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Adapting to new-onset type 1 diabetes in adults: The LADDER Study

Submission date
28/03/2022

Recruitment status
No longer recruiting

Registration date
26/05/2022

Overall study status
Completed

Last Edited
16/08/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 1 diabetes causes the level of glucose (sugar) in your blood to become too high. It happens when your body cannot produce enough of a hormone called insulin, which controls blood glucose. You need daily injections of insulin to keep your blood glucose levels under control.

In this study, we will test and optimise a programme of support for adults (aged 20 years or older) with new onset type 1 diabetes (T1D) to help them adjust to living with diabetes and integrate the diabetes self-care responsibilities such as taking insulin and blood sugar tests multiple times each day as part of their lives.

The programme was designed with adults with new onset T1D and health care professionals to address the support needs of adults following the diagnosis. The programme is called the Living with and ADapting to DiabetEs PRogramme (LADDER). The aim of this study is to see if participating in the programme improves the physical, psychological, and social wellbeing of adults with new onset T1D.

Who can participate?
Adults aged 20 years or older who have recently been diagnosed with T1D

What does the study involve?
The programme has two elements: early psychological support using visual conversation tools in both one-to-one sessions with health professionals in clinical settings at GSTT and KCH, and group sessions conducted at GSTT co-delivered by a person with T1D and a health professional. The programme covers the emotional, physical, and social impact of diabetes in everyday life and understanding diabetes care.

The study lasts 18 months, and we aim to assess the participants' experiences within the programme and the way it impacts on their social and psychological wellbeing and how they look after their diabetes. In so doing we will identify the views of adults with new onset T1D on the different programme components. This understanding together with the assessment of the programme's impact will enable us to improve the programme before we test it in a larger study. In addition, we aim to collect information which will help us design a future study by

considering issues in relation to the recruitment of adults with new onset T1D to the study; how many participants complete the programme; and the measures we use to assess the impact and the delivery of the programme.

What are the possible benefits and risks of participating?
Based on the findings from our previous studies, potential benefits for adults with new onset type 1 diabetes will include:
1. Enhanced psychological adjustment to living with diabetes
2. Enhanced social confidence and well-being
3. Increased attention to self-management behaviours and participation in diabetes care
4. Improved sugar levels in the short-term, reducing acute and long-term health risks
5. Reduced psychological distress, anxiety, and depression
6. Prevention of hospital admissions and diabetes-related health events
These benefits will be experienced in the short-term by those who participate in the study; and in the longer-term, should a larger study be successful, to the wider population of adults with new onset type 1 diabetes. In terms of the latter benefit, provided the outcomes of the studies are positive then it is conceivable that the programme could be made available nationally. An additional benefit of participation in the LADDER study B could be the development of peer support. Such peer support can be very powerful for some as most adults with new onset type 1 diabetes do not have much interaction with peers living with diabetes.

We do not consider there to be any major risks associated with this study, as we have worked very closely with adult with new-onset type 1 diabetes in both developing the LADDER programme and in designing the current study. Therefore, we are confident that the approach we have proposed will be acceptable to participants. As with any study of a new care provision that involves collecting personal information from participants, there are some potential hazards to consider. In respect of LADDER, these mainly relate to the potential for causing emotional upset (either through their experiences in the programme or during interviews) and safeguarding issues. The interventionists will monitor these issues carefully by listening closely to how participants express their experiences in the programme and during the interviews. They will be mindful of any signs of emotional upset and where required ensure the appropriate additional care is instigated via their diabetes clinicians. All the researchers involved in the study will have safe-guarding training and will adhere to the safeguarding policies of KCL and the participating NHS Trusts. Any adverse occurrences that occur during the study will be logged and reported to the PI and CI for appropriate action, They will also be presented anonymously to the advisory board. The main burden will be the time commitment to completing the consent procedures, questionnaires and attending the one-to-one sessions or the group sessions. However, we have addressed this by working together with adults with new onset type 1 diabetes to identify which measures we would use in the questionnaires. Participants will be free to withdraw from the study at any point.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
From March 2022 to March 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Angus Forbes, angus.forbes@kcl.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
298717

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52114, NIHR 202263, IRAS 298717

Study information

Scientific Title
A feasibility study and process evaluation of an integrated support programme for adults following a diagnosis of type 1 diabetes - the Living with and ADapting to DiabetEs PRogramme (LADDER)

Acronym
LADDER

Study objectives
The main objective of this study is to test the feasibility of the two components of the LADDER programme in terms of programme acceptance, implementability, recruitment, and completion; and to investigate if there is a signal of effect on clinical, psychological, social, and health care outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2022, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, HRA NRES Centre, Manchester, M1 3DZ, UK; +44 (0)2071048290; preston.rec@hra.nhs.uk), ref: 22/NW/0053

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
The purpose of the study is testing the feasibility of the LADDER programme, the research design and the study outcomes. The study has been designed to evaluate both components of the LADDER programme independently; we will use a preference model in Study-A; and a waiting list design in Study-B.

Study A:
Participants (n=26) will be exposed to the LADDER sessions or an active control of four standard diabetes appointments in their usual diabetes clinic. Eligible participants will be allocated to either the intervention or the control group if they consent to be randomised; and those that decline randomisation will then be given the option of a preference for one allocation or the other (the preference option will only be revealed if the participant declines randomisation so we can fully estimate the proportion of participants who may decline). Outcomes will be assessed at baseline with follow-up at months 2, 4 and 6.
Study A involves attending 4 one-to-one sessions (at 2 weekly intervals) starting <4 weeks after diagnosis, addressing: experiences, thoughts, and emotions about the diagnosis; expectations and practical questions; and diabetes in everyday life. The sessions involve two visual conversational tools developed in the co-design project focussing on:
1. Diabetes in everyday life (work and relationships)
2. Diabetes practicalities
3. Developing diabetes acceptance
4. Understanding diabetes care.
The active control condition for study A consist of four standard diabetes appointments in a similar period delivered by equivalent diabetes nurses who have not had training in the LADDER programme.
Participants in Study A will be recruited from two large diabetes centres in South London: Guy's and St Thomas' NHS Foundation Trust (GSTT) and King's College Hospital (KCH). Study A will be delivered to protocol by a clinical team at each site who are all fully trained and experienced in delivering the LADDER programme to ensure fidelity of delivery.

Study B:
This study will use a waiting-list RCT design, with a 10-month follow-up post programme exposure. Participants (n=40) will be randomised to phase 1 group exposure or waiting-list control and followed up for 5 months, at which point the waiting-list participants will be exposed to the intervention in the phase 2 group exposure. Outcomes will be assessed at baseline with follow-up at 2,5,7 and 10 months. This ensures that all eligible participants will have the opportunity to participate in the programme while maintaining a controlled structure to the exposures so we can consider differences. Also following the phase 1 exposure for a further 5 months will enable us to consider how sustainable any effects are over a longer period.

As with study A, we will moderate for possible preference and will study this as part of the process evaluation. The adoption of a waiting-list design in study B helps to overcome the ethical dilemma of denying control participants the opportunity to benefit from the LADDER programme. We will also undertake a process evaluation in parallel with study A and study B to consider the experiences of participants and study recruitment and completion rates.
Study B is a group-based psychoeducational course provided 3-12 months post-diagnosis, addressing: common psychological and social diabetes challenges; and strategies for managing diabetes in everyday life. The course sessions will involve the use of additional visual conversation tools, based on a series of illustrations depicting common experiences related to the diagnosis and the early experience of the condition. The course also involves simulated experiential learning techniques focussing on common challenges, such as: diabetes in the workplace/education; hypoglycaemia; and getting more out of diabetes consultations. In these sessions, participants will be able to develop and rehearse strategies for navigating these scenarios in a supportive environment.
Those randomised to phase 2 in study B will attend usual appointments at their local diabetes centre while waiting for their exposure to the LADDER programme.
Study B will be delivered from GSTT by a clinical team at each site who are all fully trained and experienced in delivering the LADDER programme to ensure fidelity of delivery, and a peer educator. We do not anticipate significant centre level effects on outcomes, although we will study variations in the general diabetes care provided in each centre.

Data collection of the following will take place at for Study A and at baseline, 3, 5, and 9 months for Study B:
1. Acceptance (Illness Identity Questionnaire)
2. Illness perception (Brief Illness Perception Questionnaire)
3. Depression and low mood (Patient Health Questionnaire-9)
4. Diabetes distress (Problem Areas in Diabetes Scale)
5. Diabetes resilience (Diabetes Empowerment Scale-short form)
6. Interactions with Health care professionals (Health care climate questionnaire)
7. Perceived Stress (perceived stress scale)
8. Impact of diabetes on everyday life (DAWN-2 questionnaire)
9. Engagement with diabetes care (attendance at screening and diabetes appointments)
10 Hypoglycaemia (blood glucose <3.5 mmol/L) and severe hypoglycaemic events (where 3rd party assistance is
required)
11. Glycaemic control (HbA1c)
12. Social support (Experiences in Close Relationships Scale - Short Form) (Study B only; at baseline and 9 months only)
We will also monitor significant diabetes-related health events, including emergency care events (ambulance call-outs, Accident and Emergency (A&E) attendance or hospitalisations); and hypoglycaemia (blood glucose >3.5 mmol/l) or severe hypoglycaemic (3rd party assistance) occurrences and HbA1c. Additional background data collected at baseline will include socio-demographic characteristics (education, occupation, partner status, deprivation and ethnicity); diabetes education, treatment, and technology (insulin, glucose monitoring) exposures; and a biological profile (age, BMI, past medical history, insulin antibodies).

To determine progression to a full trial, we will consider the following factors: minimum 40% recruitment of eligible participants; and >60% completion to final follow-up. To assess the impact of the intervention ingredients we will consider impact on target outcomes, including: activation of self-management; engagement in diabetes health care; and improved psychosocial functioning. These effects, alongside impact on glycaemic levels will be used to consider whether the programme is adequately potent to justify a full trial.

Participants in study A will be randomised 2:1 to LADDER programme or active control depending on their consent to participate in the randomisation.
Participants in study B the phase 1 or phase 2 LADDER exposures using the minimisation method to achieve balance in baseline age and gender between those in phase 1 intervention and those assigned to the waiting-list (phase 2). The randomisation processes will be blinded using computer generated allocations. Although it will not be possible to blind the allocation to participants, we do not anticipate a significant risk of bias in study B as both groups within 5 months will have been exposed to the LADDER programme.

The process evaluation will consider the: setting, implementation, and mechanisms of action of the programme to support interpretation of the outcomes. The evaluation will assess: the reach, fidelity, and receipt of the programme; acceptability, appropriateness, and feasibility; unintended consequences; potential sustainability; and implementation costs and strategies.
We will use a mixed-method approach with brief validated implementation outcome surveys and one-to-one interviews with adults with new onset type 1 diabetes, their relatives and healthcare professionals. The data collection procedures have been reviewed and refined with the study PPI groups.
The validated brief implementation outcomes scales will be completed by participants after they have been exposed to the LADDER programme. The scales will also be completed by the healthcare providers delivering the programme. Semi-structured interviews exploring the impact of the programme within the first month from the completion of the programme will be conducted with a sub-sample of participants, which is estimated to allow saturation of the themes we anticipate will emerge from the interviews (n=6 from each intervention arm of the study, and n=3 from the active control in study A). In addition, if they consent, we will interview adults who were eligible for the programme but did not attend or exited the study to explore their reasons for this with them in a positive way; participants' relatives (n=3); and healthcare professionals who delivered the programme.
All interviews will be digitally recorded and transcribed verbatim in preparation for analysis using framework analysis. This analysis will identify emergent themes linking them to our underpinning theoretical framework (Bio-psycho-social model).
We will also undertake:
1. An audit of the number of eligible adults with new-onset type 1 diabetes that decline participation, considering their clinical and sociodemographic profiles
2. An audit of intervention fidelity using an adherence checklist based on the protocol for the LADDER programme
3. Exit questionnaires to rate programme satisfaction and utility; and to identify 3 strengths, weaknesses and areas for improvement
The audit and questionnaire data will be analysed to provide descriptive data on the acceptability, utilisation and satisfaction of the programme. Intervention fidelity will be assessed from the audit data detailing the delivery of the different intervention components. We will monitor control conditions in the first 6 months to consider whether any extraneous interventions or clinical changes occurred that might impact on the observed outcomes.

A full health economic analysis is beyond the scope of this feasibility study. However, we will collect data as part of the process evaluation that could be used by a health economist to inform the health economic analysis for a future definitive trial. The analysis will have 4 elements:
1. A full economic costing of the programme delivery costs, including: NHS staff time; additional appointments costs; associated blood tests and procedures; and any administrative costs
2. An audit of medical records to consider health care utilisation and impact on high cost emergency care episodes, such as incidents of severe hypoglycaemia and diabetic ketoacidosis (DKA) (Study B only)

3. Estimate potential cost-benefits by considering the risk of long-term complications based on impact of the intervention on glycaemic control using established health economic assumption (Study B only)

Intervention Type
Behavioural

Primary outcome(s)
Following current MRC guidance for feasibility studies we have not identified an individual primary outcome for this study, as the interventions are modelled to multiple outcomes. The following measures will be used:

Study A:
1. Acceptance is measured using the Illness Identity Questionnaire (IIQ) at 2, 4, and 6 months
2. Illness perception is measured using the Brief Illness Perception Questionnaire (BIPQ) at baseline, 2, 4, and 6 months
3. Depression and low mood are measured using the WHO-5 Wellbeing Index at baseline, 2, 4, and 6 months
4. Diabetes distress is measured using the Problem Areas in Diabetes Scale (PAID) at 2, 4, and 6 months
5. Diabetes resilience is measured using the Diabetes Empowerment Scale - Short Form (DES-SF) at 2, 4, and 6 months
6. Interactions with health care professionals is measured using the Health Care Climate Questionnaire (HCCQ) at baseline, 2, 4, and 6 months
7. Perceived Stress is measured using the Perceived Stress Scale (PSS) at baseline, 2, 4, and 6 months
8. Impact of diabetes on everyday life is measured using the DAWN-2 questionnaire at baseline, 2, 4, and 6 months
9. Social support is measured using the Experiences in Close Relationships Scale - Short Form (ECR-SF) at baseline and 6 months
10. Engagement with diabetes care is measured using attendance at screening and diabetes appointments at end of the study
11. Glycaemic control is measured using HbA1c at baseline, 2, 4, and 6 months

Study B:
1. Acceptance is measured using the Illness Identity Questionnaire (IIQ) at baseline, 3, 5, and 9 months
2. Illness perception is measured using the Brief Illness Perception Questionnaire (BIPQ) at baseline, 3, 5, and 9 months
3. Depression and low mood are measured using the Patient Health Questionnaire-9/WHO-5 Wellbeing Index at baseline, 3, 5, and 9 months
4. Diabetes distress is measured using the Problem Areas in Diabetes Scale (PAID) at baseline, 3, 5, and 9 months
5. Diabetes resilience is measured using the Diabetes Empowerment Scale - Short Form (DES-SF) at baseline, 3, 5, and 9 months
6. Interactions with health care professionals is measured using the Health Care Climate Questionnaire (HCCQ) at baseline, 3, 5, and 9 months
7. Perceived Stress is measured using the Perceived Stress Scale (PSS) at baseline, 3, 5, and 9 months
8. Impact of diabetes on everyday life is measured using the DAWN-2 questionnaire at baseline, 3, 5, and 9 months

9. Social support is measured using the Experiences in Close Relationships Scale - Short Form (ECR-SF) at baseline and 9 months
10. Engagement with diabetes care is measured using attendance at screening and diabetes appointments at 9 months
11. Hypoglycaemia (blood glucose <3.5 mmol/l) and severe hypoglycaemic events (where 3rd party assistance is required) are measured at intervention, 3, 5, and 9 months
12. Glycaemic control is measured using HbA1c at baseline, 3, 5, and 9 months

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Study A:
1. Have been diagnosed with type 1 diabetes within the last month

Study B:
1. Have been diagnosed with T1D >3 months and ≤12 months

Studies A & B:
1. Aged ≥20 years (giving a higher likelihood of a participant living independently with responsibility for their own diabetes self-management)
2. Capacity to consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Severe physical/mental illness
2. Pregnancy (a pregnancy with type 1 diabetes involves intensive intervention to regulate glucose levels with weekly care in diabetes pregnancy clinics for monitoring)
3. Acute unstable retinopathy
4. Significant learning difficulties
5. Planned or current attendance at other structured education programmes
6. Unable to speak or understand English
7. Planned attendance in other structured education programmes

Date of first enrolment

11/05/2022

Date of final enrolment
15/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 16/11/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mette Due-Christensen (mette.due-christensen@kcl.ac.uk) and Prof Angus Forbes (angus.forbes@kcl.ac.uk).

Previous IPD sharing statement:
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No