A quasi-experimental comparative study of the effect of an educational, pragmatic intervention to improve the quality of continence care in continuing care homes.

Pro00165968

Structured Utilization of Continence Care Innovations in Nursing Care Trial (SUCCINCT)

Information for Staff

You are being invited to participate in a study entitled **Structured Utilization of Continence Care Innovations in Nursing Care Trial (SUCCINCT).** The study is part of the ProCon (Boosting innovation, entrepreneurship and training for PROmoting CONtinence in nursing homes) project (https://www.proconproject.eu/). This information sheet provides information to enable you to make a decision about your participation. Please take the time to read this information carefully.

What is the purpose of the study?

In this study (SUCCINCT) we will examine if a front-line team comprised of care unit staff like you, can co-create an intervention designed to improve the continence care or delivery of continence care for residents, implement the intervention and measure the improvements.

What will taking part in the study involve?

The study is completed over a four-month period and will involve:

- The facility Director of Care selecting a clinical care unit to take part in the study.
- The care unit will then be randomly allocated to the “intervention” or “usual care” group.
- SUCCINCT Research team members will provide information sessions to staff about the study for both intervention and usual care units. You have the opportunity to be part of this team.
- In units assigned as intervention units a “Continence Care Champion” (leader) and a minimum of four front line staff from the unit will be invited to form a continence improvement team.
- In units assigned as usual care units, members of staff will not need to form a team, but will be invited to participate in all study data gathering activities as below.

- If you participate in the study we encourage you to not share information regarding the intervention components between staff members of the “intervention” versus the “usual care” groups.
- Each member of the clinical unit continence team on the intervention units will be required to undertake a basic continence course, delivered either in person or virtually, either within or outside of working hours, depending upon local circumstances. Team members on the usual care units will not need to take the course, but will be offered the opportunity to do so after the trial has finished.
- Each member of the intervention team will take part in implementing their intervention and measuring its effect over the twelve weeks of the study.
- During the study, the Continence Champion and team will work with residents to implement their intervention and measure the effect. They will be supported in this by a SUCCINCT researcher who will facilitate meetings, either in person or online, discuss progress and assist with measurement, as necessary. Support from facility leadership in assisting the team with addressing barriers to implementation and making time available for team meetings may be required.
- The continence team will identify 4-6 residents with urinary incontinence on the unit who would potentially benefit from the team’s created intervention and gain their, or their surrogate decision maker’s, consent to discuss the study with the SUCCINCT researcher. The SUCCINCT researcher will then gain consent or assent to participate in the study and conduct required data collection throughout the study.
- All team staff on both intervention and usual care units will be asked to answer four questionnaires which assess work engagement and empowerment, the degree to which tasks are rushed (called organizational headroom), their opinion on effectiveness and usability of the intervention and their opinion on changes in workload associated with the intervention. The SUCCINCT researcher will help with the completion of these questionnaires, which should take no more than fifteen minutes. The questionnaires are
  filled in twice, once at the beginning of the study (work engagement and empowerment) and once at the end (all questionnaires).

- After the study has finished, staff in the intervention unit team will be invited to take part in a focus group or interview to discuss their intervention, and things that were difficult or easy in implementation. A separate information sheet and consent form will cover this part of the study, should you be interested in taking part at the end of the study.

What are the possible benefits of taking part in the study?

Participating in the study will provide you with information that may help you improve resident care. Your unit will receive a report containing information from the study and feedback on your implementation efforts with residents. Intervention teams will gain experience in quality improvement techniques which can be translated to other areas of clinical care in need of care improvement. Usual care teams will gain experience in research participation and the opportunity to take part in basic continence education, after the study period finishes.

What are the potential risks of taking part in the study?

There are no known risks to participating in this study.

How will you ensure confidentiality?

All information provided to researchers will be confidential. Information collected during this study will not identify your unit or facility. We will adhere to strict data handling and confidentiality protocols in accordance with the EU General Data Protection Regulation 2016/679 (GDPR) and relevant local data protection policies. During the study we will be collecting data about you. We will do everything we can to make sure that this data is kept private. To ensure confidentiality, pseudo-anonymization will be implemented throughout the project, and all links with identification will be broken immediately after data collection. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.

Your study data will be coded with a unique identifier, removing direct personal identifiers such as your name and address to protect your privacy. Only the study doctor will be able to associate your coded data with your identity.

At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the Study.

Do I have to take part in the study?

Participation in any part of the study is voluntary and your facility can opt out at any time without penalty. Data collected up to the point of withdrawal from the study will be included in any data analyses.

Who is organizing the study?

The team running this project includes both university based researchers and knowledge users. This partnership approach ensures that the findings benefit the research community and have real-world applicability. The team includes a Principal Investigator who oversees the research and country Lead Investigators who will oversee the project in your region or Details are provided below.

Project Role	**Name & Title**	**Contact Details**
Principal Investigator (Canada)	Adrian Wagg, Professor	adrian.wagg@ualberta.ca
Belgium Lead Investigator		
Finland Lead Investigator		
Spain Lead Investigator	Javier Jerez Roig, Associate Professor	javier.jerez@uvic.cat

Contact Names and Telephone Numbers:

If you have any concerns about any aspects of this study, you may contact the Project Manager, Ilinca Radu (igradu@ualberta.ca / 780 492 5338)

For questions about participant rights, you may contact The University of Alberta Research Ethics board (ethics@ualberta.ca). This office has no affiliation with the study investigators.

Thank you for taking the time to read this information sheet

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Structured Utilization of Continence Care Innovations in Nursing Care Trial (SUCCINCT)

Information for Facilities

You are being invited to participate in a study entitled **Structured Utilization of Continence Care Innovations in Nursing Care Trial (SUCCINCT).** The study is part of the ProCon (Boosting innovation, entrepreneurship and training for PROmoting CONtinence in nursing homes) project (https://www.proconproject.eu/). This information sheet provides information to enable you to make a decision about your participation. Please take the time to read this information carefully.

What is the purpose of the study?

In this study (SUCCINCT) we will examine if a front-line team of staff, who have received education in the assessment and management of continence, can co-create an intervention designed to improve the continence care or delivery of continence care for residents, implement the intervention and measure the improvements.

Why has my facility been invited to participate?

We selected facilities that met the following criteria:

- Are registered with the appropriate administrative authority, and have 90% of residents aged 65 years or over.
- Facility operations should be conducted in the language appropriate to their country of location and be located within 100 km of the trial centre (University of Alberta in Canada, University of Vic-Central University of Catalonia in Spain, Turku University of Applied Sciences in Finland and KU Leuven in Belgium).

What will taking part in the study involve?

The study is completed over a four-month period and will involve:

- The facility Director of Care selecting a clinical care unit to take part in the study.
- The SUCCINCT researcher will survey the unit using the Alberta Context Tool, a survey which collects information on people's perceptions of the work environment and includes information on leadership, culture, interactions, resources and time. The researcher will feed back the results of this survey to the Director of Care; if the unit does well then the unit will be selected. If not, an alternative care unit will be selected and the survey repeated.
- The care unit will then be randomly allocated to the "intervention" or "usual care" group.
- SUCCINCT Research team members will provide information sessions to staff about the study for both intervention and usual care units.
- In units assigned as intervention units, the Director of Care and unit staff will then select a "Continence Care Champion" and a minimum of four front line staff from the unit to form a continence improvement team.
- The SUCCINCT researcher will gain staff consent and explain relevant data collection processes for the study.
- The Continence Champion will complete two online courses: a basic continence care course (approximate duration of 6-8 hours) and an advanced continence care course (approximate duration of 6-8 hours) and three workshops (virtually delivered), each lasting approximately 90-120 minutes. The latter teach change techniques and the theory behind them. Support for the time involved is required.
- The clinical unit continence team will be required to undertake the basic continence course, delivered either in person or virtually, within working hours. Support for this time is required. We envisage allowing a month prior to the start of the intervention period for these. Release from work time will be required for this.
- On intervention units, the continence team members will be required to undertake a basic continence course, delivered in person, taking approximately four hours for which release from normal duties will be required. Staff on usual care units will be required to undertake no pre-course work but will be offered the chance to participate in online courses after the study.

- Over the 12 weeks of the study, the Continence Champion and team will work with residents to implement their intervention and measure the effect. They will be supported in this by a SUCCINCT researcher who will facilitate a weekly meeting, either in person or online, discuss progress and assist with measurement. Support from facility leadership in assisting the team with addressing barriers to implementation and making time available for team meetings may be required.
- The continence team will identify 4-6 residents with urinary incontinence on the unit who would potentially benefit from the team's created intervention and gain their, or their surrogate decision maker's, consent to discuss the study with the SUCCINCT researcher. The SUCCINCT researcher will then gain consent or assent to participate in the study and conduct required data collection throughout the study.

What are the possible benefits of taking part in the study?

Participating in the study will provide you with information that may help you improve resident care. Your facility will receive a report containing information from the study, care teams will receive feedback on their implementation efforts with residents, and we will bring Directors of Care and Unit Managers together to discuss findings. Clinical unit staff will gain experience in quality improvement techniques which can be translated to other areas of clinical care in need of care improvement.

What are the potential risks of taking part in the study?

There are no known risks to participating in this study.

How will you ensure confidentiality?

All information provided to researchers will be confidential. Information collected during this study will not identify your unit or facility. We will adhere to strict data handling and confidentiality protocols in accordance with the EU General Data Protection Regulation 2016/679 (GDPR) and relevant local data protection policies. To ensure confidentiality, pseudo-anonymization will be implemented throughout the project, and all links with identification will be broken immediately after data collection. Local de-identified data will

be exported to a central dataset held in Catalonia Spain.

Do I have to take part in the study?

Participation in any part of the study is voluntary and your facility can opt out at any time without penalty. Data collected up to the point of withdrawal from the study will be included in any data analyses.

Who is organizing the study?

The team running this project includes both university based researchers and knowledge users. This partnership approach ensures that the findings benefit the research community and have real-world applicability. The team includes a Principal Investigator who oversees the research and country Lead Investigators who will oversee the project in your region or Details are provided below.

Project Role	**Name & Title**	**Contact Details**
Principal Investigator (Canada)	Adrian Wagg, Professor	adrian.wagg@ualberta.ca
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Structured Utilization of Continence Care Innovations in Nursing Care Trial (SUCCINCT)

Information for Residents

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What is the purpose of the study?

In this study (SUCCINCT) we will examine if your care staff, can improve the continence care or delivery of continence care for residents, like you, with bladder or bowel control problems, and measure the improvements.

What will taking part in the study involve?

The study will take place over approximately four months. Taking part will involve care staff on your unit and members of the research team being involved in the study. Participants both staff and residents will be assigned to either a usual care group or to a group receiving the new way of delivering ca

If your unit is part of the intervention group:

- Care staff will introduce and use a new approach to continence care on your unit.
- Your care team will support and monitor how this approach works overtime.

If your unit is part of the usual care group:

- Your care will continue as usual, with no changes to your current continence care during the study period.

For all participants:

- Your continence (bladder and bowel) patterns will be recorded over a short period of time.
- Your continence status will be assessed at the beginning and end of the study.
- Basic information about your health (age, general health, number of medical conditions and medications) will be collected from you.
- You will be asked to complete a short questionnaire about your satisfaction with continence care at the beginning and end of the study.

What are the possible benefits of taking part in the study?

Taking part in this study may provide you with the opportunity to receive enhanced continence care if you are part of the intervention group. This may help improve comfort and overall care experience. As a participant, you will also be asked to share your satisfaction with continence care through a questionnaire. This feedback may help improve continence care for you and for other residents in the future. Continence will be assessed and monitored at the beginning and end of the study. This may help the care team better understand individual needs and support more personalized care.

What are the potential risks of taking part in the study?

There are no known risks to participating in this study.

How will you ensure confidentiality?

All information provided to researchers will be confidential. Information collected during this study will not identify your unit or facility. We will adhere to strict data handling and confidentiality protocols in accordance with the EU General Data Protection Regulation 2016/679 (GDPR) and relevant local data protection policies. During the study we will be collecting data about you. We will do everything we can to make sure that this data is kept private. To ensure confidentiality,

pseudo-anonymization will be implemented throughout the project, and all links with identification will be broken immediately after data collection. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private.

Your study data will be coded with a unique identifier, removing direct personal identifiers such as your name and address to protect your privacy. Only the study doctor will be able to associate your coded data with your identity.

At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the Study.

Do I have to take part in the study?

Participation in any part of the study is voluntary, and you can opt out at any time without giving a reason without penalty. Data can be withdrawn from the study up until two weeks after study end.

Who is organizing the study?

The team running this project includes both university based researchers and knowledge users. This partnership approach ensures that the findings benefit the research community and have real-world applicability. The team includes a Principal Investigator who oversees the research and country Lead Investigators who will oversee the project in your region or Details are provided below.

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Thank you for taking the time to read this information sheet

Resident Consent Form

By signing below, you confirm that:

- You have read and understood the information provided and have had the opportunity to ask questions. Any questions you had have been answered to your satisfaction.
- You agree to take part in the study.
- Your participation is voluntary, and you may withdraw from the study at any time without penalty.
- You understand that relevant health information (such as age, general health, and continence-related information) will be collected for the purposes of this study.
- You do not waive any legal rights by participating.
- The legal and professional responsibilities of the researchers and institutions are not affected by your participation.

SIGNATURE OF STUDY PARTICIPANT

_____

Name of Participant

_____ _____

Signature of Participant Date

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE (if applicable)

If the participant is unable to provide informed consent, a legally authorized representative may consent on their behalf.

_____

Name of Participant

_____

Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____

Name of Person Obtaining Consent Contact Number

_____

Date

A copy of this consent form has been given to you to keep for your records and reference.