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TOGETHER study: Better care for young adults with diabetes using group clinics

Submission date
26/06/2017

Recruitment status
No longer recruiting

Registration date
29/08/2017

Overall study status
Completed

Last Edited
28/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. A person with diabetes usually receives medical care that relies on one-to-one time with health care professionals. This style of health care may not meet a patient's needs related to their condition or the wider impact it has on their life as a whole. The experience of living with diabetes is a difficult one, and at particular times of life, e.g. young adulthood, a person's diabetes rarely stands alone from other challenges (e.g. leaving home, starting work, having financial worries). Current NHS care may not meet these wider challenges and therefore patients may not attend appointments, find looking after their condition is increasingly difficult, and have unexpected stays in hospital, or develop diabetes complications. The aim of this study is to design and test diabetes services that better meet the needs of people using them. Past research suggests that medical care delivered in a group setting may be one way to do this. The findings of recent research suggest that group clinics may be particularly successful for young adults, minority ethnic groups or people who have previously been poor clinic attenders.

Who can participate?
Patients aged 16-25 with diabetes, patient representatives, health care professionals and community-based organisations

What does the study involve?
The participants help design group clinics for people with diabetes in a process called co-design. These co-designed group clinics are then run for young adults with diabetes alongside their existing medical care at Newham Hospital (part of Barts Health NHS Trust). The group clinics are compared with 'traditional' clinics at Newham and other hospitals and the researchers use different tools (e.g. observation, financial analysis, questionnaires and comparison to other studies) to understand the difference that group clinics make.

What are the possible benefits and risks of participating?
Participants benefit from being directly involved in designing services for young adults with diabetes that will meet their specific health and social requirements. The risks are minimal, apart from the possible inconvenience of attending workshops/group clinics, and care is taken to keep this to a minimum.

Where is the study run from?
1. Newham University Hospital (UK)
2. Whittington University Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2017 to November 2019

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33672

Study information

Scientific 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?

Acronym
TOGETHER

Study objectives
Research questions:
1. Could an innovative new care model using group clinics meet the complex health and social needs of young people with diabetes?
2. Could this new model of care be a better way of promoting diabetes self-management than traditional care? 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?
3. What are the feasibility, acceptability, costs and impact on outcomes of introducing these group clinics, and what is the organisational impact to the NHS and other stakeholders of this model?
4. Do group clinics show sufficient promise to warrant a cluster-randomised controlled trial into their clinical benefits and associated costs? If so, what would be the optimal design of such a study?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 23/02/2017, ref: 17/NI/0019

Study design
Non-randomised; Both; Design type: Process of Care, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes

Interventions

The TOGETHER project will employ participatory methods to co-design, deliver and evaluate a new model of group clinic-based diabetes care that addresses the needs of young people (aged 16–25 years) from socioeconomically deprived backgrounds. This project is developmental in nature and follows realist, participatory and implementation methodology and can be seen as incorporating feasibility and pilot work that may lead to an at-scale cluster-randomised trial. This is not a randomised controlled trial and participants will be invited to join one or two of the following three groups via purposive sampling and sampling by clinical centre.

1. Co-design group:
Participants: young adults, family members and healthcare professionals/stakeholders at any of the recruiting sites
Methodology: methods for co-designing clinical services vary, but it is proposed to use the Experience-Based Co-Design model (EBCD) (https://www.kingsfund.org.uk/projects/ebcd) with adaptations for the 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 the local area, 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.
The co-design process will have two concentrated phases, an initial phase of co-design at the beginning of the project to inform and contribute to the design of the group based model of care. The second co-design phase will occur mid-way through the project after the new care model for young people with diabetes has been implemented and will involve the patient and staff members involved in the initial co-design process, as well as new members.
There is no treatment or follow up for these participants.

2. Group clinic participants
Participants: young adults with diabetes at any recruitment sites
Methodology: group clinics will be implemented following the process outlined in the co-design group above. Implementation of the new model of care for young adults with diabetes will be iterative and will evolve according to the wishes and needs of young adults with diabetes and healthcare professionals, guided by co-design. Group clinics (the 'intervention') will be offered initially as an additional part of routine care and, once the new care model has developed and is running well, the group clinics will be offered as an alternative to some routine care appointments. Group clinic participants will be recruited throughout the project until the end of recruitment date (31/08/2019). There is no follow-up phase but during the lifetime of the research some participants will be asked for their views on the group clinic model as part of the ongoing qualitative research associated with the project.

3. Control group
Participants: young adults with diabetes at any recruitment sites, not entering group clinics
Methodology: comparative data will be collected to guide the design of a future at-scale evaluation of the new care model, e.g. in a cluster randomised trial, and choice of outcomes.

Definitive evaluation of the impact of group clinics is not possible within this study for several reasons:
1. 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

2. The timescale of our study is not long enough to evaluate the full impact of new behaviours such as increased exercise, diet changes, and clinic attendance
3. The 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
4. 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).
Nonetheless, 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. In addition, the study 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.
There is no treatment or follow up for these participants.

This is a piece of developmental health services research that does not have a trial format or explicit primary/secondary outcomes. Instead, the study has a participatory and embedded research methodology which will use collaborative techniques and qualitative methodology and analysis to determine attitudes to, experience, and perceptions of the new care model (group clinics), and the active ingredients of their success. Quantitative data (e.g. biological markers of diabetes control, attendance rates etc) will be collected and analysed to look at the potential impact of the group clinics compared to existing (1-to-1) care, but this is as a test of feasibility and will be used to design and scale future cluster randomised trials using hard clinical endpoints.

Intervention Type
Other

Primary outcome measure
Quantitative outcomes:
The study is not powered to detect a difference in quantitative outcomes and these will be used to guide future at-scale evaluation, e.g. a cluster randomised trial. Quantitative data will be collected from all group clinic and control participants at study entry and annually whilst they are in the study. Data collected will include:
1. Biological markers of diabetes care and control: HbA1c, foot check, retinal screening, blood pressure, cholesterol, frequency of blood glucose self-monitoring, severe hypoglycaemia, medication history, attendance at structured education, other medical conditions, diabetes technology used
2. Administrative activity and cost data: attendance rates at scheduled care, unscheduled care contact, staff contact time
3. Experience: Problem Areas In Diabetes (PAID) scale, Patient Enablement Instrument (PEI), analogue rating of overall clinical care (0-10)

Qualitative outcomes:
1. Attitudes to, experience, and perceptions of the new care model (group clinics), and the active

ingredients of their success, assessed through interview and direct observation throughout the course of the study, and will include participants from all 3 groups (co-design, group clinics and control) described above

Secondary outcome measures
1. 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 design a scaled-up cluster randomised trial of the group clinic model
2. Clinical outcomes, process and cost data from participants in the group clinics model and control participants at other designated units running similar clinics for young adults with diabetes
Timepoint(s): October 2019

Overall study start date
08/05/2017

Completion date
31/05/2020

Eligibility

Key inclusion criteria
Patients aged 16-25 with diabetes, patient representatives, health care professionals and community-based organisations

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 155; UK Sample Size: 155

Total final enrolment
155

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
31/05/2017

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newham University Hospital
Glen Road
Plaistow
London
United Kingdom
E13 8SL

Study participating centre
Whittington University Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Mile End Road
London
England
United Kingdom
E1 4NS

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/026zzn846

Funder(s)

Funder type

Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
A number of further publications are being planned for peer review in high impact journals over the coming two years. Dissemination will also take place at academic conferences, through PPI groups and via links with charities.

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
Due to the nature of this developmental study, it will not be possible to meta-analyse data collected and therefore individual patient level data will not be made available. Transcripts from qualitative interviews will not be made available at individual level as it would not be possible to maintain anonymity.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/06/2017		Yes	No
Interim results article	Year 1 report	30/11/2017	26/11/2021	Yes	No
Results article		25/11/2022	28/11/2022	Yes	No
HRA research summary			28/06/2023	No	No