Study protocol v0.13, 14/06/2019

Evaluation of the Care City NHS England Test Bed: Wave 2

Principal Investigator:
Christopher Sherlaw-Johnson

Co-investigators:
Sophie Castle-Clarke, Nuffield Trust
Naomi Fulop, University College London
Rachel Hutchings, Nuffield Trust
Stephanie Kumpunen, Nuffield Trust
Sarah Scobie, Nuffield Trust

Start date: 01/10/2018
End date: 31/03/2020

Sponsoring organisation: Nuffield Trust

Funder: Department of Health and Social Care

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Contents

Background

The NHS Test Beds programme has been set up to bring together NHS organisations and commercial providers of digital technologies in order to test new ways of delivering care with a potential for improving patient experience and outcomes. Wave 1 of the programme ran for two years, starting in January 2016, and a second wave of Test Bed sites was announced in 2018. There are seven Wave 2 sites in all: three, funded by NHS England, are focussing on self-management of diabetes and the other four are funded directly by the Department of Health and Social Care (DHSC).

Care City was established as a joint venture between North East London Foundation Trust (NELFT) and the London Borough of Barking and Dagenham with the purpose of improving health and social care within one of the more deprived parts of London. It is one of the four DHSC-funded Test Beds in Wave 2, receiving just under £1.4 million over 18 months from October 2018 to March 2020. Care City is the only Test Bed site to receive funding in both Waves 1 and 2 of the programme.

The Nuffield Trust have been invited by Care City to be their evaluation partners for the Wave 2 Test Bed. Of the total money provided to the Test Bed, they are receiving approximately £300,000 to deliver an independent mixed-methods evaluation of processes and outcomes.

The technology chosen by Care City for the Test Bed are digital applications intended to improve outcomes and experiences for patients with long-term conditions. These are to be supported by junior NHS and care staff. Each of these apps are already being used by some NHS clinicians and patients, yet digital exclusion is preventing their wider use.

The innovations being tested are grouped into three clusters, intended to reflect the demand of long-term conditions and enhance the skills of non-clinical support staff (care home workers and domiciliary carers, healthcare assistants in primary care and hospital administrators). Within these three roles, Care City and delivery partners seek to:

- Improve patients' confidence, health outcomes and ability to self-manage

- Increase skills and workforce productivity
- Remodel areas of the workforce and service pathways across East London
- Scale these models to adoption partners, backed by training, investment and dedicated adoption partnerships

Further detail on the innovations is provided in Table 1.

Table 1: Innovations included within the Care City Wave 2 Test Bed

Cluster	Smart phone applications and their suppliers
Cluster 1: Expert Carers	Care home workers and Domiciliary carers using digital diagnostics and data to spot deterioration and better manage medication, using: • Whzan Digital Health – digital measurement of vital signs • Healthy.io – digital urine analysis • Echo – digital pharmacy
Cluster 2: Digital prescribers	Healthcare assistants in primary care prescribing digital applications – and supporting people to benefit from them - to prevent deterioration of long-term conditions, using: • Our Mobile Health – the platform for digital prescribing, integrated into EMIS • Sleepio – proven digital medicine for sleeplessness • LIVA Healthcare – a digital platform connecting patients and health professionals to drive behaviour change
Cluster 3: Administrative patient supporters	Hospital administrators using digital pathway tools to support patients to change their lives, using: • DrDoctor – digital appointment and pathway management • Tickerfit – digital programmes of education and exercise for heart failure

Cluster 1 context

Whzan

The Whzan telehealth kit will be used by trained domiciliary care workers ('enhanced carers') employed by three Havering-based domiciliary care agencies over 12 months. Enhanced carers will use the toolkit to regularly measure their service users' vital signs and produce a 'national early warning score' (NEWS) indicating whether the service users' health status is normal or abnormal (deteriorating). The kits include a blood oxygen meter, blood pressure cuff, and a thermometer – all of which are connected by Bluetooth to a tablet that calculates the NEW score. The Healthy.io urine dipstick will also be used in combination with the Whzan toolkit (see more below).

Participating service users have been recruited on the basis that they are at risk of hospitalisation and represent a number of different health conditions (e.g. COPD, diabetes, etc.). Enhanced carers will create a baseline reading for each service users on each piece of equipment, which will provide a baseline NEW score. Readings will then be taken regularly and a decision making protocol will suggest who enhanced carers should contact (e.g. 111, local rapid response team, service user's GP, 999), in addition to their agency's registered manager.

The aims of the Whzan toolkit (including the Healthy.io UTI test) in the Test Bed are to improve service users' awareness of their health status and decrease their use of hospital and emergency services by detecting when people are just at the point of starting to decline in health status. For enhanced carers, the aim of the toolkit is to improve their digital readiness and confidence in communicating with health professionals.

Healthy.io

Healthy.io provides two urine testing kits that can be used with a smart phone to test for: 1) signs of a urinary tract infection on a regular basis, and 2) signs of chronic kidney disease annually. The tests involve a patient using their smart phone to colour match a urine dipstick to a booklet to provide the outcome: normal or abnormal. All results are sent to the service users' GP to interpret and take action when abnormal, which would normally involve inviting patients in for a repeat test. Both kits will be used with service users of two domiciliary care agencies, but it may also be expanded to other local agencies at a later time.

The UTI test will be used in combination with the Whzan toolkit across all recruited service users (who have a range of health conditions), while the CKD test will only be used with those who have diabetes (potentially among other conditions).

The aims of Healthy.io CKD test are to improve carer confidence in diabetes care and for service users to detect cases of CKD earlier. The aims of the UTI test are described above.

Echo

Echo is a smart phone app that provides reminders to take medication and re-order prescriptions, it also provides functionality to request new medicines be approved by patient's GPs and be delivered to their home. Service users will need to have access to a smart phone and repeat prescriptions. The Test Bed has access to up to 200 licences in perpetuity. A use case for Echo is under development.

Cluster 2 context

LIVA Healthcare

LIVA Healthcare is a digital lifestyle intervention. Users are paired with a health coach who they interact with via Skype and online/text messages. The aim of the innovation within the context of the Care City Test Bed is to develop a pathway in which it can be used with patients with type 2 diabetes in a real world setting. Care City also hopes to up-skill healthcare assistants to support digital prescribing in primary care, and LIVA Healthcare will be used as a test case for this.

LIVA Healthcare is due to be implemented in early June 2019. All patients who are diagnosed with type two diabetes during the recruitment window will be offered LIVA Healthcare. Of these, there will be two patient cohorts:

- For patients with an HbA1c of 48-58 only LIVA Healthcare will be offered in the first 3 months. If a 3 month check reveals any drop in HbA1c the patient will continue with LIVA Healthcare only. If the HbA1c level has increased they will start metformin and continue with LIVA Healthcare.
- For patients with an HbA1c of >58, they will be prescribed metformin and recommended LIVA Healthcare as first line therapy. If their HbA1c level has not improved at 3 months, the metformin dose will be increased or the patient will start a second drug and continue with LIVA Healthcare.

These patients will be offered LIVA Healthcare by either a GP or a diabetes nurse. Based on existing trends, we expect to be able to recruit around 40 patients via this method.

The rest of the patients for this cohort (160), will be recruited by going back through GP data to identify patients diagnosed with type 2 diabetes in the last year. The vast majority of these patients will have already started pharmacological therapy, and LIVA Healthcare will be offered in addition to treatment as usual.

Once LIVA Healthcare has been prescribed, their main day-to-day interaction will be with LIVA Healthcare's health coach. Healthcare assistants will take blood tests at 3 months and 9 months, rather than 6 months and 12 months, to fit in with the timeline of the test bed. The diabetes nurse will see all patients at 3 months, and others at other time points if their HbA1c has increased above 54. This is part of the usual pathway, but these touchpoints provide opportunities to offer further support with LIVA Healthcare and diabetes management more generally.

Sleepio

Sleepio offers digital CBT for insomnia. As with LIVA Healthcare, the aim is both to deploy it in a real world setting and up-skill healthcare assistants to support digital prescribing in primary care.

For prospective patients, GPs will prescribe Sleepio whenever insomnia or sleep disturbances are raised during a consultation. Patients will be asked to make a telephone or face-to-face follow-up appointment 12 weeks after referral.

Healthcare assistants will also identify patients who have been prescribed hypnotics for insomnia or sleep disturbances and ask them to make an appointment with them if they are interested in using Sleepio. During a face-to-face appointment HCAs will introduce patients to Sleepio and send them the link to download the app. Again, HCAs will phone users at the three week mark to check their engagement with Sleepio and offer support and encouragement via a pre-defined protocol. Patients will be asked to make a telephone or face-to-face follow-up appointment 12 weeks after referral.

Our Mobile Health

Our Mobile Health is no longer part of the Test Bed.

Cluster 3 context

TickerFit

TickerFit is due to be implemented at Barts Health NHS Trust in the heart failure and cardiac rehab teams. Individuals with heart failure who attend the heart failure clinic will be offered a referral for cardiac rehab – if they decline, the team will offer TickerFit. Those who accept a referral will be seen at an initial face-to-face appointment. For those that decline traditional face-to-face rehab, they will also be offered TickerFit.

The TickerFit course lasts eight weeks. TickerFit includes a dashboard which professionals can use to monitor usage, and the team will also contact anyone who is not engaging with the app to offer support. At the end of the programme, patients should return for a final face-to-face assessment. In both routes for on-boarding, patients will attend an initial and final face-to-face appointment, which is part of the usual clinical pathway for patients receiving cardiac rehab. Patients that have been referred via the cardiac rehab team will also attend a midpoint face-to-face assessment to see how they are progressing, and also receive weekly motivational calls.

It is worth noting that since the beginning of the Test Bed, two innovations have been dropped and will not be implemented. They do not feature in this protocol, although our process evaluation will explore why that happened and how it could be avoided in future.

DrDoctor

Dr Doctor is now no longer part of the Test Bed

Research questions and approach

We will undertake a mixed-methods evaluation that assesses both processes and service outcomes.

The process evaluation will examine:

1. The process sites went through to design their programme/ testing
2. Whether interventions were delivered in line with the proposed plans

3. Whether the partnership of implementing sites, innovator firms and Care City worked as intended and why
4. Whether changes had to be made during implementation to ensure effective delivery of the intervention, and why
5. The barriers and facilitators to effective delivery (and uptake of technology/ services) and how were they overcome / ensured
6. Any unintended consequences that needed to be managed and how this was done
7. Whether the intervention likely to be scalable and why

The outcomes evaluation will examine:

1. Uptake and sustained use of implemented innovations, and the relationship to patient characteristics.
2. The measurable impact over the time of the study on resources and health outcomes.
3. The qualitative impact on patient experience and satisfaction – including acceptability of the innovations.
4. The experiences of staff of working with the innovations and their broader role.
5. The likely longer-term outcomes and costs of each innovation pathway compared to usual care, where possible.

The evaluation framework in Appendix 1 sets out the metrics and approach we will use to answer each of these questions.

We have divided the different evaluative methods into separate sections for ease of reading, but will integrate our analyses and interpretation of findings across clusters and across methods throughout the study (Caracelli and Greene, 1993). The key vehicle for synthesising the various elements of this project will be through weekly research team meetings, where we will share emerging findings and discuss implications for each cluster and method.

The evaluation will not be covering:

1. Quantitative analysis of workforce metrics, such as productivity, turnover and retention rates except where it is relevant for measuring costs.
2. Measures of overall job satisfaction pre and post innovation implementation.
3. Analysis of the effectiveness of each innovation beyond the context of each cluster.

Our approach will be informed by some of the learning from evaluation of Wave 1. For example, we are planning a qualitative evaluation from the outset; we will investigate digital exclusion; and we will make use of individual patient-level data to track their use of healthcare resources and their outcomes.

Working with Care City

Our process evaluation will be an active assessment with formative elements such that findings will be regularly fed back to Care City and all relevant stakeholders across the Test Bed in order to monitor progress and guide any changes in implementation. This will be combined with summative outcomes at the end of the study, including recommendations for further follow-up and spread by the service.

Throughout the evaluation of the Test Bed, the evaluation team will maintain regular contact and a close working relationship with Care City Test Bed staff and delivery partners. It is likely that Care City will be involved in recruitment and administration of data collection – but will not take part in data collection or analysis itself – maintaining the independence of the results and all linked publications.

Scoping activity

In order to guide the future course and scope of the evaluation we have planned or been involved with a number of activities. These include:

1. Meetings with each of the eight innovators;
2. Meetings bringing together the relevant stakeholders across each cluster;
3. Examination of previous evaluations and literature related to the interventions;
4. Co-development of initial logic models relevant to each cluster and each innovation within their cluster;
5. Discussions with local organisations concerning access to linked data-sets;
6. Discussions around information governance and research ethics with the Wave 2 Test Bed advisors and with local research networks;
7. Assessments of sample sizes and power calculations for estimating projected outcomes.

Delivery partners and Nuffield Trust's role

Care City will lead the delivery of this programme, supported by the following partners

1. Innovation Unit – service design
2. Good Things Foundation – digital exclusion and co-design
3. UCL Partners – system change
4. East London Health and Care Partnership

Care City also has a number of adoption partners who will assist with scaling the innovations beyond the test bed. These are:

1. North London Partners in Health and Care
2. Mid Essex Hospital Services NHS Trust
3. Basildon and Thurrock University Hospital NHS Foundation Trust
4. Southend University Hospital NHS Foundation Trust

The Nuffield Trust will carry out an independent evaluation of the Test Bed and advise on aspects of the Test Bed that will affect their ability to evaluate, such as how users are selected or sample sizes. Because the evaluation will be formative we will provide information through the course of the project for Care City to consider in deciding whether changes are needed in the implementation.

Methods

We will undertake an active process evaluation. This will incorporate elements of a formative evaluation: regularly updating Care City with findings in order that they can modify implementation as the test bed progresses, as well as an outcome evaluation of shorter and longer term impacts. The stages of the evaluation will include:

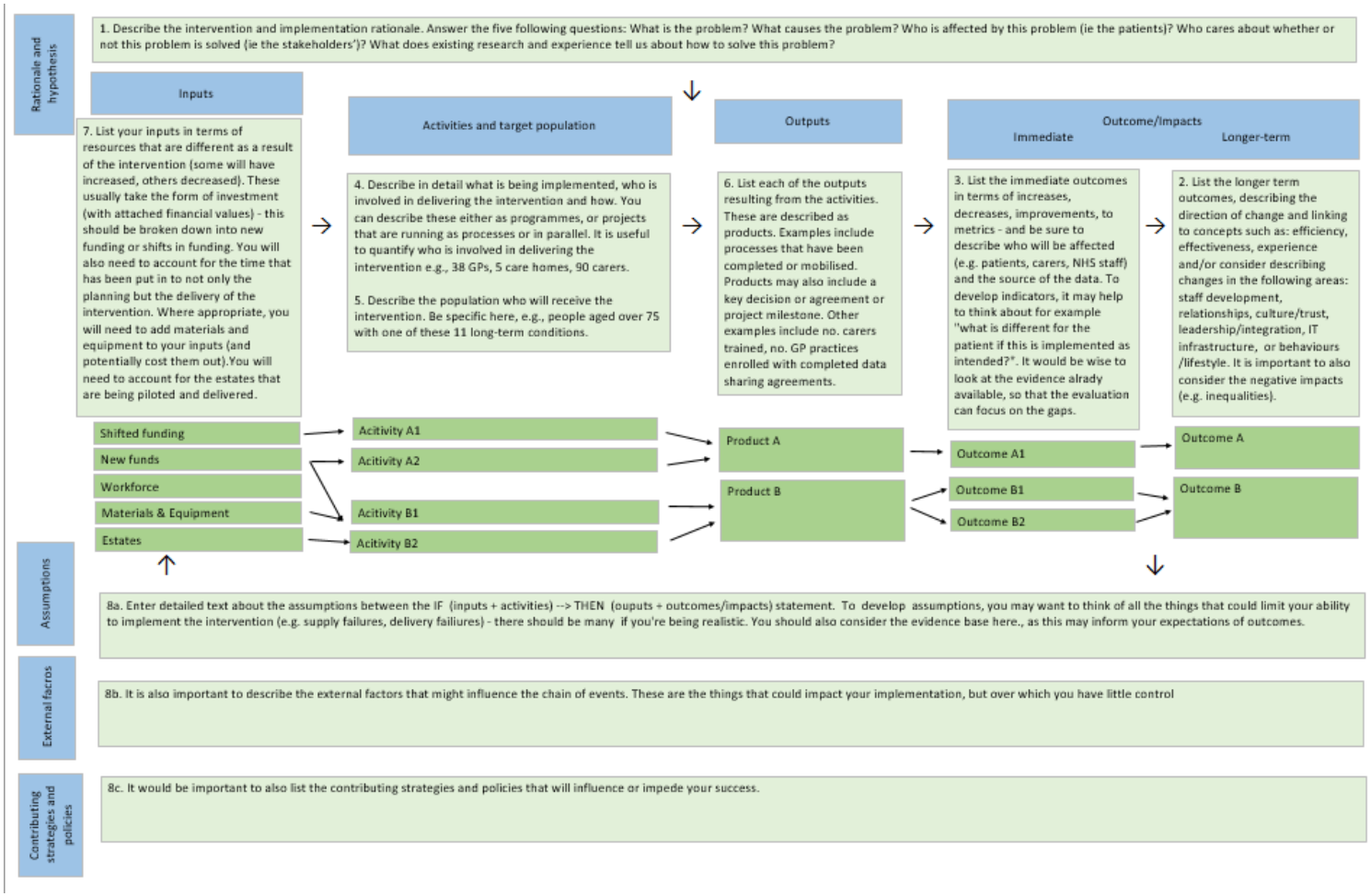
- Co-development of logic models
- Collating available evidence on the impact of each innovation
- Staged interviews with users and care professionals and surveys

- Obtaining routine linked datasets and data from suppliers, as appropriate
- Analysis of the process of adoption and use of the digital innovations
- Analysis of the impact over the period of the study
- Estimating the longer term impact on outcomes, cost and the use of health and social care resources, where possible

Co-development of logic models

We will work collaboratively with programme designers (Care City) and implementation teams (Clinical teams in Clusters 1, 2 and 3) to develop logic models for each cluster. The evaluation team will first create a draft model, drawing on available evidence and the implementation plans set out by Care City. The draft model will then be discussed in a workshop with Care City, innovators and clinical leads with the aims of clarifying inputs and assumptions, as well as developing consensus on which outcomes and impacts should be prioritised. The logic models will provide frameworks for summarising the programme designers' theories of change for each innovation and cluster, as well as for identifying the gaps in evidence and assumptions (The Strategy Unit, 2016). The logic model will also help the evaluation team communicate with other stakeholders, the key components of the programme theory and the relationships between them. As the innovations are implemented and spread beyond pilot sites, the logic models will be reviewed regularly by Care City and the evaluation team. Our initial logic model structure is shown in Figure 1. This is being used to guide initial discussions and development.

Figure 1: Logic model template



Qualitative approach

Figure 2 sets out a high level overview of the qualitative evaluation, including when tools will be used throughout the course of the test bed.

T1: Pre-implementation

Literature review

We will conduct a rapid scoping review of:

- Innovation implementation theory – including principles of staff and patient engagement - to inform the process of implementation where appropriate
- Literature associated with each of the innovations, including existing evaluations and RCTs of the innovations themselves as well as evaluations of similar interventions in order to inform implementation; calculate power calculations; and develop appropriate outcome measures
- Evidence underpinning programme theory assumptions for each cluster. For example, for cluster one we will look at the evidence regarding how domiciliary carers have been up-skilled elsewhere including feasibility; acceptability; context-specific lessons and any evidence of impact.

In each case we will undertake a rapid scoping exercise, focusing on systematic reviews and meta-analyses where appropriate (although reviews of individual studies are likely to be necessary in some cases).

Document review

We will conduct a thematic analysis of national policy documents about the NHS England test bed programme, with a particular focus on intended process and outcomes. We will also survey the NHS innovation policy landscape more broadly to understand how the test bed fits in to wider efforts to implement and spread innovation across the NHS (for example, existing financial incentives such as the Innovation and Technology Tariff and previous initiatives such as Innovation, Health and Wealth; national programmes to digitise such as the National Programme for IT; and recent accelerator programmes to fast-track promising technologies among others). This will give us a good understanding of the national context and how the test bed fits into the broader narrative (Bowen, 2009).

We will also conduct a descriptive and thematic analysis (Bowen, 2009) of internal Care City documents, particularly their implementation plans; risk registers (including regular

updates to monitor how things change and are resolved); governance arrangements within the test bed and governance arrangements and contracts with all test bed partners. As part of the analysis of costs and budget impact, we will also ask Care City for financial information such as the amount of money they have given to implementing sites in back-fill payments for training, implementation and new pathways; licence and equipment costs for the innovations; and time paid for labour to the innovators (also see Costs, budget impact and economic analysis below).

We will also conduct a descriptive and thematic analysis (Bowen, 2009) of site implementation plans (to the extent they exist) as well as any protocols developed to help staff perform new roles; new job descriptions or formal documents setting out changes to roles; and any training documentation developed.

Planning and meeting participation

The evaluation team will be involved in planning and implementation from the beginning. To date, the team has attended meetings with each innovator; cluster meetings which brought together each innovator within the cluster, the clinical lead and Care City leads; IG sessions for the test bed as a whole as well as the evaluation; and ad-hoc meetings with lead implementers/implementing sites and innovators as and when they have occurred. The evaluation team has also led logic model sessions for each cluster, which not only helped to agree the rationale and problem statements, stakeholders, output and outcome measures, but also gave an opportunity for substantive conversations about appropriate patient cohorts and pathway redesign to make best use of the innovations.

Going forwards, we have agreed with Care City that we will be involved in planning and implementation meetings with clinical leads and implementation sites as key decisions are being made. Given this is a formative evaluation, we have also agreed that we will feed back any emerging process points around theory or implementation failure at monthly face-to-face meetings and offer solutions as to how they might be addressed.

Non-participant observation

We will undertake non-participant observation (Liu and Maitlis, 2010) of training and engagement sessions with staff at pilot sites. We are particularly interested in how the innovations and participation in the test bed will be explained to staff including:

- How the purpose and intended outcomes of the innovations are described

- How the innovations are explained – e.g. how to use them, the evidence base behind them, why the patient cohort was selected, how they fit into the patient pathway
- How (if at all) the overall purpose of the test bed and the cluster are described
- Staff reactions and any questions or concerns raised

With participant consent, we will audio-record these sessions and note key issues relating to the above points. Sessions will be transcribed by a third party organisation based in the UK. We will then conduct a descriptive and framework analysis according to key themes arising from training sessions across the clusters.

Semi-structured interviews

We will begin our interviews by speaking with the programme development team, including the cluster leads at Care City, as well as Care City's programme manager, Executive Lead and Chief Executive, to gain insight into their individual interpretations of the programme theory. Much of this we will already know due to development of the logic models and participation in planning meetings, but this will offer the opportunity to record it formally and determine whether there is agreement among the programme development team.

At this time we will also conduct an interview with the lead implementer at each of the pilot sites (e.g. the registered manager at domiciliary care providers, four GP practices for cluster 2; cardiac rehab and heart failure clinics in an acute trust for cluster 3) to understand their understanding of the purpose of the Cluster as well as the role of Care City; their interpretations of the problem being solved through implementing the innovation(s); the innovation(s) itself and the new pathway it requires – including any benefits and drawbacks relative to usual care; their implementation plan and preparatory work (including training); any anticipated barriers or challenges, and mitigation strategies.

We will also do one interview with a lead contact at the innovators involved in the cluster to probe on their understanding of how their innovation fits into the cluster approach, the problems being solved by their innovation and the cluster more generally, expectations of participating in the test bed in terms of resource and what they will need to contribute, any anticipated risks or barriers and what they hope to gain from being part of the test bed. These results will be drawn on to inform follow-up interviews at the end of the test bed.

T2 and T3: 1-2 months and 6-7 months after implementation

Data collection from healthcare professionals: Semi-structured interviews

Cluster 1

We will conduct in-depth interviews with 4-6 enhanced carers delivering Whzan and Healthy.io (2-3 at each agency) within four weeks of implementation and again nearing the end of the Test Bed. It may also be necessary that nearing the end of the Test Bed that we interview local GPs and rapid response teams involved in providing health care to Whzan service users. Recruitment would be informed through an initial set of nominations from enhanced carers, followed by snowball sampling.

Cluster 2

We will interview healthcare assistants (HCAs) supporting both Sleepio and LIVA Healthcare across the four practices (n=4). These will focus on their view of the innovations (the value proposition); practice characteristics (particularly readiness to adopt); training; HCA experience and impact on their role; and scale and spread. These interviews will be carried out once, 6-7 months after implementation. We will conduct similar interviews with other support staff involved in the Sleepio and LIVA pathways (four diabetes nurses and one admin assistant).

We will also interview up to 8 GPs (2 from each practice), with a particular focus on Sleepio as they will be more involved in the Sleepio pathway. Again, these will be carried out once, 6-7 months after implementation.

Cluster 3

There are approximately twenty healthcare professionals that will be working with TickerFit across the heart failure and cardiac rehab teams. We plan to conduct semi-structured interviews with up to eight of these individuals 6-7 months after implementation starts.

As with cluster 2, the purpose of the interviews will be to understand their opinion of the innovations and the pathway; their confidence recommending and supporting use of the innovation (including their view of training); impact on their role and satisfaction; and their perceived impact on patients and patient experience.

Data collection from service users: Non-participant observations, surveys and semi-structured interviews

Cluster 1

Within one month of having started using Whzan and Healthy.io, all service users (who have given consent for an interview) will be telephoned by the research team. The team will use a structured interview guide to examine service users' levels of engagement and satisfaction with the innovations. This data collection event will involve the completion of a demographic form, enabling researchers to describe the sample. We could expect 20-30 service users to agree to take part.

We would then like to undertake in-depth interviews with 6-8 service users with mixed experiences of engaging with the innovations (who have demographically diverse backgrounds). Interviews will ask questions about service users' levels of satisfaction with the innovations and the reasons behind their satisfaction/dissatisfaction. These in-depth interviews could take place immediately following the structured interviews described above (i.e. during the same telephone call) or they could be arranged for another time convenient to the service use. We will ask service users to state their preference.

Nearing the end of the Test Bed (potentially 6-7 months after the innovations have launched), the same 20-30 service users who took part in a brief structured interview at stage 1 will be invited to take part in a follow-up interview asking similar questions (e.g. having used the innovation for around six months, how satisfied are you now?). Furthermore, the same 6-8 service users who took part in an in-depth semi-structured interview at the outset of implementation will also be invited to take part in a follow-up interview to determine how their views have changed over time.

It is important to note that in Cluster 1, due to the frailty and vulnerable nature of the research participants:

a) no data collection will take place in service users' homes (i.e. unlike in clusters 2 and 3, no observations of the innovation delivery will take place), and

b) all service users will have the opportunity to have an informal carer/relative join them in data collection events (or if requested, to undertake these data collection events on their behalf).

Cluster 2

We will undertake observations of clinical contacts to understand how patients are being on-boarded to use the innovations and provided support. For Sleepio, we will observe a healthcare assistant clinic in which they phone Sleepio users at the 3 week mark, as well as a follow-up appointment with a GP. We will conduct up to 5 observations in total. We may also observe an on-boarding session with retrospective patients.

For LIVA Healthcare, we will undertake observations of a GP or diabetes nurse offering LIVA Healthcare, a mid-way appointment with the diabetes nurse and an appointment with a GP or diabetes nurse at the end of the intervention. We will conduct up to 5 observations in total.

Patients using LIVA Healthcare will be asked to complete a Patient Activation Measure (PAM) questionnaire, with support from a healthcare assistant, both during on-boarding and on completion of the LIVA programme. We will also send an online survey to LIVA patients, 3 months after referral (after the first 3 month blood test). The survey will collect demographic and health status data; information on how patients were on-boarded; their engagement and their levels of satisfaction – which will draw on the diabetes treatment satisfaction questionnaire. A second online survey will be sent 6-7 months after referral, which will focus on engagement, satisfaction and perceived impact on outcomes. We anticipate a low response rate to the surveys and therefore may follow up with non-responders via telephone.

Users of Sleepio will be sent an online survey 12 weeks after initial referral. The survey will collect demographic and health status data; information on how patients were on-boarded; their engagement and their levels of satisfaction. As with LIVA, if we have a low response rate we will follow up with non-responders via telephone.

In both cases we will use the surveys to sample patients for in-depth semi-structured interviews (up to 10 patients after each LIVA survey and up to 20 patients using Sleepio throughout the course of the testing period). We may also randomly sample patients that have not completed the survey. The interviews will be used to better understand issues highlighted in the surveys.

Cluster 3

For TickerFit we will observe an initial face-to-face assessment in the cardiac rehab clinic, as well as a final face-to-face assessment on completion of the rehab programme. We also intend to observe a mid-point assessment where one of the members of the cardiac rehab team will check in with patients. Patients using TickerFit will also be asked to complete the Patient Activation Measure (with support from healthcare professionals), at the first and last face-to-face assessment. Users of TickerFit will also be sent an online survey 8-10 weeks following their first appointment. As with the innovations described above, the survey will collect demographic and health status data, information on how patients were on-boarded, their levels of engagement with TickerFit and their levels of satisfaction. If we have a low response rate, we will follow-up by telephone.

We will use the survey to sample up to 12 patients for in-depth semi-structured interviews. We may also randomly sample patients that have not completed the survey. These interviews will be scheduled continuously throughout the Test Bed and will be used to better understand the issues highlighted in the surveys.

T4: April 2020

Finally, at time point 4 – April 2020 – we will conduct final interviews with those interviewed pre-implementation, that is, lead implementers; Care City staff; and innovators. We will use these to understand how the test bed progressed in comparison to pre-implementation expectations; their reflections on the programme and lessons for the transferability of the innovations and pathways across the NHS.

After each phase of data collection, all interviews will be recorded and transcribed, with patient identifiable information such as name, or pertinent personal details being removed. We will then code the interviews using the software NVivo and conduct a thematic analysis to explore key issues around process of implementation, patient and staff experience and satisfaction and the role of Care City.

Sampling

Sampling users for semi-structured telephone interviews

As noted above, we will use the user survey/structured interview to recruit users for the in-depth semi-structured telephone interviews. We are not anticipating large numbers of patients to self-select for these interviews, but where possible we will sample based on levels of engagement and satisfaction with the innovation(s).

A limitation of this approach is that patients are self-selecting, which may mean our sample will be overly positive or overly negative compared to the group of users as a whole. However, we will use the survey to gauge an overall impression of engagement and satisfaction – and only use the interviews to gain a deeper understanding of what is working well and where things need to be improved.

Sampling frontline professionals for semi-structured telephone interviews

We will ask lead implementers at participating sites to gain consent from frontline clinicians to take part in the evaluation, and to pass their names and e-mail addresses to the Nuffield Trust.

If relevant, we will aim to speak to a range of different professionals involved in implementation. For example, in cluster 3 while working with TickerFit will likely be the role of nurses, different people from the cardiac rehab team such as physiotherapists may also be involved. Therefore, we will also seek to collect physiotherapist views.

Quantitative approach

Collating available evidence on the impact of each cluster

During initial scoping we are reviewing the available evidence for the clusters of new technologies. This helps to decide on appropriate metrics and to support the initial implementation of the innovations. Projected benefits based on this evidence will also support our power calculations and inferences of long-term outcomes.

There are a few other evaluations of the same technologies in other parts of the country, for example there is a health economic evaluation of the Sleepio app that is in progress in Oxford. We will establish contact with these evaluations and maintain contact over the course of the project as necessary.

Obtaining routine and linked data for quantitative analysis

With our quantitative analysis, we aim to monitor progress with how the digital innovations are being adopted, their subsequent use, and their impact. The extent to which we are able to do this will depend on how the patient pathways are designed during the implementation phase, and hence what datasets are available and the links that can be

made between them. For clusters 1 and 2 our main source of routine data will be patient-level GP records and, for cluster 3, it will be data collected by heart failure and cardiac rehabilitation clinics at the Royal London Hospital, as well as the National Audit of Cardiac Rehabilitation. Over the course of the project, routine linked primary and secondary care data may become available which would enhance our evaluation of clusters 1 and 2.

For some apps, we aim to collect data on how they are being used by individuals from the digital suppliers themselves. However, the amount of individual patient-level data coming from these sources may be limited and we may need to rely on pre-specified summary reports. We will also explore the feasibility of arranging the linkage of app usage data from the suppliers with routine care records, and this may be easier with some apps than others.

For clusters 1 and 2 there are mechanisms that should enable information on who is prescribed an app (cluster 2) or been tested with an app (cluster 1) to appear on the GP EMIS record and, therefore, within the pseudonymised care record. Unless the links with the supplier data are made, as described above, then this will only provide us with information on who is prescribed the app rather than on how they are used. For cluster 3, we will facilitate a process for recording who is offered the apps and the linking of this information to routine care records as necessary.

Monitoring adoption and use of the digital innovations

The aims of this analysis are:

- to monitor how the apps are being recommended or prescribed and subsequently used;
- to identify how this varies according to the type of individual and whether particular groups are over and under-represented;
- to provide regular feedback to Care City and the clinical leads to guide any changes that may need to be made to better achieve their goals.

How we achieve these aims will depend on the data that become available, as outlined in the previous section, and the extent to which linkage would be possible.

Feedback to Care City would take the form of regular reports of numbers of app recommendations, and uptake rates.

Analysis of the impact over the period of the study

The primary outcome measure for the majority of the innovations relates to uptake. For example, for Sleepio we will assess the proportion of people that have used the innovation

once offered it, and the proportion that have completed four or more sessions (used as the definition for completing the course in existing literature). We will then study variations in uptake between patient groups defined by characteristics such as age, gender, health status and ethnicity.

Parts of the qualitative evaluation will feed into explaining the level of uptake - for example patient satisfaction with an app and the support they received to understand and use it as well as clinician confidence in introducing it and their belief in the benefits. If our surveys or interviews suggest that patients of a certain age, health status, gender or ethnicity are not engaging with the app, then it may lead to further hypotheses to test quantitatively. Conversely, findings from quantitative analyses may lead to new questions to raise with staff or patients, depending on whether there are still rounds of interviews to complete.

Over the period of the study we will measure the impact on clinical outcomes and use of health care resources, where relevant. Appropriate metrics will be identified through literature review and logic modelling with stakeholders. These will focus on where changes are likely to be seen over the course of a year given the sample sizes and types of intervention. For example, in several cases, the combination of the length of the follow-up time and sample sizes would not be high enough to observe the impact on many secondary care outcomes and we will use power calculations and available evidence to guide us on the appropriateness of doing this analysis. More appropriate measures are likely to include combinations of:

- Changes in clinical measurements such as HbA1c levels for diabetics or weight loss, (e.g. LIVA Healthcare)
- drug prescribing patterns, (e.g. Sleepio, LIVA Healthcare)
- use of primary care resources (e.g. WHZAN, LIVA Healthcare) and
- uptake of cardiac rehab (TickerFit).

Details of the metrics we are proposing, together with rationales for choosing these indicators for direct observation over the period of the Test Bed, are described in Appendix 1. Sample sizes are constrained by the number of licences available for each technology, so with our power calculations we have aimed to determine whether, or when these numbers would be sufficient to detect any impact. The results of the power calculations are presented in Appendix 2.

The approach will be a combination of:

- analysis of outcomes for individuals before and after offered the use of an app, and

- case-control follow-up matched at individual patient or practice level,

Our choice of approach will depend on the measure, the context and our ability to identify control groups.

For practical reasons, some metrics that have been used to evaluate innovations in previous studies will not be directly measured in this study. This includes information that would require separate bespoke data collections such as improvements in insomnia symptoms and sleep-related quality of life. These impacts will be inferred from combinations of existing evidence and our observed uptake.

For clusters 1 and 2, because the new innovations will not be rolled out across the entire local area, where we have sufficient criteria from which to define a control group, these would be identified from individuals in the local primary care data. Over time the control groups will act as counterfactuals. For cluster 3 control groups will come from other similar cardiac centres across the country and we are making arrangements for the case-control comparative analysis to be undertaken by an analyst within the Department of Health Sciences at the University of York who manage the NACR data.

Costs, budget impact and economic analysis

Three questions will be addressed regarding the cost, budget impact and value of the test bed innovations. Table 2, below, summarises the approach which will be taken for each question.

A costing framework will be used to identify relevant costs for each intervention, and how these will be captured. The framework will set out the resources which will be included, and how unit costs per resource will be derived or estimated. For example, training and set-up costs will be captured at a service level, whereas some costs relating to staff time to deliver interventions are more appropriately captured at the patient level, in terms of time per patient with costings based on staff band.

Table 2: Costing framework

Question	Scope and approach
What are the costs to innovation partners of participating in the Test Bed programme?	Costs relating to being in the Test beds, for example attending meetings about implementation or evaluation.
What is the **budget impact** of delivering the innovation?	Costs relating to delivering the innovation – what costs would another site need to bear in order to implement the innovations? This could include set-up costs which all new sites would encounter (such as training staff, buying equipment) as well as ongoing running costs (staff time etc.). Resource use estimates for how resource use has changed as a result of implementing the innovation. Considers financial costs and savings (but not other benefits). This analysis would inform decision makers about the budget impact of implementing the innovations more widely.

Question	Scope and approach
What are the costs v benefits of the innovations?	This is addressing the question of whether the innovation is an effective way of achieving benefits, compared with alternatives/usual care. Based on recently published NICE guidance, a cost consequence analysis will be undertaken, given that the innovations have relatively low financial risks (from a payer's perspective). The aim of the cost consequence analysis (Drummond et al., 2005) is to present costs and benefits/outcomes, for the innovation compared to "usual care", to enable able decision makers to assess whether any differences in expected cost (between using the innovation or not using it) can be justified in terms of expected benefits/outcomes (for example, improved patient outcomes, patient experience, staff retention, reduced use of other services or other outcomes). The cost-consequence analysis will be undertaken from an NHS perspective. Where feasible, more detailed economic analysis may be undertaken for some innovations (see below).

Analysis of the longer term impact on outcomes, resources and cost

The quantitative analysis will focus on short term changes in process of care. Due to the relatively short nature of the study, some potential benefits of the new processes such as on secondary care resources will not be observable. Therefore, where the evaluation identified improvements in process measures, we may be able to extrapolate from these to estimate the impact on longer term outcomes. Depending on the innovation, this work would use

modelling approaches to combine the evaluation data on process changes with our knowledge of how the study population matches the overall target populations and evidence from the literature. For example, there is extensive literature on the advantages of cardiac rehabilitation for patients with heart failure from which we could infer how any changes in the uptake of cardiac rehabilitation due to TickerFit affects subsequent emergency cardiac events.

Project management and governance

The evaluation team meet weekly to discuss plans and progress, including reviews of risks and challenges. They also have weekly catch-up calls with the project manager for the Test Bed, the leads for each Cluster and the manager of the co-design panel that includes patient and public representation. Once a month this will be a face-to-face meeting. Further ad hoc meetings are arranged as required.

Ethical issues

We have completed the Health Research Authority (HRA) tool regarding whether this project constitutes research. Given that participants will not be randomised; the test bed will not be changing care from accepted standards for any of the patients or service users involved; and any findings will be highly context-specific to understand issues of scale and spread (rather than generalizable) the project has been classified as service evaluation rather than research that needs HRA approval.

Some approvals for use of data and access to patient contact details are still being processed. The Nuffield Trust has an appropriate level of indemnity cover and documents covering this annual calendar can be made available upon request.

Data management and information governance

As the research involves patients it is important to clearly specify how personal information will be protected. This will be addressed as follows:

1) The participant information sheet will outline the purposes of the research so that participants can see that the information they are providing is necessary to accurately address the research objectives.

2) The participant information sheet will outline that participants will not be personally identifiable in the reporting of the results.

3) Only relevant information about the participants will form part of the data collection such as age, gender, health status and ethnicity.

4) Data will be securely stored at Nuffield Trust offices and access to computer data will be password protected. Data will only be accessible to individuals who are directly part of the research team.

5) Those involved in the project will comply with the law.

6) All data will be stored in accordance with the Data Protection Act (2018) and the General Data Protection Regulation (2018).

With individual person-level quantitative data we will, in all instances, work with others to enable the extraction of this information in ways that are both practical and meet relevant governance requirements. We are aiming to ensure any linking of data is undertaken before being sent to the Nuffield Trust for analysis.

Dissemination and outcome

The first report from the evaluation will be an interim report for Care City and NHS England for September. A final evaluation report is planned for the summer of 2020.

Over the course of the evaluation we will produce blogs for the Nuffield Trust website, to share emerging learning.

After the final report has been delivered, the Nuffield Trust is planning to release our own outputs for public dissemination, which will focus on findings that are most relevant to national health policy.

References

Bowen, G. A. (2009). Document analysis as a qualitative research method. Qualitative research journal, 9(2), 27-40.

Caracelli, V.J., & Greene, J.C. (1993). Data analysis strategies for mixed-method evaluation designs. Educational evaluation and policy analysis, 15,195-207.

Drummond, M.F., Sculpher, M.J., Torrance, G.W., O'Brien, B.J. & Stoddart, G.L. (2005). *Methods for the economic evaluation of health care programme*, 3rd ed. edn, Oxford University Press, Oxford.

Liu, F., & Maitlis, S. (2010). Nonparticipant Observation. In Albert J. Mills, G. Durepos, & E. Wiebe (Eds.), Encyclopedia of Case Study Research. (pp. 610-612). Thousand Oaks, CA: SAGE Publications. Retrieved from: http://srmo.sagepub.com/view/encyc-of-case-study-research/n229.xml

The Strategy Unit. (2016). Using logic models in evaluation, briefing. NHS Midlands and Lancashire Commissioning Support Unit. [Online]. Available at: https://www.strategyunitwm.nhs.uk/publications/using-logic-models-evaluation

Appendix 1: Evaluation metrics

Table A1: Process evaluation

Process evaluation questions	Metrics	Approach to data collection
Understanding of relevant national and local contexts	Thematic analysis of national policy documents about the NHS England test bed programme, with a particular focus on intended process and outcomes. Descriptive analysis of NHS innovation policy landscape to understand how the test bed fits in to wider efforts to implement and spread innovation across the NHS (for example, existing financial incentives such as the Innovation and Technology Tariff/payment. Descriptive and thematic analysis of internal Care City documents Descriptive and thematic analysis of site implementation plans (to the extent they exist) as	Document review of national policy documents; internal Care City documents particularly their implementation plans; risk registers (including regular updates to monitor how things change and are resolved); governance arrangements within the test bed and governance arrangements and contracts with all test bed partners. Document review of site documents.

	well as any protocols developed to help staff perform new roles; new job descriptions or formal documents setting out changes to roles; and any training documentation developed.	
The process sites went through to design their programme/ testing	Descriptive analysis of the process, including the narrative the test bed started with and whether/ how that changed over time; what influenced any change; and how barriers were overcome	Analysis of implementation plans (site-specific plans and Care City plans) Logic model workshops and sign-off Semi-structured interviews with lead implementers Participation in planning and design meetings
Whether interventions were delivered in line with the proposed plans	Descriptive analysis of how implementation differed from plans from the perspective of Care City and the implementing sites. Analysis of what caused the changes – including whether they occurred due to theory or implementation failure	Analysis of implementation plans (site-specific plans and Care City plans) Semi-structured interviews with lead implementers Semi-structured interviews with Care City
Whether the partnership of implementing sites, innovator firms and Care City worked as intended and why	Descriptive analysis of roles and responsibilities for all parties at the beginning of the test bed;	Analysis of contract/document setting out governance arrangements including

	Descriptive analysis of roles and responsibilities for all parties at the end of the test bed Analysis of: - Extent of engagement of each partner (observed via meetings and asked in interviews) - Whether partners perceive their own or others' roles and responsibilities have changed and if so why - Whether partners perceive expectations of them or others have changed and if so why - Level of satisfaction with working with other partners - Level of satisfaction with test bed process	roles and responsibilities of all partners Semi-structured interviews with innovators Semi-structured interviews with lead implementers Semi-structured interviews with Care City Semi-structured interviews with healthcare professionals Participation in planning and design meetings
Whether changes had to be made during implementation to ensure effective delivery of the intervention, and why	- Description of successful implementation by Care City and implementing sites - Comparison with what happened through interviews with lead implementers, Care City and non-participant observations - Thematic analysis of factors affecting change collected via interviews	Logic model development and review Analysis of implementation plans (site-specific plans and Care City plans) Semi-structured interviews with lead implementers Semi-structured interviews with Care City Non-participant observations of clinical contacts Survey and interviews with frontline clinicians
The barriers and facilitators to effective delivery (and uptake of	Identification of specific factors that hindered and facilitated implementation,	Semi-structured interviews with lead implementers

technology/ services) and how were they overcome / ensured	from the perspectives of Care City, front line clinicians and lead implementers Analysis of actions by all partners to overcome/ensure barriers and facilitators	Semi-structured interviews with healthcare professionals Semi-structured interviews with Care City Analysis of changes to workforce documents e.g. job descriptions, formal role changes, new staff recruited, staffing structure to support implementation and on-going use Analysis of documents setting out governance arrangements
Any unintended consequences that needed to be managed and how this was done	Analysis of intended outcomes at baseline. Analysis of outcomes at month 18 of test bed. Analysis of governance and management approach throughout test bed.	Semi-structured interviews with lead implementers Semi-structured interviews with healthcare professionals Semi-structured interviews with Care City
Whether the intervention is likely to be scalable and why	Transferability of the model with a particular focus on context including: • Outcomes • Workforce • Governance arrangements • Care City's role • Commercial viability	Semi-structured interviews with lead implementers Semi-structured interviews with staff at implementing sites at end of test bed, otherwise not involved in the evaluation Cost data collection template combined with supplier data on costs.

Table A2: Outcomes evaluation

Outcomes	Metrics	Approach to data collection	Rationales
Uptake and sustained use of implemented innovations and the relationship to patient characteristics	Volumes of tests carried out by domiciliary care providers and relationships to type of individual client (Cluster 1) Uptake rates by person characteristic (Cluster 2 and 3) Use of innovations (e.g. frequency engaging with the app, step counts, Sleepio sessions completed)	1. Data collected via the innovation and passed from innovators directly to Nuffield Trust (aggregate, de-identified) 2. Individual patient-level data linked to GP care records (clusters 1 and 2) or clinical audit data (cluster 3)	Numbers of tests and follow-ups are also direct measures of resource use (see below)
The measurable impact over the time of the study on resources and health outcomes	Contacts with primary care (clusters 1 and 2) Lab follow-ups (healthy.io)	Individual pseudonymised records collected via primary care data linked (where possible and as required) to data from the innovators passed to Nuffield Trust.	. Healthy.io aims to improve early identification of chronic kidney disease. This is the purpose of a single test and so should be

	Chronic kidney disease identified (healthy.io) Urinary Tract Infections identified (healthy.io) Number of prescribed medications (Echo) Weight and BMI (LIVA Healthcare) Waist circumference (LIVA Healthcare) HbA1c change (LIVA Healthcare) Blood pressure (LIVA Healthcare) Medications for control of type 2 diabetes (LIVA Healthcare) Patient Activation Measure - PAM (LIVA Healthcare, TickerFit) Prescriptions of hypnotic drugs (Sleepio)	Data collected for control groups from the local primary care data.	measurable over the course of the Test Bed. Healthy.io in combination with WHZAN will provide information that will help to identify early urinary tract infections. The use of Echo aims to reduce unnecessary medications which should be observable over a short period. Randomised controlled trials of lifestyle innovations have demonstrated significant reductions in weight, BMI and other biometric measures within 12 months. Sleepio is a direct alternative to hypnotic drugs, and the GPs will not be prescribing both at the same time, so the impact on prescriptions should be observable with a big enough sample

	Body mass index (TickerFit)	Individual pseudonymised records collected locally and linked to data from the innovators passed to Nuffield Trust. Data for control groups held by the research unit responsible for the national audit data with aggregated results sent to the Nuffield trust.	
	Emergency A&E visits (WHZAN, LIVA Healthcare)	Secondary care data in East London (linked to primary care data if available)	Studies using WHZAN in care homes have shown reductions in A&E attendance and emergency admissions, although sample sizes were small. Studies of changing management residents of care homes have shown reductions in A&E visits or emergency admissions within 12 months. The rationale is that similar reductions may be possible in domiciliary care

	Changes in staff time (All clusters)	Staff contacts to deliver innovations – activity data from innovations and service data.	
The impact on patient experience and satisfaction – including acceptability	Patient experience – may use questions from existing patient surveys such as the GP Patient survey	Surveys of service users Semi-structured interviews with service users Non-participant observations of clinical contacts (if satisfaction/reasons for disengaging arise)	
The experiences of staff of working with the innovations and their broader role	Staff experience – may use questions from existing national staff survey and compare data against national datasets	Semi-structured interviews with healthcare professionals Surveys of healthcare professionals Semi-structured interviews with lead implementers Semi-structured interviews with people at pilot sites not previously engaged in the evaluation (at month 18 of test bed)	
The likely longer-term outcomes and costs and benefits of each	Numbers of cases of severe chronic kidney	Inferred from observations made over the course of the study in combination with evidence of	

innovation pathway compared to usual care	disease prevented (healthy.io) Emergency hospital admissions for diabetes-related complications (LIVA Healthcare) Reductions in insomnia (Sleepio) Reductions in emergency admissions and readmissions for heart failure (TickerFit)	longer term impacts from the literature.	

Appendix 2: Power Calculations

This Appendix presents results of power calculations. In some cases intervention cohorts are yet to be finally agreed and, once done so, we will revisit these calculations and add new tables. The aim of these currently is to inform some of the decisions about which cohorts are feasible and what outcome measures are appropriate given the constraints on numbers of licences or testing kits that are available.

WHZAN

Tables B1 to B3 show the number of unique individuals to be tested with WHZAN kits in order to achieve 80% power for detecting true differences between cases and controls. Event rates per person are assumed to be Poisson distributed and the statistical test is the difference in z-scores. Due to low rates, a square root transformation was used for the emergency admissions.

Table B1: Primary care contacts – table of sample sizes

True reduction in contacts	Baseline rate of contacts per year						
	4 per year	5 per year	6 per year	7 per year	8 per year	9 per year	10 per year
10%	380	300	250	220	190	170	150
15%	170	140	110	100	90	80	70
20%	90	80	60	60	50	40	40
25%	60	50	40	40	30	30	30
30%	40	40	30	30	20	20	20
35%	30	30	20	20	20	20	20
40%	30	20	20	20	20	10	10
45%	20	20	20	10	10	10	10
50%	20	20	10	10	10	10	10

So, suppose that among the group selected for WHZAN there are six contacts per year with primary care services. If their rate drops by 20% after they have started to use WHZAN, then 60 individuals should be enough to detect this change.

Larger sample sizes are required to observe reductions in A&E attendance (Table B2) and emergency admissions (Table B3). With a projected number of 80 home-based patients using WHZAN reductions in emergency admissions wold need to be of the order of 40% to 50% to be reasonably detectable.

Table B2: A&E attendance – table of sample sizes

True reduction in attendance	Baseline rate of A&E attendance per year						
	0.8 per year	1.0 per year	1.2 per year	1.4 per year	1.6 per year	1.8 per year	2.0 per year
10%	>500	>500	>500	>500	>500	>500	>500
15%	>500	>500	>500	470	410	360	330
20%	450	360	300	260	230	200	180
25%	280	230	190	160	140	130	120
30%	190	150	130	110	100	90	80
35%	140	110	90	80	70	60	60
40%	100	80	70	60	60	50	40
45%	80	70	60	50	40	40	30
50%	60	50	50	40	30	30	30

Table B3: Emergency admissions – table of sample sizes

True reduction in admissions	Baseline rate of A&E attendance per year						
	0.8 per year	1.0 per year	1.2 per year	1.4 per year	1.6 per year	1.8 per year	2.0 per year
10%	>500	>500	>500	>500	>500	>500	>500
15%	>500	>500	>500	>500	>500	>500	>500
20%	>500	>500	>500	>500	450	400	360
25%	>500	440	370	320	280	250	230
30%	370	300	250	220	190	170	150
35%	270	220	180	160	140	120	110
40%	200	160	130	120	100	90	80
45%	150	120	100	90	80	70	70
50%	120	100	80	70	60	60	50

Sleepio – hypnotic prescribing

Table B4 shows the number of individuals to be offered Sleepio in order to achieve 80% power for detecting true differences in hypnotic prescribing between cases and controls.

Table B4: Sample sizes for different combinations of baseline prescribing rates and the impact of Sleepio

Reduction in rate of prescribing	Baseline rate of prescribing hypnotics for people eligible for Sleepio						
	10%	20%	30%	40%	50%	60%	70%
10%	>500	>500	>500	>500	>500	>500	>500
15%	>500	>500	>500	>500	390	270	190
20%	>500	>500	370	250	170	120	90
25%	>500	330	200	130	100	70	50
30%	440	200	120	80	60	40	30
35%	280	130	80	60	40	30	20
40%	200	90	60	40	30	20	20
45%	140	70	40	30	20	20	<10
50%	100	50	30	20	20	<10	<10

LIVA Healthcare – impact on bodyweight

Table B5 shows the number of individuals who would need to complete the LIVA Healthcare course in order to achieve 80% power for detecting 10% and 15% reductions in bodyweight. A previous trial of lifestyle interventions observed a reduction of 10% over 12 months. Weights are assumed to be normally distributed, and differences in means are assumed evaluated using a t-test.

There are 200 LIVA Healthcare licences available to the Test Bed.

Table B5: Sample sizes by average weight of the cohort eligible for LIVA Healthcare

Reduction in bodyweight	Mean weight of cohort		
	80kg	90kg	100kg
10%	70	60	50
15%	40	30	20

TickerFit – impact on uptake of cardiac rehabilitation

Uptake of cardiac rehabilitation for patients with heart failure at the Test Bed site in Barts Health NHS Trust is relatively high in comparison with the England average. With a baseline rate of 90% TickerFit would need to be offered to 440 patients to have an 80% chance of detecting a significant increase to 95% (Table B6).

Table B6: Sample sizes by changes in uptake of rehabilitation

	Baseline uptake		
New uptake rates	80%	85%	90%
85%	>500		
90%	200	>500	
95%	80	140	440
96%	70	110	280
97%	60	90	200

Appendix 3: Rapid literature scoping

Cluster 1

The key assumption underlying Cluster 1 is that if home carer workers are trained and supported to take on 'health-related tasks', then they can help older people with multiple long term conditions living in the community to proactively manage their health and medications, avoiding potentially more serious and expensive contact with the NHS.

Strong support for enhancing the role of home care workers

A rapid scoping review identified literature with a number of implications for creating new 'enhanced home care workers'. Broadly, the review found that para-professional home care workers internationally are regularly transferred complex care activities (e.g. medicines support and administration, motion exercises, tube feeding, complex lifts and transfers and intermittent catheterisation) from registered health professionals (Saari et al., 2018a and 2018b). Therefore 'enhanced care workers' are well positioned to provide more consistent care (than a wider health and care team) and could reduce the number of care providers entering the care recipient's homes. They are also well placed to act as the "eyes and the ears" of the home healthcare system and to bridge the gap between social care service users and other healthcare professionals (Bystedt et al., 2011, Craftman et al., 2013). However, there are no known studies exploring care workers' use of smart home technologies (Martin et al., 2008), which make it: a) difficult to predict how challenging it will be to introduce technology to care workers, and b) important to document the training and on-boarding processes to best enable knowledge transfer and increased scale.

Yet processes need to be in place to support enhanced home care workers

Formally recognising new skills and autonomy

While there is potential for expansion of home care workers' roles, it should be recognised that a US study of 33 home care workers found that felt constrained by the high demands and few material rewards associated with their care. Specifically, workers identified three broad work constraints that compromised their ability to do a good job or to experience their work as meaningful: overwork and added responsibilities; increased risk; and the physical and emotional strain of the job (Stacey, 2005). They also reported that their rewards stemmed from three main sources: practical autonomy on the job, especially relative to prior work in the service sector; skills building; and doing dirty work. This study highlights the importance of ensuring that home care workers have an opportunity to shape their rotas and the additional tasks being asked of them, as well as the potential importance of finding a non-financial approach to recognising their new skills, perhaps through a certificate. Addressing all of these factors will help to ensure that the new enhanced role is satisfying for them.

Creating supportive policies and processes

Articles identified in the scoping review revealed that home care workers with enhanced roles were often not supported to meet the increased responsibilities assigned to them. They were frequently requested to provide basic nursing tasks without additional training, professional support, supervision or remuneration. Researchers also identified competence gaps, poor work environments and a lack of co-ordinated patient care (Saari et al., 2018).

The review authors suggested that based on evidence, utilisation of a team-based model can help establish positive relationships among home care providers, provide increased support for enhanced home care workers, allow for easier scheduling of initial training and ensure regular reassessments of enhanced home care workers' competence among enhanced home care workers providing added skills. A strong and stable support mechanism drawing on the lessons from this body of literature should be developed for all enhanced care workers throughout the lifetime of the Test Bed.

Finally, key findings related to the governance and training of enhanced care workers from the scoping review suggest that transfers of skills outside basic home care worker training requires that a competent registered health professional is engaged in the 'new health assignment' and the training surrounding the new assignment, as well as the supervision and evaluation of the home care worker. Additionally, it is necessary that policies and procedures are in place that can articulate: a) the care workers core competencies, b) a care plan for each service user, c) the standardised processes that

will be used to transfer care activities, as well as d) the processes that will be used to ensure that adequate time is allocated for service user assessment and home care worker training and supervision (Smyth, 2015, Saari et al., 2018b).

Summary

The training and support provided to these new roles will be substantial, and some of these support functions will need to come from Care City, while others will need to come from the home care agencies themselves. It would be useful to outline the Test Bed requirements for home care agencies at the outset to provide the best chance for success in this cluster.

References

Bystedt, M., Eriksson, M., & Wilde-Larsson, B. (2011). Delegation within municipal health care. Journal of Nursing Management, 19, 534–541. https://doi.org/10.1111/j.1365-2834.2010.01202.x

Craftman, A. G., von Strauss, E., Rudberg, S. L., & Westerborn, M. (2013). District nurses' perceptions of the concept of delegating administration of medication to home care aides working in the municipality: A discrepancy between legal regulations and practice. Journal of Clinical Nursing, 22, 569–578. https://doi.org/10.1111/j.1365-2702.2012.04262.x [doi]

Craftman, A. G., Westerbotn, M., von Strauss, E., Hilleras, P., & Marmstal Hammar, L. (2015). Older people's experience of utilisation and administration of medicines in a health- and social care context. Scandinavian Journal of Caring Science, 29, 760–768. https://doi. org/10.1111/scs.12207

Gransjön Craftman, A., Hammar, L.M., von Strauss, E., Hillerås, P. and Westerbotn, M., 2015. Unlicensed personnel administering medications to older persons living at home: a challenge for social and care services. *International journal of older people nursing*, *10*(3), pp.201-210.

Martin S, Kelly G, Kernohan WG, McCreight B, Nugent C. Smart home technologies for health and social care support. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD006412.DOI:10.1002/14651858.CD006412.

Roy, D.E. and McKechnie, R., 2017. Non-regulated Home Support Worker role in medication support and administration: a scoping review of the literature prepared for the Home & Community Health Association.

Richardson, S. and Pearson, M., 1995. Dignity and aspirations denied: unmet health and social care needs in an inner-city area. *Health & Social Care in the Community*, *3*(5), pp.279-287.

Saari, M., Xiao, S., Rowe, A., Patterson, E., Killackey, T., Raffaghello, J. and Tourangeau, A.E., 2018a. The role of unregulated care providers in home care: A scoping review. *Journal of nursing management*.

Saari, M., Patterson, E., Kelly, S. and Tourangeau, A.E., 2018b. The evolving role of the personal support worker in home care in Ontario, Canada. *Health & social care in the community*, *26*(2), pp.240-249.

Sandberg, L., 2018. Living at home with cognitive impairments: risks during daily living and support from home care service.

Sandberg, L., Borell, L., Edvardsson, D., Rosenberg, L. and Boström, A.M., 2018. Job strain: a cross-sectional survey of dementia care specialists and other staff in Swedish home care services. *Journal of multidisciplinary healthcare*, *11*, p.255.

Stacey, C.L., 2005. Finding dignity in dirty work: The constraints and rewards of low-wage home care labour. *Sociology of health & illness*, *27*(6), pp.831-854.

Cluster 2

Learning for the process evaluation

Part of the rationale for cluster two is that healthcare assistants will take on an enhanced role to support patients to use digital innovations. There is fairly good evidence that clinical contact can help to support uptake and engagement with digital innovations. For Sleepio for example, existing evidence suggests many patients are interested in using a digital solution for insomnia. However, drop-out rates can be high – a systematic review of digital CBT for insomnia found an average of 24.7% across 11 RCTs (Zachariae et al., 2016). Similarly a study specifically of Sleepio showed that drop-out is likely to increase for people with lower levels of education and lower incomes – a group represented in the intended patient population for the test bed (Cheng et al., 2018).

However, the same systematic review found that personal clinical support was associated with a larger effect size for sleep efficiency at post-treatment and for insomnia severity at follow-up (Zachariae et al., 2016). Another study of Sleepio found engaging with the online community was positive and appeared to contribute to sustained engagement (Coulson et al., 2016), so this feature should be emphasised during on-boarding. The sleep restriction component of Sleepio (introduced in the third session of the course) can be considered demanding, so there may be a need for increased support at this time (Coulson et al., 2016). The current plan for healthcare assistants to telephone patients at the three week mark is therefore in line with existing evidence.

Clinical engagement is particularly important in order to support behaviour change. A survey of over 1000 patients in Denmark found 962 preferred lifestyle changes to medication for diabetes (Jarbol et al., 2017). Determinants for not opting for lifestyle changes were being self-employed, having poor self-rated health and smoking. Low education, lifestyle risk factors and prior experience with heart disease were associated with low belief in ability to maintain lifestyle changes (Jarbol et al., 2017). Again this is a group represented in the intended patient population and there is a significant risk of low levels of uptake. That said, enablers for change with lifestyle interventions for diabetes include a trustworthy relationship with healthcare professionals and for patients to monitor outcomes with realistic goals and feedback from a trusted person (Brandt et al., 2018). One study found the most important driver for change was a strong relationship with a healthcare professional and having strong positive support on a day-to-day basis (Brandt et al., 2018). The health coach will perform this role with LIVA Healthcare, although there may be scope for additional support from the practice.

What's more, where patients have low levels of patient activation, engagement is likely to be low. Patient activation refers to the knowledge, skill and confidence necessary to meaningfully participate in your own health and care (Hibbard and Gilburt, 2014). It is not clear why some patients engage with their health and care and others do not. There is no clear link between levels of activation and type of illness, symptom severity or demographic and socioeconomic characteristics (see Hibbard and Gilburt, 2014). Studies have found that age, level of education, income and gender explain only 5-6 per cent of variation in levels of activation (Greene et al., 2005). It is possible to increase levels of patient activation. Programmes that are effective in improving activation usually focus on the development of skills and improving confidence. As patients' activation levels increase, they gain a greater sense of control over their health and feel empowered to take action (Hibbard and Gilburt, 2014).

The literature also raises important issues to consider with regard to up-skilling healthcare assistants. There is no standard training for healthcare assistants. Most usually have NVQ Level 2 or 3 training, but capability and level of education is likely to vary, which will be important when considering scaling the model. Also, there is some evidence that healthcare assistants are more likely to deliver task-based rather than holistic care which a nurse could offer (Daykin and Clarke, 2000). Therefore, although the initial intention had been for healthcare assistants to support and educate patients within the cluster, deploying the existing diabetes specialist nurse within the pilot practice to play this role makes more sense.

Learning for the outcomes evaluation

A systematic review of digital CBT for insomnia found that the effects were comparable to those found for face-to-face CBT-I, and were generally maintained at 4–48 week follow-up (Zachariae et al., 2016). Sleepio has been tested in numerous randomised control trials (RCTs) and has shown to be effective in comparison to sleep hygiene and education and treatment as usual – which usually involves minimal clinical input (Epsie et al., 2018; Cheng et al., 2018; McGrath et al., 2017; Freeman et al., 2017; Bostock et al., 2016; Espie et al., 2012).

The RCTs that have tested Sleepio have usually used pre- and post- intervention PROM measures such as self-reported measures of functional health (PROMIS; Global Health Scale); psychological well-being (Warwick-Edinburgh mental well-being scale); sleep-related quality of life (Glasgow sleep impact index); and the insomnia severity (insomnia severity index). Given that this trial data exists, we will use uptake data to infer outcomes on insomnia severity and other clinical outcomes as appropriate.

There is also evidence that lifestyle interventions can reduce HbA1c levels and enable diabetes remission (see, for example, Lean et al., 2018).

References

Barnes, C.M., Miller, J.A. and Bostock, S., 2017. Helping employees sleep well: Effects of cognitive behavioral therapy for insomnia on work outcomes. Journal of Applied Psychology, 102(1), p.104.

Bostock, S., Luik, A.I. and Espie, C.A., 2016. Sleep and productivity benefits of digital cognitive behavioral therapy for insomnia: a randomized controlled trial conducted in the workplace environment. Journal of occupational and environmental medicine, 58(7), pp.683-689.

Brandt, C.J., Clemensen, J., Nielsen, J.B. and Søndergaard, J., 2018. Drivers for successful long-term lifestyle change, the role of e-health: a qualitative interview study. BMJ open, 8(3), p.e017466.

Cheng, P., Luik, A.I., Fellman-Couture, C., Peterson, E., Joseph, C.L., Tallent, G., Tran, K.M., Ahmedani, B.K., Roehrs, T., Roth, T. and Drake, C.L., 2018. Efficacy of digital CBT for insomnia to reduce depression across demographic groups: a randomized trial. Psychological medicine, pp.1-10.

Coulson, N.S., Smedley, R., Bostock, S., Kyle, S.D., Gollancz, R., Luik, A.I., Hames, P. and Espie, C.A., 2016. The pros and cons of getting engaged in an online social community embedded within digital cognitive behavioral therapy for insomnia: survey among users. Journal of medical Internet research, 18(4).

Daykin, N. and Clarke, B., 2000. 'They'll still get the bodily care'. Discourses of care and relationships between nurses and health care assistants in the NHS. Sociology of health & illness, 22(3), pp.349-363.

Espie, C.A., Emsley, R., Kyle, S.D., Gordon, C., Drake, C.L., Siriwardena, A.N., Cape, J., Ong, J.C., Sheaves, B., Foster, R. and Freeman, D., 2018. Effect of digital cognitive behavioral therapy for insomnia on health, psychological well-being, and sleep-related quality of life: A randomized clinical trial. JAMA psychiatry.

Espie, C.A., Kyle, S.D., Williams, C., Ong, J.C., Douglas, N.J., Hames, P. and Brown, J.S., 2012. A randomized, placebo-controlled trial of online cognitive behavioral therapy for chronic insomnia disorder delivered via an automated media-rich web application. Sleep, 35(6), pp.769-781.

Freeman, D., Sheaves, B., Goodwin, G.M., Yu, L.M., Nickless, A., Harrison, P.J., Emsley, R., Luik, A.I., Foster, R.G., Wadekar, V. and Hinds, C., 2017. The effects of improving sleep on mental health (OASIS): a randomised controlled trial with mediation analysis. The Lancet Psychiatry, 4(10), pp.749-758.

Greene, Jessica, Judith Hoffman Hibbard, and Martin Tusler. How Much Do Health Literacy and Patient Activation Contribute to Older Adults' Ability to Manage Their Health? AARP Public Policy Institute Washington, DC, 2005

Hibbard, and Helen Gilburt. Supporting People to Manage Their Health: An Introduction to Patient Activation. King's Fund, 2014.

Jarbøl, D.E., Larsen, P.V., Gyrd-Hansen, D., Søndergaard, J., Brandt, C., Leppin, A., Barfoed, B.L. and Nielsen, J.B., 2017. Determinants of preferences for lifestyle changes versus medication and beliefs in ability to maintain lifestyle changes. A population-based survey. Preventive medicine reports, 6, pp.66-73.

Lean et al. Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. Lancet 2018; 391: 541-551

Luik, A.I., Bostock, S., Chisnall, L., Kyle, S.D., Lidbetter, N., Baldwin, N. and Espie, C.A., 2017. Treating depression and anxiety with digital cognitive behavioural therapy for insomnia: a real world NHS evaluation using standardized outcome measures. Behavioural and cognitive psychotherapy, 45(1), pp.91-96.

Luik, A.I., Machado, P.F. and Espie, C.A., 2018. Delivering digital cognitive behavioral therapy for insomnia at scale: does using a wearable device to estimate sleep influence therapy? npj Digital Medicine, 1(1), p.3.

McGrath, E.R., Espie, C.A., Power, A., Murphy, A.W., Newell, J., Kelly, C., Duffy, N., Gunning, P., Gibson, I., Bostock, S. and O'Donnell, M.J., 2017. Sleep to lower elevated blood pressure: a randomized controlled trial (SLEPT). American journal of hypertension, 30(3), pp.319-327.

Miller, C.B., Espie, C.A., Bartlett, D.J., Marshall, N.S., Gordon, C.J. and Grunstein, R.R., 2018. Acceptability, tolerability, and potential efficacy of cognitive behavioural therapy for Insomnia Disorder subtypes defined by polysomnography: A retrospective cohort study. Scientific reports, 8.

Pillai, V., Anderson, J.R., Cheng, P., Bazan, L., Bostock, S., Roth, T.A. and Drake, C.L., 2015. The anxiolytic effects of cognitive behavior therapy for insomnia: preliminary results from a web-delivered protocol. Journal of Sleep Medicine & Disorders, 2(2), pp.a-7.

Zachariae, R., Lyby, M.S., Ritterband, L.M. and O'Toole, M.S., 2016. Efficacy of internet-delivered cognitive-behavioral therapy for insomnia–a systematic review and meta-analysis of randomized controlled trials. Sleep medicine reviews, 30, pp.1-10.

Cluster 3

Cardiac rehab has been shown to be effective and cost-effective for people with cardiovascular disease including those with heart failure, the primary focus of this cluster [Cochrane Review 2014, Shields et al 2018]. Domestic and international guidelines recommend cardiac rehab for individuals with a diagnosis of heart failure [NICE 2018 and ESC 2016], although uptake is low. The National Audit of Cardiac Rehabilitation Quality and Outcomes Report from 2018 showed that uptake for people with heart failure is well below the national ambition of 33% set by NHS England [NHSE Cardiovascular Disease Outcomes Strategy 2013]. The authors suggest that low uptake of cardiac rehab for people with heart failure may be attributed to the lack of wide-scale adoption of alternatives to group-based therapies, which still make up around 77% of the delivery of cardiac rehab [NACR, 2018]. Consequently, one of the recommendations is that home-based modes of cardiac rehab delivery should be offered to all patients including those with heart failure.

Given this, studies have examined alternative methods of delivering cardiac rehab for people with chronic heart disease, as well as the impact of mode of delivery on outcomes more generally [Harrison and Doherty 2018] and of mode of delivery on psychosocial outcomes specifically [Harrison and Doherty 2017]. The recent NIHR funded REACH-HF study looked specifically at home-based therapy for people with heart failure [Dalal et al 2018]. REACH-HF is an intervention for people with heart failure comprising of exercises, facilitated conversations with healthcare professionals and information for the patient and their caregivers. The study showed that, compared with usual care, people who received the REACH-HF intervention had higher Health-Related Quality of Life scores as measured by the Minnesota Living with Heart Failure Questionnaire (disease specific PROMs questionnaire). This intervention is being rolled-out further in 2019.

Web-based options such as TickerFit also offer an alternative to traditional therapy. The WREN feasibility trial tested the 'Activate Your Heart' intervention which was developed by the University of Leicester as an alternative to group-based therapy [Houchen-Wolloff et al 2018]. This programme was not limited to heart failure, but included anyone with a diagnosis of chronic heart disease who declined or dropped out of traditional cardiac rehab. The trial demonstrated that web-based rehab is safe, and can lead to improvements associated with traditional methods of rehab such as exercise capacity. This study also highlighted interesting findings of relevance to the process evaluation and are detailed below. Findings from the literature relevant to the outcomes and cost evaluation are also detailed below.

Learning for the process evaluation

Houchen-Wolloff et al, 2018: Web-based cardiac REhabilitatioN alternative for those declining or dropping out of conventional rehabilitation: results of the WREN feasibility randomised controlled trial.

- The study acknowledges that various reasons have been cited for potential drop-out, and that the most cited reason by patients who do not complete a CR programme is the need to return to work. As such, a web-based alternative may facilitate greater flexibility for those who are for whatever reason unable or unwilling to complete a traditional group-based therapy.

- Using the internet arguably not only permits greater flexibility, but also has the potential to reach a wider population (e.g. those from rural areas). Some other studies have also suggested that web-based interventions can improve the knowledge of people with chronic health conditions, and that there may be benefits to the service such as releasing capacity for CR specialists to manage more complex patients in hospital classes.

- More patients dropped out/ were lost to follow-up from the web intervention group compared to the control group by six months

- Retention rates were excellent and 82% of individuals attended all three assessment visits.

- There were two adverse events in the web group and four in the control group but none were deemed related to the interventions

- Most fruitful method of recruitment was to capture patients at the point of declining rehab in a one-to-one assessment (>80%) compared with retrospectively contacting those who had declined or dropped out of a programme previously. May be that uptake at this stage was influenced by the healthcare professional introducing the study rather than the research team.

- Change in MacNew score at 6 months met suggested minimum difference for clinical importance in web group

- Feasible to measure costs and outcomes using Resource Use Questionnaire designed for this study (completion was 90% across both groups at 6 months)

- Patients were able to double their exercise time (in minutes) from baseline to 8 weeks and this was maintained at 6 months. Average number of log-ins was three times a week at 8 weeks and twice a week at 6 months. Phone calls and emails to staff were low and patients did not use the group forum.

- Data shows that a web-based CR programme has the potential to be an acceptable way to increase the provision of CR for those unable or unwilling to attend a conventional programme – if alternative forms of CR allow more patients to access a service, this in turn could reduce the risk of future cardiac events for those able to attend a programme.

- A quarter of those eligible decided to participate – for future studies, may need to review the inclusion criteria to allow those with more complex needs to access the programme (including those with low shuttle walk test performance or high levels of anxiety or depression).

- Also expect over time that the numbers of web literate patients will increase (recent internet use statistics suggest that internet use in the 65+ age group is increasing and catching up with younger people)

- Aware that the NHS priorities around the use of technology in healthcare are changing and we would expect the capacity for digital health interventions to continue to grow

- Offer of web-based CR should not be limited to only those who decline a conventional, class-based programme. CR ought to be a full menu with genuine choice and resources that support patient preference.

- Mood (anxiety and depression) and self-efficacy did not really improve in either group but important to note a potential floor effect since both groups had low anxiety and depression and high self-efficacy scores at the start.

- Large change in ISWT (exercise capacity) in control group at six months and unsure of reasons for this. May be argued that the mere act of performing an outcome measure may influence the subsequent outcome i.e. the performance of an ISWT in itself could be considered an intervention and have an effect on the patients" confidence to complete the tes.t in a full-scale trial, may be appropriate to 'perform a sensitivity analysis to examine the extent to which

results are affected by changes in methods, models, values of unmeasured variables, or assumptions.'

- The researchers were encouraged by high levels of engagement (78% completed at 6 months with others still working on completion) – but it was surprising that patients took longer than the anticipated 8 weeks but they had access to the programme for 1 year so it can be completed at their own pace. Access to the programme over this protracted period had potential to improve maintenance but long-term follow-up outcomes were not measured as part of this study.

- Patients required minimal support from health staff in terms of calls and emails. This is the only part where costs increase with increasing numbers of participants (increased staff time) suggesting that costs with increasing numbers would remain low.

- There is potential for a trial looking at the effectiveness of the web-based programme in decliners and the scope to evaluate web-based CR as part of a full menu of options.

- Intervention has the opportunity to increase access to CR for patients who would otherwise not attend or to be an alternative mode of CR delivery.

Learning for the outcomes evaluation

Widely accepted that there is variation in cardiac rehab.

- *Salman and Doherty, 2019* examined the link between quality of rehab and patient characteristics.

    - No significant differences in age, gender, employment status or Index of Multiple Deprivation (IMD) were noted between the three categories [low, middle, high quality]. In the high-quality programmes, patients at baseline tended to be in the most deprived 10% nationally compared to those in the low and middle quality programmes.

    - BMI differed significantly among the categories. CR programmes with high-quality delivery included more patients at higher risk – higher BMI

and waist circumference, high blood pressures, more smokers and more severe anxiety or depression at enrolment than low-quality programmes. Patients in high-quality programmes also had poorer physical capacity and lower self-reported physical activity status at baseline.

- CR programme more likely to be categorised as high-quality if it included patients with a higher mean total of comorbidities, including diabetes, stroke, asthma and high BMI. Acc. to these findings, high-quality programmes recruit more patients with multiple comorbidities, who are more representative of the broader CVD population than those with few comorbidities. Presence of multiple comorbidities including stroke, diabetes and COPD is an important factor associated with a lower likelihood of a patient being referred to and participating in CR.

- *Harrison and Doherty, 2018* observational study investigated whether mode of delivery, supervised or Facilitated Self-Management, was associated with similar cardiac rehabilitation outcomes.

  - The FSM group were significantly older, female and predominantly in lower socioeconomic groups. The results showed that all patients on average benefit from cardiac rehabilitation, independently of mode of delivery, across all risk factors.

  - Both modes of delivery were associated with comparable statistically significant positive outcomes. Despite having equivalent outcomes, FSM cardiac rehabilitation continues to be underutilised, with less than 20% of patients receiving this mode of delivery in the UK.

- *Harrison and Doherty, 2017* observational study comparing the populations receiving supervised and facilitated self-delivered modes for differences in psychosocial outcomes.

  - Analysis showed a greater proportion of females, employed and older patients in the self-delivered group – extremely important as female and older patients are often deemed in the evidence to be 'hard to reach' and not taking up the offer of CR. If there is a preference in these demographics for self-delivered CR then a more diverse menu based approach to CR could influence uptake.

- No significant association between different CR types and psychosocial outcomes – this is likely to be because CR is structured and patient-tailored thus following the structure results in positive change.

- It was shown that patients in the self-delivered group were less likely to be in the normal group at baseline [in terms of psychosocial health] however they experienced the greater change post. This supports the idea that those with the most to gain experience the highest change and the supervised group was experiencing a ceiling effect.

Learning for outcomes evaluation (costs)

- *Shields et al, 2018* conducted a systematic review of economic studies of CR and its components.

    - The majority of studies concluded that CR was cost-effective versus no CR, but there was more variation in the results of studies focusing on single components or delivery of CR.

    - Key drivers of cost-effectiveness were risk of subsequent events and hospitalisation, hospitalisation and intervention costs, and utilities.

This evaluation will build on existing literature in this area by focussing specifically on the use of web-based interventions in cardiac rehab for people with heart failure.

References

British Heart Foundation, 2018. The National Audit of Cardiac Rehabilitation: Quality and Outcomes Report 2018.

Dalal, H.M., Taylor, R.S., Jolly, K., Davis, R.C., Doherty, P., Miles, J., van Lingen, R., Warren, F.C., Green, C., Wingham, J., Greaves, C., Sadler, S., Hillsdon, M., Abraham, C., Britten, N., Frost, J., Singh, S., Hayward, C., Eyre, V., Paul, K., Lang, C.C., Smith, K., 2018. The effects and costs of home-based rehabilitation for heart failure with reduced ejection fraction: The REACH-HF multicentre randomized controlled trial. Eur J Prev Cardiolog 2047487318806358.
https://doi.org/10.1177/2047487318806358

Department of Health, 2013. Improving cardiovascular disease outcomes: strategy.

Harrison, Alex S, Doherty, P., 2018. Does the mode of delivery in routine cardiac rehabilitation have an association with cardiovascular risk factor outcomes? European Journal of Preventive Cardiology 25, 1925–1933. https://doi.org/10.1177/2047487318798923

Harrison, Alex S., Doherty, P., 2018. Does the mode of delivery in Cardiac Rehabilitation determine the extent of psychosocial health outcomes? International Journal of Cardiology 255, 136–139. https://doi.org/10.1016/j.ijcard.2017.11.056

Houchen-Wolloff, L., Gardiner, N., Devi, R., Robertson, N., Jolly, K., Marshall, T., Furze, G., Doherty, P.J., Szczepura, A., Powell, J., Singh, S., n.d. Web-based cardiac REhabilitatioN alternative for those declining or dropping out of conventional rehabilitation : results of the WREN feasibility randomised controlled trial. Open Heart 9.

National Institute for Health and Care Excellence, 2018. Chronic Heart Failure: Management of chronic heart failure in adults in primary and secondary care. Clinical guideline CG106.

Peters, M., Crocker, H., Dummett, S., Jenkinson, C., Doll, H., Gibbons, E., Luengo-Fernandez, R., Fitzpatrick, R., 2013. Pilot study of patient reported outcome measures (PROMs) in primary care. Department of Public Health, University of Oxford.

Ponikowski, P., Voors, A.A., Anker, S.D., Bueno, H., Cleland, J.G.F., Coats, A.J.S., Falk, V., González-Juanatey, J.R., Harjola, V.-P., Jankowska, E.A., Jessup, M., Linde, C., Nihoyannopoulos, P., Parissis, J.T., Pieske, B., Riley, J.P., Rosano, G.M.C., Ruilope, L.M., Ruschitzka, F., Rutten, F.H., van der Meer, P., Filippatos, G., McMurray, J.J.V., Aboyans, V., Achenbach, S., Agewall, S., Al-Attar, N., Atherton, J.J., Bauersachs, J., John Camm, A., Carerj, S., Ceconi, C., Coca, A., Elliott, P., Erol, Ç., Ezekowitz, J., Fernández-Golfín, C., Fitzsimons, D., Guazzi, M., Guenoun, M., Hasenfuss, G., Hindricks, G., Hoes, A.W., Iung, B., Jaarsma, T., Kirchhof, P., Knuuti, J., Kolh, P., Konstantinides, S., Lainscak, M., Lancellotti, P., Lip, G.Y.H., Maisano, F., Mueller, C., Petrie, M.C., Piepoli, M.F., Priori, S.G., Torbicki, A., Tsutsui, H., van Veldhuisen, D.J., Windecker, S., Yancy, C., Zamorano, J.L., Zamorano, J.L., Aboyans, V., Achenbach, S., Agewall, S., Badimon, L., Barón-Esquivias, G., Baumgartner, H., Bax, J.J., Bueno, H., Carerj, S., Dean, V., Erol, Ç., Fitzsimons, D., Gaemperli, O., Kirchhof, P., Kolh, P., Lancellotti, P., Lip, G.Y.H., Nihoyannopoulos, P., Piepoli, M.F., Ponikowski, P., Roffi, M., Torbicki, A., Vaz Carneiro, A., Windecker, S., Sisakian, H.S., Isayev, E., Kurlianskaya, A., Mullens, W., Tokmakova, M., Agathangelou, P., Melenovsky, V.,

Wiggers, H., Hassanein, M., Uuetoa, T., Lommi, J., Kostovska, E.S., Juillière, Y., Aladashvili, A., Luchner, A., Chrysohoou, C., Nyolczas, N., Thorgeirsson, G., Marc Weinstein, J., Di Lenarda, A., Aidargaliyeva, N., Bajraktari, G., Beishenkulov, M., Kamzola, G., Abdel-Massih, T., Celutkiene, J., Noppe, S., Cassar, A., Vataman, E., Abir-Khalil, S., van Pol, P., Mo, R., Straburzynska-Migaj, E., Fonseca, C., Chioncel, O., Shlyakhto, E., Otasevic, P., Goncalvesová, E., Lainscak, M., Díaz Molina, B., Schaufelberger, M., Suter, T., Yilmaz, M.B., Voronkov, L., Davies, C., 2016. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failureThe Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J 37, 2129–2200. https://doi.org/10.1093/eurheartj/ehw128

Salman, A., Doherty, P., 2019. To what extent is the variation in cardiac rehabilitation quality associated with patient characteristics? BMC Health Services Research 19. https://doi.org/10.1186/s12913-018-3831-1

Shields, G.E., Wells, A., Doherty, P., Heagerty, A., Buck, D., Davies, L.M., 2018. Cost-effectiveness of cardiac rehabilitation: a systematic review. Heart 104, 1403–1410. https://doi.org/10.1136/heartjnl-2017-312809

Taylor, R.S., Sagar, V.A., Davies, E.J., Briscoe, S., Coats, A.J., Dalal, H., Lough, F., Rees, K., Singh, S.J., Mordi, I.R., 2014. Exercise-based rehabilitation for heart failure. Cochrane Database of Systematic Reviews. https://doi.org/10.1002/14651858.CD003331.pub4

Appendix 4: Governance arrangements

Nuffield Trust project team – roles and responsibilities

The key members of the evaluation team from the Nuffield Trust are summarised below.

Name	Job title	Roles in project	Expertise
Chris Sherlaw-Johnson	Senior Research Analyst	Principal Investigator Lead for quantitative and impact evaluation	Quantitative evaluations Statistical methods and analysis NHS data expertise
Sophie Castle-Clarke	Senior Fellow	Lead for qualitative evaluation and lead for cluster 2 (Digital prescribers)	Qualitative methods Digital health policy Project delivery
Stephanie Kumpunen	Senior Fellow	Lead for logic models and cluster 1 (Expert Carers)	Evaluation methods Qualitative methods

Rachel Hutchings	Researcher	Lead for cluster 3 (Cardiac rehab)	Qualitative research methods
Lucina Rolewicz	Research analyst	Quantitative analysis	Quantitative analysis NHS data expertise
Sarah Scobie	Deputy Director of Research	Senior supplier for evaluation Health economics methodology	Quantitative methods including health economics NHS data expertise Project management

The team are supported by additional staff within the Nuffield Trust as required, for example, Data Protection Officer, project officer support.

In the event of a member of the team leaving the organisation, the Nuffield Trust would identify alternative team members from suitably experienced researchers in the Research and Policy teams.

Management, accountability

Dr Sarah Scobie, Deputy Director of Research, is accountable for the delivery of the evaluation within the Nuffield Trust. Sarah provides regular input to the team's internal project team meetings, and chairs the monthly face to face evaluation meetings with Care City.

The purpose of the monthly face to face meetings with Care City is to share emerging findings, and address significant changes in the implementation which impact on evaluation. The agenda includes the following:

- Emerging evaluation findings
- Logic models – review main changes and discuss in more detail quarterly

- External environment – policy, research or other intelligence which impacts on evaluation or provides opportunities
- Communications – opportunities to share learning
- National team requirements
- Risks and issues

Governance and quality assurance

Quality assurance for the project is provided through a number of mechanisms:

- Professor Naomi Fulop, Professor of Health Care Organisation and Management, UCL is an advisor to the Nuffield Trust for this project, providing qualitative research and overall evaluation research expertise
- The Nuffield Trust also engages a Statistical Advisor, Audrey Laurence, to provide quality assurance of statistical methods
- The team are able to draw on specialist skills within the organisation, for example Professor John Appleby, Chief Economist at the Nuffield Trust
- The Trust engages expert peer reviewers for external publications