

WHAT HAPPENS TO THE INFORMATION COLLECTED?

All research information will be treated confidentially by assigning a number (and not your name) to your study forms.

WILL THE STUDY COST ME?

Neither you nor your insurance company will be charged for the study evaluation and follow-up visits.

Any medical care required for you outside of the study will be billed to you or your insurance company in the usual manner.

Compensation will be provided to partially cover your personal time and expenses related to study participation.

CAN I DROP OUT OF THE STUDY ONCE I HAVE BEGUN?

Yes. Participation in the study is voluntary. You may remove yourself from the study at any point.

If you decide to drop out of the study, medical care will continue to be provided to you, if desired.

If you would like more information about the study, please call:

205-934-5498

PARTICIPATING UAB PROVIDERS:

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This study will be conducted by the UAB Urogynecology Care Clinic, which sees patients at both The Kirklin Clinic of UAB Hospital and the UAB Women and Infants Center. The study is a collaboration between the UAB Division of Urogynecology & Pelvic Reconstructive Surgery and the UAB Division of Gerontology, Geriatrics, & Palliative Care.

UROGYNECOLOGY & RECONSTRUCTIVE PELVIC SURGERY

UAB MEDICINE

The University of Alabama at Birmingham

uabmedicine.org/women

FECAL INCONTINENCE TREATMENT (FIT) STUDY



A STUDY COMPARING BIOFEEDBACK AND INJECTABLE BULKING AGENTS FOR TREATING FECAL INCONTINENCE

UAB MEDICINE

The University of Alabama at Birmingham

WHAT IS THE FIT STUDY?

The FIT study will evaluate 2 different treatment approaches for fecal incontinence (accidental bowel leakage). These treatments include biofeedback therapy (similar to Kegel exercises) and bulking agent therapy (injections in the anal canal).

All participants will first undergo “enhanced medical management” to see if educational materials, conservative lifestyle changes, and medication treatment can improve your bowel symptoms before undergoing “advanced” treatments.

WHAT IF YOU DO NOT RESPOND TO THE MEDICAL MANAGEMENT?

You will randomly receive 1 of the 2 well known and approved therapies for fecal incontinence:

- Biofeedback: supervised anal muscles and rectal sensation training to improve muscle strength and sensation for bowel control
- Bulking agent: A bulking agent (dextranomer) will be injected (in the clinic) under the anal canal lining, to help create a more effective barrier to bowel leakage

- Sacral nerve stimulation: At your 3-month follow-up visit, if it is determined that you have not responded to the study treatment, then alternative sacral nerve stimulation treatment will be discussed with you.

YOU MAY BE ELIGIBLE TO PARTICIPATE IF:

- You are age 18 or older
- You are not pregnant or planning to become pregnant for the next 2 years
- You have had fecal incontinence (or accidental bowel leakage) for at least 6 months
- You have 2 stool leakage episodes per week, on average
- You have not had uncontrolled diarrhea
- You have no history of colorectal cancer or inflammatory bowel disease
- You have not had a bowel resection procedure or radiation therapy
- You have not received chemotherapy or taken immunosuppression medications in the last 12 months
- You have not had anal pain in the last 6 months

WHY IS THIS STUDY IMPORTANT?

Many women suffer from accidental bowel leakage that negatively affects their quality of life and overall health.

Investigators from medical centers across the United States are committed to improving the level of knowledge about fecal incontinence and offering effective treatment options for this bothersome condition.

This study is sponsored by the National Institutes of Health (NIH) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

285 adults will be asked to participate in the FIT study across the United States. About 60 women will be enrolled at UAB.

