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Psychosocial support to adults with newly diagnosed type 1 diabetes

Submission date
20/12/2024

Recruitment status
No longer recruiting

Registration date
27/12/2024

Overall study status
Completed

Last Edited
23/12/2024

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 and group sessions 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 current study will test the first element, the one-to-one sessions. Group sessions will be tested in the UK.
The study lasts 15 months, and we aim to assess the participants' experiences within the programme and the way it impacts 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 one-to-one session programme component. 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 both in Denmark and in the UK.
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 safeguarding training and will adhere to the safeguarding policies of the hospitals. 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, and questionnaires and attending the one-to-one 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?
Steno Diabetes Center Copenhagen

When is the study starting and how long is it expected to run for?
February 2018 to March 2023

Who is funding the study?
1. The Novo Nordisk Foundation (Denmark)
2. Jascha Foundation (Denmark)

Who is the main contact?
Dr Mette Due-Christensen, mdue0015@regionh.dk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Protocol serial number
VD-2018-196

Study information

Scientific Title
A feasibility study and process evaluation in Denmark 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 the study is to test the feasibility of one-to-one LADDER sessions in terms of programme acceptance, implementability, recruitment and completion and to explore any effects on clinical, psychological, and social outcomes

Ethics approval required
Ethics approval not required

Ethics approval(s)
Ethics approval is not required In Denmark for studies that do not involve blood tests or invasive tests. Approval from the Danish Data Protection Agency was required and has been obtained (VD-2018-196).
Approval from the Danish Data Protection Agency was sought and granted for both the development phase and the feasibility testing of the study.

Primary study design
Interventional

Study design
Non-randomized multi-centre trial

Study type(s)
Treatment

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

Interventions
The purpose of the study is to test the feasibility of one component of the LADDER programme, the research design, and the study outcomes. The study is a non-randomised multicentre trial testing component A of LADDER, namely one-to-one sessions.

The LADDER intervention was developed through a co-design process involving both people with type 1 diabetes and healthcare professionals. Two intervention components (A: one-to-one sessions and B: group sessions) underpinned by a bio-psycho-social model of adaptation were developed to provide an overarching framework and to reflect the multiple changes the diagnosis of T1D in adulthood introduces. It draws on acceptance and commitment theory; person-centered counselling; and self-determination theory. The intervention consists of the use of three visual dialogue tools developed specifically for and by adults with new-onset T1D to address the psychological and social impact of the diagnosis and how to adapt to life with diabetes.

In the feasibility study participants will be exposed to the LADDER one-to-one sessions or usual care (UC) in their diabetes clinic. Eligible adults with new-onset type 1 diabetes will be allocated to either intervention or UC group 2:1 depending on whether the HCP they see at the first study consultation is trained in using the LADDER tools.

Participation involves attending two one-to-one sessions starting 1-3 months post-diagnosis. The sessions will address their 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 focusing on:
1. Diabetes in everyday life (work and relationships)
2. Diabetes practicalities
3. Developing diabetes acceptance
4. Understanding diabetes care
Usual care consists of two standard diabetes appointment in a similar period delivered by healthcare professionals who have not received training in LADDER.

Participants will be recruited from two diabetes centres in Denmark: Steno Diabetes Center Copenhagen and Steno Diabetes Center Odense. The intervention will be delivered by trained healthcare professionals in both settings.

Alongside the quantitative evaluation the researchers will collect qualitative data from participants and healthcare professionals to explore the benefit of participating in the intervention, the acceptability, appropriateness, and feasibility of the intervention as well as any unintended outcomes. The researchers will conduct interviews with participants after they have completed the sessions (n = 15) and healthcare professionals who deliver the intervention (n = 5). All interviews will be recorded digitally and transcribed word by word and analysed using framework analysis.

Intervention Type
Behavioural

Primary outcome(s)
The researchers have not identified an individual primary outcome for the feasibility study because the intervention has been modelled to affect multiple outcomes. They will use the following outcome measures:
1. General health is measured by SF-36 at baseline, 6 and 9 months
2. Acceptance is measured by the Illness Identity Questionnaire at 3, 6 and 9 months
3. Illness perception is measured by the Brief Illness Perception Questionnaire at baseline, 3, 6 and 9 months
4. Well-being/depression is measured by WHO-5 at baseline, 6 and 9 months
5. Diabetes distress is measured by Problem Areas in Diabetes Scale at 3,6, and 9 months
6. Diabetes resilience is measured by the Diabetes Empowerment Scale-short form at 3, 6, and 9 months
7. Interactions with health care professionals measured by health care climate questionnaire at baseline
8. Impact of diabetes on everyday life measured by DAWN questionnaire at baseline, 3 and 6 months and by SF-36 role function (physical and emotional) at baseline and 3 months
9. Social support is measured by experience in close relationships at baseline and by the DAWN questionnaire at baseline, 3 and 6 months
10. Perceived stress is measured by the perceived stress scale at baseline, 3 and 6 months
11. Engagement with diabetes care is measured by attendance at screening and diabetes appointments at the end of the study
12. Hypoglycaemia (blood glucose <3.5 mmol/L) and severe hypoglycaemic events (where third-party assistance is required) measured using data collected from patient medical records at the end of the study
13. Glycaemic control is measured by HbA1c at baseline, 3, 6 and 9 months

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

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Diagnosed with type 1 diabetes within the last 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

20 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
49

Key exclusion criteria
1. Severe physical or mental illness
2. Unable to engage in conversation with the dialogue tools
3. Unable to speak or understand Danish

Date of first enrolment
29/01/2021

Date of final enrolment
17/03/2022

Locations

Countries of recruitment
Denmark

Study participating centre
Steno Diabetes Center Copenhagen
Borgmester Ib Juuls vej 83
Herlev
Denmark
2730

Study participating centre
Steno Diabetes Center Odense
Kloevervaenget 6, Indgang 93
Odense
Denmark
5000

Sponsor information

Organisation
Steno Diabetes Center Copenhagen

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk Fonden

Alternative Name(s)
Novo Nordisk Foundation, Novo Nordic Foundation, NNF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Funder Name
Jaschafonden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mette Due-Christensen (mdue0015@regionh.dk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			20/12/2024	No	Yes