status>       |
| 890438 | Maria De Rossi  | stable        | Treatment title | <side effects> | new            |

Add new patient

Figure 4.1.2 Enrolment/Adding a new Patient.

REGISTRATION DATE: 1 JUNE 2021

## Create New Patient Profile

Save draft

1

2

General information & questionnaires

Device Config & review

Name

Maria

Surname

Rossi

Date of birth

1947

November

11

Gender

Female

Ethnicity

Caucasian

Weight

62

kg

Height

160

cm

Email

maria.rossi@gmail.com

Phone number

+39

3 565 898 787

**BMI is 24.2**, indicating the weight is in the Normal category for adults of such height.

Figure 4.1.3 Enrolment/Adding a new Patient - General information and feedback from the system (on the right hand side, example about automatic Body Mass Index calculation).

## Caregiver Contacts

Name

Giulio

Surname

Rossi

Email

giulio.rossi@gmail.com

Phone number

 +39 ▼

## Type of cancer

Choose type of cancer

Melanoma stage IV ▼

## Baseline information

WHO score

ECOG grade 0

BRAF MUTATION

NO

LDH level

265 U/L

S100b

Normal

Figure 4.1.4 Enrolment/Adding a new Patient - Caregiver information, Cancer information.

## Metastases

Lymph node metastases (macroscopic)

**NO**

Distance metastases

**YES**

Total number of metastases

**Multiple**

Metastasis site

**Lung**

## Physical activity

Do you perform regular physical activity ?

☐ Yes

☒ No

Figure 4.1.5 Enrolment/Adding a new Patient - Questionnaires.

## Nutrition

Do you follow a particular diet?

1-2 per week

Note for diet

Do you regularly eat fruit and vegetable?

☒ Yes ☐ No

Do you drink alcohol?

☐ Yes ☒ No ☐ Text

Do you have a history of alcohol abuse?

☐ Yes ☒ No

Have you recently lost weight without trying?

☐ Yes ☒ No ☐ Unsure

How much weight have you lost?

Not selected

Do you drink alcohol?

☐ Yes ☒ No

MST is **0 — not at risk.**

Eating well with little or no weight loss

If length of stay exceeds 7 days, then rescreen, repeating weekly as needed.

## Smoking

Are you a smoker?

Text

Figure 4.1.6 Enrolment/Adding a new Patient - Questionnaires. MST is Malnutrition Screening Tool. The texts on the screens will be updated through the whole development process. These texts are not final ones.

### Sleeping

Do you have issue with sleeping?

☐ Yes ☒ No ☐ Text

### Past relevant information

Diabetes

☐ Yes ☒ No ☐ Text

Hypertension

☐ Yes ☒ No ☐ Text

Collagen vascular

☐ Yes ☒ No ☐ Text

IBD

☐ Yes ☒ No ☐ Text

Previous intestinal surgery

☐ Yes ☒ No ☐ Text

Next step →

Save draft

Figure 4.1.7 Enrolment/Adding a new Patient - Questionnaires, Past relevant information - part of a clinical history of a patient that could be used by the CAPABLE guidelines.

Registration date: July 29, 2020

Create New Patient Profile

SAVE DRAFT

1

GENERAL INFORMATION & QUESTIONNAIRES

2

DEVICE CONFIG & REVIEW

### Actions To Do .

☐ 1. Instal the App

screenshot / illustration

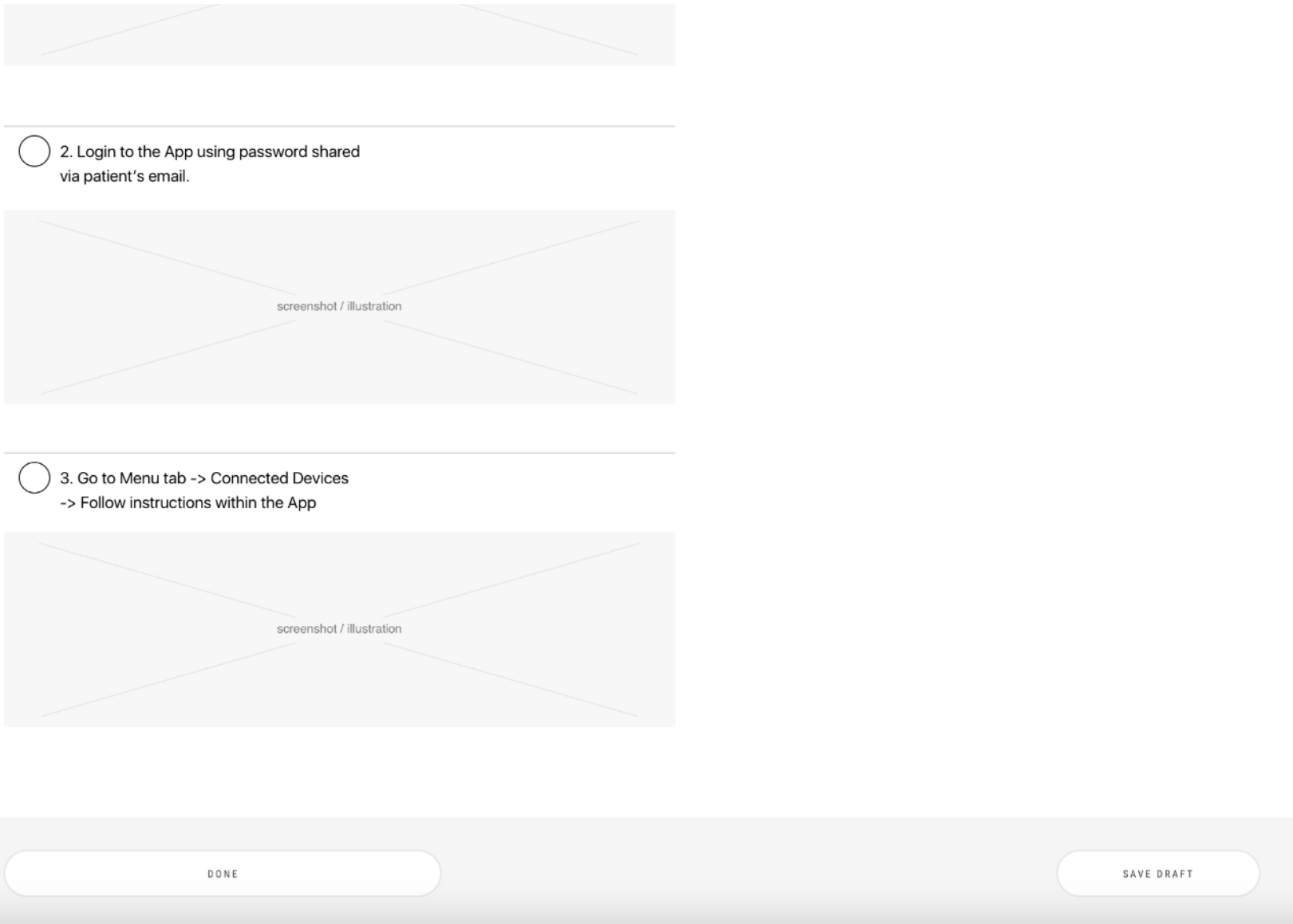
☐ 2. Login to the App using password shared via patient's email.

DONE

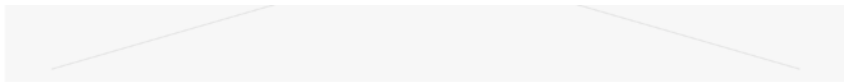
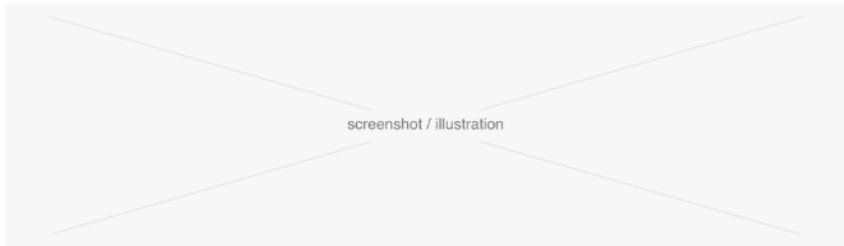
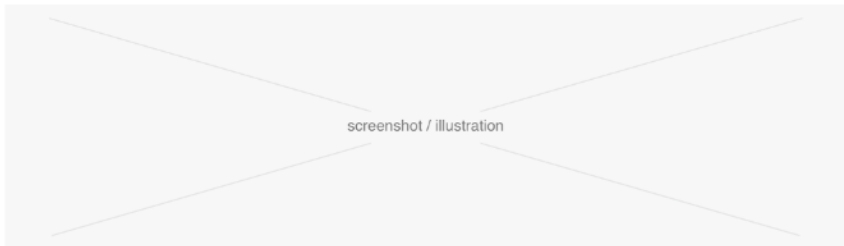
SAVE DRAFT

Figure 4.1.8 Enrolment/Adding a new Patient - Checklist for the activation of the Patient's mobile app.






The image shows a checklist for the activation of the Patient's mobile app. It consists of three steps, each with a corresponding screenshot or illustration placeholder.

- ☐ 1. Login to the App using email shared via patient's email.  

- ☐ 2. Login to the App using password shared via patient's email.  

- ☐ 3. Go to Menu tab -> Connected Devices  
-> Follow instructions within the App  


At the bottom of the form, there are two buttons: "DONE" and "SAVE DRAFT".

Figure 4.1.9 Enrolment/Adding a new Patient - Checklist for the activation of the Patient's mobile app.


## 4.2 Patients list


**CAPABLE** *for Doctors*

John Fogg ▾

|   | ID     | NAME, SURNAME   | CANCER STATUS | TREATMENT       | ADVERSE EVENTS | STATUS           |
|---|--------|-----------------|---------------|-----------------|----------------|------------------|
| ⌵ | 890438 | Maria Floss     | stable        | Treatment title | <side effects> | ● Action Needed! |
| ⌵ | 947474 | Felix Cruase    | progression   | Therapy         | Skin rash      | ● <Status>       |
| ⌵ | 890438 | Susanna Gerra   | stable        | Treatment title | Diarrhea       | ● <Status>       |
| ⌵ | 947474 | Arina Rotterman | remission     | Treatment title | Diarrhea       | ● <Status>       |
| ⌵ | 890438 | Anna Boti       | stable        | Treatment title | <side effects> | ● <Status>       |
| ⌵ | 947474 | Gustavo Rude    | remission     | Treatment title | <side effects> | ● <Status>       |
| ⌵ | 890438 | Alex Ro         | stable        | Treatment title | <side effects> | ● Action Needed! |
| ⌵ | 947474 | Jamed Collins   | remission     | Treatment title | <side effects> | ● <Status>       |
| ⌵ | 890438 | Felicia Rose    | stable        | Treatment title | <side effects> | ● <Status>       |
| ⌵ | 999998 | Maria Rossi     | stable        | Treatment title | <side effects> | ● <Status>       |
| ⌵ | 890438 | Maria De Rossi  | stable        | Treatment title | <side effects> | new              |

Figure 4.2.1 List of patients with possibility to filter the patients


**CAPABLE**
*for Doctors*

John Fogg

Settings

Tutorials

Log out

|  | ID     | NAME, SURNAME   | CANCER STATUS | TREATMENT       | ADVERSE EVENTS |   |
|--|--------|-----------------|---------------|-----------------|----------------|---|
|  | 890438 | Maria Floss     | stable        | Treatment title | <side effects> | <span style="color: red;">●</span> Action Needed! |
|  | 947474 | Felix Cruase    | progression   | Therapy         | Skin rash      | <span style="color: orange;">●</span> <Status>    |
|  | 890438 | Susanna Gerra   | stable        | Treatment title | Diarrhea       | <span style="color: green;">●</span> <Status>     |
|  | 947474 | Arina Rotterman | remission     | Treatment title | Diarrhea       | <span style="color: green;">●</span> <Status>     |
|  | 890438 | Anna Boti       | stable        | Treatment title | <side effects> | <span style="color: green;">●</span> <Status>     |
|  | 947474 | Gustavo Rude    | remission     | Treatment title | <side effects> | <span style="color: green;">●</span> <Status>     |
|  | 890438 | Alex Ro         | stable        | Treatment title | <side effects> | <span style="color: red;">●</span> Action Needed! |
|  | 947474 | Jamed Collins   | remission     | Treatment title | <side effects> | <span style="color: orange;">●</span> <Status>    |
|  | 890438 | Felicia Rose    | stable        | Treatment title | <side effects> | <span style="color: green;">●</span> <Status>     |
|  | 999998 | Maria Rossi     | stable        | Treatment title | <side effects> | <span style="color: green;">●</span> <Status>     |
|  | 890438 | Maria De Rossi  | stable        | Treatment title | <side effects> | <input type="button" value="new"/>                |

Figure 4.2.2 List of patients - Settings, tutorials/guidelines and Log out functionality.

| ID   | Name, Surname   | Cancer status | Treatment | Adverse events | Status         |
|--|-----------------|---------------|-----------|----------------|----------------|
| 890438   | Maria Floss     | Stable        | Treatment | Adverse events | Action Needed! |
| 947474   | Felix Cruase    | Progression   | Treatment | Adverse events | <Status>       |
| <Additional info about the patient might be placed here> |                 |               |           |                |                |
| 890438   | Susanna Gerra   | Stable        | Treatment | Diarrhea       | New            |
| 947474   | Arina Rotterman | Remission     | Treatment | Diarrhea       | <Status>       |
| 890438   | Anna Boti       | Stable        | Treatment | Adverse events | <Status>       |
| 947474   | Gustavo Rude    | Remission     | Treatment | Adverse events | <Status>       |
| 890438   | Alex Ro         | Stable        | Treatment | Adverse events | Action Needed! |
| 947474   | Jamed Collins   | Remission     | Treatment | Adverse events | <Status>       |
| 890438   | Felicia Rose    | Stable        | Treatment | Adverse events | <Status>       |
| 947474   | Anna Boti       | Remission     | Treatment | Adverse events | <Status>       |

50 items per page
1 2 3 4 ... 12

Figure 4.2.3 List of patients - UI Design.

## 4.3 Patients Profile

←

ID: 890438

**Maria De Rossi**

1947 Nov 11 (73 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

Current

Past

Treatment for cancer

EDIT

**Systemic therapy**

None

**Surgery**

None

**Radiotherapy**

None

Treatment for comorbidities

EDIT

None

Treatment of adverse events

EDIT

None

Other treatment

EDIT

None

Figure 4.3.1 Patients Profile with Treatment tab - Treatment for cancer, Treatment for comorbidities, Treatment of adverse events, Other treatment subsections.

Treatment for comorbidities

EDIT

None

Treatment of adverse events

EDIT

None

Other treatment

EDIT

None

Goals

|                    |  |   |  |
|--------------------|--|---|--|
| Sleep              | <input checked="" type="radio"/> Up to Patient (default) | <input type="radio"/> Prescribed (by physician) | <input type="radio"/> Contraindicated (by physician) |
| Nutrition          | <input checked="" type="radio"/> Up to Patient (default) | <input type="radio"/> Prescribed (by physician) | <input type="radio"/> Contraindicated (by physician) |
| Mental Wellbeing   | <input checked="" type="radio"/> Up to Patient (default) | <input type="radio"/> Prescribed (by physician) | <input type="radio"/> Contraindicated (by physician) |
| Social Connections | <input checked="" type="radio"/> Up to Patient (default) | <input type="radio"/> Prescribed (by physician) | <input type="radio"/> Contraindicated (by physician) |
| Physical Wellbeing | <input checked="" type="radio"/> Up to Patient (default) | <input type="radio"/> Prescribed (by physician) | <input type="radio"/> Contraindicated (by physician) |

Figure 4.3.2 Patients Profile with Treatment tab - Goals subsection.

ID: 890438

←

Maria De Rossi

1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

Current

Past

Treatment for

Systemic therapy

Sunitinib 50 mg/2

Surgery

12 October 2018

Radiotherapy

12 December 201

Treatment for

Levotyroxine (23 I

Hypothyroidism

Treatment of adverse events

Loperamide 4 mg/4 hours, As needed medication

Diarrhea

Other treatment

St. John's-wort 300 mg/1 day (23 March 2017)

Schedule next visit

Date

Time

Note (for e.g. if the patient have to bring urine samples)

+ ADD VISIT

ACCEPT

DECLINE

GLD\_RM1]

nd

St. John's

ance St.

Figure 4.3.3 Patients Profile - Schedule next visit function.

←

ID: 890438

Maria Rossi

1954 Nov 11 (66 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

Current

Past

Treatment for

Systemic therapy

None

Surgery

None

Radiotherapy

None

Treatment for

None

Treatment of adverse events

None

Other treatment

None

Goals

Choose Predictive Model

Survival model

"Model for predicting Overall Survival (OS) for Melanoma patient treated with Immunotherapy. Predicted survival graphs will be presented for Nivolumab and Nivolumab+Ipilimumab.

VIEW

Response model

"Model for predicting response to the treatment for Melanoma patient treated with Immunotherapy. Predicted probabilities of having response will be presented for Nivolumab compared to Nivolumab+Ipilimumab

VIEW

GLD\_RM1]

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Figure 4.3.4 Patients Profile - Run predictive model function - a list of available models for a specific Patient.



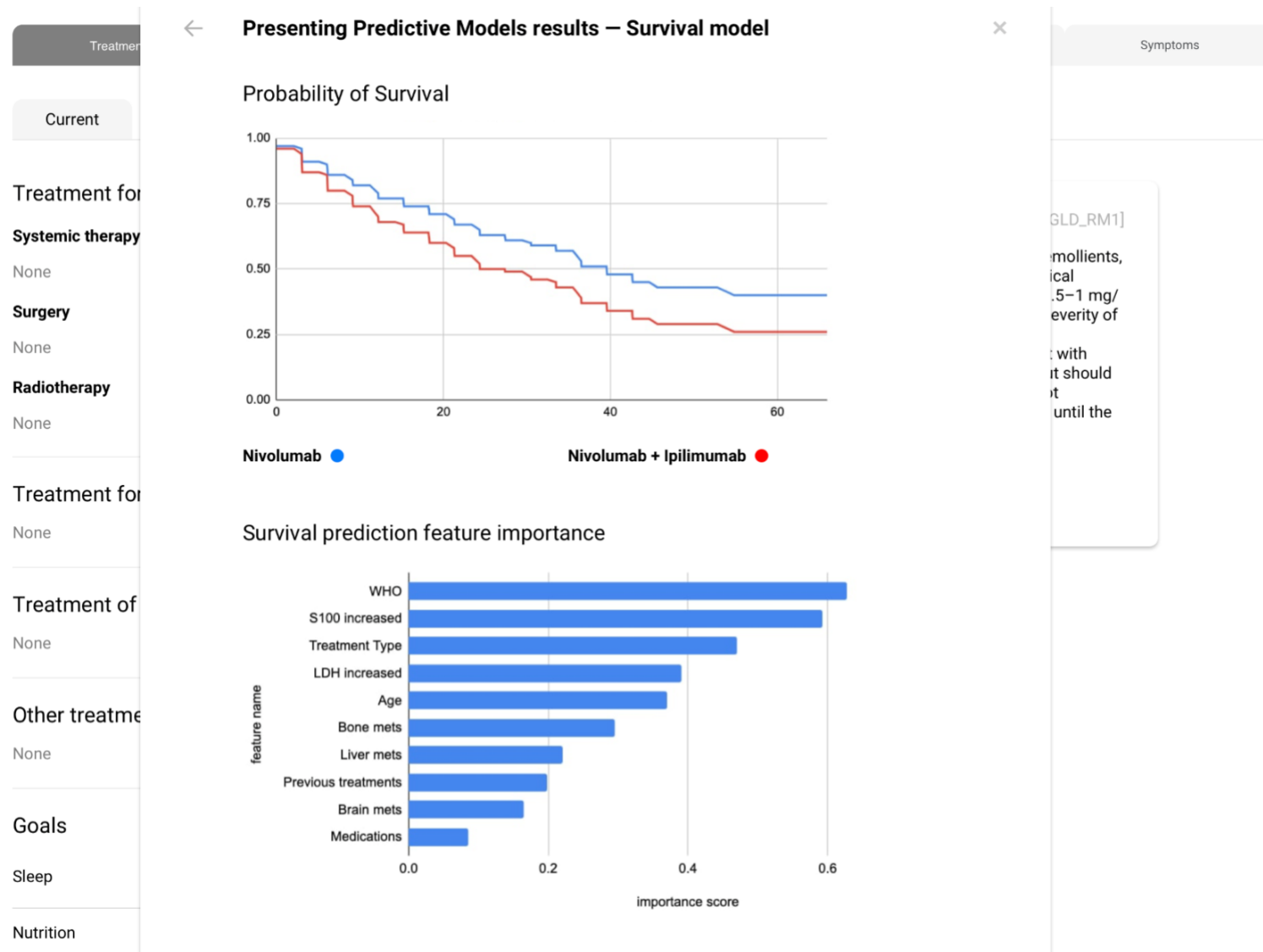


Figure 4.3.5 Patients Profile - Run predictive model function - Survival model.

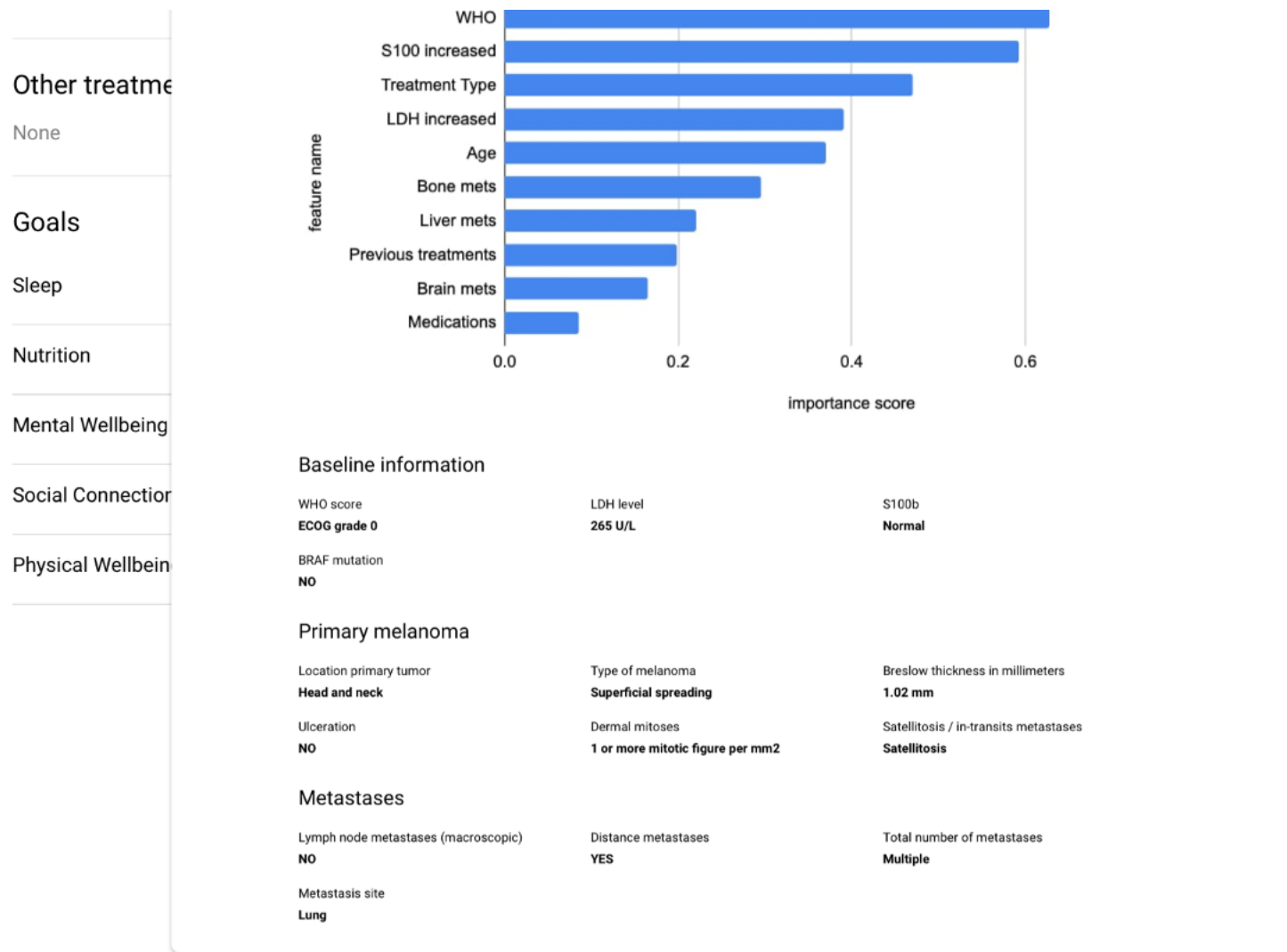


Figure 4.3.6 Patients Profile - Run predictive model function - Survival model.

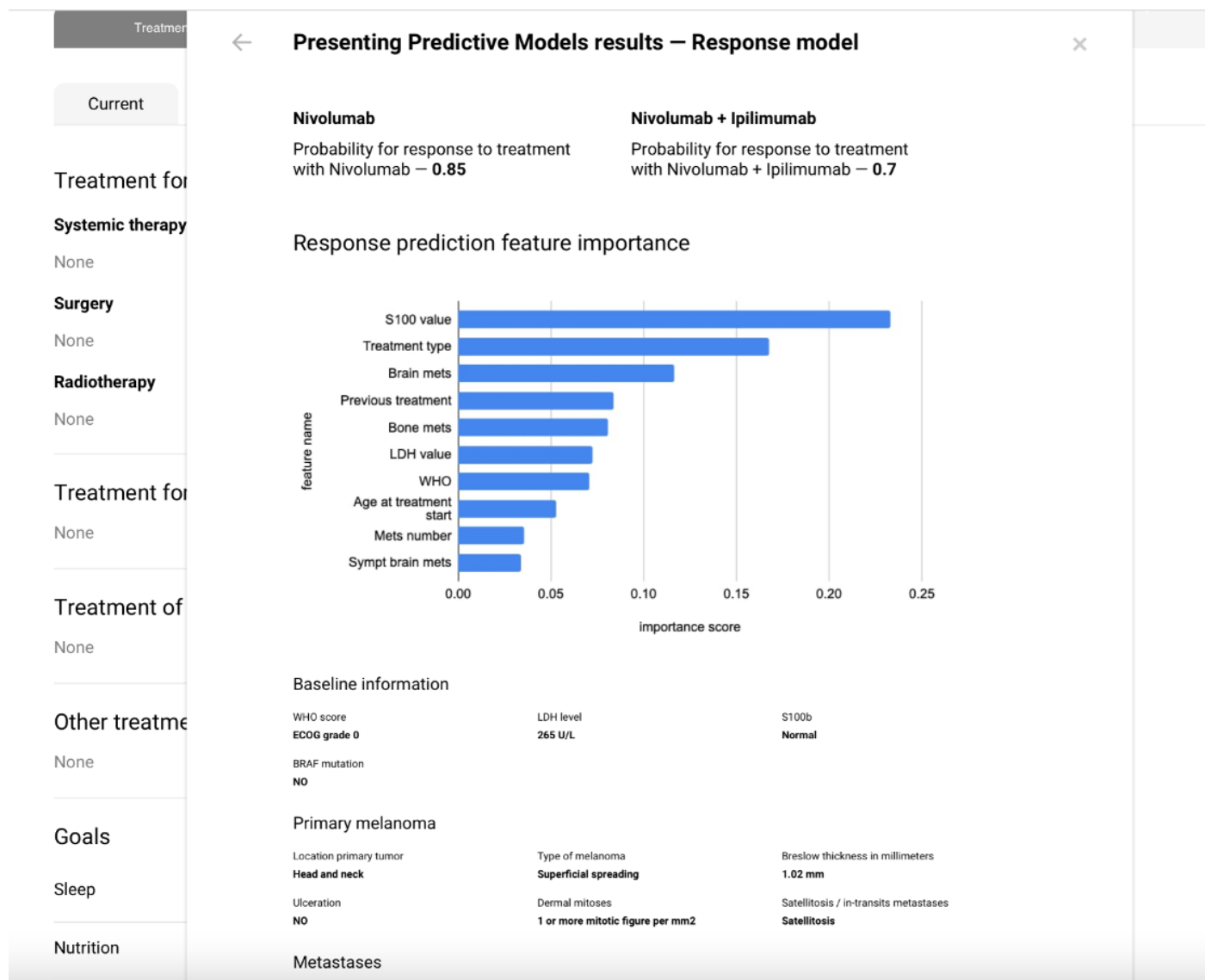


Figure 4.3.7 Patients Profile - Run predictive model function - Response model.

←

ID: 890438

Maria De Rossi

1947 Nov 11 (73 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

Current

Past

Treatment for cancer

CANCEL

SAVE

Systemic therapy

Select medication

--

▼

Surgery

+ ADD SURGERY

Radiotherapy

+ ADD RADIOTHERAPY

CANCEL

SAVE

Treatment for comorbidities

EDIT

None

Treatment of adverse events

EDIT

None

Figure 4.3.8 Patients Profile - Treatment tab - Prescribing a new treatment.

←

ID: 890438

**Maria De Rossi**

1947 Nov 11 (73 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

Current

Past

Treatment for cancer

CANCEL

SAVE

Systemic therapy

Select medication

Not Selected

Start input here..

☐ Codeine

☐ Ipilimumab

☐ Loperamide

☐ Morphine

☒ Nivolumab

☐ Pazopanib

☐ Pembrolizumab

☐ Sunitinib

☐ Tivozanib

SAVE

EDIT

Treatment of adverse events

EDIT

None

Figure 4.3.9 Patients Profile - Treatment tab - Prescribing a new treatment.

Treatment for cancer

CANCEL SAVE

Systemic therapy

Select medication

Nivolumab

1. Nivolumab

Therapy line N°

--

Start date

--

End date

--

☒ Hospital admin.

Frequency of intake

--

Weeks

Initial dose

-- mg

+ REPEAT

Surgery

+ ADD SURGERY

Radiotherapy

+ ADD RADIOTHERAPY

CANCEL SAVE

Figure 4.3.10 Patients Profile - Treatment tab - Prescribing a new treatment.

1st surgery

Date

12 October 2018

Intervention type

Free text goes here

+ ADD SURGERY

1st radiotherapy

Start date

12 December 2018

End date

22 December 2018

Total dose (Gy)

-

Site

Not Selected

Bones

Lungs

Brain

Soft tissues

Nodes

Other

Treatment for comorbidity

Levotyroxine (23 March 2017)

Hypothyroidism

EDIT

Treatment of adverse events

None

EDIT

Figure 4.3.11 Patients Profile - Treatment tab - Prescribing a new treatment.

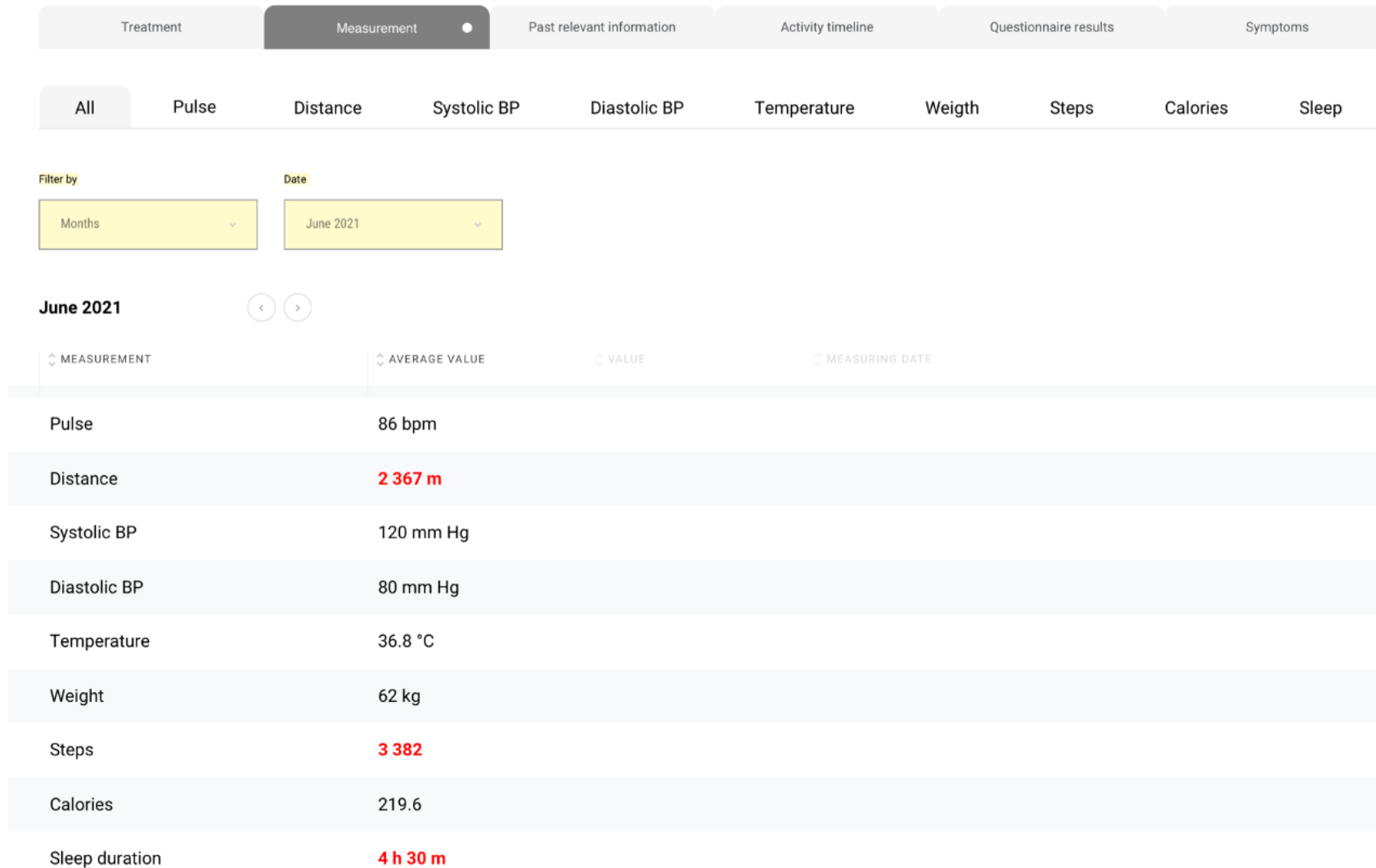


Figure 4.3.12 Patients Profile - Measurement tab - Subtab with the Data from connected Sensor and the Vital signs entered by a Patient.



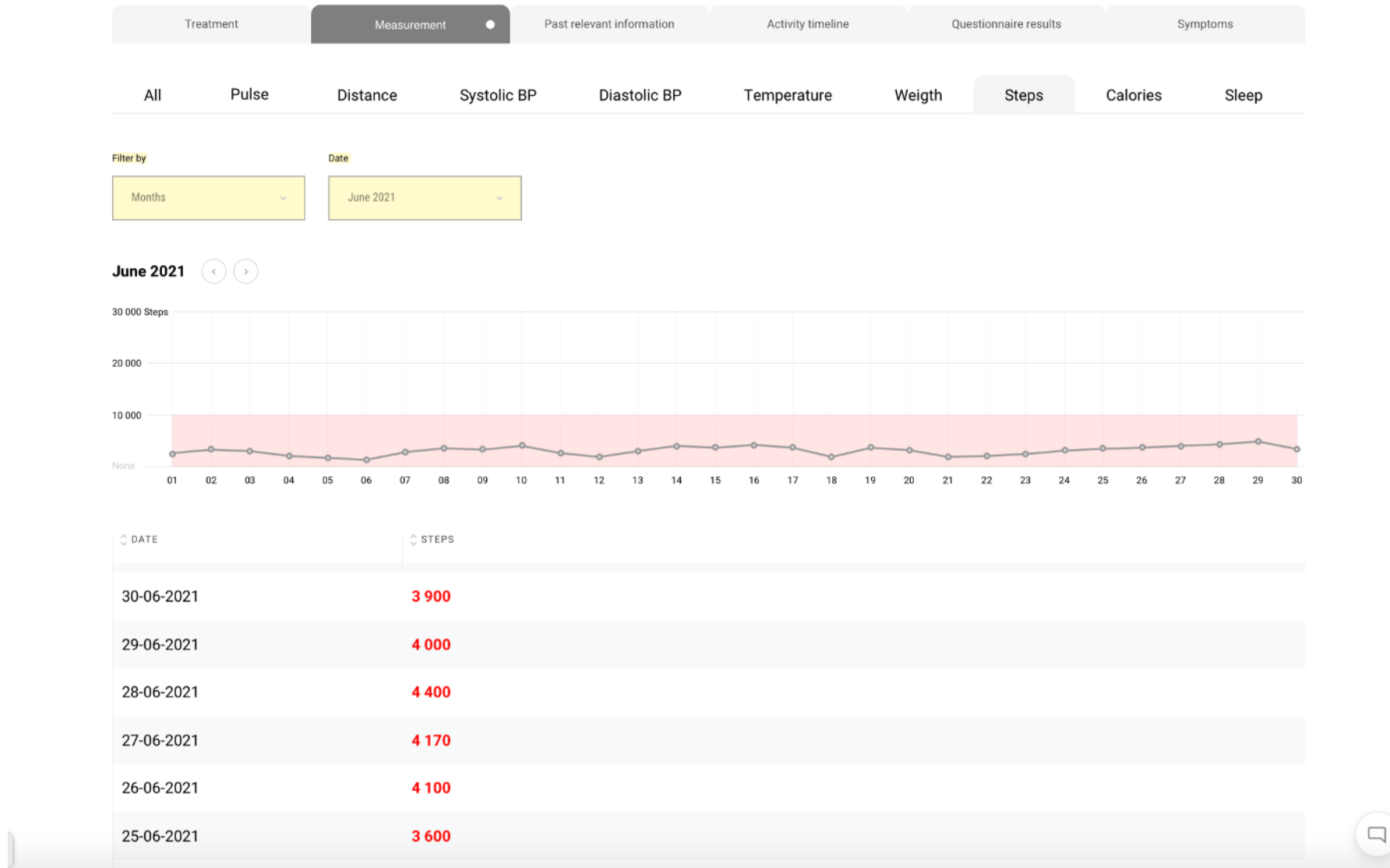


Figure 4.3.13 Patients Profile - Measurement tab - Example of a subtab with a parameter trend visualisation.

ID: 890438

**Maria De Rossi**

1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

**Symptoms**

Filter by

Date

Filter by symptom name

Days

June 2020

Symptom name

EXPORT PDF

ADD NEW SYMPTOM

**June 2020**

4 Grade

3

2

1

0

01

02

03

04

05

06

07

08

09

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

29

30

**Diarrhoea**

SYMPTOM

START DATE

END DATE

GRADE

DRUGS

LOCATION

NOTES

REPORTED BY

STATUS

ACTIONS

Diarrhoea

03 June

-

2

-

Stomach

-

Patient

Ongoing

VIEW REPORT

01 June

-

1

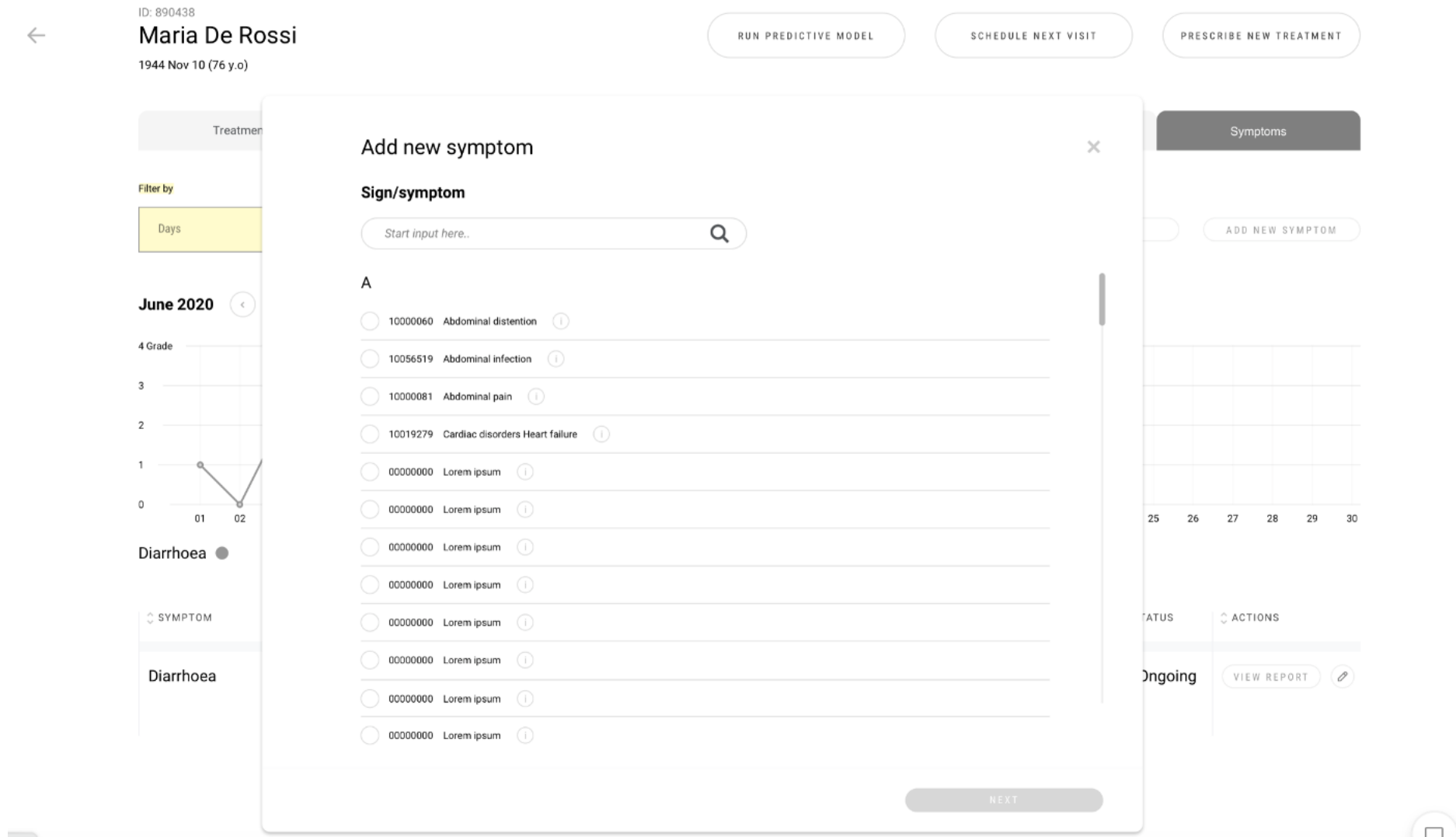
-

Stomach

-

Patient

Figure 4.3.14 Patients Profile - Symptom tab - reported symptoms with a visualisation, possibility to view, edit, add new symptom by a physician.



The screenshot displays a web application interface for a patient's profile, specifically the 'Symptoms' tab. A modal window titled 'Add new symptom' is open in the center. The modal has a search bar labeled 'Sign/symptom' with the placeholder text 'Start input here..'. Below the search bar, a list of symptoms is displayed, each with a radio button and a code: '10000060 Abdominal distention', '10056519 Abdominal infection', '10000081 Abdominal pain', '10019279 Cardiac disorders Heart failure', and several 'Lorem ipsum' entries. A 'NEXT' button is at the bottom right of the modal. In the background, the patient's profile for 'Maria De Rossi' (ID: 890438, 1944 Nov 10 (76 y.o.)) is visible. The interface includes buttons for 'RUN PREDICTIVE MODEL', 'SCHEDULE NEXT VISIT', and 'PRESCRIBE NEW TREATMENT'. A line graph on the left shows 'Diarrhoea' levels over time, with a peak on '01' and a low on '02'. A table on the right shows a calendar view for the month of June 2020, with dates 25 through 30. A 'VIEW REPORT' button and a chat icon are also present.

Figure 4.3.15 Patients Profile - Symptom tab - Adding a new symptom by a physician.

←

ID: 890438

Maria De Rossi

1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Filter by

Days

June 2020

4 Grade

3

2

1

0

01

02

Diarrhoea ●

SYMPTOM

Diarrhoea

←

Add new symptom

×

10019279 Cardiac disorders Heart failure

If left sided use Cardiac disorders: Left ventricular systolic dysfunction; also consider Cardiac disorders: Restrictive cardiomyopathy, Investigations: Ejection fraction decreased.

Grade 1

Grade 2

Grade 3

Grade 4

Grade 5

Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide I]) or cardiac imaging abnormalities

Symptoms with moderate activity or exertion

Symptoms at rest or with minimal activity or exertion; hospitalization; new onset of symptoms

Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical hemodynamic support)

Death

Start date

Date stop

Relation with cancer treatment

Note

ACCEPT

Symptoms

ADD NEW SYMPTOM

25

26

27

28

29

30

STATUS

Ongoing

ACTIONS

VIEW REPORT

Figure 4.3.16 Patients Profile - Symptom tab - Adding a new symptom by a physician.

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←

ID: 890438  
**Maria De Rossi**  
1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Filter by  
Days

June 2020

4 Grade  
3  
2  
1  
0  
01 02

Diarrhoea ●

SYMPTOM  
Diarrhoea

←

Add new symptom

10019279 Cardiac disorders Heart failure  
If left sided use Cardiac disorders: Left ventricular systolic dysfunction; also consider Cardiac disorders: Restrictive cardiomyopathy, Investigations: Ejection fraction decreased.

☐ Grade 1  
Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities

☒ Grade 2  
Symptoms with moderate activity or exertion

☐ Grade 3  
Symptoms at rest or with minimal activity or exertion; hospitalization; new onset of symptoms

☐ Grade 4  
Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical hemodynamic support)

☐ Grade 5  
Death

Start date  
05 June

Date stop  
Date stop may be empty if the symptom is ongoing

Relation with cancer treatment  
Not Selected  
The AE is clearly NOT related to the intervention  
The AE is doubtfully related to the intervention  
The AE may be related to the intervention  
The AE is likely related to the intervention  
The AE is clearly related to the intervention

ACCEPT

Symptoms

ADD NEW SYMPTOM

25 26 27 28 29 30

STATUS  
Ongoing

ACTIONS  
VIEW REPORT

Figure 4.3.17 Patients Profile - Symptom tab - Adding a new symptom by a physician.

ID: 890438

**Maria De Rossi**

1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

**Past relevant information**

Activity timeline

Questionnaire results

Symptoms

+ ADD DISEASE

Filter by date:

Filter by disease:

Date

Disease

| DATE         | TITLE                       | NOTES | ACTIONS |
|--------------|-----------------------------|-------|---------|
| 2019         | Diabetes                    | -     | EDIT    |
| 2018         | Hypertension                | -     | EDIT    |
| 2018         | Collagen vascular           | -     | EDIT    |
| 2015         | IBD                         | -     | EDIT    |
| 08 June 2013 | Previous intestinal surgery | -     | EDIT    |

Figure 4.3.18 Patients Profile - Past relevant information tab - Possibility to filter by date and by name.

←

ID: 890438  
**Maria De Rossi**  
1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

| QUESTIONNAIRE TITLE     | DATE TAKEN | RESULTS                            | ACTIONS                 |
|-------------------------|------------|------------------------------------|-------------------------|
| Insomnia Severity Index | 01-08-2020 | Moderate insomnia: 17 of 22 points | <div>VIEW RESULTS</div> |
| QoL. EORTC QLQ-C30      | 14-07-2020 | -                                  | <div>VIEW RESULTS</div> |

Figure 4.3.19 Patients Profile - Questionnaire results tab.

←

ID: 890438  
**Maria De Rossi**  
1944 Nov 10 (76 y.o)

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Past relevant information

Activity timeline

Questionnaire results

Symptoms

QUESTIONNAIRE TYPE

Insomnia Severity Index

QoL, EORTC QLQ

Insomnia Severity Index.

01-08-2020

Result — clinical insomnia moderate intensity. 17 points

Q. Difficulty falling asleep in past 2 weeks

A. Moderate

Q. Difficulty staying asleep in past 2 weeks

A. Mild

Q. Problem waking up too early in past 2 weeks

A. Severe

Q. How satisfied/dissatisfied are you with your current sleep pattern?

A. Moderate satisfied

Q. To what extent do you consider your sleep problem to interfere ....

A. Much

×

ACTIONS

VIEW RESULTS

VIEW RESULTS

Figure 4.3.20 Patients Profile - Questionnaire results tab - View report.

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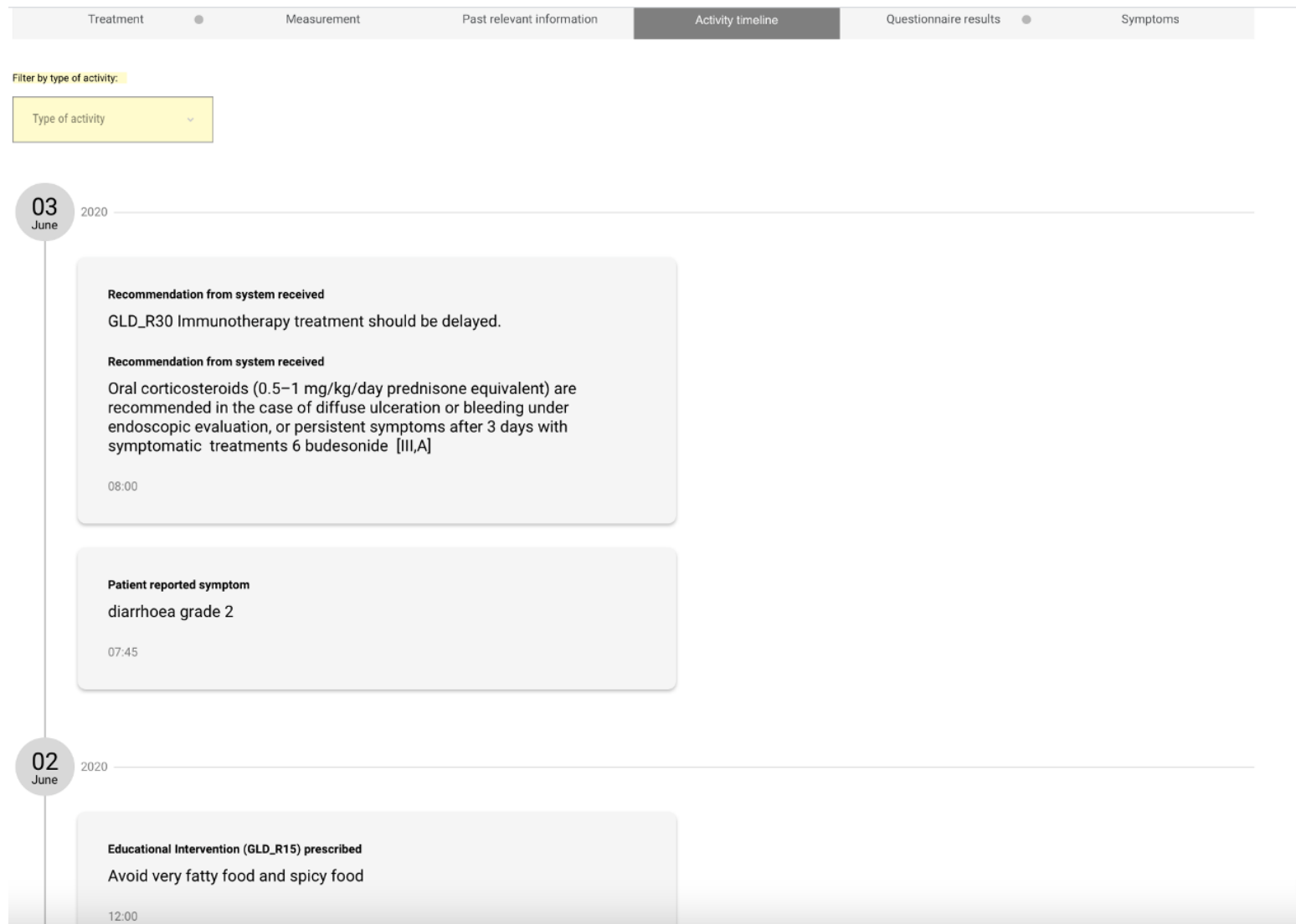


Figure 4.3.21 Patients Profile - Activity timeline tab - shows all the events regarding a Patient - recommendations, Notifications, Symptoms, Treatments.

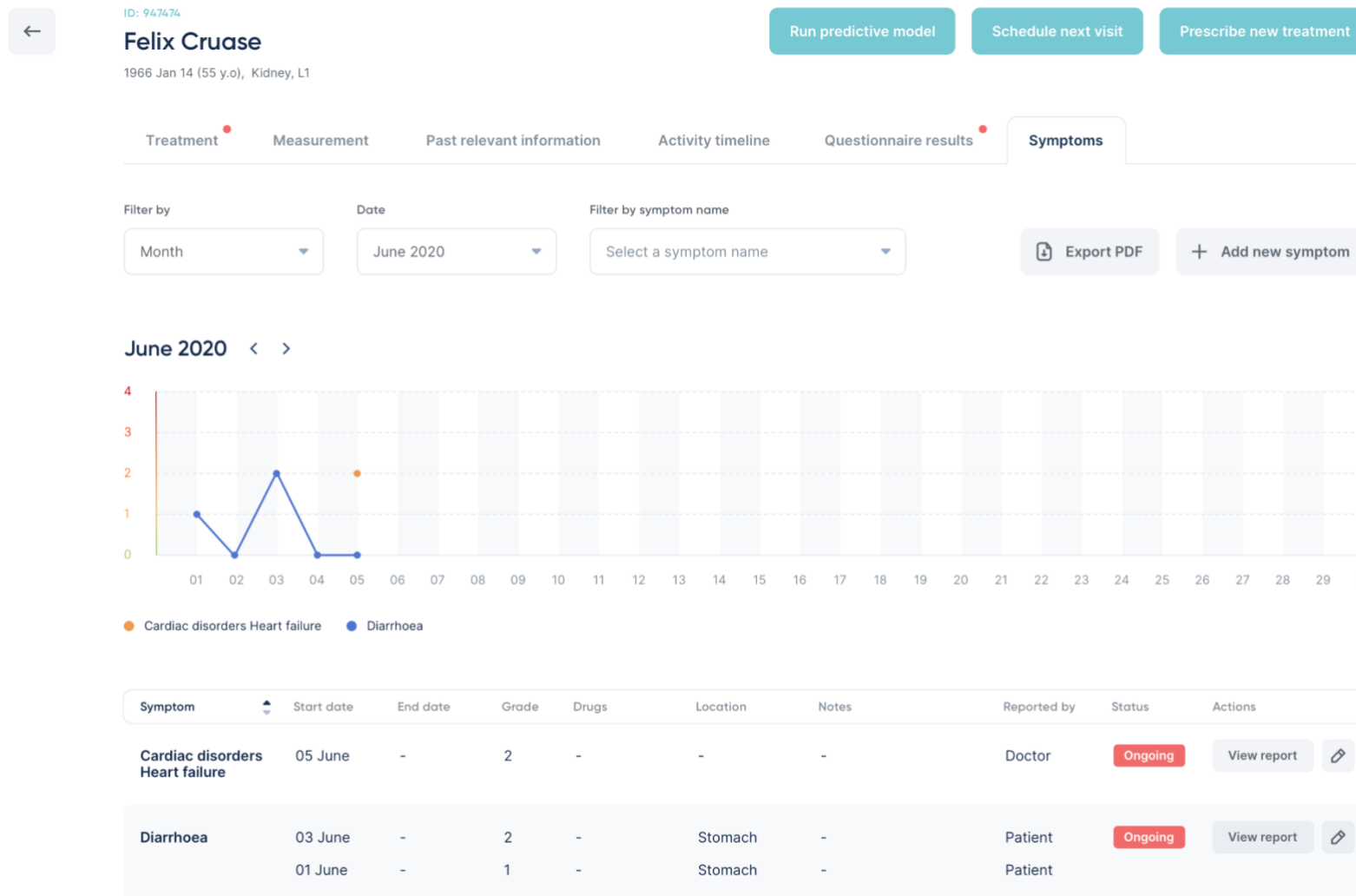


Figure 4.3.22 Patients Profile - Symptom tab - reported symptoms with a visualisation, possibility to view, edit, add new symptom by a physician - UI Design.

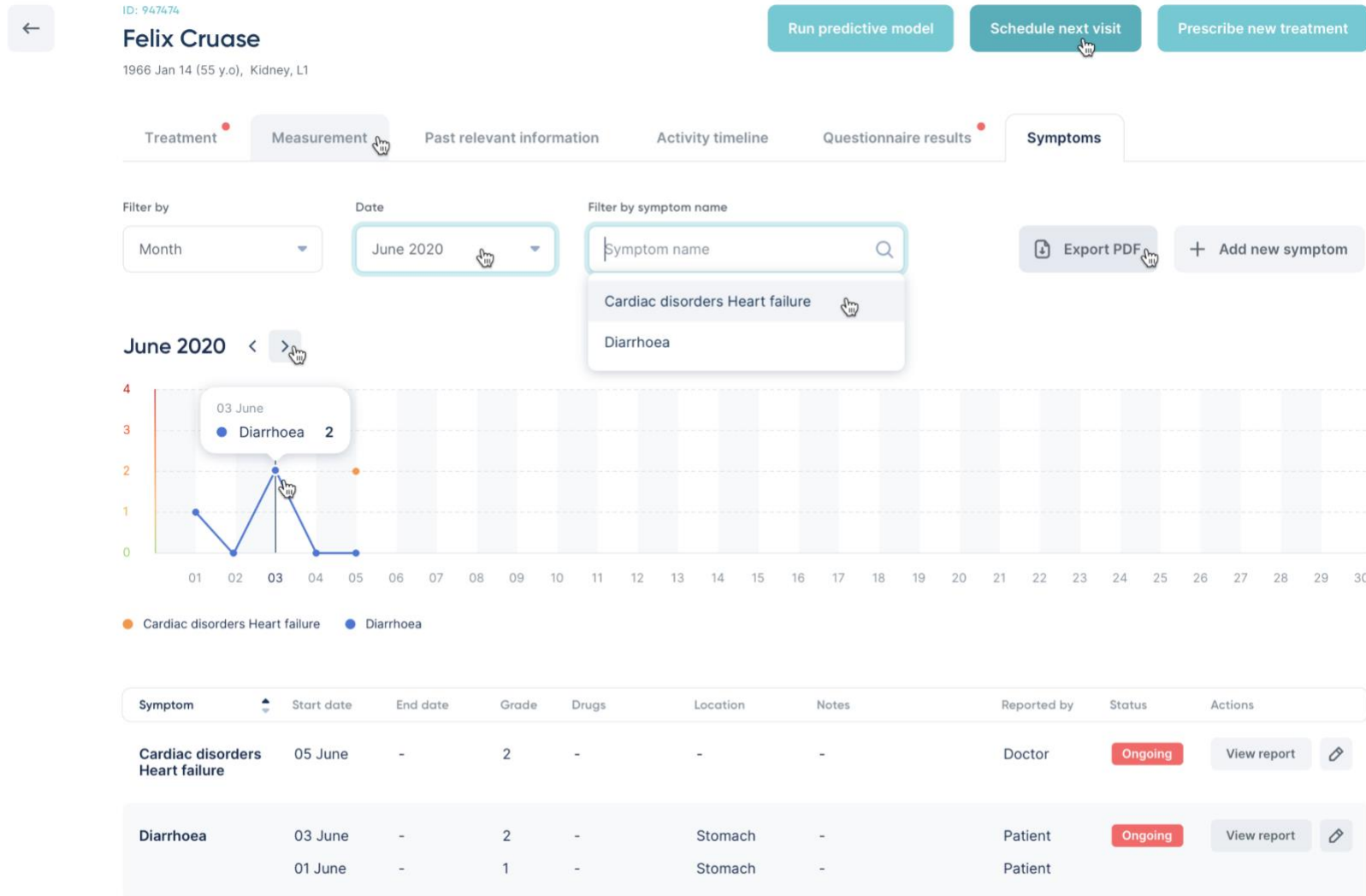
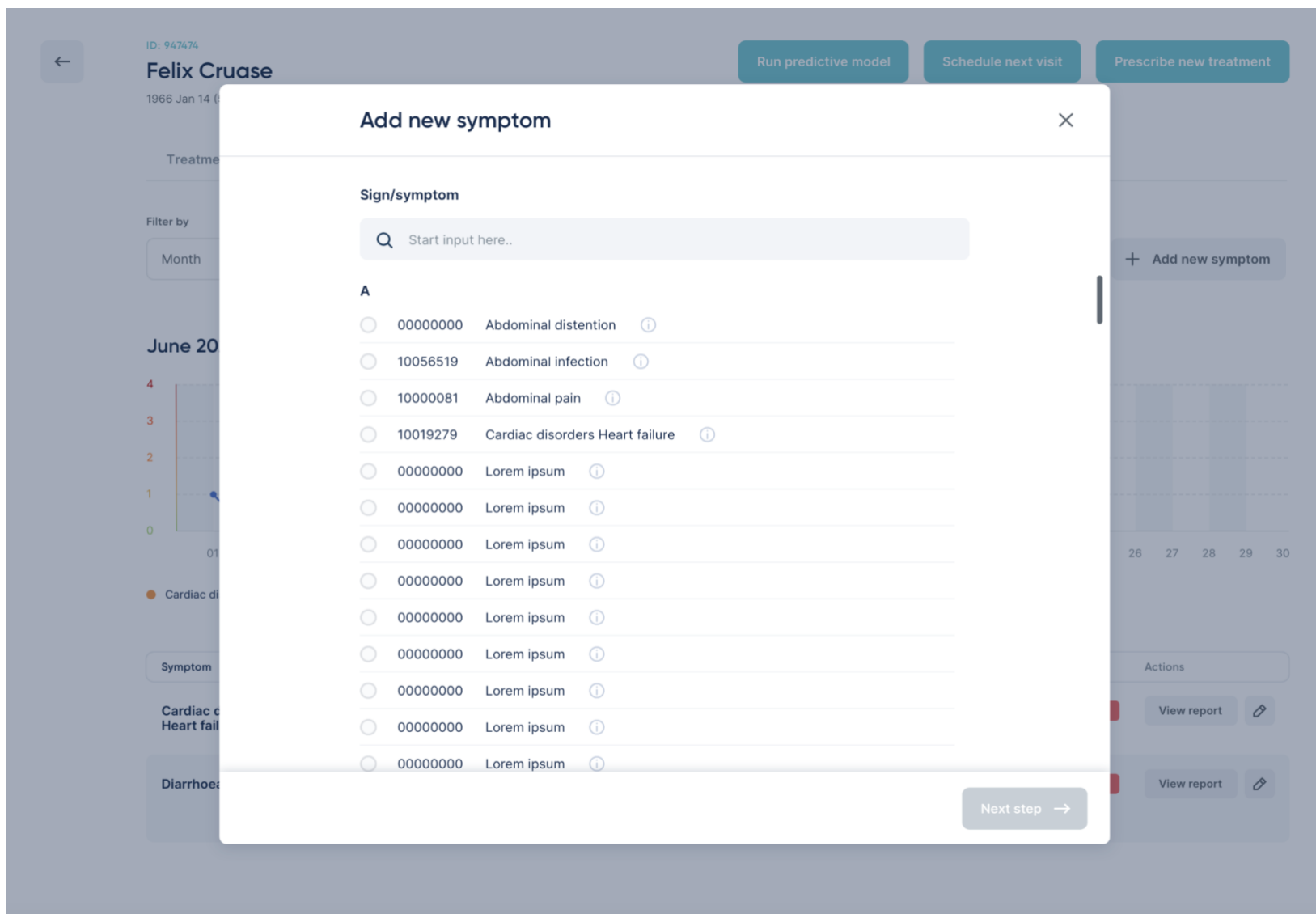


Figure 4.3.23 Patients Profile - Symptom tab - reported symptoms with a visualisation, possibility to view, edit, add new symptom by a physician - UI Design.



ID: 947474  
**Felix Cruase**  
 1966 Jan 14 (

Run predictive model   Schedule next visit   Prescribe new treatment

Add new symptom

Sign/symptom

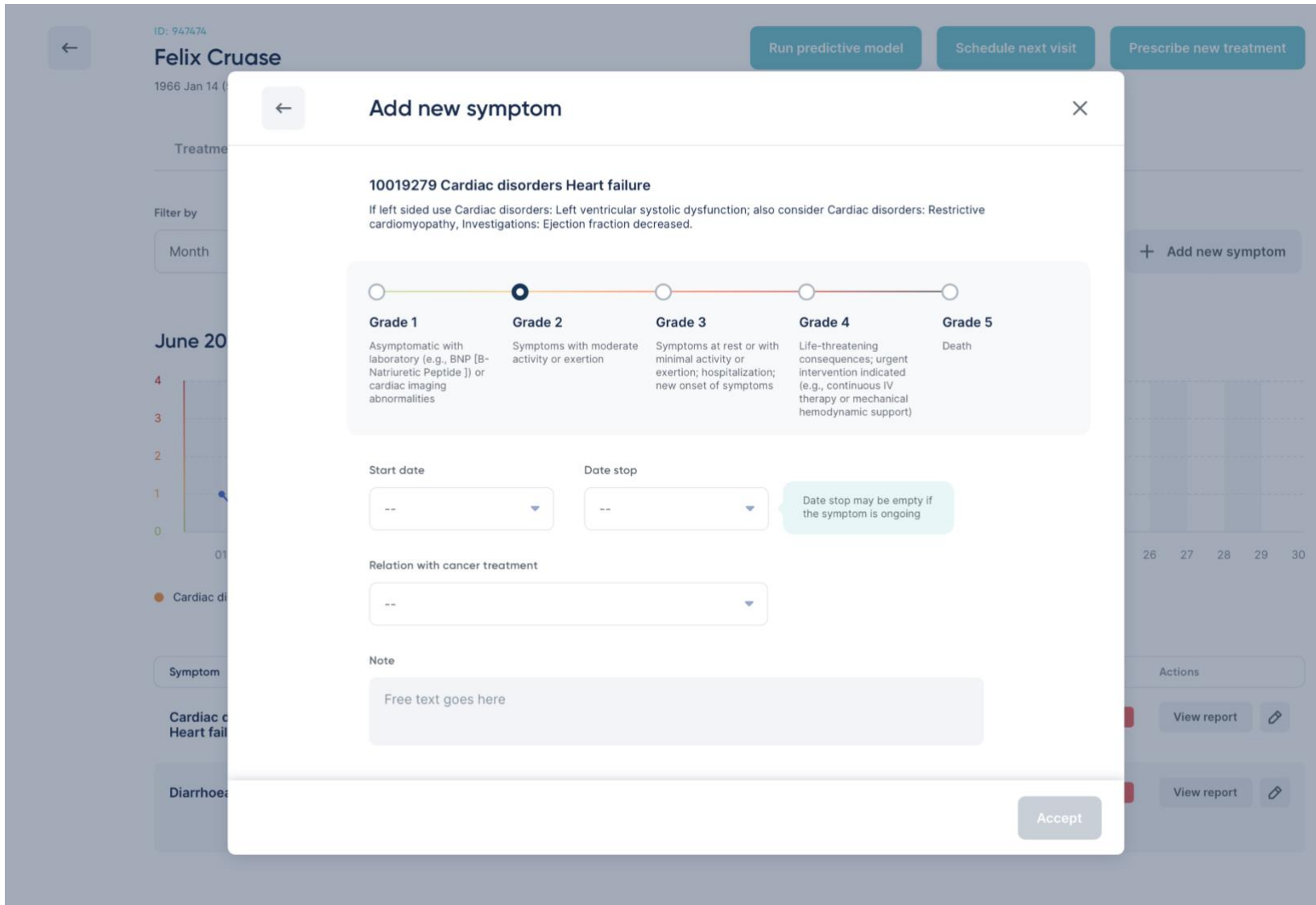
Search Start input here..

A

- ☐ 00000000 Abdominal distention ⓘ
- ☐ 10056519 Abdominal infection ⓘ
- ☐ 10000081 Abdominal pain ⓘ
- ☐ 10019279 Cardiac disorders Heart failure ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ
- ☐ 00000000 Lorem ipsum ⓘ

Next step →

Figure 4.3.24 Patients Profile - Symptom tab - Adding a new symptom by a physician with controlled vocabulary codes (CTCAE - Common Terminology Criteria for Adverse Events) - UI Design.



← ID: 947474 Felix Cruise 1966 Jan 14 (

Run predictive model Schedule next visit Prescribe new treatment

← Add new symptom X

**10019279 Cardiac disorders Heart failure**  
If left sided use Cardiac disorders: Left ventricular systolic dysfunction; also consider Cardiac disorders: Restrictive cardiomyopathy, Investigations: Ejection fraction decreased.

Grade 1 Grade 2 Grade 3 Grade 4 Grade 5

Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide ]) or cardiac imaging abnormalities

Symptoms with moderate activity or exertion

Symptoms at rest or with minimal activity or exertion; hospitalization; new onset of symptoms

Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical hemodynamic support)

Death

Start date Date stop

-- --

Date stop may be empty if the symptom is ongoing

Relation with cancer treatment

--

Note

Free text goes here

Accept

+ Add new symptom

June 20

4 3 2 1 0

26 27 28 29 30

Actions

View report

View report

Figure 4.3.25 Patients Profile - Symptom tab - Adding a new symptom by a physician - UI Design.

## 4.4 Recommendations

←

ID: 999998

Maria Rossi

1954 Nov 11 (66 y.o), stable

RUN PREDICTIVE MODEL

SCHEDULE NEXT VISIT

PRESCRIBE NEW TREATMENT

Treatment

Measurement

Clinical history

Activity timeline

Questionnaire results

Symptoms

Current:

EDIT

→ Treatment for cancer:

1. Nivolumab 240 mg every two weeks (june 15 - july 12)

2. Sunitinib 50 mg, daily, for 28 days (june 15 - july 12)

→ Treatment for adverse events:

1. Loperamide 4mg + 2mg/4hours ( as needed)

→ Other treatment:

1. St. John's-wort 300 mg, daily, for 28 days (june 15 - july 12)

→ Capsules

1. Sleep

2. Nutrition

3. Mental Wellbeing

4. Social Connections

Stop St. John's wort

[GLD\_RM1]

Goal: Treatment of Depressive disorder

Explanation: An interaction has been found between St. John's wort and loperamide: St. John's wort inhibits the effects of loperamide. Hence St. John's wort has to be stopped

Source: FAERS

Grade of evidence: Auto generated

ACCEPT

DECLINE

Figure 4.4.1 Patients Profile - Treatment tab - Example of treatment recommendations and the goals for which they have been prescribed.

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ID: 890438  
**Maria De Rossi**  
1947 Nov 11 (73 y.o)

RUN PREDICTIVE MODEL
SCHEDULE NEXT VISIT
PRESCRIBE NEW TREATMENT

Treatment
Measurement
Past relevant information
Activity timeline
Questionnaire results
Symptoms

Current
Past

Treatment for cancer

EDIT

**Systemic therapy**  
Nivolumab, hospital admin. (1 June 2021)

**Surgery**  
None

**Radiotherapy**  
None

**Please contact the patient** [GLD\_RM1]  
**Explanation:** Symptom inserted = rash  

REVIEW

Treatment for comorbidities

EDIT

None

Treatment of adverse events

EDIT

None

Other treatment

EDIT

None

Figure 4.4.2 Patients Profile - Treatment tab - Example of a recommendation with its explanation (here the patient had a rash response to cancer treatment and the physician is asked to contact the patient).

**Please contact the patient** [GLD\_RM1]

**Goal:** ?

**Explanation:** Symptom inserted = rash

**Source:** FAERS

**Grade of evidence:** Auto generated

ACCEPT

DECLINE

Figure 4.4.3 Patients Profile - Treatment tab - Example of a recommendation.



oral antihistamines - loratadine

Patient's side effect:

271807003 | Eruption of skin

Aroute of administration

Oral

☐ As needed medication

Repeat every

1

^

v

Day

v

Initial dose

10 mg

Following dose

- mg

Max dose per period

10 mg

PREScribe

CANCEL

Figure 4.4.4 Patients Profile - Treatment tab - Example of a prescription.



## 5 Glossary

---

|       |  |
|-------|--|
| UI    | User-Interface                                 |
| CTACE | Common Terminology Criteria for Adverse Events |
| GDPR  | General data protection regulation             |