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

D5.8: End-user involvement for design and evaluation - 2nd year

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Abstract

The goal of RE-SAMPLE is to develop an ecosystem of innovative eHealth services that support patients and healthcare professionals (HCPs) to manage Chronic Obstructive Pulmonary Disease (COPD) and accompanying complex chronic conditions (CCCs) in a more optimal and personalised way. Continuous engagement with end-users and other stakeholders is key to ensuring that the design of the virtual companion and the integrated care protocols respond well to their needs, values, and expectations, as well as to their daily practices in life and work.

This deliverable gives an overview of the end-user involvement activities carried out from M12 until M23. It describes the results of the second round of stakeholder analysis and network inventory, the adaptations we made to the end-user panel, the continuous and bi-directional feedback exchanged between end-users and the RE-SAMPLE consortium, and the results of 4 iterations of end-user studies: two with patients and two with HCPs. Furthermore, the initial plan for the next iterations of end-user studies is outlined.

This deliverable will be updated in M39 (D5.9) to report on end-user studies that are performed in the respective time frames.

Contents

List of Figures

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Symbols, definitions, abbreviations, and acronyms

ABC	Assessment of Burden of COPD
Citizen science	A participatory research model in which non-professionals are actively involved in scientific research
CAT	COPD Assessment Test
CCC	Complex Chronic Condition
CCQ	Clinical COPD Questionnaire
CeHReS	Centre for eHealth and Wellbeing Research
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous positive airway pressure
D	Deliverable
DPO	Data Protection Officer
EFA	European Federation of Allergy and Airway Diseases Patients' Associations
ELF	European Lung foundation
EPIK	Estonian Chamber of Disabled People
EQ5D	Euro Quality of Life 5 Dimensions questionnaire
GP	General Practitioner
HADS	Hospital Depression and Anxiety Scale
HCP	Healthcare professional
HUBBI	eHealth UsaBility Benchmarking Instrument
ISO	International Organization for Standardization
M	Month
mMRC	modified Medical Research Council dyspnea scale
MREC	Medical research ethics committee
NVALT	Nederlandse Vereniging van Artsen van Longziekten en Tuberculose
PPI	Patient and public involvement
RIC	Respiriamo Insieme Community
SEP	Social economic position
SEA	Search Engine Advertising
SEO	Search Engine Optimisation
SUS	System Usability Scale
TWEETS	TWente Engagement with Ehealth Technologies Scale
THOON	Twentse Huisartsen Onderneming Oost Nederland, organisation of and for general practitioners in Twente and surrounding area.
WP	Work Package

1. Introduction

The goal of RE-SAMPLE is to develop an ecosystem of innovative eHealth services that support patients and healthcare professionals (HCPs) to manage Chronic Obstructive Pulmonary Disease (COPD) and accompanying complex chronic conditions (CCCs) in a more optimal and personalised way. Considering that the design problem, application and implementation domain are very complex with many heterogeneous stakeholders, early and continuous involvement of key stakeholders in the design process is crucial. Stakeholder involvement is one of the principles in human-centred design for interactive systems (International Organization for Standardization (ISO), 2019), which is also the foundation of the CeHReS[1] roadmap, a widely used holistic approach to improve the uptake and impact of eHealth technologies in practice (van Gemert-Pijnen, et al., 2011). Furthermore, the benefits of involving citizens/patients have been increasingly acknowledged in the field of health and medical research, for example, through Citizen Science, patient and public involvement (PPI), action research or similar participatory approaches (Borda, Gray, & Laura, 2019; Wiggins & Wilbanks, 2019). Through continuous engagement with end-users and other stakeholders, we can learn from their expertise and experience regarding living with and/or managing the conditions. This knowledge can help us to identify how the RE-SAMPLE programme can be best incorporated into the daily lives of patients and the processes in the healthcare setting. This in turn can then be tested and evaluated with the end-users to ensure that their needs and expectations are correctly translated and taken into account in the design of the virtual companion and the integrated care protocol.

The first iteration of end-user studies was described in D5.7 *End-user involvement for design and evaluation*, which focused on the early detection of barriers and usability issues of the Healthentia app used in the monitoring cohort. This deliverable gives an overview of the end-user involvement activities carried out from M12 until M23. It describes the results of 4 iterations of end-user studies:

- Second iteration (section 6.1): Usability benchmarking and user experience assessment. This iteration focuses on assessing the user experience and usability of the Healthentia app in real life.
- Third iteration (section 7.1): Workshops with HCPs about feedback on data visualizations on the clinicians' dashboard.
- Fourth iteration (section 7.2): Workshops with HCPs on risk prediction and shared-decision making.
- Fifth iteration (section 6.2): Interviews with patients on data utilisation, risk prediction and use of a virtual coach.

This deliverable will be updated in M39 (D5.9) to report on end-user studies that are performed in the respective time frames.

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[1] CeHReS is an acronym for Centre for eHealth and Wellbeing Research

2. Objective

The objective of this deliverable and its future updates is to report on the activities of continuous involvement of end-users, the end-user panel and the results of end-user studies performed to support the iterative design and evaluation of the RE-SAMPLE virtual companionship programme.

Section 3 presents the second iteration stakeholder analysis and network inventory, which was conducted during a consortium meeting. Section 4 outlines adaptations we made to the end-user panel. This section also includes how we promoted the end-user panel, and how we can promote the end-user panel in the coming year. Section 5 shows the continuous and bi-directional feedback exchanged between end-users and the RE-SAMPLE consortium. Furthermore, section 6 presents two end-user iteration studies with patients, and section 7 two end-user iteration studies with HCPs. Next to this, the initial plan for the next iterations of end-user studies is outlined in section 8. Finally, in section 9 we conclude this deliverable and describe future work.

3. Stakeholder analysis and network inventory

As described in D5.7 *End-user involvement for design and evaluation*, an initial stakeholder analysis was conducted in a workshop during the M3 consortium meeting. To further investigate the opportunities and identify concrete actions, another workshop was carried out during the M12 consortium meeting. After the workshop, a network inventory was carried out to identify suitable partners for dissemination. The results of these activities are described below.

3.1 Workshop “End-user involvement and dissemination”

The workshop was planned and facilitated by the project coordinator and carried out during the consortium meeting on the 23rd of March 2022 (online). This workshop was a continuation of an earlier brainstorming held at M3, was facilitated by using Mural[2] and had a duration of about 45 minutes. The outcomes of the earlier brainstorming activity on end-user involvement served as the starting point. The aim of this workshop was to identify end-users and other stakeholders to develop a practical approach for involvement in studies and design activities, as well as dissemination. The planned outcome was to have a plan for the ecosystem involvement per pilot site with specific activities for the upcoming 6 months.

The consortium members were split in groups representing the three different pilot sites (Estonia, The Netherlands, Italy) and answered different questions:

1. Who are our end-users? (5 minutes)
2. Involve in what in the upcoming 6 months (10 minutes)
3. Via which organizations / associations / networks? (5 minutes)
4. How to involve/inform (tools)? (10 minutes)
5. Action points with responsible partner and timeframe (10 minutes)

Table 1 shows an overview of the answers given to each of these questions.

Then, partners received the instructions to focus on patients first and be as specific as possible related to the names of end-user organisations or associations in their ecosystem and what role is exactly needed or expected.

Table 1: Questions and answers from all three pilot countries during the workshop.

Question	Estonia	The Netherlands	Italy
Who are our end-users?	COPD patients with comorbidities, Lung physicians, cardiologists, family members that assist with use	COPD patients with comorbidities, lung physicians, nurse practitioners, formal caregivers of COPD patients, family members or other informal caregivers that assist with use, physiotherapists, comorbidities physicians and nurses, researchers outside consortium, peers, hospital IT personnel, case managers	COPD patients with comorbidities, caregivers, general practitioners (GPs), pharmacists, nurse specialists, region health system, health insurance company, region, assurance companies
Involve in what in the upcoming 6 months?	WP8: create awareness, recruitment for medical research	Recruitment for METC studies, recruitment for co-design studies,	Recruitment for MREC studies.

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[2] Online whiteboard for facilitating discussions: https://mural.co/

	ethics committee (MREC) studies, recruitment for iterative design of the virtual companionship programme, continuous feedback on UI/UX directly in the Healthentia app, guidance for pre-selection of features for machine learning models (HCPs), explainability model options and visualisations of explanations (HCPs)	recruitment for evaluation studies. Co-design: activities edge node integration with hospital technology, coaching modules, shared decision making, dashboard for HCPs Testing of prototypes, evaluation of RE-SAMPLE	Face 2 face / online interviews to understand their expectations and lessons learnt, design thinking > workshops with stakeholders to understand how we can contribute in “improving” their daily life, interviews to get feedbacks about application and workflows; scenarios > concrete use cases about how it would work in daily life (with patients, GPs, pharmacies, nurses) Use social channels of associations (lung societies or patient associations) Dissemination activities: newsletter (also via associations), events for both clinicians and specialists and patients, e.g. Associations. Reports and events targeting insurance companies and regional systems. Social media > move to Facebook/Instagram, mainly using the website and the social media accounts of patient associations > creation of posts / funny and surveys. Direct contact with hospital clinicians and GPs. Present concrete user cases and get feedback

Via which organizations / associations / networks?	(Letters) via hospital. Estonian respiratory society (for HCPs), general media (no association), social media groups? Regional GP practices, regional pharmacies, day-care centers, RE-SAMPLE user panel.	Netherlands Respiratory society, THOON (GP association in East Netherlands), Fysio Twente (COPE ACTIVE), Longpunt, social media / support groups, Local physical therapists, Local GPs, Dutch lung foundation, MST patient panel, Local newspapers, NVALT (Dutch Association of Physicians for Pulmonary Diseases and Tuberculosis)	COPD patient associations, insurance companies, lung associations/organisations. Use associations and clinical iSight to select testimonials and champions, support groups of COPD, regional system.
How to involve/inform (tools)?	Selection from hospital data base. Paper letters. Engagement tools. Paper flyers general info + are you a COPD patient, contact. Organise "fun" activity to test new eHealth app -> improve digital literacy of the pop	Social media, events, paper letters, e-mail, personal contact, website	Social media, events, personal contact
Action points with responsible partner and timeframe?	TUK/HOPE Check Facebook groups or WhatsApp groups in Estonia (in collab with WP2). No newsletter for patients TUK: select from hospital database, change ethics approval, say that we call them, ask them for recruitment and design. Check possibility to perform short co-design activities within day-care centres.	MST panel: add a button so that they can also join.	HOPE can support (join work with the local team) in DISSEMINATION activities via social media and newsletter, for instance. LOCAL TEAM (Generator and clinicians) will lead WORKSHOPS with the support of RRD, leveraging on their expertise. CLINICIANS including nurse specialists, to lead the targeted communication to GPs, regional institutions and, possibly, insurance companies.

After the groupwork activity, the results were summarised as follows:

- For **Estonia**, a lot of things were overlapping with the other two countries, but there is also one big difference: there are no patient associations and no online channels for contacting patients. Therefore, one thing to check is whether there are any informal (e.g., Facebook) patient groups that we could reach out. Spreading a newsletter at local level is not possible. It is only possible at a more general level like with the European Lung Foundation. We need to find out if there are any day-care centres that might be useful for co-design activities. There is also an option to do it via paper flyers at the GP's level, at community pharmacies' level, and even at the local outdoor markets (e.g. grocery markets). The last option is to select from the hospital database all suitable patients and send them a paper letter saying we will call them and offer them to participate in RE-SAMPLE.

- For the **Netherlands**, the most important topics for the co-design sessions are: shared decision-making, testing prototypes, and dissemination. Channels are: the Respiratory Society, GPs, the Dutch Pulmonary Physician Organisation, local newspapers and MST Patient Panel. How to involve are: social media, website, events, and paper letters. Action points with responsibilities and timeframe are unfinished. We need a separate session to define how are we going to contact them and how are we going to ask them to participate.
- For **Italy**, there are three main actions: (1) Workshops for the patients and patient organisations on the user scenarios, in other words, to show how life will change with the help of RE-SAMPLE, what benefits will come. Responsible actors are clinicians with support from RRD on methodology. Localisation is very important. (2) Newsletters more targeted to associations, both the local subsidiaries of the European Lung Foundation and patient groups. This should be a joint work between HOPE and local teams. (3) Leveraging the social media of the associations and putting our content in their social media channels. We can start with the content that is already available and disseminate it through their channels, but eventually create more ad hoc type of material.

3.2 Network inventory

After the workshop, potential partners for dissemination were identified. For each pilot site, potential partners, a description of the organisation, and contact details were specified. These initial lists are the starting point of the network inventory for RE-SAMPLE, new organisations or other potential partners can be added to the document. The initial list, including the name of the organisation and a short description can be seen in Table 2Table 5 below.

Table 2: Initial network inventory Estonia

Name organisation	Description
TUK patient panel	RE-SAMPLE patient panel from TUK
Estonian Respiratory society	Society of Estonian Lung doctors
Estonian Chamber of Disabled People (EPIK)	EPIK consists of disability organisations in Estonia and aims to support people with disabilities and chronic diseases.
Estonian Lung association	The Estonian Lung Association is a representative organisation of people suffering from lung diseases in Estonia, and belongs to the EPIK

Table 3: Initial network inventory Italy

Name organisation	Description
GEM patient panel	RE-SAMPLE patient panel from GEM
Associazione Italiana Pazienti BPCO Onlus: COPD patient association	The Italian Association of COPD Patients.
Italian Respiratory society	Italian society of pulmonologists.
Respiriamo Insieme Community (RIC)	A non-profit organisation that aims to finding the right cure for patients with breathing, immunological and allergic pathologies.
Federasma and Allergy Patient Federation	Federation that supports patients in recognizing and managing their conditions.

Table 4: Initial network inventory the Netherlands.

Name organisation	Description
MST patient panel	RE-SAMPLE patient panel from MST
Longpunt	Nationwide Network (from Longfonds)
Luchtgenoten	Patient organisation for patients with COPD, asthma, and other lung conditions.
Luchtwerk	Rehabilitation program for COPD patients
Netherlands Respiratory society	Society of researchers and pulmonologists in the Netherlands
THOON netwerk	Research and development network among general practitioners in the Netherlands.
Longfonds	Lung organisation that focuses on healthy living, medical breakthroughs and taking control.
Nederlandse vereniging van Artsen van Longziekten en Tuberculose (NVALT)	The Dutch scientific association for pulmonologists and pulmonologists in training.
Tactus	Dutch organisation that provides addiction care.
Facebook support group: Ons leven met COPD	Patient support group on social media (Facebook)
Facebook support group: Positive COPD group	Patient support group on social media (Facebook)

Table 5: Initial network inventory European organisations.

Name organisation	Description
European Lung foundation (ELF)	ELF is a patient-led organisation that aims to improve lung health and advance diagnosis, treatment, and care.
European Federation of Allergy and Airway Diseases Patients' Associations (EFA)	EFA connects different patient associations in Europe.

These organisations are being and will be contacted to share our initial results and asked to collaborate with us, for example, in disseminating the results (e.g., summaries of end-user activities in WP5 (see section 5.2)) and invitations for participation (e.g., surveys or to join the end-user panel).

4. RE-SAMPLE End-User Panel

The RE-SAMPLE end-user panel was initially set up in the Netherlands and has been slightly changed. The initial focus was on patients only, who were asked to sign up either for the ‘user panel’ or the ‘expert group’ (as described in D5.7 *End-user involvement for design and evaluation*). The difference between these two groups was not completely clear and it is also possible that a member of one group would like to join the other group. Furthermore, as RE-SAMPLE is not only relevant for patients, we also wanted to make the panel inclusive for healthcare professionals, caregivers and other stakeholders and also for Italy and Estonia. So, we made some adaptations to the end-user panel. These adaptations were developed by RRD and the UT.

4.1 Adaptations

First of all we started by having only one group, the RE-SAMPLE end-user panel. In the options for people to engage with the RE-SAMPLE project, we added this option as well (see Figure 1). Besides this, healthcare professionals can now also join the RE-SAMPLE end-user panel (see Figure 2).

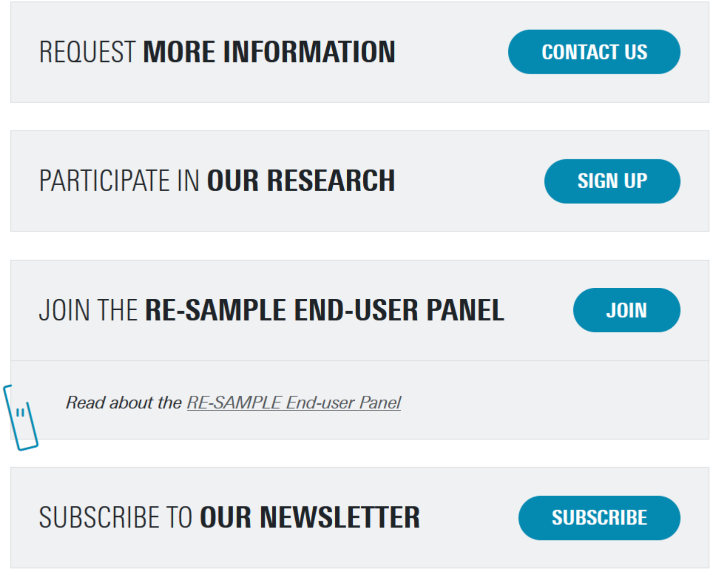


Figure 1: Options for patients to engage with the RE-SAMPLE project.

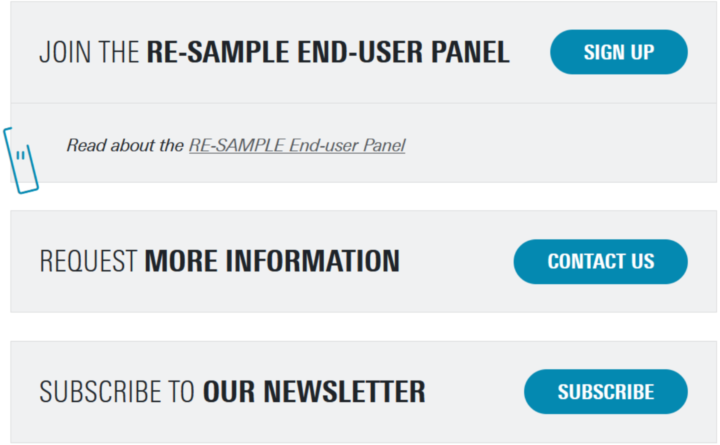
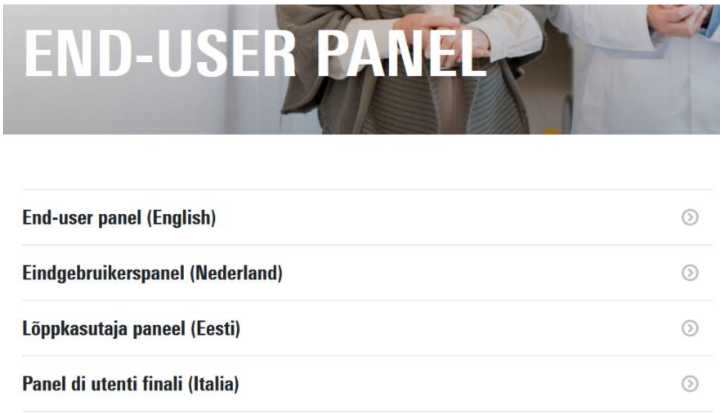


Figure 2: Options for HCPs to engage with the RE-SAMPLE project.

Furthermore, we did not want participants only from the Netherlands within this panel. We also involve patients and healthcare professionals from Italy and Estonia in our end-user studies. By involving all these groups, we can develop a RE-SAMPLE technology, which fits all three countries. So now, patients and healthcare professionals from these countries also have the opportunity to join the panel. The page of the end-user panel gives people the option to choose a country. The end-user panel pages are now multi-language (see Figure 3).



END-USER PANEL

End-user panel (English)

Eindgebruikerspanel (Nederland)

Lõppkasutaja paneel (Eesti)

Panel di utenti finali (Italia)

Figure 3: Multi-language RE-SAMPLE end-user panel.

After choosing one of the countries, people can read about the RE-SAMPLE project and understand why we need input from potential end-users. Next to this, we explain what they can do when they are interested in joining the panel, what happens after they signed up for the panel, and what we will do with their data. If they have any questions, they can contact us via the following e-mail address: re-sample@utwente.nl. At the bottom of the text, they find a button to join the RE-SAMPLE end-user panel (see Figure 4, Figure 5 and Figure 6).

END-USER PANEL (ENGLISH)

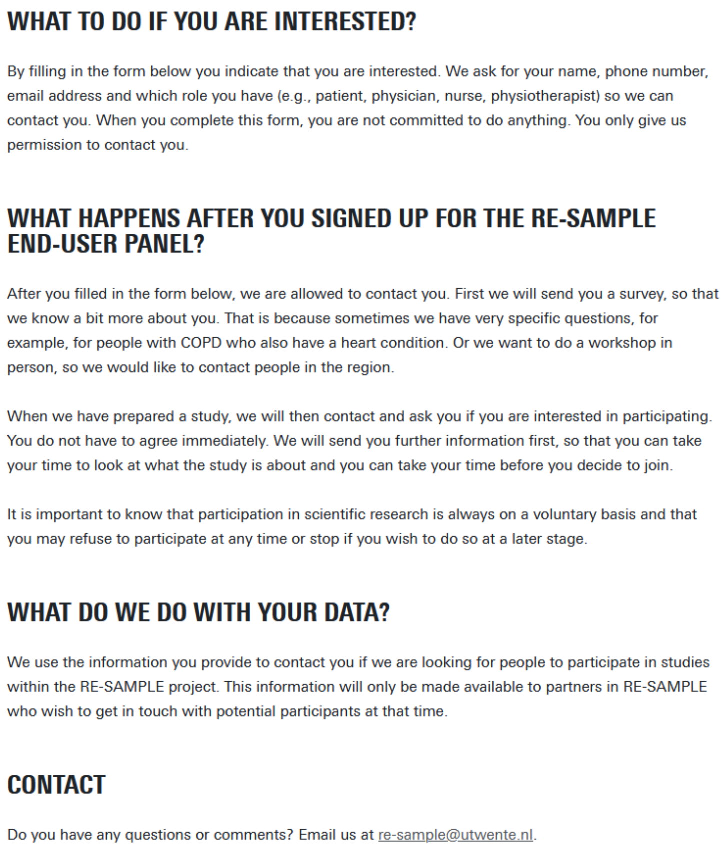
BECOME INVOLVED IN THE RE-SAMPLE END-USER PANEL

RE-SAMPLE started in March 2021 and is a four year project funded by the European Horizon 2020 research programme. Together with ten European partners, we want to develop an eHealth technology that can help investigate what can cause COPD symptoms to worsen (=exacerbation or flare ups) so that these can be treated faster and that possible damage can be limited. Furthermore, the RE-SAMPLE eHealth solution aims to support

- **patients** in self-managing their condition,
- **healthcare professionals** in getting support when treating their patients and also getting a better overview of risk factors and treatment options,
- **both patients and their healthcare professionals** in making treatment decisions **together** so that the care is tailored to the patient and in line with their preferences and values.

To develop RE-SAMPLE, we need input from potential end-users, as they are experts on what it means to live with COPD and other chronic conditions, how to provide treatment and in what way technology can support these activities. For this purpose, we often invite patients and healthcare professionals to participate in RE-SAMPLE, for example, by filling in a survey, being interviewed, join a workshop with other patients or professionals, etc.

Figure 4: RE-SAMPLE end-user panel text part 1.



WHAT TO DO IF YOU ARE INTERESTED?

By filling in the form below you indicate that you are interested. We ask for your name, phone number, email address and which role you have (e.g., patient, physician, nurse, physiotherapist) so we can contact you. When you complete this form, you are not committed to do anything. You only give us permission to contact you.

WHAT HAPPENS AFTER YOU SIGNED UP FOR THE RE-SAMPLE END-USER PANEL?

After you filled in the form below, we are allowed to contact you. First we will send you a survey, so that we know a bit more about you. That is because sometimes we have very specific questions, for example, for people with COPD who also have a heart condition. Or we want to do a workshop in person, so we would like to contact people in the region.

When we have prepared a study, we will then contact and ask you if you are interested in participating. You do not have to agree immediately. We will send you further information first, so that you can take your time to look at what the study is about and you can take your time before you decide to join.

It is important to know that participation in scientific research is always on a voluntary basis and that you may refuse to participate at any time or stop if you wish to do so at a later stage.

WHAT DO WE DO WITH YOUR DATA?

We use the information you provide to contact you if we are looking for people to participate in studies within the RE-SAMPLE project. This information will only be made available to partners in RE-SAMPLE who wish to get in touch with potential participants at that time.

CONTACT

Do you have any questions or comments? Email us at re-sample@utwente.nl.

Figure 5: RE-SAMPLE end-user panel text part 2.

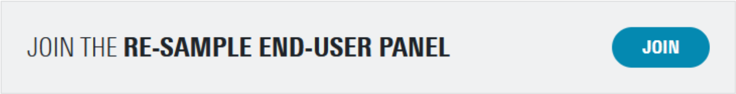
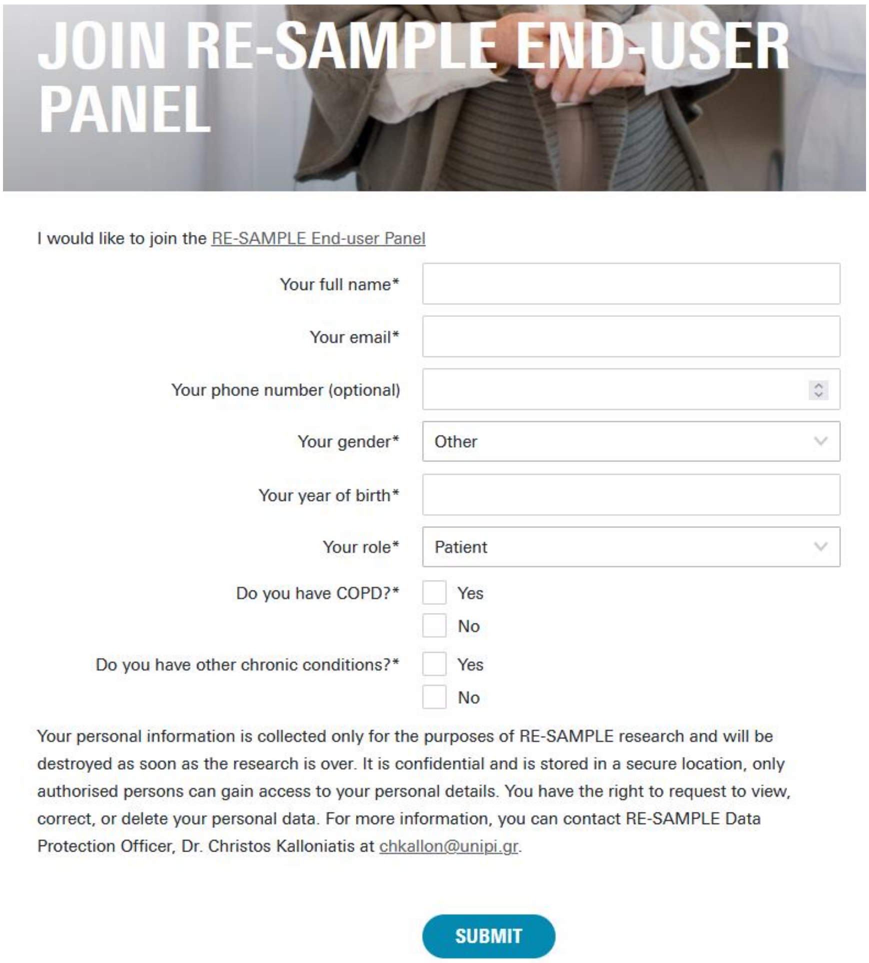


Figure 6: RE-SAMPLE end-user panel join-button.

When signing up, people need to fill in some questions. In the first version, these questions were only about their full name (mandatory), e-mail address (mandatory), and phone number (optional). These questions are still there, but we added more: their gender, their year of birth, their role, whether they have COPD and whether they have other chronic conditions. All these new questions are mandatory. For gender, they can choose between male, female, other, or prefer not to tell. For role, they can choose between patient, healthcare professional, caregiver, or other. As explained, we need their inputs as well within the RE-SAMPLE project, so they can join our panel too. Furthermore, beneath the questions, we explain how we will act upon their personal information and that they can contact the Data Protection Officer (DPO) from RE-SAMPLE (Dr. Christos Kalloniatis, UPRC) (see Figure 7).



JOIN RE-SAMPLE END-USER PANEL

I would like to join the RE-SAMPLE End-user Panel

Your full name*	
Your email*	
Your phone number (optional)	
Your gender*	Other
Your year of birth*	
Your role*	Patient
Do you have COPD?*	☐ Yes ☐ No
Do you have other chronic conditions?*	☐ Yes ☐ No

Your personal information is collected only for the purposes of RE-SAMPLE research and will be destroyed as soon as the research is over. It is confidential and is stored in a secure location, only authorised persons can gain access to your personal details. You have the right to request to view, correct, or delete your personal data. For more information, you can contact RE-SAMPLE Data Protection Officer, Dr. Christos Kalloniatis at chkallon@unipi.gr.

Figure 7: Registration page for joining RE-SAMPLE end-user panel.

4.2 Process following sign-up

After a person signed up for the end-user panel, an automatic e-mail will be send to re-sample@utwente.nl. This person will be added in the list of panel members. This overview is confidential as only people responsible for the end-user panel can access it. Then, the person will receive a welcome e-mail (sent by the UT) including the baseline/demographic questionnaire that (s)he is being asked to complete.

4.3 Process recruitment for a study

In order to better manage the end-user studies, we defined a standard process in the consortium for the organisation of such studies and the recruitment of end-users to be involved. To support this process, we created an Excel file listing all the members from the end-user panel.

1. A month before something is asked to the end-users, the researchers will inform each other via email. (To avoid that too many studies are being conducted simultaneously and end-users will be spammed with e-mails).
2. The study description, start and end date, number of participants will be filled in in the end-user panel Excel file (tab "studies").
3. In the end-user panel Excel file (tab "general"), the contact date of each end-user for each study will be filled in.
4. The template of the e-mail sent to the end-users is added to the document "Templates emails sent".

During this process, researchers will try to contact the right people for the study based on their interests measured through the baseline/demographic questionnaire, see end-user panel Excel file (tab "general").

4.4 Promotion

To promote the RE-SAMPLE project and the end-user panel, a flyer was created by RRD and HOPE that included a very short summary of the initial end-user studies and a QR code to the video (see more on this in section 5.2).

Furthermore, the material was also sent to the network of associations identified (see section 3) in November and December 2022.

Besides this, a student group assignment was conducted in the Netherlands. This assignment focused on how we can recruit patients with COPD and a low social economic position (SEP). People with a low SEP, have more often a lower level of education. These people do need other recruitment strategies, which fit their situation. This group assignment started in September 2022 and ended in January 2023. During this assignment, the student group searched in literature, sent a questionnaire to HCPs and completed face-to-face questionnaires together with patients with COPD and a low SEP. Based on all these results, the students wrote an advisory report about different recruitment strategies. This report is in Dutch, so we will summarize the results below. During future recruitment activities for the end-user panel, we will take the results of this assignment into account.

In the advisory report, the students describe four alternatives for recruitment strategies:

1. **An online campaign**. Based on the results, the students explained how we can recruit end-users via Facebook, Search Engine Optimisation (SEO) and Search Engine Advertising (SEA). They also discuss the pros and cons of this strategy.
2. **A physical campaign**. The students explained how we can recruit end-users via billboards, promotional items, brochures, flyers, newspapers and sponsoring clubs or events. Again, they discuss the pros and cons of this strategy.
3. **Video and audio**. The students explained how we can recruit end-users via advertisements on television and on the radio. Again, they discuss the pros and cons of this strategy.
4. **Expand the focus area**. In the Netherlands, we mainly focus on people from the Eastern region, as all partners involved in RE-SAMPLE are from there. The students explained that we can benefit from including people from other areas too. Furthermore, they explain how we can do this, and the pros and cons of this strategy.

For the first three recruitment strategies, the students created an example tool we can use, for example: a design for an online campaign on Facebook, a design for flyers, or an audio recording for a radio advertisement.

For each strategy, the students looked at its feasibility in terms of: financial feasibility, organisational feasibility, economic feasibility, technological feasibility, social feasibility, legal feasibility and ecological feasibility (see Table 6). Based on this, we can choose which strategy/strategies we want to focus on.

Table 6: Feasibility of recruitment strategies.

Strategy	F	O	E	T	S	L	E
Online campaign	4	4	3	3	5	4	5
Physical campaign	4	4	4	3	5	5	1
Video and audio	2	4	3	3	5	2	3
Expand focus area	5	5	4	2	5	3	3

4.5 Current status end-user panel and future activities

As of the 2nd of February 2023, N=32 people have signed up to be part of the end-user panel in total. In addition, 40 patients and 22 HCPs who participated in the Dutch studies gave their consent to be contacted again in the future by RRD.

The RE-SAMPLE end-user panel was utilised to recruit participants for a feedback session about the information brochure for cohort recruitment. 10 members participated in this session. Furthermore, the

RRD contact list was utilized to recruit participants for the fifth iteration (see section 6.2) and for a study from a student at RRD. For the fifth iteration, all patients received an e-mail, and 10 signed up and participated. The student made a re-design of the Healthentia app and tested its usability. Again, all patients received an e-mail, and 7 signed up and participated. The results of this study are not available yet, but will be included in the next Deliverable.

In the coming months, we will change the process a little bit after a person signs up for the end-user panel. We will choose, for each country, the contact person of the end-user panel. This contact person will then be responsible for contacting the members of the end-user panel from their country. Furthermore, we will change the introductory survey a little bit, and we will incorporate a survey for the other roles as well.

5. Continuous end-user feedback

5.1 Participants in the cohort study

Some participants of the cohort study shared unprompted feedback with the RE-SAMPLE consortium about the Healthentia app. This feedback is listed in Table 7, and most errors were fixed directly. Only one error could not be replicated, so we are not completely aware of what caused it. We did not receive this comment multiple times.

Table 7: Feedback from participants in the cohort study.

Time	Cohort	Description	Comment
April 2022	MST (NL)	Participant reported that the text box in the COPD questionnaire allows only for one line of text and she prefers a bit more space.	Error could not be replicated
April 2022	MST (NL)	Text in COPD questionnaire was in English not Dutch ('type here')	Fixed
April 2022	MST (NL)	Participant experienced an exacerbation and was notified to receive additional laboratory tests. This notification was in English.	Fixed
June 2022	MST (NL)	Participant reported that some of the texts in the Sleep widget was appearing in English, even when the application was set to Dutch	Fixed

5.2 Participants in the end-user studies

Feedback is not a one-way pathway. When building a relationship with end-users, it is also important to keep them in the loop and to share early results and/or summaries of the studies they participated in. Sometimes this also led to unprompted feedback by phone or email by some participants.

Sharing results from the end-user sessions is important. By doing this, the project also gives something back and not only asks for information *from* participants. Furthermore, the responses we received afterwards also illustrate that sharing initially results is important as it encourages participants to stay engaged and share further thoughts and provide valuable feedback.

5.2.1 User needs studies – May 2022

After the initial round of end-user studies to elicit the user needs and requirements, a summary of the results was sent to the Dutch participants as text document and video. The following quote is a response from a participant we received via email (translated from Dutch to English for this deliverable):

> *"Thank you for the outcome so far.*
>
> *However, there are factors that need to be better highlighted.*
>
> *People talk about loneliness while there should also be looked at acceptance and learning to deal with this disease.*
>
> *Furthermore, there could be attention for the family, also for them it is difficult if your partner has this disease.*
>
> *And one wonders how it goes in other countries with different patients and doctors."*

Another participant called one of the researchers to tell that (s)he watched the feedback video several times. (S)he was very enthusiastic, (s)he thought it was beautifully done, and that this was a nice way to see what has been done in the project.

As the first summary from the user needs studies was highly appreciated, it was decided to also share it with patients and healthcare professionals who had not participated. As the first version was addressing the Dutch participants directly (i.e., thanking them for their participation and input), the summaries were slightly adapted to be appropriate for the wider audience and translated also to English (see text in *Appendix A: Summaries shared with study participants, cohort participants and panel members*
Summary user needs, and video in Dutch https://www.youtube.com/watch?v=gmbBlR--RHc and in English: https://www.youtube.com/watch?v=5Jfrm1eykYE&t).

5.2.2 Service model – November 2022

The service model was designed iteratively through a series of workshops involving various stakeholders in all three countries. The results from the different workshops were used to make a summary and a feedback video. This was sent to the participants of the service model studies in all pilot sites, Dutch cohort participants within RE-SAMPLE, healthcare professionals, Dutch physiotherapist practices, and the initial Dutch network inventory list. Two participants responded on this feedback with the following quotes (translated from Dutch to English for this deliverable):

> *"Nice and clear explanation.*
>
> *I like to stay connected and I am certainly also personally interested in self-management and support through a smart Watch.*
>
> *I like to stay informed and good luck with further research."*

and

> *"I watched the video with interest.*
>
> *[. . .]*
>
> *If necessarily, I would like to participate in future studies."*

The feedback videos are available online in Dutch (https://www.youtube.com/watch?v=S-PkshYyHMI) and in English (https://www.youtube.com/watch?v=Yh54A0il6AM). The text is available in this deliverable in *Appendix A: Summaries shared with study participants, cohort participants and panel members*
Summary user needs.

6. Iterative development of the Virtual Companion for patients

6.1 Usability benchmarking and user experience assessment (Ongoing)

The second iteration of end-user studies focuses on assessing the user experience and usability of the Healthentia app in real life. For this, patients included in the cohort study were asked to report their experience of daily use and assess the usability of the current system used for data collection (i.e., the Healthentia app). This section describes the first results of this iteration.

6.1.1 Methods

6.1.1.1 Study design

As described in D5.7 *End-user involvement for design and evaluation*, the HUBBI questionnaire that was used during the first iteration will also be used during the next iterations of the end-user studies. This benchmarking allows us to assess and compare the usability of the Healthentia app over time. This questionnaire was completed one week after a patient starts using the Healthentia app.

Next to the benchmark, the second iteration end-user studies includes also two additional studies with cohort participants who have used the Healthentia application for a longer period. This gives us insights into the user experience, the extent of usability and the nature of usability issues that might not be detected during a one-time and guided use during a short period in the lab setting. Two additional questionnaires were developed, in which special attention was paid to the issues identified in the first iteration of end-user studies. These questionnaires were prompted 4 weeks after starting using the Healthentia app, and 1-2 weeks after experiencing an exacerbation.

6.1.1.2 Participants

For evaluating the usability and user experience of the Healthentia app in real life, patients from the cohort study were asked to complete several questionnaires. The aim is to gather a total of 120 completed HUBBI questionnaires, 40 from each pilot site (the Netherlands, Italy and Estonia), a total of 120 completed user experience questionnaires after 4 weeks of use, also 40 from each pilot site, and a total of 60 completed user experience questionnaires after 1-2 weeks after an exacerbation, 20 from each pilot site.

6.1.1.3 Study procedure

Patients are continuously being recruited for the cohort study. One week after patients start using the Healthentia app, they receive the HUBBI questionnaire via the app. This questionnaire consists of 18 statements measuring Healthentia's usability. Four weeks after patients started using the Healthentia app, they receive a link to the user experience questionnaire via the app. This questionnaire is being asked outside of the Healthentia app, within Qualtrics. The questionnaire consists of a total of 33 questions. Furthermore, 1-2 weeks after patients experienced an exacerbation, they receive a link to another user experience questionnaire via the app. This questionnaire is also being asked outside of the Healthentia app, within Qualtrics. The questionnaire consists of a total of 24 questions. The study procedure and all questionnaires are shown in *Appendix B: Study procedure and instruments second iteration end-user study*.

6.1.1.4 Data analysis

Participants' responses to the HUBBI questionnaire were exported from Healthentia as a comma-separated file with an entry for each question that was answered. Each entry listed information that included details such as the participant ID, study site, questionnaire ID, questionnaire name, question ID, and response. These data were then processed and plotted using R (version 4.2.2) which involved the following steps:

1. The table with responses was inverted to get a row with responses per participant.
2. The dataset was then relabelled to become more human-interpretable. That is, 'ds.ShortId' was relabelled to 'SubjectID' and the response fields for the specific questions were re-labelled from their database numbering to question IDs that indicated the subscale they corresponded to (e.g., '7563' would become 'BSP3').

3. Scores for the basic system performance subscale questions 3 and 4 were reversed. These were ‘I experienced system errors’ and ‘I get stuck when using the system’, respectively.
4. Then, as pre-processing for creating the plots, the mean scores for each subscale per participant were computed.
5. To generate the radar plots, the mean value per subscale was computed for the included set of participants using the ‘radarchart’ function.
6. To generate the boxplots the preprocessed responses for the questions in each subscale were plotted using the ‘boxplot’ function.

This process was followed with the data for all participants and for each of the sites specifically.

6.1.2 Results

6.1.2.1 HUBBI

We report on the HUBBI data collected until January 13th, 2023 (date of exporting the responses from Healthentia). A total of 67 responses was collected for all three pilot sites, of which 15 from MST (the Netherlands), 15 from GEM (Italy) and 37 from TUK (Estonia).

In the previous deliverable for Task 5.5 (D5.7 *End-user involvement for design and evaluation*), the Healthentia app scored an overall score of 3.8 on a scale of 1 (bad usability) to 5 (good usability). For purpose of comparison with the new results, scores for the specific subscales of those previously reported results are shown in Figure 8. As previously stated, when observing this HUBBI outcome radar chart, all scores in the green field indicate that that part is good, yellow means okay but can be improved and orange or red means that aspect of the usability is bad. For the previously reported outcomes, the dimensions task-technology fit and satisfaction were considered good. There were no scores in orange or red, which is also good, but there were quite a few in yellow (interface design, navigation & structure, information & terminology and guidance and support).

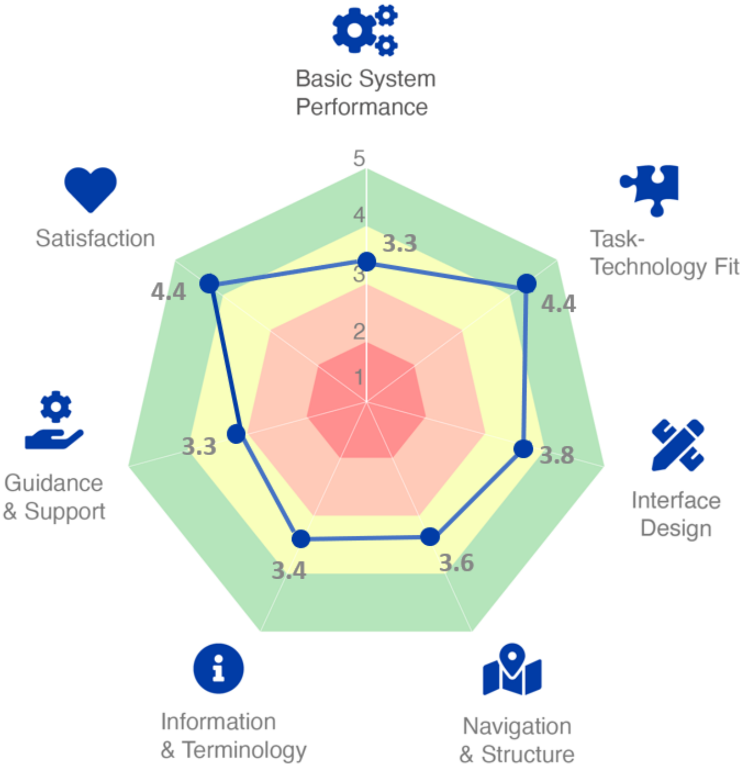


Figure 8: HUBBI scores of the Healthentia app as reported in D5.7.

A depiction of the HUBBI scores for all participants in the cohort can be found in Figure 9. As can be seen, most scores stayed relatively the same for the subscales, but Task- Technology Fit and Overall Satisfaction received lower scores.

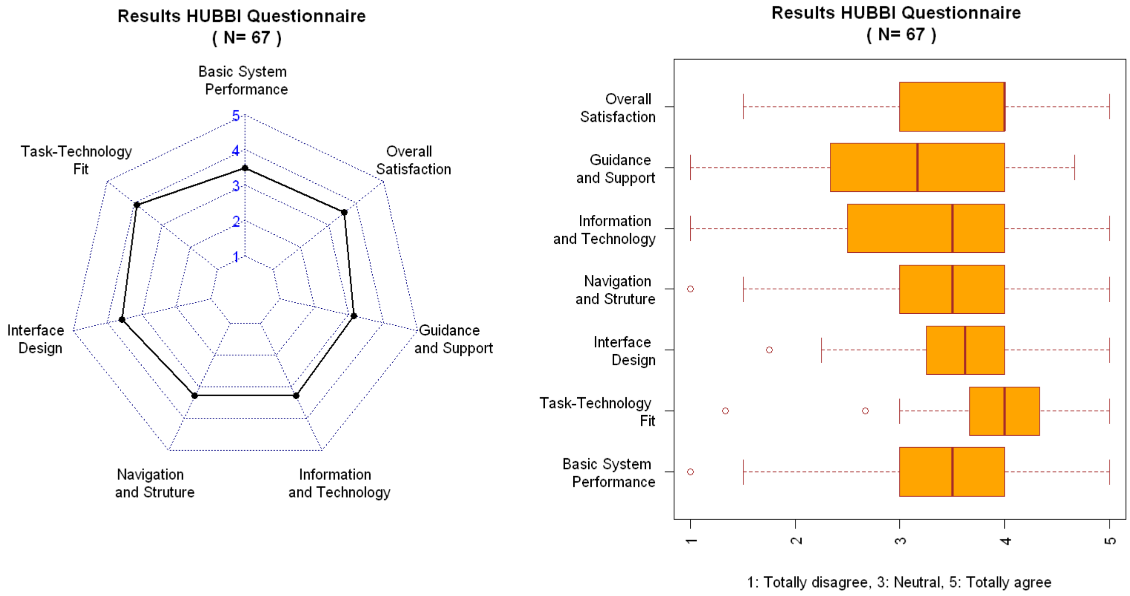


Figure 9: A spider plot and boxplot showing the responses to the HUBBI questionnaire for all participants in the cohort.

Figure 10-Figure 12 show the responses split out for the three study sites, MST, GEM, and TUK, respectively.

As can be seen (Figure 10), participants at MST gave a higher score than then average for all participants for Basic System Performance and Overall Satisfaction. They gave slightly lower scores for Guidance and Support and Information and Technology.

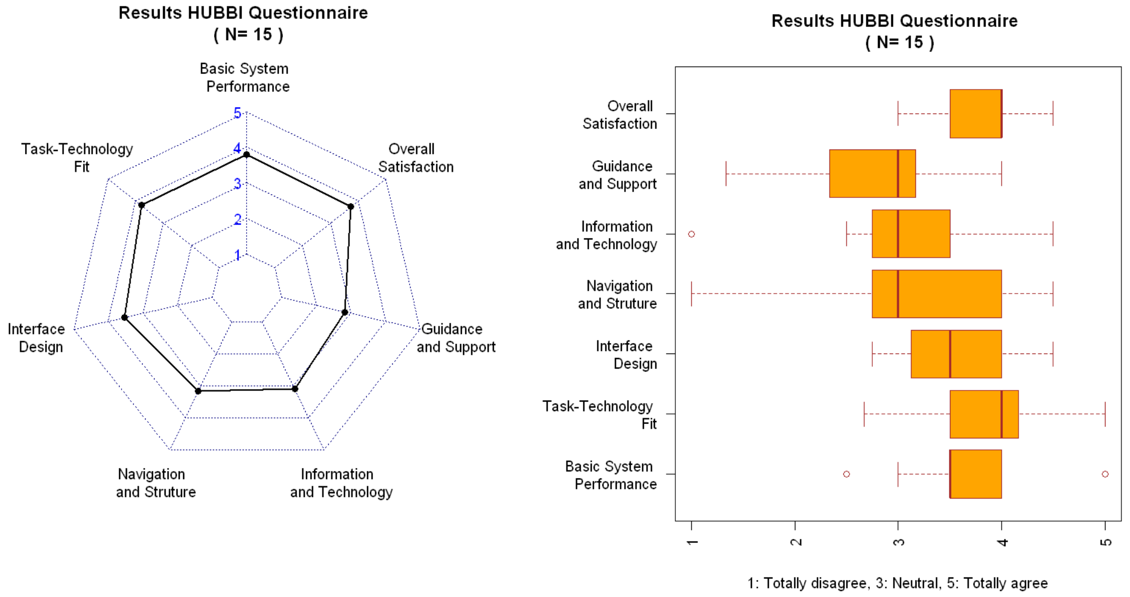


Figure 10: A spider plot and boxplot showing the responses to the HUBBI questionnaire for participants from the MST site.

Participants at the GEM site (Figure 11) were also more positive about Basic System Performance than all participants in RE-SAMPLE on average, but otherwise their scores on the other subscales were in agreement.

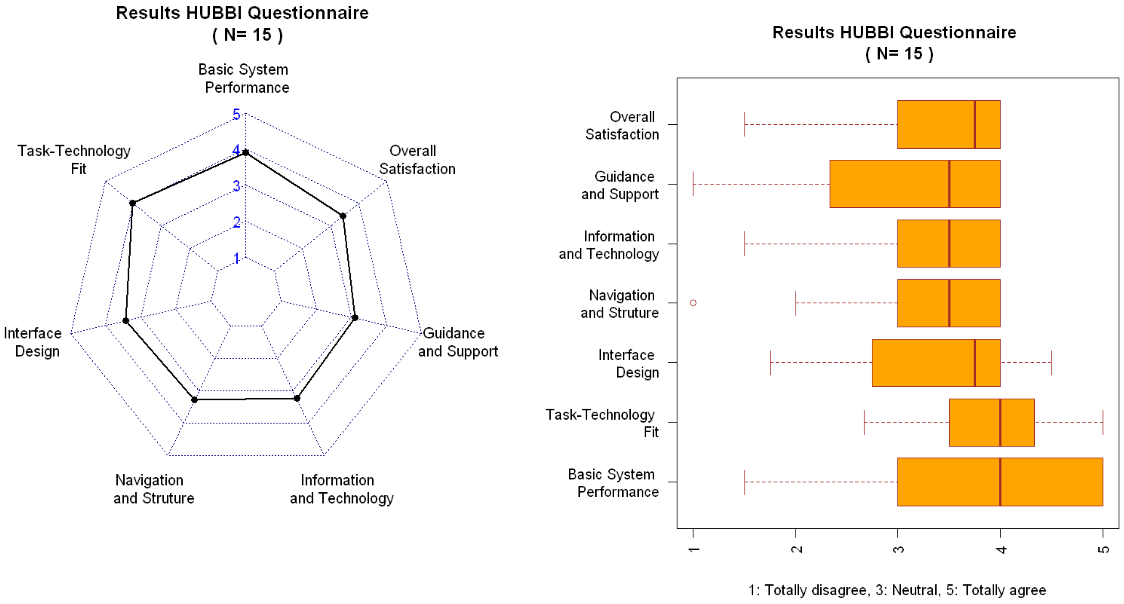


Figure 11: A spider plot and boxplot showing the responses to the HUBBI questionnaire for participants from the GEM site.

Finally, participants at the TUK site (Figure 12) agreed with the average of the full population on most subscales, but they did give a lower score for Basic System Performance.

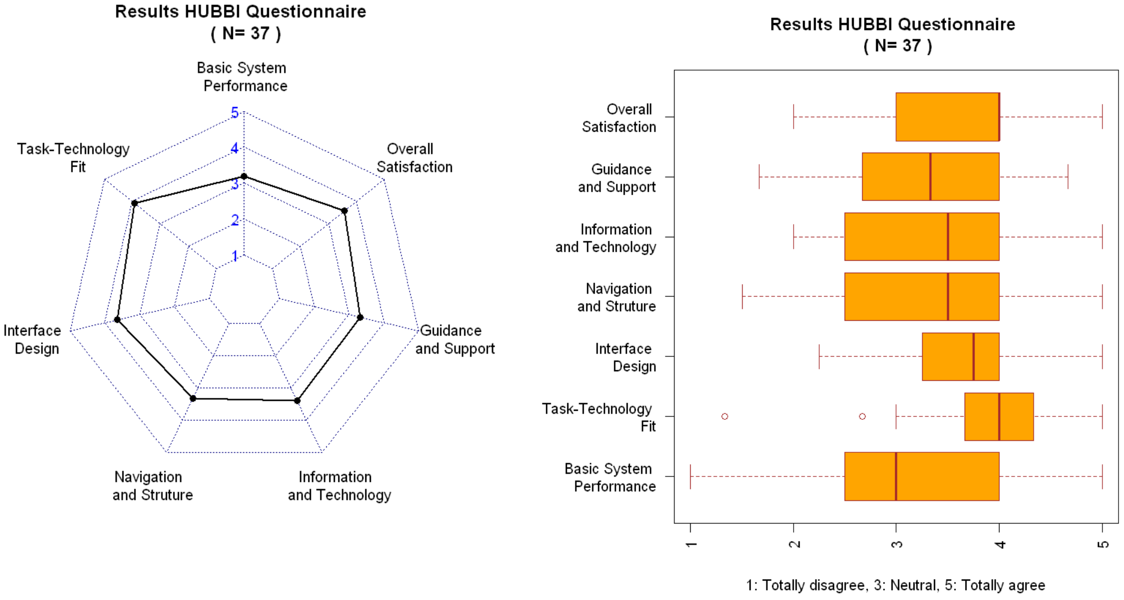


Figure 12: A spider plot and boxplot showing the responses to the HUBBI questionnaire for participants from the TUK site.

Overall, considering that the previous evaluation in D5.7 *End-user involvement for design and evaluation* was performed with 8 older adults (45+) from the Netherlands who did not have COPD, it is good to see that the scores for most items remained similar when the application is used by participants from the target population and in all three countries. The decrease in scores for Task- Technology Fit and Overall Satisfaction can most probably be contributed to a difference in study setup. That is, the previous usability evaluation took place in a controlled lab setting with participants being asked to perform a few specific tasks, while this evaluation took place in users' daily life after a longer period of using the application.

6.1.2.2 User experience questionnaires

The user experience questionnaires 4 weeks after use and 1-2 weeks after exacerbation are not completed yet. When adding these questionnaires to our protocol, the current patients within the cohort study were using the Healthentia app already for a longer time period. We chose to not prompt these questionnaires afterwards for these patients, as we want to measure the user experience when patients are accustomed to using the Healthentia app, but not using it too long. Furthermore, due to the recruitment problems we ran into within the cohort study (as described in D5.4 *Mid-term recruitment report*), we have not collected completed user experience questionnaires. Measures are being taken to compensate the delays in recruitment. These measures are also described in D5.4 *Mid-term recruitment report*. Recruitment for the cohort study will continue in the following months, as will continue collecting user experience questionnaires.

6.2 Interviews: Data utilisation, risk prediction and use of a virtual coach (Autumn 2022)

The fifth iteration we planned was with patients again. We conducted semi-structured interviews, which started in the Autumn of 2022 in the Netherlands, Italy and Estonia. The aim of this iteration was to discuss with patients how the RE-SAMPLE technology needs to communicate with the patient. We discussed different topics: health data utilisation (in general and to monitor their health), risk predictions and the use of a virtual coach.

6.2.1 Methods

6.2.1.1 Study design

We conducted semi-structured interviews, which were audio-recorded. Starting with the health data collection, we first discussed four statements with the participants, and then we showed and discussed some example mock-ups of a future health technology for self-managing COPD. Next, we continued with the topic of predicting your health. We first asked some general questions about their attitude towards this, and then we showed and discussed again example mock-ups of a technology in which health predictions were shown. The final part of the interviews was about the use of virtual coaches. Participants could see mock-ups of screens and read a small conversation between a fictional patient Linda and her virtual coach Marc, and then were asked some questions about their attitude.

6.2.1.2 Participants

The aim was to include 20 patients with COPD, divided in the different countries participating.

6.2.1.3 Study procedure

Before participation, participants signed an informed consent form. Then, the study started and participants first completed a questionnaire focusing on their demographics. After completion, the interviews commenced. This interview was divided into four parts:

1. **Part 1: data utilisation**
   Participants received four theses about this topic and could give their first impression about each thesis. Then we asked some follow-up questions to let participants explain their opinion. An example of a thesis was: “Gathering my own health data by means of a wearable or another device is important to monitor my complaints.” In *Appendix C: Materials used during iteration 5 (autumn 2022)* you can find all theses and follow-up questions.
2. **Part 2: monitoring your health**
   We showed participants different mock-ups of an example future RE-SAMPLE technology. These mock-ups showed several aspects of health data: activity measured in number of steps, mood, positive health questionnaire data, visits to healthcare professionals (agenda), and data about their visits (just like a medical record). Participants were asked what they think of these mock-ups, whether they were interested in seeing this information, what they would do with the information and whether they would share it with their HCPs. In *Appendix C: Materials used during iteration 5 (autumn 2022)* you can find the questions, and the mock-up screens.
3. **Part 3: predicting your health**
   We first asked participants in general what they think of the idea of receiving health predictions, on what topics they would like to receive a prediction, how they want to receive the prediction and whether they would use a tool which gives them health predictions. After discussing these topics, we showed them again mock-ups of a technology which shows health predictions. These predictions were about mood and dyspnoea with and without explanation. We asked them about their opinion towards these mock-ups. In *Appendix C: Materials used during iteration 5 (autumn*

2022) you can find the questions, and the mock-up screens.

4. **Part 4: the use of a virtual coach**
   Finally, we told the participants that the future RE-SAMPLE technology would include a virtual coach. We showed them an example conversation between a user and the coach. After reading through the conversation, we asked participants about their attitude towards this. In *Appendix C: Materials used during iteration 5 (autumn 2022)* you can find the questions, and the mock-up screens.

After part 3 and after part 4, participants completed a short questionnaire: the TWente Engagement with Ehealth Technologies Scale (TWEETS). This questionnaire measures users' engagement with an eHealth technology on three constructs: behavioural engagement, cognitive engagement and affective engagement (Kelders & Kip, 2019; Kelders, Kip, & Greeff, 2020). We first asked them to fill out this questionnaire after showing the mock-ups of health prediction to see how patients expect their engagement with such a technology would be. Then, we asked them to complete this questionnaire again after being introduced to the virtual coach to see whether this would change their expectations towards engagement with the technology. This questionnaire can be found in *Appendix C: Materials used during iteration 5 (autumn 2022).*

6.2.1.4 Data analyses

For describing the demographics of the participants, we used descriptive statistics like mean, standard deviation, minimum, maximum and percentages. The audio-recordings of the interviews were transcribed, added in a data analysis Excel file, and then coded. For all three constructs of the TWEETS questionnaire, a mean was calculated on a scale ranging from 1 (low engagement) to 5 (high engagement). We wanted to test whether there is a difference in patients' engagement with the future RE-SAMPLE tool between two time points during the interviews: after discussing the risk predictions and after discussing the virtual coach. As all variables were not normally distributed, we used the Wilcoxon Signed Ranks test for this.

6.2.2 Results

6.2.2.1 The Netherlands

Demographics

A total of 10 adults with COPD participated in the interviews, 7 of them also suffer from other chronic conditions (e.g. cardiovascular disorders, Diabetes Mellitus type 2). The study population's mean age was 69 years (SD=3.9), and the majority of the population was male (70%). The participants were all living with COPD for at least 6 years, so the chronic condition was not something new to them. Table 8 gives an overview of the measured demographics.

Table 8: Overview demographics of the 10 participants in the Netherlands.

Demographic	**Sub-category**	**% or M (SD) | Min-Max**
Gender	Male	70
	Female	30
Age		69.0 (3.9) | 64.0 – 75.0
Comorbidities	Cardiovascular disorders	30.0
	Hypertension	10.0
	High cholesterol	10.0
	Diabetes Mellitus type 2	10.0
	Fibromyalgia	10.0
	Muscle cramp fasciculation syndrome	10.0
	Asthma	10.0
	Rheumatoid arthritis	10.0
	None	30.0
Number of years diagnosed with COPD	<1 year	0 .0

	1-2 years	0.0
	3-5 years	0.0
	6-10 years	40.0
	>10 years	60.0
Highest level of education	Primary school	0.0
	High school	30.0
	Trade school	40.0
	University	30.0
Employment status	Full time	0.0
	Part time	0.0
	Seeking opportunities	0.0
	Retired	60
	Unable to work	30
	Retired but doing voluntary work	10
Number of family members living together		1.1 (1.0) | 0.0 – 3.0
Health related quality of life		2.9 (1.1) | 1.0 – 4.0
Health literacy		4.1 (0.6) | 3.0 – 4.7
Digital skills		3.1 (0.7) | 2.0 – 4.0
Devices in use	Computer/laptop	90.0
	Smartphone	100.0
	Smartwatch	10.0
	Tablet	60.0

Data utilisation for COPD monitoring

Statements about data utilisation

Statement 1: "Gathering my own health data by means of a wearable of another device is important to monitor complaints".

When we presented the participants the first statement, the majority agreed with it. The reasons why they thought it is important is because this can help them to adjust their treatment remotely, to inform the HCPs and to monitor the oxygen saturation: *"Well, for me it's important because I'm often struggling with my oxygen saturation. Heart rate is okay, but saturation goes up and down, that's what most people who have this disease experience. […] For me, it's more and more going down, instead of also going up. Then at some point, when I have a too low saturation, my health deteriorates even further. […] So for me, that's actually viable."* [NL-010]. Three participants expressed some remarks regarding the statement: (1) it is important, but the health data gathered by for example a wearable does not always reflect how you feel, (2) for that particular participant it is not important, but (s)he thought that for persons with more severe COPD, it is important to gather health data, and (3) it is not important, but it is useful to gather your health data if you are interested in it. This last person also indicated (s)he rather measures health data somewhere else: *"I take another path [to measure health data]. Then you get among people again, and you have a conversation. You're moving again, which is good for a lung patient."* [NL-008].

Participants were asked which health data they gather on their own. Almost all of them measure their oxygen saturation. Reasons why they measure this is to check the oxygen saturation when they do not feel well, just for their own interest because they are diagnosed with COPD, or to monitor their activities to prevent going too far. Some patients also measure other parameters: sleep, blood pressure, heart rate and steps. Only two participants indicated they do not measure anything on their own, their physical therapist measures for example saturation, blood pressure or heart rate during the therapies. Most of them do not write down the measurements they take: *"I did for a while, but at some point, it was no longer necessary because it, yeah, one time it is very high, another time it is very low again. It's so different every time.*

And that, I didn't get diagnosed with it yesterday or today, but for a couple of years already." [NL-010]. Only two participants do write down their measurements or how they felt that day in a notebook. Those who write it down, also share this data with healthcare professionals, one with his/her diabetes nurse and the other with his/her remedial therapist: *"Because he thinks it is important to know. He wants to know what I do. I write down my oxygen saturation, heartbeat and how much time it takes me to recover. He wants to know this. He reads this twice a week. I bring with me my notebook to our appointments. This notebook records what I did every day."* [NL-004].

Statement 2: "I think it is important to have access to my health data gathered by my healthcare professional".

Almost all participants agreed with this statement. Reasons mentioned why they think it is important to have access are: (1) with having this access they have more control over their health and their healthcare professionals have more control over their patients' health, (2) just to check the data/results, (3) to keep track or to have an overview of how they are doing, (4) when being in another healthcare organization and the referral HCPs do not have access, you can show your data, (5) to check what is written down, if it is not coherent with what has been discussed during the consult, they can contact the healthcare professional, and (6) these data is about their health, so it is their data. Two participants did not agree with the second statement. One said that during the consults, the healthcare professionals explain everything, so that is enough. The more you know, the more worried you become. *"I've been to the specialist, I've been to the general practitioner, they know what I have. They tell me everything, what to do or whatever. And I'm satisfied with that. […] If you see more, you won't get happy either. […] There are people, who do want to know everything, but then I think, no please not. […] I think sometimes you worry about things. If you see something, or something is noticed, then I think you will get a bit worried about this."* [NL-007]. The other participant said that it is not important to have access to this data, but it could be useful. His/her healthcare professionals explain everything, it is only useful as a look-up tool to have a quick look, or when you are curious about your blood values.

Even though most of the patients think it is important to have access to the health data gathered by their healthcare professionals, most of them still do not have access to their medical records of the hospital. Some do have access to the records of the GP. Most of them have not asked about their access to the records. They are not aware whether it is or is not possible.

Statement 3: "I trust the health data I receive from my healthcare professional more than the health data I gather myself".

The participants who gather health data themselves, did not agree with this statement. Almost all have the same trust in both health data (*"No, both equally, there is no.. Yes I have trust in both."* [NL-003]), except for one participant. This participant experienced previously that health data which has been sent from a healthcare professional to another healthcare professional was not correct. Due to this, his/her trust in health data from the HCPs fluctuates.

Statement 4: "It is difficult to receive the requested health data from my healthcare professional".

Regarding this last statement, participants either never requested health data from their HCPs, or it was very easy to receive this through an app or by logging in into a website with their digital identity (DigiD). *"I'm not curious enough to go and ask for this."* [NL-001]. *"No I don't think so. No, you have to log in with your DigiD and that's it. With that I can access everything. So no, I don't think that is a problem.*" [NL-002].

Monitoring your health

When going through the different mock-ups for monitoring their health, participants were asked about their first impression. The majority reacted positively: nice, organised, funny, looks good, amazing, interesting. With having such a technology, one thought the number of visits to the healthcare professional could decrease: *"Yes, you know what I think, it's sooo amazing this is possible.* […] *You know, I think that the visits to the pulmonologist or the general practitioner decrease. You can share that with your general practitioner and pulmonologist through the app."* [NL-004]. Another one said it is educational, you can check your own progress. It was also seen as a positive prompt or nudge to be physically active. However, two participants had some comments about the mock-ups. One thought it gives too much information, which can work counterproductive. The other one indicated something is lacking: having an average about the different health aspects. By having insight into this, people could better accept their conditions and learn how to deal with it: *“When you accept what you have, and you can live with that, your life becomes totally different.* […] *These are tools to gain a certain amount of control in your life at some point. That’s how I see this. With this, at some point you could get structure in your life.”* [NL-010].

The mock-ups with the physical activity measured in number of steps and with the positive health spiderweb were considered as most favorable. Several reasons were given for preferring the physical activity mock-up: (1) to check whether you were active enough and if not, thinking about why not, (2) to have a clear overview of number of steps per day in an app which can be shared with a healthcare professional, and (3) to have an incentive to be more active. The reason given for preferring the mock-up with the positive health spiderweb was because it shows how positive your mind-set is in your life and how you deal with the COPD. After these two, the calendar with visits to healthcare professionals and the overview with mood, were favorites. Furthermore, one indicated to have most preference to the mock-up with data of their healthcare visits, and another one indicated there is no difference in which was preferred the most.

The mock-up which gives an overview of mood was mentioned by most as least favorite, because it is not applicable to their life situation: *“Yeah, the mood. I’m actually never feeling down or whatever. Yesterday, I also had to complete some forms with a question: ‘Do you ever feel down?’ Well, no actually.”* [NL-005]. Besides this one, the mock-ups with the calendar and data of their healthcare visits were mentioned as least favorable.

Furthermore, participants were asked what would be their goal in using a technology to monitor their health with, and whether having such a technology would help them to deal with their complaints. Goals mentioned were: just out of curiosity, to continue staying positive about health situation, to have a nice overview of all health data, to be more active, and to gain stability in your life. We found a discrepancy between whether this example technology would help them to deal with their complaints. Some think it will help them, but others commented they already know themselves and how to deal with this: *“I feel like I’m already good in dealing with this.* […] *When I barely knew what was going on, I think having this would have helped me a lot.”* [NL-002]. Participants do think that for someone who was recently diagnosed with COPD, such a technology which monitors their health, would have added value: *“I think if this technology was available 20 years ago, it would have helped me.* […] *I think especially for people with starting COPD, this could be a supportive hand,* […], *an incentive and positive prompt or nudge.”* [NL-003].

Almost all participants are interested in seeing their health data in a technology which monitors their health, except for two who do not see added value in having this. The participants who were interested, would use their health data to check how it is going with their health, and maybe to change some lifestyles if necessary. When asking them whether there is any other information they want to see which was not shown in the mock-ups, they found it difficult to come up with an answer. One said: *“I don’t know if there are any other important aspects concerning COPD. But then I would actually like to have all the information as far as that applies to me.”* [NL-006]. What health information this would be, the participants could not answer. Besides this, most of them wanted to know everything, only two mentioned something could be left out of the future technology: *“I think that part about depression, that’s nothing for me.* […] *When I see that mock-up, I think: ‘Oh no, go away’.”* [NL-004].

If these participants would use an app to monitor their health, most of them would share the gathered health data with their healthcare professionals. Reasons for this are: *“Because my healthcare professional also needs to know how I’m doing. I’m feeling bad and I say: ‘I want to have medication’. He should be able to see what is causing this. At least, that is my opinion.”* [NL-003], *“That data should be available. And I have little value considering privacy. I rather have convenience, that another doctor can see everything with just one touch.”* [NL-006]. Two participants would not share their health data gathered through an app, because: *“Because sometimes there is a data breach.* […] *Privacy.”* [NL-007], *“Because*

I think, everything they do at the hospital, also goes to the general practitioner. [question: but looking at steps, positive health, mood] *If the general practitioner has interest in that, I can share it with him.* [question: but you don't think it has added value?] *No, I don't think so."* [NL-009].

Predictions about health

Participants were asked how they feel regarding receiving predictions about their health. Some participants were positive about this, because: *"It is good.* […] *You can take them into consideration, if they are correct."* [NL-006], *"That is nice of course. Because you can check it out for yourself.* […] *You learn a lot more about your health with this."* [NL-004], *"Fun! And no more and no less. I won't get upset."* [NL-008]. However, others were reluctant, because: *"Reluctant.* […] *Because I think, well something will be predicted I'm not ready for."* [NL-007], *"I don't think i want to know now that maybe in five years' time, things will be very bad for me. No, I don't need to know that. I can see that on my own.* […] *I don't believe that would make me happy."* [NL-009]. One participant was partly positive about this, because with having a prediction, (s)he could prepare him/herself. But, receiving a prediction could also make this person anxious. Furthermore, one participant believes it is not possible to predict your health, and another one thinks a prediction is unnecessary as you will notice yourself how you feel.

The topics participants came up with to receive predictions about were: age, weather, health in general, well-being, dyspnea and COPD health in 10 years. Two participants did not want any predictions. One participant could not think of any topics, but after asking about well-being, fatigue, dyspnea and exacerbations, (s)he indicated (s)he would want to have those predictions. With respect to exacerbations, most participants thought it is not predictable: *"You get that all at once. One time, on a Friday, I didn't feel well. Saturday morning I'm still not feeling well, I called the general practitioner and he came. At four o'clock, I went with the ambulance. I don't know it from that moment, Saturday and Sunday. Until Monday: 'Hey, I'm in the hospital.'. So, it is actually unpredictable, you just get it, even though you're still being very careful."* [NL-003]. Overall, participants thought it would be nice to have predictions about different kind of topics, but they do not always think it is predictable: *"That seems very difficult to do, because it depends on so many factors."* [NL-002].

Most participants want to receive the prediction as a notification or within the home screen of an application as a short message. It differs between them how often they would check the prediction. Some would like to check it every day, others once a month, and one participant would only check it as a one-time thing. Participants would want to know the reasoning behind the prediction: *"Yes, then I'll know what I, for example it's my fault you know, then I know I shouldn't do that again next time."* [NL-005]. When asking whether they would use an online tool including all of the above, so health data monitoring and predictions, some said they would and other would not. The added value of using such a tool is: *"It belongs to your life. It is, how can I phrase this? It's part of a lung patient."* [NL-004], *"That you can focus on your COPD.* […] *Your life is controlled by it anyway. With everything you do, you notice that you have COPD."* [NL-006]. Participants who want to use such a tool, indicated they would not need incentives to be motivated to use the tool. Participants who do not want to use it, also indicated they would not need incentives to change their attitude.

After the first discussion about predictions, we showed participants three slides with mock-ups of predictions. In general, participants had a positive opinion: *"I do think they are funny, or well funny, I think they are interesting. I'm actually very curious about it."* [NL-002]. Only one participant was less positive for having this for him/herself: *"Maybe it's nice for Linda to know, but I don't want it."* [NL-009]. This same person said the following when seeing the mock-up about mood predictions: *"That's terrible!* […] *If it had been here* [pointing to a bad mood], *I would think: 'Well it's better if I stay in bed all day'.* […] *In my opinion, it's not good to know this in advance."* [NL-009]. Most participants preferred the mock-up of dyspnea with reasoning behind the prediction, because: *"I'm constantly thinking about that, like how come today I have less air than yesterday, why is that? Is it because I had two alcoholic drinks, or ate too much, or didn't move enough or whatever?"* [NL-002]. Whether such a predicting tool would be helpful in learning how to deal with complaints or not, opinions were divided. They thought it would be helpful, because you can act upon those predictions. However, some also thought it would not be helpful, because they already know their body, their complaints. For people who have been recently diagnosed for COPD, such a tool would have more added value.

Virtual coaching

When looking at the screens during the interviews, most of the participants identified that the current context was missing in the dialogues, especially when there was a concrete recommendation that due to their decrease of physical activity, they could ask the neighbor to go for a walk. Several participants commented that there was no question about the underlying reasons for why they might have been less active but instead the coach made recommendations on how to increase activity. *"I would indeed first ask as a virtual coach: can you indicate whether it has a cause? Then the patient can say: 'yes, I was sick', or 'I had the flu', or 'I don't know'. This already assumes you have to go to the neighbor for a walk."* [NL-002]. This is especially important when patients are not feeling well and a physical activity might worsen this. *"No what good does that do me with the walking. I already feel bad, and then I'm going to break down my body even more by saying come I'm going for a walk."* [NL-001]. Besides the very specific reference to a neighbor that might not fit their context, one participant also commented on the recommended activity itself, because for them biking is easier than going for a walk.

Participants considered the coach useful in terms of stimulation and motivation and raising awareness. For example, that the coach raises awareness that the steps count is dropping was seen positively. *"I think that's important. That the coach sees 'Hey you're going backwards instead of forwards'."* [NL-001]. Such a coach could help to be more active, because *"it kind of forces you to face the facts"* [NL-005]. The coach adds accountability which can help with commitment. *"It's more a stick. God, Marc sees that I haven't walk much today. I better should go for a bit."* [NL-009]. However, the tips or recommendations should not be commanding: *"You know, with most people, if people come and say 'You have to do this. You have to do that.' We merely ask 'Would you, please.' This 'You have to' does not exist for me. I don't have to do anything."* [NL-008].

Another important role is to encourage reflection in relation to current behavior (e.g., decrease in physical) or predictions (e.g., symptoms might be worsening in the coming week). Participants emphasised the importance on inviting subjective reflection about potential causes and how they are currently feeling. Several patients reported that they already know quite well how they feel and would not need a technology to tell them that (i.e., based on the collected data). *"[Reading out loud the dialogue] 'Looking at the data you've collected, I see you're doing well.' No, you feel that yourself. I can tell myself: I feel good or I don't feel good."* [NL-001]. It was considered that the coach asks how it is going and that they also can express how they feel: *"Yes, that, that you can indicate how or what, especially with that it says: 'Well, the coach has collected this data and that next week the shortness of breath can increase', what can be the cause of that."* [NL-005]. Next to adding subjective information that may contribute to the cause, one participant also commented that they wanted to know what the prediction is based on. *"For example, he says it's going well, but next week it's going to be worse, there's only a very short period of time in between. And then you start thinking yes, but how do you know? I don't notice it myself, my data is good, and yet it's going to get worse next week, so that could be, for example, due to weather conditions."* [NL-010].

Some patients mentioned that this program would be specifically beneficial for patients newly diagnosed with COPD: *"But someone who is say younger and now gets COPD, they have a lot to learn, of course."* [NL-004]. *"With COPD just starting, it is a little bit more important that you really stimulate movement. And whether that's biking or walking or something else, that's the most important thing."* [NL-003]. However, also patients who already know a lot might still benefit from a virtual coach: *"I have already learnt to deal with my symptoms. Still, maybe he has a different perspective from me, that there is still room for improvement, I don't know."* [RSP029]. Furthermore, the aforementioned aspects of raising awareness and motivation might also be useful for patients who already live with their condition for a longer time. One patient was unsure whether they would use it on a daily basis and suggested it was most useful when it is not going very well: *"Daily maybe not, I would only benefit or be interested in it at a time when things are going down."* [NL-006].

TWEETS

The TWEETS questionnaire was completed twice during the interviews (after discussing the risk predictions and after discussing the virtual coaching). Table 9 shows the results of the engagement scale for the different categories. At first sight, we see an improvement in engagement after discussing the virtual coaching part within the future RE-SAMPLE tool. We tested this hypothesis with the Wilcoxon Signed Ranks test. This test showed us that there is a significant difference (Z=--1.956, p=0.05) between the total TWEETS scores. For 7 out of the 10 patients, there is an increase in TWEETS after discussing the virtual coach. For 2 patients, there is a decrease. For 1 patient there is no difference in the TWEETS score.

Table 9: TWEETS scores (average, SD, min and max) for the Netherlands.

TWEETS category	After discussing risk predictions M (SD) | Min-Max	After discussing virtual coaching M (SD) | Min-Max
Behavioural engagement	3.7 (1.1) | 2.0-5.0	4.0 (0.8) | 3.0-5.0
Cognitive engagement	3.7 (0.9) | 2.0-5.0	3.9 (1.0) | 2.0-5.0
Affective engagement	3.5 (1.2) | 1.7-5.0	3.8 (1.1) | 1.7-5.0
Total TWEETS score	3.7 (1.0) | 2.0-4.9	3.8 (0.9) | 2.2-5.0

6.2.2.2 Italy

Demographics

A total of 5 patients participated in the interviews, of which 60% was male and the mean age was 75.0 (SD=8.6) years old. Four patients are also diagnosed with other chronic disease(s), for example hypertension, cardiovascular disorders or diabetes. Most of the participants were diagnosed with COPD more than 5 years ago. See Table 10 for all demographics.

Table 10: Overview demographics of the 5 participants in Italy

Demographic	Sub-category	% or M (SD) | Min-Max
Gender	Male	60.0
	Female	40.0
Age		75.0 (8.6) | 60.0-81.0
Comorbidities	Hypertension	40.0
	Cardiovascular disorders	20.0
	Diabetes Mellitus type 2	20.0
	Lung tumor	20.0
	Obstructive sleep apnea syndrome	20.0
	Gastro-oesophageal reflux disease	20.0
	Infectious pustular balanoposthitis	20.0
	Stenosi carotidea	20.0
	Thyroid nodules	20.0
	None	20.0
Number of years diagnosed with COPD	<1 year	0.0
	1-2 years	20.0
	3-5 years	0.0
	6-10 years	60.0
	>10 years	20.0
Highest level of education	Primary school	0.0
	High school	0.0
	Trade school	0.0
	University	100.0
Employment status	Full time	20.0

	Part time	0.0
	Seeking opportunities	0.0
	Retired	80.0
	Unable to work	0.0
Number of family members living together		0.8 (0.4) | 0.0-1.0
Health related quality of life		3.2 (1.1) | 2.0-4.0
Health literacy		3.9 (1.2) | 2.3-5.0
Digital skills		1.8 (0.4) | 1.0-2.0
Devices in use	Computer/laptop	60.0
	Smartphone	100.0
	Smartwatch	20.0
	Tablet	20.0

Data utilisation for COPD monitoring
Statements about data utilisation

Statement 1: “Gathering my own health data by means of a wearable of another device is important to monitor complaints”.
All five patients agreed with this statement. Reasons why they thought it is important to gather their own health data were: to share them with their HCPs, to evaluate their trends over time, to have reassurance, to better control their own health, and to take action upon the health data (e.g.: *“Especially the oxygen saturation measurement is useful, because it is very simple and intuitive. For example, I notice that when I move my oxygen saturation increases compared to when I'm still, and therefore it stimulates me to keep active.”* [IT-002]. Some patients did mention they gather data themselves. The data they gather are oxygen saturation, blood sugar levels, blood pressure, and use of a continuous positive airway pressure (CPAP) machine. Furthermore, some patients talked about sharing the collected data with their HCPs. They indicated they are willing to share data or are already sharing their data. Only one indicated that (s)he would not automatically share the data, but only: *“when I see something wrong.”* [IT-005].

Statement 2: “I think it is important to have access to my health data gathered by my healthcare professional”.
Three patients agreed with this statement. They think it is interesting, it would save them unnecessary visits and another one said: *“Knowing that all the data is available at any time from any hospital in my city is a certainty and makes me feel more relaxed.”* [IT-002]. One patient had not a strong opinion when talking about this statement. For this person it is more important that the HCP has all health data: *“But the most important aspect for me is that my doctor has them available, because he is the one who must make the right choices for my health.”* [IT-001]. One thought it was not really important for him/her to have access to these data. (S)he did not explain his/her opinion.

Statement 3: “I trust the health data I receive from my healthcare professional more than the health data I gather myself”.
Four patients agreed that they trust the data from the HCP more: *"I rely on the doctor or health care professional. He/she knows how to read the data and understand it."* [IT-001], *"I consider those of the professional to be more reliable. I consider the data I collect adequate if they are periodically verified by a health professional."* [IT-002]. The patient who disagreed explained that (s)he also trusts his/her own ability to measure oxygen saturation and blood pressure.

Statement 4: “It is difficult to receive the requested health data from my healthcare professional”.
Three patients disagreed with this statement. For them it is easy to receive requested health data from their HCPs. One patient indicated that it differs depending on the healthcare organisation. In some it is easy, in others (s)he experiences difficulties with receiving the data. The other patient did not answer this statement as (s)he never tried.

Monitoring your health

When showing the different mock-ups to the patients, they were positive in general. They thought the mock-ups look simple, effective and intuitive for collecting health data. One of them did mention that data collection entering the visits and exams need to be automatic, because: *“it is difficult for these data to be collected by all the specialists and doctors in the area.”* [IT-002]. No one indicated a preference for one of the mock-ups. One patient only mentioned that (s)he does not understand the usefulness of collecting mood data.

Patients were asked what would be their goal in using such a technology. Goals mentioned are to provide their healthcare professionals with ad much data so (s)he can make the right decisions, and are health-related (e.g., to be more physically active, to avoid worsening).

When asking patients whether they are interested in seeing this kind of information about their health, they all were interested. The main reason why they were interested was because they want to see how they can improve themselves: *“I am very interested and curious to see my progression over time, especially to see where I can improve (steps covered, physical activity).”* [IT-001], *"To understand if I can actually improve my symptoms based on the daily activity I do.”* [IT-002], and *“I'm interested to see my progression over time, especially to see where and what I can improve.”* [IT-005]. One patient was interested, but does not think it is necessary to have all this information on their phone, because: *“I have two doctors who know all my medical history. I don't see the need to upload everything to the phone app. It would just be a waste of time and work.”* [IT-003].

Furthermore, we also asked patients what they will do with this information about their health. They all said they would share it with their HCPs: *“Share it with my doctors of course.”* [IT-003], *“Maybe I would create a collection for my general doctor.”* [IT-004]. One patient did mention that, besides all the health data discussed during the interview, (s)he would also like to share health data about his/her vital signs with the HCPs.

Predictions about health

First of all, patients were asked how they think about receiving predictions about their health status. Two patients had a positive attitude towards this. However, one did state that the person receiving the predictions need to be able to change his/her life habits, otherwise the purpose of the prediction is useless. One patient was a bit doubting about this whole concept, as it could have psychological effects. And another one would not want to receive predictions at all: *"It would generate anxiety."* [IT-004]. The topics mentioned patients want to receive predictions about were: dyspnoea, exacerbations, physical activity, health in general and fatigue.

The patients were asked how they would like to receive predictions and at what time intervals. The answers given were: via an app, a message or a push notification. However, one patient would prefer to be contacted by a HCP instead of digitally. Another one indicated the following: *“It must be confirmed by the healthcare professional. Having an interface within the app with the professional, something like a chat would be sufficient, and then evaluate if a visit is necessary. I would like the app to notify me when I need to go to the doctor.”* [IT-002]. Patients did not want to receive predictions on a daily basis. Monthly would be enough, or even only when there is a deterioration.

Overall, the majority indicated they would use a tool which gives predictions about their health. Explanations given were: “*If it quickly brought me answers on therapies to be performed, suggestions on my state of health."* [IT-001], “*By knowing my current and future condition, I will be able to monitor myself and change my wrong habits, or insert the right therapy."* [IT-002], *“I would listen to this alarm bell and immediately contact my pulmonologist to modify the therapy or to have me examined.”* [IT-003], “*I would like that my pulmonologist is contacted and could modify the therapy.”* [IT-005]. Only one patient indicated that (s)he wants to receive predictions from her GP, face-to-face, and not online.

When we showed the different mock-ups of the predictions, we noticed patients were quite positive: “*I* *like them because they are very easy to understand."* [IT-005]. One patient was a bit sceptic about the prediction of the mood, because (s)he thinks it is not possible to predict. But overall, patients were positive. One even said: *"I consider the predictions reported to be reliable and intuitive. I have no doubts about the reliability of the collected data and the work of the algorithm."* [IT-001].

Virtual coaching

When introducing the patients to the virtual coach and let them go through the conversation, patients were positive. One patient liked the immediate feedback on his/her health. (S)he would also try to follow the advice given by the virtual coach, and his/her main goal would be: *"to have a better life than when I'm sick."* [IT-001]. Others indicated that a virtual coach could be very useful and would be a positive prompt/nudge to adapt his/her lifestyle. Another one sees the usefulness of the virtual coach, but would not interact with the virtual coach for his/her own health. Finally, one patient also sees its usefulness, but his/her health condition is too bad to be able to use an online tool.

TWEETS

The TWEETS questionnaire was only completed after discussing the virtual coaching. Table 11 shows the results of the engagement scale for the different categories. Because the questionnaire was not completed after discussing the risk predictions, no Wilcoxon Signed Ranks test could be conducted.

Table 11: TWEETS scores (average, SD, min and max) for Italy.

TWEETS category	After discussing risk predictions M (SD) | Min-Max	After discussing virtual coaching M (SD) | Min-Max
Behavioural engagement	NOT MEASURED	3.4 (1.0) | 1.7-4.0
Cognitive engagement	NOT MEASURED	3.7 (0.8) | 2.3-4.3
Affective engagement	NOT MEASURED	3.2 (0.8) | 2.0-4.0
Total TWEETS score	NOT MEASURED	3.4 (0.8) | 2.0-4.1

6.2.2.3 Estonia

Demographics

A total of 6 patients participated in the interviews. The majority of the patients was male (83.3%), and the mean age of the patients was 66.2 (SD=1.8) years old. All patients also have cardiovascular disorders besides their COPD, one patient also has diabetes, another patient also has gout, and two other patients also have sleep apnoea. Most of the patients are already for more than 10 years diagnosed with COPD. Table 12 shows an overview of all the demographics.

Table 12: Overview demographics of the 6 participants in Estonia

Demographic	Sub-category	% or M (SD) | Min-Max
Gender	Male	83.3
	Female	16.7
Age		66.2 (1.8) | 63-68
Comorbidities	Cardiovascular disorders	100
	Diabetes Mellitus type 2	16.7
	Gout	16.7
	Sleep apnoea	33.3
Number of years diagnosed with COPD	<1 year	0.0
	1-2 years	0.0
	3-5 years	16.7
	6-10 years	16.7
	>10 years	66.7
Highest level of education	Primary school	16.7

	High school	0.0
	Trade school	33.3
	University	50.0
Employment status	Full time	16.7
	Part time	33.3
	Seeking opportunities	0.0
	Retired	33.3
	Unable to work	0.0
	Retired but doing voluntary work	0.0
Number of family members living together		1.5 (1.8) | 0.0-4.0
Health related quality of life		2.8 (1.0) | 1.0-4.0
Health literacy		3.4 (1.5) | 1.7-5.0
Digital skills		2.5 (1.4) | 1.0-4.0
Devices in use*	Computer/laptop	33.3
	Smartphone	33.3
	Smartwatch	
	Tablet	
	None	50.0

* All participants do have a smartwatch and tablet in use because they also participate in the cohort study. Both are not their own, but are given to them for the duration of the study.

Data utilisation for COPD monitoring

Statements about data utilisation

Statement 1: “Gathering my own health data by means of a wearable of another device is important to monitor complaints”.

All participants, except for one, agreed with this statement. The reason why one participant did not agree was because (s)he indicated (s)he would not understand that health data. So, it will not help him/her to monitor the complaints.

All participants gather their own health data. Examples of data they gather were: weight, wellbeing, being able to cycle uphill and blood pressure. Participants gather their data through the RE-SAMPLE smartwatch and tablet they received for the cohort study, scale for weight and blood pressure monitor. Different reasons were mentioned why they gather health data: *“To not go to the doctor so often.”* [EE-001], *“For the hospital or doctors.”* [EE-002], *“If something is wrong, I can fix it. For example, high body weight, I can eat less. If I can change something I will do it.”* [EE-003], *“I want to take care of my health. We are responsible for our mistakes.”* [EE-004], *“To keep control of everything”* [EE-005], and *“To know my state of health.”* [EE-006].

Furthermore, all participants, except for one, indicated they share their measured health data with others: their HCP, their children or their friends. The one who did not share his/her health data, indicated that if it is really needed, (s)he would share it with his/her doctor or nurse.

Statement 2: “I think it is important to have access to my health data gathered by my healthcare professional”.

All patients agreed with this statement, and indicated they did receive previously health data from their HCP. The reason why they think it is important to have this access is mostly because it gives them information to keep control of their health state, as in, with this information they: *“Know whether I need to improve my lifestyle.”* [EE-001]. One patient indicated that besides this, (s)he is also curious about his/her health data.

Statement 3: “I trust the health data I receive from my healthcare professional more than the health data I gather myself”.
The attitude was a little more divided towards this statement. Some agreed with the statement, others did not. The reason why they trust the health data from HCPs more is because they studied for this and they have experience. From the two patients who did not agree, one feels there is no difference in health data gathered by HCP and health data gathered by him/herself. The other one said that the reason for not agreeing with the statement was because: *“I don’t believe my general practitioner. I believe my device”* [EE-006].

Statement 4: “It is difficult to receive the requested health data from my healthcare professional”.
All, except for one, disagreed with this statement. They indicated it is easy to receive the requested data: *“Everything is available in digital records and at visits everything is explained.”* [EE-002], *“If I ask, I get what I want.”* [EE-003]. The one who did agree with the statement indicated the following: *“Sometimes it is hard to get access to the doctor, especially the specialised doctor.”* [EE-001]. When asking about an example when it is difficult to receive health data, this patient said: *“I did not get information about my blood.”* [EE-001].

Monitoring your health

When going through the different mock-ups for monitoring their health, patients were asked about their first impression. They indicated: it is clear, easy to read and easy to understand. However, they also foresaw some changes to improve them. First of all, the slide showing the user’s mood would be clearer if it has 3 levels instead of 4 and with an explanation about the levels. The slide showing positive health needs to include explanations for all the pictograms to better understand it. The slide of the calendar of healthcare visits could be more specific: with who in the hospital. Furthermore, they missed an average within the slide showing the number of steps.

Different slides were mentioned as most favorable. First of all, the slides showing the calendar and data of healthcare visits were favorable, because they thought these are useful for them. Next, the slide showing the mood, because: *“It is useful to know how to tune my energy for the next day, to prepare to do something better.”* [EE-004]. Furthermore, the slide showing the positive health spiderweb, because it is useful and interesting. Finally, the slide showing the number of steps, because it is clear.

Some of the above-mentioned favorable slides are also mentioned by others as least favorable slides. First of all, concerning the slide showing mood one said: *“What does the mood scale give to me? I will never start providing this data. I don’t believe that the machine can compute it.”* [EE-002]. Furthermore, concerning the slide on positive health spiderweb, one said that (s)he would not complete such a questionnaire regularly, only when something is wrong. Finally, concerning the slides showing the calendar and data of healthcare visits (s)he does not think it is useful to have them.

Two patients were asked what their goal would be when using such a technology as presented in the mock-ups. One said: *“To keep track of the average.”* [EE-001]. The other patient said: *“It would give me notion whether I have to make efforts. The general picture is useful, it helps me to arrange me life.”* [EE-005]. The patients who were asked whether they think such a technology would help them dealing with their complaints, all said yes, because it shows them how to change their lifestyle for example. However, even though it would help, one said: *“I don’t like the computer, I cannot use it”* [EE-005]. When asking the participants in general what they would do when having information about their health, all said that having health information would give guidance in how to improve their health by making adaptations in their lifestyle. If the patients would use an app to monitor their health, all of them would share the gathered health data with their healthcare professionals.

The patients are interested in seeing information about their health, because it could help them for example to: *“cope with my complaints and direct my attention.”* [EE-001]. It could also give them insight in the development of the disease, and it could help them with recalling the different visits they had with HCPs. Other information they would like to see was: suggestions on what to do when complaints are getting worse, suggestions for preventive measures, health data about other diseases they have, and body weight and advice on how to lose weight. One participant said (s)he does not want to know how long (s)he will live.

Predictions about health

Within this part, we started with discussing the topic predictions about health in general. When thinking about this idea, patients indicated it could be interesting to have such predictions, because you can check whether it is true or not, or because you can prepare yourself for changing something. Regarding this last reason, one patient said: *"It will be good to have predictions. When you are old, it will be harder to cope with changes that come abruptly. I need time to prepare. I like even if my child calls me beforehand if he wants to come to visit me."* [EE-005]. However, some were in doubt whether predictions are needed, and one was more negative towards this idea. According to this person it is better to have suggestions for improving your health instead of receiving predictions, because: *"The future predictions are not reliable. The given correlations are logical: being more active, better results in health. Furthermore, there may also be overload! The predictions could be false as well, saying that everything is OK, but in a week time you are out. This results in bad mood, depression, drops in reliability of predictions. So, why predict? It is better to have suggestions."* [EE-001].

Topics that were mentioned to receive predictions about were bad mood (because it could help you to prevent conflicts), which diseases you are prone to (because if you already have it, you are too late with preventing it), dyspnoea, exacerbation (because that would prepare you, make it easier to cope with) and health state in general. However, the patient who indicated health state as a topic, also said that (s)he does not want to have any negative predictions, because: *"it will make me nervous, or even furious."* [EE-006]. On the other hand, positive predictions are also to no use according to this person. This person rather prevents in general all negative outcomes by improving his/her lifestyle.

The patients were asked how they would like to receive predictions, for example on a home screen of an application, or as notifications, or how many times they want to have those. Opinions differed among the patients. One wants to have predictions on a home screen of an application, another one does not want to have this on the home screen (as long as it is easy to find). Regarding notifications, one wants notifications for predictions of every symptom separately for 3 or 4 times a year, at the same time as the visits to the HCP, another one does not want any notifications. Most patients agreed with how many times they would check the predictions: once a week. Ideas regarding how the predictions could look like were: *"With three traffic light colours with explanations, which helps to specify, understand and conclude what to do by myself or when to go to the doctor."* [EE-001], and *"It might be a picture with an explanatory text."* [EE-003]. Furthermore, patients do think having reasoning behind the predictions would be favourable, because: *"it will raise the credibility"* [EE-006].

When patients were asked whether they would use a tool which gives predictions about their health, some indicated they would, and others would not. The reasons why they would use such a tool were to satisfy their curiosity, to learn what to change about their lifestyle, to better care for themselves, and to decrease the burden on healthcare for HCPs. The reason why they would not use such a tool was because all these things are not predictable. One patient who indicated (s)he would not use the tool, indicated that if (s)he gets suggestions besides or instead of those predictions, would motivate him/her to use the tool.

After discussing the different aspects of predictions, we showed the patients three mock-up screens of predictions (about mood, dyspnoea without explanation, dyspnoea with explanation). The patients' impressions were okay, not really outspoken opinions. One patient said that the simpler the screens, the better it is. Furthermore, another patient said that (s)he thinks it would be worth trying out such a tool.

Virtual coaching

When introducing the patients to the virtual coach and let them go through the conversation, patients were very positive. One thinks this could reduce visits to the HCPs. Another one likes the attention from the coach, which would improve his/her mood. Another patient feels having such a coach would give a positive prompt or nudge to change lifestyle permanently. Especially for people living on their own, such a coach would be really helpful. Furthermore, there was one patient who is not savvy with technology, but (s)he would like to try such a tool. However, if possible, this person rather has a voice-controlled coach.

Most of the participants do not care how the appearance of the virtual coach should be. There was only one who wanted to have the coach to be an older person.

Two patients would want to have multiple short coaching sessions per week: 3 or 4 times for 5 minutes, or every day for 5-10 minutes. One patient thinks it would be nice to have longer coaching sessions (30 minutes), but only once a week. The goals for what they would interact with the virtual coach was to have help nearby online, instead of waiting for an appointment with their HCP, and to be motivated to change their behaviour. Patients do think having such an online tool with a virtual coach would help them dealing with their complaints. However, one said that it would help in the future: *"In the future, when I am old and helpless, this all can help, right now i am already active."* [EE-002].

TWEETS

The TWEETS questionnaire was completed twice during the interviews.

Table 13 shows the results of the engagement scale for the different categories. At first sight we see a slight improvement in engagement after discussing the virtual coaching part within the future RE-SAMPLE tool. We tested this hypothesis with the Wilcoxon Signed Ranks test. This test showed us that there is no significant difference between the scores after discussing risk predictions and after discussing virtual coaching.

Table 13: TWEETS scores (average, SD, min and max) for Estonia.

TWEETS category	After discussing risk predictions M (SD) | Min-Max	After discussing virtual coaching M (SD) | Min-Max
Behavioural engagement	3.7 (0.4) | 3.3-4.3	3.7 (0.5) | 3.3-4.3
Cognitive engagement	3.9 (0.7) | 2.7-4.7	4.1 (1.0) | 2.3-5.0
Affective engagement	3.7 (0.9) | 2.3-5.0	3.7 (0.9) | 2.3-5.0
Total TWEETS score	3.8 (0.6) | 2.8-4.2	3.9 (0.8) | 2.7-5.0

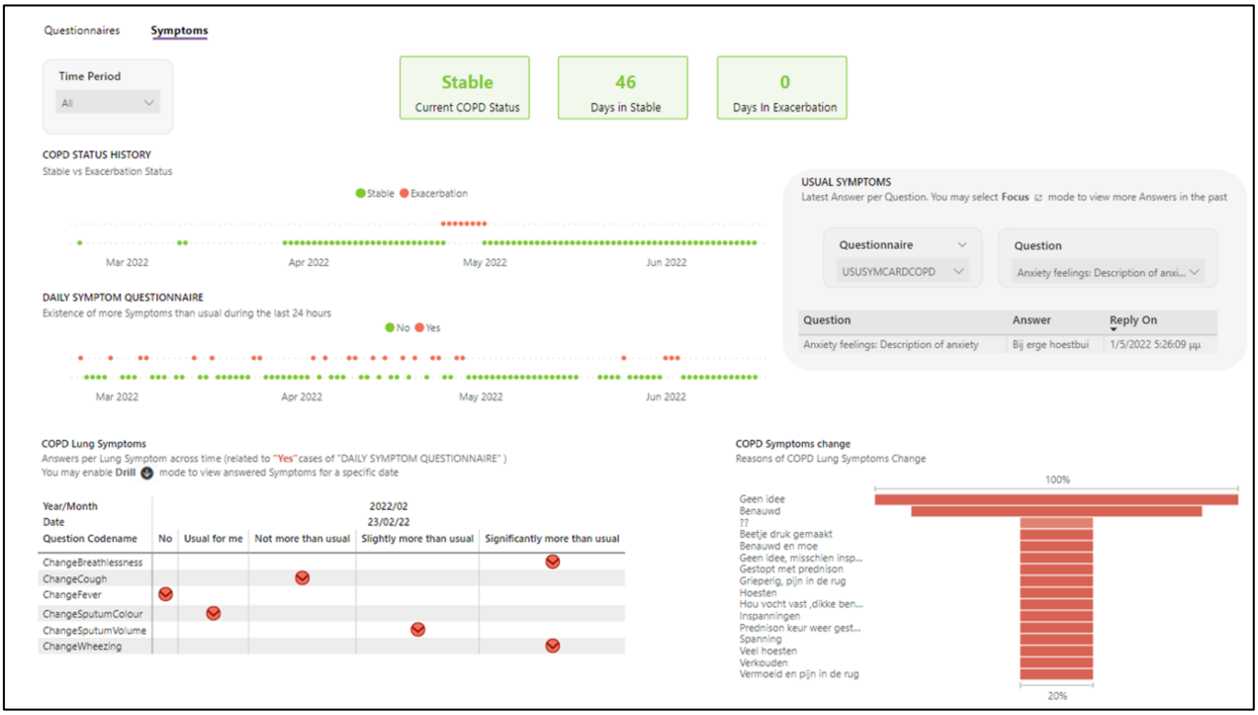
7. Iterative development of the Active Support Programme for healthcare professionals

7.1 Workshop: Feedback on data visualizations on the clinicians' dashboard (summer 2022)

Three workshops took place in the summer of 2022 with the clinical partners of the RE-SAMPLE project. The primary aim of this series of workshops was to gather feedback on the dashboards developed for the first prototype of the Active Support Programme (M18). The secondary aim of the workshops was to gather requirements for the second prototype of the Active Support Programme (M25). These workshops were the third iteration of the end-user studies.

The first prototype of the Active Support Programme provides graphical visualizations of the Real-World Data collected with the Healthentia application. In this series of workshops, we gathered feedback on two specific pages: the Symptoms Monitoring page and the Behavioural Parameters page.

The Symptoms Monitoring page – displayed in Figure 13 – provides subject-level information on the data collected related to the COPE-III protocol (Lenferink, et al., 2013). This protocol is used to determine the start and end of an exacerbation based on the monitoring of changes in daily symptoms self-reported by the patient through the app.



Questionnaire: USUSYMCARDCOPD

Question: Anxiety feelings: Description of anxi...

Question	Answer	Reply On
Anxiety feelings: Description of anxiety	Bij erge hoestbui	1/5/2022 5:26:09 μμ

Year/Month	2022/02				
Date	23/02/22				
Question Codename	No	Usual for me	Not more than usual	Slightly more than usual	Significantly more than usual
ChangeBreathlessness					✓
ChangeCough			✓		
ChangeFever	✓				
ChangeSputumColour		✓			
ChangeSputumVolume				✓	
ChangeWheezing					✓

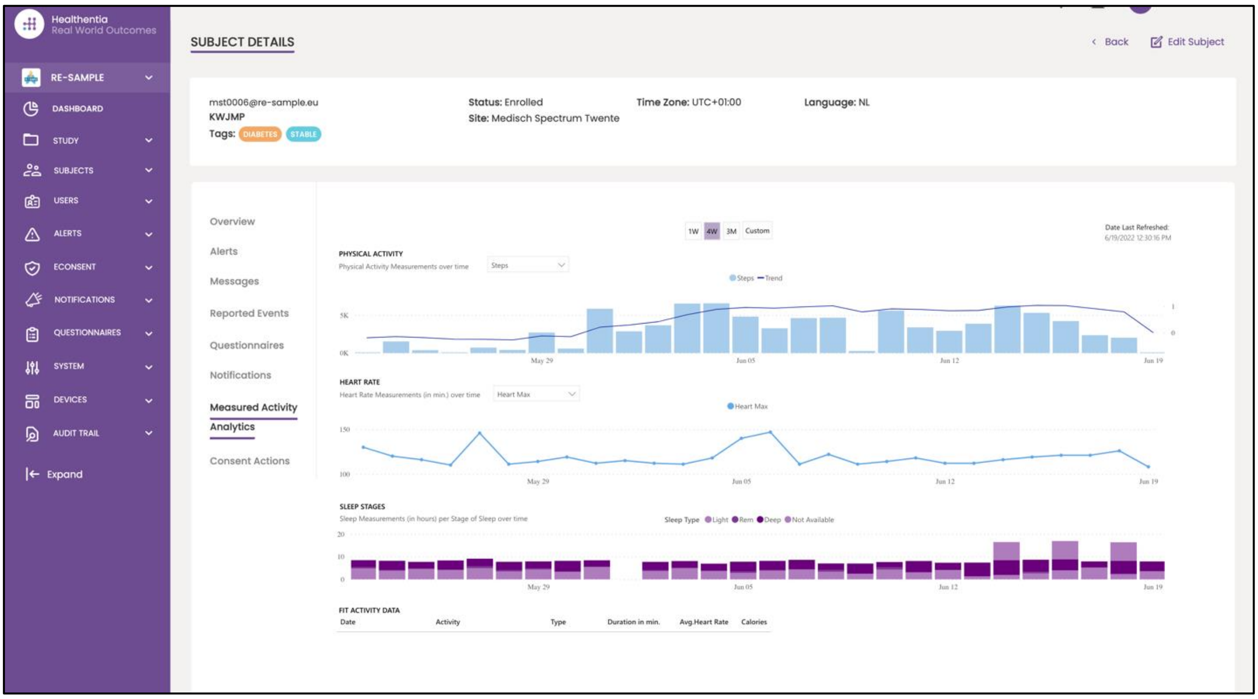
Figure 13: Screenshot of the prototype of the Symptoms Monitoring page on the Healthentia web portal. This image was printed in A3 format and given to the workshop participants.

The Symptoms Monitoring page can be split into 6 sections, each one discussed in detail in the workshops:

- **Summary blocks** show the current COPD status (either 'stable' or 'exacerbation'), the current strike of days in "stable" state and the current strike of days in "exacerbation state".
- **COPD Status History** contains a timeline that illustrates in which days the patient is in 'stable' and in 'exacerbation' state.
- **Daily Symptom Questionnaire** provides a similar timeline as in the COPD Status History, but this time showing in which days the patient reported that there was a change in symptoms in the previous 24 hours.
- **Usual Symptoms** contains the answers given to the Usual Symptoms Card, where the patient describes a set of symptoms in their own words.

- **COPD Lung Symptoms** shows the answers to the follow-up questions asked in case a patient reported that they had experienced changed in symptoms in the previous 24 hours. This section shows the severity of the changes per symptom.
- **COPD Symptoms change** provides the frequency distribution of the reasons for changes in symptoms, as perceived by the patient.

The Behavioural Parameters page – displayed in Figure 14 – illustrates the daily variation of physical activity, heart rate and time of each sleep state. On top of it, it also shows the trend on the variation of the number of steps per day. The web portal user can select between specific time intervals – 1 week, 4 weeks, and 3 months – or define a specific time interval.



mst0006@re-sample.eu
KWJMP
Tags: DIABETES STABLE

Status: Enrolled
Site: Medisch Spectrum Twente
Time Zone: UTC+01:00
Language: NL

Date Last Refreshed: 6/19/2022 12:30:16 PM

Figure 14: Screenshot of the Behavioural Parameters page on the Healthentia web portal. This image was printed in A3 format and given to the workshop participants.

The next sub-sections describe the settings, protocol and findings of each one of the workshops.

7.1.1 *Medisch Spectrum Twente*

7.1.1.1 Setting

Six clinicians from the Pneumology Department of the Medisch Spectrum Twente participated in a 30-minute workshop on the 20th of June 2022. The workshop was conducted at the hospital premises, and it was hosted by team members from Roessingh Research and Development and Innovation Sprint.

Printed versions of the screenshots of the Symptom Monitoring page were given to each group of 2 clinicians. The participants in the workshop were invited to write down on the page all thoughts on the visualizations.

7.1.1.2 Protocol

1. [5 min] Welcome & introduction
    a. Ask consent to audio record the session
2. [5 min] Display RE-SAMPLE introductory video[3]

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[3] RE-SAMPLE project (Nov 2021) *Het RE-SAMPLE-project: AI-aangedreven zorg voor patiënten met COPD en andere chronische ziekten [NL]* [Video]. Youtube. https://www.youtube.com/watch?v=9PYOwiE9Buk

3. [15 min] Reflection on Screenshot of the **Symptom Monitoring** page
    a. First impression
    b. Scribble suggestions on the paper and discuss in the group
    c. Post-its (top's and tip's)
4. [if time available] Reflection on Screenshot of the **Behavioural Parameters** page (Figure 14)
    a. First impression
    b. Scribble suggestions on the paper and discuss in the group
    c. Post-its (top's and tip's)
5. [5 min] Wrapping up
    a. Would you use this technology?
        i. Why? Why not?
        ii. Follow-up actions

7.1.1.3 Findings

Symptom Monitoring page

All participants in the workshop shared that the first impression of this screen was that it was "too busy". Participants referred that it would be better to only have crucial information on the first screen, and then the rest of the information in a second or third page.

Regarding the **Summary blocks** section, the clinicians mentioned only being interested in the number of exacerbations in a certain time period. They would like to have an option to select a specific time period (e.g., 6 months or 1 year) and then see the number of exacerbations that occurred in that period.

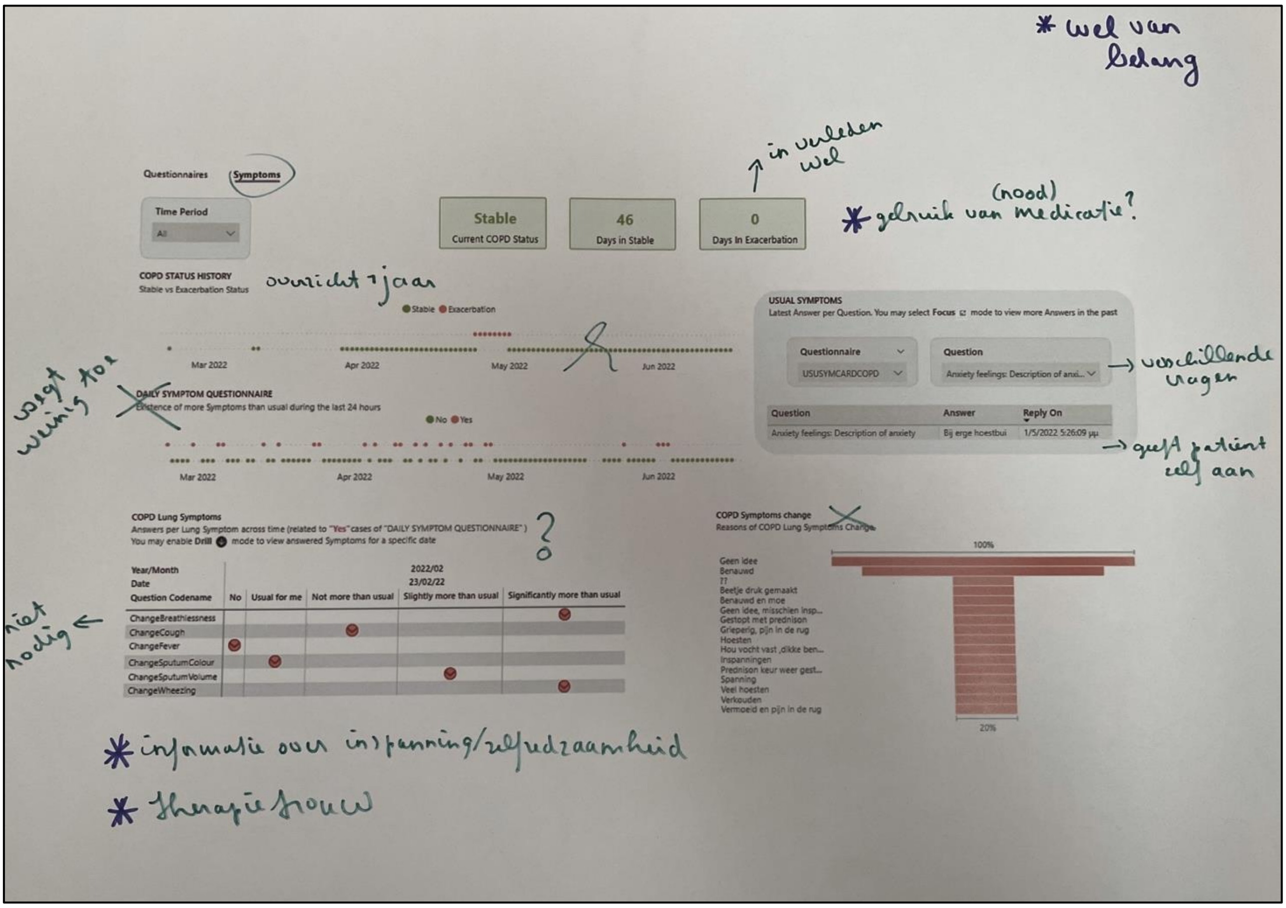
The **COPD Status History** was perceived as useful as it provides a clear view of when an exacerbation occurs and for how many days. This section can be kept as it is.

Although not consensual, the **Daily Symptom Questionnaire** was also perceived as useful, and at the end, agreed that it should be kept as it is.

According to the clinicians, the remaining three sections of the Symptoms Monitoring page – i.e. Usual Symptoms, COPD Lung Symptoms, and COPD Symptoms change – can be removed. The reason for removal is that the clinicians are of the opinion that the displayed information does not had value to the discussions with the patients. The COPD Symptoms change visualization was not understood.

When asked about what they were missing in this page, the clinicians answered "Medication intake" (in particular Prednison) and, most generally, which measures did the patients take during an exacerbation. Second, the clinicians would like to see the changes over time on the results of the Clinical COPD Questionnaire (CCQ), the Euro Quality of Life 5 Dimensions questionnaire (EQ5D), the Hospital Depression and Anxiety Scale (HADS), and the modified Medical Research Council dyspnea scale (mMRC). The clinicians highlighted that, even in the absence of exacerbation, the disease can progress and, with it, there can be a worsening of the quality of life. Finally, clinicians would like to see the results of the stress test.

Figure 15 provides an example of a scribbled page at the end of the workshop.



Existence of more Symptoms than usual during the last 24 hours

USUAL SYMPTOMS

Latest Answer per Question. You may select **Focus** mode to view more Answers in the past

Questionnaire: USUSYMCARDCOPD

Question: Anxiety feelings: Description of anxi...

Question	Answer	Reply On
Anxiety feelings: Description of anxiety	Bij erge hoestbui	1/5/2022 5:26:09 μμ

COPD Lung Symptoms

Answers per Lung Symptom across time (related to "Yes" cases of "DAILY SYMPTOM QUESTIONNAIRE")
You may enable **Drill** mode to view answered Symptoms for a specific date

Year/Month Date Question Codename	2022/02 23/02/22 No	 Usual for me	 Not more than usual	 Slightly more than usual	 Significantly more than usual
ChangeBreathlessness					●
ChangeCough			●		
ChangeFever	●				
ChangeSputumColour		●			
ChangeSputumVolume				●	
ChangeWheezing					●

Geen idee
Benauwd
??
Beetje druk gemaakt
Benauwd en moe
Geen idee, misschien insp...
Gestopt met prednison
Grieperig, pijn in de rug
Hoesten
Hou vocht vast ,dikke ben...
Inspanningen
Prednison keur weer gest...
Spanning
Veel hoesten
Verkouden
Vermoeid en pijn in de rug

Figure 15: Example of a screenshot of the Symptom Monitoring page scribbled by one of the participants in the workshop at the Medisch Spectrum Twente.

Behavioural Parameters page

Clinicians appreciated the visualization on the variation of physical activity. Contrarily, variation of heart rate and sleep was perceived as not important. It should be noted that the clinicians thought that patients would need to manually log their sleep and wake-up times. As dedicated time to the workshop was finished, we did not have time to clarify and investigate in-depth if they would be interested in the visualizations of heart rate and sleep, in case the measurement is of low burden for the patients. The clinicians also mentioned that the heart rate data might be relevant for the cardiologists, but not for their medical specialization (pneumology). Figure 16 provides an example of a scribbled page at the end of the workshop.

Figure 16: Example of a screenshot of the Behavioural parameters page scribbled by one of the participants in the workshop at the Medisch Spectrum Twente.

7.1.2 Foundation University Polyclinic Agostino Gemelli IRCCS

7.1.2.1 Setting

Four HCPs and three members of the research team of the Gemelli hospital joined a 1-hour online session on the 4th of July 2022. The session was hosted by two members of the Innovation Sprint team and one member of Roessingh Research and Development.

7.1.2.2 Protocol

Agenda of the online presentation:

1. What is RE-SAMPLE
2. Virtual Companionship Programme
3. RE-SAMPLE protocol
4. Group discussion on clinical dashboard in RE-SAMPLE
    a. Daily Symptoms Monitoring page
    b. Behavioural parameters page
5. Wrap-up

As all participants were familiar with the RE-SAMPLE study, we briefly went through points 1-3 of the agenda and the remaining time was spent in the group discussion on the clinical dashboard (Agenda point #4). During the discussions, we showed the screenshots of the Daily Symptoms Monitoring page and Behaviour Parameters page, shown in Figure 13 and Figure 14, respectively.

7.1.2.3 Findings

Symptom Monitoring page

We started by discussing the **Summary blocks** section. The counting on stable days was unclear. It was not understood whether the counter referred to all "stable" days since enrolment, or to the number of consecutive "stable" days since the last exacerbation. When asked about the most important information to have on these blocks, the HCPs said that they are mostly interested in the number of exacerbations in a time period. In particular, the HCPs explained that if a patient has two or more exacerbations in a year, the therapy plan needs to be adapted.

The HCPs found that the **COPD Status History** section was very useful and clear. In particular, one HCP explained that this visualization allows them to see whether there are periods of worsening of symptoms, even if not leading to exacerbation.

The HCPs consensually agreed that the **COPD Lung Symptoms** section provides meaningful information and should be kept in the clinical dashboard. According to the HCPs, even small changes in the symptoms are relevant to understand the disease progression.

Regarding the **COPD Symptoms change**, the HCPs referred that the information is very relevant but the current visualization is unclear. If possible, HCPs would like to see the perceived reasons for change in symptoms coupled with the COPD Lung Symptoms section.

The current design of the **Usual Symptoms** block was perceived as confusing. However, the information provided is very useful to match the patient with the symptoms. The participants suggested to change its design to a static table.

The participants mentioned that they would like to see in the header more general patient information, including the comorbidities, as this information is useful for "more generic positioning of the patient". The challenge is how to show the full picture of a patient, but also be able to lower the granularity to go to the day level information.

Finally, the clinicians mentioned that the most relevant questionnaires in clinical practice are the mMRC, HADS and COPD Assessment Test (CAT).

Additionally, the HCPs mentioned that it is very important that the dashboard provides a very clear overview, ideally with alerts, of the patients whose condition is worsening. A very important alert is coupled with the change from "stable" to "exacerbation" state. It is not possible for clinicians to check the patients one by one in the portal every day, so an alert system is crucial.

The HCPs also mentioned that it is important to know that anxiety is one of the most important subjective factors related to the progress of COPD. The patients do not know per se which symptoms changed but they do know "*I am not able to do the same things as yesterday*".

Behavioural Parameters page

The clinicians appreciate the visualizations at the moment and would like to keep the plots for physical activity, heart rate, and sleep. The clinicians explained that heart rate variability is one of the most important parameters in early detection of exacerbation, especially during exercise and sleep. In the future, it would be interesting to look at intraday, or even, intrahour, variation of heart rate. One clinician suggested to look at Poincaré plots (e.g., [4]) for heart rate variability analysis.

As a final remark, the HCPs explain that trend analysis might give some indications of disease progression, but even more important, is to make a multi-parameter analysis combining *lungs* (e.g., oxygen saturation), *heart* (e.g., heart rate), and *feelings* (e.g., anxiety).

7.1.3 Foundation Tartu University Hospital

7.1.3.1 Setting

One clinician of the Tartu University Hospital participated in an online session on the 6th of July 2022. The session was hosted by three members from Innovation Sprint (internal coordinator, Business Intelligence expert, and Business Intelligence intern) and one member from Roessingh Research and Development.

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[4] Hoshi RA, Pastre CM, Vanderlei LC, Godoy MF. Poincaré plot indexes of heart rate variability: relationships with other nonlinear variables. Auton Neurosci. 2013 Oct;177(2):271-4. doi: 10.1016/j.autneu.2013.05.004. Epub 2013 Jun 5. PMID: 23755947.

7.1.3.2 Protocol

The protocol was the same at that followed in the workshop with clinicians from the Gemelli hospital (see 7.1.2.2). As the clinician in the session is very active in the RE-SAMPLE project, we started the session from agenda point #4.

7.1.3.3 Findings

Symptom Monitoring page

We have started the discussion with the **Summary blocks** section. The HCP explained that the most relevant information is the number of exacerbations in a certain period. The counter of stable days since the last exacerbation is not relevant and, moreover, this information can also be retrieved from the COPD Status History visualization. The Business Intelligence expert explained that the goal of these three blocks is to reflect the progress in Key Performance Indicators.

The **COPD Status History** section was perceived as very useful and easy to understand. The HCP referred that it would be useful to be able to change the time interval of the window (e.g., 1 or 2 years).

The information provided in the **Daily Symptom Questionnaire** section is also perceived as useful and there were no further comments.

The HCP agreed with the level of detail provided in the **COPD Lung Symptoms** section. He explained that if some days are marked in red in the Daily Symptom Questionnaire section, the detailed overview on the variation of each symptom varied adds significant value.

The **Usual Symptoms** section was perceived as very informative as it provides an overview of the general complaints of a patient. This is very relevant as it helps the clinician remembering what might have been said in previous sessions.

The **COPD Symptoms change** section is difficult to understand at first sight. After explanation from the Business Intelligence expert, the HCP understood the visualization and agreed on its value. However, it was discussed that the value of the relative frequency visualization might be hindered by the fact that we are counting entries provided in free text, and therefore, prone to error. Nevertheless, the factors mentioned by the patients to justify the change in symptoms is very valuable information as “when people come to the hospital, they don’t know their reasons for worsening of their symptoms”. The value of such plot should be tested in clinical practice.

Finally, when asked about the questionnaires that are relevant for clinical practice, the HCP selected the CAT as the most relevant. The CCQ is not used in his clinical practice, the mMRC is quite stable, and the EQ5D provides general information available by talking to the patient.

Behavioural Parameters page

The HCP would like to keep the information on the three behavioural parameters: physical activity, sleep, and heart rate. It was added that it is only possible to know exactly how relevant some data is when using it in clinical practice; that is not the case at the moment in the hospital where he works.

As concluding remark, the HCP mentioned that it would be very interesting to combine behavioural information with exacerbation occurrence (e.g., physical activity and exacerbation). The HCP would also like to see the results of the lab tests. It was clarified that at this moment we are only displaying the data stored in the Healthentia platform. The clinical data only available in the edge nodes at the hospital premises will be displayed in the next iteration of the prototype.

7.1.4 Summary Results

The conclusions of the workshops with HCPs from the three clinical sites are summarized in

Table 14 and Table 15 concerning the Symptoms monitoring page and the Behavioural parameters page, respectively.

Table 14: Actions to take related to each of the sections in the Symptoms Monitoring page per clinical site.

	MST	GEM	TUK
Summary Blocks	Only state the current status and the number of exacerbations in the time period	Include number of exacerbations in the time period	Keep current status and number of exacerbations in a time period
COPD Status History	Keep	Keep	Keep
Daily Symptoms Questionnaire	Keep	Keep	Keep
Usual Symptoms	Not relevant	Keep but change interface	Keep
COPD Lung Symptoms	Not relevant	Keep	Keep
COPD Symptoms Change	Not relevant	Keep but change interface	Keep, consider changing interface
What is missing?	Medication use; Questionnaire scores variation (CCQ, mMRC, EQ5D, HADS) Results stress test	Questionnaire scores variation (mMRC, CAT, HADS); medical history of the patient in the header; overview of patients with clear worsening of symptoms alert; combine *lungs – heart – feelings*	Questionnaire score: CAT; cross-parameter information (e.g., physical activity and exacerbation); lab results

Table 15: Actions to take related to each one of the sections in the Behavioural parameters page per clinical site.

	MST	GEM	TUK
Physical activity	Keep	Keep	Keep
Heart rate	Not relevant	Keep, very important, especially heart rate variability	Keep
Sleep	Not relevant	Keep	Keep

7.1.5 Final list of requirements from the workshop session

A final list of requirements elicited in the workshops with clinicians in the Summer of 2022 is provided in Appendix D: User Requirements Gathered in the Workshops with Clinicians Summer 2022.

7.2 Workshops: Feedback on risk prediction and shared-decision making (autumn 2022)

During the fourth iteration, we conducted workshops with HCPs on the topic risk prediction and shared-decision making. This iteration was in collaboration with WP6. Methods of the workshops and results of the shared-decision making part are already written down in D6.4 *Strategy for user interaction and shared decision making*, which was submitted in December 2022. In the current deliverable, we will shortly recap the methods and we will focus our results on the risk prediction part. The workshops were conducted in the Netherlands (Medisch Spectrum Twente), Italy (University Polyclinic Agostino Gemelli IRCCS), and in Estonia (Foundation Tartu University Hospital).

7.2.1 Medisch Spectrum Twente

7.2.1.1 Setting

Ten HCPs of Medisch Spectrum Twente participated in this workshop on the 14th of September 2022. The session was hosted by one member from the University of Twente and one from Roessingh Research and Development. Furthermore, two other members from Roessingh Research and Development joined the workshop to listen.

7.2.1.2 Protocol

As described in D6.4 (part 5.2.4), the fourth part of the workshop was about the risk predictions. The goal was to investigate if HCPs accept the RE-SAMPLE risk-predictions. To this direction, user-stories, developed within the RE-SAMPLE project, were presented to the HCPs. The key visualisations which were discussed during the workshop are mentioned below in Figure 17Figure 19. An overview of all user stories and visualizations can be found in *Appendix E: Overview of user stories used during iteration 4 (autumn 2022)*.

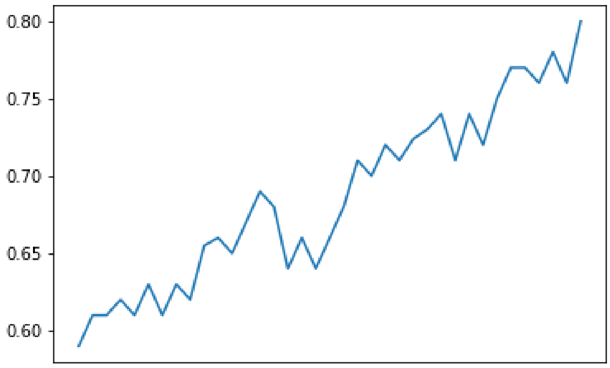


Figure 17: Visualisation of the exacerbation risk of a fictive patient which increased from 60% to 80% at last follow-up

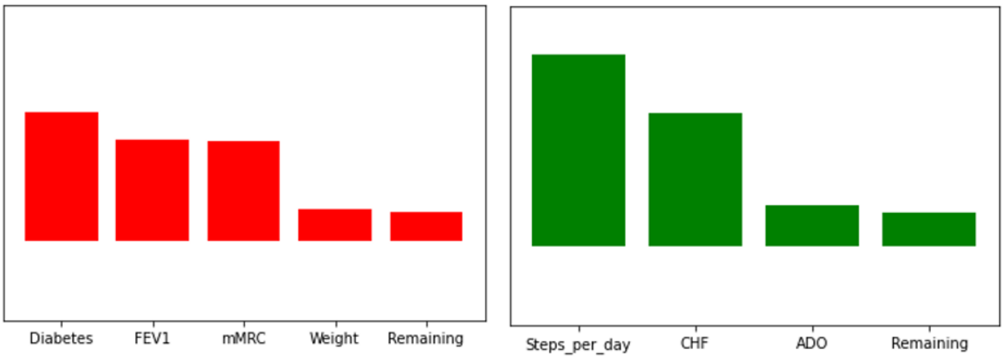
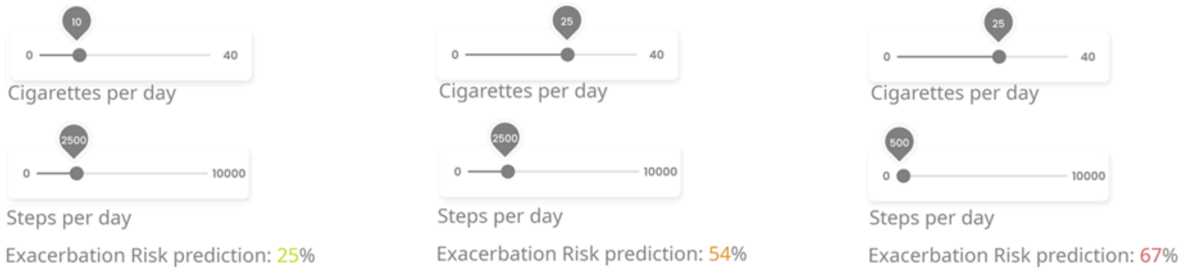


Figure 18: Left - Features that had an increasing influence on the exacerbation risk. Right - Features that had a decreasing influence on the exacerbation risk



Exacerbation Risk prediction: 25%

Exacerbation Risk prediction: 54%

Exacerbation Risk prediction: 67%

Figure 19: Scenario where the clinician runs some simulations that are proposed by the system, e.g. an

increase for cigarettes per day or decreased steps per day. The exacerbation risk would increase in any of these scenarios so the clinician advises to stick to the current behaviour

7.2.1.3 Findings

The HCPs indicated that they believe that predicting exacerbations is useful and important, since an exacerbation with hospital admission has a very bad outcome for the patient when it concerns disease burden on care consumption and costs. Furthermore, they mentioned that it is important that a risk-model can indicate whether the disease progression of the patient improves or worsens since they can't keep an eye on the patient all day long. The discussion about Figure 17 has shown that the HCPs do not find this visualization informative for patients because they may not understand it well enough. They also indicated that this visualisation lacks important context information for both the patient and themselves. This makes it unclear, for example, at what risk of an exacerbation they should take immediate action.

The HCPs agree that Figure 18 has more context information compared to Figure 17. In Figure 17, you only observe what the exacerbation risk is, and not which variables influenced the exacerbation risk, which can clearly be observed in Figure 18. They mentioned that information about variables will be useful to them, because this way they can work more purposefully on the disease progression with the patient. However, they believe that for certain patients, the variable “smoking status” will never turn green in similar visualisations and therefore may be useless. One HCP proposed to visualize a pie-chart instead of the green and red bar-plots. A pie-chart from 0 to 100%, where up to 30% is green, 30% to 70% is orange and 70% to 100% is red. Then you can agree to take action when the percentage is over 50% for example, by clicking on the pie-chart. A next step would be that a tool similar to the Assessment of Burden of COPD (ABC) tool (Slok, et al., 2016) shows up after clicking on the pie-chart which indicates which variables had an increasing (red balloons) or decreasing (green balloons) influence on the exacerbation risk. With these visualizations (balloons) you can also explain the variables and the exacerbation risk more clearly to the patient.

The HCPs agree that the scenario of Figure 19 is most convenient to be used in their consultation room, since it is also very challenging for them to estimate the risk by themselves based on relevant variables. However, they mentioned that they are not in favour of negotiating with the patient about their smoking habits. They are willing to discuss about other variables such as for example weight and the number of steps per day. Besides estimating the exacerbation risk, the HCPs find it useful to estimate mortality as well, since patients are always sensitive to this topic. In this case, it is also important that the relevant variables are mentioned and visualized. This way, patients become more aware of their health status which may lead to improving their disease progression when discussing this with their HCP.

7.2.2 Foundation University Polyclinic Agostino Gemelli IRCCS

7.2.2.1 Setting

Five HCPs of University Polyclinic Agostino Gemelli IRCCS participated in this workshop on the 11th of November 2022. The session was hosted by one member from the University of Twente.

7.2.2.2 Protocol

The protocol was the same at that followed in the workshop in Medisch Spectrum Twente (see section 7.2.1.2).

7.2.2.3 Findings

The discussion about Figure 17 has shown that the HCPs believe that this visualization may be useful. They also mentioned that they sometimes use these kinds of graphics already to show the patient some life expectancies. Furthermore, they agree that Figure 18 was also useful. However, although it is important to mention or visualize variables associated with an increased exacerbation risk, it is also important to focus on the positive feedback. Therefore, the HCPs found the green bar-plots, which visualized variables associated with a decreased exacerbation risk, very useful. According to the HCPs, this positive feedback may create a collaboration with the patient. The next step would also be to consider how to decrease the risk of exacerbation based on the known variables.

The HCPs mentioned that the scenario of Figure 19 is also very useful, especially for patients since it is a very simple graphic. Implementing a slider bar is also useful, because it can motivate patients if they can see how the risk of an exacerbation changes if they change their behaviour (e.g. smoke less and walk more). However, the HCPs were not completely in favour of the smoking variable in the slider bar, because the main goal is always to quit smoking. Other relevant variables (e.g. sleep, weight) should also be considered in the slider-bar if they are able to easily work on this in their daily life, for example: improving sleep or losing weight. The HCPs also agree that the slider bar should only be used during follow-up visits and not by the patient alone. At last, the HCPs mentioned that it is very important for them to trust the predictions first, if they want their patients to trust the predictions as well. They believe that we are at the beginning of something new. In the future, there will be tools that predict exacerbations, which they may trust completely.

7.2.3 Foundation Tartu University Hospital

7.2.3.1 Setting

Six HCPs of Foundation Tartu University Hospital participated in this workshop on the 8th of November 2022. The session was hosted by one member from the University of Twente.

7.2.3.2 Protocol

The protocol was the same at that followed in the workshop in Medisch Spectrum Twente (see section 7.2.1.2).

7.2.3.3 Findings

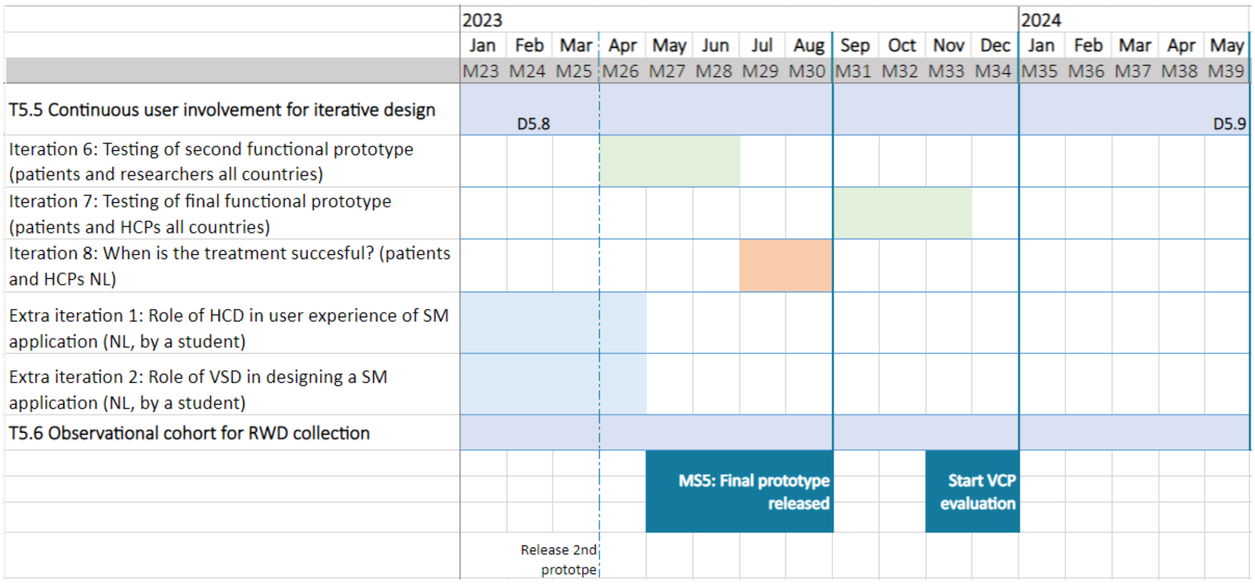
Following the discussion about Figure 17, HCPs are not in favour of discouraging patients with information about for example risks, hospitality rates and mortality. However, they agree that is may be useful in some cases when the patient urgently needs to do something about the risk of an exacerbation. The HCPs found Figure 18 useful was well. One HCP mentioned that patients sometimes feel lost and don’t know where to start as they don’t know which variables will make a difference in their disease progression. Therefore, these visualisations would help the HCP to have a discussion with the patient about the variables which increased or decreased the risk of an exacerbation, which may also lead to more shared decision making. Another HCP mentioned that it is important that HCPs are convinced that all the calculations behind the risk prediction and variables are true. If HCPs are confident in these calculations and understand these visualizations, patients will believe this information as well.

The HCPs mentioned that the scenario of Figure 19 may be helpful, however they are not sure all patients will understand the message. For certain type of patients it may be very informative, but especially for patients, which tend to see the medical world extremely black and white. The HCPs believe that fine-tuning the risk like this will probably do no harm. However, they think it is important to be very attentive with this risk information and only use it for situations where you can make good comparisons. For example if you stop smoking, your risk will decrease by half. They were not in favour of using the scenario in Figure 19 to predict the chance of mortality because patients are very sensitive for this.

Finally, as we presented different types of visualizations, the HCPs were of opinion that they would limit these materials to their patients and not overburden them. Although these visualisations may be useful, they believe that their patients can’t take more than three of these visualisations as they get tired of the charts.

8. Next iteration end-user studies

The next iteration of end-user studies in the coming year will be mainly about usability testing the second functional prototype (iteration 6) and final functional prototype (iteration 7) among patients and HCPs in all three pilot sites. Besides the usability tests, we are planning to assess when patients and HCPs define a treatment as successful (iteration 8). Furthermore, two master students are working on their graduation assignment within T5.5. One student is investigating how human-centred design can enhance the user experience of older adults with COPD and CCCs for a self-management support application (extra iteration 1). The other student is investigating how an engaging eHealth technology powered by artificial intelligence that supports self-management needs to be designed with value sensitive design. Figure 20 gives an overview of the planning of the next iterations.



	2023												2024				
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38	M39
T5.5 Continuous user involvement for iterative design	🟦	🟦 D5.8	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦 D5.9
Iteration 6: Testing of second functional prototype (patients and researchers all countries)				🟩	🟩	🟩											
Iteration 7: Testing of final functional prototype (patients and HCPs all countries)									🟩	🟩	🟩						
Iteration 8: When is the treatment succesful? (patients and HCPs NL)							🟧	🟧									
Extra iteration 1: Role of HCD in user experience of SM application (NL, by a student)	🟦	🟦	🟦	🟦													
Extra iteration 2: Role of VSD in designing a SM application (NL, by a student)	🟦	🟦	🟦	🟦													
T5.6 Observational cohort for RWD collection	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦	🟦
					MS5: Final prototype released						**Start VCP evaluation**						
		Release 2nd prototpe															

Figure 20: Planning next iteration of end-user studies.

9. Conclusions and future work

This deliverable presented the end-user involvement activities carried out from M12 until M23. It described the results of the stakeholder analysis and network inventory, the changes we want to make in RE-SAMPLE's end-user panel in the coming year, the continuous end-user feedback, the results of two iterations of end-user studies with patients, and the results of two iterations of end-user studies with HCPs.

The next activities include finalising the last changes in our end-user panel and inviting more people to the RE-SAMPLE end-user panel through our website. Furthermore, in the coming year we will plan and conduct the next iteration of end-user studies to give feedback to the iterative design of our RE-SAMPLE technology.

References

Borda, A., Gray, K., & Laura, D. (2019). Citizen Science Models in Health Research: an Australian Commentary. *Online Journal of Public Health Informatics*.

Broekhuis, M., van Velsen, L., Peute, L., Halim, M., & Hermens, H. (2021). Conceptualizing usability for the eHealth context: A content analysis of usability problems of eHealth applications. *JMIR Formative Research*.

Brooke, J. (1996). SUS - A quick and dirty usability scale. En P. .Jordan, B. Thomas, B. Weerdmeester, & I. McClelland (Edits.), *Usability evaluation in industry* (págs. 189-194). London: Taylor & Francis.

Chew, L. D., Bradley, K. A., & Boyko, E. J. (2004). Brief questions to identify patients with inadequate health literacy. *Family Medicine*, 588-594.

Duh, H. B.-L., Tan, G. C., & Chen, V. H.-h. (2006). Usability evaluation for mobile device: a comparison of laboratory and field tests. *Proceedings of the 8th conference on Human-computer interaction with mobile devices and services*, (págs. 181-186).

Holden, R., & Karsh, B. (2010). The Technology Acceptance Model: Its past and its future in health care. *Journal of Biomedical Informatics*, 159-172.

International Organization for Standardization (ISO). (2019). ISO 9241-210:2019 Ergonomics of human system interaction -- Part 210: Human-centred design for interactive systems. International Standardization Organization (ISO). Switzerland.

Kelders, S., & Kip, H. (2019). Development and initial validation of a scale to measure engagement with eHealth technologies. *Conference on Human Factors in Computing Systems - Proceedings.* doi:https://doi.org/10.1145/3290607.3312917

Kelders, S., Kip, H., & Greeff, J. (2020). Psychometric Evaluation of the TWente Engagement with Ehealth Technologies Scale (TWEETS): Evaluation Study. *Journal of Medical Internet Research, 22*(10), e17757. doi:10.2196/17757

Lenferink, A., Frith, P., van der Valk, P., Buckman, J., Sladek, R., Cafarella, P., . . . Effing, T. (2013). A self-management approach using self-initiated action plans for symptoms with ongoing nurse support in patients with Chronic Obstructive Pulmonary Disease (COPD) and comorbidities: The COPE-III study protocol. *Contemporary Clinical Trials, 36*(1), 81-89. doi:10.1016/j.cct.2013.06.003

Lewis, J. R. (1991). Psychometric evaluation of an after-scenario questionnaire for computer usability studies. *ACM SIGCHI Bulletin*, 78-81.

Peerson, A., & Saunders, M. (2009). Health literacy revisited: What do we mean and why does it matter? *Health Promotion International*, 285-296.

Sauro, J., & Lewis, J. R. (2012). *Quantifying The User Experience. Practical Statistics for user research.* Morgan Kaufmann.

Slok, A. H., Kotz, D., van Breukelen, G., Chavannes, N. H., Rutten-van Mölken, M. P., Kerstjens, H. A., . . . van Schayck, O. C. (2016). Effectiveness of the Assessment of Burden of COPD (ABC) tool on health-related quality of life in patients with COPD: a cluster randomised controlled trial in primary and hospital care. *BMJ Open, 6*(7), e011519. doi:10.1136/bmjopen-2016-011519

van Gemert-Pijnen, J. E., Nijland, N., Ossebaard, H. C., Kelders, S. M., Eysenbach, G., & Seydel, E. R. (2011). A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. *J Med Internet Res, 13*(4), e111.

Wiggins, A., & Wilbanks, J. (2019). The Rise of Citizen Science in Health and Biomedical Research. *The American Journal of Bioethics*.

Appendices

Appendix A: Summaries shared with study participants, cohort participants and panel members

Summary user needs

RE-SAMPLE is a European project that focuses on people who are living with COPD. The goal of RE-SAMPLE is to develop a technology that will support patients and caregivers. This technology will help patients manage their COPD and other chronic conditions.

To understand what patients and professionals need and how the technology should be designed, several activities were carried out. For example, we interviewed patients and healthcare professionals; several patients kept a diary for some time and we organized several workshops. We collected a lot of valuable information when talking with patients and healthcare professionals and the RE-SAMPLE project benefited greatly from these conversations. In this presentation we want to give an overview of what we learned so far.

During the conversations, we came to a number of important insights. These can be divided into three topics, namely: 'Data and data collection', 'self-management', and 'communication'. These topics will now be further explained.

1. *Data and data collection*

During the interviews and workshops, it became clear that both people with COPD and healthcare professionals would like to have insight into certain parameters. By parameters we mean, for example, weight, heart rate, saturation and blood pressure. In this way, people with COPD can also look at the daily variations in their health and actively try to recognize symptoms that lead to a flare-up. Although the daily variations might be very interesting for people with COPD, healthcare professionals told us, that they don’t need that level of detail. They prefer to see a general trend over a certain period of time. This way they can see at a glance what has happened in the past period, it may help them to understand what the possible cause is, and whether adjustments need to be made.

In addition to all the data that needs to be collected about the disease COPD, healthcare professionals are also interested in the psychological and social side of living with COPD. All these aspects have an influence on the life of that person and are therefore just as important. Because there is often only limited time to talk with patients, the social and psychological aspects are easily overlooked during a visit. Healthcare professionals told us that this is missing in current care, and if they would look beyond the clinical parameters they thought that this could actually help them to see the bigger picture.

For healthcare professionals to be able to gain insights from the collected data, it must be shared with them. Because health related data can be very sensitive, data sharing should not be done lightly. Patient must give permission first. Many patients told us that they want to decide for themselves with whom the collected data can be shared. This way, they remain in control of who has access to it. This means that in RE-SAMPLE, people with COPD should have the opportunity to decide for themselves with whom their data is shared and with whom not.

2. *Self-management*

Several interviews with both healthcare professionals and people with COPD made it clear that a lot of work is currently being done on self-management. We learned from patients that they found out through 'trial and error' what does or does not work for them. Although many people with COPD said that they still need extra support, they have also often found their own ways to deal with certain difficult situations. The most important ways of coping with COPD were resting, taking medication, raising the alarm in time and various forms of exercise. It also became clear that it is still very difficult for people with COPD to find a balance in seeking out their own boundaries and not going over their limits. The majority of people told us that they are missing support and would like more help with this.

Based on the information we got, a workshop was organized. During this workshop we looked at which parts people with COPD would like to have more help with. We learned that there are various parts where coaching can be done. These components were: exercise, information about COPD, quitting smoking, lifestyle adjustments, frequent check-ups, loss of certain activities, mental well-being, meaning, nutrition, taking action on time, being and remaining independent, and consulting with doctors. As you can see, these are many and sometimes diverse topics. Nevertheless, people with COPD have told us that they would like that more attention to these topics are paid or that they struggle with them. Therefore, RE-SAMPLE will take these topics into account.

There are several ways to coach people on topics. For example, there may be a coach who is very strict and where no consultation is possible – like a general. Or a coach where there is an equal relationship – the coach as a partner. A coach who works together with a person towards a certain goal reminds us of a sports coach. Sometimes, a coaching style might resemble that of a caring parent. That is why during this workshop we also wanted to find out which type of coach patients prefer. We learned that people have different opinions about what the best coach for them is. For example, there are people who like a strict approach while others prefer consultation and dialogue. This made it clear that the preference for coach is different per person and not every approach works for everyone.

*3. **Communication***

In some hospitals there is a kind of calling system. With this system it is possible to call the lung department of the hospital directly in case of any complaints or worsening of symptoms. If the patient calls at a certain time in the morning, they are called back the same day by their lung physician. In addition, both patients and professionals told us that it is often difficult for patients to know whether a call is really necessary. This leads to the situation that they often wait too long and only know afterwards that they should have called earlier. As a result, people often wait too long to ask for help.

Some people with COPD in our study told us, that they often think they were a burden or that they felt their symptoms were not bad enough yet to call the hospital. However, raising the alarm early can prevent a worsening of the situation. This means that if this calling system is available to everyone and people with COPD call at the right time, a lot of misery can be prevented. The short lines of communication between patient and care provider are highly appreciated by both patients and healthcare professional.

This call system seems like a good approach. But as with any system, there are also disadvantages. Healthcare professionals cannot guarantee to call patients back within a certain time. It is of course possible that professionals are very busy in the hospital and it’s not possible for them to call patients back shortly. For some patients in our study, this means that they may be disappointed or even irritated because they feel like they are not being heard or even feel like they are not being taken seriously. Although this call system is not in place at every hospital, it also became clear that some similar alternatives exist. For example, some patients told us that they have a WhatsApp group with, their physiotherapist and other patients who are in the same physiotherapy group. Using WhatsApp they exchange information, for example, about social events in the neighborhood or new apps to support their COPD. This ensures that the therapist and patients can easily come into contact with each other if something is wrong.

Loneliness

Finally, loneliness was a recurring topic for people with COPD. It was shared, by patients and healthcare providers, that a decrease in mobility also causes a decrease in social contacts, because not being as mobile anymore makes social activities difficult or too energy-consuming. Because of this, and (of course) also because of the COVID measures, the social activities that can also provide a lot of relaxation are often suspended.

Healthcare professionals recognize this problem and highlighted the importance of social activities. They emphasized that the social aspect should be included in any treatment options and that people with COPD should participate in the social activities they can still do. Highlighting the social aspect, and in particular coming into contact with fellow patients, was mentioned as an important part of the process. The opportunity to be with a group of people who also have COPD and talk about common things can be very nice and reassures patients that they are not alone having these experiences or complaints.

What's next?
Although we already collected a lot of information, RE-SAMPLE continues involving patients and care providers. This means that new studies are constantly being set up to learn more about COPD, on managing COPD and how the technology should look like to support patients and healthcare professionals.

Would you like to be involved and think along with us in the RE-SAMPLE project? Then, please feel free to contact us.

Thank you for your time and attention,
The RE-SAMPLE team of Roessingh Research and Development

Summary service model
RE-SAMPLE is a European project that focuses on people with COPD. The goal of RE-SAMPLE is to develop a technology that supports patients and caregivers. This technology will help patients manage their COPD and other chronic conditions. In the end, we want that RE-SAMPLE is useful and will be used in practice. But how should RE-SAMPLE be introduced in clinical practice? It is very important to look into this from an early stage. One way of doing so is to develop a service model.

A service model is a representation of how technology and the whole service around it will look like in practice. The model describes who needs to do what so that RE-SAMPLE is optimally used in daily life. The people who have a role in RE-SAMPLE are called stakeholders. Stakeholders can be healthcare professionals (for example, the pulmonologist, or the pulmonary nurse) or the patient with COPD who is going to use the service. Because these people are using RE-SAMPLE in the future, it is very important to involve them in the design process of the service model so that we can include their needs and wishes.

Roessingh Research and Development (RRD) developed the RE-SAMPLE service model based on 5 rounds of studies with stakeholders from three different countries: Italy, The Netherlands and Estonia. This was very important, because there are a lot of differences between the countries in terms of how care is organized. For example, in the Netherlands pulmonary nurses spends much more time with the COPD patients than for example a pulmonologist, while in Italy the physician plays a most important role in their care. These are small details but very important to know when developing a service model, because otherwise, there might be a chance that RE-SAMPLE doesn't fit with actual practice.

Here you can see the final service model, which is based on all the conversations with stakeholders It is important to mention that not all activities that are described in this model are already existing in practice. The service model describes how it should be implemented so that it is optimally used. This model will be explained in the following slides:

Introducing RE-SAMPLE. In this service model, there are 3 different stakeholder groups involved; the healthcare professionals, the patients with COPD, and others. There are a couple of things that need to be done before RE-SAMPLE will be used by patients with COPD. The first step is that the patient with COPD has to know about its existence. Healthcare professionals or others can inform the patient about RE-SAMPLE, or the patient might hear about RE-SAMPLE from their own search (for example, by reading flyers in the waiting room of their pulmonologist or by finding information online). When a patient wants to join, their care team ensures that they can do so and helps them to get started. For example, the patient gets information about RE-SAMPLE, gets introduced to the wearable, and fills in some questionnaires.

The RE-SAMPLE application. The model also describes the different parts in the app: the chat with peers, self-management, and data collection. Both self-management and data collection contain different activities. For self-management, goal setting, education about COPD, action plan, and coaching will all be included. For data collection, the monitoring will enable so see trends and progress and a risk overview. In this way, potential changes in usual symptoms can be early detected. If there are more symptoms than usual there will be an option to ask healthcare professionals to take a look at the data Additional tests may be needed, following with a consult to discuss the results and the next steps. Unfortunately, sometimes symptoms may be worsening, so that the patient with COPD might need to undergo treatment. After the recovery, the patient is invited to reflect on what might have caused the worsening. This can be very useful also for their self-management. There are a lot of different activities that need to be carried out. Without the help of stakeholders we would not be able to understand the different responsibilities in each country. This shows again, how important it is to involve stakeholders during the project. They are the experts when it comes to living with and managing COPD and we are very grateful for their time. We learn a lot from them.

What's next?

The development of the RE-SAMPLE solution is ongoing, and we will continue to involve end-users so that we get feedback at different points in time. Only then we can make sure that we understood well what people need and that our technology is well developed.

Would you like to be involved and think along with the RE-SAMPLE project? Please feel free to contact us.

Thank you for your time and attention,
The RE-SAMPLE team of RRD

Appendix B: Study procedure and instruments second iteration end-user study

Study procedure

Phase	Name	Description
1	eHealth Usability Benchmarking	Administration of HUBBI questionnaire as *usability baseline measure* 1 week after initial usage. Questionnaire is implemented in Healthentia and will be triggered automatically 7 days after the first log-in into the Healthentia app.
2	User experience assessment "4 weeks usage"	Administration of questionnaire "UX assessment: 4 weeks after usage". The questionnaire is implemented in Qualtrics and preferred language can be chosen. All questions are the same for each country. The questionnaire will be administered by providing the URL in a notification in the Healthentia app. This notification will be triggered automatically after a patient has used the Healthentia for 4 weeks.
	Qualtrics URL	
3	User experience assessment "exacerbation"	Administration of questionnaire "UX assessment: 1-2 weeks after exacerbation". The questionnaire is implemented in Qualtrics and preferred language can be chosen. Depending on the country selected at the beginning of the survey, questions not applicable for TUK (Estonia) will not be prompted. The questionnaire will be administered by providing the URL in a notification in the Healthentia app. This notification will be triggered manually through the pilot administration in the Healthentia dashboard. A manual is provided by iSprint on how to this is done.
	Qualtrics URL	

Usability benchmarking (1 week after initial usage)

eHealth Usability Benchmarking Instrument (HUBBI)

HUBBI was adapted to include the name of the system (i.e., “Healthentia”) to be assessed. Rated on a 5-point Likert Scale

1. I experienced system errors while using the Healthentia app.
2. I get stuck when using the Healthentia app.
3. The Healthentia app is convenient to use at home.
4. The Healthentia app is suitable for me.
5. The Healthentia app is helpful to monitor people with one or more chronic health conditions.
6. I can see everything clearly in the Healthentia app.
7. The signals, warnings and cues in the Healthentia app are easy to interpret.
8. The layout of each page of the Healthentia app is appealing.
9. The messages in the Healthentia app are well-structured.
10. I know where in the Healthentia app I can find the information I need.
11. I understand the relationships among the different parts of the Healthentia app.
12. The Healthentia app information is easy to understand.
13. The Healthentia app offers clear explanations for difficult medical topics.
14. The error messages in the Healthentia app tell me how to fix problems clearly.
15. The Healthentia app sufficiently explains how to perform system procedures e.g. create account, log on, change settings, connect with other devices.
16. The Healthentia app provides sufficient feedback to support me in managing my health.
17. Overall, I am satisfied with the Healthentia app.
18. I like how the Healthentia app contributes to my health.

User experience assessment: 4 weeks after use (exported from Qualtrics)

RE-SAMPLE: Usability- 4 weeks after use

Start of Block: Introduction and informed consent RE-SAMPLE

This questionnaire is part of the European project RE-SAMPLE. The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions.

Who are we?
Roessingh Research and Development (RRD) is a research organisation in the area of rehabilitation technology and digital health care assistance located in Enschede (The Netherlands) and one of the project partners in RE-SAMPLE.

Participation
Completing this survey will take you approximately 10 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data
The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at RRD. The privacy regulations that are applied to all research conducted at Roessingh Research & Development can be found here: http://www.rrd.nl/en/privacy-declaration/

○ Yes, I agree to participate in this study.

End of Block: Introduction and informed consent RE-SAMPLE

Start of Block: Demographics RE-SAMPLE

Q1 What is your gender?

○ Male
○ Female
○ Prefer to self-describe: ____

Q2 What is your year of birth?

▼ 1900 ... 2003

Q3 What is the highest degree or level of education you have completed?

○ Primary School
○ High School
○ Trade School
○ University
○ Other ____

Q4 What is your employment status?

1. Full time employment
2. Part time employment
3. Seeking opportunities
4. Retired
5. Unable to work
6. Voluntary work
7. Other: ____

Q5 How many family members do you live together with?

○ 0
○ 1
○ 2
○ 3
○ 4
○ more than 4

End of Block: Demographics RE-SAMPLE

Start of Block: Digital literacy RE-SAMPLE

Q6 I think that my level of digital skills (like the use of smartphone, tablet, laptop) is as follows:

○ 1: really low
○ 2: low
○ 34
○ 4: high
○ 5: really high

End of Block: Digital literacy RE-SAMPLE

Start of Block: Usability

Q7 In the RE-SAMPLE study, you are using the Healthentia mobile application for some time now to monitor your symptoms and disease progression. What is your general and overall experience with the Healthentia mobile application?

○ Very good
○ Good
○ Acceptable
○ Poor
○ Very poor

Q8 Could you explain your answer?

____

Q9 Could you tell us how you use the app? What features to do use?

____

Q10 Did you have problems during the first weeks of using the Healthentia mobile application?

- No
- Yes

Q11 Could you explain your answers?

____

Within the Healthentia mobile application there are multiply ways to find technical help, the tutorial, the FAQ and the conversational agent. Did you use the following technical help feature?

Q12 The tutorial

- Yes
- No

To what extend do you agree to the following statements:

Display This Question:
If Q12 = Yes

Q13 The tutorial of the Healthentia mobile application was very informative

- Strongly Agree
- Agree
- Undecided
- Disagree
- Strongly agree

Display This Question:
If Q12 = Yes

Q14 The tutorial of the Healthentia mobile application help me to understand the application better

- Strongly Agree
- Agree
- Undecided
- Disagree
- Strongly disagree

Display This Question:
If Q12 = Yes

Q15 The tutorial of the Healthentia mobile application help me to navigate through the application better

- Strongly Agree
- Agree
- Undecided
- Disagree
- Strongly disagree

Display This Question:
If Q12 = Yes

Q16 Could you explain your answers?

____

Did you use this technical help feature?

Q17 The FAQ

- o Yes
- o No

To what extent do you agree with the following statements:

Display This Question:
If Q17 = Yes

Q18 The FAQ of the Healthentia mobile application was very informative

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:
If Q17 = Yes

Q19 The FAQ of the Healthentia mobile application help me to understand the application better

- o Strongly Agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:
If Q17 = Yes

Q20 The FAQ of the Healthentia mobile application help me to navigate through the application better

- o Strongly agree
- o Agree
- o Undecided
- o Disagree
- o Strongly disagree

Display This Question:
If Q17 = Yes

Q21 Could you explain your answers?

____

Did you use this technical help feature?

Q22 The conversational agent

- o Yes
- o No

Display This Question:
If Q22 = Yes

Q23 To what extent do you agree with the following statements:

Display This Question:
If Q22 = Yes

Q24 The conversational agent of the Healthentia mobile application was very informative

- ○ Strongly agree
- ○ Agree
- ○ Undecided
- ○ Disagree
- ○ Strongly disagree

Display This Question:
If Q22 = Yes

Q25 The conversational agent of the Healthentia mobile application help me to understand the application better

- ○ Strongly Agree
- ○ Agree
- ○ Undecided
- ○ Disagree
- ○ Strongly disagree

Display This Question:
If Q22 = Yes

Q26 The conversational agent of the Healthentia mobile application help me to navigate through the application better

- ○ Strongly Agree
- ○ Agree
- ○ Undecided
- ○ Disagree
- ○ Strongly disagree

Display This Question:
If Q22 = Yes

Q27 Could you explain your answers?

____

One of the features of the Healthentia mobile application is to complete questionnaires to monitor your symptoms and disease progression.

Q28 To what extent do you agree with the following statements:

	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
In general, I have some problems to fill in the questionnaire	○	○	○	○	○

In general, I understand how to fill in the questionnaires.	o	o	o	o	o
The start and end of a questionnaire are clear to me.	o	o	o	o	o

Q29 Could you explain your answers?

____

Q30 What do you think of the time that it take to complete the questionnaires in the Healthentia mobile application?

____

Q31 Is there anything else you would like to tell us about your experience using the Healthentia mobile application?

____

End of Block: Usability

Start of Block: Continuous feedback RE-SAMPLE

Q32 May we approach you for one of the options below?

- o Yes, I would like to receive a summary of the results of this questionnaire.
- o Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)
- o No

Display This Question:
If Q32 = Yes, I would like to receive a summary of the results of this questionnaire.
Or Q32 = Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)

Q33 Enter your e-mail address here. Your e-mail address will only be used for the options you have indicated above. The answers to the questionnaire will not be linked to your email address.

____

End of Block: Continuous feedback RE-SAMPLE

User experience assessment: 1-2 weeks after exacerbation (exported from Qualtrics)

RE-SAMPLE: Usability- 1-2 weeks after exacerbation identification

Start of Block: Introduction and informed consent RE-SAMPLE

This questionnaire is part of the European project RE-SAMPLE (https://www.re-sample.eu). The purpose of RE-SAMPLE is to develop eHealth applications that support patients and healthcare professionals. This technology will help patients to manage COPD and complex chronic conditions.

Who are we?
Roessingh Research and Development (RRD) (http://www.rrd.nl/en/) is a research organisation in the area of rehabilitation technology and digital health care assistance located in Enschede (The Netherlands) and one of the project partners in RE-SAMPLE.

Participation
Completing this survey will take you approximately 15 minutes. Participation in the questionnaire is entirely voluntary. You can quit with the questionnaire whenever you want. You do not need to fill in a reason for this. You can stop by closing the tab or window of this survey. Only responses from completed questionnaires will be used in this study.

Privacy protection and processing of your data
The data in this questionnaire will be collected without your name and contain no personal data that can be traced back to you. The answers you give will only be used as part of the RE-SAMPLE project and processed by researchers at RRD. The privacy regulations that are applied to all research conducted at Roessingh Research & Development can be found here: http://www.rrd.nl/en/privacy-declaration/

- ○ I agree to participate in this study.

End of Block: Introduction and informed consent RE-SAMPLE

Start of Block: Demographics

Q1 What is your gender?

- ○ Male
- ○ Female
- ○ Prefer to self-describe: ____

Q2 What is your year of birth?

▼ 1900 ... 2003

Q3 What is the highest degree or level of education you have completed?

- ○ Primary School
- ○ High School
- ○ Trade School
- ○ University
- ○ Other ____

Q4 What is your employment status?

1. Full time employment
2. Part time employment
3. Seeking opportunities
4. Retired
5. Unable to work

6. Voluntary work
7. Other: ____

Q5 How many family members do you live together with?

- 0
- 1
- 2
- 3
- 4
- more than 4

End of Block: Demographics

Start of Block: Digital literacy RE-SAMPLE

Q6 I think that my level of digital skills (like the use of smartphone, tablet, laptop) is as follows:

- 1: really low
- 2: low
- 34
- 4: high
- 5: really high

End of Block: Digital literacy RE-SAMPLE

Start of Block: Usability

Q7 From which country are you?

- Estonia
- Italy
- The Netherlands

Skip To: Q14 If Q7 = Estonia

Q8 Due to worsening in symptoms you were recently invited to do a blood test. Was the blood draw done?

- Yes
- No

Display This Question:
If Q8 = Yes

Q9 I found the process clear.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

Display This Question:
If Q8 = Yes

Q10 I needed more guidance to know what was expected from me.

- Strongly agree
- Agree
- Undecided

- Disagree
- Strongly disagree

Display This Question:
If Q8 = Yes

Q11 It was useful that the Healthentia application determined that the blood draw was needed.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

Display This Question:
If Q8 = Yes

Q12 How did you experience this?

____

Display This Question:
If Q8 = No

Q13 Why were the laboratory tests not done?

____

Q14 Because of worsening of symptoms you were asked to fill in additional questionnaires in the Healthentia mobile application. Did you complete those?

- Yes
- No

Display This Question:
If Q14 = Yes

Q15 To what extent do you agree with the following statements:

Display This Question:
If Q14 = Yes

Q16 In general, I have problems to fill in the questionnaires.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

Display This Question:
If Q14 = Yes

Q17 In general, I understand how to fill in the questionnaires.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

Display This Question:
If Q14 = Yes
Q18 The start and end of a questionnaire are clear to me.

- ○ Strongly agree
- ○ Agree
- ○ Undecided
- ○ Disagree
- ○ Strongly disagree

Display This Question:
If Q14 = Yes
Q19 How did you experience this?

____

Display This Question:
If Q14 = No
Q20 Why did you not complete the questionnaires?

____

Q21 What do you think of the time that it take to complete the questionnaires in the Healthentia mobile application?

____

Q22 Is there anything else you would like to tell us about your experience using the Healthentia mobile application?

____

End of Block: Usability

Start of Block: Continuous feedback RE-SAMPLE

Q23 May we approach you for one of the options below?

- ○ Yes, I would like to receive a summary of the results of this questionnaire.
- ○ Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)
- ○ No

Display This Question:
If Q23 = Yes, I would like to receive a summary of the results of this questionnaire.
Or Q23 = Yes, I am happy to be approached for follow-up research. (We may send you information about new research in the future. At that time you can decide whether or not you want to participate in that study.)
Q24 Enter your e-mail address here. Your e-mail address will only be used for the options you have indicated above. The answers to the questionnaire will not be linked to your email address.

____

End of Block: Continuous feedback RE-SAMPLE

Appendix C: Materials used during iteration 5 (autumn 2022)

Semi-structured interview protocol

Introduction

Thank you for being here and agreeing to this interview. During the upcoming 60 minutes I would like to discuss with you the RE-SAMPLE project and how the new developed technology within this project needs to communicate with the user. As you properly know the RE-SAMPLE project focuses on changing the care for COPD patients with comorbidities by offering patients a virtual companion tool to self-manage their complaints.

During the interview, we first start with some theses to get an idea how you think about communication in general and communication with your healthcare professionals. Then I would you like to introduce you to a friend from the future, Linda. Linda uses the virtual companion developed in RE-SAMPLE project. During the final part of this interview, I am curious to your ideas on how the virtual companion can help you to self-manage your complaints.

But before we start, I have to ask you if it is okay to audio record this interview and to sign this informed consent.

Before starting the study, I first want to complete the demographics questionnaire together with you.
[Complete demographics questionnaire together with participant.]

Part 1 – theses supported by the presentation

Let's start with the first thesis [slide 2]:

1. Gathering my own health data by means of a wearable or another device is important to monitor my complaints.

What do you think?

Optional questions:

- Do you gather you own health data?
- How do you gather you own health data?
- Why do you gather your own health data?
- Do you share this data with someone? With whom and why?

The second thesis [slide 3]:

2. I think it is important to have access to my health data gathered by my healthcare professionals.

What do you think?

Optional questions:

- Did you ever receive health data from your healthcare professional?
- Why is it or is it not important to have access to this data?

Let's continue with the third thesis [slide 4]:

3. I trust the health data I receive from my healthcare professional more than the health data I gather myself.

What do you think?

Optional questions:

- Could you explain why?

And the final thesis [slide 5]:

4. It is difficult to receive the requested health data from my healthcare professional.

What do you think?

Optional questions:

- Any experience with requesting health data from your healthcare professional?
- Can you give an example?

These were the four thesis I wanted to discuss with you. Any comments on this part of the interview? Any thoughts? No, then let’s continue to the second part.

Part 2 – Step into the further – monitoring your health

In this part of the interview, I want to introduce to you a friend from the future, Linda. Linda suffers from COPD and depression and uses the virtual companion developed in RE-SAMPLE project. This virtual companion is developed 10 years ago and Linda is really pleased with this tool.

The tool needs sufficient data to work properly and to help Linda with her complaints related to her COPD and depression. To make sure the tool has sufficient data Linda wears a wearable, this wearable registers Linda’s daily steps, sleep pattern and heartrate. The tool also asks Linda to complete questionnaires. Short ones on a daily / weekly base or a longer one on a monthly basis. These questionnaires focus on Linda’s wellbeing and complaints. Next to these two sources of data, the tool receives all Linda’s health data from her GP and hospital but also her physiotherapist and psychologist. All Linda’s data is safely stored in a database and only Linda has access to this data and can give others access to this data of parts of it.

Based on various algorithms the data of Linda is used to help her to self-manage her complaints. Before we continue, I have to ask,

5. Do you know what I mean with an algorithm?

If Yes: Can you explain it to me?

If No: No problem! It will explain it to you and give an example.

An algorithm is a set of actions or steps needed to solve a problem or to achieve a specific goal. In healthcare an algorithm can be a flowchart or a set of rules to follow. Like a recipe you need to follow to prepare your favourite dish. One of the things that algorithms need to work properly is data. Data from one of two questions or all the available health data of a patient. A lot of variety! Within the RE-SAMPLE project an algorithm is developed to do predictions on the health status of a patient.

Next to these predictions the RE-SAMPLE tool also provides Linda with a lot of knowledge on her health. I would like to show you some screens.

These are mock-up of the foreseen RE-SAMPLE tool. [slides 6-10]

6. What do you think of these screens?

Optional questions:

- What screen do you prefer and why?
- What screen do you dislike and why?
- What would you want to do with this technology? What would be your goal?
- Do you think this technology could help you dealing with your complaints? Why/Why not?

7. Are you interested to see this information on your health?

Optional questions:

- Can you explain why?
- What other information about your health do you want to see?
- What information about your health don’t you want to see?

8. What will you do with this information on your health?

Optional questions:

- Can you give an example?

9. Is this the information you also would like to share with your health care professional?

Optional questions:

- Why or why not?
- If no: What kind of information would you want to share with your HCP?

Part 3 – Step into the further – predicting your health

The screen I showed you are all presenting information of Linda's current health status. But with all the data and the algorithms we can also provide Linda with information on the future. The RE-SAMPLE tool can predict how the health status of Linda can changes due to for instance whether conditions, or medication use, or wellbeing.

10. What do you think of this idea. The idea of receiving a prediction on your health status?

Optional questions:

- Can you explain your answer?

11. On what kind of topics you would like to receive these predictions?

Optional questions:

- Can you explain why?
- If anything was possible, what would you like to see in your application?
- What do you think of the following topics: well-being / fatigue / dyspnoea / energy level / exacerbation / depression

12. How would you like to receive these predictions?

Optional questions:

- When would you check these predictions? How many times a week?
- Should the prediction be visible on the home screen?
- Are there health status predictions that you would like to receive notifications of?
- If yes, at what interval would you like to receive a notification? At a specific time interval: once a day/week? Or whenever it's relevant?
- What should these predictions look like in the app? How should these predictions be conveyed?
- Would you like to be informed about the reasoning behind the prediction by the app?

13. Would you use a tool like this?

Optional questions:

- Why? / Why not?
- What will be the added value for you to use this tool?
    - If no added value: What can we change in order to have a tool that would have an added value for you to use?
- What incentives do you need to stay motivated to keep using the tool for a longer period of time?

I can show you some of Linda's screen with the predictions she received from the foreseen RE-SAMPLE tool. [slides 11-13]

14. What do you think of these screens?

Optional questions:

- What screen do you prefer and why?
- What screen do you dislike and why?
- What would you want to do with this technology? What would be your goal?
- Do you think this technology could help you dealing with your complaints? Why/Why not?

[Ask the participant to complete TWEETS questionnaire on slide 14.]

Part 4 – Step into the further – the use of virtual coaches

The RE-SAMPLE tool not only offers Linda a lot of knowledge on are health to tool also provide her with a Virtual Coach, Marc. By short chats Marc explains Linda's data or helps her to changes here behaviour.

I can you some you some screen of a chat between Linda and Marc. [slides 15-19]

15. What do you think of these screens?

Optional questions:

- What screen do you prefer and why?
- What screen do you dislike and why?
- What would you want to do with this technology? What would be your goal?
- Do you think this technology could help you dealing with your complaints? Why/Why not?

[Ask the participant to complete TWEETS questionnaire on slide 20.]

End

16. Is there anything else you would like to address or mention.

Okay, this is the end of this interview. Thank you very much for attending and helping us. Based on all the will interviews we write a summary and will share this summary with you.

Demographics questionnaire

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:

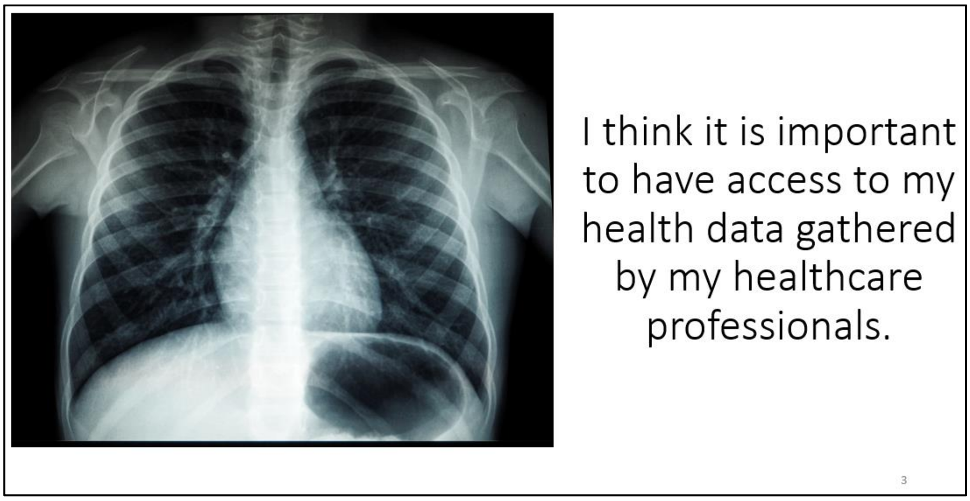
Really low				Really high
1	**2**	**3**	**4**	**5**

eHealth technologies

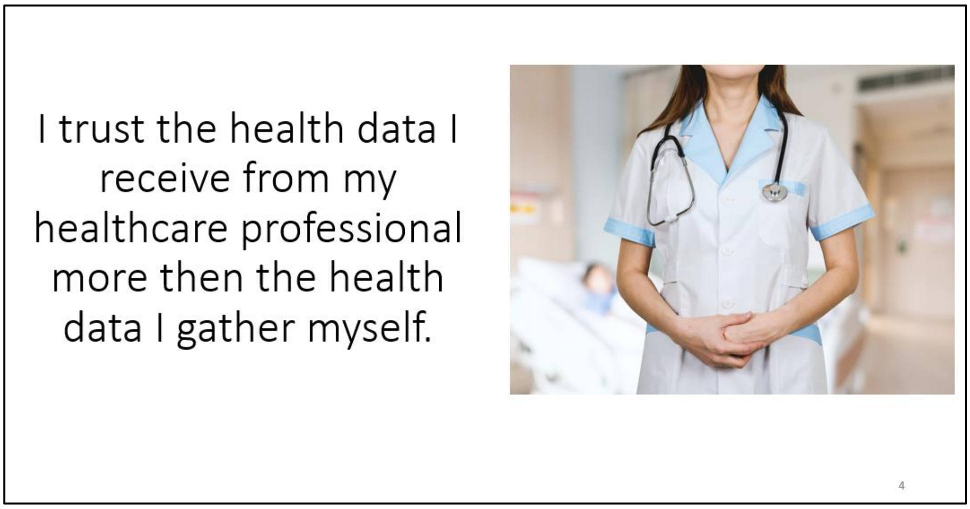
13. Which of the following devices do you use?
    - ☐ Computer/ laptop
    - ☐ Smartphone
    - ☐ Smartwatch (Fitbit/Garmin/applewatch)
    - ☐ Tablet
    - ☐ None
    - ☐ Other: ______________________________

Mock-ups used during interview

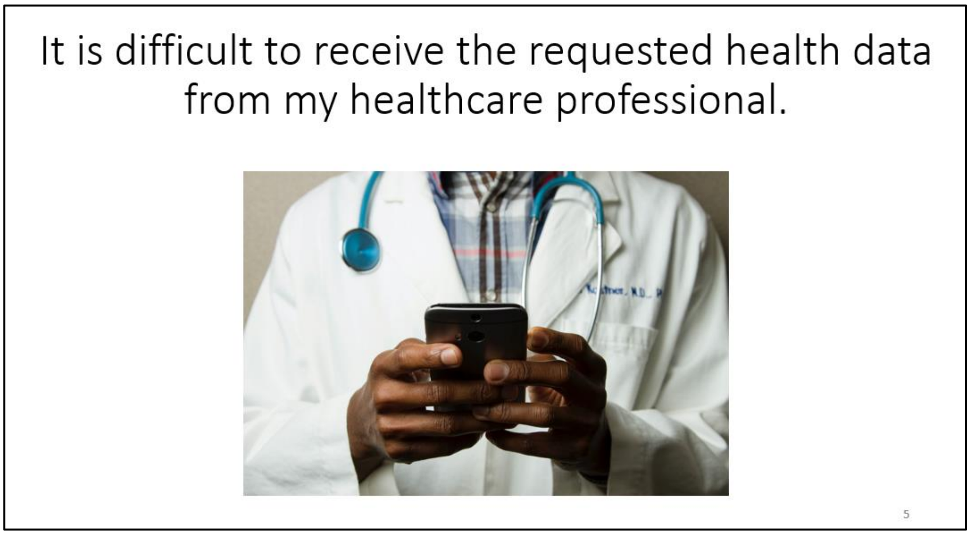
Gathering my own health data by means of a wearable or another device is important to monitor my complaints.



I think it is important to have access to my health data gathered by my healthcare professionals.



I trust the health data I receive from my healthcare professional more then the health data I gather myself.



It is difficult to receive the requested health data from my healthcare professional.

Your Health data

Activity data – steps per day

Personal goal is 4500 steps a day.

Your Health data

Wellbeing - Mood

Your Health data

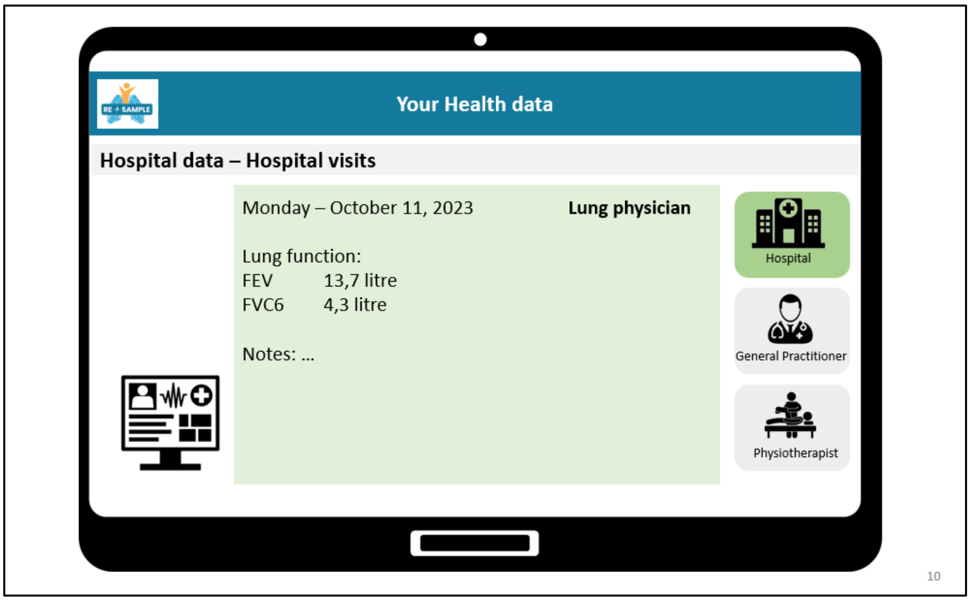
Wellbeing – positive health

8

Your Health data

Hospital data – Visits

9



Your Health data

Hospital data – Hospital visits

Monday – October 11, 2023 **Lung physician**

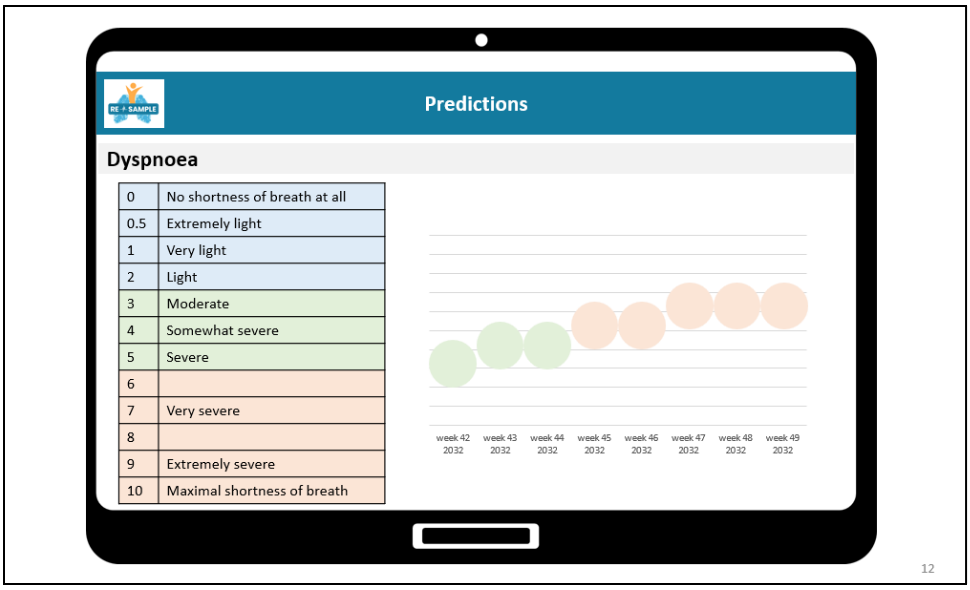
Lung function:
FEV 13,7 litre
FVC6 4,3 litre

Notes: ...

10

Predictions

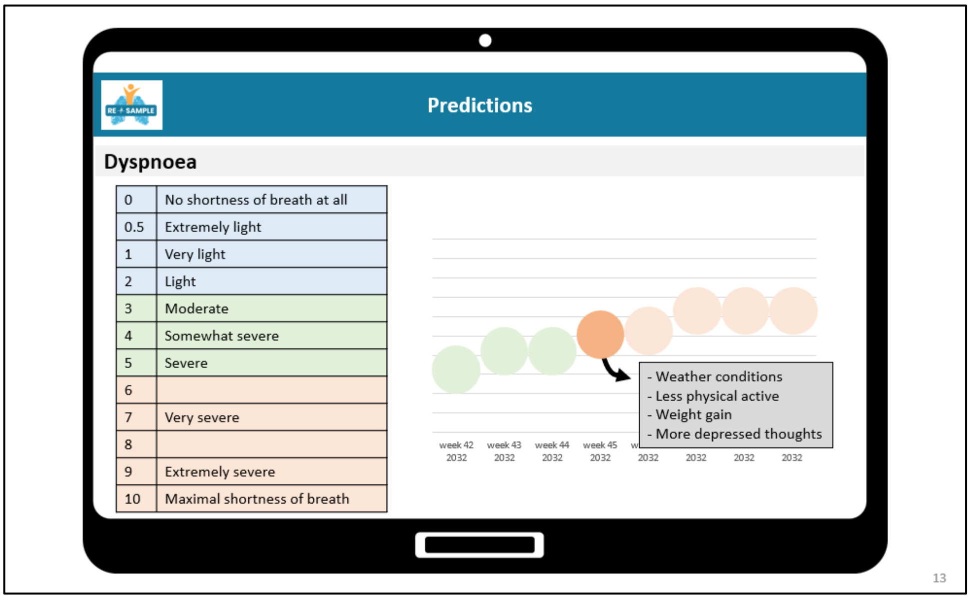
Wellbeing - Mood



Predictions

Dyspnoea

0	No shortness of breath at all
0.5	Extremely light
1	Very light
2	Light
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Extremely severe
10	Maximal shortness of breath

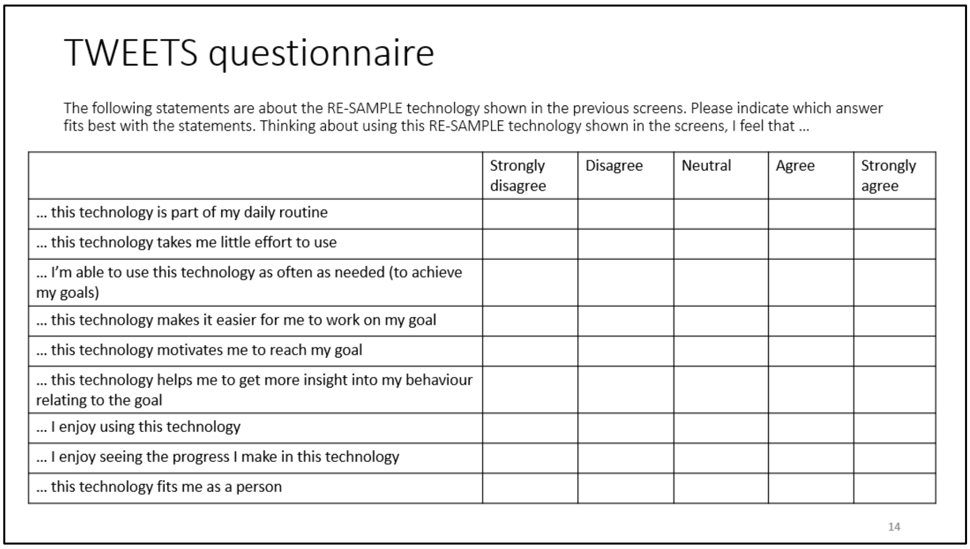


Predictions

Dyspnoea

0	No shortness of breath at all
0.5	Extremely light
1	Very light
2	Light
3	Moderate
4	Somewhat severe
5	Severe
6	
7	Very severe
8	
9	Extremely severe
10	Maximal shortness of breath

- Weather conditions
- Less physical active
- Weight gain
- More depressed thoughts



TWEETS questionnaire

The following statements are about the RE-SAMPLE technology shown in the previous screens. Please indicate which answer fits best with the statements. Thinking about using this RE-SAMPLE technology shown in the screens, I feel that …

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
… this technology is part of my daily routine					
… this technology takes me little effort to use					
… I'm able to use this technology as often as needed (to achieve my goals)					
… this technology makes it easier for me to work on my goal					
… this technology motivates me to reach my goal					
… this technology helps me to get more insight into my behaviour relating to the goal					
… I enjoy using this technology					
… I enjoy seeing the progress I make in this technology					
… this technology fits me as a person					

Hello Linda! I'am your Vitual Coach Marc. Are you available for a quick chat?

Great! Given the data you gathered you are doing well at this moment. But I foresee some more shortness of breath the upcomming week.

Virtual Coach:

Your are not as physical active as before and you step count is dropping. When you are less active this has a effect on your shortness of breath.

Your response:

Okay, what can I do?

Virtual Coach:

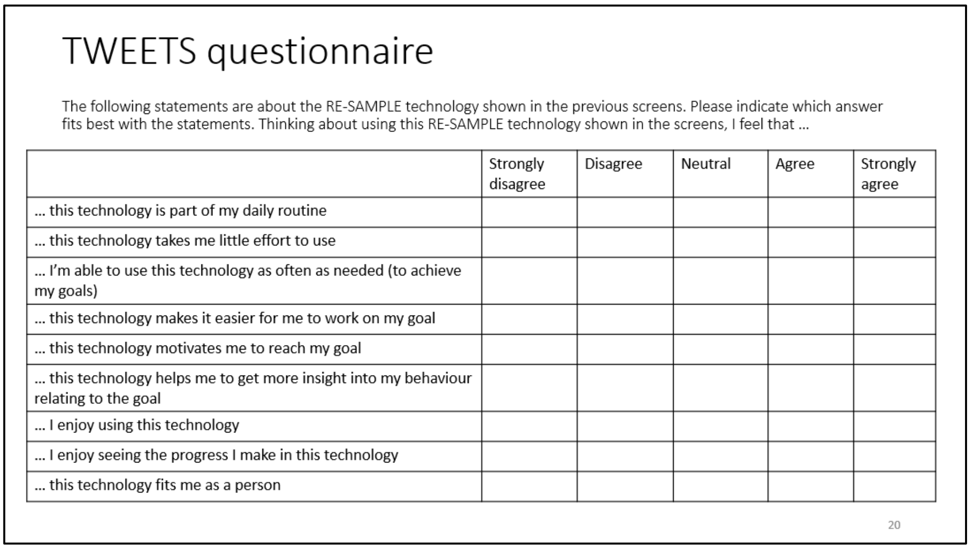
What you can do is ask your neighbor for a stroll through the neighbourhood. What do you think?

Your response:

That's a good idea!

Virtual Coach:

Goodbye!



TWEETS questionnaire

The following statements are about the RE-SAMPLE technology shown in the previous screens. Please indicate which answer fits best with the statements. Thinking about using this RE-SAMPLE technology shown in the screens, I feel that …

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
… this technology is part of my daily routine					
… this technology takes me little effort to use					
… I'm able to use this technology as often as needed (to achieve my goals)					
… this technology makes it easier for me to work on my goal					
… this technology motivates me to reach my goal					
… this technology helps me to get more insight into my behaviour relating to the goal					
… I enjoy using this technology					
… I enjoy seeing the progress I make in this technology					
… this technology fits me as a person					

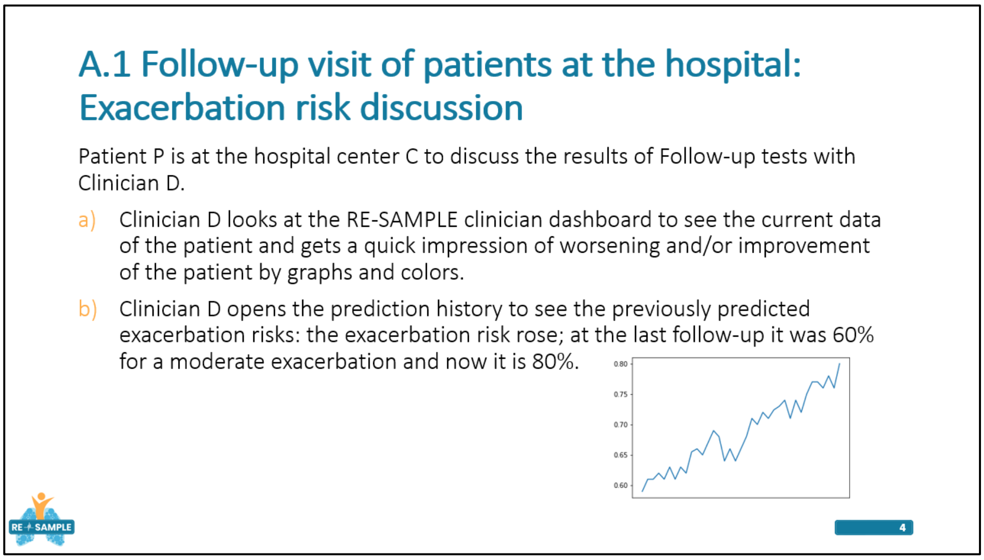
Appendix D: User Requirements Gathered in the Workshops with Clinicians summer 2022

ID	Type	Description	Rationale	NL	IT	EE	Priority	Conflicts	Fit Criterion	History
C10	Content	The HCPs shall be able to see at a glance the current COPD status of a patient (i.e., stable or exacerbation) in the clinician dashboard.	One of the goals of RE-SAMPLE is to support patients in preventing and managing exacerbations. It is crucial for the HCp to know the COPD status of a patient at any given moment.	x	x	x	Must have	n/a	1. Usability Testing: when opening the custom report on the clinical dashboard, the HCP can immediately see the COPD status of a patient within seconds.	Created on July 14, 2022
C11	Content	The HCPs shall be able to see at a glance the number of exacerbations in a time period (e.g., three/six months, one/two/three years) in the clinician dashboard.	The frequency of exacerbations in a time period influences the therapy plan of the patient. For example, if a patient has more than two exacerbation per year, the therapy plan needs to be adapted.	x	x	x	Must have	n/a	1. Usability Testing: when opening the custom report on the clinical dashboard, the HCP can immediately see the number of exacerbations in the defined time period.	Created on July 14, 2022
C12	Content	The HCPs shall be able to see the COPD status of a patient (i.e., stable or exacerbation) per day, since the enrolment in RE-SAMPLE.	A visualization of the COPD status throughout time provides a clear iverview of when an exacerbation occurs and for how many days.	x	x	x	Must have	n/a	1. Usability Testing: HCPs can correctly identify the COPD status of a patient at any given day.	Created on July 14, 2022
C13	Content	The HCPs shall be able to see in which days the patient experienced a change in symptoms in the previous 24 hours (answer to the first question of the symptom diary).	Changes in symptoms are perceived as important to assess disease progression, even when these changes do not lead to exacerbation.	x	x	x	Must have	n/a	1. Usability Testing: HCPs can correctly identify whether a patient experienced a change in symptoms at any given day.	Created on July 14, 2022
F24	Functional	HCPs shall be able to change the time period of the visualizations of the number of exacerbations (#C11), the COPD status throughout time (#C12), and the change in symptoms in the previous 24 hours(#C13).	It is intended that RE-SAMPLE is used in regular care for long periods of time. Therefore, it is important to adapt the time period of the visualizations to the time that has passed since enrolment.	x	x	x	Must have	n/a	1. Usability Testing: HCPs can successfully change the time period they are interested 2. Technical Testing: When the HCPs change the desired time period, the visualizations from (C11-13) adapt as expected.	Created on July 14, 2022

C14	Content	The HCPs shall be able to see the latest and previous answers to My Symptoms Card.	The HCPs stated that they cannot always remember how the disease affects each patient. Therefore, the answers to this questionnaire help having an overview of the status of the patient.		x	x	Should have	n/a	1. Usability testing: HCPs can answer the question " what is the normal experience of this patient for symptom X?"	Created on July 14, 2022
C15	Content	The HCPs shall be able to see the intensity of changes for each symptom, in the days when the patient experienced a change in symptoms during the previous 24 hours.	In line with #C13, even minor changes in symptoms can be relevant when understanding disease progression.		x	x	Should have	n/a	1. Usability testing: HCPs can answer the question " what was the intensity of change of symptom X on day Y?".	Created on July 14, 2022
C16	Content	The HCPs shall be able to review the self-reported perceived reasons to change of symptoms, in days when the patients report a change in symptoms in the last 24 hours.	The HCPs would like to see this information coupled to the detailed view on the intensity of changes in symptoms (#C15)		x	x	Should have	n/a	1. Usability testing: HCPs can answer the question " what was the perceived change for COPD symptoms on day X?".	Created on July 14, 2022
C17	Content	The HCPs shall be able to see the score of the EQ5D questionnaire over time.	The EQ5D is used to monitor disease progression in clinical practice.	x			Should have	n/a	n/a	Created on July 14, 2022
C18	Content	The HCPs shall be able to see the score of the mMRC questionnaire over time.	The mMRC is used to monitor disease progression in clinical practice.	x	x		Should have	n/a	n/a	Created on July 14, 2022
C19	Content	The HCPs shall be able to see the score of the CCQ questionnaire over time.	The CCQ is used to monitor disease progression in clinical practice.	x			Must have	n/a	n/a	Created on July 14, 2022
C20	Content	The HCPs shall be able to see the score of the HADS questionnaire over time.	The HADS is used to monitor disease progression in clinical practice.	x	x		Should have	n/a	n/a	Created on July 14, 2022
C21	Content	The HCPs shall be able to see the score of the CAT questionnaire over time.	The CAT is used to monitor disease progression in clinical practice.		x	x	Must have	n/a	n/a	Created on July 14, 2022
C22	Content	The HCPs shall be able to see the medication used during an exacerbation.	The medication taken during an exacerbation might explain the change in symptoms.	x			Should have	n/a	n/a	Created on July 14, 2022
C23	Content	The HCPs shall be able to see results of laboratorial and clinical tests.	Laboratorial results and other clinical tests provide useful information to understand the disease progression.	x		x	Should have	n/a	n/a	Created on July 14, 2022

C24	Content	The HCPs shall be able to see the comorbidities of a patient at a glance.	Knowing the comorbidities of a patient helps HCPs interpreting eventual changes in symptoms or exacerbations.		x		Should have	n/a	1. Usability Testing: when opening the custom report on the clinical dashboard, the HCP can immediately see the comorbidities of a given patient.	Created on July 14, 2022
C25	Content	The HCPs shall be able to see cross-parameter visualizations (e.g., physical activity and exacerbations or heart rate and anxiety feelings)	Trend analysis might give some indications of disease progression, but even more important, is to make a multi-parameter analysis combining *lungs* (e.g., oxygen saturation), *heart* (e.g., heart rate), and *feelings* (e.g., anxiety). Also, combination of behavioural information (e.g., physical activity) with occurrence of exacerbation, might help understanding the factors that led to an exacerbation.		x	x	Should have	n/a	1. Usability Testing: when opening the custom report on the clinical dashboard, the HCP can immediately see the comorbidities of a given patient.	Created on July 14, 2022
C26	Content	The HCPs shall be able to visualize the physical activity performed per day (e.g., number of steps, distance, active minutes).	Physical activity is crucial in the management of COPD. HCPs would like to see how active participants are.	x	x	x	Must have	n/a	n/a	Created on July 14, 2022
C27	Content	The HCPs shall be able to visualize variations in heart rate across days.	Heart rate variability is one of the most important parameters in early detection of exacerbation, especially during exercise and sleep.		x	x	Should have	n/a	n/a	Created on July 14, 2022
C28	Content	The HCPs shall be able to visualize variations in sleep across days.	No detailed explanation was given on how sleep data is relevant for COPD management.		x	x	Could have	n/a	n/a	Created on July 14, 2022

Appendix E: Overview of user stories used during iteration 4 (autumn 2022)

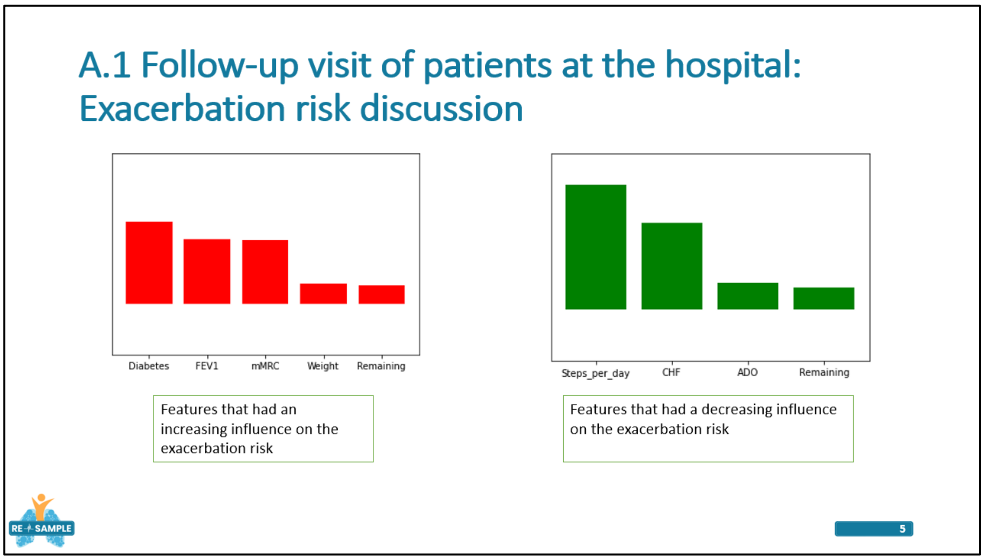


A.1 Follow-up visit of patients at the hospital: Exacerbation risk discussion

Patient P is at the hospital center C to discuss the results of Follow-up tests with Clinician D.

a) Clinician D looks at the RE-SAMPLE clinician dashboard to see the current data of the patient and gets a quick impression of worsening and/or improvement of the patient by graphs and colors.

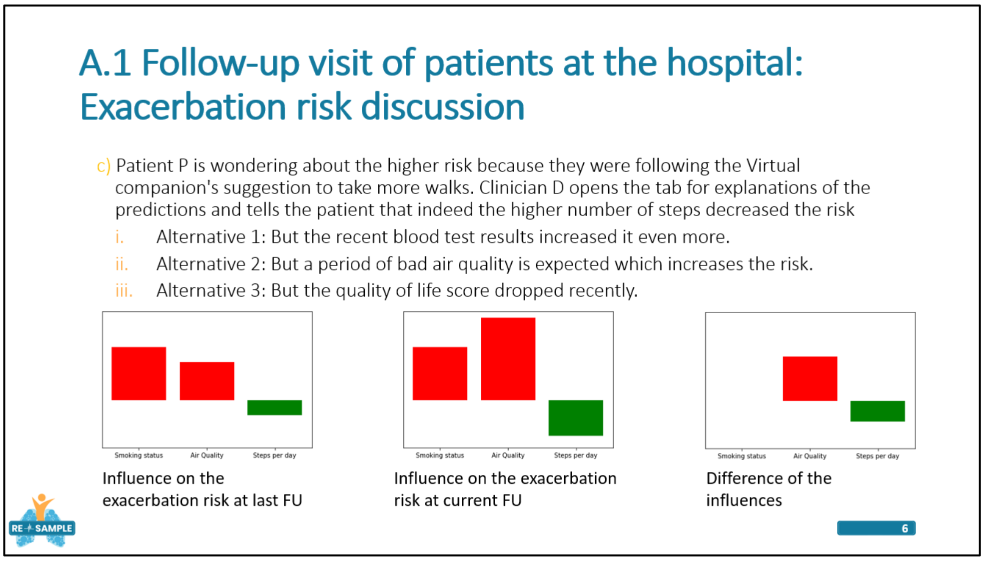
b) Clinician D opens the prediction history to see the previously predicted exacerbation risks: the exacerbation risk rose; at the last follow-up it was 60% for a moderate exacerbation and now it is 80%.



A.1 Follow-up visit of patients at the hospital: Exacerbation risk discussion

Features that had an increasing influence on the exacerbation risk

Features that had a decreasing influence on the exacerbation risk



A.1 Follow-up visit of patients at the hospital: Exacerbation risk discussion

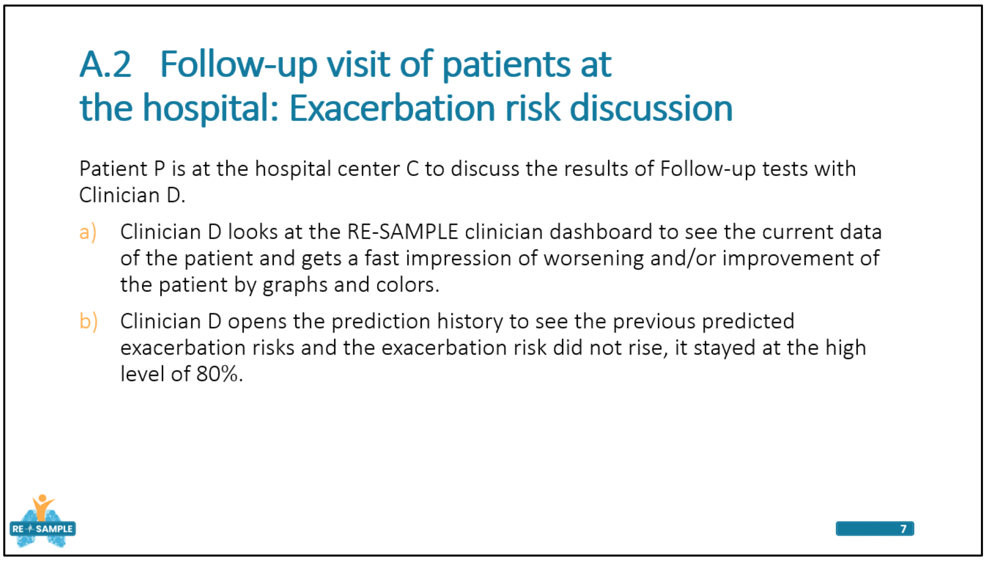
c) Patient P is wondering about the higher risk because they were following the Virtual companion's suggestion to take more walks. Clinician D opens the tab for explanations of the predictions and tells the patient that indeed the higher number of steps decreased the risk

  i. Alternative 1: But the recent blood test results increased it even more.
  ii. Alternative 2: But a period of bad air quality is expected which increases the risk.
  iii. Alternative 3: But the quality of life score dropped recently.

Influence on the exacerbation risk at last FU

Influence on the exacerbation risk at current FU

Difference of the influences

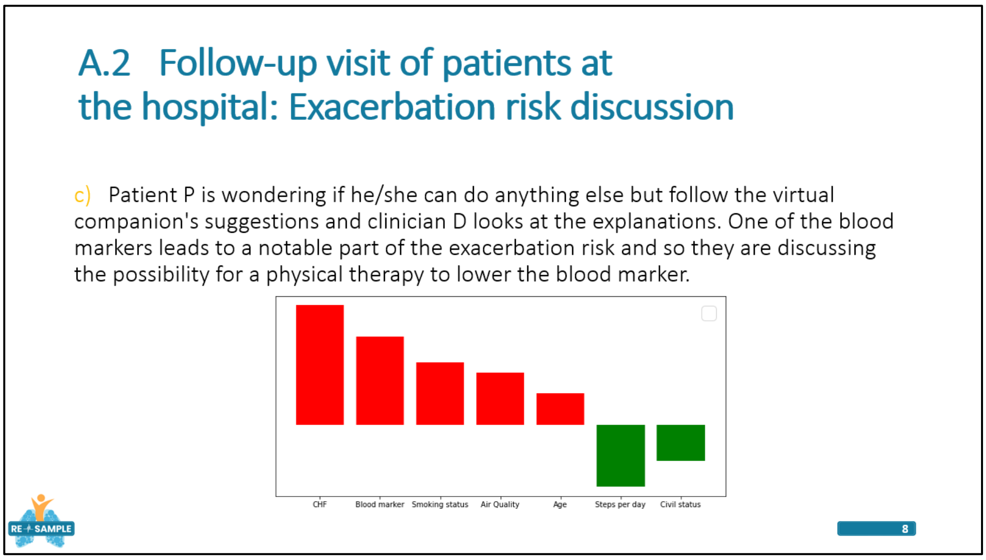


A.2 Follow-up visit of patients at the hospital: Exacerbation risk discussion

Patient P is at the hospital center C to discuss the results of Follow-up tests with Clinician D.

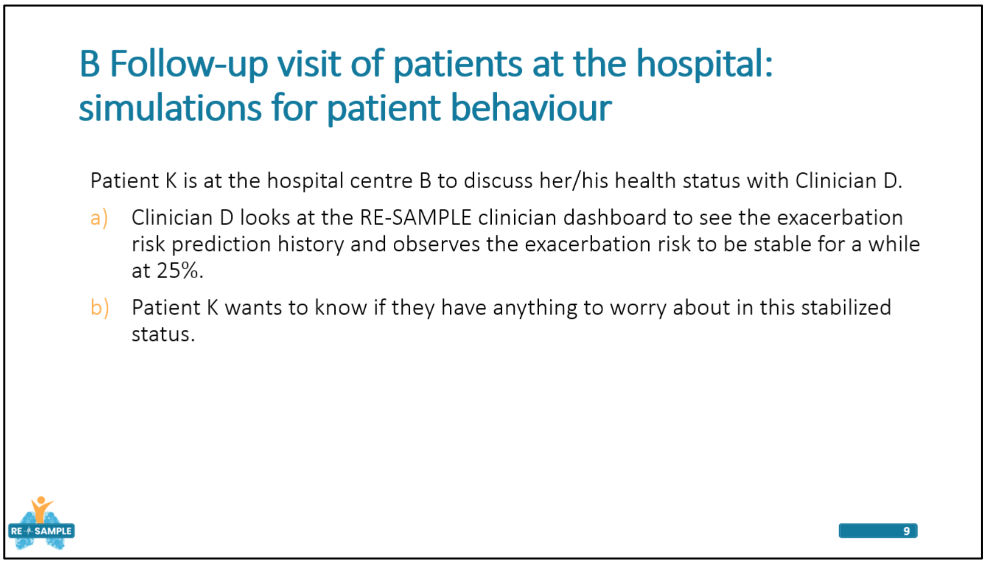
a) Clinician D looks at the RE-SAMPLE clinician dashboard to see the current data of the patient and gets a fast impression of worsening and/or improvement of the patient by graphs and colors.

b) Clinician D opens the prediction history to see the previous predicted exacerbation risks and the exacerbation risk did not rise, it stayed at the high level of 80%.



A.2 Follow-up visit of patients at the hospital: Exacerbation risk discussion

c) Patient P is wondering if he/she can do anything else but follow the virtual companion's suggestions and clinician D looks at the explanations. One of the blood markers leads to a notable part of the exacerbation risk and so they are discussing the possibility for a physical therapy to lower the blood marker.

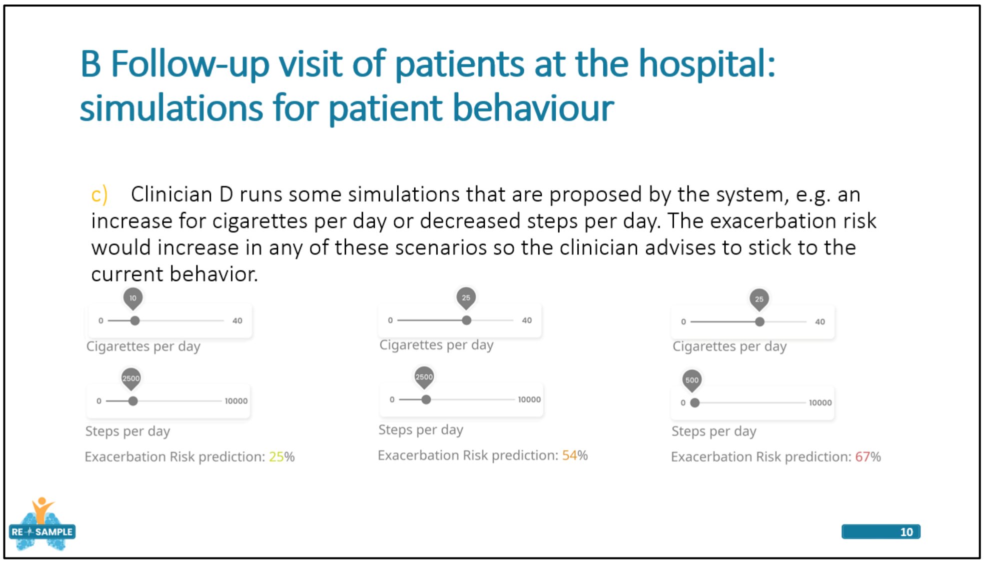


B Follow-up visit of patients at the hospital: simulations for patient behaviour

Patient K is at the hospital centre B to discuss her/his health status with Clinician D.

a) Clinician D looks at the RE-SAMPLE clinician dashboard to see the exacerbation risk prediction history and observes the exacerbation risk to be stable for a while at 25%.

b) Patient K wants to know if they have anything to worry about in this stabilized status.



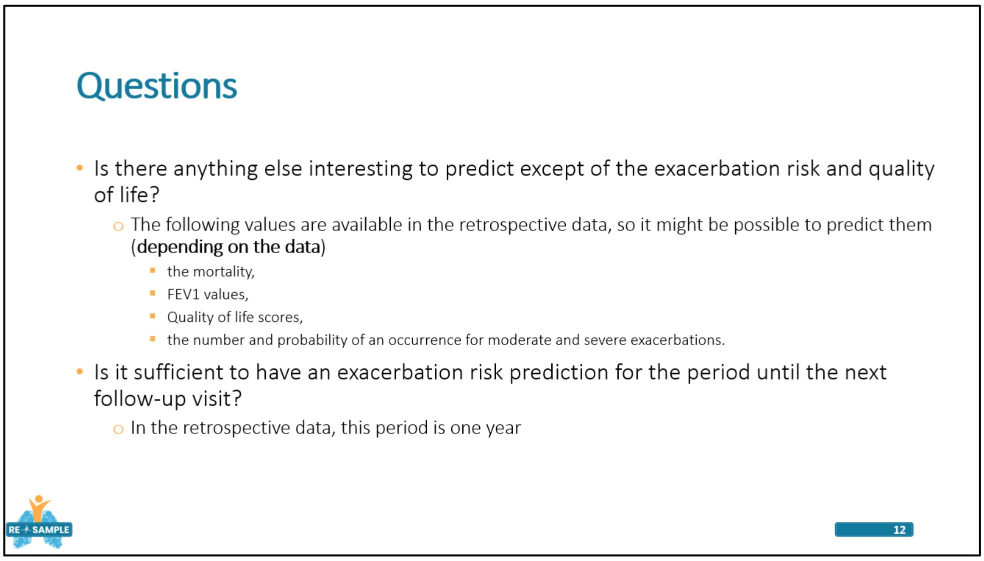
B Follow-up visit of patients at the hospital: simulations for patient behaviour

c) Clinician D runs some simulations that are proposed by the system, e.g. an increase for cigarettes per day or decreased steps per day. The exacerbation risk would increase in any of these scenarios so the clinician advises to stick to the current behavior.

Exacerbation Risk prediction: 25%

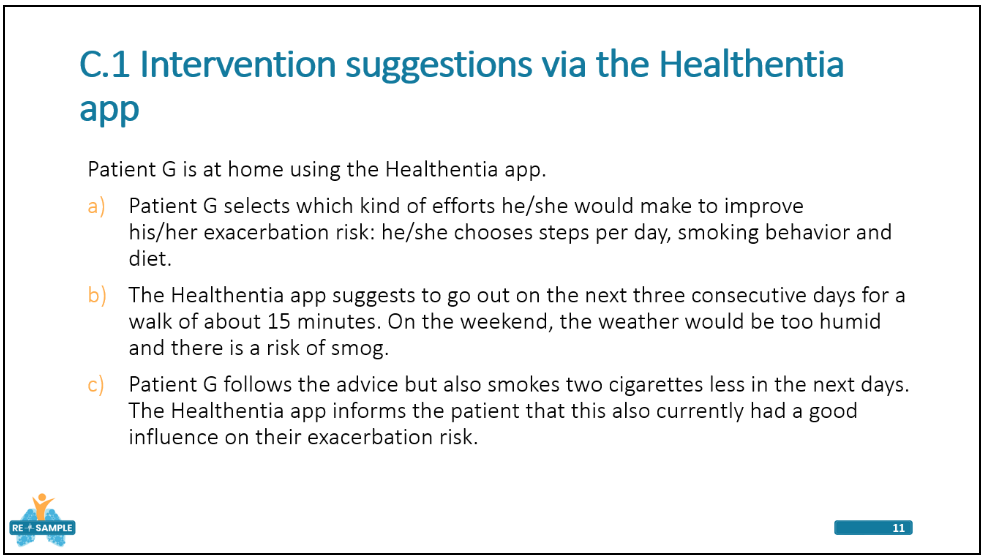
Exacerbation Risk prediction: 54%

Exacerbation Risk prediction: 67%



Questions

- Is there anything else interesting to predict except of the exacerbation risk and quality of life?
  - The following values are available in the retrospective data, so it might be possible to predict them (**depending on the data**)
    - the mortality,
    - FEV1 values,
    - Quality of life scores,
    - the number and probability of an occurrence for moderate and severe exacerbations.
- Is it sufficient to have an exacerbation risk prediction for the period until the next follow-up visit?
  - In the retrospective data, this period is one year



C.1 Intervention suggestions via the Healthentia app

Patient G is at home using the Healthentia app.

a) Patient G selects which kind of efforts he/she would make to improve his/her exacerbation risk: he/she chooses steps per day, smoking behavior and diet.

b) The Healthentia app suggests to go out on the next three consecutive days for a walk of about 15 minutes. On the weekend, the weather would be too humid and there is a risk of smog.

c) Patient G follows the advice but also smokes two cigarettes less in the next days. The Healthentia app informs the patient that this also currently had a good influence on their exacerbation risk.