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# Smart Personalized Continence Care for People With Profound Intellectual and Multiple Disabilities: A Theory and Practice- Based Implementation Guideline for a Digital Innovation

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## ABSTRACT

Introducing smart technologies can personalize and improve continence care for people with profound intellectual and multiple disabilities within residential care facilities. Currently, continence care is provided according to fixed schedules. This can lead to oversaturated incontinence materials, leading to leakages and an increased chance of incontinence-associated dermatitis or unnecessary changes. Both result in an unneeded burden for individuals with profound intellectual and multiple disabilities and their caregivers. Smart technologies that notify caregivers when incontinence materials need to be changed can improve the quality of life for individuals experiencing incontinence and lead to a more efficient care process for their caregivers. Yet, implementation is challenging. We present a Guideline for Smart Continence Care (SCC) Implementation in Residential Disability Care. The guideline is systematically and iteratively developed by combining implementation literature and daily practice. Lessons learned from applying a draft version at six residential care facilities are integrated. Eight steps are identified and detailed to guide the SCC implementation process: (1) analyze and determine goals for each target group, (2) analyze the innovation, (3) analyze the context, (4) arrange preconditions, (5) formulate implementation strategy, (6) carry out and monitor the implementation, (7) evaluate and adapt implementation strategy, and (8) continued use and upscaling. The guideline is illustrated by examples from actual SCC implementation practice. This guideline is not only useful for those who lead the implementation of SCC in residential care, but may offer guidance for other care technology implementations in various care settings as well.

## 1 | Introduction

The use of incontinence material is common in people with profound intellectual and multiple disabilities (Saloviita 2002; Giesbers et al. 2012; Yang et al. 2010; Van Laecke et al. 2010).

Estimates of incontinence in these groups vary depending on the type of study and reach up to 96% (Giesbers et al. 2012). Toilet training may not always be possible as it requires a combination of communicative skills, mobility, and cognitive ability, which are commonly underdeveloped in individuals

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## Summary

- Personalized Continence Care: Using notifications generated by sensors can make continence care more personal for persons with severe disabilities in residential facilities.
- How It Helps: Caregivers get alerts when incontinence materials need changing, preventing leaks and unnecessary changes.
- Step-by-step implementation: A guideline for implementing incontinence material with a sensor was created and tested in six care facilities.
- Broad Application: The guideline provides detailed steps and examples for implementation, and it can be helpful for other care technology projects in different settings as well.

with profound intellectual and multiple disabilities (Pawlyn and Carnaby 2008). Therefore, most individuals who experience incontinence wear incontinence materials or use catheters. In residential care facilities, incontinence materials are often manually checked and changed at scheduled moments by professional caregivers (hereafter: caregivers) (Raepsaet et al. 2021). Leakages occur when the material is oversaturated, leading to an additional change of clothing or bed sheets and possible washing or showering of the person. Prolonged exposure to wet incontinence materials may result in skin problems, such as incontinence-associated dermatitis (Beeckman et al. 2009). In addition, some scheduled changes are unnecessary as the incontinence materials are still (relatively) dry. Leakages of incontinence material, skin problems, and unnecessary changes of incontinence materials can be prevented if caregivers receive real-time information on the need to change incontinence material. Smart continence care (SCC) is a technological development that may solve these issues (Raepsaet et al. 2021; Agholme et al. 2023; Rajabali et al. 2023; Yu et al. 2014; Bouman et al. 2019; Nap et al. 2020; Van Cooten et al. 2022). SCC uses sensors to assess the saturation of the incontinence material; then an alert is sent to a mobile device notifying the caregiver of the needed change of incontinence materials. This may potentially prevent leakages and unnecessary changes and possibly improve the quality of life for individuals experiencing incontinence. It may also lead to a more efficient care process for their caregivers.

Since “digital transformation isn’t really about technology” (Kane et al. 2015, page 4), implementing digital solutions like SCC in residential care is not simply a matter of technical change. Instead, it requires a change in human attitudes and skills and the entire care process, broader services, and decision processes within the care facilities. Care technology implementation is stressed as important in Dutch politics, where SCC is mentioned as a time-saving technological solution (de Jonge 2021). The Ministry of Health, Welfare and Sports initiated an 8-year program (van Ark 2020; Helder 2024) in which residential care facilities are supported in implementing care technologies, knowing that implementation is challenging, as part of their agenda for future-proof disability care (Rijksoverheid 2022).

The present paper presents a Guideline for Smart Continence Care Implementation in Residential Disability Care, directed at project leaders and innovation managers in charge of care technology implementation. It is based on our systematic development and documentation of the implementation process for integrating SCC into daily continence care for individuals with profound intellectual and multiple disabilities living in residential care facilities in The Netherlands. The guideline can be used to guide SCC implementation in residential care and may serve as a blueprint for developing implementation guidelines for other care technologies. The Checklist for the Reporting on Digital Health Implementations (iCHECK-DH) (Perrin et al. 2023) was used to ensure all relevant implementation elements are presented (Appendix A). The guideline was developed as part of a cluster randomized trial conducted by the present authors, in which the effectiveness and cost-effectiveness of smart continence care for people with profound intellectual and multiple disabilities in Dutch residential care facilities are studied (Van Cooten et al. 2022). Results will be published in due course.

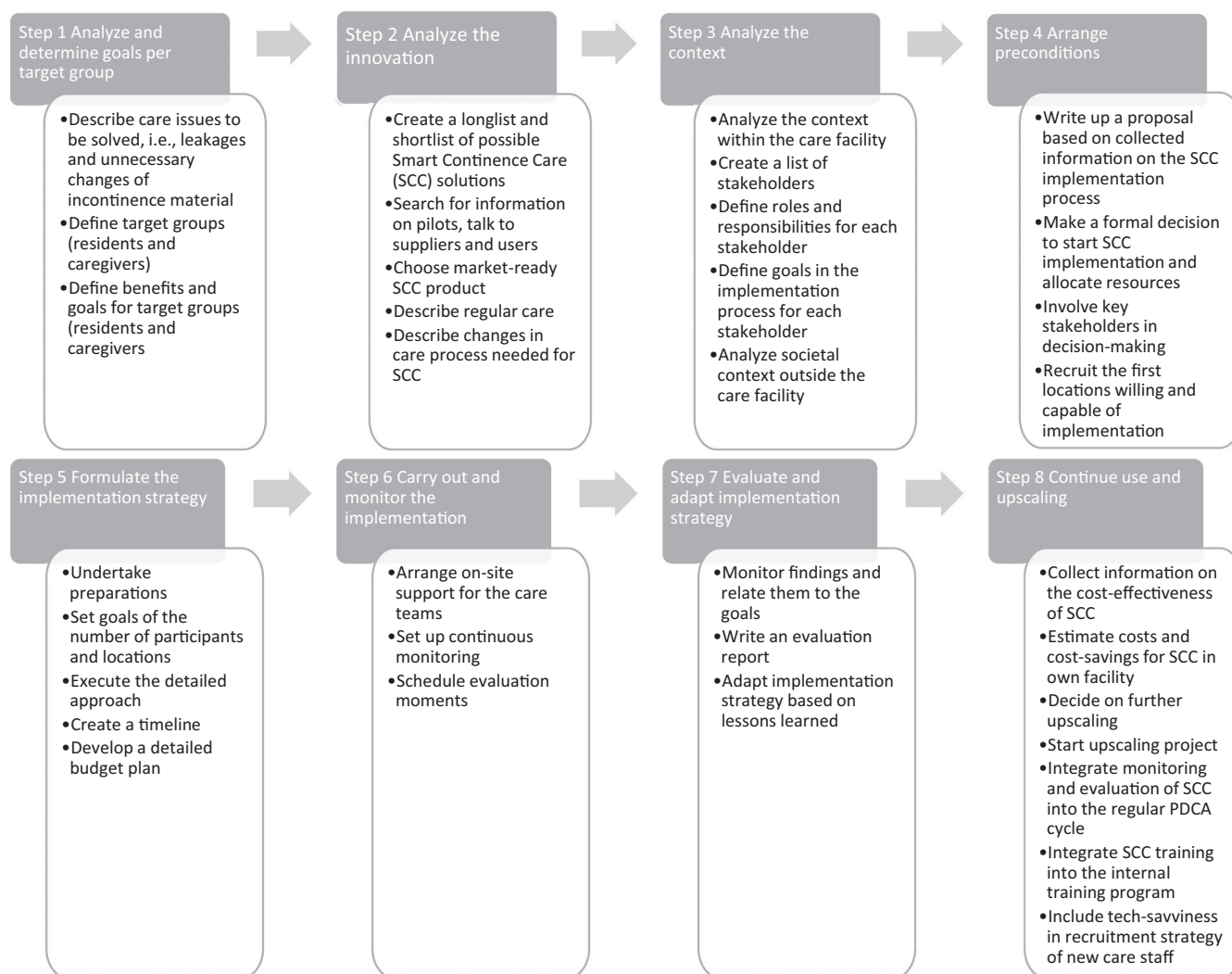
## 2 | Method: Development of the SCC Implementation Guideline

The implementation guideline for SCC was developed in five subsequent phases:

- I. a first draft of the guideline was developed based on theory and implementation models;
- II. evidence from specific eHealth implementation literature was included;
- III. each implementation step was detailed based on continence care daily practice information;
- IV. the draft version developed in phases I-III was tested and refined in a small pilot;
- V. lessons learned were integrated into the guideline throughout our research trial, resulting in the final guideline presented here.

### 2.1 | Phase I: Implementation Models

To identify general characteristics of implementation, several implementation models were studied: Replicating Effective Programs model (REP) (Kilbourne et al. 2007), Wensing and Grol’s Implementation model (Grol 2017), ZonMw’s implementation model (van der Linden 2016; ZonMw 2019), the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009) and The Measurement Instrument for Determinants of Innovations (MIDI) (Fleuren et al. 2014). The REP model is aimed at the successful implementation of evidence-based prevention programs. It contains four phases (pre-conditions, pre-implementation, implementation, and maintenance and evolution). Wensing and Grol’s Implementation model mainly focuses on facilitators and barriers within the implementation process. ZonMw’s implementation model is based on Wensing and Grol’s Implementation model and offers practical tools and checklists for use throughout the implementation process. CFIR offers a more



**FIGURE 1** | Guideline for smart continence care implementation in residential disability care.

holistic view of the implementation process as it includes not only factors related to the innovation itself and the processes within the organization but also societal conditions such as economic or political factors. The MIDI (Fleuren et al. 2014) is an instrument that contains evidence-based implementation determinants as it was developed using the DELPHI method with input from implementation experts and studied in a meta-analysis of eight empirical studies. Eight steps for successful implementation were identified (Figure 1). We drafted the guideline by filling in the details of each step directed at our specific case of implementing SCC.

## 2.2 | Phase II: Evidence From eHealth Literature

None of the aforementioned implementation models were designed with the specific purpose of implementing eHealth or technology. We thus looked into empirical evidence focused on technology implementation in healthcare. For this, we used a systematic review of systematic reviews in which determinants of successful implementation of several eHealth solutions, ranging from electronic health records and communications systems (telemedicine) to home telecare systems and computerized decision support systems (Ross et al. 2016). Each step of our draft implementation guideline was enriched with relevant evidence on

technology implementation based on the review. For example, the guideline pays attention to changes in workflows and habits as a consequence of embedding technology since Ross and colleagues stressed that “alterations to workflows created by the introduction of e-health systems may also disrupt established professional roles, responsibilities and working styles” (page 8).

## 2.3 | Phase III: Evidence From Daily Practice

To understand the daily routines in continence care for individuals with severe disabilities, the care process was observed, and caregivers and continence care experts were interviewed. Furthermore, we studied three SCC pilot studies in residential care facilities and interviewed the project leaders of these pilots. Moreover, the supplier was interviewed to specify the guidelines for the product chosen in our trial.

## 2.4 | Phase IV: Piloting the Implementation Guideline

The draft version of the implementation guideline, resulting from phases I–III, was tested at one location of a residential care

facility with two participants. These two participants have a moderate intellectual disability combined with a physical disability and were able to share their experiences with us. They used the SCC product for 1 week. Four care teams were involved: 2 day care teams, one night care team, and one activity center team. The caregivers of both participants were instructed on using SCC. The implementation process was evaluated and provided valuable insights for the implementation guideline. For instance, it highlighted the importance of a project team with sufficient skills (see Tables 4 and 5), a specific order of preparations, training all care teams, and the importance of discussing the suitability of SCC for each potential user of the product.

## 2.5 | Phase V: Optimization of the Implementation Guideline

The guideline version from phase IV was used in our research trial, aiming to implement SCC for 160 persons (18+) with profound intellectual and multiple disabilities evenly distributed over six residential care facilities (Van Cooten et al. 2022). The design of the trial was a staggered-entry cluster randomized trial. The facilities were divided into three pairs. Then, within each pair, the care facilities were randomly assigned to receive either SCC immediately or after a three-month waiting period in which regular continence care was provided. When the SCC implementation period for the first pair was over, the second pair started implementation. This design allowed for iterative optimization of the implementation guideline, as the lessons learned from the first residential care facilities were included in the guideline for the next, and so on.

During the trial, meetings were organized with the six project leaders of the participating facilities to exchange best practices and difficulties they experienced in embedding SCC into the care process. Project leaders kept visiting these meetings even after their own initial implementation had ended, which enabled us to include their experiences. Next to these group meetings, the project leaders had weekly to monthly individual consultation sessions with members of our research and implementation team. This flexible approach to implementation is essential for implementation projects in healthcare (Verweij et al. 2015). Along this way, we enhanced the guideline by incorporating the fostering and inhibiting factors encountered during implementation.

## 3 | Results: SCC Implementation Guideline in 8 Steps

The guideline contains eight steps, identified in phase I and optimized in subsequent phases II–V. These are: (1) analyze and determine goals for each target group, (2) analyze the innovation, (3) analyze the context, (4) arrange preconditions, (5) formulate implementation strategy, (6) carry out and monitor the implementation, (7) evaluate and adapt implementation strategy, and (8) continued use and upscaling. Figure 1 summarizes each step in the Guideline for Smart Continence Care Implementation in Residential Disability Care. To fully benefit from using SCC, one needs to adapt the continence care process and service processes related to it. Although the guideline appears to represent a linear

process, in reality, implementation is iterative (Grol 2017). To create a better understanding of the steps, the guideline illustrates practical examples of events encountered during the implementation process.

### 3.1 | Analyze and Determine Goals per Target Group

The first step is to specify the characteristics of the target groups, determine inclusion and exclusion criteria, and establish the target groups' goals. Here it is important to define the exact care issue that needs to be solved. For our guideline, this issue is incontinence care-related problems experienced by persons with profound intellectual and multiple disabilities and their caregivers. Can this be prevented by providing more personalized care? In our case, there are thus two target groups for which goals need to be set.

#### 3.1.1 | Persons With Profound Intellectual and Multiple Disabilities

Persons with profound intellectual and multiple disabilities are characterized by a developmental age of up to 24–36 months (Pawlyn 2008), combined with a profound motor disability and, usually, secondary disabilities or impairments (Nakken and Vlaskamp 2007). In the Netherlands, approximately 9500 (April 1, 2013) persons live with such a disability, of which 95% are in a residential care facility (Vugteveen et al. 2014; VGN 2019).

Table 1 lists the in- and exclusion criteria for participants of the cluster randomized trial to study the effectiveness of SCC. Since the criteria are technology-dependent, it is important to consult the supplier's criteria and refine these with experts on the target group.

In our case, there were also so-called soft exclusion criteria. Caregivers are encouraged to make thoughtful decisions to determine whether SCC adds value for each individual and how potential impediments can be mitigated. Short-term use of SCC for gaining insights into urinary patterns can also be considered. For each participant, consent was obtained from their legal representative.

The possible benefits of SCC, as compared to regular continence care, can be direct benefits, such as reduction of leakages or insight in urinary patterns, as well as indirect benefits, such as a positive impact on the persons wearing the smart continence material due to fewer disturbances of their day. In our case, we defined the following goals (Table 2).

#### 3.1.2 | Caregivers

The second target group consists of professional caregivers for persons with profound intellectual and multiple disabilities. This includes all the care teams from daycare, night care, and day activity centers. Their work routine will change when providing SCC. The possible benefits of SCC for caregivers can vary. In our trial, the goals are displayed in Table 2.

**TABLE 1** | List of eligibility criteria for participants in residential care facilities for SCC.

Eligible	Not eligible	Soft exclusion criteria
Use incontinence products	Use a permanent catheter	Do not accept strange things on their bodies
Not able to communicate the need for a change of incontinence material	Show risk behaviour that may result in harming themselves when wearing smart incontinence material (e.g., pica disorder)	Show behavior (e.g., restless behavior) that can hinder the successful use of SCC, e.g., removing incontinence material or clip
SCC is expected to be beneficial for the participant according to their caregiver		Have $\geq 3$ times falls per 24 h, as this may interfere with the technology detecting urine

**TABLE 2** | Predefined goals of using SCC.

<b>Goals for persons wearing smart continence products</b>
Reduce the number of leakages, as well as their consequences, such as additional changes of clothing or bed sheets, extra washing or showering the resident, skin problems due to prolonged exposure to wet incontinence materials
Reduce the number of changes of incontinence material, since (scheduled) changes that are unnecessary if the incontinence materials are still (relatively) dry can be prevented
Enhance residents' quality of life since reducing leakages, skin problems, and unnecessary changes may prevent the extra burden of agitation and additional transfers
<b>Goals for caregivers providing SCC</b>
Reduce the time spent on continence care due to the reduction of unnecessary changes and leakages, therefore leaving more time for other activities
Decrease the physical burden by decreasing unnecessary changes and leakages
Enhance the work perception as a consequence of the above-described changes
<b>Goals for residential care facilities providing SCC</b>
By optimizing care and changing incontinence materials when needed, the number of incontinence materials which are disposed of could be reduced
More efficient use of personnel's time by reducing the time spent on continence care due to the reduction of unnecessary changes and leakages leaves more time for other care activities

Furthermore, implementing SCC in residential care facilities targets not only the persons eligible for SCC and their caregivers, who are suspected to benefit from this directly, but also all stakeholders involved in or related to the care process. For the latter, see Step 3 since this relates to the context in which SCC is implemented. Note that SCC might also be beneficial for the residential care facilities in their contribution to more sustainable continence care, since the total amount of waste of incontinence material may be reduced if the number of leakages—and related laundry—and number of incontinence material changes are indeed decreased conform expectations. If so desired, specific goals regarding sustainable continence care should be formulated in this phase.

### 3.2 | Analyze the Innovation

The innovation involves replacing regular continence care (RCC) with smart continence care. It thus consists of two main

aspects: the technology itself and the adaptation of the continence care process. Both should be analyzed in Step 2.

#### 3.2.1 | The Technological Solution

Each care facility should choose its technological solution carefully since technological developments are fast and new (releases of) products appear on the market regularly. Based on the care issue that needs to be solved and the specific goals of the target groups, as set in Step 1, it is key to invest in activities presented in Table 3.

In our case, several SCC solutions were available on the (Dutch) market, varying from a 72-h observation of the voiding pattern, which is registered by a small sensor device attached to the incontinence product (TENA 2020), solutions for continuous monitoring, including notifications which indicate the need for change of incontinence material with either sensor



**TABLE 3** | Analyze the technological solution.

<b>Activities for analyzing the technological solution</b>	
Create a longlist of possible technical solutions that can solve the care issue	
Make a selection (shortlist) based on criteria related to the specific target groups and context	
Search for information about the use of the selected products in other residential care facilities, if available look for scientific or pilot studies	
Talk to the suppliers of the selected products, ask for specifications and ensure market readiness	
Choose the product that best fits the care issue, the target groups and the context	

strips and a clip attached on the outside of the incontinence material or incontinence material with integrated sensors with a removable and reusable clip (TENA 2020; Abena 2020). The latter product was chosen, Abena Nova, which sends real-time notifications to a mobile phone when a change of incontinence material is needed (Abena 2020). When the sensors become moist, the clip transmits this information to the receiver nearby. This receiver is a portable device plugged into a socket or a mobile power bank. The receiver sends this information via servers within EU/EER (Abena n.d.) to the mobile app Wetsens (available on Android and iOS) and a web portal. When an individually set threshold level for saturation is reached, caregivers receive a notification. Reaching the first threshold level triggers the “change desired” notification and displays an orange sign; caregivers have approximately 60 min to change the product. If the next threshold level is reached, a red sign is shown with the notification “risk of leakage.” Each receiver and app can monitor multiple users of SCC simultaneously, and each SCC user can be monitored on several mobile devices at once. The sensor registers only urine. Feces are not detected and could even interfere with the registration of urine by blocking the sensors (Abena 2020). Next to the described benefits, this product was selected for its high market readiness. Previous pilot studies in residential care for either persons with disability or older persons showed that using the technology led to fewer leakages, as well as a reduction in the number of changes of incontinence materials (Bouman et al. 2019; Nap et al. 2020).

### 3.2.2 | Adaptation of the Continence Care Process

Adapting the continence care process is key for incorporating SCC in daily care practice. Regular continence care consists of changing incontinence products, providing skin care if needed, and other hygienic activities, such as changing bed sheets and showering the person if a leakage has occurred. Most of the time, regular continence care is provided by following a fixed schedule, such as standard changes in the morning, around noon, and before bed (routines might vary among care teams) (Raepsaet et al. 2021). Leakage, specific behavior, or feces can cause deviations from this fixed schedule. Some individuals have their incontinence materials changed at night according to a fixed schedule or when general nightwatch monitoring technology picks up signs that may indicate the need for (continence) care.

For successful SCC implementation, the continence care process changes from scheduled moments to on-demand changes of

incontinence materials based on the notifications from the SCC technology. Thus, not only do the caregivers have to learn to use the technology, but they also have to co-design and get used to a new way of working—a way of working that also affects other stakeholders, such as the IT department that in many care facilities is not yet used to supporting care technology, as opposed to workplace technology. This asks for a thorough examination of the context, arrangement of preconditions, and a comprehensive implementation strategy that should be evaluated and optimized along the way. These processes are described in Steps 3—7 below.

## 3.3 | Analyze the Context

This step examines the context of SCC implementation within the care facility and the broader societal context in which the facility operates.

### 3.3.1 | Context Within the Care Facility

SCC touches upon the roles, responsibilities, and ways of working of a vast number of stakeholders working at the care facility. It is of great importance to know who all these stakeholders are and (in steps ahead) to make sure all of them do their part in the implementation process.

Specifically relevant to implementing technological solutions in residential disability care is that care facilities often have multiple residences (in The Netherlands, sometimes up to 200) for individuals with all kinds of intellectual and/or physical disabilities, each with their own teams and team leaders or location managers.

Table 4 lists the stakeholders, their roles, responsibilities, and goals for SCC implementation. Stakeholders range from the board of directors to caregivers and from IT departments to patient councils.

### 3.3.2 | Societal Context

To ensure that every stakeholder does their part in the implementation process, it is essential to understand the broader context in which they work. Roles and responsibilities, goals and timelines need to be adapted if stakeholders cannot fulfill their roles due to broader societal issues. It is important to

**TABLE 4** | Stakeholders within the context of the care facility, roles, responsibilities, and goals.

Stakeholders	Roles and responsibilities	Goals directed at successful implementation of SCC
<b>Decision making &amp; project management</b>		
Board of directors	Overall responsibility for the decision and process of the implementation of SCC	Allocate budget Arrange preconditions Develop and communicate a vision and strategy
Project/Implementation leader	Responsible for the implementation Lead the implementation process	Lead SCC implementation by overlooking all participating teams and locations Make sure that all preconditions are fulfilled Make the role of each stakeholder explicit Enable proper embedding of SCC in daily practice
Care director	Gives the order to implement SCC in the care unit Responsible for the implementation	Allocate time and budget to purchase and use the technological solution, invest in training
Team leader/location manager	Gives the order for SCC at specific locations	Arrange commitment in the team for SCC implementation Support caregivers in the new way of working Provide time for training Evaluate proper embedding in daily practice
<b>Execution implementation project in daily care</b>		
Case managers	Select participants according to the inclusion criteria Support the implementation process	Understand SCC and the changes needed in the care process Decide for which persons in their caseload SCC are suitable or not, considering the in- and exclusion criteria
Behavioral and target group experts	Involved in the selection of participants Provide knowledge of specific demands of the target group	Understand SCC Involved in the decision for which person SCC is (not) suitable
Practitioners (such as doctors, occupational therapists and physiotherapists)	Provide treatment to individuals that may be related to continence care	Understand SCC Provide knowledge on specific characteristics important for the decision for which person SCC is suitable
Continence care expert	Provide knowledge on the characteristics of individuals related to their continence care	Understand SCC Involved in the decision for which person SCC is suitable
Caregiver with a 'SCC ambassador role', in day- and night care team (appointed in each team)	A daily caregiver who provides on-the-job assistance in implementing SCC	Receive extra training Maintain close contact with the product supplier Support colleagues with the use of SCC
Coordinator and daily caregivers	Provide SCC during the day	Receive training on how to use SCC technology Adapt continence care process
Coordinator and caregivers of the day activities centre	Provide SCC at the day activity centre	Receive training on how to use SCC technology Adapt continence care process

(Continues)

TABLE 4 | (Continued)

Stakeholders	Roles and responsibilities	Goals directed at successful implementation of SCC
Coordinator and caregivers night care	Provide SCC during the night	Receive training in how to use SCC technology Adapt continence care process
Coordinator and professionals of Care Control Center (Zorgregiecentrale)	Coordinate care based on signals from (general) care technology, other than SCC technology, or from care professionals. These signals may or may not be related to continence care	Understand SCC Involved in the adaptation of the continence care process
<b>Support services</b>		
IT department or service desk	Management and maintenance of the SCC mobile devices and applications	Arrange the availability of SCC technology Arrange WIFI and other technology-related preconditions, such as interoperability Provide helpdesk
Purchasing department	Arrange the contract with the SCC supplier	Purchase SCC materials for all locations/teams Include agreements on training, Service Level Agreement
Logistics department	Deliver SCC materials to locations	Agree with locations on time and amount of delivery
Communications department	Provide internal communication	Internal communication on SCC implementation Provide information for all internal target groups Share practice-based stories to create commitment
Data protection officer	Guard residents' data protection	Arrange the data processing agreement between the care facility and the supplier
Supplier of the technological solution	Provide the SCC materials and support	Provide SCC materials as agreed in the contract Provide training on the practical usage of SCC Provide onsite support and evaluation of SCC use Offer a helpdesk for tech problems
Client council	Represents residents' perspectives	Understand SCC and the changes needed in care processes Think along in designing the implementation process
<b>Extra stakeholders involved in upscaling</b>		
Internal training and education office	Provide training on SCC	Include training on SCC in their regular training offer
HR department	Select new personnel	Define skills for caregivers regarding the use of SCC in daily practice
<b>Other stakeholders involved</b>		
Legal representatives of SCC-eligible persons	Represent participants' interests related to SCC	Awareness of the transition to SCC Understand what SCC means for the person they legally represent

(Continues)



TABLE 4 | (Continued)

Stakeholders	Roles and responsibilities	Goals directed at successful implementation of SCC
Relatives	Help with evaluating the transition to SCC	Awareness of the transition to SCC Understand what the transition means for their relatives, the persons wearing smart continence material Share their experiences in the evaluation of SCC
Volunteers	Help with, for example, daytime activities	Awareness of the transition to SCC Understand what the transition means for the persons wearing smart continence material

monitor any events or issues affecting the implementation in the broader context and seek solutions to reach the implementation goals.

In our case, such an event was the COVID-19 pandemic. Due to the strict behavioral rules set by the Dutch government aimed at protecting especially the most vulnerable groups in our society, we could not enter the care locations for training and site visits. Some care facilities and caregivers struggled to find the time to invest in the SCC-related new ways of working. Locations were thus forced to postpone the implementation. There is an increasing shortage of caregivers within disability care throughout the Netherlands, which was even worsened by the COVID-19 pandemic (VGN 2023), leading to time constraints and the need to prioritize daily care practices over changing work routines to support SCC.

Another societal factor that needs to be considered is how care technology is paid for within the healthcare system. For example, in The Netherlands, some care technology solutions must be paid for by an individual's health insurance, whereas in other cases, the healthcare provider pays for it as part of the per-resident fee they receive. Regulations may differ between municipalities and insurance companies. Funding for using new technologies also may be arranged with specific innovation budgets. In the latter case, it may not be evident how continued use and upscaling after the initial pilot will be paid for.

### 3.4 | Arrange Preconditions

Several preconditions must be met before the SCC implementation strategy can be detailed. In fact, the preconditions described here can also be seen as part of Step 5, in which the detailed implementation strategy is formulated. The following order of Steps 4 and 5 is thus not set in stone. However, in our case, we found that the following preconditions were key in starting Step 5:

#### 3.4.1 | Collect Information on SCC Implementation Aspects and Write Up a Proposal

To prepare for the decision to start SCC implementation, it is essential to collect key information on what implementing SCC entails, what it requires in terms of organizational change and motivation, plus estimates of a timeline and budget. A project proposal contains this information, directed at the Board of Directors. Collecting information and writing up the proposal can be done by, e.g., an already appointed project leader, the innovation department, or the quality management department. This can be done by collecting experiences from other care facilities, reading pilot reports, and having conversations with possible suppliers.

#### 3.4.2 | Make a Formal Decision to Start SCC Implementation and Allocate Resources

The implementation must be formally decided upon by those with the authority to allocate resources. This decision can be

**TABLE 5** | Preparations for SCC implementation.

Actions	Elaboration
Appoint project/implementation leader (if not already done so in former steps).	This person should have ample experience in leading organizational changes, preferably within residential care facilities and with the use of technology. They should be able to inspire their colleagues, make strategic choices, create coalitions, work systematically and have the courage to change ways of working
Set up a project team and advisory board	Involve key stakeholders, and define and agree on each stakeholders' role (see Table 4)
Make a detailed implementation strategy	Include goals, approach, timeline, and budget. The strategy should be agreed on by the board and discussed with the client council
Launch the SCC implementation	The board of directors announces and communicates their decision to start SCC implementation through internal communication channels in cooperation with their communication department
Communicate clearly to the care units	Care directors for relevant care units communicate the start of SCC implementation within their units and, if needed, involve the communication department
Organize a Project Startup meeting	Inform all stakeholders at the start of the project, provide information on the technical solution chosen and the change of care and services processes needed, and make sure each stakeholder knows their role
Arrange technical preparations	Prepare hardware, software, and support of the IT department
Sign a contract with the supplier of the technical solution, including a Service Level Agreement	Agree upon the conditions for implementation, the supplier's responsibility and tasks, i.e., the support provided by the supplier during the initial and later phases of implementation. Sign the SLA

made in a Care Directors meeting or by the Board of Directors, who can also request some further preconditions, such as some performance indicators or implementation ratios. They establish go/no-go moments and the criteria for these go/no-go decisions. In our case, most decision-makers established one or more go/no-go moments. For example, to implement SCC in two or three pilot locations within their care facility, they needed to be sure that the care teams have the capacity and ability to take on these changes. In our case, there was one facility in which this capacity appeared insufficient, and it was decided not to start SCC implementation. Furthermore, a formal decision about upscaling or not after initial implementation is necessary and should be based on the practical findings and business case. In our case, this was challenging for some facilities as this urges for a priori set of criteria on which to base this decision, which was omitted in some cases.

The formal decision should obviously include the allocation of resources. Investing in the organizational change needed for the successful implementation of SCC requires allocating time and budget. A project leader should be appointed; the technological solution may initially be more expensive than the regular incontinence materials, and teams need time for training and changing their way of working. Allocating resources is crucial for successful implementation.

### 3.4.3 | Involve Key Stakeholders in Decision-Making

It is important to involve relevant stakeholders in the decision-making, such as care directors, team leaders, location managers, the IT department, and the client council. Even though they may not formally be the ones who decide, doing so creates support early on. This is important since implementing SCC touches upon the facility's general vision of care (e.g., should we wake our residents to provide SCC, or is the night for sleeping?) and asks for considerable changes in the traditional way of working. Implementing SCC also requires technical support and WIFI in all participating locations; thus, involving the facility's IT department in this early stage is necessary to explore possibilities and formulate requirements from their side. Another relevant stakeholder is the client council. They should be informed and involved in the decision-making at an early stage and, later on, in the phase in which care processes are redesigned.

### 3.4.4 | Recruit the First Locations That Are Willing to Start the Implementation

To raise the odds for successful implementation, it is key to have a positive attitude from the first (limited) number of locations and their managers and team leaders regarding SCC implementation. They may serve as pilot locations preceding the go/no-go moment for upscaling, or be the first locations starting the implementation if the initial project already entails upscaling. In any case, it is important to start SCC implementation at a limited number of locations to be able to collect lessons learned that can be useful for the next locations. It is

recommended to explore the willingness and capacity of the starting locations in advance.

## 3.5 | Formulate Implementation Strategy

Given that the formal decision to implement SCC has been made and resources allocated in Step 4, it is now essential to detail the implementation strategy. This should include preparations, goals, an approach, a timeline, and a specification of the allocated budget. The implementation strategy should specify activities for all (groups of) stakeholders (listed in Table 4) involved in reaching these goals.

### 3.5.1 | Preparations

The preparations are listed in Table 5.

### 3.5.2 | Goals: Number of Participants and Locations to Be Included

Define clear goals for implementing SCC at a predetermined number of locations, as well as for the number of participants. In our case, as defined by the study protocol, approximately 27 participants needed to be included within each care facility, which meant we needed 2–7 locations depending on the number of eligible persons living at each location. The locations recruited for our study were considered pilot locations, and based on the findings, the boards would give a go or no-go for upscaling.

Special attention should be paid to the characteristics of the (pilot) locations. In our case, we advised implementing at locations with no shortage of caregivers and preferably a steady team of caregivers (not too many new or frequently changing team members). Recruit, select, and onboard locations in cooperation with relevant stakeholders, i.e., care director, location manager, or team leader. Provide information on the technical solution chosen and the change of care and services processes needed for location-related stakeholders to understand what participation means.

### 3.5.3 | Approach

Table 6 summarizes the implementation approach. Note that this does not reflect a linear approach. All elements need attention, often in parallel processes, sometimes going back and forth in an iterative way.

### 3.5.4 | Timeline

Set a total scope and duration for the project, either including upscaling or until the go/no-go decision on upscaling. Make sure to plot all activities on a timeline. This timeline should also include the monitoring and evaluation activities mentioned in Steps 6 and 7. If upscaling is part of the project, Step 8 should also be included. In that case, the timeline should be extended

TABLE 6 | The implementation approach.

Actions		Elaboration	In our case ...
Set up SCC implementation team	Include stakeholders from 'Execution implementation project in daily care' in Table 4, supplemented with the project leader and team leader. Thus, all those involved in providing continence care 24/7. The SCC ambassador should be appointed for each location to guide and support the implementation of SCC on the work floor, and report back to the project leader. Again, provide information and education on SCC and the needed changes in care and service processes		The implementation team also has a task to involve the stakeholders such as, e.g., 'Support services'. We organized a demo afternoon in which we demonstrated the technology by pouring water into the incontinence material so the participating teams could see when and how the signal that an incontinence material change is needed is given in the app. This helped them understand the technology, but also their role and responsibility in the implementation process
Co-design an adapted continence care process	To fully benefit from using the technology, the implementation team should transform the care process from fixed scheduled moments to on-demand changes of incontinence materials based on notifications generated by SCC		Three weekly meetings were organized in which the ambassadors and project leader discussed the success and failure stories of the SCC implementation, including the (struggles with) changing work routines. Each participant was discussed individually. Tips and tricks were shared, and any technical malfunctions were reported. Changing the care process is an ongoing process that should be paralleled with discussing the vision of continence care (see also Step 6)
Co-design the vision on continence care 24/7	Discuss the care facility's and/or location's vision on continence care during the day and night as an element in the co-design. Discussing the vision should start as early as possible, preferably in Step 1		We noticed that even though we stressed the importance of addressing the vision, in practice, the teams merely started this too late, i.e. just before the start of using SCC, or even later as part of the decision-making process to continue and scale up or not. A recurring issue we experienced was the vision that "the night is for sleeping". However, teams should decide whether this means that incontinence materials should be changed if so signaled in the SCC app since preventing wet incontinence materials and bed sheets guarantees good sleep during the rest of the night; or that caregivers should ignore signals from the app during the night in order not to wake up the resident. Moreover, the vision needs to be readdressed if changing one resident's incontinence materials wakes up other residents
Organize a project startup meeting for each location	Inform all location-related stakeholders on the start of the project, provide information on the technical solution chosen and the change of care and services processes needed, and make sure each stakeholder knows their role		Within each care team, the caregiver that is the ambassador led this meeting, introducing and explaining SCC technology to their colleagues, instead of the supplier doing this. This reinforces the ambassador's position and visibility. In most cases, the supplier was also present for extra explanation and backup
Set up a practical agreement with the supplier	Appoint a supplier contact person, connect the ambassador with the contact person, and agree on how service is delivered based on SLA and moments for evaluation		The ambassadors received extra training and are the first in line in case of questions or problems, and should be able to assist on-the-job with (minor) technical problems or tech-related questions of the caregivers. They were responsible for contacting the supplier if they could not help their colleagues

(Continues)

**TABLE 6** | (Continued)

Actions		Elaboration	In our case ...
Select participants for SCC within each location		Determine for whom SCC is suitable in cooperation with relevant stakeholders (see Table 4). The case manager may be the one to propose participants (Table 1). The product specialist of the supplier, behavioral experts, and other experts within the care facility need to be available for consultation if there are any doubts about inclusion	In consultation with the behavioural expert, it was decided to try using SCC for participants who did not accept strange parts on their body, and evaluate this after a short period
Set goals for each participant, and determine goals for the care teams		Apart from preventing leakages and/or unnecessary changes of incontinence materials, and thus time savings, goals may be, for example, gaining insight into urinary patterns, and fewer wet bed sheets in the morning	One participant often showed restless behaviour. In this case SCC was implemented to gain insight into the possible relationship between wet incontinence materials and restless behaviour. An ambassador shared that their care team could now make time for proper lunch breaks, as only those individuals in need of a change were taken care of
Ensure regular, continence care for non-users		Pay attention to the participants at SCC implementation locations who are not eligible for SCC, and agree on how to maintain regular care with fixed schedules intact for them	At almost all the locations there was a mix of participants getting SCC and RCC, as not everyone was eligible. Yet, as during the training of SCC, good application of incontinence material was instructions, this knowledge was also applied to the ones receiving RCC
Provide training sessions designed for (groups of) specific stakeholders		Special attention is needed for training caregivers on how to use the technical device, as well as on the change in working routine Caregivers should no longer change incontinence materials at predefined scheduled moments but do this on demand. This means an invasive change in standard routines	A few teams indicated that during the evenings, they did not wait for the notification to indicate the need for change. Instead, they visited the web portal and looked into the individual graphs, displaying the current volumes of urine and incontinence material. Based on this information, they decided who needed a change in the evening, thereby increasing the chance of a dry bed in the morning
Educational session for participants' relatives		Inform relatives about the SCC technology and what it would mean to their relatives	We organized this in cooperation with an organization that specializes in involving patients (depending on the context, these could also be clients or residents (s) and relatives in care-related decisions (Ikone 2024)). Some relatives expressed worries about privacy and wanted to know what happened with the data collected with the technology. Other relatives posed questions about increasing seizure activity if their relative would be woken up at night for a change of incontinence materials
Set a starting date		Define the exact moment to start the implementation process with each location and start the monitoring process (see Step 6)	It required careful planning to train all the teams just before the implementation of SCC on the work floor



to well over 6 months. The duration of the upscaling activities depends on the number of locations and users.

### 3.5.5 | Budget

Budget estimating should be based on the latest information regarding prices for the chosen technological solution and tailored to the organizational context. Consult the supplier as well as internal stakeholders to estimate how many items are needed (e.g., the number of receivers, incontinence materials, number of clips) and hours/personnel needed to conduct the implementation activities, such as attending the training. Total costs for purchasing SCC products and services for one residential facility were between € 18.500 and € 22.500 for approximately 28 participants over 12 weeks.

## 3.6 | Carry out & Monitor the Implementation

All components of the implementation strategy are executed according to the timeline defined in Step 5. It is crucial to provide on-site support and continuously monitor the process at each participating location, enabling timely interventions if necessary (Van Calis et al. 2024).

### 3.6.1 | On-Site Support for the Care Teams

Immediate on-site support should be provided when the care teams encounter problems in using SSC. At each location, at least three support options should be established: First, every team appoints an ambassador who knows all the ins and outs of the technology as well as the adapted care process. They can solve problems on the spot, such as enabling sound notifications and assisting colleagues in attaching clips to incontinence material. Second, the care facility's IT department offers a helpdesk for technological and/or WIFI-related issues. Third, the contact person (product specialist) of the supplier is on standby to offer help according to the Service Level Agreement. It may differ between facilities how support is delivered exactly. In our case, one of the facilities installed a weekly online consultation hour where the project leader and product specialist were both present to answer any prevailing questions from the care teams.

### 3.6.2 | Continuous Monitoring

The project leader, team leaders, ambassadors, case managers, and caregivers should each play their role in monitoring the implementation process daily. This should be done in two ways. First, the project leader needs to be present and easy to find at each participating location in order to monitor and review the ongoing process. This kind of actual proximity enables quick actions. Besides, the project leader must keep track of changes in the composition of the team: i.e., if new colleagues join the team, they should receive training on SCC; if a new team leader is appointed, they should know their role and responsibilities regarding the SCC implementation process. The project leader has this role as long as SCC is not yet considered care as usual and part of standard care within the organization.

Second, ensure to systematically collect data on the progress of the set goals per participant. In our case, the SCC product offered a web-based dashboard that presents data on the number and time of incontinence material change, as well as the response time after notifications indicated the need for change. In addition, pen and paper diaries were used to collect data on the number of leakages, laundry resulting from a leakage, and time spent on continence care. Involve the care team in choosing the mode for registration that fits their capabilities.

### 3.6.3 | Scheduled Evaluation Moments

At least monthly evaluation moments should be scheduled by the project leader for each location. Location managers or team leaders, ambassadors, case managers, and the supplier's product specialist should be present. Then, all issues related to the implementation process are discussed. Review the experience of each person wearing smart incontinence material using collected data and discuss this in relation to their specific needs and SCC goals. Work routines or goals should be adapted if needed. In our case, some participants stopped SCC because insight into their urinary patterns was gained, and the team established a personalized incontinence material changing schedule without the need to keep using the sensor technology. Other participants stopped because of an increase in leakages. Leakages may occur as a consequence of differences in the quality and capacity of the new incontinence material or as a consequence of struggles with the proper use of SCC.

## 3.7 | Evaluate and Adapt Implementation Strategy

In this step, an evaluation is conducted. The evaluation report integrates information collected through the supplier's dashboard, systematically gathered data (Step 6), and interviews conducted by the project leader. When appropriate, this report includes assessments per location and/or per participant, indicating whether the overall and personal goals were achieved. The evaluation serves two main purposes: (1) to adapt the implementation strategy based on the lessons learned and (2) to inform the decision on further scaling up (see Step 8). In our case, the following goals were defined:

- Reduction of the number of leakages, as well as their consequences (laundry, washings, etc.);
- Reduction of the number of changes of incontinence material;
- Enhanced quality of life for individuals with profound intellectual and multiple disabilities wearing smart continence material;
- Reduction of time spent on continence care for caregivers;
- Decrease the physical burden for caregivers;
- Enhanced work perception for caregivers.

In our case, this resulted in two suggestions for further upscaling. First, it was recommended to appoint two ambassadors per care team. They can support each other in the task of changing the work routines and ensure a better availability of the

ambassadors throughout the week. Second, creating or emphasizing the position of a continence expert within the organization, which also has the task of considering SCC for individual residents, is mentioned by a few organizations.

3.8 | Continued Use and Upscaling

The evaluation in the former step provides the information needed to decide whether the implementation of SCC was successful and whether SCC should be continued at the present locations and scaled to all locations where potential users of SCC reside within the facility. Making this decision may require insight into the cost-effectiveness in addition to the outcome of the evaluation in Step 7.

Knowledge of the cost-effectiveness of SCC in disability care is still limited, even though the potential benefits seem promising. If SCC leads to fewer leakages and a reduction in the number of incontinence material changes, this may lead to cost savings that may outweigh the additional costs for the somewhat more expensive SCC materials as compared to RCC materials. However, a health economic evaluation is needed to assess if these potential benefits can indeed be reached (article in preparation). Nevertheless, since situations may differ between facilities, the expected costs and benefits of SCC should be systematically mapped using a mini Health Technology Assessment (mini-HTA) instrument, such as the mini-HTA decision support tool for the hospital service (Ehlers 2005; Ehlers et al. 2006), which was translated (in Dutch) and adapted to the residential disability care setting by Patel and colleagues (Patel et al. 2022, 2023). This instrument includes initial start-up costs, such as costs for buying the product and changes in technological infrastructure, extra personnel costs, and ongoing costs. Not only costs but also possible cost savings are listed, such as less washing costs due to fewer leakages, less time spent on continence care due to a reduction in the number of changes of incontinence materials, etc. Even though scientific evidence is lacking, this cost and savings overview can inform the board's decision on further upscaling.

In our case, we shared findings on the number of incontinence material changes, the change in the number of leakages, and subsequent additional activities, as collected in our trial for the

period when RCC was provided and after 12 weeks of SCC. The project leader combined this information with the caregivers' experiences and, in some cases, with data from the product's dashboard into an evaluation report. This report was shared with the decision-makers within the residential care facility. This facilitated the decision-making process and garnered support for determining whether to proceed with or discontinue the use and further scaling of SCC.

Once—and if—the decision is made in favour of further upscaling, implementation activities can start according to the implementation strategy previously formulated. Note that upscaling should be seen as an implementation project on its own, requiring its own project leader, implementation strategy as well as monitoring and evaluation activities (Steps 5–7). However, these activities can gradually be scaled down to a light version of the steps and eventually become part of the facility's regular care quality policy, such as the Plan-Do-Check-Act cycle (Taylor et al. 2014), which is commonly used to maintain high-quality care standards.

Several extra activities are employed in this step, as presented in Table 7, to make SCC a standard care procedure.

4 | Conclusion and Discussion

The Guideline for SCC Implementation in Residential Disability Care presented here is based on general implementation models (Grol 2017; van der Linden 2016; ZonMw 2019; Damschroder et al. 2009; Fleuren et al. 2014), scientific literature on e-health implementation (Ross et al. 2016), observations, interviews, and a pilot in residential care practice. It was then optimized based on all lessons learned in a research trial in which it was used for implementation at six residential care facilities for almost 160 persons with profound intellectual and multiple disabilities. It contains 8 steps, and each step comprises detailed information on how to conduct SCC implementation projects up until upscaling and complete integration in regular care practice. Implementing SCC becomes more and more urgent, considering that residential care facilities aim to optimize care by improving personalized approaches, as well as care efficiency, due to shortages of care personnel (VGN 2023).

TABLE 7 | Extra activities to realize SCC as a standard care procedure.

Steps to make SCC standard care procedure
Reporting on SCC experiences and evaluating the personal goals for using SCC is now part of the regular general resident's report
A continence expert is available to discuss each newly admitted resident and evaluate the current users
Ambassadors are still present; however, they can gradually become experts in supporting other technological solutions as well
The internal training and education office structurally integrates SCC into the facility's standard training program for new caregivers
The HR department includes the capability to work with technologies, such as SCC, in its recruitment strategies for newly recruited caregivers or the deployment of hired personnel
Service departments have established work routines to support the use of SCC on the work floor

A thorough and detailed implementation process is important and key to achieving the full potential of care technology. As the steps indicate, measuring the situation of continence care before and after the start of the implementation is needed to see whether predefined goals are reached. Yet, it is important to be aware that there is a learning curve in using a new technology, and it takes time to reach its full potential. If goals are not met, one should ask themselves if this is due to implementation impediments and, if so, how these can be solved.

The guideline may not only be useful for SCC implementation in residential disability care, but also in other care settings, such as residential care for elderly persons, as well as for target groups within disability care other than persons with profound intellectual and multiple disabilities, such as individuals with a physical disability in combination with a mild cognitive disability, or aging individuals within disability care. These are examples of target groups mentioned by caregivers during our trial.

Moreover, project leaders mentioned that executing the implementation of SCC in such a detailed and structured way helped them understand the important and necessary steps for implementation in general, which is useful for the implementation of various other technological solutions in the future.

#### 4.1 | Strengths and Limitations

The SCC implementation guideline, in our case, was part of a research trial, and target groups and goals for this target group were defined in the context of this trial. Using the guideline in other care settings or for different target groups may mean that target groups and goals per target group need altering or tweaking.

Related to this, the technological solution implemented in our case was also chosen within the context of our cluster randomized trial. This may have influenced certain elements of the content of the guideline. It is key that care facilities make an informed decision on which technological solution is to be implemented. It should fit the facility's target groups and goals, and the specifications of the technology should be considered when detailing the implementation strategy.

#### 4.2 | Further Research

As part of our research trial, we provided this Guideline for SCC Implementation in Residential Disability Care. It builds upon scientific literature and the experiences and efforts of at least six residential care facilities. Further research should focus on monitoring and evaluating this guideline when other residential care facilities use it to implement a similar SCC technology or even adapt it to fit an implementation process for other care technologies within residential disability care.

Another viewpoint for further research is to evaluate the differences in implementation processes between residential care facilities using the guideline. Although in our case, the residential care facilities all worked according to the presented guideline, we observed differences in how it was applied. For example, the

composition of the project teams differed, as well as the level of involvement of management. A fascinating question would be how these differences in implementation approach affect the success rate of SCC implementation.

#### Ethics Statement

This study has been reviewed and approved by the Medical Ethics Committee of Radboudumc (NL72751.091.20).

#### Conflicts of Interest

The authors declare no conflicts of interest.

#### Endnotes

<sup>1</sup> M: Mandatory item.

<sup>2</sup> Stages adapted from WHO Digital Health Atlas.

<sup>3</sup> <https://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf?sequence=1&isAllowed=y>.

<sup>4</sup> NM: Non-mandatory item.

<sup>5</sup> Eccles, M. P., Weijer, C., & Mittman, B. (2011). Requirements for ethics committee review for studies submitted to Implementation Science. *Implementation science*, 6 (1), 1–3.

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## Appendix A

### Checklist of iCHECK-DH Guidelines. iCHECK-DH: Guidelines and Checklist for the Reporting on Digital Health Implementations

**Completed for:** Smart personalized continence care for people with profound intellectual and multiple disabilities: A theory and practice-based implementation guideline for a digital innovation

Section		Item	Description	Section/paragraph or answer and elaboration
Title	1	Title (M <sup>1</sup> )	Identification as an implementation report, and description of the implementation in the title and/or keywords	'theory and practice based implementation guideline for a digital innovation' AND 'smart personalized continence care'
Abstract	2	Abstract (M)	Provide a summary of the key elements of the implementation report, including a description of the implementation strategy, the intervention, defining the key elements of the implementation and health outcomes and specify the key KPIs/Outputs. We recommend describing the main aspects of the research in the following order: Background—Objectives—Methods—Implementation (Results)—Conclusions—(Optional: Trial Registration).	See abstract, also followed Journal's guidelines
Introduction	3	Context (M)	Describe the geographical areas, organizations, target populations and implementation context. Consider social, cultural, economic, political, health care and organizational barriers, infrastructures and facilitators that may influence implementation elsewhere. Explicitly highlight whether a national digital health strategy exists and whether implementation is aligned with the strategy. Describe the stage of the implementation (Developing or Adapting Solution/Piloting and Evidence generation/Package and Advocacy/Acceleration/Deploying/Scaling up/Hand over or Complete). <sup>2</sup>	See introduction, Second and third paragraph of this section.
	4	Problem statement (M)	Description of the health care or public health problem, challenge, or deficiency that the implementation aims to address. (If applicable, include a reference to the 'health system challenge' of the WHO Classification of Digital Health Interventions <sup>3</sup> in the description)	See introduction, first paragraph
	5	Similar Interventions (M)	Mention whether this implementation was inspired by another existing one, and if so, what is the added value of your intervention, if any, compared to the initial one? And what, if anything, has been done differently?	See introduction, first paragraph
Methods	6	Aims and Objectives (M)	Describe the main objectives and the overall aim of the implementation. Describe how these will be measured using predefined primary and secondary outcome(s) and key performance indicators for this implementation and the expected intervention(s). <i>For example: indicators or proxy-indicators measuring direct health outcomes (e.g., HbA1c for diabetic patients); Key Performance Indicators (e.g., number of users, number of users that are properly trained, user satisfaction); Indicator assessing a particular process (e.g., administrative time for patient admission); (If there was no evaluation, provide detailed explanation for reasoning)</i>	The (cost) effectiveness of SCC is published elsewhere, and not the focus of this paper
	7	Blueprint summary (M)	Describe the design and key features of the intervention and key points of the implementation strategy and roadmap.	The intervention section named (2) Analyze the innovation The implementation strategy is the focus of the whole article. See Figure 1 and section named 'Results: SCC implementation guideline in 8 steps'



Section	Item	Description	Section/paragraph or answer and elaboration
8	Technical Design (M)	Reasons for developing or choosing this tool. Does it combine several tools? Provide a brief description of the tool(s) (functionality and architecture) and how it fits into the health enterprise architecture and investment roadmap (if applicable). Indicate whether the solution is based on an existing solution or has been developed or purchased specifically for this intervention. Describe the type of technology used (e.g., AI applications), license of the technology (open source, free, commercial, IP ownership etc.), include code documentation (if available), link to the application, link to wiki or project website.	The intervention is described in section (2) Analyze the innovation references are included.
9	Target (M)	The target refers to the focus or recipient of the intervention. It is the specific person, group, system, or problem that the intervention aims to change or improve. The characteristics of the targeted "site(s)" (locations, staff, resources, etc.) for implementation and any eligibility criteria. The population targeted by the intervention and any eligibility criteria.	Eligibility criteria of population: see Table 1. Stakeholder overview (Table 2) with roles, responsibilities and goals for implementation are presented in Table 4
10	(M)	Describe the data governance, including life cycle (collection, processing, storage, modification, sharing, suppression), the data ownership (mention whether patients actually have access to the data), data protection measures, confidential use of routine data, expected level of data integration, data for research, cross-border data agreement, if any, the applicable legal framework, and how the project complies with it. Data consent: Has patient consent been obtained? Describe the approach to data protection and cybersecurity (e.g., security by design, privacy by design, etc.) and where the data is hosted. (e.g., in-country, cloud based, hybrid model etc.). Describe, if applicable, the government preferences in terms of data policies.	Answer: EU/EER located services for data storage of SCC. Mentioning of data protection officer (Table 4) to ensure taken care of. It goes into much detail to describe governmental preferences and laws.
11	Interoperability (M)	Describe the interfaces (what other systems does the tool connect to) and the standards that were used (which specific ones and rationale of choice) (e.g., semantic ontologies such ICD as SNOMED, LOINC or technical standards such as HL7 FHIR, etc.).	Table 4 mentions this as a point of attention. The IT department is responsible for checking the interoperability of its internal systems. It goes into much detail to describe more and is not the focus of this article.
12	Participating entities (M)	Describe the implementing organization(s): Type of organization(s), mission, leadership, vision, etc. Government involvement: Describe whether the government was involved in the implementation, at what level and at what stage(s). Partners: Describe all partners (organizations) and their role in the implementation. Fundors: List all actors and stakeholders who have funded or invested in the development of the implementation (if different from the implementation, e.g. using an existing digital health intervention). Indicate their level of involvement in terms of funding. Mention which entity will own the final product and intellectual property after the implementation phase.	Type of organization: see section 'phase V. Optimization of the implementation guideline'. More details on the organization will be published in the Effect paper. Government and Funder: Funding. Residential care facilities did finance the implementation of SCC (material and hours) themselves. They did get a reimbursement for the research activities (mentioned in protocol paper). Also see paragraph before '(4) arrange preconditions'
13	Budget Planning (M)	Describe the planned budget for implementation (include costs such as change management, user training, project management, technology pricing, total cost of ownership). If possible, include actual costs, otherwise describe the range or percentage of the total budget. Indicate the period covered by the budget. Describe the budget for the intervention (e.g., development, purchase or adaptation of a free tool); if possible include real costs, otherwise describe as a percentage of the total budget. Indicate the duration covered by the budget.	See section 'budget'.

Section	Item	Description	Section/paragraph or answer and elaboration
RESULTS	14 Sustainability (M)	Describe the Business model including the sustainability model (financial, economic, environment etc.). If possible, put outcomes in relation to cost to assess sustainability. Describe long term exit strategies, and all dimensions considered to sustain the project after the end of funding. If applicable, describe potential institutionalization of the project.	The whole implementation guidelines focusses on sustainable implementation by paying attention to those aspects that support sustainable implementation, such as determining goals and priority, involving management from the beginning, etc. We include formal decision-making processes and evaluation SCC and its effect during the implementation process, to make exit possible. We also mention that sustainable personal continence care might be possible without the future use of SCC. Furthermore, the development of a business model is mentioned at page section '(8) continued use and upscaling'.
	15 Coverage (M)	Describe whether the coverage of implementation is international, national, regional or at the level of e.g. municipalities. If coverage is sub-national, describe the regions. Provide information on the relative importance of the coverage (e.g., % of eligible population covered).	Implementation guideline focusses on organizational level.
	16 Outcomes (M)	Primary and other outcome(s) of the implementation. Detail the actual outcomes, using the pre-defined outcome measures (if applicable).	See reference to (cost) effectiveness study mentioned in introduction line 38, last paragraph of section 'Persons with profound and intellectual and multiple disabilities', see Table 2.
	Lessons learned (M)	Describe any lessons learned from the implementation experience that could be used to improve future outcomes. This could include, but is not limited to, success factors, implementation challenges or budget considerations. Success factors: Describe factors that positively influenced the implementation (e.g., involvement of key stakeholders). Also describe contextual factors that may have positively influenced the results (e.g., new legal requirements that facilitated adoption).	Lessons learned are integrated in the result section and represent the detailed 8 steps. Examples of fostering of hampering factors are presented throughout in the 'in our case' sections.
	17	Challenges to implementation: Describe challenges (process-related, such as resistance to change, but also technical). Include contextual factors that may have affected the achievement of outcomes such as an unexpected change of government, or 'opposing key players' who, despite potential participation, may hinder implementation (e.g., software companies managing regional digital health may act as barriers to innovation). Budget: Describe whether the implementation budget was adhered to, and if not, why not. Also detail the expected operational costs (e.g., license, maintenance, human resources, updates to in-house developments) to estimate the total cost of ownership. Include real costs, otherwise describe them as a percentage of the total budget. What recommendations can be drawn from the lessons learned?	
Discussion	18 Unintended consequences (NM <sup>4</sup> )	Describe unintended consequences (positive or negative), harms or negative side-effects (if any).	Last paragraph in section 'schedule evaluation moments'
	19 Conclusion (M)	Summary of the conclusions and future implications.	See discussion and conclusion

Section		Item	Description	Section/paragraph or answer and elaboration
General	20	General (NM)	If applicable, include statement(s) on regulatory approvals (including, as appropriate, ethical approval, governance approval), trial or study registration (availability of protocol), and conflicts of interest. For implementation reports with a research component, ethical approval or a waiver from an appropriate ethics committee is required. For those without a research component, ethical considerations may still be relevant, but do not necessarily require approval or waiver. Authors may consult this article <sup>5</sup> for further guidance on ethical considerations in their specific context	See title page