

Background

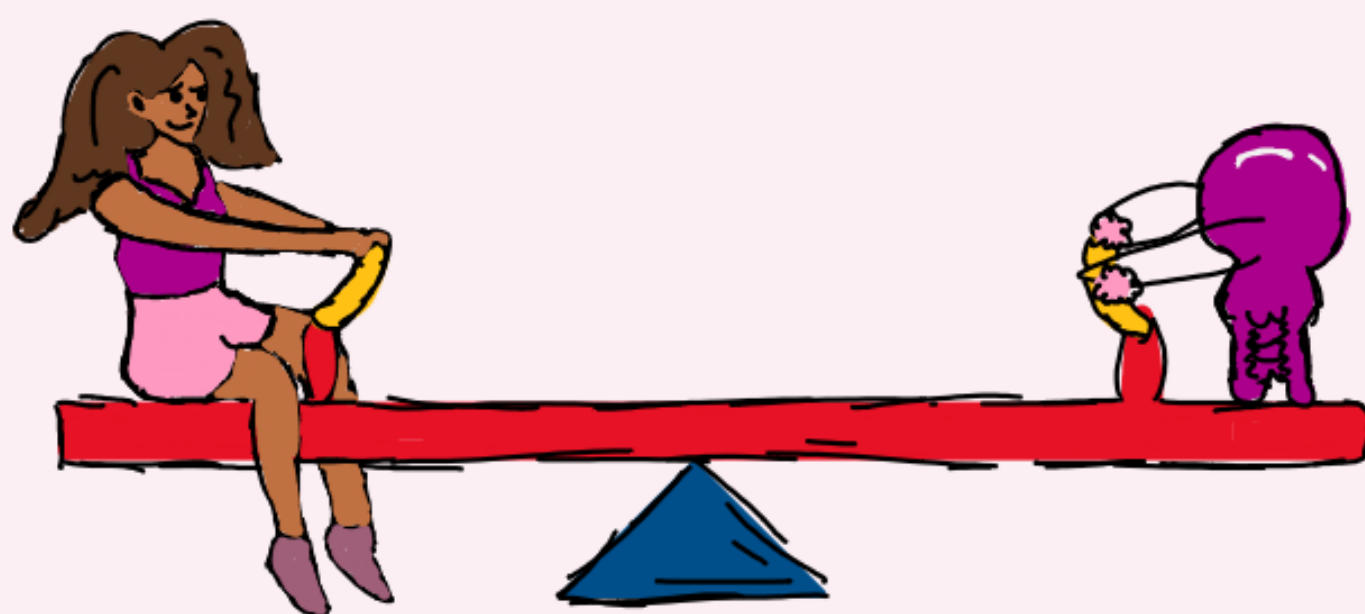
Primary dysmenorrhea (PD) is a gynecological condition defined by a cramping pain in the lower abdomen in the absence of a pelvic pathology. Its prevalence ranges between 25% and 90% in various studies observing the disorder in adolescent females (Direkvand-Moghadam & Khosravi 2012).

There are two types of Primary Dysmenorrhea, each with distinguishable symptoms:

Congestive PD Pain: “heavy”, “dull” “aching pain in the lower abdomen”.

Spasmodic PD Pain: severe, “spasmic” pain.

(Chesney & Tasto 1974).



Current Solutions:

Management strategies for the disorder fit in two categories, each with their own benefits and drawbacks:

Hormonal Contraception/Analgesics:

Benefits:	Drawbacks:
• Rectifies root cause of PD	• Artificial
	• Unsustainable

Non-Pharmacological Alternatives:

Benefits:	Drawbacks:
• Helps with PD pain externally	• Inconvenient
	• Unpredictable efficacy

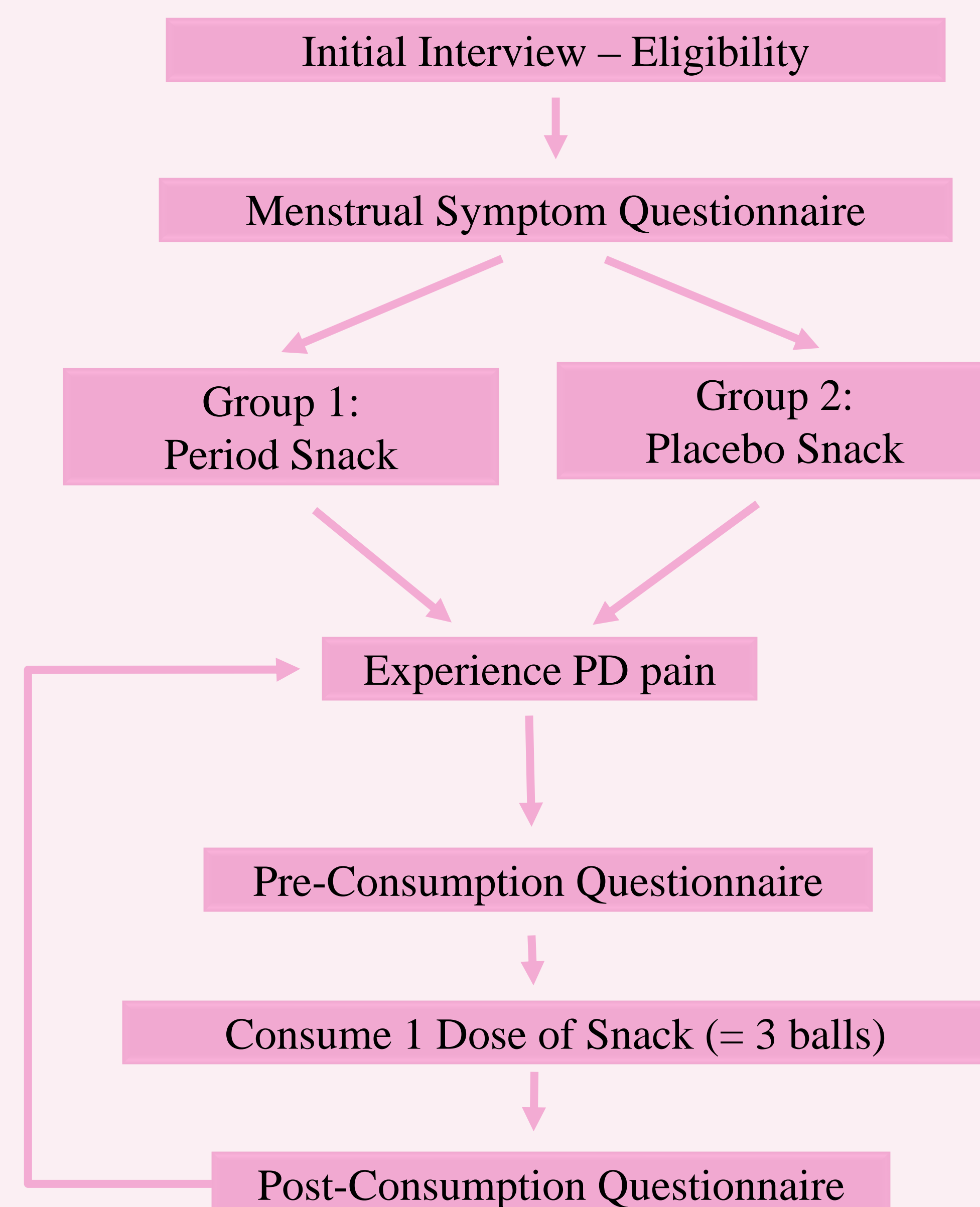
There lies a gap for solutions to period cramps/menstrual pain that both improve the root cause of PD pain and serve to be convenient and sustainable from the consumer side.

Objectives

- In this pilot clinical trial, we will test whether a ‘period snack’ – classified by a mixture of previously researched ingredients shown to help with primary dysmenorrhea – alleviates PD pain of women aged 18-25.
- We will distinguish whether the nutraceutical alleviates congestive symptoms and/or spasmodic symptoms.
- A power analysis will be conducted to determine how many participants will be needed to prove statistical significance.

Methods

- This study was done as a single blinded crossover study. There are a total of 12 participants in this study. The study design is as follows:



Results

Data suggest that the period snack demonstrates some efficacy in alleviating both congestive and spasmodic PD pain. Though the data are not statistically significant, a larger study will be needed to examine the extent to which the period snack proves to be effective in alleviating PD pain.

Descriptives				
	Placebo vs. Period Snack	Congestive Pain Variance	Spasmodic Pain Variance	
N	PL PS	9 12	9 10	
Mean	PL PS	13.1 20.8	0.333 16.1	
Median	PL PS	6 19.0	0 5.00	
Standard deviation	PL PS	20.7 22.7	10.7 25.8	
Minimum	PL PS	-10 -2	-22 0	
Maximum	PL PS	60 80	20 80	

Fig. 1: Comparison of pain scores before and after snack (PS) and placebo (PL) consumption.

*Score was defined by a visual analogue scale

Congestive vs. Spasmodic Variance

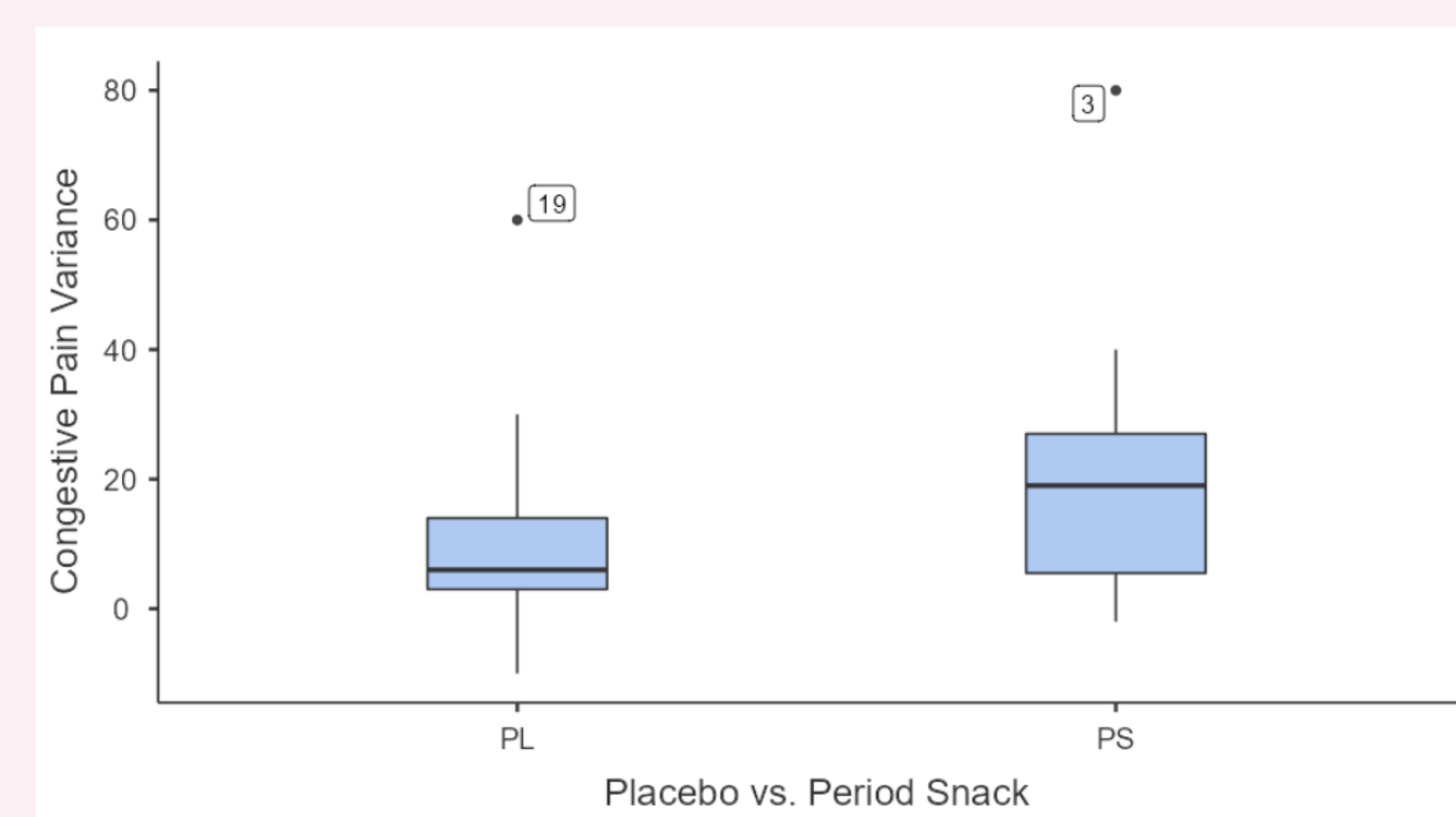


Fig. 2: Congestive pain variance between control and test group

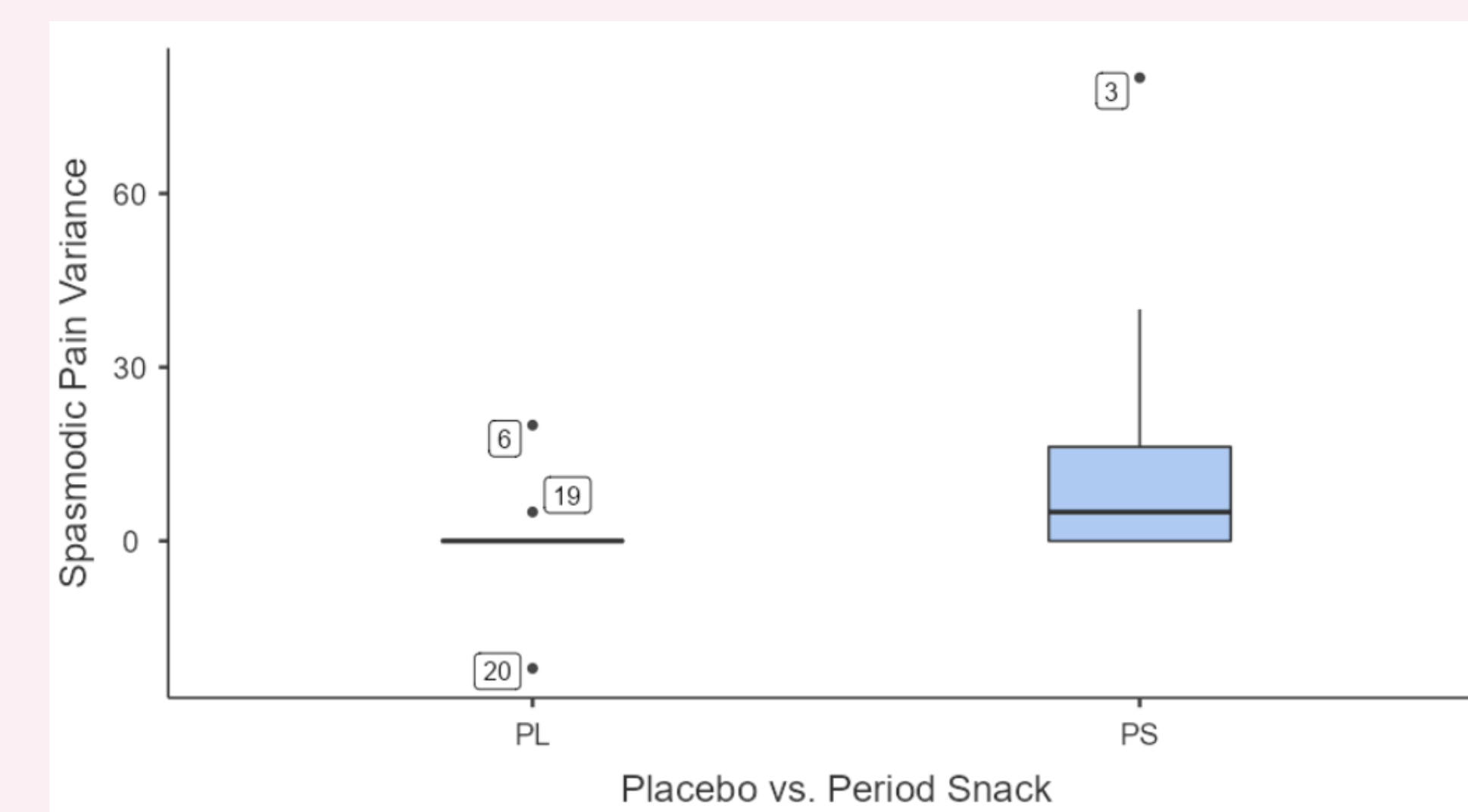


Fig. 3: Spasmodic pain variance between control and test group

T-test and Power Analysis

Independent Samples T-Test

Independent Samples T-Test						
	Statistic	df	p		Effect Size	
Congestive Pain Variance	Student's t	-0.801	19.0	0.433	Cohen's d	-0.353

Independent Samples T-Test						
	Statistic	df	p		Effect Size	
Spasmodic Pain Variance	Student's t	-1.70	17.0	0.107	Cohen's d	-0.783

Fig. 4: Determination of statistical significance: congestive and spasmodic pain variance

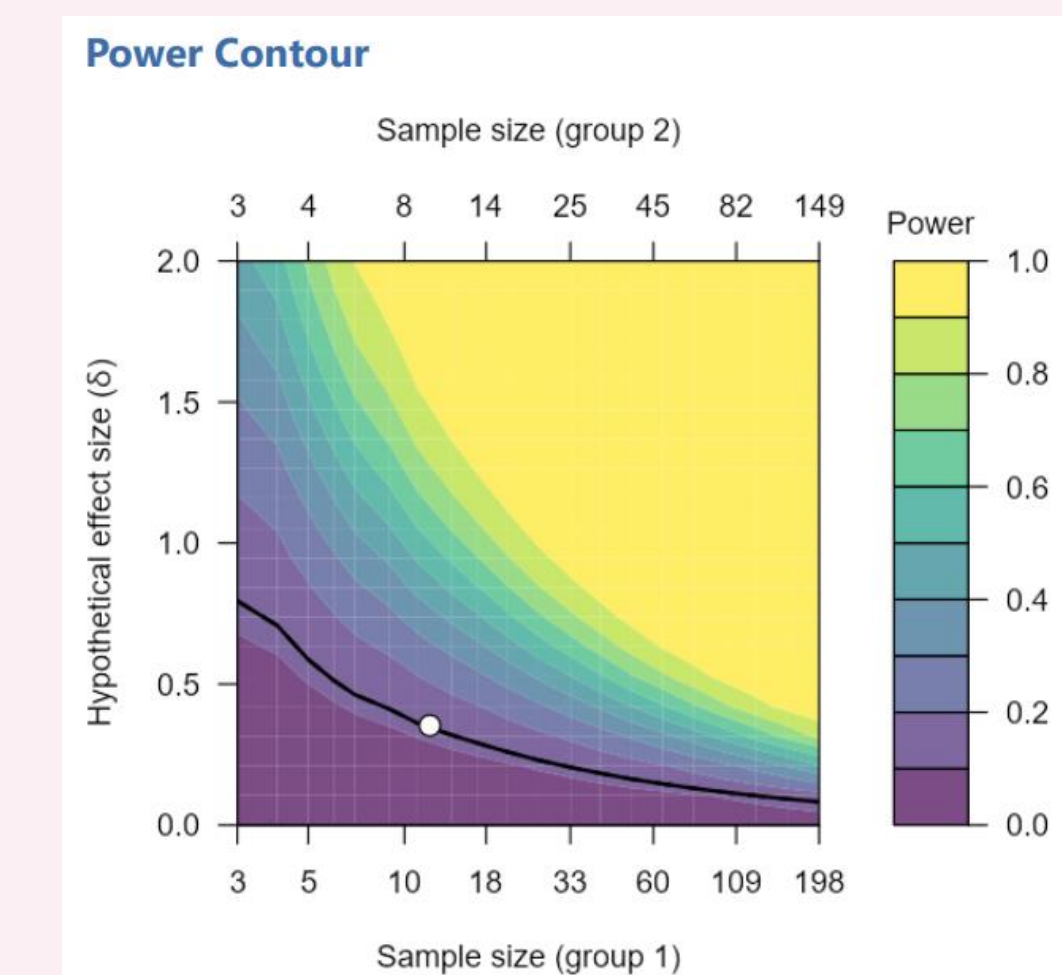


Fig. 5: Power contour plot demonstrating how the sensitivity of the test changes with the hypothetical effect size.

A sample size of 86 in each group will be needed to reliably detect an effect size of $\delta \geq 0.5$

Conclusion

Primary dysmenorrhea is currently the leading cause of school and work absenteeism in adolescents and young adults (Negriff et. al 2009). A pilot clinical trial was conducted to determine if a potential nutraceutical could alleviate congestive and/or spasmodic PD pain, and the optimal sample size needed to demonstrate statistical significance for this study design.

Results demonstrate that in a larger study of the same design, 172 participants will be needed to demonstrate statistical significance. The data suggest the nutraceutical could be effective in both alleviating congestive and spasmodic PD pain, however a larger study is needed to verify statistical significance. The nutraceutical tested in this study could potentially yield an effective and more convenient solution for women suffering from period cramps of ages 18 to 25.

References

Chesney, M. A., & Tasto, D. L. (1975). The development of the menstrual symptom questionnaire. *Behaviour research and therapy*, 13(4), 237–244. [https://doi.org/10.1016/0005-7967\(75\)90028-5](https://doi.org/10.1016/0005-7967(75)90028-5)

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Negriff, S., Dorn, L. D., Hillman, J. B., & Huang, B. (2009). The measurement of menstrual symptoms: factor structure of the menstrual symptom questionnaire in adolescent girls. *Journal of health psychology*, 14(7), 899–908. <https://doi.org/10.1177/1359105309340995>