K-HEALTHinAIR (KHiA)

Knowledge for improving indoor air quality and health

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PROTOCOL 1 – FOLLOW-UP OF 200 PATIENTS DURING THE PROJECT LIFETIME

1.1 RATIONALE

Chronic obstructive pulmonary disease (COPD) is one of the major disorders included in the WHO program addressing non-communicable diseases. It is currently the third leading cause of death. Despite COPD prevalence is not expected to increase in developed countries, projections for the next decade indicate an escalating burden of this condition on both health and social support systems, mainly due to population ageing.

Prevention of acute episodes (exacerbations) in patients with COPD[1], as well as enhanced management of comorbidities[2], are the two major actionable factors to reduce the societal burden of the disorder.

The 2023 GOLD guidelines[1] for COPD management states that *"exacerbations are mainly triggered by respiratory viral infections although bacterial infections and environmental factors such as ambient air pollution and temperature changes may also initiate, or amplify, these events"*.

The current protocol has been primarily designed to assess the impact of altered indoor air quality (IAQ) on acute events (exacerbations) in patients with COPD showing comorbidities assessed by Adjusted Morbidity Groups (GMA)[3,4] scoring.

The follow-up of a cohort of 200 vulnerable patients over a period of three years offers a unique opportunity to explore the potential of digitally supported integrated care services for enhanced management of chronic patients. To this end, the current observational study protocol aims to assess the impact on patients' empowerment for self-management, as well as potential healthcare efficiencies generated by a nurse case manager supporting the relationships between patients and their primary care physicians.

The study design also allows to capture a variety of patients' self-reported data that, in turn, should facilitate detection of subclinical events eventually related with impaired IAQ. Consequently, there are clear synergies between the two goals addressed in the protocol.

1.2 OBJECTIVES

- ***Project objectives:***
  - Analyse the relationships between patient's home IAQ and health status with focus on acute health effects.

- ***Local research group objectives***:
  - To assess the potential of digitally enabled integrated care for community-based preventive management of exacerbations.

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- To explore enhanced assessment of lung function at community level by combining measurements of forced oscillation technique (FOT) and forced spirometry (FS).

❖ ***The results of this study will be also used to:***

- Provide the information needed to design in vivo or in vitro studies facilitating the identification of sources, health impact, and mechanisms of action that ultimately should enable the generation of recommendations for the prevention of undesirable health effects of impaired IAQ (PHASE II, > M18).

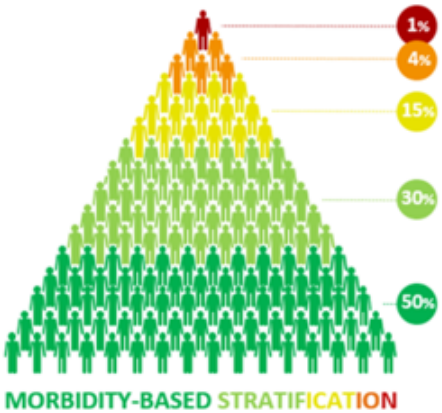
1.3 METHODS

1.3.1 Study Population (n=200)

The pilot will be entirely developed in the Integrated Healthcare District of Barcelona-Esquerra (AISBE) (surface of 74,668 m^2 and with 520 k citizens).

From AISBE, **200 multimorbid outpatients with chronic obstructive pulmonary disorders (COPD, bronchiectasis, and severe asthma refractory to therapy) will be recruited for the study.** The study will be focused on moderate to high-risk outpatients identified through the AMG score, among them, the patients with cardiovascular disorders and type II diabetes mellitus will be prioritized.
As described in detail below (**1.3.1.1**), a first candidate screening will be made through the Catalan Health Surveillance System[5] (CHSS), identifying all the potential candidates that meet the conditions exposed above.

As part of the RAE consulting sessions, the research protocol will be explained to primary care professionals and the role of the nurse attached to the project, who will join the primary care team (CAPSBE and Numància) as case manager nurse. This nurse will contact, on behalf of the primary care team, the candidates and inform them about the study within a rutinary follow up visit If the candidate manifests the willingness to participate, the study nurse to provide him sufficient information to judge whether or not participating in the study, as well as clarifying any question that may arise Before being enrolled in the study the participants must sign an informed consent.



✓ The AMG is the risk assessment tool used in Spain to generate, and update, population-based risk stratification pyramids at regional level.
✓ It is based on number of morbid conditions (multimorbidity), complexity and impact of those conditions on the healthcare system
✓ It is updated every six or twelve months for health policy purposes. But it is also increasingly used for clinical purposes.
✓ The high potential of the AMG has been recognized by WHO and it has been included as one of the core features being transferred to different EU regions within the Joint Action JADECARE (2020-23) https://www.jadecare.eu/

1.3.1.1 The elaboration of the study dataset & the patients' enrolment procedure

Preparation of the study cohort

Due to the uniqueness of the process adopted in the current study protocol, the generation of a pre-study database is deemed necessary to perform a detailed screening of potential participants. The rationale of the process for generation of the pre-study dataset relies on three considerations indicated below. The approach will be constrained to the development of the Barcelona pilot of the K-Health in Air project.

a) Safe access to the CHSS dataset owned by CatSalut - Since January 2021, key personnel of the research team (IDIBAPS and CatSalut-DS3) has been collaborating with the *OECD Action to Support JADECARE (https://www.jadecare.eu/)* under HaDEA *(https://hadea.ec.europa.eu/) supervision.* The IP of the current research is the coordinator of the Catalan original Good Practice in JADECARE. This ongoing collaboration allows a safe extraction of a dataset of approximately 40 thousand including all patients with chronic obstructive disorders living in the AISBE district. Data on diagnoses, GMA scoring and use of health and social care resources are available. High-quality standards for data management ensuring patients' privacy have been well established. Data management will be conducted by Rubén Gonzalez Colom (RGC, IDIBAPS) in collaboration with Emili Vela (EV, CatSalut-DS3).
b) Secure merging of the CHSS dataset with the corresponding Electronic Health Records at Hospital Clinic - The main purpose is to validate the diagnosis of chronic obstructive pulmonary disease and assess disease severity. Accordingly, the two main inclusion criteria (Section 1.3.1.2), GMA scoring and severity of respiratory condition, will be properly evaluated. Such merging will be done, within the Hospital Clinic premises, by RGC in collaboration with the Clinical Informatics team (Dr X. Borrat) keeping identical standards of quality for data management.
c) High quality and potential of the final dataset. The elaboration of the list of potential candidates for the study, as described, is limiting potential selection bias to the following two factors: i) willingness to participate, and ii) level of digital literacy. We believe that the approach can facilitate generalization of the results of the clinical management protocol. Moreover, it offers clear logistics advantages for the recruitment of candidates while following good practice for clinical research.

The database created through this process will strictly serve the intended purpose and will not be utilized for any other purposes or studies.

Enrolment of candidates

Step 1 - *Engagement of primary care professionals* - The elaboration of the dataset of potential candidates will allow the identification of the corresponding primary care physicians. The study protocol will be initially constrained, within AISBE, to the primary care units pertaining to CAPSBE and Numancia. Several sessions, aiming at engaging the primary care physicians into the study, are planned. Full information on the IAQ protocol will be provided and share care agreements between primary care and specialists (Dr Josep Roca, with the support of the home hospitalization team and the pneumology service) will be proposed. The nurse case manager (Alba Gomez) will have two main roles in the study: i) collection of information for the IAQ study protocol, and ii) ensure care continuum. Main actions of the nurse case manager will be: i) promotion of patient's empowerment for self-management/early detection of exacerbations, and ii) bridging between primary care teams and specialized care.

Step 2 - *Initial contact with potential candidates* **–** An initial phone visit of the nurse case manager on behalf of the primary care team will be used to: i) introduce the project, ii) do a short screening of the potential candidate assessing inclusion/exclusion criteria, and, if the patient agrees, iii) set the first face-to-face visit at patient's home.

Step 3 – *Recruitment and characterization of the candidates* - We plan three, face to face visits of the nurse case manager at the patients' home to complete the process of recruitment and characterization of each patient.

> **Visit 1 - Detailed information on the study protocol and signature of the consent form** *(estimated 30-45 min)*
>
> **Visit 2 - Clinical assessment and agreement on the clinical support plan**, to be shared with the primary care physician, and patient's education for self-management mimicking the protocol recently reported in [6]. Instructions for use of the chat and sensors (home-based IAQ sensor and wrist sensor) *(estimated 60-90 min)*
>
> **Visit 3 – Administration of the K-Health in Air questionnaires for baseline characterization and pulmonary capacity assessment through FS and FOT measurements** *(estimated 45 minutes).*

At the end of visit 3, the patient will be fully recruited and characterized. The follow-up plan will be guided by the IAQ study protocol described below, but the clinical management of the patients will be personalized according to the individual share care plan agreed with the patient and their primary care physician. The communication channel (chat) managed by the nurse case manager will have a central role in the decision-making process. A close follow-up of the evolution of the clinical setting with be done with the supporting role of the PI (Dr Josep Roca). The information provided by the wrist sensor will not be used to take clinical decisions by the nurse case manager. The use of the data provided by the wrist sensor is described in detail below.

1.3.1.2 Inclusion criteria

- ✓ Patients must be allocated in the moderate, high, and very high-risk tiers of the population-based risk pyramid deducted from the AMG score distribution of the entire region of Catalonia.
- ✓ Patients must have at least a chronic obstructive pulmonary disease (COPD, bronchiectasis, or severe asthma). Clustering of COPD, cardiovascular disorders and diabetes type II will be prioritized.
- ✓ Patients must be able to participate throughout the entire study period (3 years).
- ✓ Patients must be autonomous for their daily life activities.
- ✓ Patients must sign the informed consent for secondary use of the data collected.
- ✓ The patients must have the commitment to wear a wrist sensor during the entire study period.
- ✓ The patients must live in AISBE health district.

1.3.1.3 Exclusion criteria

- × Patients with dementia and/or unable for follow-up purposes/unable for independent daily life activities will not be considered for the study.
- × Patients with Wi-Fi internet connection available at home will be prioritized, but it will not be an exclusion criterion, in these cases the connection might be granted through GSM-SIM.
- × Patients with a smartphone and acceptable skills for digital tools management will be

prioritized, but it will not be an exclusion criterion. To guarantee the inclusivity of the protocol, the study also considers the participation of patients who might have limitations in using digital technologies. In this regard, three participation modes based on the patients' digital skills and resources are proposed:

Basic participation (Minimum requirement to participate in the study): implies the collection of fundamental data along with a subsequent telephonic follow-up for patient management.

Intermediate participation: In addition to the basic modality, this level involves the use of a wrist sensor to monitor physical activity, heart rate and derived variables (Requires a smartphone - Passive data collection).

Complete participation: In addition to the intermediate modality, this level considers using a digital application (App) for the patient's follow-up and management (Requires a smartphone and digital literacy).

Detailed information on the implications for the study can be found in the section 1.3.3.4 "Modes of participation." This section elucidates the specific data collection methods employed within each participation mode.

1.3.2 Study period

July 2023 – March 2026. The recruitment of participants will be initiated on early July 2023 and completed within two-months. The follow-up will last until March 2026, and a first assessment of the results will be done at M18 (February 2024).

1.3.3 Variables

The information collected to explore the relationship between the IAQ and health status is structured in two domains, that is: IAQ information (**1.3.3.1**) and health-related data (**1.3.3.2**).

Regarding IAQ information, the study will make use of intelligent sensors installed at patients' homes (MICA-INBIOT sensors) to continuously and automatically monitor IAQ.

Regarding health-related data, different sources of information are considered: i) Standardized questionnaires covering several dimensions administered periodically, ii) patients' self-tracked information (incidences, chat with the nurse case manager, short questionnaires using Likert scales, etc…) collected through an App (Health Circuit-KHiA) (see General Project Description); iii) Biological (Heart rate, pulse oximetry, body temperature) & physical activity information collected through a wrist sensor (One Beat); iv) Clinical records, including lung function measurements), and v) Registry data obtained from the Catalan Health Surveillance System (CHSS).

All data collected in the study will be gathered using a study ID. For the subsequent analyses, the data will be totally anonymized to the investigators after removing all direct and indirect identifiers. Data transfer will follow two well-differentiated paths. It will be either directly

transferred to INBIOT premises (automatic and continuous acquisition of IAQ) or administered through a dedicated REDCap project at https://redcap.clinic.cat.

Two key roles have been identified for the management of the study protocol:

1. Project manager taking care of all non-health related logistics, as well as scientific aspects of the project. Such role will be covered by Ruben Gonzalez-Colom
2. Nurse case manager with the following roles: i) collection of health data; ii) supporting patients; and iii) coordinating the interactions between patients and health professionals, fundamentally the primary care team.

1.3.3.1 Air Quality measurements

All the Air Quality measurements will be preceded by an environmental characterization addressing different aspects such as the living surface in m2, the number of dwellers, the number of ventilation points, the use of fireplaces, the presence of moulds, etc. The environmental characterization will be performed at study entry and updated along the pilot if needed.

A) IAQ continuous monitoring will be performed using the MICA-INBIOT smart device. One desktop MICA-INBIOT device will be installed at each patient home. Connectivity will be ensured via Wi-Fi.

Detailed information on the specs of MICA device and its integrated sensors is available in the Annex 1 and the manufacturer's webpage (https://www.inbiot.es/soluciones/dispositivos-mica/mica).

TABLE 1 – Continuously monitored IAQ features with MICA device.

Feature	Units
Indoor temperature	ºC
Relative humidity	HR %
Formaldehyde	µg/m^3
Total VOCs	ppb
PM 1/2.5/4/10	µg/m^3
CO_2	ppm

B) OAQ (Outdoor Air Quality) continuous monitoring of the district will be imported to REDCAP from the Open Data Portal of Catalonia and/or the Aeris Weather platform.

TABLE 2 – Continuously monitored OAQ features.

Feature	Units
NO	µg/m^3
NO_2	µg/m^3
NOX	µg/m^3
SO_2	µg/m^3
O_3	µg/m^3
CO	µg/m^3
PM 10	µg/m^3

1.3.3.2 Patients' health status and use of healthcare resources

The clinical information of the patients enrolled in the study will be obtained from different sources:

C) **Electronic Health Records,** from the Hospital Clinic of Barcelona (SAP) and primary care (eCAP) will be used as a source of information on clinical episodes and procedures.

TABLE 3 – Health information retrieved from hospital and primary care health records.

Feature	Units
Disease diagnosis	ICD10
Clinical procedures	ICD10
Hospital admissions - Length of stay	date - days
ICU length of stay (if applicable)	days
Lab tests	miscellaneous
Visits (outpatients, ER, day hospital, etc…)	Episode date, type
Frailty (functional, social, etc...)	Standardized records

D) **Standardized questionnaires** will be utilized to assess general and mental health, quality of life and patient's experience. The questionnaires will be dispensed at study entry and periodically administered throughout the study period (for detailed information on the questionnaires see Annex 2).

TABLE 4 – General health, mental health, quality of life and patient reported experience questionaries administered.

Feature	Units	Periodicity
General Health Questionnaires	ICHOM Adult Set	Every 6 months
Mental Health Questionnaires	PHQ-9	Every 2 months
Quality of Life Questionnaires	EQ-5D-5L	Every 2 months
Patient Reported Experience	PARIS (adapted)	Every 6 months

E) **Registry data will be yearly extracted from the Catalan Health Surveillance System (CHSS)**, encompassing:

TABLE 5 – Health information retrieved from health registries.

Feature	Units
Disease diagnosis	ICD10
Medication prescribed	ATC
Utilization of healthcare resources	Number of encounters with healthcare professionals at different levels; primary care visits, outpatient care visits, mental health ambulatory visits, emergency room visits, day hospital visits, intermediate care admissions, hospital admissions, admissions in mental health centers.
Total healthcare expenditure	€

F) **Assessment of pulmonary capacity through FOT and FS measurements** that will be performed at entry into the study and every 6 months. Measurements will be done using Lothar-Medtech equipment (https://alds.health/).

TABLE 6 – Features utilized to assess the pulmonary capacity.

Feature	Units	Periodicity
FS (FVC, FEV1, FEV1/FVC ratio)	(ml, ml, %)	Every 6 months
FOT resistance (R5 and R5-20)	Pressure/meter/second	Every 6 months
FOT reactance (X)	Pressure/volume	Every 6 months
Resonance frequency	Hz	Every 6 months

G) **Patients' self-tracked information**. Recording of **steps** walked and **heart rate** will be continuously monitored by the **Beat One** watch (https://beat-one.com/producto/la-salud-en-tu-mano/). Heart rate variability, stress level and sleep structure will be calculated from continuous monitoring of heart rate. Pulse oximetry, arterial pressure and body temperature can be measured by Beat One, on demand by the nurse case manager. Moreover, **record of incidences** will be extracted from the chat messaging with the nurse case manager, through the patients' App). Additionally, assessment of patients' will be obtained from short questionnaires (Likert scale) supported by the App.

Measurements provided by Beat One will not be used for clinical purposes. Clinical decision making by the nurse case manager (and supporting physicians) will be patient-nurse interactions wherein the chat and phone, will be core elements. If a face-to-face visit is required, conventional measurements (lung function, arterial pressure, heart rate) could be done by the nurse case manager, as needed.

The information obtained through the Beat One watch will be used as follows:

The initial purpose of the measurements generated by Beat One is to use them to explore patterns that might contribute to identify early exacerbations and/or reflect the health status of the patient [7,8]. Such measurements will only have a research purpose within the first 12 months of the follow-up.

If the initial research data suggest potential value of such continuous measurements, we will plan specific validation protocols using equipment registered as medical devices. To this end, different commercial companies are being considered. Such future validation protocols will be submitted to the CEIC for approval on due time, likely after month eighteen of the follow-up.

A final step to be achieved within the project lifetime, if the results of the validation studies are endorsing our hypothesis on the potential predictive role of heart rate variability, will be to submit the entire digital solution (App + selected sensors) to the corresponding accreditation agencies for future use for clinical decision-making, following the steps indicated in our recent work reported by *Baltaxe E et al. The Assessment of Medical Device Software Supporting Health Care Services for Chronic Patients in a Tertiary Hospital: Overarching Study. J Med Internet Res 2023;25e40976 https//www.jmir.org/2023/1/e40976. 2023;25(1): e40976. doi:10.2196/40976.* Final submission to the AEMPS for approval will be considered upon results.

1.3.3.3 Data collection calendar (1st year)

Table 7 summarizes the characteristics and schedule of the measurements.

TABLE 7 – Data collection calendar.

	Operation	Entry	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Air Quality Measurements														
A	IAQ – Continuous monitoring	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM
B	OAQ - Continuous monitoring	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM
Patients' health status and utilization of healthcare resources														
C	Health follow-up	X	X	X	X	X	X	X	X	X	X	X	X	X
D	Health, mental health, quality of life and patient experience questionnaires	X	-	RS	-	RS	-	X	-	RS	-	RS	-	X
E	Utilization of healthcare resources	-	-	-	-	-	-	-	-	-	-	-	-	X
F	Pulmonary capacity assessed with forced oscillatory technique and forced spirometry	X	-	-	-	-	-	X	-	-	-	-	-	X
G	Patients' self-tracked information	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM	CM

CM stands for continuous monitoring and RS for reduced set of questionnaires.

1.3.3.4 Modes of participation

1.3.3.4.1 Basic Participation

Participation in the basic mode allows the study of the relationship between the air quality in patients' home and health. The participation under the basic regime involves:

* Continuous home IAQ monitoring using a smart device (MICA) and OAQ monitoring exported from Aeris weather.

* Access to patients' medical history and health registry data from the Catalan health system.

* Periodic assessment of the lung capacity using forced spirometry and forced oscillation techniques.

* Periodic administration of health questionnaires.

* Telephonic follow-up

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1.3.3.4.2 Intermediate Participation

Participation in the intermediate mode, in addition to the commitments and benefits of the basic mode, allows the study of biomarker identification for early detection and appropriate prevention of pulmonary disease exacerbations. In addition to the data collected in the basic mode, this mode involves:

* Continuous monitoring of daily physical activity and heart rate using a smart bracelet (Beat One).

1.3.3.4.3 Complete Participation

Participation in the complete mode, in addition to the commitments and benefits of the intermediate mode, enables integrated management of patients' disease through a digital application installed on patients' smart phone, allowing detailed monitoring and more direct and continuous interaction with healthcare personnel. In addition to the data collected in the intermediate mode, this mode involves:

* Installation of the Health Circuit app on patients' smart phone as a means of communication with the case manager nurse and managing future appointments.

* Periodic administration of health questionnaires through the Health Circuit app.

As a summary,

1- The patients participating in all three categories (basic, intermediate, and complete) will be included in the analysis of the core question of the project; that is, assessment of the relationships between IAQ and health.
2- The patients participating in the intermediate and complete categories will be included in the elaboration/evaluation of predictive modelling for identification of exacerbations and early preventive interventions through the corresponding primary care physician.
3- The patients participating in the third option (complete) will be candidates for evaluation of the Health Circuit App as a tool for data capture and enhanced community-based management of multimorbidity aiming at preventing unplanned hospitalizations.

1.4 ETHICAL ASPECTS

The study protocols will be conducted in compliance with the Helsinki Declaration (Stronghold Version, Brazil, October 2013) and in accordance with the protocol and the relevant legal requirements (Biomedical Research Act 14/2007 of 3 July).

All participants in the study must sign an informed consent ahead of any procedure. The participants can withdraw their consent at any time without altering the relationship with their doctor or causing any harm to their treatment.

1.4.1 Data management

At study entry, a unique study ID will be assigned to all the participants. Subsequently, all the data collected during the study will be referred by the patient's study ID and totally anonymized removing all direct and indirect identifiers, guaranteeing the confidentiality of the patient's personal information.

Once anonymized, the data will be transferred to a central repository coordinated by the consortium partners ATOS and IIIA-CSIC and gathered through the study ID. These partners will be also in charge to determine the protocols for explorative data analytics and feature engineering techniques that will be applied to extract features and to discover correlations from the collected information.

The data collected within the study will be transferred to the central repository following two independent paths:

The IAQ parameters captured by the MICA devices will be recorded into My inBiot, the manufacturer's IoT data platform, and directly transferred to the central repository.

All other study data, collected by the Hospital Clínic / IDIBAPS research team, will be managed and gathered through a dedicated RedCap project at https://redcap.clinic.cat. The data will be periodically sent to the central repository.

1.4.1.1 My inBiot - Data management

At study entry, a desktop MICA IAQ monitor will be installed at patient's home by the nurse case manager. All the devices will be set up and managed by a single user (khelathinair@gmail.com) controlled by the nurse case manager and the project manager, thus avoiding the need of creating a user linked to a patient email account or providing any type of personal or contact information to the manufacturer.

During the installation the MICA serial number will be associated to the patient study ID, allowing gathering the data while preserving the anonymization.

The MICA devices will transfer the IAQ monitoring data to My inBiot platform, an AWS cloud infrastructure that provides full control and security of information using TLS1.2 encrypted communications between the client application and devices, as well as encryption at rest of the data in the databases through symmetric KMS keys.

In case of device dysfunction or breakdown, it will be replaced by the nurse case manager.

If abnormal indoor measurements indicating poor IAQ were detected at the patient's home, the information will be communicated to the patient/carers, as well as to the primary care physician. Informed offline decisions will be shared (and agreed) among all actors to introduce the corrections needed.

1.4.1.2 Health Circuit - Data management

K-HEALTHinAIR study protocols in Barcelona consider the use of a digital health tool for the follow-up of study participants.

The digital health tool will be provided by the spin-off **Health Circuit SL** (www.healthcircuit.es), with a prototype-level digital health platform hosted in a private cloud in European servers that will be released in April 2023 for the inclusion of the first study participants.

Study participants will be registered in the Health Circuit platform by the nurse case manager at study entry using a project email account (khelathinair@gmail.com). The patient's study ID will be set as username, and the password will be defined by the patient at this moment. Patient identifiers, either direct or indirect, will not be used to define the patient user, nor will they be collected at any time through the Health Circuit application.

Figure 1 depicts the data management flow chart of the Health Circuit application. After the inclusion of a study participant, the research protocol will dictate the release of monitoring tasks to study participants. Monitoring tasks will include regular follow-up questionnaires, PROMs/PREMs using Likert scales and monitoring of daily physical activity (steps and minutes of moderate/vigorous physical activity), stress, heart rate variability (HRV) and sleep patterns that will be monitored by the **Beat One** watch. In addition, study participants will be able to communicate with the nurse case manager with an off-line chat. The communication channel is expected to be key in keeping the study participant adherent to the research protocol. **The data collected through Health Circuit will be periodically imported by the nurse case manager to a dedicated REDCap project at https://redcap.clinic.cat.**

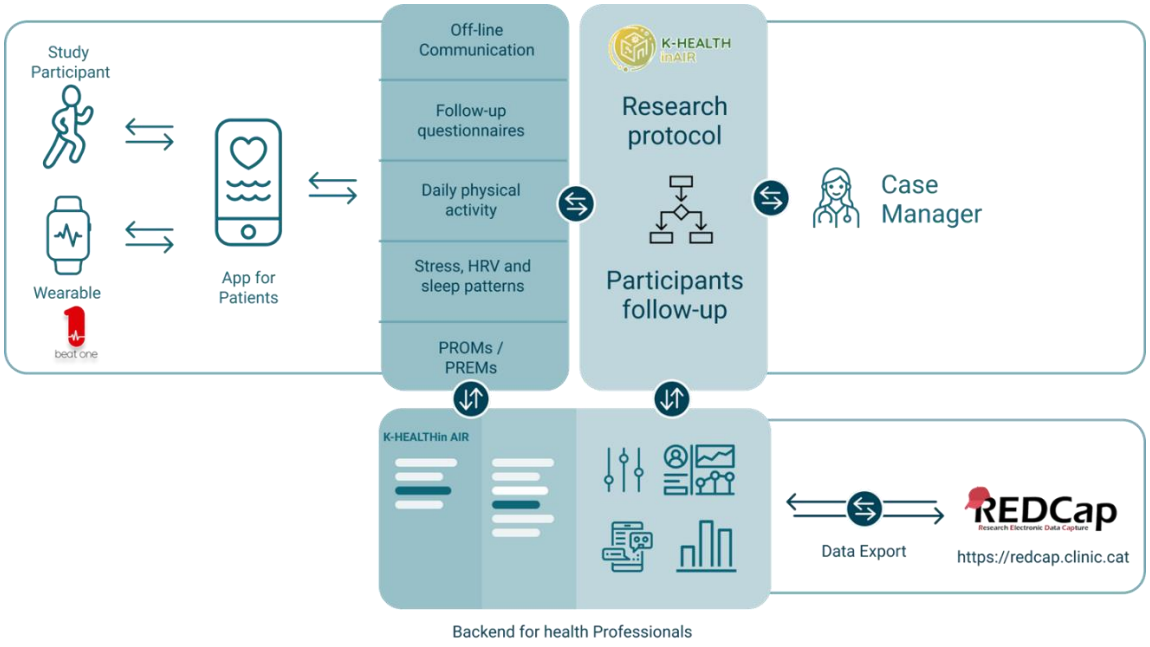

Figure 1: Data acquisition flow diagram of the Health Circuit application.

From the Health Circuit App in the smartphone of the study participant to the Health Circuit servers hosting the research protocol, the following information will be exchanged. The exchange of data

with the APP is always carried out using only the patient study ID). The data will not be shared with any other entity unless there is a legal obligation of a competent body.

The APP data is stored in three independent databases:

- **Authentication data (username and password).** A token persists on the participant's device to identify the active session. This token is deleted when the participant uninstalls the App.
- **Monitoring data:** answers to follow-up questionnaires, PROMs/PREMs, and monitoring of daily physical activity (steps and minutes of moderate/vigorous physical activity), stress, HRV and sleep. They are stored encrypted.

  The data monitored by the **Beat One** sensor, will be directly exported to the Health Circuit "monitoring data" database through Bluetooth connection (SDK) and linked to the participant username (study ID).

- **Communication data:** multimedia content exchanged through the off-line communication channel. They are stored encrypted.

The following security measures apply to the APP and the server to ensure that study participants are not identified:

- All communication between the APP (client) and the server is done over HTTPS to prevent data traffic from being spied on.
- Passwords are never stored in text format on the server, but instead use Bcrypt (https://en.wikipedia.org/wiki/Bcrypt) to generate a "hash" code, which prevents a potential attacker from obtaining the user's credentials in case they gain access to the application database.
- The data stored in each database has role access control, so a properly authenticated user can only access the data they have access based on their role.
- The application will be published by means of Git to ensure complete traceability and transparency.

1.4.2 Data processing and archive of records

The data collected in the Health Circuit App for the research protocols will be identified only by the patients' study IDs, so no information will be included to identify the participants. This will also apply to the continuous IAQ monitoring provided by the device MICA from manufacturer INBIOT (https://www.inbiot.es/soluciones/dispositivos-mica/general). Both Health Circuit App data stored in a dedicated REDCap project as well as the continuous IAQ monitoring data will be encrypted and shared to the K-HEALTHinAir project database hosted by partner ATOS Spain, which in no case will contain information that can directly identify the participant (such as name and surname, initials, address, social security number, etc.). In the event that this transfer was to occur, it would be for the same purpose of the study described and guaranteeing confidentiality.

Only the study case manager and her collaborators with the right of access to the source data (medical history), may relate the data collected in the study with the patient's medical history. The identity of the participants will not be available to any other person except for a medical emergency or legal requirement. They may have access to the personally identified information, the health authorities, the Research Ethics Committee and personnel authorized by the study sponsor, when necessary to verify data and procedures of the study, but always maintaining confidentiality in accordance with current legislation.

Statement of compliance with EU regulations

The processing, communication and transfer of personal data of all participants shall comply with EU Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and the free movement of data, being mandatory from May 25, 2018 and Organic Law 3/2018, of December 5, Protection of Personal Data and guarantee of digital rights. The legal basis justifying the processing of data is the consent signed by the patient, in accordance with Article 9 of EU Regulation 2016/679.

Only the encrypted data will be transferred to third parties and other countries, which in no case will contain information that can identify the participant directly (such as first and last name, initials, address, social security number, etc.). In the event of this assignment, it would be for the same purpose of the study described and guaranteeing confidentiality.

If a transfer of encrypted data is made outside the EU, whether in entities related to the hospital where the patient participates, to service providers or to researchers collaborating with us, the participants' data will be protected by safeguards such as contracts or other mechanisms established by the data protection authorities.

As promoters of the project, we are committed to processing the data in accordance with EU Regulation 2016/679 and, therefore, to keep a record of the processing activities that we carry out and to carry out a risk assessment of the treatments we carry out, to know what measures we will have to apply and how to do so. The information used will only be processed within the framework of this project, preserving the integrity, confidentiality and security of the information.

In addition to the rights already provided for by the previous legislation (access, modification, opposition and cancellation of data, deletion in the new Regulation) participants can now also limit the processing of data collected for the project that are incorrect, request a copy or move to a third party (portability). To exercise these rights, they must contact the principal investigator of the study or the Data Protection Officer of the Hospital Clínic de Barcelona through protecciodades@clinic.cat. You also have the right to contact the Data Protection Agency if you are not satisfied.

Data cannot be deleted, even if a patient leaves the study, to ensure the validity of the investigation and comply with legal duties and drug authorization requirements.

The Investigator and the Promoter are required to retain the data collected for the study for at least 5 years after completion. Subsequently, personal information will only be kept by the health

care centre and by the promoter for other scientific research purposes if the patient has given consent to it, and if permitted by applicable law and ethical requirements.

1.5 EXPECTED OUTCOMES AND CLINICAL IMPACT

- ***Study of the relationships between patient's home IAQ and health status with focus on acute health effects.***

The analyses will be done considering two different levels: i) Barcelona pilot, and ii) information obtained at consortium level (using data from different scenarios). The methodological approach proposed by the project EU-Stands4PM: Standards for In Silico Models for Personalized Medicine (https://www.eu-stands4pm.eu/) will be adopted in the current project. Briefly, EU-Stands4PM combines data driven analyses and knowledge-based approaches to address the target objective.

The main expected outcome is the identification of IAQ-related factors with potential deleterious impact on health status. Subsequent studies to be planned in PHASE II (≥ M18) may help to analyse causality and identify thresholds for specific pollutants.

- ***Identifying factors triggering exacerbations in high-risk patients with respiratory diseases.***

The study design, including continuous patients' monitoring with the wrist sensor (One Beat) and registry of incidences using the chat, as well as continuous IAQ monitoring (MICA-INBIOT), should allow early identification of acute clinical episodes facilitating: i) the identification of factors triggering exacerbations and, specifically, the role of IAQ, and ii) early management of exacerbations preventing progression and subsequent need for emergency room visits and/or hospitalizations.

- ***Assessing the potential of digitally enabled integrated care for community-based preventive management of exacerbations.***

Previous studies[10,11] and recent pilot data support the hypothesis that digital support of integrated care services for preventive management of chronic respiratory patients with co-morbidities generates healthcare efficiencies by enhancing patients' empowerment for self-management and reducing the use of healthcare resources, mainly emergency room visits and hospitalizations. Both incidences and health outcomes, after one year, will be assessed in comparison with a control group generated using propensity score matching techniques.

- ***Exploring enhanced assessment of lung function at community level by combining measurements of FOT and FS.***

FS is the gold standard test for characterization of patients with COPD and for monitoring the evolution of the pulmonary disease. However, performance of the test at community level can show quality issues disturbing interpretation. Moreover, the test may not be well tolerated by

advanced patients. FOT testing may provide useful information for monitoring of chronic respiratory patients. The test does not require patients' collaboration and is well accepted by all patients.

We hypothesize that the two tests have complementary roles. While FS is the standard test for patients' characterization, FOT would be an ideal test for patients' monitoring (or self-monitoring).

During the project we will assess concordance between the two modalities of testing and explore the potential benefits of introducing FOT measurements for patients' monitoring at community level: primary care premises and patients' home. Moreover, the equipment (https://alds.health/) will allow to explore interoperability issues between specialized and primary care that may have a positive impact in the design of collaborative service workflows with high potential for generating healthcare efficiencies.

1.6 REFERENCES

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ANNEX 1 – IAQ MONITORING DEVICE

CONTINUOUS IAQ MONITORING: MICA-INBIOT

IAQ Parameters	Features
Indoor temperature	Universal communication
Relative Humidity	High connectivity
Formaldehyde	Cloud Platform Visualization
TVOC	BMS Integration
PM1/PM2.5/PM4/PM10	HVAC Control
External weather	BI Data Analysis
CO2	Data security
	Modular design for self-installation and maintenance

MICA - inBiot		
Particulate Matter	**Removable laser-based light scattering sensor**	
Particle Size	µg/m³	0.3 - 10
Measuring Range: PM2.5/PM10	µg/m³	0-5000
Sensor Output Resolution	µg/m³	1.00
Accuracy	%	0-35 µg/m3 - ±5 µg/m3 35 - 500 µg/m3 - ±15% reading
TVOC	**Removable MEMS metal oxide sensor**	
Measuring Range	ppb	0-6000
Sensor Output Resolution	ppb	0.2% reading
Accuracy	%	±15
Baseline Correction	-	Automatic
Carbon Dioxide (CO2)	**Non dispersive infrared sensor**	
Measuring Range	ppm	0-5000
Sensor Output Resolution	ppm	1
Accuracy	-	±(30+3%) ppm
Baseline Correction	-	Automatic/based on ventilation system
Temperature		
Measuring Range	°C	-0-90
Sensor Output Resolution	°C	0.01
Accuracy	°C	±0.2 - ±0.1
Relative Humidity		
Measuring Range	%RH	0-100
Sensor Output Resolution	%RH	0.01
Accuracy	%	±2
Formaldehyde		**electromechanical sensor**
Measuring Range		0-6250
Sensor Output Resolution		-
Accuracy		<200 µg/m3: ±30 µg/m3 >200 µg/m3: ±20% measured

ANNEX 2- HEALTH QUESTIONNAIRES

PART A. SOCIO-DEMOGRAPHIC DATA

Patient ID:_____

1. In what year were you born? __/__/__

2. Please indicate your sex at birth:
   1= Male 2= Female 3= Other

3. Please indicate your highest level of schooling:
   0= None
   1= Early. Childhood education
   2= Primary education
   3= Lower Secondary education
   4= Upper Secondary education
   5= Short cycle Tertiary education
   6= Bachelor's or equivalent level
   7= Master's or equivalent level
   8= Doctoral or equivalent level

4. Please indicate your current relationship status:
   0= Not married/partnered
   1= Married/partnered
   2= Divorced/separated
   3= Widowed
   4= Unknown

5. What is your work status?
   0= Unemployed
   1= Part-time employment
   2= Full-time employment
   3= Retired
   4= Unpaid work (student, caregiver, homemaker, volunteer, etc.)

6. Living arrangements:
   0=Lives alone
   1=Lives with others
   2=Lives in supported home (i.e. assisted living, congregate care, skilled nursing home, etc.)
   3=Homeless

PART B. THE ICHOM DATA SET FOR ADULT POPULATION

CLINICAL FACTORS

1. Have you ever been told by a doctor that you have any of the following?
   0= I have no other diseases
   1= Heart disease (angina, heart attack, heart failure)
   2= High Blood Pressure
   3= Lung Disease (asthma, chronic bronchitis, emphysema)
   4= Diabetes
   5= Stomach disease or ulcer
   6= Kidney disease
   7= Liver disease
   8= Blood disease or anemia
   9= Cancer

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10= Depression
11= Osteoarthritis
12= Back pain
13= Rheumatoid Arthritis
14= Other medical problems: _____

If some of the other previous questions is YES:
Do you receive treatment for (the related diseases answered yes)?
0=No 1=Yes
Does your (the related diseases answered yes) limit your activities?
0=No 1=Yes

2. Systolic Blood Pressure: _____mmHG

3. Diastolic Blood Pressure:_____mmHG

4. Body mass index (kg/m2) : _____ (or ask for height and weight)

5. What is the patient's total cholesterol? _____

6. What is the patient's HDL cholesterol? _____

7. What is the patient's diabetes status?
0=The patient is not diagnoses with diabetes
1= The patient is diagnoses with Type I diabetes
2= The patient is diagnoses with Type II diabetes

LIFESTYLE FACTORS

8. Please indicate your smoking behavior? *More detailed definitions are as follows: Daily smoker: A person who smokes daily. Weekly smoker: A person who smokes at least weekly but not daily. Former smoker: A person who does not smoke at all now but has smoke.*
0= Daily smoker
1= Weekly smoker
2= Former smoker
3= Never-smoker
4= Others
999=unknown if ever smoked

9. How many standard alcoholic drinks do you drink per week? *One standard drink is equal to 12.5ml of pure alcohol, or roughly 1 small glass of wine/25cl of regular beer (5% alcohol).*

_____

10. Physical activity.
    a. On average, how many days per week do you engage in moderate to strenuous exercise (like a brisk walk, slow biking, general gardening)?_____
    b. On average, how many minutes, per day, do you engage in exercise at this level?_____
    c. On average, how many minutes, per day, do you engage in exercise at this level?_____
    d. Total minutes per week of physical activity (multiply PAVSDAY by PAVSTIME)

0= 0 minutes 1= 1-150 minutes 2= >150 minutes

SEEING

11. At the present time, would you say your eyesight, with glasses or contact lenses if you wear them is…
5= excellent
4= very good
3=good
2= fair
1= poor

HEARING

12. Would you say your hearing is
    5= excellent
    4= good
    3=a little trouble
    2= moderate hearing trouble
    1= a lot of trouble
    0=deaf

OUTCOMES

13. In general, would you say your health is:
    5 = Excellent
    4 = Very good
    3 = Good
    2 = Fair
    1 = Poor

14. In general, would you say your quality of life is:
    5 = Excellent
    4 = Very good
    3 = Good
    2 = Fair
    1 = Poor

15. In general, how would you rate your physical health?
    5 = Excellent
    4 = Very good
    3 = Good
    2 = Fair
    1 = Poor

16. In the past 7 days, how would you rate your fatigue on average?
    5 = None
    4 = Mild
    3 = Moderate
    2 = Severe
    1 = Very severe

17. In the past 7 days, how would you rate your pain on average?

    0 1 2 3 4 5 6 7 8 9 10

18. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?
    5 = Completely
    4 = Mostly
    3 = Moderately
    2 = A little
    1 = Not al all

19. In general, how would you rate your mental health, including your mood and your ability to think?
    5 = Excellent
    4 = Very good
    3 = Good
    2 = Fair
    1 = Poor

20. In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
    5 = Never
    4 = Rarely
    3 = Sometimes
    2 = Often
    1 = Always

21. In general, how would you rate your satisfaction with your social activities and relationships?
    5 = Excellent
    4 = Very good
    3 = Good
    2 = Fair
    1 = Poor

22. In general rate how well you carry out your usual social activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)?
    5 = Excellent
    4 = Very good

3 = Good
2 = Fair
1 = Poor

23. In the past 30 days, how much difficulty did you have in standing for long periods such as 30 minutes?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

24. In the past 30 days, how much difficulty was taking care of your household responsibilities?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

25. In the past 30 days, how much difficulty was learning a new task, for example, learning how to get to a new place?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

26. In the past 30 days, how much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

27. In the past 30 days, how much have you been emotionally affected by your health problems?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

28. In the past 30 days, how much difficulty was concentrating on doing something for ten minutes?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

29. In the past 30 days, how much difficulty was walking a long distance such as a kilometer [or equivalent]?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

30. In the past 30 days, how much difficulty was washing your whole body?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

31. In the past 30 days, how much difficulty was getting dressed?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

32. In the past 30 days, how much difficulty was dealing with people you do not know?
0 = None
1 = Mild
2 = Moderate
3 = Severe
4 = Extreme or cannot do

33. In the past 30 days, how much difficulty was maintaining a friendship?
    0 = None
    1 = Mild
    2 = Moderate
    3 = Severe
    4 = Extreme or cannot do

34. In the past 30 days, how much difficulty was your day-to-day work?
    0 = None
    1 = Mild
    2 = Moderate
    3 = Severe
    4 = Extreme or cannot do

35. Over the past 2 weeks: 1. I have felt cheerful and in good spirits
    5= All of the time
    4= Most of the time
    3= More than half the time
    2= Less than half the time
    1= Some of the time
    0= At no time

36. Over the past 2 weeks: 2. I have felt calm and relaxed
    5= All of the time
    4= Most of the time
    3= More than half the time
    2= Less than half the time
    1= Some of the time
    0= At no time

37. Over the past 2 weeks: 3. I have felt active and vigorous
    5= All of the time
    4= Most of the time
    3= More than half the time
    2= Less than half the time
    1= Some of the time
    0= At no time

38. Over the past 2 weeks: 4. I woke up feeling fresh and rested
    5= All of the time
    4= Most of the time
    3= More than half the time
    2= Less than half the time
    1= Some of the time 0= At no time

39. Over the past 2 weeks: 5. my daily life has been filled with things that interest me
    5= All of the time
    4= Most of the time
    3= More than half the time
    2= Less than half the time
    1= Some of the time
    0= At no time

PART C ADAPTATION OF THE PARIS SURVEY

ACCESIBILITY

1. How easy or difficult is it to get medical care in the evenings, on weekends, or holidays without going to the hospital?
   1= Very easy
   2= Somewhat easy
   3= Somewhat difficult
   4= Very difficult
   6 (DO NOT READ) Never needed care in the evenings, weekends, or holidays
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

2. How quickly did you get an appointment to see your doctor?
   1= Very quickly
   2= Somewhat quickly
   3= Somewhat difficult
   4= Very difficult
   6 (DO NOT READ) Never needed care in the evenings, weekends, or holidays
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

3. Was the time you waited for the appointment for your doctor? (in days)
   _____ [RANGE 0-96]
   1 (DO NOT READ) More than one doctor but doesn't know exact number
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

4. On the actual day of the consultation, how long did you wait (for example in the doctor's waiting room) before you were actually seen? (in minutes)
   _____ [RANGE 0-96]
   1 (DO NOT READ) More than one doctor but doesn't know exact number
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

5. Was the time you waited to be seen a problem for you?
   1 =Yes
   2 =No
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

COMMUNICATION

6. Did the doctor/nurse spend enough time with you?
   1 =Yes
   2 =No
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

7. During your communication with the health staff, how often did your doctor/nurse treat you with courtesy and respect?
   1 =Always
   2 =Often
   3 =Sometimes
   4 =Rarely or never
   5 =(DO NOT READ) Never tried to contact by telephone
   D (DO NOT READ) Not sure

R (DO NOT READ) Decline to answer

8. Did this give you an opportunity to ask questions or raise concerns about recommended treatment?
   1 =Yes
   2 =No
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

SHARED DECISION MAKING

9. During the past year, when you received care, has any health care professional you see for your [insert condition] discussed with you your main goals or priorities in caring for this condition
   1 =Yes
   2 =No
   D (DO NOT READ) Not sure
   R (DO NOT READ) Decline to answer

10. Did this involve you as much as you wanted to be in decisions about your care and treatment?
    1 =Yes
    2 =No
    D (DO NOT READ) Not sure
    R (DO NOT READ) Decline to answer

CONTINUITY AND COORDINATION

11. Is there one doctor you usually go to for your medical care?
    1 =Yes, have a regular doctor/GP
    2 =(DO NOT READ) Yes, but have more than one regular doctor/GP
    3 =No
    4 =Yes, have nurse practitioner or physician assistant
    D (DO NOT READ) Not sure
    R (DO NOT READ) Decline to answer

12. Not counting any time you may have been hospitalized, how many different doctors have you seen in the past 12 months?
    _____ [RANGE 0-96]
    1 (DO NOT READ) More than one doctor but doesn't know exact number
    D (DO NOT READ) Not sure
    R (DO NOT READ) Decline to answer

13. Now thinking about the past 2 years, when receiving care for a medical problem, was there EVER a time when doctors ordered a medical test that you felt was unnecessary because the test had already been done?
    1 =Yes, this happened
    2 =No
    3 =(DO NOT READ) Not Applicable
    D (DO NOT READ) Not Sure
    R (DO NOT READ) Decline to Answer

14. In the past 12 months, has a doctor or pharmacist reviewed with you all the medications you take?
    1 Yes
    2 No
    D (DO NOT READ) Not sure
    R (DO NOT READ) Decline to answer

PART D. QUALITY OF LIFE (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ϒ
I have slight problems in walking about ϒ
I have moderate problems in walking about ϒ
I have severe problems in walking about ϒ
I am unable to walk about ϒ

SELF-CARE

I have no problems washing or dressing myself ϒ
I have slight problems washing or dressing myself ϒ
I have moderate problems washing or dressing myself ϒ
I have severe problems washing or dressing myself ϒ
I am unable to wash or dress myself ϒ

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ϒ
I have slight problems doing my usual activities ϒ
I have moderate problems doing my usual activities ϒ
I have severe problems doing my usual activities ϒ
I am unable to do my usual activities ϒ

PAIN / DISCOMFORT

I have no pain or discomfort ϒ
I have slight pain or discomfort ϒ
I have moderate pain or discomfort ϒ
I have severe pain or discomfort ϒ
I have extreme pain or discomfort ϒ

ANXIETY / DEPRESSION

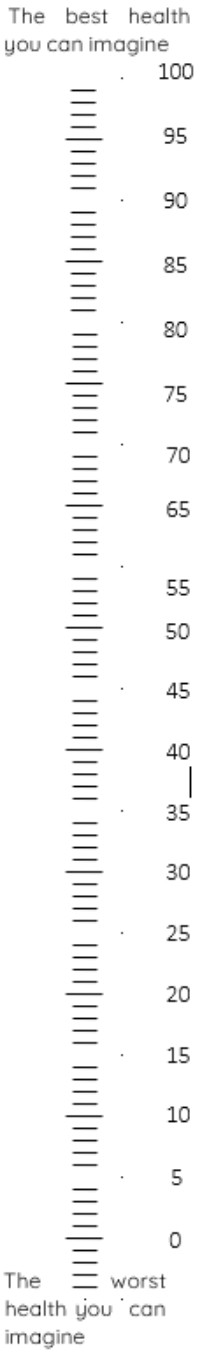
I am not anxious or depressed ϒ
I am slightly anxious or depressed ϒ
I am moderately anxious or depressed ϒ
I am severely anxious or depressed ϒ
I am extremely anxious or depressed ϒ

- We would like to know how good or bad your health is TODAY.

  This scale is numbered from 0 to 100. →100 means the <u>best</u> health you can imagine / 0 means the <u>worst</u> health you can imagine.

  Please mark an X on the scale to indicate how your health is TODAY.

  Now, write the number you marked on the scale in the box below.



YOUR HEALTH TODAY = ☐

PART E. MENTAL HEALTH (PHQ-9)

ID:_____ **DATE:_____**

Over the last 2 weeks, how ofter have you been bothered by any of the following problems?

	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF DAYS	NEARLY EVERY DAY
1. Little interest or pleasure in doing things.	0	1	2	3
2. Feeling down, depressed, or hopeless.	0	1	2	3
3. Trouble falling or staying asleep or sleeping too much.	0	1	2	3
4. Feeling tired or having little energy.	0	1	2	3
5. Poor appetite or overeating.	0	1	2	3
6. Feeling bad about yourself-or that you are a failure or have let yourself or your family down.	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television.	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so figety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself.	0	1	2	3
	____ + ____ + ____			
	TOTAL:_____			
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	• Not difficult at all ____ • Somewhat difficult ____ • Very difficult ____ • Extremely difficult ____			

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