Full Title	**Can group clinics offer a better way to meet the complex health and social care needs of young adults with diabetes in an ethnically diverse, socioeconomically deprived population?**
Short Title/Acronym	**Together Study**
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SIGNATURE PAGE

Chief Investigator Agreement

The clinical study as detailed within this research protocol **(Version 4, dated 8th April 2019)**, or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Chief Investigator Name: Dr Sarah Finer (except maternity leave, expected 1/5/19-1/12/19)

Chief Investigator Site: Blizard Institute, Queen Mary University of London

Signature and Date: 8th April 2019

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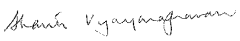
Chief Investigator Site: Barts Health NHS Trust

Signature and Date: 8th April 2019



Summary of Research

There is an urgent need for new care models to improve guidance and support to potentially vulnerable groups of people with diabetes including young adults. The current care model for this patient group relies heavily on one-to-one time with specialist services in primary and secondary care, necessitating Consultant-led multidisciplinary care and frequent hospital outpatient attendances. Group clinics offer an alternative way of delivering care which may be particularly suitable to young people living with diabetes. Participants of group clinics can learn from each other as well as from health professionals, and groups may be particularly effective for people with long-term conditions and when they address both health and social needs. This proposal outlines a participatory research project to design, implement and evaluate a new model of group clinic-based care. We hypothesise that this new care model could better meet the health and social care needs of young adults with diabetes, help them attain self-management goals in a developmentally appropriate way, and improve patient experience and clinical outcomes.

The aim of this project is to explore the scope, feasibility and potential scalability of group clinics for young adults with diabetes and complex health and social care needs. The design is intended to elucidate the mechanisms underlying the efficacy (or otherwise) of group clinics for these patients and contextualise these findings within current evidence for group clinics, existing service design and the need for redesign and improvement. This developmental project will also guide the future design of a scaled-up, definitive trial of group clinic-based care. As such, this project will contribute to potential redesign of NHS services to improve care for people with long-term conditions and wide health and social care needs.

The project incorporates five workstreams, each relating directly to one of five operational objectives:

- **Workstream 1: Scoping and realist review**, as a basis to define the scope of current practice using group clinics in diabetes care, the need to develop these further, and to understand the qualitative factors affecting 'process' and 'outcome' in existing studies.
- **Workstream 2: Co-design of a group clinic-based care model**, co-ordinated by voluntary sector partners with expertise in patient participation, and following established methods including Experience Based Co-Design.
- **Workstream 3: Implementation of the group clinic-based care model**, resulting in the delivery of a co-designed group clinic-based model of care to young adults with diabetes.
- **Workstream 4: Evaluation of the group clinic-based care model,** employing an innovative Researcher-in-Residence to conduct a rigorous test of how the group clinics work in practice, and to identify their active ingredients, mechanisms of action, enablers and constraints. The evaluation of these group clinics will follow qualitative methodology and will be guided by the findings of the initial realist review. Evaluation will also include a detailed analysis of how and to what extent our findings may be generalisable to other patients group and settings. Quantitative analysis will indicate the potential for group clinics to improve clinical outcomes and patient engagement and/or reduce care costs, by comparison of national audit data and benchmarking against other centres delivering care to young adults with diabetes. This analysis will inform the future design of a cluster-randomised clinical trial of group clinics for young people with diabetes to generate definitive quantitative clinical and health economic outcomes.
- **Workstream 5: Dissemination,** in order to share the findings with participants, user groups, local staff, the wider stakeholder group, the academic community and policy makers, strategic decision makers and funders.

The project will be managed in teams closely aligned to each workstream, and with an overarching project advisory group. In addition, patient and public involvement is central to the development, implementation, evaluation of and dissemination from of this project.

Background and Rationale – why this research is needed now

1. Current practice of diabetes care and who/what it fails to reach

This proposed research is important for people who have diabetes and for the NHS for a number of reasons. First, many young adults with diabetes report poor experience of transition from paediatric to adult care, dissatisfaction with the care they receive and poor engagement with self-management. These findings are reflected in low clinic attendance rates and poor outcomes compared to young adults in other EU countries, in contrast to the UK's good performance in diabetes care overall. Second, there is an urgent need for new care models that use resources more efficiently while ensuring that a high level of patient experience and clinical outcomes are maintained.

These challenges are particularly evident in ethnically diverse areas, such as the London Borough of Newham, where socioeconomic deprivation (Index of Multiple Deprivation 42.9) and high diabetes prevalence (9.4% compared to 4-7% nationally) lead to both increasing demand on services and disengagement among local service users. Traditional models of diabetes care, based on one-to-one clinic appointments with health professionals, do not meet the needs of these hard-to-reach populations consistently, most of whom are likely to see their medical care as only one issue in a complex pattern of health and social care priorities. Furthermore, the ability to self-manage long-term conditions is increasingly considered to be the optimal means to achieve good health outcomes but can lead to power struggles between patient and provider. There is a need to co-design and evaluate new care models which address diabetes care in the context of these wider needs, offer alternative support in attaining self-management goals and engagement with their health, and improve patient experience and clinical outcomes.

The focus on young adults living with diabetes reflects a key point in an individual's life course at which effective intervention has the potential to lead to major improvements in long-term health outcomes. Those who develop diabetes early in life have the highest risk of long-term complications, but, as with other long-term conditions, disengagement from health care services, poor disease control and avoidable complications increase rapidly during adolescence and early adult life. Adolescence and young adulthood represent an opportunity to promote better self-care and better engagement with services in ways that can potentially impact on lifelong health behaviours. Yet findings from the pilot work done at Newham with this age group suggests low engagement with the largely "medical" model of healthcare that does not address the wider concerns of young people. These young adults have frequently expressed their concern by saying "there is more to me than my diabetes" and the failure to address their wider needs has been seen to impact adversely on their health. It is hoped that participation of service users and staff members in the co-design of group clinics, will develop an innovative new model of care that addresses the concerns young adults have raised, meets their wider health and social needs, fosters self-management and sees a positive impact on service-level and clinic outcomes.

In targeting these individuals living with diabetes, we hope to develop a model of group-based care that can inform a more generic model of group-based care for people with long-term conditions tailored to their health and social care needs. This project will develop an innovative model of group-based care through co-design, and will extend the evidence base regarding feasibility, acceptability and mechanism of action of group clinics in long-term conditions. Following the realist review and national scoping work, this participatory approach will run in parallel alongside the iterative co-design work and qualitative evaluation, enabling us to examine both process and outcome and ask the question "what works, for whom and under what circumstances?". Furthermore, we anticipate being able to examine specific mechanisms by which groups work, including their ability to provide greater security for individuals, create norms, harness social conformity, use peer influence positively to change behaviour, facilitate experiential learning and provide social support in self-care and empowerment. It is also hoped that the participatory approach that includes both service users and staff, will facilitate the development of a group clinic model that maintains the integrity of individualised care plans, whilst also offering an innovative model that can meet the wider needs of patients and be sustainable in the NHS.

2. How could group clinics enhance the care of people with diabetes?

Group clinic-based care (also known as 'shared medical visits') for people with diabetes has been used and evaluated before in specific contexts. This work builds on a wealth of literature in diabetes showing the benefits of group-based education in models such as DAFNE and DESMOND (1,2). A study of Italian adults with diabetes who underwent group-based care focused on lifestyle intervention maintained better glycaemic control and were less time-consuming overall for their clinicians, compared to those receiving standard one-to-one care (3,4). This trial identified that group care requires "reallocation of tasks, roles, and resources and a change in providers' attitudes from the traditional prescriptive approach to a more empathic role of facilitator", highlighting the need for innovation away from standard models of care in the delivery of such an intervention. Group clinics have also been studied in other contexts, including in those care pathways, such as antenatal care, where service users have reported negative experiences of existing services. Group antenatal care that incorporates longer appointments (2 hours compared the 15 minutes in standard care) is a means by which an NHS service can offer a feasible means to increase the amount of time that a pregnant woman spends with a midwife and provide social support amongst group members (5,6). Continuity in the person(s) providing care has been found to be particularly beneficial for ethnic minority women, delivering enhanced communication and interpersonal rapport (7). Recent advances in neuroscience and psychology highlight that peer influences are likely to be particularly important for controlling risk behaviour and that this may have a significant

impact in adolescence and young adulthood (8). The development of group clinics have exploited the potential for peer support to improve health-related behaviour, for example in the successful introduction of a group clinic for young adults following renal transplant which led to a significant reduction in the incidence of graft loss (9).

Further trials applying group clinic-based care to diabetes and other conditions are underway, e.g. (10) but, to our knowledge, have not been designed with such extensive participation of service users, have not been designed to meet such a wide range of health and social care needs, and have not been evaluated extensively in young adults with diabetes. Furthermore, recent systematic reviews have found that group clinics often had a positive effect on clinical and patient-reported outcomes but did not elucidate the mechanisms by which group clinics worked in specific contexts (11,12).

3. How should group clinics be designed to best meet the needs of people with diabetes?

The NHS Long-Term Conditions Improvement programme seeks to support the transformation of care and quality of life for people living with long-term conditions such as diabetes. This programme of quality improvement builds on accumulating patient experience that suggests current care models do not adequately support individuals to take control of their health and work as part of a team with their care providers to achieve their desired outcomes and experiences (13). The concept of person-centred care is central to these quality improvement programmes and has been widely adopted by organisations designing, delivering and evaluating complex care models, such as the NHS, Health Foundation and Kings Fund. A number of different approaches to developing person-centred care have been proposed, including collaborative care models, personal health budgets, House of Care, and Experience-Based Co-Design (EBCD) (14). EBCD allows service users and staff to use their personal experience to redesign services that are reframed to within the perspective of patients. The co-design process has been successfully applied to the design of new services and evaluated against other service developments, identifying its ability to change both operational factors (e.g. efficiency) and interpersonal care dynamics (15). We therefore propose to use the EBCD model to design group clinics that meet the needs of people with diabetes, and fit within an overall organisational structure of these services. The use of EBCD in this study, and its methods, will be discussed in more detail later.

We anticipate that key factors determining the success of group clinics will include both logistical factors (e.g. ease of access to clinic venues, availability of high-quality staff training in group facilitation,) and personal factors (e.g. the experience of individuals within a group setting, variation in cultural and language differences, individual aims and objectives). EBCD offers an approach to examine, test, review and refine the new care model it designs; it is therefore hoped that the EBCD process itself will identify and address the key factors determining successful implementation and outcome of the group clinics.

4. How should group clinic-based care be evaluated, and by whom?

The co-design of new group clinic-based care models for young adults with diabetes in this proposal responds to the complex health and social issues that these groups face, and the need to expand the scope of current care models to address these needs. Evaluation of these new group clinic-based care models therefore needs to address their main aims, i.e. that the co-design process produces a care model that enhances patient experience (e.g. through qualitative measures) and patient engagement (e.g. through validated questionnaires and by measuring attendance rates). In evaluating a co-designed care model, it is important to recognise the process by which it was developed, and ideally, evaluation should also follow an approach that meets the needs of service users and stakeholders, e.g. through participatory research methods and through analysis of processes and mechanisms. Additional evaluation of group clinic-based care, focusing on clinical endpoints and health economic analysis, is important and can be initiated in this project to guide future scaled up definitive studies. Definitive studies of group clinic-based care will be most valuable and informative if they are performed downstream of early developmental studies and if there is clear progression between the two. For this reason, our evaluation of this proposed new group-based care model includes quantitative clinical and health economic analysis that will be used to inform the design of a subsequent rigorous and adequately powered comparison to standard care across a variety of settings in a cluster randomised controlled trial.

5. Background work by this research group

Our research and advisory group comprises a group of clinicians, academics, patient representatives and third sector organisations. Together, we provide expertise in diabetes care (including specialist care of young adults with diabetes), quality improvement, primary care, NHS commissioning, participatory research, qualitative and quantitative analysis and health economics. This application has evolved out of the research group's collective experience of working within the NHS and with its staff and service users, their awareness of the limitations of current models of care in long-term conditions, and the additional challenges faced by those working and living in the socioeconomically and ethnically diverse population in the London Borough of Newham. Newham has a population of approximately 250,000 that is relatively young (30% of its population are aged less than 20 years), and is the sixth-most deprived borough in England. Sixty-eight percent of the population of Newham is from non-White ethnic groups, the majority being of South Asian origin. These socio-demographic factors present specific challenges to the effective delivery of health care, and existing research and clinical expertise amongst the project team will facilitate the development of a new care model that can overcome these challenges. Comparison of clinical and care process outcomes obtained from a different specialist centre delivering care to young adults with diabetes, as well as national audit data, will enhance the generalisability of our findings to other settings within the UK.

Previous work by DH and RV has shown that mortality among young adults with diabetes in the UK is significantly worse than in other European countries and rose significantly between 1990 and 2010 (16). This is consistent with other data we have published showing that young adults report the worst NHS experience of any age group, and have distinct healthcare needs and priorities compared to other age groups. Work by members of this research team (SV, DH) has explored the potential for new care models and service innovation (e.g. Skype-based consultations, peer support via Diabetes Champions) to improve access to clinical care for young adults with diabetes, with promising initial results (now being evaluated tin the NIHR-funded VOCAL study, PI Trish Greenhalgh). Complementary work on the diabetes services for children and young people is also being undertaken by members of this group within the North Thames CLAHRC (AH, SV).

Members of the research team and advisory group are developing models of group-based clinical care in other settings: AH is designing and evaluating a group-based antenatal care model to address these barriers as part of an NIHR programme grant. Others (SF, TG, AC, GH) have explored the multiple cultural, practical and material experience constraints that are often in conflict with their experience of diabetes-related healthcare (17) and how story-sharing groups have harnessed the benefits of peer support in diabetes self-management (SV, AC, TG) (18).

Aims and objectives

Aims
To explore the scope, feasibility, impact and potential scalability of group clinics for young adults with diabetes and complex health and social care needs.

Strategic objective
To contribute to NHS service redesign to improve care for people from hard-to-reach groups with long-term conditions.

Operational objectives
- To perform a scoping exercise and realist review of the use of group clinics in diabetes care ***(workstream 1)***
- To use experience-based co-design to design a group clinic-based care model that meets the complex needs of young adults with diabetes within their socio-cultural context ***(workstream 2)***
- To implement the co-designed group clinic-based care model ***(workstream 3)***
- To conduct a comparative evaluation of the model against current standard care at Newham University Hospital, in order to elucidate patient and provider perceptions and mechanisms of action. To analyse and compare quantitative data on care processes, outcomes and costs from the new care model for young adults in Newham against national benchmark data (from the National Diabetes Audit) and against data from two other comparable local diabetes services (at Royal London and Whittington Hospitals). To use this quantitative analysis to guide the design of a future cluster-randomised clinical trial to determine clinical and health economic outcomes ***(workstream 4)***
- To disseminate the outcomes of our scoping and realist review, the co-designed new care model and its evaluation to service users and relevant stakeholders and generalise them to a wider context ***(workstream 5)***

Research Questions
- Could an innovative new group clinic-based care model meet the complex health and social needs of young people with diabetes? ***(workstream 1+2)***
- Could this new care model be a better way of promoting diabetes self-management than traditional care ***(workstreams 1+2)***? If so, what do the experiences of participants, the functioning of the group, and the wider context in which the new model takes place tell us about its active ingredients? ***(workstream 3+4)***
- What are the feasibility, acceptability, costs and impact on outcomes of introducing these group clinics for their users and stakeholders, and what is the organisational impact to the NHS and other stakeholders of this model? ***(workstreams 3,4+5)***
- What would be the optimal size and study design of a cluster-randomised controlled study to evaluate the clinical benefit and costs of offering group clinics to all young adults with diabetes? What other factors should be considered when planning such a RCT (e.g. factors relating to patient characteristics, existing models of service delivery, acceptability and mechanisms of actions of group clinics on clinical outcomes)? ***(workstreams 3,4+5)***

Anticipated outputs
- A realist review on the evidence of group clinics in diabetes.

- A co-designed group-based new model of care that meets the needs of young adults with diabetes.
- An enhanced understanding of the role of experience-based co-design in redesigning conventional NHS services to better meet the health and social care needs of specific hard-to-reach groups with long-term conditions.
- A better understanding of the role of participatory research in mobilising academic expertise more effectively
- A test of the generalisability of a co-designed new care model evaluated through participatory research methods to a wider context
- A platform on which to design a robust cluster-randomised controlled trial of group clinics to determine their clinical benefit and health economic impact on young adults with diabetes across wider settings.

Research Plan / Methods

Theoretical and conceptual framework

Development and evaluation of new models of healthcare are frequently hindered by lack of a robust, appropriate and explicit theoretical framework (19). Others emphasise that researchers must be clear whether their intervention is in the innovation, testing or scale-up phase, and use an evaluation strategy that is well aligned with the intent and maturity of the intervention (20).

This study spans the innovation stage (co-design of a new service model) and early testing stage (evaluation of the acceptability, feasibility, costs and mechanisms of action of group clinic models). In contrast to studies that start with a clear idea of the intervention and evaluate the impact of introducing this intervention, we do not yet know the optimal role of, or the best way to implement, group clinics, especially among these patient groups in this geographical context. The care model for young adults with diabetes we propose to develop in this project is relatively immature in its current description and will evolve during the course of our study. For these reasons our evaluation framework will focus largely on the developmental nature of this project and will use qualitative methods to best address our five research questions.

This developmental process and outcomes in this project will provide a platform with which to design a future cluster-randomised controlled trial that will be able to evaluate the impact of group clinics on clinical outcomes, care processes and service costs with rigour and confidence. To facilitate this longer-term objective, our current study will include, (i) relevant qualitative elements, e.g. which outcome measures are felt by patients, families and professionals to be the most appropriate for evaluation of group clinics for young adults with diabetes, and would cluster randomisation by health care provider be acceptable to potential research participants? and, (ii) quantitative elements, e.g. what are the feasibility and acceptability of collecting high-quality data on the proposed clinical, process and cost-related outcomes, and what sample size might be required? To guide future cluster randomisation, sample size calculation and choice of endpoints, this project will collect clinical, process and cost data from Newham University Hospital, where the study is based, as well as comparable external unit-level data (from the Whittington Hospital and the Royal London Hospital) and national level (National Diabetes Audit data).

Qualitative evaluation – general principles

As part of the mixed-methods approach introduced above, qualitative research methods will allow the research team to develop a better understanding of the context and mechanisms by which group clinics work. The chosen methods will provide rich data on the impact of participating in group clinics on patients' attitudes to managing their diabetes and interacting with health services, in the wider context of individual, family, employment and wider social factors. The proposed study focuses on some key theoretical and practical principles, which will enhance our understanding of the key factors leading to success/failure (active ingredients) in the co-designed model of care. The four key concepts of our qualitative evaluation will now be discussed:

(i) Co-design: Health services often have limited success in changing health-related behaviours unless they take into account the perspectives and priorities of their patients and the staff providing that service (15). This is particularly true of patient groups (e.g. those defined by age, ethnicity or deprivation) who are poorly served by standard care models and/or may be traditionally hard-to-reach. The Experience-Based Co-Design process (14) will weave patients and staff into every stage of the project, supported by experienced co-design facilitators, allowing direct collaboration with the team who are implementing the new, co-designed care models, with regular review and iteration. In this way, the co-design process will facilitate the development, review and refinement of user-centric services and care pathways. The co-design process will also integrate closely with a continuous thread of dissemination activities. Should this co-design process produce a new care model that is rated favourably by patients and providers, it may be important to consider that any downstream generalisation and scaling up should incorporate both co-design and implementation to deliver a customised group clinic-based service to other settings and/or patient groups.

(ii) Participatory research evaluation: In traditional health services research, the evaluator would typically operate independently of the intervention under study; a separation that acknowledges the different skills of researchers and practitioners and considers this to add to the objectivity of evaluation. Whilst this model is reasonable (notwithstanding a longstanding social science critique that objectivity is often overplayed and sometimes illusionary), the separation between researcher and practitioner fails to recognise the potential contribution of the researcher to implementation, and the practitioner to evaluation. Furthermore, this separation is often cited as an important contributing factor to the difficulties with mobilising research knowledge and the lack of impact of much health services research on practice (21).

These criticisms of traditional health services research have led to a growing interest in the use of participatory methodology that allow the expertise of researchers and practitioners to come together for the benefit of service users. Participatory research has a long track record in sectors outside health, in particular in education and community development. In the US and Canada the approach is commonly used in the health sector, resourced by major mainstream funding organisations; UK funders have been more reticent to embrace the approach.

The principles underpinning participatory research are well described (22): a focus on collaboration across a broad range of stakeholders; a motivation to solve practical problems; a focus on reflection, collective inquiry and shared learning; a strong emphasis on the importance of context; a willingness to find common ground through negotiation; and an orientation to agency and democracy. Many of the methods are the same as those used in research that does not adopt a participatory approach, e.g. in participatory qualitative research, individual and group interviews, observation and documentary analysis are used. Recent emphasis on the co-creation of knowledge has brought with it interactive methods to gaining shared insight, including creative design and visual ethnographic methods.

We have chosen to use a participatory approach because we think that these principles are closely aligned to the aims of this proposal. A participatory approach can bring about significant benefits to the development and evaluation of interventions such as ensuring cultural and practical relevance; building capacity amongst researchers, practitioners and service users to engage in productive conflict and negotiation; enhancing recruitment and retention; and creating system change and sustainability (23).

(iii) Using an embedded researcher: The 'Researcher in Residence' model, developed by UCLPartners and others across the UK, is a practical manifestation of a participatory approach to research and evaluation. The model has three defining features (24). First, the researcher is an integral member of the implementation team and, rather than working solely in an academic institution, spends much of their time in the front line of the service under study. Second, the researcher is explicit about the expertise that they bring to the team, a body of expertise that is different from, but complementary to, the expertise held by practitioners. This includes an understanding of the evidence base underpinning the intervention being developed and tested, an understanding of conceptual frameworks and theories relevant to the task in hand, expertise in rigorous though pragmatic evaluation and an ability to use systematic data to influence change. Third, and most importantly, the researcher is both able and willing to negotiate these bodies of expertise, rather than to state or even impose them. Essentially, they present science based knowledge in the context of the other ways of knowing that front line practitioners use on a daily basis – political pragmatism, personal experience, ideology and intuition.

The model is being applied successfully in a number of different settings: an anthropologist in an acute hospital, an operational researcher in a children's hospital, an organisational management researcher in general practice, a critical discourse social scientist in an integrated care programme and many others. This work has clarified that the most effective embedded researchers should be relatively senior and experienced because this contributes to their effectiveness in negotiating established evidence and new evaluation findings with senior stakeholders. They also need to have a high level of self-awareness, emotional intelligence and personal resilience. Whilst the specific model is relatively new and its merit and challenges are being explored, the principles underpinning it are well established and evidence suggests that it is both a reasonable solution to the 'rigour versus relevance' challenge and an appropriate methodology to achieve the aims of this project. The use of a researcher-in-residence in this project will offer an opportunity to incorporate an ethnographic analysis of the role itself, its ability to help deliver health services research, and the facilitators and barriers of that role within the institutional context of this research.

(iv) Elucidating key mechanisms of the impact of group clinics: We will use the key themes identified by young adults and in the co-design process to explore the factors and mechanisms by which the co-design and implementation of our group clinics are more/less successful, by considering the following themes and questions in the qualitative analysis:

- Does prior attendance at/engagement with clinical services affect the co-design process and success of the group clinic model, e.g. through differences in engagement, attendance, need for flexibility, frequency of appointments?
- How well are an individual's specific experience and needs addressed by group clinics, and do the self-perceived aims of individuals affect the chance of its success?
- Do differences in an individual's role within his/her wider social and cultural context, e.g. peer pressure, parental control, financial independence, influence the successes/limitations of group-based clinics amongst young adults?

- Does the duration, frequency and flexibility of appointments affect the qualitative outcomes and economic evaluation of the new care models and their ability to be scaled up into a commissioned service?
- Does the need for close integration with other health care providers, e.g. primary care, impact the feasibility and costs associated with delivering the new care model?

Quantitative evaluation – general principles

A range of quantitative data (clinical, process-driven and economic) will be collected and analysed as part of a mixed methods evaluation in this project. However, definitive evaluation of the impact of group clinics is not possible within this study for several reasons. First, the intervention is not yet sufficiently developed; the intervention will be co-designed at the beginning of the study period; it will then be refined and improved throughout the remainder of the study period. Second, the timescale of our study is not long enough to evaluate the full impact of new behaviours such as increased exercise, diet changes, clinic attendance. Third, our study focuses on in-depth analysis of a relatively small group of patients, so is not powered to detect a small/moderate effect of group clinics. For example, to show a statistically significant improvement in HbA1c results in the 214 patients attending the young adult clinic, the average HbA1c result would have to decrease from 68 to 57mmol/l for people with Type 2 diabetes, and 86 to 79mmol/l for those with Type 1 diabetes; we do not think is a realistic goal within the timeframe of this project. Lastly, there is uncertainty about the most appropriate outcome measures with which to evaluate impact (i.e. we do not know whether traditionally-used outcome measures for diabetes studies will be the most relevant for these populations and for the anticipated effects of this intervention).

With these limitations in mind, the quantitative analysis will instead focus on:
- Detailed, descriptive comparisons of clinical and service-based outcomes in Newham before/after the introduction of group clinics for young adults.
- Comparison of clinical and service-based outcomes (i) at unit level, between comparable services at Newham University Hospital, the Royal London Hospital and the Whittington Hospital, and (ii) at national level, using National Diabetes Audit data to understand heterogeneity and generalisability.
- Assessing the feasibility of collecting clinical, process and cost data at patient- and unit-level to enable the design of a future cluster randomised controlled trial.
- Estimating the resources and associated costs of implementing group clinics, including comparison to external unit-level costs.
- Describing use of other process variables, e.g. clinic attendance rates, to gauge the extent of substitution of old with new model of care, and thus the potential for efficiency savings for the NHS.

Together, these data will provide an early indication of the potential advantages to patients and the NHS from group clinic models; importantly, they will also inform the future design of a definitive evaluation of a group clinic models in a cluster-randomised controlled trial.

Research plan

The plan of research incorporates 5 workstreams, each relating directly to one of five operational objectives. These will be discussed as follows:

Workstream		Operational objective
1	Evidence synthesis and scoping	To perform a scoping exercise and realist review of group clinics and their use in diabetes care.
2	Co-design of a group clinic-based care model	To use experience-based co-design to design a group clinic-based care model that meets the complex needs of young adults with diabetes within their socio-cultural context
3	Implementation of the group clinic-based care model.	Implement the co-designed group clinic-based new care model
4	Evaluation of the group clinic-based care model	To conduct a comparative evaluation of the model against standard existing care to elucidate patient and provider perceptions and mechanisms of action. To analyse the potential for group clinics to improve clinical and service-level outcomes, patient engagement and/or reduce care costs, in order to inform the design of definitive future studies (workstream 4)
5	Dissemination	To disseminate the outcome(s) of our scoping and systematic review, the co-designed new care model and its evaluation to service users and relevant stakeholders and generalise our findings to a wider context

Workstream 1: Evidence synthesis and scoping

Operational objective: *To perform a scoping exercise and realist review of group clinics and their use in diabetes care*

Timescale: Q1-Q2

Methodological approach:
- Realist review of evidence for group clinics in diabetes and other long-term conditions.
- Scoping exercise of the current/potential use of group clinics in diabetes.
- Formative evaluation and mapping of existing local services for young adults with diabetes at Newham University Hospital

Settings: Local to national
Participants: All relevant stakeholders

(i) Realist review (not included in HRA/REC submission)
A realist review undertaken using the RAMESES methodological standards (25). This review will set the scene for the co-design process of the new care model, enabling us to investigate "what works for whom under what circumstances?" using existing qualitative and descriptive elements of primary studies (and linked sister papers). The findings of the realist review will allow us to tailor the qualitative and participatory evaluation of the new card model.

(ii) Scoping exercise (not included in HRA/REC submission)

A survey-based national scoping exercise will be performed using an online questionnaire tool (SurveyMonkey). We will identify key stakeholders and staff involved in delivering care to people with diabetes and investigate current and potential use, perceptions and opinions of group clinics in diabetes. We will also identify patient groups, voluntary groups, support groups, representatives and individual patients to contribute to the scoping exercise and will investigate the same. We will also apply our scoping exercise to policy-making groups and commissioners to investigate the current and potential application of group clinics to large-scale care models and service provision. Diabetes UK has agreed to support this scoping exercise via its wide communication channels (patients and stakeholders) and we would also promote this exercise through social media, email and other connections

The results of our scoping exercise will contextualise the results of our realist review, inform the co-design process and facilitate future generalisation and scaling up of the new care model. We anticipate that the scoping exercise, and the networks of communication built as part of it, will also facilitate effective dissemination of results of the group-based intervention by identifying interested groups and settings for dissemination activities.

(iii) Formative evaluation
We will perform a formative evaluation and mapping of existing local services for young adults with diabetes at Newham University Hospital e.g. number of new/existing patients per year, appointment frequency, attendance rates, questionnaire-based assessment of experience and acceptability, service-level and patient-centred outcomes, numbers of patients with type 1 vs. type 2 diabetes and number of patients using continuous subcutaneous insulin infusion (pump) therapy and uptake of structured education. This process will allow us to contextualise the co-design process and implementation of the group-based intervention.

The formative evaluation will occur at 3 units delivering diabetes care to young adults:
- Newham University Hospital: where the proposed project is centred and the co-designed new care model of group clinics for young adults with diabetes will take place
- Whittington Hospital NHS Trust: a comparison unit delivering diabetes care to young adults, in a clinic led by Dr Maria Barnard, Consultant Diabetologist
- Royal London Hospital: a comparison unit delivering diabetes care to young adults, in a clinic led by Professor Graham Hitman

Delivery: The researcher-in-residence will have a central role, supported by other members of the research team, in the realist review, survey and mapping exercise, in particular ensuring that the voice of service partners influences these scoping activities. At this stage, draft logic models and associated theories of change will be prepared.

Process: as above

Anticipated outputs:
- Publication of a realist review of the evidence for group clinics in diabetes in a peer-reviewed journal
- Results of national scoping exercise and formative evaluation of local services to feed into Workstreams 2 and 5 (co-design and dissemination)

Workstream 2: Co-design of a group clinic-based care model

Operational objective: *To use experience-based co-design to design a group clinic-based care model that meets the complex needs of young adults with diabetes within their socio-cultural context*

Timescale: Q2-3, Q6-7

Methodological approach: The involvement of service users and staff in the co-design of all stages of this project is essential for ensuring that the new group clinic-based care model meets the needs of its users and that its implementation within existing care pathways is feasible. Early involvement of service users and staff in the design of new services ensures that the outcomes from it are more likely to meet the needs of patients and increases the likelihood that it will succeed. The formal process behind this early service user and staff involvement, 'Co-design' contributes to building the support and confidence of staff, patients and the wider public and has been shown to make research more relevant and more widely disseminated (26). Methods for co-designing clinical services vary, but we propose to use the Experience-Based Co-Design model (14) with adaptations for our specific client group (young adults with diabetes). EBCD draws together qualitative experiences of patients and staff, via in-depth interviewing, observations and group discussion; staff and patients then work together to identify the priorities for service development. The EBCD process is iterative, allowing ongoing redesign and adaptation throughout the process of implementing the new service. Whilst the group clinics that are designed through EBCD will have a bespoke design, tailored to their participants and setting in Newham, the process of co-design and implementation of group clinic-based diabetes care arising from it will be will be generalisable to wider contexts and patient groups.

Setting: Community-based facilities in the London Borough of Newham, a deprived, ethnically diverse population with a high prevalence of long-term conditions and reduced life expectancy compared to UK averages.

Participants: Young adults with diabetes, staff and relevant stakeholders (n=15-20)

Delivery: The co-design element of our group clinic intervention will be coordinated by the Association of Young Peoples' Health, whose staff have experience of these processes as well as of working with service users (patients and their families) and staff members involved in delivering their care. The researcher-in-residence will embed academic expertise within the process of intervention design and, with the support of the project steering group, will guide the interaction between co-design and qualitative evaluation of the implemented group clinics. The embedded researcher will participate in all of the EBCD meetings and use results of the scoping exercise and systematic review in workstream 1 to consolidate the evolving co-designed model within relevant conceptual frameworks and theories. In doing so, the embedded researcher will negotiate the evidence, needs and requirements of the new care model and facilitate a consensus view about the most appropriate intervention design.

The co-design process will have two concentrated phases, an initial phase of co-design 'from scratch' during Q2+3, and a second 'revision' phase during Q6+7. The co-design revision phase will occur after the new care model for young people with diabetes have been implemented and will involve the patient and staff members involved in the initial co-design process, as well as new members. All co-design will be facilitated by AYPH, with close input from the researcher-in-residence and supervision from the project steering group.

The project steering group will provide regular supervision of the entire co-design process, its interaction with the planned evaluation (workstream 4) and dissemination activities (workstream 5). Service users and staff involved in the EBCD process will be encouraged to become involved in dissemination activities.

Process: See Gantt chart.

Anticipated output:

- Co-designed new model of group-based care for young adults with diabetes.

Workstream 3: Implementation of the group clinic-based care model

Operational objective: *Implement the co-designed group clinic-based care model*

Timescale: Q3-10

Methodological approach: Co-designed group clinics will be implemented following the process outlined in Workstream 2. Implementation of the new model of care for young adults with diabetes will have a strong focus on quality improvement based on knowledge of background evidence (workstream 1), and an inclusive approach to services design using EBCD (workstream 2). A second phase co-design process 'Revised implementation: co-design' will inform iterative revisions to the new care model during its implementation.

Setting: we anticipate that group clinics will take place in a range of settings, with onsite childcare available, determined by the co-design process, including community-based health centres, (e.g. Ludwig Guttman Centre), Newham Town Hall, Food Academy, Active Newham, and Newham University Hospital.

Participants: young adults with diabetes (group clinic participants, n=80-100)

Group structure

- Groups will comprise 8-12 individuals
- Rolling structure
- Daytime and evening clinics

Delivery

- The implementation team, led by SF, will comprise a project manager and key clinical staff trained in delivering diabetes care to young adults (e.g. a diabetes specialist nurse, psychologist and dietician). Clinical staff delivering group clinics will be joined by external partners from Food Academy, Active Newham, and other groups identified to meet the needs of patients, as identified in co-design. Those delivering diabetes care to the groups will be offered training in group facilitation, where necessary. Local training programmes in group facilitation for clinical staff exist already, e.g. a successful programme for midwives to deliver group-based clinics for routine antenatal care (via the NIHR-funded REACH project, PI Angela Harden).
- The researcher-in-residence will be an integral part of the implementation team. The potential for a gap to exist between design intent and practical implementation is well recognised in clinical research studies and the researcher-in-residence will bridge that gap, holding up a mirror to the implementation team to reflect where implementation falls short of intent and to surface any compromises that might need to be made.
- Other general considerations: Supervision of group clinics will maintain patients' individualised care plans. Safety parameters will be set and any deviation from that expected in standard care will trigger appropriate intervention.

Proposed care models for young adults with diabetes: delivery of clinical care for young adults with diabetes at Newham is led by Dr Shanti Vijayaraghavan (a co-applicant) and a close-knit clinical team including specialist diabetes nurses, dieticians and psychologists. This group have a proven track record of quality improvement and service redesign, e.g. in introducing and evaluating Skype-based clinical consultations (the NIHR-funded VOCAL project, PI Shanti Vijayaraghavan).

The content of group clinics will be determined by the co-design process, but it is anticipated that it will cover aspects of their clinical care (e.g. blood glucose self-monitoring and control, sick day rules, diabetes complications, how to manage diabetes around an unpredictable lifestyle, promotion of healthy diet and active lifestyle) and social needs (e.g. finding a job, the impact of diabetes on entitlement to benefits, improving resilience and learning stress-management skills).

Similarly, the relative number of group clinic and individual appointments will be decided during the co-design process. However, we present two possible models below, in order to illustrate the potential for group clinics to be offered in addition to, or as partial substitution for, the current model of care at Newham University Hospital.

- CURRENT model: Standard care for young adults with diabetes at Newham includes 4-monthly clinic visits.

- ADDITION model: Implementation of the co-designed group clinics for young people with diabetes who have consented to join this research project could replace the 'CURRENT' clinical model with an 'ADDITION' model that combines current clinical care with additional group clinic care from the co-designed model; up to 5 additional group clinics will be offered.

- SUBSTITUTION model: following implementation and iterative revision of the co-designed model, and according to its success, the ADDITION model could be replaced by a SUBSTITUTION model. The SUBSTITUTION model is anticipated to deliver some existing elements of current care (e.g. one-to-one clinical consultations at 0 and 12 months) but will replace other planned clinical contacts with the co-designed group clinics, resulting in a care pathway that offers no other routine clinical contacts and replaces the current one-to-one clinical contacts at 4 and 8 months with group-based clinics. It is anticipated that 4 cohorts of group clinics will run, but this will depend on recruitment rates.

Anticipated Output

- Implementation of co-designed group clinics young adults with diabetes
- Transition from CURRENT care to an ADDITION model in which group clinics are additional to existing care.
- Transition of the ADDITION model to a SUBSTITUTION phase where the new care model replaces existing care

Workstream 4: Evaluation of the group clinic-based care model

Operational objective: *To conduct a comparative evaluation of the model against standard care to elucidate patient and provider perceptions and mechanisms of action. To perform preliminary analysis on the potential for group clinics to improve clinical outcomes and patient engagement and/or reduce care costs, in order to inform the design of definitive future studies (workstream 4)*

Timescale: Q3-Q11

Setting: evaluation of group clinics will be embedded in their delivery and via collection of clinical data

Participants: those delivering and receiving care in group clinics (group clinic participants, n=80-100) and in standard care control data participants, n=60)

(i) Qualitative evaluation

Methodological approach: the researcher-in-residence will conduct a rigorous evaluation of how the group clinics work in practice, identifying their active ingredients, mechanisms of action, enablers and constraints. They will evaluate the experience of the patients using the new service and the staff providing it, using a selective case study methodology. Comparative case studies in traditional services will allow the relative merits of the new service to be better understood, given the established evidence that improvement interventions are more successful when practitioners can see a relative advantage over current practice (27). The embedded researcher will bridge the qualitative evaluation and the economic/quantitative evaluations, helping to feed practitioner views into the design and conduct of these evaluations and to feedback early findings to other stakeholders. At all times, the researcher will adopt a process-oriented and formative approach to the evaluation, negotiating the analysis and interpretation of the emerging evidence and maximising the impact of the interventions.

Data collection: Data will be collected through individual and group interviews with service users and group facilitators; observations of a sample of group clinics and standard care; and documents produced during co-design sessions, steering group meetings, group clinics and the daily lives of participants, including photos and other visual representations (e.g. diagrams, drawings). Data collection proformas and prompts will be informed by our research questions, draft logic models and hypotheses about active ingredients and mechanisms of change (e.g. peer support, vicarious learning, going beyond health needs to tackle wider social determinants). The data collected via interviews in the co-design phase will be combined with the evaluation data as appropriate.

- Individual and group interviews: Interviews will be conducted with a sample of service users including those who drop out of the groups and those who receive standard care. Sample size will be determined by data saturation and is expected to comprise between 20 and 30 participants. Purposive sampling will ensure variation in salient characteristics including type of diabetes, type of clinic attended, ethnicity and language. Group interviews will be conducted with all group clinic facilitators and practitioners delivering standard care. Photos will be used to stimulate discussion and co-creation of data. Interviews will be audio-recorded and transcribed. Bi-lingual health advocates and research assistants will be used for those who do not speak English or for those who feel more comfortable speaking in their first language.

- Observations of group clinics: All group clinics will be observed using a flexible proforma to aid capture of clinic characteristics such as session content, context, group dynamics, and facilitation style. A sample of standard care consultations will be observed as a point of comparison of content and interaction between patient and clinician.
- Documents: All documentation produced during co-design sessions, steering group meetings and group clinics will be collected for analysis. Service users and group facilitators will also be asked to document their experiences inside and outside of clinics using cameras and/or reflective journals.

Data analysis: this will be conducted in three main stages (with some iteration between the stages):

- All data will be analysed thematically using a process of open coding. An initial list of codes will be generated a priori based on findings from the co-design stage, our research questions (e.g. acceptability, feasibility) and hypotheses around active ingredients (e.g. peer support). Codes will be added to this initial list inductively as necessary. Memo writing alongside the coding process will lead to the generation of higher level codes and categories to capture patterns and connections in the data. Analysis will be supported by the use of NVivo (v9).
- Using principles of realist evaluation, the embedded researcher will begin to build and test context (first group clinic for young adults) mechanism (group facilitator creates open and friendly atmosphere) and outcome (e.g. acceptability) configurations to address the question of how group clinics work and comparison to standard care. These configurations will also be the mechanism for combining the qualitative data with the quantitative data.
- The researcher will feedback the emerging analysis to Co-I's MM and TG and to the wider advisory group for sense checking. In this way the analysis will be co-created with practitioners and service users. The rigour of the analysis will also be enhanced by checking for negative cases which challenge emerging interpretations of the data.
- We will incorporate ethnographic analysis of the researcher-in-residence role itself, its ability to help deliver health services research, and the facilitators and barriers of that role within the institutional context of this research

(ii) Quantitative evaluation

Methodological approach: The detailed qualitative evaluation of the new care model will be complemented by a quantitative evaluation, which will investigate the potential impact of group clinics on clinical outcomes, processes and costs. This will include analysis of biological markers of diabetes control, routinely-collected activity and process data, and completion of the Patient Enablement Instrument (PEI) and the Problem Areas in Diabetes (PAID) questionnaire. of engagement and self-management. In addition, we will investigate the feasibility of conducting a future cluster randomised controlled trial of the impact of group clinics for young adults with diabetes, including an assessment of which outcome measures are most appropriate for evaluating impact, and what sample size might be needed.

Data collection: the principle clinical outcome measures will reflect:

- Biological markers of diabetes control and complications: we will use markers of control and complications that are also benchmarked as key care processes in the National Diabetes Audit (run by the HSCIC). These are: HbA1C (a measure of glycaemia), blood pressure, serum cholesterol, creatinine, albuminuria, foot surveillance, body mass index, smoking. We will also analyse data on retinal screening if this is included in future national audits. These data will also be collected from, (a) individuals recruited as 'control data participants' (n=60) at external units running young adult diabetes clinics, at the Whittington Hospital NHS Trust, and Barts Health NHS Trust (including Royal London, Mile End, Barts and Whipps Cross Hospitals), and (b) national level data from the HSCIC National Diabetes Audit in an age-matched group.

- Routinely-collected data on outpatient hospital activity: The principal measure for both will be Did Not Attend (DNA) rates in outpatient clinic. (currently 28% at Newham University Hospital). It is important to note that attendance at consultant-led, hospital clinics is often seen as a key measure of patient engagement, but its role in evaluating group clinic deserves further investigation. It may be that attendance at group clinics is perceived by both patients and professionals as a reason to decrease the frequency of clinic attendance. So the quantitative analysis of DNA rates for hospital clinics must be interpreted alongside attendance rates at group clinics and the qualitative findings about the optimal role of group clinics for different patients. Another caveat is that the relationship between DNA rates and clinical outcomes may vary when the frequency of hospital clinic appointment visits changes, e.g. reduce from 6 monthly clinics to annual review. As noted above, preliminary quantitative findings will be discussed and the value of each measure will be explored by the qualitative research team in their evaluation. These data will also be collected for unit-level comparison from the young adult diabetes clinics at the Whittington Hospital NHS Trust, and Barts Health NHS Trust (including Royal London, Mile End, Barts and Whipps Cross Hospitals).

- Indirect markers of clinical outcome: data on unplanned hospital admissions and GP attendance frequency related to diabetes in the target group will be collected as part of a costing analysis of resource use.

- Resource use: resource inputs associated with the implementation of group clinics will be recorded on specifically designed staff- and researcher-completed logs. We will measure all relevant staff contact and non-contact time e.g. for delivery of and participation in staff training, group clinic delivery to patients and time take for other associated activities such as note writing. We will also record patient attendance rates at the level of groups and patients. Given the potential complexity of this data collection, we will seek feedback on the design of the logs from a sample of those who will be expected to complete them, provide accompanying written guidance for reference (and training where feasible) on their completion and check completeness and quality of data on an ongoing basis. Broader resource us data related to use of other core services will be extracted from patient records.

Data analysis: there will be two types of quantitative analysis of clinical outcomes and patient activation:

- Intention to treat: simple descriptive statistics will be used to compare clinical outcomes among young adults with diabetes attending the group clinics with controls from the same clinic over the previous year.
- Comparison of baseline characteristics, clinical outcomes and patient activation among patients who receive the intervention (n=80-100) with control data participants (n=60). The first stage of this process will complement the qualitative findings into which patients are most attracted by the idea of group clinics. We will compare baseline socio-demographic and clinical characteristics of those who accept versus those who decline the opportunity to participate in group clinics. We will then use longitudinal data to compare the trajectories of clinical and activation measures over the following year for individuals in the accept vs. decline groups (difference in difference analysis).
- Comparison to external individual (control data participants) and unit-level data using clinical outcome (and indirect clinical outcome) data collected from young adult diabetes clinics at the Whittington Hospital NHS Trust and Royal London Hospitals. This data analysis will inform a future scaled-up cluster-randomised controlled trial of group clinics by (i) testing the feasibility of unit-level data collection, (ii) identifying differences in the case mix of patients attending young adult diabetes clinics, (iii) characterising the clinical and process outcomes of young adults with diabetes under the care of different units.
- Comparison to national clinical outcome and process benchmark data in an age-matched population from the National Diabetes Audit.

(iii) Costs analysis

We will apply national unit costs to all resource use to estimate relevant staffing capital and running costs related to running the standard vs. group clinics at Newham University Hospital. We will then fully describe resource inputs and costs associated with delivering group clinics (e.g. venue, consultancy and staffing costs) and the impact on use and costs of other core services. Data will be presented in both aggregated and disaggregated form, and for different scenarios e.g. group clinic costs according to variations in attendance rates. Using the comparative approach described above for each patient group, we will assess the impact on use of other services and associated costs, and thus the extent to which the group clinic model substitutes for, rather than adds to, standard care. This in turn will provide an early indication of any potential for efficiency savings for the NHS.

Delivery

Qualitative and quantitative evaluation and analysis of costs will be performed by a research team, independent and external to the implementation team, which includes specific expertise in quantitative evaluation of clinical and economic outcomes in diabetes trials, as well as broad experience evaluating studies into other long-term conditions and the health economic impact of new models of care. The research team will also be supported by the Institute of Child Health Statistical Support Service, who will advise on, and quality assure all stages of the quantitative evaluation including study design, analysis and use of study data to inform a future cluster-randomised controlled trial.

Anticipated outputs

- An understanding of the acceptability and feasibility of the group clinic models
- Theories of changes and associated logic models that identify key mechanisms, active ingredients, and potential generalisability.
- Preliminary data on the potential impact of the group model and identification of parameters to include in future larger scale evaluation.
- An understanding of the heterogeneity of different clinics providing diabetes care to young adults and how to incorporate this in the subsequent design of a cluster randomised controlled trial.

Workstream 5: Dissemination

Operational objective: *To disseminate the outcome(s) of our scoping and realist review, the co-designed new care model and its evaluation to service users and relevant stakeholders and generalise our findings to a wider context*

Timescale: Dissemination activities will be arranged at regular time points throughout the project from Q4 onwards. Dissemination events are likely to occur every 4-6 months throughout the duration of the project, but will be guided by the project steering committee and PPI groups. There will be a concentrated phase of dissemination in Q11+12.

Methdological approach, setting, participants: this will be discussed in the following section.

Delivery: The researcher-in-residence researcher will be responsible for disseminating both provisional and substantive learning within the wider stakeholder group of the project throughout the formative evaluation. They will also contribute to all elements of the dissemination of the final project results.

Anticipated outputs:

- We will write regular reports summarising our research activity and outputs, and these will be available via publicly-accessible portals, e.g. institutional websites.
- We anticipate publishing academic papers in peer-reviewed, open access journals. These publications will describe the process of co-designing and implementing group clinics for these populations, present our findings about the potential for group clinics to improve clinical outcomes and patient engagement and/or reduce costs, and discuss the implications and transferability of our findings for other services and populations.

Dissemination and projected outputs

The aims of dissemination for this project include:

- Sharing findings with participants, user groups and local staff
- Informing the wider stakeholder community (including clinical networks) of the main outcomes
- Sharing findings with the academic community
- Communicating main messages to policy makers, strategic decision makers and funders.

The products needed to achieve these aims will be very varied. We will prepare user-friendly versions of the main findings, briefing statements, summaries and academic papers, tailored for at a range of different audiences. Some will be local (e.g., Newham centred, and wider pan-London), others national (e.g., Department of Health, NHSE etc), and potentially international (eg, Society for Adolescent Health and Medicine). Academic outputs will include journal articles in, for example, Diabetic Medicine, the NIHR HS+DR journal, and national and international conference presentations. We will use a dedicated project page on the Association for Young People's Health website, set up a project Facebook page and Twitter account.

Dissemination will be an ongoing process throughout the project, including activity at the outset to raise awareness of the project, at the mid-point to keep interest engaged and to feed back to participants, and at the end and beyond to share the main messages. It is anticipated that regular dissemination events will be scheduled, approximately every 4-6 months during the project, and will culminate in final dissemination events in Q36. The team has a wide range of connections that we will draw on for dissemination, covering statutory, voluntary and patient sectors. These include:

Local London-based and Newham networks

- Institution-based: QMUL, UCL, UCLP, University of East London, Barts Health NHS Trust, Newham CCG, Newham Borough Council.
- Newham CCG have agreed to support dissemination activities, via their Patient and Public Engagement Officer, Sabeena Subba, and their existing network of Diabetes Champions and community neighbourhoods. Their Diabetes champions include individuals who have particular interest in supporting young adults with diabetes. Sabeena Subba has said "it is a great opportunity to get the community involved in an important redesign programme", and we intend to establish their involvement in formal PPI activities, e.g. co-design, as well as implementation and evaluation and dissemination at each stage. We will also invite patient representatives to join our project steering group
- Local Transforming Services Together programme - we will regularly update this commissioning group which is signed up to by 4 inner London CCGs and has prioritised young adults.
- NHS England London Region Children and Young People's Programme: Members of the group are represented on the clinical leadership group for children and young people, which has a diabetes program, offering opportunities for dissemination across the London borough.
- Improvement Science London (led by MM) will share results across wider academic partnerships and cross-sector groups e.g. NHS England, Greater London Authority

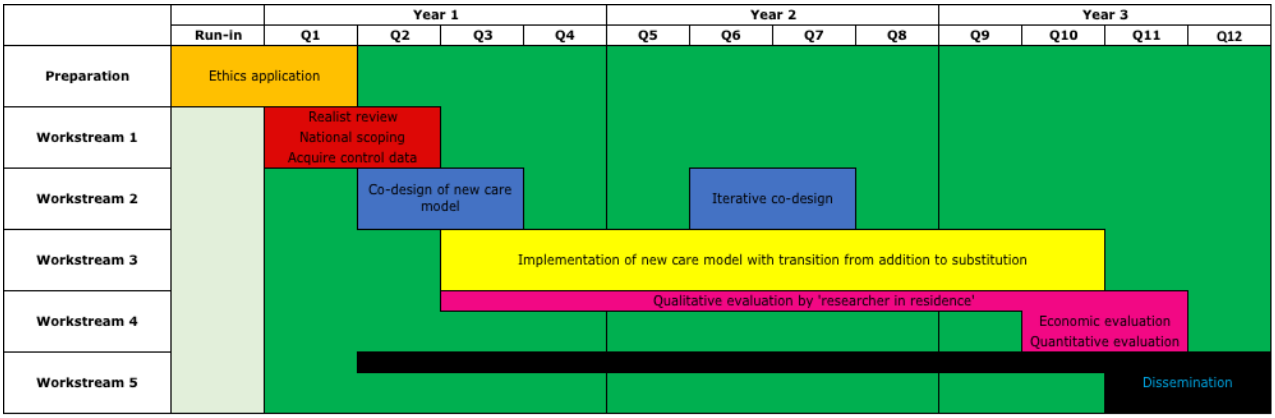
Clinical and patient networks

- Diabetes UK have agreed to support our national scoping exercise and Richard Elliot, their Research Communications Manager, has said that they will "support our study for inclusion in Diabetes UK communications", allowing us to reach all patient and professional members.
- NIHR Clinical Research Networks (N.Thames); if funded, we look forward to the study being adopted to the CRN portfolio adopted and plan to use their existing structures to disseminate output to their members and lay committees. SF has already presented the proposal to the diabetes lay panel. We anticipate presenting our work to the North Thames CLAHRC and engaging this proposal in their applied health portfolio and we have received a positive response to this from Professor Rosalind Raine (Director of the CLAHRC).

Strategic and national networks

- National Children and Young Adult Working groups chaired by the National Leads for Children and Teenagers and Young Adults; members of the team are represented and will report to them regularly on the project. Royal Colleges: Members of the team sit on special interest groups relevant to the project at the following colleges: Royal Colleges of Paediatrics & Child Health, of General Practice and of Physicians.
- National policy forums: AYPH, DH and RV will engage the Children and Young People's Outcomes Forum, Voluntary Sector Health, Social Care Strategic Partnership and Child & Maternal Health Intelligence Network

Plan of investigation and timetable



Project team	WTE	Expected commitment to project	Funding Duration
Sarah Finer	20%		3 years funding
Dougal Hargreaves	10%		
Trish Greenhalgh	5%		
Martin Marshall	5%		
Project Manager	60%		
Researcher-in-residence	50%		
Ann Hagell	20%		2 years funding
Research nurse	40%		
Anne Claydon	0%		
Shanti Vijayaraghavan	2%		
Anita Patel	2%		1 year funding
Russell Viner	2%		
Natalia Hounsome	10%		
Barts Health Manager	5%		

Project management

1. Project leadership:

Sarah Finer: Co-Principal Investigator and Chief Investigator
Dougal Hargreaves: Co-Principal Investigator
Shanti Vijayaraghavan: Chief Investigator (to cover Dr Finer's maternity leave, expected 1st May 2019 to 1st December 2019)
Trish Greenhalgh: Co-Principal Investigator (to cover Dr Finer's maternity leave, expected 1st May 2019 to 1st December 2019)

2. Evidence synthesis and scoping team:

This team will focus on the activities in workstream 1, i.e. scoping and realist review
Led by SF. Includes TG, project manager, researcher-in-residence

3. Co-design and PPI team:

This team will focus on the activities in workstreams 2 and 5 and will integrate closely with the implementation team. In the early phases of the study, this team will focus their input into the scoping and co-design processes and, as they proceed, into the refinement of the co-designed clinical model and dissemination of its output for an early stage. As the new care model develops, this team will also be involved in regular dissemination of the evaluative stages of the project. This team and its members are likely to evolve and change during the length of the project, but will have an over-arching structure to facilitate continuous PPI and dissemination adapted to the stage of the project
Led by AHagell. Includes SF, DH, project manager, researcher-in-residence.

4. Implementation team:

The implementation team will run workstream 3 and will include the academic and clinical teams responsible for delivering the new care model. They will integrate closely with the existing clinical teams delivering clinical care to young adults with diabetes, facilitated by SV who runs this clinical services at Newham already. The implementation team will also integrate closely with the co-design team and the PPI and dissemination team to optimise the delivery of the intervention.
Led by SF. Includes SF, SV, AMMV, AC, diabetes clinical team, project manager, researcher-in-residence.

Please note that our CCG Diabetes Commissioning lead, Anne-Marie Maher-Vyas has agreed to be a Co-Investigator but is currently on maternity leave and unable to submit her online acceptance.

5. Evaluation team:
This team will run workstream 4 and will include an independent team of researchers who have not been directly involved in the co-design and implementation of the new care model. This team will integrate with the co-design and implementation workstreams via the researcher-in-residence and the project steering group.
Led by DH. Includes TG, MM, RV, AP, project manager, researcher-in-residence, Institute of Child Health Statistical Support Service.

6. Project management:
Clear definition of the teams above will allow smooth and efficient project management of a large and geographically-divided research team. Each team will have regular (fortnightly) meetings, and teams will join together every 2 months to provide oversight and ensure that each team is operating and delivering appropriately. Meetings will take place using a combination of skype and face-to-face meetings, minimising the impact of any geographical separation. The researcher-in-residence, whilst officially employed at the University of Oxford, has been chosen as someone that is able to travel regularly to, and work at, Newham University Hospital with appropriate honorary contracts at Barts Health NHS Trust and QMUL. Travel expenses have been costed into the proposed budget.

6. Project advisory group:
The project advisory group will have a crucial role in supporting and supervising the project from its inception to its close. They will help the 5 workstreams to integrate, e.g. in adapting the evaluation to the co-designed model as it evolves, and will ensure appropriate dissemination activities. The project advisory group will also be involved in drawing the project to a close and directing future activities (e.g. the proposed cluster-randomised controlled trial) according to its results. The project advisory group will also be responsible for the financial oversight of the project, according to the directions set out by NIHR should the project be funded.

Includes: SF (QMUL), DH (UCL), SV (Barts Health), MM (UCL), AHagell (AYPH), TG (external), project manager. Additional members of the project advisory group that have agreed to join, should the project be funded are: a representative from the local community-based organisation Social Action for Health; Prof. Angela Harden, University of East London; Prof Graham Hitman, QMUL; a Patient Champion from the young adult clinic with experience of research involvement via the VOCAL project; Carlos Montes, Director, Food Academy; Dr Maria Barnard, Consultant Diabetologist, Whittington Hospital. The advisory group will have a lay chair and will be coordinated by the project manager, under supervision by TG and SF.

7. Mentoring
Both SF and DH are relatively junior in their research careers and the management of large programmes of research. They will therefore receive formal mentorship from senior clinical academics involved in the project. SF is mentored by GH and TG (via the Academy of Medical Sciences), and DH will be mentored by RV. Between them, SF and DH have worked with all other co-investigators before, either as clinical or academic colleagues, and have themselves worked together in a clinical environment for a number of years. TG will act as lead mentor with oversight and responsibility for the whole project; she will also supervise convening of the project advisory group.

Approval by ethics committees

If this application is successful, we will submit a full request for ethical approval to the City and East London Research Ethics Committee. Following advice that we will receive a final funding decision we would plan to start the ethics application process in June 2016 and aim for this process to be near completion by the start date of the project on 1st September 2016 (see Gantt chart for full project timetable).

A wide range of ethical issues will be addressed in the ethics application, including (but not limited to) the following:

- Participants in the PPI process must give full, informed consent to participating and know that they are free to withdraw this consent at any time without it affecting their clinical care. They will also be reimbursed for their time, following INVOLVE guidance.
- Similarly, patients will give full, informed consent to participating in the group clinics.
- The project advisory group will regularly review qualitative and quantitative findings to assess whether there is any evidence that group clinics may cause harm to patients. This harm could be at group level (on average, the experience or outcomes of patients attending group clinics deteriorated) or individual level (some patients may find the experience of group clinics unpleasant or harmful).
- Particular attention will be paid to patients in the substitution model, where some aspects of usual care are replaced by the new care model, and to potentially vulnerable patient groups. We hope that the use of bilingual

health advocates will facilitate participation of patients where a language barrier exists, and we will monitor progress and barriers. Although our study will not include any participants under the age of 16, particular attention will also be paid to the needs of those aged 16-18, and those with learning disabilities or other relevant needs.
- Informed consent will be secured in order to access routinely collected NHS data on participants. Subject to approval by the ethics committee, we will also ask participants to consent to long term follow up and appropriate linkage of their data.
- All staff members will have up-to-date Good Clinical Practice qualifications.
- Information governance procedures will be followed and regular data and process audits will take place.

Patient and Public Involvement

Patient and Public Involvement (PPI) is central to the development of this project and for the plans on how it will be executed. PPI has already directly informed the development of the initial idea and will be critical to the design of the group clinics, and the patient community will be closely involved with the project's evaluation. Patients and the local public will also be central to dissemination activities. Proposed PPI activities will strengthen the relevance, accessibility and success of the project.

The **initial proposal and project design** were informed by patients and the public in the following ways:
- A 1-year pilot project was undertaken in Newham exploring scope and feasibility of peer-support groups to improve patient engagement and self-management for young people 16-25 years with diabetes. This led to suggestions from patients that health and social care needs should be integrated, and that projects should include age appropriate content, multi-agency work and increased use of social networks.
- Women receiving antenatal diabetes care at Newham recently completed a peer-support diabetes education programme and identified a clear challenge in accessing structured diabetes care.
- The Association for Young People's Health has an active youth participation strand that has provided messages about the positive contribution of groups in promoting health in vulnerable groups, and collaboration with a young adult living with diabetes has provided expert patient input.
- In the planning stages a lay summary of the proposal was drawn up & shared with (a) a group of 6 young people (aged 15-24) from the Royal College of Paediatrics and Child Health's Youth Advisory Panel, and (b) a focus group of women with diabetes in the antenatal clinic at Newham Hospital. Feedback from both groups was extremely useful and fed directly into the research design

As the project unfolds, patients and other local community members will be actively engaged in the following ways:
- The project will use the Experience Based Co-Design Toolkit, adapted for our specific patient groups and their sensitivities, as a basis for designing the content of the group clinics and ideas about how they will work in practice. This work will be led by the Association for Young People's Health.
- Young adults with diabetes will be supported as members of the project advisory group and other project management groups, or alternative ways of getting their input to these groups will be designed with them, as appropriate.
- There will be ongoing collaboration with the Newham CCG Youth Champion who will work closely with the research team, and be involved in facilitating the local user-group.
- The Researcher in Residence model will enable us to communicate with patients informally as well as formally as the project develops, as the researcher will be visible and available on the premises
- We will engage wider canvassing of PPI input on the findings, using SurveyMonkey & social media (e.g. Twitter), pulling in a broader group than the patients and local stakeholders directly involved, for discussion and validation of main messages.
- Working with patients, we will prepare lay versions of research outputs for PPI and stakeholder audiences, including a practitioner & policy brief.
- Links have already been made with local PPI experts such as Newham CCG's PPI Officer, with whom we will work collaboratively again to ensure a wider group is reached.
- A final PPI event is proposed, reflecting on messages and their implications.

Expertise and justification of support required

- Sarah Finer is a Consultant Diabetologist & Senior Lecturer in transition from basic science to translational/health services research. She was an NIHR Clinical Lecturer (Cambridge), has designed/run clinical and qualitative studies in diabetes and pregnancy at Barts Health, has an interest in PPI, and has worked closely with CRN networks. She is a member of the Diabetes UK James Lind Alliance Priority Setting Partnership Steering Group.
- Dougal Hargreaves is a Consultant Paediatrician, Health Foundation fellow, past Harkness Fellow and has expertise in health services research and complex evaluations, with specific interest in adolescent/young adults.

- Our research group provides expertise in diabetes care (including specialist care of young adults with diabetes) (SF, SV, ST, GH, TG, DH, AC), quality improvement (MM, DH, TG, AH), primary care (MM) and NHS commissioning (SV, MM, AMMD). Please note that our CCG Diabetes Commissioning lead, Anne-Marie Maher-Vyas has agreed to be a Co-Investigator but is currently on maternity leave and unable to submit her online acceptance. Our research team has an extensive track record in designing and delivering complex interventions with quantitative analysis and realist review (RV and TG), health economic analysis (AP) and qualitative evaluations (MM, TG, SF, AC) as well as quality improvement projects and participatory research methods (MM, TG). The members of this research group have worked together previously in the clinical setting and/or research, communicate well, and have excellent working relationships.
- Newham provides an excellent setting for this project with wide networks of community- and service-level support for quality improvement and research. Strong connections exist already between primary and secondary care, as well as with other organisations delivering health promotion and healthy behaviour. The applicants have been able to select a group of high performing organisations and individuals to collaborate and offer components of the group clinic intervention, should it be funded.
- Specific expertise relating of the applicants is detailed in the "Background and Rational" section above.

List of abbreviations

EBCD – Experience-Based Co-Design, SF=Sarah Finer, DH=Dougal Hargreaves, SV=Shanti Vijayaraghavan, MM=Martin Marshall, AHarden=Angela Harden, AP=Anita Patel, AHagell=Ann Hagell, AYPH=Association for Young People's Health, TG=Trish Greenhalgh, GH=Graham Hitman, AMMD=Anne-Marie Maher-Dyas, AC=Anne Claydon, RV=Russell Viner.

Amendment history

Version 1: protocol approved for funding by NHIR. Uploaded to Netscc MIS on 2/11/16.

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