



Protocol for the CLASSIC

Comprehensive Longitudinal Assessment of Salford Integrated Care (CLASSIC): a study of the implementation and effectiveness of a new model of care for long-term conditions

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Full title of project

Comprehensive Longitudinal Assessment of Salford Integrated Care (CLASSIC): a study of the implementation and effectiveness of a new model of care for long-term conditions

Summary of Research

The Salford Integrated Care Programme (SICP) is a large scale transformational project to improve care for older people with long-term conditions and social care needs in Salford. SICP will deliver improved care through 3 core mechanisms:

- Improved access to community resources and targeted support for self-management
- Better integration of care through multidisciplinary health and social care groups providing structured, population based care.
- An 'Integrated contact centre' to support navigation and self-management

The Comprehensive Longitudinal Assessment of Salford Integrated Care (CLASSIC) is an evaluation framework designed to provide a rigorous test of the ability of the SICP to deliver enhanced experience of care, improved well-being and quality of life, and reduced costs of care and improved cost effectiveness

The CLASSIC evaluation framework will adopt a variant of the cohort multiple randomised controlled trial, where a large population cohort is recruited and followed over time, with the cohort used to assess high level impact over time, while subgroups of the cohort are used to evaluate different SICP interventions.¹

Here we present a proposal for funding an initial stage of CLASSIC, to support:

- setting up the evaluation framework, including the cohort
- assessment of the early implementation of core components of the SICP
- evaluation of the outcomes of particular SICP components

In the initial phase, we will undertake 4 studies, 2 on implementation, and 2 on outcomes. If the initial phase is successful (see section on Management), bids for further funding to NIHR HS&DR and other funders may be made to undertake more detailed assessments of other aspects of the programme (such as the community assets, and the introduction of economic incentives with SICP), and to assess outcomes in the longer term.

The setting for the study is Salford in the North West of England, which has a population of 234,916 (34,000 aged 65+) and contains 52 practices, clustered in 8 neighbourhoods. The area has high levels of deprivation and long-term illness.

The health and social care system in Salford is largely coterminous, with one local government partner (Salford City Council), a single health commissioner (Salford Clinical Commissioning Group), mental health provider (Greater Manchester West) and a principal provider of acute and community health services (Salford Royal). There is a history of partnership working, and Salford uses an integrated care record (Salford Integrated Record) to integrate primary care, community care and secondary care information.

Background and rationale

The burden of disease in Salford, the UK and most parts of the world is shifting to long-term conditions. Although significant advances have been made in effective service delivery, major challenges have created a ‘burning platform’ for change: projected increases in those aged 65+, increases in demand associated with an ageing population, and central government pressure for major efficiency savings (£20 billion by 2014/15).

Current services are organised around single long-term conditions, but many people have multiple conditions, which means that care is often fragmented and unresponsive to needs, with low levels of involvement.^{2,3} A raft of policy and patient consultation around long term conditions has repeatedly emphasised the need for integration, recommending that every person with long-term or complex needs has access to a named contact who can coordinate care.^{4,5} The SICP aims to support this function on a population wide scale.

Despite major investment in health research, previous work has limitations. Studies rarely focus on people with multimorbidity,⁶ often test single innovations, and often represent academic priorities, rather than the needs of patients. Only research assessing change across an health economy, taking account of context, and involving multiple methods will provide blueprints for future service delivery. However, funders have traditionally faced a tension between the delivery of tightly controlled, small scale projects (which then face major barriers in terms of implementation and up-scaling), or large scale evaluations of ongoing service developments, which lack an ability to test causal hypotheses.

This application presents an attempt to deliver a research programme which effectively balances these tensions. The SICP represents a large scale service transformation with significant buy-in across multiple partners, a clear vision, and appropriate quality improvement to drive change. The CLASSIC project will deliver a comprehensive evaluation framework, to provide high level assessments of global impact and cost effectiveness, as well as detailed assessments of individual components and patient experience.

The SICP is an example of large system transformation’, defined as ‘interventions aimed at coordinated, system wide change affecting multiple organizations and care providers, with the goal of significant improvements in the efficiency of health care delivery, the quality of patient care, and population-level patient outcomes’.⁷ Many of the ‘core conditions’ supportive of such ‘transformation’ are present in the SICP, including appropriate leadership, small scale pilots of change, physician engagement and patient and public involvement.⁷ Other ‘core conditions’ (such as feedback on implementation) are planned.

CLASSIC builds on our expertise in assessment of NHS policy initiatives (the QoF, Advancing Quality, Whole Systems Demonstrators, EPP, Evercare),⁸⁻¹⁴ delivering high quality academic products in the rapidly changing context of service settings.

Evidence explaining why this research is needed now

Health systems worldwide face the challenge of providing effective services to an ageing population with high levels of multimorbidity. Service delivery for these patients in the NHS is based on evidence that is limited in scope and rigour, and at present decision makers cannot undertake quality improvement with confidence.

Stakeholders have made it clear to the NIHR HS&DR Programme that generating evidence relating to new models of delivery for long-term conditions represents their number one research priority. There is an opportunity to undertake high quality research alongside on-going service development to make a substantive contribution to our understanding of effective responses to the challenges facing health and social care services.

Aims and objectives

The overall aim of CLASSIC is to test the ability of the SICP to deliver significant and sustained improvements to the care of older people with long term conditions and social care needs.

In the initial phase, we will explore the following research questions.

Implementation:

- 1- How do key stakeholders (commissioners, strategic partners) view the SICP, what do they expect from it, and how is it aligned with their objectives and incentives?
- 2- What is the process of implementation of two key aspects of the SICP – the ‘multidisciplinary health and social care groups’, and the ‘integrated contact centre’

Outcomes:

- 1- What is the impact of the ‘multidisciplinary health and social care groups’ on the outcomes and costs of people with long-term conditions?
- 2- What is the impact of health coaching from the ‘Integrated contact centre’ on the outcomes and costs of people with long-term conditions?

Research Plan and Methods

We require a framework for the evaluation of the SICP which provides flexibility, while ensuring the maximum achievable level of control and rigour.

To achieve this, we will adopt a variant of the cohort multiple randomised controlled trial. In this design, a large population cohort is recruited and followed systematically over time. The cohort provides an on-going assessment of the impact of the SICP changes over time, while subgroups of the cohort used to evaluate different interventions.¹ Within and alongside this cohort, we will have the potential to deliver other research projects (both qualitative and quantitative) to explore other research questions.

CLASSIC will recruit a cohort of older people with long term conditions (N=4000) in Salford prior to full implementation of the SICP, sampling people with varying numbers and types of conditions to ensure representation of older people at all levels of the Kaiser pyramid, and including people with varying social care needs.

Participants will be followed up every 6 months with brief measures of service experience, health and care outcomes and utilisation. Measures will be linked to routine data in the Salford Integrated Record and a social care dataset to provide data on clinical parameters, medication use, and interactions with NHS and social care services.

Return of the initial CLASSIC cohort questionnaire will be taken as consent for the data to be used, and as agreement that people will allow us to seek further data over the lifetime of the cohort. We will also seek consent to contact people about further CLASSIC sub studies. Although formal consent to these sub studies will still be required by ethics, the cohort will facilitate recruitment by allowing proactive contact with respondents. In this application, we present detailed plans for two substudies based on the cohort.

Implementation I

The SICP has been introduced in the context of the Health and Social Care Act, which has significantly altered NHS structures (through the introduction of clinical commissioning groups), and changed the role of Local Authorities (through Health and Well Being Boards and the new system of public health provision). The SICP reaches across many of these new structure as well as a mental health and hospital Foundation Trust (the latter which vertically integrated with the community service provider in 2011), and the main mental healthcare provider.

Aims

Implementation I will investigate the dynamics of this new system, exploring how the SICP, (which crosses organisational boundaries and includes a range of stakeholders), is maintained in the new context. In particular, we will seek to understand:

- how commissioners view the programme, what they expect from it and how it is seen in terms of their performance objectives;
- how the programme is viewed by strategic partners such as the local authority;
- how the programme is being financed and monitored
- how the financial incentives (explicit and implicit) in the local health and social care system are aligned with the ambitions of the SICP
- change over time, with a focus on how commissioners see the SICP developing

This work will explore the contextual factors which may impact on long term viability. For example, there are features of the SICP which may facilitate shifting care into the community (e.g. one of the two Foundation Trust is also the supplier of community services, and will not lose out financially). Interviewees will also be asked how financial mechanisms facilitate or hinder change. We will review the financial flows in the health and social care system and summarise the mechanisms that are used for payment and their expected behavioural effects on different providers.

Methods and analysis

The theoretical approach will be realist evaluation,¹⁵ seeking to explore the programme theories espoused by those responsible for commissioning the SICP and comparing these with the findings from other aspects of the evaluation. In keeping with the realist approach, the contexts and mechanisms associated with the commissioning process will be explored, with a view to providing wider lessons for those responsible for commissioning similar programmes elsewhere,

Methods for this evaluation will involve initial qualitative interviews with key stakeholders to gauge opinions about the SICP and how it fits with their commissioning plans. Interviewees will include senior managers in the clinical commissioning group, Health and Well Being Board leaders, senior local authority public health staff and senior social care commissioners, foundation trust and community care senior staff and the chief executive from both foundation trusts (N around 30). Interviews will consider their understanding of the SICP; their involvement in its development; how it fits with their overall strategy; 'programme theories' of why the programme should deliver improvements; and issues relating to sustainability. Interviews will be repeated (largely via telephone) later in the study to explore experiences of the SICP over time, views on what it has delivered and its sustainability and potential for re-commissioning.

Analysis of interview data will be facilitated by a computerised data analysis package. Initial coding will be carried out using a priori codes derived from our existing understanding of the issues associated with commissioning complex programmes.¹⁶ These will be supplemented by inductive coding arising from the data. Analytical memos will be written and discussed to develop a collective understanding of the issues represented in the data. Findings relating to the commissioning of the programme will be shared with the wider research team and further explored in interviews with those responsible for the implementation of the project.

Economic pressures are an important stimulus to the implementation of the SICIP and part of the development of the SICIP involves a prospective assessment of expected costs and benefits undertaken by a third party. Additional cost effectiveness calculations will be undertaken within CLASSIC in Outcomes 1 and 2. Additionally, as part of Implementation 1, we will review the financial flows in the health and social care system and summarise the mechanisms that are used for payment and their expected behavioural effects on different providers. On-going discussions will explore whether incentive schemes designed with the CLASSIC research team and potentially introduced by the SICIP Board could be effective in encouraging adoption and a cost-effective use of resources. Full evaluation of such schemes will be based on additional funding applications to NIHR HS&DR and other funders.

Implementation 2

Both the proposed ‘multidisciplinary health and social care groups’ and the ‘integrated contact centre’ are complex interventions with multiple components and varied mechanisms of action, and their implementation, delivery and maintenance over time may be impacted by contextual factors such as variation in working relationships prior to implementation of the SICIP, aspects of the local environment, and the nature of the patient populations.

Although the Outcomes studies conducted under CLASSIC (see below) will provide assessments of the effectiveness and cost-effectiveness of particular SICIP components in specific populations, a process evaluation is required, both to illuminate their operation in the context of the Outcomes studies, and to assess the wider impacts of these services outside the formal context of the Outcome studies. We will explore the following areas:

Aims

‘Multidisciplinary health and social care groups’

- What are the characteristics and composition of the groups?
- How do the groups function as teams, and in collaboration with other providers?
- How well do the groups achieve fidelity to the original SICIP model?
- What are the key barriers to and facilitators of effective functioning and outcomes?
- How is the work of the groups experienced by patients and carers?

‘Integrated contact centre’

The contact centre will have a number of functions for people at various levels of the Kaiser pyramid. We intend to assess the effectiveness and cost effectiveness of one core aspect (‘health coaching’) on a particular patient subgroup through the Outcome 1 study (see below). However, we will also undertake a broader study of implementation of the ‘integrated contact centre’, to explore:

- What services are provided by the centre, and which staff provide those services?
- What is uptake and usage of the contact centre services?
- What are the key barriers to and facilitators of effective functioning and outcomes?
- How are contact centre services experienced by patients and carers?

Methods and analysis

For analysis, we will draw on our experience of process evaluation of organisational change and quality improvement in primary care, developed through the large scale NIHR CLAHRC for Greater Manchester, and our portfolio of trial based, health technology focussed process evaluations.^{17;18}

For the broader assessment of the adoption of the ‘multidisciplinary health and social care groups’ and the ‘integrated contact centre’ as part of the SICIP, we will draw on the realist model adopted in Implementation 1. We will explore the relationships between the proposed mechanisms underlying the ‘multidisciplinary health and social care groups’ and the ‘integrated contact centre’, and wider contextual factors at play in the SICIP (including themes identified in Implementation 1). We will use the ‘five simple rules of large scale transformation’ identified by previous realist studies (designated and distributed leadership, presence and use of feedback, attention to historical factors; provider

engagement; and patient and public involvement)⁷ as a framework to understand the process of implementation of these two aspects of the larger SICP.

For the ‘health technology’ perspective on the ‘multidisciplinary health and social care groups’ and the ‘integrated contact centre’, we will adopt Normalisation Process Theory (NPT) to guide our analysis. NPT offers a conceptual and explanatory framework to investigate how complex interventions become routinized and embedded in social and material contexts, allowing for exploration of the degree to which innovations are feasible and the extent to which they are sustainable over time. It is based on four generative mechanisms that underpin implementation of complex interventions: *coherence* (what is the work to be done?); *cognitive participation* (participants have to buy-in to the work, individually and collectively); *collective action*: (what work has to be done to enact and enable new practices?); and *reflexive monitoring* (what work can be done to help appraise new practices?). These constructs can be used to guide the analyses of both patient and professional experiences of the impact of the multidisciplinary health and social care groups and the integrated contact centre^{19;20} and will explore over time whether early adoption and experience of intervention components translates into routine delivery or whether pre-existing modes of care delivery persist, preventing full translation of the interventions at a patient and professional level.²¹ This combination of models has been adopted in current NIHR HSDR projects (HSDR project 10200136).²²

Methods - ‘multidisciplinary health and social care groups’

We will undertake individual face to face or telephone interviews with a sample of professionals within each ‘multidisciplinary health and social care group’, including group managers, seeking to eventually sample at least one group working in each of the eight neighbourhoods, and around 4 professionals per group (n=32 interviews). We will use routine data collected by the services on its activities (workload and throughput, patient characteristics, links with other services) to contextualise the richer qualitative data. We will continue to collect data from a subsample of interviewees approximately 6 months later through brief telephone interviews, to assess maintenance of the groups, potential changes to their composition and function over time, and the potential for unintended consequences (e.g. the groups generating additional health care utilisation by identification of need in patients). Following the evaluation of English integrated care pilots,²³ key themes to be explored will include: importance of pre-existing and emerging relationships between partner organisations, scale and complexity of intervention components, the role of clinical information systems, financial resources and infrastructure (e.g. co-location of staff).

At the level of the patient, we will describe the interaction between the ‘multidisciplinary health and social care groups’ and individual patients through individual interviews with patients and carers, exploring the impact of the work of the groups on patient experience, delivery of care and outcomes.¹⁸ We aim to conduct interviews with around 24 patients and carers, sampled on severity of illness and social care needs.

Methods - ‘Integrated contact centre’

We will describe the characteristics of the centre, its staffing and technology, and how the existence and function of the centre is communicated to patients. We will use routine data collected by the services on its activities (workload and throughput, patient characteristics, onward referrals from the contact centre) to contextualise the richer qualitative data. We will explore the various services provided by the centre through individual interviews with participating staff and managers, aiming to interview around 20 staff, with short follow up telephone interviews 6 months later, to assess maintenance of the various services over time, the degree to which staff achieve fidelity in terms of the delivery of the model and the potential for unintended consequences.²⁴

At the level of the patient, we will describe the interaction between the staff at the ‘integrated contact centre’ and patients, both through observation of staff taking calls, and through individual interviews with patients and carers, exploring the impact of the various integration centre services on patient experience, delivery of care and outcome. We aim to interview around 24 patients and carers who have used the services of the contact centre (including some who have taken part in the Outcomes 2 study)

Outcomes – overall framework

The initial phase of CLASSIC will assess the outcomes of two aspects of the SICP

- 1- What is the impact of the ‘multidisciplinary health and social care groups’ on the outcomes and costs of people with long-term conditions?
- 2- What is the impact of ‘health coaching’ from the ‘Integrated contact centre’ on the outcomes and costs of people with long-term conditions?

As detailed earlier, CLASSIC will recruit a cohort of older people with long term conditions (N=4000) in Salford prior to full implementation of the SICP, sampling people with varying numbers and types of conditions to ensure representation of older people at all levels of the Kaiser pyramid, and including people with varying social care needs. The exact classification to be used to stratify the population of older people in Salford has yet to be confirmed, but is likely to use a four strata classification based on current levels of support required.

Participants will be followed up every 6 months with a questionnaire including brief measures of service experience, self-efficacy, health and care outcomes and utilisation. Measures will be linked to routine data in the Salford Integrated Record and a social care dataset to provide data on clinical parameters, medication use, and interactions with NHS and social care services.

Return of the initial cohort questionnaire will be taken as consent for the data to be used, and to allow us to seek further data over the lifetime of the cohort. We will also seek consent to contact people about further CLASSIC substudies. Although formal consent to these substudies may still be required by ethics, the cohort will facilitate recruitment by allowing proactive contact with respondents. This will allow us to evaluate aspects of the SICP as they are implemented at different times, and in different populations.

The University of Manchester team has experience in the delivery of large scale cohorts of patients with long-term conditions in the Salford setting. The WISE study (NIHR RP-PG-0407-10136) recruited 44 practices from Salford and surrounding trusts and recruited 5,599 patients with COPD, IBS and diabetes, following 81% at 6 months and 73% at 12 months.^{11;25} Although such large scale data collection is challenging, we are confident that we can replicate this in the CLASSIC project.

The cohort will provide a platform for a number of relevant analyses.

- population level (to assess the effect of the SICP on overall population experience, self-management and outcomes over the timeline of the cohort);
- cluster level (implementation of aspects of the SICP delivered at the level of the practice or neighbourhood)
- patient level (where individual components of the SICP, such as ‘health coaching’ are allocated to individuals)
- external comparators: comparisons with sites and cohorts outside Salford, using routinely available data on service experience, health care utilisation, and mortality

Data collection:

We will recruit people meeting inclusion criteria to a cohort.

Final decisions about questionnaire content will be made after appropriate PPI consultation as part of the CLASSIC study, and the final measure list may be modified or reduced if multiple scales are seen as redundant or excessively burdensome by PPI representatives, especially in the population of older adults. The survey may be augmented by additional measures at points in the cohort which relate to particular issues, such as patient perceptions of issues concerning patient safety in long-term conditions.

We will assess people at baseline (before full implementation of the SICIP) in terms of their demographic and clinical characteristics using validated measures and categorisations designed to maximise comparability with existing surveys and the 2011 population Census. We will then use a small set of core outcomes to assess the impact of the SICIP over time.

- *Baseline assessment*

We will use socio-demographic questions from the General Practice Patient Survey,²⁶ including gender, age, current work situation, and qualifications. Ethnicity will be assessed using the 17 Census 2011 categories. We will include a single item health literacy measure which has demonstrated good reliability and validity^{27;28} and a measure of the number and impact of long-term conditions.²⁹

We will use the ENRICH measure of social support, a seven item scale with items on partners, tangible help and emotional support.³⁰

We will follow participants up at regular periods using short, person oriented assessments of a range of validated outcomes.

- *Health experience and self-management*

PACIC. We will use the *Patient Assessment of Chronic Illness Care (PACIC)*, a validated measure of patient assessments of service delivery for long-term conditions.^{31;32} The original PACIC includes 20 items in 5 subscales: patient activation; delivery system design; decision support; goal setting; problem-solving; and coordination.³² **We will use the short 11 item version.**³³

PAM. The Patient Activation Measure is a self-report measure of patient knowledge, skills and confidence in self-management for long-term conditions.^{34;35} **We will use the short 13 item version.**³⁶

We used a modified version of the Summary of Self-Care Activities (SDSCA) measure to assess the number of days per week respondents engage in healthy and unhealthy behaviours (i.e. eating fruit and vegetable, eating red meat, undertaking exercise, drinking alcohol, and smoking).³⁷

Patient experience of managing multiple conditions. We will use 16 items from the MULTIPLES scale exploring patient experience of managing multimorbidity.³⁸

- *Health and social care outcomes*

EQ5D. The five-item EQ-5D is a generic measure of health-related quality of life, suitable for people with long-term conditions and recommended by NICE for economic evaluations.³⁹ The self-report measure consists of the EQ-5D descriptive system and EQ Visual Analogue Scale (EQ VAS). The first part consists of 5 items: mobility, self-management, usual activities, pain, anxiety and depression. Each dimension has three levels of severity and provides a utility value based on a population tariff.⁴⁰ The VAS records an individual's perceived self-rated health. **We will use the new EQ5D-5L version.**

Mental Health Inventory (MHI-5). The MHI-5 is a 5-item scale which measures general mental health, including depression, anxiety, behavioural-emotional control and general positive affect.^{41;42} **This will be complemented by a single item measure of 'entrapment'.**⁴³

The ICECAP-O index of capability measures quality of life for people aged 65 or over in terms of 5 core dimensions: attachment, security, role, enjoyment and control. It is anchored at 0, for no capability, and 1 for full capability.^{44;45}

The World Health Organization Quality of Life brief measure (WHOQoL-BREF) is a 26-item measure of global QOL, which has been validated in a large international population with physical and mental long term conditions. QOL is measured across four domains: physical, psychological, social, and environmental, as well as a single-item scale for QOL.⁴⁶

We will use items on health care utilisation, based on our previous CAPITOL⁴⁷ and CHOICE studies (<http://choice.mhsc.nhs.uk/home.aspx>), an item on difficulties in

accessing health care from the Canadian Community Health Survey,⁴⁸ and an item on use of community resources from the Health Survey for England,⁴⁹ as well as items on continuity of care and care planning from the General Practice Patient Survey.²⁶

We will use items on patient experience of safety from the integrated care pilots evaluation.⁵⁰

We will use bespoke measures assessing use of email communication around health care, and three items assessing issues of interest to stakeholders in the Salford Integrated Care Programme.

We will include a shorter assessment for carers of those identified in the main CLASSIC cohort, including EQ5D, PHQ 9, ICECAP-O and the Modified Caregiver Strain Index used in our recent assessment of the Whole System Demonstrators.⁵¹

Care utilisation and costs

We will obtain information on rates of utilisation of most of the major elements of health and social care through linkage to the Salford Integrated Record. These will be costed using national tariffs or published unit costs. We will also include short questions taken from previous evaluations of WISE and the EPP on patient out-of-pocket payments, time spent on self-care, and amount of informal care received from personal social networks.

- *Follow up assessments*

Assessments will use a combination of telephone and postal administration, with appropriate support to enhance response rates and maximise internal and external validity. We have extensive experience of the delivery of large scale surveys among people with long-term conditions and the appropriate mix of postal surveys and telephone support, and we have costed for travel for face to face visits to support frail respondents, and intensive telephone support for those who require more limited assistance. In recent studies (including Salford samples) we have recruited large samples of 2000-5000 patients with long-term conditions and achieved good retention rates over 12 months.^{11:32}

Outcomes - 1 Multidisciplinary health and social care groups

Services are increasingly faced with management of complex patients with multiple problems and needs, who are at high risk of hospitalisation, and who require input from multiple health and social care agencies to better manage and co-ordinate their care, and avoid poor health and expensive hospital admissions. One key component of the SICP is the creation of 'multidisciplinary health and social care groups' providing structured, multidisciplinary population based care for patients with long-term conditions, based broadly on a 'case management' model.

'Case management' is a broad term that refers to a model of service delivery with core components of case finding, assessment, care planning and care co-ordination.^{52:53} There is a developing evidence base concerning the effectiveness of care management, with some schemes reporting positive effects, but generally findings are variable,⁵⁴⁻⁵⁸ with some evidence that schemes that are effective in one context may not generalise to the UK.¹⁴

There is developing knowledge about the factors that can impact on the success of case management schemes, such as factors relating to the case manager (accountability, remit and skills), programme design (patient eligibility, caseload, access and continuity) and wider system factors (shared objectives, social care links, alignment of incentives).^{23:52} It is also known that case manager responsibilities and tasks vary widely and can also be variably implemented⁵⁹ even when there is a high degree of coordination.⁶⁰

At present, case management remains core to the improvement of long-term care in the NHS long-term conditions model, but the evidence base is sufficiently unclear to require further evaluation to test models of case management in particular contexts and to generate wider knowledge about the key ingredients and facilitators of this model of care.

Case management in the SICP

The case management function in the SICP is being undertaken by ‘multidisciplinary health and social care groups’.

These groups have been piloted in a limited way in two neighbourhoods in Salford as part of the development of the SICP, supported by appropriate quality improvement personnel to maximise learning from the pilots and to ensure that a coherent, practical model is developed for delivery across the SICP. The development work involves formal quality improvement through development, piloting and formal PDSA cycles to undertake local ‘tests of change’ to feed into the emerging SICP model.

The model underlying these groups is as follows. The multidisciplinary health and social care groups involve a mix of professionals (with a maximum of around 10) who dedicate time and resources to regularly attend meetings of the group. All groups involve recruitment of a project manager, and professional disciplines represented in the group include GPs, practice managers, practice nurses, social workers, district nurses and staff from the local authority. Groups meet monthly at a minimum to identify people at risk, deliver appropriate interventions, and assess the impact of those interventions.

Study design

Implementation of the ‘multidisciplinary health and social care groups’ will be undertaken in the 8 Salford neighbourhoods in a staged manner over time, allowing neighbourhoods using later adoption to act as controls for those adopting earlier.

We will use a cluster design and two patient groups: the first group represents patients in the CLASSIC cohort for whom we have the full range of outcomes collected through the planned assessment; the second is all patients (both inside and outside the cohort) for whom we can obtain routine health and social care service use data from the Salford Integrated Record. Depending upon the precise nature of the roll-out of the ‘multidisciplinary health and social care groups’, we may adopt a ‘stepped wedge’ design in order to maximise statistical power.^{61;62}

Intervention

‘Multidisciplinary health and social care groups’ will hold a register of all 65 year olds in a ‘neighbourhood’ of federated practices. Appropriate risk stratification tools will be applied to assess risk of hospitalisation and care home admission. Shared care protocols will be agreed, including care plans. Support will be proportionate to need, with patients at high risk further supported by multidisciplinary care conferences to better plan, co-ordinate and deliver their care.

In control neighbourhoods, implementation of the ‘multidisciplinary health and social care groups’ will be undertaken at a later date in the roll out of the SICP, and routine care for these patients will apply.

Patient populations

The core impact of the ‘multidisciplinary health and social care groups’ is expected to be on patients at the highest tier of the current 4 strata classification system used in the SICP, which are the patients who are at highest risk of hospitalisation, and who will stand to benefit most from significant

multidisciplinary input. We will focus our analyses on this group of patients. However, the nature of the cohort is such that secondary analyses can compare outcomes in other strata within the cohort (and across the whole cohort).

We estimate that 10-15% of patients in the CLASSIC cohort will be eligible for support from the 'multidisciplinary health and social care groups', providing around 400-600 patients for detailed analysis of the impact of the groups on patient experience, health outcomes and utilisation.

There will be approximately 3-4000 patients across Salford in the highest tier, for analyses of the impact on care utilisation and hospital admission. Additional analyses will compare impacts across Salford with matched data from outside the Salford area.

Allocation

We will negotiate with the managers of the SICP to seek agreement that the order of roll-out of the 'multidisciplinary health and social care groups' to Salford neighbourhoods is randomised, or at least allocated in such a way as to maximise comparability between neighbourhoods adopting earlier and later, to minimise potential selection bias.

Outcomes

For analyses of patients in the CLASSIC cohort, the outcomes are those discussed previously as part of their assessment. For analyses across Salford, and external comparisons, outcomes will be utilisation of health and social care services (including GP consultations, hospital admissions, hospital bed days, emergency admissions, admission to care homes and social care at home) and all-cause mortality, obtained from the Salford Integrated Record.

Analysis and sample size

For analyses of practice-level allocation to 'multidisciplinary health and social care groups', we will compare between practices allocated/not allocated to 'multidisciplinary health and social care groups' using analyses of covariance within a multi-level model framework (to account for clustering of patients within practices, and practice-level factors), tailored for a stepped wedge design if suitable, and controlling for pre-specified patient- and practice-level covariates. The number of 'multidisciplinary health and social care groups' will be too small to reliably take clustering at this level into account in the primary analysis, and we will therefore examine consistency of effect across groups using post-hoc analysis.

For patients in the CLASSIC cohort we will conduct a separate analysis for each outcome collected through their questionnaire assessments. For the set of all patients with linked Salford Integrated Record data we will analyse use of each health and social care element separately and also in combination (using unit costs) as a measure of total service use costs. All-cause mortality will be analysed using a Cox proportional hazards model to determine the impact of the 'multidisciplinary health and social care groups' groups on survival.

For analyses of the impact of 'multidisciplinary health and social care groups' using a clustered design, 40 practices (in total) and 15 patients per practice would provide 80% power to detect a standardised effect of 0.24 (alpha 0.05, ICC for patients within practices 0.05, assuming correlation between pre and post measures of 0.6). In the analysis of routine data in all patients in Salford, 32 patients per practice will give 80% power to detect an effect of 0.2 (on the same assumptions).

To assess external validity and generalizability and measure the impact of the 'multidisciplinary health and social care groups' in the context of wider changes in the care system, we will undertake comparisons with sites and cohorts outside Salford, using routinely available data on service experience, health care utilisation, and mortality.

This evaluation will be undertaken in two ways: (1) by matching the participants in the 'multidisciplinary health and social care groups' intervention to non-participants outside of Salford on the criteria that would have made them eligible for the intervention in Salford; and (2) by comparing all of the population that qualify for inclusion in the intervention in Salford with all of the population that would qualify for inclusion in other matched sites. We will obtain and use linked patient-level data from Hospital Episode Statistics and Office for National Statistics death records. Historical information on diagnoses from previous hospital admissions and patient characteristics will be used to populate the inclusion rules and identify matching patients. Historical information on patterns of care and population demographics will be used to identify sites that match to the Salford context. We will consider numbers of admissions and length-of-stay as indicators of costs and emergency readmissions, discharges to usual place of residence and mortality as indicators of outcomes. We will adopt a difference-in-differences framework to control for differences between sites at baseline and common trends over time that influence both the study and control sites.

Outcomes 2 – Health coaching in the contact centre

The contact centre will involve a number of services, which will provide support, navigation and other activities to support older patients in Salford. For the purposes of Outcomes 2, we will focus on the evaluation of a ‘health coaching’ function conducted by the contact centre for patients with long term conditions. Other functions undertaken by the contact centre will be captured by the process evaluation in Implementation 2.

Health coaching involves ‘a regular series of phone calls between patient and health professional...to provide support and encouragement to the patient, and promote healthy behaviours such as treatment control, healthy diet, physical activity and mobility, rehabilitation, and good mental health’.⁶³

Health coaching is designed to provide an accessible, proactive service to patients, improving support and potentially reducing inappropriate care utilisation. However, current evidence on the effectiveness of health coaching is mixed. Although systematic reviews have identified a number of effective models, outcomes are variable and it is not entirely clear what distinguishes effective models from those that fail to show effects. Some of the evaluations have used non-randomised designs which are vulnerable to bias.⁶⁴ Many of the evaluations have been undertaken in the United States, and it is not clear that the results will generalise to populations with different characteristics, living in different contexts. A recent evaluation of the Birmingham OwnHealth service in 2698 patients and matched controls did not find reductions in health service utilisation associated with a nurse led health coaching service, although other outcomes (such as empowerment and quality of life) were not measured.⁶⁵

Attempts to identify key drivers of effectiveness of health coaching have focussed on the content of the coaching (self-management versus ‘preference sensitive’ decision making), the types of coaches (health professionals versus paraprofessionals), the scope of the calls (such as whether mental health and substance abuse issues are dealt with alongside physical health and self-management) and the presence of additional interventions (such as telemonitoring).⁶⁶

Two relevant evaluations have been conducted in services in the North West. The PACCTS study randomised 591 patients with Type 2 diabetes to telephone support from paraprofessionals, backed up by diabetes specialist nurses (the so-called Diabetes CareCall model http://www.salforddiabetescare.co.uk/index2.php?nav_id=1324). The study found reductions in HbA1c compared to usual care controls, with the most marked and clinically significant changes in those with poor glucose control at baseline.⁶⁷

The BRIGHT study funded by the NIHR CLAHRC for Greater Manchester randomised 436 older patients with CKD to a telephone support intervention, conducted by paraprofessionals and supported by a bespoke website,⁶⁸ and focussed on increasing patient access to health and other relevant resources in local networks. The study (analysed but unpublished) found that health coaching led to improvements in health related quality of life and blood pressure control, and was highly likely to be cost-effective.⁶⁹

These effective local evaluations suggest that there is a role for health coaching interventions, although the pattern of results suggest that it is easier to improve quality and outcomes rather than reduce utilisation.⁷⁰ The CLASSIC evaluation of health coaching will test a combination of the Diabetes CareCall and BRIGHT models, widening the interventions to include patients with a wider range of conditions (including multimorbidity) and extending the telephone model to include a greater focus on mental health, given the importance of mental health in populations with long-term conditions and the potential impact on health care utilisation.^{71;72}

Outcomes 2 - Study design

We will use a randomised controlled trial design based on the CLASSIC cohort.

Interventions

The model of 'health coaching' to be delivered involves 3 components.

- Proactive telephone self-management support using a modification of the diabetes CareCall model designed for a range of long-term conditions, delivered by paraprofessionals and supported by experienced nurses.⁶⁷
- Access to resources in the local network through the PLANS website⁶⁸ and facilitated by the protocol used in the BRIGHT trial.⁶⁹
- Assessment of mental health and delivery of appropriate support for those where needs have been identified, based on our previous telephone treatment trials.⁷³

The health coaching will involve monthly calls of 20-40 minutes for a period of six months, delivered by a variety of staff, all working to a written protocol, and supported by additional training. We have extensive experience of the design and delivery of training for telephone based interventions and long-term conditions.⁷⁴⁻⁷⁶

Patient populations

We will recruit older people within the CLASSIC cohort, focussing on those within the two middle tiers of the current four strata classification in the SICP. For inclusion, patients will have to have 2 or more existing long-term conditions (including one index condition), and assessed as needing some assistance with self-management (defined in terms of scores on the validated self-management scales in the cohort assessment, with the exact thresholds to be decided on the basis of data from baseline). Index conditions will include diabetes and CKD (conditions where evidence about the effects of the interventions already exists); additional conditions will be decided prior to implementation of the study, but are likely to include COPD. We will sample to include roughly equal numbers in each strata. We will allocate patients randomly to 'health coaching' or usual care using appropriate central randomisation through an accredited trials unit to ensure concealment of allocation.

Controls

Controls in the Outcomes 2 study will be managed using current services provided by local services. This will include other services provided through the contact centre. However, they will not have access to the proactive 'health coaching' model under test. We will describe usual care via data collected from the cohort on service utilisation.

Outcomes

The outcomes are those discussed previously as part of the assessment of patients in the cohort. The primary outcomes will be changes in experience of care for long term conditions (as assessed by the LTC6) and health-related quality of life (EQ5D). We will conduct a full economic analysis, using EQ5D and an assessment of costs from utilisation measures in the cohort.

Analysis and sample size

We will report the trial and analysis according to CONSORT standards, including full details of use of the various telephone coaching components, linking to analysis of patient data in Implementation 2 to contextualise the quantitative findings.

We will use conventional analyses of covariance, controlling for pre-specified covariates and design factors. A sample of 500 patients (allowing 20% attrition at follow-up) would provide 80% power to detect a standardised effect of 0.20 (alpha 0.05). We will present a small number of pre-planned moderator analysis to examine effects for subgroups of patients within the CLASSIC cohort.

For the economic analysis, the primary outcomes will be the incremental cost-effectiveness ratio, the associated net benefit statistic and probability of cost-effectiveness derived from the cost-effectiveness acceptability analysis.^{77;78} For outcomes, we will use quality-adjusted life years from the EQ5D measurements, and published utility tariffs. Costs will include costs of the 'health coaching' intervention (including training costs associated with staff), as well as health and social care services utilised by the patients in the trial, which will be collected from the patient survey and related information in the Salford Integrated Care Record. Analysis will use intention to treat, with appropriate imputation of missing data, and sensitivity analyses will explore the impact of assumptions about key parameters (such as the costs of training the 'health coaching' staff).

Dissemination and projected outputs

The University of Manchester team will look to disseminate the results of relevant studies in a range of academic journals, including general medical and health services research journals, as well as specialist policy, economics, informatics and mental health publications. We will support open access publication where possible and have requested funds to support this. We have a track record of publishing the results of policy relevant research in a range of high impact journals including the New England Journal of Medicine and the British Medical Journal.^{8;9;13;14;25;79}

As well as conventional academic publications, we will also use our previous and current experience of dissemination through the NPCRDC and the NIHR CLAHRC for Greater Manchester to develop more accessible guidebooks to assist in the dissemination of aspects of the programme to a wider audience, including professionals, older people and carers (as supported by our relevant PPI partners). For example, protocols for the delivery of health coaching would be one potential focus. We will seek to ensure that identified benefits of the SICP can be effectively implemented outside the Salford context by providing practical guidance on implementation, through web and social media, alongside the dissemination activities being run by the SICP Board.

Salford is well positioned to disseminate and share the findings of this research, as founding members of AQuA (the Advancing Quality Alliance) which is a quality improvement body that supports NHS organisations in North West of England and beyond. Salford Royal is also an active member of QUEST, which is a national network of 11 Foundation Trusts focussing on improving quality and safety. QUEST members work as partners on improvement projects, learn together and from one another, galvanising collective leadership and staff capability.

Applicant Camacho works for Haelo (www.haelo.nhs.uk), recently established by NHS partners across Salford to bring together quality improvement activities. Haelo has a simple core purpose: to improve health communities through action, measurement and evaluation. It works with local, regional and national partners to focus on innovation in improvement across healthcare and academia, focusing on 3 key areas: safety; measurement; and large scale change. Haelo will share the work of the CLASSIC team through regular updates, blogs, videos, animation and publications.

Plan of investigation and timetable

The broad structure and timeline of the CLASSIC project is shown in the accompanying diagram.

Development of the SICP will continue until late December 2013. We will plan the first cohort survey as soon as possible in 2014, with repeat assessments at 6 monthly intervals.

We propose that an NIHR steering group be planned to occur at the point of the completion of the initial CLASSIC survey (around August 2014), to allow an early assessment of the viability of the proposed design, as well as to assess the continued development of the SICP (especially the 'multidisciplinary health and social care groups' and the 'health coaching' intervention) and their amenability to the proposed evaluation.

For Outcomes 1, we expect that the full implementation of the 'multidisciplinary health and social care groups' will begin in April 2014 in two neighbourhoods, taking around 3-4 months from initial roll out to full implementation, with staggered roll out across other pairs of neighbourhoods continuing over 12 months.

The start dates of the Outcomes 2 study could begin at any time after the delivery of the initial CLASSIC survey, but is likely to begin around late 2014, allowing 9 months for recruitment from the cohort, 6 months for initial follow up, and 3 months for analysis and write up.

We would suggest a further NIHR steering group around August 2015, which would allow an assessment of the ongoing recruitment/retention to the cohort and to the nested Outcomes 2 study, allowing a decision on the viability of the cohort model and an ongoing assessment of the viability of the SICP. Major threats to validity at this point would allow a decision to be made about more rapid tapering of funding until the eventual close of the first phase of CLASSIC in 2016. If the project was judged a success, a further NIHR steering group meeting in 2016 could make

recommendations about further funding in line with the original 5 year CLASSIC bid (subject to further peer review).

The CLASSIC team would meet every 9 months to review findings (months 0, 9, 18 and 27), and a core outcome of those meetings would be interim outputs. Early in the timeline, such outputs would include protocol papers, descriptions of the development and nature of the SICP and its components, and early findings from the cohort, followed by findings from Implementation 1 and 2, and eventually the quantitative analyses of Outcomes 1 and 2.

All these conventional academic publications and outputs will be complemented by appropriate dissemination for a service audience (through relevant organisations such as QUEST and Haelo) and for patients and the public. A key focus of service related work will be on describing the intervention in such a way that other organisations in other settings can replicate the process, and understand what aspects of the programme are dependent on particular conditions within Salford. We will also describe the QI process underlying implementation of the SICP in detail as this represents a major strength of the SICP.

A key focus of work for patients and the public will be understanding the experience of the SICP among older people (including perceived advantages and disadvantages) and understanding how that experience is patterned by patient and local contextual factors.

Project management

Management of CLASSIC

The PI will be responsible for the overall management of CLASSIC and will take overall responsibility for the delivery of the cohort and the substudies. The PI will be responsible for co-ordination of all project related activities, liaison with the NIHR steering group and reporting to NIHR, working together with a full time research fellow on the academic side, and a half time project manager within the NHS. The core team of applicants will involve the PI, Reeves as senior statistician, key staff for the delivery of each project (Checkland for Implementation 1, Coventry for Implementation 2, Reeves for Outcomes 1, and Blakeman for Outcomes 2), and from the NHS side, applicant Camacho and the NHS project manager.

The core CLASSIC team will meet every month during the first 15 months of the project (transitioning to every 2 months at that point if progress is good). Individual projects will organise meetings of appropriate frequency. We will have half day 9 monthly meetings for the entire CLASSIC team (with other SICP partners where appropriate) to assess learning from the study, share insights and ensure that research and other findings are actively disseminated through the lifetime of the project.

Management of the relationship between CLASSIC and SICP

The SICP Board meets monthly and includes senior representation from all the partner organisations. There are a number of subgroups which sit under the board, including the Evaluation subgroup which also meets monthly. The CLASSIC PI or research fellow will attend the Evaluation subgroup of the SICP board, and CLASSIC staff will attend other meetings as appropriate. This bid includes funding for core SICP staff to liaise with CLASSIC as we are aware of the importance of close working and the need for protected time to achieve effective liaison.

Prior to any NIHR HS&DR funding, the NIHR CLAHRC for Greater Manchester is funding a Research Associate for 6 months to work alongside the SICP and provide regular communication between the CLASSIC team and the SICP Board, including feeding back the results of evidence syntheses as part of the intervention development and quality improvement activities. This is to allow pre funding development activities, and is not double funding.

Management of the relationship between SICP, CLASSIC and the NIHR

One of the advantages of the CLASSIC evaluation is that it is based around an existing service development initiative, which means that traditional concerns about upscaling and implementation are less acute.

However, this brings with it additional risks, as there is a danger of fundamental changes in the strategic or operational direction of the SICP Board, which may lead to major changes in the programme, which would in turn threaten the validity and impact of the research (although the SICP board have made a long term commitment to the programme - see uploaded letter of support)

We propose that NIHR establishes an independent steering group including senior academic and service representatives which would meet at the beginning of the project, and at 18 months. The CLASSIC team would provide reports about developments, especially in terms of the SICP model and components, and the eventual nature of the nested substudies within the main cohort when these are finalised. The steering group will be able to comment on these proposals, feed back to the CLASSIC team in terms of their adherence to the protocol, and provide an annual summary for the NIHR HS&DR Board, including recommendations to review funding and potentially close the study early, if initial implementation of the SICP intervention and/or the research design were felt to show insufficient fidelity to the funded plan, or there were threats to the relevance or impact of the work.

Approval by ethics committees

Ethical approval will be required for patient focussed work. The main ethical challenge concerns acceptance of the cohort multiple randomised controlled trial, as the design is relatively new and may be unfamiliar to ethics committees. However, there are published examples of successful applications around this design⁸⁰ and we will seek advice from researchers known to have applied previously to inform our application and ensure that our design is robust and ethically acceptable.

A strength of the project is the potential for the use of the Salford Integrated Record to support research, and applicant Sanders is initiating a project to investigate service user views on dynamic consent for use of such integrated records which will inform our approach within CLASSIC.

Patient and Public Involvement

We expect to have 3 levels of PPI in CLASSIC

Intervention design: PPI is already integrated into the development of the SICP and the components, and we will support that process and document the impact of PPI as part of our description of the development of the SICP.

Cohort: ‘Citizen Scientist’ (www.citizenscientist.org.uk) will also be involved. This project brings together health researchers and the public to collaborate on research which aims to improve the healthcare for local communities. People can take part in many ways from shaping research questions to participating in clinical trials. The project is managed at Salford Royal NHS Foundation Trust. While recruiting people for the CLASSIC cohort, we will encourage them to sign up as Citizen Scientists, to become part of a wider network supporting research in Salford

Research delivery and dissemination: We will involve our local patient and public involvement group (PRIMER www.populationhealth.manchester.ac.uk/primer). Given the other PPI components, we will focus their efforts on the dissemination of the results. PRIMER members have extensive experience of working with researchers within the Centre for Primary Care on a range of projects relating to long-term conditions.

Expertise and justification of support required

The team has the necessary skills and expertise to conduct this multi-method evaluation.

Implementation 1

Checkland is a GP and health services researcher with extensive experience in the analysis of policy around commissioning in the NHS,¹⁶ through her work with the DoH PruComm Unit. Sutton is an international expert on the role of incentives in health care and the evaluation of their impact.⁹

Implementation 2

Boaden and Campbell will lead on the broader systems level perspective of Implementation 2, while Coventry, Reilly and Sanders will lead on the 'health technology' assessment aspects. Coventry has experience of the mixed method evaluations of health technologies and complex interventions,^{21;81} while Reilly has specific expertise in the analysis of case management in the context of long-term conditions.^{59;82} Sanders brings specific expertise in the assessment of patient experience of health care innovation, especially among older people.^{18;83} Boaden is Deputy Director of the NIHR CLAHRC for Greater Manchester, with extensive experience of the theory and practice of quality improvement, including assessment of the Evercare case management scheme and the evaluation of the Advancing Quality scheme.^{9;24} Campbell has expertise in quality measurement and quality improvement. He was principal investigator on the evaluation of the new GMS contract in the UK⁸ and leads the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre.

Outcomes 1 and 2

Bower and Reeves have extensive experience in the design and analysis of trials and non-randomised evaluations of policy, including self-management, new models of delivering primary care, and assessment of the impact of the GMS contract.^{8;12;79} Reeves is also highly experienced in analysis of longitudinal health service data.^{84;85} Sutton is an econometrician who specialises in the use of secondary data sets to explore the effects of large scale policy interventions, such as AQA,^{9;86} and who has contributed to published guidance on these methods.⁸⁶

Blakeman has extensive knowledge of the theoretical and empirical literature concerning self-management, and co-led the initial test of the BRIGHT telephone coaching intervention,⁶⁹ and will lead on Outcomes 2. He will work alongside Lovell, a Professor of Mental Health Nursing with an international track record in telephone delivery of mental health care,⁷³ and Waheed (psychiatry) who also has experience of delivery of depression care to patients with long-term conditions through the NIHR CLAHRC for Greater Manchester.¹⁹

We have added applicant Skevington to the resubmitted bid. We are using the WHOQoL-BREF in the cohort, and Skevington (a recent recruit to Manchester) is an acknowledged expert in this scale, and the measurement of quality of life generally, and we feel that her addition will provide key expertise and extend our ability to generate useful findings from the cohort.

Buchan and Ainsworth lead the new Health eResearch Centre (<http://www.herc.ac.uk/>), and will provide expert assistance on the use of large scale data sets (especially the Salford Integrated Care Record) for analyses in Outcomes 1 and 2, working alongside the information manager in the NHS.

Support requested

The original NIHR brief stated the desire for large scale and ambitious projects, and the first costing reflected this ambition. In response to the Board's comments, we have cut the project to 30 months, which provides time to set up the evaluation framework, assess implementation, assess the impact of the 'multidisciplinary health and social care groups; and conduct an initial trial of 'health coaching' in the 'Integrated Contact Centre'.

At the University of Manchester, we are requesting funding for the applicants to support delivery of the initial academic programme. We are also requesting 1 Research Fellow (100%, 30 months) as co-ordinator for all evaluation activities and to support the principal investigator. We are also requesting 2 Research Associates (100%, 30 months) to co-ordinate data collection in the cohort, and to conduct the intensive qualitative research in Implementation 1 and 2. We are also requesting one secretary (50%) to provide administrative support to the research team.

We have also requested funding for the costs of running the cohort (postage, return, data entry, and consumables from a third party provider), as well as travel (to practices and patients) and telephone charges for the intensive support of the cohort recruitment and retention. We have costed for PPI for the PRIMER group (travel, subsistence and payment at INVOLVE rates), for research team travel (to practices for the cohort, and to interviews), for extensive transcription to support the implementation projects, and for secure randomisation. For equipment, we have costed for 2 PCs

and 2 encrypted voice recorders. For dissemination, we have costed for 5 Open Access publications, 4 UK conferences (e.g. HSRN, SAPC) and two international conferences (e.g. AHRQ, NAPCRG).

The NHS team are requesting funding for the time of the SCIP Board to support the research, although the members to be supported has been reduced to 3 (Dalton, Chief Executive of Salford Royal Foundation Trust, Sharp, Director of Service Reform, SICP, and Camacho, CLASSIC applicant). We request support for a jointly appointed Programme Manager (100%, 30 months) across academic and NHS partners, to ensure a robust interface between the SICP partners (foundation trust, CCG, local authority) and the University of Manchester academic team in this complex, multi-agency programme. Our request is based on experience from the NIHR CLAHRC for Greater Manchester, where project management experience of this type identified through NHS channels has proven invaluable in ensuring effective delivery across NHS and academic boundaries. We request support for a Quality Improvement lead (50%, 12 months only) to both shape and test the inventions developed in this programme (Salford Royal Foundation Trust has a strong background in leading change using QI methods) and to ensure that the development and delivery process is transparent, fully documented, and delivered in a robust way that meets standards of fidelity required of a research study. We request support for an Information manager (50%, 30 months) who will work across the service delivery partners (foundation trust, CCG, local authority) to ensure that the relevant activity information is being captured and communicated to the CLASSIC team, and also support the improvement collaborative work. The NHS team will be support by a research administrator (now 50%, 30 months).

Additionally, there will be an NIHR contribution to Salford Royal for administration, contracting for the award and databases, for publicity and information materials for SICP staff and stakeholders (including support for a website for the SICP/CLASSIC project), and for PPI through the SICP PPI group, and the Citizen Scientist project.

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