Study Title

Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening.

NCT Number

NCT ID not yet assigned

Protocol Date

March 28, 2024

STUDY PROTOCOL

Study Title

Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening.

Acronym: DA-CRC

Protocol Version and Date: Version 2 — March 28, 2024

1. Rationale

Colorectal cancer (CRC) accounts for approximately 10% of all cancers diagnosed worldwide[1]. Numerous studies have shown that CRC screening using the faecal occult blood test (FOBT) can reduce mortality; however, the procedure is also associated with certain drawbacks, including false negatives and false positives, overdiagnosis, overtreatment, and potential complications from colonoscopy[1]. Therefore, the decision to undergo or not undergo screening should be an informed one[2].

To support this process, Decision Aids (DAs) have proven useful[3,4]. These are decision-support tools designed to help individuals make informed choices about their health.

The scientific literature[4–6] reports several studies related to cancer screening tests, which in some cases have been associated with increased adherence to screening programs[5]. In Italy, where three national screening programs are currently active (CRC, breast cancer, and cervical cancer), only a recent development of a DA specifically for mammography screening has been documented[6].

To ensure that the decision to undergo FOBT screening is well informed, the use of a smartphone application has been proposed as a supportive tool. Such an application can also serve as a platform to assess the effectiveness of new communication strategies—such as tailoring language to educational level and adapting content feedback based on Locus of Control (i.e., the extent to which individuals believe that life events are determined by their own actions or by external factors beyond their control[7])—as well as elements of Gamification[8], a relatively new approach that applies game mechanics to non-game contexts to enhance user engagement. This technique introduces an element of enjoyment into routine activities, which can increase motivation and knowledge—in this case, serving as a tool to promote primary prevention and healthy lifestyle behaviours.

The use of eHealth, particularly smartphone-based applications, has been increasingly documented in the literature as effective across various clinical fields[9–12].

2. General Objective of the Study

The general objective of this study is to evaluate the impact of a mobile application on informed decision-making regarding participation in colorectal cancer screening among individuals who will receive their first invitation to undergo the faecal occult blood test (FOBT), residing in the area covered by Brescia LHA.

Secondary objectives include assessing the impact of using the application on screening adherence rates, evaluating decision conflict, customer satisfaction, and the acceptability of a smartphone

application, as well as examining its effectiveness in conveying information about primary prevention and healthy lifestyle behaviours.

2.1. Primary Objective

To evaluate the impact of using a smartphone application on users' awareness and understanding regarding colorectal cancer prevention.

2.2. Secondary Objectives

1. To assess and compare screening adherence rates between the two study arms.
2. To assess and compare, between the two study arms, the level of knowledge related to healthy behaviours and primary prevention.
3. In the intervention arm, to evaluate decision conflict, customer satisfaction, and the acceptability of the mobile application.

3. Endpoint

3.1. Primary Endpoint

The primary endpoint is users' awareness in the field of cancer prevention, specifically regarding colorectal cancer screening. This will be assessed as a dichotomous variable by combining measures of knowledge, attitudes, and intentions, according to the three-dimensional framework by Marteau et al.[13,14] and comparing results between the two study arms. A participant will be considered to have made an informed choice if they have adequate knowledge and if their attitudes and behaviors are consistent. Among these three dimensions, adequate knowledge and consistent attitudes must be satisfied for the choice to be classified as "informed".

3.2. Secondary Endpoint

1. Screening adherence rate, calculated as the ratio between the number of individuals who completed the screening and the total number of individuals invited to participate in the screening program in the two study arms.
2. Level of knowledge related to healthy behaviors and primary prevention in the two study arms will be measured using a digital questionnaire containing 13 questions on primary prevention and healthy lifestyle behaviors.
3. Decision conflict, customer satisfaction, and the acceptability of the application will be assessed through additional questions included in the same digital questionnaire.

4. Study Plan and Design

Studio clinico randomizzato controllato monocentrico. I partecipanti allo studio verranno assegnati al braccio di controllo oppure di intervento mediante randomizzazione semplice, che prevede l'utilizzo di una sequenza di numeri casuali preparata dallo statistico, generati con il supporto del computer.

5. Inclusion and Exclusion Criteria

Participants will be included in the study if they meet the following criteria:

- Male and female citizens born between January 1, 1973, and December 31, 1974, who turned 50 years of age in 2023 or will turn 50 in 2024, thereby becoming eligible for the national colorectal cancer screening program.
- Residents in the area covered by Brescia LHA.

- Individuals who have provided informed consent to participate in the study.

Participants without a smartphone will be excluded from the study

6. Intervention

Smartphone application not classified as a Medical Device.

6.1. Intervention Procedures

All subjects who meet the inclusion criteria will receive, through an attachment to the invitation letter (Annex 1) for screening, the instructions on how to download the application on their smartphone. Once downloaded, the application will allow exclusively to complete the informed consent (Annex 2), to read the privacy policy (Annex 3) and subsequently the baseline questionnaire (T0) (Annex 4), in digital format. Afterwards, the users will be progressively randomized into an intervention arm and a control arm. Recruitment will be stopped upon enrollment of subject number 2500.

Subjects assigned to the control arm will have access to the mobile application in a limited version. In a specific section, there will be standardized and digitalized scientific dissemination documents aimed at providing information on primary prevention, healthy and correct lifestyles, and on colorectal cancer screening.

Subjects assigned to the intervention arm will have access to the full version of the application. In particular, in addition to the specific section available for the control group, users will be presented with the aforementioned information in the form of daily "pills." Moreover, by completing one quiz per week and one twice a week, the user will be able to earn points based on the number of correct answers provided. The quizzes will be of two types: the first, weekly, will consist of 10 questions, 5 regarding primary prevention topics and 5 on general knowledge; the second, every 3 days, will consist of 3 prevention-related questions. Users will have 15 seconds to answer each question, and the score, in case of a correct answer, will be assigned based on the time taken to select it.

For both arms, it will be possible to fill in a follow-up questionnaire at T1 and T2 (Annex 5), respectively at 3 and 6 months from enrollment.

The project foresees a total duration of 30 months.

It is possible to identify three main phases:

Phase 1, called **Project Start-Up**, consists of:

1.1 Drafting of the Study Protocol

1.2 Design of the CRF, creation of the electronic database and related completion manual

1.3 Definition of the Statistical Analysis Plan (SAP)

1.4 Preparation and submission of the documentation to the relevant Ethics Committee

Phase 2, called **Study Set-Up**, includes:

2.1 Identification of the cohort, patient enrollment and randomization

2.2 Data quality control and query resolution (completeness, accuracy and consistency analysis)

2.3 Progress meetings and related minutes

Phase 3, called **Statistical Analysis**, consists of:

3.1 Data analysis and dissemination of results (publications and conference materials)

6.2. Data Collection Tool

Two digital questionnaires (to be completed directly within the App) will be used: one at time T0 (baseline) and the second at time T1 (three months) and T2 (six months). In particolar:

1. Within the questionnaire administered at baseline, the validated Multidimensional Health Locus of Control (MHLC) questionnaire[15] is included. It contains eighteen questions through which the Locus of Control of the participants will be assessed.
2. Informed choice will be evaluated through three items: knowledge (score of at least 7 out of 13), attitude (score > 24), and intention (actual behaviour). Among these, the first two items must necessarily be satisfied[5–8] in order to define that the subject is informed about the choice.
3. The level of knowledge related to healthy behaviours and primary prevention will be assessed through the 13 questions on primary prevention and healthy lifestyle behaviours. Based on the number of correct answers, subjects will be classified into three categories: low knowledge (0 to 5 out of 13), good knowledge (6 to 8 out of 13), and excellent knowledge (9 to 13 out of 13).
4. Decision conflict, customer satisfaction, and the acceptability of the App will be assessed at T1 and T2 through specific items of the second questionnaire (decision-making process, satisfaction, and decision-aid acceptability).

In addition, Brescia LHA will provide data on residents born in 1973 and 1974, by sex, and the number of subjects, by sex, who actually completed the FOBT screening.

7. Study Duration and Planned Assessments

The duration of the study will be 30 months. The enrollment period will take place from January 2023 to August 2024, in conjunction with the invitation sent by Brescia LHA to citizens born in 1973 and 1974 to undergo FOBT screening. Following the completion of the informed consent and the baseline questionnaire, users will be progressively randomized.

The total enrolment period will last 20 months. Assessments for each subject will be performed at baseline (T0), at 3 months (T1), and at 6 months (T2).

T0: questionnaire collecting information on socio-demographic data, risk perception, knowledge, attitude, intention, and Locus of Control.
T1: questionnaire collecting information on risk perception, knowledge, attitude, intention, decision-making process, customer satisfaction, and application acceptability.
T2: same questionnaire administered at T1.

8. Statistical Aspects

8.1. Sample size

Based on previous studies[4,16], we considered an absolute difference of 10% between the proportion of individuals who make an informed choice and those who do not to be the minimum important difference for the sample size calculation. Assuming that the proportion of individuals making an informed choice is 50%, with a power of 90% and a two-sided significance level of 5%, 519 subjects per group are required, for a total of 1,038 subjects.

Considering an estimated colorectal cancer screening adherence rate of 50% in the province of Brescia and a probable drop-out rate of 20%, at least 2,492 subjects will need to participate in the study.

8.2. Statistical Methods

Descriptive statistics will be used to describe the collected variables: mean and standard deviation, median and interquartile range for quantitative variables, and absolute frequencies and percentages for qualitative variables. The comparison between the proportion of subjects making an informed choice in the two groups will be evaluated using the Chi-square test, as will the comparison between the proportion of subjects adhering to screening in the two arms.

Median scores obtained from the knowledge questionnaire will be evaluated using the Friedman test at the three time points.

9. CRF and Data Management

The subject data — collected through the electronic Case Report Form (CRF) (Annex 6) — will be kept confidential and used in accordance with the applicable legislation on the protection of sensitive data and privacy regulations.

The ownership of the results generated by the study belongs to University of Pavia.

10. Personal Data Processing

Within the scope of personal data processing instrumental to the activities foreseen for the implementation of the predefined program PP02 “Active Communities” and the free program PL14 “Oncological Screening” of the Piano Regionale Prevenzione 2021-2025, dated February 12, 2020, Brescia LHA and University of Pavia, Department of Public Health, Experimental and Forensic Medicine (hereinafter jointly referred to as the “Parties”), will act as independent data controllers with respect to the data subjects, in compliance with the principles of lawfulness, necessity, fairness, relevance and proportionality. Data will be processed exclusively for research purposes and limited to processing activities strictly related to such purposes, in accordance with the applicable legislation on personal data protection.

For all personal data processing activities, the Parties shall adopt all necessary technical and organizational measures to ensure that the rights of the data subjects, pursuant to Regalement (UE) 2016/679 (GDPR), can be guaranteed at any time and within the time limits set by law. The Parties undertake to make available to each other, where necessary, any information useful to demonstrate and verify compliance with their respective obligations under the current data protection legislation, and to cooperate in the event of requests from the Supervisory Authority or the Judicial Authority concerning the processing of data related to the activities governed by the existing agreements.

The Parties undertake to restrict the circulation and processing of personal data collected for the execution of the research project (e.g., storage, archiving and preservation of data on their own servers or in the cloud) to countries belonging to the European Union, with an explicit prohibition on transferring data to non-EU countries that do not ensure (or in the absence of) an adequate level of protection. In the absence of safeguards required by Regulation (EU) 2016/679 (third country deemed adequate by the European Commission, BCR, standard contractual clauses, etc.), the Parties also commit to carrying out a Data Transfer Impact Assessment (DTIA) prior to transferring any personal data processed under this Agreement to non-EU countries.

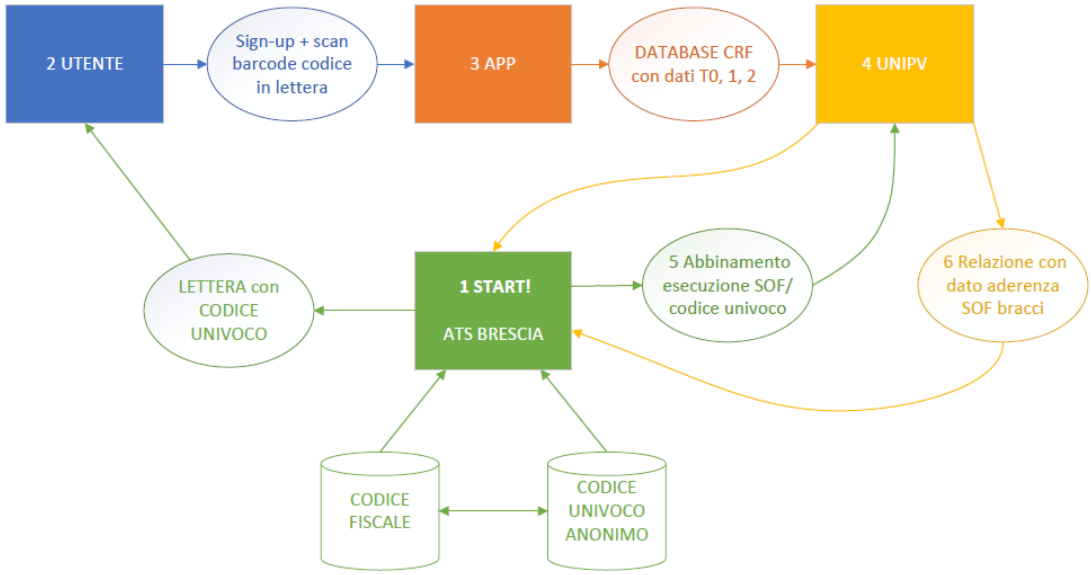
In particular:

1. Brescia LHA will be responsible for promoting the research among subjects who may be eligible for recruitment. Brescia LHA will send invitation letters to the cohort of users born in 1973 and 1974, who will receive their first invitation to undergo the faecal occult blood test screening, residing in the Brescia LHA area. In the letter, citizens will be invited to download a smartphone application, through which they will provide their consent to the use of their data by the University of Pavia.
   Brescia LHA will provide the University of Pavia with informational material containing notions on primary prevention and healthy lifestyles, as well as data on the number of residents born in 1973 and 1974 by sex and the number of individuals, by sex, who will have completed the screening by the end of the year.

2. The Department of Public Health, Experimental and Forensic Medicine of the University of Pavia will be responsible for:
   - Defining the research project operationally;
   - Collecting data and consent from participants;
   - Developing a communication and information tool aimed at the population in order to achieve the objectives of the regional programs PP02 and PL14.

The evaluation of the research results will be returned to Brescia LHA in anonymous form.

The data flow diagram is shown below.



11. Informed Consent

The informed consent will be administered through the App upon first access. A copy of the consent will be stored in a dedicated file.

12. Costs

The study will be funded by Brescia LHA with a total amount of €30,000.00, VAT included.

13. Data Ownership and Publications

The Department of Public Health, Experimental and Forensic Medicine of University of Pavia is responsible for collecting consent for the processing of personal data for research purposes related to individuals registered in the healthcare registry and will collaborate with Brescia LHA to identify subjects eligible for the study. The data will be kept strictly confidential and processed in accordance with Legge 196/2003 (so-called Privacy Law), using manual and/or electronic tools to ensure their security and confidentiality. A data protection officer will be appointed as the privacy contact person for the management of these data.

The results of the study may be presented to the scientific community in the form of publications in national and international peer-reviewed journals and conference presentations, as well as for dissemination purposes (e.g., articles in newspapers or on websites), after prior sharing with Brescia LHA. The final version of such publications and dissemination material will be communicated (from the University to Brescia LHA) for a 15-day comment period.

14. References

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15. Annexes

1. Information Sheet and Informed Consent Form for Participation
2. Information Notice on Personal Data Processing
3. Letter to General Practitioners
4. Approval Record of Study NP 5686 DA-CRC

Study Title

Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening.

NCT Number

NCT ID not yet assigned

Protocol Date

March 28, 2024

INFORMATION SHEET AND DECLARATION OF CONSENT TO PARTICIPATE

Dear Sir / Madam,

University of Pavia and Brescia Local Health Authority (LHA) are conducting a study entitled: "Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening". The aim of this study is to evaluate the impact of a smartphone application on users' awareness regarding colorectal cancer prevention.
This document explains why we believe you may be eligible to participate in this study.
You have been selected because, having been born in 1973 or 1974, you have either received in 2023, or will receive in 2024, your first invitation to participate in the colorectal cancer screening program (this screening campaign is targeted at people aged 50 – 69 years) and you reside in the area covered by the Brescia LHA.
This research, conducted exclusively among residents in the area covered by the Brescia LHA, requires the collaboration and availability of individuals like you who meet the above eligibility criteria.

Before deciding whether to accept or decline participation, please read this document carefully, take all the time you need, and do not hesitate to ask for clarification if anything is unclear. You may contact the dedicated email address provided. If you wish, you can also consult your trusted physician before deciding.

STUDY OBJECTIVES

The primary objective of this research is to evaluate the impact of a mobile application on informed decision-making regarding colorectal cancer screening. After you provide your consent to take part in the study, you will be randomly placed in either the control group or the intervention group.

- If you are assigned to the **control group**, within the smartphone application, in a dedicated section, you will have access to digitized scientific educational documents providing you with information on primary prevention, healthy lifestyle habits, and colorectal cancer screening.
- If you are assigned to the **intervention group**, the smartphone application will provide you with the same documents as the control group. In addition, the information will also be presented through short daily "information pills". You will also could take part in quizzes on primary prevention and general knowledge topics. Based on the number of correct answers, your chosen nickname (selected during app registration) will appear on a leaderboard.

Secondary objectives include:

1. Evaluating and comparing adherence rates to the screening program between the two study groups.
2. Evaluating and comparing the level of knowledge related to healthy behaviors and primary prevention in both groups.
3. Assessing the decision-making process, satisfaction, and acceptability related to the application.

BASELINE AND FOLLOW-UP ASSESSMENTS

Regardless of the group you are assigned to, immediately after providing your consent and being enrolled in the study, you will be asked to complete a questionnaire. This will collect socio-demographic data, risk perception, knowledge, attitudes, intention to participate in the colorectal cancer screening program, and Locus of Control.

At 3 months and 6 months after enrollment, you will be asked to complete a follow-up questionnaire collecting the same information (except for socio-demographic data) plus additional questions regarding the decision-making process and satisfaction with the use of the application.

POTENTIAL RISKS

No specific risks are expected as a result of participation in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is entirely voluntary. You may withdraw from the study at any time, without any consequences and without affecting your right to participate in the colorectal cancer screening program.

OTHER IMPORTANT INFORMATION

The study will be conducted in accordance with internationally recognized Good Clinical Practice (GCP) guidelines and in compliance with the ethical principles set out in the Declaration of Helsinki and the Oviedo Convention.

Your participation in the study is entirely voluntary. Should you decide to participate, you will be asked to provide your informed consent as set out at the end of this document, before any procedures or assessments required by the study are carried out. By signing the consent form, you acknowledge that you have received full information and have freely agreed to participate in the study.
The data collected during the study through the application will be shared with Brescia LHA.

How is the confidentiality of information ensured? Who should I contact for further information?

The data controller is the University of Pavia. For any further information, you may contact the dedicated email address.

INFORMED CONSENT FORM

I, the undersigned ……., declare that I have carefully read and fully understood the information provided in this document. I hereby:

☐ Consent ☐ Do not consent

to participate voluntarily in the study, having understood the nature of the request and the potential benefits involved. I acknowledge that I may withdraw from the study at any time without any consequences.

Study Title

Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening.

NCT Number

NCT ID not yet assigned

Protocol Date

March 28, 2024

Information Notice on the Processing of Personal Data pursuant to Articles 13 and 14 of Regulation (EU) 2016/679

Pursuant to Article 13 of Regulation (EU) 2016/679 and in compliance with the principle of transparency, the following information is provided to ensure that you are fully informed about the nature and methods of personal data processing for the purpose of participation in the research project : "Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening" carried out by the University of Pavia in collaboration with the Brescia LHA.

The general objective of the study is to evaluate the impact of a mobile application on informed decision-making regarding participation in colorectal cancer screening among individuals residing in the Brescia LHA area who will receive their first invitation to undergo a faecal occult blood test (FOBT).

Secondary objectives concern the impact of the use of the application on screening adherence rates, the assessment of decision-making conflict, customer satisfaction and acceptability of the smartphone application, as well as its ability to effectively convey information on primary prevention and healthy lifestyles. The study characteristics and procedures are described in detail in the document "*Information sheet and declaration of consent to participate"*.

The University of Pavia (hereinafter, "University"), as Data Controller, will process your personal data only to the extent strictly necessary to achieve the study's objectives and in compliance with applicable data protection legislation, including Regulation (EU) 2016/679 (General Data Protection Regulation), Legislative Decree No. 196 of 30 June 2003 as amended (Italian Data Protection Code), and all applicable provisions and guidelines issued by the Italian Data Protection Authority (Garante per la Protezione dei Dati Personali).

a) Data Controller and contact details

The Data Controller is the University of Pavia, represented by the Rector pro tempore, with registered office at C.so Strada Nuova 65, IT-27100 Pavia, Italy. PEC: amministrazione-centrale@certunipv.it

b) Data Protection Officer (DPO) contact details

The Data Protection Officer (DPO) can be contacted at the following email address: privacy@unipv.it

c) Purpose of processing and legal basis

The University of Pavia is a public institution of higher education and research, entrusted with **institutional tasks aimed at pursuing educational and scientific objectives** (Article 1 of the Statute of the University of Pavia), in implementation of Article 33 of the Italian Constitution.
The University will process personal data for research purposes related to the project "Personalised and gamification-based Decision Aid (DA): a randomized controlled pilot study about colorectal cancer (CRC) screening" on the basis of agreements with the Brescia LHA.

The University of Pavia processes personal data following the acquisition of the explicit and unambiguous consent of the data subject for the processing of personal data pursuant to Article 6(1)(a) of Regulation (EU) 2016/679, in accordance with the provisions set out in the Ethical Rules for the processing of personal data for statistical or scientific research purposes.
The project complies with the provisions set out in Article 6 of the Ethical Rules for the processing of personal data for statistical or scientific research purposes.
The research is carried out on the basis of a protocol drafted in accordance with the methodological standards of the relevant scientific disciplines, in order to demonstrate that the processing of personal data is performed for appropriate and legitimate statistical or scientific purposes. When processing health-related data, all parties involved comply with the confidentiality and security obligations applicable to healthcare professionals or with equivalent confidentiality and security standards.
The research complies with Article 6 of the aforementioned Ethical Rules.
It is conducted according to a protocol drafted in compliance with the methodological standards of the relevant scientific fields to ensure that personal data processing serves appropriate and effective statistical or scientific

purposes. When processing health-related data, all parties involved must comply with the confidentiality and security obligations applicable to healthcare professionals or equivalent standards.

d) Types of data processed

If the data subject gives their consent to participate in the study, certain personal data concerning them will be collected using electronic tools (in particular, the data will be collected through an electronic Case Report Form, or "eCRF"). The application used for the study will identify the data subject by means of a unique code.

The personal data collected and processed for the purposes indicated above include:

- Socio-demographic information and psychological characteristics, as well as data related to risk perception, knowledge, attitudes, and intention to participate in colorectal cancer screening programs.

To ensure data quality and accuracy, all questions must be answered; however, participants may stop completing the questionnaire and withdraw from the study at any time. Results will always be presented in aggregated form.

e) Provision of data

Participation in the research is entirely free and voluntary, and refusal to participate will have no consequences for the data subject.

Participation in the project by the data subject implies the provision of the personal data requested, as described in section (d) of this information notice. Failure to provide the required data or to participate in the research project will make it impossible to carry out the project and the related activities.

f) Methods of processing

The processing of personal data will be carried out using IT and telematic tools designed to ensure the security and confidentiality of the data.
The University of Pavia, in agreement with the Brescia LHA, has decided to administer the questionnaires to the following cohort:

- Citizens, both male and female, born between 1 January 1973 and 31 December 1974, who turned 50 years of age in 2023 or will turn 50 in 2024, thereby entering the national colorectal cancer screening program;
- Residents in the Brescia LHA area;
- Individuals who have given their consent to participate in the study.

The data and information will be collected through an application specifically selected by the University, also based on its security profile. The University will process the data in a pseudonymized form, identifying each participant using a barcode printed on the invitation letter sent by the Brescia LHA. Only the Brescia LHA will be able to link the barcode to the participants' names. The analysis results will subsequently be transmitted to the Brescia LHA in anonymous form.
To achieve the purposes described above, the data will be processed by persons authorized to handle personal data under the responsibility of the Data Controller, who have been properly instructed and trained for this purpose.

g) External data processors

In light of the activities described above, the application provider – that is, the provider of the service necessary for the implementation of the study and solely responsible for managing the technical data required for the functioning of the application — will act as an External Data Processor pursuant to Article 28 of the GDPR, under a specific agreement with the University of Pavia.

Upon completion of the study, the anonymized data will be stored by the University of Pavia for a period of five years.

h) Categories of recipients of personal data

The Data Controller pays particular attention to defining the organizational structure and identifying the personnel responsible for data collection, providing them with appropriate instructions regarding the procedures for carrying out data processing activities. This is done to ensure compliance with ethical rules and to safeguard the rights of the data subjects.

i) Data transfer to third countries

The University undertakes to limit the scope of circulation and processing of personal data collected in connection with the research project (e.g., storage, archiving, and retention of data on its own servers or in the cloud) to countries that are part of the European Union.

j) Data retention period

Personal data will be retained only for the time strictly necessary to achieve the purposes of the processing (in compliance with the principles of necessity and purpose limitation) and will therefore be deleted after five years.

k) Data subject rights

Data subjects may exercise their rights regarding their personal data, as provided for in Article 15 et seq. of Regulation (EU) 2016/679, where applicable, free of charge by submitting a specific request with the subject line "*Privacy Rights*" to the email address indicated above, with a copy to the Scientific Project Lead.

Pursuant to Article 7(3) of Regulation (EU) 2016/679, data subjects have the right to withdraw their previously given consent at any time and to exercise the right to the erasure of their personal data, in accordance with Article 17 of Regulation (EU) 2016/679 (GDPR).
Withdrawal of consent shall not affect the lawfulness of processing based on consent prior to its withdrawal.

l) Complaints

Data subjects have the right to lodge a complaint with the supervisory authority and may contact the Italian Data Protection Authority: https://www.garanteprivacy.it/

m) Profiling

The Data Controller does not use any automated decision-making processes for profiling purposes.

By acknowledging the information provided above, participation in the study implies that the individual:

- **has read and understood this information notice on the processing of personal data and freely and voluntarily agrees to take part in the research;**
- **gives their consent to the processing of their personal data for the purposes and according to the procedures described in this information notice.**