If you are interested in this study, please ask your provider or contact a Research Coordinator.

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Don't forget to sign up to Participate in Future Studies

Controlling Anal Incontinence by Performing Anal Exercises with Biofeedback or Loperamide
A Randomized Placebo Controlled Trial

HRPO # 14-064
What is the study about?

This study will compare the use of an anti-diarrheal medication to oral placebo and compare the use of anal sphincter exercise training with biofeedback to usual care (educational pamphlet) in the treatment of fecal incontinence (FI) also known as accidental bowel leakage.

- There are currently no placebo/usual care (educational pamphlet) trials using either of these two commonly used treatment options for fecal incontinence.
- This study will allow us to compare these first-line treatment options for fecal incontinence and evaluate the value of both therapies versus one treatment.

Eligible subjects will be assigned by chance (randomly) to one of four groups:

1) Oral placebo plus Usual Care (Educational Pamphlet), or
2) Anti-diarrheal medication plus Usual Care (Educational Pamphlet), or
3) Oral placebo plus Anal exercises with biofeedback and Usual Care (Educational Pamphlet), or
4) Anti-diarrheal medication plus Anal exercises with biofeedback and Usual Care (Educational Pamphlet)

What is involved in this study?

This study will involve a time commitment of a little more than 6 months.

Based on the group you are randomized to:

- You may have up to 7 clinic visits
- Your visits may last 1-3 hours
- There will be telephone interviews and coordinator calls throughout the study.

All visits are at no cost to you.

You can participate if:

- You are 18 years old or older
- You have fecal incontinence (accidental bowel leakage) that occurs at least monthly over the past 3 months and is bothersome enough to desire treatment
- Women between the ages of 50-75 should have a current negative colon cancer screening.

Note: This study does include compensation.

You cannot participate if:

- You cannot speak English or Spanish
- You do not have a phone
- You are unable to provide written consent
- You are planning on becoming pregnant in the next 6 months
- You have given birth within the last 3 months
- You have a diagnosis for colorectal or anal cancer
- You have a rectal bulge (prolapse)
- You are allergic to certain medications or taking certain medication
- You have a neurological disorder

Please ask your provider about the other requirements that need to be met for participation and enrollment.

This study is part of the Pelvic Floor Disorders Network (PFDN)