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Probiotic supplementation for maternal depression

Submission date
26/01/2024

Recruitment status
No longer recruiting

Registration date
02/02/2024

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Studies show the pregnancy period as a 'window of opportunity' in terms of public health. Although there is a lot of evidence on the effect of probiotic supplementation on healthy pregnant women, there is a lack of evidence in individuals with gestational diabetes. The aim of this study is to contribute to science on the effects of probiotic supplements and the Mediterranean diet on mental health in individuals with gestational diabetes (GDM). GDM is high blood sugar (glucose) that develops during pregnancy and usually disappears after giving birth.

Who can participate?
Pregnant women aged between 20 and 40 years with GDM

What does the study involve?
Participants were divided into two groups: the control group, receiving a standard diet compatible with the Mediterranean diet, and a probiotic supplementation group receiving both the standard diet compatible with the Mediterranean diet and probiotic supplementation. The participants' sociodemographic data, medical history, pregnancy data, and adherence to the Mediterranean diet were recorded at 24 and 36 weeks of pregnancy. The mother's pre-pregnancy body mass index was measured. The sociodemographic data included participants' age, marital status, education and profession. The medical history included habits (smoking, alcohol), presence of diabetes mellitus in the family history, history of depression, birth history, delivery method, data related to previous pregnancies, data related to the current pregnancy (pregnancy planning, method of conception), the baby's gender and data related to postpartum breastfeeding preferences. The impact of the Mediterranean diet on maternal mental health was examined.

What are the possible benefits and risks of participating?
In individuals with GDM, adherence to the Mediterranean diet and probiotic supplementation may have a healing effect on depression and anxiety, and may also have a positive effect on attachment to the baby. They were kept under the supervision of a gynecologist to check the side effects of probiotic supplements on pregnant women. If side effects were observed, they were removed from the study.

Where is the study run from?
Osmaniye Park Hospital Gynecology Polyclinic (Turkey)

When is the study starting and how long is it expected to run for?
September 2022 to June 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Effect of probiotic supplementation on maternal depression, anxiety and attachment in gestational diabetes by improving Mediterranean diet quality: a randomized controlled trial

Study objectives
Probiotic supplements and the Mediterranean diet affect maternal mental health

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/10/2022, Eastern Mediterranean University Health Sciences Ethics Committee (Eastern Mediterranean University, Famagusta, 99628, Cyprus; +357 (0)90 392 630 11 11; info@emu.edu.tr), ref: 22/12

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment

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
Mental health in individuals with gestational diabetes

Interventions
With an allocation ratio of 1:1, the participants were divided into two groups: the control group, receiving a standard diet compatible with the Mediterranean diet (MD), and a probiotic supplementation group receiving both the standard diet compatible with MD and probiotic supplementation. The randomization was designed using double-blind randomization. The distribution of the participants was determined by an individual outside the study. The researcher planned a medical nutrition therapy (MNT) according to GDM, in accordance with the Mediterranean diet. Energy requirements were calculated using equations that estimate resting energy expenditure by multiplying the pre-pregnancy weight and height with the physical activity level, as determined by Henry's equations. Because all participants were in the third trimester, 537 kcal was added. The estimated energy requirement was reduced by 30% if the participant was overweight (prepregnancy BMI >25 kg/m2) or achieved the optimal gestational weight gain as recommended by the Institute of Medicine (IOM). The macro-nutrient components were designed to align with current clinical practices for gestational diabetes.

Despite the limited evidence for diet modification in GDM, many centers recommend a slight reduction in carbohydrates and a slight increase in protein for satiety. In this study, the planned intervention included 40% carbohydrates and 25% protein. The higher protein intake at these levels was considered to be in relation with the reduced birth weight. Carbohydrate sources were obtained from low glycemic index food, following the guidelines of the National Institute for Health and Care Excellence (NICE).

The group receiving probiotic supplementation was given products containing Lactobacillus acidophilus (4.3 × 10e8 cfu/sachet), Lactobacillus rhamnosus (4.3 × 10e8 cfu/sachet), Bifidobacterium bifidum (4.3 × 10e8 cfu/sachet), Bifidobacterium longum (4.3 × 10e8 cfu /sachet), and Enterococcus faecium (8.2 × 10e8 cfu/sachet), as well as prebiotics (fructo-oligosaccharides (FOS) 625 mg, lactulose 400 mg) and vitamins A (6 mg), B1 (1.8 mg), B2 (1.6 mg), B6 (2.4 mg), E (30 mg), and C (75 mg) (NBL Probiotic Gold®, Nobel Pharmaceuticals, Turkey). Each participant receiving probiotics was given 84 capsules (one per day for 12 weeks in total). The researcher instructed all participants to take the probiotics orally on an empty stomach with 100 ml of water and to store them in their original packaging at room temperature (with an aim to equalize the effect of probiotics). The participants were requested to refrain from taking any other probiotics throughout the entire trial period.

Intervention Type
Supplement

Primary outcome measure
1. Mother's pre-pregnancy body mass index obtained retrospectively from routine gynecologist examination records
2. Body weight measured using Tanita BC 545 N bioelectric impedance device-BIA at the 24th week of pregnancy
3. Participants' sociodemographic data, medical history, and pregnancy data recorded at the 24th week of gestation (at the beginning of the intervention): a record was kept with a questionnaire during the routine gynecologist examination
4. The mother's prenatal depression level was measured using the Edinburgh Postnatal Depression Scale (EPDS) at the beginning (24th week of gestation) and at the end (36th week of gestation) of the study
5. Prenatal anxiety level was measured using the Pregnancy-Related Anxiety Scale (PrAS) at the beginning (24th week of pregnancy) and at the end (36th week of pregnancy) of the study
6. The mother's attachment level was measured using the Prenatal Maternal Attachment Scale (MAAS) at the beginning (24th week of gestation) and at the end (36th week of gestation) of the study

Secondary outcome measures
Mediterranean diet score measured using the MedDiet scoring system at the 24th and the 36th week of pregnancy

Overall study start date
01/09/2022

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Pregnant women
2. Aged between 20 and 40 years
3. Diagnosed with GDM
4. Had complete data
5. Agreed to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
64

Key exclusion criteria
1. Multiple pregnancies
2. Prenatal diagnosis of diabetes mellitus
3. Hypertensive disorders
4. Chronic diseases such as liver and/or kidney disease
5. Body mass index (BMI) of ≥30 kg/m2 or <18.5 kg/m2
6. Presence of abnormal fetal structures or chromosomal findings based on second-trimester ultrasound screening and/or invasive prenatal diagnosis
7. Planned pregnancy termination
8. Diagnosis of a psychiatric illness
9. Presence of intrauterine growth restriction (IUGR) complication in GDM diagnosis
10. Insulin therapy after GDM diagnosis
11. Requirement for special dietary intervention (severe food allergy)
12. Receiving probiotic supplementation
13. Sleep problems
14. Stressful events
15. Sedentary physical activity

Date of first enrolment
30/11/2022

Date of final enrolment
10/05/2023

Locations

Countries of recruitment
Türkiye

Study participating centre
Park Hospital
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ROR
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
26/03/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			13/02/2024	No	No