ISRCTN96432637 https://doi.org/10.1186/ISRCTN96432637

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

Submission date
27/02/2025

Recruitment status
No longer recruiting

Registration date
20/05/2025

Overall study status
Completed

Last Edited
20/05/2025

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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
Prof Sanjay Kinra

Contact details
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
sanjay.kinra@lshtm.ac.uk

Type(s)
Public, Scientific

Contact name
Dr Laura Oakley

Contact details
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom

WC1E 7HT
+44 (0)2079272901
laura.oakley@lshtm.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT03937050

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

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

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

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 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes