



Current standing of PERSIST: Clinical studies

**Date 30th
June 2021**

WP6 Leader: UL (Institute of clinical and preventive medicine; University of Latvia)
Clinical partners: SERGAS, CHU, UKCM
Other partners: NPO, EMODA

PERSIST - Multicentre clinical study

Medical needs for the project

Project focuses on **breast and colorectal cancer survivors** after treatment. High incidence and survival rates, making up a relatively large survivor population whose follow-up can be improved.

Many cancer survivors have **unmet needs**, especially when it comes to improving the quality of life. Fear of cancer recurrence, late toxicity limitations, second diseases, nutritional disorders and the high levels of psychological distress, are generally not appropriately assessed in the guidelines in follow-up after treatment.

PERSIST offer the possibility of remote support and monitoring of patients.



PERSIST - Multicentre clinical study

mHealthApp will collect **objective markers** (vital signs) and **subjective markers** (PREMs/PROMs and symptoms of depression).

The clinical decision support system will enable oncologist to personalize treatment and care plans/follow-up for efficient management of patients.

Hypothesis: Performing a comparison at the beginning and at the end of the intervention, **participants will significantly increase their self-efficacy following the personalized intervention supported by the mHealthApp.**



PERSIST - Multicentre clinical study / summary description

The PERSIST multicenter clinical study involves four hospitals from different EU countries:

Country	Clinical Partner	Institution where patient involvement take place.
Latvia	UL (University of Latvia)	Riga East Clinical University Hospital (Latvian Oncology Center)
Belgium	CHU (Centre Hospitalier Universitaire De Liège)	Centre Hospitalier Universitaire De Liege
Slovenia	UMC (University Medical Centre Maribor)	University Medical Centre Maribor
Spain	SERGAS (Servizo galego de saude)	Complejo Hospitalario Universitario de Ourense



PERSIST - Multicentre clinical study

Design: A single-case experimental prospective study within each individual serve as its own control group with first measurement done prior to intervention, during recruitment and subsequent measurements done every 6 months during follow up.

	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
WP6: Multicentre clinical study												
T6.1: Clinical study requirements and approval										D6.1		
T6.2: Patient recruitment												
T6.3: Data collection and usability clinical study												
T6.4 Full clinical validations												
MS2 Clinical study approved by Ethical Committees										MS2		



PERSIST Multicentre clinical study

Achieved results

- Clinical study protocol, patients informed consent.
- Ethical committee approval (all countries).
- Hospital Ethics and Medical committee approval (where necessary).
- Training materials for patient recruitment:
 - informative brochure
 - user manual
 - smartband usage video.
- Training materials for clinical research staff and training.



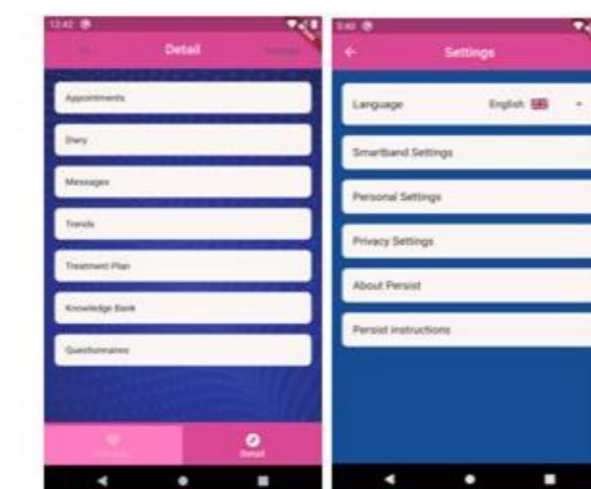
PROJEKT PERSIST:
Cilj projekta PERSIST je izboljšati kakovost življenja pacientov, ki so preboleli raka dojke ali raka debelega črevesa in danke (kolorektalni rak), z razvojem inovativnega ekosistema, ki deluje kot podpora zdravnikom pri sprejemanju odločitev. V okviru projekta bodo osebe prejele dve pametni napravi, ki zbirata podatke in omogočata stik z zdravnikom.

Osebe (v nadaljevanju sodelujoči), ki bodo vključene v pilotni projekt PERSIST, bodo prejele pametni telefon **Huawei Y6 2019** in **pametno zapestnico M4**.



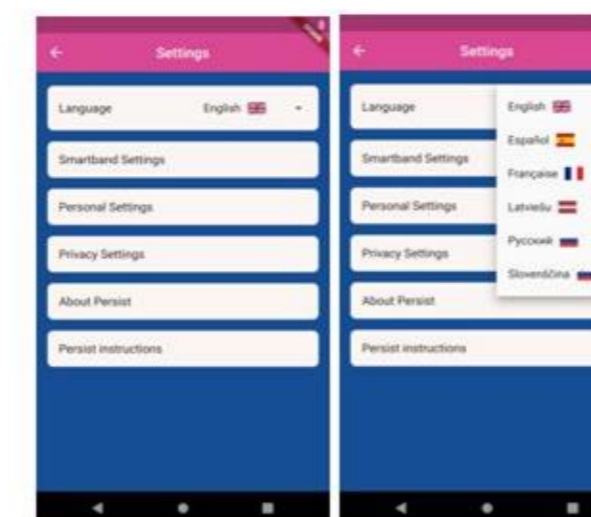
Sodelujoči lahko uporabljajo mobilno aplikacijo PERSIST mHealth in komunicirajo z zdravniki ter pametno zapestnico z uporabo telefona.

4.13 Display Settings



The **Settings** can be accessed by using the button on the top right corner of the Detail page. The Language Settings, SmartBand Settings, Personal Settings, Privacy Settings, About Persist and Persist Instructions will be displayed in this page.

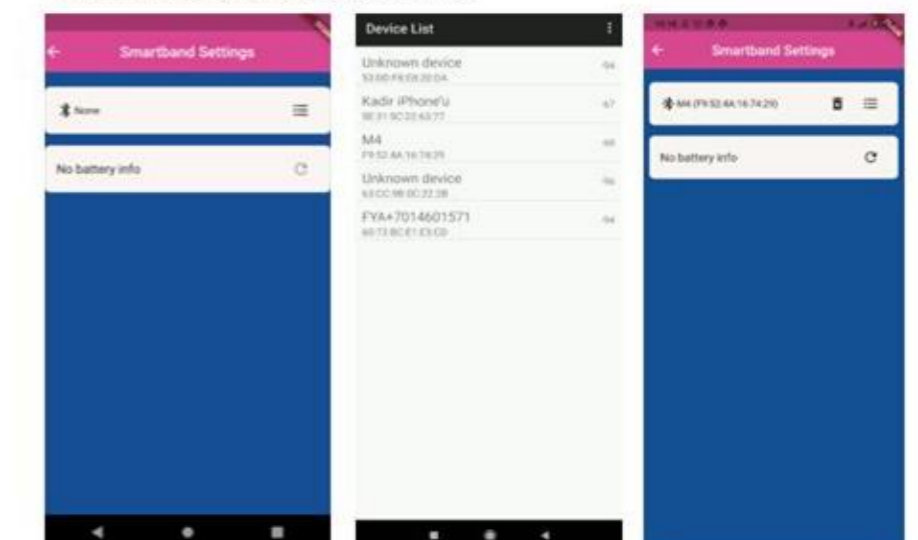
4.14 Language Settings



The user can display language options by using the arrow on the language section. The available languages will be listed as shown in the figure. Clicking on any of the languages will update the application language.

4.15 SmartBand Settings

4.15.1 Connect to Smart Band



In **SmartBand Settings** page, on click of "list icon" opens the device selection page. From that page, the user should choose his/her smart band to connect. By clicking on the related smart band name will connect the mobile phone to the band. Once the connection is successful, the connected smart band information is displayed on screen.

4.15.2 Display Smart Band Battery Information



PERSIST Multicentre clinical trial

80 patients who have survived breast cancer (C50) and 80 patients who have survived colorectal cancer (C18/C19). The population sample is split equally among four clinical pilots.

In 2 piloting countries (Slovenia, Spain), **80 individuals** will donate blood samples for **CTC counting**, recognized as new prognostic biomarkers.

Two subgroups (chemotherapy and non-chemotherapy). **At least 33%** of patients that have had **chemotherapy**.

General inclusion criteria

≥18 and ≤75 years old at the moment of recruitment.

Stable clinical situation.

Survive **without recurrence beyond 3-24 months after the end of treatment** (surgery ± radiation therapy ± chemotherapy)

Life expectancy of more than two years according to researcher opinion.

Ability to **understand study instructions**.

Fulfil **follow-up visits** and sign **informed consent**.

Enough **technology literacy** that enables the patient to manage with mobile terminals (smartphones, smartphone apps, tablets).

Good **cover to internet connection** in his/her place of residence.



General exclusion criteria

Life expectancy, under the physician opinion, of **less than one year**.

Diagnosis of **dementia** or **cognitive decline** that makes him/her **unable to understand study information and/or sign informed consent**.

Unable for self-management due to **dependence on other person** for medication compliance, or measuring blood pressure and daily weigh.

Lacking of decision capacity in relation with diet or preparing meals.

Current **participation in other clinical study**.

Patient has **no further follow-up possibilities** with enrolling investigation during planned study period (such as anticipated relocation).

Patients with **major depression, psychiatric medication** that hinders their daily activity.



PERSIST Multicentre clinical trial

Current status

- Patients recruited, signed consent form, PAM, CASE cancer questionnaires filled, received device set (smart bracelet, smart band).
- Feedbacks from patients are constantly obtained and used for improvement of system.
- Doctors can follow-up patients via mHealth clinicians app. For now it's possible to see heart rate, steps etc.

The screenshot displays the 'Patient List' interface. On the left, a list of patients is shown with IDs: emoda-86 (highlighted), emoda-88, emoda-87, emoda-85, emoda-84, emoda-83, emoda-82, emoda-81, emoda-80, and emoda-79. A '+ New patient' button is at the top. On the right, the 'General' information for patient emoda-86 is shown. It includes a note about privacy and the requirement to use Persist IDs. The Persist ID is emoda-86 and the Mobile App Pin Code is 353371. Personal details include Gender: Male, Birthdate: 5/2/1981, Ethnicity: European (ethnic group), Marital status: Never Married, Occupation/Job: Teacher, and Vital status: Alive. Physical metrics are Weight (kg): 91, Height (cm): 178, and BMI: 28.1. The Cancer type is listed as Breast cancer type. Below this is the 'Medical History' section, which includes a 'Family predispositions' dropdown with an 'Add >' button and a list of conditions, currently showing 'Diabetes Mellitus (father)'. At the bottom, there is a navigation bar with tabs for 'General and Medical History', 'Diagnosis and symptoms', 'Tests', 'Treatment', and 'Recurrent Tests'.



PERSIST Multicentre clinical trial

The key results expected

Increased self-efficacy of patients and satisfaction with care (measured by Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer) and Strengths Self-Efficacy Scale (SSES)). Self-efficacy has been highlighted as a protective effect for survivors who have higher perceived risk of recurrence.

Reduced psychological stress for a better management of the consequences of the cancer treatment and the disease, resulting in an **improvement in health and wellbeing**.

Faster integration into the labour market, where applicable.

Increased effectiveness in cancer treatment and follow-up by providing prediction models from Big Data that will support decision-making and contribute to optimal treatment decisions with positive consequences in the QoL and the health status of survivors;



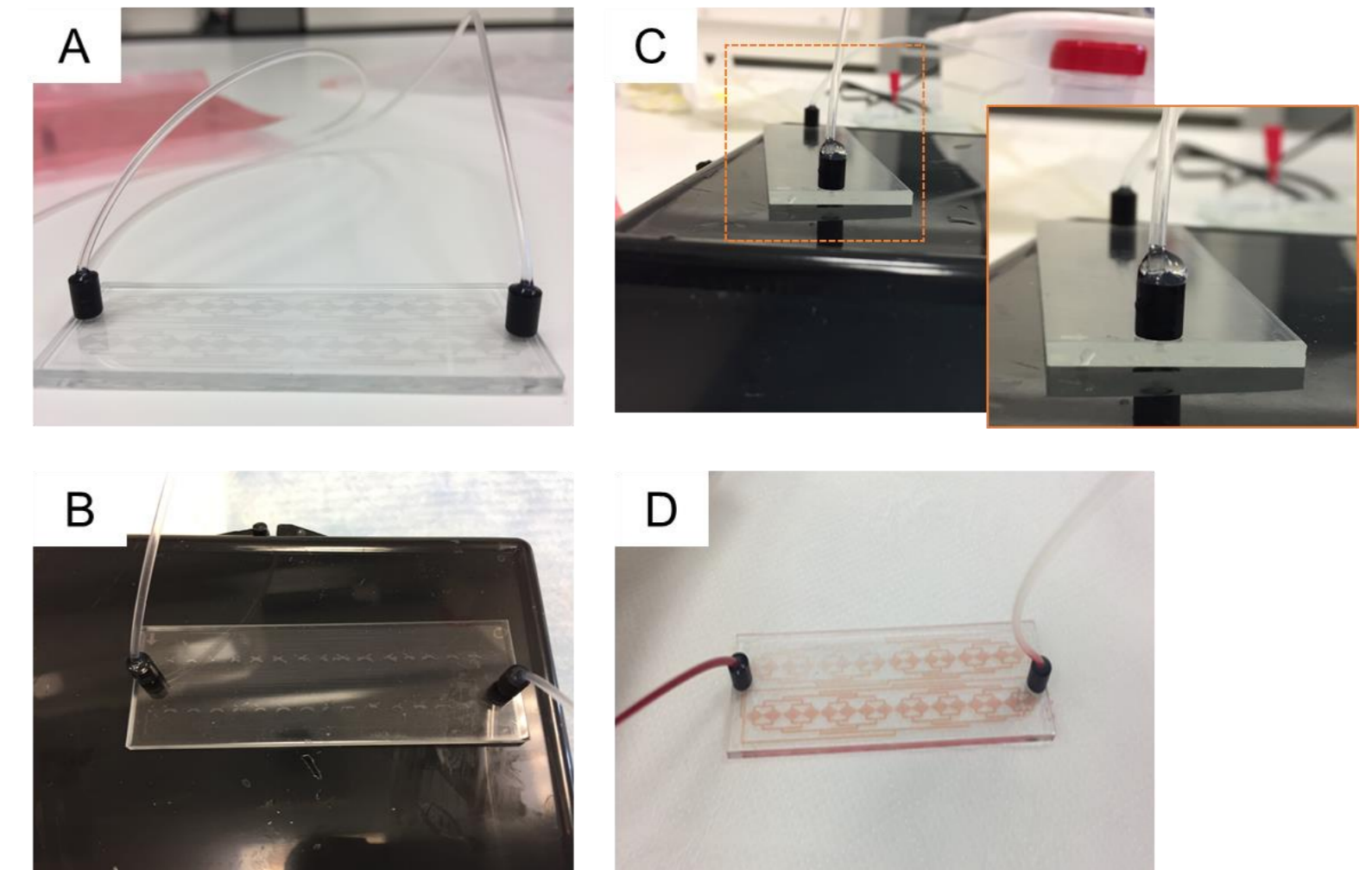
PERSIST Multicentre clinical trial

The key results expected

Improved information and evidence to **advance the efficacy of management, intervention and prevention policies/strategies** in order to **timely treat side effects** and, if possible, **avoid secondary diseases and fatal events**.

The long-term result will be to **reduce the socio-economic burden related to cancer survivors' care**.

Establish evidence on the use of to count circulating tumor cells in blood, analyzed using the RUBYchip technique to the follow-up of breast and colorectal cancer patients.



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