Utility of an Animated Bowel Biofeedback Training Routine to Improve Bowel Function in Individuals With SCI

NCT02406859

INFORMED CONSENT FORM

September 12, 2016

VA Department of Veterans Affairs

VA RESEARCH CONSENT FORM

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Subject Name:	**Informed Consent Date:**
Principal Investigator: Mark A. Korsten, MD	**VAMC: James J Peters**
Title of Study: Utility of an Animated Bowel Biofeedback Training Routine to Improve Bowel Function in Individuals with SCI	

1. *Purpose of study and how long it will last:*

You are being asked to participate in a research study looking at anorectal muscle function. These are the muscles that normally help you expel or retain stool, but may not be working properly after your spinal cord injury. You are being asked to participate in this research study because you are between the ages of 18-75; you are either able-bodied (control) or have had a spinal cord injury for longer than one year and (for SCI) currently have problems with your bowels. These problems may include the inability to move your bowels without assistance, constipation (difficulty passing stool) or incontinence (bowel accidents). If you have an incomplete SCI injury (ASIA B, C, and/or D) and consent to participate, you can participate in one or both parts of the study. If you have a complete SCI injury (ASIA A) or are able-bodied, you can only participate in part 1 of the study.

Part 1 of the study will last for 1 visit and is completed in approximately 1 hour. This study will test how functional your anorectal muscles are. A second, optional part of the study is using a new type of therapy to help you regain control of those muscles. This consists of a series of exercises which should improve control and strength of those muscles. These exercises will be taught to you over 6 weeks of training at the laboratory. You will be asked to come in 2 times per week and each training session will last for approximately 30 minutes. After the 6 week of training, you will be asked to return to the laboratory to repeat the pressure study performed during Part 1 of the study. After the pressure study, we will teach you a series of exercises which we will ask you to perform at home for another 6 weeks. After the six weeks of home exercises, you will be asked to return to the research laboratory for a third pressure study. Part 2 of the study lasts for approximately 2 weeks, and will involve a total of 14 laboratory visits (12 training session and 2 pressure study visits). If you consent to participate, you will be one of approximately 50 subjects to participate in Part 1 of the study, or one of 20 to participate in Part 2 of the study. All study procedures will take place in the SCI Research Laboratory of the Bronx VA Medical Center

This project is sponsored by the Small Projects in Rehabilitation Research (SPiRE) Funds (Grant # B1915-P).

If any of the following apply to you, you cannot take place in the study. You do not have to tell study investigators which condition applies to you, only that you cannot participate.

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Inclusion Criteria:

- Chronic SCI (duration over 1 year),
- Able-bodied (non-SCI)
- Between the ages of 18-75.

Exclusion Criteria:

- Contraindication to bowel biofeedback,
- Currently pregnant or trying to become pregnant,
- Inability to provide informed consent.

2. Description of the Study Including Procedures to be Used:

If you consent to participate in this research study, you may be asked to take part in one or both parts of the study. You will be asked to come to the SCI Research Laboratory (Room 7A-13, Bronx VA Medical Center) on the day of all scheduled appointments. Part 1 of the study will last for 1 visit (approximately 1 hour), and will consist of an ASIA examination for SCI subjects (if greater than 1year since last examination) and test how well your anorectal muscles function. Your muscle function will be measured through a pressure test, which will be performed as follows:

Pressure Study (1 time during Part 1 and 2 times during Part 2): All pressure studies will be scheduled on your regular bowel care days in the afternoon. Upon arrival at the laboratory, we will help you change into a hospital gown. You will be transferred to a commode bed (bowel care bed) and asked to lie on your left side. A lubricated sheathed probe approximately 4 inches long will be inserted up your rectum. This probe will measure how much you use your muscles by monitoring electrical activity and pressure during the maneuvers described below. Once the probe is inserted, we will ask you to perform the following:

1. Baseline assessment- after a period of adjustment, you will be asked to relax for a 30 second period, during which you will be asked to refrain from performing any squeezing or bearing down maneuvers.
2. Squeezing maneuvers- you will be asked to squeeze your sphincter muscles as if you are retaining stool. Squeezing maneuvers will be performed until 3 consistent attempts are made.
3. Bearing down maneuvers- you will be asked to bear down as though you are attempting to move your bowels. Bearing down maneuvers will be performed until 3 consistent attempts are made.

4. Assessment of the rectoanal inhibitory reflex (RAIR)- the rectal balloon attached to the pressure probe will be gradually filled with air starting at 30ccs and in 10cc increments until a RAIR reflex occurs. This reflex occurs when your rectum senses that it is filled and attempts to move the object by relaxing some muscles while contracting others.

We will also ask you to complete 5 surveys. The first survey consists of 10 items which will assess the general function of your bowel care, and includes questions about bowel care, incontinency (have bowel accidents), and constipation. The second survey assesses in detail, how often and to what extent you may be incontinent. The third survey assesses your views on your current bowel management program. The fourth and fifth surveys assess your bladder management as well as any complications. The purpose of the previous 3 surveys is to test the sensitivity of the SCI-Quality of Life (QOL) measures within the context of existing interventional studies by comparing it with the legacy tool(s) being used. Your answers will be recorded or inputted through a secure website sponsored by the National Institute of Health. This internet program is maintained and secured at Northwestern University in Aurora, Illinois. On this website, you will provide your age, sex, and duration and type of spinal cord injury along with your answers to the study questions. None of your personal health information will be entered or retained in this database.

You will be assigned a code under which your information will be entered. Only the Bronx VA will have access to the code key that is assigned to your name. This study should take approximately 1 hour to complete. If you decide to participate in the second part of the study, we come up with a six week training schedule that begins within 2 weeks of the pressure study. If the waiting time is longer, the pressure study may need to be repeated.

Part 2 of the study is using a new type of therapy called Bowel Biofeedback. This training consists of a series of exercises which should improve control and strength of those muscles. These exercises will be taught to you over 6 weeks of training at the laboratory, during which you will come in twice a week for approximately 30 minutes per session. After the 6 week of training, you will be asked to return to the laboratory to repeat the pressure study performed during Part 1 of the study. You will also be asked to complete both bowel surveys again.

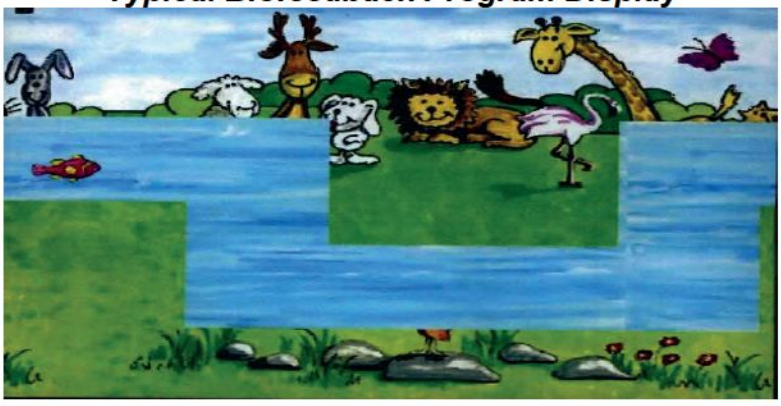
We will teach you a series of exercises which we will ask you to perform at home for another 6 weeks. After the six weeks of home exercises, you will be asked to return to the research laboratory for a third pressure study and to complete the surveys a third time. Part 2 of the study lasts for approximately 2 weeks, and will involve a total of 14 laboratory visits. All study procedures are detailed below:

Pressure Study (1 time during Part 1 and 2 times during Part 2): *These studies are identical to the pressure studies performed during Part 1 of the study.*

Typical Biofeedback Training Session (12 times during Part 2- twice weekly):

You will be asked to come to the laboratory on the day of the scheduled appointment. As with the pressure studies, we will try to work with you to schedule all study visits on bowel care days, immediately after bowel care. On the day of the visit, you will be asked to change into a hospital gown if you choose, and transferred to a commode bed. You will be asked to lie on your left side. A small probe approximately 2 inches long will be inserted into your rectum. A visual display of your muscle activity will be displayed on a computer monitor. A training program will be started, and you will be coached on how to squeeze (as if you were trying to retain stool) and bear down (as if you were trying to have a bowel movement) in order to guide a target through the path. As you improve through the sessions, these training programs will increase in difficulty. A picture of a typical training display is shown below. In this program, you would be asked to try and guide the fish through the pond by squeezing and relaxing your bowel muscles.

Typical Biofeedback Program Display



Typical at Home Exercise Regiment (12 times during Part 2- twice weekly):

The intensity of your exercise regimen that you will be assigned will be based on how you performed during the laboratory biofeedback training. Below is an example of a typical training schedule:

Twice a Week:

50 squeezing maneuvers sustained for at least 3 seconds, separated by no more than 5 seconds between squeezes.

50 bearing down maneuvers sustained for at least 3 seconds, separated by no more than 10 seconds between squeezes.

5 sets of squeeze to bear down maneuvers performed in rapid succession (as in panting) sustained over 15 seconds.

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All procedures will take place at the James J. Peters VA Medical Center, in the SCI Research Center (Room 7A-13). All procedures described above are for research purposes only, and are not a part of clinical care. During this test we may see something that should be checked by your primary care doctor. If that happens, we will call you within a week of the test to let you know. We will then send the test results to your primary care doctor. If you do not have a primary care doctor, we will refer you to one within the VA system. Please note that we are not specifically looking for any medical problems so it is very unlikely that we will find any underlying issues. This test is not the same as regular medical care.

3. *Description of any Procedures that may Result in Discomfort or Inconvenience:*

Anorectal Pressure Study: Insertion of the probe may be temporarily uncomfortable, but should resolve once the probe is removed. Likewise, the pressure from the balloon inflation may result in some abdominal discomfort or the urge to defecate.
Biofeedback Training: The insertion of the probe may result in some discomfort which should resolve once the probe is removed. ***For both the anorectal and biofeedback training visits, there is a chance that a bowel accident may occur, due to the insertion of probe and the maneuvers performed.***
Surveys: The surveys administered are of a sensitive nature and as such, you may be uncomfortable providing answers.
Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time.

4. *Expected Risks of Study:*

Anorectal Pressure Study and Biofeedback Training: There is a slight risk of irritation to the anus from the insertion of the probe. To lessen the irritation to sensitive skin, the probes are lubricated prior to insertion and the skin checked for intactness before and after the training.

5. *Expected Benefits of the Study:*

There are possible benefits by taking part in this study such as improved bowel function. Conversely, there may be no direct benefit to you from this study if you do not choose to participate in the treatment arm, or if you do not respond to treatment. But, any information we get from this study will help others.

6. *Other Treatments Available:*

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There are few options currently available to treat incontinence from muscle dysfunction. A consistent and thorough bowel care routine can be used to prevent overflow incontinence and constipation.

7. Use of Research Results:

We will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. All research materials generated from this study will remain in the possession of the James J. Peters VA Medical Center, under the supervision of Dr. Mark Korsten and his research team. Access to data will be restricted to current research team members. All electronic data will be coded and stored on the VA network behind firewalls and in password protected, access restricted folders. All physical data such as case report forms and data collection sheets will be locked in a cabinet in a locked file room within the SCI Research Center at the James J. Peters VA Medical Center, and will not be removed from the facility. Your medical records will be maintained according to this medical center's requirements and all electronic and hardcopy Research Records are currently not scheduled for destruction and will not be destroyed. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law. In order to comply with federal regulations, research records identifying you may be reviewed by the following:

Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and the Office for Human Research Protections (OHRP).

8. Special Circumstances:

As a patient of this medical center, a copy of this consent form and signed HIPAA authorization will be placed in your medical record.

9. Compensation and/or Treatment in the Event of Injury:

The VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA medical center.

10. Voluntary Participation:

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You are not required to take part in this study; your participation is entirely voluntary you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

11. Termination of Participation:

You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment, if you are a patient. The PI retains the right to terminate your study participation for any reasons, including reasons of non-compliance, failure to show up for study visits, or for medical reasons.

12. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study.

The exception is:

For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.

You will be reimbursed for your participation for this study as follows:

- Pressure Study (Anorectal Manometry): For each pressure study, you will be reimbursed $50. There is one pressure study in Part 1 of the study and two in Part 2 of the study. For AB subjects only, you will receive $100 for your participation in Part 1.
- Biofeedback Training: For each training session, you will be reimbursed $25. You will receive an additional $50 for six week period of home exercises.

If you complete the study partially, you will be reimbursed for all study visits completed to date. If you complete the study in its entirety, you will be reimbursed $500 after the 12 week study. You will receive payment approximately 8 weeks after the completion of the last study visit.

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13. Contact Person(s):

To obtain answers to questions about the research, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following:

- *During the Day: [Mark Korsten, MD (718) 584-9000 x 6753]*
- *After Hours: [Mark Korsten MD (917) 968-1064]*

To voice concerns or complaints about the research from someone outside of the research team, contact the following:

I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints, or to offer input.

RESEARCH SUBJECTS' RIGHTS: *I have read or have had read to me all of the above.*

Dr. Mark Korsten or his delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	*Date*	*Time*

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	*Signature of Person Obtaining Informed Investigator or Delegate as indicated on Assurance Page Consent*	*Date*

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VERBAL CONSENT IF THE PARTICIPANT LACKS UPPER LIMB FUNCTIONS TO COMFORTABLY WRITE

_____ *is unable to sign the consent form or make his/her mark due to impaired arm function. I certify that I have carefully explained the purpose and nature of this research to him/her in appropriate language and he/she has had an opportunity to discuss it with me in detail. I have answered all of his/her questions and he/she has consented to participate in this research. I, therefore, am signing the consent form to document that he/she has given his/her consent to participate in this research study.*

_____	_____
Person Obtaining Verbal Consent	*Witness Name*
_____	_____
Signature	*Signature*
_____	_____
Date	*Date*