ISRCTN10671396 https://doi.org/10.1186/ISRCTN10671396

Testing a traditional food-based intervention for weight loss and type 2 diabetes remission

Submission date
10/09/2023

Recruitment status
No longer recruiting

Registration date
13/09/2023

Overall study status
Completed

Last Edited
10/09/2024

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
This study will evaluate a low-cost, easily accessible food-based treatment for type 2 diabetes in overweight patients. The diet treatment uses only traditional local Nepali foods, designed to provide all the essential vitamins and minerals, in amounts to cause a weight loss of 10 kg in 8 weeks, if it is followed carefully.

Who can participate?
People living in Kathmandu, aged 30-70 years, with type 2 diabetes up to 5 years after diagnosis, not on high-dose insulin treatment, who are overweight.

What does the study involve?
The researchers will assess how many people are able to follow the diet plan to achieve remission of their diabetes (their blood tests show they no longer have diabetes, while off anti-diabetes medications for at least 2 months).

What are the possible benefits and risks of participating?
There may be other benefits from weight loss, including better blood pressure control, and improved quality of life. There are no important hazards or risks from participation, but diet control is always hard and requires commitment.

Where is the study run from?
Metro Hospital (Kathmandu)

When is the study starting and how long is it expected to run for?
September 2020 to December 2023

Who is funding the study?
All Saints Educational Trust (UK)

Who is the main contact?
Prof. Michael Lean, mike.lean@glasgow.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Michael Lean

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Additional identifiers

Study information

Scientific Title
Hospital-based Diabetes Remission Clinical Trial in Nepal (Ho-DiRECT-Nepal): a food-based educational and home-economics intervention for type 2 diabetes remission

Acronym
Ho-DiRECT-NEPAL

Study objectives
A diet intervention, based on the UK Diabetes Remission Clinical Trial (DiRECT), but using only low-cost traditional foods, will generate significant weight losses from baseline, and remissions of recent-onset type 2 diabetes, in people attending hospital-based diabetes clinics in Kathmandu, Nepal

Ethics approval required
Ethics approval not required

Ethics approval(s)
Opinions were sought from the Nepal Health Research Council (NHRC) and Kathmandu University Institutional Review Committee (IRC), who concluded that with no randomisation, and with no new experimental intervention, this study would be considered a service evaluation, which does not require ethical approval.

Primary study design

Interventional

Study design
Single-centre pragmatic single-arm evaluation

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Remission of type 2 diabetes in overweight patients

Interventions
Patients aged 30-70 years attending hospital diabetes clinics who have had type 2 diabetes up to 5 years, and with Body Mass Index above 23 kg/m² will be invited to participate. Participants will be educated about T2D and its multimorbid complications and offered a dietary intervention program. The health workers and nutritionists will contact the participants to provide support twice weekly up to week 10, and then 4-weekly. Anthropometric measurements and biochemistry will be conducted routinely. Weight-control support will continue irrespective of T2D remission, aiming to limit related multimorbid conditions. Patient recruitment and dietary intervention will be conducted within the care of diabetes specialists and nutritionists/dieticians.

The dietary program:
1. A Total Diet Replacement (TDR) Phase for weight loss induction, which will last for the first 8 weeks, using only low-cost traditional foods, similar to the Scottish 'No Doubts Diet' based on porridge and lentil soups
2. Reintroduction of meals, again using only low-cost traditional foods, for weight loss maintenance

Intervention Type
Behavioural

Primary outcome(s)
Remission of type 2 diabetes (HbA1c <48 mmol/mol [<6.5%]) after 6 months

Key secondary outcome(s)
1. Body weight measured with scales at 3, 6 and 12 months
2. HbA1c measured by standard laboratory method at 6 and 12 months
3. Blood pressure measured by electronic sphygmomanometer at 6 and 12 months
4. Microalbuminuria measured by dipstick and standard laboratory method at 6 and 12 months
5. Liver function tests measured by standard laboratory method at 6 and 12 months
6. Ultrasound liver fat measured at 6 and 12 months (if available)
7. Quality of life measured using WHO-BREF – QoL (Nepali version) at 6 and 12 months
8. Glucose-lowering and antihypertensive medications prescribed at 3, 6 and 12 months
9. Participant experience measured by qualitative interviews in a subset at different study stages

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Age 30-70 years
2. Men and women
3. Type 2 diabetes of duration up to 4 years since diagnosis
4. Not insulin-dependent/type 1 diabetes
5. Body mass index >23 kg/m²

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
85

Key exclusion criteria
1. Weight loss of >5 kg within the last 6 months
2. Pregnancy/lactation
3. MI or stroke in the past 3 months
4. Chronic pancreatitis, alcohol dependence, psychiatric illness and learning disability
5. Patients using insulin more than 30 units basal, or other complex insulin regimen

Date of first enrolment
29/03/2022

Date of final enrolment
19/09/2022

Locations

Countries of recruitment
Nepal

Study participating centre

Metro Hospital
Kathmandu
Nepal
P8RQ+42C, Kathmandu 44600

Sponsor information

Organisation
Kathmandu Medical College Teaching Hospital

ROR
https://ror.org/00tcmr651

Funder(s)

Funder type
Charity

Funder Name
All Saints Educational Trust

Alternative Name(s)
The All-Saints Educational Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Mike Lean (mike.lea@glasgow.ac.uk). Data will be anonymised and provided to researchers for any reasonable scientific purpose for at least 10 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/08/2024	10/09/2024	Yes	No
Protocol file			13/09/2023	No	No