

# Remote Clinical Trial on a Shoestring Budget

Prospective, On-Market,  
Patient-Reported Outcomes for  
Milli™ Vaginal Dilator  
(POMPOM)



All-in-one expanding  
vaginal dilator

# POMPOM Study

## Prospective On Market Patient-reported Outcomes for Milli Vaginal Dilator (POMPOM)

- **Enrollment:** 50+ patients utilizing a remote study format\*
- **Compensation:** \$100 Amazon Gift Card for completion of each of the 3 time points (up to \$300)
  - **Baseline collection:** demographics, Ob/ GYN history, Lamont/ Pacik, prior treatment history, goals for Milli dilation
  - **Validated Surveys at 3 Timepoints:** before 1<sup>st</sup> use, 3 months, and 6 months (exit)
    - Penetration Efficiency Questions (7)
    - Pain/ Anxiety Scale Questions (3)
    - Female Sexual Function Index Questions (19)
    - Medication Log (if applicable)
    - Goal assessment on exit

Inclusion	Exclusion
<ul style="list-style-type: none"><li>• Adults who've just purchased a Milli dilator</li><li>• Sexual partner with a functional penis</li><li>• Seeking and unable to achieve vaginal penetration with intercourse</li></ul>	<ul style="list-style-type: none"><li>• Prior use of Milli</li><li>• Contraindicated to Milli</li><li>• Pregnant</li><li>• Partner with a condition preventing intercourse</li><li>• Untreated major mental health disorders</li></ul>

### Join the POMPOM Clinical Study and Share Your Milli Experience

By participating in this study, you will be contributing valuable research that will help clinicians learn more about women with vaginismus and associated painful sex. Your contribution is a meaningful step towards a better future facing these challenges.


We are confidentially and remotely collecting data with questionnaires to track changes in these key dimensions: pain, sexual and emotional well-being, Milli Vaginal Dilator satisfaction, and usage (frequency, time, vibration).

This study will **not require in-person office visits**—we call these “Virtual Visits.” We will provide you with access to a study physician when requested. All questionnaires will be sent via email with a link to complete electronically. Here’s what you can expect from the POMPOM study:


- 1** POMPOM study consent—to review, visit [info.hellomilli.com/pompom](https://info.hellomilli.com/pompom)
  - If you want to join the POMPOM study, electronically sign the consent form.
  - If you have any questions about the study or the consent form, we will connect you with a study physician for further explanation.
- 2** Next, you will receive emails with a link to questionnaires to confirm your eligibility and collect baseline information, including the date of first use.
- 3** At specific time intervals—3 months (checkpoint) and 6 months (exit)—you will receive an email with a link to the same questionnaires.
- 4** For your time, we will pay you \$100 for each completion—baseline, 3-month (checkpoint), and 6-month (exit).
- 5** Between the above intervals, we will send an email touchpoint to keep you engaged in the study. Those touchpoints also allow you to specify your final set of questionnaires.
- 6** You are eligible to participate in the POMPOM study and exclusion criteria. Please review the table below.

The Milli Vaginal Dilator is an FDA-cleared medical device with permission for use.

We hope you will join the POMPOM study. Cheers to improved health for everyone!



[info.hellomilli.com/pompom](https://info.hellomilli.com/pompom)



Participate in the POMPOM Study!

- IRB approved, enrollment period May 1-Nov 20, 2024  
[ClinicalTrials.gov NCT06397885](https://ClinicalTrials.gov/NCT06397885)
- <https://www.hellomilli.com/pompom/>

# Real-world data collection & reporting

- ➔ **Data collection:** Collected digitally through an online mechanism
- ➔ **Recruitment:** Invitations to join before, during, and after purchase.
- ➔ **Consent:** Informed consent secured using a compliant e-consent system.
- ➔ **Enrollment Goal:** Target is 50+ participants.
- ➔ **Endpoints Measured:**
  - Penetration
  - Pain and anxiety related to sexual penetration
  - Sexual and emotional wellbeing
  - Satisfaction with Milli use
  - Adverse events inquiry

## STUDY SYNOPSIS



### Purpose

Evaluate outcomes for Milli as an OTC device, obtaining data that is meaningful to clinicians, patient customers, and payers



### Method

- Prospective, Single-Arm, Observational On-Market Study
- Primary endpoints reported at 3 and 6 months after baseline using validated Penetration Efficiency Questionnaire (PEQ)
- Secondary endpoints comprised of additional validated questionnaires (Female Sexual Function Index Questions (FSFI), Pain/ Anxiety Scale Questions) and qualitative questions



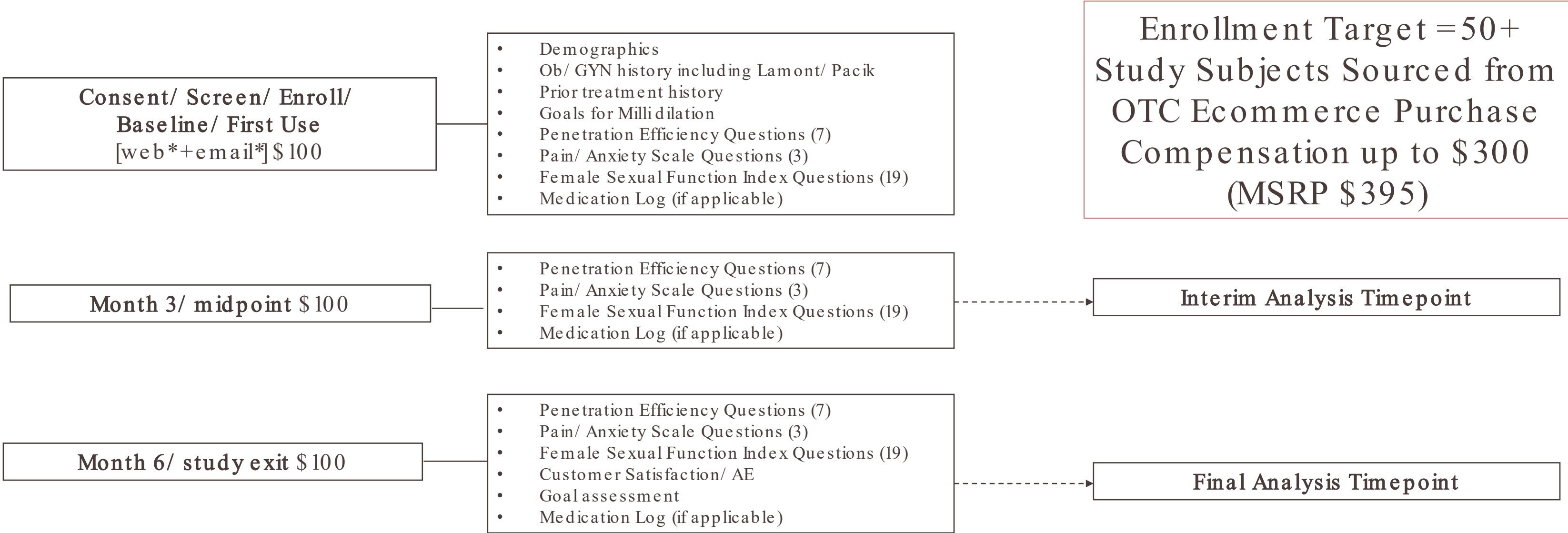
### Additional Analyses

- Evaluate as per pre-specified cohorts
- Per baseline Pain Score
  - Per baseline Anxiety Score
  - Per treatment goal (Patient-identified)
  - Per prior therapies/ medication history
  - Per device usage patterns

# Screening Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"><li>You are a female at birth aged <math>\geq 18</math> years of age.</li><li>You purchased a Milli Vaginal Dilator</li></ul>	<ul style="list-style-type: none"><li>You have previously participated in any studies by the company in the past 12 months</li><li>You have used Milli before enrollment.</li></ul>
<ul style="list-style-type: none"><li>You currently have a sexual partner with a functional penis</li><li>You are currently seeking vaginal penetration to achieve sexual intercourse</li><li>You are currently unable to tolerate vaginal penetration to achieve sexual intercourse</li></ul>	<ul style="list-style-type: none"><li>You are currently pregnant</li><li>You or your partner experiences other conditions preventing intercourse (e.g., erectile dysfunction, lack of libido).</li></ul>
<ul style="list-style-type: none"><li>You meet vaginismus and related painful sex criteria (genito-pelvic pain/ penetration disorder) as confirmed by having one or more of the following for greater than 6 months:<ul style="list-style-type: none"><li>Pelvic pain</li><li>Vaginal pain</li><li>Pain with vaginal intercourse</li><li>Pain with vaginal penetration</li><li>Fear or anxiety about vaginal or pelvic pain with vaginal penetration</li><li>The inability to achieve vaginal penetration</li></ul></li></ul>	<ul style="list-style-type: none"><li>You have a prior history of any of the following:<ul style="list-style-type: none"><li>gender-confirming surgery</li><li>vaginal reconstruction surgery</li><li>pelvic radiation</li><li>vaginal procedures that result in extensive scarring</li></ul></li><li>EXCEPT hysterectomy procedures</li></ul>
<ul style="list-style-type: none"><li>You are able to read and understand the approved informed consent form (ICF).</li><li>You are able and willing to comply with the study protocol.</li></ul>	<ul style="list-style-type: none"><li>You have active pelvic infections.</li><li>You have open wounds in the tissue inside or surrounding the vagina.</li></ul>
	<ul style="list-style-type: none"><li>You have an untreated major mental health disorder (e.g., affective disorder, psychosis, PTSD)</li></ul>

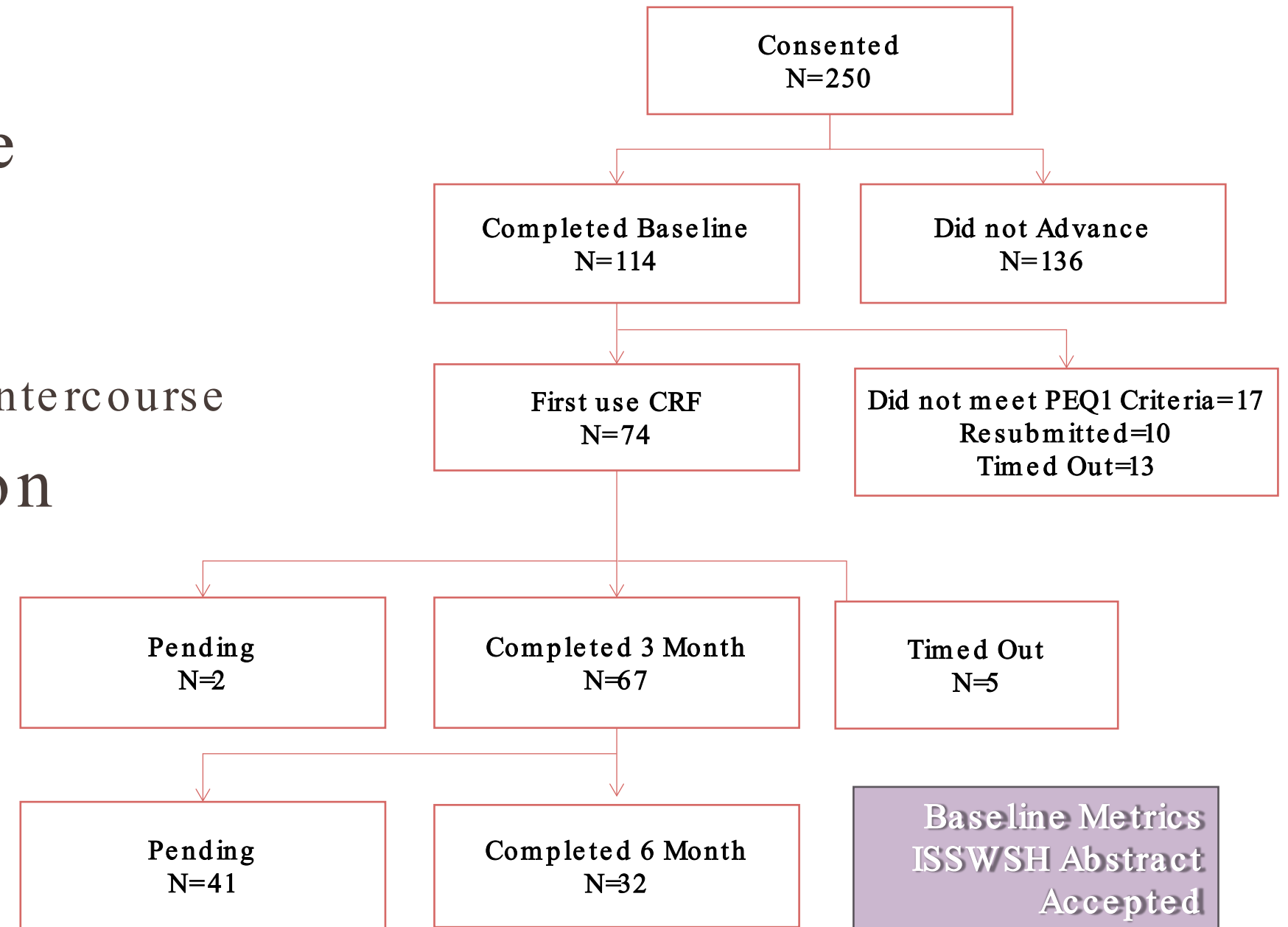
# Protocol Overview





# POMPOM Study Early Look

- Enrollment May 1-Nov 20, 2024  
1075 eligible upon device purchase
- Primary Inclusion Criteria
  - Meets diagnostic criteria for Vaginismus/ GPPPD
  - Seeking but currently unable to tolerate vaginal intercourse
- Most challenging to treat population
- Retention of 94%
- First abstract accepted less than a year after enrollment began



# POMPOM Subject Demographics

## Baseline Data

- The mean age of participants is 50.8 years (range 18-77).
- The majority were nulliparous (62.2%).
- Before participation, 45.9% of participants had seen at least 2 healthcare providers for evaluation and treatment.
- Over two-thirds (70.3%) of the participants had reported symptoms associated with vaginismus for over 3 years, with 23.0% for 3-5 years and 47.3% for over 5 years.
- 43.2% reported past or current static dilator use.

74 subjects	
Race [Ethnicity]	<u>90.5% White</u> 6.8% Asian 1.4% Black 1.4% Unknown [ 2.7% Hispanic ]
Education	<u>81.2% College Degree</u> 13.5% Some College 5.4% High School Degree
Pregnancies	<u>48.7% None</u> 16.2% 1 24.3% 2 10.8% 3+
Vaginal Deliveries	<u>86.5% None</u> 5.4% 1 5.4% 2 2.7% 3
History of Static Dilator Use	56.8% None <u>28.4% Past</u> <u>14.9% Current</u>

# Learnings & Next Steps

## **Socio-Economically Homogenous**

Majority had employer-based insurance  
Lacked diversity (racial & educational)

## **Inclusion Criteria Too Tight**

PEQ Q1 0-1 score  
didn't include a range of intimate penetration or same-sex couples

## ***NIH Grant: provide free devices***

Study Milli vs. Static Dilators (current standard of care)



# POMPOM Baseline Scores

Validated Questionnaires used:  
PEQ,<sup>1</sup> FSFI,<sup>2</sup> VAS Pain and Anxiety,<sup>3</sup>  
Lamont-Pacik,<sup>4</sup>

- On the Lamont scoring system
  - 47.2% were Grade 1
  - 18.1% were Grade 2
  - 19.4% were Grade 3
  - 15.3% were Grade 4
  - two subjects did not provide a grade
- A visceral reaction – extreme nervousness, palpitations, tremors, hyperventilation, sweating, and shaking – was reported by 32.4% of the participants. (Pacik)

Subject Scores by Age Groups				
Age Groups	All Subjects n=74	Under 40 n=27	40-64 n=34	65+ n=13
PEQ <sup>3</sup> Composite Score Mean ±SD median Composite Score Range 0-21	8.3±4.3 8 0-17	9.1±4.1 10 1-16	7.8±4.6 8 0-17	7.8±3.8 7 3-14
FSFI <sup>4</sup> Score Mean ±SD median Score Range 0-36	13.3±7.3 14.5 1.2-24.8	16.5±7.1 18 1.2-24.8	11.5±7.1 13.2 1.2-24.0	11.5±6.6 12.6 2.4-22.2
Pain Score <sup>5</sup> with Intercourse Mean ±SD median Score Range 0-10	8.3±1.9 9 0-10	7.9±1.6 8 5-10	8.4±2.0 9 0-10	9.0±1.8 10 4-10

1. van Lankveld JJ. J Consult Clin Psychol. 2006 Feb;74(1):168-78. (PEQ). 2. Rosen, R., Brown, C., Heiman, J., Leiblum, S., Meston, C., Shabsigh, R., Ferguson, D., & D'Agostino, R. (2000). The Female Sexual Function Index (FSFI): A multidimensional self-report instrument for the assessment of female sexual function. Journal of Sex & Marital Therapy, 26(2), 191-208. (FSFI). 3. Huskisson, E. C. (1974). Measurement of pain. The Lancet, 304(7889), 1127-1131. (VAS Pain and Anxiety). 4. Lamont, J. A. (1978). Vaginismus. American Journal of Obstetrics and Gynecology, 131(3), 312-316.



# Thank You!



All-in-one expanding  
vaginal dilator



# Debbie Donovan

Commercial Operations



## Providing life science companies with:

- Digital marketing solutions that drive product sales
- Compliant, co-op customer marketing programs
- Policies and procedures for social media engagement



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# Online Observational Clinical Trial for Assessing the Effectiveness of an FDA-Cleared Expanding Dilator

Sheryl Kingsberg, Ph.D<sup>1</sup>

1. University Hospitals Cleveland Medical Center

## Introduction

Women are increasingly using the internet for self-diagnosis and treatment of medical problems.

Vaginismus a condition included in genito-pelvic pain/penetration disorder (GPPPD), is a disabling condition associated with an inability to tolerate voluntary vaginal penetration, such as with tampons, intercourse, or exams. Because of the stigma associated with this disorder, many women are reluctant

to seek professional help and may benefit from web access to services. Little is known about women seeking online care for vaginismus and their experience with the healthcare system.

## Objective

To investigate the baseline characteristics and medical history of women self-diagnosed with vaginismus who are purchasing an expanding vaginal dilator online.<sup>1</sup>

## Method

Data was extracted from an online survey as part of an observational clinical trial to assess the effectiveness of an FDA-cleared expanding dilator.

Women purchasing the device through a commercial website completed a baseline questionnaire on gender, age, symptoms associated with penetration disorder, sexual function, pain scores, and previous experience with healthcare professionals.

Diagnosis of vaginismus was based on meeting the DSM-5 criteria for GPPPD.

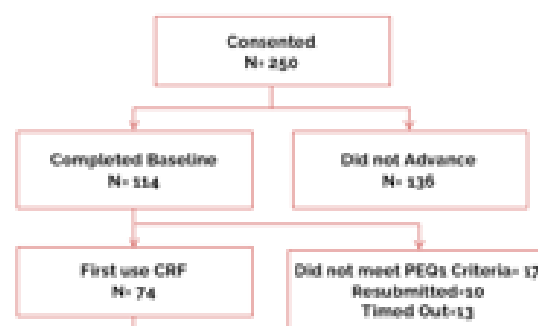
The severity of vaginismus was determined by use of the Lamont classification system, ranging from Grade 1 (able to relax for a pelvic exam) to Grade 4 (generalized retreat, buttocks lift up, thighs close). Participants indicated their average pain intensity during intercourse on a

scale from 0 (no pain at all) to 10 (extreme pain).<sup>2</sup>

Successful heterosexual intercourse over the previous four weeks was measured by experience with the partner's insertion, the first item of the Primary Endpoint Questionnaire (PEQ), scored on a Likert scale of 0 (not attempted) to 4 (attempted and always successful).<sup>3</sup>

Women with GPPPD were only included in the study if they scored ≤1 (attempted but unsuccessful) on PEQ Item 1.

Of the 1075 individuals who purchased Milli during the enrollment period May 1-Nov 20, 2024:



## Results

Baseline Demographic Data from 74 participants:

- The mean age of participants is 50.8 years (range 18-77).
- The majority were nulliparous (62.2%).
- 43.2% previously used or were current static dilator users
- Before participation, 45.9% of subjects had seen at least 2 healthcare providers for evaluation and treatment.
- Over two-thirds (70.3%) of the participants had reported symptoms associated with vaginismus for over 3 years, with 23.0% for 3-5 years and 47.3% for over 5 years.
- On the Lamont scoring system, 43.8% were Grade 1, 19.2% were Grade 2, 21.9% were Grade 3, and 15.1% were Grade 4 (two subjects did not provide a grade).<sup>2</sup>
- A visceral reaction – extreme nervousness, palpitations, tremors, hyperventilation, sweating, and shaking – was reported by 28.4% of the participants.<sup>2</sup>



**Milli® Expanding Vaginal Dilator**  
All-in-one device patient-controlled expansion 1mm at a time. The device provides 25 dilator sizes from 15mm to 40mm with optional vibration (low and high settings). The first and only FDA-cleared for over-the-counter sale.

## Subject Demographics

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History of Static Dilator Use	58.8% None 28.4% Past 14.9% Current

## Subject Scores by Age Groups

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## Conclusion

Women who self-diagnose vaginismus and purchase an expanding dilator using a web-based platform report significant limitations and discomfort associated with this disorder. Providing these women with an online option for accessing healthcare may help overcome barriers to diagnosis and treatment.

## References

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**Acknowledgments** Materna Medical, Inc. supported the study: Prospective on Market Patient-reported Outcomes for Milli (POMPM) <https://clinicaltrials.gov/study/NCT08397885>