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## The VASelfCare T2D project plan: fostering innovation through the *StartUp Research* program

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### Abstract

Diabetes represents a tremendous burden at a global scale. Changing and sustaining desirable health behaviours, such as engaging in a healthy diet, physical activity and taking prescribed medication, is key to achieve better health outcomes in people with type 2 diabetes (T2D). This paper describes the first stage of a plan to translate an innovative a mobile application to facilitate self-care of older adults with T2D from bench to daily life. The project plan emerged in the context of the StartUp Research program for scientists, held by ITQB NOVA and NOVA SBE. PMBOK was selected as the project management framework; we briefly explain its knowledge areas - scope, time, quality, human resources, stakeholders' management, communications, costs, procurement and risks- in relation to VASelfCare T2D.

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**Keywords:** diabetes; conversational e-coach; mobile application; virtual human assistant; relational agent

### 1. Introduction

Diabetes is one of the four major noncommunicable diseases [1]. Type 2 diabetes (T2D) is responsible for 90% of all diabetes cases [2]. The number of persons with diabetes, predominantly type 2, nearly quadrupled in the last

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decades [3]. The prevalence of diabetes increases with age. In 2019, roughly 136 million people 65 years+ lived with diabetes. This number is expected to rise to 195 million by 2030 [2]. Diabetes management consists of diet, physical exercise and, often, medication. Less than 50% of people achieve glycaemic control due to lack of adherence to diabetes management [4], which leads to health complications and premature death. Globally, direct costs with diabetes tend to increase. It is expected that these costs will reach 825 billion USD by 2030 [2]. Changing and sustaining health behaviours, such as engaging in a healthy diet, physical activity and taking prescribed medication is key in achieving better health outcomes in people with T2D.

A previous project led by one of the authors researched a prototype of a mobile application for Android operating system with a conversational intelligent virtual human assistant, to facilitate the self-care of older adults with T2D [5]. “Vitoria” was designed to coach older users in long-term interactions, supporting adherence to antidiabetic agents, physical activity and healthy eating. The **VASelfCare T2D project** draws on the backbone technology created - an intelligent dialogue engine to support change in behaviours that affect health – to advance the prototype from the current technology readiness level 5<sup>†</sup>, corresponding to validation in a relevant environment, through usability tests conducted with 11 older people with T2D, 9 nursing experts and 17 health professionals, to TRL 7 - demonstration in operational environment.

In addition to the “Introduction” section, the paper is comprised by three key sections. In section 2 an overview of diabetes self-management support in the e-health era is provided. Section 3 describes the theoretical framework employed. Finally, the VASelfCare T2D project plan is presented in section 4.

## 2. Related work

British data indicate that people with chronic conditions spend on average 4 hours per year with a health professional;

the remaining 8756 hours are spent self-managing [6]. The average number of diabetes appointments in the Portuguese National Health Service per registered patient was 3 per year [7]. Opportunistic education and counselling performed by health professionals in scheduled consultations is often insufficient to change behaviours [8].

Global data show a consistent upward trend in smartphone penetration in those 65+ [9]. For example, in the USA, smartphone ownership in this group increased from 10% in 2010 to more than 20% in 2018. Contemporary smartphone penetration rates represent a substantial market; currently in the US there are around 55 million people aged 65+ [10], comprising 11 million smartphone users. Moreover, household ownership of smartphone can be considered, which further expands current access to end-users who do not possess their own smartphone. Therefore, mobile technology presents today a significant opportunity to aid older adults with T2D self-managing their condition in a sustainable and scalable fashion. Seniors of tomorrow, who are 55 to 64 today, will inevitably have higher ownership rates of smartphones. For instance, in the US over 90% of people in this age group owned a smartphone in 2018 [9]. Research shows a growing interest of older adults to integrate technology in the self-management of chronic conditions, in particular in diabetes [11,12].

Mobile applications to support T2D self-management have demonstrated a positive effect in improving glycaemic control. For example, a systematic review on the effect of these applications found a significant reduction in glycated hemoglobin (HbA1c) by -0.40% (95% confidence interval -0.69 to -0.11%, 6 randomised controlled trials, total of 1022 patients, average age 45.2 to 66.6 years) [13]. Typically, a change in HbA1C of 0.5% is considered clinically significant [14]. The effect of self-management T2D mobile applications seems under-researched in seniors, as most trials included younger samples [13]. Mobile applications for older adults should be designed considering the needs of this population group.

A systematic review of free applications in English for smartphones highlighted limitations of currently available products. This review found that the majority of the mobile applications (56/65) in the most popular stores did not meet minimal requirements or work properly [15]. Another systematic review pointed out flaws in the development of mobile phone applications for diabetes self-management; health behavioural theory and user involvement was considered in only one of the 11 trials analysed [16]. VASelfCare T2D competitive advantage entails a unique

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<sup>†</sup> TRL definition according to the HORIZON 2020 – WORK PROGRAMME 2014-2015, General Annexes, Extract from Part 19 - Commission Decision C(2014)4995)

combination of features: 1) personalised verbal coaching, 2) interface developed for seniors and 3) intervention design based on scientific evidence and behaviour change theory [5], embedded in a user-centred approach.

### 3. Theoretical framework

We have approached project planning according to PMBOK [17]. This framework underpins several books on health management [18] and was adopted in the StartUp Research program, a post-graduation aiming at increasing the translational value of ideas and technologies emerging from academic research. PMBOK encompasses five project management processes groups - initiation, planning, execution, monitoring and closure - and ten management knowledge areas - integration, scope, time, costs, quality, human resources, communications, risks, procurement and stakeholders [17].

### 4. VASelfCare T2D Project plan

VASelfCare's mission is therefore to research and develop intelligent and caring “Virtual Assistants” and other novel technologies to empower people to achieve better health outcomes and well-being.

In doing so, the project settles on the following core **values**: **Interdisciplinarity**: we recognize that innovation is supported by knowledge from different disciplinary domains and that looking at a problem with varied lenses may shift paradigms; **Openness**: we strive to create an environment where everyone is comfortable to share ideas, views and knowledge contributions; **Responsibility**: we honour our commitments with final users and to each other. We take ownership of our work and are willing to improve it whenever needed; **Creativity**: we look at challenges from different perspectives and embark on a lean approach to generate new solutions; **Dynamism**: we tackle tasks with a sense of strategy and accept that we will learn by doing; **Proximity**: we work closely with end-users and other relevant stakeholders to maximize value generation. We nurture a high-performance team by turning to each other when we need help.

Our **SMART objectives** are: 1) Finish the exploratory trial in a sample of about 20 users by month 7; 2) Produce the first internal report on the improved intervention components (e.g. educational content, behaviour change techniques operationalisation into prototype features) by month 8; 3) Produce an internal report on the findings from the modelling process by month 14; 4) Finish the randomised clinical trial by month 23.

This project is **expected to benefit** older people with T2D by improving diabetes-related outcomes and well-being; benefits to other stakeholders are envisaged by increasing scalability, sustainability and potentially cost-effectiveness of health care.

The **success factors** identified as critical encompassed 1) Obtaining ethical approval for the clinical studies; 2) Recruiting of human resources with the right technical skills; 3) Close cooperation with clinical sites where data is collected and their governance bodies; 4) Training older people with T2D in using the prototype; 5) Commitment from target users; 6) Cohesiveness of the interdisciplinary team.

#### 4.1. Scope, time and quality management

VASelfCare T2D requirements were set for quality planning purposes. Examples of core requirements are 1) “About the prototype” describes the prototype development and data security; 2) Dialogues follow key intervention design features, specified in writing and 3) Information in the local database is retrieved to tailor each interaction.

The **Work Breakdown Structure (WBS)** of the VASelfCare T2D project is divided in three work packages, depicted in Table 1. The overall project duration is 24 months. A set of milestones (M), detailed in the full version of the project plan, has been defined. A3.1 consists of the exploratory trial in a sample of about 20 users. This single-arm study will ascertain feasibility and acceptability of prototype usage, as well as effectiveness, as a secondary outcome. A3.2 is a randomised clinical trial in older people with T2D, in which relevant endpoints (e.g. HbA1c, health related quality of life) will be compared among groups using the VASelfCare virtual coach versus human coach versus regular care. Subsequently, economic evaluation will be carried out.

Table 1. Work Breakdown Structure of VASelfCare T2D.

Work Packages/Activities	Timing
<b>WP1: Project Management</b>	
A1.1: Manage ethics approval (M1)	From day 1 to the last working day of month 3
A1.2: Manage schedule	From day 1 to the last working day of month 24
A1.3: Manage cost	From day 1 to the last working day of month 24
A1.4: Manage quality	From day 1 to the last working day of month 24
A1.5: Manage human resources	From day 1 to the last working day of month 24
A1.6: Manage communication (M2, M3, M5, M9)	From day 1 to the last working day of month 24
A1.7: Manage risk	From day 1 to the last working day of month 24
A1.8: Manage stakeholders	From day 1 to the last working day of month 24
<b>WP2: Software Research and Development</b>	
A2.1 Iterative design of the intervention	From day 1 to the last working day of month 24
A2.2 Iterative development of the prototype	From day 1 to the last working day of month 24
A2.3 Prototype testing with target users (modelling) (M4, M7)	From first working day of month 4 to the last working day of month 14
<b>WP3: Prototype demonstration</b>	
A3.1: Prototype TRL6: demonstration in a relevant environment (M8)	From first working day of month 2 to the last working day of month 7
A3.2: Prototype TRL7: demonstration in an operational environment (M6)	From first working day of month 15 to the last working day of month 23

Independent internal review, internal tests of the prototype and review by external experts exemplify quality control actions for activities 2.1 and 2.2.

#### 4.2. Human resource management

The **Organizational Breakdown Structure (OBS)** represented in Figure 1 describes the team members and their roles. A responsibility matrix will be employed to list the responsibilities of each team member.

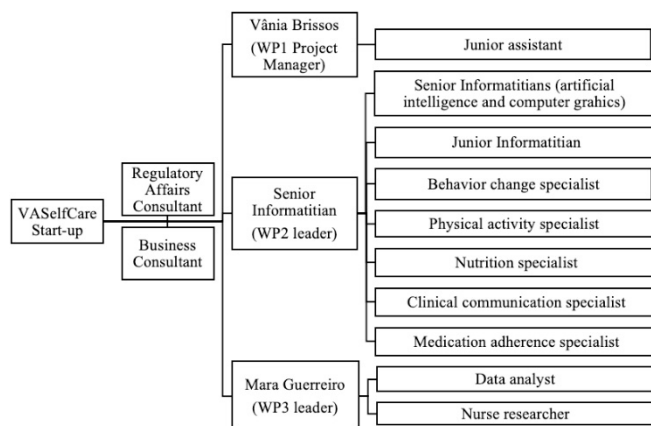


Fig.1. Organizational Breakdown Structure of VASelfCare T2D.

#### 4.3. Stakeholder management

Key stakeholders for this project were identified through discussion and analysis of previous projects; identification can be further expanded by seeking expert input through individual or group consultations (e.g. interviews and meetings). Identified stakeholders were classified in a power/interest matrix (Table 2), based on their level of interest

regarding the project outcomes and their level of influence over the project and its deliverables (i.e. power).

Table 2. Stakeholder management matrix of VASelfCare T2D.

Stakeholders	Power	Interest
Investors	High	High
Project team	High	High
Older people with T2D	High	High
Health professionals (e.g. primary care physicians and nurses)	High	High
Patient associations (e.g. Associação Protectora dos Diabéticos de Portugal)	High	High
Ethics committees	High	Low
Health care organizations (e.g. Unidades de Saúde Familiar)	High	Low
Scientific societies (e.g. Sociedade Portuguesa de Diabetologia)	Low	High
Policy makers (e.g. Direção-Geral da Saúde)	Low	Low
Media (e.g. newspapers, health magazines)	Low	Low

#### 4.4. Communication management

The communication plan will comprise internal meetings (e.g. kick-off, regular team and project close-out) and external events (e.g. initial workshop, research seminars). The project website will be a key element of external communication; other elements include documents such as newsletters and progress reports.

#### 4.5. Cost and procurement management

The overall budget estimation is 300 000 euros, encompassing six sources of cost (human resources, hardware, facilities and equipment, licenses, intellectual property and contingencies). Procurement processes for purchasing materials, equipment, services and tasks linked with contracts management will be mapped building on the experience of A3.1 and A3.2.

#### 4.6. Risk management

The risk planning of VASelfCare T2D, presented in Table 3, was performed to minimize the occurrence and the impact of risks. Impact evaluation was based on a likelihood scale (low < 30%; medium between 30% and 70%; high > 70%) and a consequence scale (1-low consequence: it would not result in significant changes to the project timeline or results; 2 – Medium consequence: it would require changes in interdependent tasks or changes in project results that are not extreme; 3 – High consequence: it would result in significant changes to the project timeline or results, jeopardizing the agreed outputs). Risk reduction includes action plans, to avoid risks, and contingency planning, to mitigate risks.

Table 3. Risk reduction plan of VASelfCare T2D.

Risk identification		Impact evaluation			Risk Reduction	
Risk ID	Risk description	Likelihood	Consequence	Impact (probability x consequence)	Action plan	Contingency plan
R1	Insufficient patient recruitment for the prototype validation	3 (High)	3 (High)	9	Increase cooperation with clinical sites & close monitoring	Involve other health care institutions
R2	Patient difficulty in using the prototype	1 (Low)	3 (High)	3	Include a family member in the training process	Weekly follow-up calls to sort potential use issues
R3	Insufficient engagement of clinical sites	2 (Medium)	3 (High)	6	Communication and reward throughout the project lifetime	Involve supplementary health care institutions

## 5. Conclusions and future work

The VASelfCare T2D project plan, aligned with the SMART objectives derived, covers a first stage of translating research into a product able to deliver value to customers. Future work as part of the StartUp research program includes revising the project plan (e.g. identifying risks from a PESTEL analysis), and developing a business model canvas.

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