Title: Efficacy and Feasibility of an eHealth Intervention for Pregnant Women on Diet, Physical Activity and Knowledge Related to Pregnancy (EmbarApp)

NCT number: 2021.490

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1. Type of study

A randomized pragmatic trial with a control group without intervention, with the aim of evaluating the effectiveness and feasibility of using of a mobile application used by women during their pregnancy, on the nutrition, physical activity, knowledge related to pregnancy, and obstetric and perinatal indicators.

2. Study population

The target population will be made up of pregnant women who carry out pregnancy control visits in health area III of the Health Service of the Principality of Asturias (SESPA) during the date of study.

The study population will result from those women who meet the inclusion criteria: i. be of age; ii. be pregnant with a single fetus; iii. have a low-risk pregnancy; IV. own a smartphone with ability to download the mobile app. As exclusion criteria will be consider: i. No fluent Spanish speaker; ii. inadequate or non-completion of the questionnaires.

Those who meet the above criteria will be invited to take part. Those who agree to participate in the study and submit the informed consent will form the study sample.

A random sample of 153 individuals is enough to estimate, with a confidence of 95% and a precision of +/- 5 units percentages, a population percentage that is expected to be around 15%. The percentage of necessary replacements has been foreseen which will be 1%.

3. Development

A researcher will be in telephone contact with the recruited women during the first trimester of her pregnancy informing about the research project in which they have agreed to participate. They will be sent via email a web link that will direct them to the knowledge quiz about the pregnancy and the questionnaire of adherence to healthy diet behaviors and physical activity Motiva-Diaf. In this first telephone contact, the women of the IG will be aimed to use iNATAL free-app previously selected by researchers based on: contest, quality and behavior change techniques included.

Anthropometric data (weight, height, BMI), clinical data (blood pressure, blood tests, urinalysis, ultrasound data), and indicators obstetric and perinatal, will be obtained from the medical records of both the hospital care setting, as well as the primary care setting, in each scheduled pregnancy consultation, and in each episode of hospitalization, and will be recorded in a coded document per woman.

In the last trimester of pregnancy, contact will be made again with the pregnant women via email, providing the link to the questionnaire of knowledge about pregnancy, to the questionnaire of adherence to behaviors healthy diet and physical activity Motiva-Diaf and in the case of the women of the IG to the questionnaire to assess app quality Users Mobile Application Rating Scale (uMARS).

4. Intervention

Women of the control group are going to receive the usual care. Women in the intervention group are going to combine usual care with iNATAL app usage.

5. Data analysis

A descriptive study of the variables of the sample and of the variables related to the healthy behaviors studied and the knowledge related to pregnancy, before and after intervention, as well as the variables related to the feasibility of use of the application. The statistical indices will be used descriptive: absolute frequencies, means and standard deviations. To determine if the variables adjust to normality, the Kolmogorov-Smirnov statistic.

To compare the behaviors and knowledge between the CG and IG groups, will use the Chi-square test (when the variables are qualitative), or the t-Student or the Wilcoxon test depending on whether they fit a normal distribution or not, respectively.

To know the influence of personal and knowledge variables on behavior, multivariate regression analyzes will be carried out linear or logistic multiple when the dependent variables are quantitative or qualitative respectively.

Results will be considered statistically significant when the p value is < 0.05. Data will be analyzed with the software SPSS version 27.0.