# FEASIBILITY STUDY OF A 4-WEEK EPI-NO® PROTOCOL IN PREGNANT WOMEN

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## Abstract

**Introduction**: The purpose of using the Epi-No device would be to stretch the vaginal wall up to its maximum diameter; once done repeatedly, it would facilitate perineal distension during birth and labor.

**Objective**: To determine the feasibility of a supervised daily four-week Epi-no® protocol in pregnant women.

**Methods**: Pregnant women received a 20-session protocol with daily progression of the balloon diameter over four weeks, and a satisfaction form at the end. Postpartum obstetric data, fetal values, and ICIQ-SF scales were collected.

**Results**: Nine pregnant women performed an average of 12 sessions, after which they claimed to be completely satisfied (55.6%) or satisfied (44.4%) with the obtained scores. The balloon diameter was progressing but unrelated to the episiotomy procedure.

**Conclusion**: The 4-week protocol with Epi-No® is feasible, safe, well accepted by pregnant women and may benefit the flexibility of the perineal muscles.


**1.** anatomically shaped inflatable silicone balloon

**2.** Handpump

**3.** pressure gauge

**4.** air release valve

**5.** connecting tube

**Figure 1.** Epi-No ® device.

## Introduction

Evidence shows that childbirth is the leading risk factor for pelvic floor dysfunctions. The Epi-No® is an inflatable balloon device designed to allow women to stretch the vagina and perineum gradually from 37 weeks gestation onwards. It has been claimed to shorten the 2nd stage of labor and reduce analgesic use and episiotomy rates.[1] Still, this hypothesis has not been confirmed, with several studies showing no protective effect of the Epi-no device on pelvic floor structures during vaginal childbirth.[2] However, the self-administration of the device could compromise its correct use and the progression of balloon inflation. Additionally, the duration of Epi-no use varied among the studies, and compliance with using it was not assessed in all of them, which could potentially interfere with the results obtained.[3]

## Methods and Materials

A feasibility study addressed aspects of a supervised Epi-no® protocol for pregnant women attending antenatal physical therapy visits. Women were recruited consecutively from February to April 2022. The supervised Epi-no® protocol consisted of attending a daily four-week supervised program using Epi-no®. Feasibility was assessed in terms of the recruitment capability, sample characteristics, data collection procedures, outcome measures, and retention (attendance to Epi-no® protocol visits, Epi-no® protocol adherence, participant experiences) of the program. Data were collected using self-reported questionnaires.

**Table 1.** Demographic variables at the start of the protocol.

| | Min-Max | Mean ± SD | N (%) |
|---|---|---|---|
| Age (years) | 25-35 | 34,4±3,2 | - |
| Gestational age (weeks) | 34-36 | 34,3±0,7 | - |
| Previous BMI | 21-33 | 24,4±3,5 | - |
| Weight gain (Kg) | 6-15 | 9,8±2,7 | - |
| University Education | - | - | 7 (78%) |

## Results

16 women volunteered, and nine were included, matching the inclusion criteria. The retention rate was 90%, attending five or more supervised Epi-no supervised sessions. The mean number of sessions was twelve.

All women declared to be completely satisfied with the program and its results and that it would be probable to recommend it to someone. Although adherence does not confirm it, all women considered the daily frequency adequate. When asked about the individual use of the device, 77.8% admitted being unable to use it autonomously. As for undesirable effects, only 2 (22.2%) users claimed to have experienced pain or discomfort during the procedure, and on no occasion did they cause them to drop out of the project.

In each session, the level of discomfort at insertion and expulsion of the device, on a scale from 0 to 10, where 10 corresponds to the maximum possible discomfort. The level of discomfort with balloon insertion was between 0 and 5, with a rating of 2 being the most frequently mentioned. The minimum value of discomfort when expelling the balloon was one, and the maximum was 6, with grade 4 being the most frequently applied. A positive correlation was established between a higher number of sessions performed and a higher final diameter of the device (p=0.05 and r=0.666). The higher the frequency of sessions, the closer to the goal of 22 cm of the device. No statistically significant differences were found in the number of sessions having a protective effect on the occurrence of episiotomy. However, women having cesarean section completed an average of 9 sessions, compared to the 14 performed by women who had a vaginal delivery.

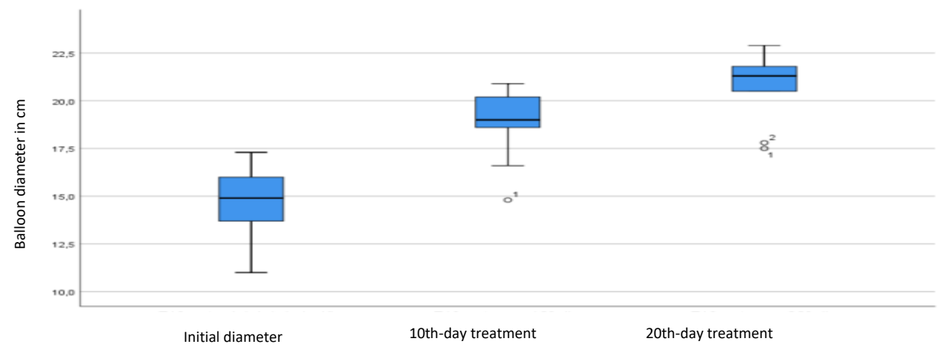


**Chart 1.** Diameter of the inflatable balloon at start, midle and end of protocol

## Discussion

Pregnant women adhere to a 4-week protocol of Epi-No, which is safe and can positively affect the elasticity of the perineal muscles. The daily frequency during the four weeks can be considered exhaustive.

Although the influence of the Epi-no® device in preventing perineal trauma was not statistically significant in this small sample, and attendance was lower than expected, no anal sphincter injuries were reported.

Many studies dedicated to Epi-no® do not mention the number of sessions carried out by pregnant women but only say that the device is provided from the 37th/38th week of pregnancy, and they are instructed to use it every day until the moment of delivery. There is, therefore, a need to standardize methodologies, duration of use, gestational period, and how to use the device. Additionally, the treatment protocol dosage under a specialist's supervision may affect the results obtained, as shown in this study. Comparing supervised protocols of 3- and 4-weekly sessions is pertinent in the future.

## Conclusions

The supervised Epi-no® protocol is feasible. The daily supervised frequency may be considered exhaustive, suggesting a frequency of three times per week of supervised treatment to be more appropriate. Future studies are needed on the effect of the supervised Epi-no® protocol in preventing perineal trauma.

## References

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