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

D5.7: End-user involvement for design and evaluation

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Authors	Christiane Grünloh (RRD), Marijke Broekhuis (RRD), Eline te Braake (RRD), Anke Lenferink (UT), Marjolein Brusse-Keizer (MST)
Reviewers	Marie Nabbe/Sofía Carbonell (HOPE), Rain Jõgi (TUK)
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Partners

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

Abstract

The goal of RE-SAMPLE is to develop an ecosystem of innovative eHealth services that support patients and healthcare professionals (HCPs) to manage COPD and accompanying complex chronic conditions (CCC) 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 the beginning of the project until M11. It describes the results of the initial stakeholder analysis and network inventory, the instalment of the RE-SAMPLE end-user panel, a general patient survey to engage with the larger patient community, and the results of the first iteration of end-user studies. Furthermore, the initial plan for the second iteration of end-user studies is outlined.

This deliverable will be updated in M24 (D5.8) and M39 (D5.9) to report on end-user studies that are performed in the respective time frames.

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Symbols, definitions, abbreviations, and acronyms

ASQ	After-Scenario Questionnaire
Citizen science	a participatory research model in which non-professionals are actively involved in scientific research
CCC	Complex Chronic Condition
CeHReS	Center for eHealth Research and Disease Management
COPD	Chronic Obstructive Pulmonary Disease
D	Deliverable
DoA	Description of Action
DPO	Data Protection Officer
GP	General Practitioner
HCP	Healthcare professional
HUBBI	eHealth UsaBility Benchmarking Instrument
ISO	International Organization for Standardization
M	Month
RWD	Real World Data
SUS	System Usability Scale
TAM	Technology Acceptance Model
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 COPD and accompanying complex chronic conditions (CCC) 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 protocols.

This deliverable gives an overview of the end-user involvement activities carried out from the beginning of the project until M11. It describes the results of the initial stakeholder analysis and network inventory, the instalment of the RE-SAMPLE end-user panel, a general patient survey to engage with the larger patient community, and the results of the first iteration of end-user studies. Furthermore, the initial plan for the second iteration of end-user studies is outlined.

This deliverable will be updated in M24 (D5.8) and M39 (D5.9) to report on end-user studies that are performed in the respective time frames.

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 initial stakeholder analysis and network inventory, which was conducted within the consortium. The installation of the RE-SAMPLE end-user panel is described in section 4, including the results of the introductory questionnaire that was sent to all panel members after subscription. Section 5 outlines a general patient survey, which aimed to engage with the larger community of patients to introduce RE-SAMPLE, receive further information and invite more people to join the panel in the future. Section 6 details the first iteration of end-user studies that was conducted in summer 2021 to ensure early detection of potential barriers and usability issues of the Healthenthia app that is being used in the cohort study. The deliverable ends with the initial plans for the second iteration of end-user studies in section 7 and a conclusion in section 8.

[1] CeHReS is an acronym for Center for eHealth Research and Disease Management

3. Stakeholder analysis and network inventory

The initial stakeholder analysis was conducted in a workshop during the consortium meeting at M3. Due to the COVID-19 measures, the consortium meeting and workshop were held online on 31.05.2021 through Microsoft Teams.

3.1 Method

The workshop with the consortium partners aimed to make an inventory of the most important end-users and other stakeholders that should be involved in the RE-SAMPLE project. Furthermore, the aim was to identify at what stage and in which activities they should be involved, as well as to brainstorm the potential of regional, national and international ecosystems to reach these stakeholders.

The workshop combined brainwriting and brainstorming, which facilitate idea generation either in discussions (brainstorming) or as a solo exercise (solo-brainstorming or brainwriting) to get initial ideas out without being interrupted by discussions and lowering the barriers for everyone to participate (e.g., not everyone feels confident to speak up in brainstorming sessions). The workshop was conducted in a video conference using Microsoft Teams and MURAL[2], a web-based tool for visual collaboration to facilitate interaction among the consortium members. A MURAL board was prepared in advance to support and guide the inventory. Besides outlining the aim of the workshop, one area outlined the brainstorming questions in different colours:

- Who do we want to involve as END-USERS? (yellow)
- Who do we want to involve as other STAKEHOLDERS? (orange)
- These end-users are important to involve WHEN to do WHAT? (purple)
- We can recruit the end-users through which ASSOCIATIONS or CHANNELS? (green)
- How do we keep end-users INTERESTED and ENGAGED? (blue)

Furthermore, the board displayed different areas to which the participants could contribute by adding notes that corresponded to the colours of the initial brainstorming questions. The first space was for the solo brainstorm exercise, where partners could add their initial ideas uninterrupted. The second space was for the group brainstorm exercise and had different headings: Involvement, Recruitment/Information, Engagement, and Next Activities.

At the beginning of the workshop, the aim and procedure were outlined and participants could familiarise themselves with the MURAL board before having 4-5 minutes to fill in their initial ideas in the solo-brainstorming area. This was followed by a brainstorming session with the whole group to discuss the notes and future activities.

3.2 Results

The workshop was attended by N=27 participants and took about 40 minutes. The solo brainstorming exercise resulted in many filled-in notes (see Figure 1), which are summarised below.

[2] https://www.mural.co/

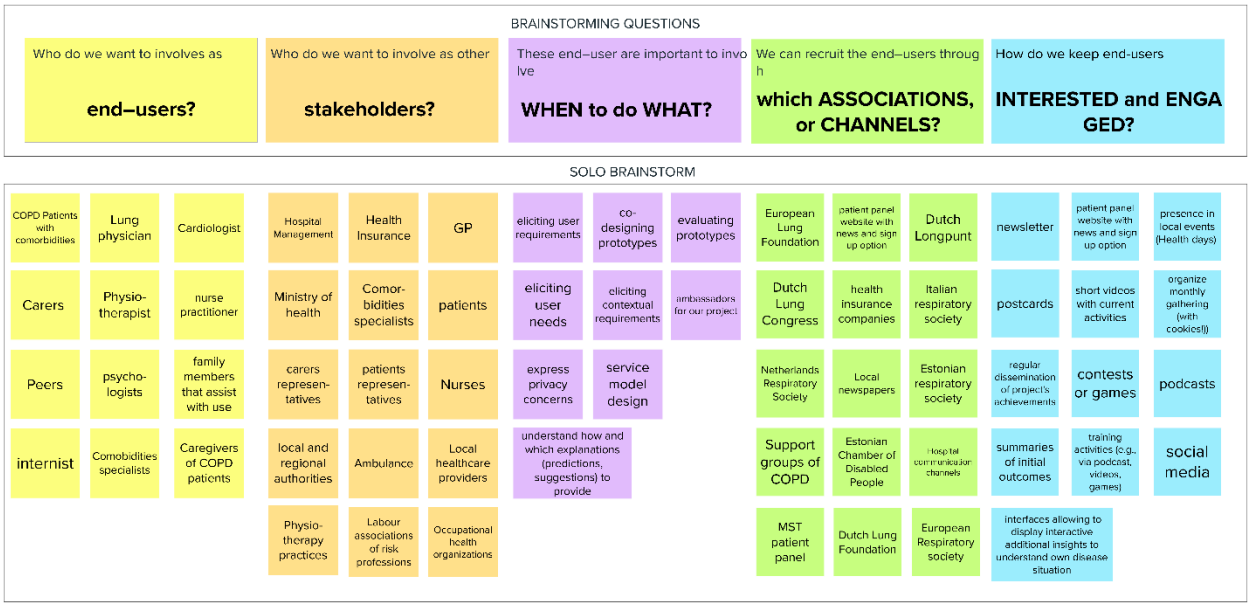

Figure 1: MURAL board after solo brainstorming exercise

3.2.1 End-Users

Next to COPD patients with comorbidities, caregivers of COPD patients were mentioned (i.e., carers, caregivers of COPD patients, family members that assist with use) as well as peers, which related to family members as well. Several HCPs were mentioned: lung physician, cardiologist, physiotherapist, nurse practitioner, psychologist, internist, and comorbidities specialist.

3.2.2 Other stakeholders

Next to the end-users who are expected to interact directly with the RE-SAMPLE technology, other important stakeholders that should be involved in the project were mentioned. These were organisational departments in the hospitals (hospital management and ambulance) and HCPs (General practitioners (GPs), local healthcare providers outside the hospitals, physiotherapy practices, comorbidity specialists). Other organisations mentioned were health insurance providers, occupational health organisations, labour associations of risk professions and governing bodies such as local/regional authorities and the ministry of health. Lastly, representatives of the end-users were deemed important to involve (i.e., carer and patient representatives).

3.2.3 Involvement at what stage for which activities

Several suggestions regarding when to involve stakeholders related to activities such as eliciting user needs, eliciting contextual requirements, eliciting user requirements, co-designing prototypes, evaluating prototypes. These activities are well known in human-centred design and have been carried out in task T2.1 and T2.3 within WP2, for which stakeholders were involved. In addition, it was added that they should be involved to express privacy concerns, which may be related both to early design phases and to later stages when the system is in use. Next to being involved in the service model design, it was also added that stakeholders' involvement is important to understand their information needs. For example, when it comes to predictions and suggestions that RE-SAMPLE offers, how should these be explained to the stakeholders? Stakeholders should be involved in an early phase of development (e.g., early prototyping) but also in later stages to understand how the outcomes of RE-SAMPLE (i.e. predictions and suggestions) can be explained to end-users in a good way. Finally, the stakeholders can also act as ambassadors for our project to support communication and dissemination, and to invite more stakeholders to become involved.

3.2.4 Associations and channels

At the European level, the European Lung Foundation and European Respiratory Society were mentioned. For each country, participants suggested specific associations or venues: Dutch Longpunten[3], Dutch Lung Congress, Netherlands Respiratory Society, and Dutch Lung Foundation in The Netherlands; Estonian Respiratory Society and Estonian Chamber of Disabled People in Estonia; and the Italian Respiratory Society in Italy. Furthermore local channels such as health insurance companies, hospital communication channels, and local newspapers were named. The patient panel (see section 44) was also mentioned. Initiatives or support groups of patients (e.g., online groups, support groups for COPD) were mentioned as channels to reach patients and other stakeholders that are not associated with or under the umbrella of larger organisations such as the hospitals involved in RE-SAMPLE. These more informal channels may be a good way to disseminate our results and keep people in the loop.

Some of the partners are already in close contact with various local associations and groups based on previous collaborations (e.g., Dutch Longpunten, Netherlands Respiratory Society). Some channels have to be explored further to identify and establish a contact for RE-SAMPLE.

3.2.5 Keeping up interest and engagement

As the project runs for several years, it can be a challenge to keep stakeholders informed and engaged and also to make sure to give something back to them. Continuous end-user involvement can also be seen as developing a close relationship with the community (i.e., in this case, the community of patients living with COPD and the community of HCPs working closely with COPD patients). One way to do this is to develop a relationship with the community, sharing and exchanging information in a way that is accessible and engaging. As part of regular dissemination activities, one participant suggested that project's achievement should be shared on a regular basis also with stakeholders and end-users. For example, summaries of initial outcomes, short videos with current activities, and training activities (i.e., taking the idea of mini-lectures, podcasts, games or other activities through which end-users can be trained on relevant topics and innovations of RE-SAMPLE). Communication media that were mentioned were the RE-SAMPLE patient panel website with news, newsletter, podcasts, postcards, short videos with current activities, and social media. Other means of engagement suggested included contests or games (e.g., small games to be played together, which might keep them motivated), interfaces that allow to display interactive additional insights to understand their own disease situation (i.e., to exploit the technology we have to provide additional and interactive insights for the patient in terms of what could have an impact on their disease), presence in local events (e.g., Health days) and organising monthly gatherings ("with cookies", which means that these gatherings should be more informal and social).

The group discussed potential next steps, for example, making an inventory of associations and groups on the local and international level and developing and implementing the RE-SAMPLE end-user and expert panel on our website. One idea was to add buttons through which interested patients can easily get more information and join the panel, which makes it easier to contact them through a mailing list as well. For the Italian pilot, it was discussed that the panel might be rather locally organised.

The outcome of this stakeholder analysis workshop is of use to several work packages that are directly involving stakeholders in their tasks (WP2, WP5, WP7), and work packages engaged in dissemination, communication and outreach activities (WP8. See also D8.1 *Dissemination and exploitation plan*).

[3] https://www.longfonds.nl/activiteiten/longpunten "Longpunten" (Dutch for lung points) are meetings for patients, partners and family members organised by volunteers from the Dutch Lung Foundation *Longfonds* in about 60 locations in The Netherlands. These meetings aim to provide information (e.g., a healthcare professional giving a presentation) and support exchange of experience between patients and carers.

4. RE-SAMPLE end-user panel

Following the Description of Action (DoA) and the stakeholder analysis workshop, an end-user panel was installed in July 2021 for optimal and continuous engagement with experts and patients.

4.1 End-user panel installation

Together with the client board of MST, it was discussed how to approach the potential end-users to ask advice on the design and realisation of the RE-SAMPLE project. It was decided to install two groups:

1. **A user panel** of patients with COPD and/or other chronic diseases which can be contacted for different end-user studies (e.g., user needs studies; prototype testing; design sessions for service model, coaching, self-management, shared decision making, personalised interventions) and evaluation of the virtual companion and the RE-SAMPLE programme. This panel will be mainly approached by e-mail.
2. **An expert group** consisting of 5-10 patients with COPD and/or other chronic diseases to join physical meetings to discuss the progress and steps to be taken in the RE-SAMPLE project (e.g., how to approach potential participants for recruitment of the cohort study, how to communicate results, improvement points from a patient's perspective).

As outlined in D8.2 *Project website*, the RE-SAMPLE website[4] provides information for patients with COPD and chronic diseases about the possibility to participate in RE-SAMPLE. The page informs the patient about the project and through call-to-action buttons allows to a) request more information, b) participate in the research, or c) subscribe to the RE-SAMPLE newsletter (see Figure 2 and Figure 3).

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

[4] https://www.re-sample.eu/project/patients/for-patients/

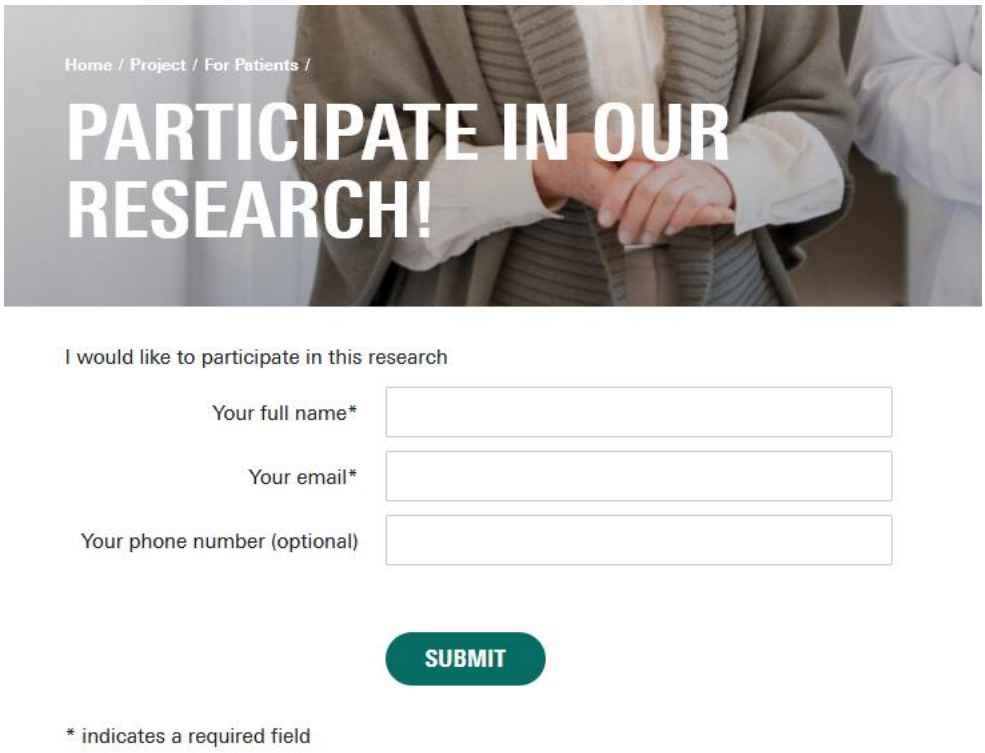

Figure 3: Sign-up form to participate in the research (i.e., to join the patient panel)

In The Netherlands, all members from the client panel of MST (with COPD and/or other chronic diseases) were asked to participate. This client panel represents more than 2000 patients with COPD and/or other chronic diseases and was contacted through a newsletter. The newsletter included an invitation to participate in the user panel and/or expert group with a link to the sign-up form at the RE-SAMPLE website.

4.2 Method

In August 2021, an introductory questionnaire was sent to 22 patients who had signed up via the RE-SAMPLE website to join the user panel and/or expert group. This introductory questionnaire aimed to get to know the potential end-users, especially concerning:

- the type of chronic diseases they live with (e.g., COPD, diabetes, cardiovascular disease);
- which activities in the RE-SAMPLE project they are interested in to participate (e.g., data collection, user-friendliness of mobile phone applications, communication with patients, development of personalised care for patients with chronic diseases);
- which aspects in the collection and storage of personal (real-world) data they consider important to pay attention to;
- their wishes or ideas concerning personalised care.

The introductory questionnaire of the patient panel can be found in *Appendix A: Introductory questionnaire patient panel*.

4.3 Results

The introductory questionnaire was filled in completely by N=20 panel members. The results showed that nine patients in the panel have COPD, often in combination with cardiovascular diseases (e.g., heart failure), and sometimes in combination with feelings of anxiety, depression or diabetes. The most important activities in the RE-SAMPLE project that patients find interesting to participate in were: data collection (e.g., surveys), measurements (e.g., spirometry, blood sampling), and development of personalised care (e.g., personal disease support). Aspects that participants considered important for assessing disease progression were: medication use, weather, diet, vitamins, stress, seasonal effects, living environment, regular checks (e.g. blood sampling), motivation to exercise, allergic reactions, and age.

The participants reported various important issues for the collection and registration of data:

- ensure privacy and data protection;
- being aware that not everything can be measured;
- adopt a multidisciplinary approach and sharing information with all stakeholders involved;
- prevent too many or long surveys;
- ensure the app is user-friendly and uses easy to understand language;
- take into account communication with HCPs and that next steps should be considered together with the HCP (shared-decision making).

Finally, the following suggestions were made regarding personalised care:

- combine new developments with existing treatment;
- make patients and healthcare professionals aware of new approaches;
- improve communication between all stakeholders;
- consider video consultation or home visits when video consultation is impossible;
- have the ability to adapt medication use more frequently;
- connect people from the neighbourhood to provide support;
- consider a case manager/team who can maintain contact with various disciplines to ensure continuity and quality of care.

4.4 Participant consent for follow-up contact

Next to the RE-SAMPLE end-user panel, patients and healthcare professionals who participated in the user requirements studies (WP2) in The Netherlands were asked whether they a) are interested in receiving results of the studies, and b) whether the research team is allowed to contact them again for follow up research. Furthermore, the questionnaire that was developed for the engagement with the larger patient community (see section 5) also included a consent to be contacted again. As these consents relate specifically to being contacted again by the partner carrying out that respective study (in both cases Roessingh Research and Development, RRD), contact details of the participants who gave consent were stored only at the research institute. However, when the results of the particular study are shared with participants, they are provided with information about the RE-SAMPLE end-user panel and invited to sign up through the RE-SAMPLE website.

4.5 Current status end-user panel and future activities

As of February 2022, N=30 people have signed up to be part of the end-user panel in total. Of these, N=28 signed up for the patient panel and N=18 for the expert panel. In addition, 40 patients and 21 HCPs who participated in the Dutch studies gave their consent to be contacted again in the future by RRD.

The RE-SAMPLE panel was utilised to recruit participants for the co-design workshop on coaching (D2.4 *Functional specifications for the virtual companionship programme*). Via email, 15 members of the RE-SAMPLE patient panel were contacted, three of which were interested in participating in the workshop.

Due to COVID-19 measures, no physical meetings with the patient expert group could be organised yet. In 2022, the clinical partners (MST, TUK, GEM) hope to collaborate with the European Lung Foundation to advertise the panel and expert group in other European countries. Furthermore, as healthcare professionals will also be end-users of RE-SAMPLE, the end-user panel will be extended to also give HCPs the opportunity to sign up.

5. Engagement with larger patient community

Another strategy to engage with patients was to reach out via different channels than the pilot hospitals and to distribute a survey both digitally and on paper. This method aimed at reaching patients for whom a digital survey might be a barrier. The survey was also a way to introduce RE-SAMPLE to this group and enable the first contact in order to ease their involvement them in future studies.

5.1 Method

5.1.1 Survey design

Participants needed to be 18 years or older and diagnosed with COPD. The survey could either be filled in online or on paper, and took about 15 minutes. After a short introduction of the RE-SAMPLE project and of the structure of the survey, participants could start the survey after giving their informed consent. Questions regarding COPD experiences in general and their exacerbation management were asked first. The survey ended with the collection of demographics and health status: age, gender, health literacy, and digital literacy. Both open-ended, multiple-choice, and Likert-scale questions were included. The questionnaire can be found in *Appendix B: General patient survey*.

5.1.2 Distribution strategy

The survey was published online in English and Dutch (23.11.2021), Estonian (20.12.2021) and Italian (19.01.2022). A poster with relevant information about the online survey was developed by HOPE in cooperation with RRD to enhance easy and quick distribution (see Figure 4).

Figure 4: RE-SAMPLE patient survey poster

This poster was made available in English and Dutch. The survey was distributed via various channels. In The Netherlands, physiotherapy practices in and nearby Enschede were asked to spread this survey among their COPD patients. In total, 2 practices cooperated in distributing this survey. A total of 30 paper versions were distributed among these physiotherapy practices. The survey was also shared with local newspapers in Twente and their surroundings. Of the total of 26 mailed newspapers, 2 replied. Of those who replied, one would only publish for payment, and one would publish when having enough space, the rest did not respond. The online survey was also shared with the addiction care organisation 'Tactus'. They employ HCPs at various locations in The Netherlands and were asked by mail to share the survey with their COPD patients. Besides distributing the survey with newspapers or physiotherapy practices, the survey was also shared by RE-SAMPLE on the social media channels and in the February newsletter. The COPD patient organisation 'Luchtgenoten', the THOON network[5] and MST were asked to distribute this survey.

5.2 Results

The general patient survey is still online to collect new data and get in contact with patients who might be interested to participate in future studies. As of 3 February 2022, a total of 47 Dutch COPD patients filled in the general patient survey (N=30 online version, N=17 paper version). Of the total amount survey, 9 were incomplete. As mentioned in section 4.4, the questionnaire included a question of whether the partner carrying out this study is allowed to contact them again for follow-up studies in the future. In total, 21 patients consented to be contacted again (N=17 from the online survey, N=4 from the paper version) and can subsequently also be invited to join the RE-SAMPLE panel.

5.2.1 Demographics

From the total amount of participants, 15 were male, 21 were female, and two participants preferred to self-describe and stated their age instead. The mean age of participants was 63. The mean age of patients who filled in the paper version was higher than those who filled in the online version with a mean difference of 18 years. The majority was retired. Some (N=5) were not capable of working anymore, some worked either full- or part-time (N=7), and one did voluntary work. Trade school was most frequently mentioned (N=17) as the highest degree of education, with a few finishing elementary school (N=5), high school (N=8), or university (N=5). It is notable that results from the paper version revealed that the majority of those participants mentioned elementary school (N=5) or high school (N=5) to be their highest degree of education. The years of diagnosis with COPD ranged from less than one year to more than 20 years. However, the majority of participants (N=21) live between 3 and 10 years with their COPD. The other conditions besides COPD varied: diabetes, chronic heart failure, heart disease, hypertension, and rheumatoid arthritis were among the most frequently mentioned conditions. However, there were also several participants (N=12) who did not mention having any other chronic condition.

5.2.2 COPD and exacerbations

Results revealed that the majority received the most useful information about COPD from their GP, doctor, or pulmonologist. Some also stated to receive the most useful information from other COPD patients (N=4) or nurses (N=6). One stated to receive useful information from the internet or books. When asked about their current level of COPD knowledge, the majority of the participants (N=28) stated to know as much about COPD as they need to know. However, there were also some participants (N=6) that stated to know too little. Only one participant stated to know nothing about COPD but also did not want to know anything about it.

Results regarding how much COPD affects their daily activities varied. Eleven participants in the online survey stated to have small problems but could still perform all their daily activities. Only a few (N=2) were unable to perform their usual activities. Remarkedly, seven participants in the paper version stated to experience several difficulties which makes performing daily activities difficult. Four participants from the paper version stated to experience many struggles and were unable to perform their daily activities.

[5] THOON is an acronym for Twentse Huisartsen Onderneming Oost Nederland, which is an organisation for general practitioners in Twente and the surrounding area.

Results regarding the exacerbation revealed that the majority does not feel it coming. The participants who do feel an exacerbation coming (N=15) mentioned shortness of breath to be the most dominant symptom. Symptoms like tiredness and coughing were mentioned by some of the participants. Activities performed when feeling these symptoms coming were taking rest, medication intake (either inhaler, Ventolin, or prednisolone), and staying calm. Physical activity in any form (walking, biking, taking stairs) and effort during daily activities were mentioned as things that participants currently struggle with. These were also the events that could cause a worsening of symptoms, along with smoke (from cigarettes, fireplaces, or from fireworks), being in crowded places, stress, and weather conditions. However, there were also several participants (N=13) who stated that a worsening of symptoms could not be predicted nor caused by any specific event. Results regarding ways to improve health revealed that the majority of the participants (N=32) seem to know what to do to improve their health. Every participant could mention activities in one or more of the domains: physical exercise, mental exercise, lifestyle adaptions, and social activities. Exercising was most frequently mentioned (N=29) as a way to improve health.

5.2.3 Health literacy and technology use

Almost all participants (N=21) stated to never experience problems understanding texts about health or an illness. Only two participants mentioned having problems with this often. The confidence of filling in medical forms ranged from reasonably confident to very much confident. With only six participants mentioning their confidence to range from a little confident to not confident at all. Although most participants (N=19) stated their level of digital skills to be average or high (N=11), the answers of the minority were divided. Meaning that answers ranged from really low to really high. Despite the level of digital skills, the majority of participants still mentioned using a smartphone, computer or tablet. Only four participants stated to use no device at all. When looking at measuring one's own health, most participants (N=19) stated to use an oximeter, three participants (also) used a smartphone app, and two a smartwatch. Thirteen participants stated to not use any device to measure their health.

6. First iteration end-user study

As preparation for the execution of the Real World Data (RWD) monitoring cohort, a first end-user study was conducted to ensure early detection of potential barriers and usability issues of the Healthenthia app. The study set-up was designed at the beginning of June 2021. The study was piloted (with N=4, convenience sampling) from the end of June to the beginning of July. Data was collected from the beginning of August (N=8). The final analysis and report were shared with iSprint on 20 September 2021.

6.1 Method

6.1.1 Study design

To answer our objective, a usability evaluation study with a mixed-methods approach was set up. Participants were asked for a single usability evaluation session in a lab setting. Five different tasks, that the participants had to complete, were formulated. These tasks reflected the most important functionalities of the application. The execution of these tasks was accompanied by a think-aloud protocol and the measurement of task metrics (task completion, time on task, task satisfaction). Afterwards, two usability benchmarking questionnaires were administered. Each session concluded with a short semi-structured interview. All participants provided informed consent prior to participation.

The study set-up was piloted with N=3 participants to see whether the test design was feasible, the tasks understandable and the tests could be carried out as planned. The participants struggled with some of the tasks, consequently a tutorial was added by iSprint explaining for example the Plus-Button as an interactive element in the application (e.g., to add new information). Furthermore, in the study design, a task was added to explore the application and look at the tutorial. This new set-up was tested again with N=1, after which some minor bugs were fixed by iSprint and the study set-up was slightly adapted to its final version. An overview of issues identified when piloting the study setup can be found in *Appendix C: Overview of usability issues identified in pilot tests of the first iteration end-user study.*

6.1.2 Participants

For the evaluation of the Healthentia app, we focused on adults of 45 years or older in general. We aimed to include eight participants. Participants had to own a smartphone to enter this study. Exclusion criteria were (1) not being able to read and speak Dutch, and (2) not being willing to provide informed consent. As this first end-user study aimed at detecting general usability issues of the application and as the RE-SAMPLE end-user panel had not been set up yet, we recruited the participants via a combination of the research panel of RRD and convenience sampling in the network of the researchers. This RRD research panel was in place already before the start of RE-SAMPLE and does not specifically focus on people with COPD.

6.1.3 Main study parameters

The main study parameters are: (1) number of usability issues, (2) task metrics, and (3) usability benchmarking scores.

Number of usability issues: the elicitation of usability issues is considered one of the most important elements in usability testing. It provides a list of identified usability issues that need to be addressed before the implementation of the system. These usability issues often are joined with a severity score, to prioritise the issues that are most important to solve. Usability issues are collected via a think-aloud protocol, in which participants verbalise their thoughts, and screen capture recordings to see which actions they made while using the app. Each usability issue is given a severity score using the index of Duh et al. (Duh, Tan, & Chen, 2006) that distinguishes three severity levels:

- A **minor** usability problem occurs infrequently among the participants and/or the problem only increases task completion time slightly;
- A **serious** usability problem occurs frequently among the participants and/or the problem severely increases task completion time;

- A **critical** usability problem occurs when all participants have the same problem and/or the problem prevents participants from completing tasks.

Task metrics: usability task metrics are one of the most objective measures to get an indication of the system's usability. It measures how well a participant performs on a task. In this study, we measure the following task metrics: task completion, time on task, and task satisfaction. *Task completion* is measured by whether the participant completes the task or not. *Time on task* is measured in seconds and *task satisfaction* with the After-Scenario Questionnaire (ASQ), a three-item questionnaire (Lewis, 1991).

Usability benchmarking scores: usability benchmarking is necessary to get a general indication of the system's usability. In this study, this will be measured by the System Usability Scale (SUS) (Brooke, 1996) and the eHealth Usability Benchmarking Instrument (HUBBI). The SUS consists of 10 statements in which every participant has to score each statement on a 5-point Likert scale. The HUBBI is developed as a new eHealth usability tool based on an ontology of specific usability factors (Broekhuis, van Velsen, Peute, Halim, & Hermens, 2021). The HUBBI comprises eighteen items in which users will have to score each statement on a 5-point Likert scale ranging from strongly disagree to strongly agree.

6.1.4 Secondary study parameters

The secondary study parameters are (1) demographics, (2) health literacy, and (3) user experience.

Demographics: the following demographics will be measured: gender, age, educational level, number of chronic conditions, and experience with digital devices.

Health literacy: health literacy is the knowledge and skills of an individual to seek, understand and use health information to maintain or improve one's health (Peerson & Saunders, 2009). It is assessed via the scale by Chew et al. (Chew, Bradley, & Boyko, 2004) . This health literacy scale was chosen as it is a short scale (three items) that does not heavily increase the workload of participants.

User experience: user experience was measured using Technology Acceptance Model (TAM) factors (Holden & Karsh, 2010). The following factors were included: perceived usefulness, perceived ease of use and intention to use. These constructs were assessed via a short interview with each participant.

6.1.5 Study procedure

Before participation, each participant filled in an informed consent form. Then, the usability test commenced. First, participants received the demographics questionnaire and the health literacy scale. Then, they had some time to freely explore the application and to read the tutorial. Next, a concurrent think-aloud protocol was administered in which they were given several tasks to complete within the respective eHealth application while verbalizing their thoughts. This data is supplemented by screen capture software. At the same time, usability performance metrics (task completion, task completion time, task satisfaction) were assessed. Participants had five minutes to complete each task using the Healthenthia app. These tasks were:

1. **Questionnaire:** complete the Quality of Life questionnaire.
2. **Physical Data:** check to see how many steps you have walked on June 20.
3. **Symptoms card:** your normal health problems have changed after a recent hospital admission. Please report this to Healthentia. You are now short of breath after walking more than 500 meters, you experience vertigo when you stand up and you don't use urinary tablets.
4. **Overview Weight:** check to see how your body weight fluctuated in the week of June 14-20 and say on which day of the week your body weight was the lowest.
5. **Adding Weight:** you have weighed yourself today and want to report this weight (74.7 kilos) to Healthentia. Please do so in the app.

After each task, the participants were given the ASQ to measure task satisfaction. After carrying out all tasks, they filled out the SUS and the HUBBI. Last, a short interview was conducted to discuss participants' acceptance of the technology. The usability tests have an average length of 60 min. The tests are conducted in a usability lab or on location. Each test was performed in a closed room to minimize distraction. Audio

and screen capture recordings were made during the tests. The general study procedure can be found in *Appendix D: Study procedure and instruments first iteration end-user study.*

6.1.6 Data analysis

Descriptive statistics (frequency, mean, percentages) are computed for the demographics and the task metrics. For the usability issues, audio transcripts are used to identify usability issues using the following process:

- One researcher identifies all errors in the think-aloud transcripts and observational notes.
- A second researcher also examines this dataset. Discrepancies are solved and the first researcher re-analyses the full data set with this final list.
- The first researcher creates an overview of usability issues by grouping similar errors into one usability issue (e.g., recurring errors from clicking on non-clickable elements are grouped as 'the user has difficulty distinguishing clickable from non-clickable elements in the interface').
- The second researcher examines this usability issue overview. The researchers discuss discrepancies and create a final overview.
- The first researcher assigns each usability issue with a severity score (minor, serious, or critical), following a procedure from (Duh, Tan, & Chen, 2006). The severity ratings are verified by the second researcher.

The semi-structured interview was analysed per TAM factor: perceived usefulness, perceived ease of use and intention to use. A summary of the main themes per factor was written.

6.1.7 Ethics

The medical-ethical committee of East Netherlands has reviewed this study (reference number 2021-13175) and concluded that it does not fall under the Medical Research Involving Human Subjects Act (WMO). This means that no medical-ethical approval is needed to conduct this study.

6.2 Results

6.2.1 Demographics

A total of eight participants took part in this study: four (50%) male and four (50%) female participants. The average age was 70 years. Four (50%) participants did not have any chronic health condition. Two (25%) participants had one chronic health condition and two (25%) participants had two or more chronic health conditions. There was one (12.5%) participant who completed a lower vocational education, three (37.5%) participants who completed a vocational education and four (50%) participants who completed higher vocational education. All participants owned a smartphone and PC or Laptop. In addition, three (37.5%) participants used a tablet.

6.2.2 Usability issues

A total of 107 usability issues were identified: 98 issues via the think-aloud protocol and an additional 9 issues via the interviews afterwards. After deduplication (participants who had similar issues), there remained 47 unique usability issues left: 9 minor issues, 26 serious issues and 12 critical issues. A complete overview of these usability issues can be found in *Appendix E: Overview of usability issues first iteration end-user study.*

Minor issues are issues that happen infrequently across participants or do not have a large effect on task completion time, for example, because participants find a workaround or find out quickly the correct procedure. It does not prevent the user from completing his or her task. Examples of minor issues are:

- It is unclear that with the Quality of Life questionnaire only one answer per health domain can be chosen.
- The user does not see on the Home page the Quality of Life questionnaire and goes to the Diary instead.
- The user does not know how to go back to the previous question in the Quality of Life questionnaire.

Serious issues are issues that occur often or have a serious impact on task completion time. The user is however able to complete the task within the allocated time. Examples of serious issues are:

- It is not clear that the number of steps per day can be found via the Activity module.
- It is difficult with the Quality of Life questionnaire scale from 0-100 to choose an exact percentage.
- It is unclear that the body weight per week can be found in the Diary.

Critical issues are issues that happen to all participants or prevent the user from completing the task. Examples of critical issues are:

- It is not clear that changes in health status can be submitted via the plus-button on the Home screen.
- System crash during the Quality of Life questionnaire, after the five dimensions, which makes the user believe he or she has completed the questionnaire.
- The user believes the second question in Changes in Health Status is a yes/no question with which further specification is required.

6.2.3 Usability benchmarks

The usability benchmarks were assessed using the SUS and the HUBBI. The SUS provides a unidimensional score on the usability of the application. For the Healthentia app, the average SUS score was 68.1, which means that the usability is okay (Sauro & Lewis, 2012), but there is room for improvement. The HUBBI provided an overall score of 3.8 on a 1-5 scale. However, it also provides a score per subdimension: basic system performance (i.e., no crashes, errors), task-technology fit (suitable for the user, context, health goals), interface design (i.e., visibility, readability, lay-out), navigation & structure (i.e. understanding of system elements and awareness of location within system), information & terminology (i.e. understandability of medical and non-medical terminology), guidance & support (i.e. error support, sufficient feedback) and satisfaction (i.e. satisfaction with system and support towards health goals). Figure 5 shows the scores per subdimension.

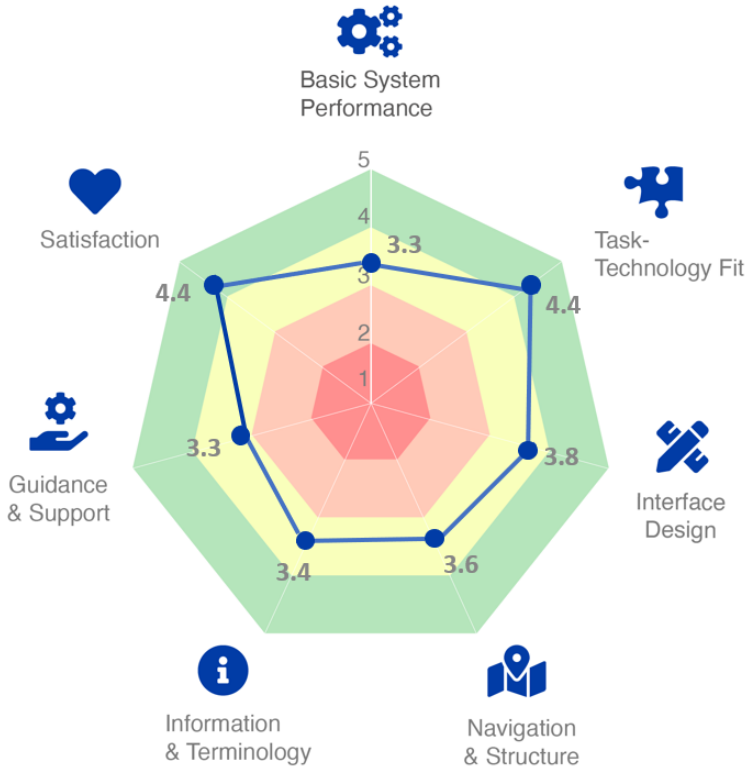

Figure 5: HUBBI scores of the Healthentia app

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. The dimensions task-technology fit and satisfaction are considered good. There are no scores in orange or red, which is also good, but there are quite a few in yellow (interface design, navigation & structure, information & terminology and guidance and support).

6.2.4 Task performance

All participants had to complete five tasks: (1) to fill out the Quality of Life questionnaire, (2) to check the number of steps the user had walked on a specific day, (3) to report changes in his or her health status, (4) to see on which day of a specific week the user had the lowest body weight, and (5) to report the current body weight.

The easiest task was task 5, which all participants were able to complete. The average completion time was below 1.5 minutes. The task satisfaction was 5.9, which is lower than expected since all participants were able to complete the task quite fast. This low score can be partly explained by participant 2 who had a lot of trouble with this task and thus gave it a low score of 2 in comparison to the other participants who gave a score between 6 and 7 on task satisfaction. The most difficult task was task 4. Only two participants were able to complete this task. Participants had a lot of difficulties finding the weekly overview so some tried to deductively analyse the correct day by the weight reports in the diary. Others who found the weekly overview had trouble interpreting the scores since the points did not correspond with the days in the overview. Task 3 was correctly performed by half of the participants. They did not know where to enter the health status report (via the 'plus button' on the home screen or the 'add report' button in the diary). When they did find it, the questions were ambiguous for them, causing them to answer the questions incorrectly. **Table 1** provides a complete overview of the task performance scores per task.

Table 1: Task performance scores

Task	n	Task completion rate (%)	Av. task completion time (sec.)	Task satisfaction (N=8)
T1:Quality of Life survey	5 out of 8	62.5%	109.2	6.5
T2: Number of steps	7 out of 8	87.5%	85.4	5.4
T3: Changes in health status	4 out of 8	50%	188.8	5.3
T4: Lowest weight	2 out of 8	25%	175.5	3.8
T5: Reporting current weight	8 out of 8	100%	83.8	5.9

6.2.5 User experience

User experience was measured using TAM factors (Holden & Karsh, 2010): perceived usefulness, perceived ease of use and intention to use.

Perceived usefulness

"If I had a chronic health condition, I would definitely use it." (participant 2)

All participants were positive about the usefulness of the app to support one's health. They like how the app provides a kind of journal for them to check how their health problems are in comparison to other days or weeks. This can, as some participants said, help to reassure that what one is feeling is normal. Also, the app can help remind a person to do things they would otherwise forget, like drinking more water. However, some participants did say there are certain conditions to be met to make the app fully useful for them. These conditions are:

- The app is used in combination with treatment and communication with a health professional (n=2);
- The app should provide some form of feedback on the data the user entered in the app (n=2);

Perceived ease of use

"It is easy to use the app if you know exactly what you have to do." (participant 7)

All participants liked the design of the app, especially the colours. Most participants had no problem reading the texts but they did say that for older people, the text will probably be too small. Participants like how the app is quite 'sober', which makes it easy to use the app and see the information on the screen. However, they did say that, especially in the beginning, they really had to take their time to read and understand the app before they could properly use it. Two participants also thought there was too much information on the home screen. Several participants wanted more training before using the app. They also said that the app lacks information on how to use it or perform certain actions and one participant mentioned that it is difficult to retrieve the information they reported in the app.

Intention to use

"Yes, I would use it…in combination with a doctor." (participant 4)

All participants said that they would use the app if it was necessary for their health or recommended by a doctor for their treatment. There has to be a reason or usefulness for them to use the app. Most participants want the app to be an addition to a treatment program. This would also motivate them to keep using the app for a longer period.

7. Second iteration end-user studies

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

The HUBBI questionnaire that was used during the first iteration will also be used during the next iterations of the end-user studies. Since the HUBBI was only available in either English or Dutch, it was translated by using back-and-forth translating. With this method, the original English version of the HUBBI was first translated to Italian and Estonian by partners in the consortium. These translated versions were sent back to the moderator, who sent these to different persons to translate it back from Italian / Estonian to English without seeing the original HUBBI in English. When these versions were complete, differences between the original HUBBI and the back-and-forth translated versions were compared and discrepancies resolved together with translators.

Besides the HUBBI questionnaire itself, the introductory text of the HUBBI and the instructions were also translated into Italian, Estonian, and Dutch. After the translations were complete, the HUBBI was integrated into the Healthentia app so that every new subject in the RE-SAMPLE cohort study will receive the HUBBI questionnaire once, seven days after the "baseline" (or account creation) date. After integration, the HUBBI was tested on an Apple smartphone in Dutch and English within the Healthentia app by researchers. All questions were stated correctly and the features within the application worked as expected.

At the time of writing, no patients have been included in the cohort study yet. One week after a new cohort participants starts using the Healthentia app, he or she will get a request to fill in the HUBBI questionnaire. This way they will not be overwhelmed with requests to fill in too many questionnaires at baseline, have some time to get accustomed to the application, but can still be considered novice users. Administering the HUBBI questionnaire shortly after participants start using the app provides us with a baseline benchmark to which we can compare future adaptations and determine progress during development.

Next to the benchmark, the second iteration end-user studies will include 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. Special attention will also be paid to the issues identified in the first iteration of end-user studies (see section 6.2).

8. Conclusions and future work

This deliverable presented the end-user involvement activities carried out from the beginning of the project until M11. It described the results of the initial stakeholder analysis and network inventory, the instalment of the RE-SAMPLE end-user panel, a general patient survey to engage with the larger patient community, and the results of the first iteration of end-user studies.

Following the stakeholder analysis, the next activities include reaching out to associations and groups on the local and international level to invite more people to the RE-SAMPLE end-user and expert panel on our website. In addition, future activities include a collaboration between the European Lung Foundation and the clinical partners MST, GEM and TUK to advertise the panel and expert group in other European countries. Furthermore, the end-user panel will be extended to also give HCPs the opportunity to sign up.

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Appendices

Appendix A: Introductory questionnaire patient panel

1. What is your year of birth?

_____

2. What diseases do you have? (Multiple answers possible)
- ☐ COPD (chronic lung disease)
- ☐ Diabetes
- ☐ Cardiovascular diseases (e.g. heart failure)
- ☐ Anxious feelings (e.g. panic attacks)
- ☐ Feelings of depression (e.g. feeling down)
- ☐ Other, namely: _____
- ☐ Not applicable

3. Which steps of the RE-SAMPLE research seem interesting for you to think along? (Multiple answers possible)
- ☐ Collection of data (e.g. complaints, questionnaires)
- ☐ User-friendliness of a program on a mobile phone
- ☐ Measurements in patients (e.g. lung function, blood collection)
- ☐ Communication with patients (e.g. recruitment, sharing results)
- ☐ Development of tailor-made care (personal support for the disease)
- ☐ Introduction of tailor-made care
- ☐ Privacy: protection of patient data
- ☐ Other, namely: _____

4. We want to investigate what can cause the symptoms of COPD to worsen for patients with COPD and one or more other chronic diseases. We do this by recording data in 710 patients (263 in MST) for a maximum of 38 months. Do you already have ideas for capturing this data (what do you think are important points to pay attention to)?

_____

5. Next, we want to use this data to be able to offer treatment that is better suited to the patient. Do you already have wishes or ideas for this customised care?

_____

Appendix B: General patient survey

Block: Introduction and Informed Consent

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. In this questionnaire, we want to learn from patients who live with COPD about their experience and how they manage their disease. We also would like to know where they would like to receive more support.

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
For this survey, we are looking for people aged 18 years or older who have been diagnosed with COPD. 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/. If you have any questions about this survey please contact Christiane Grünloh c.grunloh@rrd.nl or Eline te Braake e.tebraake@rrd.nl.

Statement of Consent
o I agree to participate in this study. I hereby declare that I have read the information on the study. I understand that my data will be anonymised and may be used for scientific publications. I voluntarily participate in this study and know that I can stop my participation at any time.

Block: COPD Background

1. Since when do you have COPD?
o Less than 1 year
o 1-2 years
o 3-5 years
o 6-10 years
o 11-20 years
o more than 20 years
o I don't know.

2. Besides COPD, what other conditions do you have?
☐ Diabetes
☐ Chronic heart failure
☐ Heart disease
☐ Anxiety
☐ Depression
☐ Other:_____
☐ None

3. What do you know about COPD?
o I believe I know everything on this topic
o I know as much as I need to know
o I know too little
o I do not know and I do not want to know

4. How much does your health affect your daily activities (e.g. work, study, housework, family or hobbies)?
o 1: I have no problems with performing my daily activities
o 2: I have small problems but can perform all my daily activities
o 3: I have some problems and performing all my daily activities takes a lot of effort
o 4: I have many problems and therefore I cannot perform al my daily activities
o 5: I am unable to perform my usual activities

Block: COPD experience and self management

5. When your complaints worsen or when you experience a lung attack, do you feel this coming?
o Yes
o No

If Yes

5a. How do you feel that coming? How do you know?

_____

5b. What do you do when you feel it coming?

_____

6. Is there anything you struggle with at that point?

_____

7. Are there any events in which you know for yourself your complaints will worsen?

_____

8. Do you avoid certain events or situations to prevent a worsening of your complaints?

_____

9. Are there any activities that you perform to prevent a worsening of your complaints or a lung attack? Or in general to make your feel better? (You can enter multiple answers)
☐ Physical exercise, like: _____
☐ Mental exercise, like: _____
☐ Lifestyle adaptions, like: _____
☐ Social activities, like: _____
☐ Other, namely: _____

10. What activities do you know that could improve your health?

_____

11. Living with COPD often means trying out what works for you and what not. Is there anything that you learned when living with COPD that you would have wished to know earlier?

_____

12. If you could wish for anything that would help you controlling your COPD, what would that be?

_____

13. Who or what gave you the most useful information for coping with the disease?
o Conversation with the doctor
o Conversation with the nurse
o Conversation with another COPD patient
o Books, leaflets
o Television, Internet
o Other: _____

Block: Technology use

14. Which of the following communication devices do you use? (you can choose several)
☐ Smartphone
☐ Tablet
☐ Laptop
☐ None of these devices
☐ Other _____

15. Do you use any devices to measure your health? (e.g. smartwatch to measure your steps, sleep pattern, oxygen or your heartrate?)
☐ Smartwatch
☐ Oximeter
☐ Activity Tracker (e.g. Pedometer)
☐ Smartphone App
☐ None
☐ Other _____

16. Do you use any apps or programs on your phone to measure your health at the moment? (E.g. an app that encourages you to exercise)
o No
o Yes, namely: (you can enter multiple apps)
_____

Block: Health literacy

17. How often do you experience problems understanding texts (such as leaflets) about your health or an illness?
o Never
o Few
o Sometimes
o Often
o Always

18. How much confidence do you have when you fill out medical forms?
o No confidence at all
o A little confidence
o Reasonable confidence
o Much confidence
o Very much confidence

19. How often does someone help you to read information leaflets, forms or letters from the hospital, pharmacy or your GP?
o Never
o Seldom
o Sometimes
o Often
o Always

Block: Demographics

We are almost at the end of the survey. The last questions are related to general demographics and help us to check whether this survey is characteristic of people with COPD.

20. What is your gender?
o Male
o Female
o Prefer to self-describe: _____

21. What is your year of birth?

22. What is the highest degree or level of education you have completed?
o Primary School
o High School
o Trade School
o University
o Other _____

23. What is your employment status?
☐ Full time employment
☐ Part time employment
☐ Seeking opportunities
☐ Retired
☐ Unable to work
☐ Voluntary work
☐ Other: _____

24. How many family members do you live together with?
o 0
o 1
o 2
o 3
o 4
o more than 4

Block: Digital literacy

25. I think that my level of digital skills (like the use of smartphone, tablet, laptop) is as follows:
o 1: really low
o 2: low
o 3: average
o 4: high
o 5: really high

Block: Feedback and future research participation?

26. 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

If Yes
26a. 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 survey

Appendix C: Overview of usability issues identified in pilot tests of the first iteration end-user study

Initial pilot test (N=3)	Follow-up pilot test (N=1)	Suggestions, comments
During the first three tests, the participants were focused on the EQ-5D questionnaire. And start to complete it when they had no idea what to do… or if they were lost.	The task "explore the app and check out the tutorial" did not work well. The participant constantly forgot he had to find the tutorial and started filling out the EQ-5D-5L questionnaire instead (which is the last task).	Adapt the task description to make it more clear, for example: "Find the tutorial and read this."
	The location of the tutorial is confusing. The participant was not able to find the tutorial on his own. It is located on the "help" page.	A suggestion is to move it to the home page or make a separate page, that you see in the hamburger menu the option "tutorial".
	Participant thought that he could click on the buttons that are illustrated in the tutorial.	
	The tutorial was confusing, there was a lot of information on it and the way it was presented made it difficult for the participant to understand the information.	Including more images in the tutorial in which each element is explained separately to avoid having too much information all at once.
Participants struggled to understand how to use the Healthenthia app.	He did not understand how to use the Healthentia app after reading the tutorial.	
	Not clear how to exit the tutorial. He tried the back-button on his phone but this did not work. Confusing that one has to click on "next" to exit the tutorial.	
The home screen was too busy for the participants. There are too many elements on it.	The home screen was too busy for the participant. There are too many elements on it.	
	The back button of the phone does not work within the Healthentia app. This is confusing.	This issue was fixed by iSprint.
Participants had problems with the hamburger menu. But we did not focus on that part, so if they had problems, we guided them back to the home screen.	The hamburger menu is unclear. The participant had trouble finding it.	
	It is confusing that when filling out a questionnaire, one has to click on the button "next" to continue to the next question. Participant believes that then the questionnaire is finished. He suggested using arrows instead.	
	When filling out the questionnaire, the exit-cross on the top-right did not work.	

Participants struggled with this task as there were some unnecessary buttons and steps to take.	When filling out one's weight, it is confusing that after you entered your weight, you are asked "would you like to submit questionnaire?". It is unclear that the weight question is a questionnaire, so he entered "no".	Changing this question into something like "would you like to submit your weight?" iSprint changed the text on the button to "Confirm submission".
Participants had no idea what to do and did not recognise the "plus-button" as a button. The biggest problem during the first three usability tests.	The "plus" button on the home screen is unclear. Participant found it by accident, not because the tutorial informed him that this was the place to go or that he understood that he could enter data via the plus-button.	
Test account. Activity log was visible after "enabling activity tracking" in the menu, but no data was shown.	The activity log was unavailable, but this may be due to the test-account version.	

Appendix D: Study procedure and instruments first iteration end-user study

Phase	Topic	Description	Min.	Materials
1	Welcome	Welcome participant, offer coffee/tea/cookie Introducing yourself. You are going to do several tests in a moment, I will first give you some background why we are conducting this study.	2	Coffee/tea, cookies
2	Explanation of research	In this research we want to map the usability of the Healthentia app. The results of this study will be used for the development of a healthcare technology in the European Horizon2020 project RE-SAMPLE. The RE-SAMPLE project aims to develop a healthcare technology that supports patients and caregivers in a personal way in managing COPD and other chronic conditions, such as chronic and/or ischemic heart failure, diabetes mellitus, anxiety disorders and/or depression. With the results of this research, we hope to make the healthcare technology developed in RE-SAMPLE as usable as possible.	3	
3	Informed Consent		3	Informed Consent Form
4	Demo-graphics		3	Questionnaire 1 and 2
5	Scenario description	Give the participant time to read the scenario. Explain that with this scenario in mind, he or she will soon get started with the Healthentia app.	8	Scenario description
6	Think Aloud	You're about to get started with Thinking Aloud. This means that while you perform a number of tasks with the Healthentia app, you are sharing your thoughts at the same time. We ask you to tell us what you think while you are busy with the tasks. What do you notice, what do you doubt and what choices do you make? We will practice this first. When you are silent for more than 5 seconds, I will ask you if you can speak your thoughts out loud.	2	
		Exercise: Take a few minutes to look around in the Healthentia app	5	
		Start audio recorder + screen capture	1	Audio recorder
		In the Healthentia app there is a tutorial that explains the app. Check out this tutorial. Moderator accompanies the participant if he/she cannot find them.	3	
		Task 1: Complete the EQ-5D-5L questionnaire completely.	5	Printed task description 1 + Stopwatch
		Task 1: after-scenario questionnaire	2	Task 1: ASQ

		Task 2: Indicate, how many steps you walked on 19 June 2021. You can say this to the researcher.	5	Printed task description 2 + Timer
		Task 2: after-scenario questionnaire	2	Task 2: ASQ
		Task 3: Your usual symptoms have changed after a recent hospitalisation. Please report that in Healthentia by filling in what is now "normal" for you. You are now short of breath if you walk more than 500 metres, you are dizzy when standing up, and you do not use tablets.	5	Printed task description 3 + Stopwatch
		Task 3: after-scenario questionnaire	2	Task 3: ASQ
		Task 4: Find out how your body weight was in the week of 14-20 July and indicate on which day of the week you weighed the least. You can say this to the researcher.	5	Printed task description 4 + Stopwatch
		Task 4: after-scenario questionnaire	2	Task 4: ASQ
		Task 5: You have weighed yourself today and want to record your body weight (74.7 kg) in the app. Do this in the app.	5	Printed task description 5 + Stopwatch
		Task 5: after-scenario questionnaire	2	Task 5: ASQ
7	SUS Questionnaire		5	Questionnaire 3
8	HUBBI Questionnaire		8	Questionnaire 4
9	Short interview		5	Interview Questions
10	Conclusion and thanks		3	

Questionnaire 1 – Demographics

In this section, we ask a number of questions about yourself. Can you fill in the following questions?

1. What is your gender?
   - ☐ male
   - ☐ female
   - ☐ other
   - ☐ I'd rather not say that

2. What is your age?

3. What is the highest degree or level of education you have completed?
   - ☐ Primary school
   - ☐ Secondary school (vmbo)
   - ☐ Secondary school (havo/vwo)
   - ☐ Secondary vocational education (MBO)
   - ☐ Higher vocational education (HBO)
   - ☐ University education (WO)

4. Do you have one or more chronic conditions?
   - ☐ Yes, I have 1 chronic condition
   - ☐ Yes, I have 2 or more chronic conditions
   - ☐ No, I don't have a chronic condition

5. Can you tick all the devices you use at home? You can tick multiple answers.

- ☐ Smartphone
- ☐ PC / Laptop
- ☐ Tablet
- ☐ Smartwatch
- ☐ Game computer
- ☐ Other, namely: _____

Questionnaire 2 – Health literacy

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

- ☐ Always
- ☐ Often
- ☐ Sometimes
- ☐ Seldom
- ☐ Never

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

- ☐ Very confident
- ☐ Confident
- ☐ Fairly confident
- ☐ Somewhat confident
- ☐ Not confident at all

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

- ☐ Always
- ☐ Often
- ☐ Sometimes
- ☐ Seldom
- ☐ Never

After-scenario Questionnaire (ASQ)

After each task, participants are asked how much they agree with the following statements (rated on a scale from 1 to 7).

1. I found performing this task easy
2. Performing this task did not take me much time
3. The website gave me enough help to complete this task

Questionnaire 3: System Usability Scale (SUS)

SUS was adapted to include the name of the system (i.e., “Healthenthia”) to be assessed. Participants are asked to indicate to what extent they agree with the following statements (rated on a 5-point Likert Scale):

1. I think that I would like to use the Healthenthia app frequently.
2. I found the Healthenthia app unnecessarily complex.
3. I thought the Healthenthia app was easy to use.
4. I think that I would need the support of a technical person to be able to use the Healthenthia app.
5. I found the various functions in the Healthenthia app were well integrated.
6. I thought there was too much inconsistency in the Healthenthia app.
7. I would imagine that most people would learn to use the Healthenthia app very quickly.
8. I found the Healthenthia app very cumbersome to use.
9. I felt very confident using the Healthenthia app.
10. I needed to learn a lot of things before I could get going with the Healthenthia app.

Questionnaire 4: eHealth Usability Benchmarking Instrument (HUBBI)

HUBBI was adapted to include the name of the system (i.e., "Healthenthia") 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.

Interview Questions

1. You have now performed a number of tasks with the Healthentia app. What is your impression of the app?

    Follow up questions:
    - What do you like or dislike about it?
    - What, in your opinion, went well or badly?

2. Did you find it easy to use the app? Why or why not?

3. What do you think about the appearance of the Healthentia app? Do you like the colours? Is everything easy to read?

4. Do you think the Healthentia app could support you with your health? Why/ why not?

5. Would you like to use the Healthentia app? Why/ why not?

Appendix E: Overview of usability issues first iteration end-user study

Nr	Usability issue	Location	Occurrence	Severity
1	The Tutorial is difficult to locate in the app	Tutorial	2	Critical
2	The user does not understand that the three horizontal stripes represent the app's menu	Tutorial	3	Critical
3	It is not clear that the user has to click on 'ok' to submit the Quality of Life questionnaire	EQ-5D-5L	1	Critical
4	It is not clear that the number of steps per day can be found via the Activity module	Home	2	Serious
5	It is not clear how to return to the Home screen from the Quality of Life questionnaire	EQ-5D-5L	1	Critical
6	It is not clear that changes in health status can be submitted via the plus-button on the Home screen	Home	7	Critical
7	It is not clear that in the Diary the user has to click on 'add report' to submit changes in his or her health status	Diary	4	Critical
8	Within the Quality of Life questionnaire, it is not clear how the scale form 1-100 is to be used	EQ-5D-5L	3	Serious
9	The user believes that changes in health status have to be submitted via the Quality of Life questionnaire	Home	4	Critical
10	In the Diary, it is not clear that the button 'Insights' or “Weekly” show the body weight per week	Diary	5	Critical
11	The user does not know that the weight can be reported via the plus-button on the Home screen	Home	6	Critical
12	The abbreviation 'GDPR' is unclear for the user	Chatbot	1	Serious
13	The word “Healthentia” is unclear for the user	Chatbot	1	Serious
14	The user expects the Chatbot to provide information about the app, which is not there according to the user	Chatbot	1	Serious
15	After clicking on “Healthentia” in the Chatbot, there is an option menu instead of more information, which creations confusion with the user	Chatbot	1	Serious
16	The user believes that the first question with health status (in Add Report) is a choice between exercise and rest instead of a question in which the user has to explain when during exercising he or she experiences health problems	Add report	1	Serious
17	The user does not know that the Daily Reports on weight are integrated into a weekly overview	Diary	4	Serious
18	It is not clear that in the Insights module, the user can click on “weekly” to do back to a certain week instead of having to go back per day	Diary	2	Minor
19	It is not clear that in the Activity module, the user can click on “weekly” to go back to a certain week instead of having to go back per day	Activities	5	Serious
20	The user does not know that weight can be reported via the “Add Report” button in the Diary	Diary	4	Serious
21	There is English language in the app while it is meant for Dutch users	App-general	2	Serious
22	It is not clear that the Tutorial is an infographic and thus not-clickable	Tutorial	1	Serious
23	It is difficult with the Quality of Life questionnaire scale from 0-100 to choose an exact percentage	EQ-5D-5L	3	Serious
24	It is unclear that with the Quality of Life questionnaire only 1 answer per health domain can be chosen	EQ-5D-5L	1	Minor

25	With the Quality of Life questionnaire, the use of a 0-100 scale instead of a 0-10 scale creates confusion	EQ-5D-5L	1	Minor
26	It is unclear that while reporting changes in health status, every question is about one aspect of one's health (shortness of breath, vertigo, urinary tablets)	Add report	1	Serious
27	The user expects the Chatbot to provide information about reporting the Health status, which the user cannot find there	Chatbot	1	Serious
28	The user believes the second question in "Changes in Health Status" is a yes/no question with which further specification is required	Add report	2	Critical
29	System crash during the Quality of Life questionnaire, after the five dimensions, which makes the user believe he or she has completed the questionnaire	EQ-5D-5L	1	Critical
30	App does not respond while clicking on the Activity module on the Home screen	Home	1	Serious
31	User uses the back button on the phone instead of the back button of the app	Activities	1	Minor
32	The app does not respond when clicking on the Quality of Life questionnaire in the Diary	Diary	1	Serious
33	The user does not understand the explanation in the Tutorial	Tutorial	1	Critical
34	In the Tutorial, it is not possible to go back to the previous page	Tutorial	1	Serious
35	The user believes that information about weight can be found in the Activity module	Home	2	Serious
36	It is unclear that the body weight per week can be found in the Diary	Home	2	Serious
37	The distinction between clickable and non-clickable elements in the App is unclear	Tutorial/ Activities	1	Serious
38	The user does not know how to go to the next page of the Tutorial (is clicking instead of swiping)	Tutorial	1	Serious
39	The user does not see on the Home page the Quality of Life questionnaire and goes to the Diary instead	Home	1	Minor
40	The user does not know how to go back to the previous question in the Quality of Life questionnaire	EQ-5D-5L	1	Minor
41	It is unclear for the user that the number of steps on July 20 is the number of steps the user walked that day	Activities	1	Serious
42	The user believes that the Chatbot is required to report changes in Health Status	Chatbot	1	Serious
43	When using the back button of the phone in the "Frequently Asked Questions" section, the user is thrown out of the app	FAQ	1	Serious
44	In the weekly overview of body weight, it is not clear which scores correspond to which days	Weekly overview body weight	4	Serious
45	The readability of the texts is low because of the low font size	App-general	6	Minor
46	There is too much information on the home screen	Home	2	Serious
47	Elements in the app (like buttons) are be placed too closely together	App-general	1	Minor