Official Title of the study: Restore: Improving Sexual Outcomes of Gay and Bisexual Prostate Cancer Survivors

NCT: NCT03343093

Consent form approved on January, 2019

Welcome to the Restore Study

Restore is the worlds' first treatment study examining the effects of prostate cancer rehabilitation in gay, bisexual, and other men who have sex with men. It is designed to answer the question whether an online rehabilitation program designed specifically for and by gay/bisexual men is helpful in treating the sexual and urinary effects of prostate cancer treatment. If successful, this program may become a new standard of rehabilitation in the comprehensive treatment of prostate cancer.

This study is funded by the National Cancer Institute at the National Institutes of Health (NIH) in Bethesda, MD (Grant number: 1RO1CA218657-01). The study is led by Dr. B. R. Simon Rosser and a team of researchers and clinicians at the University of Minnesota. For more information about our investigators, please click <here>.

This online survey study is for gay, bisexual and other men who have sex with men living in the United States who are in care or have been treated for prostate cancer. It compensates up to $300. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota, the NIH, or any of our recruiting partner organizations (e.g. *Malecare*, your urology clinic, your physician, LGBT Centers, etc.)

Please choose *only one* of the following:

I know this is a University-based online study about prostate cancer rehabilitation in gay, bisexual and other men who have sex with men. I WANT to continue.

I DO NOT want to continue

What's Involved?

You will be asked to complete 6 online surveys over two years. Each survey will take about 30-90 minutes to complete. You will be paid $50 for the first, longest survey, and $25 for each of the five follow-up surveys. If you do all six surveys in a timely manner, you'll receive a $25 bonus, so total compensation is $200 . There is no payment for incomplete surveys.

Please know that you can take breaks as you need, and skip any questions you prefer not to answer. The questions ask about your experience with prostate cancer, especially sexual and/or urinary challenges. Whether you are someone who has recovered well, someone who is not currently sexually active, someone with incontinence, or anyone in between, your experience is valuable to us and we welcome your participation.

To ensure your confidentiality, we recommend you complete each online surveys in private. Your survey responses on the website will be kept confidential, and only group results will be reported.

Please know your participation is entirely voluntary. You can choose not to answer any question, take breaks in answering questions as you need, and you can stop your participation at any time.

Please choose *only one* of the following:

I understand the survey asks in-depth questions about sexual and urinary functioning and that I will be paid up to $200 when I complete all the surveys. I WANT to learn more about the study.

I DO NOT want to continue

Who is this study for?

To participate in this study, you need to be:

- Born biologically male (i.e., born with a prostate).
- Identify as gay, bisexual, or a man who has sex with men (regardless of whether you are currently sexually active). Transgender women are also welcome to participate.
- Be in treatment or have been treated for prostate cancer. This includes anyone who has had prostate cancer surgery, radiation, or similar treatment. This study is not for men who are not in treatment, including men who are currently only on "active surveillance".
- The focus of this study is rehabilitation. For men who have been treated, you need to have some current sexual and/or urinary challenge to work on. For those just starting prostate cancer treatment, you are welcome to participate, even before your treatment begins.
- Living in the US, as we do not make payments or provide materials to anyone outside the US.
- Able to read English, since the program and surveys are in English.
- Please note we welcome diversity. If you are a man of color, living with HIV/AIDS, HIV-negative, have advanced prostate cancer, or additional health concerns, married or single, out or in the closet, you are still most welcome to participate.

Before you start this study, a staff member will confirm whether you are eligible. If you have questions, please email us (restorestudy@umn.edu) or call us (612-625-4799)

Please choose *only one* of the following:

I am eligible to participate. I WANT to learn more about the study

I DO NOT want to continue

What does the study involve?

This is a randomized controlled study, where on the basis of chance, you will assigned to one of two groups. A computer program will automatically choose who ends up in which group.

Control Group Activities: Half the participants will be assigned to the control group. In this group, you will be asked to complete 6 surveys, one at the start of the study, at 3 months, 6 months, 12 months, 18 months and 24 months. (Note: There are no restrictions, so you are free to access any other treatment or help you wish).

Intervention Group Activities: The other half of participants will be assigned to the intervention group. In this group, you will also be asked to complete the 6 surveys. In addition, you will have the opportunity to participate in the first online rehabilitation program tailored for men who have sex with men. This is a comprehensive program. It includes access to medication, behavioral exercises, a guide to good gay sex after prostate cancer treatment, monthly health coaching, and goal setting exercises. You will be encouraged to follow a 30-minute rehabilitation program several times a week for a year. (Note: There are no other restrictions. In this group, you are also free to access any other treatment or help you wish).

Both groups are equally important to the study. A randomized, controlled trial is the “gold standard” in medical research. Only with a comparison group can we tell if, when, how, and for whom rehabilitation works.

We ask that you think carefully before choosing to participate in this study. You should only participate if you are willing to be in either group. If assigned to the intervention group, we ask that you genuinely try the rehabilitation program. You cannot change groups.

Please choose *only one* of the following:

I understand that this is a randomized study. I am willing to be in either the rehabilitation group or the control group. I want to continue.

I DO NOT want to continue

<u>The Components of the Intervention</u>

If you are randomly assigned to the rehabilitation program, you will have access to a website that has educational content, videos, and opportunities to talk with a health coach and other users about your progress. The website is interactive. You will be asked to set personal goals and to choose exercises to help you achieve these goals. You will be able to track your progress online.

We are testing the world’s first gay/bisexual-specific prostate cancer rehabilitation program. The educational content focuses on sex between men and is sexually explicit. It includes a guide to good gay sex after prostate cancer (based on gay prostate cancer patients’ real experience), sexual and urine rehabilitation programs designed by specialists, instructional videos, help for gay couples, programs to treat specific issues such as painful receptive sex and urine challenges in sex, and a FAQ section where you can ask questions and have them answered.

The rehabilitation exercises are behavioral and focus on strengthening muscles to restore sexual function and urinary continence. Because not all men experience both challenges, you can choose which exercises you undertake. A health coach will also be available to answer

questions and to support you. In addition, we will supply, at no cost to you, sexual aides to help restore sexual function, including a vacuum pump device and butt plug.

Please note that while we will encourage you to explore the website and read the materials, you are free to only engage in whatever exercises and activities are respectful and right for you. Because rehabilitation from prostate cancer treatment can take a long time, we will ask you to participate for a year (with an option of continuing for a second year if you so wish).

Please choose *only one* of the following:

I understand that if I am randomized to the test group, there is sexually explicit content focused on gay sex, and exercises intended to aid in my rehabilitation. I know I can choose what goals and exercises I do. I wish to continue

I do not wish to continue

The use of erectile enhancing medication

If you are randomized into the intervention group, we will pay for you to have access to sildenafil (i.e., generic Viagra) for one year. We will give a letter to hand to your doctor that explains you are in a prostate cancer rehabilitation study which will pay for you to receive a dose of Viagra.

How will this work? Your doctor will determine if Viagra is a safe medication for you to take. Since Viagra is only legally available by prescription, your doctor will need to write a prescription, which you can then fill through our pharmacy partner. Please note, even though we encourage all participants to get full benefit from the program, taking Viagra is not mandatory. You can still participate in this intervention even if the doctor says no, you choose not to take Viagra, or prefer to take a different medication.

Please choose *only one* of the following:

I understand that if I am randomized to the intervention group I will be offered a year's supply of sildenafil. I understand that there will be no cost to me and I will need a prescription from my doctor to participate in this aspect of the study. I want to continue.

I do not wish to continue

Confidentiality

Confidentiality at your end: The surveys ask sensitive questions and the website includes sexually explicit content (that should not be viewed by minors). To protect your confidentiality, we ask that you only view study materials in private.

Confidentiality at our end: To contact you, we will ask for your email and phone contact. We are required by law to keep your personal information, confidential. We will not share this information with anyone outside the study, sell it, or use it for any other purpose.

Research Confidentiality: All data is encrypted before uploading. All survey data are stored in password protected files on our secure server according to standards of data protection at the University of Minnesota. We do track IP address to prevent duplicate users. All information is kept confidential and destroyed at the end of the study. No identifiable information will be published. A study ID number will be used to track your responses over the two years. The file of names and study ID numbers will be destroyed at the end of the study.

After the Study: At the end of the study, a copy of the survey data (with all names, addresses, and other personal identifiers removed) will be archived at the University of Minnesota so other researchers can access it.

Please choose *only one* of the following:

I understand what is being done to keep my information confidential. I WANT to continue

I DO NOT want to continue

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality related to participation in this study. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Please choose *only one* of the following:

I understand that the study team will use the Certificate of Confidentiality to resist any demands for information that would identify me. I WANT to continue

I DO NOT want to continue

Risks

The risks in this study are minimal, and not beyond usual care. To help assess risks, we highlight the following aspects of the program:

1. The surveys ask questions about sexual and urinary functioning that some people may find embarrassing. To lessen this risk, we recommend you complete the surveys in private.
2. If assigned to the intervention, there are some additional risks to consider. Keeping in mind all activities in the intervention are voluntary:

- *Website:* The website includes sexually explicit content, including explicit videos. We recommend you view this in private, and ask that you do not share this with others.
- *Sildenanfil (also called "Viagra")* This is a common drug for treating erectile difficulties with known side effects. We highlight it should never be taken with nitrites (i.e., poppers) as this can lead to severe hypotension and death. Your doctor will assess whether it is safe for you to take Viagra. You do not need to take Viagra to participate in this study.
- *Urinary rehabilitation exercises*. It is possible to overdo any exercise program, leading to muscle strain (e.g., cramps). The website includes content on the maximum number of recommended exercises, how to avoid strain, and what to do if strain occurs.
- *Sexual rehabilitation exercises.* Some sexual aides have warnings of problems that can occur with prolonged use or misuse. These problems are typically mild and self-correcting. Penile rings should not be used for more than 30 minutes at a time. Butt plugs should not be so large or used so vigorously as to cause pain or bleeding. Anyone experiencing an erection for more than 4 hours should go to an emergency room to have it treated.
- *Over-expectations*. With any new treatment or unproven program, there is a danger of initial excitement or over-expectations, leading down the road to disappointment. We warn that rehabilitation for prostate cancer typically takes one to two years to work. We caution against having unrealistic expectations or being overly-optimistic. These may lead to feeling depressed if and when results are not immediately obvious.
- *Information.* Finally, those in the intervention group may receive requests from other men to access the intervention. To protect the integrity of the study, it is very important to us that only those in the intervention group (and their partners) have access to the intervention. Participants in the intervention are asked not to share the intervention content with anyone not in the intervention until the study has ended.

Please choose *only one* of the following:

I understand the risks of participation and I WANT to continue.

I DO NOT want to continue

<u>Benefits</u>

This study is designed to test the effects of the first comprehensive rehabilitation program for prostate cancer survivors who are gay, bisexual, or a man who has sex with men. Because the effectiveness of this new program is not yet known, we cannot say whether it will benefit you. It may well work for some men but not others, which is why the study is needed and everyone's participation is so important. We seek to learn from your experience.

Some people report participating in research helps them feel empowered. Cancer survivors may want to participate in studies designed to advance new or better treatments. Gay, bisexual and other men who have sex with men may feel especially proud, by participating in the first prostate cancer treatment study designed by and for men like us.

For those who request it, we will be pleased to share a copy of any results as they are published. A lay summary will also appear on our website.

Please choose *only one* of the following:

I understand there are no guarantee of benefits to me personally by participating in this research. I WANT to continue

I DO NOT want to continue

Questions

If you have questions about the study or your involvement, please email us (at restorestudy@umn.edu) or call the project coordinator, Mr. Chris Hoefer (612-625-4799)

This study is being led by Dr. B. R. Simon Rosser (email: rosser@umn.edu; cell: 612-356-1711).

If you have concerns or would like to speak with someone outside the study team about your experience, you can contact the University of Minnesota Research Subjects' Advocates Line at 612-625-1650 or by email at irb@umn.edu

Next Steps

If you agree to participate, you will be asked to provide your contact and payment details. Our staff will contact you to welcome you to the study, confirm eligibility, answer any questions, and direct you to the survey.

This study is intended to improve the lives of men after prostate cancer. Thank you for your willingness to read all the above information and consider being involved. If you wish to volunteer to participate, please check below. If you have further questions, please feel to contact us at the numbers listed above.

Please choose *only one* of the following:

I confirm I am eligible and wish to volunteer to participate.

I DO NOT want to continue