

Community based lifestyle intervention for management of Type 2 diabetes in Nepal – A randomized controlled trial

Data analyses plan:

The data analyses plan and protocol will be developed before the start of the actual data analyses. The baseline characteristics will be summarised by intervention and usual care arms. These baseline characteristics will be summarised by their means and standard deviations or medians and inter-quartile ranges. The primary analysis of the primary outcome, HbA1c levels at 12 months, will follow an intention-to-treat (ITT) approach, with participants analysed according to the trial group to which their district was randomised. Comparisons between the two groups will be implemented using random effects regression, allowing for the clustered nature of the data, and adjusted for the following covariates: age, sex, add. The multivariate analyses will use analyses of covariance (ANCOVA) to avoid baseline imbalance.

We can expand this one to address the secondary outcome, sensitivity analyses, and missing values.

And a pre-specified sub-group analysis.

As randomisation will be at the cluster level, appropriate statistical methods to account for the clustering will be used in the analysis. The primary aim of the study is to evaluate whether HbA1c level differs between the participants of two arms. In statistical terms this null-hypothesis (no difference) can be tested using a mixed effect generalised linear model with appropriate link function. Primary analyses will be unadjusted but secondary analyses will be adjusted for a priori set of pre-specified covariates.

Planned subgroup analyses: An examination of whether any difference in outcomes between usual care and intervention arms varies by HbA1c levels. The significance of subgroup effects will be assessed by tests of interactions of covariates and the treatment effect. The study will have low power to detect all but the largest differences. We will also look at differences in outcome by subgroup of fidelity of uptake (broadly classified as low, medium or high).

Economic evaluation

An economic evaluation will be undertaken to determine the short-term and long-term cost-effectiveness of the community-based lifestyle intervention versus usual care. This evaluation will be undertaken from the perspective of the health care system. Information on all relevant resource use incurred during the intervention follow-up period will be collected and compared between the two study arms. These costs will include all resources required to deliver the intervention and relevant health care utilisation during follow-up. The cost of delivering the intervention will be determined from a number of the participating villages to ensure generalisability. The effectiveness of the intervention will be measured in terms of proportion reduction of HbA1c level and prevention of complications in both study arms, to determine the additional number of cases delayed/avoided. An incremental cost-effectiveness analysis will be undertaken to determine the cost per case of T2DM managed effectively. An incremental cost-utility analysis will also be performed to estimate the cost per quality adjusted life year (QALY) gained over the 12 months follow-up period, using data from the Nepali version of the EQ-5D 5L administered to participants at baseline and 12 months. Sensitivity analysis will be undertaken to test robustness of the analysis in terms of cost inputs and health outcomes, which will enable us to explore potential translation of results across a range of similar settings within Nepal and neighbouring countries.