Approximately 5 million people in the European Union suffer from psychotic disorders. The largest group among them is that of schizophrenic patients, of which between 30-50% can be considered resistant to treatment. Standard intervention in patients with treatment resistant schizophrenia (TRS) is complex: i.e. presence of persistent positive symptomatology, extensive periods of hospital care, and greater risk of multi-morbidity. Up to date, standard treatment has not proven to be sufficient to achieve remission in resistant schizophrenic patients. Therefore, an improved understanding of TRS and the development of innovative evidence-based interventions adjunctive to pharmacological and psychosocial treatment are necessary.

The main objective of m-RESIST has been to develop an innovative disease management solution based on a mobile ICT system and an intervention program addressed to: i) integrate psychiatric and psychological assistance with other medical health-carers; ii) better monitors patients with resistant schizophrenia through a personalized and optimized therapeutic process; iii) promote acceptance and self-management of the disease and its co-morbidities; and iv) encourage the involvement of patients
and their caregivers in the therapeutic process.

During the project, requirements have been collected from patients, caregivers and professionals in Spain, Israel and Hungary. Design, development and testing has been performed to reach a final version of the m-RESIST system, which provides a new therapeutic process for TRS supported by a set of tools addressed to patients, caregivers and health professionals, which rely on a mobile app connected to a smartphone for patients, a web dashboard for clinicians, and one back-end system for management of data. This solution considers specific mHealth intervention modules specially designed for patients with TRS, divided in “basal modules” (Treatment Adherence, Healthy Lifestyle, and Symptom Management-CBTp) and “risk modules” (Symptom Management-Risk).

The conclusion of the m-RESIST project shows that new therapeutic interventions based on the use of mobile technologies have clearly a positive impact in the improvement of self-management of treatment-resistant schizophrenia, and the engagement of patients, caregivers and professionals. Acceptability and usefulness of the interventions and tools developed has been confirmed by the overall good results of piloting activities and the engagement of users. Furthermore, some areas of improvement have been identified, mainly related to the use of technology (smartwatches), the consistency of large dataset for further research, and the need for more rewarding feedback from the system to patients.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

Project Management tasks have provided a consolidated work and fluent communication between partners. Quality standards have been monitored and guaranteed by means of a clearly defined operational management and coordination structures.

During the user requirement activities, needs, wants and preferences of the system’s users (patients, family members and personal caregivers) have been identified by focus groups and interview-based methodologies. Also, an Ethical roadmap was developed to deploy and test the m-RESIST solution in the three piloting countries. Design and development tasks helped developing and integrating stand-alone components as a first Beta Prototype. After a pre-trial with healthy users for system adjustment, the m-RESIST Prototype V0 was built and tested with real patients. Performance results and user experience information was collected, used for the final refinement of the system, with the m-RESIST Prototype V1 as the final version.

The final m-RESIST solution developed is composed by: first, a mobile app installed in a smartphone connected to a smartwatch for patients and caregivers; second, a web-based dashboard for follow-up and monitoring for clinicians; and third, a back-end system for managing patient data, interventions and communication between patients, caregivers and clinicians (m-RESIST back-end system). The main modules developed are: a sensor module, the m-RESIST Information Repository, a Clinical Decision Support System (CDSS), a Recommender, a Predictive module and an Integration layer.
The piloting activities performed involved a total of 42 patients. Pilot results have shown acceptance of the tools and usefulness of the interventions designed. m-RESIST is seen as a complement for the usual treatment, and the therapeutic program helps patients to be more engaged and feeling “in contact” with their professionals. An effective communication with patients has helped towards a positive attitude of connectedness and reliability. Also, the three interventions and the psycho-educational content helped users towards better self-management of patient’s condition. Areas of improvement have been found, like the use and familiarity with the technology (smartwatch), user-rewarding feedback and consistency of data.

Finally, communication and dissemination activities have reached stakeholders from different target groups. Attendance to events was combined with the project website and Twitter account as channels of dissemination. The exploitation plan has provided an analysis of the current market to which m-RESIST is addressed, as well as a specific business approach to exploit the m-RESIST solution beyond the project duration. The three clinical partners have shown intention to keep using m-RESIST as a clinical tool, and a final IPR and exploitation agreement is being produced for further research and health practice in a sustainable way for local and international health ecosystems.

**Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)**

The final m-RESIST solution provides a therapeutic program supported by IT tools. This approach represents a new model for TRS attention and self-management, and goes far beyond existing healthcare processes and models. The final m-RESIST system developed is composed by a combination of three main technological parts, which operate under the interaction and information flows determined by two categories of mHealth clinical interventions.

The m-RESIST process allows training the patient and collecting personalized baseline information, like copying strategies, early warning signs, problem lists, interface language and the like. This personalized intervention can be useful to make patients feel more “connected” to their health professionals, without necessarily have an increased number of fate-to-face visits.

m-RESIST is mainly seen as a full-service solution including technology and clinical services, which also includes the possibility to incorporate 3rd party services to existing health systems. The personalization capabilities of m-RESIST offer the possibility to build business models approaches towards patient-centred care, linked to the analysis of big data sets and the optimization of resources by analysing clinical outcomes and patient satisfaction.
WHAT IS SCHIZOPHRENIA?

Schizophrenia is a complex multifaceted mental illness that features neurotic, negative, affective, and delusional symptoms. 

- Hallucinations
- Delusions
- Disorganization
- Isolation