

A community-based dietary programme for type 2 diabetes prevention and remission, clinical trial and implementation evaluation, in Nepal

Submission date 21/04/2026	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/04/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/04/2026	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This project was initiated by Nepali community empowerment agencies contacting the Glasgow Diabetes Remission (DiRECT) team, seeking a novel solution to the growing devastation of families and underserved communities caused by disabilities from T2D. The main driver of T2D, and related NCDs, revealing genetic potential, is adult weight gain. It is largely preventable by western-style intensive interventions, which are unavailable and unaffordable in Nepal.

In pilot work, the DiRECT diet programme for T2D remission has been adapted to use local traditional foods, acceptable and effective, leading to 43% T2D remissions at 4 months, 29% at 12 months, despite only 4.3kg weight loss in long-standing patients with T2D, including some on insulin. Papers on the primary outcome and qualitative research have been published.

A further 3-year preparatory trial, Co-DIRECT (funded by MRC-Global Alliance for Chronic Disease) 2024-2027, is developing community HbA1c screening and delivery of diet advice with the help of the existing 'Female Community Health Volunteers', to evaluate short-term remission of T2D and explore sustainability through implementation research. A paper on baseline implementation landscape is shortly to be submitted for publication, and recruitment of 120 people found to have T2D is progressing well.

The present project will add to our ongoing collaborative research experience with large-scale targeted screening and recruitment, primarily to tackle the prevention of T2D in a high-risk population. It will involve long-term community-led actions to administer dietary interventions with potential health and environmental co-benefits, stimulating real-life action against chronic disease with support from local media publicity, awareness and education to optimise retention, adherence and outcomes for both primary prevention and remission of T2D. Community penetration, stakeholder engagement and positive environmental impacts will be nurtured, with qualitative research to guide education and training, addressing beliefs, attitudes and behaviours among health staff and communities (schools, women's groups and politicians).

Who can participate?

Adult patients aged >30 years, overweight (BMI >30), with prediabetes or type 2 diabetes (HbA1c >39mmol/mol, using Nepal/US criterion).

What does the study involve?

The study will engage community leaders and trained local community health and volunteer teams. Targeted HbA1c screening (n~8000) for prediabetes and T2D, using a validated finger-prick test method; large studies where whole groups, such as schools or communities, were randomly assigned to different programmes. The studies were designed to be very likely to detect meaningful benefits over three years, including slowing the rise in blood sugar levels or reducing the number of people who develop type 2 diabetes by about onethird, and helping about one in five people with type 2 diabetes return to normal blood sugar levels. This will be versus minimal advice, of a low-cost, low-carbon, climate-resilient, traditional diet intervention, plus local education and support, delivered by community teams.

Once the core project funding is agreed, separate funding will be sought for three stand-alone sub-studies, built around PhD training for Nepali researchers at UK universities. These will add value to the core project and provide capacity-building in Nepal, to modify future exposure to western-style 'obesogenic' foods and environments and enhance future 'health by stealth' efforts to modify attitudes and encourage sustainable changes among families and the wider community. The sub-projects will explore:

- i. Potential cultural and perceived barriers to weight control, including fear of 'weakness' and effects of intentional weight loss on muscle volume, strength and endurance.
- ii. Different culturally-acceptable dietary strategies, programme community penetration, environmental impacts through Life Cycle Analysis (LCA), and interviews to assess community engagement and stakeholder interaction.
- iii. Underutilised 'Forgotten' Foods and Cuisines of Nepal. Plants which are grown and eaten locally, but not marketed, are of multi-sectoral interest by offering genetic resilience against extreme climate conditions, and nutritional and cultural value for combatting the rise of ultra-processed foods and T2D.

Timelines for delivery: Set up with existing trained and experienced staff and community teams (mo 1-3), community HbA1c screening and recruitment (mo 3-9), randomised trials (mo 3-45), analysis and initial dissemination (mo 45-48).

Anticipated impact and dissemination: Community/ family engagement, capacity-building and training will provide local programme sustainability to reduce burdens of ill-health and reduce demands on limited healthcare services. Wider innovative dissemination with active stakeholder support, including government, WHO, World Bank, using a documentary video, policy modelling and eLearning, will promote wide adoption of community-led T2D prevention programmes in Nepal and beyond.

What are the possible benefits and risks of participating?

There are benefits to participants from early detection of prediabetes or diabetes, and being offered an effective early treatment to reduce health risks and costs. There are no risks associated with the diet intervention.

Where is the study run from?

Glasgow Royal Infirmary, UK.

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

November 2026 to January 2031.

Who is funding the study?
The Howard Foundation (UK).

Who is the main contact?
Prof Mike Lean, University of Glasgow, UK, mike.lean@glasgow.ac.uk.
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Study information

Scientific Title

A community-based dietary programme for type 2 diabetes prevention and remission, clinical trial and implementation evaluation, in Nepal (Co-DIAPREM-NEPAL)

Acronym

Co-DIAPREM-NEPAL

Study objectives

Research question/objective: Can a low-cost community programme, to tackle overweight using local traditional foods, be effective and sustainable for type 2 diabetes (T2D) prevention and remission, in a vulnerable low-income country setting?

Ethics approval required

Ethics approval required

Ethics approval(s)

notYetSubmitted

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Cluster-Randomisation by administrative ward (recruitment centre)

Purpose

Prevention, Screening, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Overweight (BMI >30)

Prediabetes or type 2 diabetes (HbA1c >39mmol/mol, using Nepal/US criterion)

Interventions

Local, traditional, low-cost diet:

(1) Energy-restricted for 8 weeks, designed to induce 8-10kg weight loss

(2) Energy-balanced thereafter, designed for long-term weight maintenance

People found to have prediabetes or diabetes at voluntary community screening with finger-prick HbA1c testing will be invited to participate. All will receive a brief medical consultation and will be given simple advice to lose weight if possible and to attend a medical check annually. Those in recruitment sites pre-randomised to the Intervention arm, after giving informed consent, will receive detailed guidance, together with their home-keeper or close relative, for an energy-restricted diet to be followed for 8 weeks, after which a diet plan for long-term weight maintenance will be provided. The recruitment sites will be given weighing scales, and each participant will have a personal target weight. They will be supported with telephone/text and in-person group meetings led by local health workers and Community Health Volunteers. Those at sites randomised the Control group will receive simple diet advice. All participants will be weighed and have fingerprick HbA1c tested, after 6, 12, 24 and 36 months. After 24 months, those in the Control sites with diabetes will be offered the intervention (unless the preliminary data indicate no benefit). Any participant who develops symptoms of diabetes or its complications will be referred to a hospital diabetes clinic.

Intervention Type

Behavioural

Primary outcome(s)

1. HbA1c: Prevention or remission of type 2 diabetes measured using Afinion-2 HbA1c test at 3 years for (1) the prevention of diabetes for people with prediabetes and 2 years for (2) the remission of type 2 diabetes

Key secondary outcome(s)

Completion date

31/01/2031

Eligibility

Key inclusion criteria

For community screening:

1. Age 30-65
2. BMI >23 and/or gestational diabetes and/or first-degree family history of diabetes

For randomisation:

1. HbA1c >39mmol/mol

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

30 years

Upper age limit

65 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Planned emigration
2. HbA1c > 9% (>75mmol/mol)
3. Already receiving pharmaceutical treatment for diabetes
4. Symptomatic illness requiring immediate referral for treatment

Date of first enrolment

01/11/2026

Date of final enrolment

31/10/2028

Locations

Countries of recruitment

Nepal

Study participating centre
Dhulikhel Hospital

-

Dhulikhel
Nepal

-

Sponsor information

Organisation

Dhulikhel Hospital

ROR

<https://ror.org/01abdqw97>

Funder(s)

Funder type

Funder Name

The Howard Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available