A smart diaper solution (Orizon SMART) for incontinence management: a potential system to improve quality of care in institutional settings.

Index

Abstract

Introduction: Urinary incontinence (UI) is the involuntary leakage of urine. Age plays an important role in rising prevalence rates as individuals get older. UI is widely known to have a significant impact on both physical and psychological well-being, especially among elderly residents in care homes. In this context, the Orizon Smart diaper solution (Orizon SMART) is a digital incontinence care assistive technology, including a rechargeable transmitter, that attaches to smart incontinence products to notify caregivers when the product requires changing. The objective of the study was to describe the efficiency of Orizon SMART in both cost and time savings for caregivers and whether it facilitates their workload, while improving patient quality of life.

Material and methods: The data was collected in seven care centres throughout Europe (two from both Belgium and Germany and one from France, Italy, and the United Kingdom, respectively). Each study consisted of four phases. The first phase included signing the agreements with each centre. The second phase involved data exchanging and staff training. The third phase, the actual study, consisted of implementation of the trial over four weeks with a gradual decrease in guidance. Finally, the evaluation phase included drafting the customer-targeted report by evaluating the hard data.

Results: Orizon SMART provided accurate information about the residents' diaper status, reduced the number of wet beds and use of incontinence products, and optimized the procedures of nursing staff by being a time saver. It proved to be cost-effective (including significant savings in waste reduction, diapers & pads, and other equipment), and provided more comfort for patients (translating into a sleep-through policy and most residents being able to sleep through the night). In addition, post-trial questionnaires showed that 80% of the nursing staff and residents were satisfied with the solution (France), and 100% of the staff would recommend it (Germany). These results have

shown a huge potential for the improvement in both the quality of care and well-being of the residents and the nursing staff and patients being satisfied with this new solution.

Conclusion: Orizon SMART has shown big potential in the improvement of the sleep quality of the resident, optimise the work schedule of care staff, be a more cost-effective solution by reducing the costs of laundry and diaper use and, subsequently, make incontinence care more sustainable.

Introduction

Urinary incontinence (UI) is defined as the involuntary leakage of urine [1]. Urinary incontinence is usually classified into three different subtypes. While stress UI is characterised by involuntary urine loss triggered by physical activity like coughing, laughing, or sneezing, urge UI involves a sudden urgency to void, with the feeling being too difficult to control. The pathophysiology of stress UI involves a weakening of the muscular support at the ureterovesical junction, causing urethra hypermobility during increased intraabdominal pressure conditions. On the other hand, urge UI is usually caused by idiopathic factors that lead to an inability to inhibit detrusor muscle contraction. Finally, mixed urinary incontinence is characterized by a strong, uncontrollable urge to void accompanied by urine loss triggered by physical activity [2].

Age, gender, injury during childbirth, neurological conditions affecting either the brain or spinal cord, obesity, injury nearby or of the bladder, urinary tract infections, specific medications, congenital conditions, constipation, fluid intake, and physical disabilities that reduce mobility or dexterity are among the main risk factors that contribute to the development of UI [3]. The global prevalence of UI ranges from 5% to 70%, with values differing due to different definitions, study designs, questionnaires to assess the condition, response rates and the population under study [4-6], with age playing an important role in growing prevalence rates as individuals get older [7]. However, because UI is more common among women, prevalence varies greatly between the sexes, with estimations between 5% and 69% for female individuals, and 11% and 34% for males [8,9]. Nevertheless, it is widely thought that the reported values are underestimated due to both the embarrassing nature of this condition and social stigma [10,11].

This condition is known to have a significant impact on both physical and psychological well-being, especially among elderly residents in care homes [12,13]. Incontinence-

associated dermatitis, an inflammatory skin condition due to prolonged urine exposure, is the most common condition related to UI, with estimations that range from 5.7% to 22.5% among long-term care residents [14]. In addition, between 68.6% and 76.2% of residents experience poor sleep quality and sleep disturbances, with the subsequent impact on their quality of life. In fact, sleep disorders and fatigue pose a negative effect on both physical and mental health, causing problems such as anxiety, depression, and high psychological stress, which may, in turn, unfavourably affect UI symptoms [15,16]. Apart from the direct impact of UI on quality of life, it also poses a significant financial burden [17]. In the case of the Netherlands and Germany, the direct health costs per patient of managing UI have been estimated to reach €392 and €515, respectively, with diapers and other absorbent products accounting for €200 and €261 [18,19].

To avoid these negative impacts and economic burden, comprehensive urinary incontinence management is needed. Nowadays, the standard protocol in nursing homes includes time-consuming regular diaper checks that occur 24 hours per day, thus disturbing residents during the night and disrupting their sleep in the process. However, this protocol may be ineffective as it does not represent the actual voiding behaviours of the residents and may lead to either premature or delayed product changes. In this context, Orizon SMART is a digital incontinence care assistive technology, including a rechargeable transmitter, that attaches to smart incontinence products and notifies caregivers when the product requires changing. It can represent a change in incontinence care culture, transitioning from the current routine standard into personalized care, ultimately improving ward care for patients as well as improving their comfort, dignity, and sleep. The objective of the study was to describe the efficiency of Orizon SMART in both cost and time savings for caregivers and whether it facilitates their workload, while improving patient quality of life.

Material and methods

Study design

The scope of these studies involved two parts. In the first part, the algorithm, user interface, training procedure, and hardware were validated, and the hard and soft benefits were mapped. In the second part, the alerts were fine-tuned, the false positives were reduced, customer support was streamlined, and both the hardware and user interface were optimised. In addition, the studies were diversified by involving both hospitals and nursing homes and by including different countries with different care approaches.

Each pilot study consisted of four phases: prospecting, preparation, testing, and evaluation. In the first phase, the initial agreements with each centre had to be defined, with the centres agreeing to participate in the study and signing either a Joint Controlled Data Processing Agreement or a contract. Depending on the trial, several goals were set, such as reducing the number of products, residents having more than eight hours of sleep, reducing the number and/or severity of leakages, ease of use of the mobile app, reducing the time spent on incontinence care, the need for minimal hardware setup, and either waste or cost reduction.

During the preparation phase, data was exchanged and staff were trained. In this phase, data on the residents or patients (name, room, protocol of incontinence materials, etc.), staff (name, department, work shifts during the study, etc.) and floor plan were collected. In addition, agreements with the director, head nurses, and Information Technology managers were signed regarding change management, follow-up periods and procedures. In addition, the hardware and software setup, a survey on the current situation, and the training of at least 80% of the participating nurses and caregivers were carried out.

Regarding the test phase, it consisted of four weeks over the course of which guidance was gradually reduced. In the first week, all services started with one-to-one guidance, making sure every caregiver had the opportunity to ask questions while performing the first changes. In addition, each team was guided in the change management, with the company available for troubleshooting and to follow up on the nightshift when the procedures stopped and started. In the second week, company staff presence in the department was reduced, depending on the work schedules of the care home teams, shifting towards a combination between being present at the centre and available either online or over the phone. The objective this week was to optimise the incontinence protocols of the residents.

In the third and fourth weeks, company staff was available on demand and reachable by either phone or email. At the end of the fourth week, after the completion of the trial, a questionnaire was sent to the centre. In addition, at the start of each day during this phase, a daily meeting was held with the head nurse and/or director.

Lastly, in the evaluation phase, A customer-targeted report was created by evaluating the hard data, which included the evolution of the number of changes, the absorbency of the products, and the team's alarm response time. The completed questionnaires were also evaluated, analysing the improvement in resident comfort and the ease of use of both the mobile app and the solution. In addition, if the centre was willing to share data on costs, the cost savings was also calculated. Finally, time saving for the centre staff was also included in this report.

Studied variables

The data collected included both objective and subjective variables. In the case of objective data, this included the information on transmitters, alarms, and protections. In

addition, an overview of changes based on their saturation level (for the selected period), the average number of connected changes per day and the wetness status at change per day, the number of diapers used per size and absorption, and the average time a certain diaper type was worn were also recorded. Moreover, the data included variables such as the number of alarms per day and the team's reaction time to wetness.

Regarding the subjective data, this included insights gathered through the surveys and meetings with the customer. MS Forms was used to collect these data, providing feedback without the risk of copying errors in the answers. Afterwards, this data was translated into Excel files in order to build graphics. In some cases, these variables included information gathered from own reports generated by the centre.

Results

France study

This study was performed throughout February 2022 over the course of four weeks, and involved 15 residents and more than 20 employees distributed across three floors. According to the results, 80% of the residents experienced an improvement in both comfort and dignity. From the caregiver's point of view, more than 80% reported this improvement in patient care, which in addition led to a time savings of 30 minutes per day and caregiver, with all interviewees stating that their physical burden was reduced. Finally, regarding cost savings, a reduction of 21% in costs, 70% in unnecessary checks, and more than 70% in bed changes/leaks was reported (Table 1).

It was concluded that Orizon SMART reduced the number of wet beds, optimising procedures by providing more comfort to patients while being cost-effective.

First Germany study

In this study performed in March 2022 over four weeks and involving 10 residents and more than 25 employees, from the resident's point of view (through observations made by the care staff), 80% experienced an improvement in comfort and dignity, mostly due to overall 7 hours of uninterrupted sleep while 90% stated that they were more comfortable compared to the regular protection. Given these results, 100% of the caregivers would recommend this new solution, mainly due to a time gain of 3.2 hours per day per caregiver, a higher value than that reported in the previous trial. This outcome was due to the fact that the care staff followed up on alerts in under 30 minutes, on average, which led to almost no wet beds or accidents with leakage during the day and, therefore, the gain of those hours. Finally, a 25% reduction in product costs and a 100% decline in bed changes due to leakages and leaks were also observed (Table 1).

Table 1. Outcomes regarding perception and cost savings in the France and Germany studies.

Focus	Outcome	France study	Germany study
Resident	Residents who experienced an improvement in comfort and dignity	80%	80%
	Uninterrupted sleep time	N/A	7 hours
	Perception of at least the same or more comfortable than regular protection	N/A	90%
Caregivers	Caregivers who corroborated improvement	>80%	N/A
	Caregivers who would recommend the solution	-	100%
	Time gain (per day and per caregiver)	30 minutes	3.2 hours
	Caregivers who reported a reduction in physical burden	100%	N/A
Savings	Reduction in cost	21%	25%
	Reduction in unnecessary checks	70%	-
	Reduction in bed changes/leaks	>70%	100%

From the results of this trial, it was concluded that the solution has a potential to provide more comfort to patients, translating into a sleep-through policy which saw most residents being able to sleep through the night. The reduction in wet beds led to greater cost effectiveness, with the annual savings for 10 residents projected to amount to €3,190.85. Combined with product savings, waste cost reduction, and reductions in the use of other equipment such as gloves and wash gloves, the total savings would account for 9%.

First and second studies in Belgium

Both these studies were conducted between April and May 2022. The first study involved 10 residents and 28 staff members, and the second study 12 residents and 49 staff members. Knowledge acquired from previous studies was applied in the second trial from the very start. According to the obtained results, there was a reduction in dry diaper changes from 40% to 28% in the first study and 27% in the second study, while the change of saturated diapers increased from 35% to 42% and 45%, respectively, in the first and second trials. In addition, 8.5% and 13.8% reductions in diaper consumption were reported, respectively, with a shift towards lighter absorption products. Finally, two and one low battery status alarms were reported in the first and second trials, respectively, with a decrease in disconnection alarms observed throughout the study (Table 2).

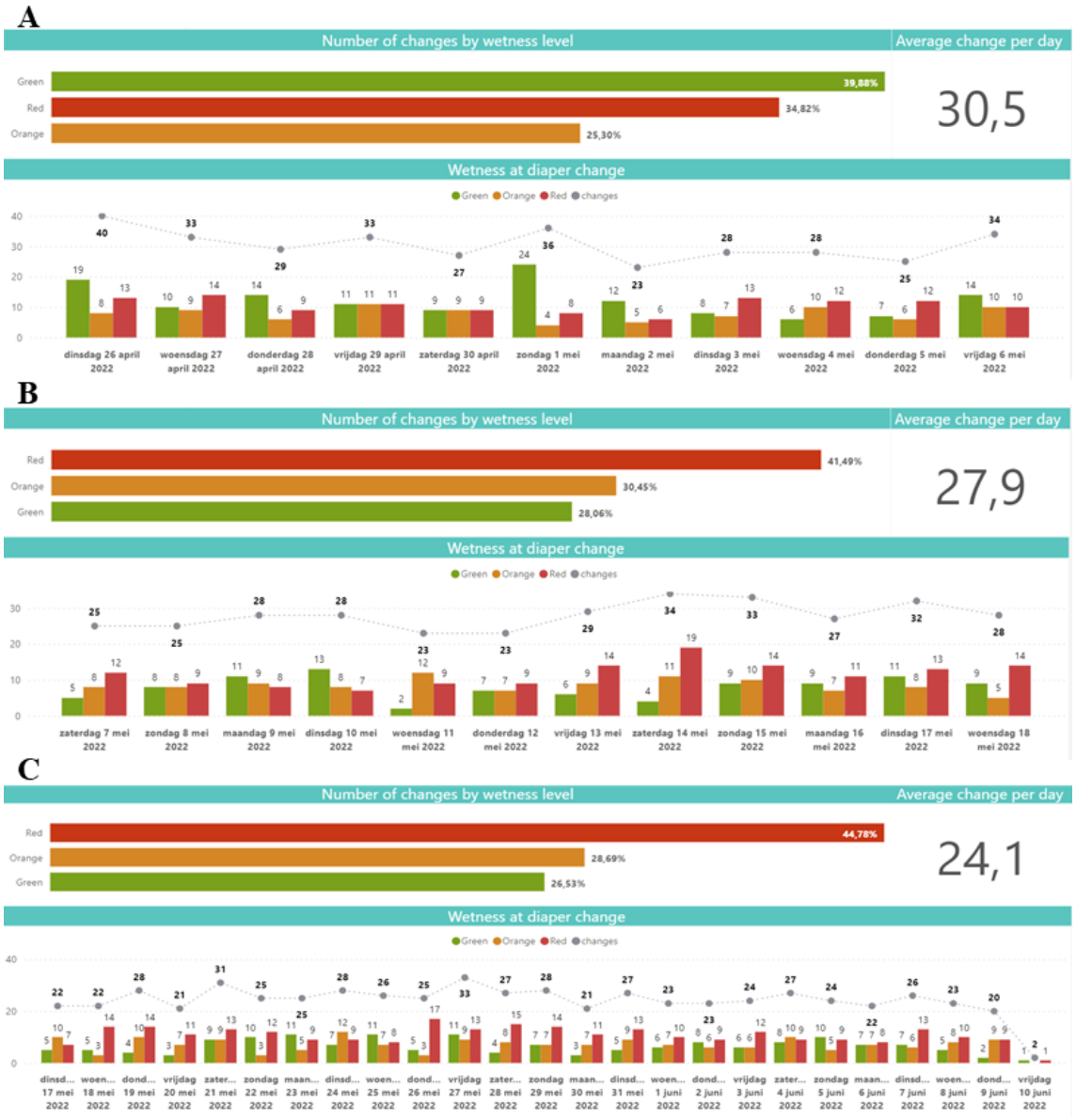
Table 2. Change management results from the 1st and 2nd Belgium studies.

Focus	Outcome by the end of the study	Belgium study #1	Belgium study #2
Diaper optimisation	Reduction in dry diaper changes	40%-28%	27%
	Saturated diaper changes	35%-42%	45%
	Reduction in number of diapers consumed	8.5%	13.8%
	Shift towards lighter absorption products	Yes[1]	
Alarms	Low battery status alarm	2	1
	Decrease in disconnection alarms throughout the study	Yes[2]	Yes[2]

[1]Light absorption diaper use increased, improving comfort and decreasing costs due to a reduction in heavy absorption diapers.
[2]Staff learned to work with the solution.

Before the solution was implemented at the first centre, an average of 3.4 diapers were used per resident. Additionally, 39.9% of the diapers were still in a dry (green) state when they were replaced, with only 34.8% of them being replaced following a saturation alarm (red status; Figure 1A). After optimisation through ONTEX, a 9% diaper consumption reduction was achieved, resulting in an average use of 3.1 diapers per resident. In addition, the number of dry diapers (green state) during change was reduced from 39.9% to 28.1%, while the number of saturated diapers (red status) rose from 34.8% to 41.5% (Figure 1B). Therefore, the results improved over the entire trial, since diaper consumption decreased even further, reaching 15% less than the first trial after using the solution. Likewise, changes of dry diapers with a green status were reduced to 26.5% (6% less than the previous study), with 44.8% of diapers being changed in the event of a saturation alarm (red status), which represented an 8% increase from the first trial (Figure 1C).

Figure 1. Initial status (A) and status after ONTEX optimisation (B) in the first Belgium study, and results from the second Belgium study (C).



According to these results, Orizon SMART provides accurate information about residents' diaper status, reducing the number of incontinence products used and leading to a reduction in the number of wet beds. Therefore, this solution is both more comfortable for residents and more cost-effective for the centres, as well as being a time saver for nursing staff.

Study in Italy

In this study, an average of 10-11 post-surgical (orthopaedic) rehabilitation and cancer patients between 70 and 90 years of age with an average length of stay ranging from three weeks to two months were included. The results showed that, regarding time savings, it was no longer necessary to undress the patient each time to check the diaper and that the number of wet beds decreased from 8-10 per week to one. In terms of staff satisfaction, they were enthusiastic. While at first they needed more time to adapt to the new solution, by the end of the trial they all appreciated the system. Patients were also satisfied with the new solution since they were not disturbed with the same frequency for diaper checks, with the centre staff having more time for other tasks. Lastly, there were considerable cost savings, since the number of diapers per patient and per day was reduced from five to three (Table 3).

Table 3. Results from the Bonvicini (Italy) study.

Focus	Result
Time saving	No longer necessary to undress the patient each time to check the diaper
	Decrease in number of wet beds from 8-10 per week to one during the trial
Staff satisfaction	They are enthusiastic
	The nurses needed more time, but all came to appreciate the system after the trial
Patient satisfaction	Not disturbed with the same frequency for diaper checks
	Staff has more time for them
Cost saving	From five to three diapers per patient and day

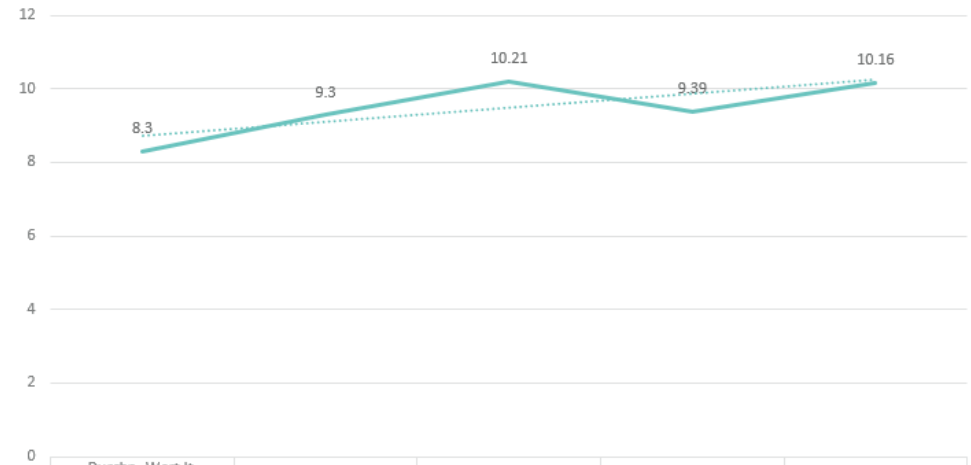
According to these results, Orizon SMART saved time for the nursing staff while saving money for the centre due to the reduction in number of incontinence products used. In addition, both the staff and the patients were satisfied with this new solution.

Second Germany pilot

This trial was performed from November 2022 to March 2023 in two facilities (Johanniterstift, Plochingen and Palmscher Garden, Deizisau), which involved 19 and 10 participants respectively. In this study, an increase in diaper wearing time during the night was observed throughout the study (Figure 2A), which led to a reduction in both workload and time for the nursing staff due to the avoided leakages (Figure 2B). In addition, a reduction in laundry costs, which included the cleaning of both fitted sheets and bed protections, was reported (Figure 2C). Moreover, a 10% reduction in the number of used incontinence products was observed, as well as a shift from high absorption products towards light absorption ones. After changing the schedule for 7 residents, the average for all residents was reduced from 3.37 products per day per resident to an average of 3.07 products per day per resident for the following five days. In addition, seven residents went from five to three products per day. After this period, the staff went back to the original schedule for five residents, with the average consumed incontinence products increasing to 3.33. It was also observed that patients remained undisturbed during the night, since products were better selected for each patient.

Figure 2. Diaper wear time (A), reduction in workload and time (B) and laundry expenditure (C) results from the second Germany trial.

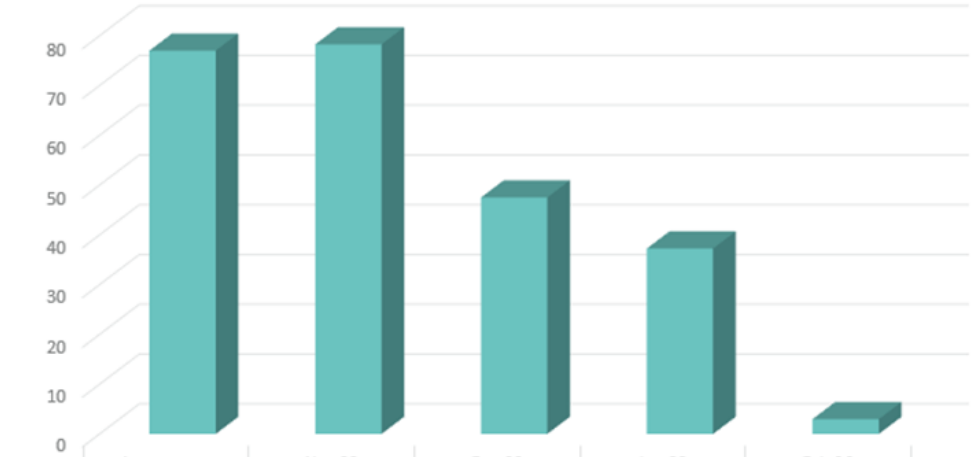
A



	Durchn.-Wert lt. Befragung	Nov 22	Dez 22	Jan 23	Feb 23
Wearing time in hours	8.3	9.3	10.21	9.39	10.16

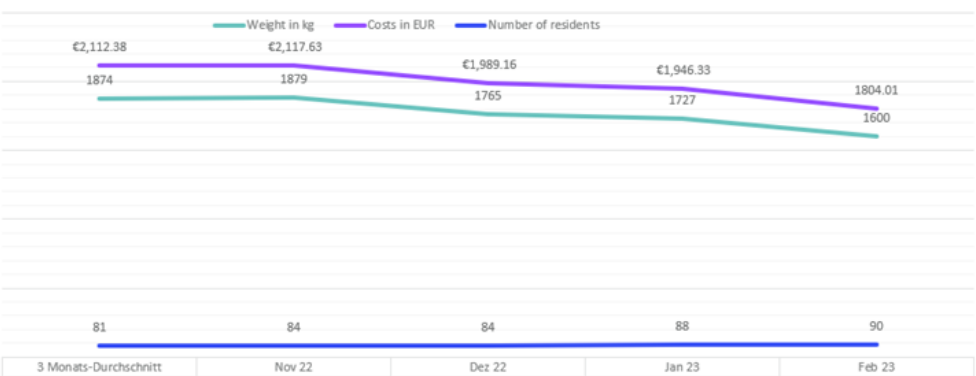
Wearing time in hours Lineal (Wearing time in hours)

B



	Auswertung Fragebogen	Nov 22	Dez 22	Jan 23	Feb 23
Time expenditure in hours	77	78	47	37	3

C



	3 Monats-Durchschnitt	Nov 22	Dez 22	Jan 23	Feb 23
Weight in kg	1874	1879	1765	1727	1600
Costs in EUR	€2,112.38	€2,117.63	€1,989.16	€1,946.33	1804.01
Number of residents	81	84	84	88	90

These results indicates that the Orizon SMART technology increased the quality of care and well-being of the residents while reducing costs associated with the number of incontinence products used.

Wales study (United Kingdom)

This trial involved 15 residents and 40 staff members. Before the trial, the status at the centre was that diapers had to be changed every four hours (87.5%), with participants having different feelings about how nervous they were to start using the new solution (20.8% and 29.2% strongly disagreeing or disagreeing and 20.8% and 8.3% agreeing or strongly agreeing). However, most of them thought that the new technology could help improve care (58.3% agreed and 29.2% strongly agreed) and were looking forward to taking part in the study (33.3% strongly agreed and 58.3% agreed; Figure 3). In addition, at the start of the study, the majority of residents were using diapers with a higher absorbency than needed. As time passed, the higher absorbency products were switched to lower ones, leading to most of the patients using low absorbency products (Figure 4).

Figure 3. Staff responses prior to the trial in Wales (United Kingdom). Answers include how often they changed patient diapers (A) and their opinions about several statements (B).

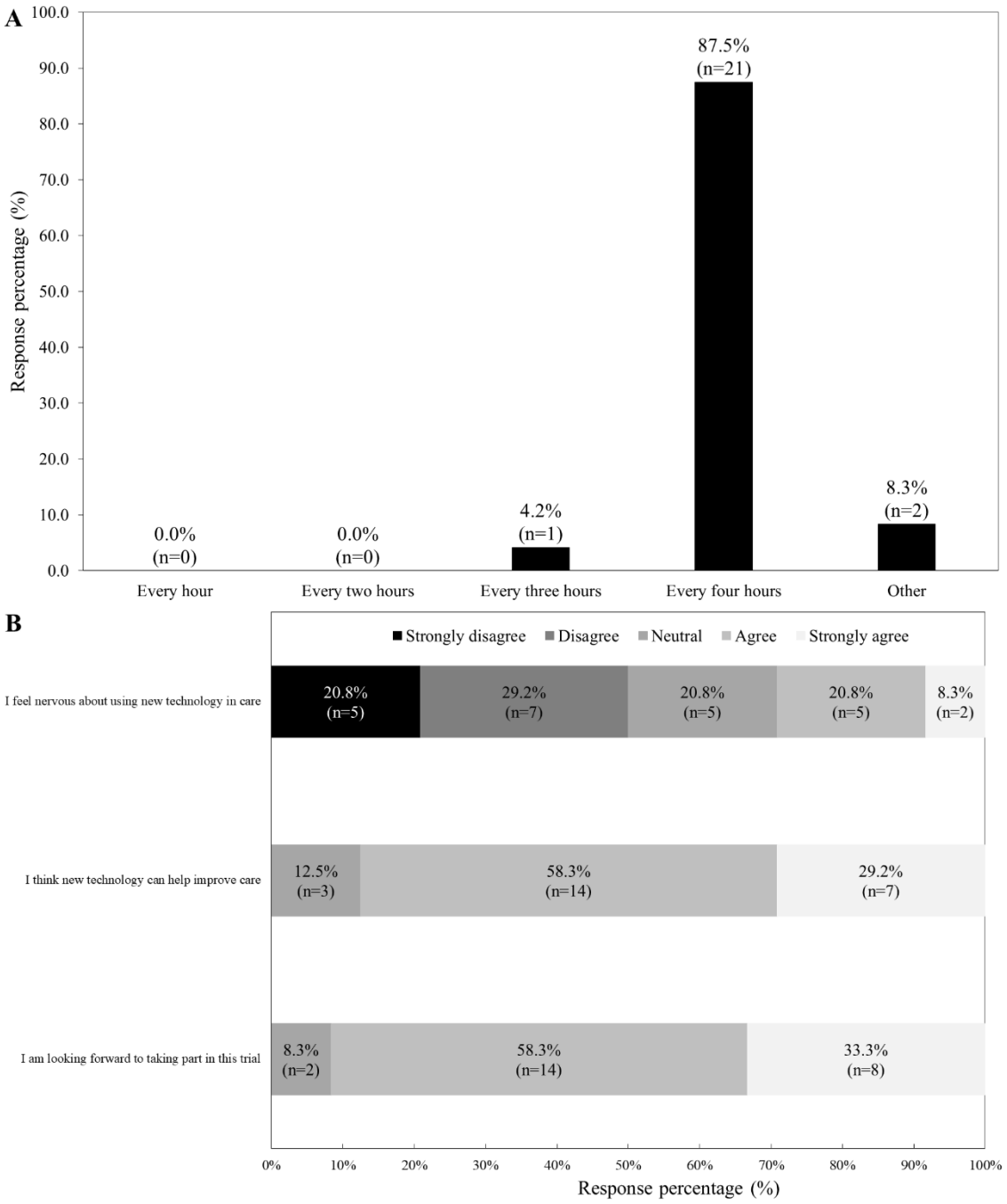
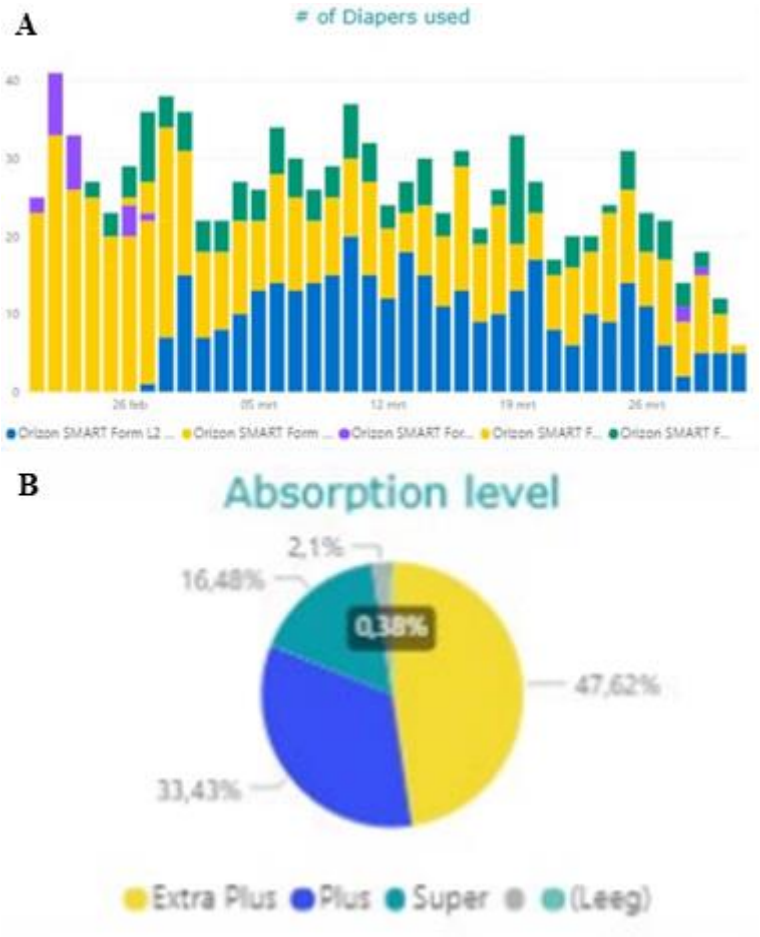


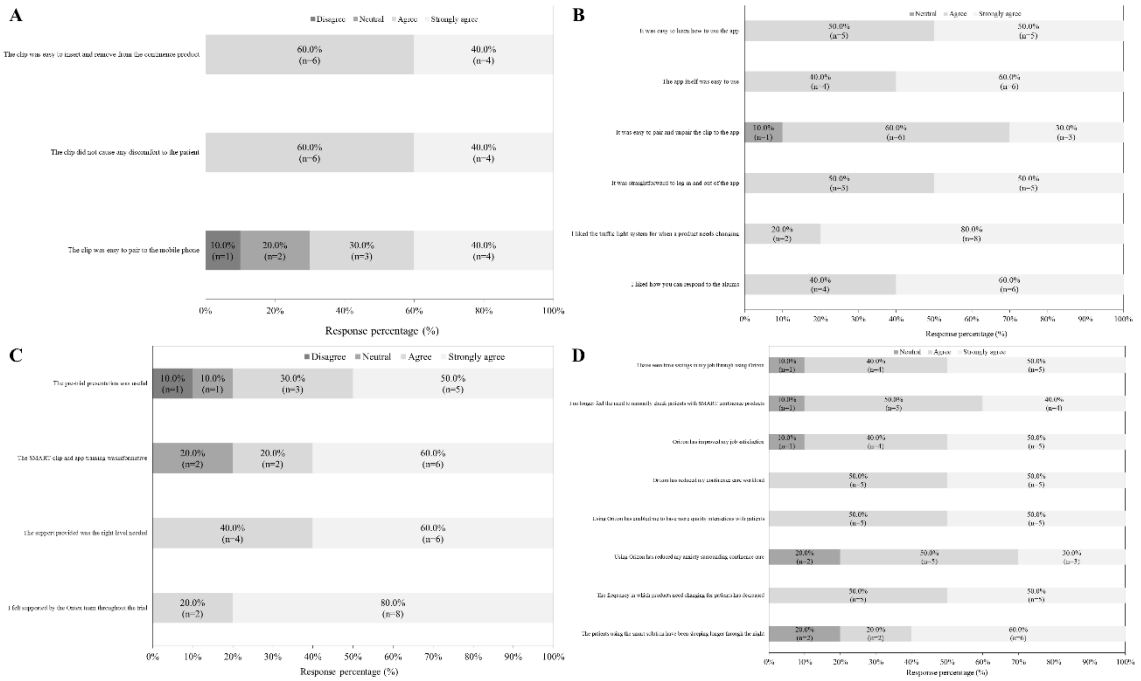
Figure 4. Number of diapers and their absorbency (A) and their overall absorption levels (B) throughout the trial in Wales (United Kingdom).



After conclusion of the trial, most participants thought that the clip was easy to insert and remove from the incontinence product and that it did not cause patients any discomfort (60.0% strongly agree responses for both), while the ease of pairing with the mobile app received mostly positive responses (40.0% strongly agreed and 30.0% agreed; Figure 5A). Regarding opinions on the mobile app, all participants considered it was both easy to learn (50.0% strongly agreed and 50% agreed), easy to use (60.0% strongly agreed and 40.0% agreed), and to pair and unpair the clip to the app (60.0% agreed and 30.0% strongly agreed). In addition, they thought it was easy to log in and out, and they liked both the traffic light system for when a product needs to be changed and how they can respond to the alarms (100.0% either agreed or strongly agreed for all these statements; Figure 5B). In the case of the training and support the staff received, overall, the pre-trial

presentation was useful (50.0% strongly agreed), the SMART clip and app training was informative (80% strongly agreed and agreed), the provided support was at the right level (60.0% strongly agreed) and they felt supported by the Ontex team throughout the trial (80.0% strongly agreed; Figure 5C). Finally, regarding the statements about patients, the respondents agreed that the solution represented a time savings (90.0% either agreed or strongly agreed), they felt no need to manually check residents for urine voiding (90.0% either agreed or strongly agreed), improvement in job satisfaction and a reduction in workload was perceived (90.0% and 100.0% either agreed or strongly agreed, respectively), patient interaction quality improved (100.0% either agreed or strongly agreed), and a reduction in staff anxiety was also reported (80.0% either agreed or strongly agreed). What's more, the frequency with which patient products needed changing decreased (50.0% agreed and 50.0% strongly agreed), which led to a perception of patients sleeping longer through the night (60.0% agreed and 20.0% strongly agreed; Figure 5D). When asked whether the trial was a positive experience for the participating centre, an overall rating of 4.8 out of 5.0 was reported, with a score of 4.6 in the case of the positive experience for the patients.

Figure 5. Staff opinion regarding the ORIZON smart clip (A), the mobile app (B), the training and support received (C), and the patients (D) after conclusion of the trial in Wales (United Kingdom).



Overall, thanks to Orizon SMART, residents experienced fewer interruptions, providing them longer sleeping intervals which translates into patient comfort and dignity. In addition, the staff saved time on these tasks, allowing them more time to interact with their patients and build relationships with them. Overall, it was beneficial to both the patients and staff, while being a cost-effective solution due to the reduction in incontinence products used.

Discussion

The data gathered in these studies provide evidence that the Orizon Smart solution can represent the future of incontinence care based on four important pillars: improved resident sleep, optimisation of work routines, reduction in costs, and enhanced sustainability.

Regarding resident sleep, the impact of general environmental noise and nursing staff incontinence care rounds on sleep fragmentation among nursing home residents has been

previously described [20]. In addition, most residents perform frequent movements at the shoulder and hip levels to prevent frequent repositioning movements performed by nursing staff. However, these efforts are usually unnecessary, as the residents are still woken due to incontinence care protocols [21]. Here, we provide evidence that uninterrupted sleep intervals may be as long as seven to ten hours, which leads to improved comfort, dignity and quality of life. In addition, nursing staff might benefit from a more optimised work schedule of nursing care that considers sleep to be of equal importance to incontinence care[21], since there is important time saving to be had due to the elimination of unnecessary wet bed checks supported by the gathered data.

In the case of cost reduction, as stated before, the direct health costs per patient of managing UI have been estimated to reach up to €515, with diapers and other absorbent products accounting for €200 and €261 [18,19]. In these studies, we have reported reductions in product expense of about 20 to 25%, excluding additional cost savings coming from a significant decline in bed changes, leaks and waste.

Regarding sustainability, while the health impact from pollution and climate change are well recognised, the environmental impact of health care is not well known. This impact could include a wide variety of air, water, and soil pollutants, which might lead to an unintended and negative impact on health. In a study by Lenzen et al. [21], it was concluded that globally the environmental footprint of health care included greenhouse gas emissions, particulate matter, air pollutants (nitrogen oxides and sulphur dioxide), malaria risk, reactive nitrogen in water, and scarce water use. In the specific case of diapers, these pose a serious threat to the environment during their entire life cycle, with their impact becoming especially severe at their end-of-life due to their short life cycle. A study by Muthu et al. [22] concluded that diapers create a considerable carbon and eco-footprint, with both the generation of electricity for polypropylene and the production

processes of cotton being major contributors to this impact. In the results presented here, we provide evidence that the Orizon Smart diaper solution leads to a reduction in the number of used diapers both per patient and per centre, which impacts the costs of the care centre. According to the data, the use of this novel product might help to alleviate the high ecological impact of incontinence products in the environment, due to both the use of fewer diapers and the shift towards lower absorbency products.

Conclusion

Orizon SMART has proven to be an easy-to-use solution that provides accurate information about diaper status. Thanks to this new solution, resident sleep is improved, thus potentially providing residents with enhanced comfort, quality of life and dignity, allowing them to sleep throughout the night without interruptions. In addition, care staff work schedules are optimised, reducing workloads and optimising tasks thanks to a decrease in the overall number of wet beds. This leads to the solution being more cost-effective, as is reduces the costs of laundry, diapers, and absorption levels. Lastly, thanks to the significant decrease in the number of incontinence products, it has an impact in its ecological footprint, making incontinence care more sustainable.

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