Community-based lifestyle intervention for diabetes management in rural Nepal: a cluster randomized trial (SU13)

Prof. Tomohiko Sugishita (apology), Tokyo Women’s Medical University, Japan
Dr. Lal Rawal, CQ University, Australia
Dr. Haruka Sakamoto, Tokyo Women’s Medical University, Japan
Dr. Abha Shreshtha, Dhulikhel Hospital, Kathmandu University, Nepal
Nepal Overview

- Population: 28,087,871
  - 30% 0-14 years
  - 64% 15-64 years
  - 6% above 65 years

- Population growth: 1.65% (annually)

- GDP (current US$): 28.81 billion
- GDP growth (annual): 6.7%
- GNI per capita, PPP (current international $): $3,090

Source: World Development Indicators database, 2018

Health expenditure, total (% of GDP):
1995: 5.3%; 2005: 5.7%; 2014: 5.8% (or approximately $40 USD per capita)

In 2014, 6.4% of the total government expenditure on health was for NCDIs out of 11% of total government health expenditure.

Out-of-pocket health expenditure (% of total expenditure on health)
1995: 69.6%; 2005: 52.7%; 2014: 47.7%
Dhulikhel Hospital, Kathmandu
University Hospital, Nepal
Diabetes and NCDs burden in Nepal

- NCDs and injuries are attributable to over 2/3 death in Nepal
- Diabetes (8%+) and CVDs (17%+) are considered as major NCDs.
Diabetes and NCDs self-management (evidence base)

- Globally, evidence is supportive to engaging CHWs for prevention and management of communicable as well as non-communicable diseases.

- Recent systematic review (Jeet et al., 2017) showed the potential of engaging CHWs for prevention and management of NCDs and related risk factors in LMICs.

- Peer support interventions are effective in improving clinical and behavioural outcomes among patients with DM - Gatlin et al. (2017) and Patil et al. (2016),

- Kerala Diabetes Prevention program (KDPP), has shown promising and strong evidence base to using peer supporters for diabetes prevention - KDPP, 2018

- Use of regular telephone calls also have shown positive changes in clinical and behavioural outcomes - Piette et al., 2013 and Wild et al., 2016
Evidence also available from other studies

- Nurse Practitioner/CHW-led intervention reduced cardiovascular health disparities. (Allen et al., 2014)
- CHW-led community based intervention improved blood pressure in a low income developing country setting. (Jafar et al., 2011)
- CHW-led intervention for household smokers reduced secondhand smoke exposure among children in China. (Abdullah et al., 2015)
- Diabetes group education led by CHWs improved behavioral and health outcomes in underserved communities in South Africa. (Mash et al., 2015)
- Task-shifting intervention for common mental disorders in India improved mental health wellbeing/health outcomes. (Buttorff et al., 2012)
Aim/ Research Questions

Aim: determine the effectiveness of a culturally appropriate lifestyle intervention in improving management and care of people with T2DM.

Research questions:

RQ1: What is the effectiveness of a culturally appropriate lifestyle intervention... on:

Primary outcomes: Hypoglycaeted Haemoglobin (HbA1c) levels and lipids levels.

Secondary outcomes: quality of life, diabetes distress, blood pressure, waist circumference, total cholesterol, body weight, body mass index (BMI), physical activity levels, diet, health care utilization, episodes and use of telephone calls with CHWs etc.

RQ2: What is the intervention adherence, study retention and measures-completion rates?

RQ3: What are the likely costs (Health systems and societal) of the lifestyle intervention?

RQ4: What are the common facilitators and barrier and potentials of scale up?
Figure: CONSORT diagram of the proposed community based T2DM intervention in Nepal
Phase wise implementation process

Phase I
situation analyses and intervention design

Phase II
Implementation of program

Phase III
Evaluation

Phase IV
Sustainability (evidence into policy and practice)

- Capacity Building of the CHWs and FCHVs
- Awareness and Prevention of Diabetes
- Peer support groups
- Kitchen Clubs
- support calls messages
- Peer support groups
- Kitchen Clubs

Phase wise implementation process

Reach → Effectiveness → Adoption → Implementation → Maintenance
Intervention development and delivery:
• Development of an intervention protocol (in process)

Progress to date:
• Ethics application (to be submitted soon for review in the Nepal Health Research Council, Nepal)
• District mapping to the field sites completed and relevant details collected
• District level stakeholder meetings completed
• Identification of clusters
• Literature review and systematic analysis is ongoing

To be completed by March 2020:
• Clusters randomization, participants selection and random allocation
• Identification and selection CHWs and peer supporters for training
• Development of training manuals and ICT data input app.
• Develop contextual and locally acceptable intervention protocol

Starting April, 2020
• Baseline data collection
• Design and deliver diabetes self-management education for all participants
• Organise group-based monthly sessions facilitated by trained CHW
• Implement community-based lifestyle intervention for 12-month duration
• Monitoring and supervision to the field intervention sites
Assessing effectiveness of the intervention

3rd and 4th year (2021 – 2022)

• Measurements of primary and secondary outcomes, after the intervention against baseline levels and by intervention and control/usual care groups

• Data analyses plan:
  ➢ Quantitative: Descriptive and inferential/advance statistical analyses using Intention to treat (ITT) analyses, on primary and secondary outcomes
  ➢ Qualitative data analyses: Experience of participants, CHWs and peer supporters
  ➢ Economic evaluation: Health systems perspective and Societal cost perspective

• Publication, Presentation and Policy implication
  ➢ Journal submission
  ➢ Presentation in Domestic/International Community Health/NCDs Associations
  ➢ Policy brief to MOH, JICA, UNs, NGOs
Our research team

Professor Tomohiko Sugishita
Professor Rajendra Koju
Professor Andre Renzaho
Dr. Lal Rawal
Dr. Biraj Karmacharya
Dr. Haruka Sakamoto
Dr. Archana Shreshtha
Dr. Abha Shrestha
Dr. Berhe Saleh
Mr. Prabin Shakya
Dr. Samikshya Neupane
Ms. Deepa Shrestha

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