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Trial Protocol

A lifestyle intervention programme for the prevention of Type 2 diabetes mellitus among South Asian women with gestational diabetes mellitus [LIVING study]: protocol for a randomized trial

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Abstract

Aim This study aims to determine whether a resource- and culturally appropriate lifestyle intervention programme in South Asian countries, provided to women with gestational diabetes (GDM) after childbirth, will reduce the incidence of worsening of glycaemic status in a manner that is affordable, acceptable and scalable.

Methods Women with GDM (diagnosed by oral glucose tolerance test using the International Association of the Diabetes and Pregnancy Study Groups criteria) will be recruited from 16 hospitals in India, Sri Lanka and Bangladesh. Participants will undergo a repeat oral glucose tolerance test at 6 ± 3 months postpartum and those without Type 2 diabetes, a total sample size of 1414, will be randomly allocated to the intervention or usual care. The intervention will consist of four group sessions, 84 SMS or voice messages and review phone calls over the first year. Participants requiring intensification of the intervention will receive two additional individual sessions over the latter half of the first year. Median follow-up will be 2 years. The primary outcome is the proportion of women with a change in glycaemic category, using the American Diabetes Association criteria: (i) normal glucose tolerance to impaired fasting glucose, or impaired glucose tolerance, or Type 2 diabetes; or (ii) impaired fasting glucose or impaired glucose tolerance to Type 2 diabetes. Process evaluation will explore barriers and facilitators of implementation of the intervention in each local context, while trial-based and modelled economic evaluations will assess cost-effectiveness.

Discussion The study will generate important new evidence about a potential strategy to address the long-term sequelae of GDM, a major and growing problem among women in South Asia. (Clinical Trials Registry of India No: CTRI/2017/06/008744; Sri Lanka Clinical Trials Registry No: SLCTR/2017/001; and ClinicalTrials.gov Identifier No: NCT03305939)

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Background

Gestational diabetes mellitus (GDM) is defined as diabetes diagnosed in the second or third trimester of pregnancy that is not overt diabetes [1]. According to International Diabetes Federation (IDF) estimates, about one in every four pregnancies in South East Asia is affected by hyperglycaemia, 90% of which is GDM [2].

A recent meta-analysis has shown that women with GDM are nearly eight times more likely to develop future Type 2 diabetes mellitus compared with those with normal glucose

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tolerance (NGT) in pregnancy [3]. Asian Indians are at higher risk for earlier conversion to diabetes, compared with European and North American white populations. Studies from India have found high conversion rates to Type 2 diabetes even within 5 years of childbirth [4–8]. This indicates that, for greater benefit, any preventive intervention should start as early as possible in the postpartum period [3].

Between 2017 and 2045, the prevalence of diabetes is expected to increase by 48% globally (425 to 629 million), and by 84% in South East Asia (82 to 151 million) [2]. Therefore, prevention strategies are critical to reduce the burden of diabetes, and its sequelae, in terms of morbidity, mortality and costs. Women with GDM constitute a high-risk group for targeted prevention strategies.

It is likely that the development of Type 2 diabetes can be prevented or delayed by lifestyle interventions in women with previous GDM [9,10]. The most relevant long-term follow-up data are available from the Diabetes Prevention Program (DPP), a multicentre randomized trial in which the subgroup of women with a history of GDM allocated to intensive lifestyle support experienced 53% lower progression to diabetes compared with those in the control group. However, the intervention in DPP was very intensive, its participants were older, being on average, ~ 12 years from their last pregnancy [9]. DPP enrolled only individuals with impaired glucose tolerance at baseline.

In a systematic review of randomized controlled trials (RCTs) in which the intervention commenced within 4 years of childbirth, lifestyle interventions were found to be effective in preventing Type 2 diabetes among women with a history of GDM. However, most of the studies were conducted in the USA, Australia and China, with one in Malaysia. The numbers of women involved were small (resulting in wide confidence intervals around the effect estimates) and follow-up was short in the majority of studies (3–60 months, with a median of 11 months) [10]. Interventions in high-income countries were intensive, and utilized expensive trained staff, which is likely to be difficult to adopt and scale in resource-constrained conditions. Therefore, an important knowledge gap related to the effectiveness, sustainability, affordability and scalability of a practical lifestyle intervention programme in South Asia remains.

Pragmatic trials are designed to show the real-world effectiveness of the intervention in broad patient groups. They inform clinical or policy decisions by providing evidence for adoption of the intervention into real-world clinical practice.

The Lifestyle InterVentionIN Gestational Diabetes (LIVING) study is a lifestyle intervention programme for the prevention of Type 2 diabetes among South Asian women with recent GDM. This trial is focused on a low-intensity lifestyle intervention programme that builds on previous diabetes prevention programmes, and aims at high feasibility, acceptability and cost-effectiveness in the South Asian context for women with recent GDM.

Aim

To determine whether a resource - and culturally appropriate lifestyle intervention programme in South Asian countries, provided to women with GDM after childbirth, will reduce the incidence of worsening of glycaemic status, in a manner that is affordable, acceptable and scalable.

Study design

A pragmatic prospective randomized open-label blinded outcome evaluation (PROBE) controlled trial, in 1414 women allocated in a 1:1 ratio to intervention or usual care, with concomitant process and economic evaluations.

Participants and methods

Study setting

The study will be conducted in participants recruited from 16 hospitals and their catchment communities in three countries: India (~ 700 participants from approximately eight hospitals), Bangladesh (~ 350 participants from approximately four hospitals) and Sri Lanka (~ 350 participants from approximately four hospitals). All study centres are urban tertiary facilities, with nearly 75% being public hospitals catering to lower income communities.

Participant selection and eligibility criteria

The registration inclusion criterion for women is GDM diagnosis in their most recent pregnancy. At each participating hospital, women with GDM will be identified at 24–34 weeks of gestation using International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria (Fig. 1). In view of the WHO 2013 guidelines [11], many centres also perform an oral glucose tolerance test (OGTT) or a fasting plasma glucose test to diagnose GDM earlier in pregnancy. As per the IADPSG criteria [2016] and in contrast to 'standard' GDM testing after 24 weeks of gestation, insufficient data exist to confidently recommend cut-off points for OGTT in early pregnancy [12]. Therefore, the women tested by participating sites before 24 weeks of gestation, and found to have normoglycaemia, or GDM controlled on lifestyle only, will undergo repeat testing at 24–34 weeks of gestation and will be included if they satisfy IADPSG criteria for diagnosis of GDM.

Participants registered during pregnancy will receive usual GDM care. Further contact will be made with potential participants on at least one occasion after hospital discharge, and prior to 6 months post-childbirth, when women will be invited for an OGTT to determine trial eligibility.

The inclusion criterion for randomization is the absence of Type 2 diabetes, i.e. confirmation of normal glucose tolerance (NGT), impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) at the 6-month postpartum OGTT.

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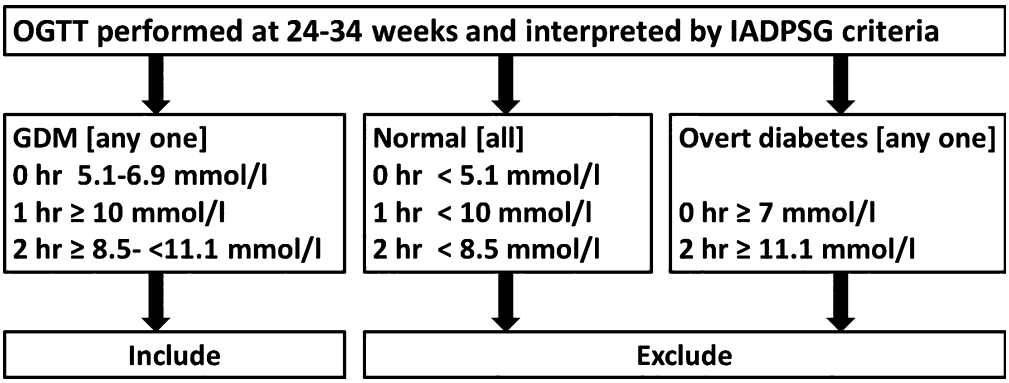

FIGURE 1 Identification scheme for women with gestational diabetes (GDM) at 24–34 weeks of gestation using International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria.

Consistent with design features of a pragmatic trial, additional exclusion criteria will be few, limited to:

- travel time to hospital > 2 h;
- lack of availability of a household mobile telephone;
- use of steroids during pregnancy other than for lung maturation of the baby; and
- likelihood of moving residence in the next 3 years.

Interventions

The participants will be randomized 1:1 to usual care or the intervention.

Usual care arm

Participants will continue to receive care consistent with the usual postpartum practice at the participating centre and the patient's healthcare providers. Data on healthcare practice and utilization will be captured during follow-up.

Intervention arm

The intervention, described in detail below, will be delivered over a 12-month period from randomization. Broadly, the LIVING intervention (Fig. 2) comprises four face-to-face group sessions (of 5–10 individuals) combined with remote on-going support, through SMS, voice messages and

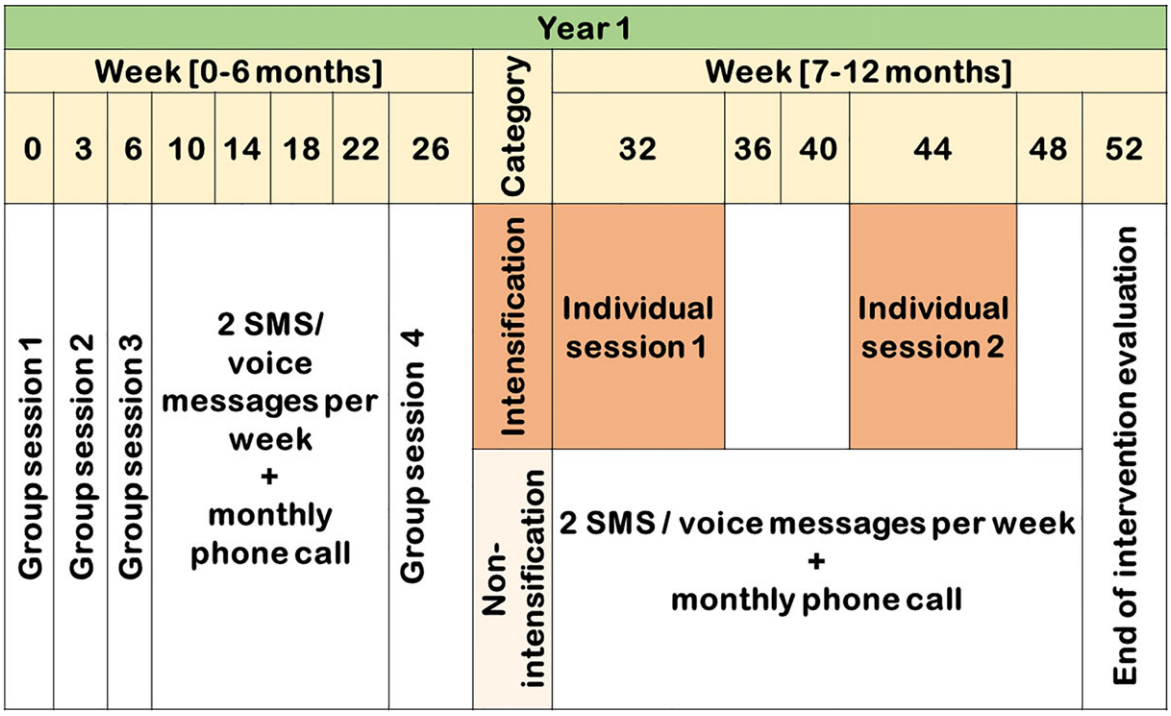

FIGURE 2 Design of the intervention programme.

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telephone calls, and intensification offered where appropriate (Fig. 2; details in Doc. S1).

Outcomes

The primary study outcome is the proportion of women with change in glycaemic category, at or prior to the final visit: (i) NGT to IFG or IGT, or Type 2 diabetes; and (ii) IFG or IGT to Type 2 diabetes. Glycaemic category will be defined using ADA criteria (Doc. S1) [1].

Secondary outcomes are differences in:

- fasting blood glucose (measured using venous blood after 8–14 h of fasting);
- body weight (measured using Omron HN 286 weighing balance);
- waist circumference (measured using Seca 201 measuring tape);
- blood pressure (measured using Omron Jpn-1 automatic sphygmomanometer, with average of two readings taken at a 5-min interval);
- physical activity level (measured using the Modified Global Physical Activity Questionnaire); and
- diet (measured using a 24-h diet recall instrument).

Outcome adjudication

As the primary outcome is entirely dependent on changes in absolute values from OGTT (and does not involve any other non-laboratory criteria), independent outcome adjudication will not be required. To ensure the accuracy of relevant data, 100% source data verification against laboratory reports will be undertaken by appropriately qualified central study staff who are blinded to intervention allocation.

Sample size

The inclusion of 1414 women with GDM will provide 90% power (two-sided $\alpha = 0.05$) to detect a relative risk of ≤ 0.65, assuming that the cumulative incidence of an increase in glycaemic category in the control group will be 20%, and allowing for 20% drop-out from follow-up (follow up rates in our pilot PregDiabCare was > 90% at 6 months). In a recently completed study in Delhi, the prevalence of diabetes and prediabetes (based on OGTT results, and categorized by ADA criteria) in women with previous GDM diagnosed by IADPSG criteria were 10.5% and 32.9% respectively, at median follow-up of 20 months after childbirth [13]. Therefore, a combined incidence of 20% is deemed conservative, and expected to be observed even in regions where the combined incidence of diabetes and prediabetes may be lower. A relative risk reduction of 53.4% for progression to diabetes was achieved in the DPP in women with GDM after 3 years of follow-up [9], suggesting that this study is powered for a justifiable effect size, which would be considered clinically important. The sample size will provide 90% power (two-sided $\alpha = 0.05$) to detect a difference of 1.80 kg between the intervention and control groups, assuming mean body weight of 64.2 kg (SD 10.4) in the control group, for this key secondary outcome.

Recruitment

Women will be recruited prospectively at all centres. Retrospective recruitment will be conducted at centres where recently delivered women with GDM in the index pregnancy can be reliably identified from medical records based on study inclusion criteria.

Randomization and allocation

Allocation to the LIVING intervention or usual care will be conducted through a central, computer-based randomization service, and will be stratified by centre, and whether or not insulin was used during pregnancy. Randomization to the intervention or usual care arm will occur at 6 ± 3 months postpartum. This period reflects a pragmatic balance between avoiding commencing the intervention during typical periods of exclusive breastfeeding, but not delaying the intervention too long such that deterioration in glycaemic status might have occurred in some individuals.

Blinding (masking)

By necessity, neither site investigators nor participants will be blinded to intervention allocation. However, all central study staff (including laboratories and those responsible for laboratory report verification), and statisticians will remain blinded until final database lock.

Follow-up, data collection, management and analysis

Follow-up

Recruitment commenced in October 2017, and is expected to be completed by December 2019. Final study visits are anticipated to occur in December 2020. Whereas the duration of the intervention, including in-person and remote components, is 1 year, the follow-up will continue until 3 years from baseline visit, until till the end of the project duration or until censoring due to any of the reasons identified below (see statistical methods), whichever occurs earlier. With a minimum follow-up of 12 months for each participant, we expect the median follow-up period to be ~ 18 months. Attempts to minimize loss to follow-up will be made by contacting patients between visits by telephone in both groups.

Data collection methods

An electronic case record form using the Medrio electronic data management system will be utilized to capture and store

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study data. Only authorized users with appropriate permissions will have database access. Data on numbers screened, registered, randomized and lost to follow-up will be maintained for all participating sites. Post-randomization follow-up data collection will focus on obtaining the minimum information required to evaluate the major quantitative study outcomes. Data will be collected at randomization and 6-monthly intervals thereafter, with OGTT and HbA_{1c} tests alternately conducted at the follow-up 6-month visits, with both conducted at the final study visit (Table 1). On visits comprising only HbA_{1c} testing, OGTT will be done for women with HbA_{1c} of 6.5% or more.

Statistical methods

Analysis will be based on the principle of intention-to-treat. The effectiveness of the study intervention on the primary outcomes will be determined using a Cox model of time from randomization to change in glycaemic category. Patients who die, develop a subsequent pregnancy during follow-up or are lost-to-follow up without changing glycaemic category will be censored at the time of their last known OGTT test. The model will include factors randomized group and stratification factors. Depending on the distribution of participants by centre, the study centre will be included as either a fixed or random effect. This will be confirmed at the time of the blind review and prior to unblinding. Given that the occurrence of primary outcomes can be registered only at given intervals corresponding to the date of study visits, other methods (e.g. Poisson regression) for the primary analysis will be explored. A blind review will be conducted prior to database lock to inform the choice of primary analytical method. Continuous secondary outcomes such as blood glucose, body weight, waist circumference, blood pressure and physical activity levels will be analysed using repeated-measure linear mixed models with baseline value as a covariate. A detailed statistical analysis plan including mock tables will be finalized prior to database lock and unblinding. The statistical analysis plan will include details about subgroup analyses, missing data handling and potential sensitivity analyses.

Monitoring

Study monitoring will be implemented by experienced staff from each of the regional coordinating centres utilizing a standard monitoring plan developed to ensure compliance with the protocol, good clinical practice principles and any other local requirements.

Ethics and dissemination

Research ethics approval

Ethics approval has been obtained from the respective Human Research Ethics Committees of the All India Institute of Medical Sciences, New Delhi, India, and University of Sydney, New South Wales, Australia. Approval has also been obtained from the Health Ministry Screening Committee, Ministry of Health and Family Welfare, Government of India. Ethics approval has been obtained from the institutional ethics committees of the participating sites in India. In Sri Lanka and Bangladesh, approval for trial conduct at all participating hospitals has been obtained from the central Ethics Review Committees at the University of Kelaniya, and International Centre for Diarrhoeal Disease Research, Bangladesh (iccdr,b) respectively. A Written informed consent will be obtained from all participants recruited to the study.

Process evaluation

A detailed process evaluation will be conducted to understand the implementation and potential for scale-up of the intervention. It will also aim to ascertain for whom effectiveness was greatest, and under what conditions or circumstances. A detailed awareness of local contextual factors will be critical in the process evaluation. As with the

Table 1 Data collection procedures

	Visit			Month visits					
Assessment	Screening	Registration	Randomization/baseline	6	12	18	24	30	36
Informed consent	X		X						
Eligibility	X		X						
Reasons for non-participation		X	X						
Demographics, medical history and examination, anthropometry			X	X	X	X	X	X	X
Questionnaires: Diet, Physical activity, Healthcare utilization			X	X	X	X	X	X	X
OGTT		X			X		X		X
HbA_{1c}		X		X		X		X	X
Serious adverse events			X	X	X	X	X	X	X

OGTT, Oral glucose tolerance test.

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Table 2 Comparison of LIVING study (current study) with MAGDA and LINDA-Brasil trial and the Tianjin Gestational Diabetes Mellitus (GDM) Prevention Program

Trial/study parameter	MAGDA Trial	LINDA-Brasil trial	Tianjin Gestational Diabetes Mellitus (GDM) Prevention Program	LIVING Study
Number of women to be randomized	573	740	1180	1414
Region	Australia	Brazil	China	South Asia
Main characteristics of women to be enrolled	Prediabetes or normoglycaemia postpartum	Use of insulin during pregnancy or prediabetes postpartum	Prediabetes or normoglycaemia postpartum	Prediabetes or normoglycaemia postpartum
Intervention	One individual session and five group sessions over a 3-month period, followed by telephone calls at 6 and 9 months	Principal approach: phone sessions, complemented by phone texting (SMS). Phone sessions occur initially at a weekly interval (three sessions), then biweekly and, when weight goal is achieved, monthly for about 1 year. After the first year the frequency of phone sessions decreases and phone texting becomes the principal way of communication. Group sessions and social events are optional, to be used when felt needed throughout the study	Major elements of the intervention include six face-to-face meetings with study dietitians and two telephone calls in the first year, and two additional sessions and two telephone calls each year subsequently	The period of intervention will be 1 year. Participants will attend four group sessions, and receive 84 SMS (text messages) or voice messages, and review phone calls, in total. There is a provision of two additional individual sessions in the latter half of the intervention year for participants who will require intensification
Timing of commencement of intervention	Approximately 6 months postpartum	Women are encouraged to enter the trial as early as 10 weeks, and are permitted to do so up to 2 years after a pregnancy with GDM	Participants are included with mean (SD) 27.2 (10.4) months after childbirth	6–12 months postpartum
Follow up period	12 months	18 to 60 months	4 years	12–36 months
Primary outcomes	Change in weight, waist circumference, and fasting blood glucose	New onset diabetes	New onset diabetes	The primary study outcome is the proportion of women with an increase of glycaemic category like normal to prediabetes or diabetes, prediabetes to diabetes
Incidence of diabetes/ prediabetes as one of the outcomes	No	Yes	Yes	Yes
Results	Difference of 0.95 kg in weight, 0.5 cm in waist measurement and 0.05 mmol/l in fasting blood glucose in favour of intervention was found	Ongoing trial	Among 79% of participants who completed the year 1 trial, mean weight loss was 0.82 kg (1.12% of initial weight) in the intervention group and 0.09 kg (0.03% of initial weight) in the control group ($P = 0.001$). Trial is ongoing	Ongoing trial

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Table 2 (*Continued*)

Trial/study parameter	MAGDA Trial	LINDA-Brasil trial	Tianjin Gestational Diabetes Mellitus (GDM) Prevention Program	LIVING Study
Highlights	8031 women were approached to randomize 573 and it took 41 months for same Only 10% of women attended all sessions and 34% attended no sessions Loss to follow-up was 27% and 21% for the intervention and control groups, respectively Study limitations include low exposure to the full intervention and glucose metabolism profile being near normal at baseline	To enroll this number of women, 7400 women has been estimated to be initially screened.	79% of participants completed the Year 1 trial The 1 year lifestyle intervention led to significant weight losses after delivery in women who had GDM, and such an effect was more pronounced in overweight GDM women	The study will generate important new evidence about a potential strategy to address the long-term sequelae of GDM, a major and growing problem among women in South Asia

formative research, the process evaluation will be informed by normalization process theory and Michie's behaviour change theories [14,15]. The RE-AIM framework will be adopted to inform translation of research findings to practice, considering both the individual and population impact of the intervention, and sustainability of behaviour changes over time [16]. Mixed methods will be used to evaluate the intervention from the perspectives of the women receiving the intervention, intervention facilitators, site investigators and project management staff. The process evaluation will utilize evaluation data sets, administratively collected process data accessed during monitoring visits, checklists and logs, quantitative participant evaluation surveys, semi-structured interviews and focus group discussions.

Economic evaluation

The economic evaluation will comprise a trial-based component, and a modelled evaluation of long-term costs and outcomes. Intervention costs, based on salaries, training materials and travel, will be assessed from study records. A within-trial comparison of associated healthcare costs (e.g. blood tests, hospital and clinic visits, and medications) of participants in both arms of the study will enable estimation of potential cost-offsets associated with the intervention. Because we do not expect an effect of the intervention on survival, the (within-trial-based) incremental cost-effectiveness ratio will be determined by average differences in utility observed between treatment arms in the trial, weighted by duration of follow-up. To capture costs and outcomes beyond the trial, a decision-analytic model will be developed to enable long-term morbidity, quality of life and survival to be simulated. Sensitivity analysis will be conducted to determine the robustness of base case estimates to assumptions used in the economic evaluation.

Discussion

The intervention in the LIVING study is an innovative adaptation of existing programmes for young women who are at high risk of Type 2 diabetes post childbirth, in resource-poor settings. Implementation strategies that maximize accessibility, engagement, uptake and retention have been incorporated. Although the behavioural content is similar across all programmes that have informed its development, the intervention is potentially unique in how women are engaged and retained, and how the intervention is packaged to ensure low burden on participants, and to allow delivery by minimally trained healthcare workers, as well as involvement of family members. To maximize accessibility and uptake, while minimizing attrition and cost, face-to-face meetings are few, offering an intensity step-up only for those who particularly need it. In addition, a range of technologies is employed to deliver follow-up support and information to participants. The intervention will be delivered during a

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period of substantial caregiving demands on the women when the feasibility of adoption of lifestyle modification is challenging. Although a successful lifestyle modification programme has the potential to reduce the risk of progression to diabetes, data are required to demonstrate its feasibility and scalability in resource-constrained environments. The LIVING study, along with other completed and ongoing studies of relevance summarized in Table 2, is designed to provide practical new evidence in this critical area of need [17–19].

Despite its strengths in multiple domains, this study may face challenges in terms of recruitment, engagement with programme, and retention for long term follow up, as has been observed in other similar recent published trials [17].

In summary, the LIVING study is a large multinational South Asian trial investigating a low-intensity intervention in culturally diverse South Asian women, starting within the first year after childbirth, with the aim of developing an affordable and sustainable programme with the potential of scalability and scope of integration into national programs. This study will provide useful insights in this field.

Funding sources

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Competing interests

None declared.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Doc. S1. Supplementary data.

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