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Research and Innovation action

# Mobile Therapeutic Attention for Patients with Treatment Resistant Schizophrenia


Mobile Therapeutic Attention for Patients
with Treatment Resistant Schizophrenia

# Deliverable 1.4 – M36
# Final Project Report including Overall Assessment

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## Authors

| Date | Name | Partner |
|---|---|---|
| **Document leader** | TicSalut | TICSALUT |
| **Participants** | | |
| | Margarita Hospedales | TICSALUT |
| | Elisenda Reixach | TICSALUT |
| | Jesús Berdún | TICSALUT |
| | Margarita Hospedales | TICSALUT |

## Document History

| Date | Version | Author | Change | Status |
|---|---|---|---|---|
| 11/12/2017 | 0.0.1 | Jesús Berdún | Outline and first proposal | Draft |
| 02/02/2018 | 1.0.0 | Margarita Hospedales, Jesús Berdún, Eli Reixach | Final review and harmonisation | Final |
| 05/02/2018 | 2.0.0 | Jesús Berdún | Public version | Final |

# Table of Contents



# Index of Tables

# 1 Introduction

## 1.1 Purpose

The purpose of this deliverable is to provide an activity progress and management report including a qualitative and quantitative assessment of the project results.

## 1.2 Document structure

The document structure is as follows:

- Section 1 is the introduction
- Section 2 provides a technical report, including: overview of results, objectives and conclusions; work performed; and progress beyond the state of the art
- Section 3 provides an overall quantitative and qualitative assessment of results
- Section 4 provides conclusions of the action

# 2 Technical report

## 2.1 Overview of results, overall objectives and conclusions of the action

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.

Intervention strategies based on m-Health have demonstrated their ability to support and promote self-management-based strategies. 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.

Through the different project activities, requirements have been collected from focus groups with patients, caregivers and professionals in the three piloting countries: Spain, Israel and Hungary. After different rounds of design, development and testing (internal, healthy users and real users), a final version of the m-RESIST system has been achieved, which provides not only an ICT-based tool, but also new therapeutic process for TRS. The final m-RESIST solution provides 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” oriented to develop abilities in the patient (Treatment Adherence, Healthy Lifestyle, and Symptom Management-CBTp); and “risk modules” oriented to deal with specific problems, especially in risk situations (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), and the need for more rewarding feedback from the system to patients.

## 2.2 Work performed

Project Management tasks have provided a consolidated work and fluent communication between partners, allowing the identification of conflicting issues, setting up mitigation measures, arranging planned and unplanned meetings, monitoring time and quality-compliant achievement and submission of high quality deliverables. Quality standards have been monitored and guaranteed by means of a clearly defined operational management and coordination structures.

During the "User requirements and Healthcare routes" work package, needs, wants and preferences of the system' users have been identified. An Ethical Roadmap was developed, guiding the legal and ethical requirements to deploy and test the m-RESIST solution in the three countries conducting the pilots. Also, an analysis of end user needs, requirements and preferences (patients, family members and personal caregivers) was conducted by using focus groups and interview-based methodologies. As a result, innovative healthcare routes were described, as well as a definition of functional and non-functional requirements and components.

The main activities of design and development were executed. First, design and development of stand-alone components was conducted. Second, all modules were integrated, providing a first Beta Prototype to be tested by healthy users. Finally, a pre-trial was conducted with healthy users for system adjustment. Out of this first test, improvements were identified, as well as functionalities adjusted. The outcomes of the pre-trials led to the m-RESIST Prototype V0, the version to be tested with real patients. During the test 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, with 32 patients completing the full intervention study. Pilot results and testing activities with users have shown acceptation 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 different aspects covered by the three interventions (lifestyle, adherence, symptoms) and the psycho-educational content help patients, caregivers and professionals to have better tools for self-management of the patient's condition.

Regarding areas of improvement different aspects have been found, like the use and familiarity with the technology (smartwatch). Data gathered from the devices showed in some cases gaps of information, which makes data analytics less consistent. User engagement and training is essential to ensure good quality of data. User feedback has also been another area of improvement, as users felt sometimes that the system lacks more rewarding messages. Notifications are sent to users according to their interaction

with the feedback, but mostly to collect information from the patient, rather than to reward or send other useful information. From the total of drop-outs of the project (10/42), most of them were caused by cultural stigma, distrust on IT or stigma of wearing the devices (7). The rest were mental worsening (2, adverse events) not directly related to m-RESIST and lack of interest in the project (1). For the rest of users, clinicians dedicated added effort to explain about which information is collected by m-RESIST, by showing them the web-dashboard, so patients felt more confident about the use of this information for their treatment.

Communication and dissemination activities have reached stakeholders from different target. Apart from the attendance to different events and workshops, the project website and Twitter account have been another channel used throughout the project duration to host the needs of our targeted stakeholders to find information about the project deliveries and news related to our activities the last three years.

Finally, 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. Provided the will of the three clinical partners involved in the pilots to keep using m-RESIST as a clinical tool, the m-RESIST consortium is working on a final IPR and exploitation agreement to keep using the system for research and health practice while ensuring economic sustainability and scalability in local and international health ecosystems.

## 2.3 Progress beyond the state of the art

m-RESIST aimed to provide an innovative solution for the self-management and attention to treatment resistant patients. The solution envisioned was composed by two elements, the m-RESIST system, including all technical components, and the m-RESIST therapeutic program, as the basis for the clinical intervention pathways. 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.

Regarding the impact of strengthened evidence and improved knowledge about individuals' behaviour related to wellbeing, disease prevention or management facilitating the creation of new personalised behavioural health interventions, the m-RESIST therapeutic process starts with a "pre-intervention period" which aims to recruit the patient, collect information for the patient schema, train the patient in the use of the technical devices and collect 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. Personalized interventions available allow patients to better know their condition (through the pre-intervention and baseline assessment), as well as to identify early warning signs and coping strategies. Combination with other tools outside the m-RESIST system (like videoconferencing) has shown a good attitude from most patients towards new mHealth interventions.

Considering the improve service offering, m-RESIST is mainly seen as a full-service solution including technology and clinical services, which also includes the possibility to incorporate services as

"independent services", as they provide value on their own, like the symptoms management intervention, treatment adherence intervention, healthy lifestyle intervention, prediction alerts, sensor data analysis, mobile-based assessments, Psychoeducation and services for other severe mental health disorders. 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. As future research activities, more effort should be invested in building a larger dataset related to TRS patients, in order to improve the predictive model built in the project, and to perform further evidence in cost-effectiveness of mHealth interventions.

The m-RESIST therapeutic process, in combination with the m-RESIST tools, allows an early detection of signs and severe episodes. The combination of the CDSS, the predictive model and the recommender, based on information collected by the sensor module and stored in mIR, allow the interaction with the user on a daily basis, and helps to detect deviations from the baseline of each patient (personalization). The piloting activities has been performed over a relatively short period of time (3 months), considering a chronic disease such as TRS. However, during that time there has been evidence that a better control of the disease may lead to a decrease in the number total of severe episodes, considering the complexity of treatment-resistant patients.

Therefore the main success factors that can be identified are related to the development of a tool, validated in three different health ecosystems, which helps and promotes participants' engagement, monitors achievements and milestones, and assesses risks and alternatives. Patient's receptiveness has been one of the major concerns to achieve the project's results through different methods (focus groups, workshops, and pilots), involving clinicians, patients and caregivers by explaining the benefits of the project, making them "part of the team", and emphasizing their role as "testers" and the importance of their feedback towards a more patient-centred care.

## 2.4 Next steps beyond the project

Given the results of the piloting activities in the three pilot sites (Hungary, Israel, Spain), the three pilot partners (SEMMELWEIS, GERTNER and IR-HSCSP) have already expressed their will to keep using the m-RESIST system after the projects ends, and to keep monitoring some of the patients, specifically those who have had more positive outcome from participating in the project. To this regards, technical partners have verbally expressed to keep the system available and running, with minor bug fixing for 2018. In order to fix the conditions for this Operation & Maintenance services for 2018, an agreement is currently being defined by the m-RESIST consortium, which is not finished by the time of submitting this deliverable.

Regarding the further exploitation of results, and considering "Product Licensed" as the most suitable approach, the m-RESIST consortium is currently working on a "JOINT OWNERSHIP AND EXPLOITATION AGREEMENT", which will establishing the allocation of ownership over the Joint Results, as well as the framework for the protection, defence, assumption of costs and exploitation thereof. This document is

currently undergoing by the time of submitting this deliverable, and it is planned to be finished within six months after the end of the project. This agreement constitutes a first step for the commercialization of the m-Resist product.

In the specific case of TICSALUT as Project Coordinator, and given its role as part of the Catalan Health Ministry, action are already being performed to exploit the outcomes of m-RESIST, for the definition of a telemonitoring model for healthcare services in Catalonia. All the lessons learned and materials produced in the project, both related to the three therapeutic interventions defined and the IT tools developed will be used as a reference to assess the Catalan Health Ministry about new eHealth and mHealth care models as part of the healthcare services provided to the Catalan population.

# 3 Overall assessment

## 3.1 Methodology

The methodology used for the overall assessment of the project is based on measuring the outcomes of the project, both in terms of project execution and results produced. Given that, both quantitative and qualitative aspects have been assessed, considering as a reference the Project Management Plan defined in D1.1.

TICSALUT, as project coordinator, set the Project Management Plan at the beginning of the project, specifying the procedures for project execution, ensuring quality of outcomes and good communication among the consortium, as well as with the EC and other relevant stakeholders. Measures to ensure quality of work and deliverables have been put in place and defined within the Project Management Plan, which included a communication plan and a quality management plan.

This section provides the results of the overall assessment, which include quantitative and qualitative results. Regarding qualitative results, the aspects assessed have been the following:

- Overall project management and quality of results: measures the accomplishment of project management and coordination within the consortium
- Design and development activities: assesses the activities related to gathering requirements, designing the solution and developing the different modules of m-RESIST and therapeutic interventions
- Piloting activities and evaluation: measure the results of pilots in the three countries and the evaluation process
- Exploitation and business: evaluates the results of the different exploitation and business activities

Regarding the quantitative results we have assessed:

- Deliverables and milestones produced and achieved
- Meetings performed
- Dissemination activities
- Use of resources during the project and financial aspects

## 3.2 Qualitative results

**Project management and quality of results**

The overall project coordination has been performed according the methodology and procedures defined in D1.1 Project Management Plan. The management structure composed by the project coordinator (TICSALUT), the Technical Leader (IMEC) and the Clinical Leader (IR-HSCSP) has helped to ensure an overall good coordination among partners from different backgrounds. Different communication and document repository tools have been used throughout the project, adapting their

use to the specific needs of partners, and the particular objectives of each WP (MyMinds platform, Dropbox, GoogleDocs, JIRA, Slack, GoToMeeting). The procedures established for deliverable production and submission have been generally followed by all partners, ensuring a good quality of results. No major delays have occurred during the project, and the proper mitigation tools have been put in place when required, mitigating the effect of delays in the achievement of project's objectives.

**Requirements, Design and Development activities**

In general, the tasks related to needs and requirements gathering have been performed with good results. Users involved in the focus groups participated with a positive attitude towards the project, thanks to the active involvement and willingness of the clinicians from the three piloting countries. Once the requirements where gathered, design of the project started. **The transition from requirements to system design has been one of the main challenges of the project, due to the complexity to translate clinical requirements to system specifications, and the multi-disciplinary approach required. On the one hand, clinical partners lacked a deep knowledge about the capabilities of IT tools considered for the project (smartwatch, sensors, mobile apps), added to the complexity inherent to the TRS condition. On the other hand, technical partners were not knowledgeable about TRS, and the mental health implications of TRS patients interacting with technology. Defining new therapeutic interventions for TRS, with the support of mobile IT tools, has been the major challenge that the m-RESIST consortium has overcome.** Through different approaches (face-to-face meetings, remote conferences, workshops, hackatons, testing and evaluation), all partners have put together their knowledge to build the m-RESIST solution. Once the development of the different modules started, more discussions were held about changes and how to advance with development tasks. Through templates and mock-ups, technical partners started collaborating with clinicians, in order to finalize the specifications of each of the m-RESIST modules. Regarding m-RESIST therapeutic interventions, a huge effort was spent on defining the different workflows and their interaction with the IT tools.

**Piloting activities and evaluation**

Piloting activities, including both healthy users and real users, have been performed according to the updated plan presented during the 1st Periodic Review. Given that, due to delays in system specification, pilot overlap was introduced, in order to maintain project's results. In order to minimize the impact of pilot overlapping, early involvement of users and more effort has been spent in user engagement in the three piloting sites: Hungary, Israel and Spain. In general, the results obtained from the pilots has been satisfactory, although more time for piloting would have allowed more in deep results and a larger database of sensor data to correlate with clinical outcomes.

**All piloting partners and technical partners have provided the effort to implement piloting activities, despite the difficulties to integrate the work between the technical team and clinical team from different countries. Although all functionalities were tested by each technical partner responsible, testing of integrated functionalities into the pilot context was difficult, due to the complex interaction between components and the clinical interventions. Clinical workflows were update during and after healthy users' pilots and real pilots, in order to implement and test improvements only detected with real patients, due to the limited time for testing and system improvement. Thanks to the approach followed by clinicians, by engaging users as an essential part of system development and**

**improvement, pilots have provided very relevant information regarding acceptability, usability and further lines of research and innovation in both mental health and IT fields.**

Regarding the evaluation of results, in general the project has provided very relevant knowledge about TRS and the use of mobile tools for self-management of the condition and the involvement of patients, caregivers and professionals. Although the amount of data is rather small (collected from 42 real users), and not in all cases consistent (gaps have been identified in users about sensor data), m-RESIST has set the baseline and the tools for a wide research trial with a larger set of users and a longer time for observation.

**Exploitation and business**

As mentioned before, the three pilot sites, pilot partners have expressed their will to keep using the m-RESIST system after the projects ends, and to keep monitoring some of the patients, specifically those who have had more positive outcome from participating in the project. The on-going agreements of "Operation & Maintenance of m-RESIST for 2018" and the "Joint Ownership and Exploitation Agreement" are indicators of future opportunities of exploitation for the m-RESIST results. Also, **pilot partners have expressed their intention to look for further opportunities and exploitation options for the implementation of activities towards the validation of m-RESIST with a larger set of users, in order to complement the current clinical database created and knowledge related to TRS condition.**

The list of identified m-RESIST exploitable assets and their percentage over the whole m-RESIST resulting platform is as follows (percentages have been selected according the relevance of the project):

| List of assets | Relevance % over m-RESIST system as a whole |
|---|---|
| 1. m-RESIST Clinical Interventions | 40% |
| 2. m-RESIST User Interfaces | 25% |
| 3. m-RESIST Modules | 25% |
| 4. m-RESIST Clinical Database | 10% |
| **TOTAL** | **100%** |

1. **m-RESIST interventions**: clinical interventions defined to determine the flow of information and interactions between the user and the system. Interventions are split into two categories:
   (a) Basal modules, oriented to develop abilities in the patient:
      - Treatment Adherence
      - Healthy Lifestyle, and
      - Symptom Management-CBTp,

   (b) Risk modules:
      - Symptom Management-Risk

2. **m-RESIST user interfaces: main user interfaces developed which allow users to interact with the** system. The main user interfaces are:
    (a) Mobile App
    (b) Web-based Dashboard

3. **m-RESIST modules:** individual components of the m-RESIST system, which are interconnected and constitute the core of the overall functioning of the system:
    (a) CDSS
    (b) mIR
    (c) Recommender
    (d) Predictive Module
    (e) Sensor Analysis
    (f) Integration Layer

4. **m-RESIST clinical database:** constitutes the final database with all data collected in the three pilot sites (Spain, Israel and Hungary) and the information uploaded by clinicians in the dashboard:
    (a) User data in the pilot sites
    (b) Dashboard content

## 3.3 Quantitative results

**Deliverables and milestones**

37 deliverables submitted:

- 30 reports
- 3 demonstrators
- 3 other
- 1 website

| Deliverable list | Contractual delivery month | Submission month |
|---|---|---|
| D1.1 – Project Management and Quality Plan | M02 | M02 |
| D1.2 – Period 1 Activity Progress and Management report | M18 | M20 |
| D1.3 – Period 2 Activity Progress and Management report | M36 | M37 |
| D1.4 – Final Project Report including Overall Assessment | M36 | M37 |
| D2.1 – Ethical Roadmap | M04 | M04 |
| D2.2 – m-RESIST definition of user requirements | M6 | M06 |
| D2.3 – m-RESIST services and care pathways | M6 | M06 |
| D2.4 – m-RESIST system requirements | M6 | M07 |
| D3.1 –Front-end design specification | M11 | M16 |

| | | |
|---|---|---|
| D3.2 – Back-end design specification | M11 | M16 |
| D3.3 – Integration layer design specification | M11 | M16 |
| D3.4 – Front-end beta prototype | M19 | M23 |
| D3.5 – Back-end beta prototype | M19 | M23 |
| D3.6 – Integration layer beta prototype | M19 | M23 |
| D3.7 – mRESIST Beta prototype | M22 | M27 |
| D3.8 – mRESIST PrototypeV0 | M24 | M30 |
| D3.9 – mRESIST prototype V1 | M34 | M35 |
| D4.1 Definition of the Pre-trial phase with healthy users | M23 | M27 |
| D4.2 Pre-trial: m-RESIST system readiness evaluation | M24 | M30 |
| D5.1 – Pilot Definition: design of study protocol and evaluation approach | M21 | M23 |
| D5. 2 – Psychoeducational training document regarding m-Resist devices for patients and caregivers | M23 | M29 |
| D5.3 – List of recruited patients | M29 | M32 |
| D5.4 – Pilots results and m-RESIST system improvement | M33 | M36 |
| D5.5 – Copies of Ethical approvals | M23 | M27 |
| D6.1 – Clinical impact evaluation report | M34 | M37 |
| D6.2. Satisfaction and acceptability of interfaces in m-RESIST by end users | M34 | M37 |
| D6.3. Economic evaluation report | M34 | M37 |
| D6.4. Organizational impact of the application of m-RESIST | M34 | M37 |
| D6.5 – Lessons learned, guidelines and requirements for future deployment of m-RESIST | M36 | M37 |
| D7.1 – m-RESIST website | M03 | M03 |
| D7.2 – Communication Plan | M06 | M06 |
| D7.3 – First Report on Dissemination Activities | M12 | M12 |
| D7.4 – Second Report on Dissemination Activities | M24 | M24 |
| D7.5 – Third Report on Dissemination Activities | M36 | M36 |
| D7.6 – Training Activities Report | M30 | M31 |
| D7.7 – Exploitation and Business Plan (preliminary) | M18 | M19 |
| D7.8 – Exploitation and business Plan - Final | M35 | M37 |

**Table 1. List of deliverables**

| Milestones | Contractual delivery month | Submission month |
|---|---|---|
| MS01 m-RESIST Kickoff | M01 | M01 |
| MS02 User requirements are identified and new healthcare routes are defined | M06 | M06 |
| MS03 End of main development and integration activities | M20 | M23 |
| MS04 m-RESIST Beta Prototype is ready | M22 | M27 |
| MS05 m-RESIST V0 is ready | M24 | M29 |
| MS06 Begin of Field Trials with Real Users | M25 | M29 |

| | | |
|---|---|---|
| MS07 End of Field Trials with Real Users | M33 | M36 |
| MS08 m-RESIST Prototype V1 is ready | M34 | M35 |
| MS09 Business Model for m-RESIST has been defined | M35 | M36 |
| MS10 Evaluation of m-RESIST have been done and next steps are defined | M36 | M36 |
| MS11 End of m-RESIST project | M36 | M37 |

**Table 2. List of milestones**

## Meetings

25 meetings held:

- 6 General Assembly meetings
- 3 project reviews
- 16 WP meetings

| Meeting Name | Date | Location | Purpose and Outcome | Partner(s) involved |
|---|---|---|---|---|
| 1st General Assembly, Kick-Off Meeting | 29/01/15 - 30/01/15 | Barcelona, Spain | Kick-Off meeting for m-RESIST Project. | All partners |
| 2nd General Assembly | 02/06/15 – 03/06/15 | Barcelona, Spain | Overall project follow-up and on-going tasks review. | All partners |
| WP 2 and 3 meeting | 11/06/2015 | Israel | System's technical discussions based on WP2 results | IMINDS, GERTNER |
| WP3 General Meeting | 21/10/15 – 22/10/15 | Ghent, Brussels | WP3 follow-up and on-going tasks review. | WP3 partners |
| WP3 General Meeting | 17/11/15 | Athens, Greece | WP3 follow-up and on-going tasks review. | WP3 partners |
| 3rd General Assembly | 27/01/16 – 28/01/16 | Tel-Aviv, Israel | Overall project follow-up and on-going tasks review. | All partners |
| WP3 Meeting, CDSS Workshop | 19/04/16 – 20/04/16 | Barcelona, Spain | WP3 follow-up and on-going tasks review. | WP3 partners and OULUN YLIOPISTO |
| WP1 Meeting | 20/04/16 | Barcelona, Spain | WP1 follow-up and on-going tasks review. | TICSALUT, IR-HSCSP, iMINDS |
| WP Leaders Meeting | 07/06/16 | Oulu, Finland | Project review preparation. | WP Leaders |
| 4th General Assembly | 08/06/16 – 09/06/16 | Oulu, Finland | Overall project follow-up and on-going tasks review. | All partners |
| WP3 General Meeting | 12/07/16 – 13/07/16 | Barcelona, Spain | WP3 follow-up and on-going tasks review. | WP3 partners |
| WP3 General Meeting | 12/07/16 – 13/07/16 | Barcelona, Spain | WP3 follow-up and on-going tasks review. | WP3 partners |

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|---|---|---|---|---|
| 1st Period Review Meeting | 04/10/16 - 06/10/16 | Brussels, Belgium | Preparation and review of 1st Period outcomes with the European Commission | EC, m-RESIST Consortium |
| WP3 Hackaton | 21/11/16 – 23/11/16 | Barcelona, Spain | WP3 activities towards final integration of m-RESIST modules and Beta Prototype development. | WP3 Partners, TCC |
| WP3 Predictive Model | 20/12/16 | Barcelona, Spain | WP3 activities regarding development of Predictive Model. | IBM, IR-HSCSP, TICSALUT |
| Integration Days | 17/01/17 – 19/01/17 | On-line | WP3 activities towards final integration of m-RESIST modules and Beta Prototype finalization. | WP3 Partners |
| 5th GA Meeting | 06/02/17 – 08/02/17 | Budapest, Hungary | Overall project follow-up and on-going tasks review. Development status and update of WP5 pilot planning. Review on exploitable assets. | m-RESIST Consortium |
| EC DEMO Meeting | 23/05/17 | On-line | Remote review requested by the EC. Feedback for future work and next activities. | TCC, IBM |
| WP5, WP6 Meeting | 04/09/17 – 05/09/17 | Barcelona, Spain | WP5 and WP6 activities review, agreement on WP5, WP6 pending deliverables content and planning. | WP5, WP6 Partners |
| Exploitation plan | 02/10/17 | Barcelona, Spain | Discussion on the exploitable options for further use of m-RESIST beyond the project. Exploitation plan review and discussion. | TICSALUT, IBM |
| 6th GA Meeting | 16/10/17 – 18/10/17 | Barcelona, Spain | Overall project follow-up and on-going tasks review. Status of piloting activities, evaluation and last system updates. | m-RESIST Consortium |
| Pre-review and Final Review | 19/02/18 – 19/02/18 | Brussels, Belgium | Preparation and review of 2nd Period outcomes with the European Commission and Final Review | EC, m-RESIST Consortium |

**Table 3. List of project meetings**

## Dissemination activities

Publications (22):

- 12 congress abstracts
- 9 articles in journals
- 1 conference paper

| | Type | Title | Authors | Journal | DOI |
|---|---|---|---|---|---|
| 1 | Congress abstract | **Somatic comorbidity and its outcomes in schizophrenia during lifespan** | J. Seppala, H. Korpela, E. Jääskeläinen, J. Miettunen, M. Isohanni, J. Auvinen, T. | European Psychiatry | 10.1016/j.eurpsy.2016.01.870 |

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|---|---|---|---|---|---|
| | | | Nordström, R. Marttila, S. Keinänen-Kiukaanniemi, M.R. Järvelin, H. Salo, N. Rautio | | |
| 2 | Congress abstract | **Treatment-resistant schizophrenia during life span: Epidemiology, outcomes and innovative M-Health treatments within M-RESIST Project** | K. Rubinstein | European Psychiatry | 10.1016/j.eurpsy.2016.01.869 |
| 3 | Congress abstract | **What do we know about treatment-resistant schizophrenia? – A systematic review** | A. Seppälä, J. Miettunen, N. Hirvonen, M. Isohanni, J. Moilanen, H. Koponen, J. Seppälä, E. Jääskeläinen | European Psychiatry | 10.1016/j.eurpsy.2016.01.2175 |
| 4 | Congress abstract | **Definition, epidemiology, clinical course and outcomes in treatment-resistant schizophrenia** | Seppälä Jussi, Miettunen Jouko, Jääskeläinen Erika, Isohanni Matti, Seppälä Annika, Koponen Hannu, m-RESIST Group | European Psychiatry | 10.1016/j.eurpsy.2017.01.070 |
| 5 | Congress abstract | **Emerging sensor-based m-health interventions in the assessment of psychotic symptoms** | Bulgheroni, M. | European Psychiatry | 10.1016/j.eurpsy.2017.01.071 |
| 6 | Congress abstract | **Identifying service and care needs from the users' perspective in treatment-resistant schizophrenia** | Rubinstein, K. | European Psychiatry | 10.1016/j.eurpsy.2017.01.072 |
| 7 | Congress abstract | **m-RESIST project as an example of m-health approach in schizophrenia: Content, aims and realization** | Corripio, I. | European Psychiatry | 10.1016/j.eurpsy.2017.01.073 |
| 8 | Congress abstract | **Treatment-resistant and difficult-to treat schizophrenia as a challenge for clinical practices. Data from Finnish samples: Northern Finland Birth Cohort 1966 and Perfect** | Seppälä Jussi, Seppälä Annika, Isohanni Matti, Miettunen Jouko, Jääskeläinen Erika | Eur Arch Psychiatry Clin Neurosci | 10.1007/s00406-017-0824-8 |
| 9 | Congress abstract | **Predictors of response in treatment-resistant schizophrenia: a meta-analysis** | A. Seppälä, J. Miettunen, M. Isohanni, A. Ahmed, E. Grasa, I. Corripio, H. Koponen, J. Seppälä ,E. Jääskeläinen | Eur Arch Psychiatry Clin Neurosci | 10.1007/s00406-017-0824-8 |
| 10 | Congress abstract | **Predictors of functioning improvement in difficult-to-treat schizophrenia** | Kinga Farkas | Eur Arch Psychiatry Clin Neurosci | 10.1007/s00406-017-0824-8 |

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| 11 | Congress abstract | **mRESIST, an innovative m-health tool addressed to improve humanistic burden in difficult-to-treat schizophrenia** | Iluminada Corripio | Eur Arch Psychiatry Clin Neurosci | 10.1007/s00406-017-0824-8 |
| 12 | Congress abstract | **Somatic comorbidity and its outcomes in schizophrenia during lifespan** | J. Seppälä, Oulu, Finland M. Isohanni, E. Jääskeläinen, J. Miettunen, T. Nordström, J. Auvinen, N. Rautio | European Archives of Psychiatry+Clinical Neuroscience | N/A |
| 13 | Article in Journal | **Prognosis Of schizophrenia spectrum disorder may not be predetermined during early development – the Norther Finland Birth Cohort 1966** | Nina Rautio, Juha Käkelä, Tanja Nordström, Jouko Miettunen, Sirkka Keinänen-Kiukaanniemi, Leena Ala-Mursula,Jaro Karppinen, Matti Penttilä, Erika Jääskeläinen | Schizophrenia Research | 10.1016/j.schres.2016.02.038 |
| 14 | Article in Journal | **What do we know about treatment-resistant schizophrenia? A systematic review** | Annika Seppälä, Conrad Molins, Jouko Miettunen, Noora Hirvonen, Iluminada Corripio, Teija Juola, Matti Isohanni, Hannu Koponen, Jani Moilanen, Jussi Seppälä, Erika Jääskeläinen and m-RESIST GROUP | Psychiatria Fennica 2016 | N/A |
| 15 | Article in Journal | **Measuring Users' Receptivity Toward an Integral Intervention Model Based on mHealth Solutions for Patients With Treatment-Resistant Schizophrenia (m-RESIST): A Qualitative Study** | Elena Huerta-Ramos, Maria Soledad Escobar-Villegas, Katya Rubinstein, Zsolt Szabolcs Unoka, Eva Grasa, Margarita Hospedales, Erika Jääskeläinen, Elena Rubio-Abadal, Asaf Caspi, István Bitter, Jesus Berdun, Jussi Seppälä, Susana Ochoa, Kata Fazekas, M-RESIST Group, Iluminada Corripio, Judith Usall | JMIR mHealth and uHealth | 10.2196/mhealth.5716 |
| 16 | Article in Journal | **Response to antipsychotic drugs in treatment-resistant schizophrenia: Conclusions based on systematic review** | C. Molins, A. Roldán, I. Corripio, M. Isohanni, J. Miettunen, J. Seppälä, A. Seppälä, H. Koponen, J. Moilanen, E. Jääskeläinen, m-RESIST Group | Schizophrenia Research | 10.1016/j.schres.2016.09.016 |
| 17 | Article in Journal | **Do adverse perinatal events predict mortality in schizophrenia during midlife?** | Nina Rautio, Jouko Miettunen, Erika Jääskeläinen, Tanja Nordström, Matti Isohanni, Jussi Seppälä | Schizophrenia Research | 10.1016/j.schres.2016.09.031 |
| 18 | Article in journal | **Age at onset and the outcomes of schizophrenia: A systematic review and** | Immonen J, Jääskeläinen E, Korpela H, Miettunen J. | Early Intervention in Psychiatry | 10.1111/eip.12412 |

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| | | **meta-analysis** | | | |
| 19 | Article in journal | **Association between family history of psychiatric disorders and long-term outcome in schizophrenia – The Northern Finland Birth Cohort 1966 study.** | Käkelä J, Marttila R, Keskinen E, Veijola J, Isohanni M, Koivumaa-Honkanen H, Haapea M, Jääskeläinen E, Miettunen J. | Psychiatry Research | 10.1016/j.psychres.2016.12.040 |
| 20 | Article in Journal | **m-RESIST, una solución m-Health integral para personas con Esquizofrenia Resistente estudio cualitativo de necesidades y aceptabilidad de usuarios en el área de Barcelona** | Elena Huerta Ramos, Silvia Marcó García, Maria Soledad Escobar Villegas, Elena Rubio Abadal, Susana Ochoa, Eva Grasa Bello, Anna Alonso Solís, Mireia Rabella, Jesús Berdun, Margarita Hospedales, Group m-RESIST, Iluminada Corripio Collado, Judith Usall i Rodié | Actas Españolas de Psiquiatría | - |
| 21 | Original article | **Treatment choices of treatment resistant schizophrenia** | Jääskeläinen E, Isohanni M, Seppälä J, Seppälä A, Miettunen J, Koponen H | Duodecim | N/A |
| 22 | Conference paper | **Free context smartphone based application for motor activity levels recognition** | V. Simonetti, W. Baccinelli, M. Bulgheroni, E. d' Amico | 2016 IEEE 2nd International Forum on Research and Technologies for Society and Industry Leveraging a better tomorrow (RTSI) | 10.1109/RTSI.2016.7740601 |

**Table 4. List of publications**

Number of dissemination and communication activities linked to the project:

| Type | Number |
|---|---|
| Organisation of a Conference | 0 |
| Organisation of a Workshop | 13 |
| Press release | 5 |
| Non-scientific and non-peer-reviewed publication (popularised publication) | 6 |
| Exhibition | 0 |
| Flyer | 3 |
| Training | 13 |
| Social Media | 2 |
| Website | 1 |

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|---|---|
| Communication Campaign (e.g. Radio, TV) | 2 |
| Participation to a Conference | 26 |
| Participation to a Workshop | 1 |
| Participation to an Event other than a Conference or a Workshop | 13 |
| Video/Film | 8 |
| Brokerage Event | 0 |
| Pitch Event | 0 |
| Trade Fair | 0 |
| Participation in activities organized jointly with other H2020 projects | 1 |
| Other | 30 |
| **TOTAL** | **124** |

**Table 5. Number of dissemination and communication activities**

Estimated number of persons reached, in the context of all dissemination and communication activities, in each of the following categories:

| Type | Number |
|---|---|
| Scientific Community (Higher Education, Research) | 15107 |
| Industry | 144000 |
| Civil Society | 70 |
| General Public | 6089 |
| Policy Makers | 215 |
| Media | 4246 |
| Investors | 0 |
| Customers | 4158 |
| Other | 3734 |
| **TOTAL** | **177619** |

**Table 6. Estimated number of persons reached**

# 4 Conclusions

From a managerial perspective, project results have been delivered with good quality, and following the procedures established for project management, consortium management and financial management. Project partners have been contributing to the project to ensure good quality of results, and no major issues have arisen within the consortium. All the risk (foreseen and unforeseen) have been addressed and mitigation measures have been applied, to minimize minor deviations faced during the whole project duration.

From an achievement of results' perspective, deliverables produced have been delivered with good quality standards. Some deviations have been faced mainly in delivery time of project's deliverables, due to the complexity of integrating clinical and technological knowledge in the definition and interrelation of novel therapeutic interventions with IT mobile tools. A mitigation plan of overlapping pilots and major user engagement has been put in place, with successful results in terms of accomplishment of project's objectives. Evaluation tasks after the pilots have been performed with less time available, although results of those deliverables have not been significantly affected. However, a deeper analysis can still be performed with data and results available.

Regarding impact, m-RESIST has reached a good achievement of expected results, delivering a validated platform for TRS patients, caregivers and professionals, which integrates personalized therapeutic interventions with mobile tools, testing its usability and performance. The system has been tested in different countries with different health procedures, providing the baseline for future research on a wide set of patients for research and innovation purposes. Organizational and economic impacts has been assessed, and an exploitation plan has been provided, complement with an on-going IPR and exploitation agreement, which sets the grounds for future exploitation of project's results.