

**ENHANCING MEDICATION ADHERENCE WITH MOBILI®:
A CROSSOVER RANDOMIZED CONTROLLED TRIAL IN
PORTUGUESE COMMUNITY**

MobiMAd@PT RCT

Lisbon, Portugal, August 26th 2025

NCT Number: not yet assigned

EudraCT number: not yet assigned

Trial Protocol: Mobili® RCT
Version 1.0
Date of protocol commencement: 01-01-2025
CBIOS
Universidade Lusófona, Lisboa, Portugal

Enhancing Medication Adherence with Mobili®: A Crossover Randomized Controlled Trial in Portuguese Community Pharmacies

Full Study Protocol

Version 1.0

August 26, 2025

Research Center for Biosciences & Health Technologies (CBIOS)

Universidade Lusófona, Lisboa, Portugal



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LIST OF ABBREVIATIONS

ADD: Automated Dose Dispensing

AWS: Amazon Web Services

BMQ: Beliefs about Medicines Questionnaire

CBIOS: Center for Biosciences & Health Technologies

DAA: Dose Administration Aids

DHTTs: Digital Health Technology Tools

DMP: Data Management Plan

DRP: Drug Related Problems

EQ-5D: EuroQol Five-Dimension Questionnaire

FCT: Fundação para a Ciência e a Tecnologia

GDPR: General Data Protection Regulation

GP: General Practitioner

MAD: Multidose Automated Dispensing

MSQ: Medication Satisfaction Questionnaire

NAS: Network Attached Storage

RCT: Randomised Control Trial

ADMINISTRATIVE INFORMATION

This protocol outlines the background, methodology, and ethical considerations of the trial titled “*Enhancing Medication Adherence in Portugal: Implementation of Mobili®, an eHealth Medicine Dispensing Solution for multimorbidity Patients*”. It has been prepared in accordance with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2025 (Chan et al., 2025) and the TIDieR (Better reporting of interventions: template for intervention description and replication) checklist and guide (Hoffmann et al., 2014). Administrative details of this trial are provided in Table 1, while the protocol revision history is documented in Table 2. Any modifications to the trial procedures will be transparently reported and justified in an updated version of this protocol.

Table 1 Administrative Information

Open Science framework Page	
Trial Protocol Version	1.0
Date of Trial Protocol Commencement	01.01.2025
Date of Trial Start	15.10.2025
ClinicalTrials.gov Identifier	
Date of Trial Registration	26.08.2025
Contact Information	mobimadpt@gmail.com
Addendum Documents	
Appendices	

Table 2 Trial Protocol Revision History

Version	Date of change	Change(s)	Justification
1.0	26th of August		Finalising the document

1. BACKGROUND RATIONALE

1.1 ABSTRACT

Medication non-adherence is a critical challenge for global health systems, with evidence suggesting that up to half of patients may not follow their prescribed medication. Given the rates of medication non-adherence and its detrimental effects on health outcomes and health systems sustainability, numerous Dose Administration Aids (DAA) interventions have been developed. Most of them are packaging and dosage modifications, either in single and manually prepared *dosette* boxes, or in Multidose Automated Dispensing (MAD) systems, prepared in community or hospital pharmacies. However, in spite of their success, most MAD are cumbersome and lack long-term sustainability.

In an era where digital health technologies are reshaping healthcare delivery, this project introduces Mobili® in Portugal, a portable MAD system developed by the Norwegian start-up *Medthings*. Mobili® combines portability, automated dose dispensing and real-time monitoring, facilitating a more manageable medication regimen for chronic patients.

This research project aims to explore the effectiveness of Mobili on medication adherence among chronic multimorbidity patients and its adaptability in a different health system. Achieving these aims will provide valuable insights into the deployment of technology-driven interventions in actual healthcare settings, potentially transforming digital adherence solutions for chronic patients.

This project's findings will contribute to better understand the impact of digital health interventions on medication adherence, patients' health and healthcare systems' efficiency, and will be valuable to researchers in medication adherence and implementation science. The project also holds substantial scientific and commercial potential, through: the delivery of a research protocol for a large-scale study to assess Mobili's clinical and economic value to European health systems initial insights into a disruptive DAA service business model.

The successful real-world application of the project's outcomes could enhance medication adherence and patient management, promoting a culture of adherence within the community, significantly improving care quality and generating economic benefits for patients and health systems.

1.2 STATE OF THE ART

Medication adherence refers to the extent to which patients take their prescribed medications as directed by their healthcare providers (Nieuwlaat et al., 2014). Prevalence of medication non-adherence can be as high as 50% (Foley et al., 2021), meaning that 1 in 2 people do not take their medication as prescribed. Non-adherence to medication regimens can have significant consequences for patients, including decreased therapeutic effects and a significant impact on the sustainability of health systems (Cutler et al., 2018).

Many determinants might affect medication adherence (Kardas et al., 2013). Moreover, multimorbidity (i.e. more than 2 chronic conditions per patient) and the associated polymedication (i.e more than 5 medications), also increase the likelihood of poor adherence (Maffoni et al., 2020). Recent evidence shows that up to a third of European patients aged 65 and older are polymedicated (Midão et al., 2018).

Remembering to take many medicines concomitantly, often several times daily is challenging and prone to errors. Therefore, community pharmacies are increasingly providing more medication adherence services (Martins et al., 2015), with overall positive evaluation and a high degree of patient satisfaction (Policarpo et al., 2019; Twigg et al., 2019). There is a wide array of successful DAA interventions to increase medication adherence implemented in the community pharmacy that have shown their effectiveness, but the heterogeneity of the type of interventions has hampered a definitive conclusion on their impact (Al-Arkee & Al-Ani, 2023; Wiecek et al., 2019). Most of these interventions are packaging and dosage modifications (either in single and manually prepared dosette boxes, or multidose automated dispensing systems) (Hersberger et al., 2013). In Portugal, the most prevalent DAA interventions are supported by manually filled dosette boxes and manually or automatically filled blisters (Vicente et al., 2021).

The World Health Assembly recognized the value of digital technology to achieve the Sustainable Development Goals in its resolution on digital health in 2018 (WHO, 2021). Digital Health Technology Tools (DHTTs) have been touted as the next big leap in terms of health systems efficiency, supported by new medical devices, Artificial Intelligence, or even the combination of these two elements (Arora, 2020; Ayalew et al., 2022). The implementation of DHTTs is increasingly on the research agenda, since the gap between clinical validation and integration in the health system persists (Marwaha et al., 2022). Moreover, where DHTTs have

been implemented, the impact on equity brought by the digital divide is also a problem that must be addressed (Gregório et al., 2023).

Lately, there has been an increased attention given to DHTTs developed to support pharmaceutical services and track real-time medication intake (Gregório et al., 2021; Patel et al., 2022). One of these DHTTs are Automated Dose Dispensing (ADD) robots. ADD robots are installed in patients' homes and autonomously provide medication without assistance from a caregiver, with the exception of refilling (Tahvanainen et al., 2021). Nevertheless, a major drawback is that the current ADD systems are cumbersome and non-portable. Portability is a leading specification of automatic medication dispensing systems, contributing to the patient centred aspect of these interventions (Aldeer et al., 2018; Mertz et al., 2021).

Medthings®, a Norwegian start-up, has developed one fully portable ADD system - Mobili®. Beyond portability, Mobili® is integrated with a real-time monitoring system, transforming an otherwise high-tech reminder system into a complete *eHealth* system. Mobili® has two main components: the hard case, which contains the electronics and software, and the *eDosette*, where the medications are filled. This *eDosette* differs from traditional systems since it has a RFID chip that guarantees the medication is dispensed to the correct patient at the right time and can be re-used. Depending on the complexity of the therapeutic regimes, the *eDosette* provides patients with up to 28 opportunities for taking medicines.

Implementing this project in Portugal, will allow to study Mobili's effectiveness and adaptability to a different Health care system and setting. To do so, the project's main aim is: To assess the effectiveness of Mobili® on medication adherence rates among chronic multimorbidity community dwelling patients in Portugal.

The results of this project will provide valuable insights into the usefulness of Mobili®. The findings will inform the development and implementation of similar technologies and will contribute to the scientific knowledge about the implementation and impact of DHTTs in improving medication adherence and patient-centred care, critical factors for the sustainability of global health systems.

Mobili® will be used in the context of a medication management service provided by community pharmacists. We hypothesize that multimorbidity patients will experience improved medication management and adherence.

1.3 OBJECTIVES

This project has four main objectives:

1. Assess the effectiveness of Mobili® on medication adherence rates among multimorbidity patients, compared to today's systems and practices
2. Assess the usability of Mobili® in a real-world setting, both by patients and healthcare professionals.
3. Characterise Mobili®'s adaptability to a different Health care system and setting
4. Develop a study protocol that can assess Mobili®'s impact in clinical, economic and humanistic outcomes in a future large-scale multi-centre project

1.4 PROJECT OUTLINE

To achieve the objectives stated above, the project has a detailed outline, divided in four distinct tasks.

Task 1 – Project Management and Dissemination (Duration: 18 months)

The Project Management task is longitudinal, through the duration of the project. Its aim is the overall management of the project to ensure the achievement of seven specific objectives:

1. to provide a streamlined and efficient decision-making structure.
2. to ensure the involvement of all consortium partners in decision-making.
3. to provide a sound management and administration that will keep the project performing to schedule, quality and budget.
4. to ensure transparent and efficient communication among the consortium partners, towards stakeholders.
5. to coordinate the quality of results and deliverables including the adherence to the work plan, the project aim and contractual obligations and the management and supervision of the internal review processes.
6. to provide a Data Management Plan for Data Governance, to be issued as deliverable in month 3 and updated as needed.

7. to communicate and disseminate results by disclosing them to the public by appropriate means, including (but not exclusively), in scientific publications and scientific communication conferences.

Task 2 – Adaptation of Mobili® to the Portuguese Context (Duration: 4 months)

This task focuses on adapting Mobili® for use in the new setting. Additionally, it aims to guarantee sufficient participant recruitment capabilities, and trained staff for an effective intervention.

The task is divided in two sub-tasks. One sub-task will be dedicated to the training of pharmacists in the use of Mobili® and in the recruitment procedure and participant follow-up. On the other hand, the second sub-task will aim to gather pharmacists' perceptions through a focus-group about internal and external factors that will impact the implementation of the intervention in the Portuguese setting, such as compatibility of Mobili® with existing workflows, the perceived advantages and challenges of using Mobili®, etc.

Task 3 – Usability and Effectiveness Evaluation of Mobili® for Chronic Patients
(Duration: 9 months)

This task focuses on evaluating the usability and effectiveness of Mobili® in supporting medication management of non-institutionalized multimorbidity patients. To do so, a Parallel-group, Staggered enrolment Randomised Control Trial (RCT) will be implemented, with 1:1 allocation ratio.

Task 4 – Development of a Study Protocol to Evaluate the Impact of the Mobili® System on Adherence to Therapy (Duration: 3 months)

The aim of this task will be to develop a study protocol that allows the evaluation of the impact of Mobili® on adherence (primary endpoint), and other health indicators (secondary endpoint), in a large-scale multicentre RCT. Only after this potential prospective study is completed the evidence of the impact of Mobili® as an aid for medication adherence will be fully known.

2. METHODOLOGIES

2.1 TRIAL DESIGN

The study will employ a Parallel-group Crossover RCT design with a 1:1 allocation ratio, involving two arms: one intervention group using Mobili and one control group. The diagram presented below (figure 1) represents the path of participants in the RCT, evaluating the impact of Mobili® compared to usual DAA practice.

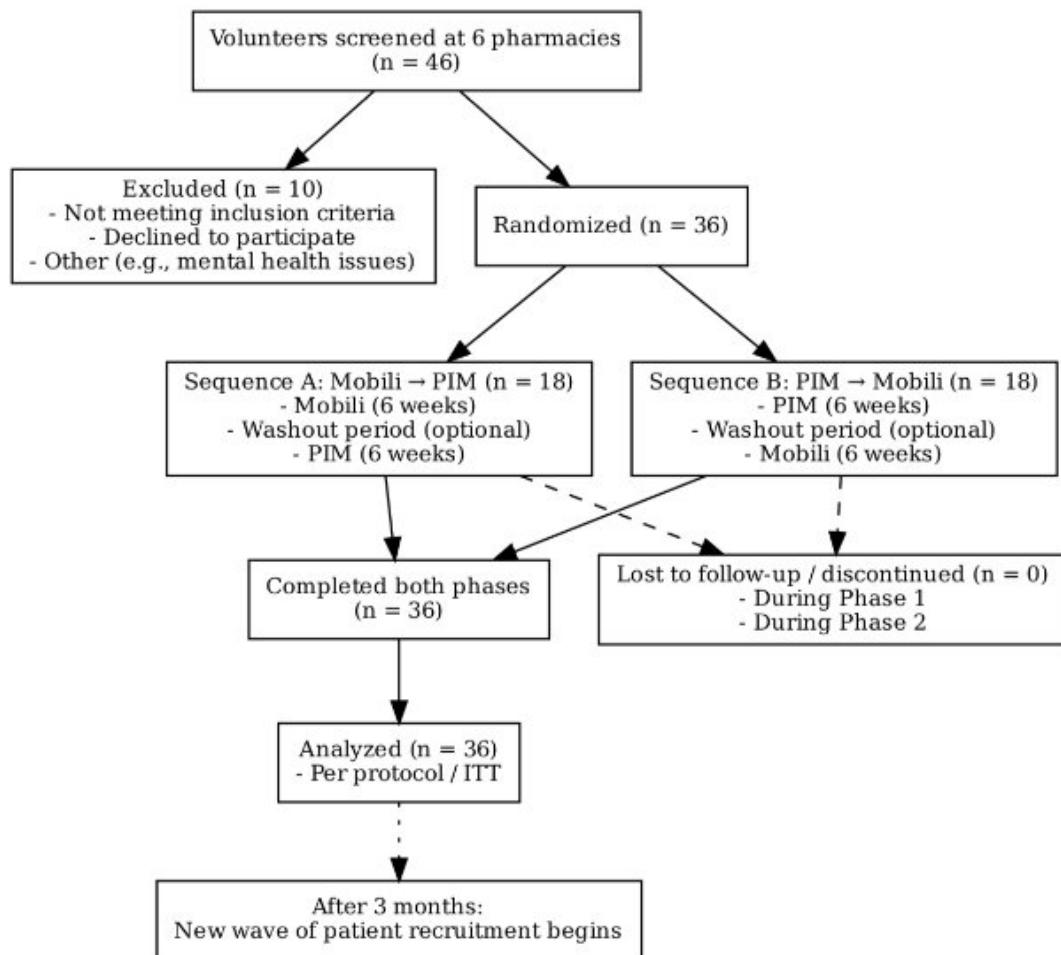


Figure 1: RCT Study Protocol Scheme

2.1.1 OBJECTIVES

Over a 9-month period, this task aims to assess the usability and effectiveness of Mobili® in supporting non-institutionalized chronic patients.

The task will have two main aims:

1. To assess the effectiveness of Mobili on medication adherence rates and disease management of chronic multimorbidity patients
2. To evaluate Mobili usability for patients and pharmacists.

2.2 PARTICIPANTS

2.2.1 ELIGIBILITY CRITERIA

Participants will be selected by pharmacists in the participant community pharmacies. These will be identified upon the presentation of a prescription and according to the following criteria:

- non-institutionalised multimorbidity patients
- aged ≥ 18 years
- requiring only regular oral medication that can be dispensed in the *eDosette*

No limits as to the number of medications were set as exclusion criteria. However, the following exclusion criteria were applied:

- one participant per household (either intervention or control group), to avoid confusion
- cognitive impairments preventing independent use of Mobili®
- patients using medication that does not fit or is incompatible with being dispensed in the *eDosette* (i.e. some capsules, solutions, insulins or GLP-1 analogues, transdermal patches, eye-drops)

2.2.2 RECRUITMENT AND INFORMED CONSENT

Participants will be recruited from six community pharmacies, where a total of 20 Mobili devices will be allocated. Potential participants will be identified when they visit the

pharmacy with a prescription for chronic-use medications. Those who meet the inclusion criteria will be invited to join the study. If they agree to participate, a type II medication review will be conducted by the pharmacists, followed by the completion of a baseline survey. After this, participants will be randomly assigned to one of the two study arms.

Participants will receive both verbal and written information detailing their rights in relation to the research project, including information regarding their rights to retract their consent of study participation without justification and without any impact on their future care. The project coordinator will obtain the informed consent, ensuring that participants comprehend the information provided and that their participation is given freely and willingly.

2.2.3 SAMPLE SIZE CALCULATION

As this RCT is a pilot study, the sample size will be determined by the number of available Mobili® devices. Due to budget constraints, a limited number of Mobili® units will be allocated to the intervention group, as confirmed by Medthings. To maximize the number of participants in the intervention group, a staggered enrollment strategy will be implemented. This approach is expected to allow for the inclusion of 96 participants.

2.3 GROUP ALLOCATION

Upon acceptance of the terms in the informed consent, an initial consultation with the pharmacist will be scheduled to collect all the baseline data. Participants will be subject to an initial screening of clinical parameters supporting a type II medication review (Foppe van Mil et al., 2016), aiming to ensure no Drug Related Problems (DRP), namely adverse drug reactions, are present. If such DRPs are detected, the pharmacist will contact the General Practitioner (GP) (or assistant physician) of the participant, and if the DRP cannot be resolved, the participant will be excluded from the study. Only after this procedure is complete the participant can be randomly assigned to either one of two arms.

2.4 TRIAL GROUPS

2.4.1 INTERVENTION GROUP

The intervention group will only be using Mobili® independently and overseen by pharmacists. Participants will receive the maximum number of *eDosettes* their therapeutic regime allows, to minimize visits to the pharmacy.

2.4.2 CONTROL GROUP

The control group will consist of participants using the Dose Administrating Aid intervention currently available in the participant pharmacies, which can be either manual *dosette* boxes or automatically filled blisters.

2.5 OUTCOMES

2.5.1. PRIMARY OUTCOME

Medication adherence will be assessed using both objective and subjective measures. Objectively, adherence will be evaluated *using* the pill count method, while subjectively, it will be measured using a validated medication adherence scale. Additionally, clinical markers relevant to the prescribed medications, such as blood pressure for antihypertensive treatment, will be monitored to provide further insights into adherence.

Expected results: Significant differences in medication adherence rates between the two groups.

2.5.2 SECONDARY OUTCOMES

Patient satisfaction and quality of life will be assessed through structured interviews with both patients and pharmacists at the beginning and end of the intervention. Instruments such as the EuroQol Five-Dimension Questionnaire (EQ-5D), the Medication Satisfaction Questionnaire (MSQ), and the Beliefs about Medicines Questionnaire (BMQ) are expected to be used. Additionally, a focus group with participating pharmacists will be conducted to gather further insights on how the service is integrated into the pharmacy workflow. Combining quantitative measures (e.g., medication adherence rates) with qualitative approaches (e.g., satisfaction interviews) enables a comprehensive evaluation. This mixed-methods approach

captures not only measurable outcomes but also the experiences and perceptions of patients and healthcare providers.

Expected results: Enhanced patient satisfaction, reduced incidence of medication errors, and improved quality of life measures in the intervention group.

2.6 INTERVENTION

The intervention consists of the use of Mobili® by patients for a two-month period, with pharmacists providing initial training and ongoing support. A staggered enrolment scheme will allow for the rotation of Mobili® devices among participants to increase the sample size.

Pharmacists will provide initial training and ongoing support to participants during the course of the intervention, either in person (e.g. when delivering the *eDosette* with the therapeutic regime), or via telephone. All the contacts made should be registered. The initial training and setup will take place in community pharmacies, with ongoing use in participants' homes. The duration, intensity, and frequency of interactions with the pharmacist will be registered, since the intervention will be personalized based on each participant's medication regimen (i.e. can have a minimum of one interaction per month, or a maximum of one per week). The control group will consist of participants using the DAA intervention currently available in the participant pharmacies.

Each participant in the intervention group will expectedly use the Mobili® during a minimum period of two-months. Due to the nature of this intervention and the determinants of adherence it tackles, such as: forgetfulness, complexity of regimens, and lack of motivation (Kardas et al., 2013). This period is considered enough to see changes in the medication adherence rate (Wiecek et al., 2019). During the duration of the study, the research team will visit the pharmacies monthly, tracking the progress of the study.

2.7 DATA MANAGEMENT

The Data Management Plan (DMP) will define the protocols for secure and compliant data handling throughout the project. All data will be stored on the CBIOS Network Attached Storage (NAS) at the Lusófona Data Center, which provides a secure and resilient infrastructure with built-in redundancy. Data transfers will be conducted via encrypted networks and secure cloud services that comply with applicable data protection regulations. The Mobili software,

which does not process any patient-identifiable information, and the MedThings application, hosted on Amazon Web Services (AWS), are both fully aligned with General Data Protection Regulation (GDPR) requirements.

A designated Data Protection Officer will oversee compliance with data protection laws and ensure that robust data security measures are consistently applied.

2.8 PROTOCOL AMENDMENTS

Any modifications to trial procedures will be documented with the date of change and justification on our OSF page and ClinicalTrials.gov. If necessary, we will also seek ethical approval for these changes.

3. ETHICS

3.1 APPROVALS

The trial will soon be presented before the local ethics committee and registered both on ClinicalTrials.gov and EudraCT.

3.2 PARTICIPANT CONFIDENTIALITY

Data collection will occur in three phases: baseline (medication adherence rates, demographics, health status, etc.), during the study (system usage monitoring), and post-study (medication adherence reassessment, patient satisfaction surveys, and qualitative interviews with pharmacists). The research team will not have access to any patient data, ensuring data privacy and patient security. Only the pharmacists will know patient details.

Patients are identified in the Mobili® information system with a single ID number, that only pharmacists can cross-check with patient data. Pharmacy records of this study will be kept in paper, in a secured locker inside the pharmacy. All the data available for the research team for the purpose of the effectiveness evaluation will be anonymized.

Data collection will be carried out through encrypted online platforms to ensure secure and anonymous entry. To safeguard confidentiality and maintain data integrity, all project data

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will be both anonymized and encrypted. Access to the data will be limited through role-based permissions, and security will be further strengthened with regular audits and mandatory data protection training for all team members.

4. DECLARATION OF INTERESTS

The authors declare no conflict of interests.

5. FUNDING

This trial is funded by Fundação para a Ciência e a Tecnologia (FCT), as part of the *Call for Exploratory Projects in All Scientific Domains 2023* (2023.11968.PEX). The funders have no roles in the study design, data collection, management, data analysis and interpretation, writing of the reports, or the decision to submit the reports for publication.

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Trial Protocol: Mobili® RCT

Version 1.0

Date of protocol commencement: 01-01-2025

CBIOS

Universidade Lusófona, Lisboa, Portugal

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