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Title: There is no effect on adverse events with the adoption of Protected Engagement Time in inpatient older people's mental health wards

Concise Title: PET care for older people with dementia

Authors: Smith TO, Clark A, Dodd E, Khoo M-E, Heneker S, Cross J, Cheston R, Gray R, Fox CG, Nolan F

Affiliations:

Dr Toby Smith, School of Health Sciences, University of East Anglia, Norwich, UK

Dr Allan Clark, Department of Population Health and Primary Care, Norwich Medical School, University of East Anglia, Norwich, UK

Emily Dodd, Department of Health and Social Sciences, University of the West of England, Bristol, UK

Mary-Ellen Khoo, Camden and Islington NHS Foundation Trust, St Pancras Hospital, London, UK

Sarah Heneker, Camden and Islington NHS Foundation Trust, St Pancras Hospital, London, UK

Dr Jane Cross, School of Health Sciences, University of East Anglia, Norwich, UK

Prof Rik Cheston, Department of Health and Social Sciences, University of the West of England, Bristol, UK

Prof Richard Gray, Nurse Education and Research, Hamad Medical Corporation, Doha, Qatar

Prof Chris Fox, Norwich Medical School, University of East Anglia, Norwich, UK

Prof Fiona Nolan, School of Health Sciences, University of Essex, Colchester, Essex, UK

Corresponding Author:

Prof Fiona Nolan, School of Health Sciences, University of Essex, Wivenhoe Park, Colchester, Essex, CO4 3SQ, UK Email: f.nolan@essex.ac.uk

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DECLARATIONS

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DESCRIPTION OF AUTHORS' ROLES

Formulating the research question: TS, AC, ED, MEK, SH, JC, RC, RG, CGF, FN

Designing the study: AC, ED, MEK, SH, RC, RG, CGF, FN

Carrying out the study: AC, ED, MEK, SH, CGF, FN

Analysing the data: TS, AC

Writing the article: TS, AC, ED, MEK, SH, JC, RC, RG, CGF, FN

ABSTRACT

Hospital adverse events such as falls, violence and aggression, security, self-harm and suicide are difficult to manage in older people with dementia. The purpose of this study was to determine whether Protected Engagement Time (PET) resulted in lower adverse events and incidence compared to comparable non-PET wards for people admitted to inpatient older people's mental health wards. Ten inpatient psychiatric units for older people were recruited. Five followed a PET management pathway, whilst five continued usual care. All adverse events and incidents were recorded in routine hospital records over 72 weeks. Data were gathered from these records and analysed as rate per person per week to assess for differences in frequency and type of adverse events between wards. 4130 adverse events were recorded. In the PET wards, a mean of 0.38 adverse events occurred per person per week compared to 0.40 in non-PET wards. No statistically significant differences were found between PET and non-PET wards for adverse events ($p=0.93$), nor for adverse events of any particular type ($p \geq 0.15$). Hence these is no evidence to suggest that PET had any impact of adverse events in older people's psychiatric wards. Further investigation with a larger cohort, is warranted on this intervention through a definitive, phase three, clinical trial.

Keywords: Care Model; Dementia; Older People Mental Health; Nursing

INTRODUCTION

Improving health and social care services for people with dementia is a national UK health and social care priority (Department of Health, 2016). As the level of cognitive impairment caused by dementia increases in an individual, the way in which that individual expresses their needs may change (Rockwood *et al*., 2014). This may be expressed with confusion and agitation as well as verbal and physical aggression (Rockwood *et al*, 2014). Unsurprisingly, behavioural and psychological difficulties are common in people with dementia (Cummings *et al*, 2015). Mechanical and physical restraint techniques are employed in approximately 13% of older people admitted onto acute mental health wards (Gerace *et al*, 2013). The confusion, agitation and aggressive behaviours which these individual may express can be challenging and distressing for all types of carers both formal and informal, especially family members (Van Vracem *et al*, 2015).

One factor which has been frequently discussed as possibly contributing to agitation and other signs of distress in people affected by dementia, particularly in institutional care, has been the lack of purposeful or meaningful activity (Edvardsson & Nordvall, 2008; Van Vracem *et al*, 2015). Edvardsson and Nordvall (2008) reported that people with dementia experience considerable boredom during a hospital ward admission. Pulsford (1997) suggests that there is an absence of activities on wards for people with dementia because nurses lack both time and confidence in their abilities to provide such activities as they perceive themselves as under-skilled in meeting the individual care needs of this population.

Protected Engagement Time (PET) is a strategy within hospital inpatient care pathways. It was first suggested in mental health settings in response to concerns reported that patients were bored, had little contact with staff, and felt unsafe during hospital admission (Kent, 2004; Rose, 2000; Quirk & Lelliott, 2001). The Refocusing Model (Bowles & Dodds, 2002) contributed to the development of PET as an intervention. PET essentially involves an attempt to place the interpersonal relationship

between staff and patients at the centre of ward practice, by re-organising the ward routines and operational policies to allow staff to spend time with patients without interruption (Thomson & Hamilton, 2012). To do this, nursing staff may be required not to take phone calls, attend meetings, complete administrative activities or attend to other duties except for medical emergency (Thomson & Hamilton, 2012). The intention of PET is to improve the amount of high-quality contact between staff and patients, to decrease distress and agitation amongst patients, without the necessity for psychotropic medications (Banerjee, 2009). This is particularly important as such medications can have a significant effect on morbidity and mortality in people with dementia (Fox *et al*, 2014). Furthermore, it is hypothesised that if agitation and distress decreases amongst patients through the creation of a calmer ward atmosphere, the number of adverse events such as accidents, violence or aggression within the inpatient setting may reduce (Care Services Improvement Partnership, 2005). This is desirable as patients, staff members and visitors are commonly exposed to verbal and physical abuse in inpatient settings, and are at risk of other adverse events such as falls, non-adherence to medication and feeding regimes (Speroni *et al*, 2014; Tzeng & Yin, 2013; Watkin *et al*, 2012).

There is a paucity of literature assessing the effectiveness of PET in ward environments. In particular it is unknown whether adverse events in wards for older people with mental health problems, can be reduced and better managed through introducing the PET approach. Accordingly, the aim of this study was to assess the impact of PET ward interventions compared to conventional ward care for older people admitted to inpatient mental health wards. In this paper, we will examine whether there are any differences between rates or types of adverse events on wards with and without PET for patients, visitors and staff members.

MATERIALS AND METHODS

Study Design

Data for this analysis were collected as part of a feasibility study assessing a randomised controlled trial design of clinical effectiveness of PET versus non-PET care for inpatient older people's mental health wards. The protocol for this study has been previously published (Nolan et al, 2016). The study gained ethical approval from the NRES Committee London – Camden and Islington REC (ref: 13/LO/0191). Ten wards providing mental health care for older people were included in total from three NHS mental health trusts in England. . Each ward had approximately 15 beds. Wards were purposively allocated to being PET and non-PET to ensure that each site included both PET and non-PET delivered care, delivered in dementia-specific and general older persons mental health wards.

This paper reports on routinely reported data for all patients who were admitted to each of the ten participating wards and is not restricted to the patients who participated in the main study. The data were provided to the study team in anonymised form by each Trust with all patient and staff identifiers extracted, and replicated that submitted to the National Patient Safety Agency (2015) for the same period.

Intervention

PET has emerged from ward practice rather than from a defined theory or body of evidence. The Acute Care Collaborative report (2005) describes PET as involving the following changes to practice: regular times for PET are established: at least once a week and up to every day, for between one hour and half a day; during this time the ward is closed to visitors and professionals from outside the ward. Characteristics of this model were adopted in the participating PET wards. All nurses from the participating sites were involved in the implementation of PET. During PET, most ward staff did not make phone calls or complete administrative duties. Engagement activities were in one-to-one meetings, group work or games. Conventional non-PET ward care was adopted (treatment as usual) in the non-PET wards.

Cohort

Two types of older people's mental health wards were recruited to participate in the study. Firstly wards which specifically cared for people affected by dementia; and secondly, wards which cared for all older people thus including those with dementia and also other diagnoses such as depression or schizophrenia. This was justified as PET was not meant to be specific to any diagnostic group. This study reports on routinely reported data on all patients who were admitted to each ward and is not restricted to those who participated in the main study. The data were provided to the study team in anonymised form by each Trust with all patient and staff identifiers extracted.

Data Collection

Prior to commencing the study, the recording of incident data varied in quality and coding method between each of the participating hospital trusts, and were not transferable. To address this, and to synthase the categories, the first 100 adverse events from each participating hospital trust were recorded and compared to create a new set of categories which were standardised as the study incident data codes. Following this, rates of adverse events including: falls, aggressive events, injuries, medication prescription error, staff sickness and absence and length of stay on the wards were examined collected using routinely recorded data using the agreed adverse event codes. For each adverse event, routinely collected data recorded the day of the event, including the time it occurred, whether an injury was sustained or not, the type of injury, whether a service-user was injured, whether a staff member was injured and whether a visitor was injured. The severity of injury was also recorded for each event as either: no injury, minor, moderate, serious, severe, critical or maximum. Data were provided from each Trust for the participating wards, for the period correlating to the study. The overall data collection period was from 12th August 2013 to 31st December 2014, an average of 72 weeks per site.

Data Analysis

Data were analysed at the ward-level to determine: if there was a difference in accidents and incidents (adverse events) between PET and non-PET wards for older people. This was initially assessed with descriptive statistics such as mean and standard deviation (SD) values and frequencies with percentages. The differences between adverse events occurring between PET and non-PET wards were analysed for all adverse events and for each type of incident e.g. fall, staffing issues, medication prescription error. These were analysed at the ward-level by comparing the rate per-bed not the per-patient rate as although the number of patients was different between the wards, they were in hospital for different length of stays. To control for this we used the per-bed rate assuming that the PET and non-PET wards were normally at full capacity.

After assessing normality with the Shapiro Wilks W test, we analysed for the difference in adverse events between PET and non-PET wards using a Student T-Test or Mann-Whitney U Test based on the result of the Shapiro Wilks W test. If this was statistically significant for either the PET or non-PET group, a Mann-Whitney test was performed. When not significant, a Student T-Test was performed. Finally, we compared the rate of adverse events per person per week for each type of event and each sub-classification of adverse events between PET and non-PET wards. This was assessed descriptively for all adverse events. The results of all statistical tests were expressed with p-values and 95% confidence intervals (CI). A p-values of less than 0.05 denoted a statistically significant difference. All analyses were undertaken on Stata Version 14.0 (Stata, StataCorp, Texas, USA).

RESULTS

During the 72 week study period, a total of 653 people were admitted to the study wards: 240 onto the participating PET wards and 413 people to the non-PET wards. A total of 4130 adverse events were reported on the 10 participating wards. This included 2068 events in the five PET wards and 2062 events in the non-PET wards. The mean number of events per week in each ward was 6.18 (SD: 5.1), 6.1 in the PET ward and 6.3 in the non-PET ward (p=0.38). When assessed as adverse event rate per person per week, the PET wards reported 0.38 (SD: 0.24) events per person per week, whilst the non-PET wards reported 0.40 (SD: 0.34) adverse events per person per week. This was not a statistically significant difference (p=0.93).

The characteristics of the reported adverse events appeared similar between the PET and non-PET wards (Table 1). There appeared no substantial difference between the PET and non-PET wards in the frequency to which injuries were sustained, whether the accident involved a service-user, staff member or visitor, and in the severity of incident (Table 1).

Table 2 demonstrates the results of the inferential statistical analyses between the PET and non-PET wards by total and type of incident reported. Overall, there was no statistically significant difference between the two groups for the total number of adverse events which occurred across the 10 wards (p=0.93). When assessed by type of adverse event, there remained no statistically significant difference between the PET and non-PET wards (p>0.05; Table 2). Adverse events which presented with the highest rate of adverse events per person per week included violence, aggression and abuse (PET: 0.19; non-PET: 0.16), and slips, trips and falls (PET: 0.11; non-PET: 0.16).

When assessed by subcategory of adverse event, there was no substantial difference between the PET and non-PET for the majority of the types of incidences (Table 3).

DISCUSSION

The findings of this analysis of adverse event data comparing PET and non-PET ward care interventions indicates that the rate of adverse events were largely similar between wards with no statistically significant difference over the 72 week assessment period.

Whilst these findings suggest no significant difference in actual adverse events, recent surveys of nursing staff who have employed this intervention in other centres, have favourable views towards PET. Thomson and Hamilton (2012) surveyed 34 nurses and 28 medical staff who adopted PET in adult psychiatric wards and reported that staff felt PET improved patient recovery and reduced the risks of adverse events, additionally increasing patient satisfaction with their care and the nursing-patient relationship. Fifty-five percent (n=34) of respondents felt that PET could reduce the risk of adverse events on these wards such as aggression/self-harm or absconding, whilst 15% (n=9) either disagreed or strongly disagreed to this suggestion. Interesting, 73% (n=25) of nursing staff who responded felt that PET could reduce these risks, compared to only 40% (n=11) of medical staff who responded. The results from our study do not appear to support the views of these respondents who had a favourable view of PET towards reducing adverse events.

Whilst the main study aimed to ascertain the feasibility the methods used in the conduct of a prospective definitive trial to evaluate the clinical and cost-effectiveness of PET, the finding from this analyses of the data relating to adverse events only indicated no difference for many adverse events. Whilst potentially an underpowered analysis, this trend in results was interesting as it was in contrast to the research hypotheses which was that use of PET would increase contact between staff and patients. This could be attributed to two factors. Firstly, it is possible that patients were unwilling to engage in PET and the type of activities offered to them (Thomson & Hamilton, 2012). However these data were not collected as part of this study. Tailoring the activities within the PET programme to specific service-users may be an important aspect to consider regarding the fidelity of and adherence to the intervention and may be an area for further analysis of PET cohorts. Secondly, whilst

PET may increase concentrated time to individual patients, depending on staffing level and workload pressures, this may dilute time devoted to other patients on the ward and increase risks during those times. Accordingly, PET may not reduce adverse events at a ward level as previously hypothesised (Thomson and Hamilton, 2012). .

Thomson and Hamilton (2012) suggest that the therapeutic time which PET offers, may reduce the risk of specific events such as suicide. They suggest that giving patients more time and opportunity to discuss issues such as suicidal thoughts in a structured and engaging way may be valuable in acute psychiatric wards (Bowles, 2002; Thomson & Hamilton, 2012). Our analysis does not support this hypothesis as there was no significant trend for a difference between the PET and non-PET wards for self-harm or suicide. However the numbers included in this analysis were small (10 in the PET wards and nine in the non-PET wards). Thus the non-statistically significant difference could be due to a type two statistical error, and a difference may be more apparent in a larger, definitive trial. Further study to explore the relationship between PET and suicidal episodes/self-harm in inpatient settings should be considered in larger datasets. However it is acknowledged that this may be difficult in the older adult cohort where there is a low prevalence for this event (Lapierre *et al*, 2011).

These results on the types of adverse events reported mirror that of national registries such as the UK's National Patient Safety Agency (2015). This has highlighted that patient accidents (n=37,991), disruptive aggressive behaviour (patient-to-patient; n=36,381) and self-harming behaviours (n=47,601) were the three highest adverse events reported in England in 2014 (National Patient Safety Agency, 2015). Whilst the rates of adverse events recorded have not reached a statistically significant difference in this study, as Table 2 demonstrates, there were differences in the rate per patient per week for adverse events involving violence, aggression and abuse and slips and trips. Accordingly, further assessment of these measures with larger cohorts could be valuable to determine whether there is a true difference.

The findings from this study relate to older people's care in psychiatric units whereas previous literature on PET has been based in general adult mental health units. Further study would be valuable

to explore the findings of PET in different clinical settings. Furthermore, this analysis did not take into account the number of registered and non-registered nurses, nor the number of permanent staff to temporary staff. These may be important variables since Bowers et al's (2013) analysis of 136 acute psychiatric wards in England, reported that staffing had a direct impact on patient safety, with an increased ratio of registered nurses to non-registered nurses associated with reduced conflict, and similar trends reported between permanent and agency/bank staff. This has also been previously reported in wider nursing practices across acute hospitals (Aiken *et al*., 2014). Accordingly, analyses of such staffing-level data should be included in subsequent evaluations.

Implementation of PET can be challenging as Thomson and Hamilton (2012) acknowledged, where there are fluctuating staffing levels and resulting increased clinical pressures and workload. Further study to determine the components and assess the implementation of PET in a wide range of NHS settings could be useful as this may inform future service design and delivery if PET were to demonstrate clinical effectiveness in a larger trial. However the conduct of such a definitive trial is essential before such recommendations are made.

This study presented with three key limitations. Firstly, the sample size of the study was not derived from a power calculation. It is therefore not possible to assess whether these conclusions were influenced by type two statistical error. Secondly, due to the data collection process assessing the intervention at a ward-level rather than individual patient level, we were unable to analyse the results by pathology or patient characteristic e.g. age, gender, level of cognitive impairment, mental health diagnosis or physical function. Data should be recorded in future definitive studies to determine whether these factors are associated with a difference in PET on adverse events. Finally, we conducted a number of statistical tests which was decided a priori. Accordingly, a possible limitation of this study is that we tested such a large number of hypothesis which could result in an increased false positive finding. However no significant findings were observed.

CONCLUSION

The use of PET did not appear to have an overall significant impact on the rates of adverse events in older people's psychiatric wards. The components and interpretation of PET were not measured in this study. The non-statistically significant findings demonstrated may be attributed to type two statistical error, with a low number of adverse events being reported. However, the potential difference demonstrated in these results, showing a reduction in absolute numbers of a variety of adverse events, notably violence, aggression and abuse, and slips, trips and falls, and the successful study design features identified in this study, provides support for further investigation in a definitive, phase three, clinical trial, to determine the clinical and cost-effectiveness of PET in hospital care for older people.

RELEVANCE FOR CLINCIAL PRACTICE

- Falls, violence and aggression, wandering and absconding and self-harm are all challenges in caring for older people in psychiatric wards.
- Protected engagement time may not significantly impact on the majority of adverse events in these settings.
- Protected engagement time may reduce the risk of ward-based violence, aggression and abuse in older people's psychiatric wards.

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FIGURE AND TABLE LEGENDS

Table 1: Ward and adverse event characteristics

Table 2: Category of adverse events analysed per person per week (total and by PET and Non-PET ward)

Table 3: Subcategory of adverse events (total and rate between PET and non-PET ward)

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Table 1: Ward and Adverse Event Characteristics

	Frequency (%)	**PET (%)**	**Non-PET (%)**
Wards	10	5 (50.0)	5 (50.0)
Number of admissions to study wards	653	240 (36.8)	413 (63.2)
Number of incidences	4130 (100.0)	2068 (50.1)	2062 (49.9)
Number of beds	144 (100.0)	72 (50.0)	72 (50.0)
Follow-up (weeks)	668.14	341	327.14
Type of injury			
Was an injury sustained? (yes)	660 (16.0)	308 (14.9)	352 (17.0)
Was a service user injured? (yes)	550 (13.3)	253 (12.3)	297 (14.4)
Was a staff member injured? (yes)	112 (2.7)	57 (2.8)	55 (2.7)
Was a visitor injured? (yes)	3 (0.1)	2 (0.1)	1 (0.0)
Severity of injury			
No injury	3444 (83.4)	1737 (84.1)	1707 (82.7)
Minor	639 (15.5)	305 (14.8)	334 (16.2)
Moderate	20 (0.5)	6 (0.3)	14 (0.7)
Serious	0 (0.0)	0 (0.0)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	0 (0.0)
Critical	0 (0.0)	0 (0.0)	0 (0.0)
Maximum	2 (0.0)	0 (0.0)	2 (0.1)
Not determined	23 (0.6)	15 (0.7)	8 (0.4)

PET – protected engagement time

Table 2: Category of adverse events analysed by per person per week (total and by PET and Non-PET ward).

Type of Incidence	Frequency	PET		Non-PET		Shapiro-Wilk (PET)	Shapiro-Wilk (Non-PET)	PET vs. Non-PET
	Events	Events	RpPpW (mean;SD)	Events	RpPpW (mean;SD)	P-Value	P-Value	P-Value
Total Events	4130	2068	0.38 (0.24)	2062	0.4 (0.34)	0.291	0.648	0.93
Slip, trip or fall	1465	898	0.16 (0.2)	567	0.11 (0.05)	0.010	0.406	0.75[1]
Other accident/injury	223	100	0.02 (0.01)	123	0.02 (0.01)	0.384	0.416	0.99
Violence, aggression and abuse	1856	823	0.16 (0.14)	1033	0.19 (0.15)	0.203	0.872	0.77
Medical error	73	35	0.01 (0)	38	0.01 (0.01)	0.791	0.853	0.78
Devices/equipment issue	6	3	0 (0)	3	0 (0)	0.556	0.394	0.89
Estates and environment issue	16	7	0 (0)	9	0 (0)	0.001	0.092	0.60[1]
Health and safety (include fire alarms)	76	32	0.01 (0)	44	0.01 (0.01)	0.501	0.213	0.59
Staffing issue	126	40	0.01 (0.02)	86	0.01 (0.02)	<0.001	0.016	0.35[1]
Poor standards of care	21	4	0 (0)	17	0 (0)	0.289	0.211	0.17
Physical health	46	16	0 (0)	30	0.01 (0)	0.742	0.952	0.19
Death	28	16	0 (0)	12	0 (0)	0.750	0.365	0.69
Record management	6	4	0 (0)	2	0 (0)	0.005	0.560	0.43[1]
Safeguarding	16	7	0 (0)	9	0 (0)	0.453	0.394	0.98
Security	20	14	0 (0)	6	0 (0)	0.631	0.032	0.34[1]
AWOL/missing	37	11	0 (0)	26	0 (0)	0.786	0.668	0.17
Self-harm/suicide	19	10	0 (0)	9	0 (0)	0.971	0.379	0.86
Sexually inappropriate behaviour	83	42	0.01 (0.01)	41	0.01 (0.01)	0.005	0.021	0.92[1]
Infection control	8	5	0 (0)	3	0 (0)	0.227	0.551	0.49
Bed management	5	1	0 (0)	4	0 (0)	0.046	0.535	0.37[1]

PET – protected engagement time; RpPpW – Rate per person per week; SD – standard deviation

[1] Mann-Whitney Test analysis.

Table 3: Subcategory of adverse events (total and rate (per patient per ward) between PET and non-PET ward)

Type of Incidence	PET		Non-PET		Shapiro-Wilk (PET)	Shapiro-Wilk (Non-PET)	P-Value
	Events	RpPpW (mean;SD)	Events	RpPpW (mean;SD)	P-Value	P-Value	
Slip, trip or fall – service users	892	0.11 (0.05)	556	0.16 (0.2)	0.011	0.380	0.92[1]
Slip trip or fall – staff	6	0 (0)	2	0 (0)	0.106	0.171	0.53
Accident/injury – service users	86	0.02 (0.01)	109	0.02 (0.01)	0.651	0.689	0.97
Accident/injury – staff	14	0 (0)	13	0 (0)	0.729	0.104	0.76
Physical assault (no weapon) – service user on service user	229	0.05 (0.04)	260	0.04 (0.05)	0.198	0.857	0.91
Physical assault (no weapon) – service user on staff	271	0.07 (0.05)	356	0.06 (0.05)	0.263	0.884	0.81
Physical assault (weapon) – service user on service user	27	0 (0)	30	0.01 (0)	0.810	0.666	0.93
Physical assault (weapon) – service user on staff	22	0.01 (0)	40	0 (0)	0.334	0.225	0.34
Damage to property	9	0 (0)	17	0 (0)	0.001	0.727	0.35[1]
Verbal abuse/threat – service user on service user	20	0 (0)	21	0 (0)	0.291	0.004	0.75[1]
Verbal abuse/threat – service user on staff	15	0.01 (0.01)	30	0 (0)	0.302	0.436	0.49
Verbal abuse/threat – visitor on staff	8	0 (0)	4	0 (0)	0.003	0.046	0.52[1]
Physically disruptive behaviour	100	0.02 (0.02)	109	0.02 (0.01)	0.313	0.362	0.77
Harassment and bully – staff on staff	2	0 (0)	1	0 (0)	0.560	0.046	0.37[1]
Alleged assault	14	0.01 (0.01)	25	0 (0)	0.014	0.222	0.35[1]
Physical assault (no weapon) - service user on visitor	8	0 (0)	8	0 (0)	0.742	0.851	0.92
Physical assault (no weapon) - visitor on service user	1	0 (0)	8	0 (0)	0.046	0.030	0.13[1]
Patient restrained to administer medication/personal care	5	0 (0)	17	0 (0)	0.012	0.002	0.45[1]
Verbally disruptive behaviour	2	0 (0)	2	0 (0)	0.378	0.491	0.61
Verbal abuse/threats – visitor on service user	1	0 (0)	0	0 (0)	0.046	NA	0.32[1]
Service user injured during restraint	3	0 (0)	7	0 (0)	0.046	0.046	0.88[1]
Attempted assault – service user on service user	25	0.01 (0.01)	30	0 (0.01)	0.009	0.030	0.91[1]
Attempted assault – service user on staff	57	0.01 (0.01)	71	0.01 (0.02)	0.055	0.432	0.92[1]
Attempted assault – service user on visitor	1	0 (0)	0	0 (0)	0.046	NA	0.32[1]

Physical assault (no weapon) - staff on service user	2	0 (0)	0	0 (0)	0.438	NA	0.14[1]
Verbal abuse/threat – service user on visitor	1	0 (0)	0	0 (0)	0.046	NA	0.32[1]
Alleged verbal abuse/threat – staff on service user	0	0 (0)	1	0 (0)	NA	0.046	0.32[1]
Pressure ulcer	3	0 (0)	17	0 (0)	0.046	0.548	0.09[1]
Other physical health issues	11	0 (0)	13	0 (0)	0.645	0.764	0.92
Death by natural causes	14	0 (0)	13	0 (0)	0.326	0.682	0.94
Unexpected/unexplained death	3	0 (0)	4	0 (0)	0.556	0.562	0.46
Theft/missing or lost property	7	0 (0)	5	0 (0)	0.893	0.014	0.46[1]
Substance misuse	0	0 (0)	1	0 (0)	NA	0.046	0.32[1]
Other security issue	6	0 (0)	0	0 (0)	0.012	NA	0.14[1]
Attempted absconsion	5	0 (0)	16	0 (0)	0.120	0.020	0.22[1]
Missing patients	6	0 (0)	10	0 (0)	0.496	0.892	0.69
Threatened self-harm	1	0 (0)	0	0 (0)	0.046	NA	0.32[1]
Attempted self-harm	6	0 (0)	3	0 (0)	0.556	0.018	0.91[1]
Deliberate self-harm	3	0 (0)	5	0 (0)	0.001	0.057	0.58[1]
Attempted suicide	1	0 (0)	1	0 (0)	0.046	0.046	0.88[1]

NA – Not applicable; PET – protected engagement time; RpPpW – Rate per person per week; SD – standard deviation

[1] Mann-Whitney Test analysis.