Participant Information Sheet

(This is yours to keep for reference)

Research Title: Retrofit Bidet Clinical Trial

Principal Investigator: Niusha Shafiabady, Faculty of Science and Technology (Sydney Campus)

Researcher(s): Associate Professor Niusha Shafiabady

Associate Professor Rosemarie Hogan

Thank you for your interest in participating in this research project. Please read the following information about the project so that you can decide whether you would like to take part in this research. Please feel free to ask any questions you might have about your involvement in the project.

If you decide to participate in this research, please keep in mind that your participation is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to stop at any time, and you would not need to give any explanation for your decision to stop participating. If you choose to stop participating, your data will not be used in the research.

You will be given the Participant Information Sheet to read and Informed Consent Form to sign, and you will be given a copy to keep. Your decision whether you take part, or not to take part, or to take part and then withdraw, will not affect your relationship with the Charles Darwin University or your Aged Care Facility, Hospital or InteliCorp.

What is this research about?

Bidets offer back dignity to those that struggle with only toilet paper. This clinical trial presents an opportunity for patients to be given a new intervention that may be better for patient's current toileting condition or that has fewer side effects than what they are receiving now. This opportunity will also present better working conditions for Carers and Nursing staff.
InteliCorp are conducting a feasibility study on the use of bidets. InteliCorp are working with Charles Darwin University for the study, which is part of a National Clinical Trial.
This study will contribute to healthier outcomes for Aged Care and increase independent living situations
For more information about the study contact:
Craig Spence – trade1@intelicorp.com.au – 07 5591 7744
Associate Professor Niusha Shafiabady
Associate Professor Rosemarie Hogan

Study aim(s):

The aim of this work is to address the gap in knowledge by investigating the potential of the electronic bidet to support patients limitations in toileting, as well as staff who provide support for persons' daily intimate personal care needs.

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What are the possible benefits of taking part?

This trial sets out to show the bidet would be acceptable as toileting cleaning to the wide variety of individuals living in Australia and patients in hospital and in aged care services; if the bidet has capacity to adequately clean and dry, given variations in type of void, anatomy, size and shape of individual users; and whether the bidet may be acceptable and clinically useful for staff of hospitals and Australian aged care homes.
The Bidet is a promising advance in dignity & hygiene for people requiring personal care. This trial may offer participants access to the newest bidet technology. InteliCorp seek the chance to play an active role in patient's own health care.
There will be no direct reimbursement benefit to you from your participation in this research.

What are the possible risks and disadvantages of taking part?

The risks and disadvantages are minimal with the quality of bidet that will be used in the study. The consenting participants will be utilising a bidet intent to improve daily life toileting, improving hygiene, independence and dignity. The bidets are Watermarked to Australian government standards, they are not a test device, hence there are minimal risks.

Bidets and toilet paper are both methods of personal hygiene, but they have distinct differences in terms of cleanliness, comfort, and potential health benefits. Here are some clinical reasons why bidets might be considered advantageous compared to toilet paper. This study aims to examine all of these factors:

Better Cleaning: Bidets use water to clean, providing a more thorough and effective cleansing than wiping with toilet paper alone. This can help reduce the risk of irritation, infections, and other hygiene-related issues.

Reduced Friction and Irritation: Toilet paper can be abrasive and may cause friction, leading to irritation, especially for individuals with sensitive skin or certain medical conditions, such as; anal fissure, haemorrhoids, constipation, rectal prolapse, anal fistula, anal itching, ulcerative colitis, Irritable Bowel Syndrome and Crohn's Disease. Bidets, using a gentle stream of water, are less likely to cause irritation.

Haemorrhoid Relief: Bidets can be beneficial for individuals with haemorrhoids or anal fissures. The gentle cleansing action of water can be less irritating than repeatedly wiping with toilet paper, which can exacerbate existing discomfort.

Prevention of Infections: Bidets can help prevent urinary tract infections and other infections in the genital and anal areas by ensuring thorough cleaning without the need for excessive wiping.

Eco-Friendly: From an environmental perspective, bidets can be considered more sustainable than toilet paper. The production and disposal of toilet paper contribute to deforestation and environmental waste, while bidets use water, a renewable resource.

Constipation Relief: The use of bidets with adjustable water pressure can provide relief for individuals who suffer from constipation, as the gentle stream of water may help stimulate bowel movements.

Improved Personal Hygiene: Bidets promote better overall personal hygiene by ensuring a more thorough cleaning process. This can be particularly important for individuals with mobility issues or those who may have difficulty reaching certain areas.

It's important to note that personal preferences, cultural norms, and availability of bidet facilities can influence an individual's choice between bidets and toilet paper. Some people may prefer a combination of both for optimal cleanliness and comfort. As with any personal care product or practice, individual experiences may vary, and consulting with healthcare professionals can provide personalized advice based on specific health conditions and needs. This study aims to examine all of these factors.

Occupational therapists and other health professionals are increasingly recommending bidets to enhance the independence and dignity of a range of clients with disabilities.

The electronic bidet has been added to the catalogue of aids to daily living provided by the Australian Government Department of Veterans Affairs to eligible veterans, and is an eligible home modification under the National Disability Insurance Scheme, if assessors can demonstrate the bidet improves clients' functional capacity and decreases the need for addition funded supports, such as personal care services.

What will the research involve?

The study method will involve using the bidet on a regular basis, indicate via an online questionnaire, the ease of use and the benefits and/or limitations of using the bidet.
Your nurse or Carer will also be surveyed by a separate questionnaire on their experience as a Carer. The data will be collected via the secure survey portal and analysed and presented by 2 leading Associate Professors from Charles Darwin University and the results will be shared with participants and the academic community via a medical paper and published in a yet to be determined medical journal.

The industry client (InteliCorp) will be sending out the questionnaire to the participating Care Facility and the Care Facility will distribute to the consenting Carers and participants and the unidentifiable anonymous questionnaires will be collected for the study via a QR code.
The consenting participants will be over 18, they may be people with disabilities, elderly people at home or residents of an aged care facility with a full understanding of the study.

What will I need to do?

If you agree to participate you will be asked to complete a 1 minute survey questionnaire on a regular basis throughout the study undertake a brief 5 minute interview post study.

For qualitative methodologies, the data will be recorded via an online secure portal, then automatically transcribed for analysis.
Should you decide to withdraw from the project your data will be removed upon your request.

The place of data collection will be online via the secure survey portal and the interview will be conducted in person or by phone. The 1 minute survey questionnaire on your user experience will be required as often as you feel comfortable after using the bidet.

What will happen to the information about me?

All information collected about you will remain confidential. Given the small number of participants/rare identifying factors of your data, it might not be possible to guarantee complete anonymity.

No names or contact details are recorded. The only opt in personal information is Age Range, Gender, State.
Data will be stored in a secure password protected server and only the facilitators of the study will have access to data.

Collected data might be used again for future research, unless requested to be removed by you after this study.

It is anticipated that the results of this research project will be published and/or presented in a variety of forms. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your expressed permission.

The research will be published in academic journals and other publications and presented at conferences. We will also be asking your permission to use your data in other projects. This allows us or other researchers to use what you have said in interviews and in your digital story at other times rather than having to speak to you again. You do not have to give this permission. If you choose not to, your data would be destroyed after 5 years as is standard practice in other research projects.

What will happen if I decide to withdraw?

Your participation in this research is voluntary and you are free to withdraw from the research anytime without needing to provide any explanation. There will be no penalty or bias as a result of your withdrawal. Should you decide to withdraw, all the information collected from/about you will be destroyed and will not be used in the research. There may be an incidence whereby on withdrawal the data cannot be identified and/or withdrawn, all attempts to remove your de-identified data will be made

Can I hear about the results of this research?

The results of this research will be disseminated to all participants, the research will be published in academic journals and other publications and presented at conferences.

Who can I contact if I have any concerns about the project?

This project is being managed by Associate Professor Niusha Shafiabady, College of Science and Technology at Charles Darwin University and assisted by Craig Spence at InteliCorp. If you would like more information before you decide to participate, please contact Associate Professor Niusha Shafiabady by phone 02 8047 4147 or email niusha.shafiabady@cdu.edu.au or contact Craig Spence by phone 07 5591 7744 or email trade1@intelicorp.com.au. You may also use these numbers at any time during the project, if you need information or wish to withdraw.

This project has been approved by the Charles Darwin University Human Research Ethics Committee ID number EC00154. If you have any questions or concerns that you do not want to direct to the researcher, you are invited to the contact the Charles Darwin University Research Integrity and Ethics team on (08) 8946 6063, on the toll-free number, 1800 466 215 or by email, ethics@cdu.edu.au .

The Research Integrity and Ethics team can pass on any concerns to the Charles Darwin University Human Research Ethics Committee (CDU-HREC) and appropriate officers within the University.

Thank you for considering taking part in this research

Associate Professor Niusha Shafiabady
Associate Professor Rosemarie Hogan

Informed Consent Form

Retrofit Bidet Clinical Trial

H24003 – Improving the Well-being of Clients with Healthcare Needs Using the Retrofit Bidet
Researchers: Associate Professor Niusha Shafiabady and Associate Professor Rosemarie Hogan

- I have read {or had read to me} the Plain English Information Sheet which explains what this research project is about, and I understand it.
- I have had a chance to ask questions about the project, and I am comfortable with the answers that I have been given. I know that I can ask more questions whenever I like.
- I have volunteered to participate in the research. I know that I do not have to participate in it if I don't want to. I know this it will be taken over a duration of 8 weeks
- I know that I am free to withdraw at any time. If I do withdraw there will be no bad consequences for me.
- I know that the researchers will keep my information confidential so far as the law allows.
- I know that I won't get paid for participating in the research project.
- This trial may offer participants access to the newest bidet technology. InteliCorp seek the chance to play an active role in patient's own health care.
- There will be no direct reimbursement benefit to you from your participation in this research.
- Collected data might be used again for future research, unless requested to be removed by you after this study.
- There may be an incidence whereby on your withdrawal the data cannot be identified and/or withdrawn, all attempts to remove your de-identified data will be made

I have read this Informed Consent Form and I agree with it {OR appropriate format for oral consent}.

Signed by the research participant:_____

Name of the research participant:_____

Date:_____

I agree to having an audio tape made of the interview

☐ Yes ☐ No (if no, I will be able to still participate)

Signed [or orally confirmed] by the research participant:_____

Email a copy of the signed Informed Consent Form to Trade1@intelicorp.com.au with "Consent Form" in the subject line.

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