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GDM and maternal-fetal adverse outcomes rates after providing lifestyle recommendations based on a motivational video early in pregnancy. The St Carlos video_MED_DIET Study

Submission date
31/10/2023

Recruitment status
No longer recruiting

Registration date
02/11/2023

Overall study status
Completed

Last Edited
19/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is a big problem in the health world, especially for pregnant women and their babies. It can cause both short-term and long-term health issues. Recently, the number of cases in our area has been increasing, which is concerning. So, it's important to find the best way to prevent this condition.

One way to do that is by following the Mediterranean Diet, which has been shown to improve things like reducing inflammation, making insulin work better, controlling blood sugar, and managing weight during pregnancy. A study found that when pregnant women followed this diet and got some extra help with olive oil and pistachios, the rate of GDM went down by more than 30%, from 28% to 17%. These positive results were also seen in real-life situations, where the rate stayed above 15%.

But here's the problem: not everyone can see a nutritionist early in their pregnancy, and sometimes, due to limited resources, the nutritional support from a nutritionist is stopped, which makes the GDM rate go up, even beyond 23%.

So, to tackle this issue, we've created a motivational video that explains how to live a healthy lifestyle during pregnancy, following the Mediterranean diet principles we mentioned earlier. Our plan is to show this video to pregnant women during their first checkup. We want to see if this video can make a difference in how many women develop GDM.

We'll study and compare the rates of GDM, how well the mothers and babies are doing, and some health measurements of women who watch our video and follow its advice versus those who stick to the standard pregnancy guidelines, which usually include diets provided by the obstetrician.

Who can participate?
Pregnant women at least 18 years old with normal fasting blood glucose values in the first gestational assessment

What does the study involve?
A Mediterranean diet plan will be given to all pregnant women visiting the hospital for their initial checkup between the 8th and 12th week of pregnancy.

To make sure this is done fairly, a random selection method has been chosen, using an online tool, for scheduling appointments with midwives, obstetricians, or family physicians. The healthcare professional will assign each woman to either the Control Group or the Intervention Group based on their appointment order.

If you're in the Intervention Group, you'll get a video with nutritional advice, created by a nutrition expert from the endocrinology department. You can watch it by scanning a QR code with your phone, and it's available for you throughout your pregnancy.

For those in the Control Group, you'll receive standard pregnancy information and dietary recommendations during your appointments, following the regular guidelines provided by your doctor. You can also discuss any questions or concerns during your in-person visits.

Both groups will continue with their regular checkups in the Obstetrics department and, if gestational diabetes is diagnosed, they'll also have follow-up visits in the Endocrinology department. These specific appointments include the 8-12 week visit, the 24-28 week visit for gestational diabetes screening, and visits between 28 and 38 weeks for ongoing care in case of GDM. Information about your pregnancy, childbirth, and newborn will be collected from hospital records after delivery.

What are the possible benefits and risks of participating?
A reduction in GDM and maternofoetal adverse outcomes will be expected associated with greater adherence to the MedDiet. No side effects are expected

Where is the study run from?
Hospital Clinico San Carlos (Hospital Clínico San Carlos) (Spain)

When is the study starting and how long is it expected to run for?
October 2023 to January 2025

Who is funding the study?
Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC) (Spain)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CI 23/616-E

Study information

Scientific Title
The St Carlos video_MED_DIET Study

Study objectives
Early nutritional intervention based on an explanatory video of the lifestyle recommendations based on the principles of the Mediterranean diet at the first gestational visit, prior to week 8-12 of gestation, may improve adherence to the MED_DIET and to reduce GDM rate and other obstetric and neonatal complications, compared to standard treatment based on obstetrician /midwife/Family Physicians recommendations, by non-expert/specialized personnel in nutritional treatment

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/10/2023, CEIC Hospital Clínico San Carlos (Calle Profesor Martín Lagos s/n Madrid Spain E28040, Madrid, 28040, Spain; +34 913303281; ceic.hcsc@salud.madrid.org), ref: 23.616-E_

Study design
Single centre clinic-based prospective randomized interventional study

Primary study design

Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
A nutritional intervention based on the Mediterranean diet will be given to all pregnant women attending the study hospital in the first gestational visit (gestational weeks 8 to 12).

Due to the significant dispersion resulting from the decentralization of the first gestational visit to confirm pregnancy, a randomization method has been chosen in order of attendance at each consultation (online tool), The professional who performs it both midwife, obstetrician and/or family physicians, will consider inclusion 1 to 2 in Control Group or Intervention Group based on the order of appearance in the medical/ midwife consultation list.

The women included in the intervention group will provide the nutritional/lifestyle intervention in explanatory motivational video format, carried out by an expert nutritionist from the endocrinology department (which they can obtain by reading a QR code with their phone) instead of the face-to-face visit with the nutritionist, titled: Pregnancy nutritional recommendations accessible at: https://youtu.be/Sg4fx4uls64 visible in QR that will be supplied to the pregnant woman. The video will be available to the pregnant woman throughout the pregnancy and can be consulted by her at any time.

Women assigned to the Control group will receive information/recommendations during pregnancy as usual, providing different diets and the recommendations considered in the usual practical guidelines based on the provision of a set of diets written by the obstetrician in the consultation. They could make comments on each in-person visit as usual

All participants for both study arms will have the usual follow-up visits in the Obstetrics department, and also in the Endocrinology department in case GDM is diagnosed. For this study, the following visits are specifically contemplated: -Visit 1 between 8-12 gestational weeks: Visit 2: Between 24-28 gestational weeks when GDM screening is performed according to IADPSG criteria -Visits between 28 and 38 GW if they are diagnosed with GDM for the usual follow up in the Endocrinology department. - Pregnancy/childbirth/newborn data will be collected from the hospital discharge records after delivery.

Intervention Type
Behavioural

Primary outcome(s)
Incidence of Gestational Diabetes Mellitus in each group diagnosed with a 75 g oral glucose load by IADPSG criteria at 24-28 gestational weeks

Key secondary outcome(s))
1. Incidence of pre-eclampsia during pregnancy, as assessed using a blood pressure measurement and albuminuria in urine sample
2. Number of instrumental delivery and caesarean sections at birth, as assessed using obstetric medical records

3. Number of small for gestational age new-borns, macrosomic new-borns, and assessed using birth weight
4. Number of admissions to the paediatric intensive care unit at birth
5 Number of New-Borns before 37 gestational weeks
6. Weight gain is assessed weight at the 8-12 weeks gestational visit and the 38 gestational week visit and also by declared pregestational weight and that obtained at the 38 gestational week

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Pregnant women at least 18 years old
2. Normal fasting blood glucose values in the first gestational assessment

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
Female

Total final enrolment
1656

Key exclusion criteria
1. Women with fasting blood glucose >92 mg/dl in the first gestational assessment
2. Nuts or olive oil intolerance
3. Multiple pregnancy and any medical condition, treatment or diet intervention that the medical team considers to influence the effects of the study intervention.
4. Women with specific nutritional treatments

Date of first enrolment
01/12/2023

Date of final enrolment
05/07/2024

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clinico San Carlos (Hospital Clínico San Carlos)
Calle Profesor Martín Lagos s/n
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Sponsor information

Organisation
Biomedical Research Institute (IdISSC) Foundation for Biomedical Research, Hospital Clinico San Carlos

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request alfonsoluis.calle@salud.madrid.org

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/11/2023	No	Yes
Protocol file			02/11/2023	No	No

Statistical Analysis Plan	02/11/2023	No	No