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*Status of deliverables is indicated by abbreviations/terms as follows:

Draft (D): The deliverable is partially complete or complete but under review/revision before release.

Complete (C): The final deliverable document is 100% completed, reviewed and authorised for release by the partner responsible for the deliverable or the WP leader.

Revised (R): The final released document has been modified/updated with new content.

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List of Abbreviations

API	Application Programming Interface
BP	Blood Pressure
BPM	Blood Pressure Monitor
CABIE+	Context Aware Brokering and Inferencing Engine (data aggregator)
CPU	Central Processing Unit
FC	Formal Carer
FT	Friendly Trial
GP	General Practitioner
HCP	Healthcare professional
IC	Informal Carer
ICT-AT	Information Communication Technology – Assistive Technology
MDT	Multidisciplinary team
PHN	Public Health Nurse
PoC trial	The Proof of Concept trial of ProACT with end users with multimorbidity and their care network
PwM	Person with Multimorbidity
PwM kit	The technology that the PwM will receive at home
RAM	Random Access Memory
SIMS	Subject Information Management System
VPS	Virtual Private Server
WP	Work Package. The number of the WP is added e.g. WP2

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Executive Summary

This deliverable outlines the design and implementation of the piloting of the ProACT system, in a friendly trial (FT) conducted at each trial site, and examines the outcomes from this process. For the purposes of this project, **a FT is defined as a trial to test the robustness of a technology ecosystem, prior to deployment to real end-users**. The FT took place at the main trial sites in Ireland and Belgium, while a smaller scale FT took place in Italy, where a transferability study will be conducted. Participants of the FT were members of research teams at the trial sites. During the FT, participants 'acted' as ProACT stakeholders, testing the current ProACT system.

This deliverable outlines the technology deployed in the FT, the study design, how data was managed, what was evaluated and findings from this evaluation, as well as a discussion of the implications of these findings. The evaluation has focused on the following factors: technology robustness (for example, data flow between sensors, the ProACT back-end architecture and end-user interfaces; reliability of technology), user feedback (usefulness, satisfaction, user burden) and system analytics (usage and system performance). Outcomes from the FT will contribute to refinement of the technology ecosystem and the protocol for the Proof of Concept (PoC) trial.

The purpose of the FT was to test all aspects of the ProACT system to facilitate modification and adjustment of the application and processes prior to deployment in the PoC trial. Due to the timing of the FT, a full trial of the final ProACT system was not feasible, however, the FT permitted a comprehensive trial of the fundamental elements of ProACT, including the CABIE+, SIMS and SEEK elements as well as a range of self-monitoring devices expected to be used in the PoC trial, and transfer of all data from CABIE+ to the InterACT platform. The data generated during the FT is also currently being used by partners IBM and TREE in the development of Care Analytics for use in the PoC trial.

Overall, it is clear that the data gathered in the FT has been essential for the ongoing and iterative development of ProACT, by identifying potential challenges with data transfer and device usage, leading to further research and trialling of potential alternative devices for inclusion. The findings from this first intensive phase of the FT highlighted a number of challenging issues with the first iteration of ProACT, but also positive aspects. These findings are discussed in greater detail in this report, with implications for our next phase of FT testing as well as implications for the PoC trial outlined.

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1. Introduction

This document describes the formal friendly trial (FT), which consisted of a 12-week structured piloting of the current iteration of ProACT. We define a FT as a pilot of a technology ecosystem to test its robustness and ease of use, prior to deployment with end users. The ProACT ecosystem consists of various pieces of technology - including off-the-shelf third party sensors and devices, as well as custom-built back-end technologies and end-user applications, which must all integrate seamlessly. Rigorous testing of the system's robustness is therefore critical. This is particularly important given the aim of ProACT is to support the self-management of older adults with multiple chronic conditions. Relating to the selection and inclusion of potential devices for integration with ProACT, key issues to be considered are those of (1) usability and suitability of devices for our cohort and (2) accuracy, data connectivity and integration of devices with ProACT.

In addition to the formal FT, this document also outlines an evaluation of the performance of the Withings watch under different walking conditions and provides preliminary feedback on testing of additional sensor devices since the cessation of the structured FT. It is important to note that the initial ProACT FT was limited to some degree by the available iteration of the system at the time of the trial. Further development of ProACT is being informed by results from the formal FT – for example, additional sensors have been identified that may address some of the issues experienced during the FT. As such, a second phase FT of an updated version of the ProACT ecosystem will take place over the coming months - as new devices are identified and new applications are designed, developed and iterated upon leading up to the Proof of Concept (PoC) trial, researchers at trial sites will continue to test their integration, robustness and ease of use within ProACT.

The following terminology will be used throughout the remainder of this document to refer to the various testing phases:

- **Formal FT or FT** – the 12 week period of testing that took place in Ireland and Belgium with a total of 10 participants **using the integrated ProACT system**. This forms the main content of this deliverable.
- **Italian FT** – testing that took place at the Italian transferability trial site.
- **Withings Watch Experiment** – an experiment that took place at DkIT to test issues with the Withings watch discovered during the Formal FT.
- **Parallel Device Testing** – Testing of **additional devices not yet integrated** into the ProACT system, but currently under consideration.
- **FT Phase 2** – The next phase of formal FT testing that will take place from late August 2017 with the **updated ProACT system**, including new devices.
- **PoC Trial** – The ProACT Proof-of-concept trial that will take place with people with multimorbidity (PwMs) and their care network, over a 12 month period.

1.1 Friendly Trial Aims and Objectives

The aim of the FT was to deploy an integrated ProACT platform and to determine any issues with deployment or connectivity. The platform deployed to participants included devices and sensors identified as important for ProACT participants in managing their conditions (e.g.

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blood pressure, blood glucose, activity etc.) as well as custom-built interfaces for displaying data and educational material. In addition, the FT provided an opportunity to test the ProACT back-end architecture, including CABIE+ and the InterACT cloud. Components of the ProACT technology ecosystem are described in more detail in D2.1.

Specific objectives included:

- Instantiate CABIE+ to collect data from each trial site.
- Deploy the ProACT platform to FT participants.
- Evaluate data flow between all modules of the system – i.e. the sensors (inputs), CABIE+, the InterACT cloud and interfaces.
- Evaluate the reliability of the data and technologies.
- Evaluate the overall usability of the platform in real-world environments.

One of the original aims of the FT, outlined in D1.4, was to pilot the outcome measures identified for use in the PoC trial, for example to determine how long they might take to administer, or whether some questions might cause distress. However, following discussion amongst the trial sites it was agreed that it would be best to do this with our intended cohort. Thus questionnaire piloting will be an activity with our PwM research panel.

Outcomes from the FT have been fed directly into WP2 and WP3 through multidisciplinary team calls between trial site researchers and the technical team, to support the iterative re-development/improvement of the ProACT system. In parallel to the FT, sensors, devices and interfaces were evaluated as part of WP2's iterative design and testing process through Co-Design Workshops with end users (PwM and other people in their care network) who have been recruited to research panels at trial sites as part of WP1. A revised deployment plan and protocol for the final PoC trials will also be produced as an output of the FT (D1.6 (D1.4 Part B)).

1.2 Deliverable Description

The remainder of this deliverable is structured as follows: Section 2 provides a detailed description of the technology deployed during the FT, including both end user technology and ProACT backend technology. Section 3 outlines the study design and methodology of the FT in Ireland and Belgium, as well as the methodology of the Withings Watch Experiment. Section 4 describes the results from these two phases of testing, and in addition provides some preliminary feedback on the Parallel Device Testing. Details on the Italian FT, including methodology and results, are provided in Section 5. Finally, Section 6 summarises the pros and cons of devices tested, discusses the implications of our results for the PoC trial and outlines how FT Phase 2 will address some of the limitations of the FT.

This deliverable has close links with a number of other deliverables in the project:

- D1.4 should be read alongside this deliverable as it contains background information on developing the FT protocol and explains decisions made at the time the protocol was developed.

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- D2.1 provides technical descriptions of the various systems being developed and integrated into the ProACT architecture. These are referred to throughout this deliverable. An updated version of this report, (D2.6 (D2.1 Part B)), will provide the same information for the updated ProACT system prior to the PoC trial.
- D2.2 outlines the deployment plan for the technology required for the FT and (D2.8 (D2.2 Part B)) will outline the deployment plan for the PoC trial.
- D2.4 presents an initial set of guidelines for data analysis based on data from the FT.

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2. Technology Deployed

A PwM kit was prepared and deployed for each FT participant in Ireland and Belgium. Table 1 indicates the hardware deployed and a complete discussion of each item of technology, and how it performed, can be found in Section 4 below.

Table 1 - Hardware deployed

Vital signs monitoring	Wellbeing Monitoring	Other
Withings[1] Blood Pressure monitor	Smart Things Passive Infrared (PIR) Kit (ambient activity, including location in the home and time spent outside)	Peripheral supplies (batteries, extension leads etc.)
Withings Weight Scale or Withings Body Analyser (weight scale)	Withings Activité Pop watch (step count and sleep)	

Table 2 indicates the end user applications deployed during the FT. Participants acting as a PwM received a selection of the vital signs monitoring equipment dependent on their conditions, the wellbeing monitoring equipment and used their own tablet / phone and broadband service, as well as the SEEK application.

Table 2 - Software deployed

End User Application	
ProACT health and wellbeing application for PwM (SEEK)	Displays data gathered through various sensors as well as behaviour change education and tips
ProACT (SEEK) Informal Carer's (IC) app	Displays data gathered through various sensors from the PwM, as well as education
ProACT (SEEK) Formal Carer's (FC) app	Only displays wellbeing data; Formal carer could view data for multiple PwMs
ProACT (SEEK) Healthcare Professional (HCP) app	Displays data for multiple PwMs; HCPs could view data for multiple PwMs
SIMS (Subject Information Management System)	Trial site managers in Ireland (n=1) and Belgium (n=1) used SIMS to setup and manage participants during the FT

Participants were instructed by the trial site managers on the placement of sensors within the home and how to connect the various devices over Bluetooth and/or Wi-Fi. It was important for FT participants to understand this process, as many of the participants will be

[1] Note that since the start of the friendly trial, Withings has now become Nokia. Transfer of branding has now begun and the application interface has changed from that experienced during the friendly trial. It is not yet apparent how this transfer may affect API issues for Withings/Nokia branded devices identified for potential use in the PoC trial.

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involved in deploying technology to PwM homes during the PoC trial. In providing this training, trial site managers used 'help' documentation available on SIMS, that includes guidelines on setting up and deploying the various pieces of technology. These guidelines were also outlined in D2.2.

Figure 1 provides a conceptual overview of data flow amongst components of the ProACT ecosystem. As can be seen, data flows from device providers and CareApps into CABIE+, which then pushes data back to CareAPP interfaces for the various end-users. CABIE+ also sends anonymised data to InterACT for further analysis. Analysed data is returned to CABIE+ and pushed to end-user interfaces. During the FT, Care Analytics were not implemented, as outlined below in Section 2.1.2, however data was pushed to InterACT for offline work on analytics.

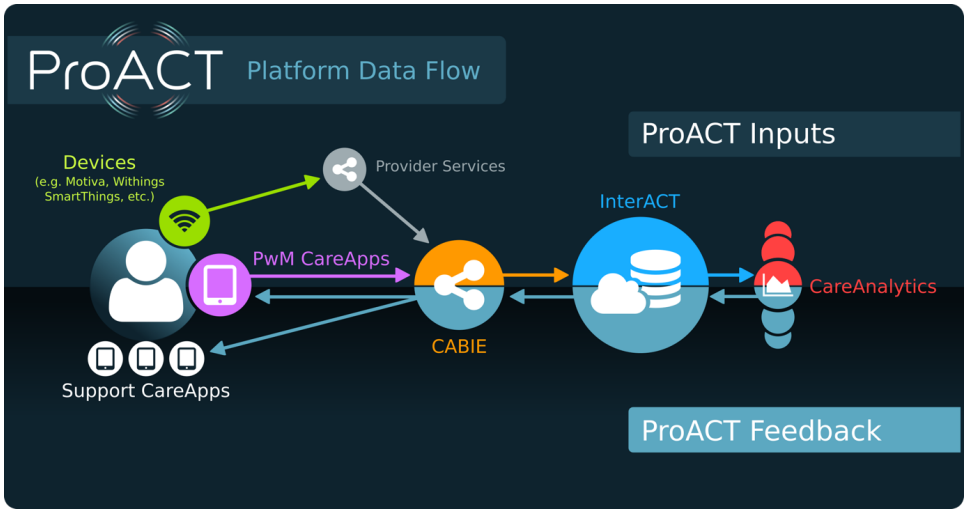

Figure 1 - Conceptual Flow of Data through ProACT Systems

For the purposes of the FT, participants used the SEEK CareApp for PwMs to view their health and wellbeing data (i.e. data from Withings and Smart Things devices), answer a short number of daily questions and questionnaires (for example, to measure breathlessness for COPD, mood, general wellbeing etc.) and input manual entry values for vital signs. The SEEK application was adapted from partner DKIT's YourWellness application, to suit the needs of the ProACT FT. It allowed testing of data transfer and display from the selected devices during the FT, and acted as a 'stop-gap' during the design and development process of the new ProACT health and wellbeing application. Versions of SEEK were created for different end-users in the PwM's care network (IC, FC, HCP), primarily to test setting up different accounts in SIMS and provision of access to certain types of data for certain end-users. The SEEK application can be seen in Figure 2.

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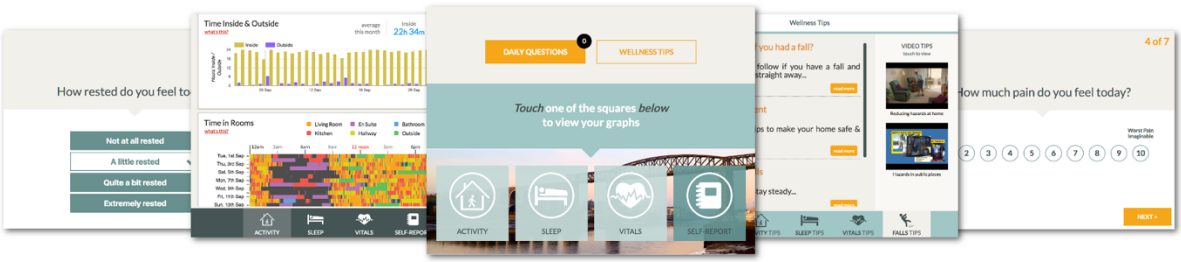

Figure 2 - DkIT's SEEK CareApp

2.1 Supporting Technology

2.1.1 CABIE+

CABIE+ is a source-agnostic data collection system developed by DkIT. Using open Application Programming Interfaces (APIs), CABIE+ pulls data from device providers (e.g. Withings, Smart Things), as well as data inputted through the SEEK app. CABIE+ normalises and anonymises this data and sends it to the InterACT cloud for analysis.

2.1.2 Interact

The InterACT platform, developed by IBM, interfaces with the major data providers to gather anonymised data and information. It then stores the anonymised data in the InterACT Cloud where a set of analytics tools, developed within the framework of WP3, will process it and make results available for the CareApps to consume. Throughout the FT, data was automatically transferred from CABIE+ (where it is anonymised) to InterACT. This took place once a day, to test data transfer, but also to support initial work on data analytics by IBM. This analytics work is described further in D2.4. In the final ProACT system, CABIE+ will retrieve results of Care Analytics from the InterACT cloud to push to end user interfaces. However, this aspect was not tested in the FT, as sample data needed to be generated (through participants using devices to take blood pressure, record steps etc.) before development of Care Analytics could begin.

2.1.3 SIMS

The Subject Information Management System (SIMS) has been developed as an in-house extension to DkIT's CABIE+ platform. It is an administrative tool to facilitate management of trial site technologies, provide an abstraction layer for managing multiple CABIE+ instances, and to provide the research and technical teams with a user-friendly, centralised service for monitoring and inspecting the integrated ProACT platform. SIMS features both a web-based administrative dashboard for the wider technology platform, and an API which enhances the feature-set of DkIT's CABIE+ technology. Within the dashboard (Figure 3), some of the key features available to trial site researchers include:

- Adding trial participants (PwMs, ICs, FCs, HCPs)

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- Assigning care network members to a PwM
- Assigning a technology kit to PwMs
- Creating and configuring questionnaires (called surveys within SIMS) and questionnaire schedules for delivery to participants
- Creating and configuring education tips for delivery to participants
- Generating graphs and reports of participant data over time.

The system also features a flexible translation module which can be employed at a later date to rebrand the web interface and associated language components, if such a change is discovered to be necessary.

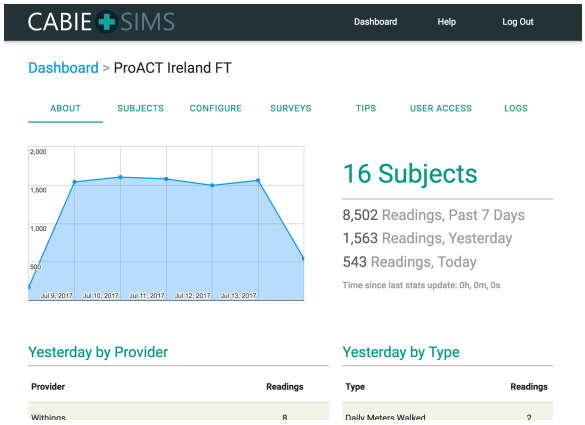

Figure 3 - SIMS Web Interface

The initial development of SIMS has been primarily guided by past experience within DkIT, and a detailed knowledge of the existing in-house systems which will be integrated into the ProACT platform. Scoping for the initial release of this system for use in the FT used researchers in DkIT as informed end-users with previous experience of managing trials similar to those to be employed for ProACT. Informal interviews were conducted with researchers to discover the areas of trial management they believed could be improved with additional technology tools, and features they believed would streamline their research processes. Feedback on SIMS was also provided to the technical team in DkIT throughout the FT, and a new version has been released taking these suggestions into account.

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3. Study Design and Methodology – Ireland and Belgium

3.1 Participants

Five participants were recruited at each main trial site. Participants were recruited from within the research teams, primarily for the following reasons:

1. Researchers within the team understand exactly what will be required in terms of testing, and this knowledge is critical for an effective FT implementation; furthermore, researchers at trial sites gained first-hand experience of setting up, deploying, using and testing the technologies. This will be valuable for their involvement in deployment and maintenance during the PoC trial.

2. The level of feedback required to fully test the system was expected to be taxing on participants (see Study Design below), requiring multiple levels of reflection on the technology.

Each participant was randomly assigned a PwM role, as well as up to two 'care network' roles Informal Carer (IC), Formal Carer (FC) or Healthcare Professional (HCP). Participants were organised into clusters, with each participant 'acting' in a primary or lead role as well as supplementary roles (see Table 3 below). To protect privacy, each participant was given a participant ID, that they had to use for the app and questionnaires, and only the trial site managers were able to link participant IDs to identities. After initial login, participants also had the possibility to change their password. The primary purpose of acting in multiple roles was to test the setup of accounts for different end-user types (PwM, IC, HCP etc.); to test the provision of certain types of data to certain users (e.g. that FCs received wellbeing data (activity and sleep) but did not receive vitals data – a finding from our requirements study outlined in D1.2) and to test that support actors could only see data for those PwMs who they had been assigned access to.

Table 3 - Friendly Trial Participant Clusters

Cluster	Participants	Lead Role	Additional Roles	Illnesses of PwM
C1	P1_Ire	PwM	IC, FC	Diabetes, CHD/CHF & MCI
C2	P2_Ire	PwM	FC, pharmacist	COPD & CHF/CHD
C3	P3_Ire	Geriatrician (with MDT)	PwM, IC, GP	Diabetes, COPD & CHF
C4	P4_Ire	FC	PwM, IC, PHN	Diabetes & CHF/CHD
C5	P5_Ire	GP	PwM, IC, pharmacist	Diabetes & COPD

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C6	P6_Be	PwM	IC, FC	Diabetes & COPD
C7	P7_Be	PwM	FC, pharmacist	Diabetes, COPD & CHF
C8	P8_Be	GP	PwM, pharmacist	Diabetes & CHF/CHD
C9	P9_Be	Hospital Specialist	PwM, GP	COPD & CHF/CHD
C10	P10_Be	FC	PwM, IC	Diabetes, CHD/CHF & MCI

3.2 Study Design

All five participants at each site were assigned a PwM role. In this capacity, each participant was 'assigned' two or more of the ProACT conditions, which determined what sensing kit they received, as well as the frequency of when they should take readings (for example, a person with CHF was asked to take daily weight, whereas weekly weight would be sufficient for a person with diabetes). Depending on their role as a PwM, participants were required to interact with the ProACT kit in the following ways:

- Place Smart Things ambient room sensors in relevant rooms (bedroom, bathroom, living room, kitchen, hall, front & back door) to record motion.
- Carry the Smart Things fob when leaving their home, to record time inside and outside the home.
- Wear the Withings watch for the duration of the FT, to record step count and sleep data.
- Complete measurements using the Withings Blood Pressure Monitor (BPM) and weighing scales as directed (daily or weekly).
- Manually enter blood glucose or pulse oximeter readings, where relevant, into the SEEK application. Any values inputted were fake values, as digital devices to record blood glucose and pulse oximetry had not been identified prior to the FT beginning. However, these have since been identified and are currently being integrated and tested.
- Answer daily questions in PwM role, presented by the SEEK application.
- Access SEEK daily and view records of their own readings to validate data transfer and accuracy of data.

To test the system as thoroughly as possible, different scenarios were set up for each user to follow. Each scenario included a description of the lead role and additional roles per cluster, as well as a description of how to use the system during the trial (see Appendix B). The additional roles were fulfilled based on a generic description of their role in the healthcare system and the ProACT system as described from findings in D1.2.

The scenarios were designed to guide participants to take different stances towards the system in their main role. For instance, to approach the system as if they were stressed

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about managing their health routines, forgetful or with colour vision impairment. These stances changed every week on Monday, and were to be followed until Thursday of that week, to capture different experiences of working with the application. The scenarios included small tasks every week on Friday. Examples of this are: 'your phone-battery died for a day' or 'someone else used your scale', followed by a question on how they and/or the system responded. The tasks were designed to test the application in the context of possible problems that may arise in every-day life for participants in the PoC trial. FT participants were prompted to complete a daily survey template on device usage.

In their care network role, participants were required to access SEEK and view the data for between one and three PwMs. The data available to participants in their care network roles was PwM data from between one to three other FT participants. This included their own PwM role data, thereby enabling participants to identify the effectiveness of data transfer and the accuracy of data content, as they were aware of their own data and what should be available within the SEEK app.

3.2.1 Recruitment Materials

Team members at each site were provided with Participant Information Leaflets (PILs) for all roles/stakeholders anticipated for the PoC trial. Feedback was provided and applied in the development of final PILs for each group of participants (PwM, IC, FC and HCPs). Likewise, consent forms were distributed to team members. Feedback provided was incorporated into the final consent forms drafted for the PoC trial. From feedback during the FT process, an additional short form PIL was developed for the PoC trial both as an informational and recruitment tool, to provide essential information necessary for potential participants to consider if they meet the criteria for possible participation in the trial.

3.3 Overview of Data Capture and Analysis

There were multiple phases of user testing during the FT. While some participants in DkIT started testing devices in late 2016, the FT period for purposes of analysis is from January 4th to April 7th 2017 - a total number of 94 trial days. During this time the system recorded 32 subjects engaging with the SEEK application. Subjects include FT participants representing each role assigned for the FT, as follows:

- 10 PwMs
- 7 Formal Carers
- 7 Informal Carers
- 8 Health Care Professionals

During this period all 10 participants in Ireland and Belgium were asked to:

1. Use devices and the SEEK app as outlined to them.
2. Complete online daily surveys to record any issues with data accuracy, transfer or other user issues. (These surveys only needed to be completed if an issue was identified).
3. Take part in a de-briefing focus group on completion of the trial.

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Throughout this period, CABIE+ recorded both usage and performance statistics. Calculating usage statistics was primarily to test the availability of statistics during the PoC trial, whilst performance statistics were important to ensure the system can effectively manage and process multiple data input and output streams for multiple participants.

In addition to these core phases of the FT, additional user testing activity included:

4. Parallel and ongoing testing of individual devices identified for potential inclusion in the PoC trial, including iHealth devices, additional Withings devices (heart rate watch and pulse oximeter) and Philips PHS devices. These devices were not integrated into CABIE+ for this phase of the FT, but some participants in Ireland and Belgium performed some initial testing. This preliminary feedback is included later in this report (Section 4.2)
5. A Withings watch walking experiment, conducted by the team at DkIT.

3.3.1 Managing Data Transfer

One of the primary aims of the FT was to ensure that data is transferred accurately and consistently. SmartThings and Withings wearable devices (watches) continuously capture data throughout the day and/or night. CABIE+ checks for the presence of this data at regular intervals and processes this information. This data is transferred to the InterACT cloud and is available on demand to be retrieved by the tablet or phone applications. A daily email alert is sent to the technical team and trial site managers outlining the number of inputs by data type for the previous day, across all participants (

Figure 4). For the PoC trial, this email alert will be modified to highlight if data is not received/sent by the server. Specifically this report will include:

- The participant ID(s) that have not sent/received data
- The devices that have not sent/received data
- The time and date of last successful data transfer for the relevant measure

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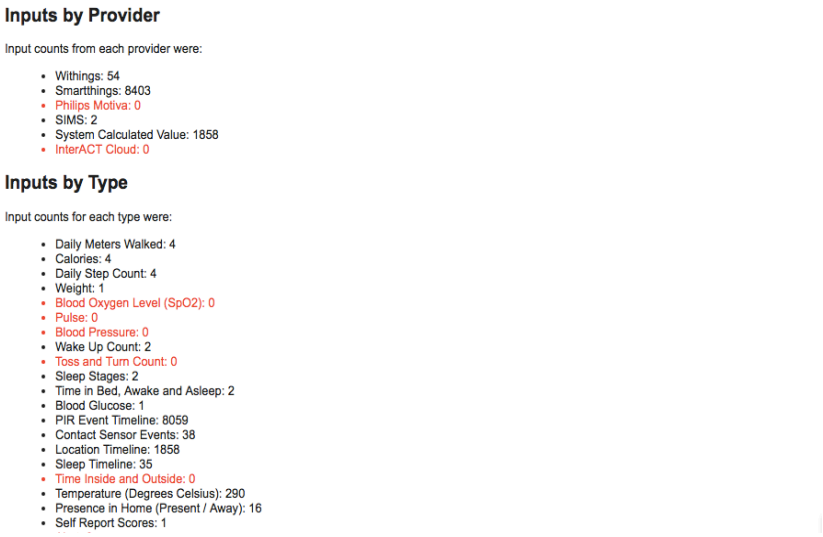

Inputs by Provider

Input counts from each provider were:

- Withings: 54
- Smartthings: 8403
- Philips Motiva: 0
- SIMS: 2
- System Calculated Value: 1858
- InterACT Cloud: 0

Inputs by Type

Input counts for each type were:

- Daily Meters Walked: 4
- Calories: 4
- Daily Step Count: 4
- Weight: 1
- Blood Oxygen Level (SpO2): 0
- Pulse: 0
- Blood Pressure: 0
- Wake Up Count: 2
- Toss and Turn Count: 0
- Sleep Stages: 2
- Time in Bed, Awake and Asleep: 2
- Blood Glucose: 1
- PIR Event Timeline: 8059
- Contact Sensor Events: 38
- Location Timeline: 1858
- Sleep Timeline: 35
- Time Inside and Outside: 0
- Temperature (Degrees Celsius): 290
- Presence in Home (Present / Away): 16
- Self Report Scores: 1

Figure 4 - Daily email alert delivered to research team

For the purposes of the FT, CABIE+ also monitored and calculated usage statistics with the SEEK application, as well as performance statistics. Further detail on these can be found in Section 4.3.

Processes for managing the privacy of trial participant data were also implemented during the FT. A process for anonymising participants' data, before it is sent to the InterACT cloud, was developed and implemented by the teams at IBM and DkIT.

3.3.2 User Questionnaires and Participant Surveys

During the FT, participants completed a daily online Friendly Trial Survey to identify any device or system related problems arising. An online survey template was made available to participants, for recording the actions they had performed with the system (see Appendix A), whether data was visible as expected on the application interfaces, and to record any issues they encountered in using both the devices and the application interfaces. In conjunction with the online daily surveys, participants were asked to take a specific user stance when using the devices (see Friendly Trial User Scenarios, Appendix B) to assist in simulating potential end-user interactions with ProACT. A different user stance was outlined for each week of the FT and included reflective questions to consider when approaching the technology from the assigned stance. Participants received a daily email with a link to this survey as a reminder to take their readings and to complete the survey if any issues were encountered. Data from the online surveys were automatically stored and downloaded as .csv files for post-trial analysis. Data were cleaned, a codebook was developed, and descriptive statistics were conducted using Excel.

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3.3.3 Participant focus groups

A focus group was held with each group of FT participants following the 12 week testing period. The focus groups were conducted to capture reflections of participants about the devices used to date and their experiences of engaging with this first iteration of the ProACT application, SEEK. Focus groups were conducted with team members, at the trial sites in Belgium (n = 4) and Ireland (n = 4), who had participated in the initial phase of the FT. Although five participants had taken part in the FT at each site, one participant from each site had moved onto new employment and thus did not take part in the focus groups. The focus group in Belgium took over 1 hour 10 minutes and the focus group in Ireland took 1 hour 20 minutes.

A protocol of themes for discussion was developed (see Appendix C) and applied with both the Belgian and Irish FT participants. Content from the focus groups was written up in a notes format, identifying key points highlighted during the discussion. Notes from both focus groups were transferred to NVivo where they were coded using a semantic thematic approach. Combined analysis was conducted on the daily surveys and focus group data using a single codebook developed iteratively through the initial coding process. Overall topics for analysis included usability, effectiveness, reliability, accuracy and acceptability of each device and the overall SEEK application.

3.4 Withings Watch Experiment

It was identified during the FT that the Withings watch pedometer may not accurately record step count where a mobility device is being used by the wearer. This was discovered when a FT participant noticed reduced steps registered when walking while pushing a child in a buggy. To assess the impact of mobility devices on pedometer readings a test was designed to evaluate the potential impact of mobility aids and differential gaits on recorded values from Withings watches being considered for deployment in ProACT.

Following observations from device testing, a walking trial was established to further assess the impact of variable gaits/postures and mobility aids (see Table 4) on the ability of the Withings watches to measure step count. The trial generated data on step count recorded by the Withings application, video evidence of walking gait and use of mobility aids, as well as survey responses from participants on their experiences and observations from adopting various gait and mobility aid postures. The objectives of the walking watch experiment were to:

- Determine the potential impact of mobility aids, gait and posture on step count readings
- Identify implications for pedometer selection, if assessment of walking levels was to be a behaviour change goal in ProACT for individual participants.

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Table 4 - Postures for Withings Watch Walking Trial

Mobility Aid	Gait/Posture
Crutches	Low impact walk/shuffle
Walking stick on watch wearing arm	Limp/leg drag on watch side
Walking stick on on-watch wearing arm	Limp on non-watch side
Walker without wheels	Watch arm immobile
Rollator (walker with wheels)	

For the purpose of ensuring all participants walked the same distance on the same surface, an indoor route was mapped out within the PJ Carroll Building at Dundalk Institute of Technology. This route was selected to ensure an even and equal surface for the duration of the test for all participants, rather than introducing the possibility of narrowing and variant path surfaces, curbing and breaks in pathways. The indoor route was measured at approximately 410 metres.

Five participants (researchers in DkIT) engaged in the walking trial. Each participant wore a Withings Activité Pop watch on the wrist of their non-dominant arm. One participant also wore a Withings Pulse O2 Tracker device on their non-dominant arm. Some of the postures adopted for the trial were video recorded for analysis. Participants completed a short questionnaire following the walking trial, to record observations as well as to identify and record any issues arising.

3.4.1 Setting Baseline Step Count

Each participant walked the route three times at a normal walking pace and gait. During one walk of the route, the participant also manually counted the number of steps taken. The number of steps recorded under both conditions, automatically by each device and manually counted, were noted in an Excel spreadsheet. An average step count was then calculated (from the four step counts acquired) as a baseline step count for each participant.

3.4.2 Mobility Aid and Gait testing

Each participant was provided with a mobility aid (walking stick, walker (with no wheels), rollator (walker with wheels), crutches) and completed the trial route once using this aid. Each participant completed the route using at least three different mobility aids. Each mobility aid was tested by at least three participants. Steps recorded by the Withings watch were logged, for each participant, in an Excel spreadsheet.

Each participant walked the test route adopting a modified gait posture as indicated in Table 4. Three rounds of the route were completed, with participants using a different gait/posture for each round. Each gait posture was trialled by at least three participants.

All step counts, displayed on the Withings watch application, for each round, were entered into an Excel spreadsheet. The participant feedback was completed directly in an Excel spreadsheet. Excel spreadsheets and the video recordings of the trial were imported into

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NVivo for thematic coding and analysis. A baseline step count was generated for each participant in the walking trial and step counts with each mobility aid and gait/posture stance were calculated as a percentage of the baseline average step count to provide an indication of the extent of impact on total step count. This was not intended to provide statistically accurate quantitative data, but rather a general guide measurement to identify if any of the trialled gaits or mobility aids affected how steps are captured by the Withings watches when worn. These initial findings have been shared with ProACT partner Tyndall, who will perform further experimentation on activity tracker accuracy. An initial outline of the Tyndall experiment protocol can be found in D2.4

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4. Results: Ireland and Belgium

A total of 60 daily surveys, where participants were asked to record issues or thoughts, were completed by participants over the course of the FT (mean surveys completed per participant = 6; range = 0 – 12). These surveys did not begin until 15th February as participants had previously been using a paper-based participant diary to record similar data, however, following discussion amongst the trial sites, it was felt the diaries were not an optimal method of data collection. Both sites, therefore, moved to an online survey.

A total of 3 participants completed diary entries on 10 or more of the 31 diary days (range = 10-12) with the remaining 7 participants completing fewer than 10 diary entries (mean = 4). More than half of all diary entries completed were submitted within the first 8 days (n = 31) of the online survey, with participation in the daily surveys reducing significantly as the FT progressed. This is somewhat expected, as the main issues were identified early on in the FT and participants reported they generally filled in the daily survey only if there was an issue of concern. Findings from the online daily surveys, relative to each device, are discussed below.

Of the submitted surveys, the majority (78.33% of responses) were completed for cases where participants had completed the relevant readings and self-report questions for their PwM personas. Seven surveys (11.67%) were completed in cases where the readings/measurements had not been completed; and in 6 surveys (10%) this information, about completion of readings, was missing. Participants reported having checked application interfaces for additional support actors in approximately half of all completed surveys (n = 29, 48.33%).

Successful transfer of data from the various monitoring devices to the SEEK application is central to the design of the final ProACT application. The majority of survey responses (n = 41; 68.33%) indicated that data transfer had been successful and data were displayed in the application interface as expected. Unsuccessful data transfer was identified in seven cases (11.67%), where readings/measurements were completed but data were reported as not displaying as expected in the application interface. In a further 6 (10%) cases, it was reported that readings had not been taken but data were visible – it is unclear whether this indicates problems with data transfer, or whether the users were referring to the visibility of historical data from previous readings and measurements – this will be monitored during the next round of testing. For the remaining 6 cases (10%), there was insufficient comments from participants to determine the success, or otherwise, of data transfer. Survey content data provides further clarification of data transfer issues which arose throughout the FT and these findings are reported in greater detail below as relevant to each device. It is important to note that, while most devices had positive aspects for their use, the purpose of this discussion is to identify the areas where challenges and difficulties arose during the FT and to consider how these were or might be addressed in preparation for the main trial. Section 6 below includes a discussion of the positives identified for the various devices during the FT and a consideration of how these pros and cons are informing final selection of devices for deployment during the main trial.

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4.1 Monitoring Kit: Technical Issues and Implications

The range of technical issues arising for monitoring devices used, are identified under separate headings for each device below. For ease of interpretation of the issues arising, actions taken in response to the issue and potential implications for the PoC trial, are outlined in brief. A discussion of the overall implications for further device testing and PoC trial planning is provided in Section 6.3 below.

Instructions on how to setup all of the devices and assign them to participants are available on SIMS, and trial site managers used these instructions for the FT setup and deployment. These setup procedures were also outlined in D2.2: Deployment Plan for ICT-AT. In the following sections we also outline feedback from the trial site managers on these processes.

4.1.1 SmartThings

Figure 5 - The SmartThings kit from Samsung deployed in the FT

The SmartThings kit consists of a number of motion sensors, a presence fob to detect periods outside the home, and a central hub for connecting the devices and transmitting data. DkIT have implemented algorithms using the SmartThings data to detect and display room location within the home, as well as time spent inside and outside the home. DkIT have also developed a custom-built application on the SmartThings platform to move data into CABIE+.

Very detailed instructions have been provided through SIMS to setup and pair the SmartThings devices and assign them to a trial participant. Despite this, setup was a cumbersome process, and if the instructions are not followed exactly, it is easy for a mistake to be made that can affect data transfer. For example, sensors need to be named using a specific naming convention. If a mistake is made in inputting the sensor name, data will not be received on CABIE+ for this sensor. While easily rectified, there was some work to ensure all sensors were firing as expected at the start of the trial. For the FT, the trial site managers set up the respective 5 kits for participants in the office, and checked that data was being sent to CABIE+. The kits were then unplugged and each participant was provided with the kit and instructed on how to install it at home. This process worked well in Ireland,

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though Belgian participants experienced an issue with the hubs remaining offline in participants' homes, even when connected to Wi-Fi. After some investigation, it was determined that this was due to an issue with the adaptor plugs. The adapter plugs, which were required to adapt the UK plugs to Belgian sockets, came with an 'add-on', piece. Some of the participants used this add-on piece when setting up the hub, and in these cases the hub appeared offline. However, it is unclear why this add on to the adaptor plug caused this issue. During the FT Phase 2, kits will be setup and deployed without using this adaptor to test that the issue has been resolved. Table 5 outlines issues that were recorded regarding the SmartThings kit, as well as some actions take to resolve the issue, and potential implications for the PoC trial.

Table 5 - Issues with SmartThings Kit

Issues Arising	Action Taken	Implications for PoC trial
SmartThings data not appearing in SEEK at times. One participant noted sensors show an 'on' status on the SmartThings application on their phone, but data was not being received by SEEK.	In some instances, this was because the participant's SmartThings account had not been fully linked with CABIE+ through SIMS. When this was done, the problem was resolved.	Researchers at trial sites should follow protocols for setting up kit very closely.
Interruption in electricity power occurred for one participant. This was queried as a possible explanation of the sensors recording that the participant was out of the house during the night on a number of occasions, when this was not the case.	A possible coding glitch on CABIE+ is currently being investigated as the source of the inaccurate fob reading rather than a power outage (SmartThings includes a back-up battery mechanism to support retention of data until the modem would return to functionality with return of power).	Potential for participants to mistrust the reliability of the data and the application, consequently impacting on their engagement with ProACT. For members of the care network looking at this data it may cause concern about the PwM.
Activity was recorded as occurring in the incorrect room.	It is possible that when this device was setup and paired, it was given an incorrect label (for example, labelled kitchen instead of bathroom).	Potential for inaccurate reporting of data to generate mistrust in the application overall or in specific data elements. Researchers at trial sites should follow protocols for setting up kit very closely. Researchers conducting home visits should check that all data is firing correctly before they leave the PwMs home. This can

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		be quickly checked through the SmartThings app on a smart phone, that shows sensors firing in real time.
Missing sensor data was reported by participants.	Battery resets and repositioning of sensors. Resets restored data transmission for some sensors but not for all.	Mistrust in consistency and reliability of data may impact value placed on ProACT by participants and therefore on willingness to use the system.
Door sensors not working.	Battery resets and relocation of sensors did not resolve door sensor issues.	Door sensors are not currently used in any algorithms within the system and thus are not essential for the PoC trial. Time inside and outside is generated from the SmartThings fob, which is carried on a key ring.
Battery in one of the fob (presence) sensors died after end of the FT (following approximately 6 months of use). Opening the fob to replace the battery was very difficult. The participant did not manage it and required assistance from someone else. Until the battery was replaced, the sensors showed the participant as always outside the home.	The battery was replaced with assistance. Once replaced, the fob sensor began to work again without further issue, and data once again began to transfer to CABIE+ and SEEK.	For the PoC trial, new batteries will be replaced just before deployment to PwMs' homes. A supply of batteries will be ordered, and these will be replaced as necessary, for example during one of the scheduled home visits at the end of each 3 month action research cycle. Trial site managers can also monitor battery levels of each SmartThings device through the SmartThings app.

An additional, non-technical issue that arose in relation to SmartThings motion sensors included concerns that participants would worry about cameras and/or microphones concealed in the sensor boxes and that this may prompt them to move sensors to less effective positions for data transfer. Protocols for deployment should include reassurance for participants that the sensors do not contain cameras or voice recorders / microphones.

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4.1.2 Withings Devices

Withings Activité Pop Watch

Figure 6 – Withings Activité Pop Watch (Black) deployed in the ProACT FT

The Withings Activité Pop watch was trialled to assess the accuracy of its key functions (pedometer and sleep tracking) for PwMs, effectiveness of data transfer and usability features including wearability. A Withings Activité Pop watch was deployed to all 10 FT participants to wear for the duration of the FT. The setup of Withings devices requires a user account for each participant. This can be done through the Withings application on a smart phone or tablet, after which devices (such as the watch, blood pressure monitor, weight scales) can be added to the account. Withings user accounts can very easily be connected to CABIE+ through the SIMS dashboard by simply pressing a button. No major issues were experienced in the setup of the Withings devices, other than difficulties in pairing the weight scales with the Withings app (discussed further below).

Data is ambiently gathered from the Withings watch. Participants were not generally expected or required to actively engage with the watch except to wear it daily. This is because

1. Withings report that background syncing is supported – i.e. that the person wearing the watch does not need to open up the Withings app to ensure syncing. This is important for participants in our study, as we want to minimise burden on them, and we also recognise that using the ProACT applications will already require significant training.
2. The battery life on the watch is approximately 8 months, so no charging is required. However, this will mean a battery change will be required at least once during the PoC trial.

One assigned task during the trial was to remove the battery from the watch for a short period of time before replacing it and checking the effectiveness of syncing and data continuity. Another task required participants to remove the watch for a few short number of days, again to assess if messages or prompts were received and if syncing and data transfer resumed when the watch was worn again, while a third task required turning off Bluetooth for a day to see how this would affect data transfer. All issues identified relating to the watch are outlined in **Error! Reference source not found.**.

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Table 6 - Issues with the Withings Watch

Issues Arising	Action Taken	Implications for PoC Trial
Data transfer to SEEK was inconsistent for most participants throughout the FT. This was primarily due to background syncing issues, which appeared to sometimes work, but most often it did not. As such, this is an issue on the Withings side, rather than ProACT. Not all data synced, for example, steps data synced for a certain day but sleep data for the previous night did not.	It was determined that opening the Withings app on the device being used by the participant is required to force syncing and therefore to push data to SEEK. Resetting Withings connection with CABIE+ and this seemed to resolve the issue.	This has implications on user burden, as training may be required to ensure the participant opens up the Withings app once a day to force data syncing and transfer. This is not ideal, and thus a query was submitted to Withings to see if this issue could be addressed. However, Withings have recently been acquired by Nokia, so no response was received and further investigation is needed. This can be identified and flagged in the daily email alert to the technical team and trial site managers. Resetting the Withings connection with CABIE+ can happen remotely, without any impact on the end user.
One participant found the watch face fogged up in the shower.	Resolved itself after a few hours and did not appear to impact syncing or readings.	Users experiencing this may remove the watch when bathing and forget to put it back on afterward, thereby impacting data collection.
Step count seems to be impacted by motion. For example, when pushing buggy the step count appears reduced.	Prompted conducting an experiment to evaluate different mobility aids and their impact on step readings.	A person with limited mobility will not have their steps counted. This will likely have considerable negative impact on motivation and engagement. Further information on this is provided in the following section.
More than half of the FT participants reported developing a rash from the watch strap and some reported not wearing the watch at night because it	For some participants, removing the watch for a period of time helped but for others the rash lingered for several days even after removing the watch.	Likely to deter PwMs from wearing the watch. Withings also sell leather watch straps, which may be preferable. However, these

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was uncomfortable to wear in bed.		are more costly. A selection of both original and leather straps will be purchased and participants provided with the option (assuming Nokia will also continue selling separate straps).
Participants questioned the accuracy of the sleep data. Waking times appeared to be accurate but sleep start time was questioned by participants.	None	This could impact trust in data and overall system. Potential ways to address this could include informing the user through education within the app, or messages delivered to them, that sleep start time is only a guide, and if the participant is reading in bed for example, that this may be recorded as sleep.
Limited linking of data in a meaningful way, for example, one participant reported returning to bed during the day to sleep while unwell: *'It was not possible to distinguish this from SEEK but if I got into the Withings graph on my iPhone I could see that I was sleeping during that time (P1)'.*	None	SEEK information may be of limited use to FC/IC/HCP if only shows the PwM was in the bedroom for an extended time without knowing he/she was asleep. Further technical work will be carried out to support identification of daytime naps, and to highlight these on the new ProACT application.

Use of Withings watches in previous trials, run by the DkIT team, identified that iOS devices provide better background syncing for watch data than Android devices. However, with the latest version of iOS, used by the majority of participants in this trial, this does not appear to be the case. Investigations on user forums identified that this may be due to privacy settings on iOS, but this requires further investigation.

It is important to note that at the end of June 2017, Nokia rebranding of the Withings Activité Pop watch included changes to the application, including logo, layout, icons, features and user-device interaction pathways. As participants of our trial will not be asked to use the Withings app other than to open it to perform background syncing, or take a blood pressure reading (see below), application changes should not pose an issue. However, further trialling of these watches will take place by team members to evaluate how changes due to the acquisition may potentially impact integration of these devices with ProACT, should they be used in the PoC trial.

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Withings Watch Walking Trial Results

The methodology for the Withings Watch Experiment was described above in Section 3.4. For the low-impact shuffle gait, in 4 out of 5 cases, the watch registered a significant decrease in total step count ranging from 4%-23% of total baseline steps (for example where baseline steps were recorded at 214 for one participant and 22 steps during a low-impact shuffle gait over the same distance). Even for the remaining participant, step count was recorded at only 83% of baseline. Higher step count was registered where participants adopted a limp, but significant variance between participants (range 40% - 207% of baseline) suggests personal gait patterns may significantly impact how step count registers on the Withings Activité Pop watch. Participant self-observation of body dynamics during the trial and video analysis of gait patterns also identified that arm swing variations during different gait postures may impact step count readings, depending on which arm holds the watch. It was noted that different gait postures resulted in variations in arm swing for individual participants, possibly due to the use of arms as a counter balance where the function of legs or feet was impaired.

Step count readings were generally higher than baseline when a walking stick was used, but there was significant variation in range from 92% to 197% of baseline steps. Step counts were slightly higher when the stick was used in the same hand as the watch. No steps were registered when participants used either the walker with no wheels or the rollator. When using crutches, however, step counts between 103% and 153% of baseline were recorded across all participants. It was unclear whether footsteps or combined 'steps' by the crutches and/or feet, were being registered by the device.

In response to variations in watch readings for gait postures and mobility aids, a Withings Pulse Ox SPO2 Tracker was tested by two participants.

Figure 7 - Withings Pulse Ox SPO2 Tracker used in FT

One participant wore the device clipped to a belt, the other placed the device in a trouser pocket. In both cases, the Withings Pulse Ox did not register any steps when the Walker (no wheels) or rollator was used. In addition, when one researcher further tested the Pulse Ox (attached to belt), no steps were recorded for either the low-impact shuffle gait or for walking with a stick in the dominant hand.

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One participant wore the Pulse Ox on the same arm as the Withings watch, across all gait and mobility aid tests. For mobility aids the watch and Pulse Ox readings were essentially the same, with the exception of the test of the walking stick in the watch hand. In this instance the Pulse Ox registered twice as many steps as the Withings watch. Likewise, when the Pulse Ox was tested on the same arm as the watch for gait postures, similar readings were registered for the low-impact shuffle and an immobile watch arm. For both limp postures there was a significant difference between the watch and Pulse Ox readings, with the Pulse Ox showing 50% to 100% higher step count.

Implications for PoC trial device selection

The Withings Activite Pop watch is easy to use but appears to have limitations in its ability to read step count where the wearer is using a mobility aid or has an impaired gait posture. While it may be expected that use of a mobility aid or an altered gait / posture may impact the number of steps taken to complete the same distance, it seems most likely that these factors would result in an increase in the number of steps taken. Readings from the devices tested, however, did not consistently reflect this expectation, thereby raising questions about the effectiveness of the devices to accurately identify and record steps taken under some of the trialled conditions. The Withings Pulse Ox device does not provide readings where poor mobility or impaired gait postures are presented by the wearer. This is the case when worn on a belt or placed in trouser pocket. It does not, therefore, present an effective alternative to a wrist worn watch / pedometer for measuring step count under these circumstances. When worn on the wrist the Pulse Ox appears to provide similar reading reliability to the Withings Activite Pop watch tested.

Withings Blood Pressure Monitor

Wireless Withings Blood Pressure Monitors (BPMs) were deployed to all participants in the trial. Setup was very easy, as described above. The BPM connects with the Withings app on a smart phone or tablet via Bluetooth.

Figure 8 - Withing Blood Pressure Monitor used in the FT

With the phone or tablet unlocked, the user should press the small button on the BPM which opens the Withings app, whereby the user must press the Start button to take a reading. Issues identified are listed in Table 7.

Table 7 - Issues with the Withings BPM

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Issues Arising	Action Taken	Implications for PoC Trial
Disrupted connection to phone when blood pressure taken. One participant noted device stated connection lost to phone but reading still came through.	None	Potential cause for confusion for PwM. Troubleshooting and training protocols required if this device is used in PoC trial.
BP measurement failure. Possibly due to positioning when using BPM.	Modified positioning and BPM worked eventually.	The Withings app when opened to take a BP reading displays instructions on how to take measurement (placement etc.). This can also be reinforced in ProACT education.
Difficulty identified in opening the device to replace the battery	None	May result in discontinued use of the device by participants if the user is unable to replace the battery themselves. Potential solution is for trial site researchers to ensure new batteries in devices at start of trial, and also replace all batteries during one of the home visits throughout the 12 month trial period (there will be home visits once every 3 months in line with the action research cycle methodology). The team will further be exploring the use of the Philips BP cuff as an alternative option

During co-design user sessions, many PwMs felt that the Withings cuff was difficult to put on, and quite stiff. Another potential issue for any device that transfers data via Bluetooth, including the Withings BPM and Withings watch, is the potential for the user to accidentally turn off Bluetooth on the tablet device they are using. While this issue didn't arise during the FT, it is a possibility during the main trial for many of the devices being considered, which could cause confusion for the user. While Withings does deliver a message to turn Bluetooth back on, it is unlikely the majority of our participants will understand what this means. During

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the PoC trial we will address this by delivering an alert to the relevant trial site manager, who can then contact the participant to troubleshoot. From ProACT's perspective, a further negative aspect is the need to open the Withings application to take a reading. However, as noted above, this may need to occur to force watch data to sync.

Withings Weight Scale

Two participants in Ireland used the weight scale (only those participants who were 'assigned' CHF). Participants were required to go through the setup procedure themselves, while at home.

Figure 9 – Withings Weight Scales used in FT

Based on previous experience of using these scales in a deployment in older adults' homes, the trial site manager at DkIT suggested that the scale be setup over Wi-Fi, as previous difficulties with syncing had been encountered when paired with Bluetooth, due to for example the weight scales being far away from the device (phone or tablet) hosting the Withings application. Issues identified are listed in Table 8.

Table 8 - Issues with the Withings Weight Scale

Issues Arising	Action Taken	Implications for PoC Trial
Not syncing after period of 4 days unused	None – this requires further testing.	The reason for this is unclear. To minimise impact, this can be highlighted in the daily alert email and a troubleshooting protocol can be implemented.
Issues syncing through both Bluetooth and Wi-Fi	Re-installation of application and resetting of Bluetooth settings. Did not always work effectively.	Installation and troubleshooting protocol should include management of Bluetooth as an issue to be addressed.

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Withings Body Analyser Scale

Figure 10 - Withings Body Analyser Scale used in FT

The Body Analyser scale was used throughout the FT by one participant in Ireland and 5 in Belgium. In addition to weight, this device measures body fat, heart rate and indoor air quality, which is relevant for COPD patients. No data transfer, syncing or technical issues were identified with this device throughout the trial in Ireland. In Belgium there were some issues with the pairing of the device via Bluetooth. When using Wi-Fi these pairing issues did not occur, however some participants experienced issues with the Wi-Fi connection and therefore the transferring of their data at the moment of measuring. Wi-Fi was used rather than Bluetooth for data transfer.

Withings Application

Given that the Withings application is required for users to take their blood pressure readings, as well as for data syncing and transfer for the watch, this application was setup on each FT participant's phone or tablet.

Table 9 - Issues identified with the Withings Application

Issues Arising	**Action Taken**	**Implications for the PoC Trial**
Most participants got a message on their phone at some point during the trial saying *'restart the Withings app to enable background syncing of your tracker'*	This notification seemed to appear when a participant had removed the watch for a period, or, it seems, if the Withings app had crashed and thus needed to be re-started.	Many 3rd party devices require an app to run in the background to support data transfer. It is almost certain such apps will crash and require a restart at some point during the trial. Further discussions will take place with the technical team to see how best to address this. Ideally, the number of such apps would be minimised.

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4.1.3 SEEK

While participants were aware that SEEK was being used within the FT as a stopgap until the new ProACT application was designed and developed, participants were asked to provide any feedback that might help the design team in making design decisions for the new application. The co-design process will continue to identify and develop features and functions for the final ProACT interface design to be deployed in the PoC trial.

Daily Questions

The daily questions to be answered by participants in the PwM role, were set in SIMS at the beginning of the FT. The questions selected related to the conditions relevant to the assigned PwM role for each participant, for example questions on sputum were only received by participants with a PwM role including COPD as an assigned condition. No changes were made to the daily questions prompted during the FT as the objectives were to facilitate the generation of wellbeing graphs over the duration of the FT, to ensure data was effectively transferring and to provide examples of data presented in a potentially meaningful manner for trial participants.

Participants noted that the daily questions became boring, as they lacked variety and the sequencing of some questions did not seem logical. It is noted that the relevance of the daily questions may need to be both evident and explained to participants in the PoC trial, to mitigate a potential impact on compliance with the daily question component of the ProACT application. It is planned that for the PoC trial that daily questions will be pushed in a different manner, with the number, frequency and variation of daily questions adjusted throughout the PoC trial, dependent on user preferences and/or care analytics.

Self-Reporting Vital Signs

The only technical issue arising, relating to the feature for self-reporting of vital signs (blood pressure, blood glucose etc.), was that the placement of the Blood Glucose section was below the screen, on a phone, requiring the user to scroll down to enter a reading. This contributed to participants forgetting to enter this data during the trial, though it was noted that a PwM with diabetes may be less likely to forget to enter the data as they would be actually checking their blood glucose levels regularly. This may also be less likely to occur on a tablet / iPad, which would most likely be used by PoC trial participants, whereas FT participants were often using their phones to access the application, thereby interfacing with a smaller screen. The new application has been designed to eliminate scrolling (on a tablet device), thus eliminating this issue in this case

A range of non-technical issues were identified by participants. These issues are listed below along with recommendations for ProACT design.

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Table 10 - Issues with data entry in SEEK app

Issues Arising	Implications for PoC Trial	Recommendations
FT users suggested that blood glucose data entry should come with an option to mention if it was after dinner, or a snack or on an empty stomach, for the values to make more sense.	Annotation of data may be required to add value to this data and/or make it more meaningful and useful for stakeholders to encourage them to support reflective motivation of participants	Support annotation for manual entry values. Testing with new iHealth devices should examine whether contextual information such as meals can be pulled from their API alongside the blood glucose value.
Multiple and unnecessary steps required in manual data entry	None expected – see Recommendation	Input will be smarter in the new ProACT app, and will be based on what conditions the PwM is monitoring. For example, a person with diabetes will be able to enter a blood glucose reading, but not SpO2 (unless they also have COPD).

4.1.4 General Experiences

Participants noted that the demands of taking daily measurements and reporting required during the FT was onerous and irritating. This included the need to take vital sign readings daily, negotiating logins/passwords to move between the different support actors participants were representing (e.g. moving between a PwM account and a HCP account) and answering questions on the system. This 'hassle-factor' highlights the potential self-management burden facing PwMs who will participate in the PoC trial. However, they will not be faced with login issues, and will likely be more motivated to take readings than participants who were not managing health conditions.

It is recognised that PwMs in the PoC trial will be engaging with the system and processes because of actual health conditions to be managed, rather than adopted roles. This real-life context may, therefore, provide greater impetus and motivation to PoC trial participants. Furthermore, FT participants only had issues with logging in and out as they were representing multiple users (e.g. PwM, IC, HCP). This will not be the case in the PoC trial. Furthermore, it is recognised that over a 12 month period, participants' usage levels will vary, and may depend on other extrinsic factors such as illness, or feeling well and thus not feeling the need to use ProACT. Reasons for dips in engagement will be explored in interviews with participants and will contribute to our understanding of self-management

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practices. Nonetheless, the demands of engaging with ProACT emerged as an essential factor to be carefully considered in the final design, to ensure that ProACT can effectively support self-management rather than contribute to the care burden of participants.

4.2 Additional Devices Tested in Parallel with the Friendly Trial

In addition to the devices outlined above, that were formally tested in the FT, participants throughout the trial sites also used other devices where they were identified as being potentially useful within ProACT. These participants were asked to keep track of any positive and negative features of the devices using a pre-defined template. A completed template from one participant who tested the Philips devices (outlined below) can be found in Appendix D. Each of the devices below are currently (July 2017) being integrated into CABIE+, and will be formally tested from August 2017.

Philips Blood Pressure Monitors

Figure 11 - Philips PHS Mobile App and Wrist Blood Pressure Wrist Cuff

Two potential blood pressure devices have been identified from the Philips range, which may have potential for use with ProACT. The arm and wrist monitors were demonstrated during the co-design workshops with stakeholders, where both devices were identified as easy to use, especially where physical strength and coordination may be an issue for the user. A feature identified as a benefit by workshop participants was that of being able to see the readings directly on the cuff screen (rather than being required to open the app on the phone/tablet). One issue noted by workshop participants was that the screen can be difficult to read (when worn) as it is positioned at an awkward angle for reading by the user. Data transfer to the Philips PHS app was not assessed, as the app was not available on the Irish Apple app store.

Two ProACT researchers tested the Philips blood pressure cuffs, with the Philips PHS app, over a period of approximately 4 weeks. Both participants found that the devices were easy to set up and to use. The straps on each were also easy to open and put on. However, it was felt that the buttons might be confusing to an older user, as it is not clear which button must be pressed to start taking a reading. The cuffs also have the ability to work with different profiles, and when turned on profile information appears, even if only one person has used the device, and this may also be confusing. Participants felt the wrist BP cuff had a

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particular advantage because you can put it on your wrist instead of the usual upper arm placement. This may be easier for older adults who may be less mobile. Furthermore, it is not necessary to take your sweater or shirt off, or roll up sleeves. An issue noted with the wrist cuff was that when it was not used for a period of time, the device needed to be removed from the device list on the PHS application, and reconnected to ensure syncing.

Philips Body Analysis Scale

Both participants found the scale easy to use when determining weight. One participant found the installation tricky, and it took a few attempts to connect the scale to the PHS app to setup data transfer. One participant also found that the scales didn't always sync with the PHS application, and sometimes it was necessary to take the weight reading again.

Figure 12 - Philips Body Analysis Scale

Philips Health Watch

Both participants felt the watch was relatively easy to use. The screen was clear and easy to read. However, at first sight it might not be completely clear to older people where to press on the watch for the features (the outside ring) or how to go back to the main screen. One participant also felt that there were a high number of features available, many of which may not be relevant to the ProACT user group. Once the watch recognised movement, it showed you this once the movement was complete and the user had to click to accept. This might be excessive for the potential older user. The charger was relatively easy to use – it needs to be clicked into place, but it is not clear enough how to do this so that it actually charges. A piece on the back of the watch needs to be in line with the charger, and participants sometimes had issues with this, resulting in the device not charging. If the watch was left idle for a period, and hadn't used the app, a login process was required to start using it again. It was also felt the Sleep function on the watch was not accurate, for example on one occasion the watch didn't calculate wake up time and recorded a sleep period of 17 hours.

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Figure 13 - Philips Health Watch

One participant felt the watch is quite heavy and thick, and the plastic wristband isn't very stylish. The clock and the other features are presented in a clear and nice way. In terms of transfer to the PHS app, participants didn't note any issues. Once the app is opened, the data syncs immediately. However, participants were unsure whether or not background syncing is supported. Participants felt positive features of the watch included the continuous heart rate measurement, recognition of other types of movement apart from walking (for instance biking or exercise) and the possibility to measure these on the watch by manually entering the start and end of an exercise session and counting of calories burned based on heart rate.

No Philips devices, including blood pressure monitors or weight scales, have been tested as part of the FT protocol. When access to the API for the selected devices is made available to partners at DkIT, it will then be possible to enable data transfer to CABIE+ and device management through SIMS. It is expected that this process will be completed to facilitate trial of these and other PHS devices by the end of July 2017 (M19).

Withings Steel Heart Rate Watch

This watch was purchased as an alternative choice for a watch monitoring heart rate. It claims to have the longest battery life for any HR tracker on the market[2] - which the website states is 25 days. In addition to heart rate, it also monitors activity and sleep, similar to the Activite Pop. It is water resistant and the strap can be changed.

Figure 14 – Withings Steel Heart Rate Watch

[2] https://www.withings.com/us/en/products/steel-hr?__t=20170226T163500%200100

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One researcher at DkIT (who was not a participant in the FT) tested the Withings Steel HR watch over a period of 13 weeks. The main positive features outlined by this tester were the usefulness of the heart rate monitor when exercising, notifications upon completing step count goals and accuracy of both the activity and sleep data. They also found the watch to be stylish and something they would like to wear day to day.

In terms of negative aspects, this person reported that the setup process would most likely be confusing for older participants. They also noted that the battery became poor over time. Initially it lasted approximately 25 days, as claimed by Withings. However, after the first few weeks the watch needed to be charged every 4-5 days. This user reported that they were continually monitoring the battery life to ensure it would not die, for example when they were going away on a trip and might not remember to bring the special charger. Similar to the Activité Pop, this tester also experienced a severe skin rash, but noted they would pay for a leather strap to avoid this. The watch was also physically difficult to charge. The charger was made to fit onto the back of the watch – two small magnets on the charger had to be aligned with the corresponding magnets on the back of the watch. When the watch had died, it seemed there was no charge pulling these together and the charger kept falling of the back of the watch. This could be quite difficult and frustrating for an older user to manage, particularly someone with dexterity issues.

Withings Pulse SP02 Tracker Watch

Figure 15 - Withings Pulse Tracker Watch

This device was purchased due to issues with the Withings watch as outlined above, particularly steps not recording while pushing a buggy. Furthermore, some female PwMs in our co-design workshops indicated that the Withings watch did not look very nice and might prevent them from using it. The pulse tracker can be worn on the wrist, but also clipped onto a belt or placed in a pocket, and the research team wanted to test whether this device could offer a potential replacement for the watch. It also records SpO2, but the data is not medical grade. As noted in Section 4.1.2, it was determined following the walking experiment that this device would not provide a reliable replacement for the Withings watch.

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iHealth Align Smart Gluco-monitoring System

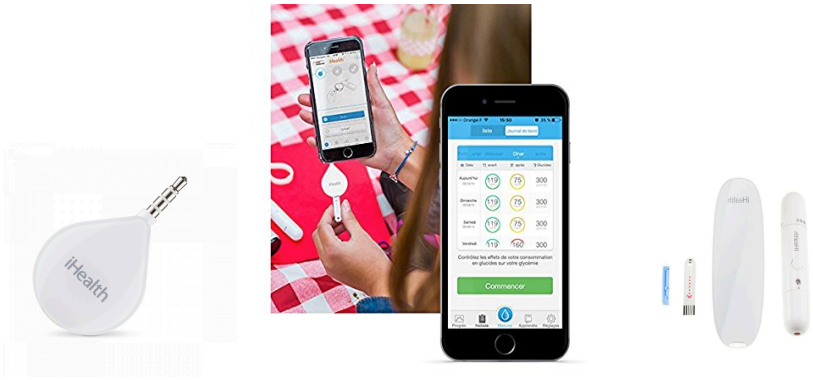

Figure 16 - iHealth Align Smart Gluco Monitoring System

This device was tested by one researcher at the DkIT trial site, over 4 days. As a device requiring blood testing it was not possible to share the device for use among multiple trial participants. The team member provided 1-3 blood samples per day over 4 days to test the device and data collection, display and transfer within the iHealth application.

Setting up and initiating this device was a cumbersome and difficult process. Setting up the application requires the user to take a blood glucose reading as part of the process. This is unexpected as the user has multiple tasks to negotiate in order to set up the device for the first time. If there is a delay at any stage of the process, for example in getting a sufficient blood sample, the app times out and the user is required to start over, which may include closing the application and starting again from the beginning. Some of these steps may be less of an issue for PoC trial participants who are already used to testing their blood glucose levels, whereas the researcher testing the device had never done so. Once the sample was placed in the correct location on the testing strip, the reading registered almost instantly and an option was provided to add a comment to the reading, such as before/after lunch/exercise etc. With some practice using the device, it was found to be easy and quick to use.

iHealth Air Wireless Pulse Oximeter

Figure 17 – iHealth Air Wireless Pulse Oximeter

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Measurement of blood oxygen levels may be required of PwMs with COPD. When tested by a team member at DkIT, this device was found to be easy to set up and use. Readings are instantaneously displayed on the device (oximeter) once the device has been applied appropriately. It is necessary to open the application, however, for the data to transfer to the app. The device is easy to manage and operate. The technical team at DkIT are currently (July 2017) working with the iHealth API to pull data from both devices into CABIE+.

Emfit Bed Sensor

Figure 18 - Emfit Bed Sensor

As noted above, FT participants reported issues regarding the accuracy of the Withings watch to record start time of sleep. Thus, a potential alternative sensor – the Emfit QS under-mattress bed sensor - was recently purchased, though testing is yet to commence. The Emfit sensor records very detailed sleep information, such as bed exits, tosses and turns, heart rate and respiration rate, as well as time asleep, time awake and time in different sleep stages. Researchers at DkIT previously used Emfit in a trial with older adults and found that while the data was accurate, data transfer was often an issue, limiting the utility of the sensor. At the time, Emfit was a young company and did not have an API available. Thus, the data transfer issue happened primarily because Emfit staff were required to manually push data to CABIE+. However, Emfit now have an API available, which may result in more robust data transfer. This will be tested in phase 2 of the FT in M20 to 21.

4.3 Usage Statistics

4.3.1 Global Overview of Engagement with SEEK

The FT system analysis verified that a range of data reports can be extracted from the SEEK/SIMS system. This includes the number of **individuals** who accessed the application on more than X days. It is possible to divide this into roles – i.e. the number of PwMs who accessed the application, the number of HCPs etc.

As an example of this, usage statistics highlighted the following engagement levels with the SEEK application for FT participants acting as PwM subjects, over the 94 day FT period:

- 5 Days or more: 10
- 10 Days or more: 7

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- 15 Days or more: 7
- 30 Days or more: 5
- 45 Days or more: 2
- 60 Days or more: 1
- 75 Days or more: 0

Thus engagement levels were relatively low amongst the majority of participants. We address possible reasons for this in the Discussion Section 6.2 and outline how we plan to resolve these in the next phase of FT testing.

At an individual level, reports can be generated by participant to identify:

- The number of survey responses attempted and the number completed
- Tips and training/information videos viewed
- The number of days for which information was input by the participant
- The number of days readings were viewed by the participant

Additionally, reports can be generated for specific and individual readings, ranging from step count to contact sensors, blood pressure, wake up counts, sleep/awake stages to presence timelines. As an example of this, the following is data from Participant 2 in Ireland (P2_IRE):

P2_IRE accessed the app on 61 days (of 94) (~65%)

- Input data on 32 days
- Viewed tips on 19 days
- Attempted survey responses on 40 days
- Completed surveys on 35 days
- Viewed readings on 46 days

Received reading of any type on 94 days (100%).

- Blood glucose on 30 days (32%)
- Blood pressure on 27 days (29%)
- Pulse on 28 days (30%)
- SpO2 on 27 days (29%)
- Weight on 25 days (27%)
- Steps walked on 94 days (100%)
- Distance walked on 94 days (100%)
- Timeline of location within the home on 94 days (100%)
- PIR data on 93 days (99%)
- Time inside/outside on 74 days (79%)
- Self-report scores on 35 days (37%)
- Sleep stages on 93 days (99%)
- Sleep timeline on 91 days (97%)
- Wake-up count on 93 days (99%)
- Temperature timeline on 93 days (99%)

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SIMS records such high-level engagement statistics with the SEEK app, however, more detailed logging of interactions with the new ProACT application will be performed during the PoC trial. For example, SIMS could record what categories of tips are being viewed most often and in what format (e.g. video, text, audio) etc.

4.3.2 Performance Analytics

Technical analytics examine elements of performance and reliability with regard to ecosystem technology components, specifically targeting the identification of issues which might affect availability or responsiveness of ProACT systems to end-users. For example, technical analytics might perform real-time (or more accurately close-to-real-time) evaluations of the load being exerted on ProACT servers. Outputs of this analytic can be used to generate alerts for technical teams, indicating a need to intervene during short-term periods of performance degradation, or may be used in historical context to identify recurring data processing bottlenecks.

A total of three CABIE+ systems were deployed by DkIT for the FT period, inclusive of a CABIE+ Core instance, a CABIE+ SIMS instance, and a CABIE+ SEEK instance (modified form DkIT's YourWellness application for ProACT use). Each service was deployed to a low-powered, single core VPS (virtual private server) equipped with 2GB of RAM (Random Access Memory). Each VPS ran an operating system, a database service, and a web application. Loads exerted on each service were tracked for the majority of the FT period.

Application RAM usage on all three virtual private servers remained under 70% utilisation for the full period tracked. Early in the trial period, a single minor error was detected in a script which required more than the available RAM to operate. This script's behaviour was modified to remove the higher RAM requirements, and did not cause any further issues.

CPU (Central Processing Unit) utilisation for the CABIE+ Core VPS fluctuated between 10 and 13%, tracked at 5 minute intervals. CPU utilisation for the remaining two VPS's peaked at 4% (CABIE+ SIMS), but for the majority of the FT period remained in the 1% to 2% range.

Collection of statistics over the FT period employed a mixture of automated and manual inspection techniques. A fully-automated system to track these numbers at 1, 5 and 15 minute intervals has now been employed, and will be available to all future iterations of the above systems.

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5. Italian FT

5.1 Participants and Methodology

In the Italian transferability site, 5 participants were recruited from the research team. Each participant took on one role. One PwM kit (Withings, SmartThings and Philips devices) was, therefore, tested in Italy, alongside the SEEK interface. This allowed researchers at the transferability site to also gain experience in using and deploying the ProACT ecosystem.

To test the system as thoroughly as possible, a different scenario was set up for each participant. These scenarios included a description of the role, as well as a description of how to use the system during the trial. The scenarios guided the participants to take different stances towards the system in their role. For instance, to approach the system as if they were stressed about managing daily routines, forgetful or with mild motor disability. These approaches were used to capture different users' experiences of working with ProACT.

Additionally, the scenarios had included small tasks. At the end of the trial, the user was asked to give some feedback on these. The tasks were put in place to ensure the application testing had included possible problems that may arise in everyday life, but also usability and accessibility issues. The feedback from the users who had participated in the Italian FT was collected at the end of the trial period through technical meetings and focus groups. The Italian FT lasted 6 weeks.

5.2 Results

The availability of a single kit required the users to do the scheduled activities in turn, swapping the devices among them week by week. The planned activities were successfully completed. The members of the Italian team were able to use the devices positively and carry out the planned tasks. The technical team had the chance to experiment with the system setup and identify possible technical issues as well as manage both the frontend and backend of CABIE+.

In relation to accessibility aspects of the ProACT system as a whole, based on hands on activities during the friendly trials and technical meetings and focus groups between the members of the AIAS Assistive Technology (AT) team (some of which included potential end users, like elderly and people with disabilities), the following main points can be highlighted:

- It is important to consider the application's international accessibility guidelines and also test the final system prototype with specific AT hardware and software, such as special input solutions (e.g. Scan mode, external switches access).
- We need to consider also the accessibility of the physical devices included in the ProACT system (wearable and sensors). For more detail we can refer to (https://link.springer.com/chapter/10.1007%2F978-3-319-40250-5_11).For example:
    - To activate the blood pressure device (Withings) it is necessary to hold a very small button on the side of the device. The device itself has no display, or any other kind of feedback to indicate to the user that the cuff is placed properly

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and the measurement procedure was ok. During the measurement, you always need to manage both the device and the smartphone/tablet, which can be very complex for some of our target users.

- Both the smartwatches (Withings and Philips) used during the Italian FT show potential accessibility issues for target users. The Withings watch is very small and the display is not clear in showing the amount of physical activity during the day and other information. Furthermore, once one has reached 100% of the target daily activity, the indicator restarts from zero, making it difficult for the user to understand his/her performance. The Philips Smartwatch has a more complete and interactive user interface but the information display is quite small and monochrome (the icons are small and it could be difficult to distinguish one from another). The touch interaction, based mainly on circular gestures may not be easy to understand for target users.

Accessibility issues will have implications for device selection for the transferability study, particularly as it is anticipated that some of the transferability cohort will have physical disabilities. Device testing and selection will continue in parallel with the main trial sites. This is discussed further in the following Section.

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6. Discussion

The purpose of the FT was to test all aspects of the ProACT system to facilitate modification and adjustment of the application and processes prior to deployment in the PoC trial. Due to the timing of the FT, a full trial of the final ProACT system was not feasible, however, the FT permitted a comprehensive trial of the fundamental elements of ProACT, including the CABIE+, SIMS and SEEK elements as well as a range of self-monitoring devices expected to be used in the PoC trial, and transfer of all data from CABIE+ to the InterACT platform. This data is also currently being used by partners IBM and TREE in the development of Care Analytics for use in the PoC trial. It is important to note, however, that a full testing of the final ProACT system will take place in researchers' homes prior to the PoC trial beginning.

6.1 Friendly Trial Kit – Summary of Pros and Cons

Overall, it is clear that the data gathered in the FT has been essential for the ongoing and iterative development of ProACT, by identifying potential challenges with data transfer and device usage, leading to further research and trialling of potential alternative devices for inclusion. Parallel co-design activities with our end-users have also been partially informed by participant feedback from the FT. The findings from this first intensive phase of the FT highlighted a number of challenging issues with the first iteration of ProACT, but also positive aspects. These findings are discussed in Table 11, with implications for our next phase of FT testing as well as implications for the PoC trial outlined.

Table 11. Pros and Cons of Devices Tested Formally in FT (i.e. with transfer to CABIE+ and SEEK interface)

Device	Cons	Pros
SmartThings Motion Sensor Kit	• Ineffective in multiple person dwellings or where resident has pets. Unable to distinguish target user. • Requires careful placement to ensure motion is correctly detected. • Intermittently requires resetting of individual room sensors or battery replacement. • Power down or battery malfunction registers as user outside the home, providing 'false' reading. • Difficulties arose in Belgium with plug adaptor provided with the sensor kit. • Users may have concerns about video and/or audio transmission from devices. • Some room and door sensors did not work or only detected motion intermittently. • Requires on-site set-up and installation by a team member, following specific	• Ambient. Requires little or no interaction by user once installed. • Key fob can be used independent of the other room sensors, to track an individual user's time inside/outside of home. • Stable transfer of data to CABIE+

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	protocols. (Other devices can be set up before deployment/the home visit).	
Withings Activite Pop watch	• Background syncing is not reliable, meaning the user typically needs to open the Withings app to force data to sync and thus transfer. • Strap can give wearer a rash. In some cases severe enough to warrant removal of watch for several days. (Alternative strap may be required). • Unattractive appearance. Users may not wish to wear the watch all the time. • Numbers difficult to read if any visual impairment. • If user active past midnight then step count resets (at midnight) and reading can be confusing. • Does not register step count for impaired or low-impact gaits, or when a mobility aid such as a rollator is used.	• Easy to use. Minimal interaction required. • Long battery life. Does not require charging. • Looks like a regular watch. Simple dual clock face. • Alternative straps available.
Withings Blood Pressure Monitor	• Stiff and may be difficult to use for a person with poor hand strength, dexterity or coordination. May require assistance of another person to use. • Requires opening Withings app to take a reading, but automated once app is instigated. • Reading is not visible on the device, only on the app.	• Easy to use once applied properly. • Easy to keep clean. • Once app initiated the device takes the reading automatically. • No issues with transfer to CABIE+
Withings Weight Scale	• Problems identified at all sites with syncing using both Bluetooth and Wi-Fi. Solutions attempted to address were not consistently successful. • May present difficulties for users with balance and/or visual impairment issues. • Reading is visible on the screen of the device, though this may be difficult for the user to see. • Not possible to set multiple profiles or delete unwanted readings.	• Easy to use, just step on, does not require app to be opened.
Withings Body Analyser weight scale	• May be issues with syncing using Bluetooth. • May present difficulties for users with balance and/or visual impairment issues. • Reading is visible on the screen of the device, though this may be difficult for the user to see. • Not possible to set multiple profiles or delete unwanted readings.	• Easy to use. Does not require opening of app. • Wi-Fi syncing effective and reliable. • Display screen provides additional information (weather, weight change graph,

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		weight gain/loss, BMI etc.).

Table 12. Pros and Cons of Devices Tested in Parallel to the FT

Device	Cons	Pros
Withings Steel HR watch	• Short battery life. • If battery dies it is difficult to recharge. • Watch strap of same material as Withings Activite Pop and likely to cause a rash for wearer (alternative strap may be required).	• Includes heart rate reading. • Alternative straps and colours available.
Withings Pulse Ox SPO2 Tracker	• Not a watch, therefore, may require being worn along with a watch. • Requires 8 button presses to see time. • Screen difficult to read in bright light. • Does not register step count for impaired or low-impact gaits, or when a mobility aid such as a rollator is used. • Watch strap of same material as Withings Activite Pop and likely to cause a rash for wearer (alternative strap may be required).	• Discreet and unobtrusive to wear. • Can be worn clipped to belt on in a pocket as well as on wrist. • Alternative straps & colours available.
Philips Health Watch[3]	• Battery life only lasts 4-5 days. • When battery dies, pairing or login may be required again. • Watch is bulky – noticed particularly at night when sleeping. • Difficult to charge. • May have too many features and buttons for older participants. • Sleep function didn't work well. • Activity recognition not always accurate (for example, when participant was sitting down and tapping leg, this was recognised as biking).	• Includes heart rate reading. • Nice, clear clock face. • Can automatically track and differentiate different types of activities. •
Philips Blood Pressure Monitor (arm)	• Readings on the device are difficult to read due to the angle of the screen. • Buttons may be confusing to the user, as it is not clear which to press to start the measurement. •	• Comfortable and easy to wear and use. • Readings show on a screen on the device. • Values on the face of the device are large and easy to read. • Easy to charge and long

[3] For more detail on the pros and cons of the Philips devices, see Appendix D.

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		battery life on charge. • Detects irregular heart rate on top of BP and heart rate.
Philips Wrist Blood Pressure Monitor	• Readings on the device are difficult to read due to the angle of the screen. • Buttons may be confusing to the user, as it is not clear which to press to start the measurement. • May place a lot of pressure on a frail wrist. • Not clear what to do when error message appears on device. • On 2 occasions the cuff did not stop inflating and had to be removed.	• Comfortable and easy to wear and use. • Particular advantage of being used on the wrist. • Readings show on a screen on the device. • Values on the face of the device are large and easy to read. • Easy to charge and long battery life on charge. • Detects irregular heart rate on top of BP and heart rate.
Philips Body Analysis Scale	• Some issues with initial setup and pairing, but these were resolved. • Some issues syncing to the PHS app.	• Easy to use, just step on.
iHealth Align Gluco-Meter	• Requires blood test as part of set-up, which is cumbersome. • A number of pieces to be assembled to take blood reading. • Device requires headphone jack on smartphone/tablet – not wireless. • Requires precise location of blood sample for device to work (may not be an issue for a user with experience of other devices).	• Provides clear and easy info about diabetes on app. • Possible to enter info, such as before/after lunch, along with reading. • App screens are clear and easy to read and understand. • Requires initiating the app on smartphone or tablet.
iHealth Blood Oximeter	• None identified.	• Easy to set up and use. • App is clear and easy to use on smartphone. • Wireless (Bluetooth connection).

6.2 Participant Engagement Levels

Participation in the FT was varied across participants, with some engaging more sporadically than others with devices, applications, daily feedback surveys, or the scenario guidelines. Analysis of the focus group data conducted at both trial sites suggest that limited engagement with the trial occurred for a number of reasons. Daily survey reminders were sent by email to participants to prompt this engagement, however, some participants noted that receiving this prompt by email was not always effective if they did not have self-

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monitoring devices to hand to complete measurements such as blood pressure. Participants, therefore, often postponed responding to the survey prompt only to then forget later to complete measurements, check data transfer and answer survey questions.

Daily questions for completion on SEEK were identified by participants as boring and repetitive, which, impacted sustained engagement over the course of the 12-week FT. This was an important finding that has implications for engagement of participants in the PoC trial. Participants also reported difficulty answering some of the questions from the stance of the personas they were required to adopt for the FT, because they could not envisage how a person in such a circumstance would react and answer the questions. Some participants, therefore, reported answering questions randomly in order to test the system's response to answers given. While not the intended approach envisaged by the FT protocol, this strategy did, nonetheless, provide an opportunity to test a range of responsive aspects of the initial version of ProACT. It should also be noted that two participants withdrew from the FT as they changed employment.

6.3 PoC Trial Implications

6.3.1 Device Selection

A number of issues were identified during the FT relating to the selection and inclusion of potential devices for integration with ProACT. Key issues to be considered are those of (1) usability and suitability of devices for our cohort and (2) accuracy, data connectivity and integration of devices with ProACT. Usability relates to the ease by which PoC trial participants are likely to be able to easily use the device, given their health conditions or other potential physical limitations. For example, the Withings BPM cuff has been identified as likely to be difficult to use by one person, especially where physical coordination or strength may be a concern, thereby requiring assistance which may or may not be available. Another usability issue which arose was the Withings watch straps causing a rash. If Withings watches will be used in the PoC trial, alternative watch straps may require to be sourced to improve the likelihood the watches are used by participants.

Connectivity and integration relate to the feasibility and practicality of including the device within the ProACT system. An example is the need to consider the selection of Wi-Fi based devices over Bluetooth-based devices due to instability of data transfer, identified during the FT, when using Bluetooth. Bluetooth syncing issues were also identified by the DkIT team in previous trials of similar technology in older adults' homes.

Most of the devices tested had significant positive features but participants also identified shortcomings. These shortcomings fell largely into the areas of data transfer and usability, with most devices performing well in one of these two areas. Ultimately, where usability challenges were identified as surmountable, for example by training, education or facilitation of end-users to engage with the devices, the greater concern was to ensure effective, accurate and efficient data transfer from devices to the ProACT system. This is the cornerstone of the PoC trial. As additional, and more user-friendly devices become available

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for potential integration with the ProACT system, the successful transfer of data will be essential for the integration of these additional devices.

The consistent unreliability of the SmartThings door sensors suggests it may be more effective to rely on the key fob instead, for data on the PwM leaving the house. The key fob should also be used, without other room sensors, where there is more than one occupant living in the home of the PoC trial participant, or where they have pets. This enables effective reading when the participant is in or out of the house (if they carry the key fob) and eliminates confusion about in-home movement caused by multiple occupants or pets.

It is important to note that when using off the shelf third party devices, issues may occur that are outside the control of ProACT. For example, the recent acquisition of Withings by Nokia, which took place after the formal FT ended, could present potential challenges, for example through potential changes to the API which DkIT use to pull data into CABIE+. While initial investigations suggest there has been no negative effects to date, it will be necessary to monitor this further.

It is expected that by early August 2017, the additional devices that have been tested in parallel will be integrated into CABIE+. This data will then be available for viewing within the new ProACT application. To date, we have determined that the Withings weight scale and the Withings pulse ox SpO2 tracker will likely not form part of the ProACT device kit. There were consistent issues with data transfer from the Withings scales over both Bluetooth and Wi-Fi, whilst the Withings pulse ox tracker did not address the issue of steps not being counted while using mobility aids. The remaining kit will be more thoroughly tested in the FT Phase 2 (see Section 6.4), but the aim is to have a number of devices available for tracking particular measures to allow us to provide choice to our PoC trial participants (for example, a participant can choose between a wrist BPM or an upper arm BPM).

6.3.2 Kit Set-up, Deployment and Management

Some FT participants who were not very familiar with the kit being deployed, had difficulties with the setup, particularly with the SmartThings kit. While detailed instructions are available on SIMS, we have decided to have specific training on device setup and deployment for trial site researchers, which will most likely take place in DkIT prior to the PoC trial. Detailed system deployment protocols will be developed and should include guidance on dealing with issues identified during the FTs – for example optimal placement of sensors to maximise effective data transfer, as well as repositioning guidance, in the event that data is not being received from some or all SmartThings sensors; or how to train end users on syncing Withings watch data. System checks may need to be included in protocols, to identify if clusters of participant data are missing or not transferring. Protocols for trial site researchers will also include instructions on replacing batteries for each of the relevant devices to be provided.

Protocols for the trial site researchers also need to include follow-up procedures to ensure troubleshooting efforts result in resolution of issues. This is especially important as older

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people are often concerned about 'being a bother' and may also be concerned about fulfilling stereotypes of older people as struggling with technology.

If data does not come through, it will be difficult to 'diagnose' why. For example, Bluetooth might have been accidentally switched off, a breakdown in transfer could take place at any point in the system (e.g. device to device provider server, device provider server to CABIE+ etc.) or the user simply might not have taken a reading. A troubleshooting manual will be collaboratively developed between the trial teams and technical teams to try identify all potential issues, based on our experiences during the FT, with protocols on how to identify the root of issues and how to resolve.

Applications that are required to run 'in the background' to collect data, but that should not necessarily need to be opened by users, could cause issues as it is almost certain that these will crash at some point during the 12-month trial period. This was seen during the FT with participants receiving a message from Withings to restart the app to allow syncing of the watch. While the technical teams have not yet identified a resolution to this issue, it is something that will be considered prior to the PoC trial.

6.4 Limitations and Friendly Trial Phase 2

One of the main limitations of the FT was that not all elements of ProACT could be tested as they were not yet developed. However, this had always been anticipated, and FT type testing was envisaged up to the PoC trial commencing. The FT as outlined in this document, however, provided invaluable learnings, including how best to go about this type of rigorous testing. Participants found the testing very onerous and it appears 12 weeks was too long a period to expect sustained engagement and detailed reporting, despite this detail being requested in participant protocols. As a result, exact analysis of frequency of issues was not possible, for example. Despite this, from our regular meetings and phone calls, it became evident what the most critical or pervasive issues were. For example, we know that all participants experienced syncing issues with the Withings watch data, however, we do not necessarily know how often this occurred for each person – as it was a recurring issue, participants tended not to record it each time.

We will aim to address these limitations in the second phase of the FT, which will begin in August 2017. Details of a new protocol are currently being developed. However, we expect to conduct shorter, more detailed testing with trial site researchers. For example, one researcher may be asked to test the iHealth glucometer over a week long period, following very specific usage scenarios. They will be asked to provide very detailed feedback, on issues, as well as recording every time an issue is experienced, what steps are taken to address the issue and what the outcome is. Other researchers will be asked to do the same with the other devices. For this second phase FT, participants will also be using the new ProACT health and wellbeing application, and from September 2017, detailed testing of Care Analytics will also be possible – thus allowing at this time for a full end-to-end testing. At least one researcher at each of the main trial sites will then test the full ProACT system,

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including all devices, the new application and Care Analytics, leading up to the PoC trial, allowing for any final issues to be addressed.

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7. Appendix A – ProACT Friendly Trial Daily Survey

Welcome to the daily ProACT Friendly Trial Survey! Please enter your PwM SEEK login email address:

Have you completed your measurements and self-report questions today as PwM?
- ❍ Yes
- ❍ No

Any comments on this? Not required

Is the data coming through to SEEK for PwM account?
- ❍ Yes
- ❍ No

Any comments on this? Not required

Have you checked in to your other profile accounts (Carer/HCP) today?
- ❍ Yes
- ❍ No

Any comments on this? Not required

Have you any issues or comments on the devices today?

Have you any thoughts or comments on the current SEEK interface or ideas for future design?

That was it for today, thanks!

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8. Appendix B - Friendly Trial Protocol User Scenarios

Detailed scenarios were developed for all 10 participants of the FT. We include two here as an example – one where the participant's lead role was as a PwM, and one where the participant's lead role was as a GP.

C2 Lead Role PwM (IRE)

General info: COPD & CHF/CHD
Week 1: Go through the educational material and get to know the application from your own point of view. Get used to it and give initial feedback on and a first impression of the wearables and application in the templates.

Week 2: Get familiar with the app in your lead role as PwM, as well as the additional roles of formal carer and pharmacist. Focus on reporting initial impression of and difficulties with the wearables, application and educational material in the templates and questionnaire.
First questionnaire: https://iminds.az1.qualtrics.com/SE/?SID=SV_eD9QBzKQIJUjqsd

Week 3: From now on till the end of the friendly trial, start using the app in your lead and additional roles. You will be given a different stance every week to try out from Monday till Thursday and are provided with tasks every Friday. Questionnaires will be pushed weekly, and the templates for the wearables are to be filled out throughout.
Example weekly questionnaire:
https://iminds.az1.qualtrics.com/SE/?SID=SV_eyTmKEkHz9wfK4J
Stance towards system: Low digital literacy: no previous experience with using internet, a tablet or apps, only worked with some standard PC functions
Task: You wanted to save battery and turned off Bluetooth for a bit, and forgot to turn it on again (leave it off for a couple of hours). Do you get any feedback?

Week 4:
Stance towards system: Rheumatic complaints: your hands and fingers get stiff and hurtful when you have to use them a lot, especially when subtle movements are required.
Task: You have entered information in the wrong place (e.g. blood glucose in the blood pressure section). What feedback do you receive? Is it clear how to re-enter the information in the correct location?

Week 5:
Stance towards system: Anxious about own health, easily scared of and by 'bad' health readings.
Task: You manually entered an extremely high blood pressure measurement (180/110) and did not notice it. What kind of feedback did you get? How easy was it to understand the feedback?

Week 6:
Stance towards system: Low engagement: wants to do as little as possible, and take as few unnecessary steps as possible.
Task: Your grandchildren also used the weighing scale, and therefore there are too many measurements done on one day. What happens? Are you able to make sure it does not show in your profile?

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Week 7:
Stance towards system: Control of information: you want accurate information on your readings.
Task: You took your watch off this morning, and forgot to put it back on today. You will only remember tomorrow. What kind of message do you get when the watch is put back on?

Week 8:
Stance towards system: Not being able to read very well due to bad eyesight.
Task: Fill a well-being questionnaire in as if you can't see it clearly (all same answers) and complete it. Are you able to find your score somewhere?

Week 9:
Stance towards system: Stressed about managing routines
Task: Your phone got stolen, and you will receive your new one on Monday so you can not synchronize data for the weekend. Does it still synchronize data collected over the weekend after the weekend once you have your telephone again?

Week 10:
Stance towards system: Forgetful
Task: You will be staying at your sister this weekend, and you forgot to bring your kit so only the watch can provide input. Are you made aware that you should have put in data? Can you see how many readings you have missed?

Week 11:
Stance towards system: Colour vision – You find it difficult to distinguish differences in colours or tones.
Task: The battery of your blood pressure device is dead for a day (take them out for a day). Is it still linked to your application when you use it again? Are you able to check if the link to previously stored data has been re-established?

Week 12:
Stance towards system: Low literacy: difficulty in understanding difficult terms both health and non-health related.
Task: Look at the tips you have received recently, were they understandable and did they make sense?

C8 Lead Role GP (BE)

General info: You work in your own GP practice, together with one other GP. You do not have a fulltime secretary, and have to do most of the administration yourself. You have been working in the same area a long time, and a lot of your patients are over 65 years old and are managing more than one chronic illness and need ongoing care and self-management. For them, you are the first port of call for advice, referrals and support. Your practice is very busy and you are often in lack of time. This especially comes up in caring for your patients with multimorbidity: you would like to provide more care, support and information than you are able to. On the other hand, sometimes these patients and their family expect too much from you as a GP. You see that the information you provide orally or via information leaflets can be hard to take in and remember for your patients. This due to the difficulty of the material and situation

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(limited time, possibly with some stress). The communication with other specialist consultants is slow: it is mainly paper based and updates on medication or care can take up to 4 months to get to you by post. Often patients bring in their own medication list or hospital letters to speed up this process. You do not see age or socio-economic background as differentiating factors in how people will engage in self-management or behavioural change: it mainly seems to depend on their personality, and motivation coming from their social context.

Week 1: Go through the educational material and get to know the application from your own point of view. Get used to it and give initial feedback on and a first impression of the wearables and application in the templates.

Week 2: Get familiar with the app in your lead role as GP, as well as the additional roles of a person with multimorbidity (Diabetes & CHF/CHD) and pharmacist. Focus on reporting initial impression of and difficulties with the wearables, application and educational material in the templates and questionnaire.
First questionnaire: https://iminds.az1.qualtrics.com/SE/?SID=SV_eD9QBzKQIJUjqsd

Week 3: From now on till the end of the friendly trial, start using the app in your lead and additional roles. You are provided with tasks every Friday. Questionnaires will be pushed weekly, and the templates for the wearables are to be filled out throughout.
Example weekly questionnaire:
https://iminds.az1.qualtrics.com/SE/?SID=SV_eyTmKEkHz9wfK4J
Task: Try to add some data for your patients. How did it go? Does it work efficient?

Week 4:
Task: Look at your dashboard. What would you like to change for it to work and look better for you?

Week 5:
Task: Have a look at the graphs you can produce for your patients and try to make one for one of the variables. Are these clear for you and your patients?

Week 6:
Task: Check how your patients are doing psychologically. Is it easy to check?

Week 7:
Task: Try to check the data entered by the hospital specialist for one of your patients. How did that go? Was it easy to find?

Week 8:
Task: One of your patients is not satisfied with the exercise tips he receives, they do not match his capabilities. Are you able to do anything about this?

Week 9:
Task: One of your patients has an unusual reading, so you would like to check how it is going. Are you able to contact this patient?

Week 10:
Task: Look at the blood pressure measurements of one of your patients. Is it easy to see for you when these readings were in the healthy range and when they were too high?

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Week 11:
Task: You want to include data from the ProACT system with a letter of referral. How easy is it to print or send the data? Can you easily select the data and/or format (text or graphs) to send/print?

Week 12:
Task: You have an appointment this week with one of your patients that's in the system. You would like to get an idea of how it went the last 12 weeks and print out some relevant graphs to show your patient (heart rate, blood pressure, step count). Are you able to get a clear picture of the situation over de last 12 weeks? How easy was it to get these graphs?

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9. Appendix C – ProACT Friendly Trial: End Focus Group Protocol

Welcome and thanks for participating in the end focus group to evaluate the ProACT Friendly Trial. We would like to get insight in your experience in using ProACT over the last 12 weeks. All data will be anonymised and aggregated.

1. Use

How much did you use the system?

-Which functionalities did you use most frequently?

-Why these/not the others?

-How did you like these functionalities? *[positives+negatives]*

-On which moments?

-What made you use it?

-What withheld you from using it?

-How did you feel about the frequency of putting in data?

What helped/would have helped you to remain motivated to consistently use the system?

What elements of the system that were difficult to use/evaluate because you did not actually have the conditions/circumstances of the target users?

-How do you suggest these could be evaluated?

2. Evaluation

<u>For each SEPARATE DEVICE (watch, bp cuff, scale, sensors):</u>

Was it easy to use? [*for you and potential target users]*

-Do you consider it user friendly?

-Was using it effortless enough? *[fewest steps as possible, successful use, able to recover mistakes]*

-Did it run smoothly *[no malfunctioning, crashes]?*

-Were there unexpected, missing or confusing elements *[alerts, messages, links, information]*

Accuracy

- Do you think the data was accurate? *[why / why not?]*
- How do you feel about it being used in the PoC trial?

Was it easy to learn?

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-What was unclear?
-Did you have to read instructions? *[did you miss instructions?]*
-Do you think it would be easy to learn for the target users?

3 good things about this device
3 bad things about this device

3. Using SEEK

Was it easy to learn?
-What was unclear?
-Did you have to read instructions? *[did you miss instructions?]*
-Do you think it would be easy to learn for the target users?

Was it visually appealing?

How did you feel about the visualization in the app?
-Where the graphs clear?
-Did it run smoothly? *[synchronization, data showing]*
-Did you miss any info in the visualization? *[or was there too much]*

Answering daily questions
- How easy was this
- How burdensome was this?

4. Expectations and adaptations

How would you evaluate the ProACT system as a whole?
-What are the 3 most positive aspects?
-What are the 3 most negative aspects?

Did it meet your expectations?
-In which way yes/no?
-What should be altered to meet your expectations?
-What should be altered to make it interesting for target users? *[make specific]*

Do you have any additional comments?

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10. Appendix D - Additional Device Evaluation Survey

Dates device tested (from-to): 27/11/2016 – 01/04/2017. This was outside the FT protocols and was just a systematic testing of features between the devices and linked PHS application. The watch was the primary device worn over this period.
(additional sporadic testing occurred from 01/04/2017 and is ongoing).

Number of days/weeks tested: 18 weeks (tested sporadically rather than daily)

Device Names and Purpose (relevant to ProACT):

Philips PHS Devices linked to the PHS application only. To date the PHS devices have not been linked to CABIE/SEEK:

- **Philips Health Watch**

  The watch allows users to continuously track: daily activity (step count); heart rate (HR); nutrition (self-report) and sleep. The device itself is based on measurements and algorithms that grade the device as a Class IIa medical device (the device meets the requirements of the Medical Device Directive MDD 93/42/EEC, with regards resting heart rate and total energy expenditure measurements). Additional features stated by the device:

  - Continuous monitoring of HR, HR zones and resting HR
  - Monitoring of resting respiration rate and estimate of VO2 Max.
  - Automatic recognition of walking, running, biking, tracking of steps, active minutes and calorie burn.
  - Insight into sleep behaviour by tracking time asleep (including time awake) and sleep efficiency.

- **Philips BP Cuff – Wrist** – Measures systolic and diastolic blood pressure (BP). The cuff is a tubeless device that uses the oscillometric method to measure blood pressure and heart rate. Before every measurement the unit establishes a 'zero' point equivalent to atmospheric pressure before inflating the cuff. During the measurement the device detects the pressure oscillations in the blood vessels generated by the heart pumping blood through the body. These pressure oscillations are used to determine systolic and diastolic BP as well as heart rate. While measuring HR the device also determines the small variations in individual heartbeats. If these variations exceed a pre-defined threshold, the irregular heart rate detector symbol lights up.

- **Philips BP Cuff – Arm** - Measures systolic and diastolic blood pressure (BP) – Same description as above for the wrist cuff.

- **Philips Weight Scale** – Provides a body composition analysis: Measures weight and shows BMI and body fat in the Health Suite App.

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The devices listed above were only tested using the dedicated iOS based PHS Application available via the UK Apple Store. The application was not available at the time of testing in the specific Irish trial region.

Integrated with ProACT or Stand Alone (for manual data entry)?

No devices were integrated to ProACT. However, all devices provided automatic input to the PHS application with the exception being self-reported nutrition on the watch. There is also the ability to manually edit within the application nutrition, sleep and activity.

Features Evaluation:

Device	Overall Comments	Positive Features	Negative Features

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Philips Health Watch 	**Ease of Use:** • Simple features with an initially straight forward set up process that is easy to systematically work through. • User functions are basic within watch, which may work well with older adults, although training on moving through features using the 'click wheel' function is recommended. • There are quite a number of features/options within the watch, which would require training and prioritisation of those most appropriate for the user to focus on within ProACT. • On main clock user interface (UI) a quick clockwise movement of the 'click wheel' accesses daily; BPM, kcal based on exercise, overall kcal, steps and number of active (exercise) minutes respectively. This is easy to operate and review. • A tap of the 'Home Icon' (square at 12 o'clock on click wheel) gives access to 5 features, these are; details on heart rate and BP (BPM, resting HR, HRR), sleep (with manual option to record sleep also),	• Comfortable to wear for long periods and with exercise • Automatically can track and differentiate activity e.g. walking/running • Initial set up easy • Battery life 4-5 days with rapid re-charging • Very basic functions, which may work well with older adults • Home screen shows time, date and battery life clearly • If static for long periods a reminder to stand up and move appears on watch with vibrate alert.	• Given the range of features training will be required to help users navigate and prioritise which are important for ProACT. • Click wheel can be tedious to use. • Sleep function can be faulty and it is unclear how to reset • Only 3 exercise options • On occasion the automatic sleep reading not captured • On one occasion: Sleep function didn't switch off recorded 17 hours of sleep. A clear way to reset/change on watch is not present. • Bespoke charger - If charger is lost would need to be recorded via Philips. • While wearing watch at desk and moving

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	food and calorie intake (manual entry also), activity (walking, running and cycling with option for manual input), Alarm and Stopwatch and finally the user settings. These features are easy to scroll through and use. • Option to input food on watch which allows for a selection across drink, snack, breakfast, lunch and dinner. Controls are simple guided by forward and back icons on the click wheel. Selecting either food or drink options give the user the chance to select small, medium or large of each with an estimated kcal option then added automatically on selection. While this is not accurate, it is a time saving option. However, it would be important to understand how these calculations are made. Separate kcal measures can be entered but this would assume the user knows where to obtain this data or that the option is available (e.g. If cooking from fresh food and not labelled products (e.g. a microwave dinner) where kcals presented by the manufacturer). • Exercise options are easy to add for		legs the watch automatically recorded a bike exercise • Quick food tracking on watch is inaccurate. Very generalised. The kcal option may not be useful for older users. • It is not clear where heart rate zones and VO2 max is being recorded, this is primarily linked to the app.

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	walking, running and cycling and screen changes to white with black text to indicate the user is in exercise mode (standard setting is white text on black background). • Adding alarms, timer etc. are easy and straight forward to operate with clear icons directing user. • Insights into sleep and more detailed understanding of health and well-being behaviour can only be accessed via PHS app. • User settings are straight forward and easy to use. Some good features include the ability to change the clock face to digital instead of analogue, invert screen colours and turn on or off the vibrations/backlight. The only potential issue is that there is no return option when you access the user setting sub-sections. Return to the primary user setting menu is via the home icon only. • Changing the password on the linked app if forgotten is straightforward, with a mail sent to registered user e-mail address containing directions to process the change.		

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	• Accessing app requires double tap on lock icon (6 o'clock on click wheel) to access features on screen. This is easy to use. **Comfort, style and appearance of device:** • User interface by default is the classic watch style, which is clear. This can also be changed from analogue to digital. • Watch is comfortable to wear, even during more vigorous exercise. • Backlight enables easy viewing under dark/dim light conditions (activated on screen touch). **Transfer and display of data within the device application (speed, accuracy etc.):** • Data transfer to the PHS takes only a number of seconds and is accurate (between watch and app) **Issues or problems identified and steps taken to resolution:** • No major issues to report in use. • If left idle for a while individual may be		

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	logged out of app and watch and need to remember login details to re-use. • At times the click wheel can be tedious and require a few taps on the icons to access.		

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Philips BP Wrist Cuff 	**Ease of Use:** • On following the manual, the cuff is extremely easy to use. • Screen shows simple and clear readings of systolic, diastolic BP as well as pulse. • Colour coded range bar on side allows user to understand clearly whether their BP is normal or if above normal (if above at what level – traffic light system indicating from mild to severe). • Noise indicates when the cuff is inflating and when measurement is taken. **Comfort, style and appearance of device:** • Easy to fit without need for a second person. • Device design is light, compact and modern. • Inflated cuff may be tight for some frail elderly users. **Transfer and display of data within the device application (speed, accuracy etc.):** • Fast, efficient and accurate **Issues or problems identified and steps taken to resolution:** • If the cuff is not used with app for an	• Very easy to set up and use. • Error message reads of cuff is tampered with during inflation (E3). • Cuff allows for two separate users • Once synched the device can be locked • Easy to charge and long battery life on charge. • Movement detector icon present to show user if this is happening as movement will produce inaccurate reading. • Detects irregular heart rate on top of BP and heart rate. • Detects movement accurately. • Large LCD display clearly shows outputs/readings • Measurements follow WHO classification system • No external batteries required	• Slight discrepancy from the Arm band reading – all within same value range though. • Not clear for user what to do when error message is observed. • On two occasions the cuff did not stop inflating and had to be removed – This was rare.

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	extended period it needs to be removed from device list on app and reconnected to ensure the synch option works again. • If cuff over inflates, use strap to remove. • When error message is read – use power button to reset.		

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Philips BP Arm Cuff 	**Ease of Use:** • On following the manual, the cuff is extremely easy to use. • Screen shows simple and clear readings of systolic, diastolic BP as well as pulse. • Colour coded range bar on side allows user to understand clearly whether their BP is normal or if above normal (if above at what level – traffic light system indicating from mild to severe). • Noise indicates when the cuff is inflating and when measurement is taken. • **More difficult** than the wrist cuff to use with one person but still manageable. **Comfort, style and appearance of device:** • A little bit more tricky than cuff to fit in isolation. • Device design is light, compact and modern. • **Transfer and display of data within the device application (speed, accuracy etc.):** • Fast, efficient and accurate **Issues or problems identified and steps taken to resolution:** No problems identified in use during testing.	• Very easy to set up and use • Cuff allows for two separate users • Easy to charge and long battery life on charge (wrist cuff appears to have longer battery life). • Movement detector icon present to show user if this is happening as movement will produce inaccurate reading. • Detects irregular heart rate on top of BP and heart rate. • Detects movement accurately. • Large LCD display clearly shows outputs/readings • Measurements follow WHO classification system • No external batteries required.	• Slight discrepancy from cuff reading – all within same value range though. • Wrist cuff can be locked the arm cannot.

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Philips Smart Scale 	**Ease of Use:** • Extremely easy to set up and use • Better to use on hard rather than carpeted surface (manual warns of this and provides carpet feet to deal with this, which are easily attached) • In-depth features (e.g. % Body Fat) comes via the app. These features are automatically displayed and outputted via app in seconds post synch. **Comfort, style and appearance of device:** • Stylish, modern, ease you use. **Transfer and display of data within the device application (speed, accuracy etc.):** • Fast in data transfer (in seconds), efficient and accurate in readings from scales to app. **Issues or problems identified and steps taken to resolution:** • None identified.	• Multiple user recognition (up to 8 people) • Large clear LCD screen outputs readings • Options (using button on back) to toggle between kg, lb and st.	• No major negatives identified. To note to make full use of the scales access to the app is required.

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Philips Digital Health Suite 	**Ease of Use:** • Application is straight forward to use and easy to navigate. • Application allows for easy manual update of meals, BP, weight and calorie intake. • Looking for devices and synching takes about 20-30 seconds on average. • Refreshing data synch involves a simple home screen pull down. • An overall score is presented as the focus of the app home screen. This is used to calculate how the users' lifestyle choices compare to the recommended healthy targets in each of the areas in which data is provided. Users can choose to track between 2-5 different behaviours. The score provides feedback on the data collected that day. Turning the phone on its side allows for further exploration of the data. • BP, HR and %Body fat use a traffic light system on icons to inform user of whether they are in normal or above normal categories. • A view "All Your Data" tab on home screen allows for a quick overview of all data inputted to application. • My profile tab on bottom allows for easy	• Easy to read and follow interface • News feed is a good feature with not just support on general health and well-being but also on using your selected devices. There is also a bookmark feature to track the user favourite news feed items. • Easy to add data manually. • Clear warnings given that the app is not intended to diagnose or treat serious medical conditions. • App allows for setting of daily targets • A clear, easy to use help section is indicated on home screen with a virtual assistant.	• Listed food available for input are American based. Tracking food is time consuming and not suited to EU group. • Automatic sleep reading on several occasions did not synch. • If devices haven't been used with application in a while then the initial re-synching can be quite slow (5-7 minutes). After this synching is back to normal (10-20 seconds). • Data/fonts may be too small on mobile device for older end users.

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	set-up of daily targets. • It is easy to synch devices with app. The app presents clear onscreen instructions to achieve this, without user needing the paper based manual. • Device settings can only be changed for manual input of data and the watch on the app. This is quite straight forward to execute. **Comfort, style and appearance of device:** • Design is clear and ease to follow. **Transfer and display of data within the device application (speed, accuracy etc.):** • Fast and efficient data transferred. Data displayed clearly and accurately from device. No major issues. **Issues or problems identified and steps taken to resolution:** • No major issues. • On occasion when data didn't synch automatically this seemed to rectify on the next occasion for synch (e.g. if sleep didn't register for one day, it would register the follow day). • If devices were not used with the app for		

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	an extended period the app would sign the user out. On re-signing in, it would be best practice to re-synch all devices to ensure accuracy.		

Note the following feature is not applicable to the PHS devices at this stage: **Transfer of data to SEEK/ProACT (speed, accuracy, ease of transfer etc.)**

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