University of Sunderland

Payne, A and Kane, L (2023) Establishing the impact of Vitalerter in six County Durham Care Homes – Real World Evaluation. Project Report. Unspecified. (Submitted)

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Establishing the impact of Vitalerter in six County Durham Care Homes – Real World Evaluation

The evaluation project was funded by the Department of Health & Social Care's Digitising Social Care Fund through NHS North East and North Cumbria Integrated Care Board. The project was led by the Academic Heath Science Network North East and North Cumbria (AHSN NENC) in collaboration with a North East care home provider, Porters Care, Durham County Council and the University of Sunderland. The AHSN NENC commissioned the University of Sunderland to produce this independent real world evaluation report.

There are 15 regional AHSN networks throughout the UK, the network was established by NHS England in 2013, with the primary aim of scaling up innovation within the health service, improving patient outcomes, safety, and health, whilst concurrently generating economic growth. The specific network that could be potentially impacted by this project included the North-East and North Cumbria Integrated Care System, who focus on utilising digital transformation within the region to transform pathways of care.

This project aimed to evaluate the effectiveness of the machine learning and sensors base non-wearable Vitalerter device in reducing falls within care homes and manual turns. To summarise, this mixed methods evaluation highlights the benefits, limitations and future directions for the Vitalerter.

Aims & associated Findings of the evaluation:

1) **Aim:** How effective is the Vitalerter solution in preventing falls?
   Finding: Vitalerter contributed to a statistically highly significant reduction in falls.

2) **Aim**: How effective is the Vitalerter solution in reducing turn checks for residents?
   Finding: Vitalerter evidenced a statistically significant reduction in the estimated number of turns according to resident turn protocols and the number of turns needed. The Vitalerter is an effective tool in preventing unnecessary turns by measuring residents ability to move independently.

3) **Aim:** What are the key (known/unknown) qualitative and quantitative benefits (cashable/non-cashable) that will apply to care homes, care home staff, supporting clinical services/staff and the care home residents themselves?
   Finding: Vitalerter contributed to the reduction in falls, which reduced time consuming falls-related paperwork. A reduction in falls led to a reduction in one-to-one support when a resident falls and requires support and medical attention. Vitalerter provided a more even distribution of care worker time among residents who were/were not categorised as fall risks. Thus, there were improvements in the provision of person-centred practice. Staff reported improvements in wellbeing and decreased work-related stress, indicating the potential for reduced staff sickness. The Vitalerter's ability to reduce manual turns means a greater distribution of staff time, less physical strain of staff members and greater comfort and quality of sleep for residents in the future. All of this could be economically modelled to demonstrate potential cost savings.

4) **Aim**: Is the solution viable to rollout out on a larger scale across area and the wider NENC region?
   Finding: The solution is viable to roll out on a larger scale, however this is conditional on some necessary changes to improve user experience.

Background

Human Cost of Falls

Falls and fall-related fractures are prevalent in the ageing population, and pose serious harm, increasing morbidity and mortality (Public Health England (PHE), 2017). An estimated one third of people aged 65 years and older will experience a fall annually, this number increases to half from the age of 80 and above (NICE, 2013). Falls have a biopsychosocial impact on older adults, who may experience loss of independence and confidence, and exacerbated discomfort, distress, injury, and pain (PHE, 2017; Parry et al., 2016). Older adults can also experience a fear of falling, which is common in this population and can lead to inactivity, increased fragility, and social isolation (PHE, 2017).

Risk Factors of Falls

There is a multiplicity of risk factors for falls and fractures including: history of falls, poor balance, muscle weakness and atrophy, visual impairment, psychotropic and anti-arrhythmic medications, environmental hazards, and conditions such as

Parkinson's, stroke, depression, incontinence, cognitive impairment, syncope, diabetes, and high alcohol consumption (NICE, 2013; PHE, 2017). Approximately two thirds of older people experience multimorbidity, which increases their risk of both falls and fragility fractures (PHE, 2017). Major risk factors for fragility fractures include history of previous fractures and falls, older age, low bone mineral density, female sex, glucocorticoids, smoking, low BMI, rheumatoid arthritis, visual impairment, and high alcohol consumption (PHE, 2017). Although often viewed as a natural and inevitable symptom of older age, falls should not be viewed this way, and preventative action can be taken to address this (PHE, 2017).

Total Cost of Falls

In England, the population of those aged 65 years and older experience approximately 255, 000, falls-related hospital admissions annually (PHE, 2017). The total cost of 'fragility fractures' for the UK is approximately £4.4 billion (Svedbom et al., 2013). Of this £4.4 billion, £1.1 billion is attributed to social care, and hip fractures are estimated at £2 billion. According to NHS Right Care (2016) an overnight hospital admission costs approximately £400. In addition, a pilot study by Mangar Health and CCG (2016/17), estimated ambulance attendance without requiring hospital transfer cost an estimated £211 per callout. Incidents which required transfers from care homes to Accident and Emergency hospital departments cost approximately £268 per callout. Furthermore, 45% of these callouts the person is uninjured and does not require medical attention.

The Care Setting

Residential and nursing homes are viewed as high-risk environment for falls and fractures, with ¼ of hospital admissions for hip fractures stemming from care home settings (NICE, 2011). Patients with dementia or delirium are at high risk of falls, and over 70% of residents in care homes have a diagnosis of dementia (Alzheimer's Society, 2016). Additionally, in Elderly Mentally Infirm (EMI) care homes the rate of dementia increases to approximately 90% (Alzheimer's Society, 2014). Falls occurrence in care homes is three times higher than those in community settings (Office for Health & Improvement Disparities, 2021). There are an estimated 400,000 people in the UK living in care homes and are predominantly categorised as high-risk for falls (Logan et al., 2021). Approximately 40% of hospital admissions from care home settings occur from falls, of these, 25% result in serious injury to the resident (Care Inspectorate & NHS Scotland, 2016). The leading cause of accidental death in those 75 years and older is injuries caused by falls (Care Inspectorate & NHS Scotland, 2016).

Interventions

There is a wealth of literature on reducing falls across settings including within the home, hospitals, and long-term care facilities. Interventions are categorised as single, multiple, or multifactorial, with the former being more common (Cameron et al., 2018). Such interventions span many different domains including exercise, medication, surgery, fluid or nutrition therapy, urinary incontinence management, stakeholder knowledge, environmental hazard management and assistive technology, psychological interventions, and the social environment (Cameron et al., 2018). Although there is wealth of literature published in the area, there is also significant heterogeneity (diverse factors), making it difficult to evidence meaningful impact of preventative and reductive interventions on falls across all settings (Cameron et al., 2018). Overall, the literature provides an uncertain account of the benefits across the different approaches to falls prevention and reduction, requiring more robust evidence in potentially alternative domains, not studied to a great extent thus far, such as artificial intelligence and motion sensors, particularly in long-term care facilities.

Assistive technologies in health and social care

The use of artificial intelligence (AI) in falls reduction and prevention has seen an increase in recent years, related to the advancement in health technology (O’ Connor et al., 2022). AI are used to predict, prevent, and detect falls (Ng et al., 2021). However, the literature tends to report AI’s ability to predict falls and is less focussed on describing how such technology can be utilised in care pathways relating to practice and delivery (O’ Connor et al., 2022). Furthermore, Hirvonen et al. (2022) state although there is a significant push from a policy level to digitally transform health and social care for older people, such visions overlook the heterogeneity of the ageing population and the digital and technological abilities and understanding of care workers.

According to Usmani et al. (2021) machine learning AI technology is highly accurate for fall detection and prevention, such technologies are often divided into wearable and non-wearable systems. Non-wearable systems comprise sensors fixed proximally to the person and are further subdivided into vision or floor-based sensors. Vision-based sensors include cameras, laser-range scanners, and infrared sensors (Rizk et al., 2020). Whereas floor-based sensors are commonly used to measure the force from human feet to detect falls (Serra et al., 2016). One common limitation of floor-based systems is their limited coverage. In Usmani et al., (2021) systematic literature review only 12% of studies focussed on fall prevention with 88% focussing on fall detection alone.

Tanwar et al. (2022) state fall prevention processes comprise three factors, knowledge and assessment of the parameters for a fall, predicting the falls occurrence and preventing the fall from coming to fruition. Tanwar et al. (2022) further state that fall prevention cannot be 100% accurate, however it can ensure the person’s risk of falling is minimal. This occurs through continuous monitoring and systematically examining the falls risk factors identified. In Tanwar et al., (2022) systematic review machine learning was the best approach to fall detection with a 99% accuracy, 100% sensitivity and 97.9% specificity. However, their systematic review concluded that most systems developed for falls detection and prediction are not tested within the real-world environment, hence lacking ecological validity. Many are tested with participants who do not fit the demographic profile of a falls risk. Additionally, there is a lack of cocreation and coproduction of design and implementation. Tanwar et al. (2022) highlighted studies tendency to measure effectiveness in comparison to parameters and not user experiences, which may lead to poor uptake in the real world. Furthermore, studies rarely include the views of the people themselves and their relatives.

Frennert and Ostlund (2018) assert health digitalisation and technology may increase quality of life of residents, improve services, and concurrently increase staff wellbeing and working conditions in the health and social care sector. The vision of such technologies is to enable person-centred care, reduce falls risks, social isolation, and increase coping, self-care management and independent living. Such technologies are as heterogeneous as the population whom they serve. Technology cannot be isolated from the stakeholders using it or from the context it is being used, rather such technologies are part of a socio-technical system, whereby each technology is interconnected with social and organisational processes (Feldman & Orlikowski, 2011). Frennert and Ostlund's (2018) systematic review found three key factors are paramount for successful implementation of technology in elder care; (1) clear goals, incentives, and strong leadership, (2) infrastructure, organisational structure, and collaboration, (3) economy and resources. However, technological advancements and implementation can lead to deskilling personnel from their relational roles, it can also replace person-centred care with a disease focused, technology driven, form of care work. Another concern is money being streamlined into technological devices at the cost of hiring new care personnel or replacing those already working in care. Technological advancements have the potential to change care personnels sense of identity, as their job role changes, so too will their identity, as professional work is embedded into our sense of identity.

There is a wealth of information researching community use of assistive technology from both service-user and familial caregivers' perspective, however research on long-term care settings is sparse (Siren et al., 2021). Siren et al's. (2021) study emphasised staff's mixed feelings about assistive technology, which was related to its ambiguity. Staff valued the reduction in workload and physical strain, however there were concerns around efficacy expectations, which Siren et al. (2021) associated with the assistive technology threatening the jobs of staff and the symbolism of being replaced by machinery, which could be perceived as degrading, such findings have emerged in previous studies (Saborowski & Kollak, 2015). This study also found little evidence of improved quality of care from the use of assistive technology (Siren et al., 2021).

Similarly, in an evaluation study of technological implementation conducted by Batt-Rawden et al. (2021) staff reported their frustrations with a lack of communication between themselves and the technology company, feeling forgotten and neglected which led to frustration and a lack of motivation. Some staff perceived the technology as threatening, and the experience of technical problems reduced motivation to use the technology, as staff's sense of competence, professionalism and predictability were reduced. In this study, fear of not coping was the central source of resistance to uptake. However, staff and residents did report feeling more secure and independent with the technology, increasing the efficacy of communication between staff and resident. This study reflected on the importance of ‘super-user’s’ when implementing assistive technology, who are confident and highly capable in using the technology, to provide to support others, which may reduce resistance. Another important factor for increasing uptake is to ensure trust, communication and understanding of all parties is enhanced.

Glomsas et al. (2020) state most empirical research does not examine healthcare professionals when looking at ‘user-involvement’. In their study they identified that healthcare professionals felt a sense of unpreparedness for using assistive technology, lack of training and support from management for implementing the technology into practice, lack of competence and a greater need for user-involvement from a staff perspective. Reduced sense of competence led to a lack of motivation to use technology and a negative attitude towards assistive technology. Likewise, Saborowski and Kollack (2015) state care professionals are a vital group often overlooked in the research regarding technological development in care settings. Further stating that care workers should be viewed as users and facilitators of assistive technology. Thus, care workers should be viewed as catalysts of technological transformations. In this study negative experiences outweighed positive experiences for care workers using technological devices. Care workers viewed these devices as expensive, challenging to handle, complicated to maintain, and it was felt use of devices decreased rather than increase person-centred care. Care workers felt human contact was more essential for care provisions, especially considering the population receiving such care. Care workers also understood that more money streamlined into technology meant less money invested in staff recruitment and retention. The symbolism of care workers being replaced by technological devices is viewed as degrading, particularly when care work is viewed as unskilled, and poorly paid. Furthermore, the authors assert the need to include care workers in the design and implementation of technological development. However, when devices work well, are reliable, robust, and useful, care workers can hold very positive attitudes toward using the technology and learning more about its functions.

Although there is a significant push to utilise AI and digital health technology to reduce the risk of falls, there is evidence which illustrates more traditional methods are significantly more successful in reducing falls than the current AI and digital methods (Morris et al., 2022). A systematic review and meta-analysis conducted by Morris et al. (2022) evidenced only one type of intervention yielded a significant reduction in falls rates, this being education, of both staff and patients. Whereas, bed alarms, chair alarms and wearable sensors were not identified as significantly reducing falls rates. Such sentiments have been shared elsewhere (Crogan & Dupler, 2014; Montero-Odasso et al., 2022), arguing that there is no robust evidence supporting the use of bed and chair alarms in falls reduction.

Crogan and Dupler (2014) state nursing homes typically utilise bed or chair alarms to detect resident movement and alert staff of potential falls risk. The use of bed and chair alarms were used as a positive replacement for restraints which were restrictive and harmful, however alarm sensors may also be viewed in this manner. Crogan and Dupler (2014) assert alarms lead to the behaviour being managed and the underlying need, the reason the resident is moving, remaining unmet. Alarms in whatever form can also lead to a reduction in movement, heightening the risk of falls-related injury from subsequent muscle weakness and reduced mobility. They further assert the need to gradually remove alarms and replace these with alternative approaches, requiring individualised assessments of each resident's needs and risks. Similarly, Montero-Odasso et al. (2022) World Fall Guidelines assert the need to prioritise educational intervention in hospitals for falls reduction to provide individuals with the knowledge to proactively reduce their own risk of falling. Montero-Odasso et al. (2022) highlight the need for multifaceted approaches to reduce falls in care homes which include staff training, multi-domain decision support tools, fall prevention action, nutritional optimisation, Vitamin D supplements, and promotion of physical activity.

Seppala and Van Der Velde (2022) state holistic and individualised tailored approaches should be central to falls prevention in both hospitals and care homes. Cameron et al. (2018) systematic literature review highlighted a significant lack of studies examining the efficacy of educational interventions in long-term care facilities, and further argue the need for interventions in such settings to combine psychological and educational focus to reduce falls. Likewise, a preliminary study conducted by Hang et al. (2016) found care staff in long-term care facilities had low levels of awareness and knowledge on falls and falls prevention, which Hang et al. (2016) associated to a lack of mandatory falls prevention training and education.

Although care staff lacked the capability to provide fall prevention strategies to residents, they were highly motivated, highlighting the need to provide opportunity and enhance capability via educational interventions to reduce fall risks in such settings.

A scoping review conducted by Heng et al. (2020) evidenced the value of educational interventions to reduce falls and fall related injuries and the growing body of literature supporting such interventions. This scoping review evidenced a need to include active learning styles into intervention to obtain richer engagement and understanding. Additionally, this review illustrated the value of incorporating multimedia usage in educational interventions. It was evidenced that educational interventions which utilise health behaviour change models had the most successful outcomes in patients engaging in fall prevention strategies, thus reducing the likelihood of falls occurrence. This review further supports the foundation for a combined psychological and educational intervention to reduce falls. However, this review was limited to hospital falls prevention only.

A study conducted by Hill, Beer and Haines (2013) evidenced the effectiveness of multimedia education packages with bespoke individual follow up for fall prevention of older people at the point of hospital discharge. This study found patients developed the motivation and capability to engage in preventative behaviours when provided with the opportunity via an education-based intervention compared to the control group. This study also evidenced the value of using behaviour change theories to underpin falls prevention intervention. Participants in the intervention group had significant increases in their knowledge of fall prevention strategies, confidence, and motivation in using such strategies and significantly increased awareness around risk of falls and fall-related injuries. Likewise, a study conducted by Hill et al. (2015) which implemented a ward level educational intervention programme, which educated patients, provided staff training, and enabled patients to provide feedback on perceived falls risks within their ward, each patient was provided and DVD and written workbook, combined with an individual tailored sessions to their specific needs, risks and circumstances. The personal goals set by each patient was shared with staff members who were encouraged to support patients in addressing barriers and achieving their goals. The results of this study highlighted a significant reduction in falls and fall-related injuries by using a single educational programme. Furthermore, the ward-level intervention resulted in a lasting benefit, with an overall decrease in falls post-intervention with patients which were not involved in the trial, thus creating a culture change focussed on reducing risk of falls and fostering safe practice.

Educational interventions in long-term care facilities is lacking (Cameron et al., 2018), however, given the success of such interventions in hospital settings, educational interventions should be trialled in long-term care facilities, with previous studies evidencing care workers motivation to provide fall prevention strategies, however currently lacking the capability to do so, which could be mitigated by providing the opportunity through education-based interventions (Hang et al., 2016), at both a single and multifactorial intervention level. Multi-factorial level interventions may include education combined with technological devices, as the latter do provide the potential to reduce falls considerably, although as stated by Seppala and Van Der Velde (2022), current technology does not have the specificity or sensitivity, as it is unable to clearly distinguish falls from other activities, leading to false alerts or non-alerts.

Thus, there is evidence which both supports and refutes the use of technology in reducing the occurrence of falls. The research base suffers significant heterogeneity, making it difficult to establish meaningful conclusions regarding the effectiveness of technology in falls reduction. However, common limitations within research and practice centre around usability and acceptance of technology in relevant stakeholder’s and how to enhance these, combined with a lack of ecological validity in experimental studies, which reduces one’s ability to assess the real-world applications of the technology. Therefore, more research is needed to evaluate stakeholder’s experiences and needs when implementing technology for falls reduction, and research conducted on the population the technology is created to benefit.

Pressure Ulcers

According to NICE guidance (2015) pressure ulcers occur from the result of sufficient pressure or distortion impairing the blood supply of an area of skin and tissue, resulting in damage to the area. Pressure ulcers commonly occur in individual who are predominantly confined to a bed or chair, due to illness and reduced mobility. Pressure ulcers are thus commonly referred to as bedsores or pressure sores.

There are risk factors for the occurrence of pressure ulcers which include serious illness, neurological conditions, reduced mobility, incontinence, poor posture and skin integrity, cognitive impairment, previous history of pressure ulcers, loss of sensation, thin, dry or weak skin, malnourishment or nutritional deficiencies, aged 75years and over. Those considered a high risk for pressure sores will experience more than one risk factor. Environmental factors relating predominantly to ergonomics are also a common risk factor such as chairs and mattresses which are not designed for pressure relief. Pressure ulcers occur within a number of health and social care settings which span the community, care homes and hospitals (NICE, 2015). Staffing levels also pose a significant risk to pressure ulcer development (NICE, 2014).

Pressure ulcers are a significant burden for those who experience them and their caregivers, as they reduce quality of life and increase sickness. Pressure ulcers are debilitating and can results in life-threatening complications blood poisoning such as septicaemia and gangrene (NICE, 2015). The most common measurement of pressure ulcers is the European Pressure Ulcer Advisory Panel Classification System (EPUAP, 2009), which grades severity from categories 1-4. According to NHS Stop the Pressure, most pressure ulcers are avoidable. When assessing risk for pressure ulcers the Braden scale, Waterlow score, or Norton risk assessment sale are commonly used and validated scales. NICE (2019) guidance asserts a pressure ulcer risk assessment should be conducted when a new resident moves into a long-term facility within 6 hours. Repositioning is key for those at risk of developing pressure ulcers, for those who cannot reposition themselves, support must be provided by health and social care professionals and/or familial caregivers.

Prevalence and Cost

Wood et al. (2019) state 700,000 patients in the UK experience a pressure ulcer annually, with 180,000 being newly acquired. As pressure ulcers are predominantly preventable their occurrence is representative of care provisions and delivery (Amir et al., 2017). A study conducted by Hall et al. (2014) found pressure ulcers were the most prevalent complex wound reported and 26% of people living with a pressure ulcer were situated in care homes. However, high prevalence in care homes is not surprising given that most residents experience multiple pressure ulcer risk factors. Pressure ulcers annually cost the NHS between 1.4-2.1 billion (Bennett et al., 2004), there is no availability of recent cost of pressure ulcer on the NHS, but it is estimated to have increased significantly since this period. Cost of pressure ulcers on the NHS differ depending on their grade and severity, with grade 1 pressure ulcers costing approximately £1064 and grade 4 pressure sores costing around £10,551 (Bennett et al., 2004).

Residents at risk of pressure ulcers are allocated two-hourly repositioning protocols, which occur 24/7 to prevent pressure ulcer occurrence or deterioration (Sharp et al., 2019). Repositioning is expensive and time consuming and can be particularly problematic in long-term care facilities due to its short staffing and high turnover rates (Skills For Care, 2022). Manual turns are considered invasive procedures, often waking residents from restful sleep, with authors like Sharp et al. (2019) arguing that the two-hourly turn protocol for pressure ulcers is more akin to elder abuse rather than elder safety. Additionally, the approximate cost of one turn with two staff member is £25 and takes an estimated 15 minutes.

What is Vitalerter?

Vitalerter is a care monitoring solution, which enables residents to be monitored by a single device. Vitalerter combines artificial intelligence and motion sensors. These combine to detect bed exits, and continuous measures of heart rate, respiratory rate, and precise movements of the body, without being placed on the person, and is thus non-obtrusive. Vitalerter is designed to reduce falls, pressure sores, and prevent critical and costly events leading to hospital admission and treatment. Vitalerter is attached to the bed frame of a resident using a magnet and the device run continuously and automatically when the resident is in their bed. Vitalerter amplifies the minute Ballisto-cardiography vibrations that resonate through the bedframe via a MEMs accelerator enabling the AI's algorithms to begin learning the residents' patterns. The AI learning period per resident is 24-36 hours. Following this, the Vitalerter can alert staff using mobile handsets up to 3-4 minutes before a resident attempting to exit their bed. Thus, this technology predicts and prevents falls, the alert enables staff, where possible, to assist a specific resident before they fall out of bed.

Vitalerter also monitors how frequently a resident move and repositions themselves. Long-term care facilities employ a 2 hourly manual turn protocol to reduce pressure sores. Such manual turns can disrupt the residents sleeping pattern and take up a significant amount of care worker time, However, Vitalerter continuously monitors residents and only alerts staff for residents who have not moved in the 2 hour time slot. Residents who reposition themselves will not require the manual turn, whereas those who have not are at risk of pressure sores and require a manual turn. Thus, Vitalerter can help identify those at risk of pressure sores and can reduce unnecessary turns, saving the residents sleep and care workers resources. Vitalerter resets the 2 hourly timer if the resident moves themselves or send an alert at the 2 hour time point in no movement has been made. Vitalerter also measures sleep quality, recovery, and sleep phases, whilst tracking movement, respiratory and heart rates during sleep.

Vitalerter continuously measuring heart and respiratory rates through AI algorithms which enables the system to identify anomalies in resident vitals, it will alert staff of the predicted event, for example cardiac arrest. This occurs as 6-8 hours before cardiac arrest occurs, residents will usually experience respiratory problems and irregular heart function, which may predict cardiac events.

The data from each Vitalerter is fed into the central dashboard enabling both individual and global reports to be produced an analysed daily, weekly and monthly reports can be generated.

Evaluation project process

Ethical approval was applied for and awarded from the University of Sunderland under application 017665 in April 2023. Project governance approval was applied for and awarded by Durham County Council in May 2023.

The devices were installed by the product provider and staff training was provided. Support was offered through regular stakeholder meetings. Flyer and information leaflets were distributed to care homes to encourage active participation.

The evaluation employed a mixed methods methodology, integrating both qualitative and quantitative approaches, with the aim of allowing for a more complete and holistic investigation (Creswell & Plano Clark, 2017). Mixed methods are advocated for providing greater potential to strengthen rigour, enrich findings. Moreover, mixed methods designs are endorsed where the aims are to inform policy. (Brannen, 2005). This evaluation was devised of two parts.

Part 1 Data was collected by Porters Care from the Vitalerter devices. Via a sharing agreement the data was shared with the evaluation team at the University of Sunderland. Residents who were assessed as high-falls risk by the care homes were placed under the falls category and had a Vitalerter attached to their bedframe, n = 15 devices in total. Residents who were on a turn protocol also had a Vitalerter attached to their bedframe, n = 15 devices in total. Overall, N = 40 device placements. Data collection spanned 12 weeks, during this period Vitalerter was designed to continuously monitor and collect data regarding each resident. However, difficulties emerged in the data collection period such as resident deaths and hospital admissions, and a significant change in the residents condition. This prevented some devices collecting continuous data for 3 months. This has been discussed in the results and limitations sections respectively. The data was analysed, to measure whether there was a statistically significant reduction in falls during the Vitalerter evaluation compared to the 3 months baseline data prior to the intervention. The data examining residents' ability to move independently was utilised to highlight Vitalerter's potential ability to accurately depict the correct turns protocol needed per resident, compared to the turns protocol residents had been assigned using traditional methods. There were no operational changes made as this was a data collection exercise only. If these devices were intended to activate staff, there would need to be changes made to operational guidance and procedures.

Part 2 Involved a series of interviews completed by the evaluation team at University of Sunderland to understand key stakeholders' experiences of using Vitalerter. The care home acted as gatekeeper and recruitment was facilitated by an email invitation sent out on behalf of the evaluation team directly to staff who had been trained to use the Vitalerter devices. Direct contact and consent could then be made by the staff member to the University team. A total of eight participants were interviewed, six semi-structured interviews were conducted and one small focus group, comprising two participants. All interviews were conducted and recorded online using Microsoft Teams and were transcribed verbatim. Various relevant stakeholders were interviewed including care workers, senior care workers, care home and regional managers, and directors. These interviews examined staff experiences broadly covering the positive and negative aspects and their thoughts and ideas for future use of Vitalerter. Interviews were terminated once saturation of data was achieved. This data was analysed thematically.

Qualitative Findings

The interviews were recorded and transcribed verbatim. The data was analysed for themes that emerged from the interview transcripts. Three themes were identified in this thematic analysis: (1) Benefits of using the Vitalerter; (2) Challenges of using the Vitalerter; and (3) Future directions for using the Vitalerter.

Theme 1) Benefits of using Vitalerter

This theme highlights the benefits staff experienced when using the Vitalerter in their roles. The staff experienced a reduction in falls; thus residents' biopsychosocial health and wellbeing was enhanced, in comparison to the pre-trial phase. This theme further identified the negative impact falls can have on staff members, and the positive impact of the Vitalerter reducing falls on staff wellbeing. The Vitalerter demonstrated a saving of staff members time due to the perceived reduction in falls as there was less paperwork to complete, alongside other costly factors such as staff waiting with the resident for medical assistance and potential admittance to hospital. The release of staff time seemed to benefit other residents who were not a high falls risk, and led to greater person-centred provisions of care for residents, highlighting the broader impact of predictive and preventative technology such as Vitalerter.

All stakeholders described how successful the Vitalerter was useful in predicting and preventing falls from occurring. One care home manager described a significant decrease in falls since using the Vitalerter device in the two care homes they manage:

And I mean over three-month period of using it, the people that were on it the falls and I mean we had, we had 10 falls, reported from April to now [June] for the people that *have got the device. Where in that short period of time we had on them people we had over 30 falls reported, previously to using this device* ***(P 8; Care home manager; 34-37).***

The participant reported a reduction of 20 falls since using the Vitalerter, which demonstrated the usefulness of the Vitalerter and concurrently the high fall rate of residents in care homes, further emphasising the need for predictive and preventative technology. Such sentiments were shared by other participants, who described the broader impact of predicting and preventing falls:

'It has reduced falls, reduced injuries, and hospital admissions' ***(P 1; Deputy care home manager; 15).***

Here, the participant described a considerable benefit to residents who have experienced a reduction in falls, fall-related injuries, and hospital admissions, which falls can lead to depending on severity. A senior care worker described how the alerts received by the Vitalerter device provides enough time for the staff member to intervene before a fall-related incident occur:

'As soon as it goes off, we get there straight away before there's any incidents. It. And it just reduces the risks ***(P 2; Senior Care Worker; 8-9).***

The participant emphasised the reduction in fall-related risk when utilising real-time predictive technology. Participant three felt passionate that all care homes should use the Vitalerter technology:

'I think it would be perfect. I think I think they all should have them absolutely. Like fall risks, residents, definitely' ***(P 3; Care worker; 70-71).***

The participant emphasised the value and efficiency of the Vitalerter in reducing falls for high-risk residents and their hopes for future implementation. Participant four, who worked as a director within the organisation described how unique the Vitalerter was:

'There is nothing on the market. Nothing we can buy apart from human time that can prevent falls' ***(P 4; Director; 33-34).***

They continued to describe how paramount predictive and preventative technology is for the physical and emotional wellbeing of residents:

'Then there's the human cost which is vast, really, isn't it the pain that anxiety, the worry? Um, yeah, it just doesn't bear thinking about really. So no, we're, I've been desperate for something to come along for a long time to help with prevention of falls, because nothing else really does ***(P 4; Director; 45-47).***

The participant highlighted the biopsychosocial impact of falls of residents, and a paucity of technology which can predict, reduce and prevent falls occurring, and the organisations motivation to utilise such technology for the benefit of their residents. Another participant described the long-lasting impact of falls on residents, which, at times, led to social isolation and decreased nutritional intake:

'And the social side of it as well, not having the amount falls and obviously when someone has a fall, it impacts like the entire day and going forward. So it's confidence about not being able to leave the bedrooms and which then they're not eating the meals and yeah, it's been good ***(P 8; Care home manager; 18-20).***

The participant described the experience of predicting and preventing falls positively, due to the multifactorial impact of falls on the person, including fear of falling and risk aversion to the extent it had a detrimental effect on their health and wellbeing. The impact of falls extends beyond the resident, staff witnessing falls can also experience emotional distress:

'Yeah, because obviously we had one lady before she got it, she really smashed her face in, and it is quite emotional for us to see that' ***(P 3; Care Worker; 26-27).***

Other participants also shared such sentiments:

'Absolutely, yeah. And it can be quite traumatic, you know? Yeah, absolutely' ***(P 4: Director; 60-61).***

Thus, preventing falls promotes resident and carer wellbeing. When residents do fall in care homes, families are contacted and informed, one care worker spoke of how such phone calls made her feel:

'But that that would be beneficial because then it's obviously preventing a lot because not just for us, we don't have to make them awful phone calls to the families. To say oh they've split their head open or. You know. You feel like a bad person' ***(P 6; Senior care worker; 58-60).***

The participant described feeling like a bad person, indicating that when a resident falls, staff may internalise feelings of guilt and blame, heightening emotional distress. Participants described how the Vitalerter had enhanced their wellbeing and decreased their emotional distress:

‘*Yes, it does because you can get to them as soon as it goes off, yes… Yes, mine. Yes, it does. For me personally, yes’* ***(P 2; Senior care worker; 16-19).***

The participant emphasised the importance of predictive and preventative technology in enhancing staff wellbeing by reducing falls and the subsequent emotional distress experienced when witnessing falls. A deputy manager in a care home felt that her staff had experienced a decrease in emotional distress due to the reduction in falls:

‘Yes, definitely…Yeah, because there has been less serious injuries’ ***(P1; Deputy manager; 22-27).*** The participant highlighted the psychological benefits for staff when reducing falls occurrence.

Falls also lead to considerable administrative duties for staff, which uses up a considerable amount of time:

‘Especially on the seniors, because every fall the amount of paperwork. So if they get into them before the fall. So the work load has decreased’ ***(P 1; Deputy manager 45-46).***

Here, the participant discussed how a reduction in falls and subsequently fall-related paperwork had reduced staff workload, particularly on senior staff. Such sentiments were also shared by a senior care worker:

‘From my experience, it's less paperwork’ ***(P 2; Senior care worker; 8).***

This participant also experienced a reduction in workload and work-related stress since using the Vitalerter:

‘It has, yes’ ***(P 2; Senior Care worker; 30)****.*

Paperwork is not the only time-consuming factor when falls occur as discussed by a care home manager:

‘It's the extra work, it's the extra hours that you've got to put in. So somebody has a fall you’re talking about an hour from start to finish with finding someone on the

floor to make sure they're OK, to get them off the floor to make them comfortable. That's like a full hour out of that day being used up. They have to play catch up for the rest of the day.' ***(P 8; Care home manager; 23-27)***

The participant evidenced how falls place staff under extra strain by requiring them to catch up on lost time, heightening staff stress. The time taken up by falls often depends on the severity, where severity or risk is potentially high, steps must be taken to ensure the residents health, wellbeing and safety:

'With waiting for an ambulance and a staff member staying with the person until the ambulance arrives. You know, if it's somebody with a really advanced dementia, that might be a member of his staff out of the building, you know, although we don't always send escorts, we're not contracted to send escorts. You would make a judgement. And so, there's all of that time' ***(P 5; Manager; 101-105***).

Thus, falls can lead to a shortage of staff, and overburdening of other staff remaining at the care home. In addition, prior to using predictive and preventative technology such as the Vitalerter staff were frequently checking on high-risk residents, which was also viewed as a time-consuming task:

'Yeah, definitely. Because obviously, when we just when we didn't have the Vitalerter we were checking them all the time. At least now we've got time not to check them because we've got the Vitalerter, so we know when they actually get up, we can get to them straight away' ***(P 3; Care worker; 46-49).***

The use of the Vitalerter and it's ability to predict and prevent falls, reduced staff anxiety regarding high fall risk residents, and also enabled better use and distribution of staff time and resources, as frequent checks were no longer required, unless staff were alerted to a residents movement. The participant continued to discuss how the Vitalerter had led to positive behaviour changes in residents, which also reduced the risk of falls:

'I personally think that because they've got the Vitalerter in, they know, once they get up, that machine's gonna go off so they know we're gonna be there… So, they seem to like not get up as much' ***(P 3; Care worker; 59-62).***

The participant highlighted the broader impact of the Vitalerter, leading to positive behaviour changes in some residents, indicating the potential for long-term benefits, with behaviour changes which decrease falls risk.

Other participants reflected on how time saved by using the Vitalerter enabled staff to spend more time with other residents:

> *'Yes, yes we can, yeh* ***(P 2; Senior care worker; 49****).*

One care worker felt the increased time stemmed from staff no longer having to check frequently on residents, enabling time to be shared more equally among residents:

> *'But sometimes then yes, because obviously we're not checking on them every 5 minutes to make sure they not on the floor, cause obviously we know they're not cause the Vitalerter would have gone off. So we do kind of have that more time with other residents rather than just them with the falls risks.'* ***(P 3; Care worker; 85-88)***

Here, the participant emphasised the value of the Vitalerter for residents who are not a falls risk, as they now experience more social interaction with staff, indicating the potential to enhance wellbeing of residents regardless of their falls risk. Likewise, participant one felt the increased amount of time experienced by staff enabled greater provisions of person-centred practice:

> *'Yes, definitely'* ***(P 1; Deputy manager; 50).***

Thus, the Vitalerter may be a valuable asset to promote person-centred care practice within care homes. Participant four discussed their expectations of the Vitalerter and how these expectations had been met:

> *'But it, it sounded absolutely marvellous and if that we could be alerted before somebody fell and there was some technology that could do that, why? Why wouldn't you take that on? You know and save people a lot of pain and injury and upset. So that's basically why and it's done what it said on the tin. In my opinion, I think it's marvellous* ***(P 4; Director; 9-13).***

This participant felt the Vitalerter had been successful in reducing falls and the severe impact falls can have on residents. Participant four further expressed their opinion on the cost-benefit of the Vitalerter:

'I don't actually know how much each Vitalerter costs. However, I do know the time it costs to the service and staff. Um. So for me the time that takes it takes a little bit of time to set up and all the rest of it, but the benefits far outweigh that and the staff would agree with that as well' ***(P 4; Director; 25-28).***

Here, participant four discussed how the cost of the Vitalerter was not relevant given the wide-ranging benefits experienced, which this participant felt would be the general consensus within the care homes. Other participants also perceived the experience to be positive:

'It's. We saw especially over at [Care home name] that we're seeing a reduction in falls and being able to manage somebody before they got out of bed. They've just been really positive' ***(P 8; Manager; 4-6).***

Participant two shared a similar perception of the Vitalerter experience:

'It's done. It's done good, yes. Yes' ***(P 2; Senior care worker; 3).***

When asked whether this participant would like to add, remove or improve any part of the Vitalerter for future use, they responded:

'No, I wouldn't change anything' ***(P 2; Senior care worker; 41).***

Here, the participant emphasised a valuable point of ensuring that any technology is user-friendly and has the support and thus uptake and engagement of staff. Staff also reflected on the value of having a responsive team, who communicate well when challenges emerge:

'I would say they've been really great. They've been really responsive. The guys [Name] just comes up and down as we need him to. So absolutely fab' ***(P 4; Director; 74-76).***

Participant four emphasised the positive impact a responsive team can have on their overall experience.

Challenges of using the Vitalerter

This theme explores the challenges staff members experienced when using the Vitalerter is their role. There were some technological challenges identified such as low battery power, over-sensitivity, lack of flexibility regarding placement of the device, and alert notifications either taking too long to come through to the handset or not coming through. At times the devices froze and stopped working, thus staff had to restart the handset, which decreased the effectiveness of the predict-prevent purpose of the device. There were also practical challenges experienced, which related to supply and demand per care home size and number of residents allocated devices. In addition, challenges in the assessment of need for the device were identified, with some staff reporting a lack of benefits due to the resident not requiring the device.

Participants discussed some of the challenges they experienced when using the Vitalerter in their care home:

*‘I think because we had an issue where the battery was drained and went dead quick, and we only have one battery. They have sent us a docking station and another battery now, so hopefully that's gonna resolve’ (**P 1; Deputy manager; 30-32).***

Although participant one highlighted a challenge experienced, they also evidenced how responsive the Vitalerter team were, in addressing any challenges which emerged. However, other participants also shared their concerns regarding the battery life of the technology, which may indicate a general limitation of the device:

> *‘Yeah, the battery life doesn't last enough for a long time. I don't know how long it's meant to last, but. We do a 12-hour shift, and it doesn't last the full 12 hours’ **(P 6, Senior care worker; 82-83).***

Given the nature of the device and its aim to predict and prevent falls occurring in real time, it seems pertinent that the battery life would last long enough to cover a shift. Unlike participant one, the participants from this care home were not provided with new batteries or additional charging stations:

*‘And we’ve only got one’ **(P 7; Senior care worker; 90).***

There were project leaflets developed for the homes, training by the provider, and engagement meetings to support with challenges presented. Similar sentiments were shared by participant five regarding the supply Vs demand of resources:

Within the homes was only that one handset. So you know, our homes might be over three floors and the person on the ground floor might have the handset and *but it's actually a person on the top floor and who's got the equipment on* ***(P 5; Senior regional nurse manager; 56-58).***

The participant evidenced the need to assess the supply of resources per individual care home including, size, floors, and number of residents assigned a Vitalerter, to make it more user-friendly and efficient. Participant eight also felt greater supply of handsets would have a greater impact of the effectiveness of the Vitalerter and staff uptake and engagement:

‘More devices I think we need more devices cause you have one device for the whole home. Obviously, you have different units within the home so it means. You’re up and down, ringing down, saying that person, quickly you need to go down and check that person so more devices’ ***(P 8; Care home manager; 52-54).***

Congruent with participant five, this participant also felt greater supply was needed to meet demand, particularly when care homes have multiple floors, units and residents. The Vitalerter can predict a fall occurrence three-four minutes prior to it happening, however the ability of staff preventing the fall is dependent on supply meeting demand. Participants experienced challenges relating to the sensitivity of the Vitalerter which sent a falls alert to staff due to an unrelated incident:

‘If you open the bedroom door. Yeah, when you go past it, it erm goes off’ ***(P 7; Senior care worker; 115).***

Likewise, family members visiting residents also seemed to cause alerts:

‘*When we got family members in and even if they just sort of brushing past the quilt, it will go bit alert, alert you know’* ***(P 6; Senior care worker; 113-114).***

The participants illustrated the need to examine and potentially address the positioning and sensitivity of the device, to reduce the risk of false alerts. Additionally, participants were contacted by the Vitalerter team when alerts had not been addressed quickly enough:

‘The only negative the homes have ever said is when you know an alert is going off and maybe they haven't attended to it quickly enough and then you've got the team ringing them, but they may be in the midst of an emergency or something’ ***(P 4; Director; 79-82).***

This participant evidenced the need for the Vitalerter team to be more understanding of the reasons an alert may not be immediately attended to, which may indicate the need for a more trusting relationship between the two groups. However, if the alert is not addressed within the three-minute timeframe, the ability to prevent a falls decreases significantly, thus a more creative solution may be required to ensure the safety of residents and staff.

When discussing the challenges of using the Vitalerter it was also identified that alerts did not always come through to the handset, and thus the staff member in a timely manner, effecting their ability to prevent falls occurring:

'Sometimes it is slow, but we don't know if that's our Internet. The connection, sometimes the, or I've found. I don't know if you found, if I've got it in me pocket and the screen's locked it didn't ping' ***(P 6: Senior care worker; 8-10).***

This was supported by participant seven, who had a similar experience using the Vitalerter handset:

'Nor it didn't. Sometimes no it didn't ping always' ***(P 7; Senior care worker; 11).***

Participant six continued to elaborate on their experience of this specific challenge:

'You know, if if it was sat in your hand and the screen was on there and then it would come up straight away. But if it's locked if the screen's locked. So I know with your mobile phone it will still alert you whether your phone's locked or not, but it wouldn't like ping or go off' ***(P 6; Senior care worker; 16-18).***

Here, participant six highlighted an important concern, care workers are unable to constantly hold the handset due to the nature of their roles, thus if alert notifications will not come through when the screen is locked, care workers will not have the information they need, within the timeframe needed to intervene a fall, therefore, reducing their ability to prevent falls from occurring. Likewise, other care homes experienced similar technological challenges:

'Yeah. It was. Ohh, it freezes quite a lot, or the device would come up and say that there's a, there's a call somewhere up on the screen. But It wouldn't let you click on anything, or the Internet would drop off the phone, so you'd have to restart it and

put it back on. We did get it put on the computers. In the offices, but obviously it needed, its better when it's working. It's more hands on for the carers who are dealing with that person on that floor' ***(P 8; Care home manager; 42-46).***

Participant 8 discussed multiple technological issues with the device which consequently reduced care workers ability to prevent falls as they were not receiving the necessary information within the specified timeframe to intervene and thus prevent falls. The device's ability to prevent falls is dependent on its ability to communicate information to care workers via the handset, evidencing the limitation of technological software at times. Other challenges experienced were not related to the Vitalerter device, rather whom the device was assigned too:

'The one of the ladies that it's in her room. see during the night, it's pointless because [Resident]. Yeah. See once she's asleep. She doesn't move. And then during the day she's not in her bedroom. She tends to fall in communal areas.' ***(P 6, Senior care worker; 36-38)***

Participant six identified the need to assess which residents would benefit from the Vitalerter beyond their fall risk, for example where they are most likely to fall. The Vitalerter remains on the bedframe and hence would only be appropriate for residents who are at high risk of falls from their bed. The participant illustrated the potential for niche falls risk assessments when bespoke technology is being utilised, to ensure congruency between risk and benefit. The participant also highlighted a limitation of the Vitalerter technology, common with other non-wearable devices, it can only be used in specific environments, proximity around the bed in this regard. This limitation was reflected on by other participants:

'You know when you look at our falls data, our falls happen during the day when people are mobilising, not you know, there is a small amount of our, a small percentage of our falls, um, that actually happen from somebody getting up overnight ***(P 5; Senior regional nurse manager; 122-124).***

Here, participant five emphasised an important point related to the limitation of non-wearable devices, if most falls occur when the resident is not in their bed, consideration is needed to weigh up the cost-benefit of the Vitalerter, which participant five further discussed:

‘*What I am focusing on is that we know what percentage of our falls that do actually happen overnight, what percentage of our falls does this piece of equipment, um save’?* ***(P 5; Senior regional nurse manager; 134-135).***

Participant five evidenced the need to ensure the Vitalerter is reducing falls to a meaningful extent when considering future use and purchase of the technology.

The final challenge experienced related to participants perceiving an increase in their workload and work-related stress:

‘Yeah. I know if I've got hold of it. Um. And of course, I know when [Resident] was here and it was like her bed. You were constant up, down, up, down. And we're not getting our work done or I'd give it to one of the girls. But if they want to go for a cigarette, it comes back to me and you just up and down, up and down all around the. It is a bit. Bit time consuming’ ***(P 6; Senior care worker; 105-108).***

Participant six emphasised how using the Vitalerter, especially with certain residents, decreased their ability to complete their work due to the level of intervention needed. This constant level of intervention may increase care worker exhaustion. Likewise, the need to respond to alerts regarding a select few residents raised concerns as to whether other residents may experience less interaction:

‘Yeah, I mean, it does have an impact. You know, if you had seven or eight people on the with the sensor on their bed and you were having to respond to those sensors, you know that takes time away from other residents as well ‘***(P 5; Senior regional nurse manager: 68-71).***

Participant five illustrated how vital it is to ensure the safety of all residents’ biopsychosocial wellbeing, and to further examine the impact of the assessment of resident identification for the device if used in the future.

Future directions for using the Vitalerter

This theme illustrates participants views on the future directions of the Vitalerter. Some participants felt there was no changes required, however most participants felt some changes would be beneficial to the future use and implementation of the technology. Two participants felt greater flexibility of the device would provide greater reduction of falls. Participants also highlighted the value of linking the Vitalerter system with nursing system already in place and thus remove the need for a separate handset. It was felt by some participants that the Vitalerter could be more flexible with its continuous monitoring, for example the ability to pause or stop monitoring when the resident was no longer in the bed to reduce overburdening care workers with false alerts. Care workers also identified the need to be involved in the allocation of Vitalerter's, whereby their knowledge and insight could be used to better inform the decision-making process.

When asked about their views for future implementation of the Vitalerter and whether they would recommend any changes, some participants felt no changes were necessary:

'*No, I wouldn't change anything'* ***(P 2; Senior care worker; 41).***

Participant one shared a similar viewpoint when asked whether they would use the Vitalerter in future with no additional changes:

'Yes, yes, definitely' ***(P 1; Deputy manager; 54).***

However, some participants felt there were other avenues which could be explored to make the Vitalerter more effective:

'*Devices for the chair, not just the bed. It's all right through the night, and residents at nursed in bed. But. The rest of the time would be I would be really good'* ***(P 8; Manager; 55-56).***

Such sentiments were also shared by other participants:

'*And I think, you know we've talked about that, and you know a chair. A similar piece of equipment for a chair and would be really good'* ***(P 5; Regional senior nurse manager; 110-111).***

Here, the participants emphasised the need for greater flexibility and coverage of the Vitalerter, enabling a greater reduction of falls within care homes. Other participants felt a wireless option may be beneficial:

'The only thing I find difficult with them is that obviously the wires, sometimes for the live links and stuff. Sometimes just get in the way…Yeah, yeah. Rather than a being on a wire. But that's the only thing I would like to change about it' ***(P 3; Care worker; 74-79).***

Participant three identified a wireless option as more user friendly, however they also emphasised this being the only difficulty they experienced and they only aspect they would change. Other participants had already discussed with the Vitalerter team their thoughts on future directions:

'*But talking to [Vitalerter Manager] and the technician [Name], there probably is a way of being able to apply it to the nurse call systems in homes'* ***(P 4; Director; 30-31).***

Participant four highlighted these ideas for the future directions of the Vitalerter are also welcomed by the Vitalerter team, who seem motivated to enhance the Vitalerter's efficiency and user-friendliness. The participant continued to describe other developments which had been discussed between the two parties:

'And I know all the homes [Vitalerter Manager] was talking about the homes having a dashboard that we can use. So they found that really interesting' ***(P 4; Manager; 73-74).***

The participant emphasised the value of collaboration and a shared vision of the future when implementing innovative change through technological advancements. Ultimately, the approach taken by the Vitalerter team and the perceived effectiveness of the technology had a positive impact on the participants wishes for the future:

'Absolutely, yes. Yeah, I think it despite what the Council feel at the end of it. And I'm sure it'll be really positive from [Local] County Council as well. I'll be recommending it to [Care home organisation]' ***(P 4; Director; 66-68).***

The participant felt passionate about implementing the Vitalerter in the future, regardless of the evaluation's outcome, due to their positive experience. Whereas participant six felt the option to turn off the device during certain times would decrease overburdening care workers with false alerts

'So I think we need to be able to turn it off so that we're not bugged by the machine every time someone brushes past to bed' ***(P 6; Senior care worker; 127-128).***

The participant discussed circumstances when the device should be turned off and why:

'I think we should be able to turn it off when they're not in the bedroom. I know [Resident] when [Care worker] had it, it was turned off because she wasn't in the room, which is the same with our live links. If they're not in the room, they don't get set because then they're down the lounge and they have chest sensors. But as soon as we turn it off, we got a telephone call telling us to turn it back on.' ***(P 6; Senior care worker; 121-125)***

The participant emphasised the need for greater communication and collaboration between the Vitalerter team and the care home staff going forwards to ensure all stakeholder's needs are met. The participant indicated this technology should follow the same guidance as other technology used within the home, to reduce overburdening staff. The participant continued to discuss other factors they felt were necessary to amend for future use:

'If the battery life was a bit longer and if we can somehow figure out how to alert us without having to keep hold of it in your hand and have the screen on all the time…That'd be brilliant' ***(P 6; Senior care worker; 133-137).***

Here, participant six highlighted how paramount it is to understand and address the needs of those using the Vitalerter in their role to ensure uptake and engagement of staff, and thus enhance the effectiveness of the Vitalerter. Other areas of improvement with regards to not overburdening staff utilising the Vitalerter were also identified:

'It maybe could do with being streamlined a little more maybe an e-mail to the manager once a day instead of calls to the home' ***(P 4; Director; 85-86).***

The participant emphasised the value of choosing a method of communication which works for the frontline staff within the care home, reducing perceived sense of burden and work-related strain. The final aspect identified for future changes related to the decision-making process of whom to allocate a Vitalerter to. Care worker felt they should be involved in this decision to ensure the most appropriate resident was identified:

'Yeah, I think, yeah, if those problems are sorted out and like I said, we chose what beds they went on. It would be 100% beneficial, definitely' ***(P 6; Senior care worker; 139-140)***.

The participant felt their knowledge and expertise regarding the residents most appropriate for the Vitalerter should be a central part of allocating devices to residents, and asserted how significantly this would improve the experience. For both residents and staff.

Quantitative Findings

Falls

Data collection for the 3 months prior and during the evaluation was analysed to examine whether there had been a significant reduction in falls during the Vitalerter period of instalment. Descriptive data was collected and examined via frequencies for the 25 residents with a Vitalerter. During data collection one resident died, leading to the Vitalerter being reallocated, however this information was not shared with the research team. The data examined the feedback staff provided when responding to the alert from the Vitalerter. Alerts are sent from the Vitalerter to the handset, which was monitored by a member of staff, when the Vitalerter detects movement, it indicates the possibility of a fall. Thus, it was felt important to obtain staff feedback on the reason for each alert. In total 11 different reasons for alerts were identified in the data (refer to Table 1).

Overall, these alerts show a multitude of reasons for Vitalerter alerts and emphasise some potential limitations of the device regarding both sensitivity and specificity. Likewise, the data indicates difficulty with staff engagement and understanding, for example the staff provided no feedback 37 times and did not complete the action by clicking 'done' 2041 times, which does limit the reach of data analysis when interpreting efficacy and accuracy of the device in predicting and preventing falls. The frequencies highlight potential challenges regarding the sensitivity of device as it sends an alert for a potential fall when people were near the bed, detecting other people's movements rather than the residents, due to a passive infrared sensor that is used in addition to the device under the bed, creating a false alert, which was documented 522 times.

Table 1: Frequencies of reasons for Vitalerter alerts

Type of Alert	Frequency of Alert
There are people near the resident's bed	522
The staff took care of the resident	3466
The resident was about to leave the bed	375
Staff clicked no feedback	37
Staff didn't click done	2041
The resident has already left the bed	309
The resident was not leaving the bed	1018
The resident was not in the room	106
Turned to back	3
Turned to side	2
Other	2
	Total: 7881

Additionally, there were 1018 alerts when the resident was not leaving the bed, indicating there was no risk of a fall from the movement of the resident, and an additional 106 alerts were received when the resident was not in the room, further highlighting some potential challenges of the Vitalerter's sensitivity and accuracy in predicting and preventing falls from movement. Regarding specificity, there was 309 times when the resident had already left the bed, indicating that the staff were not alerted in time to prevent the resident from leaving the bed, which could have led to a fall occurring. However, the data is not sufficient enough to evidence the occurrence of a fall at times when the resident had already left the bed. There were 375 alerts where the resident was about to leave the bed, which may suggest the risk of falls was potentially averted from timely alerts preventing the resident from leaving their bed. The most frequent response to an alert was 'staff took care of the resident', which occurred 3466, the data cannot infer that each of these alerts prevented falls, however it suggests the resident had an unmet need which staff met upon arrival. During the data collection period there was one falls-related hospital admission and two participants experienced an increase in falls, however this was by a small margin.

Baseline data was collected from each care home and resident involved in the Vitalerter trial for a 3 month period prior to installation, measuring the rate of falls per resident overnight. The evaluation team carried out two episodes of data analysis. The first was based on initial data received and the second was due to additional information around the data which led to the evaluation team scrutinising the data to ensure rigor. Baseline data was compared to the data collected during the 12 weeks of the Vitalerter period regarding the frequency of each resident's falls. This was to examine whether there was a reduction in falls during this time. Descriptive statistics were examined for pre and post falls rate. Pre falls rate M = 7.48, SD 17.568; whereas post fall rates M = 3.13, SD 7.406. The mean (M) of the data is the average score, all numbers are added together and divided by the total. The mean refers to the average set of values. Standard deviation (SD) is the amount of variance in the data, so how far away each score is from the mean value. It is a measure of how spread out the numbers are. The descriptive statistics suggest falls rates have decreased during the Vitalerter trial. The data did not meet the parametric assumptions of normal distribution (See Appendix A: Falls Histograms). Parametric assumptions are criteria which ensure the correct statistical analysis is chosen to test the data. Normal distribution is a key parametric assumption, the criteria for normal distribution asserts data points should be more frequent around the mean value, following a symmetrical pattern, which in graphical form is represented by a bell-shaped curve (for example looking at the ages of all the population you have a spread of ages through the life course). When the data set is skewed, for example when measuring a specific population that would not provide symmetry within the data naturally (such as one part of a population), a different set of analyses are used and referred to as non-parametric tests. As parametric assumptions were not met for a repeated measures design a Wilcoxin Signed Ranks inferential analysis was conducted, ***Z = -3.132, p = .002***. The Wilcoxin Signed Ranks analysis showed a statistically significant decrease in falls during the Vitalerter trial. Statistical significance means the reduction in falls has not occurred by chance; it has come to fruition from the intervention (changes made). Given the limitations of the data collected the analysis cannot state this decrease was due to Vitalerter alone, however it suggests it was a large contributory factor.

There were limitations of the data, which included the research team not being made aware of participants changes in circumstances, for example one resident died during the study, one resident had been moved to the end-of-life pathway and others were removed prior to the data collection going live. In addition one participant had a Vitalerter attached to their chair to reduce falls, the research team was not informed of which resident this was, thus was unable to separate this potentially extraneous variable. After the initial analysis was conducted changes around resident's circumstances were shared with the research team. To control for this, any of the 25 residents where there was not a 12-week data collection period, where data was missing or where cases were not reported in terms of baseline data were removed. This totalled n = 10. After removing incomplete datasets there were a total of n = 15 active devices with data for a continuous 12 week period (see Table 2). Of the 25 residents with Vitalerter's, two were removed before the go live date (EF01; EF02), one had no baseline data (EF06), two were missing from the baseline dataset (CF03; CF06). Five were excluded for not reaching the 12-week data collection threshold. One collected up to 4-week of data (DF03), and four collected between 5-11 weeks of data (DF01; CF01; BF04; BF02). The initial goal was to collect data on 15 residents.

The descriptive and inferential analysis was conducted again to increase rigour. Baseline data M = 3.87, SD 3.815. Intervention data M = 1.80, SD = 2.145. The descriptive statistics highlight a decrease in falls during the intervention period. The data was skewed and therefore did not meet the parametric assumption of normal distribution, thus a Wilcoxin Signed Ranks test was conducted, ***Z = -2.673, p = .008.*** The inferential analysis showed a highly significant reduction in falls during the intervention period. In pure numbers there was a reduction of falls incidence from 58 falls across the sample to 27 during the evaluation period. The summary of this is detailed in table 2.

Table 2. Baseline and Intervention Falls Number

Resident	**Baseline falls (3 month)**	**Intervention (3 month)**
AF01	9	6
AF02	8	1
AF06	4	0
BF01	10	4
BF03	0	0
BF05	6	3
BF06	1	1
BF07	3	1
CF02	10	6
DF02	0	0
DF06	1	0
DF07	0	0
EF07	4	3

FF01	0	0
FF02	2	2
TOTAL	58	27

Turns

Vitalerter was also used to examine resident's ability to move independently without being manually turned by staff. Residents who required a turn protocol had the Vitalerter attached to their bedframe to monitor the resident's movement. Vitalerter learnt each residents turn protocol, if the resident moved during their turn protocol period Vitalerter reset the clock, which was automatically noted on the system. There were 15 residents with a Vitalerter for turns. The frequency of turns per 12-hour period for each turn protocol was calculated and multiplied by the number of days Vitalerter was on each resident's bed to obtain an estimate of the expected turns for Vitalerter evaluation period, which was compared to the number of actual turns needed, calculated by the residents independent movement, the difference was calculated to measure whether a reduction had occurred and to what degree of significance. Descriptive statistics for expected turns, M = 467.40; SD 260.866. Whereas turns needed, M = 313.33; SD 247.051. The descriptive statistics suggest a decrease in the number of turns needed during Vitalerter evaluation period than the number originally estimated (See Table 3) Furthermore, it is important to note that the staff were not receiving the turns alerts via the Vitalerter system and were only using the turns protocol in place. For the purposes of this evaluation data was gathered to illustrate the potential impact Vitalerter could have. However, when deployed the staff would utilise the alert function and would need to make the relevant changes to operational procedures and governance.

Table 3. Reductions per resident in turns required

Resident	Turns estimated over Vitalerter period	Number of turns required (identified by Vitalerter due to lack of independent movement)	Theoretical reduction of turns needed
AT03	184	116	68
AT04	300	50	250
AT05	102	87	15
AT08	552	2	550
AT09	177	155	22
CT04	368	149	219

CT05	1104	914	190
DT04	304	268	36
DT05	368	248	120
ET03	552	390	162
ET04	552	482	70
ET05	552	515	37
FT03	424	254	170
FT04	736	567	169
FT05	736	503	233

Additionally, the number of days the Vitalerter was assigned to each bed compared to the number of dates an alert was set off highlighted an interesting finding (See Table 4 Number of days with alerts received). For some residents the number of days alerts were sent in comparison to the number of days Vitalerter was live, was quite considerable, meaning that some resident's went days and even weeks without requiring a manual turn, which may indicate the need for turn protocols to be reassessed, a limitation of the technology, or admission to hospital. Additionally, four out of the five bed managed residents have considerable differences between how many days Vitalerter was on the resident's bed frames and how many days there was alerts to turn the resident. This finding is interesting as in theory bed managed participants should have less gaps, due to these residents being permanently placed in their bed and typically being less mobile and thus less able to move independently. However, the data is not sufficient to make conclusions on why there was at times considerable gaps in the data indicating the resident was moving continuously without any assistance from staff.

Table 4: Number of days with alerts received

Resident	**Turn Protocol**	**Number of days Vitalerter on bed**	**Number of days with alerts**
AT03	3	23	18
AT04	4	50	49
AT05*	4	34	10
AT08*	2	92	83
AT09*	4	59	15
CT04*	3	92	66
CT05	2	92	55
DT04	3	38	11
DT05*	3	92	47
ET03	4	92	49
ET04	4	92	44
ET05	4	92	19

FT03	3	53	46
FT04	3	92	55
FT05	3	92	67

*Resident is bed managed

Inferential analysis was conducted to examine whether the decrease in turns was significant. However, parametric assumptions were not met as the data was not normally distributed (see appendix B Turns Histogram). Therefore, a Wilcoxin Signed Ranks inferential analysis was conducted: ***Z = - 3.408, p = .001.*** The analysis highlighted the reduction in turns performed and turns estimated was significant.

Limitations and Recommendations

There were numerous limitations during the data collection period which reduced the beneficial impact of Vitalerter and impeded meaningful conclusions obtained from data analysis. The Vitalerter device requires stable and sufficient network connectivity to send alerts notifications to the handsets. Lost of network connection affected staff experiences and led to potential missing data. It is recommended that signal enhancing options to boost and maintain network connection are implemented prior to use. Baseline data was difficult to obtain to the degree required for a robust and rigorous data analysis, prior to the project it was unknown the depth of data required, which was too time consuming to obtain towards the end of the project. This was learnt after an initial data plan had been agreed with the care home provider and the evaluation team and was believed to be sufficient. At the time it was thought the data would be easy to collate at the end of the project. It is recommended that pre-trial data collection be conducted at the earliest stages of the project to enable sufficient and accurate data. With regards to data collection a more detailed plan of the type of data required to enable generalisable claims and to ensure robust and rigorous data collection is recommended going forwards. Likewise, open communication of changes in device locations and resident circumstances would greatly benefit data analysis, providing more depth, reliability, and validity, again reflecting the need for more rigorous and detailed data collection. Other factors during data collection which limited the analysis included incorrect algorithms of devices, the Vitalerter is sensitive to noise, thus when attached to a bed using an airflow mattress a specific algorithm is required, this information was not shared by relevant stakeholder’s leading to false alerts which occurred whilst one participant was in hospital. Instances such as these highlight limitations in the inferences one can make regarding the sensitivity and specificity of the device and as such should be taken in consideration. Thus, greater communication between stakeholder's is required to ensure Vitalerter is given the most updated and relevant information to enhance its benefits. It is therefore paramount the organisation inform other stakeholder's on what conditions are required, under what circumstances to ensure they have the awareness and understanding to act on changes which may occur in such environments.

Another factor effecting data collection and analysis was Vitalerter devices being damaged or unplugged, which typically occurred when rooms were being cleaned. It was felt that the device itself could be more robust given the environment it is designed for, combined with all staff within the care homes being provided with more information on how to avoid damage to devices where possible and the implications of devices being unplugged and damaged. It was also recommended that trained staff frequently check the dashboard which would identify damaged, unplugged, and low-charged devices. Due to devices being damaged, unplugged and losing battery, gaps within the dataset were evident, which reduced the ability to make meaningful conclusions around Vitalerter's effectiveness. Furthermore, there were difficulties with the battery-life of the handsets, spare batteries and charging sets were provided, however these needed to be prioritised to ensure staff were receiving notification. For future use it has been discussed to integrate Vitalerter notifications into the existing care home systems to overcome this challenge, increasing Vitalerter's user-friendliness. In the earlier stages of the intervention handset batteries were being drained quickly due to the frequency of alerts, which often occurred due to family members visiting residents, and residents moving from their bed to their chair. To reduce the occurrence of frequent and false alerts the times were changed for Vitalerter's use to a more appropriate time (between 6pm-8am). Where battery powered handsets are still required it is recommended that specific staff are tasked with ensuring handsets do not run out of battery. It was also highlighted that greater supply of handsets, charging stations and batteries were required to ensure handsets were working at optimal capacity. However, integrating Vitalerter notifications into the existing care home system would use less staff time and remove the requirement for additional handsets.

Additional limitations experienced included devices being assigned to residents who were high falls risk, however the generic falls risk assessment was not congruent with the Vitalerter's ability, as the device can only predict and prevent falls typically occurring from the bed, therefore a bespoke falls risk assessment is required in the future to assess residents who are high falls risk from their bed. In the initial stages of the project staff engagement was high, however throughout the project engagement gradually decreased over time, this was despite there being project engagement weekly meetings with the core team offering a forum to raise and address any issues raised. It is recommended that incentives could staggered over the period of the project to maintain staff engagement. Regarding staff engagement, many of the alerts were not actioned by staff which decreased the researchers' capability to make meaningful conclusions on Vitalerter's ability to predict and prevent falls. During the project this was highlighted to the staff and the actioning of alerts improved. It is recommended that incentives and awareness are focussed on early in the project to improve an uptake and engagement. The supplier will employ a customer training operative for future use to ensure staff are supported when implementing and using the Vitalerter to ensure open communication, awareness, and engagement. For future use it is recommended the supplier provides each care home with a clear and comprehensive overview of the installation, responsibilities, resident's needs, clearly defined project goals, deliverables, timelines, and potential risks. Additionally, key stakeholders including care staff could be engaged from the early stages of the project to enhance engagement, uptake, understanding and awareness. It was deemed more appropriate for the senior team to attend project meetings; creating a reliance on dissemination of information. This may be vital to improve engagement, as post-analysis reflection highlighted many of the staff members felt anxious and out of their depth using the technology, as staff were not confident in using the device, engagement was poor initially and time consuming. It is recommended that 'super-users' or device champions may increase uptake and engagement by providing more support, particularly in the initial stages. This was initiated but the staff member left the organisation and the 'super user' was not reestablished.

Future Directions and Next Steps

1) The evaluation suggests that Vitalerter contributed to a reduction in falls experienced during the trial period.
2) The frequencies conducted on staff's responses to alerts indicates a need for greater engagement and understanding of using the technology, suggesting the need for additional training prior to use and refresher updates. There is the potential for incentives regarding engagement and uptake.
3) To enable an accurate measurement of Vitalerter's predictive and preventative ability greater assessment of need is required to ensure that only residents who are deemed at high risk of falls, particularly from the bed setting are allocated a device.
4) To overcome technological and practical challenges experienced for future use, key stakeholders should be involved in the early stages, which may increase engagement and uptake.

Whilst challenges were experienced, this evaluation does suggest the Vitalerter may increase staff wellbeing and reduce work-related stress, reduce falls and fall-related risk, and have the potential to ensure residents are on the most appropriate turn protocol, however changes are required prior to future implementation.

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August 2023

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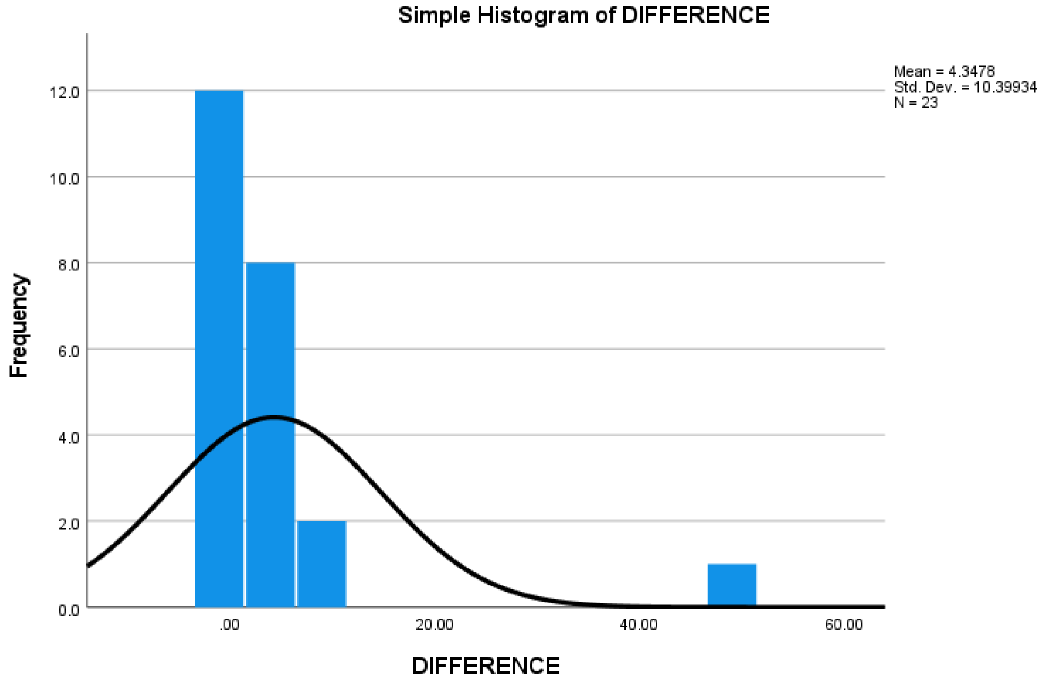
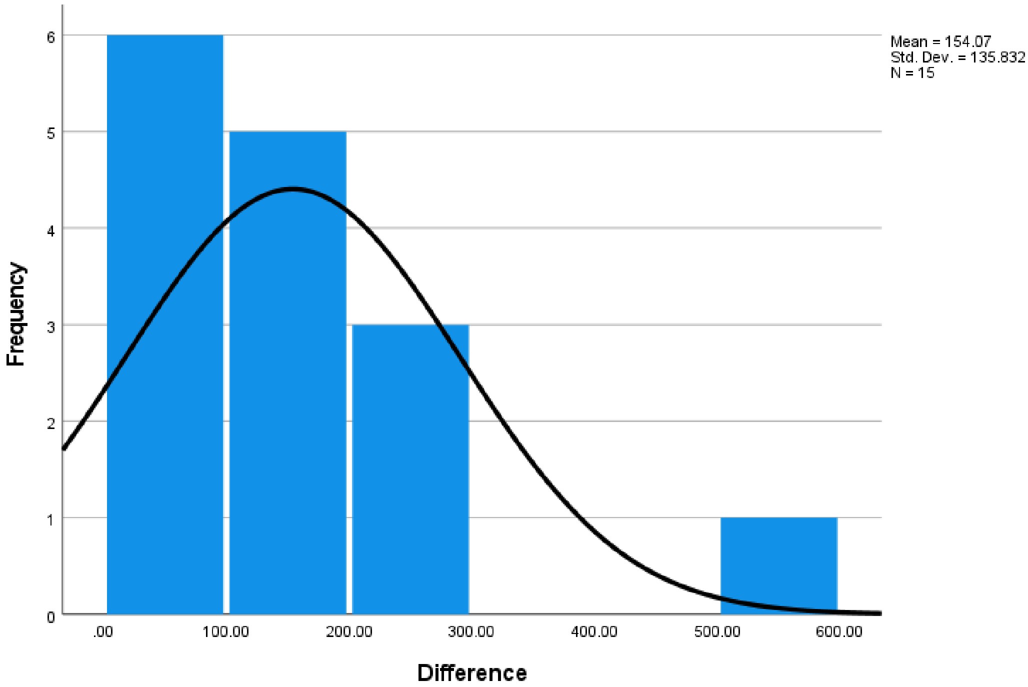
Appendix A: Falls Histogram



Appendix B: Turns Histogram



Appendix C: Histograms for recalculated falls