Care City Test Bed: Statistical analysis plan

Introduction

This document presents the statistical analysis plan for the Wave 2 Test Bed run by Care City for the purposes of sharing with other Test bed sites. It is not a final plan since, in some cases intervention cohorts, sample sizes and data sources are yet to be finally agreed. The plan will therefore evolve as the implementation plans develop. This document also excludes the economic component which is covered by a separate plan.

Background

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 originally 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 innovations

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 innovations

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 innovations

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 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.

Data sources for each cluster

Cluster 1

The data sources identified for this cluster will be:

- Individual-level routine GP data for practices within Havering CCG
- Individual-level routine secondary care data (SUS) linked to the GP data
- Individual-level data collected by the London Borough of Havering for individuals receiving domiciliary care
- Individual-level data collected by Echo
- Individual-level data collected by domiciliary care agencies
- Aggregate data collected by WHZAN

Where appropriate and possible, we plan to use link data sets. Linkage will be carried out by Barking and Dagenham, Havering and Redbridge (BHR) CCG using NHS numbers or names and addresses (where no NHS numbers exist), although this has yet to be finally agreed.

We aim to receive GP, SUS and Local Authority data going back to January 2018 to allow sufficient time to observe outcomes before the Test Bed. Data from Echo and the domiciliary care agencies will only cover patients on-boarded with the app as part of the Test Bed.

Cluster 2

The data sources identified for this cluster will be:

- Individual-level routine GP data for practices within Barking and Dagenham CCG
- Individual-level routine secondary care data (SUS) linked to the GP data
- Individual-level data collected by LIVA Life

- Individual-level data collected by Sleepio

Our plans are for the local GP and LIVA Life data to be linked by the BHR CCG using NHS numbers, and, again, this has yet to be agreed. Sleepio data will not be linked since Sleepio does not collect NHS numbers.

As for Cluster 1 we aim to receive GP and SUS data going back to January 2018 to allow sufficient time to observe outcomes before the Test Bed. Data from LIVA Life and Sleepio will only cover patients on-boarded with the app as part of the Test Bed.

Cluster 3

The data sources identified for Cluster 3 are:

- Individual-level routine data collected by the heart failure and cardiac rehabilitation clinics at Barts Hospitals NHS Trust
- Individual data collected by the TickerFit app.
- Individual-level routine data collected by the National Audit for Cardiac Rehabilitation from other hospitals

We are planning to have the Barts data linked to the TickerFit data by Barts Hospital, using NHS numbers.

We are aiming to receive data from Barts Hospital and the national audit from January 2018.

The national audit data will be used to identify control groups. We are arranging for analysis of this data to be undertaken by the controllers of this data and for us to receive aggregated results.

Analysis plans

Cluster 1

WHZAN

Table B1: Data items and analyses for quantitative evaluation of the use of WHZAN testing kits

Question	Data items	Source	Cohort	Analysis
Who has been tested?	Age, gender, hospital visit history, falls history, a flag to indicate whether the person has been tested	Havering local authority	Individuals receiving domiciliary care services by the provider selected for the Test Bed	Descriptive statistics. Univariate comparisons with people from other domiciliary care providers
	Comorbidities	Domiciliary care providers[1]	Individuals with a WHZAN test reported by the domiciliary care providers	Descriptive statistics
How frequently are people tested?	Number of tests per individual	Domiciliary care providers/ Havering local authority[2]	Individuals with a WHZAN test reported by the domiciliary care providers	Descriptive statistics
Are there mismatches between the data sources that suggest problems with reporting?	Age, gender, numbers of tests per individual	Havering local authority/ Domiciliary care providers/ WHZAN	Individuals with a WHZAN test reported by the domiciliary care providers/ local authority data and cross-checked with aggregate data from by the tool itself	Cross-checking of data sources for quality assurance
What are the test results?	NEWS scores	Domiciliary care providers	Individuals with a WHZAN test reported by the domiciliary care providers	Descriptive statistics

Question	Data items	Source	Cohort	Analysis
How does use of WHZAN impact on patient outcomes?[3]	Outcome measure: Primary care contacts Covariates from: Age, gender, comorbidities, contacts with primary care over the previous 12 months	Havering local authority linked to GP practice data	Cases: Individuals with WHZAN tests. Control group from local GP practice data receiving local authority funded domiciliary care and matched on the selected covariates.	Multivariate regression design comparing cases and controls[4]
	Outcome: Number of emergency hospital attendances Covariates from: Age, gender, admissions over the previous 12 months	Havering local authority linked to SUS	Cases: Individuals with WHZAN tests. Control group will be selected from other individuals who receive local authority funded domiciliary care and matched on the chosen covariates.	Multivariate regression design comparing cases and controls[4]
	Outcome: Number of reported falls Covariates from: Age, gender, falls over the previous 12 months	Havering local authority		
	Outcome: Admission to residential care Covariates from: Age, gender, falls over the previous 12 months	Havering local authority	Cases: Individuals with WHZAN tests. Control group will be selected from other individuals who receive local authority funded domiciliary care and matched on the chosen covariates.	Time-to-event design (e.g. Cox regression) comparing cases and controls[4].

[1] To be agreed with all providers
[2] Either data set could be used. This is taken advantage of in addressing the quality assurance question
[3] The feasibility of this analysis is strongly dependent on ultimate sample sizes
[4] Numbers of covariaties and choice of method will depend on sample size and quality of the matching

Table B2: Data items and analyses for quantitative evaluation of the use of Healthy.io

Question	Data items	Source	Cohort	Analysis
Who has been tested?	Age, gender, comorbidities	GP practice data: Havering CCG practices Havering local authority	Individuals with a Healthy.io test reported in the GP data[1]	Descriptive statistics. Havering local authority data will provide denominators
What are the results?	Test results	GP practice data	Individuals with a Healthy.io test reported in the GP data	Descriptive statistics.
What are the consequences of the results?	Number of referrals for lab results	GP practice data	Individuals with a Healthy.io test reported in the GP data	Descriptive statistics.
How does Healthy.io impact on patient outcomes?	Number of cases of early chronic kidney disease identified.[2]	GP practice data	Individual GP practices within Havering CCG area.	Practice-level multivariate regression models of cases of early CKD identified using the proportion of practice patients with a healthy.io test as a covariate. [3]
Are there mismatches between the two data sources that suggest problems with reporting?	Numbers of tests and by age and gender	GP practice data Havering local authority	Individuals with a Healthy.io test reported in either set of data	Cross-checking of data sources for quality assurance

[1] Test results are automatically sent to electronic GP records
[2] This outcome, combined with existing evidence about the value of early identification will lead to estimates of the longer-term impact
[3] Numbers of covariaties and choice of method will depend on sample size

Echo

Table B3: Data items and analyses for quantitative evaluation of the use of Echo

Question	Data items	Source	Cohort	Analysis
Who is on-boarded to use Echo?	Age, gender, ethnicity, comorbidities Numbers on-boarded	Data from Echo[1] Havering local authority	Individuals from the test bed reported to be on-boarded by Echo	Descriptive statistics Univariate comparisons with all eligible individuals. Havering local authority data will provide denominators
How long do people engage with the app?	Drop out over the course of the intervention	Data from Echo	Individuals from the test bed reported to be on-boarded by Echo	Regular reporting by type of patient over the course of the evaluation.
	Length of time on-boarded individuals continue to use the app	Data from Echo	Individuals from the test bed reported to be on-boarded by Echo	Time-to-event analysis by patient characteristic.[2]
What is the impact on medication prescribing and use?	Adherence to medication	Data from Echo	Individuals from the test bed reported to be on-boarded by Echo	Measure calculated by Echo
	Number of prescribed medications	GP practice data	Individuals from the test bed reported to be on-boarded by Echo Control group of patients with similar characteristics within the GP data	Comparison of changes in numbers of prescriptions per patient before and after the use of Echo compared to control group.[3]

[1] The plans are to receive data linking Echo to GP practices.
[2] This is only feasible if there is sufficiently high drop out over the period of the Test Bed.
[3] We are unlikely to be able to identify control patients who are also receiving domiciliary care as this is not recorded in the GP data. Controls will be selected from other GP practices and matched on covariates we are able to obtain from the GP data.

Cluster 2

LIVA Life

Table B4: Data items and analyses for quantitative evaluation of the use of LIVA Life

Question	Data items	Source	Cohort	Analysis
Who is recommended LIVA Life?	Numbers of people recommended the app. Patient characteristics: Age, gender, ethnicity, comorbidities, new or pre-existing diabetes, current use of Metformin	GP practice data	Individuals with recently diagnosed diabetes identified in the data as being offered health coaching[1]	Descriptive statistics
Who decline the programme once offered	Numbers of people reported as declining health coaching Patient characteristics (see above)	GP practice data	Individuals identified in the data as declining health coaching[1]	Rates of decline by type of patient
What is the uptake among those who are recommended?	Numbers who download the app Patient characteristics (see above)	Data from LIVA Life linked to GP practice data	Individuals identified in the data as being offered the app	Rates of uptake by patient characteristic. Univariate and multivariate analyses (e.g. logistic regression)[2]
How many complete the programme?	Numbers who complete at 3 and 9 months Patient characteristics (see above)	GP practice data	Individuals offered the app and those who are on-boarded	Rates of completion by patient characteristic. Univariate and multivariate analyses (e.g. logistic regression)[2]
How do people engage with the programme?	Frequency of app use over the previous month Patient characteristics (see above)	Data from LIVA Life linked to GP practice data	Individuals on-boarded with the app	Changes in use over the course of the programme and by person characteristic

Question	Data items	Source	Cohort	Analysis
How active are users?	Average daily step counts over previous month	Data from LIVA Life linked to GP practice data	Individuals on-boarded with the app	Changes in use over the course of the programme and by person characteristic
What is the impact on patients?	Changes in HbA1c, waist circumference and weight at 3 and 9 months compared to baseline and control group Covariates from: Age, gender, comorbidities	GP practice data linked to secondary care data (SUS)	Case cohort 1: individuals offered the app. Case cohort 2: Individuals completing 3 months Case cohort 3: Individuals completing 9 months Control group: Individuals from other local practices with similar characteristics[3]	Multivariate regression design comparing cases and controls[2] Analysis of a) Intention to treat (case cohort 1). b) Patients completing LIVA programme at 3 and 9 months v. controls (case cohorts 2 and 3)
	Changes in A&E attendance over the course compared to baseline and control group Covariates from: Age, gender, comorbidities			
What is the impact on prescribing?	Numbers of patients prescribed metformin over the course of the programme Covariates from: Age, gender, comorbidities	GP practice data	Case cohort 3 and control group as above	
Are there mismatches between the two data sources that suggest problems with reporting?	Individuals reported to be engaging with the app	LIVA Life data/ GP practice data	Individuals reported to be on-boarded with LIVA Life in either set of data	Cross-checking of data sources for quality assurance

[1] These are existing Read codes that are not currently used.
[2] The method of analysis will depend on patient mix and overall uptake/completion. For example, if uptake is high then we may not detect meaningful differences between patient groups.
[3] Control groups will not necessarily have measurements reported at the same time intervals so we shall establish rules for identifying the most suitable measures to use.

Sleepio

Table B5: Data items and analyses for quantitative evaluation of the use of Sleepio

Question	Data items	Source	Cohort	Analysis
Who is offered Sleepio?	Numbers of people recommended the app. Patient characteristics: Age, gender, ethnicity, comorbidities, diagnosis[1]	GP practice data	Individuals identified in the data as using an app on a mobile device to support communication [2]	Descriptive statistics
Who decline the programme once offered	Numbers of people reported as declining app Patient characteristics (see above)	GP practice data	Individuals identified in the data as declining advice[2]	Rates of decline by type of patient
What is the uptake among people offered?	Numbers who download the app Patient characteristics (see above)	Data from Sleepio	Individuals identified in the data as being offered the app	Compare characteristics with those offered to deduce rates of uptake by patient characteristic.
How many people complete different stages of the programme?	Number still using the app at 3 and 6 weeks since recommendation. Number of weeks using Sleepio Number of sessions completed Issues identified Patient characteristics (see above)	GP practice data/ Sleepio data	Individuals offered the app	Rates of completion by patient characteristic. Univariate and multivariate analyses (e.g. logistic regression).[3]

Question	Data items	Source	Cohort	Analysis
What is the impact on patients?	Changes in sleep efficiency, sleep condition and number of hours slept	Sleepio data	Individuals who download the app	Changes measured against baseline. Comparisons by patient characteristic (univariate analysis), and relationship to use of app (multivariate analysis)
	Patient reported sleep quality	GP practice data	Individuals offered the app	
What is the impact on prescribing?	Numbers of patients prescribed hypnotics or antihistamines before starting the programme and over the course of the programme	GP practice data	Case cohort: Individuals completing 6 weeks Control group: Individuals from other local practices with similar characteristics	Patients completing programme v controls using multivariate design.[3]

[1] Diagnoses are a set agreed by GPs and include “insomnia”, “sleeplessness” or “disturbed sleep”.
[2] These are existing Read codes that are not currently used and will be added to an EMIS template.
[3] The method of analysis will depend on patient mix and overall uptake/completion. For example, if completion rates are high then we may not detect meaningful differences between patient groups.

Cluster 3

TickerFit

Table B6: Data items and analyses for quantitative evaluation of the use of TickerFit

Question	Data items	Source	Cohort	Analysis
Who is recommended TickerFit?	Numbers recommended the app. Age, gender, ethnicity, heart conditions	Barts Hospital data	Patients attending heart failure clinics at Barts Hospitals and offered TickerFit	Descriptive statistics
What is the uptake among those who are recommended?	Numbers who download the app	TickerFit data linked to the hospital data	Patients on-boarded with TickerFit	Rates of uptake by patient characteristic. Univariate and multivariate analyses (e.g. logistic regression)[1]
How many people using the app complete different stages of the programme?	Numbers who complete different stages	TickerFit data linked to the hospital data	Patients on-boarded with TickerFit	Differences by patient type
What is the impact on completion of cardiac rehab?	Numbers who complete Covariates from: Age, gender, ethnicity, heart conditions	Barts Hospital data Data from hospitals submitting data to the National Audit for Cardiac Rehabilitation (NACR)	Cases: All patients offered a cardiac rehab programme at Barts Hospital clinics. Controls: Heart failure patients attending other hospitals who offer conventional rehab programmes	Differences by patient type. Improvements in rehabilitation completion rates compared to retrospective data and to a control group. Difference in difference design.

Question	Data items	Source	Cohort	Analysis
What is the impact on patients?	Outcome measures: • BMI, • exercise test results, • waist circumference • New York Health Association (NYHA) classification • Emergency admissions • A&E attendance Covariates from: Age, gender, ethnicity, heart conditions	Barts Hospital data Data from hospitals submitting data to the National Audit for Cardiac Rehabilitation (NACR)	Cases: All patients offered a cardiac rehab programme at Barts Hospital clinics. Controls: Heart failure patients attending other hospitals who offer conventional rehab programmes	Multivariate regression design comparing cases and controls[2]

[1] The method of analysis will depend on patient mix and overall uptake/completion. For example, if uptake is high then we may not detect meaningful differences between patient groups.
[2] Numbers of covariaties and choice of method will depend on sample size and quality of the matching