



## **STOP Platform for healthcare professionals and persons with obesity: 4 testing stages**

### **Overview**

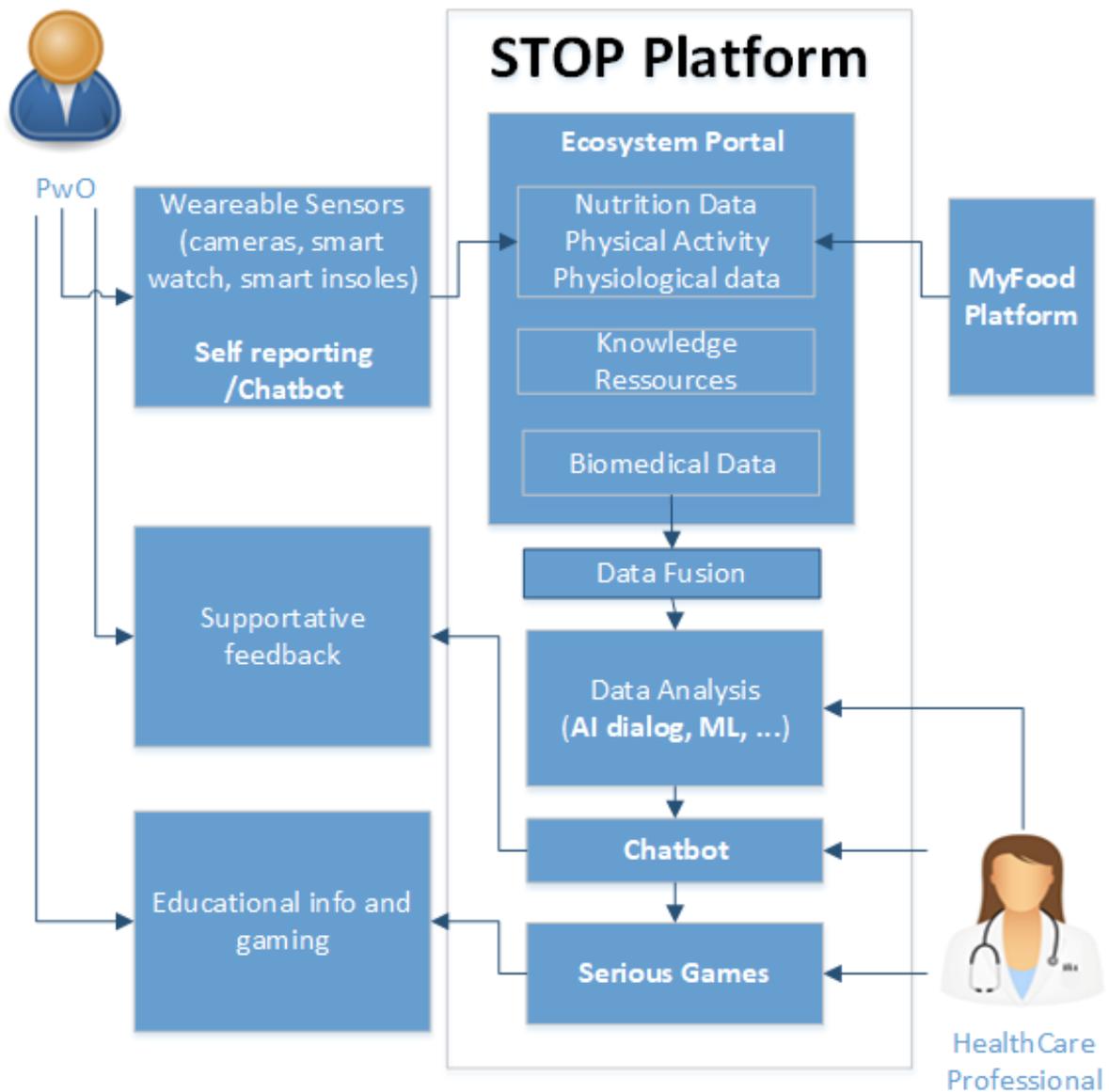
The STOP project is an interdisciplinary European research programme funded by H2020 with seven academic and industrial partners (Research Institute for Telecommunications and Cooperation, Cork Institute of Technology, University Ulster, University Napoli, INCONTEC, GLOBIT, OKKAM) to address the health societal challenge of obesity. The STOP project will address this need through the development of an innovative platform to support persons with obesity (PwO) with a better nutrition under supervision of healthcare professionals. Therefore, the STOP Platform will capture various PwO data from different kind of smart sensor streams and chatbot technology, manage and enrich available data with existing knowledge bases and fuse these by machine learned driven data fusion approaches for sophisticated artificial intelligence (AI) data analysis. Essentially, this gathered and analysed data and knowledge is accessible and usable for healthcare professionals as input for a gamification approach to teach PwO healthier nutrition. This proposal is for the usability and feasibility study and pilot RCT for this STOP Platform.

### **Background**

Obesity is a global health priority, and the World Health Organisation's latest figures are that in 2016, more than 1.9 billion adults, 18 years and older, were overweight, of these over 650 million were obese (1). That is 39% of adults were overweight in 2016, and 13% were obese. It is projected that by 2025, global obesity levels are set to reach 18% in men and surpass 21% in women. The cost of obesity is estimated at \$2 trillion - equivalent to 2.8 per cent of the world's economic output (2). Obesity is a major risk factor for a number of chronic diseases, including diabetes, cardiovascular diseases and cancer, whereat the work on obesity care related topics is highly connected to further urgent health related challenges (1-5). Therefore, the work in obesity care requires a broad range of skills and knowledge from academia and industry. From the academic partner point of view, staff from industry partners will stimulate research on a broad range of existing ICT health care market needs, trends and challenges focused on a broad set of different disease patterns. This will stimulate new research directions and opportunities for collaboration. From the industry point of view, academia will bring in recent trends in research of intelligent approaches and technologies that could open the path for new commercialisation possibilities in this broad application field.

The *STOP Platform* is being developed as part of this research programme (6). The aim of the *STOP Platform* is to establish a data and knowledge ecosystem as a basis for the *STOP Portal* to enable healthcare professionals (HPs) in decision support, and persons with obesity (PwO's) in analysis and feedback of health information to optimise healthy nutrition. The *STOP Platform* consisting of the following elements: ecosystem Portal - including nutrition, physical activity & physiological data, knowledge resources, biomedical data); data fusion; data analysis (AI dialog); chatbot, serious games; educational information and gaming; supportive feedback; wearable sensors; self-reporting/chatbot; and MyFood platform (6; **Figure 1**).

**Figure 1: Overview of the STOP Platform**







As demonstrated by Table 2 (7-17), STOP has been carefully conceived to provide real impact by going beyond the current state of the art. STOP will track and process external and internal state data on its participants(s) via a number of sensory devices such as cameras, wearables or smart insoles. STOP has the potential to be a cloud based service that can be applied and integrated into various forms of systems that require obesity and diabetes related data on individuals and groups. Services embedded with such personal and group-based state data will ultimately lead to reduced financial implications, intelligent auto-assistance/intervention(s), gamification approaches, lifestyle profiling and embedded intelligence and are all realistic benefits to be gained by using STOP in the next generation of intelligently powered healthcare platforms. STOP does not intend to compete in the emerging devices and sensory wearables marketplace. Rather it will specialise in providing a set of defined interfaces designed to process data from sensory devices such as wearables, cameras and the *Internet of Things* (IoT). Sensory data streams will be analysed in real-time by a layer of noise cancellation and fusion technologies that have been developed by the researchers during the course of research activities. Cleansed quality assured sensory data streams will then be processed by a comprehensive Machine Learning layer that forms the AI core of the STOP Platform (7-17).

## Aims:

### *Pre-testing Consortium members testing:*

To test the suitability of the different components of the Portal

### *Usability study:*

To test the usability of each unit of the Platform – portal, chatbot & gamification.

### *Feasibility study:*

To test the feasibility of the use of the STOP system for the ease of use, and to validate that the system is functions as per the design.

### *Pilot RCT:*

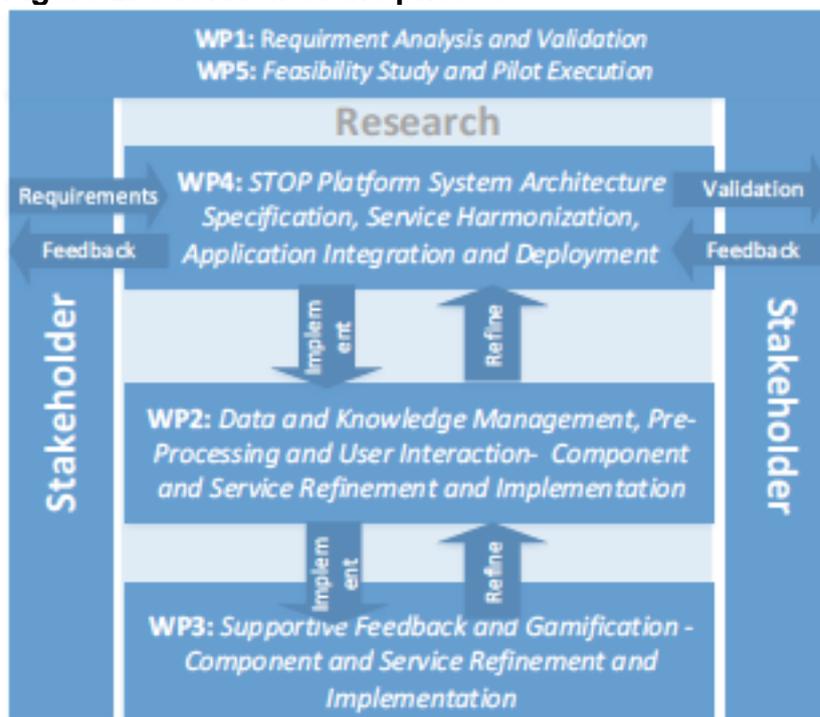
To determine the effectiveness of the newly developed system for overweight and obese adults to lose weight.

## Methods

This is development and evaluation research, as an online platform (i.e. *STOP Platform*) will be developed and evaluated. It comprises of four phases, inception, elaboration, construction and transition phases. Within the **Inception phase**, prerequisites for the software implementation are iteratively drafted and adopted. This particularly encompasses the orientation of project members in their responsibilities, extraction of the overall project goals, installation/adoption of the working environment and used terminology. In the **elaboration phase** the baseline

for system implementation through iterative specification of identified/updated *STOP* requirements is set. In the **construction phase** the *STOP* Platform is iteratively and parallel implemented and minor refinement of *platform* specification, are done. It will, continuous development, integration and testing of specified system components. In the **transition phase** the *STOP Platform* will be refined with respect to system performance, stability, deployment process and documentation. Essentially, *STOP* will be designed as an innovative platform, which will be iteratively validated and refined according to stakeholder's group requirements. Therefore, during the construction and transition phase, there will be an usability study, feasibility study followed by a pilot randomised controlled trial (**Figure 2**).

**Figure 2: Overview of the phases**



**There are 4 stages of testing:**

1. Pre-testing Consortium members testing.
2. Usability – Unit testing of the portal, chatbot & gamification.
3. Feasibility (whole system).
4. RCT.

### **Pre-testing Consortium members testing**

Pre-testing will be conducted to test the suitability of the different components of the Portal among the consortium members via demonstrations followed by group



discussions. These discussions will inform the finalisation of each unit - portal, chatbot and gamification.

## Participants & Recruitment

Participants for the usability study, feasibility study and pilot RCT will be adults who are overweight (BMI 25.0-29.9 kg/m<sup>2</sup>) or obese (BMI >30 kg/m<sup>2</sup>) through the island of Ireland (North and South).

### *Inclusion criteria:*

- Overweight and obese adults with BMI >25 kg/m<sup>2</sup>
- Aged 18+ years
- Male and female
- Access to bathroom scales or equivalent to measure weight

### *Exclusion criterion:*

- not providing consent

All participants will be recruited using convenience sampling. A range of recruitment methods will be used, including adverts for weight loss organisations/groups (Appendix 1), adverts on social media, i.e. Twitter and Facebook (Appendix 2), and University staff of and student populations ((Ulster University and University College Cork; via e-mail, Appendix 3); Interested participants will contact the researchers (contact information will be provided on the adverts), who will send them the participant information sheet (Appendix 4), screen for the inclusion and exclusion criteria via telephone, e-mail, online call (such as SKYPE, Zoom, MS Team) as is convenient for the interested participants. Written informed consent will be provided prior to participation in the research via e-mail (Appendix 5).

## Intervention

The intervention for usability study, feasibility study and the pilot RCT will be the STOP platform, online digital innovative tool that will available to participants on the STOP portal, accessible using a smartphone or device. The URL for the STOP Portal is is <https://stop.projekt.onl/> The STOP platform will capture various PwO data from different kind of smart sensor streams and chatbot technology, manage and enrich available data with existing knowledge bases and fuse these by machine learned driven data fusion approaches for sophisticated AI data analysis. Essentially, this gathered and analysed data and knowledge is accessible and usable for healthcare professionals amongst others as input for a gamification approach to teach PwO healthier nutrition. In the STOP validation an app that establishes an analogy to Dorian Gray mirror, teaching healthier nutrition (Appendix 6 STOP Portal:



Fitness Data Manager; Appendix 7 STOP Portal: Google Fit; Appendix 8: STOP Portal: Chatbot Platform User Manual).

Data will be collected on the STOP platform include:

- *Fitness profile*: gender, height, weight, fitness goal, activity level, allergies
- *Fitness data*: exercises, activities, food and water consumptions
- *Knowledge resource (added by users if any)*: publication, multimedia, questions & answers, software
- *Log*: user activities on the platform (IP, URL, referrer, visit time, visit duration, user agent)
- *Chatbot*: chat protocol

The original plan was to access the STOP Portal on a wristband and provided to the participants on the Universities campuses but due to COVID-19, this study was put online with no personal contact. Participants will be asked to measure their own weight using their own bathroom scales or equivalent and record it on the STOP portal or using an online survey for the control group within the RCT.

## Usability Study

A total of 10 adults who are overweight and obese will participate in this usability study. The purpose of this usability study is to test the usability of each unit of the Platform – portal, chatbot and gamification. Each participant will consider each unit – one at a time, accessible on the Portal <https://stop.projekt.onl/> and complete our validated usability questionnaire (**Appendix 9, usability questionnaire**). The results of the usability study will inform the final development of each unit for the feasibility study.

## Feasibility study

A total of 30 adults who are overweight and obese will participate in this feasibility study. The purpose of this feasibility study is to use the system for one week to test the ease of use, and to validate that the system is functions as per the design. The *STOP Platform* will collect the following data: physiological data, knowledge resources, biomedical data, self-reporting activity and food data, as per the intervention section above.

Participants will be required access the STOP Portal via <https://stop.projekt.onl/> for one week that records their activity and food intake. Demographic information such as gender and age will also be collected as (**Appendix 10, demographics**). Participants can request the withdrawal of the prototype at any time. This feasibility study will inform the sample size calculation for the randomised controlled trial.



## **Pilot randomised controlled trial (RCT)**

This pilot RCT will determine the effectiveness of the newly developed system for overweight and obese adults to lose weight. The duration of the intervention is up to three months.

### **Randomisation**

It will be a two-arm trial: 1. intervention (n=30) and 2. control (n=30). The intervention group will consist of adults who are overweight and obese using the newly developed system, STOP Portal, while the control group will be adults who are overweight and obese not using the system. Participants will be randomised into one of the two groups using a computer randomised programme.

### **Outcomes measures**

The primary outcome is percentage reported weight loss. Based on weight loss for health gain, 10% weight loss is recommended, thus this project will determine the percentage of participants with 10% weight loss by three months. Four data collection points for both the intervention and control groups will be at 1. baseline (month 0); 2. month 1; 3. month 2; and 4. month 3. Regardless, of what group the participants are in, their weight and height will be recorded at each of these four data collection points. The plan before COVID-19, was to measure each participant's weight and height on the University campuses by the research team but now it will be measured and reported by the participants using the online STOP Portal or online survey for the control group. Participants in the control group will submit their measures including weight using an online survey via Qualtrics.

### **Procedures**

Participants will be randomly allocated into one of two groups. Those in the intervention group, will be asked access and use the STOP Portal via <https://stop.projekt.onl/> for up to 3 months, and those in the controlled group, will not have to access and use the STOP Portal. Measurements (as above listed in the intervention section) will be recorded on four occasions, at four data collection points at baseline (month 0), month 1, month 2, and month 3. At the end of the RCT, all participants in the control group will have access to the STOP portal, if they wish, which is not part of the research.

### **Data analysis**

All quantitative data will be analysed using SPSS for frequencies and descriptives. For the Pilot RCT, paired t-tests will be used to compare data between the 2 arms, i.e. control and intervention. Weight will be compared at four data collection points at baseline (month 0), month 1, month 2, and month 3, using two-way ANOVAs. A statistician will advise the data analysis.

### **Ethical Issues**



This research project is seeking ethical approval from Communication & Media Ulster University Filter (Research Ethics) Committee. All of the participants will receive a participant information sheet and will have the opportunity to ask the researchers any questions. All participants will provide written informed consent. Participants' information will be kept confidential. Participants will not be identified on through data captured by sensors and the researchers will not share this with anyone. All data will adhere to the GDPR 2018 guidelines and Data Protection Act 2018.

Ethical issues may arise in the following areas of the project:

- Dealing with patients' medical history
- Dealing with secure transmission of patient data for connected health services
- Transmission of physiological and cognitive state data on a patient

None of the research procedures to be used will be invasive. Two sets of ethical issues are important for this research: the ethical treatment of the participants throughout the research and the ethical treatment of the data collected. All partners will undergo appropriate ethical review procedures for their research activities, as required in their jurisdictions and institutions.

Appropriate ethical procedures will be based on existing ethical procedures of all five partner organisations informed by authoritative sources and will adhere to relevant international, EU and national law, including human rights, and ethical guidance documents, including the following:

- Charter of Fundamental Rights of the European Union, 2000, [http://www.europarl.europa.eu/charter/pdf/text\\_en.pdf](http://www.europarl.europa.eu/charter/pdf/text_en.pdf)
- UN Convention on the Rights of Persons with Disabilities, 2008 <http://www.un.org/disabilities/convention/conventionfull.shtml>
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- Draft General Data Protection Regulation of the European Parliament and of the Council (currently under consideration and likely to be introduced during the lifetime of the project).
- Art. 8 of the Convention of the Council No. 5 for the Protection of Human Rights and Fundamental Freedoms.
- Convention No. 108 of the Council of Europe for the Protection of individuals with regard to automatic processing of personal data.
- European Commission. Communication from the commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: A comprehensive strategy on data protection in the European Union. Technical report, October 2010.



- Working Party on Police and Justice. The future of privacy: Joint contribution to the consultation of the European Commission on the Legal Framework for the Fundamental Right to Protection of Personal Data. Technical Report 02356/09/EN WP 168, Article 29 Data Protection Working Party, December 2009.
- Declaration of Helsinki, 2013, <http://www.wma.net/en/30publications/10policies/b3/>
- World Health Organization, Handbook for Good Clinical Research Practice.
- British Psychological Society Code of Ethics and Conduct, August 2009.
- Helsinki Declaration of 1964 (Recommendation for conduct of clinical research)
- Recommendations from the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)
- Current EU and national law regarding this matter. In particular these regulations include the EC/46/95, EC/58/2002, the Directive 95/46/EC and 97/66/EC, about Rights and interest of data subjects and the recommendations of the European group on ethics in science and new technologies to the European Commission.

#### *Data Protection and privacy*

Particular attention will be paid to establishing data protection and security requirements for personal data and the subsequent integration of data protection and privacy concerns into the design and implementation process. The STOP project will ensure that personal data collected will be minimised and fully anonymised throughout the course of the validation and protected by an appropriate cryptographic system.

The privacy of the participants will receive particular attention throughout. The manner in which research outcomes will be reported will not contravene the right to privacy and data protection. Privacy by design will intersect with the realisation of principles of dynamic consent to empower end users and, where applicable, their families and/or carers, to have input into what level of privacy they prefer and how their data will be used. Participants need to be clearly informed of the data privacy implications and especially privacy management options.

Once the participant consents, they will be assigned a unique identifier and all further identification material will be stored separately under the unique identifier and not their name. Only one master file linking the names of the participants with their unique identifiers will be kept and this will be password protected and securely stored. All data in relation to participants will only be used, stored, and disclosed using a method that prevents their identification as an individual (e.g. by only using aggregated data in reports and publications, and only using direct quotes from participants that do not in any way reveal their identities) and ensure anonymity. All information about participants (e.g. videos of sessions, files with transcriptions of discussions, interviews) will be kept on secure computers and only identified by the participants' unique identifiers. Data will not be transmitted to any third parties except with the informed consent of the participant. All data relating to the studies will be kept for seven years. At the end of that period, all data will be destroyed in a secure manner.



European Commission



## Timeline

The timeline for this research is below.

Task	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
Pre-testing Consortium members testing	█											
Recruitment of participants		█	█	█	█	█	█					
Usability study Data collection		█										
Usability study Data analysis			█									
Feasibility study data collection				█	█	█						
Feasibility study data analysis						█						
RCT – data collection							█	█	█	█		
RCT – data analysis										█	█	█
Write-up publications*											█	█

\*2 publications – 1. Feasibility study, 2. Pilot RCT



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## Appendices

- Appendix 1: Adverts for weight loss organisations/groups
- Appendix 2: Adverts on social media, i.e. Twitter and Facebook
- Appendix 3: E-mail to University staff and student populations
- Appendix 4: Participant information sheet
- Appendix 5: Consent
- Appendix 6: STOP Portal: Fitness Data Manager
- Appendix 7: STOP Portal: Google Fit
- Appendix 8: STOP Portal: Chatbot Platform User Manual
- Appendix 9: Usability questionnaire
- Appendix 10: Demographic information sheet