

## **Protocol for a Systematic Review**

**Title:** Primary Prevention of Gestational Diabetes Mellitus through nutritional factors: a systematic review.

**Author names:** Mikel Donazar-Ezcurra<sup>1</sup>, Cristina López-del Burgo<sup>1,2,3</sup> and Maira Bes-Rastrollo<sup>1,2,4</sup>.

**Author affiliations:** **1** Department of Preventive Medicine and Public Health, University of Navarra, Pamplona, Navarra, Spain. **2** IDISNA, Navarra's Health Research Institute, Pamplona, Navarra, Spain. **3** Institute for Culture and Society, University of Navarra, Pamplona, Navarra, Spain. **4** CIBERObn, Instituto de Salud Carlos III, Madrid, Spain.

**Email addresses:** Mikel Donazar Ezcurra ([mikeldoez@gmail.com](mailto:mikeldoez@gmail.com)), Cristina López-del Burgo ([cldelburgo@unav.es](mailto:cldelburgo@unav.es)) and Maira Bes-Rastrollo ([mbes@unav.es](mailto:mbes@unav.es)).

# **Primary Prevention of Gestational Diabetes Mellitus through nutritional factors: a systematic review.**

## **1. Background**

Gestational diabetes mellitus (GDM), defined as any degree of glucose intolerance with onset during pregnancy, is increasing worldwide. In fact, prevalence has increased by 10-100% in the last 20 years<sup>1</sup>. More mothers entering pregnancy as obese and of advanced maternal age has contributed to the escalation in the incidence of GDM. Several risk factors are known for GDM; advanced maternal age, obesity, physical inactivity, parity, ethnicity, family history of type 2 diabetes (T2D), history of a macrosomic baby, and a previous history of GDM<sup>2,3</sup>.

GDM is associated with adverse maternal and fetal outcomes during pregnancy and in the long term<sup>4</sup>. In order to prevent these adverse outcomes, such as T2D, one of the objectives is to understand the hormonal changes and altered glucose metabolism that are associated with the development of GDM during pregnancy<sup>5</sup>. GDM occurs when insulin receptors are not able to respond adequately to control blood sugar levels due to hormones produced in pregnancy, such as the human placental lactogen, which impacts susceptible insulin receptors. This, in turn, causes inappropriately high levels of blood sugar. Due to the similarities in the underlying pathophysiology and risk factors of GDM and T2D, it is probably that the factors that are effective in the prevention of T2D might be successful in the prevention of GDM. These factors involve dietary pattern, physical activity, reduction of overweight and obesity and gestational weight gain. It is important to identify population factors to reduce the increasing rates of GDM as it is doing for T2D.

## **2. Objective of the Review**

To systematically review literature on clinical trials and prospective cohort studies focusing on the effectiveness of nutritional factors (diet and supplements) before or during pregnancy to prevent GDM.

## **3. Methods.**

### **Criteria for inclusion and exclusion studies in the review**

Inclusion criteria: clinical trials or adjusted prospective cohort studies, originals, and primary prevention of GDM through nutritional factors. Exclusion criteria: presence of diabetes mellitus type 1 or 2 prior to pregnancy, presence of previous diseases to pregnancy requiring dietary treatment, evaluation of diet as a treatment for patients with GDM, only physical activity for prevention of GDM and research on animals.

**Databases:** PubMed, Cochrane Database and ClinicalTrials.gov.

**Time and place:** Studies published from inception up to 30<sup>th</sup> June 2016.

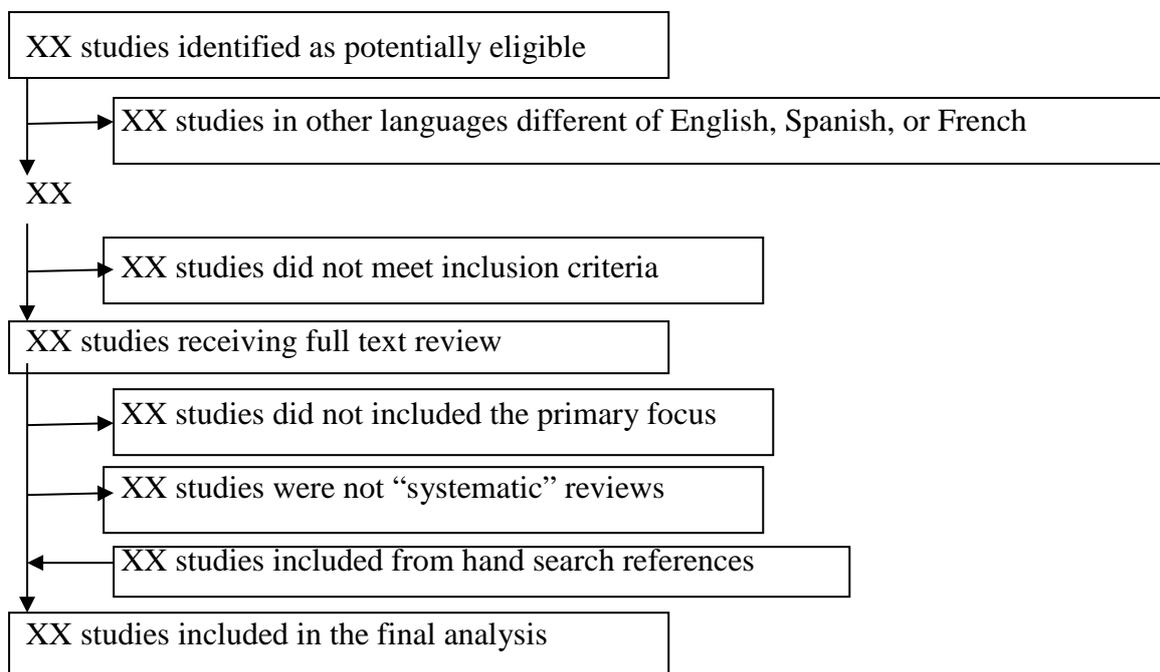
**Study characteristics:** Systematic reviews or adjusted prospective cohort studies conducted in human.

**Languages:** English, Spanish, and French

**Search strategy:** We will conduct electronic searches in the following databases: PubMed, Cochrane Databases, and ClinicalTrials.gov.

Search terms “gestational diabetes” and “diet” or “nutrition”. Another search will be conducted for the keywords “supplement” and “gestational diabetes”.

### Flow diagram of study selection procedure



**Data management:** Two reviewers will conduct the search strategy and both will classify the relevant studies to be included in the systematic review. The disagreement between the researchers will be solved by a third reviewer reaching a consensus. Only clinical trials or adjusted prospective cohort studies will be selected. Due to inherent limitations other epidemiological studies will be excluded. We will restrict publications to English, French and Spanish languages. The selection process of the articles will begin from reading the titles. After this initial stage, the selected papers will be reviewed by reading their abstracts. At that moment, these studies will be separate for further analysis to identify relevant publications, according to the inclusion/exclusion criteria. Additional articles could be included from the reference lists of relevant studies and reviews.

**Data extraction:**

- Study details:
- First author
- Year of publication
- Authors' country
- Study design and objective
- Methods in prospective studies
- Intervention in participants allocated to intervention in RCT
- Intervention in participants allocated to control group in RCT
- Results
- Covariates adjusted for in prospective studies
- Authors' conclusions

**4. Timeframe**

It is expected to include clinical trials or adjusted prospective cohort studies up to 30<sup>th</sup> June 2016.

**5. Conflicts of interest**

Reviewers have no conflicts of interest to declare.

**6. Funding**

CIBERObn Physiopathology of Obesity and Nutrition, Spanish Government Instituto de Salud Carlos III and the European Regional Development Fund (FEDER). Grants: PI13/00615, PI14/01668, the Navarra Regional Government (122/2014) and the University of Navarra.

**7. References**

1. Ferrara A. Increasing prevalence of gestational diabetes mellitus: A public health perspective. *Diabetes Care*. 2007;30:141–146.
2. Chasan-Taber L, Schmidt MD, Pekow P, et al. Physical Activity and Gestational Diabetes Mellitus among Hispanic Women. *Journal of Women's Health*. 2008;17:999-1008.
3. Teh WT, Teede HJ, Paul E, Harrison CL, Wallace EM and Allan C. Risk factors for gestational diabetes mellitus: Implications for the application of screening guidelines. *Aust NZ J Obstet Gynaecol*. 2011;51:26–30.
4. Jovanovic L and Pettitt DJ. Gestational Diabetes Mellitus. *JAMA*. 2001;286:2516-2518.
5. Ramírez-Torres MA. The importance of gestational diabetes beyond pregnancy. *Nutr Rev*. 2013;71:37-41.