REal-time data monitoring for **S**hared, **A**daptive, **M**ulti-domain and **P**ersonalised prediction and decision making for **L**ong-term Pulmonary care **E**cosystems

D2.4: Functional specifications for the virtual companionship programme

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Author(s)	Christiane Grünloh, Stephanie – Jansen Kosterink, Marian Hurmuz, Eline te Braake (RRD), Rain Jõgi (TUK), Helen Urmann (University of Tartu/TUK), Marjolein Brusse-Keizer (MST), Alice Luraschi, Agni Delvinioti (GEM)
Reviewer(s)	Charlotte Bucsán, Marjolein Brusse-Keizer, (MST), Anke Lenferink (UT), Harm op den Akker (iSprint)
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Partners

Participant No	**Participant organisation name (country)**	**Participant abbreviation**
1 (Coordinator)	University of Twente (NL)	UT
2	Foundation Medisch Spectrum Twente (NL)	MST
3	University of Piraeus Research Center (GR)	UPRC
4	Foundation Tartu University Hospital (EE)	TUK
5	Foundation University Polyclinic Agostino Gemelli IRCCS (IT)	GEM
6	European Hospital and Healthcare Federation (BE)	HOPE
7	German Research Center for Artificial Intelligence GMBH (DE)	DFKI
8	ATOS IT Solutions and Services Iberia SL (ES)	ATOS
9	Roessingh Research and Development BV (NL)	RRD
10	Innovation Sprint (BE)	iSPRINT

Abstract

The goal of RE-SAMPLE is to improve the care that is currently provided for people living with Chronic Obstructive Pulmonary Disease (COPD) and complex chronic conditions (CCC). This deliverable describes the design, application and results of the user research studies which form the basis for the identification of user needs and the specification of user requirements for the RE-SAMPLE virtual companionship programme. The focus in this deliverable is on the needs and expectations of patients and healthcare professionals related to self-management, (shared-) decision making, data visualisation, communicating and connecting, and coaching.

Successful design and implementation of the RE-SAMPLE programme necessitates a good understanding of the current tasks and activities of the end-users. It is therefore crucial to analyse their context of use, needs, expectations and values, to be able to design eHealth services in such a way that they optimally support users. The aim of RE-SAMPLE is to have a positive impact on patients and healthcare professionals in terms of manage their conditions, provide personalised care and improving both the quality of life and quality of care.

Following a human-centred design approach, an empirical study was designed that allows to investigate the context of use and elicit user needs and expectations. After a short description of the pilot sites and the additional methods designed for this deliverable, the results from each pilot site are presented by topic: context of use (including user profiles, personas, patient journey maps), self-management, decision making, data visualisation, communicating and connecting, and coaching. Based on the analysis of user needs and their expectations, the functional, service, organisational, content, usability and user experience (UX) requirements for the virtual companion programme have been specified. Utilising the requirements and the personas, scenarios are presented that describe how the future users are interacting with the technology. Furthermore, data-flow diagrams outline the two main processes for data collection, processing, data sharing and usage. Finally, prototypes of the user interface were developed and validated in end-user walkthroughs with healthcare professionals and patients in all three pilot sites.

This deliverable extends the first set of user requirements identified in D2.1 *User needs and expectations for privacy-abiding RWD collection*, and will be complemented by organisational, technical, legal requirements elicited in WP3 and WP4. The user research studies and specified requirements will inform the design of the RE-SAMPLE programme, in terms of technical design, content and interaction design (WP5, WP6), service model design (T2.4), and implementation of RE-SAMPLE in the pilot sites. Finally, the stakeholder evaluation in WP7 will assess the alignment of the design with the user needs and requirements and the general acceptance of the companionship programme and its social impact.

Corrections

v2.0	Abstract, section 1: revision to reflect inclusion of end-user walkthroughs
	Section 4: Revised number of participants to include end-user walkthroughs
	Section 6: Revision of scenarios
	Section 8: Added prototypes
	Section 9: Added results end-user walkthrough
	Section 9.3: Revision of requirements
	Section 10: Revision of conclusion section

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Symbols, definitions, abbreviations, and acronyms

CCC	Complex Chronic Condition
COPD	Chronic Obstructive Pulmonary Disease
CT	Computed tomography
D	Deliverable
DoA	Description of action
EEW	eHealth End-user Walkthrough
EPD	Elektronisch Patiëntendossier (electronic health record)
GEM	Gemelli Hospital
GOLD	Global Initiative for Obstructive Lung Disease
GP	General practitioner
HCP	Health Care Professional
HRQoL	Health-related quality of life
M	Month
MET	Metabolic Equivalent of Task
MREC	Medical Ethical Research Committee
MST	Medisch Spectrum Twente
non-WMO	Research study that is not subject to WMO
RRD	Roessingh Research and Development
RWD	Real-World Data
SCF	Shared-care facility
SES	Socioeconomic status
SpO2	Oxygen saturation
TUK	Tartu University Hospital
UX	User experience
WMO	Wet medisch-wetenschappelijk onderzoek met mensen (Medical Research Involving Human Subjects Act)
WP	Work Package

1. Introduction

The goal of RE-SAMPLE is to improve the care that is currently provided for people living with Chronic Obstructive Pulmonary Disease (COPD) and complex chronic conditions (CCC). Many patients with COPD have multiple CCCs (Negewo, Gibson, & McDonald, 2015), such as cardiovascular diseases, mental health issues, diabetes mellitus, which further increase the patient burden, mortality and costs (van Boven, 2017; Chen, FitzGerald, Sin, & Sadatsafavi, 2017). CCCs can trigger exacerbations and share common risk factors (for example, ageing, smoking, inactivity). COPD and CCCs can have overlapping symptoms, for example, breathlessness can be caused by COPD, heart failure, or anxiety. This overlap in symptoms can easily lead to delay of appropriate treatment as it complicates differentiation between diseases. The challenge of the increasing number of patients with COPD and multi-morbid CCCs requires an integrated, personalised, but holistic approach (Vanfleteren, Spruit, & Franssen, Tailoring the approach to multimorbidity in adults with respiratory disease: the NICE guideline, 2017) to support and manage care for these patients.

Nowadays, healthcare is poorly organised as there is isolation between care levels and different healthcare professionals, and lack of continuity of care along the patient's journey with the healthcare system (Vanfleteren, et al., 2020). Moreover, current disease management and monitoring of patients with CCCs relies heavily on information acquired during time-based scheduled visits when patients are usually stable, whereas the actual symptoms and changes during common daily life triggers are not quantified. Clinical decision making in patients with multi-morbid CCCs is thus still complicated by the lack of adequate recommendations regarding the management of patients with COPD who may also suffer from other CCCs. Furthermore, current care tends to be reactive, leaving room for improvement, for example, in terms of self-management and evidence-based proactive care.

RE-SAMPLE aims to support patients and healthcare professionals (HCPs) to manage COPD (accompanied by CCC) in a more optimal and personalised way, that is data-driven, evidence-based and takes into account patient preferences. This will be accomplished through the utilisation of real-world data (RWD) in an ecosystem of innovative eHealth services supporting the key actors along the patient journey:

- A **virtual companion for patients** that supports data collection and monitoring, personalised lifestyle coaching and communication with virtual and real-life case managers.
- An **active support programme for healthcare professionals** that gives an overview of data, alerts, risk and monitoring profiles for the individual patient. A shared-decision making tool, powered by an AI-driven prediction model, supports HCPs and patients with regard to decision support and tailored care plans.
- A **monitoring and communication console for shared-care facilities** (SCFs), where additional tests are carried out.

As outlined in more detail in D2.1 *User needs and expectations for privacy-abiding RWD collection,* the successful design and implementation of the RE-SAMPLE programme necessitates a good understanding of the end-users. That includes their context of use (i.e., characteristics, goals, skills, motivation, preferences, journeys), their current tasks and activities, values and needs. User research studies have been carried out to elicit the user needs and expectations and their context of use.

The following topic list gives an overview, which aspects have been focused on in the user research studies, given that each topic is much broader than what could be addressed in the studies:

- **Self-management:** The focus was on the activities that patients are carrying out to reduce their symptoms, treat or prevent exacerbations. These activities can be physical or mental in nature, or relate to their lifestyle and behaviour changes.
- **Decision making:** The focus was on the current process of making decisions that relates to the health and wellbeing of the patients, the extent of which patients are currently involved in the decision-making process and in which way their preferences and wishes are considered in the process.

- **Data visualisation:** refers to the user interface for patients and HCPs and their preferences and needs when it comes to the visualisation of collected data in terms of general overview, overview of short-term and long-term changes in the disease progression, alerts or notifications, risk and monitoring profiles.
- **Communicating and connecting:** refers to the ways patients and HCPs are currently getting in contact and communicate with each other, including individual preferences and opportunities for improvement.
- **Coaching:** refers to the topics that are valuable for patients to include in the coaching module of RE-SAMPLE and preferences regarding coaching style.

As specified in the description of action (DoA), this deliverable describes the results of the user research methods and co-design sessions for creating the virtual companionship programme, and the requirements derived from them. Furthermore, this deliverable includes the prototypes and reports on validation of the user requirements via end-user walkthroughs and the revised/added requirements.

2. Objective

The objective of this deliverable is to present the results of the user research studies with a special focus on the following four items

1. Context of use (including user profiles, personas, patient journeys)
2. User needs related to self-management, decision making, data visualisation communicating & connecting, and coaching
3. Requirements derived from the user needs
4. Validation of requirements and prototypes through end-user walkthroughs

In Section 3, a short summary of the pilot sites and an overview of the user research methods is provided. Methods that have not been discussed in D2.1 *User needs and expectations for privacy-abiding RWD collection* are described in detail. Section 4 presents a detailed account of the results from each pilot site on the above-mentioned focus points. In Section 5, the requirements for the virtual companionship programme are presented (separated in functional, service, organisational, content, usability and user experience requirements). Section 6 outlines the user scenarios accompanied by storyboards describe how the future users are interacting in collaboration with the technology. Section 7 describes the data-flow in RE-SAMPLE in relation to the onboarding, data sharing, and exacerbation alert. The prototypes presented in Section 8 have been validated with patients and HCPs in end-user walkthroughs as discussed in Section 9. This deliverable ends with a conclusion and the outlook on the future work that will utilise the results from this deliverable (Section 10).

3. Methods

The basis for the specification of user requirements is the in-depth investigation of the context of use, including the users and their characteristics, their goals and tasks, and their technical and organisational environment. For this, a set of user studies has been designed that enables us to learn from the vast experience of our primary users and also identify opportunities for the RE-SAMPLE virtual companionship programme to support their tasks.

This section describes the pilot sites, where the user research studies were conducted, the study population and the methods used. The studies were conducted in all three pilot sites (see Section 3.1), following the protocols and using materials prepared by Roessingh Research and Development (RRD), who carried out the studies at the Dutch hospital. The study setup and materials were presented to the partners in several online meetings and then adapted and translated by the Italian and Estonian partners to fit their settings and circumstances.

3.1 Pilot sites and study population

The pilot sites and the included study population have been discussed in detail in D2.1 *User needs and expectations for privacy-abiding RWD collection* and remain the same for this deliverable. The pilot sites are clinical hospitals in The Netherlands (Medisch Spectrum Twente, MST), Italy (Gemelli Hospital, GEM) and Estonia (Tartu University Hospital, TUK). The main focus was on the two primary end-users, patients and HCPs, and aimed to recruit at least N=20 patients and N=5 professionals from various medical backgrounds (pulmonology, psychiatry or psychology, physical therapy, nurse practice, cardiology, internal medicine, general practice). Inclusion criteria for HCPs were that they gave informed consent and that they have experience in treatment of patients with COPD, even if their main focus was on one of the CCCs. Inclusion criteria for patients included that they have a clinical diagnosis of COPD and preferably at least one co-morbidity (diabetes, chronic heart failure, ischaemic heart disease, anxiety, depression), are >40 years, able to understand, read and write the language spoken in the country of the pilot site, and that they gave informed consent prior to participation. Patients were contacted by each hospital with the aim to recruit participants that are representative for the general COPD population. Recruitment in all countries was, however, very difficult due to the COVID-19 pandemic that poses a particular risk for patients with COPD, which caused many patients to refrain from participating in a study. In turn, using technology to carry the studies out online and thus more safely may have posed a barrier for people who are less computer literate. Finally, weather conditions (high temperature and humidity) during the studies also meant that many patients who have severe COPD were in bad condition and understandably would not sign up to participate in a study.

3.2 Ethical approval procedures

The ethical approval procedures differed between the three countries. The hospitals in Italy and Estonia submitted one general ethical application for the cohort study (WP5) that included the user research activities conducted as part of WP2. The ethical application was approved in Estonia on 4th June 2021, and in Italy on the 4th August 2021. After that, the recruitment of patients could start in the respective setting.

In The Netherlands, medical ethical approval by an accredited Medical Ethical Research Committee (MREC) was sought for the cohort study as this is subject to the Dutch Medical Research Involving Human Subjects Act (WMO). Because people participate voluntarily in the user studies conducted in WP2 and the studies do not infringe upon the physical or psychological integrity of participants, these kind of studies are usually not subject to a medical ethical approval procedure (Peute, et al., 2020). However, an approval was sought from the board at the hospital to confirm that this was indeed a non-WMO study. The application was approved on 8th June 2021, confirming that the study is not subject to the WMO and therefore no medical ethical application was needed.

3.3 Study design

In the following, an overview is provided of methods carried out in the user research studies (see Table 1). The original setup and protocol of most of the methods were described in detail in D2.1 *User needs and* *expectations for privacy-abiding RWD collection*. Additional methods such as co-design workshops with HCPs and patients are described in detail below. Materials such as the protocol, PowerPoint slides, prototypes, and templates were provided by RRD in advance to support the pilot sites.

Depending on the practical implications at the pilot sites, the researchers on-site adapted the methods if needed. For example, due to the COVID-19 restrictions at the time, it was impossible to carry out a workshop with patients with COPD in Estonia. The researchers then decided to utilise the protocol and material to get input on “coaching” in the preparation for the diary study that was carried out later than originally planned. Similarly to Estonia, the diary study in Italy was also carried out later than planned and it was decided that in the post-diary workshop the focus would shift away from “data collection” and “data sharing” and instead move towards the “coaching” aspect.

Table 1: Overview of methods carried out in the user research studies including addressed topics

	**Workshop / Interviews with healthcare professionals:** - Current and desired parameters for the monitoring of COPD and CCCs - Learning about patient journeys from the HCPs’ point of view - Self-management and coaching - Communication with patient - Shared-decision making process - Values - Data overview, alerts, monitoring profiles
	**Diary study with patients:** - Evaluation of the day (symptoms, achievements) - Activities - Self-management
	**Interviews with patients:** - Health story - Experience with exacerbations and comorbidity - Controlling COPD - Use of eHealth - Privacy and data sharing - Self-management - Communicating and relationship with HCPs - Decision-making
	**Workshops and Co-Design with patients:** - Controlling and tracking their health - Privacy and data sharing - Values - Feedback on initial results - User interface for data visualisation and consent for data sharing - Coaching topics and coaching style
 	**End-user walkthrough with patients and healthcare professionals** - Feedback on prototypes facilitated with personas and scenarios

For each study, participants were provided an information letter which outlined the study, the process, risks and benefits, their rights to withdraw, the data processing that ensures anonymity, contact details of persons involved and the informed consent form. In addition to the signed consent, researchers again asked the participants before starting the recording for their permission. After each study, the recordings were transcribed and saved by the researcher. All data was processed and kept in coded form, for example the participant's name, initials and other data that could directly identify them were omitted from the results. Only with the key to the code can data be traced back to the participant. The key to this code is stored securely at the research facility of the pilot. The data will be kept for the legally required period, and then destroyed. Only the researchers directly involved have access to this key.

We refer the reader to D2.1 *User needs and expectations for privacy-abiding RWD collection* for a detailed description and protocols of the studies. The additional studies that have not been presented before are described in the following paragraphs.

3.3.1 Co-design workshop healthcare professionals "data overview, alerts, monitoring profiles"

Aim: The main aim of this workshop is to support HCPs in creating their own user interface that supports their work when it comes to the visualisation of data and monitoring profiles and in which instances they want to receive which type of alarm or notification. The aim of RE-SAMPLE is to provide HCPs an overview of relevant data collected by patients in an understandable and engaging way. Similarly, monitoring profiles show HCPs the optimal set of parameters that should be monitored to reliably detect short and long-term changes in disease progression for that particular patient. For the co-design exercise two examples were chosen (weight and oxygen) as a proxy that can stand also for other parameters that are monitored.

Procedure: The co-design workshop was split in four parts: An initial discussion and 3 co-design parts.

1. **Introduction**
   The workshop facilitator explains the goal of the meeting, asks for permission for audio-recording, and repeats the process that ensures participants' anonymity (as also outlined in the information letter). Participants and facilitator(s) introduce themselves to the group, before the facilitator then explains the RE-SAMPLE project and the motivation for this workshop. Participants are asked to fill in a short demographics questionnaire (gender, occupation, work experience in healthcare in years).
2. **Data overview and alerts**
   Goal: Introducing the main topics and getting an initial idea about preferences. Aspects discussed in the group are:
   a. Preference regarding raw data vs. information visualisation;
   b. Focus on data overview or on alerts;
   c. Preferences for type of data;
   d. Preferences for aggregation level (day / week / month / year);
   e. Preferences for layout;
   f. Preferences for alerts.
3. **Co-Design "Weight monitoring"**
   Goal: Identifying preferences and collecting ideas of HCPs for engaging and understandable visualisations using the example of weight monitoring.
4. **Co-Design "Oxygen saturation monitoring"**
   Goal: Identifying preferences and collecting ideas of HCPs for engaging and understandable visualisations using the example of oxygen monitoring.
5. **Co-Design "Monitoring profiles"**
   Goal: Identifying preferences and collecting ideas of HCPs on visualising monitoring profiles of patients.
6. **Closing**

The detailed protocol for the co-design workshop with HCPs can be found in Appendix A: *Protocol HCPs co-design "data overview, alarms, profiles"*.

3.3.2 Co-design workshop patients “Your favourite coach”

Aim: The main aim of the workshop is to identify potential topics for the coaching module of the RE-SAMPLE virtual companionship programme. Furthermore, the aim was to identify the preferred coaching type, which partly includes the conversation style and appearance of the virtual companion.

Procedure:

1. **Introduction**
   The facilitator explains the goal of the meeting, asks for permission for audio-recording, and repeats the process that ensures participants’ anonymity (as also outlined in the information letter). Participants and facilitator(s) introduce themselves to the group, before the facilitator then explains the RE-SAMPLE project and the motivation for this workshop.
2. **Demographics**
   The facilitator explains the demographics questionnaire and guides participants through the questions, while facilitator is noting down the answers in the form. Demographics questions are related to gender, age, CCCs, since when they have COPD, education, employment status, family situation, health-related quality of life (HRQoL), health and digital literacy, the use of eHealth technologies.

3. **Topics for coaching**
   Goal: Learn from patients which topics they received or would have liked to receive coaching on in which phase (starting phase with diagnosis, stable phase, exacerbation).
4. **Choose your favourite coach**
   Goal: Learn from patient what type of coaching style they respond to or prefer (metaphors used: military general, sports coach, parent, equal partner), and whether the coaching style differs depending on the coaching topic or phase in their disease.
5. **Positive health**
   Goal: Broadening the concept of health following Huber’s positive health approach (Huber, et al., 2016) to collect more topics for coaching that go beyond the physical dimension. Learn in which phase coaching about these new topics would be applicable and which coaching style they would prefer.
6. **Closing**

The demographics questionnaire can be found in Appendix B. The detailed protocol for the co-design workshop with patients on coaching can be found in Appendix C.

3.3.3 End-user walkthrough with patients

Aim: The aim of the end-user walkthrough with patients is to elicit their impressions, opinions, and assess their acceptance of the eHealth technology in early stages of the development. The walkthrough was conducted in-person with the use of the personas, scenarios, and prototypes described in this deliverable.

Procedure:

1. **Introduction**
   The facilitator explains the goal of the end-user walkthrough, asks for permission for audio-recording, and repeats the process that ensures participants’ anonymity (as also outlined in the information letter). The participant and facilitator(s) introduce themselves, before the facilitator then explains the RE-SAMPLE project and the motivation for this end-user walkthrough.
2. **Demographics**
   The facilitator explains the demographics questionnaire and guides participants through the questions, while the researcher is noting down the answers in the form. Demographics questions are related to gender, age, CCCs, since when they have COPD, education, employment status, family situation, health-related quality of life (HRQoL), health and digital literacy, the use of eHealth technologies, and attitude towards eHealth technologies.
3. **Presenting blocks**
   Goal: Make participants familiar with the visual overview of the personas, scenarios, and prototypes of the virtual companion user interface. Each participant will walk through three different thematic blocks to assess to what extend participants appreciate the different prototypes. For each thematic block, participants are presented with one persona, one scenario, and one prototype at a time to prevent

confusion. The facilitator will explain these blocks thoroughly with the participants and ensures that the participant understands them.

4. **Uncover opinions**
   Goal: Uncover participants' first impressions, understanding of features, and the acceptance regarding the different blocks. Participants are first asked to give answers as if they were the persona. Then, participants are asked during each block to answer from their own point of view. Differences between the persona's opinion and their own opinions are highlighted and reasons for the possible differences are asked.
5. **Rating**
   Goal: Assess participants' intention and willingness to use of the future eHealth application. To do so, questions are asked to the participants which need to be rated on a Likert scale.
6. **Closing**

The demographics questionnaire can be found in Appendix B. The detailed protocol for the end-user walkthrough with patients can be found in Appendix D.

3.3.4 End-user walkthrough with healthcare professionals

Aim: The aim of the end-user walkthrough with HCPs is to assess their acceptance of the eHealth technology early in the development process. The end-user walkthrough with HCPs was performed using online questionnaires which contained questions based on certain personas, scenarios, and prototypes.

Procedure:

1. **Introduction**
   The questionnaire starts with explaining the RE-SAMPLE project, the motivation, and the goal of the end-user walkthrough. The system will ask for permission and repeats the process that ensures participants' anonymity.
2. **Demographics**
   The questionnaire starts with demographic questions. The demographics questions are related to gender, age, location, profession, work experience with COPD, frequency of seeing patients with COPD, experience with eHealth, and attitude towards eHealth technologies.
3. **End-user walkthrough**
   Goal: Introduce the personas, scenarios, prototype, and uncover participants' impressions, understanding of features, the acceptance, and intention to use by using different questions.

   Participants are presented with a visual overview of the persona, and the scenario. Participants are asked to read these thoroughly to be able to answer questions about them afterwards. Then, the prototype of the corresponding scenario is shown. Participants are asked to answer a series of questions. After all questions regarding the first persona are answered, participants are presented with the second persona, and so on. In total, participants receive questions about three personas and will see three prototypes.
4. **Rating**
   Goal: Assess participants' perceived usefulness and perceived benefits of the future eHealth application. Participants will end the end-user walkthrough with a rating of several questions on a Likert scale.
5. **Ending**

The detailed protocol for the end-user walkthrough with healthcare professionals can be found in Appendix E.

4. Results

This section describes the results of the user studies focusing on the context of use (user profiles, personas, patient journeys) and the user needs related to self-management, shared-decision making, coaching, communicating and connecting. The overview of participants in the studies in each country is provided in Table 2.

Table 2: Overview participants in each study conducted in the respective country

	The Netherlands	**Italy**	**Estonia**
HCPs Workshop	N=12 (21.06.2021)	N=9 (24.06.2021)	N=5 (30.06.2021)
HCPs Interviews	N=7 (26.07. – 02.09.21)	n/a	n/a
Patient preDiary workshop	N=3 (24.06.2021) N=2 (19.08.2021)	N=6 (14.09.2021)	N=8 Adapted to interviews 04.-08.10.2021
Patient diary study	N=4 (25.06. – 15.07.21) N=2 (20.08. – 09.09.21)	N=9 (15.09. – 05.10.21)	N=8 (04. – 28.10.2021)
Patient interview study	N=7 (28.06. – 16.07.21)	N=12 (11.09. – 05.10.21)	N=10 (09.07. – 21.07.21)
Patient post-diary workshop	N=3 (18.08.2021) N=2 (06.10.2021)	N=8 (06.10.2021)	*Not conducted due to COVID-19 situation*
Patient co-design workshop “coaching”	N=2 (06.10.2021) N=2 (07.10.2021) N=2 (30.11.2021)	Integrated in post-diary workshop	Integrated in pre-diary interviews
HCP co-design workshop “data overview, alerts, monitoring profiles”	N=12 (23.08.2021)	n/a	n/a
Patient end-user walkthroughs	N=10 (Dec 2022 – Jan 2022)	N=10 (Jan – Mar 2022)	n/a
HCP end-user walkthrough (survey)	N=15 (12.01. – 21.03.2022)	N=12 (28.01. – 21.03.2022)	N=21 (08.02. – 21.03.2022)

In total, fifty-five unique patients with COPD (N=55) participated in the user research study (see Figure 1), some of which participated in more than one study. Of these participants, 25 were female (45.5%) and the average age was 71.0 years (SD 7.4). Figure 1 shows the distribution of age and gender of all patients with COPD participating in the user research studies, while
Table 3 gives an overview of average age and gender distribution per country.

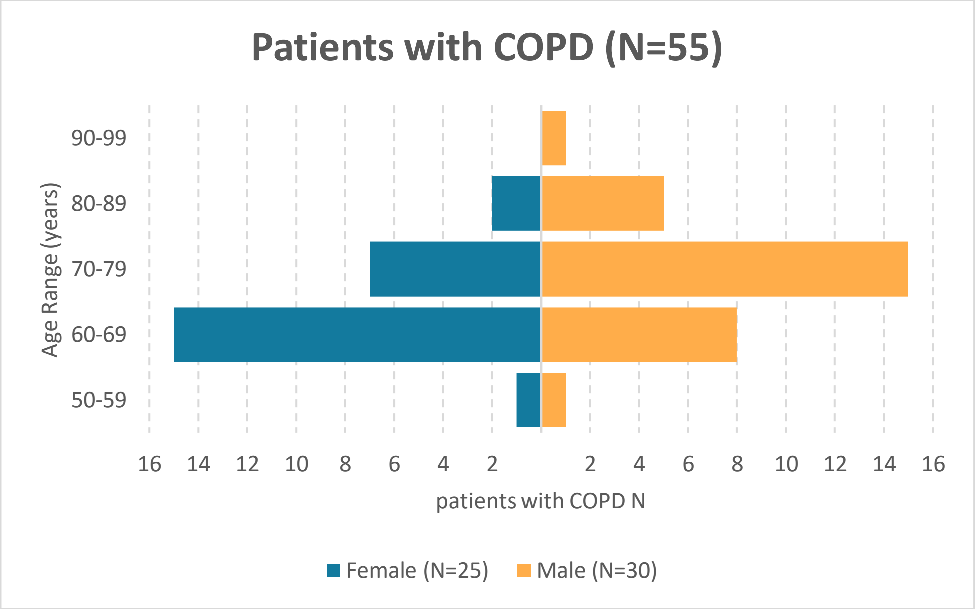

Figure 1: Age and gender of patients with COPD participating in the user research studies from all three countries.

Table 3: Detailed overview patient participants per country

Country	Mean age	Female (n)	Male (n)	Total / country
The Netherlands	68.7 (SD 5.9)	14	9	23
Italy	77.6 (SD 6.6)	4	10	14
Estonia	68.9 (SD 6.6)	7	11	18
Total	71.0 (SD 7.4)	25	30	55

In addition to the patient studies, thirty-six unique HCPs (N=36) participated in workshops and interviews (see Figure 2), some of which participated in more than one study. Of these participants, 25 were female (69.4%) and the average work experience in healthcare was 14.5 years (SD 11.9). Figure 2 shows the distribution of work experience (in years) and gender of all HCPs participating in the user research studies, while

Table 4 gives an overview of average work experience (in years) and gender distribution per country.

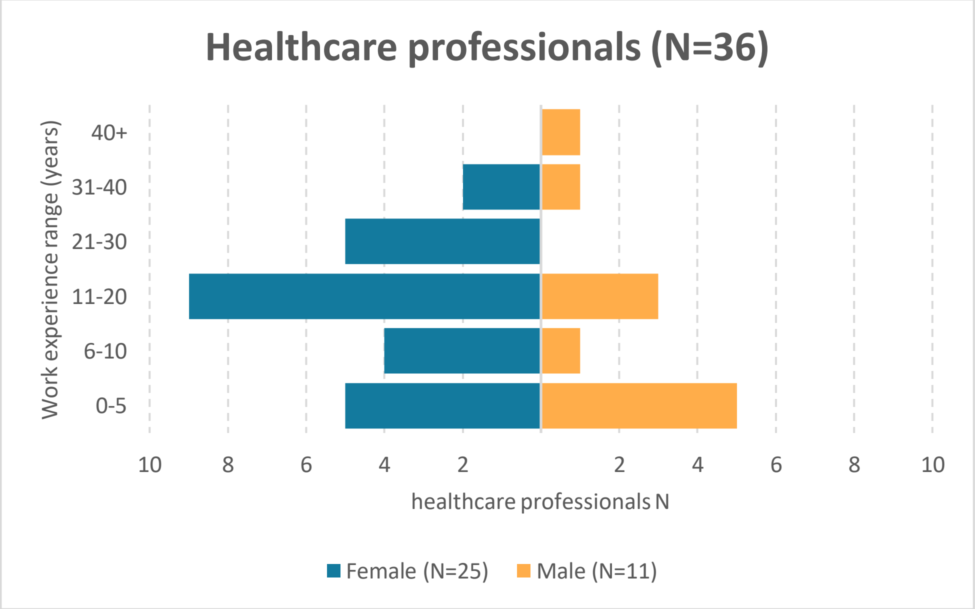

Figure 2: Work experience and gender of HCPs participating in the studies from all three countries.

Table 4: Detailed overview HCP participants per country

Country	Average work experience (years)	Female (n)	Male (n)	Total / country
The Netherlands	16.7 (SD 13.4)	17	5	22
Italy	6.6 (SD 5.7)	3	6	9
Estonia	18.8 (SD 6.5)	5	0	5
Total	14.5 (SD 11.9)	25	11	36

Not included in these figures are the healthcare professionals who filled in the anonymous end-user walkthrough survey, preventing the identification of unique HCPs in the group. The demographics of the participants filling in the survey is detailed below.

The characteristics of the specific population per study and per country, presented also in D2.1 *User needs and expectations for privacy-abiding RWD collection*, will be shortly summarised below:

The Netherlands

- **Diary study:** The diary study was conducted with six patients (N=6), split in two groups starting the three-week diary study at different times (ending in July or September 2021). Most of the patients joined both the pre-diary (N=5, online) and the post-diary workshop (N=5, face-to-face). Four of the participants were male, two were female and their age ranged from 63 to 74 (mean 67.8 years). All of the participants were diagnosed with COPD over ten years. All participants indicated to also have a chronic heart condition, one person also was diagnosed with diabetes. Their highest level of education was high school (N=2), trade school (N=1), university (N=2) or others (N=1). Most of the participants were retired (N=5), one was unable to work. Considering their living situation, N=2 participants lived alone, the others lived with 1 (N=1), with 2 (N=1), with 3 (N=1) or with more than 4 (N=1) family members together.
- **Interview study:** In total, seven patients (N=7) with COPD were interviewed between 28th June and 16th July 2021. The interviews took place online or in face-to-face meetings, given the patient's preferences. Two of the participants were male, five were female and their age ranged from 63 to 80 (mean 67.4 years). Most of the participants were diagnosed with COPD over ten years ago (N=4), two stated they had been diagnosed 3-5 years ago, one person did not remember. All participants indicated to also have a chronic heart condition. Their highest level of education was high school (N=2), or trade school (N=4) or others (N=1). Most of the participants were retired (N=4), two were unable to work and one was employed full time. In addition to being retired, two also indicated that they are unable to work. Two participants are doing voluntary work. Considering their living situation, N=3 participants lived alone, the others lived with 1 (N=3), or with 3 (N=1) family members.
- **HCPs:** In total, 22 HCPs participated in the user requirements studies, of which 17 were female (77%). Two workshops of about one hour each were conducted with healthcare professionals on 21st June and 23rd August 2021 at the pulmonology department of the hospital. Each workshop was attended by N=12 from the pulmonology department (pulmonary nurses, pulmonologists, pulmonologists in training, students, researcher), some of which attended both workshops. As it was difficult to schedule workshops with many HCPs present at the same time, and even more so from outside MST, we recruited N=7 HCPs from different backgrounds for individual interviews (psychiatrist, cardiologist, internist, physiotherapist, nurse specialist in diabetes, nurse specialist in heart failure, pulmonologist). These interviews were conducted online using Microsoft Teams. The HCP's working experience spanned from 1 to 46 years (mean 16.7 years).
- **Co-design on coaching:** In The Netherlands, three sessions were carried out with two patients in each (N=6). Four of these participants participated in the earlier diary study, one had been interviewed and two were newly recruited. Three of the participants were male, three were female and their age ranged from 60 to 74 (mean 66.2 years).
- **End-user walkthroughs:** The end-user walkthroughs with ten patients (N=10) took place between 21st December 2021 and 18th January 2022. Seven of the participants were female, three were male and their age ranged from 62 to 83 (mean 70.6 years). The online survey was filled in by N=15

HCPs, nine were female, 6 were male, with a working experience spanning from 7 to 47 years (mean 24.5 years, with one participant not responding to this question).

Italy

- **Diary study:** The diary study was conducted with nine patients (N=9) from 15th September until 5th October 2021, which was followed up by a post-diary workshop on the 6th October 2021 (online, attended by 8 diary-participants out of 9). All diary study participants except one were male with an age ranging from 59 to 80 (mean 69.5 years). Participants were diagnosed more than 10 years ago (N=3), 6-10 years ago (N=1) or 3-5 years ago (N=3) and only one participant within the last 1-2 years. The highest level of education was university (N=5), high school (N=2) or other (N=1). Three participants had no additional chronic conditions, some had cardiovascular conditions (e.g., atrial fibrillation, hypertension) or rheumatoid arthritis. Except one freelancer and one person being unable to work, all others were retired and all participants lived together with one family member.
- **Interview study:** In total, twelve patients with COPD (N=12) were interviewed in face-to-face meetings between the 11th of September and the 5th of October 2021. Most of the participants were male (N=10), two participants were female. The age of the participants ranged from 63 to 90 (mean 77.7 years). 6 participants were diagnosed with COPD over ten years ago, 3 participants were diagnosed 6-10 years ago, and 3 participants were diagnosed 3-5 years ago. All but one participant had one (N=3) or more (N=8) chronic conditions (e.g., chronic heart condition, hypertension, depression, diabetes, OSAs or others). The highest education of the participants ranged from university (N=5), high school (N=2), primary school (N=3), and other (N=2). Most of the participants were retired (N=10), only two participants were working full time. Concerning their living situation, most of the participants lived together with one family member (N=10), two participants lived alone.
- **HCPs:** In Italy, one workshop of about 1.5 hours was conducted on 24th June 2021 with nine healthcare professionals (N=9) from a variety of medical backgrounds (psychologist, pneumologists, nutritionist, internist, psychotherapist, including fellow pneumologists). Their working experience span from 6 to 14 years (mean 11 years), excluding fellow pneumologists with 1 year of experience.
- **End-user walkthroughs:** The end-user walkthroughs with ten patients (N=10) took place between 25th January 2022 and 3rd March 2022. Three of the participants were female, seven were male and their age ranged from 60 to 81 (mean 74.7 years). The online survey was filled in by N=12 HCPs, 3 were female, 9 were male, with a working experience spanning from 1 to 28 years (mean 4.7 years).

Estonia

- **Diary study:** The diary study was conducted with eight patients (N=8) from 4th until 28th October 2021. As no pre-diary workshop could be conducted due to COVID-19 measures, the workshop format was adapted to an interview format and each diary patient was interviewed face-to-face before they started with the diary study. All diary study participants except two were male with an age ranging from 55 to 78 (mean 68.6 years). Participants were diagnosed more than 10 years ago (N=3), 6-10 years ago (N=3) or 3-5 years ago (N=1) and one participant did not know. The highest level of education was university (N=3), high school (N=4) or trade school (N=1). Two participants had no additional chronic conditions, five had cardiovascular conditions (e.g., hypertension) or radiculitis (N=1). One person worked full time, one person was unable to work, while two worked part time and four were retired. Only one person lived alone, all others lived together with 1 (N=5), 2 (N=1) or four (N=1) family members together.
- **Interview study:** The interviews with 10 patients (N=10) took place between 9th and 21st July 2021. Half of the participants were male, half were female and their age ranged from 58 to 80 (mean 69.1 years). Most of the participants were diagnosed with COPD over ten years ago (N=7), two stated they had been diagnosed 3-5 years ago, one person did not remember. Except of three persons, all others also have additional chronic conditions, such as cardiac condition (N=6), diabetes (N=3), or hypertension (N=2), with four patients having two chronic conditions in addition to the COPD. Their highest level of education was primary school (N=2), high school (N=6) or trade school (N=2). Most of the participants were retired (N=8), one was unable to work and one was employed

part time. Considering their living situation, only two participants lived alone, the others lived with 1 (N=1), 2 (N=4), 4 (N=2) or more than four (N=1) family members together.
- **HCPs:** The workshop with healthcare professionals in Estonia took place on 1st July 2021 and was attended by five participants from a variety of medical backgrounds (cardiologist, physiotherapist, respiratory nurse, pulmonologists, N=5). Their working experience span from 10 to 27 years (mean 20 years).
- **End-user walkthroughs:** Due to COVID-19 measures, no interviews with patients could be conducted to carry out the end-user walkthroughs. The online survey was filled in by N=21 HCPs, 15 were female, 5 were male (one person did not fill in their demographics), with a working experience spanning from 1 to 40 years (mean 21 years).

All pilot sites worked with the same guides and materials prepared by RRD, however each pilot site used their discretion to adapt the method to fit the current situation, practical implications on the pilot site and the point in time when the particular study was carried out. The design of the study allowed for in-depth discussions of various topics, however, some aspects might not have been discussed in detail in all pilot sites (e.g., due to the lack of time or adaptations that were necessary).

This section outlines the results from the user research studies, presenting the context of use (incl. personas and patient journey maps) and the user needs and expectations related to self-management, decision making, data visualisation, communicating and connecting, and coaching.

4.1 Context of use

The studies were designed to capture a broad picture of the context of use, which are documented in user profiles, personas, and patient journey maps. User profiles and personas are conceptual models of the targeted user group, that help the project team to have a shared understanding in their communication by creating a mutually understood context (LeRouge, Ma, Sneha, & Tolle, 2013). Patient journey mapping is an adaptation of customer journey mapping which is a common tool in user experience (UX) design to provide a graphic visualisation or map of a customer's experience with the product and the business or organisation which produced it (Howard, 2014). Patient journey maps can be used to communicate current and future patient experience, to plan future processes and to understand implications of new technology (Maddox, Baggetta, Herout, & Ruark, 2019).

4.1.1 User profiles

A user profile gives an overview of users' characteristics that are relevant for the project (e.g., age, gender, experience, level of education, etc.) which typically reflect a range (Baxter, Courage, & Caine, 2015). Sources that inform user profiles are existing data sources (such as published literature, statistics from government census or health organisations) and empirical studies. The user profile for patients with COPD and CCCs is shown in Table 5.

Table 5: User profile for patients with COPD in RE-SAMPLE

Demographics	
Gender	Male and female (almost equally distributed[1])
Age	> 40 years (prevalence increases with age)
Location	The Netherlands, Italy, Estonia
Socioeconomic status (SES)	Majority low to moderate socioeconomic status[2]
Education	Range from primary school, high school, trade school to university

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[1] In the past, prevalence and mortality was greater among men than women, but later data from developed countries reported that prevalence of COPD is now equal in men and women, which might be due to changing patterns of tobacco smoking (Global Initiative for Chronic Obstructive Lung Disease, 2020).

[2] While also people with a high SES can develop COPD, lower socioeconomic status is associated with an increased risk of developing COPD (Global Initiative for Chronic Obstructive Lung Disease, 2020).

Literacy (digital, health)	Majority ranges from low to moderate[3]
Family	Single, married, widowed, with or without children
Occupation	More likely to be not working (retired, or limited ability to work)[4]
Quality of life	High symptom burden, progressing symptoms leading to reduced physical, psychological and social functioning.[5]
Social activities	Range from socially active to having no social activity or no social network at all. Loneliness is a common feature of living with COPD.[6]
Health-related characteristics	
COPD stages	All stages (I – mild, II – moderate, III – severe, IV – very severe)
Comorbidities	Diabetes mellitus, chronic heart failure, ischaemic heart disease, anxiety and/or depression[7]
Dependency / Empowerment	Ranging from fully dependent (executing doctor's orders) to somewhat independent (making decisions supported by action plan)
Activity level	Ranging from low (almost no activity, housebound or chairbound, dependent on home care), to moderate (trying to be active as much as possible, still able to perform chores, supported by caregivers) to active (not that much affected by disease yet).
Technology	
Experience with technology	Ranges from no experience at all to experience with smartphone, smartwatch, tablet, computer
Attitude towards technology	Ranges from interest to try, to trying if recommended by HCPs, to reluctant to spend energy on this.

Next to patients with COPD and CCCs, healthcare professionals are end-users of the RE-SAMPLE active support programme. The user profile for HCPs in RE-SAMPLE is shown in Table 6.

Table 6: User profile for healthcare professionals in RE-SAMPLE.

Demographics	
Gender	Male and female (higher rate of women depending on specialisation and country)[8]

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[3] While information regarding health literacy in patients with COPD is limited, limited health literacy is associated with a lower SES and more prevalent among older population (Effing & Lenferink, 2020), and at the same time people with a lower SES and of older age have a higher prevalence of COPD. Patients understanding of COPD and its implication is often poor (Gardiner, et al., 2010).

[4] Number of reports range from 30-40% of patients that have retired prematurely or are more likely to not be working (Halpin, 2019).

[5] The progression of symptoms leads to reduced functioning and greater requirements of care and many patients are also restricted by the fear associated with their symptoms worsening (Gardiner, et al., 2010).

[6] Loneliness can be due to being housebound or chairbound; patients may feel social isolation despite having access to close relations; they may feel neglected, avoid relationships themselves, feel lonely due to the inability to socialise and might feel unable to contribute when meeting others because nothing happens to them (Gardiner, et al., 2010).

[7] This list is not exhaustive, but represents the comorbidities as specified in the RE-SAMPLE proposal. Common comorbidities also include arrhythmias, cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, obstructive sleep apnoea, peripheral vascular disease, hypertension, gastroesophageal reflux, bronchiectasis, cognitive impairment, and lung cancer (Global Initiative for Chronic Obstructive Lung Disease, 2020).

[8] According to data available on Eurostat from 2019, 73.6% of physicians in Estonia were female (Netherlands 56.4 %, Italy 44.7%) https://ec.europa.eu/eurostat/databrowser/view/HLTH_RS_PHYS__custom_1487599/default. When taking into account all health workers in the EU (incl., midwives, nurses, personal care workers, etc), which amounts

Age	From under 35 to over 65[9]
Location	The Netherlands, Italy, Estonia
Work-related characteristics	
Profession	pulmonology, psychiatry or psychology, physical therapy, nurse practice, cardiology, internal medicine, general practice
Work experience	Ranges from 1 year (internship, student) to more than 40 years
Frequency of seeing COPD patient	Ranges from once or twice a year to every week and from 15 minutes to an hour per consult.
Technology	
Experience with eHealth	Ranges from low or moderate experience (technology use mandated for documentation) to extensive experience (participating in eHealth research and development)
Attitude towards eHealth	Ranges from negative to sceptic to positive to enthusiastic[10]

4.1.2 Personas

A persona is a fictional character created to describe a typical user and represents a group of end-users (Baxter, Courage, & Caine, 2015). While a persona is fictional, the characteristics are based on the user profiles which in turn are based on literature and user studies. The images of the personas below have been artificially generated by https://thispersondoesnotexist.com/.

4.1.2.1 Personas of patients

Bert van Dijk		
Age	71	
Location	Doesburg (NL)	
Family	Married to Anja, two children, three grandchildren	
COPD stage	GOLD-II	
Comorbidity	Cardiovascular disease	
Goals	Wants to learn more about this disease, to get more control and be more active.	
Bert is an 71-year-old male who lives in Doesburg, a small town in The Netherlands together with his wife Anja. Bert has two children who live on their own and is a proud grandfather of three grandchildren. Bert used to work at a store but is now happily retired. Bert used to be very busy during his week. He loved to take walks in nature, to babysit his grandchildren, and to play badminton with his dearest friends. Unfortunately, Bert is not able to perform these activities anymore. Bert is now doing voluntarily work at a library in his town. Although he found an activity that keeps him busy, this does not compare with the activities he used to do.		

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to 14.7 million people, the vast majority are women (78%) https://ec.europa.eu/eurostat/web/products-eurostat-news/-/DDN-20200409-2.

[9] According to data available on Eurostat from 2019, more than 20% of physicians in Estonia and Italy were older than 65. https://ec.europa.eu/eurostat/databrowser/view/HLTH_RS_PHYS__custom_1487599/default/table?lang=en

[10] HCPs' attitude towards new technology is influenced by whether it is perceived as helping patients and supporting the workflow process, whether it demanded extra work, whether it was seen as part of their principal work and also influenced by positive and negative experience with technology in the past (Konttila, et al., 2019).

Over 10 years ago, Bert was diagnosed with COPD and has a COPD GOLD-II stage diagnosis at the moment. Besides his COPD, Bert also suffers from a cardiovascular disease which requires a lot of attention and adaptation. Because of these two diseases, Bert tries to be active in managing his disease to stay as healthy as possible. Bert is enthusiastic to learn more about COPD, but notices that he needs more guidance regarding self-management. Bert wants to keep in control of his own health but does not know exactly how to achieve that. Unfortunately, he only has check-ups at the pulmonologist twice a year. Bert would love to have check-ups more frequently so he can keep track of his disease progression or stagnation.

Bert knows that he cannot do the same things as his friends and needs to rest more frequently or lower the intensity of his activities. Gladly, both his family and friends know that Bert needs more time to rest because of his condition and they also respect this. This really comforts Bert and prevents a lot of additional stress. Whenever Bert is experiencing an exacerbation of his symptoms, his friends and family support him and take good care of Bert. Because Bert has had COPD for many years, he wants to use and adjust his medication in the most optimal way based on his current symptoms. He still struggles with recognising an exacerbation early on. He often misinterprets symptoms and then contacts his pulmonologist way too late. When he finally contacts his doctor or the pulmonary nurse and tells them about the days before his exacerbation, they often remind him that he should call earlier. He would like to better understand those early signs, to recognise his exacerbation early and know when to contact the professionals to prevent further increase of symptoms. That is a goal that Bert would like to achieve. Because by knowing better how to listen to his body, he feels he will get a bit more control over his diseases.

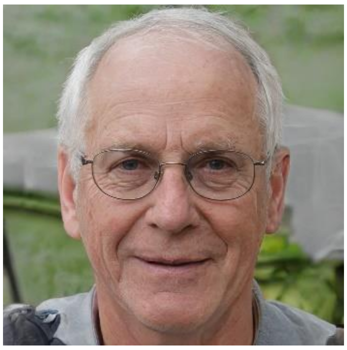
Ans Visser		
Age	62	
Location	Arnhem (NL)	
Family	Divorced, lives alone	
COPD stage	GOLD-III	
Comorbidity	Diabetes	
Goals	Becoming more active, stop smoking, improving her social activities.	

Ans is 62 years old and lives in Arnhem, a large city in The Netherlands. Ans is divorced many years ago and lives alone in her apartment since then. Ans used to work as a cleaner in a nursery home but is recently retired. Ans has had complaints for a long time before she finally was diagnosed with COPD and now she is at stage GOLD-III. Besides COPD, she also lives with diabetes and is slightly overweight. Ans knows very well what to do to maintain her health. Unfortunately, she is not quit succeeding in creating and maintaining healthy habits.

Ans tried several times to increase her activity levels by trying out different sports but still couldn’t find the right sport that fits her. She also experienced some difficulties and insecurities regarding the frequency and intensity of exercising on her own. Therefore, she finds exercising a hassle and rather ignores it. Besides exercising for creating a healthy lifestyle, Ans also tried several times to stop smoking. She even followed a course for smoke cessation. However, the temptation to smoke sometimes gets the better of her and she feels very ashamed of that.

In everyday life, Ans does not go out much. She loves to sit in her favourite chair to watch movies and series on the television. Ans also enjoys watching videos on her smartphone. When she does, she loses track of time. Ans receives care at home which helps her with bathing, cleaning, and doing groceries. She always looks forward to her weekly getaway together with her carer to get some groceries. Luckily, her apartment has an elevator because otherwise she could not manage to walk all those stairs. After she did some groceries, she is glad that she is home where she can rest for the rest of the day.

Before Ans was diagnosed with COPD, she had quit a busy life. She used to go out with friends and liked to go shopping in the weekends. Because of her COPD, this is not manageable anymore. Ans noticed that she could not keep up with her friends and didn't want to be reminded of everything she couldn't do when she was with them. Despite Ans' increased disabilities, her friends maintained doing the same activities as before her COPD diagnosis. Ans very soon realized that these activities were not manageable for her anymore. Therefore, she stopped seeing her friends which makes her very sad and lonely sometimes.

Roberto Pesci		
Age	63	
Location	Turin (IT)	
Family	Married to Maria, one son	
COPD stage	GOLD-III	
Comorbidity	Chronic heart failure	
Goals	Understand better how his COPD and heart condition interact and how to manage those. Learn how to know his limits and not go over them.	

Roberto is a 63-year-old male who lives in Turin, a large city in Italy. He lives together with his wife Maria and his son Stefano. Roberto used to work full time as a teacher at a primary school in a town nearby. He was passionate about his job and there was never a day that he wished to work somewhere else. However, this job was not feasible for him anymore and he had to start his retirement early.

Roberto is living with chronic heart failure, was diagnosed 3 years ago with COPD (currently on stage GOLD-III). He thought that he just had some sort of temporary infection and therefore the diagnosis of COPD came as a shock for him. He felt he had enough on his plate with his heart condition and in the beginning, he did not even know what COPD was. He notices that he still learns more about the disease every day. His son for instance, introduced him to a smartwatch some months ago. He first thought that was nonsense but eventually started to wear the smartwatch to monitor his health even if he does not completely understand its functioning and its potentialities. Roberto would love to learn more about his disease and the possibilities, especially how to know whether his shortness of breath is caused by his heart failure or his COPD. He used to keep a diary to measure his blood pressure and oxygen saturation, but this took way too much time, so he stopped doing that. He agrees that a smartwatch can be way more efficient even if he is not able to fully understand what his data mean and he would prefer to have the possibility to show them to a clinician, who can correctly interpret them.

In everyday life, Roberto tries to make the most out of his days. Unfortunately, he suffers from fatigue. So most days, this means that he accomplishes to get out of bed and get dressed. This is already a huge task to complete and costs a lot of energy. On good days, Roberto is also able to walk outside or even do some groceries. This is really rewarding for him but also drains his energy for days. He now knows that he has to take rest afterwards, but he thinks it is all worth it. Recently, Roberto experienced an exacerbation for the first time. He did not even know what this was, and it was traumatic for him. Luckily, he got treatment at the pulmonology department quite quickly. Although he trusts the healthcare professionals who treat him, it is important for him to understand what it is happening to him, the prescribed treatment and what to do in case he will experience a new exacerbation. He would like to manage his COPD and heart failure more independently, and if possible reduce the risk of exacerbation.

Giulia De Rossi		
Age	71	
Location	Padua (IT)	
Family	Married to Antonio, two children	
COPD stage	GOLD-II	
Comorbidity	Hypertension	
Goals	Continue to do grocery shopping, doing more things to see other people, spending little energy on technology as possible.	

Giulia is 71 years old and lives in Padua, a small town in Italy. After Giulia graduated at the high school near by her town, she helped her parents with managing their restaurant. Later, she became the owner of this small family business. Now, Giulia is already retired for a few years. Giulia lives alone with her husband Antonio and is happily married for many years. She has 2 children, but they live on their own.

Giulia was diagnosed with over 10 years ago and is currently in stage GOLD-II. This was hard for Giulia to accept. Especially since Giulia used to be very active. She could walk for days and loved to meet with her friends and family. Besides COPD, Giulia also suffers from hypertension which makes her life even more difficult. Still after all those years after the diagnosis, Giulia still notices loss of activities that she cannot do anymore on a daily basis. This makes her very sad. Nowadays, Giulia is glad that she can climb the stairs in her house and is blessed when she is able to go the market in her town once a week. This is something she really looks forward to because she sees her old friends who are also visiting the market. Mentally, Giulia want to do more things, but she just isn't capable of doing those things physically, and that is a bitter pill to swallow.

Giulia does not see her pulmonologist very often, but Giulia respects the choice of the pulmonologist. She totally relies on him and trusts him a lot. When Giulia was diagnosed, the pulmonologist discussed many treatment options with her and also some changes she could do in her life. She was also asked what she wanted to do, which was a weird thing to Giulia since the pulmonologist is the expert here. Why does she need to decide? She isn't a doctor so why would they ask her opinion? Giulia likes to follow to the decisions of health care professionals since they know what the best option is. They even told her something about self-management, where she can decide whether she increases medication. She knows from her husband, who has diabetes, that some patients have to decide many things on their own. She is not sure if that works for her. She is interested in but only if they keep it simple and easy to understand. All those new applications with the so-called smartwatch are too complicated for her. She does not want to spend her energy on something she does not understand.

Gustav Kask		
Age	69	
Location	Kohtla-Järve (EE)	
Family	Married to Galina, two adult children, three grandchildren.	
COPD stage	GOLD-III	
Comorbidity	Diabetes type 1	
Goals	Understand better how his COPD and diabetes interact and how to manage those. Reduce the risk of exacerbation.	

Gustav is a 69-year-old male who lives together with his wife Galina in a three room apartment in Kohtla-Järve, Estonia. Gustav is a skinny man who has worked all his life in a mine, but is now retired. He has a son and a daughter, who live on their own, and three grandchildren (aged 5-14). Gustav has a close relationship with his children and their families, and they often celebrate together family occasions. Aleksander has three close friends from the days of the mining, and neighbour Jüri with whom he socializes. Gustav has smoked his whole life and has no plan to give up of smoking, despite his wife and children want to convince him all the time. He also likes to drink alcohol at the family parties and with his friends. Aleksander's physical activity is low, especially after retirement.

When he was a teenager, Gustav was diagnosed with diabetes type 1. Eight years ago, Gustav was also diagnosed with COPD and is currently at stage GOLD-III. Most of time he is exhausted, has shortness of breath and a persistent cough. He is also suffering for pain in his back, neck, and joints. Gustav visits his GP randomly, usually when the cough gets worse or he gets acute respiratory infection and there are no other options. Last visit to the pulmonologist was five years ago.

Recently Gustav started measuring his daily steps using his smartphone. He does this purely for himself and doesn't share this information with health care professionals. He likes to have an overview of his activities. Especially because he learned that staying active is important and since he experienced that being active helps him with his joints. However, when Gustav has an exacerbation of his symptoms, he just doesn't do anything that would require being physically active. Gladly for Gustav, he hadn't had an exacerbation in a while, but he is still scared every day that it will happen to him again. He is afraid that he is losing control of his health and he does not want his wife to worry. This really limits his daily life activities, because he is afraid of possible breathlessness and getting an exacerbation. Therefore, Gustav feels most safe at home watching his favourite television show. That is also why his social circle got smaller, he has less contact with his former colleagues and friends. He is worried that if his health gets worse, he can't keep up with his friends anymore and sees them even less.

Gustav find it difficult to manage both his diabetes and his COPD. He notices that he often confuses the symptoms of these two diseases. This makes managing the diseases very challenging for him.

Johanna Rebane		
Age	78	
Location	Elva (EE)	
Family	Lives alone, has one older sister	
COPD stage	GOLD-II	
Comorbidity	Minor depression	
Goals	Better cope and accept her condition. Living a healthier lifestyle	

Johanna is a 78-year-old widow who lives on her own in Elva, a town in Estonia. Johanna was diagnosed with COPD-GOLD 2 over 20 years ago. When Johanna was first diagnosed with COPD, she was very active in changing her lifestyle to create healthy habits. However, this did not last very long. Johanne quickly realised that she prefers her old lifestyle. Even if she changed some habits, she still experienced difficulties because she gets older and her COPD progresses. Therefore, she does not see the benefit of changing her habits nor lifestyle.

Johanna has an older sister with who she has contact with frequently. Johanna also has contact with her neighbours. They come together every month to play games together. Johanna finds this really fun and always looks forward to this event. Especially, since she can have a good laugh with her neighbours. Gladly for Johanna, the daughter of her neighbour does the groceries for her. In this way, she does not have to go outside and go to a busy supermarket. This costs her too much energy. She used to go by herself, but as the years pass by, she noticed that she needed to rest for several days afterwards. Therefore, she made the decision to not go anymore so she can have some energy for other activities, like making puzzles. This is something that Johanna really enjoys and spends most of her time on. Although Johanna acts tough, she still finds it difficult to accept that she could not go outside that often anymore. Sometimes she feels depressed when she has not seen other people for a while.

Johanna is not really interested in the nowadays technologies. She does not understand all the hype. However, she has a phone to call her sister. Johanne chose on purpose for the cheapest phone, she gives no value towards having a smartphone. She finds it really difficult that healthcare professionals increase the use of technology in their care. This conflicts her beliefs, because she completely trusts the professionals, but she does not know anything about technology. However, if the pulmonologist says she has to do something, she will try it. Even if she is almost completely sure that this would not work for her.

4.1.2.2 Personas of healthcare professionals

Annette Lambert		
Age	44	
Profession	Pulmonary nurse	
Work experience	12	
Attitude eHealth	Enthusiastic	
Goals	Wants to empower patients to be able to manage their disease and act more like a facilitator.	

Annette is a 44-year-old pulmonary nurse working in a large hospital. She started working at a nursery home, but already works 12 years within the pulmonology department in the hospital. Although see helps patients with various diseases during her work week, her main focus is on patients with COPD. Annette sees her patients quite regularly. This is something she really likes about her job, because in this way, she gets the opportunity to build a relationship with her patients. Seeing patients regularly feels human to her, she does not like patients being just one number out of thousands.

Annette finds it really important that patients with COPD get to know their own strengths. She tries to enhance the self-management skills of her patients. Although she notices that some patients are better at self-management than others, she also notices that patients do not really trust their own capabilities when they are first diagnosed. Most of her COPD-patient do not believe in their own strengths. That is why Annette loves to empower their patients and enjoys to see the positive results after a while. Annette sees herself as a supporter of the journey of her patients, rather than a 'know-it-all'. She gives directions to the patient if needed but lies the responsibility by her patients. This works really well, and great results are achieved with this approach.

Annette is a great supporter of technology in healthcare. She knows that there are many possibilities and opportunities to improve healthcare. She would love to include psychoeducation in a technology since she frequently noticed the lack of disease knowledge with her patients with COPD. However, she also knows that especially with COPD-patients, not all patients have enough digital skills to adapt health technology. Therefore, she pleads for clear and extensive eHealth explanation for this target group. She believes, if that can be achieved, many benefits in healthcare can be achieved. In terms of an application for health care professionals, she thinks that this has to be really time efficient and easy to use, otherwise it will not be adapted.

Francesca Hendriks		
Age	39	
Profession	Psychologist	
Work experience	10 years	
Attitude eHealth	Positive towards eHealth being an addition to current care	
Goals	Care approach that is holistic, not just bodily function but also social and psychological aspects.	

Francesca is a 39-year-old psychologist working in a large hospital. She started working here while she was still an intern and had the opportunity to stay. She really likes the environment and challenges that this job has to offer. Francesca frequently treats patients with COPD. The most common complains with this target group are anxiety and depression. During her work as a psychologist, she noticed that many COPD-patients are mostly anxious for exacerbations during everyday life activities. Also, a lot of patients cannot cope with the loss of their life before diagnosis and cannot accept their disease.

Francesca finds it important that all aspects of a person after diagnosis with COPD are highlighted. Her experience shows that the focus is mainly on physical condition. However, the mental state, lifestyle habits, self-management, and a good social network are just as important. She finds it very important that there is also attention for those aspects of the disease.

Francesca noticed more and more, that patients are often referred to different specialist for different problems. Because COPD-patients have comorbidities, it may be the case that specialist refer the patient to another specialist again. This causes a lot of stress for patients because their questions are getting unanswered. In her opinion, their needs to be more multidisciplinary cooperation. This will create more efficient and comprehensive treatment for the patient.

Francesca finds that technology can be a good addition, but it does not replace care. Her opinion is that a therapeutic relation is very important in order to treat someone successfully. Technology cannot replace that. Therefore, technology should only be used to keep track of parameters and to give the patient information. That can help health care professionals with giving input to appointments with the patients. However, she thinks it would be very time consuming to do that for every patient. Francesca can see the possible benefits of using technology in healthcare but is not totally convinced.

Aksel Meyer		
Age	58	
Profession	Pulmonologist	
Work experience	26 years	
Attitude eHealth	Positive attitude to gain more insights into what patients are doing.	
Goals	Support patients through monitoring to give tailored advice	

Aksel is a 58-year-old pulmonologist. He already has 26 years of working experience. Although he knows he is aging, it does not feel like he is working as a pulmonologist for that long. He really enjoys performing his profession every day. During his work years, he saw a lot of different COPD-patients. Most of his participants were smokers or former smokers. That is why he always stresses the danger of smoking to every patient he sees in his practice.

If Aksels' patients are reasonably well and stable, he only sees them once or twice a year at the check-ups. If patients experience exacerbations or other problems, he sees his patients more often. That means that in general, he sees his COPD not that much, which also is a good sign as this means they are doing alright. Only seeing his patients twice a year may also have its downsides. Gladly, Aksel still feels that patient trust him, even if they do not see each other that much. Of course, when they are in need, he always makes time free to call them. He noticed that patients really appreciate the time he takes for them. It does not matter for Aksel how busy he is; he always tries to make time for calling his patients. Even if that means that he has to start working earlier.

Aksel would like to have an insight into the parameters of his COPD-patients. However, he does not need to know what his patients do every single day. He rather likes to see some visuals or trends. It is not that he is not interested in his patients, it is just that he is so busy with other things during his day. Besides, it is far better to draw conclusions from trends instead of daily fluctuations. This is also the reason why Aksel would like to use technology. The most important thing for Aksel would be that all data can be seen in one clear view. He does not want to click hundred times before he sees something valuable. Therefore, Aksel think that using technology in healthcare would be a great way to monitor his patients' parameters.

Marco Nunes		
Age	54	
Profession	Pulmonologist	
Work experience	30 years	
Attitude eHealth	Negative and sceptical attitude, does not see the benefit based on past experience.	
Goals	Spend as little time as possible on administrative tasks	

Marco is a 54 year old pulmonologist with almost 30 years of experience working in healthcare. He has a quite high workload and the COVID-19 pandemic has worsened the situation. He experienced also quite a change in healthcare in the last years and feels that the healthcare system is understaffed and everyone has to take care of more and more patients while doing a lot of administrative tasks. When he started working in healthcare, he actually had the time to sit with his patients, listen to them and discuss the treatment. Now he has to document so many things in the electronic health record, which is really annoying for him. In his experience, there are so many new technologies that claim to achieve a lot, but in reality, it is more work for him and he does not see any benefits. He often has to switch between windows, copy the same text from one form to the next, or search for certain information because the different systems are confusing. Based on the quite negative experience he had in the past with new technology, he is not very enthusiastic when new systems are introduced in the hospital.

He is also a bit sceptical about technology for patients. In his view, the experts should make decisions and explain patients what to do and which path to follow. Physicians studied for years and have so much experience working in practice with many patients, so he thinks that it is more efficient that the physician assesses the situation and then discusses the action and treatment plan with the patient. The patient should not be worried about all of these options and decisions, they should follow the recommendations by the doctors. For him, this is what “self-management” means: patients managing their own behaviour (e.g., smoking) and doing what the physician told them is best for them.

4.1.3 Patient journey maps

A patient journey represents a generalised map of the different touchpoints of a patient with the healthcare system. While these journeys can be quite different depending on the patient and the local healthcare system, certain steps in the process of diagnosis, treatment, and management also follow guidelines.

The committee of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) revises and publishes annually the GOLD report (Global Initiative for Chronic Obstructive Lung Disease, 2020), which is used as strategy document and tool to implement effective management programs. A general overview of what COPD management entails according to the 2021 GOLD report is depicted in Figure 3.

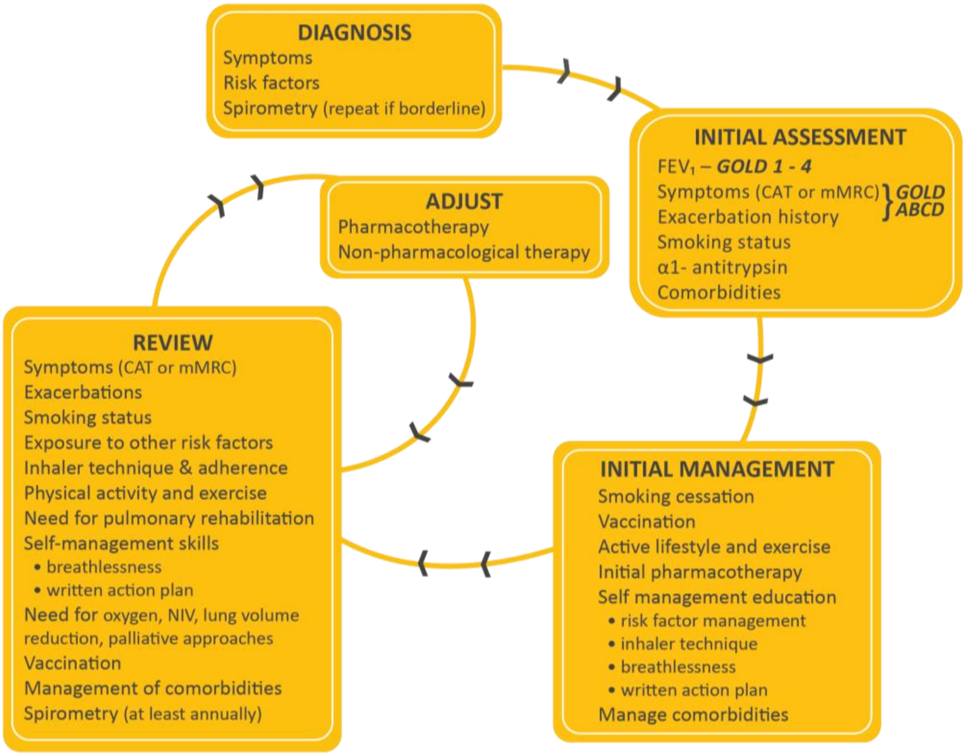


Figure 3: Management of COPD as outlined in the GOLD report 2021 (Global Initiative for Chronic Obstructive Lung Disease, 2020).

This process represents the clinical perspective and is divided in the phases *diagnosis*, *initial assessment*, *initial management*, and the iteration of the phases *review* and *adjustment*. Patient journey maps represent the patients’ perspective and depict the experience of patients going through this process, getting in touch with different actors and organisations in the healthcare system. While the detailed journey of an individual patient might be different, a generalised journey map helps to understand how a patient interacts with the healthcare system at different points in time and how the current health service of COPD disease management might differ between the three countries.

The patient journey maps developed here are focusing mainly on patients with COPD and at this point do not take into account all possible variations that include comorbidities. This means that other steps and touchpoints may be involved depending on the additional chronic condition(s) that the patient might have.

The patient journey maps depicted below distinguish three main phases: *diagnosis*, *stable phase* and *exacerbation*. They represent initial versions that can be used as tool to plan future processes and identify opportunities for the RE-SAMPLE programme to improve the patient journey and experiences of main stakeholders. They can also be extended with certain categories (e.g., how the patient feels in a particular phase, or which device touchpoints[11] they have) to identify pain points and opportunities in their journey.

4.1.3.1 The Netherlands

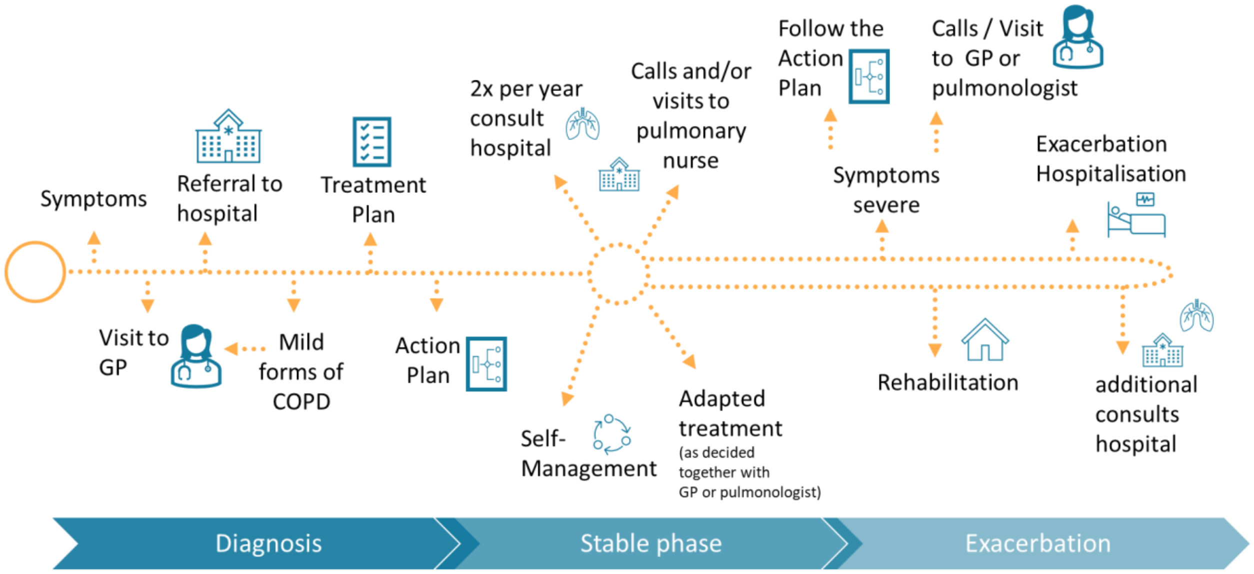


Figure 4: COPD Patient Journey – The Netherlands.

Diagnosis

Before patients with COPD are diagnosed, they first experience symptoms like coughing and shortness of breath during activities. Several Dutch participants reported that they thought these symptoms were caused by a lingering flu or some other minor virus and did not think about a potential chronic disease. Based on the symptoms that are experienced, Dutch patients visit a General Practitioner (GP). The GP either themselves examines and diagnoses the patient with COPD or they refer the patient to the hospital for further examination performed by a pulmonologist. In the hospital, additional tests are performed to determine the diagnosis. Eventually, the diagnosis of COPD is made, and the severity of the COPD is determined. In some cases, patients with mild COPD are referred back to their GP. The GP is then responsible for providing the patient the right medication, education, and treatment, supported by advice from the hospital. Severe cases of COPD are under treatment with the pulmonologist. For these patients with COPD, treatment plans are set up together with the pulmonologist and/or pulmonology nurse. Treatment plans describe in detail which medication to take, include advice (e.g., to quit smoking), and entails training regarding inhalation. In some cases a referral to the physiotherapist is made. Depending on the severity of COPD, patients are also able to receive physiotherapy. The amount of physiotherapy depends on the health insurance of patients and on the severity of their COPD. Meaning that if the participants does not have moderate or severe COPD, he or she nearly doesn't receive any physiotherapy. The treatment plan gives the patients with COPD a clear overview of medication and treatment and are used to manage their disease in the stable phase.

Stable Phase

After the diagnosis, there is an iterative process in the stabilisation phase. It is very common that Dutch patients with COPD have a 15-minute consult with the pulmonologist at the hospital twice a year. Here, check-ups are performed to determine the patient's current situation. However, due to COVID, most Dutch patients with COPD were not allowed to visit the hospital. Therefore, telephone and/or video consults by

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[11] Device touchpoints are the technological solutions utilised by the different actors (i.e. doctor, GP, patient) at each touch point (McCarthy, et al., 2016).

either the pulmonologist or the pulmonology nurse took place instead. Dutch patients also seem to find consultations with the pulmonary nurse very valuable. This nurse gives patients more information and answers questions which may not be covered during their short time with the pulmonologist. Based on the consults and current situation of the patients, the treatment can be adapted if needed. This will be determined together with the pulmonologist. Finally, the patient performs self-management in order to cope with the disease in a stable phase and when symptoms change. This can be related to medication intake (e.g., following the treatment plan), or by changing certain lifestyle behaviours that can be crucial to enhance the health of patients with COPD. Patients with COPD in The Netherlands reported to miss guidance regarding exercising, making healthy lifestyle adjustments, and coping with the disease. This lack of support leads to patients having problems with disease acceptance and other related problems.

Exacerbations

Patients who frequently experience exacerbations may also receive an exacerbation action plan. The action plan outlines when, how, and what type of action the patient should take (e.g., performing breathing exercises, starting specific medication, when to call the pulmonology department). Action plans are only given to patients who can understand and perform such a plan on their own. Patients are trained by the pulmonology nurse how to recognize COPD exacerbations and how to use the action plan when symptoms do change.

Patients who are not able to follow such an action plan, or whose current condition does not allow for self-management are advised to call the hospital to receive a treatment advice or ask for a visit. Some patients prefer to call their GP, but most call the pulmonology department in the hospital when they experience severe symptoms. In the Dutch hospital MST, local agreements are made that if they call before 9AM, they are getting called back by their pulmonologist the same day. This gives patients the feeling of being heard and taken seriously. Some Dutch participants are reluctant and wait too long to call the pulmonologist, which can have different reasons. For example, some patients think that the doctor is too busy for them, or that the current symptoms will disappear eventually and it might not be that bad, or that in their view not much can be done about it in the hospital anyway. In the most severe cases of exacerbations, patients with COPD are hospitalized. Several participants reported that they try to prevent hospitalization because they want to stay at home if they can. The frequency of hospital consultations may be increased for patients after having an exacerbation. Exacerbations often have significant negative contributions to patients' health which are partly permanent and irreversible. After the hospitalisation, patients may need to undergo rehabilitation therapy (e.g., inpatient in a rehabilitation centre our outpatient or at home).

4.1.3.2 Italy

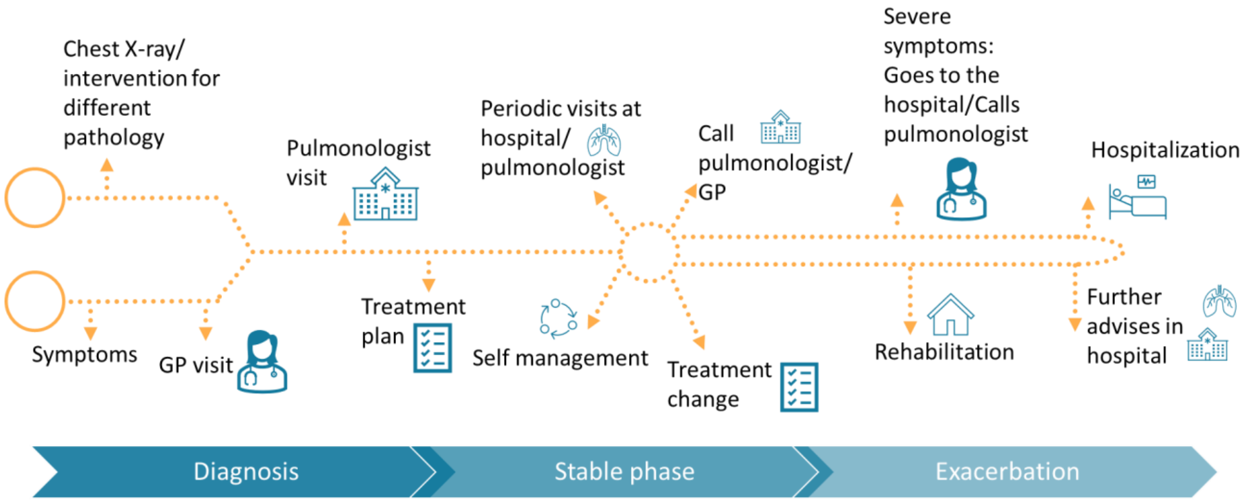

Figure 5: COPD Patient Journey – Italy.

The patient journey appears to be diverse among patients with COPD in Italy. Patients shared their experience related to their COPD diagnosis and their disease management in collaboration with HCPs during stable phase and exacerbations.

Diagnosis

Many patients had their COPD diagnosed after experiencing symptoms such as cough or after episodes of bronchitis, bronchopneumonia or flu with fever. Patients were referred to a pulmonologist, after which COPD was confirmed through a chest X-Ray and spirometry exams. Other patients were diagnosed during medical controls or interventions related to other pathologies (e.g., myocardial infarction, gastroesophageal reflux disease). One patient found out about his COPD coincidentally after receiving an alert from his smart watch, after which an exercise electrocardiogram was performed. Overall, patients usually contact their GP who later directs them to the pulmonologist to perform a chest X-Ray or spirometry and get their COPD diagnosed. In some cases, COPD is diagnosed accidentally or after controls and interventions related to different pathologies.

Stable phase

Patients go through periodic follow up visits with diverse frequency, for example, having one or two outpatient visits per year with their pulmonologist, spirometry once a year, CT scan every two years. In addition, the GP can suggest additional visits if necessary. Some patients reported that they have physiotherapy sessions as well.

Exacerbation

During exacerbation, patients reported symptoms such as fatigue, cough and dyspnea. When symptoms are worsening, either they visit their GP, who can suggest additional exams or refers them to the pulmonologist, or they directly contact their pulmonologist. In case of severe exacerbation, the patient is directly referred to the hospital.

4.1.3.3 Estonia

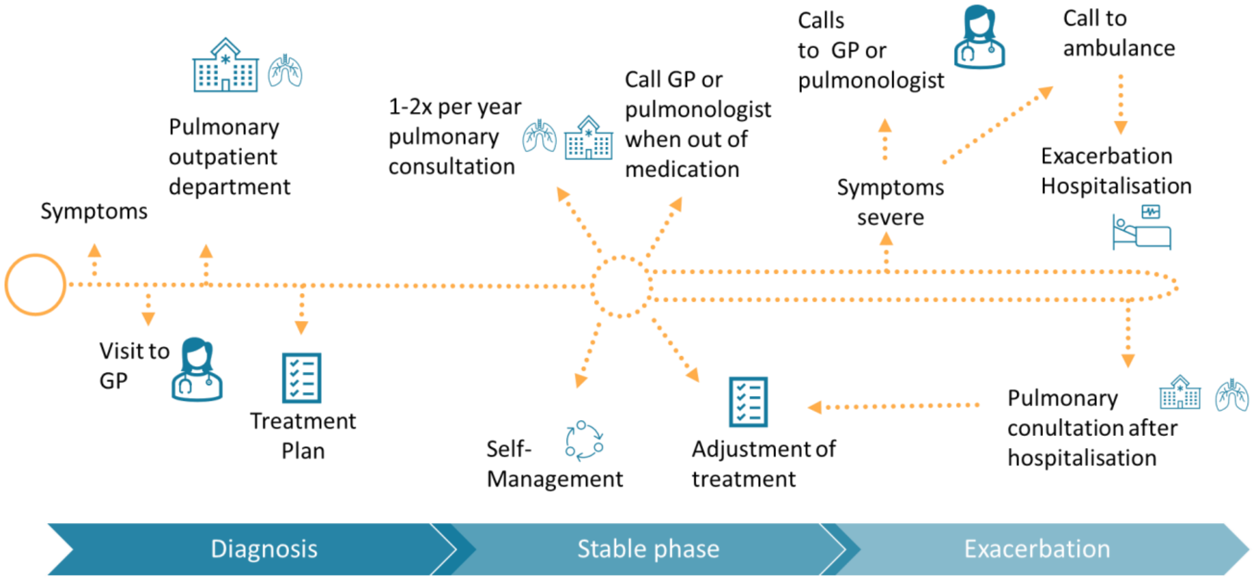

Figure 6: COPD Patient Journey – Estonia.

Diagnosis

The patient journey in Estonia is also quite individual, but the common nominator is the GP, which is due to how the healthcare system operates in Estonia. Mostly, patients visit the GP when experiencing shortness of breath and tiredness. The GP then sends the patient to specialists, often cardiologist and pulmonary physician in parallel. Symptoms tend to be severe before patients go to the doctors. Often there has been years of frequent respiratory infections and pneumonias. COPD is diagnosed by the pulmonologist and then the patients is referred back to their GP with treatment and a self-management plan.

Stable Phase

After getting the diagnosis, regular check-ups by pulmonary physician once or twice per year is recommended in case of moderate to severe disease. For mild cases of COPD, the patient will be followed by the GP who periodically extends prescriptions. If necessary, the GP can always send the patient to pulmonary consultation. Many patients, however miss their regular appointments if they feel that their condition has not changed much. In several occasions, patients reflect an *“I go to the doctor when I feel like I’m dying”* attitude.

Rehabilitation is limited to physiotherapist consultation as part of the initial appointment with the pulmonologist. Patients also visit general practitioner either for regular yearly check-up or whenever they experience a symptom they want to get addressed. Usually, patient-doctor communication takes place when patients run out of medicine and need a new prescription.

Exacerbations
In case of exacerbation, the patient contacts their GP or pulmonary physician, depending on who is responsible for the management of the patient. Usually the more severe cases are followed by pulmonary physicians and milder cases by GPs. This, however has not been very well established. Often it is then the emergency medical service that takes care of the exacerbations. In most of these cases the exacerbation will be further treated in the hospital. At discharge from hospital, an appointment with the pulmonary physician is scheduled. The pulmonologist will then determine a new treatment and self-management plan.

4.2 Self-management

According to the consensus of an international expert group, the ultimate goals of COPD self-management are a) optimising and preserving physical health; b) reducing symptoms and functional impairments in daily life and increasing emotional well-being, social well-being and quality of life; and c) establishing effective alliances with healthcare professionals, family, friends and community (Effing, et al., 2016).

In the context of the user studies, self-management relates in this context to activities that patients carry out to manage their disease, reduce symptoms or prevent exacerbations. These activities can be physical or mental in nature, or relate to their lifestyle and behaviour changes. Furthermore, patients’ potential needs related to self-management are outlined (e.g., information needs).

4.2.1 The Netherlands

Diary study
All participants in the diary study were aware of their own options to prevent exacerbation or to relieve symptoms. They carried out a variety of different self-management activities:

- Physical activity (walking, biking, golfing, exercising);
- Taking rest, being less active, taking time with activities, staying calm, doing nothing;
- Cooking;
- Social activities (dining with friends, social contacts);
- Taking medication, oxygen;
- Avoiding alcohol;
- Smoking cessation;
- Having a positive mindset (accepting the disease, enjoying life);
- (Grocery) shopping;
- Having hobbies (puzzling, making things, reading, gardening, watching TV shows, sculpturing, visiting museums, listening to music, having your nails done, sitting in fresh air, sitting on a terrace);
- Going to the sauna, steaming;
- Volunteering, helping others;
- Asking for help;
- Measuring health parameters.

Most participants from the diary study wanted to stay active, and all have their own ways for doing this (for example, walking with a dog, exercising with physical therapists, and grocery shopping). But when they experience shortness of breath, they take rest and stay calm and/or take medication. *“When I get home from grocery shopping, I’m always tired and experience more shortness of breath then before. But if I sit down* *for a while, it gets a little better. I usually take a break before I go do something else, that works for me. I really want to keep active, as long as possible."* [MST010]. Social activities and hobbies are also mentioned quite often. It does not change the symptoms, but participants do feel better mentally: *"Not directly to relieve symptoms, but today I visited a wonderful exhibition at the museum in Assen, that made me very happy and healthy."* [MST007]. Participants also enjoy having social contacts: *"... tomorrow I have a dinner with friends, I like it a lot."* [MST007]. Two participants [MST004 / MST008] really like going to the sauna. It helps them to relieve them from shortness of breath, and the effect lasts for 1-3 days for them. *"The mucus loosens up more easily. Well, that's what I think and feel. I go to the sauna every week."* [MST004].

Regarding exacerbation, one participant [MST008] indicated she/he does not feel it coming. Others indicated however that they do: *"Exacerbation is something you feel coming. You feel that things are not going well and you are getting worse and worse."* [MST010]. The symptoms differ between the participants. One participant [MST060] indicated she/he has completely different symptoms than others, which sometimes make it difficult for HCPs to recognise the exacerbation: *"It varies between patients. The regular questions they ask are: 'Do you cough, do you cough mucus?' I've never done that in my life. Then they say: 'It's not that bad then.' But it is bad."* [MST060]. Some participants contact the pulmonologist in the beginning of the exacerbation and some wait until they cannot do anything anymore.

Interview study:
All of the patients who were interviewed were aware of their own options to prevent exacerbation or to adapt to a healthier lifestyle. Especially exercising was mentioned as a solution. Three participants visit a physiotherapist on a weekly basis to exercise. One participant has the desire to exercise under the guidance of a physiotherapist but the high cost for him/her are a barrier to do this. For this participant [MST009] regularly visiting sport clubs or fitness centres are no option as the instructors don't understand her: "*I want to go to the gym again. I did it for 6 months, but I notice that I was not understood. They are not physiotherapists who are specialized, and that is very difficult. I know my limits, but at the gym they were pushing too much.*" Most participants use regular activities (e.g., walking, doing household chores and groceries) to increase their exercising levels. *"I'm not going to sit on the chair. I try to do as many things myself as possible. I do the shopping for my neighbour, I do the laundry still myself on Saturdays, I find that very hard."* [MST010]. But their complaints related to COPD or co-morbidities hamper them to exercise properly: *"My body is failing me"* [MST013] or *"I try to make a walk every day but like the past few days it's way too hot. I try to stay active at home by packing and unpacking the dishwasher".* [MST005]. Every morning there is a gym class on Dutch television, one participant follow this program when she is feeling well and in her own pace: *"I'm joining 'Nederland in Beweging' every day, because I'm no longer allowed to have physical therapy. If they do 5 exercises, I do 1."* [MST002]. Overall, the participants are very aware of the need to exercise and to be physically active: *"It is disastrous for people with COPD if they do not move. I visited my father, and then I did too much again. You have to find a balance in that. You must not do nothing, but also not too much. You have to find the middle way."* [MST008]. Being active in a balanced way is very difficult for this patient group, especially when having a good day: *"If you feel good, you keep going. Then I can no longer dose it, then I want to finish it."* [MST001]. Next to general exercises and physical activities two participants stress the need to teach patients with COPD proper breathing exercises. One participant [MST002] uses a mobile application: *"I do breathing exercises on my mobile phone, sometimes I hyperventilate then I panic a bit."*

All participants mentioned that they, after being diagnosed with COPD, changed their lifestyle to a more healthier one. Quit smoking was mentioned by three participants: *"Quit smoking. I did that too. Straight away."* [MST008]. And also eating healthier was mentioned by three participants as a change in life style: "*I eat very healthy, really very healthy. I eat vegetables every day.*" [MST002]. / *"We need to be more in control of what we eat and how much we eat."* [MST013] Weight control was mentioned by two participants; *"I weigh every Thursday. The extra weight, the weight you have to carry with you also counts."* [MST008].

Medication was mentioned by four participants to control their COPD related complaints. The participants explained that they are able to start medication on their own: *"If I don't feel great, I start with Prednisolone. If the mucus is really green, I'll take the antibiotics. I will communicate that to my pulmonologist or GP.*

When you get sick, it's usually on the weekend. And now I don't have to go to the emergency care and explain everything again." [MST008]. This way of self-management is very appreciated by the participants.

Next to exercising, a healthy lifestyle and medication participants also mentioned topics related to balance and especially a healthy balance between being active and taking breaks. Taking breaks was mentioned by four participants as their way to prevent an exacerbation. *"It doesn't bother me that much, but if I need to rest I will. I do have days when I notice that I need to slow down"* [MST009]. Especially when they feel bad and experiencing shortness of breath: *"Take more rest… stop meeting others for a while and take your rest"* [MST005]. Another option is to accept help, but this is experienced as very difficult as some do not like to accept help. Two participants also mentioned that they take time and save energy to do fun activities: *"Yes, saving energy for other things. I'd rather go out for a day than have my house cleaned again."* [MST005].

Several patients mentioned that they often wait too long to take medication or to call their doctor when there is an exacerbation. Sometimes they think that this might pass on its own and they don't want to bother their doctor with it: *"Most of the time I am too late, I wait way too long. I am not one who quickly goes to the doctor. I get that a lot, that they tell me you have to raise the alarm faster'. That is very difficult for me, because you still feel kind of good and then you think 'Do I need to bother a doctor for that?' Yes, I should. But that's still something I have to work on."* [MST008] Although patients live with COPD already for years and also decide when to start certain medication, they still sometimes have difficulties to decide whether this the right moment to start for example with prednisolone: *"When I think, now it is really going wrong [then I start the medication]. But sometimes I'm too late. Sometimes that's hard to judge, when should you start with it? Sometimes you don't know."* [MST001] Another patient told us that she/he had a maximum limit that she/he would wait whether the symptoms would improve*: "Usually 1 or at most 2 days I wait. I used to want to wait longer sometimes, but I don't do that anymore. Because then a hospitalization was needed […] I want to prevent that."* [MST005]

Self-management in terms of mental health can be related to acceptance and coping. Most participants talked about how difficult it is to accept having a disease such as COPD: "*Acceptance is very difficult. A person can't miss out on anything*" [MST001] / *"Acceptance, you don't actually do that yet. And acceptance is that you agree to it, but well, you don't agree to it. Because again and again have to give up something, and so you come back to your 'acceptance' all the time. That's just very difficult."* [MST008]

The participants experience a lot of misunderstanding from their environment: *"They often don't understand, and they don't even know what COPD is"* [MST010]. Also they have problems to explain COPD to others and ask for help: *"I should have had more information and support. I know, but how do I get it explained to my employer."* [MST001]. The participants have many complaints and sometimes they have no idea how to handle these: *"Terrible how bad a person can feel"* [MST013] / *"This is a disease that doesn't recover. A disease that's going down. There is no progress in it, only regression"* [MST009].

HCPs

In the conversations with HCPs in The Netherlands, self-management was often discussed in relation to education, training or coaching and that there is room for improvement. *"If you have like 2 visits a year, you can review the symptoms and you can adapt the medication and you can provide some kind of counselling or advice, and that's about it. Then the whole package goes back to the patient: 'Take your meds, do this advice, see you in half a year.' And this really does not work. I am not sure why HCPs are still trained to provide objective information to patients and to expect that they will absorb that, understand that and apply that to their daily lives. There are so many doctors who keep saying: 'You should stop smoking!' or 'Do this!', but it does not really work that way."* [HCP_Int1][12].

Self-management was discussed as a whole process that includes education on the roles and responsibilities as well as the learning about their own disease and how to listen to their own body. These self-management

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[12] The pseudonym indicates whether the HCP was individually interviewed [HCP_Int] or participated in a workshop [HCP_WS]

skills also have to be developed over the course of several sessions. *"COPD self-management is a whole process that people need to learn. And if they have like 2 visits a year, when are they going to learn? Patients really need repetition of what's being said. They cannot apply whatever education you give them directly into a change of lifestyle or behaviour or whatever. So, I would welcome any changes in the programme and I really do think that a self-management programme can be very helpful. Because I do think self-management requires a LOT more support and attention and training than you give in two or even four or eight sessions."* [HCP_Int1]

Furthermore, it was mentioned that when it comes to self-management the responsibility should lie with the patient, who is not passive but indeed in the driver's seat. *"[previous research with an eHealth app that included a chat function] What I remember from then: If patients can send you a message, the responsibility for doing something with it, they put it away. If they send a message and say 'I am not doing really well', they just sit and wait until someone reacts on it. I think the most important thing in wearables and everything which has to do with the health of the patient, you have to put it back. The responsibility must be in the patient, and not in the physiotherapist. Or not in the coach or in the pulmonologist or whatever."* [HCP_Int6] This perspective of being responsible and in the driver's seat might however also be part of the educational programme, as some patients might have different expectations that come from the more traditional paradigm of medicine: *"And I think this is also fuelled by the assumptions by the patients. If you expect the other person to fix your problem, then you don't want to have the package of dealing with the problem to be send back to you. So it's not unwillingness, but it is 'I am going to the doctor, they are going to fix it' and that's your expectation and that's where all your interventions land."* [HCP_Int1] While eHealth can support patients with self-management, it can also hinder it if the focus is more on data than on providing patients with opportunities to make decisions: *"Apparently, according to some lectures in eHealth, that is what you do, if you measure a lot and take in all the information, you also take away the input from the patient, you make decisions FOR the patient, you are not… not the patient making decision himself."* [HCP_Int2]

It was emphasised that patients need to be properly educated about their disease, what might trigger exacerbations so that they can start monitoring themselves and listen to their own body. *"I think every patient with a lung disease, or every patient independent of disease, you always should know about your own disease. You are your best doctor. If you listen to your body and mental status, then you can objectify it in a good way. And if I start with new people, I try to explain it. You really have to explain that!"* [HCP_Int6] / *"It's a process of finding out what are your triggers, how are you going to help patients to overcome them, what is needed and so on. So maybe the pulmonary nurses can do a bit of that as well. But I really do see a good case for providing patients with tools how to adapt their treatment strategies or self-monitoring or whatever."* [HCP_Int1]. / *"In the first years in the past, we gave advices and those were about things that for us as physiotherapist were very logical. But for the patient sometimes it wasn't! For example, some patients know they really suffer from hairspray or deodorant or whatever. But some patients don't even know they suffer from that."* [HCP_Int6].

Educating patients to listen to their body might help to identify the patterns that trigger exacerbations, which then in turn also might help them to react earlier: *"I think that should be a new way. Not just fixed questions, but for a lot of patients you should try to personalise the anamnesis. Their history should be personalised, and try to take their real story about their last two or three exacerbations. Try to find out. And most of them will tell you the pattern. They will know, it's always the same. And they wait until they have the complaints, which are in the schedule, but then it's already a week later."* [HCP_Int7] Similar to the patients, several professionals also mentioned that patients often wait too long when their symptoms worsen. One professional gave an example what the thought process of a patient might look like in such a case: *"If you are going downhill, often it's not like an acute moment. So when do you call your physician? When is it too late? 'Ah, my next door neighbour is getting the hay in, my lungs are not feeling well. I know why this is. Ok let's up my meds and let's see' And then after a week 'Hm it's still not so good. Well, it isn't really that different from last week, so why should I call now?' And then 'Ah, I have some troubles walking the stairs. Ah well, maybe I should rest a little bit more. I am feeling tired. So maybe if I rest a little bit more...' So this is very hard to say, when patients are going to call. And besides, what are they going to do for them. From the perspective of a patient who believes in the traditional medical model, they might have been very disappointed in the past: I have gotten my package of complaints, given it to the doctors. I got back a* *prescription and 'see you the next year'. So what are they going to do? I can call and they probably say 'Oh, we are so sorry for you. Have you upped your meds?'"*[HCP_Int1].

Supporting patients to listen to their own body can also include small experiments or explorations of new behaviour, accompanied with reflections to gain new insights. *"Feedback on the level of exercise people were doing. For example, you can monitor patients like 'Ok, now you are really overdoing it. Because you are breathing through your mouth, which will dry out your lung, which will be a trigger for yet another attack, so please stop doing that.' And this is like education integrated with small experiments of new behaviour. [...] Most of the patients I work with are less knowledgeable about their own bodies, about health strategies, and maybe also not that much equipped to translate medical advice into day-to-day changes. So that's where I think more intensive support programme would be very, very helpful."* [HCP_Int1] What exactly the new behaviour entails might also be different for every patient which means that an exploration is needed to find out which are the things that this patient can do that works for them. *"I don't think it is really an intervention or an exercise. I really think it's the journey you as a patient take together with your support system. And it's finding out in collaboration with your medical professionals but also with your loved ones and so on, what is helping you. For some patients it's really the exploration of all the factors that are there, which already provides new perspective. Like 'ah ok, there are so many things I can do'. Sometimes it's this one little thing that you find like 'oh this is what I can do'. I don't think there is really something that you can grasp, because it's so personal how it's going to work."* [HCP_Int1]

When it comes to supporting behaviour change, professionals emphasised that this has to be easily integrated in the daily life of patients. *"Supporting long term change, I mean, if my nurse says 'You have to clean your [inhaler] a bit more often', this is like going to the dentist. You brush your teeth a bit more before and after, and after half a year you are like 'Ok I forgot again'. That's what the patients need I think. But also maybe support... integrating it with their day-to-day life warrants continuous support to keep up with it. It is not just knowing and knowing how to, the whole process of persistence."* [HCP_Int1] / *"We did a lot of research in physiotherapy about doing the homework, but yeah, most of the people, if it is urgent they do it for a short period. But after that... They are all normal people. It's a problem and it will be a problem. Nowadays I don't focus too much on exercises, but rather try to put some movements in their daily life. So if you normally go to the supermarket by car, please put your car a little bit farther away. So you can walk for 10 minutes. Or walk another round. Or if you get a visit, ask your family or friends to go outside with you. Do something."* [HCP_Int6]

Furthermore, patients also need to be educated, trained and guided on the activities to be carried out, for example, inhaler use, medication intake. While patients are already provided with brochures with information, these might not have been very successful so far and a more adaptive education programme for patients was suggested. *"We have to improve that. So what we are doing at the heart failure patient, you have a heart failure booklet. We are now improving that and usually that was like a brochure with lots and lots of information. And what you hear from many hospitals over the years, that it is probably not such a good idea to give all those information, all those brochures to the patients. Because many patients put them aside, they don't really read it."* [HCP_Int2] In some departments, the nurse discusses with the patient whether they read something and have questions, to identify what information needs the patient has and then giving smaller amounts of information at the right point in time. It was also discussed that this personalised education and information provision could be supported by technology so that HCPs also see whether something has been read: *"Could also be nice, I think, applications that the patient has to read information and that in the end you can see that the patient has read it. That it becomes green or something like that. […] [Incorporating that in the communication] is really essential I think. Otherwise the same happens with eHealth as with the brochures. That you have no clue what the patient is reading. Probably nothing. And as a medical specialist you always have the tendency to overload the patient, because you think this is important and that is important. But people cannot adjust it all at once."* [HCP_Int2]

Listening to HCPs talking about how patients with diabetes manage their disease, it seems that with this group of patients it works already quite well, which may be because self-management in diabetes has more urgency, they really have to manage it day to day and also see direct benefits and consequences. *"With us, [self-management] is that total goal in treatment. If you can apply self-management, then you can do whatever you want with your life with diabetes. So that's the big primary goal for us. Above all. You have* *to react to everything, you have 42 factors that influence the sugar. You have to know what to do when you drink alcohol, when you do sports, when you are ill, everywhere you have to do something with your sugar."* [HCP_Int5]

Furthermore, the power of peer-to-peer support in self-management was mentioned, as patients might be motivated to adopt an action if they know from peers that it worked well: *"What I found in my study is that what modelling was very important. That when a patient had used the action plan, and he talked in a group session about his experience, that other patients also thought: 'Ok, when he uses it, as a brother in crime, then I would like to use it.' So one of the important things is modelling. Not just a nurse you can talk to in case of an exacerbation. Just your other patients."* [HCP_Int7] Furthermore, patients might more easily open up to each other and changes might have a long term effect: *"[Being in a regular training centre] And also the patients found it dreadful, because they are with healthy people and they can't just move the bicycle around and the other will do it ten times faster. So if you are in a group with brothers in crime, you feel at ease and you start talking, you start explain your complaints, you drink coffee together. It's a life changer. And that's what you do in self-management. Even if the effects you don't know but the effects are long term. That's another thing. All those studies of half a year, that's too short."* [HCP_Int7]

4.2.2 Italy

Diary study

Results of the dairy study in Italy revealed that participants perform different activities to manage their COPD. These activities can be divided in the following categories: therapies, medication adherence, social activities, physical activities, and mental well-being.

Two participants mentioned to visit therapies like physiotherapy and ozone therapy to manage their COPD: *"Today I had a physiotherapy session and after I felt much lighter"* [GEM0008], and *"I had some ozone therapy sessions that help me breath better and feel better in general. After I managed to walk more than normal."* [GEM0010].

Besides visiting different therapies, several participants also stated to adhere to their medications in order to manage their disease: *"I take my medicines very regularly to keep my disease stable."* [pre-diary workshop].

Participants also try to be as active as possible. Although they do not always succeed in being active, they keep trying: *"I try to walk more and climb the stairs but breathing calmly."* [GEM0003], *"In the afternoon I managed to go for a short walk with my dog*" [GEM0004], and *"I enjoy going swimming to the pool even though I feel little difficulty breathing."* [GEM0011].

Participants experienced struggles regarding their mental well-being: *"The fact that I cannot work or do any other activity well some days, is devastating. Working is the best medicine for me."* [GEM0004], and *"Insomnia is very hard for me. I want my calmness back."* [GEM0002]. Some participants try to undertake activities that positively influences their mental well-being: *"I like listening to music very loud on my headphones with any external distractions. It relaxes me."* [GEM0004], and "*Going to the market and walking helps me relax."* [GEM0003]. Although most participants mentioned to struggle with their mental well-being when managing their disease, one participant stated a positive experience: *"I am happy to be alive no matter my problems"* [GEM0010].

During the whole diary study, only two participants explicitly stated to participate in social activities: *"Today I called my granddaughter and some friends to feel better"* [GEM0004], and *"I had nice time with friends and lunch with my granddaughter"* [GEM0008].

Interview study

The majority of the participants mentioned to do nothing specific regarding self-management. Although participants may not be actively involved, some participants are still interested in the topic: *"At the moment I do nothing. I'm interested in self-management, but only if it's simple and easy to understand"* [GEM0016], and *"At the moment I do nothing to improve my health , but in the future, I would like to start exercising. Self-management is important to me, and I'd like to have more information and tools* [GEM0013].

One participant [GEM017] stated not to be interested in self-management. No specific reasons for his/her disinterest were mentioned.

Three participants mentioned to rest to manage their COPD: *"When I feel worse, I like to rest. I do neither exercises nor lifestyle changes to improve my condition."* [GEM0019], and *"When I feel worsening of dyspnoea, I try to take deep breaths and rest."* [GEM0022]. Another participant [GEM0014] also mentioned doing breathing exercises for managing his/her COPD. Besides taking rest and taking deep breaths, two participants mentioned to do mental exercises and to perform their hobbies: *"When I have a cough I try to rest, do mental exercises and indulge in my hobbies."* [GEM0018], and *"I usually read books that I like or talk to my wife about how I feel."* [GEM0012]. Only one participant [GEM0020] mentioned to avoid crowded and hot places in order to manage his/her COPD.

HCPs

Healthcare professionals try to motivate their patients to be active in self-managing their disease. However, concrete help to guide patients is not always available. Regarding smoking cessation, one healthcare professional mentioned this lack of help: *"During our visits we always try to induce patients to stop smoking. There is probably a lack of concrete help that can help them in everyday life to stop the vice of smoking."* [Pneumologist 3]. Another healthcare professional mentioned the importance of calling and quick responses during acute situations so that patients can manage a worsening of their COPD: "*During the first visits, when the patient isn't fully aware of his/her condition, I explain that there is a chronic treatment and an acute, similar treatment, when it will be necessary it must be stopped the chronic treatment and started the acute one. In any case I tell them that I am available for any clarification or doubt, and I give them all the contacts needed."* [Pneumologist 2]. However, this professional does not think that this is applicable for large hospitals which a large number of patients.

4.2.3 Estonia

Patients' immediate response to keeping their health at bay was taking medicine; *"Took the medicine I was supposed to take."* [TUK007D][13] or *"I follow doctors' order and take my medicine."* [TUK003]. Furthermore, in their diaries, the patients described tackling the worsening mainly by using more Ventolin[14], rather than turning to other self-soothing means.

Nevertheless, patients' main symptom on their "bad days" was the lack of energy. Thus, all the patients mentioned resting as their go-to self-help method. *"I still do everything. I don't really feel like a handicap or something. Nor do I want to look miserable. I do everything, but slowly."* [TUK001D_INT] or *"I never plan so many things that I cannot get them done. I have learned over the years that whatever I do get done, is enough – the rest I can do tomorrow."* [TUK006D]. Some people also described they avoid activities they know could trigger the worsening of their health (such as physical activity *"Exercising is a form of self-torture. I don't have any activity goals."* [TUK004D_INT], heavy lifting *"Partner carried bags to the third floor for me."* [TUK001D], physically demanding job *"Daughter and grand-children helped with household chores."* [TUK008D]. In these occasions, patients also reported asking for help if possible (e.g., with gardening, carrying bags, etc). However, this meant patient had social capital – but not all of them had.

Whilst some activities are avoided, others are indulged in. When patients wanted to improve their physical or mental health, they reported spending time in nature, visiting seaside, going for a walk, doing breathing exercises, exercising in the morning, drinking hard liqueur, and socializing. Socializing seemed to be also one of the variables having the most effect on how patients felt on certain days. Diary entries indicate that when people reported being alone or feeling alone, they also were more attentive to their health problems and reported certain symptoms (e.g., feeling down, headache, high blood pressure, stress). Socializing is

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[13] The pseudonym indicates whether the quote was taken from the diary data [TUK000D] or from the interview that was performed before the diary study [TUK000D_Int]. Pseudonyms with just the number indicate participants that took part in the interview study [TUK000]

[14] Ventolin is the brand name of Albuterol/Salbutamol, which is a medication that opens up the medium and large airways in the lungs and is used to prevent and treat wheezing and shortness of breath caused by breathing problems.

hereby be understood both in terms of spending time with relatives and friends but also feeling accomplished in social situations (e.g., feeling useful to other people).

Some patients also mentioned they keep going no matter their health, because they have no other options (e.g., they cannot avoid using stairs because they live on a higher floor, they need to keep up with their grandchildren). Thus, they simply ignored their discomfort, *"There is nothing I can do when it gets worse. I just need to get things done and I do them no matter what."* [TUK003] or *"I have no energy to walk up the stairs, but I cannot avoid it, so I just do it."* [TUK006].

Patients also tended to normalize their symptoms and conditions *"Sometimes I do nothing all day long. But this is what retired people do"* [TUK006] or *"But how do I know what is COPD and what is just me being old? Maybe I'm just lazy."* [TUK008]. Some found it was normal to feel tired and out of breath due to their age – patients found it hard to distinguish which condition causes which symptoms. Others described they have their "own normal range" of health indicators and they tend not to act when finding out some measurements are out of the conventionally normal range (e.g., a couple of patients with diabetes described they constantly measure noticeably higher than normal blood sugar levels, but they feel good and find it normal for them personally). This could also suggest that patients are lacking in understanding the long-term effects of this normalization and could benefit from more coaching.

The normalization of their condition was also reflected in apathy. The patients described awareness of measures that would make them feel better, but lacked the motivation to use them (such as going on a walk, exercising, or setting physical activity goals). However, they did not describe apathy in relation to their illness. Instead, they connected the lack of motivation to general laziness, old age, busy schedule, or personal beliefs in "alternative" means of self-help. These answers reflect the patients are relying on conventionally medical means of bettering health, but may need further consultation in order to truly understand the variety of ways different measures contribute to their well-being.

Next to taking their medication and quit smoking (*"I quit smoking because I couldn't breathe anymore. I was scared of dying and children were small at the time, too. It was difficult for about a year"* [TUK006D_INT]) patients are doing breathing exercise (*"Did breathing exercises and keep the tempo"* [TUK002D]), visiting the sauna and be physical active (*"I went for a walk in the woods*" [TUK007D]) to cope with their complaints. Especially being physical active in nature is self-soothing; or *"I started Nordic walking after my knees started hurting and did it for years. 10 000 steps daily. But this year, with the heat in the summer, I did it less and less. Now I haven't done it for a month"* [TUK008D_INT], *"When I go to the sea, the sea air is good for breathing"* [TUK007]. Also positive thinking helps them to cope; *"Positive thinking. I do not want to think about my condition at all. It is what it s. I can live. There is a lot of joy in life. I always try to remain positive"* [TUK008D].

4.3 Decision making

Decision making refers to the current process of making decisions that relates to the health and wellbeing of the patients, the extent of which patients are currently involved and in which way their preferences and wishes are considered in the process. Furthermore, patients' potential needs related to determining a course of action are outlined.

4.3.1 The Netherlands

Diary study

Diary participants indicated that they could decide themselves when they would take more medication, or add oxygen. They have a stock at home. *"I just started a course of prednisolone. […] I always have prednisolone in stock. If I think I need to take a course, I start taking it."* [MST011]. However, one participant [MST004] disagrees with this procedure: *"I can always start one of those prednisolone courses. But I don't think that's right. I think the doctor should say: 'Now you can start'. Of course it's difficult for the doctors to be sure of this."* [MST004].

Two participants [MST007 / MST060] mentioned shared-decision making, and were very positive about this. *"I do notice that it's becoming more and more accepted that you have your opinion as a patient, and* *that they listen to your opinion. If you don't want something, even though it might be good for you, it's also being respected."* [MST060]. *"I've noticed the recent years, that you are presented with choices. It's not like before: 'we're going to do this and that'. There is more consultation between yourself and the doctor. I do notice this particularly with the younger doctors."* [MST007]. Also one participant [MST010] indicated that it's okay that (s)he as a patient can take the initiative in making decisions about his/her health.

One participant [MST010] had a negative experience with the pulmonologist taking decisions without discussing it with him/her. Furthermore, the decision the pulmonologist took was tough for the participant and he/she was upset the pulmonologist told him/her about such a decision by phone. Finally, regarding decision making, one participant [MST060] indicated that he/she is the one deciding about his/her health. For example, decisions about reanimating, or decisions about when things go bad and hospitalization is needed. *"Yes, I decide myself. If I'm not sure, I can discuss it with my children or my sister. But at the end, I'm the one who decides. I'm about to get to that stage, well I'm already at that stage, that you have to make decisions about reanimation."* [MST060].

Interview study

The participants in the interview study had a conservative view on decision making. Their statements reflected that it is up to their GP or pulmonologist to make the decision concerning their health and COPD treatment. The participants have overall a good relationship with their GP: *"My GP now knows me and my disease very well and I think that is very important. He takes me very seriously."* [MST008]. Despite their positive view on their GP, pulmonologist or nurse, also negative and sceptical opinions about physicians were shared: *"Doctors are not that easy, there are very nice ones, but also monsters. Who are just antisocial and can't get along with people."* [MST009] / *"Not enough time. I don't think doctors immerse themselves enough... in the things that can play a role in the patient."* [MST013] / *"If you don't feel well and they also have that tone to you… it hurts so much."* [MST002].

Four participants indicated that they like to have access to their outcomes and to discuss these with their pulmonary physicians. But this is something they have to ask for and in their opinion not something that is commonly done: *"The lung function test. A bit of confirmation. Is it going well or is it a lot less? To discuss this together with the lung specialist. I think it's important to know."* [MST005]. One participant stated that it is difficult to disagree: *"It is very difficult to indicate that you do not want something. I have a different view and I find it very difficult to express it. No one knows what I've felt. I felt so broken."* [MST009].

HCPs

In conversations with HCPs, it has been pointed out that shared-decision making is part of a general paradigm shift in medicine, that not all HCPs involve the patient to the same extent and that patients also differ when it comes to wanting to be involved.

One HCP pointed out that the traditional paradigm of medicine sees a medical issue as something being fixed and the HCPs as being the one responsible for fixing the issue. This however does not work with chronic conditions where self-management is important and patient involvement is crucial. This paradigm shift was described as a longer process and much could be learned from a disability paradigm, where patients are taking on the responsibility and the focus is not on "fixing" but on management of and coping with the disease. *"If you are a patient in a general hospital, most of them are not a customer like they are supposed to be. They are a patient. And the word patient in English means you have to be patient. So it already expresses some kind of dependency. And I think in chronic illnesses counterbalancing that power and helping the person to assume responsibility, but not only that. (...) It's also a paradigm shift. A lot of illnesses are seen from the perspective of* acute *illnesses. Like: I have broken my leg, I go to the hospital, get a cast, it's fixed, and in six weeks we are done. (...) The perspective of healthcare is: I have a problem, you are going to solve it, and you are going to help me. And that's not like patients want to shift responsibility. Sometimes it is perceived like that. But that's how we as a society think about medical care. […] I think if both the patients and the doctors and the medical staff are helped to shift to a disability paradigm, in which shared-decision making is much more important, much more common, and the focus is not on 'how to fix the problem' but 'how to address as many little factors as possible', I think that paradigm shift needs to happen. And within that paradigm, it's also not patients who are receiving words and* *following orders (or not), but it's more a collaboration 'Ok, this is the issue, where can we tweak a little bit'."* [HCP_Int1]

One HCP pointed out the benefits of integrating subjective and objective measures to inform the decision making, for example, by including not only laboratory test results but also the subjective assessment of the patient about his/her wellbeing. *"If I see very stable lab results, a very nice low level, ok, then I am already thinking 'Ok the patient is actually doing really fine.' So if he is telling me he is not doing fine, we intensify the treatment. But if I see for example that the patient indeed rates himself also as doing really well and his wellbeing improved a lot over time, maybe then I think 'Ok the patient doing so well, maybe we discuss doing nothing at this point in time.' Then we have to wait three months and see how he is feeling then. Then it's even more tailored. That at moments when patients are really fine, then you lengthen the period until they have their next appointment. You can always have an earlier appointment if the patient needs it. And when things are going down you intensify the frequency of the follow-up. That would be helpful."* [HCP_Int2]

One nurse practitioner pointed out differences in the approach between doctors (in her example internists) and nurses: *"[They] have a very different history, couple hundred years of 'I tell you what to do and if you listen closely you get better'. Their training was focused on that for years, their objective is different. We have a lot more time. I have a different angle of work. They mainly look of course at medical issues and focus on those pillars. Our professions are different."* [HCP_Int5] Certain changes in how to approach care has been discussed also by other HCPs, where it was more prescriptive in terms of what will be done. Today, many HCPs approach a more collaborative relationship with their patients, often combined with motivational interviewing: *"What we did in the past, it was kind of 'Ok, you are here, and we are going to train this'. And nowadays it's really changing in: I give the patient information about the disease. I always ask the patient to fill in the form and show me, what they do during the week, how much energy does that cost them. What does it bring you, what does it cost you? Then I explain the importance of moving, of good breathing, everything. And then I always ask: 'What do you want? Do you think you can do this alone, or do you think you need some help?'"* [HCP_Int6]

Exploring with the patient what their goals are, is often preceded by providing a lot of information first: *"In the beginning a lot of information that you give. Later it's the other way around. Then you ask: 'What do you want, what do you struggle with, what choices do you have? Do you have that clear? What is your objective? Do you have enough information to make a good choice? Or can I give you more information there? And then you decide what you want."* [HCP_Int5] This importance of providing all information for the options was emphasised: *"[Shared-decision making] is indeed what we should do. And that is that you put the options for the patient and also put it a little bit in perspective. Because that is what I think is always difficult of shared-decision making: the patient firstly needs to be well informed. So you have to update the patient on the clinical condition and the actual situation. Is it in a quite stable good phase or not so stable or quite bad. Because that influences I think the decision. But then you have to pose several options and you have to give the patient some time to think about it. And of course with two people in the room they hear more than one person. That's why I like it that some family member or caregiver comes along, because then you are more sure of that."* [HCP_Int2] It was pointed out, however, that patients differ quite a lot. Some want to know everything, other are not really interested in knowing everything.

Whatever the decision may look like, it is important that patients can make an informed decision, in other words that consequences of the decisions are clear: *"That patient can make an informed decision trade-off to do or not to do certain things within the disease picture. Do they want medication, no medication, and why."* [HCP_Int4] Another HCP pointed out the importance that patients choose themselves knowing the consequences of their decision and to not judge them for it: *"In the outpatient clinic we pay a lot of attention to [the whole picture of the patient, not just diabetes alone]. How are you doing, how do you live, how can we line up the different possibilities together. And then we look, what are the consequences of this and what do you choose. That's up to you, no judgments. I find that extremely important."* [HCP_Int5] Furthermore, there is also value in trying to understand the reasons why someone made a certain decision, for example, why they do not take certain medication, as one HCP pointed out: *"You never know what they actually use. You prescribe something and you don't know if they use it. Probably they will even collect it, but they will not use it. That's very difficult. So, what should be important to find out in in-depth interviewing: 'Ok, the* *doctor advises you or the avatar advises you use prednisolone. But you sometimes don't use it and why don't you use it?' You will be surprised what they tell you. They hate it, because some of the patients have nasty side effects, you know. They get excited, they get sore throat, they get diarrhoea. Some of them overuse it. Because they know it is effective, but they continue to use it, so they have tremendous amounts of rounds of prednisolone."* [HCP_Int7]

Patients making their own decisions and not following advice recommended to them, for example, changing certain behaviour, might be frustrating for HCPs. However, this might be some residue from the traditional medical paradigm whereas the shared-decision making is situated in a collaborative relationship. *"So the message 'You should do THIS and you are stupid for not doing this.' This is what patients really get. I hear a lot of medical professionals saying 'I am not working with addicted patients, because they are hopeless and I cannot deal with them.' And I can feel for them if you work from a medical paradigm like 'Patients coming to me, I am going to fix them, and they are going away.' It's not going to happen. But if you work in like behavioural or disability paradigm, like 'Ok, there is a huge problem here', which is not going to go away by giving some medical advice or doing a surgery or giving some medication. How do WE deal with it? Then that is much more easy. It is a collaborative effort, you are very happy if it works, sometimes it doesn't work and I am still happy with my patients, because I am working TOGETHER with them. But what my patients often get is a message 'This is your meds, this is the medical advice, you are stupid for not following it, and oh, by the way I am actually not really expecting you to do it, because I have been there, I have seen all the smokers, are probably not going to stop, but you should stop anyway.' And they take this in, and put it in their backpacks where there is a lot of that kind of messages, so..."* [HCP_Int1]

4.3.2 Italy

Diary study

During the diary workshop, participants mentioned that therapies should be more personalized. They stated their desire for multidisciplinary disease management*: "I have many comorbidities, and this often makes COPD treatment more complicated. The different specialists don't share my exams in a regular basis. I need to report every time everything"* [pre-diary workshop]. Participants also agreed that the patient should be more in the centre of the disease management process.

Interview study

All participants mentioned to rely on their doctors' decisions: *"I adapt to the doctor's decisions, as he is more experienced than me."* [GEM021], and *"I agree with the decisions made by my HCP* [health care professional], *I trust him."* [GEM0017]. The motivator for this reliance was the trust and faith participants have in their doctor. Although participants rely on the decision of their doctor, most participant still feel involved: *"I feel quite involved during the decision making. I trust my HCP."* [GEM0013], and *"I am involved in the choices regarding my health, but I always rely on doctor's decision"* [GEM0015]. Only one participant mentioned to go against his/her doctor if he/she is not convinced: *"I agree with the decisions made by my doctor but If something doesn't convince me I don't do it."* [GEM0019].

Only one participant [GEM023] mentioned to be active in the decision-making process: *"I feel involved in the choice of therapy. I check the contraindications and decide together with the doctor what is best for me"*. One participant explicitly mentioned not to be interested in shared decision making due to the trust in doctors: *"I feel involved, but I don't really care to be part of the decision making, because I trust my doctor."* [GEM0016].

4.3.3 Estonia

Consultation with their pulmonologist is especially requested when patient experience complaints; *"When I'm feeling really bad, I can call pulmonary doctor."* [TUK002D_INT] and *"I have a really good general practitioner. I have their phone number and whenever I need, I can call them."* [TUK006D_INT]. Overall they are very positive about the care they receive and the co-operative contact they have with their pulmonologist; *"When some medicine does not work for me, I can tell and they can change it. Contact is good. I can call the doctor and nurses whenever I need help and I get all the answers."* [TUK006] and "*When I feel bad, I can call to the doctor and they help me. Prescribe hormonal pills for autumn period that help, for example. Every time I do call them, they help every way they can."* [TUK007].

When it comes to decision-making or co-operation with HCPs, some patients reported they do not need more frequent communication or consultation. They felt the opportunity to contact HCPs whenever they feel problems was sufficient. Most claimed that they don't need extra professional help to cope with their complaint: *"I feel like everything has already been made so clear."* [TUK006D_INT]. This also shows that some patients are more motivated to work on the consequences of their issues rather than prevention. But there are some request for help with quite smoking (*"I have tried to quit smoking, but I haven't succeeded. Maybe some sort of counselling would help."* [TUK005D_INT] and psychological problems ("*I would have needed psychological help*" [TUK007D]). Considering mental health's input to physical well-being, psychological consultation could also be useful.

When it comes to decision-making, the patients felt they could be open with their respective HCPs when it came to their treatment. Several of them added they have had a say in the choice of suitable medicine (based on their bodies' reaction) and they could ask for advice when they need to. This was also mentioned by the HCPs: their understanding of co-decision-making is introducing patients different alternatives of their treatment. However, there are also patient who are more ambiguous about decision-making; *"I do not know, if we are making the decisions together. Doctors give me medicine and it seems to be working and when I visit them, then we discuss how it's going. But that's all."* [TUK002]. Patients also expressed they have trust in doctors and do not expect to get a say in their treatment; *"I do what the doctors say"* [TUK005]. However, some patients' responses reflected they tend to be selective when it comes to implementing the advice their HCPs give them. Some patients are very honest about this; *"I'm stubborn. I maybe listen like 50-70% of the things they [doctors] tell me to do, but not everything. Like when I felt better, I stopped taking medicine"* [TUK002] and *"Doctors tell me to not smoke, but I only nod and continue. I don't feel that would make any difference now. I would also be stressful. I don't care about the lungs, I feel sorry for all the money it takes."* [TUK004] and *"They do talk and give suggestions what I should do. But I don't listen everything. I still continue smoking, because it is the only thing that keeps the weight under control."* [TUK002].

Patients discussed that doctors often advise them to make life-altering changes (smoking, eating habits, working out), but offer little to no insight how to effectively implement these changes (e.g., discount to nicotine patches, visit to nutritionist). Some patients' responses reflected they tend to be selective when it comes to implementing recommended lifestyle changes. For example, patients admitted they have not quitted smoking, because they feel it would cause more stress or because their social or economic situation does not support it (e.g., partner also smokes, no means to buy nicotine patches). The same goes for physical activity. *"I'm honest, I won't do anything. No one does, unless they have been in a life or death scenario. Maybe younger people are different, want to do exercises."* [TUK006D_INT]. Some people shared they needed professionals' consultations to overcome the self-built barriers for getting better, others described unwillingness to change regardless the influence of professionals. The latter can be partly due to the inability to see the positive impact of changes, but also due to an idea that chronic illnesses cannot get better. The patients that followed recommendations described having strong self-discipline. However, on some cases the stimulus was the worsening of their health to the point of "no return" (unable to breathe, fear of dying). This is another example of how patients perceive the role of the healthcare system and their role in healthcare.

4.4 Data visualisation

Data visualisation in this context refers to the user interface for patients and HCPs when it comes to the visualisation of collected data in terms of general overview of short-term and long-term changes in the disease progression, alerts or notifications, risk and monitoring profiles.

The co-design activities for the data visualisation were carried out only in the Dutch pilot. In the Italian pilot, co-designing data visualisation was not possible due to the lack of time, as only one session was conducted after the diary study, which already included the co-design activity for "coaching". Furthermore, that session was carried out online due to the COVID situation at the time, making co-designing with the target group even more difficult. In Estonia, no group session could be carried out due to the COVID restrictions.

4.4.1 Co-Design with patients

In the Dutch pilot, a co-design activity was carried out with patients during the post-diary workshop. Two participants [MST007 / MST060] indicated during the post-diary workshop, they do not want to see the data visualised in a mobile application: *"If I'm being honest, I don't care about this at all."* [MST007]. If for example you use an activity tracker, you can see your activities in the activity tracker, it is not needed to synchronise this with an app, according to these participants. The other participants [MST004 / MST008/ MST010] indicated during the workshop that data visualized on a mobile application needs to be easy to understand, but they do not really care about the aesthetics of the system. *"It must be understandable. The app must have simple controls. Easy contact with pulmonary specialist or GP."* [MST010]

Participants were asked to draw on paper how they would like to see the mobile application in case of visualising data. One participant drew the visualisation of oxygen and blood pressure: *"I drew thumbs up: '80 over 110, so you're good.'"* [MST004]. This participant indicated that it is enough to just show easily and understandable whether everything is okay with thumbs up and thumbs down (see Figure 7, left). The same participant also sketched a user interface for steps taken and also added next to the number, the assessment, a thumbs up/down, and in case of a negative assessment a statement what should be done. (see Figure 7, right. *"Heel goed, 1500 stap"* translates to *"Very good, 1500 steps"*, while the other screen indicates that not enough steps were taken, therefore the participant drew a thumbs down and wrote *"meer stappen"*, which translates to *"more steps")*.

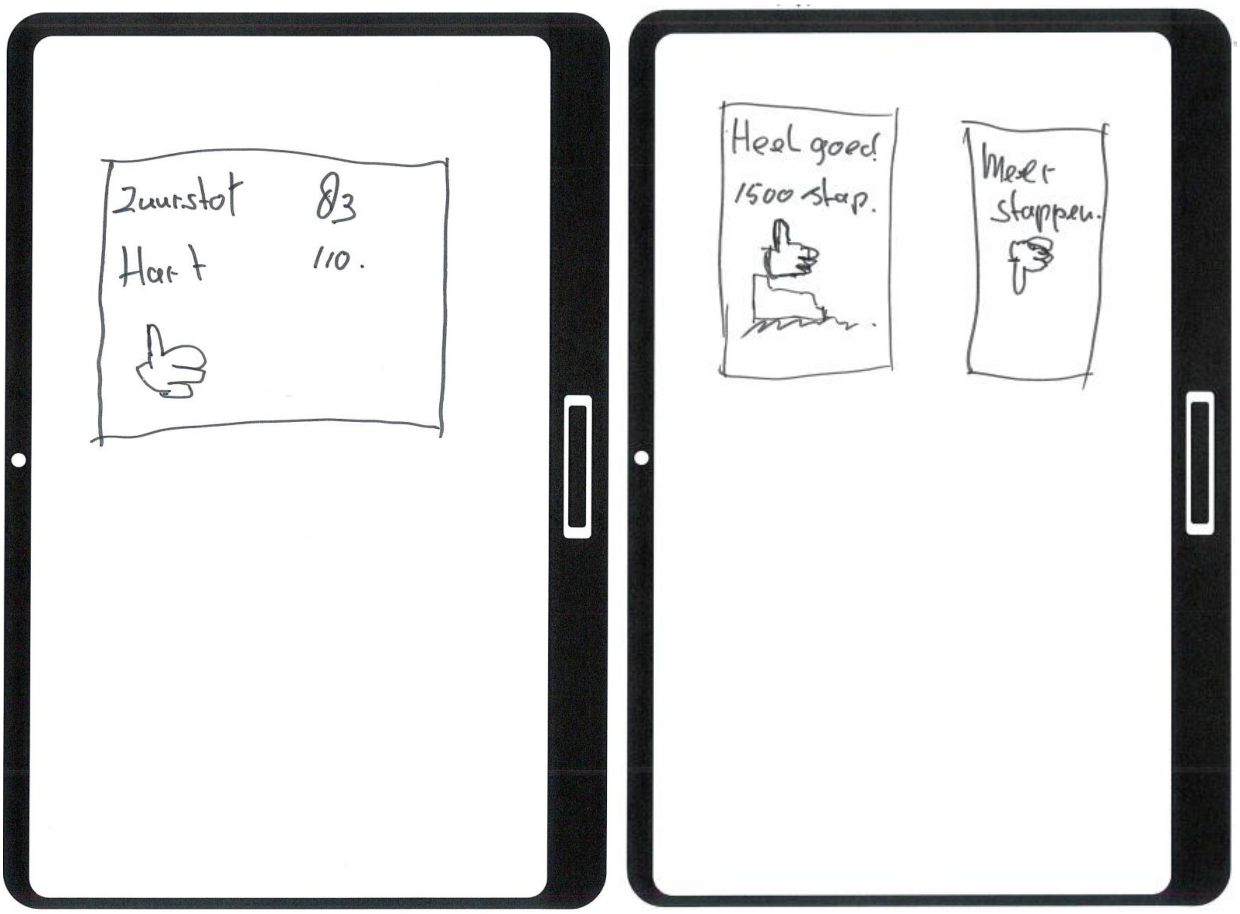


Figure 7: Sketches of user interfaces for data visualisation by participant [MST004].

4.4.2 Co-Design with healthcare professionals

In the Dutch pilot, the co-design workshop was carried out with healthcare professionals focusing on data overview, alerts and monitoring profile (see section 3.3.1). The HCPs stated, that they were not so much interested in the day-to-day changes, but are more interested in seeing trends or seeing when alarm symptoms are deviating. They have no need to see the raw data but want to see "red flags" of deviating parameters, such as increase in daily symptoms, sudden weight loss, sudden worsening in saturation, reduction in exercise tolerance. Some results from this workshop that is related to the data collection and parameters were described in D2.1 *User needs and expectations for privacy-abiding RWD collection*, including requirements (e.g., #F4 overview activity data, #F5 overview of red flags, #F6 showing trends in data).

Two possible scenarios were used by participants to sketch potential user interfaces:

1. Dina, a patient with COPD who monitors her weight with a digital scale.
2. Freek, a patient with COPD, arthritis, asthma and diabetes, who monitors his oxygen saturation.

In line with their preferences, most participants drew trends of the data that was collected (see Figure 8).

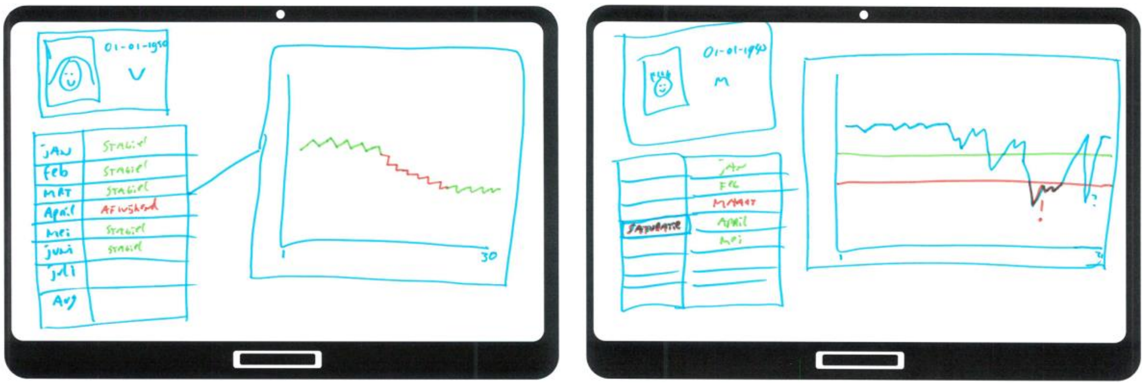


Figure 8: Sketches of user interfaces for monitoring weight (left) and oxygen saturation (right), drawn by HCP.

On the left is the visualisation for weight monitoring. A table outlines per month whether the weight is stable or deviating, colour-coded with red for deviation ("afwijkend") and green for stable weight ("stabiel"). The table is complemented by a weight graph, using the same colours as in the table.

On the right side of Figure 8 is a sketch of a user interface for oxygen saturation. Similar to the other interface, a table shows a monthly overview and is accompanied by a graphical representation of the weight, with two horizontal lines in green/red to indicate the corridor of stable and deviating saturation levels. When the saturation is way below the red line, an exclamation point highlights this measurement.

Some of the sketches gave the impression that HCPs had an interface for patients in mind, as instructions were added that seem to be addressed to the patient (see Figure 9).

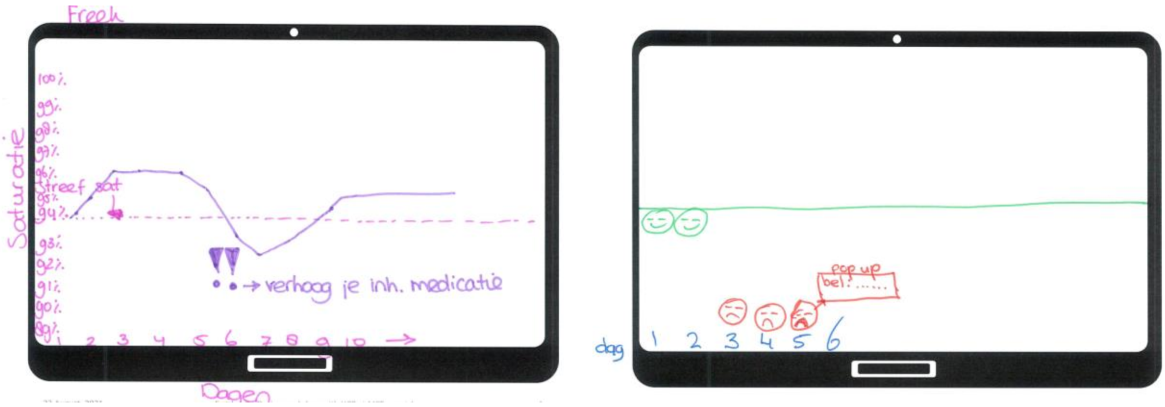


Figure 9: Sketches of user interfaces for monitoring oxygen saturation, including instruction to increase medication (left), or to call a certain number (right), drawn by different HCPs.

On the left is a graphical representation of oxygen saturation, and a horizontal line indicating the normal value. At the lowest point in the graph, two exclamation points have been added and the instruction to increase the inhalation medication *("verhoog je inh. medicatie")*. The screen on the right side show a row of numbers representing days, and green smiling emojis indicating good level of oxygen, while red frowning face indicates bad levels of oxygen saturation. The participant drew here a square as a pop-up with the text *"call…. "*, indicating the instruction for a patient who to call.

It should be added that HCPs talked in general about the importance to have technology integrated in one system, as to prevent the need to switch between systems when looking for information. *"I do think that eHealth technology could be really helpful in a way when it would be integrated in the EPD* [Elektronisch Patiëntendossier - electronic health record]. *Because that is also why I am still working with [name of a software]. It is a little bit of a hassle that I have to open it besides the EPD and takes also some time. But if it is already integrated in the EPD, the values the blood pressure, the weight."* [HCP_Int2]

4.5 Communicating and connecting between patients and HCPs

This theme relates to the ways patients and HCPs are currently getting in contact and communicate with each other, including preferences and opportunities for improvement.

4.5.1 The Netherlands

During the diary workshops, different participants [MST004 / MST008 / MST011] feel burdened to call the pulmonologist, e.g., because they think the pulmonologist is very busy, and they do not want to overburden him/her, or they think that the next day everything will be okay, or they do not feel that they are more sick. One participant [MST004] wants that the pulmonologist calls him/her every month to ask how are you feeling, is everything going okay. This participant thinks that if you use a mobile application which measures parameters and sends it to the doctor, would be easier for the patient and for the doctors. So that they can be monitored without calling the doctor. The solution according to another participant [MST011], is that the pulmonologist calls the patient after she/he ordered a new batch of medication, but not standard every month: *"I think that it would be nice if I request medication, the doctor would call after 14 days or one month. […] But calling me every month, I don't want to think about that, then I would be called by 5 specialists every month."* [MST011].

Some participants were not very pleased by consults by telephone. They rather have face-to-face contact. Other participants only have face-to-face consults, and one participant [MST010] have not seen his/her pulmonologist for a year and a half due to COVID-19. One participant [MST007] indicated that doctors say they will call before noon, but it is never before noon, which is annoying: *"They plan a phone consult, they say: 'You'll be called before noon'. However, you won't be called before noon, they called me when I was out doing grocery shopping at 2 o'clock. Yeah now I don't have time. I think these phone consults are worthless."* [MST007]. Video consults are also not appreciated by the participants that were asked about this [MST007 / MST060], as one said: *"You have different conversations if you sit across each other."* [MST060].

Participants [MST007 / MST0060] shared some negative experiences when HCPs lack information or when they have changing caregivers who are still in training, as this means they have explain their situation every time again. *"Every time I had one of those guys, to whom I had to explain it all again. That's very irritating. I do understand that they also have to learn. […] I have nothing against those interns, but if I have another one every 14 days and have to explain it all again, I get sick of it. I think: 'Well, read the file'."* [MST007].

According to two participants [MST007 / MST0060], a huge improvement in receiving care in the hospital is if the different specialists have more contact between each other. They are living with comorbidities, and all the specialists focus just on their speciality, but do not incorporate the other diseases they are living with during the treatment. They felt lost and unheard. *"The feeling of getting lost among all the specialists. They all point at each other: 'You have to be with him or her'. I'm sick of this. This should be improved."* [MST060]. / *"I think it's important if there is mutual communication between the different doctors. I sometimes said: 'Your colleague is just around the corner, is it so complicated to talk?' Then they say they will go talk, but I have never heard anything about it."* [MST007].

One participant shared how the communication and contact with HCPs could be improved. First, doctors call a patient back, they should have sufficient time to do so, instead of squeezing the telephone consult between other consults. Second, when the patient calls the doctor with symptoms, the doctor should be able to help the patient right away, instead of scheduling a phone call much later when there is a time slot available in their agenda: *"When I call the pulmonary nurse, (s)he says: 'Let me see, the doctor is not here, I will schedule a call back appointment at the end of next week.' Then I think: 'I have a question about my symptoms right now, I want to ask it right now.' But that's not possible."* [MST011].

The interview participants value a good connection with their GP. Some of the participants have yearly consults with the pulmonologist and some of them with the pulmonary nurse. There are mixed messages about both. Some participants are in favour of the pulmonologist: *"... also with my pulmonologist, yes, a good relationship."* [MST001]. Other are more sceptical: *"What should I do with the pulmonologist, he doesn't know me at all."* [MST009]. The consults with the pulmonary nurse are by some characterized as very valuable: *"That's why I also have a pulmonary nurse, who takes more time with me… I think that's very nice."* [MST001], but other don't experience an added value: *"If I have no complaints, what am I supposed to do, have a nice chat!?"* [MST009].

HCPs

Being able to quickly connect with their healthcare professionals was pointed out not only by patients but also by HCPs: *"The most ideal situation is, that they go to see a pulmonologist if they have problems. Or a little bit before they get problems. But not on a monthly basis, because they sit in front of the doctor and say 'Yeah, it's the same as it was last year.' Yeah ok, continuing. How nice would it be if they can have walking in hour during the week, where all the patients can go to, if they feel they have a little bit problems. And I think the doctors in Enschede they do it really good, because they already have a system of calling back in a day. That is already much better than it has ever been."* [HCP_Int6]

One HCP shared ideas how the communication could be improved by technology, for example, that information is provided and HCPs can see whether patients actually read it and can use this also in a follow-up conversation. *"More interactively ask the patients, what do you know, what did you look up, do you have additional questions. Then please look up this in type of information. So that is indeed the idea to more check what the patient needs and give him in a smaller amount of information. […] Or maybe that patients can put in a question, and that you when a patient comes to the appointment, that you can see the question and can answer it."* [HCP_Int2]. The same HCP also pointed out that patients may have questions when being at home but these are forgotten during the appointment. *"If the patient has specific questions and maybe he thinks about stuff at home that he thinks "Oh I would like to ask that" and maybe forgets about it when he is in the appointment with you, because also you as the doctor wants to discuss some parts, so things are being forgotten in the end. But if you have that already in the patient record, so the numbers but also these questions the patient wants to have answered, they help. Because then you really make time to get those questions answered if you know that they are there."* [HCP_Int2]

Another HCP shared that he/she communicates with patients via WhatsApp in some cases: *"I do WhatsApp as well. Patients have my phone number. […] What I did yesterday, I have a patient in a scoot mobile with extra oxygen and she has mental problems as well. She is a very severe lung patient as well, so she wasn't there yesterday afternoon. So I sent her a WhatsApp: 'How are you, are there any problems, do you need my help?' And sometimes I send them information. My patients all train in groups and they have a group of eight or ten. And sometimes I am in that [WhatsApp] group as well and sometimes when I see a nice breathing app or a nice [exercise]. Sometimes I do these kind of things for my patients."* [HCP_Int6]

Besides the connection and communication between a professional and a patient, two HCPs mentioned the connection between patients and that the support between these peers is very important and can be very motivating. For instance, patients who are doing physiotherapy together in a group and also have a WhatsApp group do not only receive information from the physiotherapist but also motivate each other: *"There is always one guy and he is in a cycling group and he invites other people 'come on cycle with us!' and, yeah, that is what they do."* [HCP_Int6] Fostering connection between patients can also tackle loneliness, which can be a serious issue in COPD as most patients cannot do as much anymore and the become isolated: *"[Publications stating that even in COPD GOLD 1 patients] 70% could not walk up the stairs in one go, they should stop in between. That makes them very isolated. They feel they can't help; most of the men are supposed to take out the garbage, you know. And they can't do that anymore. They can't do their shopping, so they stay at home. Their partner is doing the shopping and the other things. So they get* *isolated, they don't see other persons. So if you don't put the context of some social life, then they ... it will not work. It should be part of something more."* [HCP_Int007]. The same HCP emphasised that technology could add to loneliness if the programme is not embedded and specifically fosters connection between patients: *"When you offer them something at home, then they are lonely. eHealth is loneliness. […] A doctor who phones his patients, that's very lonely. For the doctor and for the patient. […] I think in this groups, that you also should [support social life], and then they get feedback from the people and from their co-patients and from their physiotherapists. […] So your programme should be embedded. And if you don't do that, it's just loneliness. It's even more lonely, when you just online with the person. Even when it looks very near, it's not. It's not personal."* [HCP_Int007]

4.5.2 Italy

Interview study

Regarding the management of COPD, many patients report a strong relationship with their doctors. This relationship is often based on a marked trust of the patient towards the decisions made by his doctor: *"I agree with the decisions of my doctor."* [GEM0012]. Often this trust comes from a lasting relationship that has been consolidated over the years during which patients have learned to trust the choices of their pulmonologist in the management of their disease: *"My doctor has known me for many years, and I have faith in him."* [GEM0014]. Throughout the interviews, many patients also reported that while following the doctor's decisions in most cases, they felt actively involved in the decision-making process: *"I feel involved in the doctor choices regarding my health, and I also know that the doctor makes the right decisions for me. I trust him."* [GEM0018]. A need that was identified from the interviews was to have a more immediate and direct contact with the doctor to be able to manage emergencies quickly and with greater serenity: *"I would like a quick contact with a doctor in case of emergency/need."* [GEM0020]. This also includes the attending physician, or a great support network.

Patients with comorbidities address the need for multidisciplinary disease management where all professionals have access to patient data and define treatment plans. "*It is very crucial that more healthcare specialists share my data. I have many serious comorbidities and often my pulmonologist does not have the complete image of my condition (exams, medications) and vice versa. Often I don't think of addressing to my pulmonologist problems other than the ones usually requested (another nuisance, medical issue)."* [GEM0004] *"The therapies should be more personalized. I have many comorbidities and this often makes COPD treatment more complicated. The different specialists do not share my exams in a regular basis. I need to report every time everything."* [Pre Diary workshop]

Patients reported difficulty in booking appointments timely at the hospital. *"There should be a possibility to request a visit through the health care system timely without having to pay a visit privately. It is often hard to find availability in the hospital."* [Pre Diary workshop] They also mentioned that follow up appointments are not scheduled in advance. "*The regular visits could be scheduled in advance. This way I would not need to call every time to book an appointment. It is frustrating for me*." [Pre Diary workshop]

HCPs

Health professionals mentioned to try establishing a relationship of trust with the patient. They state that during every visit, sincerity is essential to obtain a correct anamnesis and it is often preferable that a family member is also present to have objective feedback of the symptoms as well: *"I also prefer that my patient is accompanied by a family member in order to assess both the subjective experience of the patient and the external observation. For example, a patient can tell that the dyspnoea is stable, but a family member can tell me that the patient is moving less than before; for this reason, in my opinion, it is important to listen to two points of view and for the same one the questionnaires are more sensible."* [Pneumologist 2]. Doctors try to maintain a constant relationship with the patient even during the management of exacerbations, to have a trend of their disease: *"Actually I say to my patients to call whenever there is anything off with their symptoms, when the cough or the phlegm become more frequent or when there is even a slight worsening of symptoms. With this method I can visit a COPD patient with initial worsening of his/her condition within a week from the call. In any emergency case there is also their physician available, who can also contact me directly to arrange a visit."* [Pneumologist 2]. Health professionals also find it essential to know the background of the patients to have the right approach and to be able to guarantee the best path of care: *"As far as I am concerned, what is interesting is the quality of life of the careers. An immediate* *understanding of what are the lifestyle habits, the possible social withdrawal for example, so a possible closure in terms of housing condition or not is extremely useful to be able to then undertake effective treatment."* [Psychologist].

4.5.3 Estonia

When it comes to the communication with a pulmonologist. Some patients had experience with being handed a written guide: *"I got my tooth removed and they gave me some sort of guide of what to do, when there is bleeding. And I of course had bleeding, but I also had a change to follow the guide. It was very useful."* (TUK-007-D-INT), but patients seem to prefer face-to-face communication: "*However, person to person consultation is better. During state of emergency, physiotherapist sent me a guide on what to do. But maybe I do something wrong and hurt myself?*" (TUK-007-D-INT). They are also reluctant towards the use of virtual doctors / trainers; "*I don't think virtual trainers would be useful. I would like to read descriptions of the exercises and it is really important that they would also let me know, what is the use of that certain exercise*" (TUK-008-D-INT).

When it comes to the "form" of consultation, the patients favoured written guides and personal approach. The preferred approach depended on a situation. For example, giving overview which symptoms refer to worsening and when the patients need to contact HCPs are useful in written format. However, guiding people with certain tasks or activities should take place face-to-face. For example, one patient described their experience with physiotherapist. Their meetings reverted to online due to pandemic. The consultation was received as written guides. The patient did not like it, because they were afraid they were doing the exercises wrong and hurting them, which lead to ignoring this activity.

4.6 Coaching

Coaching in this context refers to the topics that are valuable to integrate in an educational module and preferences of patients regarding coaching style. This section reports on the results of the co-design workshop "Your favourite coach" as outlined in section 3.3.2.

4.6.1 The Netherlands

Results from the coaching workshop revealed several potential coaching topics: exercising, receiving information, smoking cessation, lifestyle, frequent check-ups, loss, mental well-being, meaningfulness, nutrition, taking actions on time, being independent, and consultation with physicians.

In terms of exercising, almost all participants mentioned exercising as important topic. Participants continuously got the advice to keep exercising as much as possible. A participant wanted to learn to recognize their own limits: "*I do think to know your limits. In that initial phase, I was like what do I do with this?"* [MST060].

All participants mentioned receiving information as an important topic for coaching. Participants missed, among other things, information regarding COPD in general, exacerbations, comorbidities, and social participation. Participants wished to receive better information during all phases of their disease: *"I think it* [receiving information] *has to be continuous. But in the beginning, I think it is important that if you diagnose someone with COPD, that they know what it is about and give it proper time and attention to also tell what it is and what is behind it and what the course can be, because that is different for everyone"* [MST007]. Honesty regarding the disease course and possible complications was valued by participants: *"Honestly tell how it* [the disease course] *can go. Temper the high expectations a bit"* [MST060]. One participant [RSP001] mentioned it to be important that physicians explain in easy-to-understand language. In his/hers experience, physicians often use medical terms when they explain something. According to this participant, these terms are mostly not understood.

Three participants [MST010/RSP001/RSP002] mentioned to experience difficulties with their medication because they often needed to test new or other medication. They mentioned this to be problem due to differences in health insurance. These struggles can cause unwanted side effect but also drains the energy of patients.

Smoking cessation was also mentioned as potential coaching topic during the disease management of the participants. All participants got the advice to quit with smoking when they were diagnosed with the disease. Some participants managed to quit smoking with help from smoking cessation therapy by the outpatient clinic in the hospital. This was not easy for the participants: *“Quitting smoking, that was a thing for me. That was very, very intense, but I’m 14 years away from that* [smoking]. *I went to smoking cessation therapy at the hospital. I had guidance for a year and that was great.”* [MST010]. Others still have difficulties with this topic. They find that they should receive more strict guidance: *“You have to stop smoking. You receive* [nicotine] *plasters, and once in a while* [the healthcare professional] *calls once, and what do I get out of it? You have to have someone who is on top of that, I think.”* [MST004].

Almost all participants got the advice to improve their lifestyle in general. Participants stated their desire to receive more help with that: *“That help* [with improving lifestyle] *was once a month, you come there for a while and then you have to do things. You go to the consult and then they say: ‘Just find everything out.’ The monitoring of this* [improving lifestyle] *is far too little.”* [MST004].

Several participants mentioned to find frequent check-ups important. They like being told what their current health status is and would like to see their values: *“I do like regular checking, about the functions. Just a status update.”* [MST007], and *“I would like to know what my lungs look like right now and what my lung function is. Because you don’t know that now.”* [MST010]. While participants mostly mentioned to find frequent check-ups important for the physical functions, one participant [MST007] mentioned to also to prefer informal check-ups: *“In the beginning it was once a week, that* [the healthcare professional] *called and asked “Gosh, how are you?’, and that helped in the beginning*” [MST007].

One participant [RSP001] mentioned that taking action on time was an important topic during the start phase of his/hers COPD: *“Well, at the start phase of the COPD, it is important to take action on time. Because often, ... due to being a bit sloppy occasionally and because it is busy in your environment and your live just continuous and all those things even more ... you procrastinate to take action, and then at some point like in the past, I was always just too late* [with taking action]”.

One participant [RSP001] mentioned to have no needs for guidance or information during the exacerbation phase: *“Surviving... No, at that moment it's just surviving”*. Only one participant [MST007] explicitly mentioned to prefer having consultations with the physician and nurses during an exacerbation. The same participant also mentioned to find nutrition important with managing COPD and received help from a nutritionist: *“That I have to keep track of my proteins. I think that’s important.”* [MST007].

In terms of mental well-being, two participants [MST010/MST060] mentioned to experience difficulties with this. They still receive either therapy or talk to a social worker. However, one participant [MST060] mentioned that this help is not available for every COPD patient while she/he considered that this could be of an added value. The same participants also mentioned “loss” to be an important topic for coaching. Since this is a reoccurring event during everyday life, coping with loss should also get attention: *“How you deal with the loss of everything. Because it remains a loss. Every time you lose something and have to say goodbye to something again. I have an electric bike that has been in the shed for two years. Yes, I have to say goodbye to that now. And yes, things like that. It’s actually a continuous theme. So more and more disappears. Saying goodbye to the vacuum cleaner is not so bad* [though]*.”* [MST060]. This participant also mentioned to struggle with finding meaning after having to quit with work: *“There’s so much to work. What you lose when you stop working, just like exercising. If you don’t do that anymore, you’ll lose everything around it. That way, a lot disappears from your life. How do you deal with that? It remains painful and the loss remains, even after all these years”* [MST060]. Two participants [RSP001/RSP002] mentioned to have no need to receive additional help regarding self-management or their mental well-being. However, these participants did express their need for some guidance. They would like to have the possibility to talk with someone that really listens to their specific situation: “*Just the part that* [someone] *sits around the table with you like ‘Well, what's going on with you? What do you think is important’. . . Just a listening ear I always say.* [Someone] *who also takes his time”* [RSP002].

Another remarkable finding was that two participants [RSP001/RSP002] explicitly mentioned their independence to be important: *“But I hope to avoid becoming dependent on someone else. Because that's* *the worst thing there is. If I can still do it all myself, I would like to do it myself. Because that is a sign of my independence. I think that is very important"* [RSP001], and "*Stay in control of your own life"* [RSP002].

Answers regarding the preference of coaching style varied. The coaching style of sports coach, and military general were mentioned the most. Results regarding the sports coach revealed that three participants only prefer this style : *"As long as you see and feel the progress, then I think such a coach* [sports coach] *is very good"* [MST004], *"The sports coach who says, 'You have to do this!', well he can also forget it. If I get a decent explanation of 'If you are going to do this and that, then this and that will be better.' Explain why and how."* [MST007], and *"That sports coach who says 'Hey, just stop. Because now you're going too far'. It* [the sports coach] *slows me down, but also stimulates me"* [RSP001]. Some participants mentioned to prefer the coaching style of military general: *"I just like a hard, straightforward approach. Just plain: 'This is what you need to do to achieve that and no whining.' If you don't, you won't reach your goals either."* [MST060]. Participants mentioned to prefer the military general during topics like smoking cessation or providing information: *"For information, that* [coaching] *is allowed to be very straightforwardly."* [MST060]. However, that participant also agreed that the military general is not suitable for every situation and cooperation is needed. Only one participant mentioned the coaching style of equal partner as preferred style. Another participant would like this style only in combination with another: *"Such a combination* [equal partner and sports coach]. *Where I tend to prefer the partner."* [MST007]. Two participants [RSP001/RSP002] agreed that the preference of coach depends on personal preferences: *"That depends on the person in question that you have in front of you. One needs a general and the other needs someone who is on the same level, can explain on a different level. Because if you are standing in front of that* [patient] *as a general, yes, you will probably get a blow in the neck"* [RSP002].

4.6.2 Italy

The coaching workshop in the Italian pilot was incorporated in the post-diary workshop that was carried out online due to the COVID-19 measures at the time.

Patients have different opinions concerning the use of technology to support them with their disease. Some of them are not familiar with the technology and find it hard to use an application. Others instead think that an application can help them know better their disease and deal better with it. "*The doctor knows how to support me. I don't think an application will be useful for me."* [GEM0010] *"An application would be very useful to me. I would feel more secure if my doctor can have access to my data more frequently."* [GEM0004]. Overall, most patients agree that a companion-like application where they can keep track of their symptoms, medicines intake etc. and get in contact with a clinician when feeling worse could provide them security and comfort in coping with their disease.

Regarding coaching styles, patients discussed the different possible advices that the application could provide related to exercise, medication intake or smoking for example. Overall, they agree that coaching style should be differentiated per functionality/advice. Quitting smoking for example appears to be very complicated for many patients that are still smokers. *"Smoking is a disease as well. You cannot quit that simply after so many years."* [GEM0010] In this case, democratic or participative style appears more desirable. The same holds for advices related to habits such as exercise or work. Patients prefer to be advised in a participative manner. On the other side, patients agreed that advices or alerts related to parameters like vitals or biomarkers or medicine/liquids intake should be more authoritarian. Finally, they stressed out the need for psychological support and assistance to accept their disease and the limitations it invokes them. *"The fatigue is so hard to manage. I wanted to accompany my wife at a social gathering but I knew I could not manage to stay there so long. I let her go alone, but it is so frustrating staying alone."* [GEM0004]

4.6.3 Estonia

The topic of coaching and coaching styles was discussed in the interviews that substituted the pre-diary workshop. For the patients in Estonia, the concept of coaching was difficult to understand. When being asked what they would in general think of coaching in the context of their disease, most patients said that they do not need any coaching. When giving examples of different aspects of coaching (e.g., physical activity, physiotherapy and exercise training to exacerbation management), patients still did not find much point in it. They had difficulties to discuss which topics they would need coaching on, but if so, they preferred written instructions.

Some of them said that if someone would call them now and then and ask how they do, that would be nice. One patient, who considered that coaching might be helpful, preferred face-to-face coaching, because then the coach could see whether the position or breathing is done correctly, which would not be possible if the coach is not present. Virtual coaching seemed more like science fiction for most of them. Mostly they thought that it could work for the next generation. *"I can't imagine an app that could help."* [TUK001D_INT] *"I don't want to be followed at home. Then you will be on guard like a slave all the time. At work, we had the cameras set up. The heart attack I had, probably was because of that."* [TUK001D_INT].

It should be noted that this particular group of patients belonged to the more younger group with less severe COPD and with at least some computer experience. As most of them never had a real severe COPD exacerbation, an explanation that they do not see benefits of coaching could be, that they have not felt that they have been left alone with their disease.

5. User requirements for the virtual companionship programme

User requirements are formal descriptions, that are written from the user point of view and describe any function, constraint or other property that must be provided to satisfy the user need (Kujala, Kauppinen, & Rekola, 2001). Consistent with the requirements specified in D2.1 *User needs and expectations for privacy-abiding RWD collection*, the requirements for the virtual companionship programme will also be documented using the eHealth notation table by Van Velsen, Wentzel, & Van Gemert-Pijnen (2013). Five different types of requirements are distinguished, each type being also indicated in the requirement identifier (Van Velsen, Wentzel, & Van Gemert-Pijnen, 2013):

- **(F) Functional and modality requirements:** technical features and the type of technology and operating systems the technology should work on. In this category we have also included privacy related requirements following users' statements.
- **(S) Service requirements:** specifying how the services surrounding the technology (e.g., marketing or user support) need to be organised.
- **(O) Organisational requirements:** specifying how the technology should be integrated in the organisational structure and working routines.
- **(C) Content requirements:** specifying the content that needs to be communicated via the technology, and (if applicable) language level, persuasive approach, special accessibility demands.
- **(U) Usability and user experience requirements:** specifying the interface and interaction design of the technology and how UX factors, such as trust or fun, should be integrated in the technology.

The requirements are prioritised using the MoSCoW method:

- **Must have:** most critical to the success of the technology
- **Should have:** important but not as critical as the must have requirements
- **Could have:** desirable, but not vital or critical to success.
- **Won't have:** least critical, not appropriate at this point in time.

As the requirements in this deliverable are an addition to the previous specifications in D2.1 *User needs and expectations for privacy-abiding RWD collection*, the numbering of the unique identifier will continue. In addition to outlining the requirements in deliverables, new requirements will be added and requirements will be revised in the requirements spreadsheet that constitutes a living document and is shared with all partners.

5.1 Functional and modality requirements

Functional and modality requirements specify technical features and the type of technology and operating systems the technology should work on. This also includes privacy related requirements.

<table>
<tr><td>Requirement #F13</td><td>Requirement type: Functional</td></tr>
<tr><td colspan="2">Description: Coaching and persuasive messages that the patient receives are context-sensitive and take into account recent activities, current level of exhaustion, their fitness level and environmental aspects that might reduce the abilities to carry out activities (e.g., high temperature).</td></tr>
<tr><td colspan="2">Rationale: Patients are well aware of the need to take breaks after they did some activity and rest if they are tired. This is an essential part of self-management and must not be counteracted by an inflexible coaching approach. This is also important to prevent patients going over their limit, respect their expertise and encourage them to trust their body.</td></tr>
<tr><td>Source: Patients (NL, IT)</td><td>Priority: Must have</td></tr>
<tr><td colspan="2">Conflicts: n/a</td></tr>
<tr><td colspan="2">Fit Criterion:
1. User experience testing: Participants using the companion over a period of time (e.g., 2-3 months) consider the type and frequency of persuasive messaging appropriate and in line with their capabilities.</td></tr>
<tr><td colspan="2">History: Created on November 14, 2021</td></tr>
</table>

Requirement #F14	Requirement type: Functional
Description: The patient shall be able to pause or skip persuasive messages and express the reason (e.g., that it is not useful or currently not possible).	
Rationale: See rational #F13. In addition: Patients already experience a high disease burden and willingness to engage with technology is limited, which is likely to be worsened when being notified when already fatigued. Furthermore, patients might experience an exacerbation and have to prioritise their energy.	
Source: Following from #F13, in line with #F9, #U1. HCP (NL, EE), Patients (NL, IT, EE), Literature **(Nunes & Fitzpatrick, 2018)**	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** The application allows the participant to snooze (for a short period) or pause (for a day or longer) persuasive messaging. The participants find the pause/snooze function and the rationale options useful.	
History: Created on November 14, 2021	

Requirement #F15	**Requirement type:** Functional
Description: Patients shall be able to communicate the symptom patterns that are commonly leading up to an exacerbation for them. These are visible for HCPs and taken into account for the monitoring profiles.	
Rationale: Many patients know or feel an exacerbation coming and for the individual patient this is often the same pattern, but this pattern differs between patients. For example, while a patients may always have mucus or fever, others never have, but in turn have other symptoms that indicate the onset of an exacerbation.	
Source: Patients (NL), HCPs (NL)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** Patient participants can add their personal symptom patterns into the system. 2. **Technical testing:** patient generated symptom patterns are integrated in the monitoring profile of that patient and presented in the HCP dashboard.	
History: Created on November 14, 2021	

Requirement #F16	**Requirement type:** Functional
Description: HCPs shall be able to see which educational material a patient has interacted with.	
Rationale: Educational material is often not read or properly understood. By indicating to the HCP which educational material the patient has looked at (or not), the HCP can integrate this in their communication with the patient, to follow-up and give feedback.	
Source: HCPs (NL)	**Priority:** Should have
Conflicts: Privacy aspects, as patients might not want this to be visible for HCPs.	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #F17	**Requirement type:** Functional
Description: The patient shall be able to allow or decline that an HCP checks their data, for example, when early signs of an exacerbation has been detected by the RE-SAMPLE system. The patient shall be able to ask for a data check (e.g., when they do not feel well).	
Rationale: Patients and HCPs reported that patients tend to wait too long to contact healthcare at the onset of an exacerbation. At the same time, patients would like to easily contact their HCP in case of emergency/need. Offering a review by HCPs from the system can encourage them to take earlier action. Manual acceptance of the review offer keeps the self-management responsibility with the patient, and preventing overburdening healthcare that might be introduced via automatic alarms.	

Source: Patients (NL, IT), HCPs (NL, IT)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #F18	**Requirement type:** Functional
Description: The HCP shall see when a patient wants to have their data checked by a professional (#F17), including available information on the identification of exacerbation risk and the factors that lead to this assessment.	
Rationale: see rational #F17. One rationale for not contacting HCPs early on was that patients do not want to burden them. A simple data review request can lower the barrier to ask additional support and HCPs can act earlier and in their own time to suggest next steps.	
Source: Patients (NL, IT), HCPs (NL, IT)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #F19	**Requirement type:** Functional
Description: The HCP shall see both the objective measures (e.g., lab values) and the subjective measures (e.g., wellbeing scores) to support reflection and shared-decision making during the consultation.	
Rationale: Combining objective and subjective measures allow for a more holistic assessment of the current situation, and supports reflection during consultation on what works for the individual patient.	
Source: HCP (NL)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #F20	**Requirement type:** Functional
Description: The patient shall be able to specify their own goals and preferences that are relevant for treatment and self-management.	
Rationale: As part of shared-decision making and self-management, HCPs take a more facilitating role, asking patients what they want and take these into account when identifying options. Furthermore, the RE-SAMPLE DoA describes that the RE-SAMPLE shared-decision making tool aims to achieve a good fit between data-driven care plan, patient preferences and expertise, and clinical expertise.	
Source: HCP (NL), RE-SAMPLE proposal	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #F21	**Requirement type:** Functional
Description: The patient shall be able to ask questions or comments that they want to discuss with their HCP (in general, and in combination with a data review).	
Rationale: Patients have regular consults once or twice a year. Questions they have to their HCP are easily forgotten until the next appointment. Similarly, when having an elevated risk of exacerbation and a data review is requested (#F17, #F18), the patient can share comments or questions that helps the HCP assess the situation.	
Source: HCP (NL), Patients (NL, IT)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #F22	Requirement type: Functional
Description: The patient shall be informed about an identified exacerbation and be able to see which factors lead to this higher risk.	
Rationale: Patients reported to have difficulties to identify early symptoms of exacerbation and want to learn more about their disease. Transparency on which factors lead to the identification of a higher risk increases trust and help patients understand which factors trigger an exacerbation.	
Source: Patients (NL, IT), HCPs (NL, IT)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 26, 2021	

Requirement #F23	**Requirement type:** Functional
Description: Patients shall be able to connect with each other to share experiences and support each other.	
Rationale: Communication and support by peers can support self-management, motivation to use the application and/or change behaviour, support acceptance of disease and improve mental health in terms of feeling understood.	
Source: HCP (NL), Literature **(Michalovic, Déziel, & Sweet, 2019)**	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on December 13, 2021	

5.2 Service requirements

Service requirements specify how the services surrounding the technology (e.g., marketing or user support) need to be organised.

Requirement #S3	**Requirement type:** Service
Description: End-user onboarding has to be accompanied by clear expectation management about what patients can expect after a data review has been requested and questions are being added to the system. (e.g., who contacts them in which timeframe; when not to use this feature but call the hospital, etc.).	
Rationale: The current service model is different in every pilot. For example, The Netherlands has a system in place where patients call before 9 and are called back the same day. Also, in Italy patients call their HCP in case of emergency. To prevent confusion, it should be explained how the data review supplements the current communication channels.	
Source: Req #O4, #F17, #F18, #F21	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

5.3 Organisational requirements

Organisational requirements specify how the technology should be integrated in the organisational structure and working routines.

Requirement #O3	**Requirement type:** Organisational
Description: When a patient has completed an educational module (see #C5, #C4), the topic of that module is included in the next consultation to be able to answer questions and provide feedback on the application of what has been learned.	
Rationale: Education on any topic is a whole process and behaviour adaptations take time. The follow-up conversation with an HCP ensures that the information in the education module is properly understood and applied. As was mentioned in the interviews with professionals and in literature, material is often	

not read, or misunderstood, or not correctly applied in practice. Patients in Estonia expressed worries to carry out exercises wrongly after reading written guides.	
Source: HCPs (NL), Patients (EE), Literature **(Hesselink, Penninx, Wijnhoven, Kriegsman, & van Eijk, 2001)**	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #O4	**Requirement type:** Organisational
Description: Data reviews for patients with an increased exacerbation risk, prompted by the system and confirmed by the patient are send to the appropriate HCP and need to be conducted within the same day to notify the patient.	
Rationale: Patients and HCPs reported that patients tend to wait too long to contact healthcare at the onset of an exacerbation. Offering a review by HCPs from the system can encourage them to take earlier action. Taking up this request quickly increases the trust between patients and HCPs, and can induce a positive experience that they are taken seriously. The importance of quick responses was emphasised in the Dutch and Italian pilot, where patients were called back at the same day. This made them feel taken seriously and patients could respond quickly during acute situations. Also in Estonia, patients can call their HCPs directly, hence, a new technology should not slow this process down. If the review request is taken up too late or not at all, this might discourage patients to accept the next data review offer and lower technology acceptance of RE-SAMPLE in general.	
Source: Patients (NL, IT), HCPs (NL, IT, EE)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

5.4 Content requirements

Content requirements specify the content that needs to be communicated via the technology, and (if applicable) language level, persuasive approach, special accessibility demands.

Requirement #C3	**Requirement type:** Content
Description: The system provides guidance on how to balance the level of activity, to prevent patients going over their limit and exhaust themselves. It notifies the patient if the activity is unusually high, initiate reflection and remind them of the importance of pacing activities (i.e., balancing activity with rest).	
Rationale: Participants addressed that patients with COPD have a limited amount of energy and need to balance their activities with rest to prevent exhaustion and fatigue. Patients reported that when having a good day, they often go over their limit to get things done, leaving them exhausted and fatigued the following days.	
Source: Patients (NL, IT, EE), HCPs (NL)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** Patient participants using different education modules test prototypes with regard to the appropriateness of language and notification frequency, understandability of information, and applicability of advice given.	
History: Created on November 14, 2021	

Requirement #C4	**Requirement type:** Content
Description: The system should educate patients on doing breathing exercises and how to use an inhaler properly.	

Rationale: Breathing exercises can be very useful for patients with COPD and improve symptoms of dyspnoea. As inhalers are often not used properly, an education module can support patients correcting their use.	
Source: HCPs (NL, IT), Patients (NL), Literature **(Gosselink, 2004; Hesselink, Penninx, Wijnhoven, Kriegsman, & van Eijk, 2001)**	**Priority:** Could have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** Patient participants test prototypes with regard to the appropriateness of language, understandability of information, and applicability of advice given.	
History: Created on November 14, 2021	

Requirement #C5	**Requirement type:** Content
Description: The system provides education on self-management topics and COPD in general, so that patients can learn how to best manage their disease. This is offered in smaller chunks as to not overload patients, and tailored to where patients are in their patient journey (e.g., after diagnosis vs. during the stable phase). Furthermore, the education includes repetition to enable long-term learning and facilitates that patients can apply this in their daily life.	
Rationale: Self-management was discussed by HCPs as a whole process that includes education on the roles and responsibilities as well as the learning about their own disease and how to listen to their own body. This is difficult for HCPs to provide, as this takes time and repetition. Often patients are given booklets or other information material, which is quite general and a lot of information to digest at once. Furthermore, HCPs do not know whether patients read the information or how patients are applying this in practice. (see also relation with #O3)	
Source: HCP (NL, IT, EE), Patients (NL), Literature **(Hesselink, Penninx, Wijnhoven, Kriegsman, & van Eijk, 2001)**	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** Patient participants using different education modules test prototypes with regard to the appropriateness of language, length of modules, understandability of information, and applicability of advice given.	
History: Created on November 14, 2021	

Requirement #C6	**Requirement type:** Content
Description: For persuasive messages and coaching on behaviour change (e.g., smoking cessation, increasing physical activity, healthy nutrition), the system provides tips & tricks on how to easily apply the recommendations in daily life.	
Rationale: Effects of behaviour change advise are often not sustainable, as people lose attention and motivation. A small change approach / habit-formation advice can support patients in adopting behaviour changes and integrate it in their daily lives.	
Source: HCPs (NL, IT, EE), Literature **(Gardner, Lally, & Wardle, 2012)**	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. **Usability testing and user experience testing:** Participants using different coaching modules test prototypes with regard to the appropriateness of language, and applicability of advice given.	
History: Created on November 14, 2021	

Requirement #C7	**Requirement type:** Content
Description: The system provides coaching on topics related to their mental health (e.g., acceptance, coping and living with COPD, defining the new normal).	

Rationale: Patients reported difficulties accepting their condition, the disease progression and struggles living with a disease that is often invisible to others.	
Source: Patients (NL, IT, EE)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #C8	**Requirement type:** Content
Description: When patients indicate that they did not follow recommendations or take medication as advised, the system requesting the patient to add their rationale, is using a language that is respectful and non-judgemental.	
Rationale: While some patients might indeed forget to take medications, others have valid reasons to postpone or not take medications, or not follow general health advice. Therefore, the priority lies with the respectful identification of their rationale. As pointed out by HCPs, this should not be met with judgement, but with curiosity to find out the underlying reason as to potentially adapt the treatment plan during a later consult that is more aligned with their wishes and abilities. According to literature, self-care technologies should support negotiations and compromises, and inform patients and carers about advantages, consequences and overall impacts of following a certain approach (e.g., delaying).	
Source: HCP (NL, EE), Literature **(Nunes & Fitzpatrick, 2018)**	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

Requirement #C9	**Requirement type:** Content
Description: Messages and notifications related to coaching or persuasion include information to what goals the prompted activities relate.	
Rationale: Shared-decision making and self-management include patients setting their own goals and incorporation of their preferences. Patient-centred care is a collaborative approach that involves explaining why a certain activity contributes to a person's health, and that the patient decides in the end whether to carry out this activity. Thus, it is not about following orders.	
Source: Patients (NL, IT), RE-SAMPLE concept	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

5.5 Usability and user experience requirements

Usability and UX requirements specify the user interface and interaction design of the technology and how UX factors such as trust or joy of use should be integrated in the technology.

Requirement #U2	**Requirement type:** Usability, UX
Description: The user interface should be easy to understand and providing easy access to the most used functionalities, and information should be clearly arranged (i.e., not overloaded).	
Rationale: High percentage of the target group is of low (health) literacy and/or does not have extensive experience with technology. Patients living with COPD and CCCs already experience a high disease burden, which has a high impact on their quality of life. Participants reported that they do not want to spend a lot of energy learning how a technology works and/or spend a lot of time using the technology.	
Source: Patients (NL, IT, EE), HCPs (NL), Literature **(Effing & Lenferink, 2020; Gardner, Lally, & Wardle, 2012)**	**Priority:** Must have
Conflicts: n/a	

Fit Criterion: 1. **Acceptance testing:** Early acceptance testing to demonstrate that the user interface is understandable. 2. **Usability testing and user experience testing:** The participants assess the application as easy to understand. The application allows participants to find the desired information in less than 1 minute. The usability test scores are high (e.g., SUS >75). 3. **Summative evaluation:** Participants are confident using the application and feel that it helps them manage their diseases.
History: Created on November 14, 2021

Requirement #U3	**Requirement type:** Usability, UX
Description: The RE-SAMPLE system is integrated and interoperable with the local healthcare system.	
Rationale: HCPs have a high workload and spend a lot of time gathering information from different sources. Furthermore, lack of integration and interoperability, and inadequate technology infrastructure are known barriers to successful implementation (both a technical barrier, and a barrier to end-user acceptance).	
Source: HCPs (NL), Literature **(Harst, et al., 2020)**	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on November 14, 2021	

6. Scenarios

Scenarios are stories that describe how a particular persona (see section 4.1.2) completes a task or behaves in a particular situation. Scenarios are a common tool in human-centred design to bring users to life, develop artifacts for research activities (e.g., tasks for usability tests) and test to see if the design meets the users' needs (Baxter, Courage, & Caine, 2015). Based on the scenarios, storyboards and prototypes were developed. The storyboards are used as supporting material in end-user walkthroughs, in which the prototypes will be validated by end-users.

6.1 Scenario "Getting started with the companion"

The first scenario focuses on the onboarding process of a patient and is depicted in Figure 10. The motivation for a HCP to recommend patients to the RE-SAMPLE companion differs and depends on the characteristics and goals of the patient. For this scenario, the characteristics and goals of the personas Johanna, pulmonologist Aksel and pulmonary nurse Annette are taken into account (see section 4.1.2). The main focus here is on getting a patient started with RE-SAMPLE who want to be more active, but is not very tech-savvy and also not very enthusiastic about technology use.

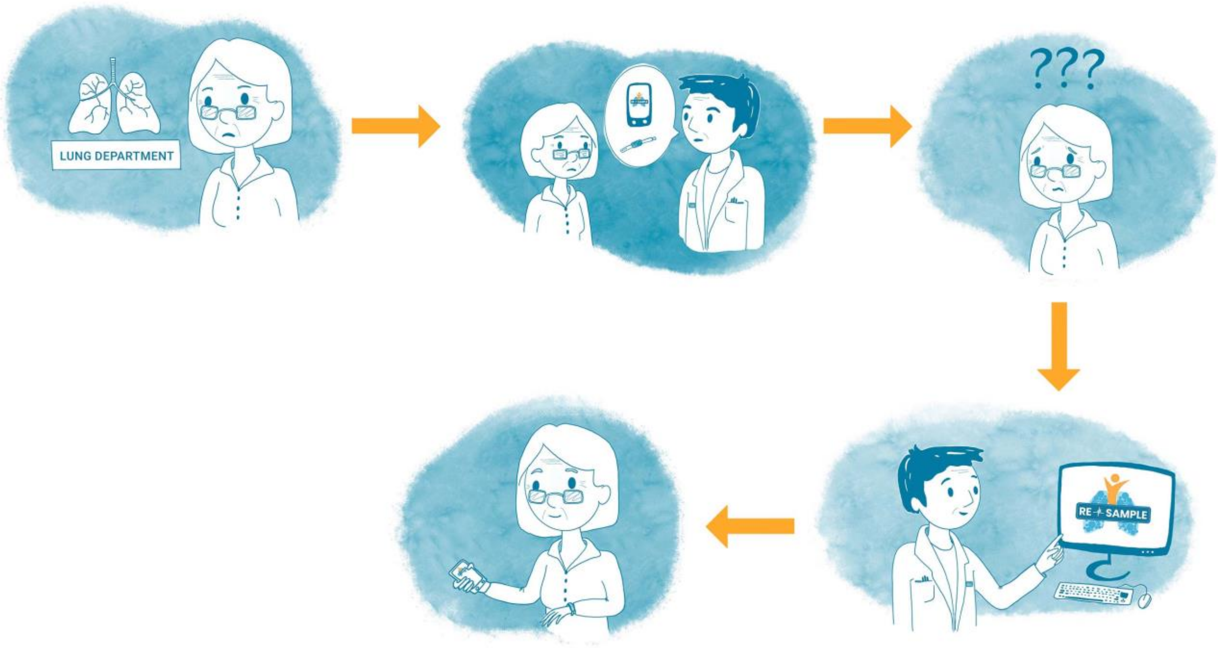


Figure 10: Storyboard Scenario "Getting started with the companion"

Johanna is visiting the pulmonary department at the hospital to get her regular COPD check-up. Her pulmonologist Aksel is worried, because he notices that her general condition is worsening. When asking about how she is doing at home, he is under the impression that she is barely moving as most chores are done for her and she mostly sits at home. At the same time, she misses meeting friends, so Aksel suggests that she joins the RE-SAMPLE programme to see how Johanna can be supported to become more active and being out while balancing the energy she has left.

Johanna is not excited about the idea to use technology and she also doubts that she can make big changes. She is often so tired and does not know how to operate these things. But if the doctor thinks it could help her, she will try it out. The pulmonary nurse Annette is helping her setting up her smartphone, gives her an activity tracker and explains her what this wristband does and how it helps Aksel to understand what she is doing in terms of physical activity, especially during the weeks and months that they don't see each other. Annette also walks her through the baseline questionnaire, so that she can make sure that Johanna knows what to expect when the next questionnaire comes up. Johanna is relieved that she is not left alone with these new things and she gets a new appointment for two weeks later to review and discuss the first results.

Until then, she only needs to wear the wristband and make sure it is charged, and respond to short questions about how she feels.

6.2 Scenario “Choosing data collection and sharing”

The second scenario focuses on choosing specific data types and who to share which type of data with, which is depicted in Figure 11. This relates to requirements identified in D2.1 *User needs and expectations for privacy-abiding RWD collection*, that patients can specify which data type to share with whom (#F1, #F2), and that data collection requests are tailored to the patient (#F12). For this scenario, the characteristics and goals of the persona Gustav and pulmonologist Aksel are taken into account (see section 4.1.2). Gustav has diabetes and wants to learn how his COPD and diabetes affect with each other. The main focus here is that additional data types can be included if necessary and that the patient decides which data are shared with his HCP.

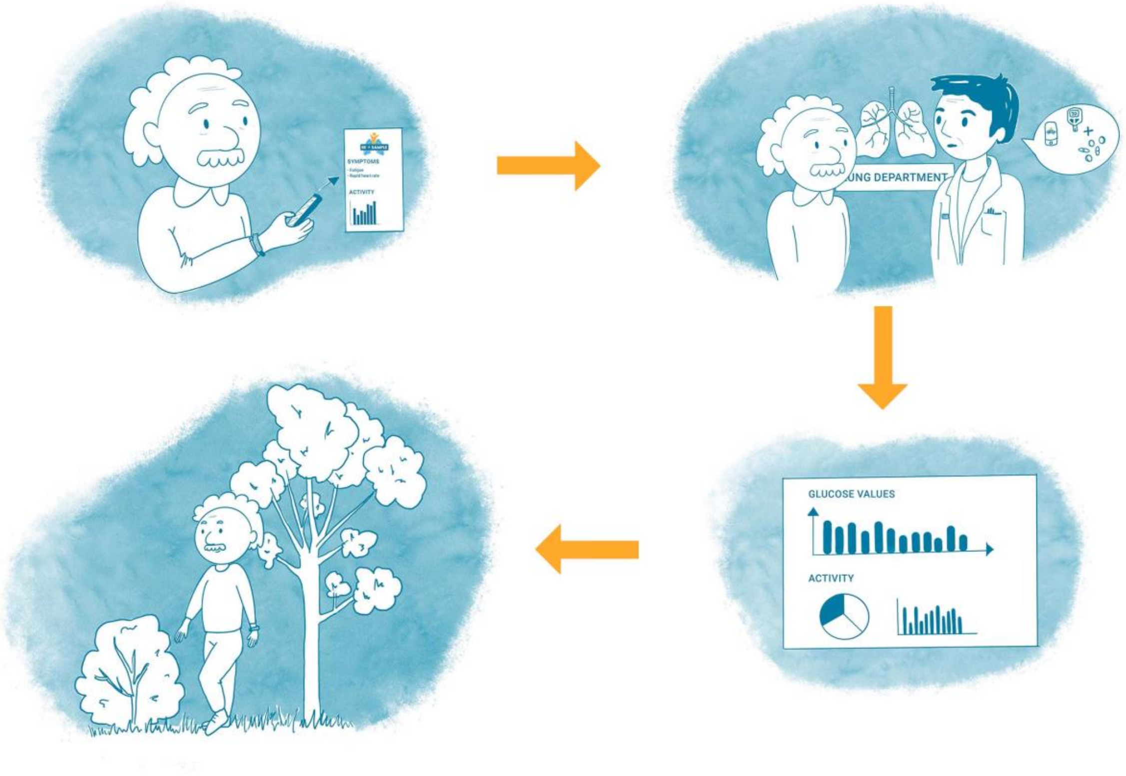


Figure 11: Storyboard scenario “Choosing data collection and sharing”

Gustav has been using the RE-SAMPLE companion for a while and has connected his activity tracker to the system. He notices that after worsening of the symptoms, his diabetes type 1 is also not well under control anymore, but is not sure what the cause is. His pulmonologist Aksel suggests that he also includes his blood glucose measures and medication into the companion, so that they can see whether the COPD medication is affecting the blood glucose. Gustav adds the dates when he has taken prednisolone and also starts including his blood glucose measures.

A couple of weeks later, he meets his pulmonologist again, who asks Gustav, whether he can see also his physical activity data and glucose measures over the last weeks. That way, the pulmonologist can see over the same period of time on which days he took prednisolone, how active he was during those days and how the blood glucose level was. This would help Aksel to assess, whether this is something for the him to take up or if a referral to internal medicine would be more suitable. Gustav agrees and shares his data with his pulmonologist Aksel. A few weeks later, Aksel reviews the data and can see that there seems no relation between the medication and the glucose levels. He notices that there is a change in physical activity that might affected Gustav’s blood glucose level. If Gustav feels well, he is outside a lot more, but during an exacerbation he mostly sits at home. This might be the cause of his changed glucose levels and might necessitate adaptation of his diabetes medication. As some form of physical activity is also important during an exacerbation, Aksel discusses with Gustav ways to be active and suggest that Gustav discusses with his internal medicine physician whether and how to adapt the diabetes medication according to his physical activities.

6.3 Scenario “Early contact exacerbation, additional tests, exacerbation story”

The third scenario depicted in Figure 12 focuses on supporting early contact with healthcare when it comes to exacerbation and the integration of the shared-care facility (SCF). For this scenario, the characteristics and goals of the persona Bert and his pulmonary nurse Annette are taken into account (see section 4.1.2). This scenario is a response to patients and HCPs reporting in the studies that patients tend to contact healthcare too late, for example, because they don’t want to be a burden. They expressed difficulties to understand when exactly is the right time to contact healthcare and when is it ok to wait. The persona Bert is motivated to learn better to recognise his exacerbation early and this scenario focuses on this aspect. Furthermore it reflects the challenge of overlapping symptoms, hence integrating monitoring profiles and additional tests carried out in the SCF.

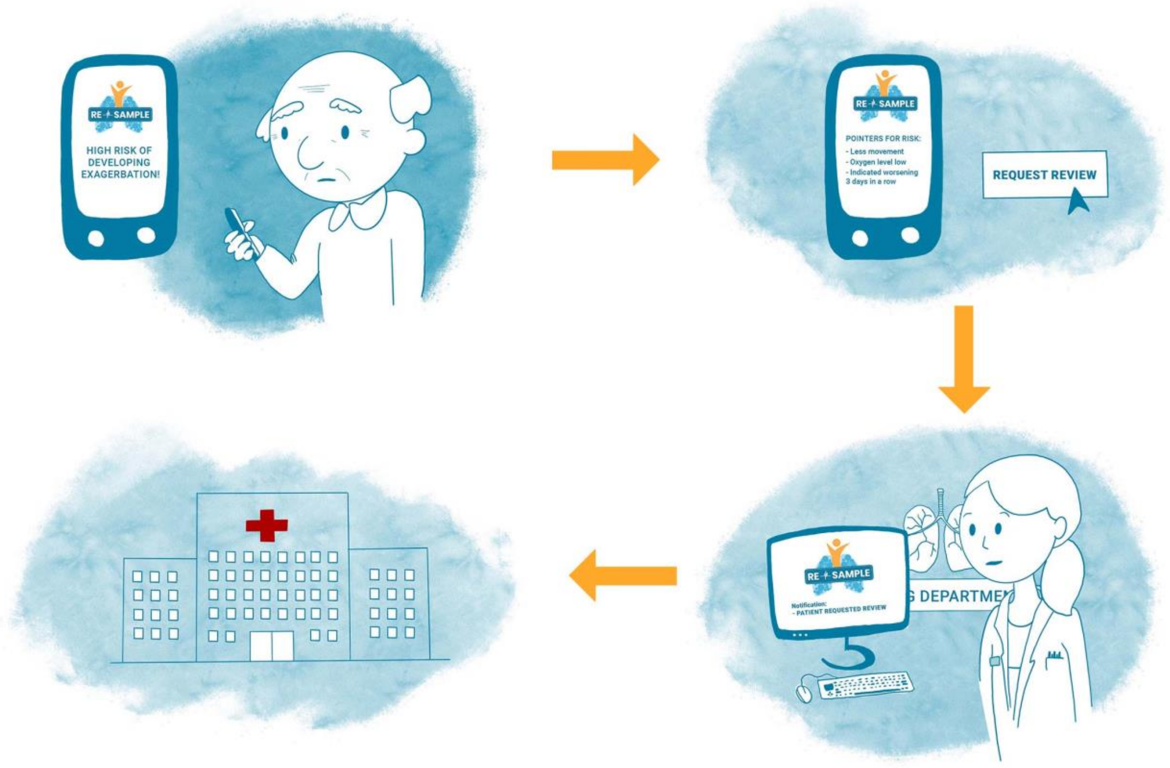


Figure 12: Storyboard scenario “Early contact exacerbation and additional tests”

Bert has been using the RE-SAMPLE companion for some time now and always fills in the questionnaires about his symptoms. One morning, he notices that he does not feel that well, but he thinks this was because the grandkids were around the last days. Maybe that was a bit too much. Or maybe the heater in his living room is set too high – so it might be the temperature. He fills in his daily symptom card, and after a while the companion notifies him that he has a risk of developing an exacerbation. He receives an overview of the pointers for that risk: he has not moved a lot in the last days, his oxygen level is too low and he had indicated a worsening of symptoms. Bert was not aware of that, so when the system asks whether it can prompt a review request to his pulmonary nurse, Annette, he agrees. Usually he waits – and often he waits too long. Maybe it is nothing, but maybe it is a good idea if Annette can have a look.

At the hospital, the pulmonary nurse Annette receives a notification from the RE-SAMPLE support programme requesting her to review Bert’s data. She looks at the data of the last days and also reviews his risk profile and monitoring profile. As Bert also has a cardiovascular disease, she sees in his monitoring profile, that in his case NT-proBNP should be monitored to distinguish whether his worsening is caused by COPD or by his heart condition. She notifies Bert that he should come to the shared-care facility (SCF) to get the lab tests done.

Bert receives the notification and the information that he can come to the hospital for additional blood tests. Usually he would have waited a couple more days, but now he is ensured by Annette and the RE-SAMPLE companion that it was good to react sooner. He goes to the SCF for additional testing after which it is confirmed that the cause is indeed the COPD and not his heart condition, so that he can immediately start with the right medication. The RE-SAMPLE companion then invites Bert to reflect on his exacerbation story, meaning what happened the days before his exacerbation and what might be triggers for him. He can then add ideas what might have contributed or triggered the exacerbation. He makes notes that his grandkids visited and that it was very warm in his house. The RE-SAMPLE companion then shows Bert, that he can add these kind of notes whenever he wants, not only when an exacerbation has occurred. Bert understands that this is like a diary of events that he suspects might worsening or improving his situation. By writing them down for a specific day, he can then later see whether these events or activities had indeed an influence on his COPD or heart condition. That way he can learn over time what triggers he have to watch out for and which activities make him feel better.

6.4 Scenario “Trends and progress”

The fourth scenario depicted in Figure 13 focuses on visualising trends and progress in the data. This responds to the problem identified, that it is difficult for patients to motivate themselves to change to and maintain a healthy lifestyle as their do not see that they improve and their disease continues to progress. For this scenario, the characteristics and goals of the persona Ans and her pulmonary nurse Annette are taken into account (see section 4.1.2). Ans wants to be more physically and socially active, but struggles to maintain her lifestyle changes and form new habits. This scenario focuses on showing users the progress they have made, even if they do not “feel” that way. In addition, some easy habit forming advice are included in this scenario (see #C6).

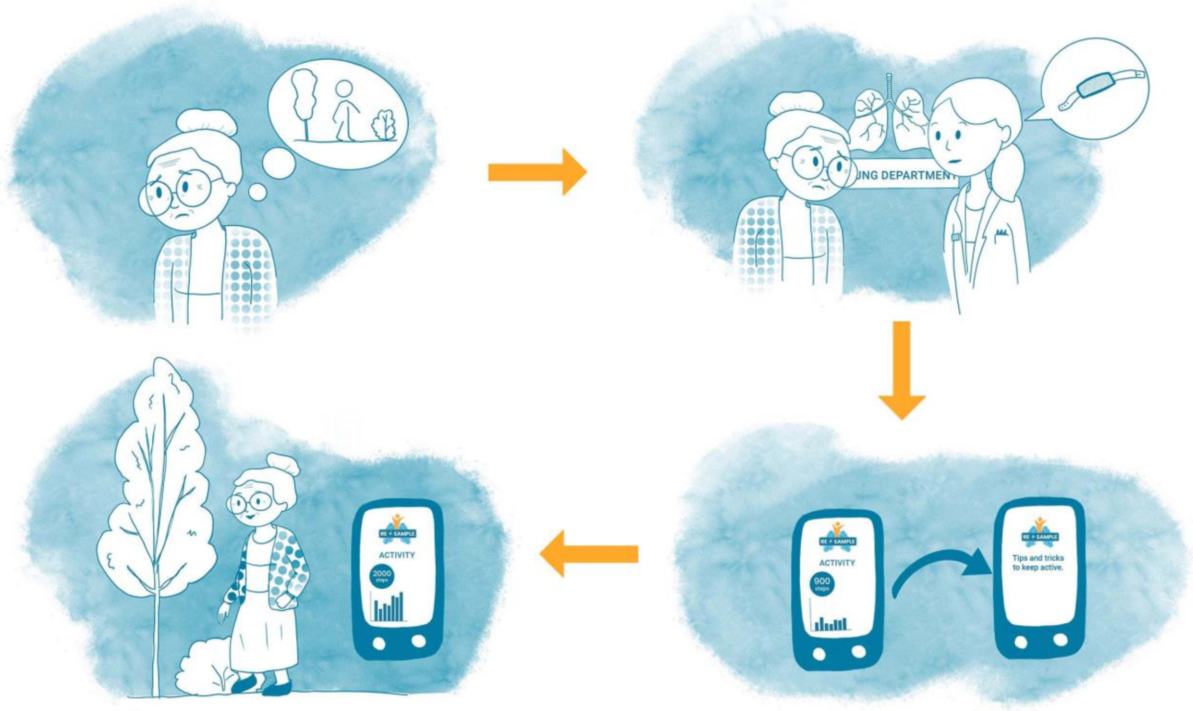


Figure 13: Storyboard scenario “Trends and progress”

Ans has been trying to be more active as she knows that this is important to keep her COPD in check and tackle that she is slightly overweight. But whenever she becomes more active again, she loses her motivation after a few weeks, thinking “What’s the point?” because she does not really feel differently or better. Her pulmonary nurse, Annette, suggested that she tracks her activity for a while so that she can also visually see that she is active and maybe even improve after a while.

Ans is using an activity tracker and can see after a few days, that she sometimes not even walks 900 steps a day. She was very surprised about that, because she thought that even when she is at home she would walk a lot more. She sees that the companion also has a coaching module which provides her with some easy tricks and tips how to slowly increase physical activity, which she tries out. A few days later she sees that she is almost having 1500 steps and she decides to just go outside her house to get over the 2000 mark. There she sees her neighbour and they have a short chat on the sidewalk. She continues to track her activity and after a few weeks she feels as if she is back to her usual habit and feels a bit frustrated. But when she looks at the overall trend and the prediction, she is still on a good way. This was just a short setback, just a couple of days where she took it a bit slower as she didn’t have a lot of energy. She can see that also in the overview that for the days she took it slow, she had made a note that she was very tired. But she is still doing much better than when she started. Seeing these small progression especially when she cannot feel that she made them, makes her happy. When she is visiting the pulmonology department again, the pulmonary nurse Annette can see the progress that she has made as she can see the overview also in RE-SAMPLE system.

6.5 Scenario “Coaching”

The fifth scenario depicted in Figure 14 focuses on coaching and takes into account the characteristics and goals of the persona Giulia and her psychologist Francesca (see section 4.1.2). Giulia represents patients that reported in the user research studies to have difficulties coping with their chronic condition and accepting that they cannot do as much as they could before. The scenario focuses on potential coaching topics (such as balancing energy and activity #C3), and that educational topics are offered in smaller chunks from which the patient can choose (#C5).

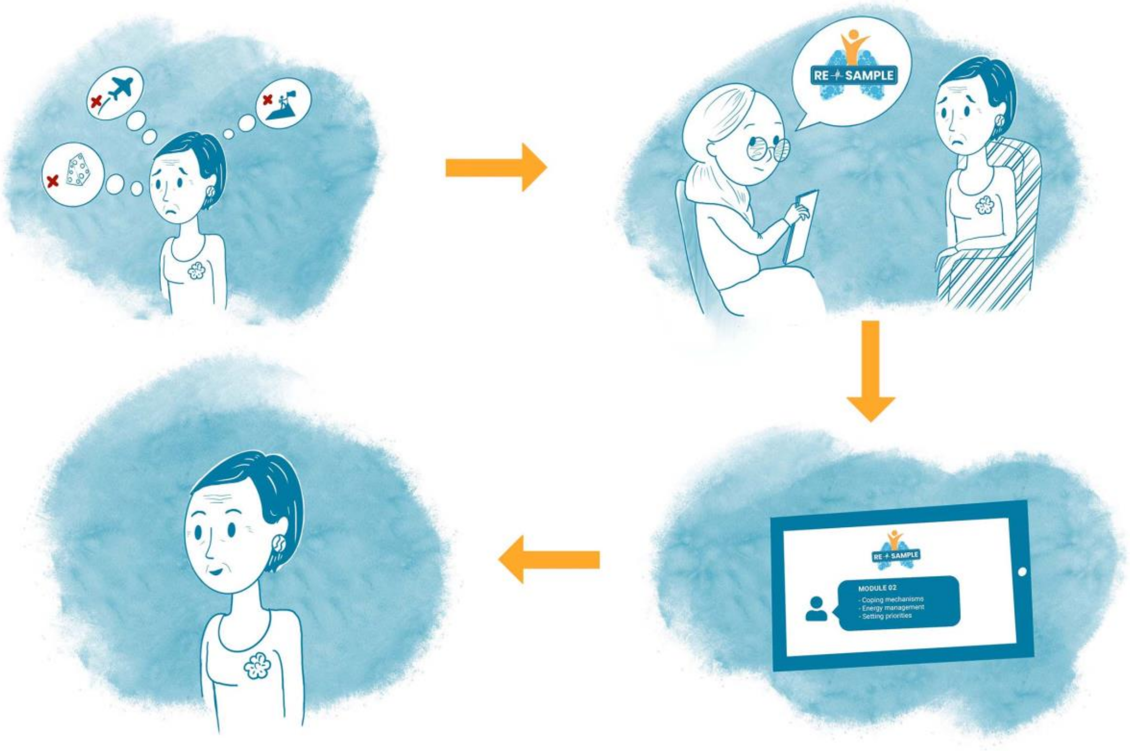


Figure 14: Storyboard scenario “Coaching”

Giulia has been living with COPD for ten years now and struggles with accepting that the disease is only going downwards and she has let go of many things that she enjoyed. Nobody ever discussed coping mechanisms with her or the mental burden that COPD has on patients. She was recently referred to a psychologist, Francesca, who recommended the RE-SAMPLE companion to her as it includes many resources on how to manage with COPD and cope with certain aspects. Giulia is not a fan of all these new technologies but Francesca is so enthusiastic that she agrees to try it out. She does not want to collect any data or wear these strange band that monitor all you do, but she would like to try out the coach.

She is introduced to the virtual coach in the RE-SAMPLE companion, that asks her a few questions on what she struggles with and what she knows about COPD. The coach then introduces some coaching modules that would fit with her needs: coping, energy management, setting priorities. She can decide whether she wants to do all of them at the same time or one after the other. She decides to do one at a time and learns from the coach that a lot of patients struggle to cope with COPD and with accepting that one cannot do certain things anymore. However, she learns in the next module how she can identify what is most important to her. She really misses her friends and family, but she often just has not enough energy to go outside. Many patients with COPD receive additional help in the household, so that energy can be spend on things that really matter and improve their quality of life. She learns from the coach about energy management and how she can then use her energy for the most important things on her priority list. She realises that while she has to let go of many things as not everything is possible anymore, she can still do some of the things that are most important to her while getting help for chores – because who misses vacuuming?

6.6 Scenario “Shared-decision making”

The sixth scenario depicted in Figure 15 focuses on the shared-decision making aspect that is supported in RE-SAMPLE by the collection and analysis of real-word data. For this scenario, the characteristics and goals of the persona Roberto and his pulmonologist Marco are taken into account (see section 4.1.2). Roberto is already using technology and he is motivated to use RE-SAMPLE because he struggles to find the right limit and often exhausts himself. The pulmonologist Roberto is not very enthusiastic about technology. The scenario describes how the data collection and analysis done in RE-SAMPLE in combination with visualisation of data and risk profiles can support both users to create a more personalised care plan.

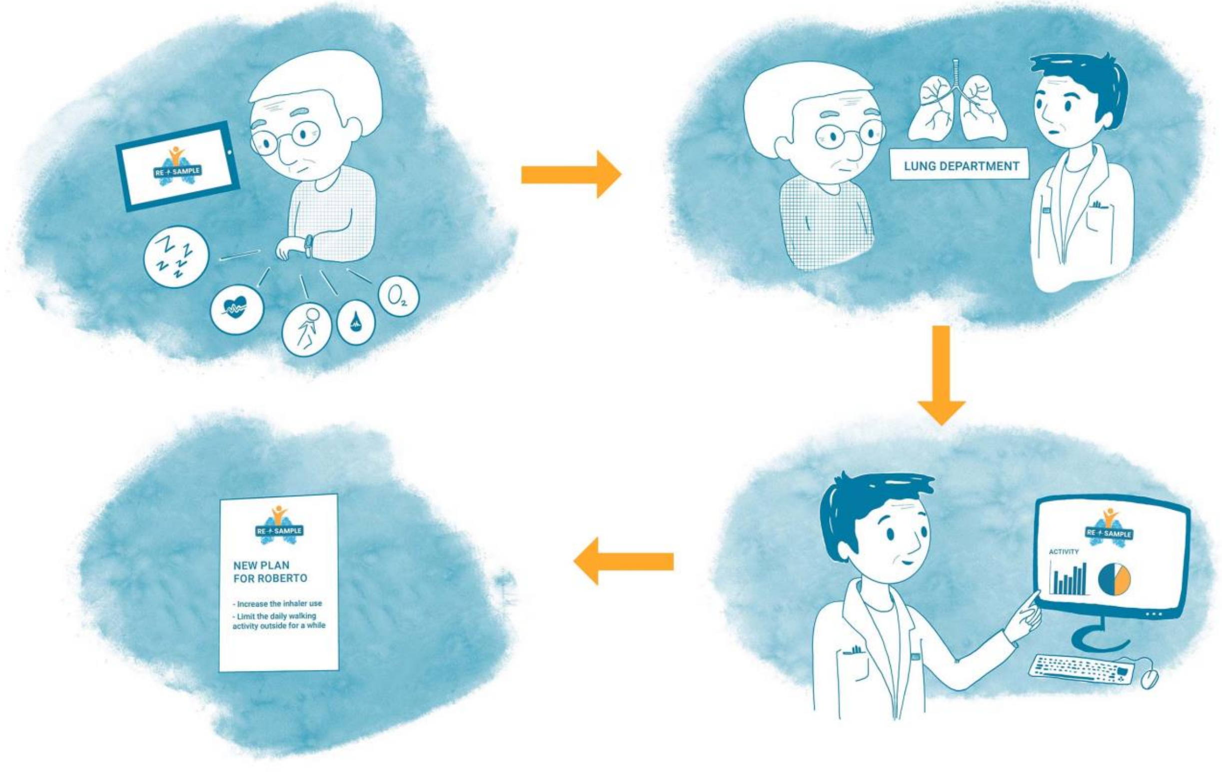


Figure 15: Storyboard scenario “Shared-decision making”

Roberto is using the RE-SAMPLE companion for a while and has connected his smartwatch, so that his sleep, heartrate and activity can be used and he can get a good overview. He also started adding his blood pressure and oxygen saturation, as it was quite easy to do and now he can also see these data together with the data from the smartwatch.

At the next yearly check-up, Roberto tells his pulmonologist Marco that he noticed by filling in the daily symptom card, that his dyspnoea and fatigue has been worsened over the last weeks. He is not sure what the cause is; the COPD or his chronic heart failure or that he was very active. He shared all his data with his pulmonologist Marco so that he can get a good overview on what happened the last days, but Marco has not really used the RE-SAMPLE yet. Marco opens the RE-SAMPLE dashboard and sees a clear overview of the data that was collected by Roberto and his risk profile. In one glance he can see that the risk for developing an exacerbation is slightly elevated, but not worrying yet.

The shared-decision support tool provides recommendations for an update in the care plan, which Marco discusses with Roberto. Marco realises that it is very important for Roberto that he is still able to go out and about, but agrees that on some days he overdid it. Looking at the data and the current care plan, they decide together to increase the inhaler use and limit the daily walking activity outside for a while. That way Roberto is still outside and active, but more evenly spread throughout the week and reducing the risk of going over his limits.

6.7 Scenario “Peer-to-Peer support”

The seventh scenario depicted in Figure 16 focuses on the communication and peer-to-peer support between patients that can also tackle loneliness in COPD patients. For this scenario, the characteristics, goals and challenges of the two personas Ans and Bert are taking into account (see section 4.1.2.1). Ans stopped meeting her friends and feels a bit lonely sometimes, while also struggles to change some of their behaviours. The scenario describes how the exchange of experiences and struggles with a fellow patient can make them feel less alone, as their social environment cannot comprehend what it means to live with COPD. They can also benefit from each others’ expertise of dealing with the condition and consequences, which can also be very motivating.

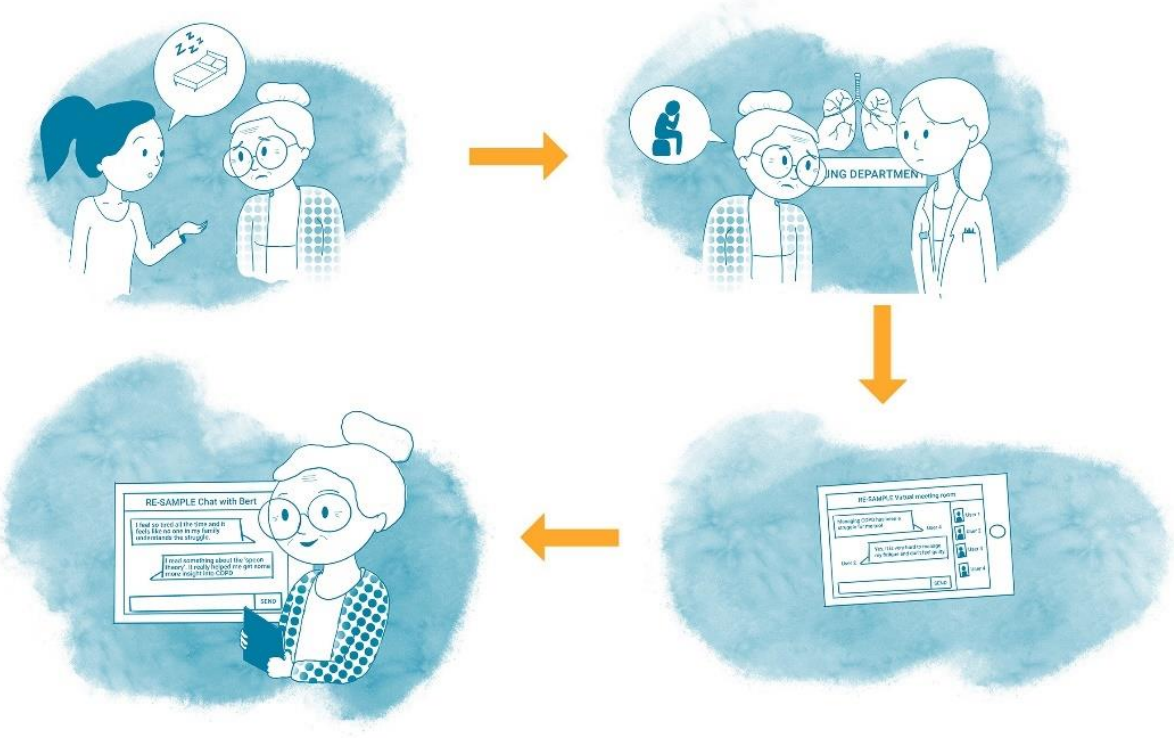


Figure 16: Storyboard scenario "Peer-to-Peer support"

Ans noticed that she struggles a lot with managing her COPD lately, because she feels extremely fatigued while also wanting to take care of things. When she tries to talk about this with her family and friends, they all advise her that she just has to ‘take a nap’ and ‘do what she can’. This really frustrates her, because if that was so simple as is, she would have done that 10 years ago. Taking a nap is not fixing her fatigue and she always feels guilty when she cannot finish things she started. Ans even gathered the courage to talk about her struggles with her pulmonologist in her next 15 minute appointment. But again, she does not feel like that her pulmonologist really understand what she means. Ans strongly gets the feeling that no one in her environment gets her nor understands what she is going through, maybe because it is also very difficult to explain to someone who does not have COPD.

Ans sees an option in RE-SAMPLE to join a virtual meeting room with other COPD patients. Here, she meets Bert. Bert also suffers from COPD quite some years now. He tries to become active in managing his health but still has his own struggles. Bert and Ans start talking and they immediate recognize each other’s struggles. Bert for instance, also struggles with fatigue. Just as Ans, he felt like his environment didn't understand how his fatigue differs from just being tired. He tells Ans about his experiences and the methods he used to explain to his friends and family what it means when he is fatigued. Recently, Bert read something about the ‘spoon theory’. This helped him with gaining a lot of insight and he shares the link to this theory with Ans. Maybe, she will benefit as much from this as Bert did. This story inspires Ans, and she feels, for the first time, motivated to look into this theory and take another approach for explaining her fatigue to her friends and family. Bert on his turn, is really amazed about how relaxed Ans is regarding her medication intake and exacerbation management at home. He would love to know how Ans can do so.

As time passed by, they noticed that they are not finished with sharing their stories at all. Ans briefly mentioned that she also struggles with quitting smoking. Bert is a former smoker and knows how hard it is for Ans to quit. He would love to share his story about how he managed to do so and to share some tips that really helped him. They decide that they will meet again tomorrow so that they can go further with their conversation. When Ans closes the RE-SAMPLE app she noticed that she feels relieved, because she felt heard and it was so easy to talk to Bert, because she did not have to explain everything. Finally, she can talk to someone who really understands what she’s been going through. This is something she really missed during the years living with COPD.

7. Data-flow diagrams

In this section, the processes for data collection, processing, sharing and use are described and represented in data-flow diagrams that also include the different actors and components of RE-SAMPLE. The data-flow is presented in two main diagrams: Onboarding and data sharing (Figure 17) and exacerbation alert (Figure 18).

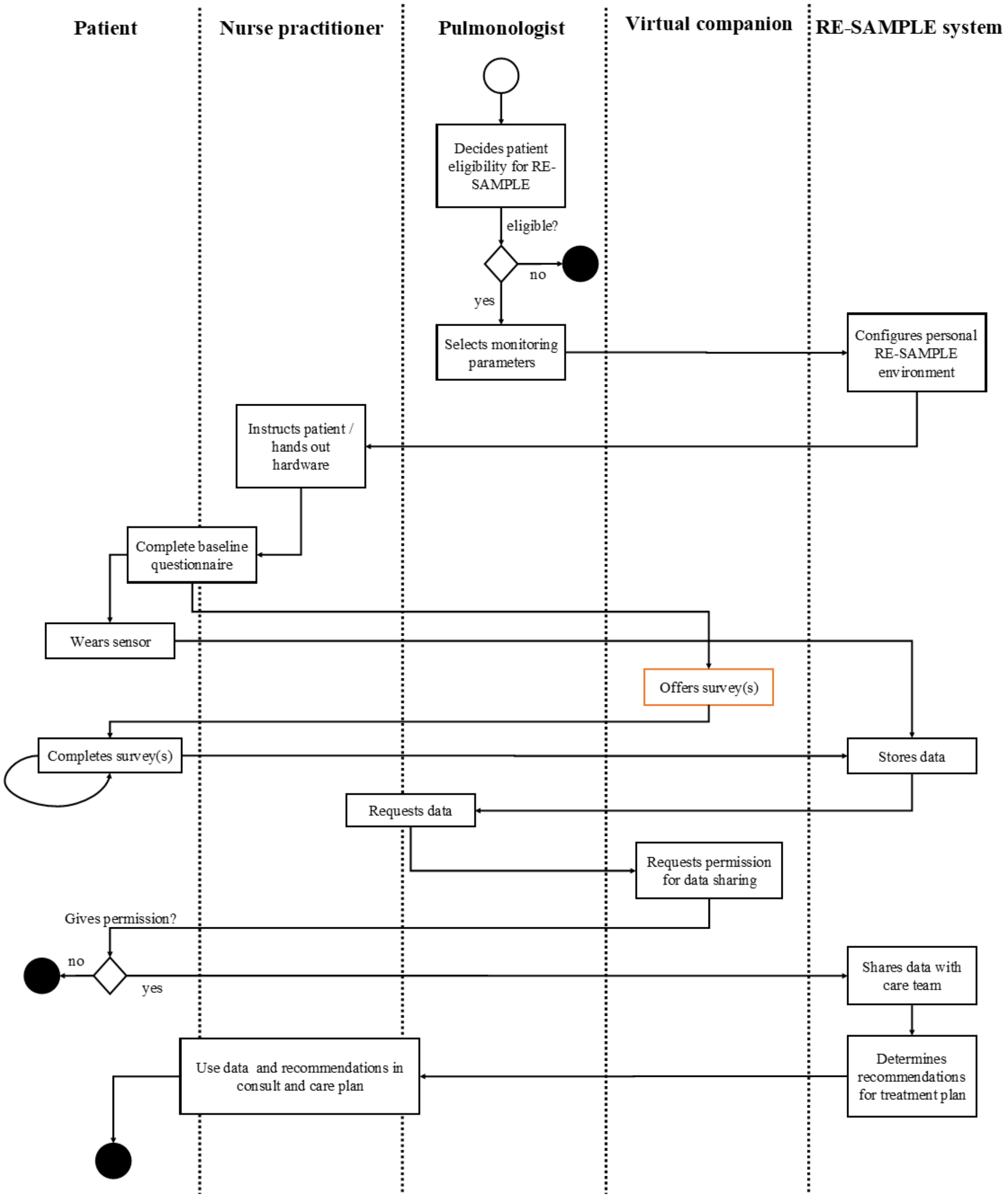


Figure 17: Data-flow diagram "Onboarding and data sharing".

The onboarding starts with the pulmonologist who decides whether a patient is eligible for RE-SAMPLE (Figure 17). If the patient is eligible, the initial parameters for monitoring are selected and the RE-SAMPLE system configures the personal environment for those patients. The nurse practitioner helps the patient setting up the system by handing out the hardware (e.g., wearable) and setting up the app (downloading the app, creating account, connecting wearable). Together with the nurse practitioner, the patient then uses the companion app to complete the baseline questionnaire. Based on the initial input, more surveys are offered, which in the appropriate frequency / timeframe are prompted via the companion app. The responses to the surveys and the data collected by the wearable are stored in the RE-SAMPLE system. Before data is shared with HCPs, the patient is requested to give permission. If the patient gives permission, data is then shared with HCPs, which is then used in consultation and when creating the care plan together with the patient.

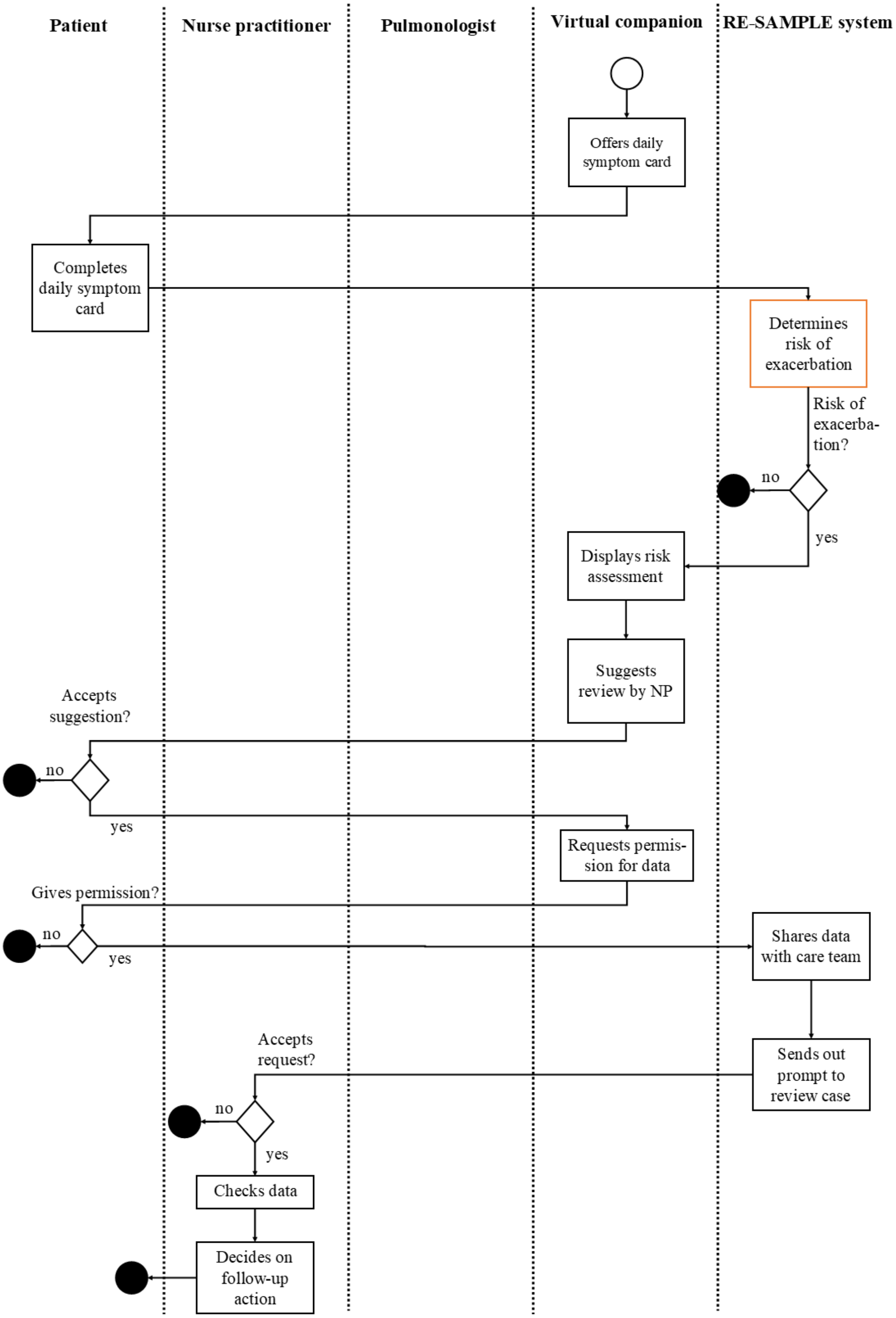


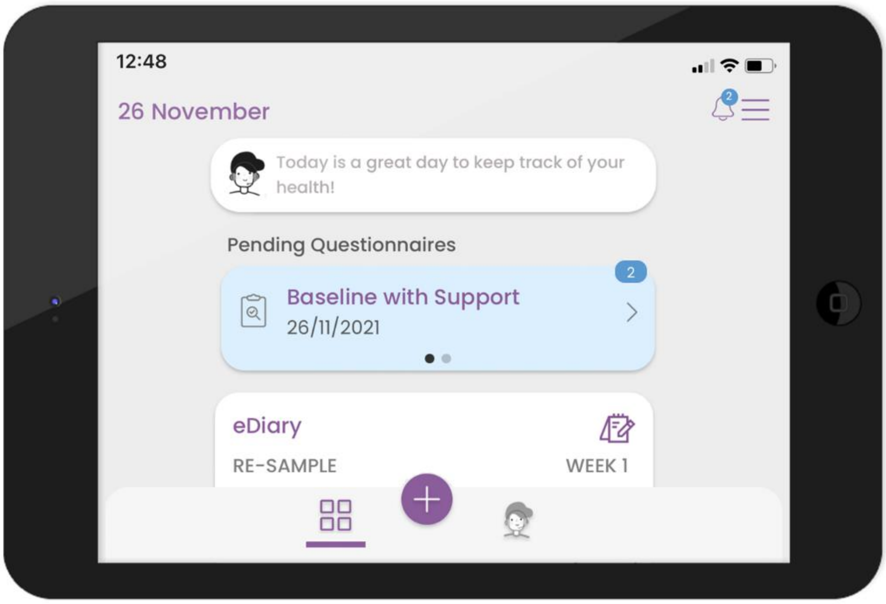
Figure 18: Data-flow diagram “Exacerbation alert”.

The dataflow of the exacerbation alert (Figure 18) begins with the companion that asks the patient to fill in their daily symptom card. The patients fills these symptom cards in and based on these and other data stored in the RE-SAMLE system (especially the “usual symptoms in a stable situation” filled in by the patient) , the risk of developing an exacerbation is predicted. If the system detects an increased risk, the patient is notified in the companion app and a data review by the nurse practitioner is offered. The patient can accept or reject this suggestion. If the patient accepts the review suggestion, the companion asks permission to share the data with the care team. If the patient consents to data sharing, the review request is sent to the nurse practitioner. Upon accepting the request, the nurse practitioner can review the data of the patient, assess the situation and decides upon her follow-up actions (for example, calling the patient or writing a note).

8. Prototypes

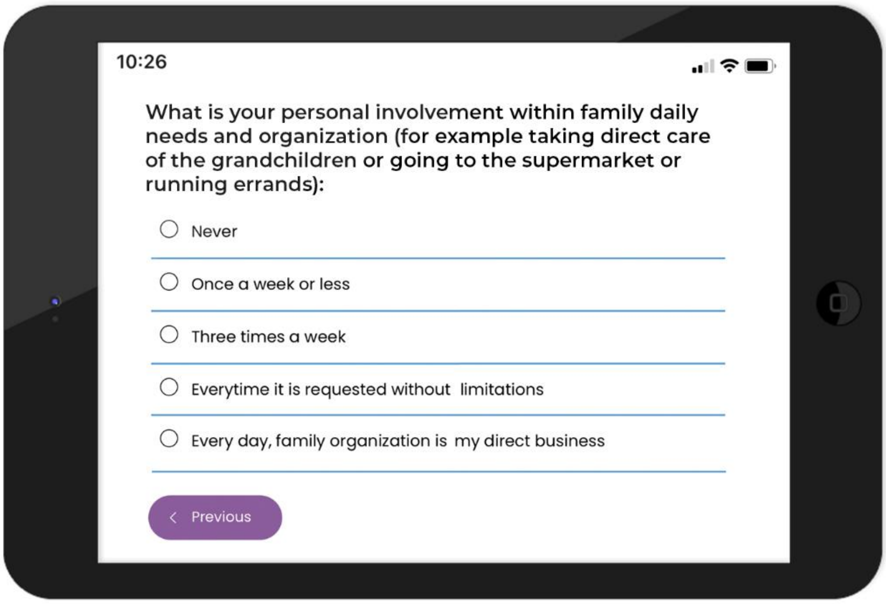
Different prototypes were developed based on the scenarios that were then used in the end-user walkthroughs.

8.1 Onboarding



Today is a great day to keep track of your health!

Figure 19: Patient: Homescreen



What is your personal involvement within family daily needs and organization (for example taking direct care of the grandchildren or going to the supermarket or running errands):

○ Never

○ Once a week or less

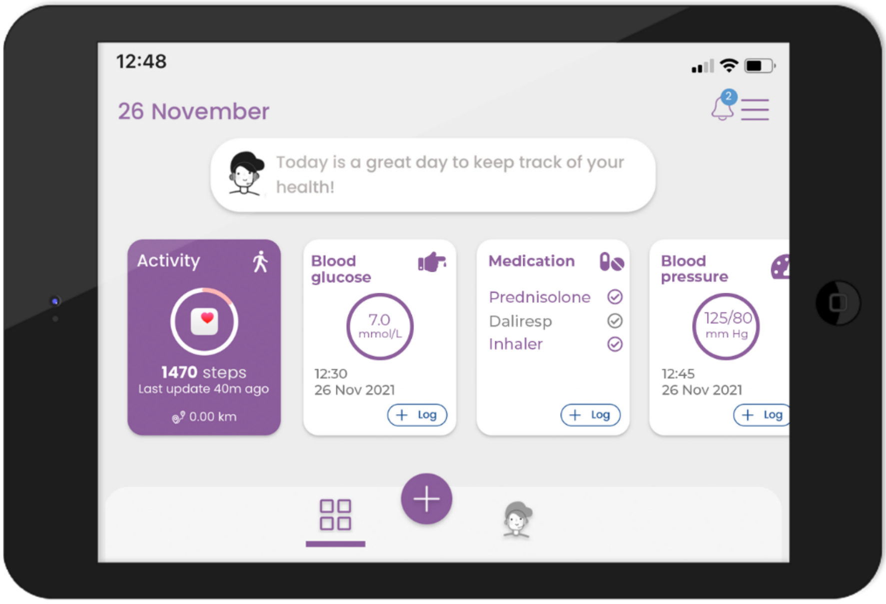
○ Three times a week

○ Everytime it is requested without limitations

○ Every day, family organization is my direct business

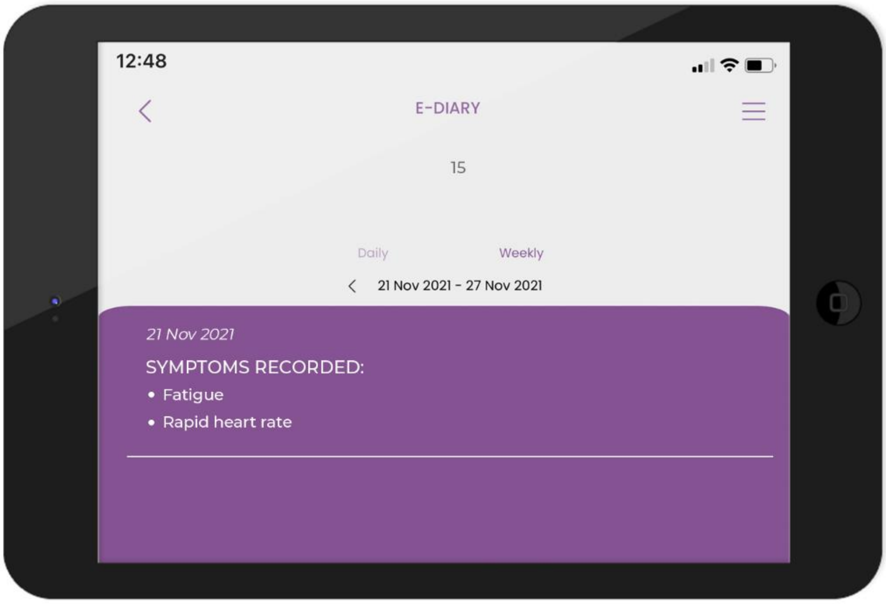
Figure 20: Patient: Baseline questionnaire

8.2 Data collection and data sharing



Today is a great day to keep track of your health!

Figure 21: Patient: Overview of activity, relevant parameters and medication



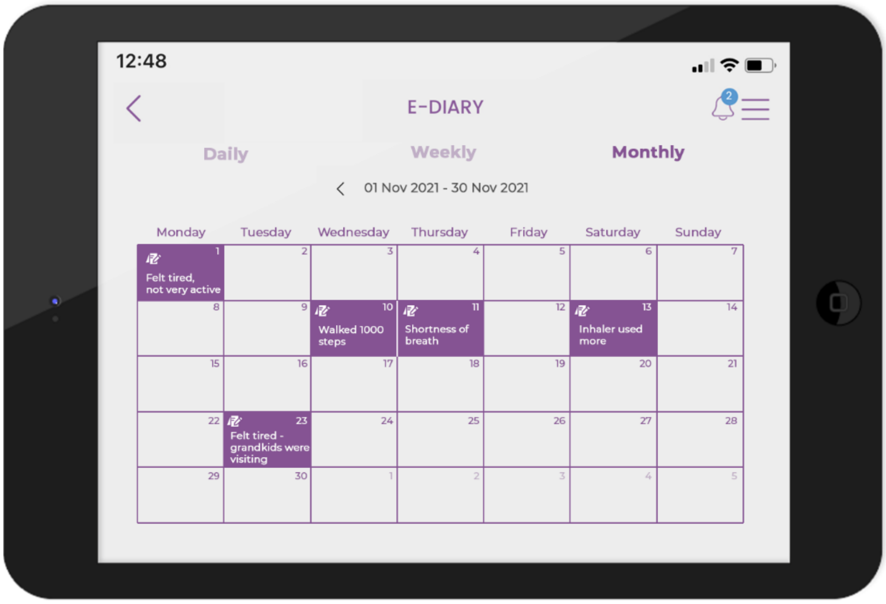
21 Nov 2021

SYMPTOMS RECORDED:
- Fatigue
- Rapid heart rate

Figure 22: Patient: Overview symptoms recorded

Figure 23: HCP dashboard: Overview of patient data

8.3 High risk exacerbation, data review, exacerbation reflection



1 Felt tired, not very active

10 Walked 1000 steps

11 Shortness of breath

13 Inhaler used more

23 Felt tired - grandkids were visiting

Figure 24: Patient: eDiary monthly overview

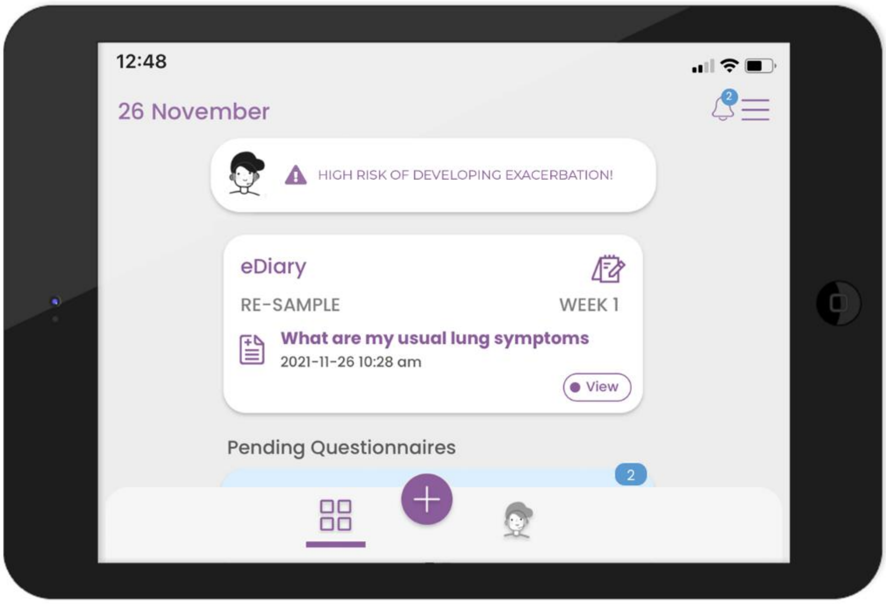
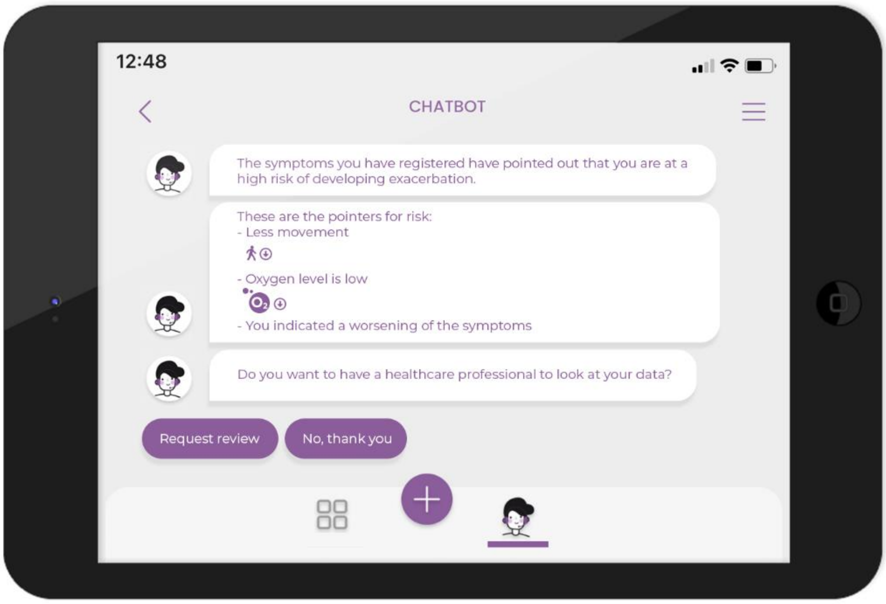


Figure 25: Patient: Homescreen with notification of high risk of developing an exacerbation

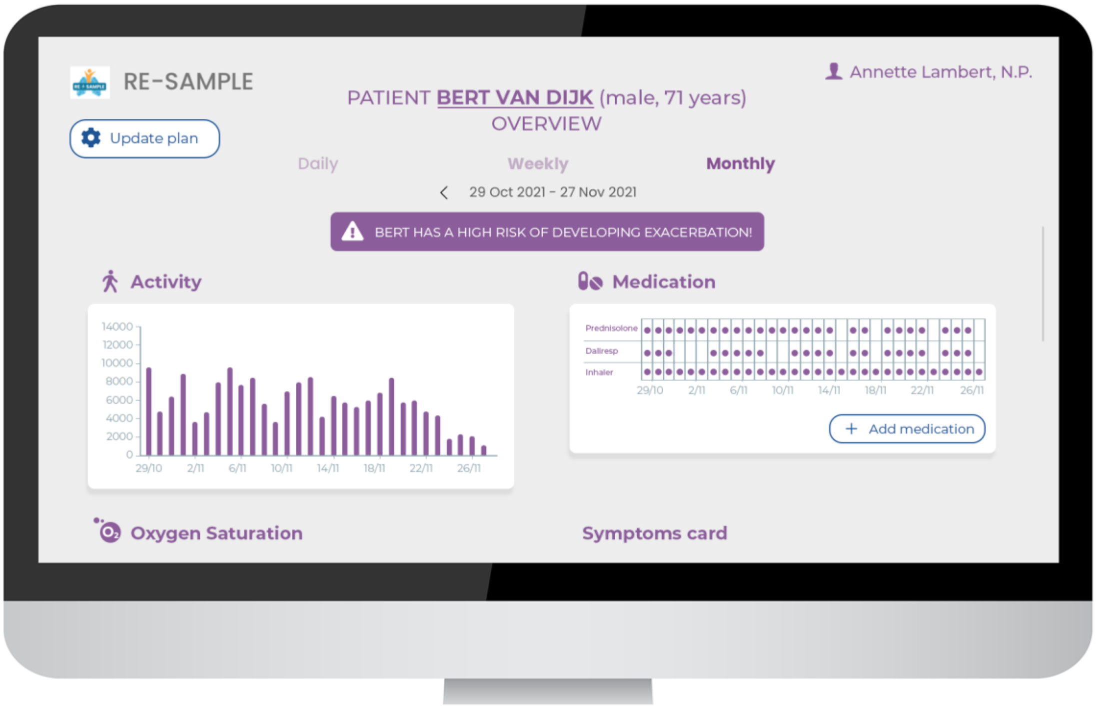


The symptoms you have registered have pointed out that you are at a high risk of developing exacerbation.

These are the pointers for risk:
- Less movement
- Oxygen level is low
- You indicated a worsening of the symptoms

Do you want to have a healthcare professional to look at your data?

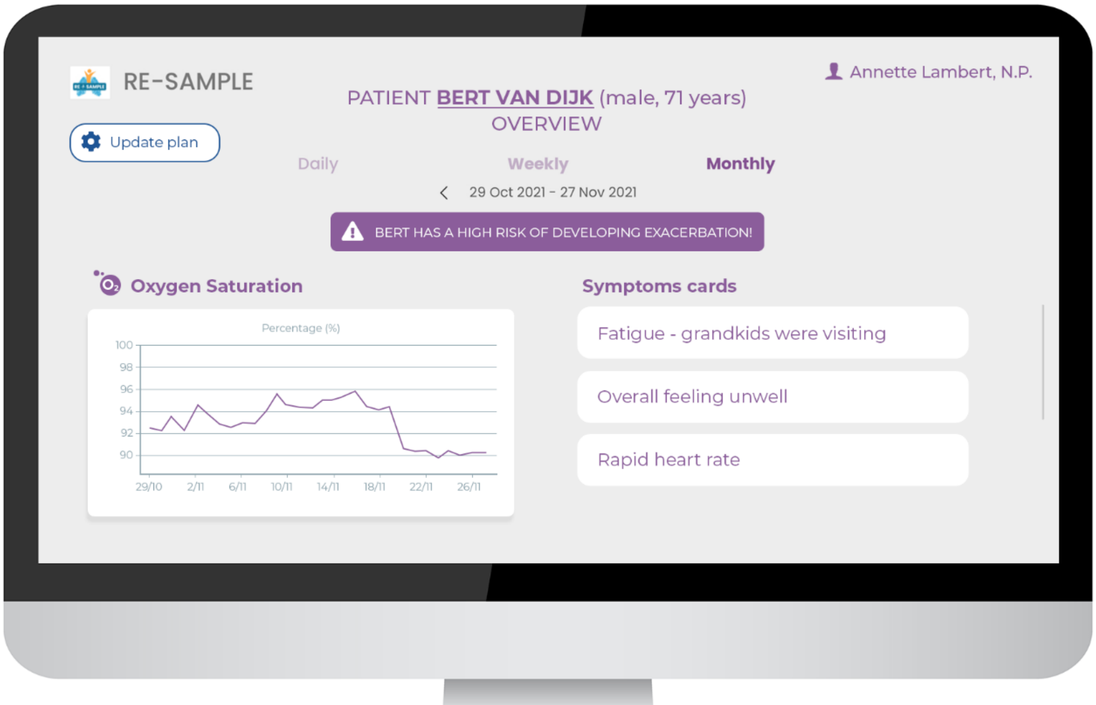
Figure 26: Patient: Dialogue about exacerbation risk alert and offering review request



PATIENT BERT VAN DIJK (male, 71 years)
OVERVIEW

BERT HAS A HIGH RISK OF DEVELOPING EXACERBATION!

Figure 27: HCP Dashboard: Overview patient activity and medication



PATIENT BERT VAN DIJK (male, 71 years)
OVERVIEW

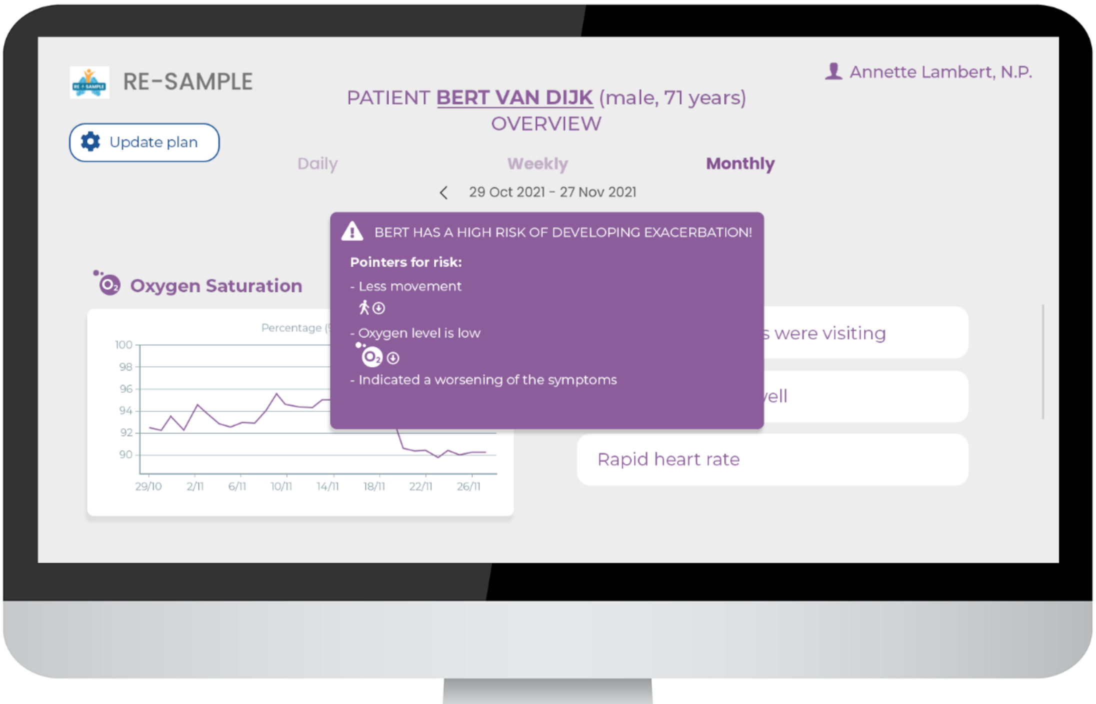
BERT HAS A HIGH RISK OF DEVELOPING EXACERBATION!

Fatigue - grandkids were visiting

Overall feeling unwell

Rapid heart rate

Figure 28: HCP Dashboard: Overview patient oxygen and symptom cards

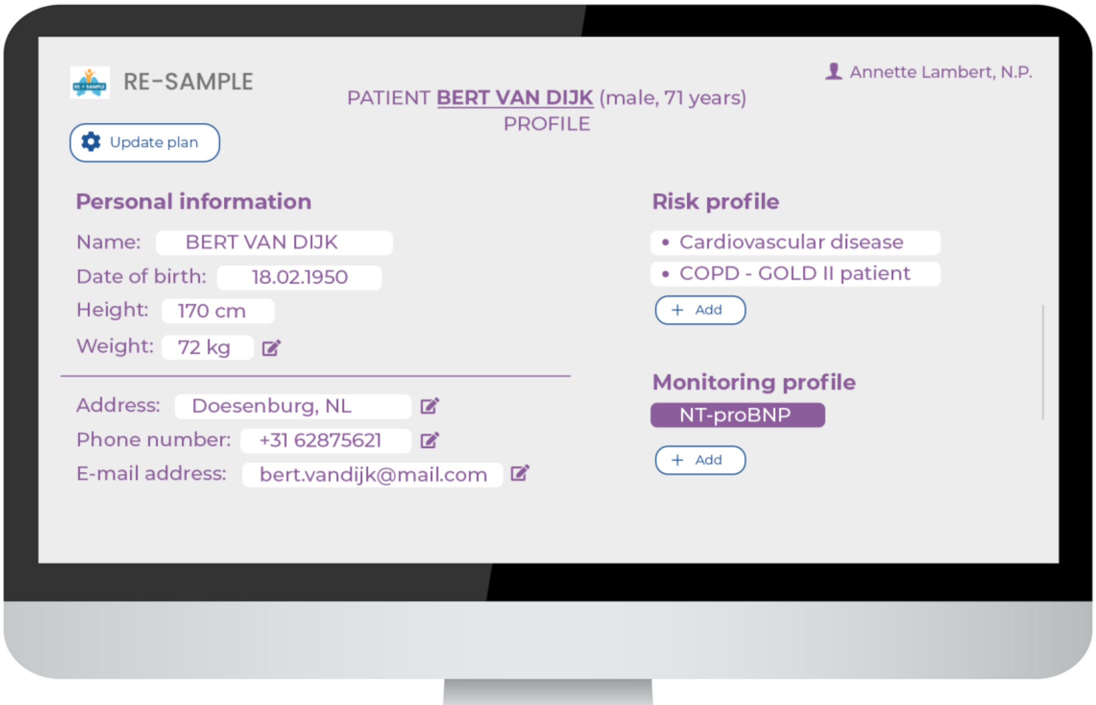


BERT HAS A HIGH RISK OF DEVELOPING EXACERBATION!

Pointers for risk:

- Less movement
- Oxygen level is low
- Indicated a worsening of the symptoms

Figure 29: HCP Dashboard: Overview patient with exacerbation alert



Personal information

Name: BERT VAN DIJK
Date of birth: 18.02.1950
Height: 170 cm
Weight: 72 kg

Address: Doesenburg, NL
Phone number: +31 62875621
E-mail address: bert.vandijk@mail.com

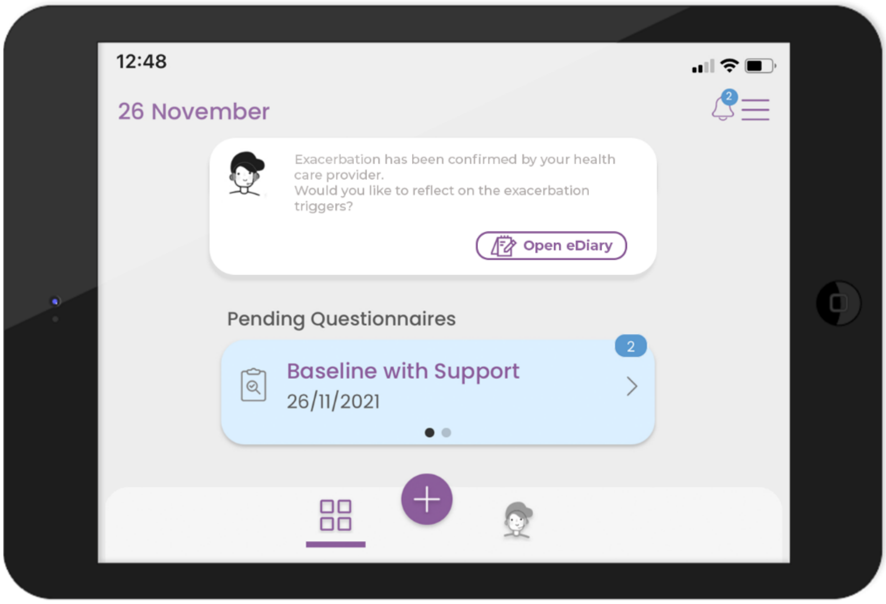
Risk profile

- Cardiovascular disease
- COPD - GOLD II patient

Monitoring profile

NT-proBNP

Figure 30: HCP Dashboard: Risk and monitoring profile



Exacerbation has been confirmed by your health care provider.
Would you like to reflect on the exacerbation triggers?

Figure 31: Patient: Invitation to reflect on triggers of recently confirmed exacerbation

8.4 Trends, motivational messages, tips for forming habits

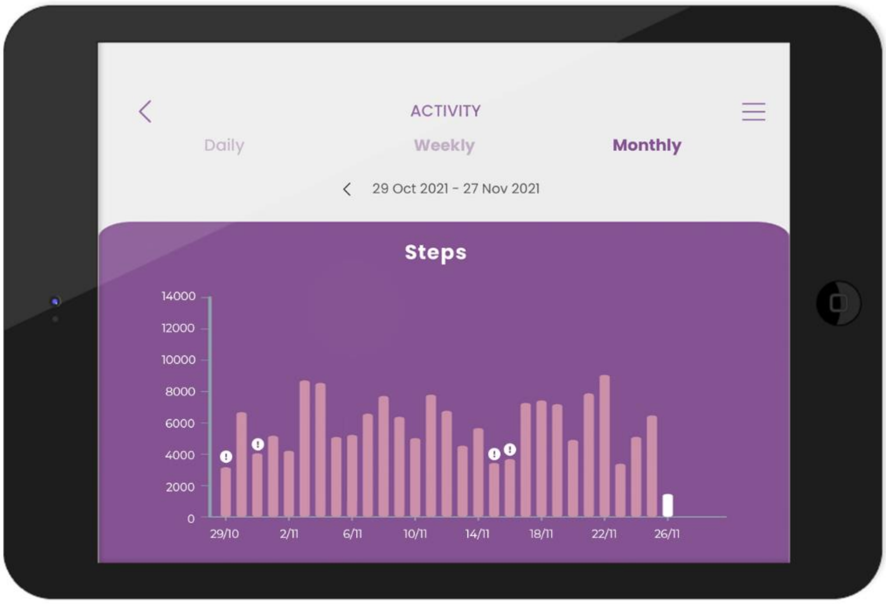


Figure 32: Patient: Trends - overview of steps

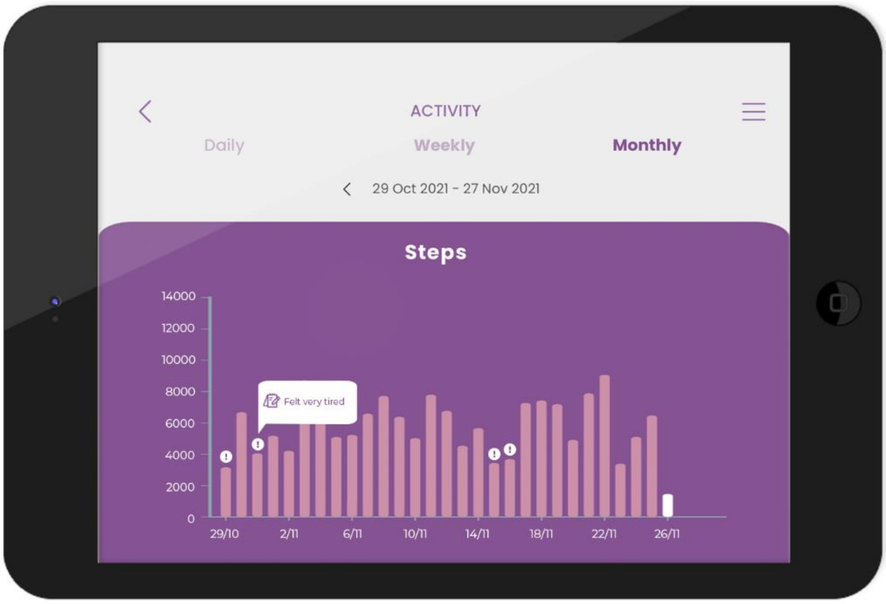
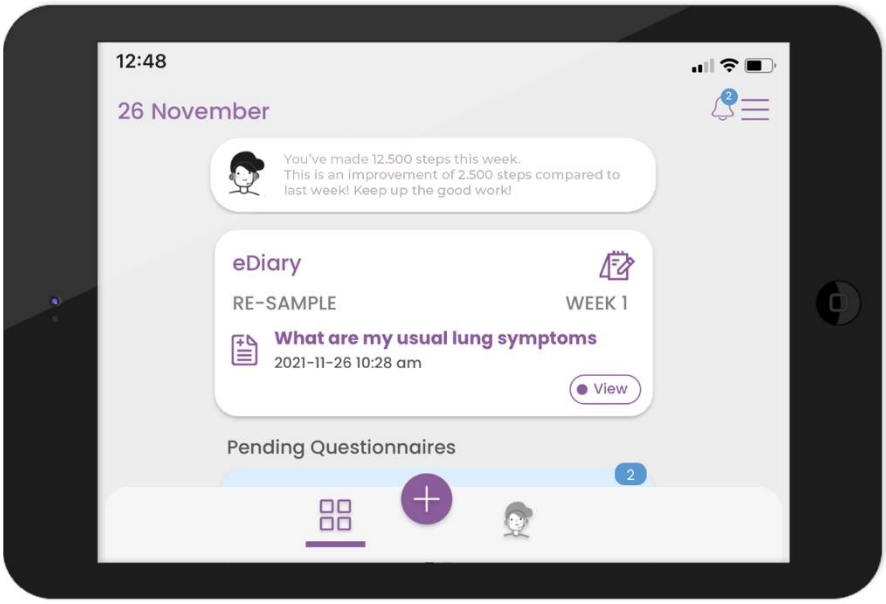


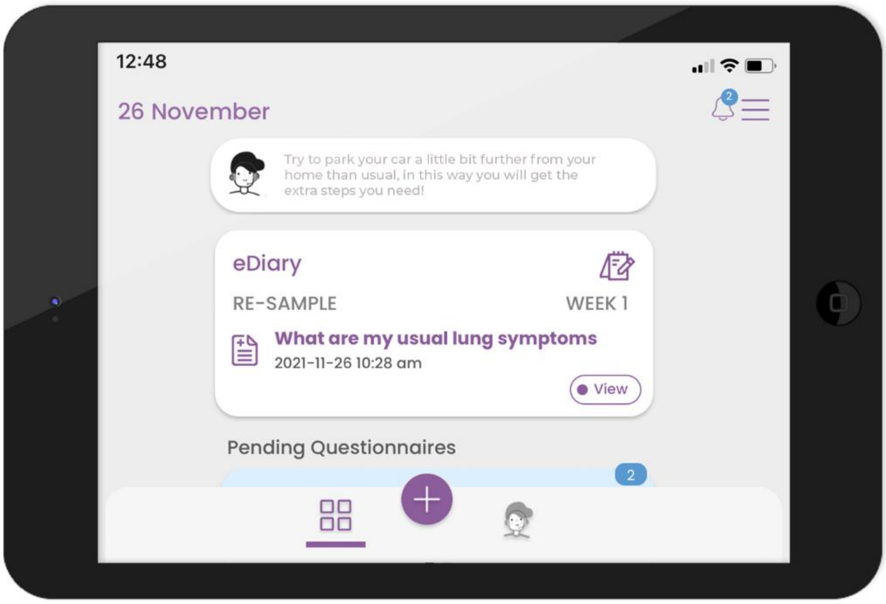
Figure 33: Patient: Trends - overview of steps with notes



You've made 12.500 steps this week.
This is an improvement of 2.500 steps compared to last week! Keep up the good work!

What are my usual lung symptoms
2021-11-26 10:28 am

Figure 34: Patient: Motivational message for having increased steps



12:48

26 November

Try to park your car a little bit further from your home than usual, in this way you will get the extra steps you need!

eDiary

RE-SAMPLE WEEK 1

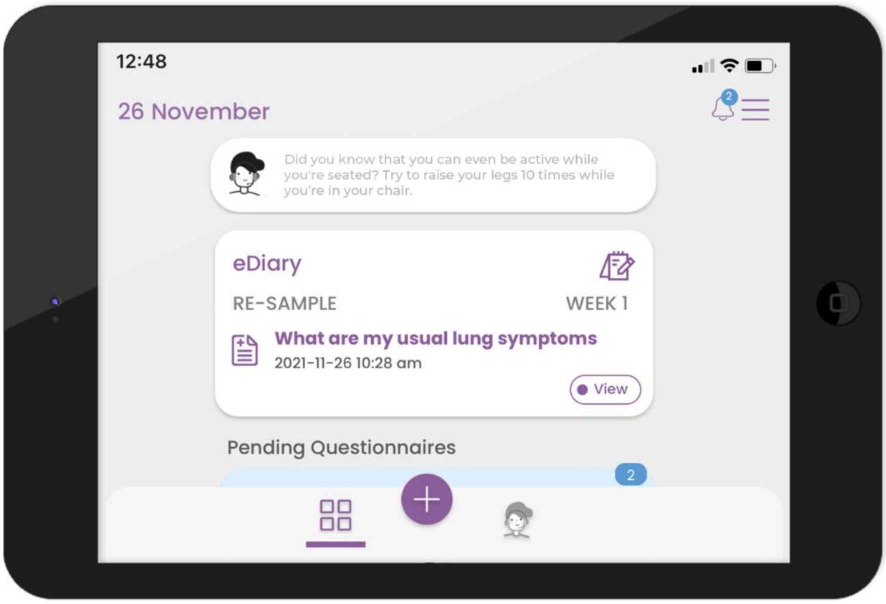
What are my usual lung symptoms

2021-11-26 10:28 am

● View

Pending Questionnaires

Figure 35: Patient: Tips to get extra steps when parking the car



12:48

26 November

Did you know that you can even be active while you're seated? Try to raise your legs 10 times while you're in your chair.

eDiary

RE-SAMPLE WEEK 1

What are my usual lung symptoms

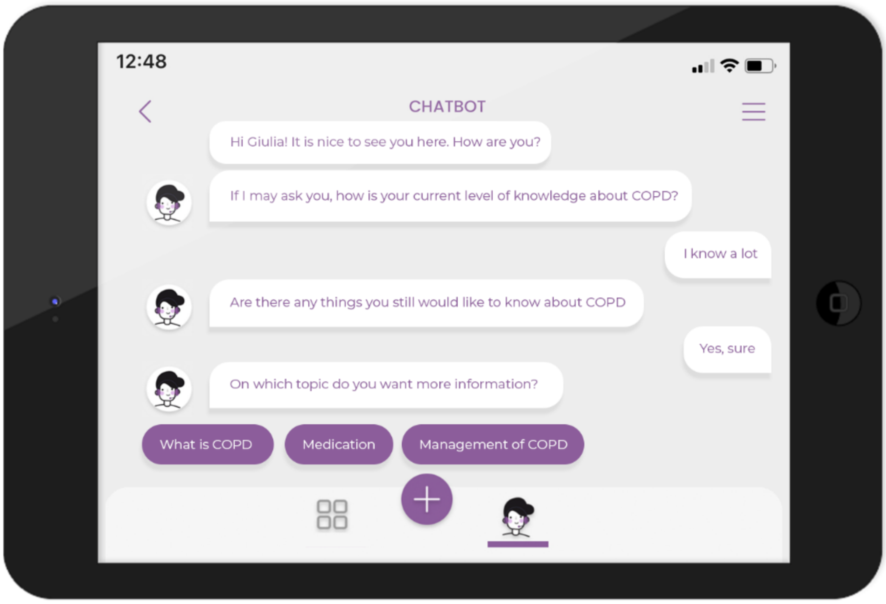
2021-11-26 10:28 am

● View

Pending Questionnaires

Figure 36: Patient: Tips to be active while seated

8.5 Coaching



Hi Giulia! It is nice to see you here. How are you?

If I may ask you, how is your current level of knowledge about COPD?

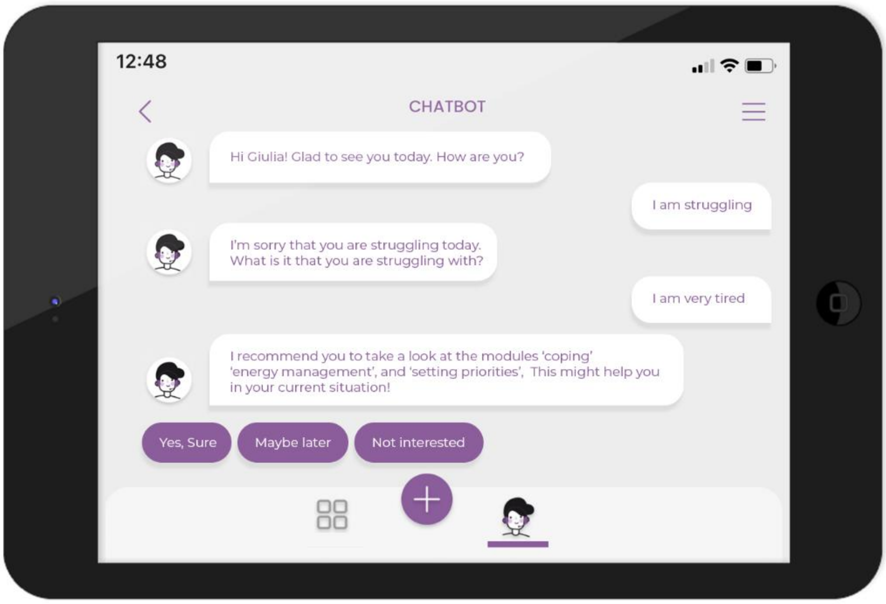
I know a lot

Are there any things you still would like to know about COPD

Yes, sure

On which topic do you want more information?

Figure 37: Patient: Dialogue providing information about coaching options



Hi Giulia! Glad to see you today. How are you?

I am struggling

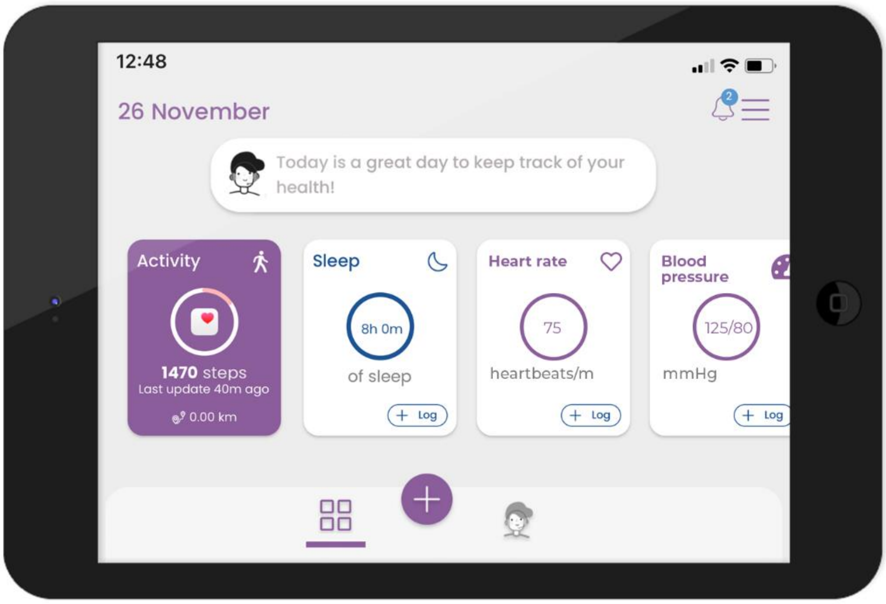
I'm sorry that you are struggling today.
What is it that you are struggling with?

I am very tired

I recommend you to take a look at the modules 'coping' 'energy management', and 'setting priorities', This might help you in your current situation!

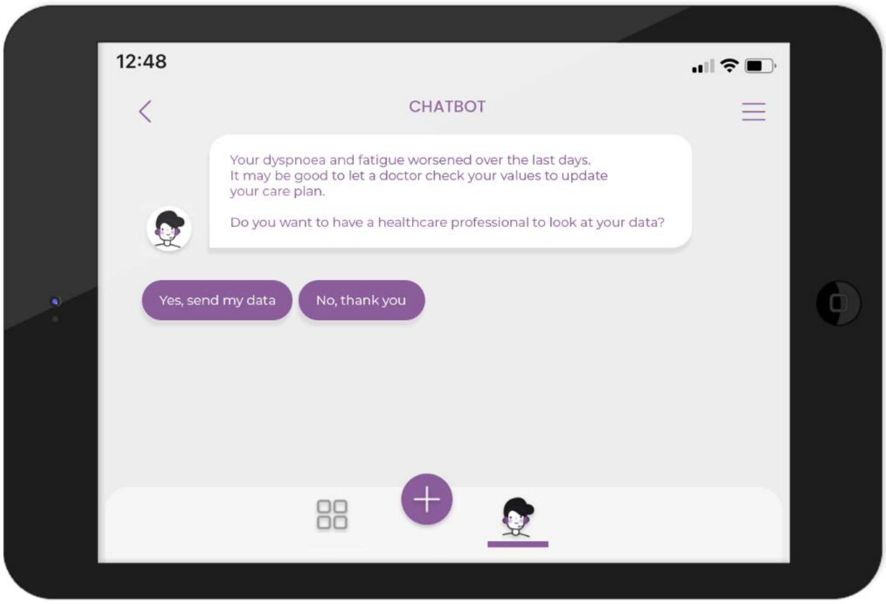
Figure 38: Patient: Dialogue suggesting specific coaching modules

8.6 Shared-decision making



Today is a great day to keep track of your health!

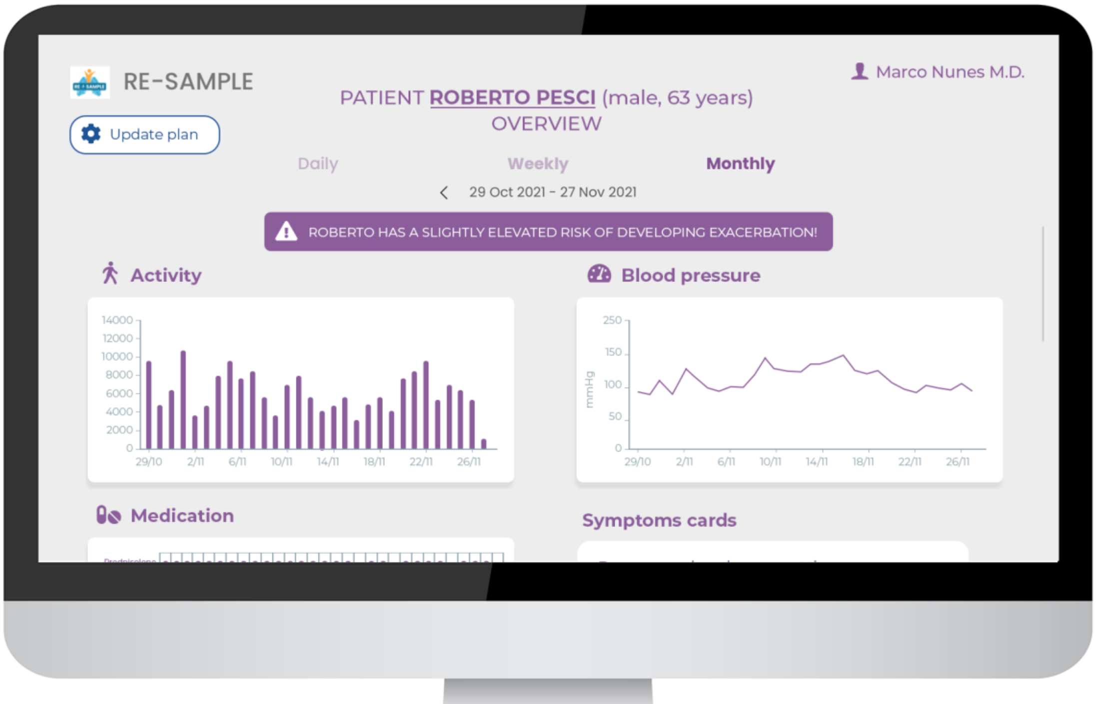
Figure 39: Patient: Overview with activity and relevant parameters



Your dyspnoea and fatigue worsened over the last days.
It may be good to let a doctor check your values to update your care plan.

Do you want to have a healthcare professional to look at your data?

Figure 40: Patient: Dialogue that symptoms are worsened and suggestion of data review by HCP

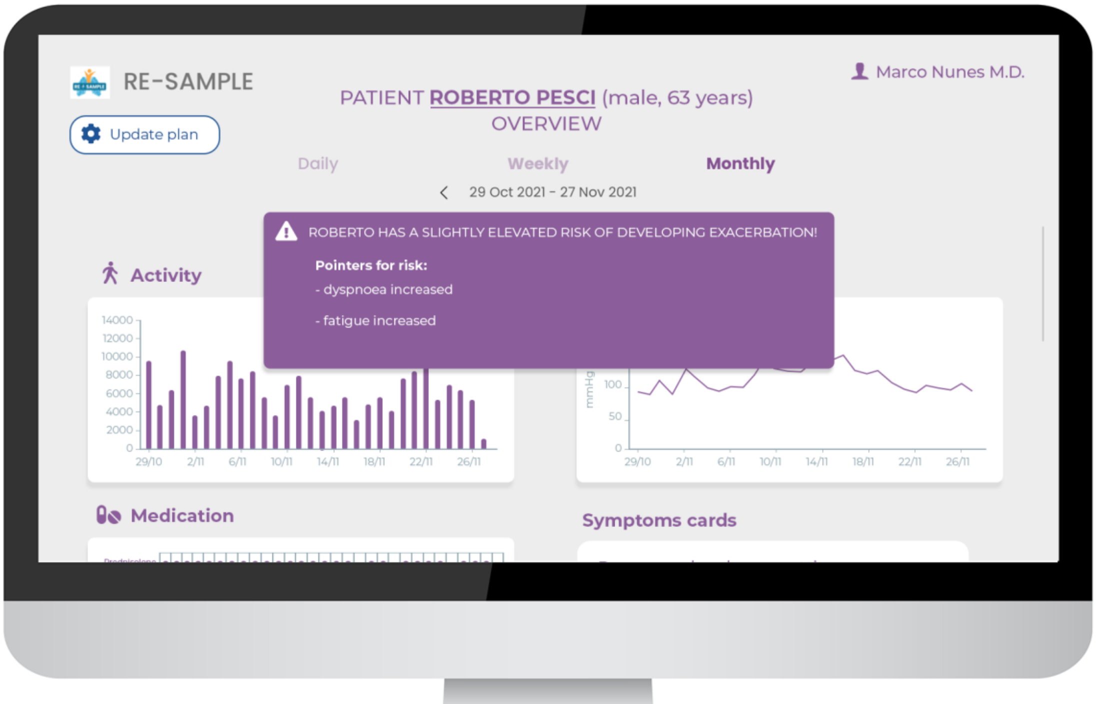


PATIENT **ROBERTO PESCI** (male, 63 years)
OVERVIEW

29 Oct 2021 - 27 Nov 2021

ROBERTO HAS A SLIGHTLY ELEVATED RISK OF DEVELOPING EXACERBATION!

Figure 41: HCP Dashboard: Patient overview with alert



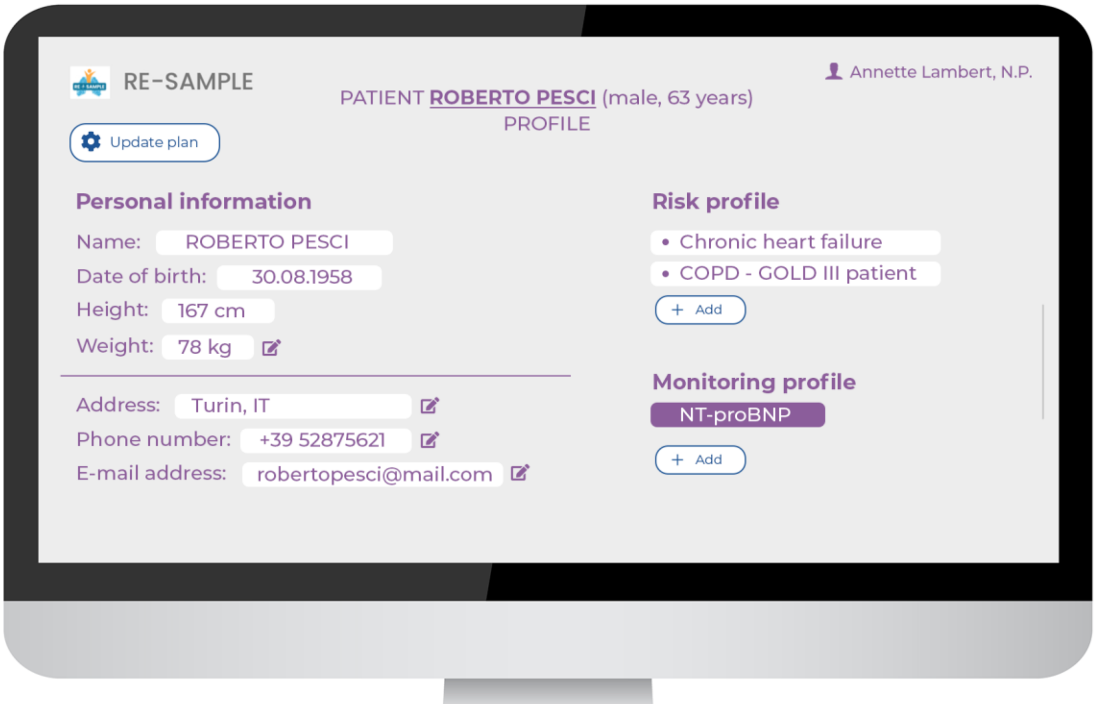
PATIENT **ROBERTO PESCI** (male, 63 years)
OVERVIEW

29 Oct 2021 - 27 Nov 2021

ROBERTO HAS A SLIGHTLY ELEVATED RISK OF DEVELOPING EXACERBATION!

Pointers for risk:
- dyspnoea increased
- fatigue increased

Figure 42: HCP Dashboard: Patient overview with alert and pointers for risk



PATIENT **ROBERTO PESCI** (male, 63 years)
PROFILE

Personal information

Name: ROBERTO PESCI
Date of birth: 30.08.1958
Height: 167 cm
Weight: 78 kg

Address: Turin, IT
Phone number: +39 52875621
E-mail address: robertopesci@mail.com

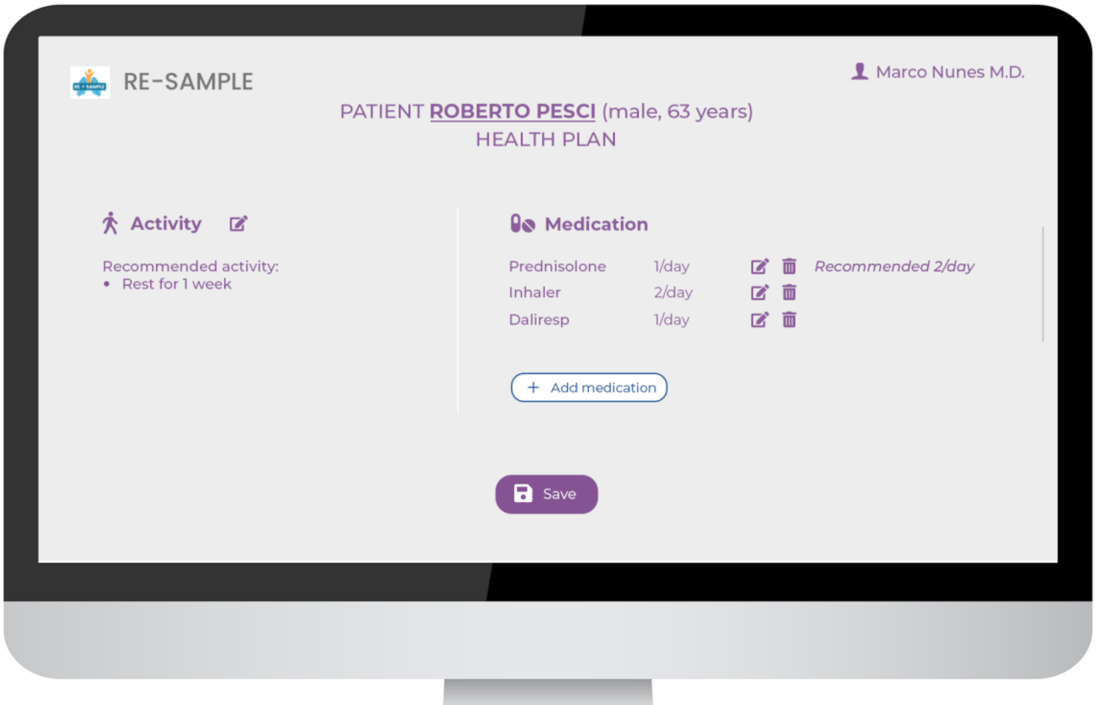
Risk profile

- Chronic heart failure
- COPD - GOLD III patient

Monitoring profile

NT-proBNP

Figure 43: HCP Dashboard: Patient risk and monitoring profile



PATIENT **ROBERTO PESCI** (male, 63 years)
HEALTH PLAN

Activity

Recommended activity:
- Rest for 1 week

Medication

Prednisolone	1/day	*Recommended 2/day*
Inhaler	2/day	
Daliresp	1/day	

Figure 44: HCP Dashboard: Decision support to update medication plan

8.7 Peer-to-peer support

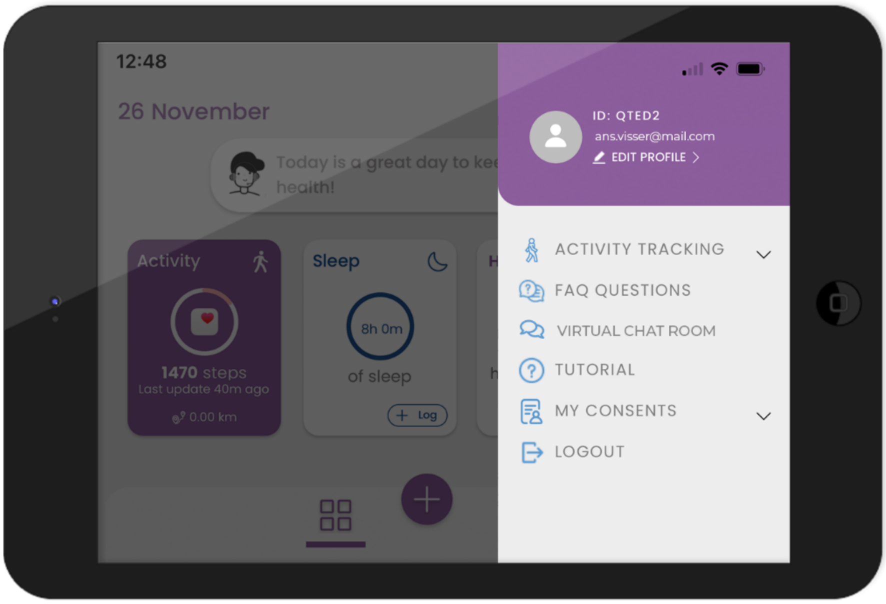
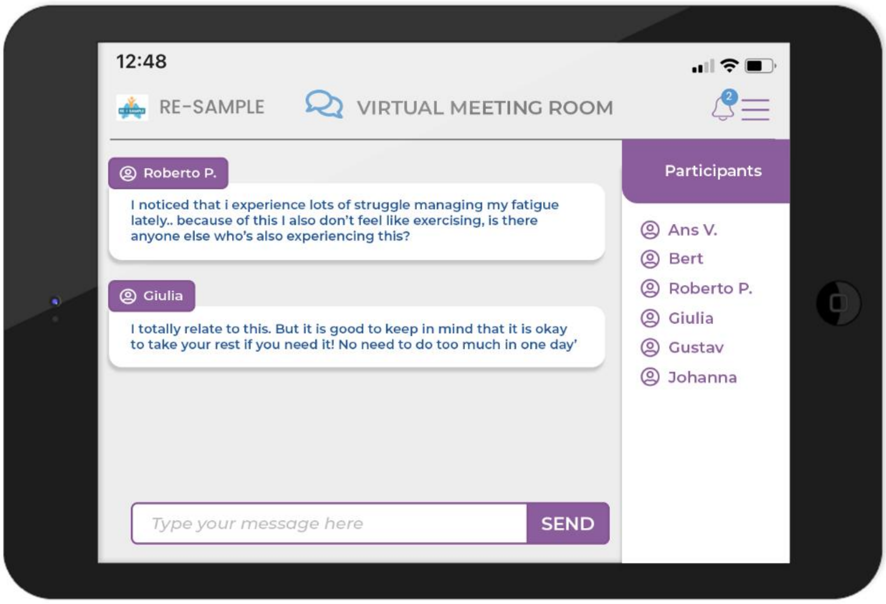


Figure 45: Patient: Virtual chat room



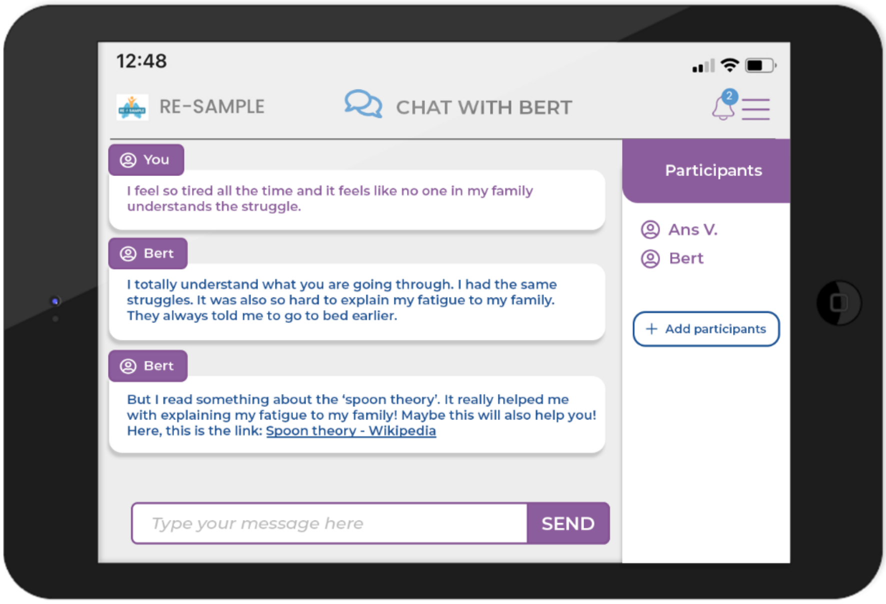
Roberto P.

I noticed that i experience lots of struggle managing my fatigue lately.. because of this I also don't feel like exercising, is there anyone else who's also experiencing this?

Giulia

I totally relate to this. But it is good to keep in mind that it is okay to take your rest if you need it! No need to do too much in one day'

Figure 46: Patient: Chat in the group



You

I feel so tired all the time and it feels like no one in my family understands the struggle.

Bert

I totally understand what you are going through. I had the same struggles. It was also so hard to explain my fatigue to my family. They always told me to go to bed earlier.

Bert

But I read something about the 'spoon theory'. It really helped me with explaining my fatigue to my family! Maybe this will also help you! Here, this is the link: Spoon theory - Wikipedia

Figure 47: Patient: Chat between two persons

9. End-user walkthroughs

The aim of the end-user walkthrough is to gather information from the target group regarding their impressions, opinions, and acceptance of the eHealth technology in early stages of the development. This section presents the results of the end-user walkthrough with patients and HCPs. The results are presented based on the scenarios that were used in the end-user walkthroughs, which are described in section 6 with the accompanying prototypes from section 8.

9.1 End-user walkthroughs with patients

The walkthroughs were conducted with patients in-person using the personas, scenarios, and prototypes previously developed (see description of the method in section 3.3.3). As described in detail in section 4, the end-user walkthroughs with patients were carried out in The Netherlands and Italy between December 2021 and March 2022 with N=10 patients in both countries. Due to COVID-19 measures at the time, no end-user walkthroughs with patients in Estonia could be carried out.

9.1.1 The Netherlands

Scenario 1: "Getting started with the companion"
First Impressions: Opinions regarding the first impressions of this scenario differed. Most participants found these screens unclear, and words used like 'baseline' were not understood*: "I don't find this very readable because here is 'baseline with support' but then what?"* [EEW5], and *"Yes, quite unclear. This is not... There is no way to work with this. 'Baseline with support', no idea what to imagine"* [EEW7]. However, this participant could see the utility of the wireframe which showed one question of the baseline questionnaire: *"Such a question in itself, that makes sense in itself. Because you want to know from someone whether they are doing certain activities. Well, then I would formulate the question very differently, for example: to what extent are you involved in the needs of an organization of your family"*. Other participants revealed no strong positive or negative first impression. They described what they could see on the wireframes instead.

Understanding of features: As also became clear during the first impressions, the majority of the participants did not understand certain things on the wireframes. Especially, regarding some English words like 'baseline' or difficult Dutch wording in general. *"Well, I don't know how you pronounce it; baseline or baseline. . . Yes, where does that even start? And then an electronic diary so I see, RE-SAMPLE yes. I don't really know what to do with that"* [EEW9]. The same participant [EEW9] also mentioned that there should be room for the positive activities of the day and not only focus on everything that was negative: "*Maybe there was a very happy phone call in the morning, someone arrived with flowers, someone has asked her* [the persona] *to come outside or to come and drink a cup of coffee with the neighbours. . . No, not just negative. Because that makes you very lonely if you stay in that*". One participant [EEW7] mentioned that even with the difficult words in the screen, it would still be doable for him/her but too difficult for the persona: *"I would know my own way around. But that Johanna certainly not. No . . . this is too difficult for her"* [EEW7]. Besides the understanding of features, questions were also asked to uncover what and how participants would change in the wireframes instead. Answers revealed that adding rewards, adding a female coach, and more information were things that should be added to these screens: *"Yes maybe, I don't know, some people like some kind of reward or something: 'Oh look, great that you're participating'. Something like that I guess"* [EEW5], and *"Then I would put a female here. Because now it is just a male. A female. . . there are some people who are like fussy about it"* [EEW3], and *"Maybe she* [the persona] *should just get some examples about what she needs to think about of that she you could do*" [EEW9].

Acceptance: Although there were overall negative comments regarding the screens, participants were ambivalent regarding the acceptance and usefulness of the features on the wireframes. Results regarding acceptance for the persona revealed that some find it useful, while others mentioned the persona itself not to be ready to change: *"Not for her... she is not really motivated to go along with change"* [EEW1], *"I think you deal with the situation a little more actively or consciously"* [EEW5]. This participant also mentioned that they do not want to be busy with this every day: *"No, not every day. . . then it's going to be* *a lifestyle I guess"*. Opinions regarding their own future use were also divided: *"Well, not* [useful] *at the moment because I just do things that I still can do"* [EEW3], and *"I would also find that useful. . . But in general, I think it is useful, but there need to change a lot in means of language"* [EEW7].

Scenario 2: "Choosing data collection and sharing"
First impressions: First impressions regarding the second scenario where slightly more positive: *"I think* [it is] *good. . . also for the walking"* [EEW2], and *"This is easy language"* [EEW6]. One participant [EEW8] mentioned that these wireframes could also cause some stress: *"On the one hand I would say, I think it's good, but on the other hand, at least for me, it can make me restless. . . Because you see this every day and then you think uh, if that is higher than what did I do, what is wrong? Those are things that work very quickly for me . . . But on the other hand, I think that this can of course reassure you that your blood sugars and blood pressure and so on, that all that is in order. That you are in a good line. So of course, there are two sides to that"* [EEW8]. This participant mentioned it to be more calming for her to see her results once a month or once a week.

Understanding of features: Two participants [EEW2/EEW6] mentioned to understand everything on the wireframes, and therefore would not change anything. Two other participants [EEW8/EEW10] explicitly mentioned to not understand certain things on the wireframes. These concerned not knowing how parameters where measured and not understanding parameters used for diabetes since this participant does not have this disease.

When asking about possible additions to the screens, two participants [EEW4/EEW10] mentioned it to be a good thing to add a feature that will motivate people: *"I think maybe there should be at the top of the screen something of 'don't give up'. . . and if there might be one screen of 'don't give up' or 'go for it' 'think about your kids' or something like that, that might be a boost"* [EEW10], and *"Yes, I think there needs to be an app added that motivates him to be a bit more active"* [EEW4]. One participant [EEW8] mentioned that the app should not force people to do something: *"If this* [the number of steps] *is an amount they impose on you, then I would hate that"*. However, this participant also mentioned it to be difficult since otherwise people would do nothing or too little.

Acceptance: Results were ambivalent regarding the acceptance. Two participants [EEW10/EEW6] explicitly stated these features would not to be useful for them. Reasons for this were that they do not use medication themselves or are still too active and thus do not need more help. One participant [EEW7] mentioned this to be useful for the persona: *"Well then, maybe this is something that serves as a pressure for him* [the persona] *to keep going. That he thinks 'hey, I did that thing well and that other one actually not so good, so I have to improve that'"*. One participant considered the data overview to be useful but that this could also cause that he/she wants to do more which may lead to doing too much: *"But I want more and that would be very difficult for me. Because I know myself, I want more"* [EEW2].

Scenario 3: "Coaching"
First impressions: First impressions regarding this scenario were positive: *"Yes, I think this is very good because I notice myself that you often get very little information about it* [COPD]. *Then, you have been to such a doctor and then there is such a booklet of the COPD and then you know that you are missing some alveoli, and one has 75%* [lung capacity] *and the other has 70% and it has 30%. But beyond that, what the possibilities are, you almost never see that. And what you say now, 'do some sport' or 'go swimming'. Those things, that is almost nowhere to be found* [EEW 4]. However, there were some words in English, and these should be translated to Dutch: *"Here, they speak again in English. So, I think you should not do that. Because a lot of people complain about 'why does everything always have to be in English'"* [EEW6].

Understanding of features: The majority of the participants understood the wireframes. Only some textual unclarities were mentioned. One participant [EEW8] did not understand what was meant with the word *'management'*, another participant [EEW6] did not understand what was meant with the feature *'eDiary'*. Despite that the majority understood the wireframes, some participants still suggested several changes to the wireframes. These changes where adding a warning, talking with a peer, and change the formulation of the questions asked by the coach: *"Actually, there should be a thing on that app that signals that you are tired and that it* [a warning] *immediately comes out"* [EEW8], *"I think she* [the persona] *can talk better* *with people who also have COPD in her circle of friends. Then she sits on the same denominator, on the equal level"* [EEW6], and *"That at least the coach asks, 'Why were you tired?' and not immediately bring up reasons like 'Were you tired because you had this or that?' No, just 'Why were you tired?' So that she herself has to give a concrete answer and not just answers a multiple-choice question. Because with a multiple-choice question, you are like 'Oh, I am saying this.' While it may not be like that at all."* [EEW6]. One participant was not sure if giving an advice was enough to actually motivate people and that there should be a follow-up, especially if an advice is given that does not fit with the capabilities of the person: *"Look, they can also tell me you have to run a kilometre. Then I say: I can't do that. If I have to run 25 meters, it's already done. But then I think, I know that about myself. An advice is never a bad thing, [but it's also about] the follow-up. Do you do something with it or not. If the coach says to me 'You have to run 10 kilometres' and I run 100 meters, an attempt has been made."* [EEW10].

Acceptance: Results regarding the acceptance of these features were divided. One participant [EEW6] considered it as less useful and would prefer group support: *"I really like that they* [healthcare workers] *all offer like 'we want to guide you' and such, but I think if you come into a group where people have the same symptoms, that it works better".* However, there were some participants who found these features indeed useful and important for them: *"I think this page* [screen with dialogue suggesting specific coaching modules, Figure 38] *is a very important page"* [EEW7], and *"If something would be in it to motivate me then. I would also like that very much myself"* [EEW 4].
Remarkedly, answers differed regarding the usefulness for the persona Giulia: *"It could be* [useful]. *But I have the feeling that she, that she does not come up with the idea to take action herself. But for Giulia this tip is of course, if she does something with it, that is good"* [EEW8], and *"Yes,* [it is useful] *because she is willing to do something, and I think she's willing to try it"* [EEW6].

Scenario 4: "Shared decision making"
First impressions: Answers regarding the first impressions revealed that the majority was slightly positive: *"This is clear. This is positive"* [EEW5], and *"I think that makes sense. . . Well, then I would not do it on a daily basis. Because one moment of recording is not that much. But you could, for example, if it stays that way for a week or two weeks that you are sleep deprived, or your heart rate is too high, or your blood pressure is too high, that you then have the opportunity to show your healthcare provider your data*" [EEW7]. One participant [EEW1] stated the texts on the screens to be contradictory: *"Well I find it a little bit contradictory this. . . The values of November 28, and then it says above 'Today is a great day to keep track of your health'. I find that contradictory because the data is already there".*

Understanding of features: Again, answers regarding the understanding of features were diverse. Some participants [EEW1/EEW3] stated to understand everything. However, later in the conversation it appeared that not everything was clear: *"Dyspnoea? I have never heard of that. Dyspnoea. So, then I would say yes? That? I wouldn't know what that means"* [EEW1]. Both [EEW1] and [EEW7] also mentioned it to be unclear what was meant with *'plus log'*. For one participant [EEW7] it was also not clear if the measures on the screens where from a daily registration or not. Despite the fact that participants mentioned some features or text to be unclear, only two additions and changes were mentioned. One participant suggested to add a warning if a person is too active: *"If he has agreed with his doctor, for example, that he can walk for fifteen minutes a day and he goes for example 20 minutes of walking. That* [the app] *then detects that and an alarm goes off"* [EEW3]. Another participant suggested to reduce the frequency of measuring: *"*[Only measure] *at the end of the week or so. But I really don't have to do that every day"* [EEW9].

Acceptance: Two participants [EEW3/EEW5] explicitly mentioned these features to be useful for him/her: *"Yes this would be very helpful for me. Because basically everything is projected on your smartwatch at once*" [EEW3]. Two participants [EEW3/EEW7] mentioned it to be useful for the persona Roberto. One participant [EEW1] considered the features on the app as unnecessary because everything is already visible on the display of their smartwatch: *"But I think you are already reading this on your* [smartwatch] *in fact. Because, honestly, it's quicker to look on the* [smartwatch] *than opening an app."* One participant [EEW5] mentioned it to be useful when patients are actually motivated to do so: *"You have to be motivated yourself or. It is all voluntary, isn't it. . . and you have to want it. . . It must add something for you, I think. . . and that's why you may need to convince people".*

Scenario 5: "Early contact exacerbation, additional tests, exacerbation story"

First impressions: Results regarding this scenario revealed overall positive first impressions, especially regarding the eDiary overview that was shown in the prototype: *"Yes, I think that's a very nice one. Then you can go into one, that is like an agenda, then you can see at a glance 'Hey, what happened?' For example, you could even add the visits you had, you name it. And then you can see if your values of anything or that has gone up or dropped or whatever. That is, I think, a very important thing. I think that is a very nice one*" [EEW3], and *"You get a nice overview of things that can play a role. That's handy"* [EEW7]. Only one participant [EEW9] was somewhat sceptic about the wireframe: *"So my first impression is that you have to have a lot of self-discipline. And that you have to know the pitfalls that actually make you sicker. So, let's say, oxygen too low so take oxygen or go outside for a while"* [EEW9].

Understanding of features: Several participants [EEW1/EEW5/EEW7] did not understand everything on the wireframes. Textual difficulties like medical terms and English words were not understood by these participants. Others stated to understand the wireframes: *"It's clear to me. But I would also like it, I believe, such an electronic diary. But I do not want to be confronted with my deficits every time"* [EEW9], and *"Yes, this is a clear overview"* [EEW 5]. Only two participants [EEW5/EEW7] made suggestions for possible additions. These additions were that daily entries should not be mandatory, and that there should be a clear distinction made between symptoms from comorbidities: *"Because of course, it's not every day that something needs to happen. . . I do not know if that should be such an obligation."* [EEW5], and *"But then again; if you have such a seizure, is it his COPD or is that his heart? Unless you make it clear 'from your heart problems, you can get these kinds of symptoms. In COPD, the symptoms are ... And then you could also work with two different colours. . . If there is one, a symptom that clearly has to do with his heart, for example, you colour it red and something that has to do with COPD colour it yellow or whatever."* [EEW7].

Acceptance: The majority of the participants stated to find these features useful for both themselves and the persona: *"I would like such an overview"* [EEW7], and *"For Bert, yes, because Bert wants to know everything. So, he doesn't know what it* [symptoms] *is because he also has that underlying disease of the heart or that COPD and you can do that* [finding out] *by filling this in, you can rule that out that it was not his heart but the COPD"* [EEW3]. Only one participant [EEW1] did not know whether this was useful for him/her: *"I do not actually know. I'm also the type of person if I don't trust something I'll raise the alarm."*

Scenario 6: "Trends and progress"

First impressions: Results regarding the wireframes for this scenario revealed positive first impressions: *"This can be very stimulating to continue* [EEW04], **"***Well, that is something that would encourage me too... That I can indeed see and that I am then triggered to do more and more. So, this, this does make me happy if that would be in that app"* [EEW8], and **"***This* [wireframe] *is better to motivate someone to continue"* [EEW10].

Understanding of features: Only one participant [EEW8] explicitly mentioned to not understand what is meant with 'usual lung symptoms': *"Well I repeatedly see there 'what are my usual lung symptoms' and then I think yes. Do you have to fill that in yourself? So, I don't understand that*". Although most participants were positive about the screens, they still had some additions. These were using rewards, motivate people, adding oxygen saturation: *"The motivating yes. I think very important. And especially if you yourself, are not so confident yourself, then it is always nice that someone says: 'You are doing well'* [EEW4], and *"Look and if then possibly the oxygen if that could still be added. Then she* [the persona] *might also be able to see how far she can go"* [EEW10].

Acceptance: Results regarding the acceptance of these wireframes were diverse. Three participants stated this to not be useful for themselves: *"No, not at the moment. I'm too tired"* [EEW2], *"I wouldn't do it"* [collect activity data] [EEW10], and *"You have to do it* [being active] *yourself"* [EEW6]. The other participants found it indeed useful for themselves and the persona: *"Yes I would* [use it], *if that was the case with me, this* [the trends] *would come in there, then I would also like that"* [EEW4], and *"Yes, she* [the persona] *can learn from that the reasons why she can make fewer steps the one time compared to the other time"* [EEW8].

Scenario 7: "Peer-to-peer contact"

First impressions: All participants were positive about the idea of peer-to-peer contact. Participants mentioned it to be really good to talk with someone who experiences the same: *"That are all people who have COPD, so they understand each other"* [EEW2], and *"But in itself, there are people who will benefit a lot from that"* [EEW3]. Only two participants [EEW8/EEW1] stated to not have interest in contact with other peers but agreed that it could be very useful for others: *"I think that's very personal. I myself would not have much need for it. But I think there is a very large group that benefits a lot from that"* [EEW8] and *"I do not really have much with that. But what I say, I think that is also because I just accepted it and that me, my family who understands me and who knows what is going on in me and that they also say 'no, you don't have to help just take it easy'"* [EEW1].

Understanding of features: There were some features that were not understood by the participants. Two participants had some questions regarding how other people could join the chat: "*But this is my app, but now I see other people on it. How is that possible? Have they been watching Bert and me? Because did I do that myself or? I don't know."* [EEW6], and *"Can you add yourself to it* [a chat] *like that? How do you get to that? But I see, there are two people chatting with each other. I think that is also something for me, so I want to get involved, I also want to participate. Will I see this* [the chat between other people] *in the first place and if so, how can I add myself as a participant?* [EEW7]. This participant also stated a possible solution for that: "*You may come into contact with a state of privacy. But you could, for example, add an option of that you would like to participate, do those people who are participating in it now object? If people say no, or don't object that you will be added"*. One participant had a question whether someone could call her and would suggest the participants to have a choice whether or not to share their phone number: *"But there is a phone call behind it and I do not really understand that very well. Well, if I do not give my phone number, they cannot call me either. So, I think that possibility is also there. Well, I would hope there's a choice in that."* [EEW8]. One participant had trouble with using difficult and English words: *"You know what I'm having some trouble with? With certain words, such as virtual. That I think maybe there are people who don't know so well what virtual is."* [EEW8]. One participant [EEW5] mentioned it to be useful to add a feature where you can see that someone has read your message.

Acceptance: Most people found the wireframes useful and would also use it in the future. Reasons for this was with this contact you can identify with each other problems: *"Look, you bring up things up which you would not do when being just by yourself. And with someone else you can explain that better and the feeling 'he has the same or he has it a little less', that is a relieve."* [EEW4].

9.1.2 Italy

Scenario 1: "Getting started with the companion"

First Impressions: The options in this scenario are roughly similar. Almost all participants had an overall positive impression of this wireframe, believing it to be simple to use and clear. Some believed that even if the person was not very tech-savvy he could benefit from this app. Others, on the other hand, believed that even being simple to use, they would not have had the perseverance to use it as it was not very stimulating. *"I would have no problems to manage this eDiary but I am not really interested in using it."* [GEM014] *"I don't think it is difficult to use it. These are simple questions. Maybe it's a repetitive act and it can be boring."* [GEM007]

Understanding of features: As already emerged from the first impressions, almost all participants understood the characteristics of wireframes. They found it difficult to imagine using it. *"It is very simple and intuitive. The closed answer allows you to make the answer faster."* [GEM006] Only one participant would change the way the questions were asked, he thought it was easier to ask direct questions. *"I would ask the question directly."* [GEM023]. The remaining participants would not have changed anything, leaving the wireframe as it is.

Acceptance: The results regarding acceptance showed that most patients despite not having any difficulty using it would not be willing to use it daily. One of the participants also specifically said that the main problem would be the absence of the human factor that only the direct relationship with your doctor can guarantee. *"I appreciate artificial intelligence and how it can continuously record data, but human* *relationship is missing."* [GEM007]. Another participant said he could use it if it weren't for the fact that the questions are too specific and he would not want to answer these questions on a daily basis. *"I would like to use it but I would prefer the questions to be less specific."* [GEM004] Participant GEM006 argued that while he understands the need to monitor symptoms on a daily basis, he would not be willing to respond every day, with the consequent need to think about his health problems every day. *"I understand the importance of monitoring the patient's symptoms, perhaps every day can be tiring in the long run."* [GEM006]

Scenario 2: "Choosing data collection and sharing"
First impressions: The impressions regarding the second scenario were very different. All patients found no difficulty in understanding it. Many participants identified with the person and felt it was useful to use this approach in the management of the pathology, but always with the help of their pulmonologist. *"I partially identify with the patient: because I prefer too to do nothing and take some rest when I have an exacerbation, but unlike the person, I am very regular in my checks with the pulmonologist."* [GEM024]

Understanding of features: All participants stated that they had no difficulty understanding how the various wireframes work. *"I think it is very easy to understand and use."* [GEM010] One patient explicitly stated that it would be useful for him to monitor his values such as those of oxygen saturation, so as to have all his health data in one place to be able to consult them quickly. *"It would be more useful if I could enter data on my blood oxygenation."* [GEM024]

Acceptance: All participants claim that they would use it, but always expressing some doubt. For example, one patient stated that he would be willing to use it, but in case someone was willing to explain the operation and follow him in his management: *"I would use it if it was easily explained to me, I find it useful."* [GEM024] Another participant, however, stated that despite being willing to use it daily he would still prefer to be followed by his doctor, not fully trusting such a dehumanized approach [GEM010]. Despite this, the collection and storage of your health data you believe could be a useful tool to use for your doctor in the management of your pathology. *"I think could be useful, but I would prefer to go to the doctor in person. However, it could be an important tool to provide more clinical data to help my own doctor to check for the best treatment and management."* [GEM010].

Scenario 3: "Coaching"
First impressions: The impressions regarding this scenario were ambivalent. While they all understood how it works, some felt that the use of a coach did not suit them. For example, one patient considered it to redundant, as even by simply looking for information on the web one could manage one's disease independently. *"If you are a person looking for some information, you do not need a virtual coach, you just need internet or a very available and reachable doctor (just like mine)."* [GEM024]

Understanding of features: All patients understood wireframe. Some patients were enthusiastic in the prospect of being able to monitor their state of health with eDiary. *"The eDiary could help patient to keep more attention to daily activities."* [GEM010]

Acceptance: As for the acceptance some patients would gladly use it, as they believe that it would be particularly useful in the management of their health. *"This feature would be incredibly important and useful."* [GEM024]. Other participants instead believed that they would never use it, even though they were aware that the virtual coach could be useful in the organization of their activities, so as to ensure proper management of their health. *"The chat with virtual coach could be useful to remind which type of activities patients can do, but I am not interested in use it."* [GEM010]

Scenario 4: "Shared decision making"
First impressions: First impressions were positive: *"I understand how it works…"* [GEM023]. *"…I think is easy to use."* [GEM014]
Understanding of features: Most participants stated that they understood the wireframe: *"I think it's all useful and easy to understand. I wouldn't change anything."* [GEM003]; *"I think it is very easy to use. This technology seems more useful to me because through an algorithm it warns me of a change."* [GEM006] One person has openly said that it can be difficult to understand these values without the help of a doctor:

"I think it is very easy to understand the use, instead it is less easy to understand how to interpret the data without the help of a doctor" [GEM011]

Acceptance: When asking participants acceptance of the screen, the answers are different. Two participants absolutely agreed to use this technology: *"I would agree to use the data taken from the app to modulate my physical activity and modify my therapy"* [GEM006]; *"It looks well done to me and I wouldn't change a thing"* [GEM023]. Two participants wanted this data to be better communicated to the physician: *"It could be used for quicker contact with your doctor."* [GEM001]; *"I would use it. I think it could be better if there was an alarm about critical symptoms which alerts the doctor."* [GEM004] Other participants showed partial interest: *"I agree with using the data to monitor my health, but it doesn't seem like a very advanced technology to me if I have to enter this data myself."* [GEM007]; *"I think is useful but there are other devices with same functions as smartwatch or smartphone"* [GEM014].

Scenario 5: "Early contact exacerbation, additional tests, exacerbation story"
First impressions: The impressions were positive*: "It is a good idea to encourage patient to focus attention on his daily activities."* [GEM010]. *"It seems to me very useful about using a symptom diary that can help prevent exacerbations"* [GEM024]. One patients could relate with the persona Bert, the other however not: *"I identify with patient, because sometimes I also underestimate the first symptoms of an exacerbation."* [GEM024]; *"I don't feel I am represented by him at all. He more often should consult his pulmonologist"* [GEM010]

Understanding of features: The two patients stated to understand the wireframe: *"The eDiary could help patient to keep more attention to daily activities."* [GEM010]; *"This screen is extremely clear and I don't think anything can be added"* [GEM024].

Acceptance: One participant was not thrilled to use it: *"I would not use it because if needed, I would directly go to my personal doctor."* [GEM010]. The other participant was really positive: *"This feature would be great! Having a symptom diary would really make a difference for my life."* [GEM024] As can be seen here, the patient who could relate to the persona and his problems, is also enthusiastic about the particular feature that tries to solve that problem.

Scenario 6: "Trends and progress"
First impressions: First impressions were positive: *"It helps to realize how much has been achieved over time and how much has improved. It can be a good start to stimulate the person to stay active."* [GEM001]. *"I understand the wireframe. It's optimal to have a weekly and monthly overview"* [GEM004]. *"I think is very useful. Framework is well-done. I appreciate column graphs, I do not prefer the curve ones."* [GEM014].

Understanding of features: All the participants showed they understood the wireframe but one thought it wasn't something new: *"It's a simple graphic found on all smartwatches."* [GEM007]. Other participants had some advice: *"It would be useful if in addition to the progress in the kilometres travelled there were also signals concerning the frequency or concerning sleep."* [GEM004] *"It would be helpful if there were any alarms telling me that what I am doing is not good enough for me."* [GEM011]. *"It could be implemented using it also for oxygen saturation"* [GEM001]

Acceptance: Most of the participants showed interest and usefulness in this function: *"It is an important incentive to stay in business. I would also use it to track how many days per month I have been more tired than usual."* [GEM006]; *"I would feel safer if I could use this device, I would live much better. I think these supports can help."* [GEM003]. One person was not totally convinced: *"It is very useful but it is related to the type of person. It can be an incentive to those who do not do regular physical activity."* [GEM007]
Scenario 7: "Peer-to-peer contact"

First impressions: Most of participants were positive about the idea: "*I think it is very useful. I also feel little understood by the people I know."* [GEM003] *"I think that talk with other people affect by my same disease is a very important tool. It can be helpful to overcome my limitations"* [GEM014]. *"Some kind of anonymous alcoholics. A constructive confrontation in order to help and be helped. Maybe a guide or a* *moderator inside the chat could help."* [GEM001] *"It seems to me the correct use of a social"* [GEM007]. One participant wasn't very impressed: *"I don't think is useful talking with others who have the same condition. I'd rather prefer talking with health professionals only."* [GEM024]; another one expressed that he only wanted to speak to doctors: *"I would like to share data only with healthcare professionals"* [GEM004]. *"I would like to help people in need. I would also use it to organize meetings."* [GEM006]

Understanding of features: All the participants showed no difficulties in understanding the wireframe: *"It's simple like an ordinary chat."* [GEM011]. *"It seems very clear to me, it shouldn't cause problems…."* [GEM023]. However, someone wanted more information: *"How many words can I put in the screen?"* [GEM014]. *"How many people can I add to the chat?"* [GEM006]. *"How do I search for people I want to chat with?"* [GEM007].

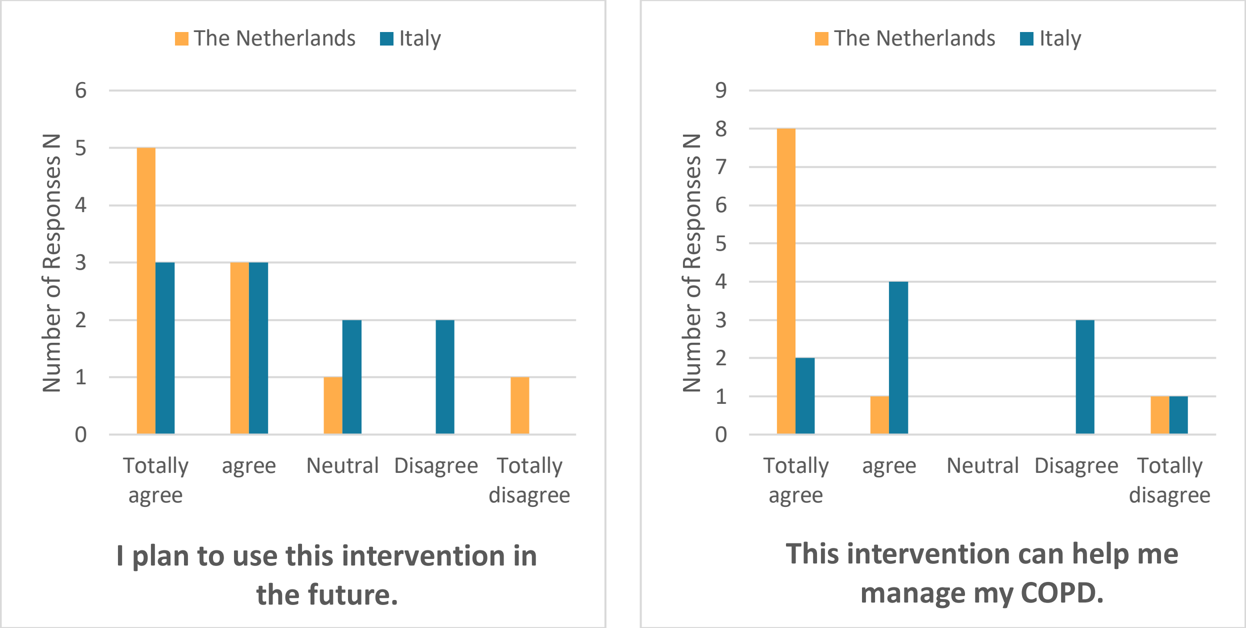
Acceptance: Several participants were positive about the use of the chat: *"It is useful for me to compare myself with other patients but they must not take the place of the doctor"* [GEM011]; *"I will use it for sure; it could be used to organize in-person meetings, although I also appreciate virtual meetings"* [GEM006]. *"I will use the chat as psychological support, a space to let off steam and ask for help"* [GEM001]. *"I would use it for sure. I think that share advices and impression make me stronger to overcome my limitations."* [GEM014]. Another participant was positive and also made a suggestion: *"I would use it. It seems to me a social network dedicated to COPD. I would like people to be divided by characteristics in order to be able to empathize better."* [GEM007] One person was rather neutral in their assessment: *"The important thing is not to overdo it. If everything is done in moderation, that's fine."* [GEM003]. One participant would not use the chat, because it was a cause for anxiety: *"I think that for someone it could be useful, I would not do it to avoid creating anxiety."* [GEM023]. The others expressed concerns of sharing data with people who were not doctors: *"I would not use it. It could be advantageous for people who need to talk about their condition, It is an outpouring. I would not use it, for my condition I think that talk with other people is not beneficial, they are not doctors"* [GEM010]; *"For someone it might be useful, I'm happy to share my data only with healthcare professionals*." [GEM024].

9.1.3 Overall Rating (NL, IT)

All participants were also asked to fill in a short survey at the end of the end-user walkthrough. This survey consisted of six short statements regarding the overall idea of the technology which could be rated on a 5-point Likert scale (1=Totally agree, to 5= Totally disagree), as seen in Table 7. Detailed results on each statement are shown in the graphs below. Both Italian and Dutch patients are overall positive about the intervention. Patients from Italy are slightly less positive regarding their future use plans to use it, that it can help managing their COPD, and being motivated to use the intervention. On average, results from The Netherlands are more positive on all statements.

Table 7: Overall rating by patient as part of the End-user Walkthrough

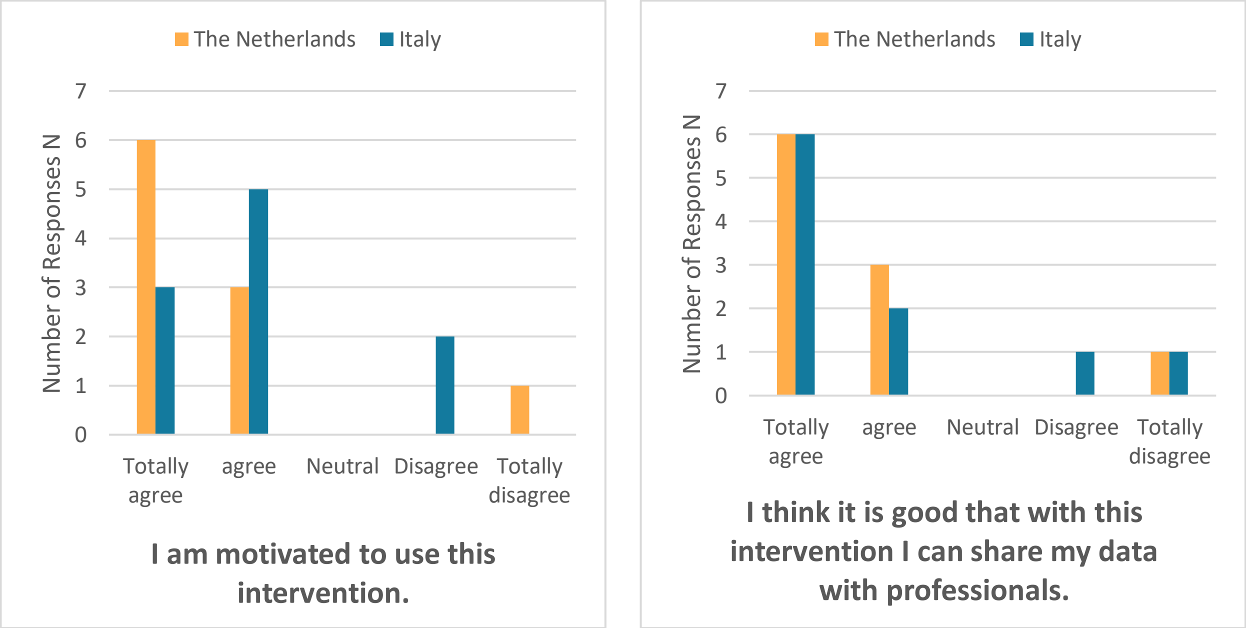
Statements	NL (N=10)	IT (N=10)
I plan to use this intervention in the future	M=1,9, SD=1,22	M=2,3 SD=1,10
This intervention can help me manage my COPD	M= 1,5, SD=1,20	M=2,7, SD=1,35
I am motivated to use this intervention	M=1,7, SD=1,19	M=2,1, SD=1,04
I think it is good that with this intervention I can share my data with professionals	M=1,7, SD=1,19	M=1,9, SD=1,37
My privacy is guaranteed when using this intervention	M=1,8, SD=1,17	M=1,9 SD=1,58
I have enough confidence in my own computers kills to start using this intervention	M=1,6, SD=,67	M=1,7, SD=1,27



I plan to use this intervention in the future.

This intervention can help me manage my COPD.

Figure 48: Detailed responses on future use and that intervention can help manage the COPD



I am motivated to use this intervention.

I think it is good that with this intervention I can share my data with professionals.

Figure 49: Detailed responses on motivation to use and data sharing with professionals

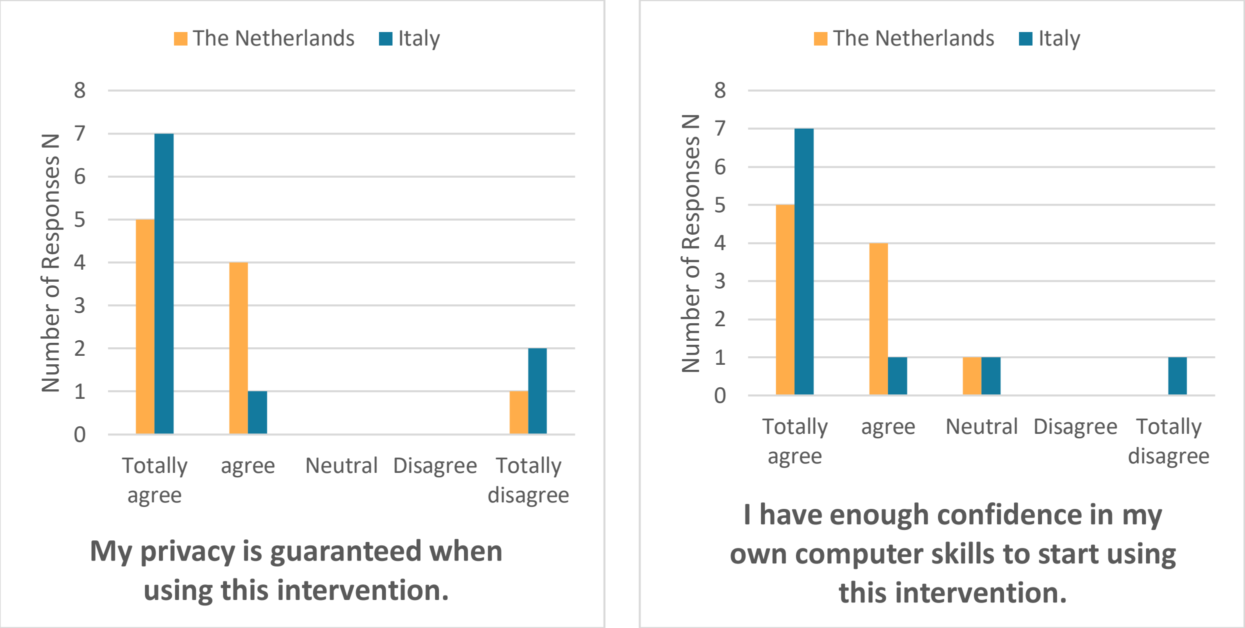


Figure 50: Detailed responses on privacy and confidence in their own skills

9.2 End-user walkthrough survey with healthcare professionals

The end-user walkthrough with HCPs was performed using online questionnaires which contained questions based on certain personas, scenarios, and prototypes (see description of the method in section 3.3.4). For these end-user walkthroughs, we focused on the scenarios that involved both patients and HCPs. The end-user walkthroughs with N=38 HCPs were carried out in all three countries between January and March 2022.

9.2.1 The Netherlands

Demographics

A total of 15 healthcare professionals from The Netherlands participated in the online questionnaire. 9 were female, 6 were male. The mean age was 50, with one participant not filling in their age. Professions ranged from psychiatrist (N=1), pulmonologist (N=5), pulmonologist in training (N=1), specialised nurse (N=3), cardiologist (N=1), and physiotherapist (N=5). The years of work experience in healthcare had a mean of 24,5 years, with one participant not filling in their years of work experience. The majority of participants (N=10) see patients with COPD daily, 2 weekly, one monthly, and 2 less than monthly. 14 participants stated to have experience with eHealth. Results towards the attitude towards eHealth revealed that 5 participants stated that eHealth can be useful at times, 5 find eHealth useful, 4 find it very useful, and responded in the free text comment that similar to online meetings, one misses the touch with the person you are communicating with.

Aksel Meyer: Choosing data collection and sharing

The first impressions regarding the wireframes were positive. Participants stated to find the wireframes ‘interesting’, and ‘clear’. They liked that the graphs in the frames were clear, the overview was not too busy, and that there is an overview over time. One participant stated to dislike the fact that the information is presented in three different plots as this would make it difficult to combine the information. Another participant stated that the wireframe was difficult to read. The information on the screen could not be zoomed in and the medication was not fully visible. Results regarding possible changes revealed that participants would like to have multiple parameters visible within one plot, and that the wireframe would be more workable if the information (e.g., activity, medication, glucose level) automatically appears on the screen. One participant stated that he/she would like to see a more incentive setup which he/she knows from her iPhone. Participants stated to understand all features presented on the screen. Different aspects were mentioned as most valuable. These aspects were: A clear overview, insight in medication and how many cures someone needs, insight into the prednisolone cures, and insight of the relation between the three (activity, medication, and blood glucose).

Despite the positive first impressions, the acceptance was not rated as positive. Participants were overall indecisive whether they found this technology useful or not. Some participants somewhat agreed with the statements that this technology: is useful, easy to use in daily practice, will positively influence the relation with patients, the privacy is assured, giving the right care will be more efficient, will positively influence care, and will create a better overview of patients.

Marco Nunes: Shared-decision making

First impressions for the scenario for Marco Nunes were ambivalent. The majority of the participants stated the following first impressions: ‘positive’, ‘clear layout’, and ‘uncluttered’. Others stated that it might be much work to fill in the information, that they cannot see why there is an increased risk of exacerbation, and question why there isn’t a component of heart failure. Results regarding likable features revealed that the simple layout, clear overview, clear graphs, and no difficult curves were most liked. Only one participant could not mention something he/she liked. Results regarding the disliked features revealed lots of different answers. These were: too many tabs that need to be open, the symptoms need to stand out more, data is spread in different screens, a lot of data is presented, and screens are incomplete. One participant questioned whether it was possible to zoom-in on the screens, and only one participant stated to have no opinions regarding this. Despite the many dislikes, participants did mention to like the design of the wireframes. They liked that it was clear, and that the use of colours was calm. Participants also mentioned to understand all features on the screen. Results regarding recommendations for change revealed several recommendations. They mentioned that the screens should be more pro-actively, the lung measures and saturation should be added, data should be integrated into one screen, data should be interpreted, the comorbidities, anamneses, and action plan should be added, and an exercise goal should be added so that the motivation increases. Participants also stated several things that they would like to see differently. They mentioned to like to have a summary of relevant data on one view, that it should be possible to convert the activity into METs (metabolic equivalent of task), an overview of physical activity and of the other disciplines should be added, as well as heart measures. When asking about which feature participants found most valuable, it became clear that the combination of the data in one view, the overview (of the care plan, physical activity, capacity), the activity, and weight were perceived as most valuable.

Opinions regarding the acceptance of the screens revealed that participants somewhat agreed or were indecisive about the statements that this technology: will positively influence the relationship with the patient, the right care will be more efficient, will positively influence the care of patients, and will lead to a better overview of patients. Two participants strongly agreed that this technology is useful, one participant strongly agreed that this technology is easy to use in daily practice, and one participant strongly agreed that the privacy of the patient is ensured.

Annette Lambert: Early contact exacerbations, additional tests, exacerbation story

First impressions for this scenario were again positive. Participants stated the wireframes to be ‘a clear overview’, ‘interesting’, ‘nice eHealth application’, ‘fine’, and ‘calm image but fragmented information’. Participants stated to like the clear overview, the fact that quickly a lot of information is presented, that it is clearly stated that patients are at risk of developing an exacerbation and also the reasons for the risk, and the fact that patients are monitored. When asking about the things that they dislike, only two participants stated something. One mentioned that a lot of information is presented on one screen. The other participants mentioned to dislike that there are multiple screens. There were also two specific recommendations for change mentioned. These were: Adding a photo of the patient so that you can directly know who it is, and presenting the information in one glance. This participant recommended to work for example with colours, and stated to use red for indicating a risk. All participants stated to understand each feature presented on the screen. Opinions regarding the most valuable feature were divided. One participant stated to find the symptom card most valuable, others found the activity, medication intake, saturation, or the risk signal and explanation why most valuable.

Opinions regarding the acceptance of the wireframes were diverse. The majority of participants expressed to be neutral, or to slightly agree with the statements regarding that the technology is: easy to use, the privacy of the patients is ensured, the right care will be more efficient, and this technology will give a better overview. One participant strongly agreed with the statement that this technology is useful. Another participant strongly agreed with the statement that this technology will positively influence the care of patients. Only one participant mentioned to strongly disagree with the statement that this technology will positively influence the relationship with their patients.

9.2.2 Italy

Demographics

A total of 12 healthcare professionals filled in the questionnaire. 9 were male, 3 were female. The mean age was 31. One participant did not fill in his/her age. Professions ranged from physician (N=6), pulmonologist (N=2), surgeon (N=2), nurse (N=1), and physician in specialized training (N=1). The mean of work experience in healthcare was 4.7 years. Most participants see their COPD patients daily (N=6), others (N=5) weekly, and one person did not give a clear answer. The majority of participants (N=9) had no experience with eHealth technology, three participants stated to have some experience. Results regarding the attitude towards eHealth revealed that the majority (N=8) thinks that eHealth is useful, N=3 think that eHealth can be useful at times, one participant stated eHealth to be very useful, and one participant stated another opinion. He/she stated that eHealth might be useful in the future but that now the target patients are not quite familiar with the technology.

Aksel Meyer: Choosing data collection and sharing

First impressions regarding the wireframe were overall positive. Participants stated the wireframes to be ‘great’, ‘useful’, and ‘excellent means to follow patients’. The clarity and completeness, the possibility to see trends, and the easiness of understanding the wireframes were mentioned as things that participants liked. Only one participant mentioned to dislike that the frames are monochromatic. Others could not state features they did not like. The design was described as ‘perfect’, ‘ok’, ‘simple and intuitive’, and ‘linear and intuitive’. Only two participants could mention something they would change. One participant mentioned to add a nutritional diary. Another participant mentioned to use different colours for various parameters, and to use the acronym COPD to be more understanding for the patient. All participants mentioned to understand all features. Results regarding most valuable features revealed that the charts, medication monitoring, and blood glucose synthetic parameter was mentioned as most valuable. When asking what participants would like to see differently, one participant recommended to make the symbols in the medication screens clearer, and another participant mentioned to add a food diary.

Results regarding the acceptance of the wireframes revealed that participants either somewhat or strongly agreed on the statements that using this technology: is useful, is easy to use in practice, giving the right care is more efficient, and will lead to a better overview of patients. Results regarding whether this technology will positively influence the relationship with the patient, the privacy of the patient is ensured, and the positive influence on patient care were diverse. Answers ranged from being indecisive to strongly agree.

Marco Nunes: Shared decision making

First impressions regarding the wireframes were again, overall positive. Participants found the frames clear, simple, essential, effective, and easily manageable. Participants mentioned to like that the wireframes are clear, simple, innovative, exciting, and useful for patients. Especially for the younger COPD patients it might be useful to introduce such a system. Despite positive impressions, there were still several things that were disliked by the participants. Participants mentioned that the compliance to this data collection method may be poor, the characters on the frames are too small, that there are multiple tabs for evaluations, and the values (e.g., for physical activity) should be specified. The design was perceived as simple to use, tidy, linear, and contain a good distribution of data at the interface. However, three participants proposed some changes. The first change mentioned was to simplify as much as possible, to allow an active and productive participation of the patient. Furthermore, there were some things that should be added: more info to the graphs, add adherence to the medication section, and also other activities that are not steps (e.g., swimming). Finally, it was mentioned that all data should be added in one tab. The tab should then include interactive tables and graphs, guidelines used to recommend therapeutic adaptations, and in-app messaging service for direct communication. All participants mentioned to understand everything on the wireframes. However, throughout further questioning, one participant mentioned to not understand the monitoring profile. Results regarding most valuable feature revealed diverse opinions. The risk chart, health plan and objectives, the overview of all parameters, saturation, symptom tracking, and adherence to therapy were mentioned as most valuable.

Results regarding the acceptance of the wireframes showed diverse opinions. Participants either somewhat agreed or strongly agreed with the statement that this technology is: useful, easy to use, and that it will result in a better overview. Participants ranged from indecisive to strongly agreeing to the statements that this technology: positively influences the relationship with the patient, the privacy is ensured, right care is more efficient, and will have a positive influence on patient's care.

Annette Lambert: Early contact exacerbations, additional tests, exacerbation story
First impressions regarding these wireframes were 'good'. One participant mentioned to like the excellent general overview of the symptoms and could not mention anything he/she did not like. Therefore, he/she could not mention anything to change about the wireframes. The design was perceived as 'quite intuitive'. All features on the wireframes were understood. The saturation and symptom chart were rated as most valuable.

Result regarding the acceptance showed that participants somewhat or strongly agreed with the statements that this technology is: useful, easy to use in practice, and that with using this technology the right care to the patients will be more efficient. Participants were indecisive regarding the positive influence on the relation with the patient, and whether the privacy is ensured. Finally, participants were either indecisive or somewhat agreed with the statements that this technology will positively influence the care of the patients, and that this technology will lead to a better overview of patients.

9.2.3 Estonia

Demographics
A total of 21 healthcare professionals from Estonia filled in the online questionnaire. One participant did not fill in their demographics. 15 were female, 5 were male. The mean age was 44, with two participants not filling in their age. Professions ranged from general practitioner (N=3), general practitioner in pulmonology (N=1), physician (N=5), nurse (N=7), pulmonologist (N=4), and physiotherapist (N=1). The years of work experience in healthcare had a mean of 21 years. The majority of participants (N=12) sees patients with COPD daily, N=7 weekly, and one participant monthly. 7 participants stated to have no experience with eHealth, 10 participants have experience with eHealth, and 3 are not sure if they have any experience. Results regarding the attitude towards eHealth revealed that 8 participants stated that eHealth can be useful at times, 5 find eHealth useful, and 7 find it very useful.

Aksel Meyer: Choosing data collection and sharing
The majority of the participants had positive first impressions. They mentioned the following words: 'interesting', 'positive', overview', 'like', 'good', and 'great'. Two participants were a bit more negative: one participant mentioned the image to be too small, and one mentioned that diabetes is poorly controlled. Participants mentioned to like several things: that all information is in one picture, that the graphs are convenient to view, the screens are simple and clear, the dynamics of the activity is well observable, and one can follow multiple charts. Although participants could mention multiple things they like, there were also some things they disliked. Participants mentioned that some things remain incomprehensible, such as

‘Update the Plan’, the medication schedule is on the lower edge which gives the feeling that a part is still below, the wireframe of medication is patchy, there are usually several inhalers used instead of one, and the part of the medication does not have enough details. Results regarding the design revealed diverse opinions. There were some participants who expressed to like the design: ‘OK’, ‘Good. It is not exaggerated by different colours’, ‘Design is nice, sticks to watch’, and ‘customary’. One participant explicitly mentioned not to know what to think about it. Participants proposed several potential changes regarding the design. These changes were that the patient's symptoms should also be visible, the administration of medication could be somehow better designed (such as Prednisolone or Ventolin with using bright colours), and combining the medication taken and the glucose by combining the two graphs together in one view. This would help to easily see the connection. Results regarding the understanding of features revealed that almost all participants stated to understand everything. Only two participants stated not to understand the medication. When asking about what participants find most valuable, diverse answers were given. Participants mentioned the activity indicator to be important because of its objectivity, the measured parameters of the patient that are displayed as a graph, the activity and medication, and that the information gives a good overview. Although participants were overall positive about the wireframes, there were also some things that they would like to see differently. Participants mentioned that there could also be a longer-term trend window, that the base activity could also be seen, and the possibility to display data on a single graph should be an option. This makes it possible to assess more conveniently what the blood sugar level and physical activity was on a specific day. Furthermore, participants also mentioned that the medicine sheet should be fuller, there should be medication graphics, especially the to single out additional drugs (e.g., Short-Acting Beta Agonists and Prednisolone), and it should be possible to combine the glucose and medication.

Results regarding the acceptance revealed that participants either somewhat agreed or strongly agreed with following statements: this technology is useful, and with using this technology. Some participants were also indecisive about some statements. One participant was indecisive about whether this technology is easy to use in daily practice, one about whether this technology would positively influence the relationship with the patient, three about whether the privacy is ensured, one about whether the right care will be more efficient, and one about whether this technology will positively influence the care of the patient.

Marco Nunes: Shared decision making

First impressions regarding this scenario were positive. Participants expressed their first impression as: ‘positive’, ‘good’, ‘great’, ‘good option for younger patients slightly familiar with technology’. ‘Quick summary, aggregated information filtered in one place’, ‘simple’, and ‘clear plan update button’. Participants mentioned to like that it is specific filtered information, and all important aspects from the point of view of the pulmonologist are present. Furthermore, they also mention to like the frames to be minimalistic, concise and not limited to monitoring by including a health plan, and a recommendation for physical activity. Results regarding things that participants disliked about the frames revealed that the diastolic blood pressure and oxygen saturation (SpO2) were missing, and data about symptoms should be added (like cough, sputum). One participant did not like the fact that, when results get worse due to the inevitable progression of COPD, the patient also can see this decline, as this might lead to aggravate hopelessness. Two participants could not mention things they disliked. Participants mentioned the design to be good, and easy to understand. One participant recommended to use the colour green, because purple would feel ‘cold’ and ‘indifferent’ in his/her opinion. Participants proposed several potential changes. These were: add the names of inhalers, write down ingredients of medications, use the colour green, include the vaccinations taken and recommended, monitor quality of sleep and propose recommendations, and indicate shortness of breath according to post-load, 5th recovery minute, SpO2, and Borg scale. Almost all participants mentioned to understand everything on the wireframes. Only three participants mentioned to miss some information about the blood pressure and one participant did not understand why blood pressure was important. One participant mentioned that the functionalities are understandable, but not COPD specific. Results regarding which feature they found most valuable showed that diverse opinions. Participants mentioned the date represented on the axis of time, warning of increased risk and activity schedule, overview of current regime, to be able to evaluate different parameters, and symptoms to be most valuable. Despite these valuable features, participants still proposed several things that they would like to see differently. Participants mentioned that they would like to include the last spirogram and the last description of CT (computed tomography), expand the map of documented symptoms, include sleep tracking, SpO2, and mention the active ingredients of the medication.

Result regarding the acceptance revealed that the majority strongly agrees with the statement that this technology is useful, only three others somewhat agreed with this statement. Results regarding the ease of use in practice, the positive influence of the technology on the relationship of the patients, and whether the privacy of the patients is ensured with this technology were diverse. Answers ranged from being undecisive to strongly agreeing. Answers regarding the statements that with using this technology care is more efficient, giving the right care is more efficient, and that it will lead to a better overview were somewhat more positive. However, they were still diverse, and ranging from indecisive to strongly agree.

Annette Lambert: Early contact exacerbations, additional tests, exacerbation story
First impressions regarding this scenario were diverse. Some participants mentioned the wireframes to be ‘good’, ‘clear overview’, and ‘very informative and practical’. Others were less positive, they mentioned the screens to contain a lot of data, and that it needs to be deepened. Participants mentioned to like that the frames are insightful, that the information is easy to read, use, and find. One participant mentioned it to like that the wireframe tells you what should be monitored. However, there were also some things that were disliked. These things were that it is difficult to find a correlation between the different parameters, the screens could be more colourful, and the schematics could be in a different colour. The design was mentioned to be simple, appropriate, and well designed. Participants also proposed some changes. These were: play with more colours to catch the eye of different categories, use different colours (e.g., traffic light colours) to distinguish between a good and a worse day, and remove the rating displayed in every view. It was assumed to become very frustrating for the patient to see every bit of data, and thus also how bad it can go. Also, praises should be included. Almost all participants mentioned to understand everything on the wireframes. However, one participant did mention to not understand the tracking profile. Participants found the following most valuable: that data is systematically collected and well visualized; the physical activity; what should be monitored; medication use; notifications by program (in case of exacerbation risk); and reviewing the patient’s indicators in case of risk. When asking about things to change, it was mentioned that the patient profile does not contain a contact person; that it is frustrating to see a warning in every screen; and that one should also see the dynamics of spirographs.

Result regarding the acceptance revealed that participants somewhat or strongly agreed that this technology is useful and that with using this technology a better overview of patients is obtained. Answers regarding the usefulness in daily practice, the ease of use, the positive influence on the relationship with the patient, ensuring patient’s privacy, and positively influence patients were diverse. This ranged from undecisive to strongly agree.

9.2.4 Overall Rating (NL, EE, IT)

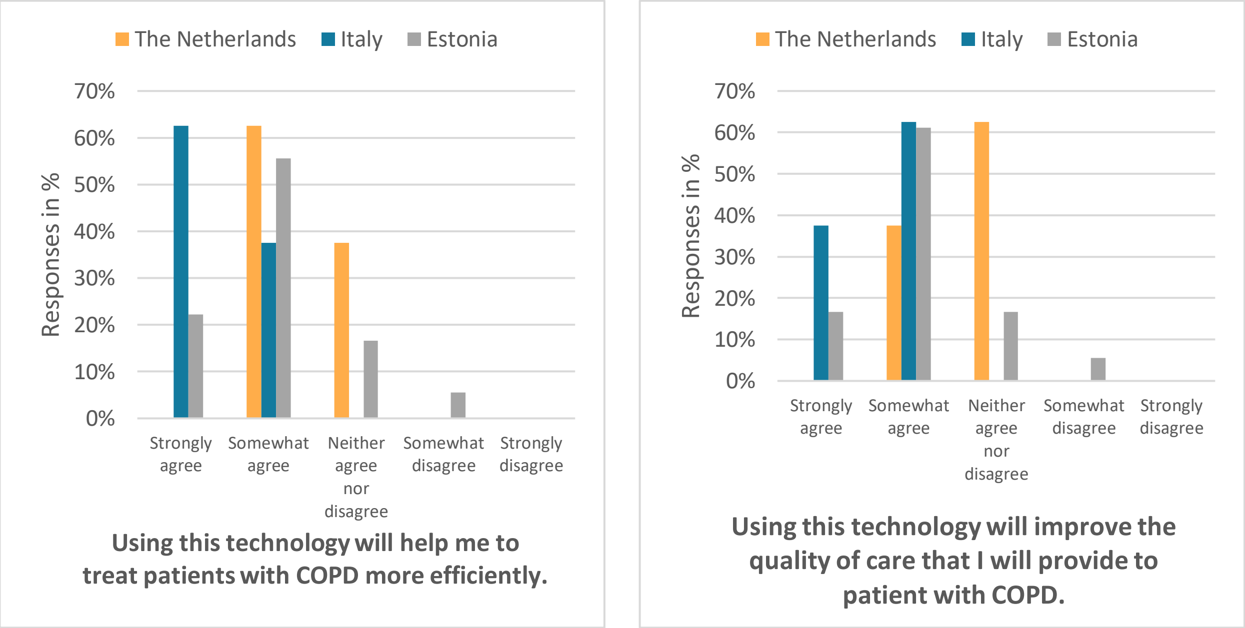
As final part of the end-user walkthrough, participants were asked to fill in their level of agreements of 8 statements regarding the benefits and usefulness of this technology. Participants could answer based on a 5-point Likert scale ranging from 1=Strongly agree to 5=Strongly disagree. In total, 34 out of 38 respondents filled in this part of the survey, the number or respondents are indicated in each country column in Table 8.

Table 8: Overall rating by HCPs as part of the End-User Walkthrough

Statements	NL (N=8)	IT (N=8)	EE (N=18)
1. Using this technology will help me to treat patients with COPD more efficiently.	M=2.38 SD=0.52	M=1.38 SD=0.52	M=2.06 SD=0.80

2. Using this technology will improve the quality of care that I will provide to patient with COPD.	M=2.63 SD=0.52	M=1.63 SD=0.52	M=2.11 SD=0.76
3. Using this technology will ease the way in which I treat patient with COPD.	M=2.5 SD=0.53	M=1.88 SD=0.64	M=2.17 SD=0.79
4. Using this technology will make my work more effective.	M=2.75 SD=0.46	M=2.00 SD=0.76	M=2.17 SD=0.99
5. Using this technology will improve the timeliness of patient care.	M=2.38 SD=0.52	M=1.63 SD=0.52	M=1.78 SD=0.65
6. Using this technology will reduce patient care and service costs.	M=2.75 SD=0.71	M=2.00 SD=0.76	M=2.44 SD=0.78
7. Using this technology will reduce unnecessary patient transfers or admissions.	M=2.25 SD=0.46	M=2.13 SD=0.64	M=2.24 SD=0.90
8. Using this technology will improve overall effectiveness of patient care.	M=2.63 SD=0.52	M=2.00 SD=0.53	M=2.22 SD=0.73

Compared to Estonia and The Netherlands, HCPs in Italy tended to be more positive in their overall rating of the RE-SAMPLE technology that was shown during the end-user walkthrough. None of the Dutch HCPs selected “strongly agreed” for any of the statements. The detailed results per statement are shown in the graphs below.



Using this technology will help me to treat patients with COPD more efficiently.

Using this technology will improve the quality of care that I will provide to patient with COPD.

Figure 51: Detailed responses on increasing efficiency and quality of care

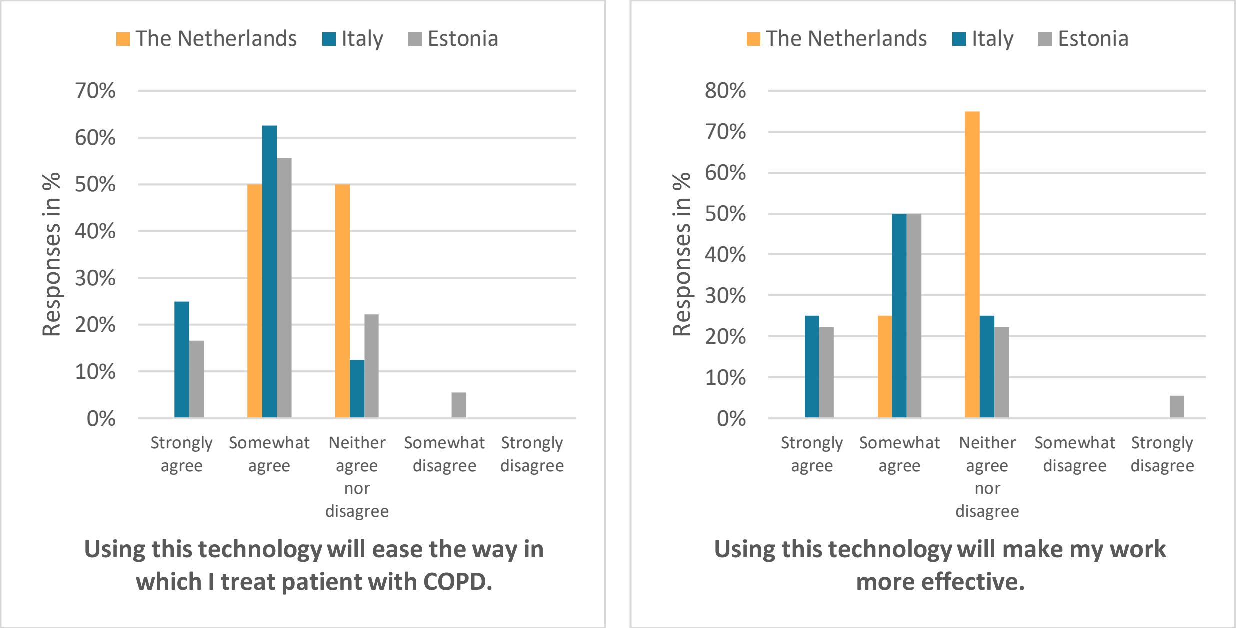


Figure 52: Detailed responses on making treatment easier and their work more effective

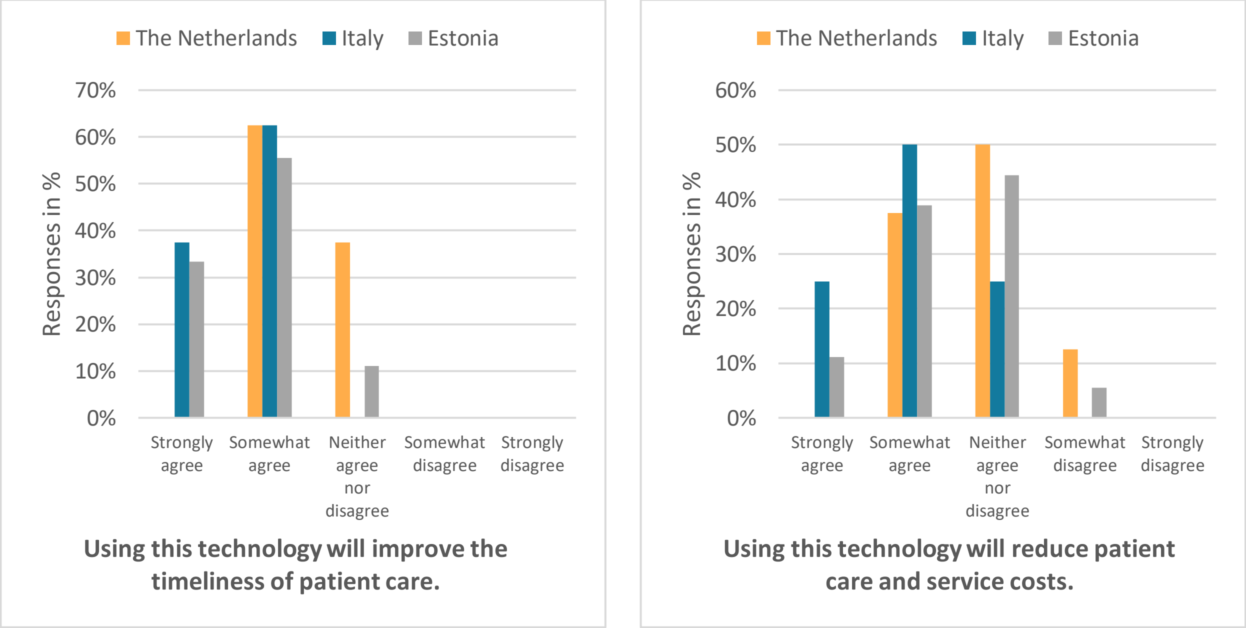


Figure 53: Detailed responses on improving timeliness of care and reducing costs

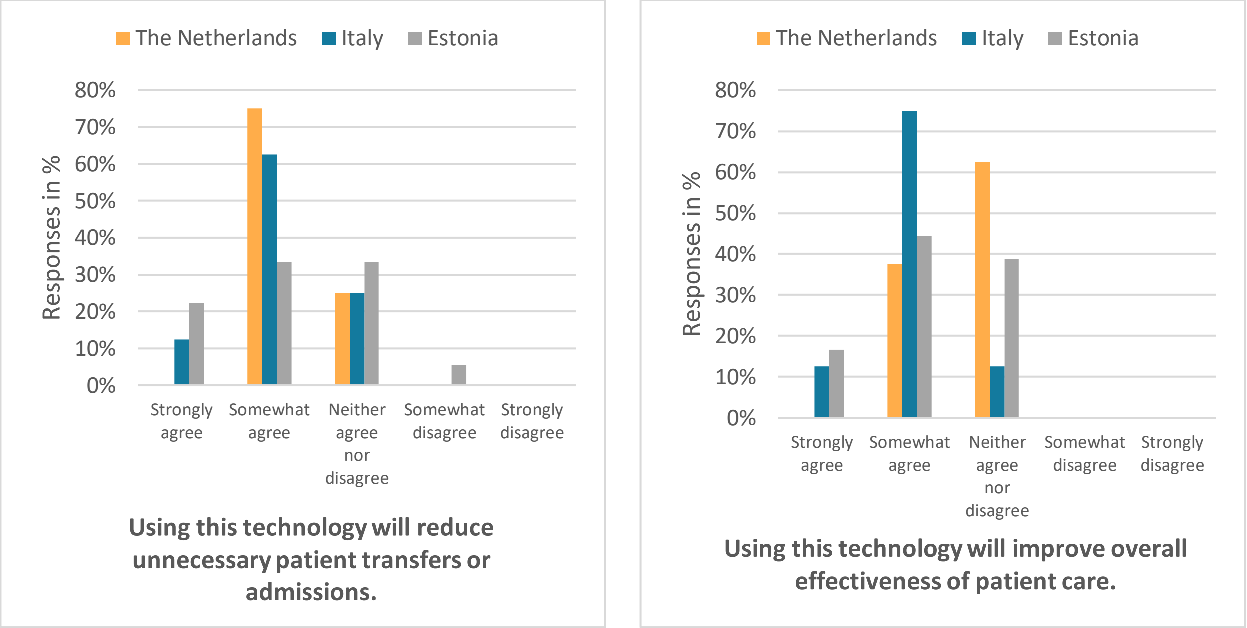


Figure 54: Detailed responses on reducing patient transfers/admissions and improving overall effectiveness

9.3 Summary end-user walkthroughs and requirements specification

Several end-user walkthroughs were carried out with both patients (N=20) and healthcare professionals (N=48) of Italy, Estonia, and The Netherlands.

Results of the *walkthrough with patients* showed ambivalent opinions regarding the wireframes. Patients mentioned a lot of recommendations for improvements. These were mainly regarding the difficulty of the language, and the use of English words. This was also the main reason why participants did not quite understand certain wireframes. In terms of features, participants recommended to add features for rewarding, motivating but not forcing people, and information (e.g., about activities or exercises). Participants were most positive regarding the features of coaching, the symptom diary, the trends and progress overview, and peer contact. The eDiary was seen as a place to make their own notes and to see in an agenda-like overview if anything had been out of order. This was appreciated and differs from the current implementation, where the eDiary is more a log book, providing a history of all interaction within the study (i.e., a list outlining the questionnaires filled in on a given day). Participants liked the coaching because they missed certain specific information about activities about what to do, and this could help them in the management of their health. However, the coach should fit and suit the participant because otherwise they would not use it. This was related to capabilities of the patient and how motivated they are, so that the suggestions made by the coach is appropriate. Furthermore, messages should be motivational and encouraging, to also acknowledge that progress was made even if a proposed activity may not have been fully completed. The use of the symptom diary and trend and progress overview was assessed to encourage patients to pay attention to their daily activities. One participant even mentioned they would feel safer when using this app. The participants were very positive regarding the possibility to contact peers and help each other. While not everyone would like that for themselves, they all agreed that a lot of COPD patients could benefit from peer contact. However, there were some concerns with sharing data with people other than their doctors. Results also showed that despite ambivalent opinions, almost all participants rated the acceptance of the wireframes high. However, several participants mentioned across the scenarios that they do not want to measure parameters or use this app every day. This would lead to thinking about his/her health problems every day and might be tiring for the participant. The overall rating of participants also showed some positive responses, especially from the Dutch patients. Meaning that although there are a lot of points of improvements, participants are somewhat positive regarding their future use plans, perceived benefits with managing their COPD, and motivation to use RE-SAMPLE.

Results of the *walkthrough with healthcare professionals* showed that most participants liked that the wireframes on itself were simple, clear, minimalistic and useful. Participants seemed to appreciate most the good overview that the wireframes provided, the insight into different parameters, medication, and activity, and the signals in case of an exacerbation risk. However, there were also several recommendations for improvements. Participants made the most recommendations regarding adding certain parameters (e.g., nutrition, saturation, lung measures, physical activity). They also mentioned recommendations regarding the design of the wireframes, for example, that most important data should be integrated in one screen. Participants mentioned that in the prototypes too many tabs needed to be open, a lot of data is presented, but that the screens are still incomplete. Other participants mentioned to miss detailed information about e.g., medication. The need for adding more and more information while keeping everything in one screen that still presents the data in a clear, minimalistic and simple way poses quite a challenge for the interface design. It was mentioned that there should be an option for direct communication with patients. Despite that participants mentioned positive first impressions and several features that they valued; the acceptance of the screens was not that convincing. Most participants found these wireframes to be useful, but results regarding the other statements (e.g., ensuring of privacy, ease of use, positive influence of care) were rated ambivalent. Resulting in that participants were indecisive or somewhat agreed with the statements regarding the acceptance of the features on the wireframes. Results of the overall usefulness, on the other hand, were overall rated as positive. Meaning that despite several recommendations for improvement and ambivalent results regarding the acceptance, the wireframes for the healthcare professionals were still rated as useful.

As a result of the end-user walkthroughs, the requirements were reviewed. Many requirements had been already specified before and were reinforced. In these cases, the source was added to the existing requirements and/or slightly adapted. Also some additional requirements were specified, as outlined below.

Requirement #F13	**Requirement type:** Functional
Description: Coaching and persuasive messages that the patient receives are context-sensitive and take into account recent activities, current level of exhaustion, their fitness level and environmental aspects that might reduce the abilities to carry out activities (e.g., high temperature). This means that messages might encourage the patient to do an activity or also to warn them and suggest to stop an activity (e.g., if they are too active).	
Rationale: Patients are well aware of the need to take breaks after they did some activity and rest if they are tired. This is an essential part of self-management and must not be counteracted by an inflexible coaching approach. This is also important to prevent patients going over their limit, respect their expertise and encourage them to trust their body.	
Source: Patients (NL, IT), EEW Patients (NL, IT)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. **User experience testing:** Participants using the companion over a period of time (e.g., 2-3 months) consider the type and frequency of persuasive messaging appropriate and in line with their capabilities.	
History: Created on November 14, 2021; Adapted August 5, 2022	

Requirement #F25	**Requirement type:** Functional
Description: The system takes into account the motivational state of the user and provides a personalised coaching strategy.	
Rationale: As the motivation to change or take up new behaviour differs per person, the messages and content of coaching needs to be adapted to successfully reach the patient.	
Source: EEW Patients (NL), Literature **(de Vries, 2017)**, DoW WP6	**Priority:** Must have
Conflicts: n/a	
Fit Criterion:	

1. User experience testing: Participants using the companion over a period of time (e.g., 2-3 months) consider the content of persuasive messaging appropriate and in line with their own motivational state.
History: Created on August 5, 2022

Requirement #C29	**Requirement type:** Content
Description: The active support programme for HCP shall provide information on the reasons for an increased risk of exacerbation.	
Rationale: HCPs gave feedback during the EEW that they need to see the reasons for an increased risk of exacerbation.	
Source: EEW HCPs (NL)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: n/a 1. Usability testing: HCPs can answer the question "what was the reason for an increased risk of exacerbation for this patient?"	
History: Created on August 5, 2022	

Requirement #C30	**Requirement type:** Content
Description: The data collection should also include positive events and not just focus on the negative.	
Rationale: During the end-user walkthroughs it was mentioned that focusing on the negative would increase loneliness and confronting. Furthermore, the eDiary was appreciated in terms of giving an overview of having good and bad days, indicating that also good days need to be recorded.	
Source: EEW Patients (NL), EEW HCPs (EE)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion: n/a	
History: Created on August 5, 2022	

Requirement #C31	**Requirement type:** Content
Description: The coaching messages that the patient receive shall be motivational, rewarding, encouraging, and acknowledge when progress is being made. Coaching recommendations should be encouraging but not enforcing.	
Rationale: Patients highly emphasised during the end-user walkthroughs the system should be motivating by acknowledging that progress has been made even if a certain goal could not be reached. Patients are not supposed to go over their limit, and therefore not forced to reach a certain goal that might not be achievable on a specific day. [see also Req #F13)	
Source: EEW Patients (NL), #F13	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. User experience testing: Participants using the companion over a period of time (e.g., 2-3 months) consider the messages motivational and encouraging.	
History: Created on August 5, 2022	

Requirement #U04	**Requirement type:** Usability, UX
Description: The active support programme for HCPs shall provide one graph that plots a variety of data in one overview.	
Rationale: HCPs in all countries provided feedback during the end-user walkthrough that having data combined in one overview would help them with the interpretation and see correlations between different parameters.	
Source: EEW HCPs (NL, IT, EE)	**Priority:** Should have
Conflicts: n/a	
Fit Criterion:	

1. Usability testing: When opening the clinical dashboard, the HCP can immediately see the most important parameters plotted in one graph.	
History: Created on August 5, 2022	

Requirement #U05	**Requirement type:** Usability, UX
Description: The active support programme for HCPs shall provide most important information on one page.	
Rationale: HCPs in all countries provided feedback during the end-user walkthrough that having multiple tabs for the different pages was not useful for them.	
Source: EEW HCPs (NL, IT, EE)	**Priority:** Must have
Conflicts: n/a	
Fit Criterion: 1. Usability testing: When opening the clinical dashboard, the HCP can immediately see the most important information on one page. 2. User experience testing: The overview of the information is assessed by HCPs as clear, informative, complete and useful.	
History: Created on August 5, 2022	

10. Conclusions and future work

This deliverable presented the results of the extensive user research studies carried out in all three pilot sites MST (The Netherlands), GEM (Italy) and TUK (Estonia). Special attention was paid to describe the context of use, and the user needs related to self-management, (shared-)decision making, data visualisation, communicating and connecting, and coaching. The user research studies resulted in in-depth description of the needs of the primary end-users of RE-SAMPLE, namely patients with COPD and healthcare professionals.

Based on the results, functional, service, organisational, content, and usability/user experience requirements have been specified. These requirements complement the ones previously specified in D2.1 *User needs and expectations for privacy-abiding RWD collection.* Furthermore scenarios, dataflow diagrams and prototypes have been developed. The personas and scenarios were utilised to assess impressions, opinions, and acceptance by patients and HCPs regarding the prototypes. Based on these assessments, requirements were revised and new requirements were specified.

The studies conducted and user requirements specified present the basis for the development of the RE-SAMPLE virtual companionship programme based on needs, expectations and insights from end-users. The patients and HCPs involved in the studies present a subgroup of the overall target group and despite extensive recruitment efforts may not be representative of the all patients and HCPs. For example, many patients were diagnosed already a long time ago and highly educated. Future recruitment efforts should continue to recruit end-users who could not been reached yet.

The deliverable presents the first iteration in the human-centred design process, where in the future other requirements will be elicited from other stakeholders (for example, technical, organisational and legal requirements within WP3 and WP4). These requirements may be congruent with the user requirements specified in WP2, but may also be in conflict with user requirements. In that case, requirements conflict management has to be carried out.

The user research studies and specified requirements together with requirements and constraints identified in other WPs will inform the design of the RE-SAMPLE programme, in terms of technical design (WP5) as well as content and interaction design (WP5, WP6), service model design (T2.4) and implementation in the pilot sites (WP7). Finally, the stakeholder evaluation will assess the alignment of the design with the user needs and requirements and the general acceptance of the companionship programme and its social impact (WP7).

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Appendices

Appendix A. Protocol HCPs co-design "data overview, alarms, profiles"

Demographics collected before the start of the workshop:

Gender ☐ male ☐ female ☐ other

Occupation and specialisation: ________________________________

Work experience in healthcare (in years): ____________

Protocol for the co-design workshop:

Phase	Time	Topic	Explanation	Materials
Introduction	9:00 – 9:10	Introduction	Welcoming participants to the workshop. Introduction of researcher and participants. Explain aim of this workshop, procedure of today. Explain the informed consent form, ask them to read and sign the form.	
	9:10 – 9:15	Demographics questionnaire	Explain the questionnaire and ask participants to fill them in (gender, occupation, work experience in healthcare in years)	
Start recording		Start recording	Inform participants that from now on the conversation will be recorded Get informed consent again on audio Start recording	Audio recording
Discussion	9:15	Data overview and alerts	Discuss the following aspects • Preference to see raw data or processed into information • Focus on data overview or on alerts? • Preferences for type of data • Preference for aggregation level (day / week / month / year) • Preference for layout? • Preference for alerts?	
Co-Design 1	9:25	User interface weight monitoring	Present scenario for monitoring body weight: • *Dina is a patient with COPD and obesity. She is asked to monitor her weight with a digital scale.* • *How would the perfect screen look for you?* ○ *Which data / information do you want to see?* ○ *Which types of alarm do you want to receive if Dina is not controlling her weight sufficiently.*	PPT, printed tablet frames, pens

			Ask participants to draw their ideas on the tablet frame paper sheets.	
Co-Design 2	9:30	User interface oxygen saturation	Present scenario for monitoring oxygen saturation: • *Freek is a patient with COPD, arthritis, asthma and diabetes. He monitors his oxygen saturation level daily. His oxygen levels are dropping 3 days in a row.* • *How would the perfect screen look for you?* ○ *Which data / information do you want to see?* ○ *Which types of alarm do you want to receive when Freek has a low oxygen saturation?* Ask participants to draw their ideas on the tablet frame paper sheets.	PPT, printed tablet frames, pens
	9:45	Discussing sketches	Participants present their ideas and discuss their preferences	
Co-Design 3	10:00	Monitoring profiles	The facilitator motivates the aim of monitoring profiles (one size does not fit all, patients with COPD have a variety of additional conditions → tailored monitoring of progression in short and long term) Present scenario for monitoring profiles: • *Freek is a patient with COPD, arthritis, asthma and diabetes.* • *Unlike other patients, he never experiences fever when having an exacerbation.* • *With his combination of chronic conditions, the RE-SAMPLE system shows the optimal set of which parameters of Freek should be closely monitored.* • *How would the perfect screen look to show you the optimal set of parameters?* Ask participants to draw their ideas on the tablet frame paper sheets.	
	10:15	Discussing sketches	Participants present their ideas and discuss their preferences	

Conclude	10:30		Give a short summary Ask participants if they have any questions or additional remarks. Thank participants and conclude workshop	
Stop recording		Stop recording		

Appendix B. Demographics questionnaire patients

Demographics

1. What is your gender?

   ☐ male
   ☐ female
   ☐ other

2. What is your year of birth? _______________ (YYYY)

3. Besides COPD, what other chronic conditions do you have?

   ____

4. For how long are you diagnosed with COPD?

   ☐ <1 year
   ☐ 1-2 years
   ☐ 3-5 years
   ☐ 6-10 years
   ☐ more than 10 years
   ☐ I don’t know

5. What is the highest degree or level of education you have completed?

   ☐ Primary school
   ☐ High school
   ☐ Trade school
   ☐ University
   ☐ Other: ______________________________

6. What is your current employment status?

   ☐ Employed full time
   ☐ Employed part time
   ☐ Seeking opportunities
   ☐ Retired
   ☐ Unable to work
   ☐ Voluntary work
   ☐ Other: ______________________________

7. How many family members do you live together with?

0	**1**	**2**	**3**	**4**	**>4**

Health-related quality of life & Health literacy

8. How much does your health affect your usual activities (e.g., work, study, housework, family or leisure activities)?

I have no problems performing my usual activities				**I am unable to perform my usual activities**
1	**2**	**3**	**4**	**5**

9. How often do you experience problems understanding texts (such as leaflets) about your health or an illness?

Never	Seldom	Sometimes	Often	Always

10. How confident do you feel when you fill out medical forms?

Not confident at all	Somewhat confident	Fairly confident	Confident	Very confident

11. How often does someone help you to read brochures, forms or letters from the hospital, pharmacy or your GP?

Never	Seldom	Sometimes	Often	Always

Digital literacy

12. I think that my level of digital skills is as follows:

Really low				Really high
1	**2**	**3**	**4**	**5**

eHealth technologies

13. Which of the following devices do you use?

☐ computer/ laptop
☐ smartphone
☐ smartwatch (Fitbit/Garmin/Apple watch)
☐ tablet
☐ none
☐ other: ______________________________

Appendix C. Protocol patients co-design workshop “Your favourite coach”

Phase	**Time**	**Topic**	**Explanation**	**Materials**
Meeting invite	7 days before	E-mail invite	Send e-mail invite for the meeting as reminder with the details	
Introduction	9:00 – 9:10	Introduction	Welcoming participants to the workshop. Introduction of researcher and participants. Explain aim of this workshop, procedure of today. Explain the informed consent form, ask them to read and sign the form.	
	9:10 – 9:15	Demographics questionnaire	Explains the motivation behind collecting demographics and asks participants the questions from the form (filled in by researcher).	
Start recording		Start recording	Inform participants that from now on the conversation will be recorded Get informed consent again on audio Start recording	Audio recording
Co-Design 1	9:15-9:30	Topics for Coaching	Show participants three different phases of COPD that we distinguish here: the starting phase of COPD, the stabilisation phase, and the phase of exacerbation. Show these different phases on a printed A3 and give each participant a printed A3. Ask participants to answer the following questions: - *On which topics did you wanted to have more help/guidance with?* - *Which topics were/are important to you in these phases?* - *Which advice did you receive from your pulmonologist or pulmonology nurse?* Ask participants whether there were different topics/needs during these different phases. Participants need to write these topics/needs down on post-its and stick it on the corresponding phase on the A3 *(Each topic is written down on a separate post-it).*	Post-its, A3 with disease phases
Presentation coaching types	9:30-9:40	Types of coaches *(Explanation)*	Explain to participants that there are different types of coaches who can help and guide patients during their disease. A definition of the different coaches is given *(Ask during the explanation of the different coaching styles whether participants can*	

			think of a person who has that specific style of coaching): - **The military general**: *The military general is very strict and straight forward. He/she determines what to do on which day and on which time. Even when you don't feel like running, if the military general says you need to run, the only option is to run. Going against the military general is not an option. You have to do what he says. No exceptions nor excuses are allowed.* - **The sports coach:** *The sports coach is very straight forward. He/she will tell you exactly what to do and when to do it. The sports coach will do everything he/she can to achieve your goals, for example: to increase your condition.* *The difference with the military general is that with the sports coach, you set your goals beforehand. The sports coach is tough, but will help you achieve the goal you said you want to achieve.* - **The parent:** *The parent is really caring and does everything for you. You have a somewhat passive attitude because the parent will pamper you and take care of everything. The parent will do anything that is in your best interest.* - **The equal partner:** *The equal partner will discuss certain topics on an equal manner. You speak about your wishes, how you see things but also about the wishes of the coach and how he/she sees things. Based on both your opinions and preferences, you decide together, in cooperation, what the best options are for you.* Check whether participants understood the explanations of the coaches and their differences. Ask participants which coach they personally prefer and why they prefer this coach.	
Co-Design 2	9:40-9:55	Types of coaches *(Visualisation)*	Refer back to the topics that were written down on the disease stages A3 form. Ask participants if they would like the chosen	A3 with disease phases, Printed cut-

			coach during the different stages and with the different topics. Then, give participants the cut-outs of the different coaches. Let patients stick (with tape) their preferred coach on the different topics in the different phases. Let participants explain why (or why not) they prefer different coaches. Ask the participants what they find important in a coach and what they specifically need from a coach during that time/topic.	outs of different coaches Tape
Presentation positive health concept – different dimensions Discussion	9:55-10:10	Pillars for Positive Health	Introduce the model of Huber with the different dimensions of positive health. Give participants a printed version of this model. Explain that during medical treatment, the attention is mostly given to the physical part of the disease (managing treatment, and medication). The model of positive health includes more dimensions than only the physical (bodily functions). Present the six dimensions: ‘*bodily functions*’: e.g., medical facts, ‘*mental well-being*’: e.g., emotional status, ‘*meaningfulness*’: e.g., acceptation, ‘*quality of life*’: e.g., experience of happiness, ‘*participation*’: e.g., social contacts, and ‘*daily functioning*’: e.g., ability to work/health literacy. Ask participants whether they recognize these dimensions of health and if there were or are any topics related to the dimensions where they wanted to have (more) coaching or guidance with? If so, which dimension, which topic, and why? What did they receive and what did they wish to receive? What where their needs during the different phases of the disease?	Printed A3 file ‘Pillars for positive health’ of Huber.
Discussion	10:10-10:20	Pillars for Positive Health combined with coaches	Refer back to the different types of coaches. Ask participants which coach they would like during the different dimensions and why. If participants like, they can stick the cut-outs of the preferred coach by the different dimensions they said they wanted to have guidance with.	Printed A3 of Huber, Cut-outs of coaches, Tape
Conclude	10:20-10:30		Give a short summary Ask participants if they have any questions or additional remarks. Thank participants and conclude workshop	
Stop recording		Stop recording		

Appendix D. Protocol patients end-user walkthrough

Phase	Time	Topic	Explanation	Materials
Meeting invite	7 days before	E-mail invite	Send e-mail invite for the meeting as reminder with the details	
Introduction	9:00 – 9:10	Introduction	Welcoming participants to the end-user walkthrough. Explain aim of this end-user walkthrough, and procedure of today. Explain the informed consent form, ask them to read and sign the form.	
	9:10 – 9:15	Demographics questionnaire	Explain the questionnaire and ask participant to fill it in.	
Start recording		Start recording	Inform participant that from now on the conversation will be recorded Get informed consent again on audio Start recording	Audio recording
EEW Block 1		Presenting persona 1 with corresponding scenario and prototype Feedback on persona and scenario Assessment of prototype from persona point of view	The end-user walkthrough starts with block 1. Each block consists of a visual overview of one persona, one scenario, and one prototype. Participants start in block 1 with either the persona of *Johanna Rebane* or *Gustav Kask*. Each persona has a corresponding scenario. In each block, participants get first a visual overview of both the persona. The researcher will first read the persona to the participants. Then, he/she will ask the following questions: - *What do you think of this persona?* - *Do you recognize yourself in this persona?* The researcher checks whether the participant understands the persona. Then, the overview of the scenario is shown to the participant. After the explanation, the wireframe(s) of the relevant scenario is shown to the participant. Participants are asked to answer a series of questions as if they were the persona. The questions are divided in different topics: - *First impression* - *Understanding features* - *Acceptance*	Visual overview of persona, scenario (A3), and prototype block 1
Uncover opinion		Assessment of prototype from participant's point of view	After participants answered the questions as if they were the persona, they are now asked to answer for themselves. The questions that need to be asked are:	Interview-guide

			- *What do you think about this prototype?* - *What do you like/dislike about it?* - *Which features do you find most valuable and why?* - *If you could change one thing, what would it be and why?*	
EEW Block 2		Presenting persona 2 with corresponding scenario and prototype Feedback on persona and scenario Assessment of prototype from persona point of view	Start with block 2. Participants are provided with either the persona *Roberto Pesci* or *Giulia De Rossi*. Each persona has a corresponding scenario. In each block, participants get first a visual overview of the persona. The researcher will first read the persona to the participants. Then he/she will ask the following questions: - *What do you think of this persona?* - *Do you recognize yourself in the persona?* The researcher checks whether participants understand the persona. Then the overview of the scenario is shown to the participant. Again, the researcher will read the scenario to the participant. After the explanation, the wireframe of the relevant scenario is showed to the participant. Participants are asked to answer a series of questions as if they were the persona. Again, a series of questions are asked. The questions are divided in the same themes as in block 1.	Visual overview of persona, scenario (A3), and prototype block 2
Uncover opinion		Assessment of prototype from participant's point of view	After answering as if the participants were the persona, questions from their own perspective are asked: - *What do you think about this prototype?* - *What do you like/dislike about it?* - *Which features do you find most valuable and why?* - *If you could change one thing, what would it be and why?*	Interview-guide
EEW Block 3		Presenting persona 3 with corresponding	Start with Block 3. Participants are provided with either the persona of *Bert van Dijk* or *Ans Visser*. Each persona has a corresponding scenario. In each block,	Visual overview of persona, scenario

		scenario and prototype Feedback on persona and scenario Assessment of prototype from persona point of view	participants get first a visual overview of the persona. The researcher will first read the persona to the participants. Then he/she will ask the following questions: - *What do you think of this persona?* - *Do you recognize yourself in this scenario?* The researcher checks whether participants understand the persona. Then the overview of the scenario is shown to the participant. Again, the researcher will read the scenario to the participant. After the explanation, the wireframe of the relevant scenario is showed to the participant. Participants are asked to answer a series of questions as if they were the persona. Again, a series of questions are asked. The questions are divided in the same themes as in block 1 and 2.	(A3), and prototype block 3
Uncover opinion		Assessment of prototype from participant's point of view General impression	After answering questions as if participants were the persona, the following questions from their own perspective are asked: - *What do you think about this prototype?* - *What do you like/dislike about it?* - *Which features do you find most valuable and why?* - *If you could change one thing, what would it be and why?* When walking through all 3 blocks, participants are asked about their overall impression and if they currently miss certain topics in the prototypes.	Interview-guide
Scenario 7			After all blocks are finished. ALL participants are presented with scenario 7. Then, the following questions are asked: – *What is your opinion about peer- to -peer contact?* – *Do you think this can be of added value? Why do you think that?* Then, questions related to the wireframes (as asked in the previous blocks) are asked again.	Material scenario 7 (Wireframes, and scenario)

Rating			Participants are asked to rate several questions about their willingness to use the intervention.	Interview-guide, rating questions
Conclude			Researcher gives a short summary Ask participants if they have any questions or additional remarks. Thank participants and conclude workshop	
Stop recording		Stop recording		

Appendix E. Protocol HCPs end-user walkthrough

Topic	**Explanation**	
E-mail invite	Send e-mail invite for the questionnaire with the details to healthcare professionals in the current network of RE-SAMPLE. Ask participants to share this questionnaire with their colleagues to include as many participants as possible. The questionnaire will be designed in an online tool (Qualtrics) and healthcare professionals will receive a link to the questionnaire.	
	Start questionnaire	
Introduction	The questionnaire starts with explaining the RE-SAMPLE project, the motivation, and the goal of the end-user walkthrough. The system will ask for permission to use their data and repeats the process that ensures participants' anonymity.	
Demographics	Age	Frequency of seeing patients with COPD
	Location	Experience with eHealth
	Profession	Attitude towards eHealth technologies
	Years of work experience	
Start block 1	The participant is presented with the persona of *Aksel Meyer*. A visual representation of both the persona and scenario are provided, and the participant is asked to thoroughly look at these. Then, the prototype of block 1 is shown. A series of questions regarding the prototype are asked to assess the first impressions, understanding of features, and acceptance of the technology. These questions are stated below:	
1. First impressions	1.1 What is your first impression?	
	1.2. What do you like about the prototype?	
	1.3 What do you dislike about the prototype?	
	1.4 What do you think of the design?	
	1.5 If you could change one thing, what would it be and why?	
2. Understanding of features	2.1 Which information can you find on the prototype?	
	2.2 Do you understand what each feature means?	
	2.3 Which feature do you find most valuable and why?	
	2.4 Are there any features you don't understand? If so, which?	
	2.5 Is there anything you would like to see differently? If so, what?	
3. Acceptance	3.1 Would you think this technology is useful?	
	3.2 What do you think of using this technology during your daily practice?	
	3.3 Do you think this technology will influence the physician- patient relation?	
	3.4 How do you think about the privacy of patient when using this technology?	
4. Intention to use (rating)	4.1 With using this technology, giving the right care to patient will be more efficient.	
	4.2 Using this technology will positively influence the care of my patients	
	4.3 With using this technology, I will have a better overview of patients.	
Start block 2	After finishing the first block, the participant is presented with the persona of *Annette Lambert*. Again, the visual representation of both the persona and scenario are provided, and the participant is asked to thoroughly look at these. Then, the prototype of block 2 is shown. The same questions as in block 1 are asked to the participant to assess the first impression, understanding of features, acceptance of the technology, and intention to use the technology.	
Start block 3	After finishing the second block, the participant is presented with the persona of *Marco Nunes.* A visual representation of both the persona and scenario are provided, and the participant is asked to thoroughly look at these. Then, the prototype of block 3 is shown.	

	The same questions as in block 1 are asked to the participant to assess the first impression, understanding of features, acceptance of the technology, and intention to use the technology.
Rating	To finalize the End-user Walkthrough, participants are asked to rate the perceived usefulness, and perceived benefits on a Likert-scale.
5. Perceived usefulness	5.1 Using this technology will help me to treat patients with COPD more efficiently
	5.2 Using this technology will improve the quality of care that I will provide to patient with COPD
	5.3 Using this technology will ease the way in which I treat patient with COPD
	5.4 Using this technology will make my work more effective
6. Perceived benefits	6.1 Using this technology will improve the timeliness of patient care
	6.2 Using this technology will reduce patient care and service costs
	6.3 Using this technology will reduce unnecessary patient transfers or admissions
	6.4 Using this technology will improve overall effectiveness of patient care
Closing	Participants are asked if they have any questions or additional remarks. They can write these down in a text box. Participants are thanked for their participation.
End of questionnaire	