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Evaluation of a community-led traditional food-based programme for remission of type 2 diabetes, in Nepal

Submission date
15/04/2024

Recruitment status
No longer recruiting

Registration date
14/05/2024

Overall study status
Ongoing

Last Edited
29/09/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
To provide a sustainable, very low-cost solution for the large and growing problem of type 2 diabetes in Nepal

Who can participate?
Adults aged 30-70 years who are detected to have diabetes at community screening

What does the study involve?
Consuming cheap, local, traditional foods designed to provide all essential nutrients and produce weight loss of 10-15kg over about 8 weeks, followed by an eating plan to avoid weight regain, for at least 12 months.

What are the possible benefits and risks of participating?
Benefit is the possibility of remission of type 2 diabetes, not requiring medication. No risks.

Where is the study run from?
Dhulikhel Hospital and its outreach centres, in Nepal.

When is the study starting and how long is it expected to run for?
September 2022 to September 2027

Who is funding the study?
Funded by the Medical Research Council (UK) on behalf of the Global Alliance for Chronic Diseases

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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
GACD Prevention in Cities Reference: GACD2023-151

Study information

Scientific Title
Co-DiRECT Nepal: a community-based diet programme for remission of type 2 diabetes and amelioration of non-communicable disease risks

Acronym
Co-DiRECT Nepal

Study objectives
The research aim is to evaluate a proven dietary intervention, for remission of type 2 diabetes (T2D) and reduction of chronic non-communicable disease (NCD) risks, culturally adapted for implementation in the context of rapidly-growing peri-urban populations in and around cities in the Kathmandu Valley of Nepal.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 23/10/2024, Nepal Health Research Council Ethical Review Board (Ramshah Path, Kathmandu, -, Nepal; +977-1-4254220 / +977-1-4254220; nhrc@nhrc.gov.np), ref: 810

2. Not yet submitted

Primary study design
Interventional

Study design
Hybrid effectiveness and implementation study incorporating a single centre randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Remission or amelioration of type 2 diabetes

Interventions
The intervention is diet plans, with support from trained community volunteers, comprising traditional, very low-cost, foods selected to provide all essential micronutrients and an energy content designed for (1) weight loss over 8-10 weeks, and then (2) weight loss maintenance up to at least 12 months.
Control group is delayed intervention, after the 4-month randomised trial.
Randomisation will use sealed envelopes.
Outcome measures are fingerprick HbA1c at 4 months (randomised trial) and 12 months (observational).

Intervention Type
Behavioural

Primary outcome(s)
Glycated haemoglobin measured using fingerprick HbA1c at baseline, 4 and 12 months

Key secondary outcome(s)
1. Body weight measured using scales at baseline, 4 and 12 months
2. Qualitative assessments of incentives and barriers to diet adherence measured using customised questionnaire during weight loss induction and maintenance phases

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Screen-detected HbA1c above 48 mmol/mol

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Known diabetes on medication
2. Non-local residents
3. Planned migration within 12 months

Date of first enrolment
06/01/2025

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Nepal

Study participating centre
Dhulikhel Hospital, and its outreach centres
Dhulikhel
Nepal
45200

Sponsor information

Organisation
University of Glasgow

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council- Global Alliance for Chronic Diseases

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			29/09/2026	No	No
Statistical Analysis Plan	version 1.0	29/09/2026	29/09/2026	No	No