PARTICIPANT INFORMATION SHEET AND CONSENT FORM
CLINICAL TRIAL / INTERVENTIONAL STUDY

Is the time to complete bowel care quicker using transanal irrigation compared to standard bowel care in adults with Spinal Cord Disorders? A randomised controlled trial.

The TAI Study

Invitation

You are invited to participate in a research study into whether using transanal irrigation instead of standard bowel care routines improves the length of time people with spinal cord disorders spend toileting. Transanal irrigation involves using purpose built equipment that delivers a volume of water into your bottom to empty your colon of stool instead of using micro enemas +/- digital stimulation or evacuation to empty your bowels.

The study is being conducted by the following people and the results will contribute to a Doctor of Philosophy being undertaken through the University of Sydney.

- Professor Lisa Harvey from the Faculty of Medicine and Health at the University of Sydney
- Ms Louise Kelly, RN, Royal North Shore Hospital and Clinical Nurse Consultant for Holistic Nursing Solutions
- Dr Lianne Nier, Senior Staff Specialist, Spinal Cord Injury Unit, Royal North Shore Hospital
- Dr Joanne Glinsky, Associate Supervisor, University of Sydney
- Ms Amy Darvall, CEO/Clinical Nurse Consultant, Holistic Nursing Solutions
- Mrs Yvette Mair, Clinical Nurse Consultant, Sydney Home Nursing Service

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. ‘What is the purpose of this study?’

Bowel care is a very important concern for most people who have a spinal cord disorder. There are two options for managing bowel care. One is ‘standard’ or usual care, that is; the bowel care that you are currently using. The alternative is transanal irrigation. Over the past five years, community nurses are anecdotally observing more people with spinal cord disorders being recommended to use transanal irrigation to shorten the time spent on bowel care. We don’t know which method is better for reducing time spent on bowel care, therefore the purpose of this study is to determine whether transanal irrigation improves the time spent on toileting compared to standard care for people with spinal cord disorders who are spending more than 30 minutes toileting.

2. ‘Why have I been invited to participate in this study?’

You are eligible to participate in this study because you have a spinal cord disorder having problems emptying your bowel, are spending more than 30 minutes on toileting and have one of the following bowel related complications:

- Inconsistent bowel results (constipation, diarrhoea, bowel accidents)
- Bleeding with bowel care

- Autonomic dysreflexia during bowel care

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'
Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the medical or nursing staff overseeing your long term health needs.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What does this study involve?'
This research project is a single blinded randomised controlled trial. Sometimes health professionals don't know the best way of treating patients with spinal cord disorders, so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better than the other. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the study nurse nor the study participant can decide which treatment the participant receives.

This research project has been designed to make sure that the researchers interpret the results in a fair and appropriate way and avoids the assessors jumping to conclusions. This is called 'blinding'. Because of the nature of the equipment used for transanal irrigation and standard bowel care procedures, you will not be blinded to the treatment that you receive, but the person collecting assessments and the principal investigators will be. You, your study nurse and carers will be asked NOT to discuss any aspect of your bowel care allocation to your assessor or site principal investigator to ensure that s/he remains 'blinded'.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study will be conducted over 6 weeks. Your involvement in the study will include a full assessment to make sure you are eligible to participate, and collection of some information about your spinal cord injury, general health and confirm some general details about you (e.g. age, sex, medical history). You will be asked to time your bowel care twice and your bowel care will be timed twice. This assessment will be undertaken by a blinded assessor, within one week of you agreeing to participate. After these data has been collected, you will be randomised into either the intervention or control group.

Intervention Group.

If you are allocated to the intervention group, you will be offered one of three commercially available transanal irrigation kits for use over the next 6 weeks. You and/or your carers will receive training on how to use the kits to make sure that you have effective bowel care results. You and/or your carers will be told how to document the results of the treatment in your participant diary. It is expected that documenting these results will take 1-2 minutes after each bowel result. You and/or your carers will continue to receive support and advice from the study nurse during the six weeks of intervention.

Control Group

If you are allocated to the control group, you will continue with your current bowel care routine (standard care). You and/or your carers will be told how to document the results of the treatment in your participant diary. It is expected that documenting these results will take 1-2 minutes after each bowel result. You will continue to receive support and advice from the study nurse during the study period.

Both Groups

In week six, you and/or your carers will be asked to time your bowel care twice during the week. This involves using a stopwatch and documenting the time into a diary. It is expected that this will take 1-2 minutes each time. The blinded assessor will time your bowel care twice and ask you questions from 5 short questionnaires at each measurement. It is expected that the total time to complete these additional activities will be approximately 45 minutes over the six week study period. All baseline and termination data will be collected in your home.

5. 'How is this study being paid for?'

The study is being funded by a grant for NSW Insurance (icare) and a philanthropic donor. There is no conflict of interest between the funder and investigators. The money will be used to coordinate the study and employ blinded assessors to complete assessments.

If you are eligible to participate in this study, the study nurse will assist you in obtaining funding to uses transanal irrigation and ordering the equipment through your funding provider (eg. icare, NDIS or NIISQ). This does take some time to arrange so the investigators will have one kit to start participants allocated to the intervention group whilst awaiting approval and ordering through the relevant funding scheme. This kit provides two weeks of bowel care. It is expected that you will give a kit back to your study nurse once you have received your order. This means that other participants can start this treatment sooner.

6. 'What are the alternatives to participating in this study?'

If you decide not to participate in this study, you will still use standard bowel care practices recommended for your condition. It is important that you discuss the alternatives to participating in this study with your doctors.

7. 'Are there risks to me in taking part in this study?'

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. Despite all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

Low Risk

- A small amount of bleeding from the rectum is a common response to transanal irrigation and not concerning if it remains small amounts and stops after a period.
- Cramping, discomfort or pain can be experienced if the irrigation is too fast or the water is not at the right temperature.
- For people at risk; Autonomic Dysreflexia can occur during irrigation, especially if it is present during standard bowel care. It is expected that any episode of Autonomic Dysreflexia will resolve quickly once bowel stimulation stops and should be

manageable without medication or other treatments. However, it is important to let your study nurse know if your symptoms do not settle, so that s/he can provide clinical support and advice, and you must make sure that you have access to your GTN spray or patch and be ready to use it if your symptoms don't go away. You can use your AD card to help guide you on what to do.

- Leakage of water between irrigations can occur if not enough time is allowed for toileting, or if too much water is used during the procedure.

Remote Risk

- Irrigation related bowel perforation has been estimated to be 1 per 50,000 (0.0002%) (1). There are 3 main reasons why this might occur. They are trauma from the rectal catheter, over-inflation of the catheter balloon and excessive water pressure during instillation. Support and training from the Study nurse is designed to mitigate this remote event from occurring.

  These risks are reduced by careful participant selection (i.e. excluding participants who have known colorectal conditions or inflammatory disorders on certain medications that can increase bleeding). They are also reduced because the study nurse will provide training, close supervision and monitoring throughout the six weeks.

  There may also be risks associated with this trial that are presently unknown or unforeseeable. Tell your study nurse immediately about any new or unusual symptoms that you get.

8. 'Will participating in this study affect my plans to start a family?'

Transanal irrigation has not been recommended for use in pregnancy but there is no documented damage to the developing foetus. There has not been any recorded damage to sperm that might affect conception. If at any time you think you may be pregnant, it is important to let your study nurse, or your medical team know immediately.

9. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact the study nurse as soon as possible, who will assist you in arranging appropriate medical assessment and/or treatment. This includes prolonged or uncontrollable episodes of Autonomic Dysreflexia.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

10. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future treatment for bowel problems (neurogenic bowel dysfunction) as a result of spinal cord disorders. However, it may not directly benefit you. You may experience an improvement in the

time it takes for you to finish bowel care or have less bowel complications (such as bowel accidents or haemorrhoids). Your individual results will be available on request from Louise Kelly or Professor Lisa Harvey after the trial has been completed.

11. 'Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything, nor will you be paid.

12. 'How will my confidentiality be protected?'
Of the people treating you, only those named above or necessary others e.g. study nurses / carers involved in your care will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above, the Human Research Ethics Committee (HREC) for monitoring purposes, those persons monitoring the conduct of the study on behalf of the sponsor, regulatory bodies (including the Therapeutic Goods Administration) will have access to your details and results that will be held securely at the office of the Site Principal Coordinator. Re-identifiable information such as the data collected during the trial will be uploaded onto a highly secure web-based file transfer and storage platform called Cloudstor by the blinded assessor. The Site Principal Coordinator will be able to access this platform from within the University computer network server to retrieve these data. This will only occur when necessary (at initial and final data collection) and the provisions of Australian privacy law will be complied with.

Your re - identifiable data will be downloaded from Cloudstor and saved into the highly protected University Research Data Storage set up for this study. These data will also be manually entered into an electronic database called RedCap. This program is a web application for building and managing online surveys and databases and is hosted by the University of Sydney. Access to the program as well as storage of data is subject to a high level of security measures. The University uses 2 separate servers to manage this program; a web server (to access the program) and a database server (to store data). Both servers sit behind the University's firewall. Only the investigators can access these data using individual passwords and only coded data will be stored on this database.

13. 'What happens with the results?'
If you give us your permission by signing the consent document, we plan to discuss/publish the results in a number of forums (e.g. Peer review journal article, conferences, other professional / educational forums). We are also required to provide final reports to Northern Sydney Local Health District and the HREC for monitoring purposes. Any information will be provided in a way that you cannot be identified. Summary data will also be used as part of a PhD thesis submitted to the University of Sydney. Results of the study will be provided to you, if you wish.

14. Use of data in future research
Data collected in this study will be stored ("banked") for possible use in future projects related to this research and other as yet unspecified projects in people with spinal cord disorders. All data will be coded, so your individual results will not be able to be linked back to you. At the end of the study all coded data will be stored on a dedicated research computer server managed by the University of Sydney for 15 years, after which time the files will be destroyed. Any future analysis of your data will be approved by a Human Research Ethics Committee before being undertaken. Using your coded

data for future research is a mandatory component of this study, and data collected in this study will be stored for potential use in the future as yet unspecified research studies. If you do not wish for us to use or store your data for future use, you should not participate in this study.

15. 'What happens to my treatment when the study is finished?'

If you are in the intervention group, you may be able to continue using transanal irrigation following completion of this study if you found it to be beneficial. If you were in the control group, you may commence using transanal irrigation if think that it will be of benefit to you. This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

16. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the study nurse will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the Site Principal Investigator Louise Kelly (in NSW) on (02) 9926 4594, the Site Principal Investigator Amy Darvall (In QLD) on (07) 5677 0153. Alternatively, you can contact the Coordinating Principal Investigator, Professor Lisa Harvey on (02) 9926 4594.

17. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference number 2020/ETH02994.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

CONSENT FORM

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The TAI Study

1. I,.....
   of.....
   agree to participate as a subject in the study described in the Participant Information Sheet set out above.

2. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the investigators or Northern Sydney Local Health District or Holistic Nursing Solutions.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Louise Kelly or Professor Lisa Harvey on (02) 9926 4594 in NSW or Amy Darvall on (07) 5677 0153 in QLD who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the Research Office on Level 13, Kolling Building, Royal North Shore Hospital, St Leonards NSW 2065

Phone 02 9926 4590 | email NSLHD-research@health.nsw.gov.au

Signature of participant	**Please PRINT name**	**Date**
_____		
Signature of witness	**Please PRINT name**	**Date**
_____		
Signature of investigator	**Please PRINT name**	**Date**

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REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Northern Sydney Local Health District, or my medical attendants

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Louise Kelly lgal2519@uni.sydney.edu.au