

Designing and evaluating information films about diabetes in pregnancy in Uganda and India

Submission date 27/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/05/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes that develops during pregnancy is known as gestational diabetes. It occurs because your body cannot produce enough insulin (a hormone important in controlling blood glucose) to meet its extra needs in pregnancy. This results in high blood glucose levels. Gestational diabetes usually starts in the middle or towards the end of pregnancy. This condition can result in a number of health problems like high blood pressure, caesarean section and large birth weight babies.

This study aims to find out whether showing films about gestational diabetes that educate pregnant women and the health professionals who care for them can increase the number of women who get tested for gestational diabetes and improve their care during pregnancy.

Who can participate?

Pregnant women aged 18 years and over who are receiving antenatal care at one of the clinics /hospitals participating in the study

What does the study involve?

Participants receiving antenatal care at intervention facilities will have the opportunity to watch a film about gestational diabetes so they can learn about what it is and why it is important. If participants are diagnosed with this condition (gestational diabetes) later in pregnancy, they will have the opportunity to watch another few films about how to look after themselves and manage their diabetes. For women who receive their antenatal care at one of the other clinics where films are not going to be shown, care will be as normal. All women who agree to take part in the study will be asked to complete questionnaires or telephone interviews at three points: at enrolment, around 32 weeks of pregnancy, and about 6 weeks after birth. Women who are diagnosed with gestational diabetes will also be asked to attend a clinic visit at 34 weeks and have a blood sample taken.

What are the possible benefits and risks of participating?

There might not be direct benefits to taking part in the study, but it is hoped that the information learned from this study will help us develop more effective prevention, screening and management strategies for gestational diabetes in low and middle-income countries (LMICs). There are some minor risks: there is the possibility that participants will feel

uncomfortable, stressed or upset when answering personal questions. Some women will be invited for a blood test. This may cause some discomfort. Blood will be drawn by trained staff.

Where is the study run from?

1. London School of Hygiene & Tropical Medicine (UK)
2. Indian Institute of Public Health Hyderabad-Bengaluru (India)
3. MRC/UVRI and LSHTM Uganda Research Unit (Uganda)

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

January 2017 to May 2023

Who is funding the study?

1. Medical Research Council (Newton Fund) (UK)
2. Department of Biotechnology, Government of India

Who is the main contact?

1. Principal Investigator: Prof. Sanjay Kinra (London School of Hygiene and Tropical Medicine, UK), sanjay.kinra@lshtm.ac.uk
2. Prof. Moffat Nyirenda (MRC/UVRI and LSHTM Uganda Research Unit)
3. Dr Giri Babu (Indian Institute of Public Health)

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

NCT03937050

Secondary identifying numbers

CTRI/2020/02/023605

Study information

Scientific Title

Gestational diabetes in Uganda and India: design and evaluation of educational films for improving screening and self-management

Acronym

GUIDES

Study objectives

Can an educational/behavioural intervention delivered through a package of culturally tailored films for pregnant women, their family members, and health providers improve timely detection, glycaemic control and clinical outcomes of women with gestational diabetes mellitus (GDM)?

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 21/03/2019, LSHTM Ethics Committee (London School of Hygiene and Tropical Medicine, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 15913
2. Approved 24/06/2019, Indian Institute of Public Health Institutional Ethics Committee (Magadi Road, Bengaluru, 560023, India; +91 (0)80-23206124; contact@phfi.org), ref: IIPHHB/TRCIEC/120/2017
3. Approved 30/05/2019, Uganda National Council for Science and Technology (Plot 6 Kimera Road, Ntinda, Kampala, PO Box 6884, Uganda; +256 (0)414 705500; info@uncst.go.ug), ref: HS 2577

Study design

Multicentre cluster randomized trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Gestational diabetes

Interventions

30 maternity units in each setting (India, Uganda) will be recruited and randomly allocated to the intervention or control arm (usual care). Randomisation will be carried out separately for each country, with clusters assigned to intervention or control in a 1:1 ratio. Covariate constrained randomisation will be used to help ensure balance with respect to the following covariates: size of facility (as determined by number of deliveries per year); Health Facility (HF) level (level I, II, and III in India or level III or IV in Uganda); and urban/peri-urban or rural setting (Uganda only). Randomisation will be performed by an independent trial statistician.

Low-cost educational/behavioural intervention delivered through a package of culturally-tailored films aimed at:

1. Improving knowledge and skills of GDM guidelines and skills of health providers
2. Raising awareness of the importance of GDM screening among pregnant women and their families
3. Improving confidence and skills in self-management among those diagnosed with GDM

Intervention Type

Behavioural

Primary outcome measure

1. Proportion of women who were tested for GDM at or after 24 weeks of pregnancy, self-reported via telephone contact at ~32 weeks of pregnancy
2. Mean fasting blood sugar in women diagnosed with GDM, measured at clinic visit at 34 weeks of pregnancy

Secondary outcome measures

Proportion of women with adverse perinatal outcomes related to GDM (composite of emergency caesarean section delivery, perinatal or neonatal mortality, and infant hospitalization within 28 days), self-reported via telephone contact post delivery

Overall study start date

01/01/2017

Completion date

01/05/2023

Eligibility

Key inclusion criteria

1. Pregnant women aged 18 years or over attending antenatal care at participating health facilities
2. Willing and able to give informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Female

Target number of participants

20,000 (10,000 in each setting)

Total final enrolment

16500

Key exclusion criteria

1. Pregnant women aged <18 years
2. No informed consent
3. Unavailable for follow-up

Date of first enrolment

05/05/2021

Date of final enrolment

01/04/2023

Locations

Countries of recruitment

India

Uganda

Study participating centre
Indian Institute of Public Health
Hyderabad
India
Telangana 500033

Study participating centre
MRC/UVRI and LSHTM Uganda Research Unit
Entebbe
Uganda
PO Box 49

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

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Sponsor type
University/education

Website
<https://www.lshtm.ac.uk/>

ROR
<https://ror.org/00a0jsq62>

Funder(s)

Funder type
Government

Funder Name

UK Research and Innovation (Newton Fund)

Alternative Name(s)

UKRI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Department of Biotechnology, Ministry of Science and Technology, India

Alternative Name(s)

Dept. of Biotechnology, Govt of India, , , Department of Biotechnology, Department of Biotechnology, Ministry of Science & Technology, India, Department of Biotechnology, GOI, Dept. of Biotechnology, Govt. of India, Department of Biotechnology, Ministry of Sc & Tech, Govt of India, DBT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

India

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journals, dissemination meetings with national policy-makers and stakeholders.

Intention to publish date

01/07/2025

Individual participant data (IPD) sharing plan

Indian Council of Medical Research guidance stipulates that the main India dataset should be retained in India. Therefore, anonymised data from either country will not be made freely available. A controlled access model will be followed: anonymised data will be shared on request, subject to approval from the steering group and Independent Access Advisor. Data sharing will be subject to ethical approval.

IPD sharing plan summary

Available on request