

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

<b>Submission date</b> 15/04/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/05/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/11/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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](mailto:mike.lean@glasgow.ac.uk)

## Contact information

**Type(s)**

Public, Scientific, Principal investigator

**Contact name**

Prof Michael (Mike) Lean

**ORCID ID**

<https://orcid.org/0000-0003-2216-0083>

**Contact details**

Hatton Castle

Newtyle

Blairgowrie

United Kingdom

PH12 8UN

+44 7720885387

mike.lean@glasgow.ac.uk

**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**

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**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. notYetSubmitted, University of Glasgow MVLS College Ethics Committee (College of Medicine, Veterinary & Life Sciences, School of Cardiovascular and Metabolic Health, New Lister Building, Glasgow Royal Infirmary, Glasgow , G31 2ER, United Kingdom; +44 (0)141 201 8519; terry.quinn@glasgow.gla.ac.uk), ref: 200240032

**Study design**

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

**Primary study design**

Interventional

**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**

Adult

**Lower age limit**

30 years

**Upper age limit**

70 years

**Sex**

All

**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**

The data-sharing plans for the current study are unknown and will be made available at a later date, using methods to be defined in accordance with funder's requirements.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date