

Community pharmacies as clinical study centres: insights from the start-up phase of the VA|PREVENTION project

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BACKGROUND

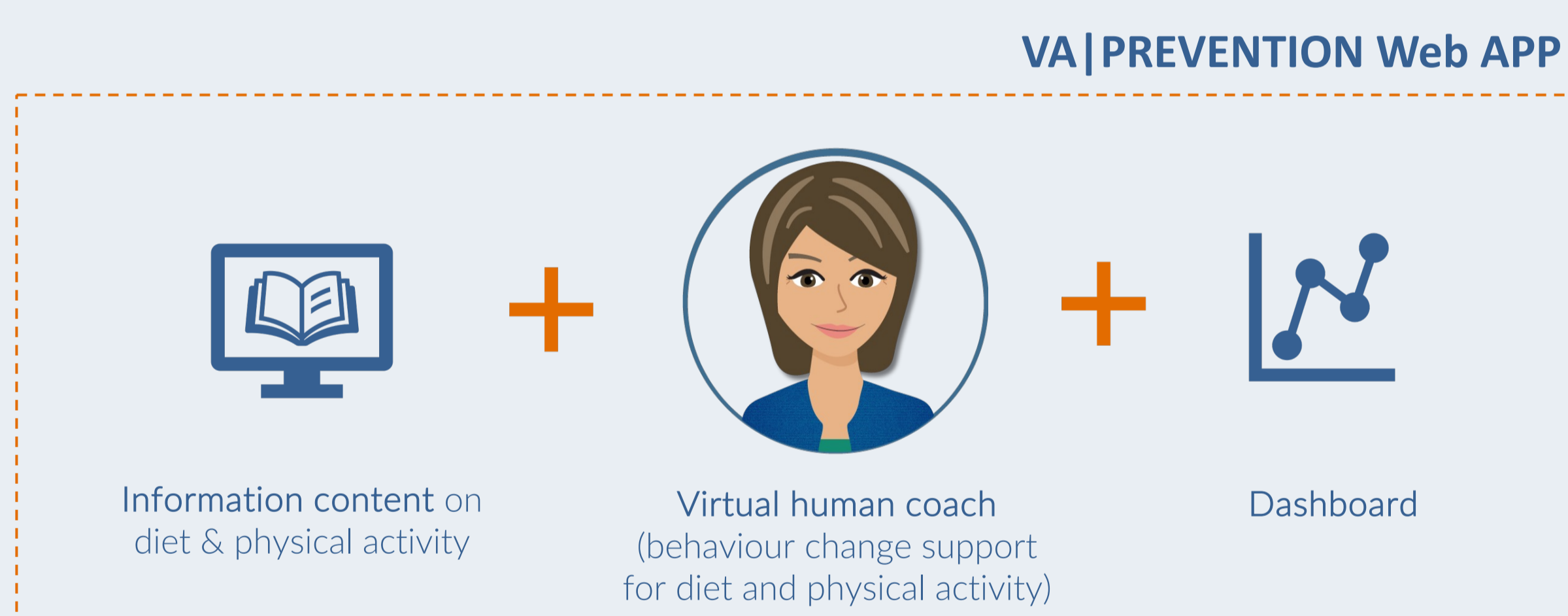
- **Clinical investigation** in Portugal, including interventional and non-interventional studies with medicines and medical devices, is regulated by Law No. 21/2014.
- Under this framework, an investigator is a **qualified individual**, possessing scientific credentials and the legal capacity to provide care required by their respective profession, and is responsible for executing the study within the designated study centre.
- Legislation governing **pharmacists in Portugal** assigns them the responsibility for **health promotion, disease prevention, and research on medical devices** (Decree-Law No. 288/2001).
- Despite its potential, the role of **community pharmacists as investigators** in clinical studies and pharmacies as study centres has been little explored in Portugal.

PURPOSE

To describe a **collaboration among a funded R&D project and a network of community pharmacies envisaged as functioning as clinical study centres**, contributing to address a gap in describing their role in clinical research.

STUDY DESIGN

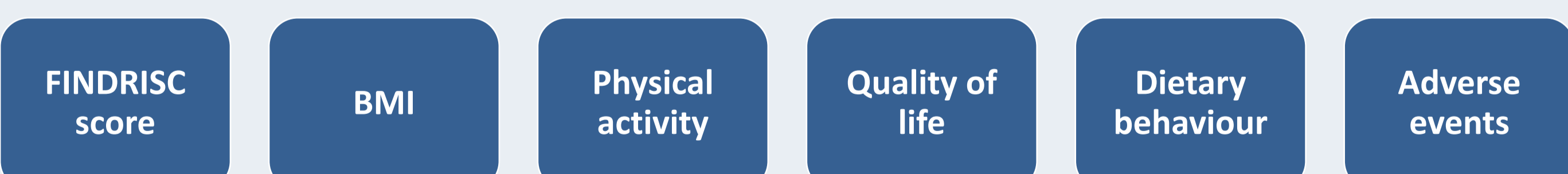
- The **VA|PREVENTION** project aims to evaluate the (cost-)effectiveness and implementation of a digital intervention for type 2 diabetes prevention in high-risk adults.
- The VA|PREVENTION web app is currently undergoing usability assessment.



- This **digital intervention** is intended to be qualified as a **medical device** in accordance with the Medical Device Regulation (EU) 745/2017.
- **Recruitment centres:** Community pharmacies, within the Ezfy network will recruit participants and collect data, supported by the VA|PREVENTION team.

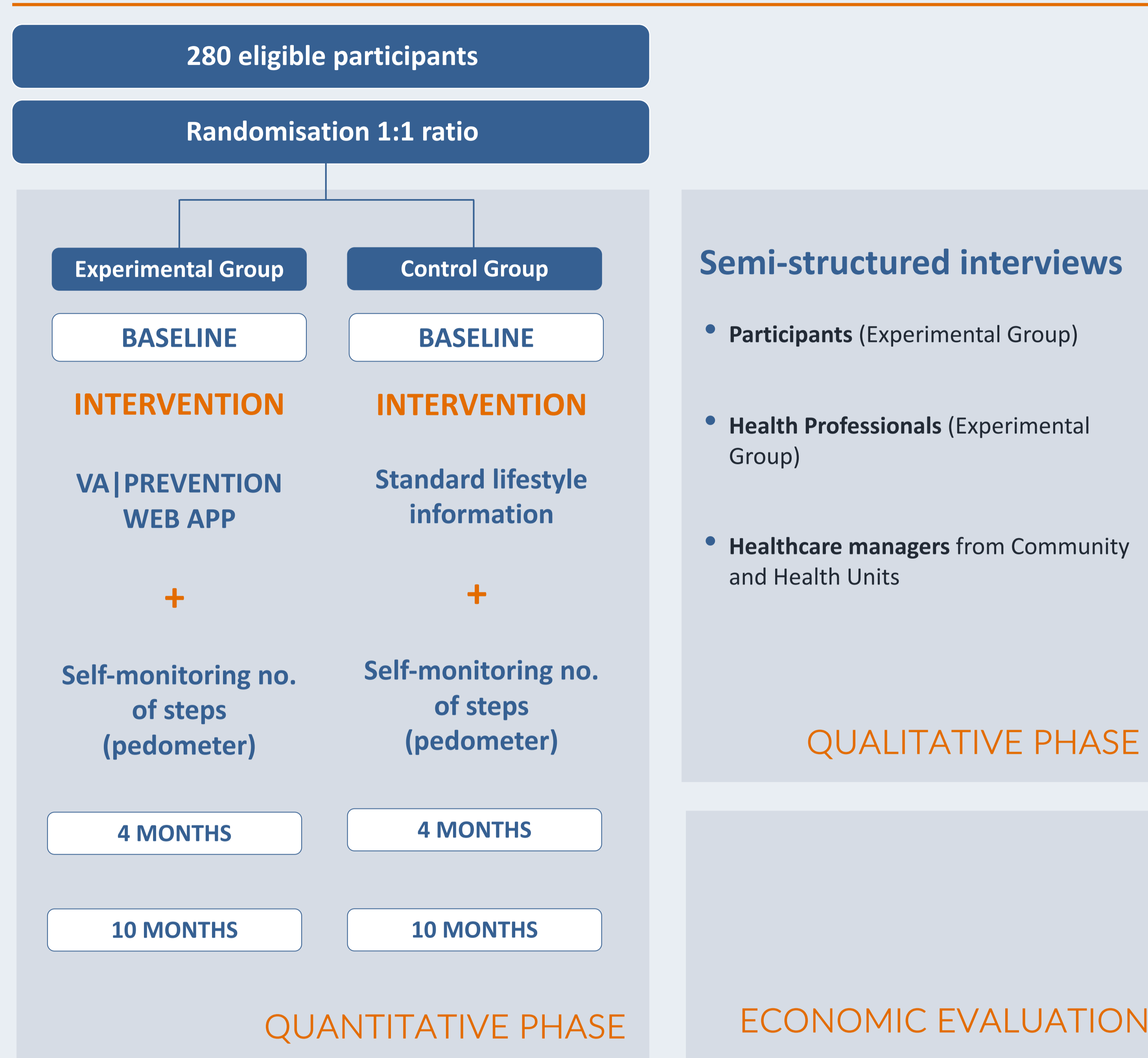
Primary Endpoint: Waist circumference (cm)

Secondary Endpoints

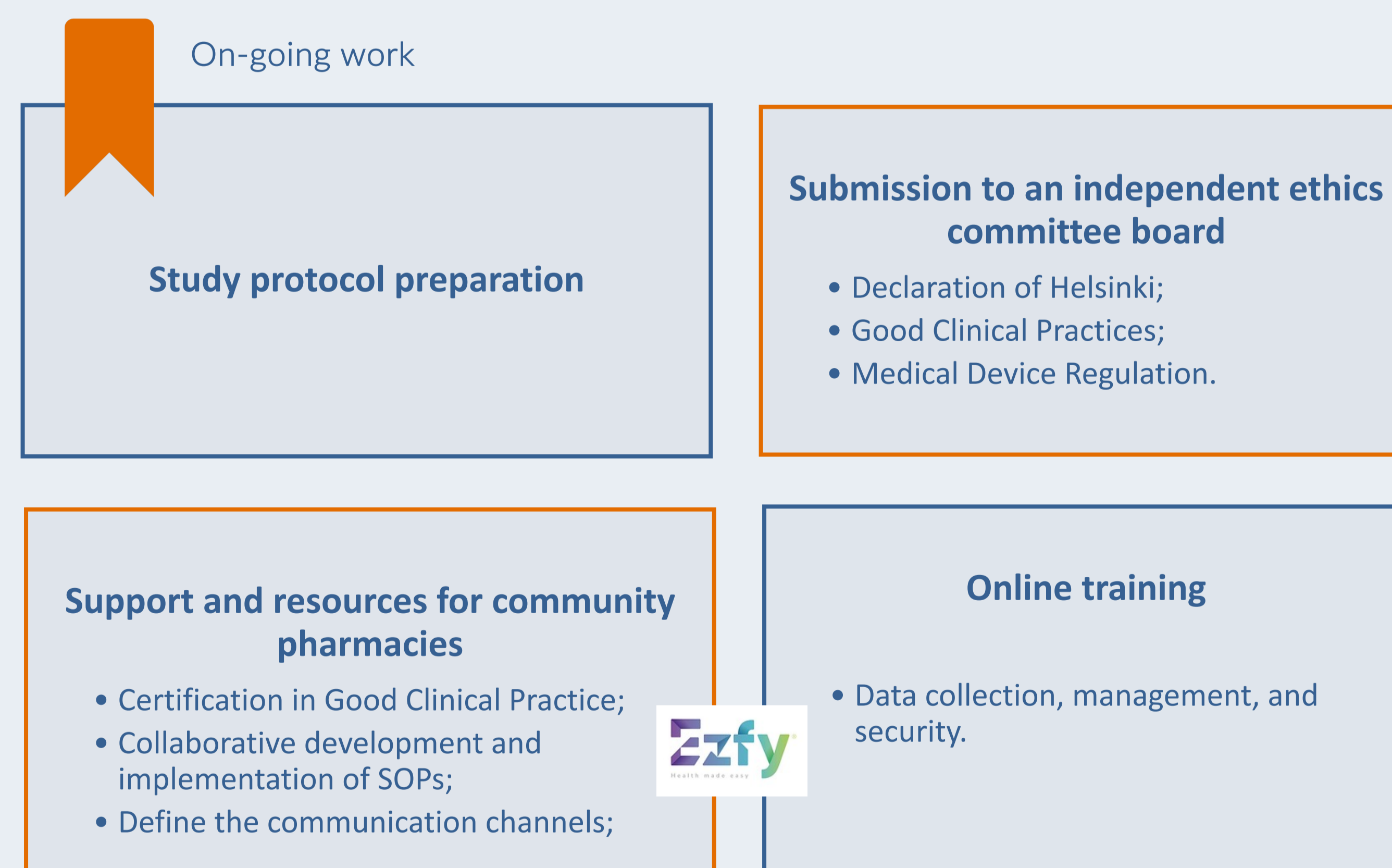


ACKNOWLEDGMENT Thank you to the entire project team for their dedicated efforts and contributions

Type 1 hybrid effectiveness-implementation trial



EXPECTED FINDINGS



CONCLUSION

- The VA|PREVENTION project integrates an **innovative approach** to the research on **diabetes prevention** within community settings.
- Our experience in the study start-up phase may assist others in leveraging the **expertise of community pharmacists as investigators** and the accessibility of community pharmacies as clinical study centres.
- Later stages of the project will provide **valuable data on their role** and performance of community pharmacists in this capacity.



VA|PREVENTION
DIABETES RESEARCH

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