

# Evaluation of the Psychosocial Effects of a Trauma-Informed Care-Based Artificial Intelligence-Supported Chatbot in Newly Diagnosed Cancer Patients: A Randomized Controlled Trial

## 1. Introduction

Receiving a new cancer diagnosis is a potentially traumatic experience that can have profound effects on individuals (Simkhaev, 2025; Davidson et al., 2023). Cancer can represent a major turning point in patients' lives, altering their goals, relationships, and sense of self (Savaş et al., 2024). This traumatic process may lead to a wide range of psychological problems, including high levels of fear, anxiety, depression, anger, concerns about the future, social isolation, low self-esteem, and suicidal ideation (Savaş et al., 2024).

During this period, patients are commonly found to have unmet psychosocial needs (Fernández-Feito et al., 2024). Between 40% and 90% of cancer patients report at least one unmet need (Schmid-Büchi et al., 2008). These needs not only directly affect medical care but also significantly impair patients' quality of life. The traumatic nature of receiving a cancer diagnosis may increase psychological distress and weaken patients' ability to access support resources. Unmet psychosocial needs are strongly associated with negative clinical outcomes, including anxiety, depression, and poor treatment adherence (Essue et al., 2020). In this context, recognizing the traumatic experience of newly diagnosed patients and addressing their unmet needs through early and holistic interventions emerges as a fundamental component of cancer care.

The psychosocial needs of cancer patients are identified through a multidisciplinary and patient-centered process (Fernández-Feito et al., 2024; Caminiti et al., 2021; Tack et al., 2022; Bussmann et al., 2023). Patients are the primary source of information through self-report, allowing for the identification of subjective experiences such as fear, anxiety, depression, coping difficulties, and social concerns (Bergerot et al., 2024). Nurses are often the first to recognize psychosocial distress through observation, therapeutic communication, and the use of validated screening tools, playing a critical role in early detection and ongoing assessment (Bussmann et al., 2023). This process is typically guided by standardized frameworks and screening tools, including those developed by the National Comprehensive Cancer Network (NCCN) and the World Health Organization (WHO), which facilitate the systematic identification, documentation, and management of psychosocial needs within holistic cancer care (NCCN, 2024; WHO, 2017).

The psychosocial needs of cancer patients are multidimensional and dynamic, requiring continuous assessment and individualized interventions (Caminiti et al., 2021). These needs include:

- **Emotional and Social Needs:** Feelings such as anxiety, depression, fear of cancer progression or recurrence, uncertainty, sadness, anger, hopelessness, and grief are common (Fernández-Feito et al., 2024; Caminiti et al., 2021; Tack et al., 2022; Bussmann et al., 2023; Tang et al., 2025). There is a high need for emotional support and coping mechanisms (Dev et al., 2024).
- **Health System and Information Needs:** Patients often report the need for adequate information about their illness, treatment process, side effects, available resources, and home care (Fernández-Feito et al., 2024; Caminiti et al., 2021; Tack et al., 2022; Tang et al., 2025). They also wish to be treated as individuals rather than merely as "cases" (The Lancet Oncology, 2023).
- **Physical and Daily Living Needs:** These include pain, fatigue, menopausal symptoms, and difficulties in performing daily activities (Fernández-Feito et al., 2024; Caminiti et al., 2021; Tack et al., 2022).
- **Sexual Needs:** Particularly in prostate or gynecological cancers, changes in sexual life and relationships are a major concern (Caminiti et al., 2021; Tang et al., 2025; Bussmann et al., 2023).
- **Patient Care and Support Needs:** Needs such as greater involvement in decision-making, timely responses to physical needs, and overall support deficiencies are frequently reported

(Fernández-Feito et al., 2024; Caminiti et al., 2021; Tack et al., 2022; Bussmann et al., 2023; Tang et al., 2025).

- **Spiritual Identity and Self-Perception Needs:** Cancer may deeply affect an individual's identity and spirituality, increasing existential questioning and the need for psychological and spiritual support (Fernández-Feito et al., 2024; Caminiti et al., 2021; Tack et al., 2022; Bussmann et al., 2023; Tang et al., 2025).
- **Childcare-Related Needs:** Patients with children may have specific needs related to childcare responsibilities (Bussmann et al., 2023; Güner et al., 2024).

## Barriers to the Delivery of Psychosocial Care

Psychosocial care is a fundamental and holistic healthcare approach that addresses not only an individual's medical treatment but also their psychological and social needs (Ambushe et al., 2023). The integration of psychosocial care into healthcare delivery is an ethical imperative in modern health systems, aiming to treat patients as whole individuals and to achieve the highest possible quality of life (Grosso, 2025).

Nurses are uniquely positioned to identify and address the psychosocial needs of cancer patients due to their close and continuous contact with patients and their families (Legg, 2011). Their responsibilities extend beyond physical care to include emotional, cognitive, and social support (Lyu et al., 2024). Holistic nursing practice emphasizes the inseparability of physical and psychosocial well-being, in line with patient-centered care principles (Moran et al., 2024).

In Türkiye, although three-quarters of nurses providing direct care to adult cancer patients report that psychosocial support services are available in their institutions, these services are mostly delivered through psychiatric consultation (Yıldırım et al., 2024). In the same study, approximately half of the nurses (49%) stated that addressing psychosocial needs is an integral responsibility of all healthcare professionals, particularly nurses. However, significant barriers persist in this area.

Nurses identify organizational conditions as the primary barrier (Yıldırım et al., 2024). Heavy workload, insufficient staffing, unclear role definitions, and lack of organizational support for psychosocial care are among the leading challenges (Güner et al., 2018). Additionally, nurses report difficulties in assessing and addressing psychosocial needs in sensitive areas such as sexual concerns and treatment refusal (Yıldırım et al., 2024). This situation indicates that the already traumatic experience of diagnosis and treatment for newly diagnosed patients can be further exacerbated by structural limitations and workforce shortages within the healthcare system.

## Trauma-Informed Care (TIC)-Based Chatbot: Addressing the Traumatic Impact of a New Diagnosis

According to the Substance Abuse and Mental Health Services Administration (SAMHSA, 2014), Trauma-Informed Care (TIC) is an approach that recognizes, understands, and responds to the effects of traumatic experiences in individuals' lives, shaping service delivery accordingly. TIC is both an individual and organizational approach that acknowledges the widespread impact of trauma and actively seeks to prevent re-traumatization by integrating this understanding into policies, procedures, and practices (Goddard et al., 2022; Sinko et al., 2024; Davidson et al., 2023).

This approach centers on the question, "What happened to you?" to better understand individuals' lived experiences (Goddard et al., 2022; Fulton et al., 2024). According to SAMHSA (2014), TIC is based on six core principles:

1. Safety (physical and psychological)
2. Trustworthiness and transparency

3. Peer support
4. Collaboration and mutuality
5. Empowerment, voice, and choice
6. Cultural, historical, and gender considerations

Integrating these principles into cancer care can help address unmet psychosocial needs and improve patient experiences (Simkhaev, 2025).

- **Safety:** A physically and psychologically safe environment is particularly effective in addressing emotional and social needs, helping reduce anxiety, fear of recurrence, and psychological distress (Reeves, 2015).
- **Trustworthiness and Transparency:** Open, honest, and consistent communication meets patients' information needs and reduces uncertainty about the future, while strengthening patient-provider trust (Davidson et al., 2023).
- **Peer Support:** Interaction with individuals who have had similar experiences reduces emotional distress and social isolation (Sinko et al., 2024).
- **Collaboration and Mutuality:** Involving patients in decision-making processes improves the fulfillment of daily living needs and enhances the care experience (Perron et al., 2024).
- **Empowerment, Voice, and Choice:** Providing patients with choices enhances emotional well-being and self-efficacy while reducing re-traumatization (Reeves, 2015).
- **Cultural, Historical, and Gender Considerations:** Delivering culturally sensitive care is essential, particularly as needs such as sexuality are closely linked to social norms and cultural perceptions (Sinko et al., 2024).

The application of TIC principles in oncology care can transform potentially re-traumatizing experiences into opportunities for healing, resilience, and empowerment (Reeves, 2015). The high prevalence of psychosocial distress and unmet needs among cancer patients highlights the necessity of integrating this approach (Ayvat & Özbaş, 2022; Jacobsen & Wagner, 2012; Andrejko & Katrichis, 2022; Simkhaev, 2025).

To overcome these challenges and provide more effective support to newly diagnosed patients, a chatbot grounded in TIC principles may offer an important solution.

Chatbots are artificial intelligence-based software systems capable of understanding human language, interacting with users, and generating appropriate responses (Adamopoulou & Moussiades, 2020). In healthcare, chatbots are used in various domains, including symptom monitoring, medical information provision, medication reminders, and psychosocial support. A randomized controlled trial by Alison Darcy and colleagues (2017) demonstrated that the chatbot *Woebot* significantly reduced symptoms of anxiety and depression and was highly acceptable to users. This fully automated system provided empathetic, cognitive behavioral therapy (CBT)-based interactions that improved psychological well-being. Similarly, *Vivibot* was found to support psychological well-being in young cancer survivors through positive psychology-based content (Greer et al., 2019). In a pilot study, *Vik* was shown to provide emotional support and effectively meet informational needs in patients with breast cancer (Chaix et al., 2019).

An AI-supported chatbot can operationalize the six core principles of TIC in a digital environment, thereby addressing unmet psychosocial needs and mitigating the traumatic impact of a new diagnosis:

- **Safety and Trust:** Provides a 24/7 accessible, safe, and non-judgmental communication channel, enhancing psychological safety while protecting patient data.
- **Access to Information and Empowerment:** Enables patients to access accurate and transparent information at their own pace, reducing information overload and supporting active participation in health-related decisions.

- **Personalization and Cultural Sensitivity:** Tailors responses according to patients' cultural values, beliefs, and social norms, supporting patient-centered care (Llave et al., 2024).
- **Early Intervention and Psychological Support:** By continuously monitoring emotional states and symptoms, the chatbot can detect anxiety, depression, and trauma-related symptoms early and encourage timely professional support, promoting better coping and treatment adherence (Simkhaev, 2025).

Receiving a cancer diagnosis is a psychologically disruptive and potentially traumatic experience. As a result, patients often face numerous unmet psychosocial needs. A chatbot grounded in Trauma-Informed Care principles may serve as an effective intervention by providing safe, personalized, and culturally sensitive support in a digital environment. Rather than replacing healthcare professionals, this technology aims to complement them, contributing to a more effective and comprehensive psychosocial care ecosystem. By facilitating early intervention, access to accurate information, and patient empowerment, TIC-based chatbots represent a strategic investment that can improve not only individual well-being but also healthcare system efficiency and overall public health.

## 2. Aim and Hypotheses

### 2.1. Aim

The aim of this study is to evaluate the effectiveness of a trauma-informed, artificial intelligence-supported chatbot in reducing the traumatic impact of diagnosis and addressing unmet psychosocial needs by providing early psychosocial support to adults newly diagnosed with cancer.

### 2.2. Hypotheses

**H1:** Patients who interact with the trauma-informed chatbot will have lower mean scores on the Impact of Event Scale-Revised (IES-R) compared to patients in the control group.

**H2:** Patients in the intervention group will have higher mean scores on the Psychosocial Needs Inventory (PNI) compared to patients in the control group.

**H3:** Patients in the intervention group will have significantly lower mean scores on the State-Trait Anxiety Inventory (STAI) compared to patients in the control group.

## 3. Material and Methods

### 3.1. Study Design

This study is designed as a randomized controlled experimental trial.

### 3.2. Study Setting and Characteristics

The study will be conducted in the Medical Oncology Unit of Koç University Hospital.

### 3.3. Population and Sample Selection

The study population will consist of adults aged 18 years and older who have been newly diagnosed with cancer and are receiving care at the Medical Oncology Unit of Koç University Hospital.

Sample size calculation was performed using the G\*Power 3.1 software. As no directly comparable study was identified based on the study design and objectives, the sample size was calculated using group comparisons in repeated measures with an effect size of  $d = 0.20$ , 80% statistical power, and a 95% confidence level. Accordingly, the required sample size was determined to be 52 participants (26

per group). Considering a potential 20% attrition rate, the final sample size was set at 62 participants (31 in the intervention group and 31 in the control group).

In randomized controlled trials, stratified randomization is recommended to ensure balance between groups in terms of sample size and to increase homogeneity with respect to key characteristics. In this study, stratification will be performed based on gender (female/male), which is anticipated to influence study outcomes.

Participants will first be stratified into two groups according to gender (female and male). Within each stratum, permuted block randomization will be applied to create block sets. Following block formation, participants will be randomly assigned to the intervention or control groups in a 1:1 ratio using a computer-based random number generator ([www.random.org](http://www.random.org)).

### ***Inclusion Criteria***

Participants who meet the following criteria will be included in the study:

- Aged 18 years or older
- Able to speak and understand Turkish
- No cognitive, visual, or hearing impairments
- Diagnosed with cancer within the past one month (Stage I, II, or III; regardless of cancer type)
- Have initiated active cancer treatment
- Have access to a digital device and internet
- Provide voluntary informed consent to participate in the study (Appendix 1)

### ***Exclusion Criteria***

Participants who meet any of the following criteria will be excluded:

- Participation in another concurrent psychosocial or digital intervention study
- Diagnosis of advanced-stage cancer (Stage IV), metastatic disease, or being in the terminal phase
- Diagnosed psychiatric conditions such as schizophrenia, bipolar disorder, substance use disorder, depression, or anxiety disorders

## **3.4. Data Collection Instruments**

### ***Sociodemographic Information Form***

The sociodemographic information form was developed by the researchers based on a review of the relevant literature (Zingler et al., 2025). The form includes variables related to adults diagnosed with cancer, such as age, gender, education level, marital status, occupation, economic status, type of treatment received, cancer type and stage, and comorbidities.

### ***Psychosocial Needs Inventory (PNI)***

The Psychosocial Needs Inventory was developed by Thomas et al. (2001) to assess the psychosocial needs of cancer patients. The Turkish adaptation was conducted by Güner et al. (2024). The inventory evaluates both the importance of psychosocial needs and the extent to which these needs are met across different domains.

The Turkish version consists of 48 items and includes seven subscales:

- Information Needs (9 items)
- Needs Related to Healthcare Professionals (5 items)
- Emotional and Spiritual Needs (15 items)
- Identity-Related Needs (5 items)
- Needs Related to Activities of Daily Living (8 items)
- Childcare-Related Practical Needs (1 item)
- Support Needs (5 items)

Each item is rated in two dimensions:

- **Importance:** “How important is this need to you?” (1 = Not important at all, 5 = Very important)
- **Level of Fulfillment:** “To what extent has this need been met?” (1 = Not met at all, 5 = Fully met)

There are no reverse-coded items. Scores are calculated by averaging the items within each subscale. Higher scores indicate that the need is perceived as more important and/or better fulfilled. In the Turkish validation study, Cronbach’s alpha coefficients for all subscales were above 0.70, indicating high internal consistency. Confirmatory factor analysis demonstrated acceptable model fit, supporting the reliability and validity of the Turkish version (Güner et al., 2024).

### ***State-Trait Anxiety Inventory (STAI)***

The State-Trait Anxiety Inventory, developed by Spielberger (1983), is a self-report instrument used to assess anxiety in individuals aged 14 years and older. The Turkish adaptation, validity, and reliability studies were conducted by Öner and Le Compte.

The inventory consists of two subscales, each containing 20 items:

- **State Anxiety Scale:** Measures how the individual feels at a particular moment
- **Trait Anxiety Scale:** Measures general anxiety tendency independent of situational factors

Each item is scored on a 4-point Likert scale. State anxiety items are rated based on intensity (“Not at all” to “Completely”), while trait anxiety items are rated based on frequency (“Almost never” to “Almost always”). Scores for each subscale range from 20 to 80.

The scale includes both direct and reverse-coded items. In direct items, higher scores indicate higher anxiety, whereas in reverse-coded items, lower scores indicate higher anxiety. Scores  $\leq 36$  indicate no anxiety, 37–42 mild anxiety, and  $\geq 43$  high anxiety. Scores above 60 may indicate a need for professional support.

### ***Impact of Event Scale-Revised (IES-R)***

The Impact of Event Scale-Revised (IES-R) is based on the original scale developed by Horowitz, Wilner, and Alvarez (1979) and later revised by Weiss and Marmar (1997) to assess symptoms of post-traumatic stress disorder.

The scale consists of 22 items rated on a 5-point Likert scale (0–4), assessing symptoms experienced over the past seven days. It includes three subscales:

- **Intrusion (Re-experiencing):** Items 1, 2, 3, 6, 9, 14, 16, 20
- **Avoidance:** Items 5, 7, 8, 11, 12, 13, 17, 22
- **Hyperarousal:** Items 4, 10, 15, 18, 19, 21

Total scores range from 0 to 88, with higher scores indicating greater distress. The Turkish validity and reliability study was conducted by Çorapçıoğlu et al. (2006). The overall internal consistency coefficient was 0.94, with subscale coefficients of 0.88 (intrusion), 0.90 (avoidance), and 0.82 (hyperarousal), indicating high reliability.

### 3.5. Features of the Trauma-Informed Care-Based Chatbot

Large Language Models (LLMs) were examined for the development of the trauma-informed, artificial intelligence-supported chatbot. LLMs are artificial intelligence models trained on very large text corpora and capable of natural language understanding and generation. These models can perform a wide range of language tasks, including sentence completion, question answering, summarization, and translation.

For the development of the chatbot, various LLMs were compared based on multiple criteria, including Turkish language support, performance metrics, accuracy, recency of knowledge, context length, quantization efficiency, cost, and compliance with data protection regulations such as the Personal Data Protection Law (KVKK). Based on this evaluation, the Gemma 3 12B model developed by Google was identified as the most suitable model for this project.

A fine-tuning approach will be employed to adapt the model. Fine-tuning involves retraining a pre-trained large language model on a task-specific dataset, enabling the model to learn domain-specific knowledge and language use in addition to its general capabilities. In this study, a Retrieval-Augmented Generation (RAG)-compatible fine-tuning approach will be applied, allowing the model to more effectively utilize externally retrieved information. Through this method, the model is expected to develop the ability to retrieve relevant information, interpret it, and generate responses grounded in supporting evidence.

Retrieval-Augmented Generation (RAG) is a method that enables large language models to retrieve information from external data sources, such as literature reviews, databases, and clinical guidelines, prior to generating responses. In this approach, the model integrates both its pre-trained knowledge and up-to-date retrieved information when producing answers. Upon receiving a query, the model first performs a retrieval step to identify relevant documents.

In this project, responses will be generated based on documents that define Trauma-Informed Care (TIC) principles and psychosocial care approaches. These documents will be incorporated into the model's input context. The dataset used for response generation will be prepared in formats such as .txt, .pdf, JSON, or structured databases.

The dataset will consist of scientific articles, clinical guidelines, case examples, and research reports related to Trauma-Informed Care. Relevant literature will be systematically reviewed by the research team and compiled into a structured data repository for model training. This process will involve collaboration with a multidisciplinary team including expert nurses, mental health professionals, artificial intelligence developers, and user representatives.

The chatbot will be designed to provide empathetic, safe, and personalized responses, deliver support that is sensitive to traumatic experiences, and guide users toward professional support resources when necessary. The chatbot will not have the capability to make medical diagnoses or provide treatment recommendations, including advice related to medications, physical activity, or nutrition.

### **3.6. Study Procedure**

#### **3.6.1. Standard Care (Control Group)**

Participants in the control group will receive standard support services provided routine clinical care. Within this scope, consultation or psychosocial counseling services may be provided when needed. Participants will be able to contact the researcher via the provided phone number for any questions or support needs related to routine care.

#### **3.6.2. Intervention Applied to the Experimental Group**

Participants in the intervention group will be introduced to a trauma-informed, artificial intelligence-supported chatbot and will receive training on its use. At first use, participants will complete the sociodemographic information form and study scales online.

Participants in the intervention group will receive psychosocial support through the chatbot over a 12-week period. The chatbot will provide content based on trauma-informed care principles, including safety, choice, empowerment, collaboration, and cultural sensitivity. The content will include emotion regulation skills, coping strategies, psychoeducation, and guidance toward professional support when necessary; however, it will not provide medical or pharmacological recommendations.

The chatbot is designed as a free-text interaction system rather than a structured, module-based program. Therefore, frequency and duration of use may vary depending on individual participant needs. No fixed usage frequency or duration will be imposed; participants will be informed that they may use the system whenever needed.

#### **3.6.3. Data Collection**

Data will be collected from both groups at three time points: before the intervention (T0), and at the 1st and 3rd months post-intervention (T1 and T2).

### **3.7. Data Analysis**

Statistical analyses of the data obtained from the study will be performed using SPSS version 24.0 (IBM Corporation, Armonk, NY, USA). Descriptive statistics will be presented as frequencies and percentages for categorical variables, and as mean  $\pm$  standard deviation for continuous variables.

The normality of the data will be assessed using the Shapiro-Wilk test. For comparative analyses, repeated measures analysis of variance (MANOVA) will be used depending on whether the variables meet the assumptions of normal distribution. For other comparisons, independent samples *t*-test or Mann–Whitney *U* test will be used for between-group analyses, as appropriate.

Results will be evaluated at a 95% confidence interval with a significance level of  $p < 0.05$ .

In studies evaluating free-text, interaction-based psychological support chatbots, adherence to the intervention is typically assessed using engagement-based metrics such as number of messages, number of sessions, and number of active usage days. Accordingly, in this study, participants' interactions with the chatbot will be monitored through system logs. Minimum adherence to the intervention will be defined as engaging with the chatbot during at least six different weeks and sending a minimum of 20 user messages in total.

To assess the potential impact of usage intensity on study outcomes, quantitative chatbot usage data (total number of messages, number of active usage days, frequency of interaction) will be recorded and



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incorporated into the data analysis. This approach will allow methodological control for variations in intervention exposure across participants.

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## **Appendix 1-Informed Consent Form**

### **INFORMED CONSENT FORM**

#### **1) Title of the Study**

Evaluation of the Psychosocial Effects of a Trauma-Informed Artificial Intelligence-Supported Chatbot in Individuals Newly Diagnosed with Cancer: A Randomized Controlled Trial

#### **2) Nature of the Study**

This document has been prepared to obtain your voluntary consent to participate in a research study.

#### **3) Purpose of the Study**

The aim of this study is to evaluate the effects of a trauma-informed, artificial intelligence–supported chatbot on early psychosocial needs, as well as the usability and acceptability of the intervention in adults newly diagnosed with cancer.

#### **4) Duration of Participation**

Your total participation in this study will be up to 12 weeks.

#### **5) Study Procedures and Intervention**

Participants will be randomly assigned to one of two groups:

- **Intervention Group:** Chatbot + standard care
- **Control Group:** Standard care (no chatbot access during the study period)

Participants in the intervention group will use the chatbot via their digital device for 12 weeks.

#### **5) Reminders and Communication Preferences**

Participants will receive reminders via in-app notifications prior to assessment time points. These messages will not contain personal or health data and will be limited to date/reminder purposes.

Participants may withdraw or update their communication preferences at any time.

If a participant does not interact with the chatbot for 7 consecutive days, the research team may contact them to provide a reminder and check on their well-being. This contact will be solely for study-related reminders and, if necessary, guidance toward appropriate support resources. It will not involve any mandatory intervention. Participants have the right to refuse such contact.

#### **6) Possible Risks and Discomforts**

No physical risks are expected. However, you may experience emotional discomfort during conversations. In such cases, you may stop participation at any time, withdraw from the study, and be referred for professional support.

If deemed necessary, the principal investigator may contact the participant and refer them to the responsible physician.

## **7) Expected Benefits**

The chatbot may help reduce anxiety and psychosocial burden in the early period following diagnosis. However, direct clinical benefit cannot be guaranteed.

## **8) Alternative Options**

You may continue to receive routine psychosocial support services at your institution without participating in this study. Your decision not to participate will not affect your treatment.

## **9) Compensation, Insurance, and Costs**

Participants will not receive financial compensation. Travel, accommodation, and meal expenses will not be covered. No additional insurance specific to this study is planned; however, institutional responsibilities under applicable regulations remain valid. In case of any adverse event, you should contact the research team immediately.

## **10) Participant Responsibilities**

Participants are expected to:

- Complete assessment forms on time
- Use the chatbot according to their needs
- Report any adverse effects or negative experiences to the research team

## **11) Confidentiality and Data Protection**

Your identity will be protected using anonymized codes. Data will be stored in encrypted digital environments, and no identifying information will be included in publications.

Authorized monitors, ethics committees, and regulatory authorities may access your original medical records when required by law; all such information will remain confidential. Personal data will not be shared with third parties or transferred abroad. Data obtained through chatbot interactions will be anonymized and used solely for research purposes.

## **12) New Informations**

You will be informed in a timely manner if new information becomes available that may affect your decision to continue participation.

## **13) Contact Information**

For questions or reporting adverse events, you may contact:

**Principal Investigator:** XXX Phone: XXX Email: XXX

## **14) Voluntary Participation and Right to Withdraw**

Participation is entirely voluntary. You may withdraw from the study at any time, without providing a reason and without any loss of rights. To withdraw, please contact the principal investigator.

Participants also have the right to refuse reminder or well-being check communications.

## **15) Withdrawal by Researchers and Post-Study Access**

The research team may withdraw you from the study if continued participation is deemed inappropriate.

## **Consent Statement**

If you agree with the statements below, please sign:

“I have read and understood all the information provided in this informed consent form. I have received both written and verbal explanations regarding the study from the authorized researcher. I understand that my participation is voluntary and that I may withdraw at any time without providing a reason. I agree to participate in this study of my own free will, without any pressure or coercion.”

## **Participant**

Name and Surname:

Signature:

Date:

## **Researcher Providing Information**

Name / Title:

Signature:

Date: