SHAPES

A non-randomised pilot study of the Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) digital app and platform for supporting medicines optimisation in older individuals with multiple long-term conditions

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1. Administrative Information

1.1 Project details

Project Title:	**A non-randomised pilot study of the Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) digital app and platform for supporting medicines optimisation in older individuals with multiple long-term conditions**
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Ethics reference number:	284743
UK Chief Investigator:	Prof Michael Scott MOIC Pine House Antrim Hospital Site BT41 2RL

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Logos:

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1.2 Funding

This pilot study is part of the overall SHAPES Innovation Action, which has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreements No. 857159. The funder has commissioned reports on the results of this pilot study (D6.4).

1.3 Roles and responsibilities

Sponsorship

The pilot is sponsored by the Northern Health and Social Care Trust.

Sponsor	Frances Johnston Research Office Governance Department Bush House Bush Road Antrim BT41 2QB 028 9442 4653 frances.johnston@northerntrust.hscni.net
Sponsor's Reference	NT21-SHAPES

Study Team

Chief Investigator	Prof Michael Scott (NHSCT) drmichael.scott@northerntrust.hscni.net
Co-Investigators	Dr Glenda Fleming (NHSCT) Glenda.fleming@northerntrust.hscni.net
NORTHERN HEALTH AND SOCIAL CARE TRUST (NHSCT) established in BRETTEN HALL ANTRIM AREA HOSPITAL SITE TRUST HEADQUARTERS, ANTRIM BT43 6DA, United Kingdom	Dr Nicola Goodfellow (NHSCT) Nicola.goodfellow@northerntrust.hscni.net
	Dr Claire Scullin (NHSCT) Claire.scullin@northerntrust.hscni.net
	Maureen Spargo (NHSCT) Maureen.spargo@northerntrust.hscni.net
	Suzanne Martin (NHSCT) Suzanne.Martin@northerntrust.hscni.net
	Katherine O'Neill (NHSCT) Katherine.ONeill@northerntrust.hscni.net
	Rachel Huey (NHSCT) Rachel.Huey@northerntrust.hscni.net
	Sara Gardner (NHSCT) Sara.Gardner@northerntrust.hscni.net
	Anita Hogg (NHSCT) Anita.Hogg@northerntrust.hscni.net
	Conor McQuillan (NHSCT) Conor.McQuillan@northerntrust.hscni.net
	Sarah McLaughlin (MEAAP)

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Mid & East Antrim Area Partnership (MEAAP) 18 Queen Street, Ballymena, BT42 2BD	Sarah.McLaughlin@meaap.co.uk
	Rosaliene Donaldson (MEAAP) Rosaliene.donaldson@meaap.co.uk
	Catriona O'Boyle (MEAAP) Catriona.OBoyle@meaap.co.uk
	Ellen Nixon Ellen.nixon@meaap.co.uk
	Úna McNaughton (MEAAP) una.mcnaughton@meaap.co.uk
	Deirdre McCloskey Deirdre.mccloskey@meaap.co.uk
	Jeanette Van Der Merwe (MEAAP) projects@meaap.co.uk
	Nicola Platt (MEAPP) nicola.platt@meaap.co.uk
EREVNITIKO IDRIMA P.L. (UNRF), established in METOCHIOU 66 EGKOMI, NICOSIA 2407, Cyprus.	Constandinos X. Mavromoustakis mavromoustakis.c@unic.ac.cy
	Andreas Andreou (UNRF) andreou.andreas@unic.ac.cy
	Costas Constantinou (UNRF) constantinou.c@unic.ac.cy
FUNDACION CENTRO DE TECNOLOGIAS DE INTERACCION VISUAL Y COMUNICACIONES VICOMTECH (VICOM), established in PASEO MIKELETEGI PARQUE TECNOLOGICO DE MIRAMON 57, DONOSTIA SAN SEBASTIAN 20009, Spain.	Nekane Larburu Rubio (VICOM) nlarburu@vicomtech.org
	Jon Kerexeta Sarriegi (VICOM) jkerexeta@vicomtech.org
	Meritxell García Perea (VICOM) mgarciap@vicomtech.org
TREE TECHNOLOGY SA (TREE), established in DE LA POMARADA 76, SIERO 33429, Spain.	
	Tatiana Silva (TREE) tatiana.silva@treetk.com
	Esteban Fabello González esteban.fabello@treelogic.com
GNOMON Informatics SA (GNOMON), established in ANTONI TRITSI 21, Thessaloniki 57001, Greece.	Fotis Gonidis (GNOMON) f.gonidis@gnomon.com.gr>;
	Korina Papadopoulou (GNOMON) k.papadopoulou@gnomon.com.gr
EDGENEERING LDA (EDGE), established in AVENIDA INFANTE D HENRIQUE NO 2 CENTRO	Barbara Guerra (EDGE) barbara@edgeneering.eu)
	Marco Manso (EDGE)

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EMPRESARIAL DO OESTE, CALDAS DA RAINHA 2500 218, Portugal.	marco@edgeneering.eu
FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V. (Fraunhofer), established in HANSASTRASSE 27C, MUNCHEN 80686, Germany. Acting as legal entity for and on behalf of its Fraunhofer Institute for Technological Trend Analysis INT	Sonja Grigoleit (FRAUNHOFER) sonja.grigoleit@int.fraunhofer.de
UNIVERSITY OF ULSTER (Ulster), established in CROMORE ROAD, COLERAINE BT52 1SA, United Kingdom.	Dewar Finlay d.finlay@ulster.ac.uk
	Raymond Bond rb.bond@ulster.ac.uk
	Susan Quinn s.quinn1@ulster.ac.uk
	Mark Donnelly mp.donnelly@ulster.ac.uk
	Jim McLaughlin jad.mclaughlin@ulster.ac.uk
	Shirley Davey s.davey@ulster.ac.uk
NATIONAL UNIVERSITY OF IRELAND MAYNOOTH (NUIM), established in CO KILDARE, MAYNOOTH, Ireland	Richard Lombard Vance (NUIM) Richard.lombardvance@mu.ie
	Deirdre Desmond (NUIM) Deirdre.desmond@mu.ie
	Rebecca Maguire (NUIM) Rebecca.maguire@mu.ie
Health Economist	Dr Claire Scullin Claire.scullin@northerntrust.hscni.net
Pilot leader centre	Medicines Optimisation and Innovation Centre, Pine House, Antrim Area Hospital Site, Bush Road, Antrim, BT41 2RL

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Committees and oversight

This medicine control and optimisation pilot study is within Work Package (WP) 6 of the overall SHAPES Innovation Action. WP6 will hold meetings independently of this pilot study. Likewise, the parties involved in this pilot will be involved in other work packages within the SHAPES programme and fall outside the remit of this protocol.

Pilot Management Group

The Pilot Management Group (PMG) will typically host a monthly meeting. Key attendees are the Chief Investigator, relevant project managers (MOIC/NHSCT), representatives from EU pilot sites. Other attendees e.g., technical partners, Sponsor representative, funder representative, WP6 leader may be invited at the discretion of the Chief Investigator. Attendance and action minutes will be recorded.

Other relevant committees

- The General Assembly (GA) is the ultimate decision-making body of the SHAPES consortium.
- The Project Management Board (PMB) is the supervisory body for the execution of the Project, which shall report to and be accountable to the General Assembly.
- The Executive Management Team assists the PMB and the Coordinator. The Coordinator is the legal entity acting as the intermediary between the Parties and the Funding Authority.
- The Ethics Advisory Board (EAB) is a consultative body to help ensure and strengthen the robust ethical standards of the SHAPES project and to support the consortium on any ethical issues that may arise.

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2. Introduction

2.1 Background and rationale

People who are aged 65 years and older account for more than one fifth (20.6%) of the population of the European Union [1]. By 2100, this proportion is projected to rise to almost a third (31.3%) of the EU population. Conversely, the proportion of EU citizens who describe themselves as being in 'good' or 'very good' health is falling and varies considerably between member states (ranges between 43.4% and 83.8%) [2]. Naturally, being in 'good health' is not only of value to the individual (better quality of life, improved wellbeing, greater social participation), but it is also important for societal and economic growth [2]. Thus, there is an imperative to keep people healthy and active as they age.

As age increases, however, so too does the prevalence of people living with long term conditions and subsequently, the number and complexity of treatment regimens to manage those conditions, also known as polypharmacy. Integrated care focuses on the needs of the recipient of care, rather than each condition in silos — coordinating diagnosis and treatment between different therapeutic areas and specialties, and between health sectors. The benefits of integrated care models are clear (improved outcomes, established chains of prevention, diagnosis, treatment and care across the system); still, the complexity of health and care systems in individual countries and regions adds to the challenge.

The location of care delivery will also need to adapt to implement a truly integrated care approach to healthcare — shifting routine care from hospitals to homes and the community. Home is a more comfortable and familiar setting for people and, as it has been the case during the COVID-19 pandemic, home is safer too. Individuals with chronic health conditions require regular and specialist care and support. Whereas much of this type of care can be delivered at home by community nurses, or allied health professionals, who coordinate with the individual's other clinicians, it is often not logistically or economically possible to provide such services to all those who need them. The use of information and communication technologies (eHealth) offers opportunities to support and enhance home care. With the right eHealth technology, changes in a patient's condition can be potentially recognised at an early stage and treatment can be quickly adjusted — resulting in better-managed conditions and fewer hospitalisations.

Health literacy and individual involvement will be key elements in the successful introduction of eHealth into the health and social care system. Citizens, including older individuals, must be seen as custodians of their own health [3], thus emerging technologies need to be both user-friendly and empowering.

Specifically designed ICT-based assistive technologies may be of great benefit to older individuals who are increasingly at risk of frailty pertaining to mobility, vision, hearing and cognitive performance. Developments in ICT-based home care, including ways of monitoring wellbeing and providing a secure home environment, as well as key emerging technologies on robotics and sensors open up the concept of 'Ambient Intelligence' and offer the potential for different environments (i.e., at home, in the street, during transportation,) to embed intelligence that helps with everyday life. To date, initiatives to achieve traction in this area have been modest, with experiments involving advanced ICT services supporting health and care through small-scale, localised initiatives.

The Smart & Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Innovation Action intends to build, pilot and deploy a large-scale, EU-standardised open access platform. The

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integration of a broad range of technological, organisational, clinical, educational and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life. Mediated by technology, in-home and local community environments interact with health and care networks contributing to the reduction of costs, hospitalisations and institutional care.

SHAPES intends to build an interoperable Platform integrating smart digital solutions to collect and analyse older individuals' health, environmental and lifestyle information, identify their needs and provide personalised solutions that uphold the individuals' data protection and trust. Standardisation, interoperability and scalability of the SHAPES Platform aims to increase efficiency gains in health and care delivery across Europe, bringing improved quality of life to older individuals, their families, caregivers and care service providers. SHAPES large-scale piloting campaign will engage over 2k older individuals in 15 pilot sites in 10 EU Member States, including six European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) Reference Sites, and involving hundreds of key stakeholders. SHAPES multidisciplinary approach to large-scale piloting is reflected across seven themes that, together, provide a clear understanding of the reality of European health and care systems and enable the validation of cost-effective, interoperable and reliable innovations capable of effectively supporting healthy and independent living of older individuals both within and outside the home.

These seven themes are as follows:

Pilot Theme 1 Smart Living Environment for Active Ageing at Home

Pilot Theme 2: Improving In-Home and Community-based Care Services

Pilot Theme 3: Medicine Control and Optimisation

Pilot Theme 4: Psycho-social and Cognitive Stimulation Promoting Wellbeing

Pilot Theme 5: Caring for Older Individuals with Neurodegenerative Diseases

Pilot Theme 6: Physical Rehabilitation at Home

Pilot Theme 7: Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals

The Medicines Optimisation Innovation Centre (MOIC), which is hosted by the Northern Health and Social Care Trust (NHSCT) in Northern Ireland. Northern Ireland is an EIP on AHA reference site and is dedicated to driving innovation in medicines use. The MOIC is leading Pilot Theme 3 of the SHAPES pilot: 'Medicine control and optimisation', wherein the SHAPES platform and selected digital solutions will be used to help participants self-monitor their health condition(s), physiological parameters and medicines adherence. The anticipated benefits of this highly personalised approach to delivering healthcare is to promote safer and more effective use of medicines in the home, thus improving the health outcomes and quality of life of the target population [4]. Data collected from participants will provide validation of a heart failure decompensation algorithm which may, in future, be used to detect precursor signs indicating the deterioration or serious complications of the older individual's condition. Within this pilot theme there are multiple 'use cases' each deploying and evaluating different digital solutions according to the type of support required. Four use-cases will be used to evaluate this pilot theme. This protocol describes the piloting of one use case (Supporting multi-morbid older individuals) in NHSCT.

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2.2 Hypothesis

This study will test the hypothesis that the SHAPES platform and Digital Solutions are capable of providing opportunities for supporting medicine control and optimisation in older people with multiple chronic health conditions.

2.3 Objectives

Primary objective

- To investigate user engagement with the SHAPES app and Digital Solutions

Secondary objectives

The following objectives are specific to the 'Supporting multi-morbid older individuals' use case:

- To validate the capability of the SHAPES platform and Digital Solutions to;
    - implement a personalised approach to achieve safe and effective use of medicines at home.
    - achieve better patient outcomes by initiating, developing and sharing best practice with regards to medicines use.
    - address and improve deficiencies with adherence to medicines and treatments.
    - identify associations between precursor signs of deterioration and unscheduled healthcare resource use.
    - improve data collection to develop predictive algorithms for heart failure decompensation.
    - improve older individuals' quality of life.
- To explore the integration of the SHAPES platform and Digital Solutions to align with current and developing care pathways.
- To explore user trust and acceptance of the SHAPES platform and Digital Solutions.

Tertiary objectives

The following objectives align with the general purposes of the SHAPES large-scale piloting campaign:

- To validate the capability of the SHAPES Platform and Digital Solutions to;
    - support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities.
    - improve the older individuals' health outcomes and quality of life.

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- gain the older individuals' trust and acceptance.
- gain the care professionals' trust and acceptance.
- contribute to the reduction of the workload of medical professionals.
- deliver efficiency gains in health and care delivery across Europe.

2.4 Pilot design

This is a non-randomised, single-armed, cross-sectional interventional pilot study with an optional qualitative interview component. The pilot will aim to recruit 30 participants who will be NHSCT service users.

Separate qualitative interviews will be held with up to 5 clinical leads employed by the Northern Health and Social Care service in Northern Ireland.

3. Methods

3.1 Study setting

The pilot will be conducted with service users from the Northern Health and Social Care Trust (NHSCT) who reside in their own home or supported living environment. Additionally, interviews will be conducted with clinical or policy leads in the NHSCT.

3.2 Eligibility criteria

Service user inclusion criteria

At point of consent;

- Northern Health and Social Care Trust service user
- ≥60 years
- Diagnosed with heart failure and/or diabetes mellitus
- If diagnosed with diabetes mellitus (and not heart failure), treatment includes regular monitoring of blood glucose
- Lives at home or in supported living accommodation (category 1 or 2).
    - Category 1 - self-contained accommodation for the more active elderly, which may include an element of scheme supervisor support and/or additional communal facilities
    - Category 2 - scheme supervisor supported self-contained accommodation for the less active elderly, which includes the full range of communal facilities
- Has stable self-reported Wi-Fi connection at home
- Has access to an appropriate android smartphone or tablet
    - Android device running version 6 or above; supports Wi-Fi; supports BLE; front facing camera for facial recognition
- Self-reported stable disease state, the participant feels well enough to take part in the pilot
- Self-reported confident user of smartphone/tablet

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Service user exclusion criterion

At point of consent;

- Participant report of cognitive impairment
- Wears an electronic medical device or implant (e.g. pacemaker, electrocardiogram)
- Allergy to rubber products

HSC staff inclusion criterion

- Knowledge of patient care pathways
- Employed by the Northern Health and Social Care service in Northern Ireland

HSC staff exclusion criteria

- Unwilling or unable to provide consent

3.3 Intervention

The intervention being piloted in this study is a novel system of supporting older individuals with multiple long-term conditions to self-manage their chronic conditions through the daily use of a digital health product that can also facilitate the remote monitoring of a person's health status.

The goals of the intervention are to help people self-monitor their health conditions, physiological parameters and medicines adherence to promote safer and more effective use of medicines in their own home. In future, the intervention will also facilitate the remote monitoring of people by health and social care practitioners and use artificial intelligence (AI) algorithms to predict deterioration in a person's health status. However, this functionality will not be investigated in the present study.

Participants will be asked to download the SHAPES app to an appropriate smartphone or tablet. Mock-up images of the app are provided as a supporting document. Four CE-marked, Bluetooth-enabled devices, specifically a body composition monitor (OMRON VIVA Smart Scale), glucometer (Roche Accu-chek Instant), blood pressure monitor (OMRON M7 Intelli IT) and pulse oximeter (Beurer GmbH PO60 Bluetooth pulse oximeter), will also be provided, as appropriate, to participants to use at home. Participants diagnosed with heart failure will be provided with the body composition monitor (OMRON VIVA Smart Scale), blood pressure monitor (OMRON M7 Intelli IT) and pulse oximeter (Beurer GmbH PO60 Bluetooth pulse oximeter). Participants diagnosed with diabetes will be provided with the glucometer (Roche Accu-chek Instant) and given the option to use the other devices according to preference. Participants will be encouraged to use the devices to take daily readings of their weight, blood pressure, heart rate and oxygen saturation, and readings of their blood glucose as per their existing diabetes care plan (if applicable). The readings are electronically transferred to the SHAPES app via Bluetooth. Participants can view their data via the app and have the ability to enter readings manually if required. Participants will also be encouraged to complete a daily survey containing questions about their health status (participants with heart failure only), and a weekly survey about their use of medicine. The participant's medication regimen will be uploaded to the app by researchers and will be available to view both as a comprehensive list of all medicines, and a daily list to serve as a reminder for what has to be taken that day. Participants will be asked via the app on a weekly basis if any changes had been made to their treatment that week so that their medication regimen can be amended accordingly.

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Participants will receive one-on-one, face-to-face introduction to the app and training on how to use both it and the connected medical devices. A user manual will contain detailed step-by-step supportive guidance and information, and will be provided to participants in hard-copy format for reference by participants during the pilot. There will be a run-in period of approximately one week wherein the participant can familiarise themselves with the app and liaise with the researchers to troubleshoot any problems they may be experiencing with the technology. Participants will be asked to use the app and connected devices for 12 weeks. Researchers will contact participants by telephone at the end of week 1, if there are three or more consecutive days were no data has been received (up to a maximum if four times during the pilot) and monthly (if required) thereafter. These telephone contacts are to enable the researchers to support participants with their use of the technology and troubleshoot any issues they may be experiencing (no health advice or clinical support will be provided by the researchers. If participants have any health concerns they will be encouraged to contact their specialist care team).

All data entered or transferred into the SHAPES app (i.e., clinical readings, survey responses) is pseudonymised and will be stored in the technical partners' (EDGE and GNOMON) servers and then uploaded to the SHAPES big data platform. Selected data is then processed by two further SHAPES digital solutions; a heart failure decompensation risk prediction algorithm (VICOM) and an analytic tool that generates personalised dynamic thresholds for participants' clinical parameters (TREE). These digital solutions have not yet been validated or CE-marked for use as medical devices. Therefore, the outputs will not be used to inform clinical care, but rather to determine whether the digital solutions are capable of producing outputs reliably using the available data, and to indicate if there are any associations between the risk scores generated and the participants' use of unscheduled care.

Participants' data and outputs from VICOM and TREE digital solutions will be uploaded to a browser-based researcher dashboard. Researchers will be able to view each participant's clinical and survey data, and manage participants' medication regimens as needed. Researchers will view the available data and information for purposes of monitoring usage of the app and inputting changes to medication regimens only.

3.4 Outcomes

Primary outcome

Participants' engagement with the SHAPES app during the pilot as defined by the number of times the app is opened per day over three months.

Secondary outcomes

- Participants' user experience with the SHAPES app as measured using the User Experience Questionnaire –short version (UEQ-S)
- Usability of the SHAPES app as measured using the System Usability Scale
- Number and rate of successful registrations of each clinical parameter per participant, per day (heart rate, blood pressure, weight, oxygen saturation, blood glucose)
- Number and rate of control limits (upper and lower) successfully generated by the 'Vitals Control' analytic tool per person (rate defined as number of pairs of limits generated per week during the pilot)

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- Number and rate of heart failure decompensation prediction (HFPred) risk scores successfully generated per person (rate defined as number of scores generated per week during the pilot)
- Change in hospitalisation rate per person (hospitalisations/month) and A&E attendance rate (attendance/month) three months prior to baseline compared with 3 months during the pilot
- Participants' self-reported medication adherence as measured using the Medication Adherence Report Scale (MARS) at baseline and at the end of the pilot
- Participants' beliefs about medicines as measured using the Belief's about Medicines Questionnaire (BMQ) at baseline and at the end of the pilot
- Correlation between participants' self-reported medication adherence and beliefs about medicines
- Number and rate (score/week) of heart failure decompensation prediction (HFPred) risk scores successfully generated per person during the pilot
- Correlation between HFPred scores and unscheduled care during the pilot (unscheduled care defined as composite of hospitalisations, A&E attendances, specialist contacts, out-of-hours contacts)
- Health-related quality of life as measured using the EQ-5D-5L questionnaire (ref) at baseline and at the end of the pilot
- Exploration of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways
- Exploration of healthcare practitioners' views about their trust and acceptance of the SHAPES platform and Digital Solutions
- Exploration of participants' views about their trust and acceptance of the SHAPES app.
- Exploration of user engagement behaviors

Tertiary outcomes

The following outcomes align with the general purposes of the SHAPES large-scale piloting campaign and data will be harmonised with outcome data from all pilots in the campaign:

- Participants' self-efficacy as measured using the general self-efficacy scale
- Participants' extent of social support as measured using the Oslo Social Support Scale (OSSS-3)
- Participants' health literacy as measured using the Single-item Health Literacy Measure (HLM1)
- Participation in society as measured using non-validated participation questions
- Participants' quality of life as measured using the WHOQOL-BREF
- Health-related quality of life as measured using the EQ-5D-5L
- Usability of the SHAPES app as measured using the System Usability Scale
- Technology Acceptance
- Exploration of participants' views about their trust and acceptance of the SHAPES platform and Digital Solutions
- Exploration of healthcare practitioners' views about their trust and acceptance of the SHAPES platform and Digital Solutions
- Change in health service utilisation for unscheduled care related to heart failure and diabetes as measured by:
    - Number of hospitalisations
    - A&E attendances
    - Out of hours contacts
    - Contacts with specialist services

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- Economic impact of the intervention as measured by comparing the cost of the intervention (devices, SHAPES platform and digital solutions; staffing) versus the cost of unscheduled care related to heart failure and diabetes during the pilot.

Table 1: Table of outcomes mapped to objectives of pilot

Objective	**Outcome measure**	**Timepoint(s) of evaluation of outcome measure (if applicable)**
To investigate user engagement with the SHAPES app and Digital Solutions	Participants' engagement with the SHAPES app during the pilot as defined by the number of times the app is opened per day per person over three months.	End of pilot
	User experience as measured using the user experience questionnaire –short version (UEQ-S)	End of pilot
	System Usability Score	End of pilot
To validate the capability of the SHAPES platform and Digital Solutions to implement a **personalised approach** to achieve safe and effective use of medicines in homes.	Number and rate of successful registrations of each clinical parameter per participant, per day (heart rate, blood pressure, weight, oxygen saturation, blood glucose)	End of pilot
	Number and rate of control limits (upper and lower) successfully generated by the 'Vitals Control' analytic tool per person (rate defined as number of pairs of limits generated per week during the pilot)	End of pilot
	Number and rate of heart failure decompensation prediction (HFPred) risk scores successfully generated per person (rate defined as number of scores generated per week during the pilot)	End of pilot
	Number and rate of views of medication list (rate as defined as number of views per week during the pilot)	End of pilot
To validate the capability of the SHAPES platform and Digital Solutions to achieve **better patient outcomes** by initiating, developing and sharing best practice with regards to medicines use.	Change in use of unscheduled care related to heart failure and diabetes as measured by: • Rate of hospitalisation • Rate of A&E attendance	 3 months prior to baseline and end of pilot 3 months prior to baseline and end of pilot

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To validate the capability of the SHAPES platform and Digital Solutions to address and improve deficiencies with adherence to medicines and treatments.	Medication Adherence Report Scale (MARS)	Baseline and end of pilot
	Beliefs about Medicine Questionnaire (BMQ)	Baseline and end of pilot
	Correlation between participants' self-reported medication adherence and beliefs about medicines	After pilot
To validate the capability of the SHAPES platform and Digital Solutions improve data collection to develop predictive algorithms for heart failure decompensation.	Number and rate of heart failure decompensation prediction (HFPred) risk scores successfully generated with complete data collection per person (rate defined as number of scores generated per week during the pilot)	End of pilot
To validate the capability of the SHAPES platform and Digital Solutions to identify associations between precursor signs of deterioration and unscheduled healthcare resource use.	Correlation between HFPred scores and unscheduled care during the pilot Association between HFPred scores and unscheduled care during the pilot (unscheduled care defined as composite of hospitalisations, A&E attendances, specialist contacts, out-of-hours contacts)	After pilot
To validate the capability of the SHAPES platform and Digital Solutions to improve older individuals' quality of life	EQ-5D-5L	Baseline and end of pilot
To explore the integration of the SHAPES platform and Digital Solutions to align with current and developing care pathways.	Exploration of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways	During or after pilot
To explore user trust and acceptance of the SHAPES platform and Digital Solutions.	Exploration of participants' views about their trust and acceptance of the SHAPES app.	End of pilot
	Exploration of user engagement behaviors	After pilot

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To validate the capability of the SHAPES Platform and Digital Solutions to support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities	General Self-Efficacy Scale	Baseline; End of pilot; 3-month follow-up
	Oslo Social Support Scale (OSSS-3)	Baseline; End of pilot; 3-month follow-up
	Health literacy as measured using the Single-item Health Literacy Measure (HLM1)	Baseline; End of pilot; 3-month follow-up
	Participation measure (non-validated)	Baseline; End of pilot; 3-month follow-up
To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals' health outcomes and quality of life	WHOQOL-BREF	Baseline; End of pilot; 3-month follow-up
	EQ-5D-5L	Baseline; End of pilot; 3-month follow-up
To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals' trust and acceptance	System Usability Score	End of pilot
	Technology Acceptance measure (non-validated)	End of pilot
To validate the capability of the SHAPES Platform and Digital Solutions to gain the care professionals' trust and acceptance	Exploration of healthcare practitioners' views on integration and alignment of the SHAPES platform and Digital Solutions with current care pathways	After pilot
To validate the capability of the SHAPES Platform and Digital Solutions to contribute for the reduction of the	Change in health service utilisation for unscheduled care related to heart failure and diabetes as measured by: • Number of hospitalisations	3 months prior to baseline and end of pilot
	• A&E attendances	3 months prior to baseline and end of pilot

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workload of medical professionals	• Out of hours contacts • Contacts with specialist services	3 months prior to baseline and end of pilot 3 months prior to baseline and end of pilot
To validate the capability of the SHAPES Platform and Digital Solutions to deliver efficiency gains in health and care delivery across Europe	Economic impact of the intervention as measured by comparing the cost of the intervention (devices, SHAPES platform and digital solutions; staffing) versus the cost of unscheduled care related to heart failure and diabetes during the pilot.	After the pilot

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3.5 Participant timeline

	T_x	T_{-1}	T_0	$T_{0\text{-}12}$	T_{12}	F_x	F_x	T_x
	Enrolment	Run-in	Baseline	Pilot	End of pilot *(+14 days)*	Participant interviews *(end of pilot visit or other suitable time)*	3-month follow-up *(+/- 7 days)*	Close out
ENROLMENT:								
Eligibility screening	X							
Eligibility confirmation	X							
Informed consent	X							
Training on SHAPES app and connected devices	X							
Run-in (familiarisation with app and devices)		X						
Contact details (name, address, email, telephone number, alternative contact details, HSC number)	X							
ASSESSMENT:								
Baseline Questionnaires *(Barthel Index; EHFS; Gijon Scale; MARS; BMQ; EQ-5D-5L; GSES; OSSS-3; HLM1; participation measure; WHOQOL-BREF)* Medical history data; Demographic data; Technical data; Laboratory results; Unscheduled care; Current prescribed medication			X					
During pilot *(collected via SHAPES app)* Blood pressure, heart rate, oxygen saturation, weight (daily); Blood glucose (as directed); Heart failure symptom survey (daily); MARS questionnaire (weekly); Unscheduled care updates (as they occur); Prescribed medication updates (weekly); SHAPES app tracking data (continuous); Adverse events; Contact with researchers.				X				
End of pilot Questionnaires *(UEQ-S; SUS; MARS; BMQ; EQ-5D-5L; GSES; OSSS-3; HLM1; participation measure; WHOQOL-BREF; technology acceptance measure);* Demographic data.					X			
Participant interview						X		
3-month follow-up Questionnaires *(EQ-5D-5L; GSES; OSSS-3; HLM1; participation measure; WHOQOL-BREF)*							X	X

HSC Health and social care; EHFS European Heart Failure Self-Care Behaviour Scale; MARS Medication Adherence Report Scale; BMQ Beliefs about Medicines Questionnaire; GSES General Self-Efficacy Scale; OSSS-3 Oslo Social Support Scale-3; HLM1 Single-item Health Literacy Measure; WHOQOL-BREF Abbreviated World Health Organisation Quality of Life questionnaire

Figure 1: Service user participant timeline

3.6 Sample size

The target sample size for this pilot study is 30 NHSCT service user participants and up to 5 HSC staff. These sample sizes were selected pragmatically to be as representative as possible of the target population, large enough to provide valid answers and within the scope of the resources available.

3.7 Recruitment

Recruitment strategy

Heart failure and diabetes are two of the most common chronic conditions affecting older people in Northern Ireland which is one of the reasons why we have included them in this pilot. People with

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these conditions are encouraged to learn more about their conditions and self-management is promoted to help maximise health and wellbeing.

No financial incentives will be provided for participating in this pilot.

Service user screening procedure

Potential participants will either be identified from hospital in-patient and clinic lists in Antrim Area Hospital by their direct care team or by a project officer from Mid and East Antrim Agewell Partnership (MEAAP). Alternatively they may contact the research team directly from a recruitment poster or the research team may contact potential participants if consent to contact is obtained.

Northern Health and Social Care Trust (NHSCT)

Screening Members of the direct care team will screen their patient lists for potentially eligible participants.

Invitation The first communication about the pilot will be from the direct care team at the hospital or via a poster advertising the SHAPES pilot that will be displayed on information boards located within NHSCT Hospitals and on official NHSCT, MEAAP and MOIC social media feeds. The poster will direct potential participants interested in the pilot to contact the research team directly. Alternatively, the direct care team may invite potentially eligible participants to participate in-person at a clinic/hospital attendance, over the phone or via a written invitation (electronic or paper).

Information sheets Information sheets will be provided to potentially eligible participants in-person or via post or email either by the direct care team or the research team (if contacted directly or consent to contact is documented). A minimum of 24 hours will be provided to allow time to consider the information provided before consent is obtained.

Consent to contact Verbal consent to be contacted may be provided by potential participants to their direct care team to allow the provision of contact name and telephone number of the potential participant to the research team. This will be documented by the direct care team. The research team may then attempt to contact the potential participant by phone.

Eligibility confirmation Eligibility may be confirmed by the direct care team. The research team may also confirm eligibility if potential participants make direct contact with them or if participants have provided consent to contact. Eligibility may be confirmed either in-person or over the phone and documented.

Consent Eligible participants will be required to provide written consent. The direct care team may obtain consent. The research team may obtain consent if contacted directly by the potential participant or if verbal consent to contact has been received. Voluntary, informed consent for all participants may be obtained in-person or remotely with the following format of signatures collected where appropriate:

- Handwritten
- Typewritten
- Scanned
- An electronic representation of a handwritten signature
- Handwritten signature posted to research personnel

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Mid and East Antrim Agewell Partnership (MEAAP)

Screening MEAAP project officers will screen their client lists for potentially eligible participants. Potentially eligible participants may be contacted in-person, over the phone or via a written invitation (electronic or paper).

Invitation The first communication about the pilot will be from a project officer from MEAAP. This may occur in-person, over the phone or a written invitation (electronic or paper).

Information sheets If potential participants are interested in the pilot their MEAAP project officer or member of the research team (if consent to contact obtained) will provide further information about the pilot. A minimum of 24 hours will be provided to allow time to consider the information provided before consent is obtained.

Consent to contact Verbal consent to be contacted may be provided by potential participants to their MEAAP project officer to allow the provision of contact name and telephone number of the potential participant to the NHSCT research team. This will be documented by the project officer. The research team may then attempt to contact the potential participant by phone.

Eligibility confirmation Eligibility may be confirmed by the MEAAP project officer. The research team may also confirm eligibility if potential participants make direct contact with them or if they have provided consent to contact. Eligibility may be confirmed either in-person or over the phone and documented.

Consent Eligible participants will be required to provide written consent. The project officer may obtain consent. The research team may obtain consent if contacted directly by the potential participant or if verbal consent to contact has been received. Voluntary, informed consent for all participants may be obtained in-person or remotely with the following format of signatures collected where appropriate:

- Handwritten
- Simple electronic signature (e.g. tickbox and declaration, typed name and date) Scanned
- An electronic representation of a handwritten signature
- Handwritten signature posted to research personnel

Withdrawal of consent

Participants can withdraw from the study at any point, no reason needs to be provided, however, the participant will be asked if they would like to state a reason for withdrawal.

Clarification will be sought as to whether the participant would like to withdraw all data or if data provided up to the point of withdrawal may be retained and used in the analysis and description of the pilot cohort.

The following details will be noted upon withdrawal of consent; date, reason (if provided), whether consent for a follow-up interview or consent to use data until date of withdrawal remains.

HSC staff recruitment

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A list of appropriate professionals will be identified from the research team's knowledge and contacts. An invitation email containing information about SHAPES and a request to conduct an interview and demonstrate the intervention will be sent. If the request is accepted an information sheet will be provided and the research team will obtain consent. Voluntary, informed consent for all participants may be obtained in-person or remotely with the following format of signatures collected where appropriate:

- Handwritten
- Simple electronic signature (e.g. tickbox and declaration, typed name and date) Scanned
- An electronic representation of a handwritten signature
- Handwritten signature posted to research personnel

3.8 Data collection, management and analysis

3.8.1 Service user data collection methods

The majority of data collection will be conducted remotely. The exception to this is the face-to-face, one-to-one introduction to the app and devices. This will be conducted in person if the current local COVID-19 situation permits and this is the participant's preference. The procedures below may be completed in person or remotely depending on the current COVID guidelines and participant preference.

Service user prior to baseline procedures

- Screening
- Eligibility confirmation
- Informed consent
- Training on use of SHAPES app and connected devices
- Run-in, familiarisation with devices
- Contact details — name, address, email, phone number, alternative contact name and phone number, Health and Care number

Service user baseline procedures

- Questionnaires — Barthel Index, Gijon Scale, EHFS, MARS, BMQ, EQ-5D-5L, GSES, OSSS-3, HLM1, participation measure, WHOQOL-BREF
- Medical history data — height, weight, left ventricular ejection fraction, heart rhythm, implanted devices, medical conditions, heart failure stage, dyspnoea level, smoking status, leg pain symptom question
- Demographic data — including DOB, education, sex, marital status, occupational status, caregiver status, housing details
- Technical data — device monitoring details e.g. model, manufacturer, serial number and preferred time of day for reminders/questionnaires, make and model of the participants own smartphone/tablet
- Laboratory results — urea, creatinine, sodium, potassium, haemoglobin, cholesterol, eGFR, HbA1c, ACR, urine creatinine, urinary albumin-creatinine ratio
- Unscheduled care — hospitalisations (previous 3 months), and previous month hospital readmissions, A&E attendances, out of hours care, specialist service contacts, emergency ambulance call outs

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- Current prescribed medication — name, frequency, strength, chronic or as required, stop date if stopped during the pilot, start date if started during the pilot.

Service user study visits and procedures

- During the pilot, the participant will be asked to record the following at least once daily, as appropriate, via the SHAPES app; blood pressure, heart rate, oxygen saturation, weight (which will include body mass index, body fat, visceral fat, skeletal muscle, basal metabolic rate).
- Participants diagnosed with diabetes and monitoring blood glucose regularly will be requested to record their blood glucose with the same frequency as directed by their doctor on the SHAPES app.
- Participants diagnosed with heart failure will be asked a series of daily questions about their heart failure symptoms administered via the SHAPES app.
- All participants will be asked about their adherence to medication with a weekly MARS questionnaire administered via the SHAPES app.
- During the pilot, the patient may view their medication list
- Unscheduled care updates — any updates to baseline hospitalisations, hospital readmissions, A&E attendances, out of hours care, specialist service contacts, emergency ambulance call outs recorded from medical notes
- Prescribed medication updates — any updates to prescribed medications notified by participant
- Tracking data — log data on how the participant uses the SHAPES app e.g., date/time of usage, what functionalities were accessed
- Adverse events — date, start time, injury description, incident description, action taken, location of incident (private home or healthcare facility)
- Researchers will document any contact received/provided regarding support required to facilitate the pilot (date, duration, reason)

Service user end of pilot visit (+14 days)

- Questionnaires — UEQ-S, SUS, MARS, BMQ, EQ-5D-5L, GSES, OSSS-3, HLM1, participation measure, WHOQOL-BREF, technology acceptance measure
- Participant may participate in an interview at this time or a separate date may be accommodated.
- Demographic data — marital status, occupational status, caregiver status, housing details

Service user follow-up study visits and procedures

- If an interview is to be conducted this may occur at a mutually convenient time after the intervention has been completed.
- 3 month follow-up data collection (+/- 7days):
- Questionnaires — EQ-5D-5L, GSES, OSSS-3, HLM1, participation measure, WHOQOL-BREF

3.8.2 Healthcare professional data collection

The interviews carried out with health care professionals may be conducted in person or remotely using video-conferencing software, e.g., Zoom.

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HSC staff prior to baseline procedures

- Screening
- Eligibility confirmation
- Informed consent

HSC staff interview

- A mutually convenient time will be sought to complete an interview. The interview will include background on the SHAPES innovation action, information on the intervention applied and demonstration of data collection (may include SHAPES front-end app interface and researcher interface).
- A semi-structured interview guide will guide the conversation which may be recorded (audio and video).
- The interview will be transcribed and thematic analysis conducted.

3.8.3 Data collection tools

Data collection for the service user will be documented on to a case report form (CRF). Paper questionnaires will form part of the CRF and the CRF will be the source for questionnaires. The source for all data points can be found in the data plan. The CRF will then be transcribed onto an online database using Microsoft Excel and analysed using Microsoft Excel and IBM SPSS Software this will be stored on NHSCT computers behind the NHSCT firewall. Specific data will be securely shared with other SHAPES partners and appropriate Data Processing Agreements will be in place.

Data collection for the interviews with healthcare professionals may be audio and visually recorded. This will be completed either by using videoconferencing software e.g., Zoom or using a Dictaphone. Interviews will be transcribed either manually or using software and the transcript validated by a second researcher.

3.8.4 Adverse incidents

It is very unlikely that any adverse incidents will occur in this pilot, however if any participant spontaneously reports an adverse incident the NHSCT policy 'Adverse Incident Management Policy (including Serious Adverse Incidents)' NHSCT/17/1102 will be followed. This includes reporting to external parties if applicable, e.g., Northern Ireland Adverse Incident Centre.

Adverse incident definition: *Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation arising during the course of the business of a HSC organisation/Special Agency or commissioned service.*

If the research team are notified of a product recall regarding the devices used in this pilot the participant will be notified as soon as practicable and requested not to use the device. Arrangements will be made to physically remove the device and replace it if possible.

Clinicians will not have access to the data collected and participant treatment will not be changed due to taking part in this pilot. This is clearly noted in the participant information sheet. If participants are concerned in any way about the readings on their devices, they are to follow their normal mechanisms for seeking healthcare.

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3.8.5 Risks to research staff

To minimise risks to researchers, the NHSCT policy 'Lone Worker' NHSCT/12/471 will be followed and appropriate personal protective equipment will used by researchers on home visits to participants.

3.8.6 Protocol deviations

Data collection will be monitored by the research team through the researcher web portal. Participants will be contacted via phone after a week of starting the intervention to see if they need any assistance. Thereafter the participant will be encouraged to contact the research team if they are having any technical difficulties. If no data are uploaded for 3 consecutive days the research team may contact the participant to see if there is a technical issue, this may occur a maximum of 4 times during the pilot. Additionally, if there are significant issues with data collection, participants may be contacted monthly to act as a reminder or to troubleshoot any issues that may occur. If the participant notifies researchers via the app that there is a change to their medication, the participant will be contacted to confirm the change and the app will be updated by researchers.

This pilot is examining the real world use of the SHAPES app and associated clinical devices therefore if participants do not enter data as requested in the pilot this will not be documented as a protocol deviation, rather this will provide an insight into the usability of this digital solution.

3.8.7 Data management

Data processed in this pilot will be subject to the Data Protection Act 2018. This is the UK's implementation of the General Data Protection Regulation (GDPR). The NHSCT will be the data controller for all data collected during this pilot. The data flow for this pilot is complex (see figure 2) and as such multiple Data Processing Agreements will be put in place between the data controller (NHSCT) and each SHAPES partner who processes this data.

Personal data minimization and purpose limitation principles have been followed so that this pilot will only process data that is adequate, relevant and limited to what is necessary to deliver the objectives of the pilot. Personal data may be processed only for these purposes. Only personal data strictly necessary to the completion of this pilot will be retained.

The data collected for this pilot will be contemporaneous and accurate. If a participant withdraws from the study, clarification will be sought as to what data may need to be erased. This data will be identified and erased without delay. Personal data will be de-identified at the end of the SHAPES Innovation Action (Oct 2023). The NHSCT de-identified data set may be retained for a period of five years after October 2023 and then deleted. An anonymous, aggregated dataset will be stored indefinitely for future use by researchers. A de-identified, dataset may be shared with other SHAPES partners if an appropriate data sharing agreement is in place.

The data for this pilot will be stored securely. The location of each data point is listed in the data plan for this pilot, this document is a working document and will be kept up to date. Personal data will be kept in a form which permits identification of data subjects by approved NHSCT staff until October 2023.

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All data in this pilot is traceable using the pilot data plan. This means that the research team are able to identify the origin of the data, how it's processed, where stored and if it has been transferred or disclosed to a third party.

Further details regarding personal data are described in the Data Protection Impact Assessment (DPIA), Personal Data Processing Descriptions document and DPIA risk assessment document for this pilot. Additionally, a detailed description of all data (including but not limited to personal data) collected can be located in the data plan for this pilot.

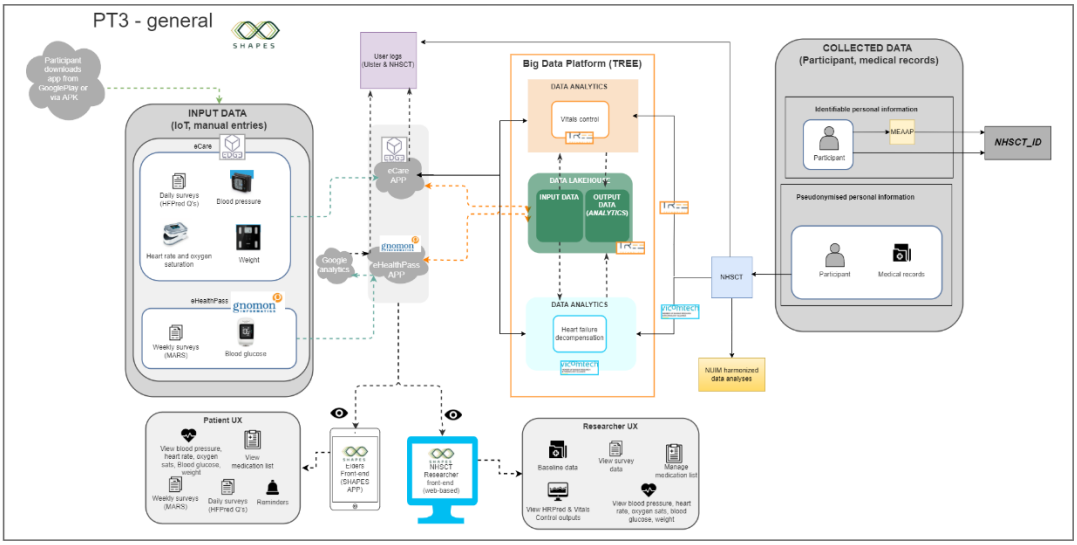

Figure 2: PT3-gen data flow/architecture diagram

3.8.8 Missing data

Every effort will be made to reduce the potential for missing data, however, if missing data occurs it will be coded '999' or if applicable, the missing data protocol for the questionnaire or SHAPES protocol will be followed.

The VICOM heart failure prediction algorithm requires a number of data fields to be completed each day in order to provide a decompensation risk. If one of these values is missing, no risk prediction can be performed. It may be necessary on occasion to populate a participant's average value, e.g., if a participant is bed bound they will find it difficult to provide a daily weight value. These exceptions will be documented. If a complete data set is not obtained, data will be imputed. It will be clear to the researcher which risk scores are based on fully completed data versus partially completed and imputed data.

3.8.9 Data duplication

Heart rate is collected by the blood pressure monitor and the pulse oximeter. The heart rate provided to the VICOM heart failure prediction algorithm will be from the pulse oximeter.

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3.8.10 Data analysis

All data will be analysed as outlined in the Data Analysis Plan. Demographic characteristics will be summarised and reported to describe the sample population. NHSCT will analyse all data pertaining to the primary and secondary outcome measures, and selected tertiary outcomes, listed above (Table 1) to determine if the objectives of the pilot have been achieved. Quantitative and qualitative data analysis methods will be employed and findings reported. Data pertaining to the tertiary outcomes that align with other pilots in the SHAPES pan-European piloting campaign (i.e., harmonisation data) will be analysed by the SHAPES coordinators at Maynooth University. In-depth analysis of user engagement and cross-comparative analysis of user engagement with qualitative data will be performed by SHAPES partners at Ulster University. In addition, the Model for Assessment of Telemedicine (MAST) framework will be used to evaluate the effectiveness and contribution of the pilot to quality of care. MAST is described as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine applications.

3.8.11 Statistical methods

Where appropriate, descriptive statistics will be reported for all quantitative data (e.g., UEQ-S, MARS, BMQ) the mean and standard deviation (SD) will be reported where data are approximately normally distributed, and the median and interquartile range (IQR) reported where data are non-normally distributed. Differences in outcomes measured at baseline and at the end-of-pilot will be compared using paired t-test or Wilcoxon Signed Rank test (or appropriate alternative), depending on the distribution of the data. Confidence intervals and effect size will be calculated and reported to provide an estimation of the size and direction of treatment effect.

4 Ethics and dissemination

4.1 Research ethics approval

Approval to conduct the pilot will be sought from a Research Ethics Committee (REC) before the start of the pilot. This protocol and all other relevant documents (e.g. participant information sheets, consent forms, user manuals etc.) will be submitted alongside an Integrated Research Application System (IRAS) form using the appropriate online booking system for REC review.

The Chief Investigator will notify the REC at the end of the pilot and a final report will be submitted to the REC within one year. Should the pilot be terminated prematurely, the REC will be notified and informed of the reasons for termination.

Prior to submission to the REC, this protocol will be reviewed and approved for submission by colleagues within the SHAPES consortium. This protocol will receive a high quality peer review by at least two independent experts in the field of health services research. Research governance at NHSCT will also review the protocol and provide approval for submission as the pilot Sponsor.

4.2 Protocol amendments

Any substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial, and all correspondence with the REC will be retained in the Trial Master File.

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4.3 Consent

All participants will be asked to provide voluntary, informed consent for their participation in the pilot.

4.4 End of pilot and termination criteria

The pilot will be stopped if there is evidence of harm caused to participants due to their involvement in the pilot e.g., data breach or device malfunction.

The end of pilot will be defined as the last participant, last follow-up.

4.5 Confidentiality

All investigators and pilot site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The Medicines Optimisation and Innovation Centre research team will have up-to-date Good Clinical Practice certification.

Participants will be pseudonymised on enrolment to the pilot and allocated a SHAPES unique identifier (ID). A folder containing the essential information for project management, including consent forms, will be retained in a in a locked office on the Antrim Area Hospital Site in Northern Ireland. The participant list, linking the participant name to their pseudonymised SHAPES ID, will be retained by approved NHSCT staff working on the SHAPES study and stored securely on NHSCT servers protected by the NHSCT firewall.

All information collected in this pilot (identifiable and pseudonymised) will be stored securely on NHSCT computers behind the NHSCT firewall. Any hard copies of identifiable (e.g., consent forms) and pseudonymised data (e.g., questionnaires) will be stored in a locked office on the Antrim Area Hospital site.

Only NHSCT staff and MEAAP staff who are approved to work on the SHAPES project will have access to identifiable participant information. Appropriate agreements will be in place to facilitate processing of pseudonymised data by other SHAPES partners.

4.6 Declaration of interests

No conflicts of interest have been declared by any members of the pilot study team.

4.7 Access to data

The Northern Health and Social Care Trust will be the data controllers and as such will have access to the full dataset. Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes. A small anonymous dataset will be shared with University College London to enable the further development of the MARS and BMQ scales.

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Matomo Analytics will be used to track how the participant uses some of the functionalities in the SHAPES app and geolocation, this is further detailed in the Data Protection Impact Assessment documentation for this pilot.

4.8 Ancillary and post-trial care

At the end of the pilot the devices provided to participants will be removed and participants will be requested to remove the SHAPES app from their phone/tablet. The exception to this may be the blood glucose meter as the meter used in this pilot is becoming the standard meter distributed in NHSCT. This will be decided on a case by case basis with their diabetes care team.

4.9 Dissemination policy

Any data that arise from the pilot study will be owned by the Sponsor, NHSCT. On completion of the study, all data will be analysed and tabulated and used to prepare a final report, available as one of the agreed deliverables of the SHAPES Innovation Action — Deliverable D6.4. This deliverable (and all other agreed deliverables) will be available to the public for review and accessible via the SHAPES website (www.shapes2020.eu). Participants will be notified of the outcome of the study via a specifically designed newsletter. NHSCT will seek to disseminate the findings from this study at conferences and in the scientific literature. As per the SHAPES Publication Protocol, all publications arising from this study will reflect the range of effort that has made them possible; including conceptualisation of the research project and research task, methodology development, data collection and analysis, interpretation and discussion of results; as well as project management. Any publications will be read and meaningfully contributed to by all named authors. NHSCT will also seek to communicate the findings of this study via social media, and in other, non-peer reviewed, media outlets. Participating SHAPES partners will have the rights to use data from this study in their own analysis and dissemination plans. As detailed under 'Access to Data', Data Processing Agreements will be in place to facilitate the sharing of pseudonymised data with specific SHAPES partners for specific purposes.

5. References

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