

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 14/05/2024	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 05/11/2024	Condition category 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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

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